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An Overview of the U.S. Public Health System in the Context of Emergency Preparedness

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Summary

This report describes the U.S. public health infrastructure: the structure, organization, and legal basis of domestic public health activities. In contrast with healthcare, public health practice is aimed at decreasing the burden of illness and injury in populations, rather than individuals. Public health agencies use epidemiologic investigation, laboratory testing, information technology, public and provider education, and other tools to support their mission, activities that in turn rely on an adequate and well-trained public health workforce. Federal leadership for public health is based in the Department of Health and Human Services (HHS) and in particular at the Centers for Disease Control and Prevention (CDC). Most public health authority, such as mandatory disease reporting, licensing of healthcare providers and facilities, and quarantine authority, is actually based with states as an exercise of their police powers. Local and municipal health agencies vary in size, governance, and authority, but they are the front line in responding to public health threats.

In 2001, terrorist attacks on the nation brought the weaknesses of our public health system into sharp focus. Prior to the 2001 terrorist attacks, Congress passed the Public Health Threats and Emergencies Act (P.L. 106-505), to address the decaying public health infrastructure and to prepare for bioterrorism and other public health emergencies. After the 2001 attacks, Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act (P.L. 107-188), expanding grants to state health departments and adding a new national hospital preparedness program, as well as adding new food safety and security authorities, protections for water infrastructure, and other provisions. Congress also passed the Homeland Security Act (P.L. 107-296), creating the new Department of Homeland Security (DHS) to serve as a coordination point for homeland security activities and to house certain public health preparedness programs.

This report describes the nation's public health infrastructure and authorities at the federal, state, and local levels. It provides a history of relevant legislation and appropriations, both prior to and after the 2001 terrorist attacks. In addition, it describes selected public health preparedness programs at HHS and DHS.

This report also discusses a number of issues in ensuring public health preparedness. Specific challenges include: ensuring the coordinated planning for and response to emergencies by a variety of public health and other governmental actors, given that public health authority rests principally with states rather than the federal government; setting goals and standards for preparedness at the federal, state, and local levels; ensuring programmatic and fiscal accountability, and steady progress toward goals; and training and sustaining a skilled workforce for public health at all levels of government. The overarching challenge for policymakers is in making sound trade-offs with finite resources; ensuring *all-hazards* preparedness for a variety of emergencies, while balancing resources appropriately between emergency preparedness and the prevention of injuries and chronic diseases that kill millions annually. This report will be updated periodically.

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Introduction

The terrorist attacks of 2001, in particular the anthrax mailings, made clear that terrorism and other public health emergencies pose unique challenges to the nation's healthcare and public health systems. The threat of bombings and similar *overt* events requires that communities plan for the triage, transport, and treatment of large numbers of casualties. In contrast, the health impacts of a biological or chemical attack can be *covert*, unfolding gradually over time. The speed, accuracy, and coordination of both the healthcare and public health responses therefore have a direct impact on the number of casualties from either type of event. Terrorism may pose the threat of both events simultaneously, the covert event deliberately enveloped within the overt. Responding to health events of this type is new to the public health and healthcare communities, and requires a level of planning and coordination not seen before.

Improving public health preparedness is expected to offer protection not only from terrorist attacks, but also from naturally occurring public health threats. This concept is often called *dual-use*. Public health officials are increasingly concerned about the spread of infectious diseases because of global travel, increased global trade in food and other commodities, and the emergence of antibiotic-resistant pathogens. They argue that if well-designed, the strong infrastructure needed to respond to natural disease threats such as West Nile virus and pandemic influenza will also improve the response to the threat of terrorism. Some have argued that much of the needed capability (improved information technology systems, or a larger workforce, for example) is so versatile that it could improve the public health response to chronic disease threats such as heart disease, asthma, and cancer as well. On the other hand, some specific scenarios, such as smallpox and pandemic influenza, have been considered to pose an especially serious threat, and each has been the subject of specific planning activities within the context of broader, dual-use planning.

Prior to the 2001 terrorist attacks, several reports described the increasing threat posed by emerging infectious diseases and terrorism, and the continued erosion of the public health system. Among the problems cited were health department closures, outmoded technology and information systems, a limited workforce with inadequate training to address new threats, poor coordination among responsible parties, and

inadequate capacity in hospitals and laboratories to respond to a mass casualty event.[1]

A number of federal public health programs to prepare for bioterrorism were actually in place prior to 2001. The Department of Health and Human Services (HHS), through the Centers for Disease Control and Prevention (CDC), launched a comprehensive program to combat emerging infectious diseases in the early 1990s, followed by a bioterrorism initiative in the late 1990s. In 2000, Congress passed the Public Health Threats and Emergencies Act (P.L. 106-505), which provided funding for state bioterrorism preparedness programs, bioterrorism training programs, and programs to combat antimicrobial resistance, among other measures. This followed earlier legislation to control the shipment of potentially dangerous pathogens.

Following the terror attacks of 2001, Congress expanded its commitment to public health preparedness in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) and through greatly enhanced appropriations for public health. These actions included expanding a number of programs at CDC, such as grants for state and local public health capacity, and programs to stockpile medications and to control the possession of potentially dangerous pathogens. Congress authorized and funded several new programs, such as a state program to bolster hospital preparedness, and expanded food safety authorities for the Food and Drug Administration (FDA). Congress also created the Department of Homeland Security (DHS) to serve as a coordination point for many emergency preparedness programs, and for enhancement of funding for public health preparedness programs throughout the federal government.

Despite a variety of efforts at the federal, state, and local levels since 2001, serious challenges remain in ensuring national preparedness for public health threats. The biggest challenge for federal policymakers is to move beyond planning for each worrisome scenario toward a strategy based on analysis of threats and vulnerabilities — in short, to understand which are the top priorities in a sea of competing urgent priorities. This task is complicated by the decentralized nature of public health, in which states and localities, rather than the federal government, are the seat of most authority and responsibility for public health. In addition, states claim, legitimately, that a nationwide priority list would fail to address the variety of different vulnerabilities that exist from state to state. Many feel that versatile or *all-hazards* capabilities make the most efficient use of resources, at least until there is a more mature strategic approach to prioritize scenario-based planning.

The public health community faces a number of specific challenges as well. They include: ensuring the coordinated planning for and response to emergencies by

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[1] See, for example, Institute of Medicine (IOM), *The Future of the Public Health in the 21st Century,* The National Academies, Nov. 2002 (Hereafter cited as IOM Report), General Accounting Office (GAO, called the Government Accountability Office as of July, 2004), *Emerging Infectious Diseases: Consensus on Needed Laboratory Capacity Could Strengthen Surveillance,* GAO/HEHS-99-26, Feb. 1999; Amy E. Smithson, and Leslie-Anne Levy, *Ataxia: The Chemical and Biological Terrorism Threat and the U.S. Response*, Henry L. Stimson Center, Report no. 35, Oct. 2000; and Eileen Salinsky, "Public Health Emergency Preparedness: Fundamentals of the 'System,'" National Health Policy Forum Background Paper, Apr. 3, 2002 (hereafter cited as Salinsky NHPF Paper).

a variety of public health and other governmental actors; setting goals and standards for preparedness at the federal, state and local levels; ensuring programmatic and fiscal accountability, and steady progress toward goals; and training and maintaining a skilled workforce for public health at all levels of government.

This report describes the *public health infrastructure:* the structure, organization, and legal basis of domestic public health activities. It discusses recent congressional activity in authorizing and appropriations for public health. It describes a number of public health programs within the Departments of Health and Human Services and Homeland Security. Finally, it discusses a number of issues and challenges in ensuring public health preparedness.

Public Health Infrastructure

Overview

The mission of public health is to promote physical and mental health and prevent disease, injury, and disability.[2] The U.S. public health system comprises a wide array of governmental and nongovernmental entities, including:

- over 3,000 county and city health departments and local boards of health;
- 59 state and territorial health departments;
- tribal health departments;
- more than 160,000 public and private laboratories;
- parts of multiple federal departments and agencies;
- hospitals and other healthcare providers; and
- volunteer organizations such as the Red Cross.

Definitions vary but, in practical terms, public health infrastructure is the federal, state, and local public health organizations and the resources they need to operate effectively.[3] These governmental organizations form "the nerve center of the public health system"and interact with a wide array of other partners to ensure public health.[4]

In the context of emergency preparedness, some key functions of the public health infrastructure include: disease surveillance to detect outbreaks and to monitor

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[2] U.S. Department of Health and Human Services (HHS), Public Health Functions Project, 1999, at [http://www.health.gov/phfunctions/].

[3] See Edward L. Baker and Jeffrey Koplan, "Strengthening the Nation's Public Health Infrastructure: Historic Challenge, Unprecedented Opportunity," *Health Affairs*, vol. 21, no. 6, Nov./Dec. 2002; and HHS, Centers for Disease Control and Prevention, *Public Health's Infrastructure: A Status Report*, prepared for the U.S. Senate Appropriations Committee, Mar. 2001 (hereafter cited as CDC Infrastructure Status Report).

[4] B.J. Turnock, *Public Health — What It Is and How It Works*, 2d ed. (Gaithersburg, MD: Aspen Publishers, 2001).

trends; specialized laboratory testing to identify bioagents, both in individuals and in environments; epidemiologic methods to identify persons at risk and to monitor the effectiveness of prevention and treatment measures; knowledge of disease processes in populations to determine appropriate responses such as quarantine, decontamination or the dissemination of treatment recommendations; and coordination with partners to establish effective planning and response.

To accomplish these tasks, the public health infrastructure relies on a number of interdependent parts that encompass all levels of government, as well as both the public and private sectors. One element is the **public health workforce**: typically this includes individuals employed in governmental public health, though this group interacts with individuals employed in the healthcare sector, in academia, and in volunteer organizations. Another element is the **healthcare sector**, which includes hospitals, clinics, pharmacies, emergency medical services, a host of ancillary services, and a diverse healthcare workforce. Another element is the national complement of **laboratories**, which function on three levels; *clinical* laboratories, which conduct testing on individual patients within the healthcare system; *public health* laboratories, which conduct testing to support population-based programs and may involve testing of individuals as well as environmental assessment during a terrorist event; and *research* laboratories, in which the study of biological agents, the effects of treatments, or other pursuits are not directly linked to detection and response in specific incidents but which provide the scientific basis to guide ongoing and future response efforts. Another element is the **information technology infrastructure** that supports disease surveillance and the rapid dissemination of information during potential emergencies. The extent to which these elements, and others, are competent, well-coordinated, and otherwise adequate for national preparedness is a matter of considerable discussion. These elements are discussed in greater detail in subsequent sections that describe federal public health programs and issues in preparedness.

Legal Framework for Public Health[5]

Public health practice is governed by federal, state, and local law. The federal government can influence public health practice through its funding decisions and by exercising its jurisdiction over interstate commerce. However, most public health authority rests with the states. This section will review the legal authorities of federal, state, and local governments in public health.

Most public health authority is based in the states, as an exercise of their *police powers*.[6] States use this authority in a number of ways to protect public health, from enforcing safety and sanitary codes, to conducting inspections, to mandating the

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[5] Much of the material in this section is found in Frank P. Grad, *The Public Health Law Manual*, 3rd ed., American Public Health Association, 2004; and CRS Report RL31333, *Federal and State Isolation and Quarantine Authority*, by Angie A. Welborn.

[6] The term *police powers* derives from the 10th Amendment to the Constitution, which reserves to the states those rights and powers not delegated to the United States. Historically these have been interpreted to include authority over the welfare, safety, health, and morals of the public.

reporting of certain diseases to state authorities, to compelling isolation or quarantine, to licensing healthcare workers and facilities. Local governments are often responsible for some of these activities, using powers largely derived from delegation of state authority. Since states are the basis for most authority in public health, the traditional relationship of state and federal agencies has placed states in a leading role, with CDC providing support through funding, training, and technical assistance, advanced laboratory support and data analysis, and other activities. The Public Health Service Act grants the Secretary of HHS the authority to declare a situation a public health emergency, which triggers an expansion of federal authority (such as federal quarantine authority) as needed. The only such declaration made in recent memory was on September 11, 2001. On the other hand, even though states already have considerable power in responding to public health events, most can also declare public health emergencies and expand their powers further.[7] Following the terrorist attacks of 2001, CDC awarded a contract for the development of a Model State Emergency Health Powers Act, and encouraged states to use the model in revamping state laws to ensure that they are adequate to meet the threats of terrorism and other public health emergencies.[8] The updated legal authorities, particularly isolation and quarantine authority, proved helpful to certain states in managing Severe Acute Respiratory Syndrome (SARS) in 2003.

Though most public health authority is based in state law, the federal government nonetheless exerts a strong influence on public health practice through its ability to tax and spend and its responsibility for regulating interstate commerce. Using its commerce authority, the federal government can act to protect the environment, ensure food and drug safety, and promote occupational health and safety. The power to tax allows the federal government to encourage certain behaviors (e.g., deductibility of employee health insurance costs encourages employers to provide insurance) and to discourage others (e.g., raising taxes on cigarettes discourages smoking). The federal government can also set conditions on the expenditure of federal funds. For example, states must set 21 as the minimum age for the legal consumption of alcohol in order to qualify for federal highway funds. Federal public health recommendations, while lacking the force of law, nonetheless often exert considerable influence on medical and public health practice, and may be incorporated into state laws.

The federal government also has authority for disease control functions concerning entries of persons, goods and conveyances from other countries, where its activities to compel disease reporting and impose quarantine mirror the activities carried out by states within their borders. These activities are carried out by the CDC Division of Global Migration and Quarantine, which operates a number of quarantine stations at major ports. Recently the Division has been involved in evaluating

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[7] For a discussion of the exercise of federal and state authorities in response to the recent shortage of influenza vaccine, see CRS Report RL32655, *Influenza Vaccine Shortages and Implications*, by Sarah A. Lister.

[8] Information on the Model State Emergency Health Powers Act and state implementation is available from the Center for Law and the Public's Health at Georgetown and Johns Hopkins Universities at [http://www.publichealthlaw.net/Resources/Modellaws.htm].

inbound international passengers for SARS and ordering a prohibition on the importation of certain African rodents to prevent monkeypox.[9]

A number of federal statutes address public health in departments across the federal government. Most federal public health activity is based in HHS through authorities in the Public Health Service Act (PHSA) and the Federal Food, Drug and Cosmetic Act (FFDCA). In general, the PHSA authorizes the activities of the public health service agencies[10] and creates important vehicles for federal funding of public health activities in states and communities. The FFDCA authorizes the FDA to regulate the safety of food and cosmetics, and the safety and effectiveness of pharmaceuticals, biologics, and medical devices.

In addition to HHS, most other departments have authorities relevant for public health, though they may be specific or limited in scope. Three separate statutes grant authority to the U.S. Department of Agriculture (USDA) to ensure the safety of meat, poultry, and processed eggs. Important environmental health authorities are contained in the National Environmental Policy Act, as well as a number of related laws that authorize the Environmental Protection Agency (EPA) to regulate the safety of the air, water, and the ecological system. Important occupational health authorities are found in the Occupational Safety and Health (OSHA) and Mine Safety Acts. The Departments of Defense and Veterans Affairs exercise authorities to protect the health of the specific populations they serve, as does the Federal Bureau of Prisons in the Justice Department. The Departments of Energy and Transportation also act to protect public health through specific authorities, such as those governing radiation safety and highway safety, respectively. Independent agencies such as the Consumer Product Safety Commission, the National Transportation Safety Board, and the Nuclear Regulatory Commission also exercise federal authorities that, at least in part, protect public health. These examples are illustrative but by no means exhaustive. They do not encompass all of the many threads of federal activity that ultimately benefit the public's health.

Other provisions of federal law address emergency preparedness and response. The Homeland Security Act created the Department of Homeland Security (DHS), and grants the Secretary of DHS a broad leadership role in planning for and responding to emergencies, as well as several specific authorities for public health (discussed in subsequent sections). The Stafford Act establishes provisions for federal assistance to states in the event of a disaster. The act requires the governor of an affected state to request a declaration of a disaster, and vests the President with

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[9] For more information, see CDC Division of Global Migration and Quarantine Home Page at [http://www.cdc.gov/ncidod/dq/index.htm], and section on Protection Against Communicable Diseases in CRS Report RL32399, *Border Security: Inspections Practices, Policies, and Issues*, coordinated by Ruth Ellen Wasem.

[10] Public health service agencies are those agencies whose activities are authorized in the Public Health Service Act, namely the Agency for Healthcare Research and Quality, CDC, FDA, the Health Resources and Services Administration, the Indian Health Service, the National Institutes of Health, and the Substance Abuse and Mental Health Services Administration, as well as a variety of activities in the Office of the Secretary of HHS.

the authority to make such a declaration and charge federal agencies to provide support to state and local efforts.

The diversity of federal authorities for public health, and the dispersion of responsibilities across almost every federal department, mean that many different agencies may be involved in protecting public health in emergencies. In creating the Department of Homeland Security, Congress called on its Secretary to consolidate existing federal emergency response plans into a single coordinated national response plan, so that multiple federal agencies would work effectively with each other and with states and localities in a response. The new National Response Plan is discussed further in a subsequent section on **Issues for the 109th Congress**.

Some have suggested that the threat of terrorism has made public health a national security issue and that the federal government should therefore play a stronger role. Others worry that a stronger federal role will reduce flexibility. They emphasize that the first response to any event is local, that localities have differing needs, and that they therefore must have a strong role in resource allocation decisions. While the primacy of states in matters of health and safety is deeply rooted in the Constitution, laws, and judicial opinions of the United States government, this decentralized approach to public health will continue to pose a challenge in achieving national preparedness for emergencies.

Federal Public Health Role and Organization

The 2002 report from the Institute of Medicine, *The Future of Public Health in the 21st Century*, identifies six main areas where the federal government plays a role in population health. The six areas are policy making, financing, public health protection, collecting and disseminating information about health and healthcare delivery systems, capacity building for population health, and direct management of services.[11]

The Department of Health and Human Services (HHS) bears primary responsibility for public health activities at the federal level. Other key activities are located in the Department of Homeland Security (DHS), the Environmental Protection Agency (EPA), the Department of Agriculture (USDA), the Department of Defense (DoD), and the Department of Veterans Affairs (VA). This section will describe the missions of various agencies within HHS and DHS that have responsibilities for public health preparedness. Selected programs within these agencies are described in greater detail in subsequent sections.

Department of Health and Human Services (HHS). The Office of the Assistant Secretary for Public Health Emergency Preparedness (OPHEP), within the Office of the Secretary (OS), was created in legislation (P.L. 107-188) following the 2001 terror attacks. The Assistant Secretary directs and coordinates HHS preparedness activities. Other public health agencies within HHS with responsibilities for emergency preparedness and response include the Centers for Disease Control and Prevention (CDC), the Health Resources and Services

[11] IOM Report.

Administration (HRSA), the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and the Agency for Healthcare Research and Quality (AHRQ). Specific public health preparedness programs at HHS are discussed in **Appendix A.**

The **Centers for Disease Control and Prevention (CDC)** is the center of federal public health activities. The CDC works with states, localities, and other nations to detect, investigate, and prevent disease and injury, to develop and implement prevention strategies, to monitor the effect of environmental conditions on health, and to study illness and injury in the workplace. In 2000, CDC published a strategic plan for biological and chemical terrorism preparedness and response, which among other things prioritized potential bioterrorism agents in categories according to their ease of dissemination and potential for causing high mortality, and laid out a blueprint for a national laboratory network for bioterrorism.[12] State and local public health agencies receive support from the CDC in a variety of ways, including training programs, technical assistance and expert consultation, sophisticated laboratory services, research activities, and standards development. CDC also provides financial assistance for a wide range of public health activities, from controlling West Nile virus to providing childhood immunizations. One of the key vehicles for support of state and local public health agencies is the state and local preparedness grant program, established in 1999. The program was greatly expanded following the 2001 terrorist attacks. After the attacks, CDC also created a public Emergency Preparedness and Response website, [http://www.bt.cdc.gov], which contains information on biological, chemical, and radiological agents, diagnostic and treatment guidelines, program descriptions, and other materials. The site has also been used to relay information about naturally occurring public health threats such as Severe Acute Respiratory Syndrome (SARS) and hurricane-related health concerns.

The **Health Resources and Services Administration (HRSA)** is responsible for improving and expanding access to healthcare in the United States, including improving healthcare and public health systems. HRSA administers the state grant program for hospital preparedness, created after the terror attacks of 2001 to ensure that hospitals and other healthcare facilities have the capacity to respond to public health emergencies. HRSA is also generally responsible for healthcare workforce development, including programs for training in emergency medicine and trauma services, as well as a program to improve medical school curricula in the area of bioterrorism recognition.

The **Food and Drug Administration (FDA)** is responsible for ensuring the availability of safe and effective drugs, vaccines, blood products, medical devices, radiological products, and animal drugs. The FDA is also responsible for ensuring the safety of most types of foods. (The FDA works in partnership with the Department of Agriculture, which is responsible for the safety of meat, poultry, and processed egg products.) The FDA operates by establishing guidance, setting regulatory requirements, conducting inspections, and removing unsafe products from

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[12] CDC, "Biological and Chemical Terrorism: Strategic Plan for Preparedness and Response," *MMWR* 49(RR04), pp. 1-14, Apr. 21, 2000.

commerce. The FDA is supported by 3,000 state and local offices responsible for monitoring retail food establishments and their employees.[13]

The **National Institutes of Health (NIH)** conducts and supports biomedical research, including research to develop *countermeasures,* which are drugs, vaccines, rapid tests and other tools to detect, prevent, or treat illness from biological, chemical, or radiological threats, whether natural or intentional. Within NIH, the National Institute of Allergy and Infectious Diseases (NIAID) bears primary responsibility for bioterrorism-related research.[14] In February 2002, NIAID released a research strategic plan, a research portfolio aimed at a better understanding of the agents of bioterrorism, the host response to them, and ways to translate this knowledge into effective interventions.[15]

The **Agency for Healthcare Research and Quality (AHRQ)** sponsors and conducts research designed to improve the quality of healthcare. An area of research emphasis is the establishment of the *evidence base* to guide medical and public health practice. In the area of bioterrorism, AHRQ's research focuses particularly on improving the clinical preparedness of healthcare providers. For example, the agency has studied how best to communicate with physicians and other private healthcare providers in the event of a public health emergency and has assessed the most effective methods for training physicians about bioterrorist threats.

Department of Homeland Security (DHS). Congress created the Department of Homeland Security (DHS) in P.L. 107-296, the Homeland Security Act of 2002, to serve as the coordinating point for domestic preparedness and response activities. The law stipulated the role of the Secretary of Homeland Security in coordinating the processes of priority-setting and strategic planning for a variety of activities with public health components, including biodefense research on human countermeasures, and coordinated delivery of services to areas affected by emergencies. Specific public health programs at DHS are discussed in **Appendix B.**

During legislative debate, there was considerable discussion about the role of the new department in managing public health programs for emergency preparedness, and of transferring a number of programs, activities, and authorities from HHS to DHS. In the end, only three existing public health programs were transferred from HHS to DHS. The management of most of the public health programs under discussion (which were at CDC or NIH, primarily) remained at HHS. Of the three programs that were transferred, one was subsequently returned to HHS, and another was subsequently moved within DHS. But initially all three were moved to the **Emergency Preparedness and Response Directorate (EPR)** of DH[16]S. The EPR's

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[13] A description of FDA's counterterrorism activities can be found at [http://www.fda.gov/oc/opacom/hottopics/bioterrorism.html].

[14] See the NIAID Biodefense Home Page at [http://www2.niaid.nih.gov/biodefense/].

[15] NIH, NIAID, *NIAID Strategic Plan for Biodefense Research*, NIH, Feb. 2002, at [http://www2.niaid.nih.gov/biodefense/research/strategic.pdf].

[16] The Metropolitan Medical Response System (MMRS), the National Disaster Medical (continued...)

mission is to improve the nation's capability to reduce losses from all disasters, including terrorist attacks.[17]

The **Office of State and Local Government Coordination and Preparedness (OSLGCP)** at DHS administers a number of grant programs for first responders and municipal preparedness, and is the current home of the Metropolitan Medical Response System (MMRS) grants which began at HHS. Some OSLGCP grants allow state and local public health agencies to receive pass-through funding for eligible activities, and many involve these agencies in some way in planning activities.[18]

The **Science and Technology Directorate (S&T)** in the new department coordinates numerous research, development, and detection activities that have implications for public health. These include certain types of biodefense research (generally related to behavior or detection of bioweapons agents in the environment, rather than in humans) and the BioWatch program of urban air monitoring.[19]

The **Information Analysis and Infrastructure Protection Directorate (IA/IP)** in the new department coordinates programs to assist the private sector in "hardening" installations of critical national importance. Examples include protecting the banking industry from cyber attack, or the electricity grid from sabotage. Relevant programs for public health include those to improve the security of food handling, shipping, and storage facilities, in which FDA and IA/IP coordinate in providing guidance and assistance to the private sector. IA/IP is also the proposed site of data-mining activities for the Biosurveillance Initiative (discussed further in **Appendix A**), in which health data from a variety of sources will be analyzed as a mechanism for the possible early detection of large-scale health events such as bioterrorism.[20]

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[16] (...continued)
System (NDMS) and budget authority for the Strategic National Stockpile (SNS) were transferred to DHS from HHS in P.L. 107-296, the Homeland Security Act. The SNS has since been transferred back to HHS, and the MMRS has been transferred to the Office of State and Local Government Coordination and Preparedness (OSLGCP) in DHS.

[17] For more information on the DHS Emergency Preparedness and Response Directorate, see CRS Report RS22023, *Organization and Mission of the Emergency Preparedness and Response Directorate: Issues During the 109th Congress*, by Keith Bea

[18] For more information on DHS grant programs, see CRS Report RL32348, *Selected Federal Homeland Security Assistance Programs: A Summary*, by Shawn Reese.

[19] For more information on the DHS Science and Technology Directorate, see CRS Report RL31914, *Research and Development in the Department of Homeland Security*, by Daniel Morgan.

[20] For more information on the DHS Information Analysis and Infrastructure Protection Directorate, see CRS Report RL30153, *Critical Infrastructures: Background, Policy, and Implementation*, by John D. Moteff.

State Public Health Role and Organization

States have considerable autonomy in delivering public health services. Authorities for professional licensing, domestic isolation and quarantine, contact tracing, and mandatory disease reporting are based largely in state statute and regulation. Historically, CDC has funded state public health agencies through *cooperative agreements*, in which both parties (and ideally local jurisdictions and other stakeholders as well) are involved in setting goals and defining priorities.

Public health services can be broadly classified into two types: traditional population-based services, such as food inspection, and personal health services. In the latter case, some state health departments provide clinical services directly to certain groups and may be providers-of-last-resort for indigent individuals. States often deliver public health services through a number of different state agencies. Thirty-five states have free-standing state public health agencies, while in others public health is part of a larger agency that is responsible for a wider range of activities (including, for example, Medicaid programs).[21] Some important public health activities may be housed outside the state's primary public health agency. For example, in 36 states, the environmental health agency is separate from the public health agency. Emergency medical services may be housed in the public safety department or governed by a separate EMS authority or board when they are not housed in the public health agency. In many states, food safety testing is performed by multiple government agencies, namely in the departments of public health, agriculture, and environmental quality.

States differ in the amount of authority they delegate to local governments. Some states provide local governments with very little authority, while others offer local jurisdictions "home rule" over public health matters. Delegation of public health authority can be classified into three categories: (1) a centralized approach in which states have extensive legal and operational control over local authorities, (2) a decentralized approach in which local governments are delegated significant control, and (3) a hybrid approach in which some public health responsibilities are provided directly by the state, while others are assumed by the localities.

States also differ in how long they have focused on bioterrorism. A number of states received funding under CDC's Bioterrorism Initiative beginning in 1999 for a variety of different capacity-building activities. While state governments vary in both the breadth and depth of services they provide and the degree to which they delegate to local governments, they nevertheless play a central role in emergency preparedness and response. Except in the largest metropolitan public health departments, local health officials will generally call on the state to provide advanced laboratory capability and epidemiologic expertise, and to serve as a conduit for federal assistance.

Officials in state and local health departments affiliate in nonprofit organizations representing all 50 states and the territories, in order to develop consensus on procedures and standards, deliver training programs, and facilitate other activities

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[21] Salinsky NHPF Paper.

where national consistency is important. For example, the Council of State and Territorial Epidemiologists, in collaboration with CDC, develops a list of *Nationally Notifiable Diseases*, those diseases for which states are advised to mandate reporting to the health department by providers and laboratories.[22] These groups, which include state epidemiologists, state public health laboratory directors, immunization program directors, county health officials within states, and others, conduct capacity assessments and other public health activities through these associations. The groups in turn work with their umbrella organization, the Association of State and Territorial Health Officials (ASTHO).[23] These associations may receive substantial funding through cooperative agreements from the CDC to facilitate their work in assessing and strengthening the national public health infrastructure. As a result, their activities often reflect their pseudo-governmental role rather than the role of a traditional health advocacy group.

Local Public Health Role and Organization

Local health departments are on the front line in responding to public health emergencies. The role and organization of local health departments varies considerably across the United States, and this variation may have important implications for public health preparedness. The diversity of local public health agencies (LPHAs) can be illustrated with a few statistics from a 2000 survey conducted by the National Association of County and City Health Officials (NACCHO).[24]

Local public health agencies vary by type of jurisdiction. The most common arrangement is a LPHA serving a single county, but 40% of LPHAs serve other types of jurisdictions. County LPHAs range in size from sparsely populated rural counties to dense metropolitan ones such as Los Angeles County. County LPHAs may or may not serve all geographic areas within the county. For example, a city within a county may be served by its own municipal LPHA. In some cases, a city and its surrounding county join together to form one LPHA. Township health departments are usually located in states with strong "home-rule" or "town-meeting" political systems such as Connecticut, Massachusetts, and New Jersey. Finally, some health departments serve more than one county, and may span large geographic areas in the western United States. Multicounty LPHAs may also include regional or district LPHAs whose health directors may report to multiple county boards of health.

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[22] States gather data on "reportable" diseases and may use this information for a number of disease control and prevention activities. In addition, when states gather information on Nationally Notifiable Diseases, they submit this information to CDC for analysis, publication, and formulation of national guidelines and recommendations. While states may mandate the reporting of certain diseases by providers, the states' reporting to CDC is voluntary.

[23] More information about the Association of State and Territorial Health Officials (ASTHO), its affiliate groups, and links to state health departments may be found at [http://www.astho.org/].

[24] National Association of County and City Health Officials (NACCHO), *Local Public Health Agency Infrastructure: A Chartbook*, Oct. 2001, at [http://www.naccho.org/pubs/detail.cfm?id=169] (hereafter cited as NACCHO Chartbook).

Local public health agencies vary by the size of the population served. Over two-thirds of LPHAs serve fewer than 50,000 people. In contrast, 4% of LPHAs serve 500,000 or more. Not surprisingly, the number of workers employed by LHPAs also varies tremendously. The average staff of a metropolitan LPHA is 108 full-time equivalent personnel (FTEs). However, half of metropolitan LPHAs have 28 or fewer FTEs. In nonmetropolitan areas, the average number of FTEs is 31, but half of the LPHAs have 13 or fewer FTEs. Administrative and clerical staff, environmental health specialists, and public health nurses are the occupational categories most commonly used by LPHAs to describe the staff they employ.

The scope of services for which LPHAs are responsible also varies. In some areas, the LPHA is responsible only for septic systems and restaurant inspections, while in others the LPHAs may support a variety of public health programs as well as run a county hospital. The most common bioterrorism-related programs and services provided by LPHAs include epidemiology and surveillance, communicable disease control, food safety, and restaurant inspections. The NACCHO survey shows that over 70% of LPHAs provide adult and child immunizations, tuberculosis testing, community health assessment, community outreach and education, environmental health services, and health education.

How Is Public Health Funded?

Funding for public health comes from a variety of sources including local, state, and federal government programs, foundations, insurance reimbursements, and patient and regulatory fees. As noted above, vast differences exist in the scope of activities, size of population served, and organization of the governmental public health infrastructure at the state and local levels. Differences in accounting practices and in definitions of public health activities make it difficult to gather comparable national information on public health expenditures from all sources. One specific difficulty involves counting all expenditures related to a common set of public health activities (for example, environmental health) regardless of where they are in the governmental structure.

Another particularly difficult problem is separating expenditures and receipts for direct medical care services to individuals from those for population-based services. A pilot study of two state and two local health departments, conducted in 1996, found that more than two-thirds of public health spending overall went toward providing personal health care services rather than to population-based services, though there was considerable variability between sites.[25] This finding was used to generate recently published estimates that showed total federal, state, and local expenditures for *population-based* public health services of $17.1 billion, representing 1.3% of total national health spending, for 2000.[26] (While that reported percentage had risen from a baseline of 0.7% in 1960, uncertainty in the estimates means that this may not represent real growth. In any case, whatever growth may

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[25] Public Health Foundation, *Measuring Expenditures for Personal Health Care Services Rendered by Public Health Departments*, Apr. 1997, at [http://www.phf.org/Reports.htm].

[26] Senator Bill Frist, "Public Health and National Security: The Critical Role of Increased Federal Support," *Health Affairs*, vol. 21, no. 6, Nov./Dec. 2002, p. 117.

have occurred in public health spending over the years, it is dwarfed by spending growth in other healthcare activities such as long-term care or prescription drugs.) Federal spending accounted for 29% of public health spending, with state and local spending making up the remainder. Estimates from a state-sponsored survey of nine states done in the early 1990s yielded similar results, with 32% of spending for population-based public health activities coming from federal sources, 50% from states, and 18% from local sources.[27] These estimates predated the terrorist attacks of 2001 and therefore do not reflect the subsequent infusion of federal funds for population-based public health preparedness activities.

A separate analysis of local health agency funding sources shows that, on average, 44% of LPHA funding came from local sources, while 30% came from state sources including pass-throughs of federal funding. An additional 3% of funding came directly from the federal government to LPHAs and 19% came from fees or service reimbursement.[28] Metropolitan LPHAs tended to receive a larger share of funding from local sources than did nonmetropolitan LPHAs.

HHS has provided support to a collaborative effort among state and local public health associations to explore methods to measure actual public health expenditures at the state and local level. Initial feasibility studies show some promise, but no systematic accounting is currently conducted on a regular basis.[29] With the recent influx of federal funds for state preparedness for health department and hospitals, Congress barred states from using the new federal funds to *supplant* existing state-funded programs, a requirement often referred to as *maintenance of effort.* Ensuring compliance with this mandate has proven troublesome in the absence of consistent terminology, program descriptions, and accounting systems from state to state. (For a broader discussion of this problem, see the subsequent section on **Fiscal Accountability**.)

Recent Congressional Action

The terror attacks of 2001, and especially the anthrax attacks, focused attention on the critical role of the nation's public health infrastructure, and in particular the vulnerabilities at the state and local levels. Authorizing legislation and appropriations passed after 2001 reflected new priorities in public health preparedness. In some cases, new programs were created and funded. In other cases, existing programs that were developed throughout the 1990s were expanded, both in scope and in funding. This section discusses relevant authorizing legislation for HHS and the Department of Homeland Security (DHS), and appropriations for selected programs within these departments.

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[27] Public Health Foundation, *Measuring Expenditures for Essential Public Health Services,* Nov. 1996, at [http://www.phf.org/Reports/Expend1/exec_summ.htm].

[28] NACCHO Chartbook.

[29] IOM Report.

The 109th Congress

A Senate leadership proposal, **S. 3, The Protecting America in the War on Terror Act of 2005** (Gregg), would provide expanded authorities to promote the development of *countermeasures* (drugs, vaccines, biologics, other treatments and tests for biological and chemical agents), begun with P.L. 108-276, the Project Bio-Shield Act. The 109th Congress is likely to consider additional incentives for countermeasures development, such as intellectual property incentives and protection of manufacturers from litigation resulting from adverse reactions to countermeasures. Congress is likely also to debate the scope of the federal role in spurring technological innovation. (Project BioShield is described further in **Appendix A.)**

In addition, S. 3 would expand other public health preparedness programs, including readiness for pandemic influenza, enhanced surveillance and border inspections for human and animal diseases, and loan repayment programs to bolster the workforce in governmental public health. The bill was referred to the Senate Finance Committee.

A number of programs in P.L. 107-188, the Bioterrorism Act, are authorized through 2006 and may therefore be considered for extension by the 109th Congress. These programs include the Office of the Assistant Secretary for Public Health Emergency Preparedness, the CDC state capacity grants, and the HRSA hospital preparedness grants.

Authority for HRSA health professions programs in Title VII of the Public Health Service Act expired in 2002, and may be considered for extension by the 109th Congress. These programs are primarily intended to alleviate shortages and maldistributions of healthcare workers, while the public health workforce has received little federal attention over the years. Congress may wish to consider Title VII programs in the context of preparedness in both the public health and healthcare sectors. Public health workforce issues may also be discussed during consideration of S. 3 or other vehicles. (Public health workforce issues are discussed in greater depth in a subsequent section on **Issues for the 109th Congress**.)

Major Legislation in the 107th and 108th Congresses

Following the terror attacks of 2001, Congress passed the **Public Health Security and Bioterrorism Preparedness and Response Act (P.L. 107-188,** signed in June 2002, often called "the Bioterrorism Act") to improve the nation's readiness for bioterrorism, emerging infectious diseases, and other public health threats and emergencies. The program of CDC grants for state and local public health capacity was reauthorized at $1.08 billion for FY2003, and such sums as may be necessary through 2006.[30] (The program had previously been authorized at $50 million for

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

FY2001, prior to the terrorist 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, 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 the Health Resources and Services Administration (HRSA). Congress authorized $520 million for this program in FY2003, and such sums as may be necessary through 2006.

The Bioterrorism Act contained a number of other provisions for public health preparedness. Title I of the Act included numerous additional provisions for building federal public health capacity, including creation of the position of Assistant Secretary for Public Health Emergency Preparedness (ASPHEP) at HHS, and expansion of security and preparedness activities at CDC. Title I also expanded the program for the national stockpile of drugs to treat potential victims of terrorism or other public health emergencies, and changed its name from the National Pharmaceutical Stockpile to the Strategic National Stockpile (SNS). Title II of the Act called on the Secretary of HHS to register facilities (e.g., laboratories) and individuals in possession of *Select Agents,* those biological agents and toxins that pose a severe threat to public health and safety, and to promulgate new safety and security requirements for such facilities and individuals. Title III contained several provisions to protect the nation's food and drug supply and enhance agricultural security. Finally, Title IV of the act included provisions aimed at protecting the nation's drinking water supply, including authorizing $160 million to provide financial assistance to community water systems to conduct vulnerability assessments and prepare response plans.[31]

In creating the new Department of Homeland Security, 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) left most public health activities in HHS. P.L. 107-296 directed the Secretary of HHS to collaborate with the Secretary of DHS in setting priorities for human-health-related countermeasures research and development and for all public-health-related activities to improve state, local, and hospital preparedness and response, though these programmatic activities remained at HHS.

The **Project BioShield Act of 2004 (P.L. 108-276**, signed in July 2004), created market incentives for the development of drugs, vaccines, biologics, other treatments, and tests for biological and chemical agents (collectively called *countermeasures)*

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[30] (...continued)
directed the Administration to continue its current approach to the awards.

[31] 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.

that would not otherwise be attractive to entrepreneurs.[32] In addition, budget authority for the Strategic National Stockpile (SNS) was transferred from DHS back to HHS in the Project BioShield 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 Stockpile, as it always has.

Major Legislation Prior to the 2001 Terrorist Attacks

Prior to the terrorist attacks of 2001, Congress passed the **Public Health Threats and Emergencies Act of 2000 (Title I of the Public Health Improvement Act, P.L. 106-505)** 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 for Bioterrorism to coordinate nationwide testing during an event.

In the **Antiterrorism and Effective Death Penalty Act of 1996 (P.L. 104-132**, signed in April 1996), Congress called on the Secretary of HHS to establish a program to identify and list specific infectious agents that could be used for bioterrorism, and to require the registration of facilities (typically laboratories) shipping those agents. The resultant *Select Agent* program is overseen by the CDC and was expanded in scope in both law and regulation following the 2001 terrorist attacks.

Appropriations

Following the 2001 terrorist attacks, an amendment to the **FY2002 Defense appropriations bill (P.L. 107-117)**, signed on January 10, 2002, provided HHS with a total of $2.8 billion for bioterrorism-related activities in emergency supplemental funds for FY2002. This included $940 million for CDC grants to states for public health capacity, $135 million for a new program of HRSA grants to states for hospital preparedness, and expanded funding for numerous federal activities including biodefense research and the Strategic National Stockpile. In FY2003, the CDC grants to states were maintained at $939 million and the HRSA hospital preparedness program funding was increased to $514 million. Both the CDC and HRSA programs have received funding at fairly comparable levels for FY2004 and FY2005, though both were proposed for reduction in the Administration budget proposal for FY2005, and again in FY2006.

In May 2004, before distributing public health capacity funds to the states, HHS advised appropriators of a planned reallocation of the FY2004 CDC funds. In a letter

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[32] 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 Fischer.

to appropriators, former HHS Secretary Tommy G. Thompson requested redirection of funds for CDC state capacity grants to create the Cities Readiness Initiative (CRI), a plan to directly fund 21 major cities to ensure their ability to rapidly deploy countermeasures from the Strategic National Stockpile in an emergency.[33] (The CRI is discussed in greater depth in a subsequent section.) In the letter, Thompson expressed concern about delays in state planning and expenditure of funds for this activity. Under the reallocation, which was approved, states received about $54.9 million less overall, about $1.08 million less per state. The 21 cities received funds that included a base amount plus a supplement determined by population.[34] Of the reprogrammed $54.9 million, $27 million went to the designated cities, and $12 million to the U.S. Postal Service to explore the use of the postal service in delivering countermeasures. The remaining $15.9 million went to certain federal programs, some of which were first proposed in the FY2005 budget: these programs included enhanced border inspection, integrated health surveillance, and expansion of the BioWatch program of urban air monitoring.[35] The HRSA grants to states for hospital preparedness were not affected by the reallocation.

Some members of Congress, state governors, and stakeholder groups voiced support for the premise of the CRI while arguing that funding should not have been taken from the state public health capacity budget to fund it. Both the House and Senate Committees on Appropriations upheld the prior CDC funding levels for state and local capacity (i.e., levels before the reallocation) in FY2005 appropriations, while providing additional funds to continue the CRI in funding for the Biosurveillance Initiative.

Table 1 shows federal funding for selected public health preparedness programs in HHS for FY2002 through FY2005, and proposed levels for FY2006.

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[33] Secretary of HHS Tommy G. Thompson, letter to congressional appropriators regarding proposal to reallocate CDC funds, May 19, 2004.

[34] Final FY2004 amounts distributed to states and cities through the CDC program are tabulated at CDC, *Continuation Guidance for Cooperative Agreement on Public Health Preparedness and Response for Bioterrorism — Budget Year Five*, FY2004 Funding Distribution Chart — Attachment M, June 14, 2004, at [http://www.bt.cdc.gov/planning/continuationguidance/index.asp].

[35] For a discussion of these newly proposed programs, see HHS, *President's Budget Includes $274 Million To Further Improve Nation's Bio-Surveillance Capabilities*, press release, Jan. 29, 2004.

Table 1. Appropriations for Selected Public Health Preparedness Programs

(dollars in millions)

Agency and Program	FY2002 enacted[a]	FY2003 enacted[a]	FY2004 enacted[b]	FY2005 enacted[c]	FY2006 request[d]
HHS Office of the Secretary (OS)	**$57**	**$62**	**$114**	**$163**	**$204**
Influenza preparedness (non-add)[e]	*NA*	*NA*	*(50)*	*(99)*	*(120)*
Centers for Disease Control and Prevention (CDC)					
State and local public health preparedness	940	1,039[f]	934[g]	927	797
Biosurveillance Initiative	NA	NA	22	79	79
CDC capacity/ anthrax research	160	176	175	159	140
CDC physical security and facilities	0	20	0	0	0
Independent studies	2	2	0	0	0
Strategic National Stockpile (SNS)[h]	1,157[i]	398	398	396	600
Federal Mass Casualty Initiative (non-add, new in FY2006)	*NA*	*NA*	*NA*	*NA*	*(50)*
Subtotal, CDC	**$2,259**	**$1,635**	**$1,529**	**$1,560**	**$1,616**
Health Resources and Services Administration (HRSA)					
Hospital preparedness and infrastructure	135	514	515	491	483
Emergency Response Demonstration (non-add, new in FY2006)	*NA*	*NA*	*NA*	*NA*	*(25)*
Medical curriculum incentives	NA	28	28	28	28
Smallpox vaccination compensation program	NA	42	0	0	0
Subtotal, HRSA	**$135**	**$584**	**$543**	**$519**	**$511**

NA: Not applicable. Programs not yet implemented, or activities not yet being funded through a discrete budget line.
Note: Columns may not add due to rounding.

a. **Source:** Except where otherwise noted, HHS Budget in Brief for FY2004, Feb. 2003, section on Public Health and Social Services Emergency Fund, and H.Rept. 107-342, Conference Report on appropriations for Labor, Health and Human Services and Education for FY2002, Dec. 19, 2001.
b. **Source:** HHS Budget in Brief for FY2005, Feb. 2004, section on Public Health and Social Services Emergency Fund, and H.Rept. 108-401, Conference Report on appropriations for Labor, Health and Human Services and Education for FY2004, Nov. 25, 2003.
c. **Source:** Congressional Budget Justifications for CDC, HRSA, and HHS General Departmental Management for FY2006.
d. **Source:** HHS Budget in Brief for FY2006, Feb. 2005, section on Public Health and Social Services Emergency Fund.
e. Amount designated for year-round influenza vaccine production and pandemic preparedness, does not include a variety of HHS research and public health activities in influenza detection, prevention, and control, principally at CDC and NIH.
f. Includes one-time funding of $100 million for the smallpox vaccination program from the FY2003 supplemental appropriation, P.L. 108-11, Apr. 16, 2003.
g. This was the amount available for distribution to states before reprogramming. With reprogramming, each state received approximately $1 million less than in the FY2003 distribution. The remaining funds were retained by HHS for the Biosurveillance Initiative, border inspection, and other activities, or distributed directly to 21 cities as part of the Cities Readiness Initiative.
h. Comparable amounts, funds transferred from HHS to the Department of Homeland Security (DHS) for FY2003, and from DHS to HHS for FY2005. The SNS, formerly called the National Pharmaceutical Stockpile, is administered by CDC.
i. Amount includes $52 million appropriated in P.L. 107-116, appropriations for Labor, Health and Human Services, and Education for FY2002, plus an additional $593 million for general Stockpile activities and $512 million for smallpox vaccine purchase in P.L. 107-117, the Department of Defense and Emergency Supplemental Appropriations for Recovery from and Response to Terrorist Attacks on the United States Act of 2002.

Issues for the 109th Congress

Overview

Since the 2001 terrorist attacks, Congress has authorized new programs, granted new regulatory authorities, legislated reorganizations, and substantially increased funding for homeland security activities across the executive branch. As a result, areas ripe for programmatic and fiscal oversight are abundant, as are the challenges in spending wisely and crafting programs that truly make the nation safer.

One such challenge is determining whether the right balance has been struck between prevention, detection, and response, given that they often fall to different departments or levels of government. Concerns about newly proposed surveillance systems such as BioWatch and the Biosurveillance Initiative are illustrative. These concerns include whether the systems will perform well enough to achieve their goal of speeding detection of large-scale events, and therefore whether they are a good use of resources, given competing demands. There is concern about federal and state roles in conducting surveillance for the Biosurveillance Initiative, in particular whether information from the system may bypass the states (which have traditionally been the central collection points for public health data) and be collected directly by federal agencies. State officials note that they may therefore be unaware of incidents within their state until they are informed by federal authorities: hence, they are interested in the means by which salient findings will be defined by federal agencies and communicated to state and local officials and others needing to know. (Both programs are discussed further in **Appendix A**.)

Despite the efforts that have gone into setting up or expanding a host of preparedness programs at all levels of government, there are larger strategic questions that remain without answers at this time. Should the emphasis be on specific scenarios such as a smallpox attack or pandemic influenza, or should it instead be on broader, all-hazards preparedness activities? Is bioterrorism preparedness properly balanced with preparedness for chemical or radiological threats? Is the emphasis on public health emergency preparedness in balance with efforts to prevent and control major killers like cardiovascular disease and cancer? Threat assessments are vital aids in these deliberations, but are often not available, or do not incorporate the breadth of analysis needed to inform these larger trade-offs.[36] In addition, setting national priorities for preparedness in public health is always complicated by its decentralized nature, with states rather than the federal government playing the lead role in response. Congress is likely to continue its consideration of the place of preparedness at the table of competing national priorities.

Some specific policy challenges are discussed in the following sections.

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[36] On April 21, 2004, President George W. Bush signed Homeland Security Presidential Directive 10 (HSPD-10), which is classified. Among other activities, the directive requires DHS to conduct ongoing capability assessments for biodefense, and a periodic national "net assessment" of biodefense effectiveness and vulnerabilities. A non-classified summary of HSPD-10 is available at [http://www.nimsonline.com/presidential_directives/hspd_10.htm].

Coordination Across Agencies and Levels of Government

In Title V of the Homeland Security Act, Congress called on the Under Ssecretary for Emergency Preparedness and Response to build a comprehensive national incident management system, and to consolidate existing federal government response plans into a single, coordinated national response plan. On February 28, 2003, President Bush issued **Homeland Security Presidential Directive/HSPD-5**, regarding the management of domestic incidents. HSPD-5 directed the Secretary of Homeland Security to develop and administer a **National Incident Management System (NIMS)**, a consistent approach for federal, state, and local governments to work effectively together in planning and response. The NIMS would establish a common set of concepts, principles, and terminology to allow for unified command during emergencies. HSPD-5 also directed the Secretary to develop and implement a **National Response Plan (NRP)**, to supersede the existing Federal Response Plan, recognizing the need for integration of federal, state, and local governments in responding to incidents. The NRP would designate federal agencies in lead or support roles depending on the type of emergency, and would lay out the responsibilities of federal agencies as well as those of state and local agencies. HSPD-5 also stipulated that beginning in FY2006, federal departments and agencies must make adoption of the NIMS guidelines a requirement, to the extent permitted by law, for recipients of federal preparedness assistance through grants, contracts, or other activities. Public health preparedness programs such as the CDC and HRSA state grants will be affected by this requirement.

On March 1, 2004, former Homeland Security Secretary Tom Ridge announced approval of the NIMS, following a protracted process of stakeholder review.[37] The National Response Plan was released on January 6, 2005.[38] In a press release, former Secretary of HHS Tommy G. Thompson announced that the plan maintains HHS as the lead federal agency in providing public health and medical services during major disasters and emergencies.[39]

In evaluating the NIMS and NRP as planning and response models, Congress is likely to be interested in how well they meet their goals of improving nationwide emergency preparedness and response, and how well states are meeting the requirement to orient their activities toward the NIMS model. Congress, as a co-equal branch of government, may also wish to consider the ramifications of separation of powers on the response to emergencies on Capitol Hill. While the legislative and judicial branches enjoy the prerogative to opt out of executive branch

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[37] DHS, "Department of Homeland Security Secretary Tom Ridge Approves National Incident Management System (NIMS)," press release, Mar. 1, 2004. See also [http://www.nimsonline.com/], a privately run website for NIMS stakeholders.

[38] DHS, *National Response Plan*, Dec. 2004, at [http://www.dhs.gov/dhspublic/interapp/editorial/editorial_0566.xml].

[39] HHS, "HHS Maintains Lead Federal Role for Emergency Public Health and Medical Response," press release, Jan. 6, 2005.

preparedness activities, they may nonetheless depend on the executive branch for a variety of activities and assets when incidents occur.[40]

Defining Goals, Setting Standards, and Measuring Progress

The term "bioterrorism" is often used as a catch-all for a variety of public health threats and emergencies, including mass casualty events, chemical terrorism, and infectious diseases that are naturally occurring. In P.L. 107-188, the Bioterrorism Act, Congress required that preparedness be prioritized first to "bioterrorism or acute outbreaks of infectious diseases," and then to "other public health threats and emergencies." A persistent challenge is establishing the minimum level of capacity that must exist in every locality, versus capacity that should be created on a more consolidated basis at state, regional, or federal levels. Goals and priorities could be informed by threat assessments conducted by national security and law enforcement personnel, but health officials may not have access to this information, or may lack experience in applying it to public health activities.

CDC and HRSA *Critical Benchmarks*. P.L. 107-188 calls for the Secretary of HHS to collaborate with state and local governments to achieve national public health preparedness, and to develop and implement a coordinated strategy that includes specific benchmarks and outcome measures. In guidance for grantees accompanying the FY2002 though FY2004 funds, HHS, CDC, and HRSA laid out required activities, called *Critical Benchmarks,* intended to balance state autonomy and disparate levels of preparedness with an obligation to assure responsible use of federal resources and adequate preparedness nationwide. (Critical Benchmarks for FY2002 through FY2004 are listed in **Appendix C**.) They were grouped by type of activity, such as epidemiology, or communications and information technology, called *Focus Areas* in CDC guidance and *Priority Areas* in HRSA guidance. In addition, a series of Cross-Cutting Benchmarks required that certain activities be coordinated across both funding programs, including Incident Management planning, pandemic influenza preparedness, formation of a joint advisory committee to oversee the CDC and HRSA cooperative agreements, and other activities.

Many of the benchmarks call for analyses, assessments, and plans to be conducted or prepared by grantees. For example, a CDC Critical Benchmark for FY2003 and FY2004 calls on states to "assess annually the adequacy of public health response to catastrophic diseases (e.g., pandemic influenza), outbreaks, and other public health emergencies." Few of the benchmarks quantify specific needs such as types of equipment or training of personnel. An example of a quantitative requirement is the HRSA hospital preparedness Critical Benchmark for FY2004 that requires states to "ensure that all participating hospitals have the capacity to maintain, in negative pressure isolation, at least one suspected case of a highly infectious disease."

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[40] The National Response Plan states, on p. 7, that the executive branch may provide assistance to the legislative and judicial branches during incidents. For more information on Continuity of Operations in the Legislative Branch, see CRS Report RL31594, *Congressional Continuity of Operations (COOP): An Overview of Concepts and Challenges*, by Eric Petersen.

The General Accounting Office (GAO) commented on the lack of specificity and utility of the benchmarks, noting that a lack of standards and performance measures has hampered state preparedness efforts, leading to unfocused activities, suboptimal use of funds, and gaps in readiness. The GAO said about the state capacity grants, "State and local officials told us that specific benchmarks would help them determine whether they were adequately prepared to respond to a bioterrorist attack."[41] With respect to hospital preparedness, GAO was told by representatives of the American Hospital Association that specific benchmarks for hospitals to use in planning were lacking.[42] And, noting the wide variations in information technology (IT) readiness in state health departments, GAO said, "IT can more effectively facilitate emergency response if standards are developed and implemented that allow systems to be interoperable."[43]

At a 2004 public meeting of the Secretary's Council on Public Health Preparedness, HHS reported aggregated results of its evaluations of state compliance with Critical Benchmarks for the CDC and HRSA programs for FY2002.[44] Also in 2004, GAO published aggregate results of its evaluation of state progress in meeting the benchmarks for FY2002.[45] Results of the two evaluations appear to concur, to the extent that it can be determined from the often highly-aggregated results. Individual states are not identified, which GAO cites as being due to security concerns. Both reports group the benchmarks by higher or lower compliance rates, clearly noting that some benchmarks proved more difficult to meet than others. While GAO stated clearly that no state met all 14 CDC benchmarks, this cannot be inferred from the corresponding CDC presentation. Except for GAO, no other parties outside of HHS are known to have access to the full suite of state proposals, budgets, and progress reports associated with the CDC and HRSA grants, and except for the limited presentations of compliance with benchmarks from HHS and GAO, there are no publicly available analyses of the range of elements of state and local preparedness envisioned in the grant guidance for the two programs.

Next Steps. There are two goals in developing performance standards — that they be measurable and that they be meaningful. The former task, discussed above, is dwarfed in complexity by the latter. To develop standards that will measure actual preparedness in a meaningful way begins with national intelligence activity to assess threats, and incorporates a web of related activities such as assessments of vulnerability and capability. Strategic planning of this scope is beginning at the

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[41] GAO, *Bioterrorism: Preparedness Varied Across State and Local Jurisdictions,* GAO-03-373, Apr. 2003, p. 5.

[42] GAO, *Hospital Preparedness: Most Urban Hospitals Have Emergency Plans but Lack Certain Capacities for Bioterrorism Response,* GAO-03-924, Aug. 2003, pp. 9-10.

[43] GAO, *Information Technology Strategy Could Strengthen Federal Agencies' Abilities to Respond to Public Health Emergencies,* GAO-03-19, May 2003.

[44] See, for example, presentations of Donna Knutson and Melissa Sanders on the CDC and HRSA programs respectively at the meeting of the Secretary's Council on May 3-4, 2004, at [http://www.hhs.gov/ophep/council.html].

[45] GAO, *HHS Bioterrorism Preparedness Programs: States Reported Progress but Fell Short of Program Goals for 2002,* GAO-04-360R, Feb. 10, 2004.

Department of Homeland Security as a requirement of Homeland Security Presidential Directive 10 (HSPD-10), but it is limited to biodefense readiness, rather than all-hazards.[46] Further, setting priorities and developing a strategy to meet goals must be carried out at the national level, but also must be flexible enough to apply to the states, with their various strengths and vulnerabilities.

The RAND Corporation has conducted a series of studies of public health preparedness in California, designed as much to develop assessment tools as to conduct the actual assessment. In one of its reports, RAND noted that:

> The Little Hoover Commission, an advisory body to the California state legislature, asked the RAND Corporation to assess gaps in California's public health infrastructure, beginning with an assessment of preparedness for a public health emergency manifested as a contagious infectious disease. Note that there are currently neither established standards for preparedness nor agreed-upon methods and measures for assessing it.[47]

CDC was reported in 2003 to be developing a new set of indicators to measure the progress of state and local jurisdictions, and was using a contractor to conduct site visits and evaluate states.[48] CDC has not made the proposed indicators publicly available. But the agency did ask the Institute of Medicine's (IOM's) Committee on Smallpox Vaccination Program Implementation, to evaluate the proposed indicators. In December 2003, the Committee reported in a letter to the CDC Director that the dual goals of the indicators — to measure grantees' compliance with the cooperative agreements and to measure state and local preparedness — could lead to an overly large set of indicators that serve neither purpose well. The Committee cautioned that evaluations based on outcomes require a longer-term, national deliberative process.[49] The Committee also opined that separate indicators should be developed and applied to state versus local jurisdictions, and that federal agencies themselves should also be held accountable through similar evaluations. In addition, based on feedback from a variety of stakeholders in response to the indicators, the Committee noted the need for greater emphasis on communication and collaboration across jurisdictions and levels of government, and commented that the proposed indicators did not support this objective.

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[46] A non-classified summary of HSPD-10 is available at [http://www.nimsonline.com/presidential_directives/hspd_10.htm].

[47] Nicole Lurie et al., "Public Health Preparedness in California: Lessons Learned from Seven Health Jurisdictions," *Technical Report 81*, RAND Corporation, Aug. 2004, at [http://www.rand.org/publications/index.html].

[48] See Jonathan Radow, "CDC Develops Bioterror Scenarios to Evaluate Preparedness Indicators," *Washington Fax*, Nov. 19, 2003; and "Preparedness; U.S. Plans to Grade States' Bioterrorism Plans," *Medical Letter on the CDC and FDA*, Dec. 7, 2003.

[49] IOM, Committee on Smallpox Vaccination Program Implementation, *Review of the Centers for Disease Control and Prevention's Smallpox Vaccination Program Implementation*, Letter Report #5, Dec. 19, 2003, at [http://books.nap.edu/html/smallpox_vac/letter_report5.pdf].

CDC and HRSA are scheduled to release updated grant guidance for FY2005 funds in the Spring of 2005. For CDC, the cooperative agreement program is slated for a complete revision, and the agency reportedly continues to work toward a meaningful set of performance measures for the program, to replace the Critical Benchmarks. Because the two programs are closely intertwined, HRSA is expected to remodel its guidance to remain compatible with the CDC program. (In the past, the agencies shared a set of *Cross-cutting Benchmarks* in guidance for common activities. These are found in **Appendix C.**) Both agencies are expected to reflect in their program guidance the new requirement that recipients of federal preparedness grants be compliant with the National Incident Management System for FY2006.

Congress may be interested in reviewing the revised CDC and HRSA guidance documents for FY2005 to determine whether they reflect sufficient progress in the development of meaningful performance measures for public health preparedness, and whether the new measures will allow Congress to better assess how much progress has been made since funding was enhanced in FY2002. In addition, Congress may wish to review the use of the enhanced preparedness funds to date, and may for example request that the Secretary of HHS provide information such as the breakdowns of funds used according to Focus or Priority Areas, or for specific functions such as equipment, personnel, and contracts. Congress may also be interested in evaluating the process by which HHS, CDC, and HRSA review state plans and progress reports. Finally, Congress may wish to evaluate state activities to determine whether certain concerns it voiced in the Bioterrorism Act have been adequately addressed, such as consideration of the special needs of children and other vulnerable populations, preparedness in rural areas, coordination with tribal nations and foreign governments, and preparedness for the mental health consequences of disasters.

Fiscal Accountability

Supplanting of Funds. In P.L. 107-188, the Bioterrorism Act, Congress authorized $1.6 billion in appropriations for the CDC and HRSA programs to prevent or respond to "bioterrorism or acute outbreaks of infectious diseases" and "other public health threats and emergencies." Congress did not impose a matching requirement on use of these funds, but it did direct that the amounts appropriated "shall be used to supplement and not supplant other State and local public funds provided for activities under this section." (This requirement to sustain state funding levels is often referred to as *maintenance of effort.)* But some states, facing across-the-board budget pressure, have cut health department funding coincident with the influx of federal funds.[50] Appropriations Committees in both the House and Senate expressed concern about supplanting in their reports on HHS appropriations for FY2004. In December 2004, Trust for America's Health (TFAH), a public health advocacy group, issued a state preparedness report card in which it found that 15

[50] See Stephen Smith, "Anthrax vs. the Flu," *Boston Globe*, July 29, 2003, p. C4; and Rebecca Cook, "Budget Cuts Imperil Health," *Associated Press*, in *The Seattle Times*, Mar. 12, 2003.

states had cut their state budgets for public health since 2003.[51] TFAH had previously reported that 32 states had cut their state public health budgets from 2002 to 2003, and recommended that CDC institute measurable preparedness standards for state and local health departments to ensure accountability and efficient distribution of funding.

In 2004, the HHS Inspector General (IG) published an audit of 17 states' use of CDC capacity funds and reported:

> In response to our questionnaire and during our onsite interviews, officials from all 17 awardees asserted that Federal bioterrorism program funding had not supplanted existing State or local bioterrorism programs... . We did not validate their assertions. We have scheduled in-depth reviews at selected awardees that will include an analysis of the supplanting issue.[52]

Ensuring compliance with the prohibition against supplanting has proven troublesome in the absence of consistent terminology, program descriptions, and accounting systems from state to state. The Office of the IG prepared an audit guide for states to assist them in managing the grants, in which it was stated that evidence of supplanting will exist when there have been decreases in state or other nonederal revenues or person-hours in any public health programs in "infectious diseases, bioterrorism, or emergency preparedness and response."[53] (These categories roughly correspond to priorities in authorizing language.) Given this broad definition of relevant programs, if states are cutting immunization and other infection control programs, as news reports suggest, then it appears that the types of trade-offs Congress intended to avoid are occurring.

In FY2003, HHS required states to adopt a comprehensive tracking system to account for federal funds from the CDC and HRSA preparedness programs. While this is likely to improve an understanding of the fate of *federal* dollars, it is not likely to illuminate the matter of supplanting, since it will not track health department revenues from other sources. Future IG audits may offer a more critical analysis of budgets in each state. But there remains the need for consistent terminology and definitions of programs for which maintenance of effort is required, and a consistent approach to budget documentation in every state. Until this is accomplished it is not clear how, as a practical matter, the prohibition against supplanting might be enforced.

Pass-Through of Funds to Local Governments and Hospitals. Concerns have been expressed that CDC and HRSA funds do not filter down from states to a variety of *sub-recipients*, including municipal and local health

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[51] Trust for America's Health, *Ready or Not: Protecting the Public's Health in the Age of Bioterrorism 2004,* Dec. 2004, at [http://healthyamericans.org/reports/bioterror04/].

[52] HHS, Office of Inspector General, "Nationwide Audit of State and Local Government Efforts to Record and Monitor Subrecipients' Use of Public Health Preparedness and Response for Bioterrorism Program Funds" (A-05-04-00027), Aug. 5, 2004.

[53] HHS, Office of the Inspector General, Office of Audit Services, "Review of Public Health Preparedness and Response for Bioterrorism Program Funds, Audit Guide," Oct. 24, 2002.

departments, smaller healthcare facilities, and tribal nations. In P.L. 107-188, Congress provided that:

> ... for fiscal year 2003, the Secretary (of HHS) shall in making awards under this section ensure that appropriate portions of such awards are made available to political subdivisions, local departments of public health, hospitals (including children's hospitals), clinics, health centers or primary care facilities, or consortia of such entities.

In accompanying report language, Congress requested that HHS report to the Committees on Appropriations detailing the amounts of FY2002 funds that are provided to subrecipients.[54]

CDC guidance does not stipulate a specific pass-through amount for local health departments, though the intent that they be adequately supported is noted in guidance for FY2003 as follows:

> Applications shall provide evidence of a process that demonstrates consensus, approval or concurrence between state and local health officials for the proposed use of these funds. ... Because of the high degree of variability in financing, organization, and governance in state and local health departments across the United States, there is no single best approach for achieving such consensus; ... Local capacity can be built through direct allocation of funds to local levels and through allocations to support state or sub-state regional capacities that directly benefit local communities. Even in those states that operate local health departments, appropriate local capacity development must be ensured. The focus of funding allocations should be on benefit achieved, not on who spends the dollars.[55]

HRSA guidance does require a specific pass-through amount, as follows:

> At least 80% of the funds awarded for direct costs must be clearly allocated to hospitals, outpatient facilities, EMS systems and poison control centers, through written contractual agreements or purchase orders.[56]

In a June 2003 report to Congress, HHS reported that it surveyed grantees (but did not review their progress reports on this matter) and found that overall, 41% of funds were directly allocated by states to local health departments or jurisdictions ("local agencies"), and an additional 33% were spent or planned to be spent by states for the benefit of local jurisdictions.[57] HHS noted that respondents had difficulty

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[54] H.Rept. 108-10, the conference report to accompany H.J. Res 2, "Making Further Continuing Appropriations for Fiscal Year 2003, and for Other Purposes," Feb. 13, 2003, p. 1121.

[55] CDC guidance, Program Announcement 99051, May 2, 2003, p. 1, at [http://www.bt.cdc.gov/planning/continuationguidance/index.asp].

[56] HRSA, *National Bioterrorism Hospital Preparedness Program, Cooperative Agreement Guidance*, May 2, 2003, pp. 25-26.

[57] U.S. Department of Health and Human Services, Office of the Secretary, *Report to* (continued...)

interpreting both "local agency," reflecting the nationwide diversity of systems of local health jurisdiction, and "benefit," noting that while the CDC provides general guidance that "benefit" refers to purchase of goods or services, many states may have chosen a broader interpretation.

CDC and HRSA guidance for FY2003 included a new requirement, designated as Critical Benchmark #1 and repeated in FY2004, for states to develop and maintain financial accounting systems capable of tracking expenditures by focus area, critical capacity or priority area, and of tracking funds provided to subrecipients. The new benchmark was developed to improve HHS's ability to compare proposed versus actual expenditures, monitor the outflow of funds to hospitals and local health departments, and otherwise improve accountability.

Congress may be interested in evaluating states' use of public health preparedness funds, and may consider requesting information from the Secretary of HHS on specific matters such as pass-through funding. Congress may wish to ensure state maintenance of effort by determining whether states may be required to provide certain information about state budget activities in order to receive federal funds, or through use of special studies, surveys, or demonstration projects to explore alternative accounting procedures for states. In addition, Congress may wish to consider alternative means to assure that federal funds are used to augment rather than supplant existing state activities, such as a requirement for state matching funds.

Public Health Workforce Shortages

Since the terror attacks of 2001, the need for a responsive public health workforce is apparent, but ensuring and sustaining a competent workforce for governmental public health is a challenge. GAO reported in 2002 that "shortages of personnel existed in state and local health departments, laboratories, and hospitals and were difficult to remedy."[58] In its 2003 report, *Major Management Challenges and Program Risks: Department of Health and Human Services*, GAO noted:

> Increasing staffing of public health departments and laboratories is a top priority for enhancing preparedness in many areas. Officials told us that they did not have enough trained epidemiologists, laboratory technicians, and other professionals to respond to the anthrax incidents while meeting normal, day-to-day responsibilities ... .[59]

Federal, state, and local governments may be in competition for a finite group of workers, as CDC Director Julie L. Gerberding noted, saying, "We're competing

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[57] (...continued)
Congress: FY2002 Bioterrorism State and Local Preparedness Funding, undated, transmitted to the U.S. House of Representatives Committee on Appropriations on June 13, 2003.

[58] GAO, *Bioterrorism: Preparedness Varied Across State and Local Jurisdictions*, GAO-03-373, Apr. 2003, p. 17.

[59] GAO, *Major Management Challenges and Program Risks: Department of Health and Human Services*, GAO-03-101, Jan. 2003.

over the same group of talented people. It takes time to hire and train people and our pipeline in our schools is not a torrent. It's more like a trickle."[60] The Partnership for Public Service reported that the federal government was unable to match salary growth in the private sector since 2001, resulting in migration of talent away from public service, and that nearly half of all federal employees in biodefense-related positions will be eligible for retirement within five years.[61] A 2003 survey of the state public health workforce showed an average age of 46.6 years (older than the average for all state government workers and the general U.S. workforce), higher-than-average rates of retirement eligibility, high turnover rates, persistent vacancies, and chronic shortages of public health nurses, epidemiologists, laboratory scientists and environmental health professionals.[62]

The public health workforce encompasses a wide range of professional disciplines and occupations. Some of the most common are physicians, nurses, environmental specialists, laboratorians, health educators, disease investigators, outreach workers and managers. Recent attempts to enumerate the public health workforce yielded estimates of roughly 450,000 workers employed approximately evenly at the local, state, and national levels.[63] Enumeration is tricky because public health workers are not captured in the standard categories used by the Department of Labor.[64] They are likely to be counted as physicians, nurses, technicians, or other practitioners, depending on which degrees they may hold (if any), but the classification scheme misses the fact that their "practice" is on populations rather than individuals. An analysis of efforts to enumerate workers in the nation's local health departments found that Department of Labor statistics did not correspond in meaningful ways with actual workers and their roles, and concluded that "no state or national system is in place to track local public health workers in any way."[65] Efforts to bolster the public health workforce suffer from this basic failure to understand who these workers are. What types of training do these individuals have? What

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[60] Testimony of CDC Director Julie L. Gerberding in the U.S. Congress, Senate Committee on Health, Education, Labor and Pensions, *Federal Biodefense Readiness*, 108th Cong., 1st sess., July 24, 2003 (hereafter cited as Testimony of CDC Director, *Biodefense Readiness*).

[61] Partnership for Public Service, *Homeland Insecurity: Building the Expertise to Defend America from Bioterrorism*, July 2003, at [http://www.ourpublicservice.org/].

[62] Association of State and Territorial Health Officials, *State Public Health Employee Worker Shortage Report: A Civil Service Recruitment and Retention Crisis*, 2004, at [http://www.astho.org/pubs/Workforce-Survey-Report-2.pdf], hereafter cited as ASTHO workforce report.

[63] HHS, Health Resources and Services Administration, Bureau of Health Professions, *The Public Health Workforce: Enumeration 2000*, Dec. 2000, available at [http://bhpr.hrsa.gov/healthworkforce/reports/default.htm].

[64] For a broader discussion of this problem, see CRS Report RL32546, *Title VII Health Professions Education and Training: Issues in Reauthorization*, section on "Defining and Enumerating the Health Workforce," by Sarah A. Lister, Bernice Reyes-Akinbileje, and Sharon Kearney Coleman.

[65] Michael R. Fraser, "The Local Public Health Agency Workforce: Research Needs and Practical Realities," *Journal of Public Health Management and Practice*, vol. 9, no. 6, 2003, pp. 496-499.

proportion of their time is spent solely on public health practice, versus personal health care, teaching, or research?

CDC maintains a public health workforce program that looks broadly at the problem from a "pipeline" perspective. Its most recent strategic plan for public health workforce development predates the 2001 terror attacks, though activities are ongoing to bolster the workforce in the context of terrorism and emergency preparedness, and workforce development is one of the strategic imperatives in CDC's strategy for terrorism preparedness and emergency response.[66]

Though HRSA has conducted analyses of the health workforce, its emphasis has been on healthcare rather than on public health functions such as surveillance, outbreak investigation, and facility inspections. More recently HRSA is funding studies of the public health workforce in several states. In addition, the agency supports a number of programs to train public health professionals on the job. Since the terror attacks of 2001, HRSA has provided grants for a new Bioterrorism Training and Curriculum Development Program, to train healthcare providers in recognition and treatment of diseases related to bioterrorism.

Despite these efforts, there have been repeated calls for a national strategy aimed at ensuring a skilled, sustainable workforce for public health preparedness, without it coming at the expense of routine public health activities.

In 2002 the Institute of Medicine proposed a plan for educating public health professionals for the 21st century, recommending degree programs in schools of public health, medicine, and nursing. The Association of State and Territorial Health Officials (ASTHO) responded that training programs alone will not remedy public health worker shortages, and that the problem requires a strategy that takes into account the human resources systems, salary structures, and incentives in governmental public health.[67] In a 2004 report on shortages of state public health workers, ASTHO called for "a well-coordinated effort on the part of the public health agencies, legislatures, institutes of higher learning, and the federal government to help improve the outlook for the future workforce."[68] The Association of Public Health Laboratories has said that "the nationwide shortage of skilled laboratorians cannot be addressed through short-term funding support, but requires a long-term national strategy."[69] The Partnership for Public Service noted, "There is no governmentwide planning effort that develops a coordinated recruitment plan for the numerous federal agencies responsible for biodefense. ...We have seen no analysis

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[66] See CDC, Office of Workforce Policy and Planning Home Page, at [http://www.phppo.cdc.gov/owpp/], and testimony of CDC Director, *Biodefense Readiness*.

[67] Institute of Medicine, *Who Will Keep the Public Healthy? Educating Public Health Professionals for the 21st Century*, Nov. 2002, and *Who Will Keep the Public Healthy?*, workshop summary, Aug. 4, 2003, at [http://www.iom.edu].

[68] ASTHO workforce report, p. 13.

[69] Association of Public Health Laboratories, "Public Health Laboratory Issues In Brief: Bioterrorism Capacity," Oct. 2002, at [https://www.aphl.org/docs/BTIssuebrief%20final%20Oct02.pdf].

that identifies the numbers and types of employees needed in response to the most likely bioterrorist threats."[70] The Gilmore Commission recommended in 2002 that "(HHS) fund studies aimed at modeling the size and scope of the healthcare and public health workforce needed to respond to a range of public health emergencies and day-to-day public health issues."[71] With the release of its fifth and final report one year later, the Commission noted that this recommendation was one of few that had not yet been implemented.[72]

Congress may wish to consider whether federal leadership to develop a national strategy for a prepared public health workforce should properly reside at CDC, at HRSA, or elsewhere. This discussion may take place in consideration of S. 3, the Protecting America in the War on Terror Act of 2005 (Gregg), which contains a provision for loan repayment programs to bolster the workforce in governmental public health. It may also be considered in the reauthorization of HRSA health professions programs in Title VII of the Public Health Service Act, which is expected during the 109th Congress, or in other venues.

Conclusion

The events of fall 2001 have heightened concern about the nation's ability to respond to terrorist attacks. The strength of the public health infrastructure at the federal, state, and local levels is an important determinant of the speed and effectiveness with which a response occurs and, therefore, of the severity of the consequences in terms of number of people affected. Recent congressional action has provided funding and guidance to improve national public health capacity. Serious challenges remain in balancing competing priorities, maintaining accountability, and coordinating efforts between and across levels of government.

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[70] GAO, *Major Management Challenges and Program Risks: Department of Health and Human Services,* GAO-03-101, Jan. 2003.

[71] Advisory Panel to Assess Domestic Response Capabilities for Terrorism Involving Weapons of Mass Destruction, *Fourth Annual Report to the President and Congress*, Dec. 2002, p. 55, at [http://www.rand.org/nsrd/terrpanel/]. Commonly known as the Gilmore Commission after its chair, former Virginia Governor James S. Gilmore III, the Panel was established in the National Defense Authorization Act for FY1999 to assess the federal, state and local capabilities for responding to terrorist incidents in the United States.

[72] Advisory Panel to Assess Domestic Response Capabilities for Terrorism Involving Weapons of Mass Destruction, *Fifth Annual Report to the President and Congress*, Dec. 2003, at [http://www.rand.org/nsrd/terrpanel/].

Appendix A: Selected Programs in the Department of Health and Human Services

In general, public health preparedness programs are coordinated by the HHS Office of Public Health Emergency Preparedness (OPHEP),[73] which may also serve as the lead for specific programs (e.g., Project BioShield). The OPHEP may also coordinate with other entities in the Secretary's Office. For example, according to the HHS Draft Pandemic Influenza Preparedness and Response Plan, the Assistant Secretary for Health (ASH) is responsible for pandemic preparedness activities and monitoring, while the Assistant Secretary for Public Health Emergency Preparedness (ASPHEP) is responsible for pandemic response activities.[74] The ASPHEP is advised by the Secretary's Council on Public Health Preparedness.[75]

This section will discuss key HHS programs to build the nation's public health capacity for responding to terrorism and other emergencies. For each program one agency typically serves in a lead role, and this agency is stated. For many homeland security programs, other agencies have complementary roles, and these are discussed as appropriate. The section is organized into two parts: programs that principally build federal or national public health capacity, and programs that principally build state and local public health capacity. These categories are selected for convenience and should not be overinterpreted. Most programs build capacity at both levels: for example, the CDC grant program for state and local capacity, by building capacity in all the states, also therefore builds capacity nationally.

Programs That Build Federal or National Capacity

Project BioShield (OPHEP). Project BioShield was announced by President Bush in his State of the Union address on January 28, 2003. The purpose of the program is to accelerate the research, development, purchase, and availability of countermeasures (e.g., drugs, vaccines, and antidotes) against biological, chemical, and radiological threats. (Often these products are unattractive to the pharmaceutical industry because they are not likely to have routine uses.) Three legislative proposals were considered in the 108th Congress, and the Project BioShield Act of 2004 (P.L. 108-276) was signed on July 21, 2004. The law includes provisions to relax procedures for bioterrorism-related procurement, hiring, and awarding of research grants; to guarantee a government market for new countermeasures; and to permit emergency use of unapproved countermeasures. The 109th Congress is likely to consider additional incentives for countermeasures development, such as intellectual

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[73] For more information, see the OPHEP Home Page at [http://www.hhs.gov/ophep/index.html]. The role of the OPHEP is further explained in HHS, "Office of Public Health Emergency Preparedness Statement of Organization, Functions, and Delegations of Authority," 70 *Federal Register* 5183, Feb. 1, 2005.

[74] HHS, *Draft Pandemic Influenza Preparedness and Response Plan*, Core Document, Aug. 2004, p. 20, available at [http://www.hhs.gov/nvpo/pandemicplan/index.html].

[75] The charter, membership, and meeting information for the Secretary's Council on Public Health Preparedness is at [http://www.hhs.gov/ophep/council.html].

property incentives, and protection of manufacturers from litigation resulting from adverse reactions to countermeasures. Congress is likely also to debate the scope of the federal role in spurring technological innovation.[76]

Biosurveillance Initiative/BioSense (CDC). On January 29, 2004, in anticipation of the Administration budget proposal for FY2005, the Secretaries of Homeland Security and HHS announced a new *Biosurveillance Initiative* (BI), involving their departments and the Department of Agriculture.[77] The initiative would gather data from existing sources of anonymous or de-identified health information, such as hospital laboratory reports and sales of over-the-counter drugs. (Collection and analysis of this type of pre-diagnostic health data is often called *syndromic surveillance.)* Environmental monitoring data, such as food testing results and findings of the BioWatch network of urban air monitors, would be integrated as well. The project is intended to gather, integrate, and analyze these data in real-time.

The BI is one of a number of public health *data mining* activities proposed since the terror attacks of 2001.[78] The initiative would expand the BioSense program at the CDC, which integrates traditional and novel sources of public health data to "enhance detection, quantification and localization of possible bioterrorism attacks and outbreaks ... [and to] support subsequent case identification, epidemiological investigation, response, medical consequence management and recovery operations."[79] Some reports have suggested that eventually data mining for the initiative will be conducted by the Department of Homeland Security, but that this activity is in its early stages and is currently performed at CDC.

In addition to improving detection and response to health emergencies, other potential benefits of the BI may include strengthening of the public health infrastructure in general, and better coordination of response partners at the local, state, and federal levels. In particular, the initiative is a means to improve ongoing collaborations between the public health and healthcare sectors. As with other event-detection systems, the trade-off for enhanced detection is the generation of false-positive findings to which state and local public health agencies must respond. This must be incorporated in program implementation.

Criticisms of the initiative are similar to those for other newly proposed surveillance systems such as BioWatch. These include concerns about whether the

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[76] For more information, 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 Fischer.

[77] HHS, *President's Budget Includes $274 Million To Further Improve Nation's Bio-Surveillance Capabilities*, press release, Jan. 29, 2004.

[78] The proposal was listed among data mining projects identified by the GAO in *Data Mining: Federal Efforts Cover a Wide Range of Uses,* GAO-04-548, May 4, 2004. For more information on data mining and examples of other federal programs, see CRS Report RL31798, *Data Mining: An Overview,* by Jeffrey W. Seifert.

[79] CDC, "BioSense: Update for Secretary's Council," presentation by John Loonsk to HHS Secretary's Council on Public Health Preparedness, May 4, 2004.

system will perform well enough to achieve its goal of speeding detection of large-scale events, and therefore whether it is a good use of resources, given competing demands. There is concern about federal and state roles in conducting surveillance, in particular the fact that certain information would bypass the states (which have traditionally been the central collection points for public health data) and be collected directly by federal agencies. State officials note that they may therefore be unaware of incidents within their state until they are informed by federal authorities: hence, they are interested in the means by which salient findings will be defined by federal agencies and communicated to state and local officials and others needing to know. In addition, while the proposed system is intended to detect health events rather than individuals (be they victims or perpetrators), there may nonetheless be privacy concerns.

Laboratory Response Network (CDC).[80] The CDC established the Laboratory Response Network (LRN) in response to Presidential Decision Directive 39 (PDD-39), issued by President Clinton in 1995 following the bombing of a federal building in Oklahoma City. PDD-39 outlined national antiterrorism policies and assigned specific missions to federal departments and agencies. CDC, along with the Federal Bureau of Investigation (FBI) and the Association of Public Health Laboratories, launched an operational network of local, state, and federal government laboratories in 1999. The network provides coordinated sample collection, transport, testing, surge capacity, and training for laboratory readiness to identify key biological and chemical agents.

The LRN was in place when the anthrax attacks occurred in 2001. Nonetheless, the attacks challenged the network's resources and exposed a gap in planning for communication of results. Between October and December 2001, the LRN processed more than 125,000 samples for anthrax (resulting in more than 1 million individual analyses), including testing directly related to anthrax cases and exposures in seven states and the District of Columbia, and testing of threat samples in all the remaining states.

Most clinical laboratories, which serve hospitals, clinics, and other first-points-of-contact for victims, are not familiar with or are not equipped to handle pathogens likely to be used in a bioterrorist attack. According to LRN protocol, clinical lab personnel contact state public health laboratories when they encounter suspected bioterrorism agents, and the state labs conduct testing to confirm the presence of the agents. At this time, more than 100 labs, including all 50 state public health labs, some large metropolitan public health labs, and labs at numerous federal agencies serve as *reference* laboratories in the LRN. CDC develops the confirmatory or *reference tests*, and transfers technology to the reference labs. In this way, reference testing is decentralized and accessible in most states within a day's drive. In addition, advanced training in the identification of rare bioterrorism agents, the specialized test methods often required to identify them, and the safety and security measures required by law when handling these organisms, need only be available in the reference labs, not in the thousands of clinical labs nationwide. LRN labs at CDC

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[80] Information for this section is found on the CDC LRN Home Page and supporting materials at [http://www.bt.cdc.gov/lrn/].

and the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) at Fort Detrick in Maryland, which have BioSafety Level-4 (BSL-4) facilities to handle the most dangerous pathogens, can provide advanced technical support such as microbial forensic analysis during an event.

The LRN incorporated chemical testing following the 2001 terrorist attacks, using a different model in which CDC and five state labs provide national reference testing for a variety of agents, while the majority of the remaining states provide limited testing for cyanide and some toxic metals. The states that provide the full menu of testing are California, Michigan, New Mexico, New York, and Virginia.

Federal funding to support state laboratory capacity for biological and chemical testing required by the LRN is provided in the CDC state capacity grants for Focus Area C (biological) and Focus Area D (chemical). The funding is used to assist states in meeting Critical Benchmarks for laboratory preparedness, such as having BioSafety Level 3 (BSL-3) capability in all states. (See Critical Benchmarks for Focus Areas C and D in **Appendix C.**)

Select Agent Program (CDC).[81] The Select Agent Program was first established by the Antiterrorism and Effective Death Penalty Act of 1996 (P.L. 104-132). The law required the Secretary of HHS to regulate the transfer (though not the possession) of so-called *select agents*, organisms and toxins that could potentially be used for bioterrorist attacks. The initial Select Agent regulation (42 C.F.R. § 72.6), administered by the CDC, required the registration of any laboratory shipping or receiving the agents, and documentation of these transfers. The CDC developed a list of select agents, which are those viruses, bacteria, fungi, and toxins that may pose a severe threat to public health and safety.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) expands the scope of the Select Agent provisions by requiring all facilities possessing select agents, not just those shipping or receiving them, to register with CDC. In addition, P.L. 107-188 instructs the HHS Secretary, in consultation with the Attorney General, to establish lab safety and security requirements for registered facilities "commensurate with the level of risk to public health and safety," and to institute background screening for all persons seeking access to select agents. It also mandates the creation of a national database with information on all facilities and persons handling select agents, and directs HHS to review and, if necessary, revise the list of select agents biennially. In P.L. 107-188, the Select Agent program was authorized through 2007 with an indefinite appropriation.

P.L. 107-188 gives the Department of Agriculture (USDA) similar authority to develop a list of biological agents and toxins that may pose a severe threat to crops and livestock and to regulate facilities that possess, use, or transfer those agents and toxins. The law instructs HHS and USDA to coordinate their activities regarding so-called *overlap agents*, those agents that affect both human and animal health and that therefore appear on both agencies' lists. Both the bioterrorism law and the USA

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[81] See the CDC Select Agent Program Home Page at [http://www.cdc.gov/od/sap].

PATRIOT Act (P.L. 107-56) prohibit certain groups of individuals — based on criminal history, immigration status, and other factors — from having access to select agents.

P.L. 107-188 grants the Secretary of HHS authority to waive Select Agent requirements as necessary in the face of a public health emergency, or when requested by the Secretary of Agriculture in the face of an agricultural emergency, in order to facilitate response activities. This emergency waiver was granted for soybean rust, a serious plant pathogen that entered the United States in the Fall of 2004.[82]

In December 2002, HHS and USDA issued interim final regulations to implement the expanded program. (The HHS regulation is codified at 42 C.F.R. § 73.0, and the USDA regulation at 7 C.F.R. Part 331 and 9 C.F.R. Part 121). All labs possessing select agents were required to submit detailed security, training, and record-keeping plans in order to be registered by either HHS or USDA. (Those in possession of only the overlap agents need only register with one of the other, not both.) In addition, researchers had to undergo security background checks by the FBI.

Institutions were to be in full compliance by November 12, 2003. An institution that had not been granted a certificate of registration by that date would not be permitted to possess, use, receive, or transfer select agents. Researchers, biosafety experts, and lab administrators complained that the deadline was unrealistic and that the substantial work needed for compliance might interrupt, delay, and possibly discourage research. In fact, the FBI was unable to complete all the security checks, and HHS and USDA were unable to finish reviewing all the applications, in time to meet the deadline. Thus, on November 3, 2003, in order to avoid a disruption of ongoing select agent research, CDC and USDA issued revised regulations allowing labs and researchers to obtain a "provisional" certification, provided they had submitted all the appropriate paperwork. The agencies are now reported to have processed their backlogs, and have certified those laboratories and individuals that met the criteria laid out in the regulation. The agencies are now able to work on new applications.

P.L. 107-188 prohibits federal agencies from releasing information about registered facilities. There was initially some confusion as to whether this provision applied to sharing information with state governments, which could use the information to identify in-state vulnerabilities for emergency planning purposes. While states and individual labs are not subject to the prohibition, CDC urges them to consider security risks that may result from disclosing information about possession of select agents. Such disclosures, as well as the informal sharing of research samples, were part of the routine conduct of scientific inquiry prior to the Select Agent regulation.

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[82] For more information, see the USDA Select Agent program website at [http://www.aphis.usda.gov/programs/ag_selectagent/index.html].

Congress expanded the Select Agent program in response to concerns that the anthrax used in the 2001 mail attacks may have been obtained from a U.S. research facility. Alarmed by reports of weak security at labs where researchers study potentially deadly viruses and bacteria, lawmakers sought to improve lab security without unduly impeding vital biomedical and biodefense research. While some academic and industry scientists have praised the government for striking an appropriate balance between science and security, many in the research community are critical.

Some scientists have discontinued research on select agents because of the security requirements and out of fear that breaking the new law, even inadvertently, could result in stiff criminal penalties. As the anthrax attacks were unfolding in the fall of 2001, officials at the Iowa State University destroyed their research collection of anthrax strains, collected over decades, fearing they would not have the resources to properly safeguard the collection in the new security climate.[83] Scientists lamented the loss of this rich source of information, which could potentially have been helpful in biodefense research and in the response to possible future anthrax attacks.

Clinical laboratories, which may happen upon select agents in the course of their diagnostic work, are required to either transfer or destroy the agents within a week to be exempt from registration, a mandate that may also lead to problems. For example, an agricultural lab recently destroyed cattle tissue samples that tested positive for brucellosis before the results could be confirmed by a state-run lab, leading to confusion about the state's brucellosis-free status.[84] The bacterium that causes brucellosis (*Brucella abortus*) is a select agent, and the lab had elected to destroy the samples (as clinical laboratories are permitted to do under the regulation) rather than transfer them or register with USDA and comply with the strict regulations for storage.

Strategic National Stockpile (CDC). The Strategic National Stockpile (SNS), formerly the National Pharmaceutical Stockpile, was created in 1999 to ensure the availability of antibiotics, antidotes, antitoxins, life-support medications, airway maintenance supplies, and other medical and surgical items needed to respond to bioterrorism or other mass-casualty events. The SNS is meant to augment state, local, and private resources during an emergency. Funds for the SNS are used to purchase, store, and rotate supplies, to assist states and localities in developing plans for deployment, and to provide training and simulation exercises for state and local officials in the use and distribution of deployed SNS assets.[85]

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[83] See Peter J. Boyer, "The Ames Strain," *The New Yorker*, Nov. 12, 2001.

[84] Associated Press, "Wyoming Case Could Lead to Lab Changes," Dec. 6, 2004.

[85] For more information on the SNS, see CDC SNS Home Page at [http://www.bt.cdc.gov/stockpile/index.asp], testimony of James M. Hughes, Director, CDC's National Center for Infectious Diseases, before the Committee on Government Reform, Subcommittee on National Security, Veterans Affairs, and International Relations, U.S. House of Representatives, May 1, 2001, at [http://www.cdc.gov/washington/testimony/bioterro.htm], and the section on state SNS activities in CDC guidance to states, "Continuation Guidance for Cooperative Agreement on Public Health Preparedness and Response for Bioterrorism (continued...)

In 2003, budget authority for the SNS, handled by the CDC prior to 2001, was transferred to the Department of Homeland Security in the Homeland Security Act (P.L. 107-296), with CDC retaining program management responsibilities. In its FY2005 budget proposal, the Administration proposed to transfer budget authority back to HHS, to take advantage of its medical and scientific expertise and its established relationship with state and local health agencies. Authority was transferred back to HHS in July 2004, in P.L. 108-276, the Project BioShield Act.

Stockpile contents are determined through a consultative process involving both medical experts in infectious diseases and toxicology, and experts in intelligence and national security. The SNS is for this reason a good model of preparedness planning, in that it incorporates threat assessment throughout the planning process. Information about the process of determining SNS contents, the decisions made, the locations of the caches, and related information, is classified or otherwise protected from public access.

The SNS has two components, *Push Packages* and *Vendor-Managed Inventories*. Push Packages are federally owned caches of supplies and medications that can be delivered to affected locales within 12 hours of request. Caches are maintained in numerous secure locations around the country, to facilitate their rapid delivery, and they are moved periodically to further safeguard them. Vendor-Managed Inventories (VMI) allow private vendors to maintain stockpiles of supplies and medications in reserve, for federal purchase only if needed. VMI caches contain frequently used products that the vendors rotate to maintain shelf-life, and are intended to be deliverable to affected locales within 36 hours.

When deployed, SNS assets are transferred to state and local public health authorities for distribution. Through the CDC state and local capacity grants, funds have been made available to health departments to prepare for distribution. The SNS has been deployed on several occasions, including the anthrax attacks of 2001 and a false-positive finding of anthrax contamination in a District of Columbia mailroom in 2003.

The most common concern about the SNS is skepticism about the ability of state and local public health agencies to rapidly disseminate stockpile contents in an emergency. States are required to prepare and submit plans to the CDC outlining how they would accomplish this task, which would require a substantial complement of personnel, involve numerous logistical tasks in patient screening and dispensing, and require the presence of public safety officials. States are also encouraged to test this capability through tabletop or "wet" exercises.[86]

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[85] (...continued)
— Budget Year Five," Focus Area A: Preparedness Planning and Readiness Assessment, June 21, 2004, at [http://www.bt.cdc.gov/planning/continuationguidance/index.asp].

[86] For more information, see Association of State and Territorial Health Officials, *Exercising the Strategic National Stockpile: Lessons Learned and Tools for Application*, Jan. 2004, at [http://www.astho.org/pubs/Exercisingthestockpile.pdf].

Food Safety Programs (FDA). Title III of the Public Health Security and Bioterrorism Preparedness and Response Act (P.L. 107-188) contains several provisions to protect the nation's food supply from intentional contamination. The act authorizes FDA to hire new border inspectors, develop new methods of detecting contaminated foods, and coordinate with state food safety regulators. The act also grants FDA several new regulatory authorities. For the first time, all foreign and domestic food facilities are required to register with the agency. Also, FDA now requires prior notice of all imported food shipments and may detain suspicious foods for inspection.

While many feel that these new authorities were essential to further the agency's mission in an age of terror threats, others are concerned about implementation of the new regulations and possible adverse effects on commerce. Some feel that new recordkeeping requirements will pose a burden for industry but will not substantially improve food safety. Further, there was initial concern that FDA would not be able to review declarations of imported food shipments expediently, and that the shipments would be delayed as a result. The FDA established phased-in implementation plans for this and some other provisions of the law, in an effort to minimize commercial disruptions.[87]

Programs That Build State and Local Capacity

State and Local Preparedness Grants (CDC). In 1999, the CDC launched a program to fund state health departments for bioterrorism preparedness, recognizing that without a dedicated source of funds to prepare for diseases not routinely seen, some states might not be able to prioritize these activities. The program, officially called the *Cooperative Agreement on Public Health Preparedness and Response for Bioterrorism*, was announced in the Spring of 1999. Technically, funding through this program is made available not through grants but through *cooperative agreements* between the CDC and states, in which the parties cooperate in designating activities to be performed. Commonly these funds are referred to as grants, though, as they will be in this report. This specific program is often referred to in HHS documents and elsewhere as "state and local capacity" or "state and local preparedness" grants for public health.

Authority for this program is established in the Public Health Service Act under provisions for public health emergencies (42 U.S.C. § 247d-3). When the program began in 1999, grants were to be competitively awarded to eligible entities, which included states, subdivisions of states, or consortia of states. Funds were to be used to address core public health capacity needs through planning, training, and laboratory and information technology improvements. The funds were not strictly limited to bioterrorism preparedness but rather were to be used to prepare for public health emergencies, including significant outbreaks of infectious diseases or bioterrorism. The program was reauthorized in the Public Health Threats and Emergencies Act of 2000 (Title I of the Public Health Improvement Act, P.L. 106-

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[87] For more information on new food safety and security provisions, see CRS Report RL31853, *Food Safety Issues in the 109th Congress*, by Donna U. Vogt.

505), and funding was authorized at $50 million for FY2001 and such sums as may be necessary through 2006.

Following the 2001 terrorist attacks, the program was reauthorized in the Public Health Security and Bioterrorism Preparedness and Response Act (P.L. 107-188), signed in June 2002, with funding authorized at $1.08 billion for FY2002 and such sums as may be necessary through 2006. This latest reauthorization converted the program to formula grants for states, with a base amount per state and an additional amount according to population. All states were to receive annual awards according to this formula, as were the District of Columbia and the Commonwealth of Puerto Rico. The territories were each to receive awards based on a different formula. In addition, the Secretary of HHS was permitted to designate for awards three additional 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." The three most populous U.S. cities, Chicago, Los Angeles County, and New York City, were designated, and the populations of these cities were subtracted from the population of the respective states in calculating the state awards.

In the FY2002 Defense appropriations bill (P.L. 107-117), signed in January 2002, Congress provided $940 million in supplemental funds for the program. Funds were distributed to awardees contingent on their completion of spending proposals, to be administered by the senior health officials in each state, territory or municipality. Most of the funds were available to awardees by August 2002. CDC expanded the existing cooperative agreement guidance for the program to reflect the increased funding level. Guidance was released in the Spring of 2002, directed at improving capacity in six *Focus Areas*:

- *Focus Area A*: preparedness planning and readiness assessment;
- *Focus Area B:* surveillance and epidemiology;
- *Focus Area C:* laboratory capacity for biologic agents;
- *(Focus Area D:* not funded for all states in 2002. See below.)
- *Focus Area E:* Health Alert Network, communications and information technology;
- *Focus Area F:* risk communication and health information dissemination; and
- *Focus Area G:* education and training.

Focus Areas F and G were added in 2002, but Focus Areas A through E were created in guidance when the program began in 1999. Focus Area D, laboratory capacity for chemical agents, was funded in four states in 1999 and a fifth in 2000, and was continued exclusively for those five states through 2002, eventually expanding to other states in subsequent years.[88] To prioritize activities for FY2002 funds, the CDC designated 13 *Critical Benchmarks* for preparedness, activities the states were required to perform. The benchmarks for FY2002 through FY2004 are listed in **Appendix C.**

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[88] States first funded for chemical terrorism laboratory preparedness were CA, MI, NM, NY, and VA.

CDC guidance for FY2003 funds followed the same general framework as the FY2002 guidance, but with some differences that reflect both the natural progression in an ongoing program and experience gained over the prior year. In January 2004, CDC presented a review of state compliance with FY2002 Critical Benchmarks as of August 2003, finding that almost all states had completed initial planning for all 14 benchmarks, and were on their way toward achieving the goals set for FY2003 funds as well.[89] While the FY2002 guidance focused mainly on planning, the FY2003 guidance placed greater emphasis on activities that would demonstrate improved preparedness. The main differences included: availability of funding to increase laboratory capacity for chemical agents; more specific guidance on smallpox preparedness activities; and explicit recommendations and requirements that planning activities address mental health needs associated with terrorist attacks. The FY2003 guidance also required that states implement a more rigorous fiscal accounting system, and document that a significant portion of local public health officials concur with the proposed use of funds.

As seen in **Appendix C,** benchmarks did not change appreciably between FY2003 and FY2004,[90] partly because states were having some difficulty meeting the requirements and partly because HHS and CDC were working toward an alternative method of programmatic accountability. An exception was the addition of a new *Cross-cutting Benchmark* (i.e., it applied to both CDC and HRSA grant program activities) for pandemic influenza preparedness. The cooperative agreement was written in 1999 to cover a five-year period and is to be entirely rewritten for the FY2005 funding cycle. New guidance, expected in Spring 2005, may no longer be organized by Focus Areas, and is expected to include a new set of performance measures that are intended to better measure actual preparedness, and to reflect the mandate that federal fund recipients plan their activities in compliance with the National Incident Management System guidelines released in March 2004 (discussed in greater depth in the section on **Issues for the 109th Congress**).

Hospital Preparedness Grants (HRSA). A program of grants to states for hospital preparedness was first authorized in P.L. 107-188, the Bioterrorism Act, and begun in 2002. The *National Bioterrorism Hospital Preparedness Program* is administered by HRSA. The goal is to improve the ability of communities to respond to emergencies that cause mass casualties, including natural disasters, explosions, and biological or chemical attacks. The funds (which are awarded as cooperative agreements but are commonly called grants) are to be used for planning, training, equipment and other activities to coordinate the variety of healthcare entities in a community, including hospitals, clinics, EMS services, laboratories, pharmacies, and others. Program priorities in law are the same as those for the CDC grants, namely preparedness for bioterrorism, other infectious diseases, and other public health threats and emergencies. Funds are awarded according to a formula of a base amount plus an amount according to population, to the same awardees as the CDC grants (50

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[89] CDC, *State and Local Preparedness — Progress in Achieving Critical Benchmarks*, presented by Joseph M. Henderson at the meeting of the HHS Secretary's Council on Public Health Emergency Preparedness, Jan. 22, 2004, at [http://www.hhs.gov/ophep/council.html].

[90] The FY2004 guidance document is available at [http://www.bt.cdc.gov/planning/continuationguidance/index.asp].

states, the District of Columbia, territories, and the cities of New York and Chicago, and Los Angeles County), and are also administered by the state, territorial or municipal health officials.

The program was first funded in FY2002 at $135 million, and grants were to be distributed to states contingent upon submission of a planning proposal. The grant guidance for FY2002 contained three required preparedness activities called *Critical Benchmarks*, along with a number of additional optional activities. (Critical Benchmarks are listed in **Appendix C.**)

The program was funded at $514 million for FY2003, and the subsequent grant guidance was more extensive, reflecting both the increased funding level and experience gained over the first year of the program. Guidance was expanded in some notable areas, including the directive for states to assure surge capacity to care for victims of different types of events. Specifically, guidance called for planning for surges in bed capacity, isolation, workforce, pharmacy/dispensing, mass decontamination and mental health care. The 2003 guidance set sixteen Critical Benchmarks across six *Priority Areas*. The Priority Areas are:

- Administration;
- Regional surge capacity;
- Emergency medical services;
- Linkages to public health departments;
- Education and preparedness training; and
- Terrorism preparedness activities.

The guidance also stipulated that 80% of the funding awarded to state health departments should be passed through to hospitals, emergency medical systems, and other healthcare entities.

In January 2004, HRSA reported progress toward achieving Critical Benchmarks in the hospital preparedness program.[91] Despite this, the program has been charged over the years with lacking sufficient focus to adequately direct funds in meaningful directions, or with failing to assure that emergency healthcare services will be available consistently across jurisdictions. The healthcare sector, in response to growing costs and constrained revenues, is marching to an ever-louder drumbeat of efficiency, and eliminating unused capacity. Ensuring that unused assets (e.g. beds, workers, equipment) will be held in reserve for a crisis will remain a challenge.

Cities Readiness Initiative (CDC). In May 2004, the Cities Readiness Initiative (CRI) was announced as a means for the federal government to provide direct assistance to cities to facilitate their ability to deliver medicines and supplies

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[91] HRSA, *National Bioterrorism Hospital Preparedness Program: Progress Toward Achieving Critical Benchmarks*, presented by Rick Smith at the meeting of the HHS Secretary's Council on Public Health Emergency Preparedness, Jan. 22, 2004, at [http://www.hhs.gov/ophep/council.html].

from the Strategic National Stockpile during a catastrophic event.[92] Twenty-one cities were funded initially. City selection was based on a number of factors, including population size. Some believe the cities chosen may be those with deployed BioWatch programs in place, though this cannot be confirmed through publicly available information.

Stated objectives for the CRI include building the capacity for cities to provide antibiotics to the city's population within 48 hours of a decision to do so, and integration of all of a city's relevant emergency services, which include Fire, Police, EMS, and health departments. One element of the program is to explore the use of the postal delivery system to meet the distribution goal. Proponents note that the U.S. Postal Service already delivers to every U.S. mailing address six days a week.

Concerns have been raised about the feasibility of the proposal and its many interdependent elements, such as the willingness of postal workers to enter quarantine zones in an emergency, and whether stockpiled medicines should be stored locally or centrally.[93]

Information Technology Programs (CDC). Several related information technology programs at CDC are designed to improve inter-connectivity and to speed data and information sharing between agencies and across levels of government, to facilitate planning, response and recovery in health emergencies. These programs are incorporated in the CDC grant program for state and local public health capacity.[94]

The **Health Alert Network (HAN)** is a nationwide information and communications system for distribution of health alerts, prevention guidelines and other information, distance learning, national disease surveillance, and electronic laboratory reporting. The HAN program allows states and localities to improve communication with CDC and each other. States are required to have 90% of key stakeholders involved in a public health emergency (e.g., local health departments, hospitals and EMS services) in their state integrated into HAN, as a requirement of the CDC grants for state public health capacity. (See Critical Benchmarks for Focus Area E in **Appendix C**.)

The **National Electronic Disease Surveillance System (NEDSS)**: NEDSS is an initiative to standardize data and information systems in public health. The goal is to have integrated surveillance systems that can transfer public health, laboratory, and clinical data efficiently and securely over the Internet.

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[92] See CDC, Cities Readiness Initiative Home Page, at [http://www.bt.cdc.gov/cri/], and Secretary of HHS Tommy G. Thompson, letter to congressional appropriators regarding proposal to reallocate CDC funds, May 19, 2004.

[93] For example, see Ian Urbina, "City Weighs Plans to Deliver Medicine to Public After Attack," *The New York Times,* Feb. 7, 2005.

[94] More information on these programs is available on CDC websites as follows: for the HAN network, [http://www.bt.cdc.gov/documentsapp/HAN/han.asp], for the NEDSS program, [http://www.cdc.gov/nedss/index.htm], and for Epi-X, [http://www.cdc.gov/epix/].

The **Epidemic Information Exchange (Epi-X)** is a secure Web-based communications network for federal, state, and local epidemiologists, laboratorians and other individuals in the public health community who are designated by their, agencies. Epi-X provides the capacity for instant notification about urgent public health events and a searchable database with information on outbreaks and unusual health events.

Appendix B: Selected Programs in the Department of Homeland Security

Public health-related programs in DHS are found in the Office of State and Local Government Coordination and Preparedness (OSLGCP), the Emergency Preparedness and Response Directorate (EPR), and the Science and Technology Directorate (S&T).

Metropolitan Medical Response System (OSLGCP)

The Metropolitan Medical Response System (MMRS) is a program of contracts with major cities to assist the coordination of local government entities in preparedness. The program began in 1995 in HHS, and was transferred to the EPR Directorate at DHS in the Homeland Security Act, effective in March 2003. In 2004 it was moved to OSLGCP, where other DHS state and local grant programs are administered. The goal of MMRS is to coordinate the efforts of local law enforcement, firefighters, HAZMAT teams, EMS, hospital, public health and other personnel to improve all-hazards response capabilities. MMRS awards allow local governments to purchase equipment and supplies (such as local stockpiles of medical countermeasures), and contracts require the development of detailed plans showing how the variety of local government entities will coordinate response to a biological or chemical event. Currently, more than 120 cities have received MMRS awards.[95]

Stating that MMRS activities can be funded through other DHS grant programs, the Administration slated the program for elimination for FY2005. Congress continued funding the program at $30 million for FY2005, which was decreased from $50 million in FY2004. In 2002 the Institute of Medicine published the report of its evaluation of the program, which discussed, among other things, the complex task of developing performance measures for preparedness programs.[96]

National Disaster Medical System (EPR)

The National Disaster Medical System (NDMS) was established in HHS in 1984 to provide medical and ancillary services when a disaster overwhelms local emergency services. NDMS was most recently reauthorized through 2006 in P.L. 107-188, the Bioterrorism Act, and was transferred to DHS in the Homeland Security Act effective in March 2003. NDMS is a partnership of HHS, DHS, the Departments of Defense and Veterans Affairs, state and local governments, and the private sector. The system consists of a number of response teams that can deploy to a scene rapidly and set up self-sustained response operations for 72 hours, until additional federal support arrives. NDMS also provides for transportation of large numbers of casualties from an impacted site to distant locations for care. There are multiple teams in a number of "specialties," including Disaster Medical Assistance Teams (DMATs) of physicians, nurses, support personnel and supplies, Disaster Mortuary

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[95] See the MMRS Home Page at [http://mmrs.fema.gov/].

[96] Institute of Medicine, *Preparing for Terrorism: Tool for Evaluating the Metropolitan Medical Response System Program*, 2002.

Teams (DMORTs) that assist in mass mortality and victim identification efforts, as well as nursing, pharmacy, and veterinary teams. NDMS teams can be requested by the Secretary of HHS, who is in the lead for public health and medical services during a disaster according to the National Response Plan. Medical professionals on the teams must be licensed to practice in at least one U.S. jurisdiction and are not generally federal employees unless deployed, at which time they are considered "federalized" for liability and compensation purposes.[97]

The NDMS is appropriated through the "Public Health Programs" budget line of the EPR Directorate, and received funding of $34 million in both FY2004 and FY2005.

BioWatch (S&T)

The Department of Homeland Security (DHS) Science and Technology Directorate (S&T) is responsible for the BioWatch program, a network of environmental sensors to detect possible aerosol releases of bioterrorism agents in several major cities. The program has three main elements, sampling, analysis, and response, each coordinated by different agencies. The Environmental Protection Agency (EPA) maintains the sampling component, the sensors that collect airborne particles. The CDC coordinates the laboratory testing of the samples, though much of the testing is actually carried out in state and local public health laboratories. Local jurisdictions are responsible for the public health response to positive findings. The FBI is designated as the lead agency for the law enforcement response if a bioterrorism event is detected. At least 30 cities have been chosen as locations for these sensors.[98]

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[97] See the NDMS Home Page at [http://www.ndms.dhhs.gov/].

[98] For more information, see CRS Report RL32152, *The BioWatch Program: Detection of Bioterrorism*, by Dana A. Shea and Sarah A. Lister.

Appendix C: Focus Areas, Critical Benchmarks, and Priority Areas for the CDC and HRSA Public Health and Hospital Preparedness Grants, FY2002 through FY2004

Focus or Priority Area	Critical Benchmarks, FY2002	Critical Benchmarks, FY2003	Critical Benchmarks, FY2004
CDC Public Health Preparedness Program			
CDC Focus Area A: Preparedness Planning and Readiness Assessment	1. Designate Senior Public Health Official within State health department as Executive Director of State Bioterrorism Preparedness and Response Program. 2. Establish advisory committee with members from a variety of health agencies and first responders. 3. Prepare timeline for development of statewide plan for preparedness and response for bioterrorist events, infectious disease outbreaks, or other public health emergencies. 4. Prepare a timeline for the assessment of statutes, regulations, and ordinances within the state and local public health jurisdictions regarding emergency public health measures. 5. Prepare timeline for the development of a statewide plan for responding to incidents of bioterrorism. 6. Prepare timeline for the development of regional plans to respond to bioterrorism. 7. Develop an interim plan to receive and manage items from the National	1. Develop and maintain a financial accounting system, tracking expenditures by focus area, critical capacity, and funds provided to local health agencies. 2. Develop or enhance scalable plans that support local, statewide, and regional response to incidents of bioterrorism, catastrophic infectious disease, such as pandemic influenza, other infectious disease outbreaks, and other public health threats and emergencies. 3. Maintain system for 24/7 notification or activation of the public health emergency response system. 4. Exercise all plans annually to demonstrate proficiency in responding to bioterrorism, other infectious disease outbreaks, and other public health threats and emergencies. 5. Review and comment on documents regarding the National Incident Management System, and maintain description of roles and responsibilities of public health departments, hospitals, and other healthcare entities in the statewide Incident Management System.	1. Develop and maintain a financial accounting system capable of tracking expenditures by focus area, critical capacity, and funds provided to local health agencies. 2. Develop or enhance scalable plans that support local, statewide, and regional response to incidents of bioterrorism, catastrophic infectious disease, such as pandemic influenza, other infectious disease outbreaks, and other public health threats and emergencies. 3. Maintain system for 24/7 notification or activation of the public health emergency response system. 4. Exercise all plans annually to demonstrate proficiency in responding to bioterrorism, other infectious disease outbreaks, and other public health threats and emergencies. 5. Review the National Incident Management System (NIMS) and complete an assessment of conforming changes needed, if any, for your state health department and partner agencies.

Focus or Priority Area	Critical Benchmarks, FY2002	Critical Benchmarks, FY2003	Critical Benchmarks, FY2004
	Pharmaceutical Stockpile, including mass distribution of antibiotics, vaccines, and medical materiel. 8. Prepare timeline for developing a system to receive and evaluate urgent disease reports from all parts of the state (or city) and local public health jurisdictions on a 24/7 basis.	6. Develop or maintain a Strategic National Stockpile preparedness program.	6. Develop or maintain a Strategic National Stockpile preparedness program.
CDC Focus Area B: Surveillance and Epidemiology Capacity	9. Assess current epidemiologic capacity and prepare timeline for providing at least one epidemiologist for each metropolitan area with a population greater than 500,000.	7. Develop/maintain a system to receive and evaluate urgent disease reports on a 24/7 basis. 8. Maintain a list of physicians and other providers with experience in the diagnosis and treatment of infectious, chemical or radiological conditions (including psychological and behavioral) that may result from terrorism. 9. Establish a secure, Web-based disease reporting and notification system. 10. Assess annually the 24/7 capacity to respond to urgent reports of outbreaks and other public health emergencies. 11. Assess annually the adequacy of public health response to catastrophic diseases (e.g., pandemic influenza), outbreaks, and other public health emergencies.	7. Complete development and maintain a system to receive and evaluate urgent disease reports on a 24/7 basis. 8. Maintain a list of physicians and other providers with experience in the diagnosis and treatment of infectious, chemical, or radiological conditions (including psychological and behavioral) that may result from terrorism. 9. Establish a secure, Web-based disease reporting and notification system. 10. Assess annually, the 24/7 capacity to respond to urgent reports of outbreaks and other public health emergencies. 11. Assess annually the adequacy of public health response to catastrophic diseases (e.g., pandemic influenza), outbreaks, and other public health emergencies.

Focus or Priority Area	Critical Benchmarks, FY2002	Critical Benchmarks, FY2003	Critical Benchmarks, FY2004
CDC Focus Area C: Laboratory Capacity — Biological Agents	10. Develop a plan to improve working relationships and communication between Level A (clinical) laboratories and Level B/C laboratories (i.e., Laboratory Response Network laboratories), as well as other public health officials.	12. Implement an integrated response plan for public health, hospital-based, food-testing, veterinary, and environmental laboratories during a public health emergency. 13. Ensure that capacity exists for LRN-validated testing as methods are approved. 14. Conduct at least one exercise annually that specifically tests laboratory readiness.	12. Implement an integrated response plan for public health, hospital-based, food-testing, veterinary, and environmental laboratories during a public health emergency. 13. Ensure that capacity exists for LRN-validated testing as methods are approved. 14. Conduct at least one exercise annually that specifically tests laboratory readiness.
CDC Focus Area D: Laboratory Capacity — Chemical Agents	*(Focus Area D was not funded for all states in FY2002. Only those states previously funded, CA, MI, NY, NM, and VA, continued to receive funding for laboratory readiness for chemical terrorism.)*	*(States can choose to meet one of three levels of preparedness, noted below. All states must achieve at least Level One preparedness.)* 15. (Level One) Hire and train a chemical terrorism laboratory coordinator and assistant coordinator. *(Six states sought funding for Level One status for FY2003: KY, MT, OH, OK, OR and WY, as well as the cities of Chicago, Los Angeles and New York.)* 16. (Level Two) Participate in at least one exercise annually that specifically tests chemical terrorism laboratory readiness to identify at least one chemical threat agent. *(Most states — all those not mentioned as seeking Level One or Level Three status, as well as the District of Columbia, requested funding for Level Two status for FY2003.)*	*(States can choose to meet one of three levels of preparedness, noted below. All states must achieve at least Level One preparedness.)* 15. (Level One) Hire and train a chemical terrorism laboratory coordinator and assistant coordinator. 16. (Level Two) Participate in at least one exercise annually that specifically tests chemical terrorism laboratory readiness to identify at least one chemical threat agent.

Focus or Priority Area	Critical Benchmarks, FY2002	Critical Benchmarks, FY2003	Critical Benchmarks, FY2004
		17. (Level Three) Participate in at least one exercise annually that specifically tests chemical terrorism laboratory readiness to detect at least two chemical threat agents. *(Only the original Level Three states requested continued funding at that level for FY2003: CA, MI, NM, NY, and VA.)*	17. (Level Three) Participate in at least one exercise annually that specifically tests chemical terrorism laboratory readiness to detect at least two chemical threat agents.
CDC Focus Area E: Health Alert Network/ Communications and Information Technology	11. Prepare a timeline for a plan that ensures that 90% of the population is covered by the Health Alert Network (HAN). 12. Prepare a timeline for the development of a communications system that provides a 24/7 flow of critical health information among hospital emergency departments, state and local health officials, and law enforcement officials.	18. Implement a plan for integrating key public health response stakeholders including a 24/7 flow of critical health information. 19. Ensure that at least 90% of key stakeholders involved in a public health response can receive and send critical information. 20. Routinely assess the timeliness and completeness of redundant means of communication for responders. 21. Ensure that the technical infrastructure exists to exchange a variety of data types. 22. Adopt the Logical Observation Identifiers Names and Codes (LOINC) as the standard codes for electronic data exchange between laboratories in health departments, hospitals, and others.	18. Implement a plan for integrating key public health response stakeholders, including a 24/7 flow of critical health information. 19. Ensure that at least 90% of key stakeholders involved in a public health response can receive and send critical information. 20. Routinely assess the timeliness and completeness of redundant means of communication for responders. 21. Ensure that the technical infrastructure exists to exchange a variety of data types. 22. Adopt the Logical Observation Identifiers Names and Codes (LOINC) as the standard codes for electronic data exchange between laboratories in health departments, hospitals, and others.
CDC Focus Area F: Risk Communication and Health Information Dissemination (Public Information and Communication)	13. Develop an interim plan for risk communication and information dissemination to educate the public regarding exposure risks and effective public response.	23. Implement a plan for crisis and emergency risk communication. 24. Conduct training, drills, and exercises using the communications system.	23. Implement a plan for crisis and emergency risk communication. 24. Conduct training, drills, and exercises using the communications system.

Focus or Priority Area	Critical Benchmarks, FY2002	Critical Benchmarks, FY2003	Critical Benchmarks, FY2004
CDC Focus Area G: Education and Training	14. Prepare a timeline to assess training needs, with emphasis on emergency department personnel, infectious disease specialists, public health staff, and other healthcare providers.	25. Initiate a one-year training plan for the state and local public health workforce, healthcare professionals, and laboratorians, across all Focus Areas.	25. Implement a training plan for the state and local public health workforce, healthcare professionals, and laboratorians, across all Focus Areas.
HRSA Hospital Preparedness Program			
HRSA Critical Benchmarks for FY2002 *(HRSA guidance for FY2003 and FY2004 divides HRSA hospital preparedness activities into Priority Areas, while the FY2002 guidance included three Critical Benchmarks encompassing the entire program.)*	15. Designate a Coordinator for Bioterrorism Hospital Preparedness Planning. 16. Establish a Hospital Preparedness Planning Committee to provide guidance, direction, and oversight to the state health department in planning for bioterrorism response. 17. Devise a plan for a potential epidemic in each state or region. Recognizing that many of these patients may come from rural areas served by centers in metropolitan areas, planning must include the surrounding counties likely to impact the resources of these cities.	*(HRSA incorporated Priority Areas in FY2003. See below.)*	*(HRSA incorporated Priority Areas in FY2003. See below.)*
HRSA Priority Area #1: Governance and Administration	*(Not applicable. Priority Areas were instituted in FY2003 guidance.)*	#1: Develop and maintain a financial accounting system capable of tracking expenditures by priority area, by critical benchmark, and by funds allocated to hospitals and other healthcare entities.	#1: Develop and maintain a financial accounting system capable of tracking expenditures by critical benchmark and by funds allocated to hospitals and other healthcare entities.
HRSA Priority Area #2: Regional Surge Capacity Plan		#2-1: Establish a system that allows the triage, treatment, and disposition of 500 adult and pediatric patients per 1,000,000	#2-1: Bed Capacity: Establish a system that allows the triage, treatment, and initial stabilization of 500 adult and pediatric

Focus or Priority Area	Critical Benchmarks, FY2002	Critical Benchmarks, FY2003	Critical Benchmarks, FY2004
		population (or no fewer than 500 patients per jurisdiction).	patients per 1,000,000 above the current daily staffed bed capacity, with acute illnesses or trauma requiring hospitalization from a chemical, biological, radiological, nuclear, or explosive incident.
		#2-2: Upgrade or maintain airborne infectious disease isolation capacity to have at least one negative pressure, HEPA-filtered isolation facility per awardee.	#2-2: Isolation Capacity: Ensure that all participating hospitals have the capacity to maintain, in negative pressure isolation, at least one suspected case of a highly infectious disease.
		#2-3: Establish a response system that allows the immediate deployment of 250 or more additional patient care personnel per 1,000,000 population in urban areas, and 125 or more additional patient care personnel per 1,000,000 of population in rural areas. #2-4: Develop a system that allows the credentialing and supervision of clinicians not normally working in facilities responding to a terrorist incident. #2-5: Establish local or regional systems whereby pharmacies based in hospitals or otherwise participating in the local or regional healthcare response plan have surge capacity to provide pertinent pharmaceuticals in response to bioterrorism or other public health emergencies.	#2.3: Worker Surge Capacity: Establish a response system that allows the immediate deployment of additional healthcare personnel in support of surge bed capacity noted in Critical Benchmark # 2-1. #2.4: Advance Registration: Develop a system that allows for the advance registration and credentialing of clinicians needed to augment a hospital or other medical facility to meet patient/victim care increased surge capacity needs. #2.5: Pharmacy Surge Capacity: Establish regional plans that insure a sufficient supply of pharmaceuticals to provide prophylaxis for 3 days to hospital personnel (medical and ancillary staff), emergency first responders and their families as well as for the general community.

Focus or Priority Area	Critical Benchmarks, FY2002	Critical Benchmarks, FY2003	Critical Benchmarks, FY2004
		#2-6: Ensure adequate personal protective equipment (PPE) to protect 250 or more healthcare personnel per 1,000,000 population in urban areas, and 125 or more healthcare personnel per 1,000,000 population in rural areas, during a biological, chemical, or radiological incident.	#2.6: Personal Protective Equipment: Ensure adequate PPE per region, to protect current and additional healthcare personnel during an incident. This benchmark is tied directly to number of healthcare personnel the awardee must provide to support surge capacity for beds.
		#2-7: Ensure that adequate portable or fixed decontamination systems exist for managing 500 adult and pediatric patients and healthcare workers per 1,000,000 population, who have been exposed to biological, chemical, or radiological agents. #2-8: Establish a system that provides for a graded range of acute psychosocial interventions and longer-term mental health services to 5,000 adult and pediatric clients and healthcare workers per 1,000,000 population.	#2.7: Decontamination: Ensure that adequate portable or fixed decontamination systems exist for managing adult and pediatric patients and healthcare personnel who have been exposed during an incident, in accordance with surge capacity for beds and workers. #2.8: Behavioral (Psychosocial) Health: Enhance the capacity and training of healthcare professionals to recognize, treat and coordinate care for behavioral health consequences of bioterrorism or other public health emergencies.

Focus or Priority Area	Critical Benchmarks, FY2002	Critical Benchmarks, FY2003	Critical Benchmarks, FY2004
		#2-9: *(Trauma and Burn Care Capacity was optional in FY2003)*	#2.9: Trauma and Burn Care: Enhance statewide trauma and burn care capacity. Ensure capability to provide trauma care to at least 50 severely injured adult and pediatric patients per million of population.
		#2-10: Establish a secure and redundant communications system that ensures connectivity during a terrorist incident between healthcare facilities and state and local health departments.	#2.10: Surge Capacity, Communications, and Information Technology: Establish secure and redundant communications that ensure connectivity during an incident between healthcare facilities and health departments, EMS, emergency management and public safety agencies, neighboring jurisdictions, and federal public health officials.
HRSA Priority Area #3: Emergency Medical Services		#3: Develop a mutual aid plan for upgrading and deploying EMS units in jurisdictions they do not normally cover, in response to a mass casualty incident due to terrorism.	#3: Enhance the statewide mutual aid plan for upgrading and deploying EMS units in jurisdictions/regions they do not normally cover, in response to a mass casualty incident due to terrorism. This plan must ensure the capability of providing EMS triage and transportation for at least 500 adult and pediatric patients per million population.
HRSA Priority Area #4: Linkages to Public Health Departments		#4-1: Implement a hospital laboratory program coordinated with currently funded CDC laboratory capacity efforts, and which provides rapid and effective hospital laboratory services responding to terrorism and other public health emergencies.	#4-1: Implement a hospital laboratory program coordinated with currently funded CDC laboratory capacity efforts, and which provides rapid and effective hospital laboratory services in response to terrorism and other public health emergencies.
		#4-2: Enhance the capability of rural and urban hospitals, clinics, emergency medical services systems, and poison control centers	#4-2: Enhance the capability of rural and urban hospitals, clinics, emergency medical services systems, and poison control centers

Focus or Priority Area	Critical Benchmarks, FY2002	Critical Benchmarks, FY2003	Critical Benchmarks, FY2004
		to report syndromic and diagnostic data that is suggestive of terrorism to their associated local and state health departments on a 24/7 basis.	to report syndromic and diagnostic data that is suggestive of terrorism to their associated local and state health departments on a 24/7 basis.
HRSA Priority Area #5: Education and Preparedness Training		*#5: (The Training benchmark was optional in FY2003.)*	#5: Awardees will utilize competency based education and training programs for adult and pediatric pre-hospital, hospital, and outpatient healthcare personnel responding to a terrorist incident.
HRSA Priority Area #6: Terrorism Preparedness Exercises		#6: Conduct at least one bioterrorism disaster exercise during FY2003 that covers a large-scale epidemic scenario affecting both adults and children.	#6: As part of the state or jurisdiction's bioterrorism hospital preparedness plan, exercises/drills will be conducted during FY2004. These exercises/drills should encompass at least one biological agent

Focus or Priority Area	Critical Benchmarks, FY2002	Critical Benchmarks, FY2003	Critical Benchmarks, FY2004
CDC/HRSA Cross-Cutting Benchmarks			
Cross-Cutting Benchmark #1: Incident Management	*(Not Applicable. Cross-Cutting Benchmarks were instituted in FY2003 guidance)*	Describe the roles and responsibilities of public health departments and the hospital community (including their supporting healthcare systems) related to incident management at the state and regional levels — including interstate as well as intrastate regions, as appropriate. Review and comment National Incident Management System draft documents, other activities.	*(Guidance states that the HHS expects awardees to have achieved Cross-Cutting Benchmarks 1, 2, 3, and 5 on or before the end of the FY2003 budget period and thus is not repeating them in FY2004 guidance. However, awardees that have not achieved these four benchmarks by the end of the FY2003 budget period may be subject to funding restrictions on their FY2004 award.)*
Cross-Cutting Benchmark #2: Joint Advisory Committee for CDC and HRSA Cooperative Agreements		Describe the activities of the advisory committees for the CDC and HRSA cooperative agreements during the FY2002 budget period. Establish an Advisory Committee to assist the jurisdiction's senior public health official in overseeing both the CDC and HRSA cooperative agreements. (Required representation on the committee is specified.)	
Cross-Cutting Benchmark #3: Laboratory Connectivity		Establish relationships among analytical laboratories in the jurisdiction (and other jurisdictions as appropriate) relevant to preparedness for and response to public health emergencies. Complete an inventory of analytical laboratories and of existing cooperative agreements among them.	
Cross-Cutting Benchmark #4: Laboratory Data Standard		Adopt the Logical Observation Identifiers Names and Codes (LOINC) as the standard codes for electronic data exchange between laboratories in health departments, hospitals,	*(Guidance states that implementation of the LOINC data standard may be limited to occasions when laboratory information systems are upgraded or replaced.*

Focus or Priority Area	Critical Benchmarks, FY2002	Critical Benchmarks, FY2003	Critical Benchmarks, FY2004
		and others.	*Therefore, the benchmark is repeated in FY2004 guidance to foster incremental introductions of the LOINC data standards when possible.)*
Cross-Cutting Benchmark #5: Jointly Funded Health Department/ Hospital Activities		Develop and maintain a database displaying activities funded jointly by the CDC and HRSA cooperative agreements and, as applicable, other sources.	*(Guidance states that HHS expects awardees to achieve Benchmark 5 before the end of FY2003 and thus is not repeating this benchmark in FY2004 guidance. However, awardees that have not achieved these four benchmarks by the end of the FY2003 budget period may be subject to funding restrictions on their FY2004 award.)*
Cross-Cutting Benchmark #6: Pandemic Influenza		*(Benchmark introduced in FY2004)*	Describe the jurisdiction's current plan for responding to pandemic influenza and discuss the envisioned approach to achieving this benchmark.