

ISSUE REPORT

EMBARGOED UNTIL TUES DEC 9, 2008 AT 10 AM

Ready or Not?

PROTECTING THE PUBLIC'S HEALTH FROM
DISEASES, DISASTERS,
AND BIOTERRORISM

2008



DECEMBER 2008

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Introduction

More than seven years after the terrorist attacks of September 11, 2001 and the subsequent anthrax-laced mailings in October of that year, and three years after Hurricanes Katrina and Rita devastated the Gulf Coast region, America has grown complacent about public health emergency preparedness. In January 2009, President-elect Barack Obama will be inaugurated as president. Periods of governmental transition, here and abroad, are often seen as a time when new leaders are tested in international affairs, especially during war-time. Many national security experts are concerned that the United States could face another terrorist attack, which requires higher levels of vigilance, including increased attention to possible bioterror threats.¹ President-elect Obama has noted the importance of assuring a smooth transition. Asked about his transition team's priorities he told CBS's *60 Minutes*, "Number one, I think it's important to get a national security team in place because transition periods are potentially times of vulnerability to a terrorist attack."²

While significant progress has been made to better protect the country from health emergencies, funding for essential programs has been cut, putting these improvements in jeopardy. Additionally, a number of critical areas of preparedness still have significant gaps, including surge capacity and biosurveillance systems, and these problems are less likely to be addressed as funding decreases.

Federal funding for state and local preparedness is down more than 25 percent from FY 2005 levels. In addition, there is no longer any supplemental funding for states and localities for pandemic influenza preparedness, even though state and local public health departments are expected to play a key role in the nation's strategy for combating pandemic influenza. State and local governments will not be able to make up for the shortfalls in the current economic climate. According to the Center on Budget and Policy Priorities, 33 states are facing shortfalls to their 2009 state budgets, and 16 states already project shortfalls to their 2010 budgets. At the current rate

of economic deterioration, and based on the course of past recessions, the Center predicts that 2010 state budget gaps will be about \$100 billion.³ Trust for America's Health (TFAH) is deeply concerned about the potential impact of these budget cuts on states' ability to be prepared for emergencies.

Pandemic flu, emerging infectious diseases, terrorism, and catastrophic natural disasters remain serious threats to our national security. Instead of cutting these programs, President-elect Obama, his administration, and the 111th Congress must prioritize public health emergency preparedness and dedicate sustained and increased funding to ensure Americans are well protected.

Americans expect and rely on the government to protect them from terrorism and natural disasters, since people have little power to protect themselves from these crises. In a recent survey conducted by Greenberg Quinlan Rosner Research and Public Opinion Strategies for TFAH, 61 per-

cent of Americans say that preparing for major disasters is a very important issue for government to focus on.

It is also clear that Americans will blame the government if preparedness is lacking during future emergencies. When Americans learn more about the details of gaps in preparedness, they are very concerned and believe the government is failing to live up to its responsibility. The fact that many U.S. cities and communities still do not have the supplies and plans necessary to deal with these emergencies causes people a great deal of concern. Eighty-two percent of Americans say this fact makes them concerned about the safety of the country, with 53 percent responding that it makes them very concerned.

TFAH has issued the *Ready or Not? Protecting the Public's Health from Diseases, Disasters, and Bioterrorism* report, which examines the progress that has been made in improving America's ability to respond to public health emergencies, since 2003. This report, the sixth annual edition, finds that on some levels, significant progress has been made in the nation's preparedness. There are important

areas, however, where continued, concerted action is needed. From assuring an adequate stockpile of pandemic influenza countermeasures to having adequate laboratory capacity to respond to a chemical or radiological event, federal and state policies still fall short of their stated goals. In many other areas, a lack of transparency makes it hard for the American people and their elected representatives to know whether their government is protecting them. The variation in preparedness among the states means that where one lives still determines how well one is protected. Until all states measure up, the United States is not safe.

The report also helps identify ongoing areas of vulnerability. Some of the key areas of concern TFAH has raised include the need to:

- Increase accountability;
- Strengthen leadership;
- Enhance surge capacity and the public health workforce;
- Modernize technology and equipment; and
- Improve community engagement.

A MODERN PUBLIC HEALTH SYSTEM TAKES ON ALL-HAZARDS

There has been increasing acknowledgment among America's leaders and current and former public health officials about the need to modernize the public health system to respond to a range of threats, including naturally occurring diseases and disasters, as well as bioterrorism. The aftermath of Hurricane Katrina, the potential for a pandemic flu outbreak, increased attention to foodborne illnesses, and growing concerns about emerging infectious diseases have contributed to a broad recognition among policy makers of the need for an all-hazards approach to public health preparedness.

In December 2006, Congress took steps to address many of these concerns when legis-

lators updated and reauthorized the Public Health Security and Bioterrorism Act, which is now known as the Pandemic and All-Hazards Preparedness Act (PAHPA). In addition, the White House issued a number of presidential directives with components aimed at improving public health emergency preparedness. The most recent was Homeland Security Presidential Directive (HSPD) 21, released in October 2007, which establishes a National Strategy for Public Health and Medical Preparedness.

The next challenge is to ensure that the measures contained in the legislation and directives are carried out and translated into improved public health preparedness, thereby keeping communities throughout

the country safer and better protected. This will require sufficient funding requests from the president and subsequent approval by Congress to carry out federal preparedness activities. Another challenge is to address federal funding levels for upgrading state and local public health preparedness, which have been decreasing yearly since 2004. This decline, along with the fluctuations and uncertainty of funding for other federal preparedness grants, has adversely affected progress.

The 2008 edition of *Ready or Not?* focuses on evaluating America's public health emergency preparedness in the context of these measures passed by Congress and issued by the Bush administration to try to improve all-hazards preparedness.

TFAH issues this report in order to provide an independent analysis to:

- Inform the public and policymakers about progress and vulnerabilities in the nation's public health preparedness; and
- Foster greater accountability for the spending of taxpayer dollars on emergency preparedness.

Congress and the public are entitled to know how well the country is being protected from health threats. Moreover, the public health system and other government entities involved in protecting the public's health must be held accountable for how well they are carrying out their responsibilities as defined by legislation and administrative directives.

In addition, without information about the status of progress and vulnerabilities, it is difficult to determine whether the resources and funds devoted to preparedness are sufficient for adequately protecting the public from health threats.

Ready or Not? 2008: Key Findings

Indicator	Finding
1. Mass Distribution -- Strategic National Stockpile	All 50 states and D.C. have an adequate plan to distribute emergency vaccines, antidotes, and medical supplies from the Strategic National Stockpile (SNS).
2. Mass Distribution -- Antiviral Stockpiling	Sixteen states have purchased less than 50 percent of their share of federally-subsidized antivirals.
3. Public Health Laboratories -- Lab Pickup and Delivery Services	Twenty-four states and D.C. lack the capacity to deliver and receive lab specimens on a 24/7 basis.
4. Public Health Laboratories -- Pandemic Influenza Planning	Three state public health laboratories are not able to meet the expectations of their state's pandemic influenza plans.
5. Biosurveillance	Six states do not have a disease surveillance system that is compatible with CDC's National Electronic Disease Surveillance System (NEDSS).
6. Health Care Volunteer Emergency Liability Protection	Eight states have limited protection for health care volunteers during times of emergency.
7. Entity Emergency Liability Protection	Twenty-six states lack statutes that extend some level of immunity to groups and/or organizations providing charitable, emergency, or disaster relief services.
8. Medical Reserve Corps Readiness	Seventeen states do not have State Medical Reserve Corps Coordinators.
9. Food Safety -- Detection and Diagnosis	Twenty states and D.C. identified the pathogen responsible for reported foodborne disease outbreaks at a rate lower than the national average of 44 percent.
10. Funding Commitment	Eleven states and D.C. cut funding for public health from FY 2006-07 to FY 2007-08.

SOME KEY 2008 PUBLIC HEALTH THREATS

- January 2008: The U.S. Food and Drug Administration (FDA) warns of potential botulism in canned green beans and garbanzo beans. Although no illnesses had been reported, FDA instructs that all cans from the infected plant should be immediately and carefully thrown away.
- February 2008: In the largest beef recall in history, 143 million pounds of beef are deemed “unfit for human consumption.” The recall occurred after the Humane Society of the United States released an undercover video showing workers at the California meat company kicking sick cows and using fork lifts to force them to walk.
- February 2008: Vials of ricin are found in a motel room in Las Vegas, Nevada after a man suffering from respiratory distress was transported to the hospital.
- February 2008: An outbreak of 11 measles cases is identified in San Diego, California. The strain is identified from an unvaccinated young boy who had recently traveled to Switzerland.
- March 2008: FDA warns of *Salmonella* risk in cantaloupes imported from a Honduran grower and packer. CDC received reports of 50 illnesses in 16 states and nine illnesses in Canada linked to contaminated cantaloupes.
- March and June 2008: Heavy rains cause severe flooding in the Midwest. In March, 17 people died as a result of the flooding, and by the end of June storms and flooding across six states caused 24 deaths, 148 injuries and more than \$1.5 billion in damages to Iowa alone.
- June 2008: In June, outbreaks of *Salmonella* are linked first to tomatoes and months later to jalapeño and Serrano peppers. Since April 2008, CDC has identified 1,442 people who were sickened by the outbreak in 43 states, the District of Columbia (D.C.), and Canada.
- June 2008: Lightning sparks thousands of California wildfires across northern California. Over 2,700 individual fires were recorded causing mandatory evacuations and damaging thousands of acres.
- September 2008: In early September, Hurricane Gustav makes landfall in Louisiana and causes widespread destruction statewide, amounting to billions of dollars in damages.
- September 2008: Just weeks after Hurricane Gustav hit the United States, Hurricane Ike hits Texas as a category 2 storm, causing extreme damage in Texas. Twenty-seven deaths are attributed to the storm that forced hundreds of thousands of residents to evacuate.
- September 2008: Melamine-contaminated infant formula and related dairy products produced in China were found in countries across the globe. U.S. food safety officials conduct a national assessment to determine if any of the contaminated product was imported illegally into the United States.

ALL-HAZARDS APPROACH TO EMERGENCY PUBLIC HEALTH THREATS

The U.S. public health system is responsible for protecting the American people from a range of potential health threats. An all-hazards public health system is one that is able to respond to and protect citizens from the full spectrum of possible public health emergencies, including bioterrorism and naturally occurring health threats. An all-hazards system recognizes that preparing for one threat can have benefits that will help prepare public health departments for all potential threats.

Under an all-hazards approach, the public health system prepares for and is able to respond to unique concerns posed by different threats. For instance, threats may be:

- Isolated at our borders, or regionally, or be national or global in scope;
- Of limited duration or occur in repeated waves; and
- Preventable and treatable through vaccines and medications, or there may be no pharmaceutical interventions available.

EXAMPLES OF MAJOR EMERGENCY PUBLIC HEALTH THREATS

Agroterrorism: The “...deliberate introduction of an animal or plant disease with the goal of generating fear, causing economic losses, and/or undermining stability.”⁴ Agroterrorism can be considered a subcategory of “bioterrorism” and foodborne diseases.

Bioterrorism: The intentional or deliberate use of germs, biotoxins, or other biological agents that cause disease or death in people, animals, or plants. Examples include anthrax, smallpox, botulism, *Salmonella*, and *E. coli*.

Blast Injuries: Explosions, whether deliberate or accidental, can cause multi-system, life threatening injuries among individuals and within crowds. Blunt and penetrating injuries to multiple organ systems are likely when an explosion occurs. Also, unique injuries to the lungs and central nervous system occur during explosions.

Chemical terrorism: The deliberate use of chemical agents, such as poisonous gases, arsenic, or pesticides that have toxic effects on people, animals, or plants in order to cause illness or death. Examples include ricin, sarin, and mustard gas.

Chemical incidents and accidents: The non-deliberate exposure of humans to harmful chemical agents, with similar outcomes to chemical terrorism.

Foodborne diseases: Foodborne illness is caused by harmful bacteria, viruses, parasites or chemicals that are found in food and beverages and enter the body through the gastrointestinal tract. The Centers for Disease Control and Prevention (CDC) estimates there are approximately 75 million pathogen-induced cases of foodborne diseases each year in the United States, causing approximately 325,000 hospitalizations and 5,000 deaths. Examples include botulism, *Salmonella*, *E.coli* O157:H7, shigella, and norovirus.

Natural disasters: Harm can be inflicted during and after natural disasters, which can lead to contaminated water, shortages of food and water, loss of shelter, and the disruption of regular health care. Examples include hurricanes, earthquakes, tornados, mudslides, fires, and tsunamis.

Pandemic flu: A novel, potentially lethal strain of the influenza against which humans have no natural immunity. According to estimates from the U.S. Department of Health and Human Services (HHS), a severe pandemic could result in 1.9 million deaths and 9.9 million hospitalizations in the United States.⁵

Radiological threats: Intentional or accidentally-caused exposure to radiological material. A terrorist attack could involve the scattering of radioactive materials through the use of explosives (“dirty bomb”), the destruction of a nuclear facility, the introduction of radioactive material into a food or water supply, or the explosion of a nuclear device near a population center.

Vector-borne diseases: Diseases spread by vectors, such as insects. Examples include the West Nile virus, Rocky Mountain spotted fever, and malaria.

Waterborne diseases: Diseases spread by contaminated drinking water or recreational water, such as typhoid fever and cholera. According to CDC, over 1,000 persons become ill from contaminated drinking water and over 2,500 persons become ill from recreational water disease outbreaks annually in the United States.⁶

Zoonotic/Animal-borne diseases: Animal diseases that can spread to humans and in some cases, become contagious from human to human. Examples include Avian flu, West Nile virus, and SARS. In 2000, the World Health Organization (WHO) identified more than 200 diseases occurring in humans that were known to be transmitted through animals.⁷ Experts believe that the increased emergence of zoonotic diseases worldwide can be attributed to population displacement, urbanization and crowding, deforestation, and globalization of the food supply.

WHAT DOES ALL-HAZARDS PREPAREDNESS LOOK LIKE? THE GOALS OF 24/7 PUBLIC HEALTH EMERGENCY RESPONSE INCLUDE:

- Rapid **detection** of emergency disease threats, including those caused by bioterrorism.
- Intensive **investigative** capabilities to quickly diagnose an infectious disease outbreak or to identify the biological or chemical agent used in an attack.
- **Surge capacity** for mass events, including adequate facilities, equipment, supplies, and trained health professionals.
- **Mass containment strategies**, including pharmaceuticals needed for **wide-scale vaccination, antibiotic, or antidote administration** and **isolation and quarantining** when necessary.
- Streamlined and effective **communication** channels so health workers can swiftly and accurately communicate with each other, other front line workers, and the public about 1) the nature of an emergency or attack, 2) the risk of exposure and how to seek treatment when needed, and 3) any actions they or their families should take to protect themselves.
- Communications must also be able to reach and take into consideration at-risk populations.
- Streamlined and effective evacuation of at-risk populations with special medical needs.
- An informed and involved public that can provide material and moral support to professional responders, and can render aid when necessary to friends, family, neighbors, and associates.

What it will take to achieve basic levels of preparedness:

- **Leadership, planning, and coordination:** An established chain-of-command and well defined roles and responsibilities for seamless operation across different medical and logistical functions and among federal, state, and local authorities during crisis situations, including police, public safety officials, and other first responders.
- **An expert and fully-staffed workforce:** Highly trained and adequate numbers of public health professionals, including health care providers, epidemiologists, lab scientists, and other experts, in addition to back-up workers for surge capacity conditions.
- **Modernized technology:** State-of-the-art laboratory equipment, information collection, and health tracking systems.
- **Pre-planned, safety-first rapid emergency response capabilities and precautions:** Tested plans and safety precautions to mitigate potential harm to communities, public health professionals, and first responders.
- **Immediate, streamlined communications capabilities:** Coordinated, integrated communications among all parts of the public health system, all frontline responders, and with the public. Must include back-up systems in the event of power loss or overloaded wireless channels.

FEDERAL, STATE, AND LOCAL PUBLIC HEALTH JURISDICTIONS

The federal role: Includes policymaking, funding programs, overseeing national disease prevention efforts, collecting and disseminating health information, building capacity, and directly managing some services.⁸ Some public health capabilities, such as the Strategic National Stockpile (SNS), are federal assets managed by federal agencies that are available to supplement a state's and community's response to a public health emergency that overwhelms or may overwhelm their capabilities. Public health functions are widely diffused across eight federal agencies and two offices.

State and local roles: Under U.S. law, state governments have primary responsibility for the health of their citizens. Constitutional "police powers" give states the ability to enact laws and issue regulations to protect, preserve, and promote the health, safety, and welfare of their residents. In most states, state laws charge local governments with responsibility for the health of their citizens. State and local health departments and first responders are the front line in any public health emergency.

Some of the ongoing problems resulting from this diffused structure include:

1. Lack of clear roles for the various state, local, and federal agencies.
2. Differing responsibilities and capacities among the some 3,000 local health departments.
3. Limited coordination among the levels of government, including determination of how federal assets would be deployed to states and localities, and across jurisdictions, such as sharing assets and resources among states.
4. No minimum standards, guidelines, or recommendations for capacity levels or services are required of state and local health departments. This results in major differences in services and competencies across state and local agencies.
5. Lack of funding flexibility and comprehensiveness due to a federal funding structure that is largely based on categorical or program grants. These often restrictive grants also lack a system of accountability.
6. Ineffective and random capacity to coordinate with nongovernmental organizations, community groups, and the private sector.

NATIONAL PREPAREDNESS GUIDELINES

In 2003, HSPD-8 directed the Secretary of Homeland Security to draft a national all-hazards preparedness goal, and in 2007 DHS released the National Preparedness Guidelines. The Guidelines include three important elements -- the National Planning Scenarios, the Universal Task List and the Target Capabilities List.⁹ These three documents illustrate the magnitude of the federal, state, and local preparedness efforts.

The National Planning Scenarios is a list of 15 potential threats including terrorist attacks, natural disasters, and other emergencies.

National Planning Scenarios

Improvised Nuclear Device	Toxic Industrial Chemicals	Radiological Dispersal Device
Aerosol Anthrax	Nerve Agent	Improvised Explosive Device
Pandemic Influenza	Chlorine Tank Explosion	Food Contamination
Plague	Major Earthquake	Cyber Attack
Blister Agent	Major Hurricane	

The Target Capabilities List includes 37 specific capabilities that all sectors of society should possess in order to respond to any disaster.

Target Capabilities List	
Communications	Critical Infrastructure Protection
Community Preparedness and Participation	Epidemiological Surveillance and Investigation
Planning	Food and Agriculture Safety and Defense
Risk Management	Laboratory Testing
Intelligence/Information Sharing and Dissemination	Mass Care (Sheltering, Feeding, and Related Services)
CBRNE Detection	Mass Prophylaxis
Information Gathering and Recognition of Indicators and Warnings	Medical Supplies Management and Distribution
Intelligence Analysis and Production	Medical Surge
Counter-Terror Investigations and Law Enforcement	Onsite Incident Management
Animal Health Emergency Support	Emergency Public Safety and Security Response
Citizen Evacuation and Shelter-in-Place	Responder Safety and Health
Critical Resource Logistics and Distribution	Emergency Triage and Pre-Hospital Treatment
Emergency Operations Center Management	Search and Rescue (Land-Based)
Emergency Public Information and Warning	Volunteer Management and Donations
Environmental Health	WMD/Hazardous Materials Response and Decontamination
Explosive Device Response Operations	Economic and Community Recovery
Fatality Management	Restoration of Lifelines
Fire Incident Response Support	Structural Damage Assessment
Isolation and Quarantine	

The Universal Task List (UTL) is a menu of over 1,600 tasks that assist efforts to prevent, protect against, respond to, and recover from the 15 scenarios listed above. The UTL is not a static list and will continue to be edited and expanded as additional tasks are addressed and considered. The UTL is organized using four levels that define the type of tasks performed -- National Strategic Tasks, Planning, Coordination and Support Tasks, Incident Management Tasks, and Incident Prevention and Response Tasks. Combining the UTL with the Target Capabilities List provides officials at all levels of government with a framework to evaluate their level of preparedness.¹⁰

State-By-State Public Health Preparedness Indicators and Scores

“MEASURING PREPAREDNESS IS CRITICAL TO EVALUATE PROGRESS.”¹¹

— U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION

All Americans have the right to expect fundamental health protections during public health emergencies, no matter where they live.

States and localities play the central role in protecting the public's health, whether in response to routine threats or emergencies, such as a bioterrorist attack or a natural disaster. Under the U.S. Constitution, each of the 50 states has primary legal jurisdiction and responsibility for the health of its citizens. **Therefore, the chief focus of this report is the capacity of the states to protect citizens from public health threats and emergencies – and the federal government's important role in developing that capacity.** The federal government also plays a crucial role by providing leadership, scientific evidence, and critical resources to assure that every jurisdiction is adequately and equally prepared. (The federal role is discussed further in Section 2.)

Since the terrorist attacks on September 11, 2001, the Bush administration and Congress have made state and local preparedness a priority, directing CDC to funnel more than \$6.3 billion to state and local health departments. The large infusion of cash has led to progress in a number of key areas:

■ Development of emergency response plans

- ▲ Eighty percent of states have response plans for anthrax, 98 percent for smallpox, 67 percent for botulism toxin, 69 percent for nuclear events, and 49 percent for nerve agents.¹²

■ Distribution of medical countermeasures

- ▲ All states have developed strategies and plans to receive and distribute SNS medical supplies.¹³

■ Expansion of laboratory capacity

- ▲ The number of Bio-Safety Level-3 Labs has grown from 69 to 139.
- ▲ The number of labs participating in the Laboratory Response Network (LRN) for infectious diseases exceeds 150, with at least one in each state.¹⁴

■ Workforce

- ▲ All state public health departments have staff on call 24 hours a day, seven days a week, 365 days a year to evaluate urgent disease reports.¹⁵

■ Emergency communications

- ▲ Public health departments in all 50 states and D.C. have trained public health professionals about their roles and responsibilities during an emergency as outlined by the National Incident Management System (NIMS) Incident Command System (ICS); in 1999 only 14 states did so.¹⁶

While TFAH applauds this progress, much work remains to be done. In addition, CDC and other agencies must do a better job of communicating progress and gaps to policy makers and the general public. The American people deserve to know how prepared their states and communities are for different types of health threats, particularly when their taxpayer dollars are being spent to support preparedness efforts. Currently, the American public is not equipped with enough information to monitor and hold public officials accountable for whether their communities are adequately prepared.

EVERY STATE IS DIFFERENT, BUT THERE ARE BASIC EXPECTATIONS EVERY STATE SHOULD MEET TO ENSURE PREPAREDNESS FOR ALL-HAZARDS

States differ in how they structure and deliver public health services. In some states, the public health system is centralized, and the state has direct control and supervision over local health agencies. In other states, local public health agencies developed separately from the state and are run by counties, cities, or townships, and usually report to one or more elected officials.¹⁷

Each state has different strengths, weaknesses, and unique challenges that affect its ability to prepare for and respond to public health emergencies. This report assesses how states are performing with respect to meeting their preparedness responsibilities.

To help assess public health emergency preparedness capabilities, each state received a score based on 10 key indicators, which TFAH derived from current publicly available data. Low state scores reflecting weaknesses and challenges are not intended to be punitive. Rather, this report is intended to help identify where and how states can improve or overcome obstacles to an all-hazards approach to public health preparedness. In addition, providing information about which states have particular strengths allows others to know which states to turn to for best practices and models to guide their own preparedness efforts.

STATE SCORES

Despite allocation of more than \$6.3 billion in federal public health preparedness funds to states and localities over the past six years, reliable, valid performance measures to evaluate emergency preparedness are still to be fully developed. Currently, CDC is using new capability-based performance measures for the state and local grantees.¹⁸ As CDC and the research community build a stronger research base on preparedness, CDC expects to roll out new objectives. Until recently, what little data that is collected on public health preparedness generally was not made publicly available. However, in February 2008, the CDC released its first report on the Public Health Emergency Preparedness (PHEP) Cooperative Agreement, *Public Health Preparedness: Mobilizing State by State*. The report included data on all 50 states and four major U.S. cities: Chicago, D.C., Los Angeles, and New York City. CDC's release of information about the progress states have made to improve public health emergency preparedness was an important step forward for transparency and accountability.

To further the discussion about state preparedness, TFAH annually develops 10 indicators focused on key areas of preparedness using the limited data currently available for

all 50 states and D.C. Each state receives one point for achieving an indicator or zero points if they do not achieve the indicator, thus zero is the lowest possible overall score and 10 the highest. Taken collectively, these indicators offer a composite snapshot of preparedness including strengths and vulnerabilities.

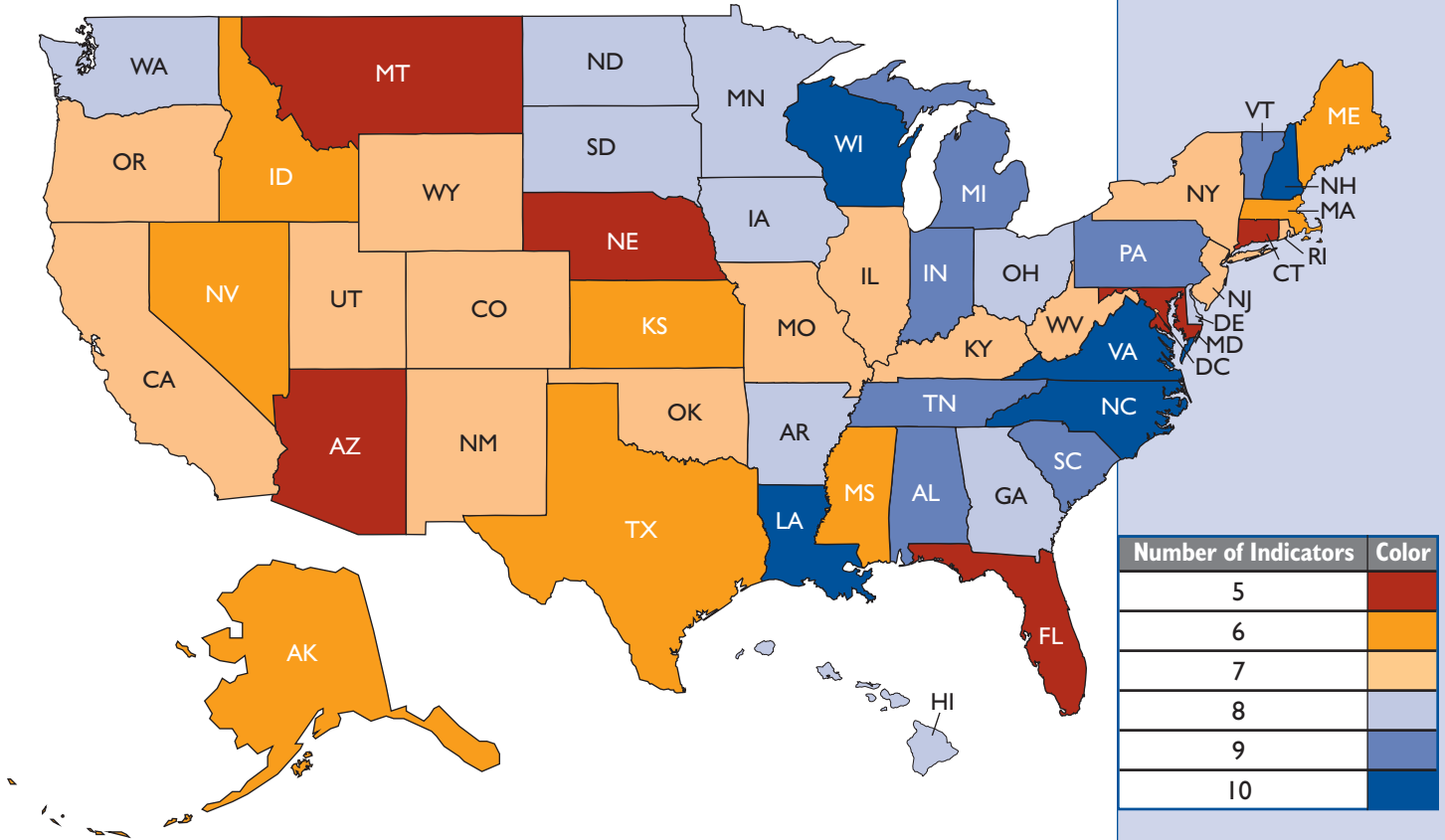
TFAH has repeatedly called for the government to develop national performance standards and to publicly release information on a routine basis about states' progress in meeting these standards. The indicators in this report were selected based on:

- Reflection of a fundamental, systemic public health need;
- Consultation with key experts about areas important to serving basic public health emergency needs; and
- The availability of state level data that were verified through independent means or in consultation with states.

Scores focus on relative achievements in areas of preparedness, and highlight areas where increased prioritization and investment must be made to address problems. TFAH is only able to assess states comparatively where there are data available for all 50

states and D.C. Many states have taken action in other areas of preparedness or may be in the process of increasing certain capabilities not reflected in this report. In some

cases, TFAH is reporting data that shows an improvement upon the state scores CDC published in February 2008, representing progress over the past year.



SCORES BY STATE					
10 (5 states)	9 (7 states)	8 (10 states)	7 (14 states & D.C.)	6 (8 states)	5 (6 states)
Louisiana New Hampshire North Carolina Virginia Wisconsin	Alabama Indiana Michigan Pennsylvania South Carolina Tennessee Vermont	Arkansas Delaware Georgia Hawaii Iowa Minnesota North Dakota Ohio South Dakota Washington	California Colorado D.C. Illinois Kentucky Missouri New Jersey New Mexico New York Oklahoma Oregon Rhode Island Utah West Virginia Wyoming	Alaska Idaho Kansas Maine Massachusetts Mississippi Nevada Texas	Arizona Connecticut Florida Maryland Montana Nebraska

STATE PREPAREDNESS SCORES

States	1 Has adequate plans to distribute emergency vaccines, antidotes and medical supplies from the SNS	2 Purchased 50 percent or more of their share of federally-subsidized antivirals	3 State public health lab has an intra-state courier system non-mail that operates 24 hours per day for specimen pickup and delivery	4 State public health lab can meet the expectations of the state's pandemic influenza plan	5 Has a disease tracking system to collect and monitor data electronically via the Internet	6 Has laws that reduce or limit the liability exposure for health care volunteers who serve in a public health emergency	7 Has laws that reduce or limit the liability for businesses and non-profit organizations that serve in a public health emergency	8 State has a Medical Reserve Corps MRC Coordinator	9 State identified the pathogen responsible for reported foodborne disease outbreaks at a rate that met or exceeded the national average of 44 percent (combined data 2004-2006)	10 Increased or maintained level of funding for public health services from FY 2006-07 to FY 2007-08	2008 Total Score
Alabama	✓	✓	✓	✓	✓	✓	✓	✓	✓	9	
Alaska	✓	✓		✓	✓			✓	✓	6	
Arizona	✓			✓	✓				✓	5	
Arkansas	✓	✓	✓	✓	✓	✓		✓		8	
California	✓	✓			✓	✓	✓		✓	7	
Colorado	✓			✓	✓	✓	✓	✓		7	
Connecticut	✓			✓		✓		✓		5	
Delaware	✓	✓	✓	✓	✓	✓	✓		✓	8	
District of Columbia	✓	✓		✓	✓	✓	✓			7	
Florida	✓			✓	✓		✓		✓	5	
Georgia	✓	✓		✓	✓	✓	✓		✓	8	
Hawaii	✓	✓		✓	✓	✓	✓	✓	✓	8	
Idaho	✓			✓	✓	✓		✓		6	
Illinois	✓	✓		✓	✓	✓		✓	✓	7	
Indiana	✓	✓		✓	✓	✓	✓	✓	✓	9	
Iowa	✓	✓	✓	✓	✓	✓	✓		✓	8	
Kansas	✓	✓	✓		✓	✓		✓	✓	6	
Kentucky	✓	✓		✓	✓	✓		✓	✓	7	
Louisiana	✓	✓	✓	✓	✓	✓	✓	✓	✓	10	
Maine	✓			✓	✓	✓			✓	6	
Maryland	✓		✓	✓	✓		✓			5	
Massachusetts	✓			✓	✓		✓	✓	✓	6	
Michigan	✓	✓	✓	✓	✓		✓		✓	9	
Minnesota	✓	✓	✓	✓		✓		✓	✓	8	
Mississippi	✓	✓	✓	✓		✓			✓	6	
Missouri	✓	✓	✓	✓	✓	✓			✓	7	
Montana	✓		✓	✓	✓				✓	5	
Nebraska	✓			✓	✓	✓		✓		5	
Nevada	✓	✓		✓		✓		✓		6	
New Hampshire	✓	✓	✓	✓	✓	✓	✓	✓	✓	10	
New Jersey	✓	✓		✓	✓	✓	✓		✓	7	
New Mexico	✓			✓	✓	✓	✓	✓	✓	7	
New York	✓	✓		✓	✓	✓	✓		✓	7	
North Carolina	✓	✓	✓	✓	✓	✓	✓	✓	✓	10	
North Dakota	✓	✓		✓	✓	✓		✓	✓	8	
Ohio	✓	✓	✓		✓		✓	✓	✓	8	
Oklahoma	✓		✓	✓	✓	✓		✓	✓	7	
Oregon	✓	✓	✓	✓	✓	✓		✓	✓	7	
Pennsylvania	✓	✓	✓	✓	✓	✓	✓	✓		9	
Rhode Island	✓			✓	✓	✓		✓	✓	7	
South Carolina	✓	✓	✓	✓	✓	✓	✓	✓	✓	9	
South Dakota	✓	✓	✓	✓	✓	✓		✓	✓	8	
Tennessee	✓	✓	✓	✓	✓	✓		✓	✓	9	
Texas	✓		✓	✓	✓		✓		✓	6	
Utah	✓			✓		✓	✓	✓	✓	7	
Vermont	✓	✓	✓	✓	✓	✓		✓	✓	9	
Virginia	✓	✓	✓	✓	✓	✓	✓	✓	✓	10	
Washington	✓	✓		✓	✓	✓	✓		✓	8	
West Virginia	✓	✓		✓	✓	✓	✓	✓		7	
Wisconsin	✓	✓	✓	✓	✓	✓	✓	✓	✓	10	
Wyoming	✓	✓	✓	✓	✓			✓	✓	7	
Total	50+D.C.	34+D.C.	26	47+D.C.	44+D.C.	42+D.C.	24+D.C.	33+D.C.	30	39	

Some indicators reflect states' use of funds received through bioterrorism and public health cooperative agreements from the CDC and the Office of the Assistant Secretary for Preparedness and Response (ASPR) at the HHS, other health capacity readiness programs, and state public health funds for health emergency preparedness. Other indicators, however, illustrate the breadth of all-hazards public health preparedness and

examine state laws and state collaboration with planning partners.

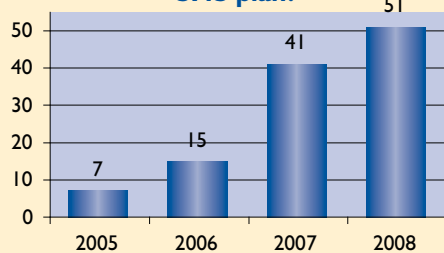
Data from these indicators were drawn from a range of publicly available sources, including CDC, ASPR, a survey conducted by the Association of Public Health Laboratories (APHL), the Association of State and Territorial Health Officials (ASTHO), public announcements from states, and interviews with government officials.

Indicators	What the Indicators Measure
<p>1. Mass Distribution -- Strategic National Stockpile - Did the state test its plan to distribute emergency vaccines, antidotes, pharmaceuticals, and medical supplies from the SNS, and receive a passing grade from CDC?</p>	<p>This indicator assesses a state's emergency response plan to quickly provide medications to communities during emergencies.</p>
<p>2. Mass Distribution -- Antiviral Stockpiling -- Did the state purchase 50 percent or more of its federally-subsidized antiviral drugs to stockpile for use during an influenza pandemic?</p>	<p>The federal government has declared stockpiling antivirals to be a shared responsibility between the federal government and the states. This indicator assesses the state's ability to provide antivirals to high-risk populations during an influenza pandemic.</p>
<p>3. Public Health Laboratories -- Lab Pickup And Delivery Services -- Does the state public health lab currently have an intra-state courier system (non-mail) that operates 24 hours per day for specimen pickup and delivery?</p>	<p>This indicator reflects whether states have the capacity to deliver and receive laboratory specimens on a 24/7/365 basis.</p>
<p>4. Public Health Laboratories -- Pandemic Influenza Planning -- Does the state public health laboratory meet the expectations of the state's pandemic influenza plan?</p>	<p>This indicator demonstrates the ability of the states to ensure surveillance and laboratory capability during each phase of a pandemic.</p>
<p>5. Biosurveillance -- Does the state use a disease surveillance system that is compatible with CDC's national system, including integrating data from multiple sources, using electronic lab results (ELR) reporting, and using an Internet browser?</p>	<p>This indicator demonstrates information about which states track health threats in a manner compatible with the standards of CDC's National Electronic Disease Surveillance System (NEDSS). This system makes it possible to quickly identify and track outbreaks and share the information in a consistent way across health agencies and states.</p>
<p>6. Health Care Volunteer Emergency Liability Protection -- Does the state have laws that reduce or limit the liability exposure for health care volunteers who serve in a public health emergency?</p>	<p>This indicator helps evaluate states' abilities to call up a health care volunteer workforce in the event of a public health emergency. The lack of liability protection is a serious deterrent to many volunteers who may want to offer their health care services but are fearful of doing so without clear liability laws.</p>
<p>7. Entity Emergency Liability Protection -- Does the state have laws that reduce or limit the liability for businesses and non-profit organizations that serve in a public health emergency?</p>	<p>This indicator helps evaluate states' abilities to work with the private sector in the event of a public health emergency. The lack of liability protection is a serious deterrent to many businesses and non-profits that may want to offer their services but are fearful of doing so without clear liability laws.</p>
<p>8. Medical Reserve Corps Readiness -- Does the state have a Medical Reserve Corps (MRC) Coordinator?</p>	<p>This indicator assesses the state MRC program on the presence of a State MRC Coordinator, who is responsible for working with all MRC units in the jurisdiction.</p>
<p>9. Food Safety -- Detection and Diagnosis -- Did the state identify the pathogen responsible for reported foodborne disease outbreaks at a rate that met or exceeded the national average of 44 percent (combined data 2004-2006)?</p>	<p>This indicator reflects the ability of states to identify the pathogen responsible for foodborne disease outbreaks.</p>
<p>10. Funding Commitment -- Did the state maintain or increase funding for public health programs from FY 2006-07 to FY 2007-08?</p>	<p>This indicator, adjusted for inflation, demonstrates states' commitment to funding public health programs, which support the infrastructure needed to adequately respond to emergencies.</p>

TREND ANALYSIS OF SELECT READY OR NOT? KEY INDICATORS

In the six years that TFAH has evaluated states preparedness, there has been considerable improvement. Although TFAH does not use the same 10 key indicators each year, the report has tracked the following six indicators over time: Strategic National Stockpile; Public Health Laboratories -- Bio-Threat Testing; Public Health Laboratories -- Workforce; Biosurveillance -- NEDSS; State Pandemic Influenza Plans; and Seniors' Seasonal Flu Vaccination Rates.

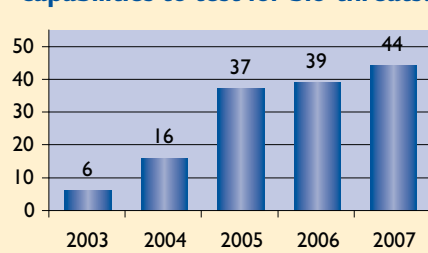
Does the state have an adequate SNS plan?



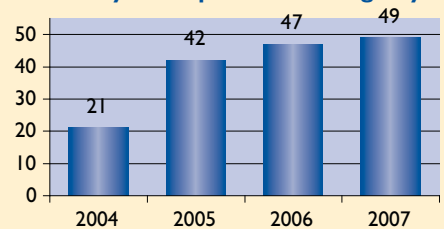
*Note: D.C. is included in the total for 2007 and 2008.

**Note: In 2007, CDC switched from a green-yellow-red stoplight model of evaluating state SNS plans to a 100-point scale, where 69 and above is deemed sufficient.

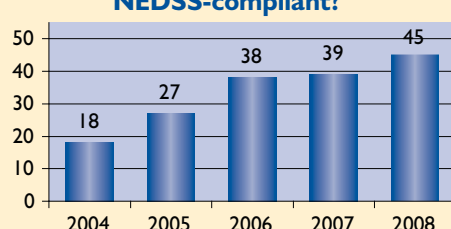
Does the state have sufficient lab capabilities to test for bio-threats?



Does the state public health lab have adequate staffing to provide 24/7 coverage to analyze samples in an emergency?

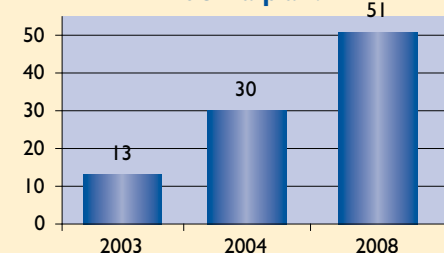


Does the state use a disease surveillance system that is NEDSS-compliant?



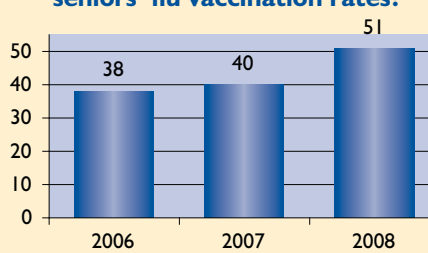
*Note: D.C. is included in the total for 2007 and 2008.

Does the state have a pandemic influenza plan?



*Note: D.C. is included in the total for 2008.

Did the state increase or maintain seniors' flu vaccination rates?



*Note: D.C. is included in the total for 2006, 2007, and 2008.

PROGRESS IN REPORTING STATE EMERGENCY PREPAREDNESS

Since 2002, CDC has administered the PHEP cooperative agreement, which channels federal dollars to state and local public health departments.

In February 2008, CDC released its first report on the progress states have made using these dollars and the existing challenges. The report, *Public Health Preparedness: Mobilizing State by State*, includes national data as well as state-specific snapshots for all 50 states and four directly funded localities: Chicago, Los Angeles County, New York City, and D.C.

Areas where progress was noted include the following:

- The number of epidemiologists in public health departments working in emergency response has doubled from 115 in 2001 to 232 in 2006;
- The number of state and local public health laboratories able to detect biological agents has increased from 83 in 2002 to 110 in 2007; and
- Seventy-three percent of states reviewed have satisfactorily documented their plans to receive, store, and distribute the SNS.

Among areas where challenges to emergency preparedness and response remain were the following:

- Sixteen states did not report any plans to electronically exchange health data with regional health information organizations;
- Thirty-one state public health laboratories reported difficulty recruiting qualified laboratory scientists; and
- No state public health laboratories can rapidly identify priority radioactive materials in clinical samples.

As CDC continues to work with state and local public health departments, the agency prioritized the following initiatives, which include:

- Increasing the use of electronic health data for preparedness and response by networking surveillance systems and using real-time data;
- Expanding laboratory testing; and
- Improving legal preparedness for public health emergencies.

In September 2008, the Public Health Emergency Preparedness Partners Workgroup, composed of members of ASTHO, APHL, the Council of State and Territorial Epidemiologists (CSTE), and the National Association of Country and City Health Officials (NACCHO) released its own survey of the PHEP Cooperative Agreement. The report, *Public Health Emergency Preparedness: Six Years of Achievement*, also highlights improvements and challenges, but fails to list any state-specific data.

Among the accomplishments listed, the report details the following:

- All states have developed all-hazards emergency response plans;
- Nearly two-thirds of state health agencies have implemented workforce planning programs to recruit, train, and retain a skilled workforce;
- State health agencies participated in more than 700 exercises of all types in 2007, and an even greater number of exercises occurred at the local level; and
- Nearly all states (96 percent) now have 24/7 communications systems linking hospitals, state and local public health officials and law enforcement, up from 80 percent in 2002.

The ongoing challenges include the following:

- Many local health departments lack plans for mass patient care and fatality management;
- Forty-three percent of small local health departments and nine percent of medium-sized ones have no staff dedicated to preparedness activities; and
- Epidemiologists, environmental health workers, and laboratorians are “very-to-moderately” affected by overall health care workforce shortages.

The report calls for “...a steadfast commitment of federal leadership, guidance, technical assistance and resources” to continue to develop and strengthen state and local preparedness.

Indicator 1: MASS DISTRIBUTION -- STRATEGIC NATIONAL STOCKPILE (SNS)

FINDING: All 50 states and D.C. have adequate plans to receive and distribute emergency vaccines, antidotes, pharmaceuticals, and medical supplies from the SNS based on CDC's technical assistance review (TAR).

50 states and D.C. scored 69 or higher on CDC's SNS TAR evaluation tool, indicating they have adequate plans in place to receive and distribute medical countermeasures from the SNS (1 point).			0 states scored below 69 on CDC's SNS technical TAR evaluation tool, indicating they do not have adequate plans in place to receive and distribute medical countermeasures from the SNS (0 points).		
State	Last TAR Date	SNS Score	State	Last TAR Date	SNS Score
Alabama ¹	9/26/2007	92			
Alaska ¹	12/11/2006	80			
Arizona	6/17/2008	83			
Arkansas	3/18/2008	93			
California	6/17/2008	100			
Colorado	5/25/2008	94			
Connecticut	1/28/2008	84			
Delaware	3/28/2008	96			
D.C.	6/16/2008	94			
Florida	1/15/2008	95			
Georgia	5/13/2008	73			
Hawaii	7/10/2008	74			
Idaho	10/10/2007	90			
Illinois	5/21/2008	96			
Indiana	6/25/2008	96			
Iowa	5/14/2008	93			
Kansas	6/17/2008	93			
Kentucky	5/28/2008	86			
Louisiana	4/4/2008	94			
Maine ¹	10/28/2008	90			
Maryland	8/1/2008	93			
Massachusetts	3/25/2008	91			
Michigan	11/28/2008	95			
Minnesota	12/17/2007	84			
Mississippi	3/7/2008	95			
Missouri	11/27/2007	96			
Montana	7/15/2008	91			
Nebraska	8/27/2008	81			
Nevada ²	11/18/2008	84			
New Hampshire	1/24/2008	86			
New Jersey	12/6/2007	98			
New Mexico	7/16/2008	71			
New York	5/22/2008	97			
North Carolina	2/12/2008	93			
North Dakota	11/6/2007	77			
Ohio	1/23/2008	90			
Oklahoma	6/12/2008	97			
Oregon ²	8/6/2008	85			
Pennsylvania	9/23/2008	82			
Rhode Island	7/29/2008	93			
South Carolina	1/10/2008	87			
South Dakota	7/17/2008	87			
Tennessee	8/12/2008	89			
Texas	9/19/2007	97			
Utah	8/6/2008	85			
Vermont	3/14/2008	93			
Virginia	7/14/2008	100			
Washington ²	7/30/2008	94			
West Virginia	9/4/2008	83			
Wisconsin ¹	12/19/2007	86			
Wyoming ²	10/16/2008	80			

¹ State had a TAR this year but the preliminary scores were unavailable as of November 19, 2008.

² State SNS score is preliminary and awaiting final review.

Source: CDC. States were evaluated between December 11, 2006 and September 23, 2008.

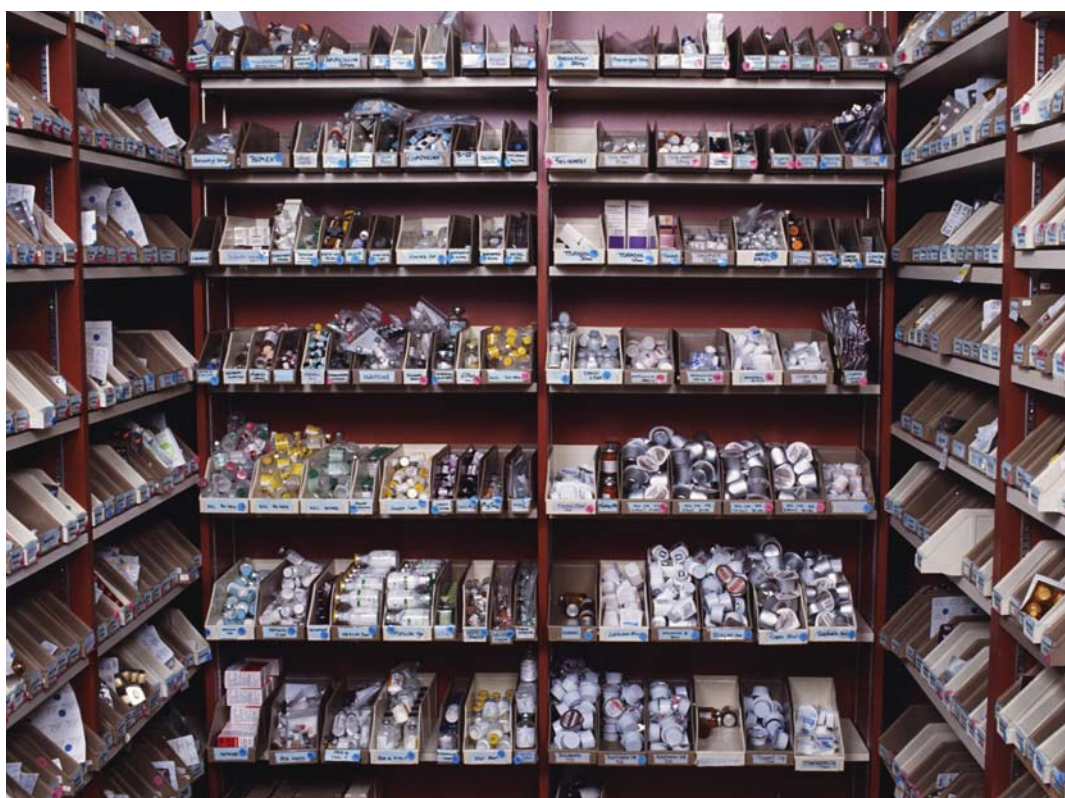
The SNS is a national repository of antibiotics, chemical antidotes, antiviral drugs, antitoxins, life-support medications, intravenous (IV) administration equipment, airway maintenance supplies, and medical and surgical items. The SNS is designed to supplement and re-supply state and local public health agencies in the event of a national emergency anywhere and at anytime within the United States or its territories. As a condition of federal public health preparedness grants, states are required to develop a plan for the receipt and distribution of SNS contents and then exercise the plan.¹⁹

According to CDC, “Preparedness to receive, stage, store, and distribute SNS materiel is essential to saving lives at risk during a public health emergency.”²⁰ For example, in a 2007 study, researchers used a computer model to illustrate the importance of rapidly receiving and dispensing medical countermeasures in the event of a bioterrorist anthrax attack. According to the study’s authors, “The number of people infected who become seriously ill can be reduced by 81 percent if mass prophylaxis is initiated two days after the release (of the anthrax) and finished two days later. If mass prophylaxis is initiated five days after the

release and finished 10 days later, the number of casualties is reduced by only 39 percent.”²¹

CDC evaluates states’ SNS distribution preparedness plans based on a zero-to-100 point scale. The agency’s TAR relies primarily on a checklist tool for evaluating SNS plans and supporting documents. The evaluation takes place over the course of one day during an on-site CDC staff visit.²² There are 13 functions on which states are evaluated.²³ The scoring system assesses **planning and management of the stockpile**. It does *not* reflect the actual capacity of the state to deploy countermeasures and other supplies from the SNS.

According to CDC, states must obtain a score of 69 or higher on the SNS TAR by December 31, 2008. As of November 19, 2008, 50 states and D.C. scored 69 or higher. When CDC published its report on state preparedness in February 2008, there were 13 states that failed to score above 69. The 13 states that brought their SNS TAR scores above 69 over the past year are Georgia, Maine, Maryland, Massachusetts, Nebraska, Nevada, New Mexico, Oregon, Pennsylvania, South Carolina, South Dakota, Utah, and West Virginia.



THE STRATEGIC NATIONAL STOCKPILE (SNS)

The SNS maintains a variety of critical pharmaceuticals and medical supplies including antibiotics such as ciprofloxacin and doxycycline, chemical nerve agent antidotes like atropine and pralidoxime, antiviral drugs such as Tamiflu® and Relenza®, pain management drugs such as morphine, vaccines for agents like smallpox, as well as radiological countermeasures such as Prussian blue and DTPA. In addition to pharmaceuticals, the SNS contains supportive care supplies like endotracheal tubes and IV supplies, burn and blast supplies such as sutures and bandages, ventilators, personnel protective equipment such as N-95 respirators and sterile gloves and other life-saving medical materiel. While this list is not comprehensive, it is representative of the items contained in the SNS.

The SNS is positioned in undisclosed locations throughout the United States and is configured to provide a flexible response strategy. Included in the formulary are a dozen 12-hour Push Packages, which contain over 50 tons of pharmaceuticals and medical materiel. These assets are pre-configured in deployable containers and strategically located to enable rapid delivery to the site of a national emergency within 12 hours of the federal decision to deploy.

The majority of the SNS formulary is maintained in managed inventory. Like the 12-hour Push Packages, these assets are also strategically located around the nation. They provide the ability to configure and deliver significant quantities of pharmaceuticals and medical materiel as an initial response if the nature of the public health emergency is well defined, or as follow-on to a “push package” delivery. Delivery of assets from managed inventory are planned to begin arriving within 24 to 36 hours after the federal decision to deploy them. Quantities in the SNS change based on national planning guidance and prioritization, modeling scenarios, and standard inventory management procedures.

In April 2007, Gerald W. Parker, ASPR Principal Deputy Assistant Secretary, testified before the U.S. House of Representatives Subcommittee on Emerging Threats, Cybersecurity, and Science & Technology regarding the development of medical countermeasures. According to Dr. Parker, some of the contents of the national stockpile include:²⁴

- Enough smallpox vaccine to protect 300 million people, or every man, woman, and child in America;
- Over 41 million regimens of countermeasures against anthrax;
- Therapeutic anthrax antitoxins to treat symptomatic patients;
- Countermeasures to address radiation exposure including over 460,000 combined doses of Calcium-DTPA (Diethylenetriamine pentaacetate) and Zinc-DTPA; and
- 1.7 million doses of liquid potassium iodide (KI) in a formulation that is more suitable for young children for use in the event of a release of radioiodines.

The SNS also has been increasing its supply of countermeasures that could be used during an influenza pandemic. For example, HHS has allocated a total of \$1.1 billion for the purchase of antiviral medications, \$660 million of which has been obligated as

of May 2007. Overall, as of November 2, 2007, the SNS contained the following pandemic flu countermeasures:²⁵

- 40 million regimens of Oseltamivir capsules;
- 10 million regimens of Zanamivir;
- 105.8 million N95 respirators; and
- 51.7 million surgical masks.

SNS and Children

As of November 2008, there are over 3.8 million regimens of pediatric antiviral formulations in the SNS to treat a potential pandemic flu for the nation's 73.6 million children.²⁶ For planning purposes, the federal government has assumed that antivirals would be needed for at least 25 percent of the population. However, they have not set any target for stockpiling pediatric antivirals, even though children and adolescents are known to often be disproportionately affected by contagious respiratory illnesses.

An Aging Stockpile

Several of the medical countermeasures in the SNS were purchased under the Project BioShield Act of 2004 (P.L. 108-276). Congress appropriated nearly \$5.6 billion for the procurement of medical countermeasures through FY 2013, of which not more than \$3.418 billion was to be obligated during FY 2004 through 2008. More than four years later, many of the vaccines and some of the drugs are beginning to expire. The BioShield Act, however, does not allow for replenishing the stockpile, nor does it factor in the storage, security, and maintenance costs associated with the SNS.

An October 2007 GAO report identified a major issue of concern with regard to anthrax vaccines in the SNS. According to the report, beginning in 2008, several lots of BioThrax will begin to expire. Annual replacement costs of the anthrax vaccine are estimated at \$100 million per year in lost stockpile. To remedy the problem, HHS/ASPR and the Department of Defense (DOD) signed a Memorandum of Understanding that enables DOD to procure, under the Economy Act, anthrax vaccine from the SNS. Moreover, all DOD anthrax vaccine was transferred to the SNS in 2008 and a joint inventory was created. The SNS maintains a rotating stock of vaccine that is appropriately distributed to military sites and civilian laboratories to minimize the amount of product that must be discarded upon expiration.

Other Concerns

- The 460,000 combined doses of Calcium-DTPA (Diethylenetriamine pentaacetate) and Zinc-DTPA are far short of what would be needed to address radiation exposure from a catastrophic nuclear event in any large U.S. city.
- The quantity of non-pharmaceutical interventions for pandemic influenza, such as N95 respirators and surgical masks, falls far short of what may be needed. The U.S. stockpile contains 105.8 million N95 respirators and 51.7 million surgical masks, while France, with a population one-fifth that of the United States, has stockpiled 300 million N95s and one billion surgical masks.²⁷

DISTRIBUTING MEDICAL COUNTERMEASURES

The Bush administration has been very concerned about the possibility of a major bioterrorist attack. In the scenario presented below, the White House estimates that a terrorist flying a small

airplane, such as a crop duster, could spray anthrax over a major metropolitan area contaminating upwards of three million people with the bacteria.

CATASTROPHIC BIOTERRORISM -- ANTHRAX ATTACKS

October 2001 Attacks: 1 gram of anthrax mailed out via letter		Future Attack: 1-2 kilograms sprayed by a crop duster over a major U.S. city	
Antibiotic Treatment	30,000	Antibiotic Treatment	1.9 -3.4 million
Illnesses	22	Illnesses	~450,000
Deaths	5	Deaths	~380,000
Decontamination	3 buildings	Decontamination	City-wide
Projected economic cost (direct costs)	>\$1 billion	Projected economic cost (direct costs)	>\$1.8 trillion

Source: White House Homeland Security Council²⁸

In light of such dire estimates, the U.S. government has developed three strategies to distribute and dispense medical countermeasures -- push, pull, and preposition.

Push

One strategy involves direct distribution, which emergency planners refer to as a “push” mechanism, because antibiotics or antivirals are pushed to people. In October 2008, HHS announced an innovative “push” approach to distribute medical countermeasures in the event of an anthrax attack: public health officials will rely on U.S. Postal Service letter carriers who volunteer to deliver medicines directly to residences in their communities in a public health emergency.

To help protect these volunteers from contracting anthrax, HHS will issue medical kits containing small quantities of antibiotics for future use by postal workers and their families during an anthrax emergency. “In an anthrax attack, time is of the essence in preventing illness and death by getting antibiotics to those who may have been exposed,” HHS Secretary Michael Leavitt said. “By providing advance protection to letter carriers who volunteer to deliver antibiotics in an affected community, we can gain the benefits of the unique capabilities of the Postal Service to get much needed medicines to those who need it quickly.”²⁹

HHS and the Postal Service have pilot tested this approach in three U.S. cities -- Seattle, Philadelphia, and Boston. In Philadelphia, 50 letter carriers, each accompanied by a police officer, reached 55,000 households in less than eight hours.³⁰ Based on the success of these early tests, the project will be rolled out in Minneapolis and St. Paul in 2009. The Postal Service will recruit 700 letter carriers, enough to cover about one-quarter of all households. The volunteers will be medically screened, fitted with N95 respirators, and issued a supply of doxycycline for their household. On October 3, 2008, FDA invoked the Emergency Use Authorization powers it has under the 2004 BioShield Act and approved the pre-positioning of doxycycline emergency kits for their use by eligible Postal Service employees and their household members in the event of an anthrax attack.³¹

Although some U.S. cities are interested in the possibility of partnering with the Postal Service, others have concerns. The

major barrier for some cities is the requirement that postal workers be accompanied by an armed law enforcement officer when delivering the countermeasures. Although sympathetic to the postal workers concern about their own security, city officials do not think they will be able to provide this type of police protection after a major anthrax attack or other public health emergency, as law enforcement personnel will be occupied with other first responder duties.

Pull

Many argue that partnering with private sector entities will be crucial to the successful mass dispensing of medical countermeasures as local health departments are unlikely to have enough staff on-hand to do the job. According to an Institute of Medicine (IOM) workshop summary, “Any private establishment that can rapidly serve large numbers of customers represents a potential opportunity for a public-private partnership.”³² (Please see Indicator 7: Entity Liability Protection for a discussion on the importance of legal protections for private sector and non-profit entities.)

The private sector would be crucial partners in the second strategy that government officials have developed, which involves point of dispensing, or PODs, also known as a “pull” mechanism because people will be pulled to the antibiotics. The IOM workshop summary report listed several activities that could be carried out through public-private partnerships, including:

- Coordinating logistics, warehousing, and distribution of countermeasures;
- Setting up PODs;
- Providing labor to staff PODs and perform other functions;
- Training and screening of volunteers;
- Preregistering individuals to screen for adverse health effects;
- Tracking and registering people who receive countermeasures;
- Providing education and communication for recipients of countermeasures; and
- Providing security for PODs.

Pre-position

While the “push” and the “pull” strategies have their strengths, some experts argue that neither will be sufficient to provide countermeasures in the necessary time frame during a disaster. These public health experts favor the pre-positioning of MedKits, small supplies of countermeasures for use at home during an emergency when directed to by public health authorities. Pre-positioning would give the public access to medical countermeasures in the event of a public health emergency, while also buying time for public health authorities to ramp up their distribution activities

Other public health officials, however, have raised doubts about the feasibility of pre-positioning. They are concerned that households will not follow the directions and may use the antibiotics or antivirals in the MedKits to treat a household member who becomes sick during a non-emergency. A CDC study conducted in collaboration with the Missouri Department of Health and Senior Services examined how 4,076 households in St. Louis would react to the distribution of a MedKit with a five-day supply of ciprofloxacin, doxycycline, or both, and detailed instructions. The survey found that 97 percent (3,946) of all study respondents returned the MedKits upon completion of the study and 99 percent of the returned MedKits were intact.³³ Of the 130 households (three percent) that did not return the MedKits, 125 of these could not find their MedKits, and five refused to return them.

Although this one CDC study suggests that with clear instructions households will use MedKits appropriately, there are still major concerns. Will the MedKits go only to the households of first responders and health care workers or the entire population? Who will pay for the MedKits? If households are expected to buy the MedKits, how will the government avoid economic disparities in coverage? If families do put their own money towards the purchase of MedKits, what happens if there is a bioterror attack several years down the road at which point there may be questions about the shelf-life of the product? Finally, in the event of an anthrax attack, exposed victims need to take 60-days worth of antibiotics, but the MedKits contain a five-day supply. How will public health officials get the remaining treatment courses to the victims and ensure that they complete their treatment regimen? According to a report from the Center for Biosecurity, “If the many thorny issues surrounding this strategy can be addressed adequately, MedKits may prove to be an innovative and useful tool.”³⁴

Indicator 2: MASS DISTRIBUTION -- STATE ANTIVIRAL PURCHASES

FINDING: Thirty-four states and D.C. have purchased 50 percent or more of their federally-subsidized antivirals to stockpile for use during a pandemic influenza.

34 states and D.C. have purchased 50 percent or more of their federally-subsidized antiviral drugs to stockpile for use during an influenza pandemic (1 point)			16 states have purchased LESS than 50 percent of their share of federally-subsidized antiviral drugs to stockpile for use during an influenza pandemic (0 points)		
State	All Antivirals Purchased by Entity as of 09/30/2008	Percent of Allocation Purchased*	State	All Antivirals Purchased by Entity as of 09/30/2008	Percent of Allocation Purchased*
Alabama	533,553	112.84%	Arizona	67,717	11.56%
Alaska	77,030	113.17%	Colorado	215	0.05%
Arkansas	382,398	133.52%	Connecticut	22,829	6.24%
California**	2,752,151	102.43%	Florida	66,000	3.70%
Delaware	121,164	141.05%	Idaho	8,567	5.97%
D.C.	45,000	76.86%	Maine	0	0%
Georgia	474,022	52.03%	Maryland	210,727	36.41%
Hawaii	172,487	131.56%	Massachusetts	50,662	7.52%
Illinois**	516,018	50.25%	Montana	8,174	8.48%
Indiana	650,912	100.00%	Nebraska	71,952	39.44%
Iowa	312,631	101.21%	New Mexico	77,409	39.25%
Kansas	286,084	100.00%	Oklahoma	54,015	14.67%
Kentucky	216,224	50.01%	Oregon	26,523	7.09%
Louisiana	471,804	100.00%	Rhode Island	11,900	10.53%
Michigan	1,076,950	101.74%	Texas	1,023,141	44.09%
Minnesota	340,640	64.07%	Utah	52,033	21.07%
Mississippi	338,648	111.89%			
Missouri	600,477	100.00%			
Nevada	135,514	57.56%			
New Hampshire	68,000	50.26%			
New Jersey	880,293	97.01%			
New York***	2,444,836	121.20%			
North Carolina	677,882	76.67%			
North Dakota	57,000	85.71%			
Ohio	1,388,858	115.65%			
Pennsylvania	1,298,792	100.00%			
South Carolina	459,960	105.59%			
South Dakota	80,310	100.00%			
Tennessee	613,706	100.00%			
Vermont	71,036	109.24%			
Virginia	827,661	107.03%			
Washington	417,902	64.92%			
West Virginia	227,561	119.65%			
Wisconsin	363,729	63.28%			
Wyoming	52,718	100.00%			

Notes: *The percent reflects total state antiviral purchases and may include unsubsidized state purchases, which is why some states exceed 100% of their federally-subsidized allocation. **The population count for California and Illinois does not include residents of Los Angeles County or Chicago, respectively. These two localities, along with D.C., received their own allocation of federally-subsidized antivirals based on their populations. ***New York State antiviral purchases include those made by New York City. Please see Appendix B: Influenza Antiviral Drug Purchases by States, Localities, and Territories for a complete breakdown of antiviral purchases.

Source: ASPR, information updated as of September 30, 2008.

The federal government's current goal is to stockpile 81 million treatment courses of antiviral drugs for use in the event of a pandemic influenza. Current HHS policy dictates that this goal is a shared responsibility between the federal government and the states. HHS is stockpiling 44 million antivirals and allocating them to states based on population. Meanwhile, states are responsible for stockpiling an additional 31 million treatment courses.

In order to encourage states to develop their own antiviral stockpiles, HHS designated \$170 million to subsidize the purchase of up to 31 million treatment courses of Tamiflu® and Relenza®. HHS will subsidize 25 percent of the cost, and states will pay the other 75 percent.

According to HHS, as of September 30, 2008, state and local jurisdictions have stockpiled nearly 22 million treatment courses of antivirals, of which almost 21 million treatment courses were purchased using the federal government subsidy. Twenty-three states have purchased 100 percent or more of their federally-subsidized antivirals; 26 states and D.C. have purchased 75 percent or more; 34 states and D.C. have purchased 50 percent or more; and 38 states and D.C. have purchased 25 percent or more.

The antivirals Tamiflu® (oseltamivir) and Relenza® (zanamivir) have been shown to reduce symptoms and help prevent the spread of seasonal influenza by suppressing the growth of the influenza virus. Antivirals differ from vaccines in that they target the virus, while vaccines trigger an immune response in

the body. Antivirals do not need to be formulated to match a specific strain of the influenza virus to be effective. As such, they can be manufactured and stockpiled in advance of a potential pandemic influenza outbreak.

States that have not purchased their entire allotment of federally-subsidized antivirals give several reasons. First, according to the National Governors Association (NGA) many have "...expressed concerns about the reliance on antivirals given that their effectiveness in treatment may be compromised by the development of resistance by the pathogen."³⁵ Some scientists believe that a combination antiviral treatment might reduce the likelihood of resistance, but this would require a broader, larger stockpiling program.

Other states have questioned the effectiveness of antivirals, particularly "...if they are used more than 48 hours after the onset of symptoms in an infected individual."³⁶ Additional limitations include concerns about the drugs' potential side effects and financial constraints. Given the projected budget shortfalls, many states are reluctant to spend resources on purchasing and stockpiling antivirals that have a limited shelf-life. Though this shelf-life recently expanded from five years to seven years, it is still too short for many state health officials.

Although TFAH recognizes these concerns, current national policy calls for the stockpiling of antivirals to be a shared federal-state responsibility. The successful containment of a pandemic is threatened by differences in capacity among states.

PRIVATE SECTOR ANTIVIRAL STOCKPILING

Under current HHS guidelines, state and local jurisdiction's stockpiles of antivirals are to be used only for treatment of pandemic influenza, rather than as a prophylaxis. However, new draft guidance on antiviral use during a pandemic recommends that private employers and health care facilities consider purchasing antivirals for use as prophylaxis (the draft guidance is not HHS policy). Such use would be undertaken in an attempt to slow the spread of the pandemic by providing them to healthy individuals who have been exposed and to key personnel, such as health care workers, who will be exposed to the new virus.³⁷

HHS draft guidance on employer antiviral stockpiling lists several reasons companies may want to buy antivirals:³⁸

- To provide prophylaxis treatment for health care workers and emergency responders;
- To protect workers who are needed to maintain essential community services;
- To provide early treatment for workers who fall ill; and
- To protect overseas employees and operations in areas where federal pandemic response activities will not reach.

According to HHS Deputy Secretary Tevi Troy, "Preparation is a shared responsibility, and businesses and private industry can contribute greatly to community resiliency."³⁹ In fact, more than 300 large U.S. businesses have already stockpiled the antiviral Tamiflu® (oseltamivir) to protect their workers and maintain business operations, according to George Abercrombie, Chief Executive Officer and President of Hoffman-La Roche, Inc., maker of the drug.⁴⁰

Some public health experts, however, have raised concerns regarding the advisability of private sector stockpiles. They note that while stockpiling of antivirals may be feasible for large corporations, there are many businesses that will not be able to afford this luxury. Stockpiling will also be difficult for businesses that lack warehouse space and employ part-time or uninsured employees. Other barriers to employers' stockpiling include concerns related to antivirals' shelf-life and the fear that state or federal governments might seize the stockpiled drugs in the event of a pandemic.

The Center for Biosecurity voiced its concerns with the proposed guidance, noting that "It is unrealistic to expect the private sector to create sufficient antiviral stockpiles or to unilaterally accept this burden, and it is especially troubling that segments of critical infrastructure are covered under the private sector's voluntary participation. If the private sector does not stockpile sufficient supplies of antivirals, serious consequences, including higher than necessary absenteeism rates among health care providers during a pandemic, will likely result."⁴¹

REAL-LIFE PUBLIC HEALTH EMERGENCIES

Meningitis Outbreak in Chicago, Illinois, April 2008.

By the end of April 2008, the city of Chicago had 10 cases of group C meningococcal invasive disease for the year -- compared with only 13 cases in all of 2007. The Chicago Department of Public Health took a proactive approach and decided to launch a mass vaccination campaign focused on the at-risk population -- children aged 11 to 18. Due to a preparedness investment in previous years, the city was able to vaccinate 7,213 children in two weeks. Not only was the city able to curb a potential outbreak, but they were also able to test the mass dispensing and mass vaccination plans they had developed with support from the PHEP cooperative agreements.

Cluster of Neurological Illnesses in Rhode Island, December 2006.

In December 2006 five school aged children in Rhode Island were found to have a severe neurological illness that was suspected to have been caused by *Mycoplasma pneumoniae* infection. After learning of the cluster of ill children, the Rhode Island Department of Health contacted the CDC for assistance and testing. The health department then distributed antibiotics to all the students, staff, and family members from the affected school. Public health authorities also closed down three nearby school districts as a precautionary measure. The investments the Department of Health made in its Medical Emergency Distribution plan facilitated the quick and efficient distribution of antibiotics to over 1,000 people.

Source: ASTHO⁴²

SEASONAL FLU VACCINATION RATES

Routine vaccinations have helped prevent countless illnesses and deaths, and are extremely cost-effective, sparing the healthcare system the expense of caring for those who might otherwise become ill.

According to CDC, five to 20 percent of Americans contract the seasonal flu, more than 200,000 people are hospitalized from flu complications, and approximately 36,000 people die from the flu each year.⁴³ Certain people, such as the elderly, the very young, and those with compromised immune systems are more vulnerable to complications from seasonal flu.⁴⁴ Complications of flu can include bacterial pneumonia, dehydration, and

worsening of chronic medical conditions, such as congestive heart failure, asthma, or diabetes. CDC's Advisory Committee on Immunization Practices (ACIP) recommends that individuals at high-risk for complications and their caregivers receive seasonal flu vaccinations at the beginning of each flu season.

Over the past three years, states have made vaccinating one key high risk group, adults aged 65 and older, a public health priority. According to data from CDC's Behavioral Risk Factor Surveillance System (BRFSS), in 2008 50 states and D.C. either increased or maintained vaccination rates for seniors, up from 39 states and D.C. in 2007.

50 states and D.C. increased or maintained rates for vaccinating adults aged 65 and older for seasonal flu (comparing 2004-2006 to 2005-2007)

STATE	2004-2006 rates	2005-2007 rates	Difference between 2004-2006 and 2005-2007	STATE	2004-2006 rates	2005-2007 rates	Difference between 2004-2006 and 2005-2007
Alabama	63.0%	64.0%	1.0%	Montana	71.4%	71.7%	0.2%
Alaska	62.5%	62.7%	0.2%	Nebraska	73.9%	74.3%	0.3%
Arizona	64.7%	65.7%	1.0%	Nevada	56.5%	57.7%	1.1%
Arkansas	67.5%	68.1%	0.6%	New Hampshire	71.0%	73.3%	2.4%
California	67.9%	67.4%	-0.5%	New Jersey	65.8%	66.8%	1.0%
Colorado	76.3%	75.5%	-0.8%	New Mexico	69.3%	68.5%	-0.8%
Connecticut	71.8%	72.3%	0.5%	New York	64.2%	65.7%	1.6%
Delaware	68.5%	70.0%	1.6%	North Carolina	67.3%	68.8%	1.4%
D.C.	56.9%	58.7%	1.8%	North Dakota	71.9%	71.3%	-0.6%
Florida	60.7%	60.7%	0.0%	Ohio	66.8%	68.5%	1.7%
Georgia	63.4%	64.5%	1.1%	Oklahoma	72.9%	73.3%	0.4%
Hawaii	73.9%	75.5%	1.6%	Oregon	70.4%	71.1%	0.7%
Idaho	65.1%	66.1%	1.1%	Pennsylvania	63.8%	66.7%	2.9%
Illinois	62.6%	63.5%	0.9%	Rhode Island	71.6%	73.9%	2.3%
Indiana	64.5%	67.1%	2.6%	South Carolina	63.2%	64.8%	1.5%
Iowa	73.1%	73.3%	0.2%	South Dakota	75.8%	75.9%	0.2%
Kansas	68.9%	70.7%	1.8%	Tennessee	66.1%	67.4%	1.3%
Kentucky	64.2%	67.3%	3.1%	Texas	65.0%	64.9%	-0.1%
Louisiana	65.2%	65.2%	0.0%	Utah	72.4%	72.7%	0.4%
Maine	70.6%	72.3%	1.7%	Vermont	68.6%	71.3%	2.7%
Maryland	63.3%	65.6%	2.4%	Virginia	68.2%	70.5%	2.3%
Massachusetts	71.1%	73.6%	2.4%	Washington	68.8%	70.2%	1.4%
Michigan	68.4%	69.8%	1.3%	West Virginia	65.9%	66.9%	1.0%
Minnesota	76.7%	77.2%	0.5%	Wisconsin	72.7%	72.6%	0.0%
Mississippi	64.6%	65.6%	1.0%	Wyoming	72.5%	73.4%	0.9%
Missouri	67.7%	67.8%	0.1%				

Note: States in red type had statistically significant ($p < 0.05$) increases. No state had a statistically significant decrease.

Source: BRFSS. Data include three year comparisons. Please note that each state has a different sample size so the rates of increase and decrease are not comparable across states -- each state has a different range to reach statistically significant changes. See Appendix C for the methodology.

Indicator 3: PUBLIC HEALTH LABORATORIES -- LAB PICKUP AND DELIVERY SERVICES

FINDING: Twenty-four states and D.C. do not have the capacity to deliver and receive laboratory specimens on a 24-hour, seven days a week basis as part of public health preparedness.

26 states report that their public health laboratories have an intra-state courier system (non-mail) that operates 24 hours a day for specimen pickup and delivery (1 point).		24 states and D.C. report that their public health laboratories do NOT have an intra-state courier system (non-mail) that operates 24 hours a day for specimen pickup and delivery (0 points).	
Alabama	North Carolina	Alaska	Maine
Arkansas	Ohio	Arizona	Massachusetts
Delaware	Oklahoma	California	Nebraska
Iowa	Oregon	Colorado	Nevada
Kansas	Pennsylvania	Connecticut	New Jersey
Louisiana	South Carolina	D.C.	New Mexico
Maryland	South Dakota	Florida	New York
Michigan	Texas	Georgia	North Dakota
Minnesota	Tennessee	Hawaii	Rhode Island
Mississippi	Vermont	Idaho	Utah
Missouri	Virginia	Illinois	Washington
Montana	Wisconsin	Indiana	West Virginia
New Hampshire	Wyoming	Kentucky	

Source: APHL 2008 Survey of State Public Health Lab Directors

Each state should have the capacity to deliver and receive laboratory specimens on a 24-hour, seven days a week basis as part of public health preparedness. Such a service, whether state-owned and operated or contracted to a designated carrier, is essential to ensure the timeliness of laboratory testing and subsequent treatment or decontamination.

According to APHL's survey of state public health laboratory directors, as of October 2008 only 26 state public health laboratories report having this capacity. Twenty-four states and D.C. do not have this capacity.

Cuts in federal and state budgets have significantly impacted the ability of states to develop and maintain courier services; further budget cuts are expected due to the current economic outlook. These cuts threaten to undermine state laboratory preparedness as rapid recognition of an event requires that samples coming from first responders, clinical or other laboratories be delivered to public health laboratories without delay. Continuous sample referral and timely ground transportation are the keys to state readiness.

PROGRESS IN LABORATORY PREPAREDNESS

Since the first *Ready or Not?* report in December 2003, state public health laboratories have made enormous strides in emergency preparedness. An annual survey of state public health laboratory directors by APHL for TFAH has revealed major gains in terms of laboratory capacity and workforce.

For instance, in 2003, only six states reported that they had sufficient Bio-Safety Level 3 (BSL-3) laboratory facilities. BSL-3 labs are equipped with technology and trained staff that allows them to safely handle infectious agents that may cause serious or potentially life threatening diseases as a result of exposure via inhalation. The number of states with sufficient BSL-3 capacity has grown steadily over the years to 16 in 2004, 37 in 2005, 39 in 2006, and 44 in 2007.

State public health laboratories have also bolstered their workforce of trained lab scientists. In 2004, only 21 states reported having sufficient, trained laboratory scientists to manage tests for anthrax or plague in a suspected outbreak. The number of states with sufficient, trained laboratory scientists to manage tests for anthrax or plague in a suspected outbreak doubled to 41 states and D.C. in 2005, and grew again to 46 states and D.C. in 2006.

In 2008, CDC received FDA clearance of a new CDC-developed test for rapidly detecting seasonal and novel influenza viruses. This test will be deployed at all public health laboratories and other laboratories participating in influenza surveillance. The test has high sensitivity and specificity and will be used to confirm the first cases of pandemic influenza in a community with subsequent initiation of community interventions.

In the midst of all this progress, there are still some gaps. For instance, while 44 state public health labs have Laboratory Information Management Systems (LIMS), only 24 have the ability to create, send, and receive Public Health Information Network (PHIN) messaging.⁴⁵ PHIN messaging uses standard messages and vocabularies to ensure interoperability among public health systems, as well as ensuring that public health systems can work with health care, environmental, homeland defense, and other external systems and networks.

State public health laboratories' progress is due in part to the influx of money from CDC for upgrading state and local public health laboratory capacity. In addition to the accomplishments detailed above, state labs have used these funds to:

- Purchase new instrumentation, adopt new technologies, and develop electronic reporting;
- Recruit and retain laboratory personnel;
- Maintain outreach programs to hospital and clinical laboratories and first responders; and
- Assure a coordinated response effort with federal partners.

However, as a result of funding cuts, much of this progress is threatened. A 2008 APHL survey of state public health laboratories found that labs are experiencing difficulties in the following areas:⁴⁶

- Hiring and maintaining personnel;
- Reduced analytical capabilities;
- Fewer employee training courses offered; and
- Inability to purchase critical equipment and supplies.

Other challenges include logistical problems with getting samples to the labs, duplicative efforts between federal and state agencies, and the lack of communication about these efforts. This is especially important in an era of declining funding.

An increase in funding would allow state public health labs to focus on new priorities, including:

- Expanded chemical terrorism detection;
- Funding for reagents, the diagnostic materials that are required to analyze suspect samples for biological agents; and
- Funding to improve public health laboratory capability to investigate or confirm radiation sickness or genetic mutations.

Indicator 4: PUBLIC HEALTH LABORATORIES -- PANDEMIC INFLUENZA PLANNING

FINDING: Only three state public health laboratories report that they cannot meet the expectations of their state's pandemic influenza plan.

47 states and D.C. report that their public health laboratories meet the expectations of the state's pandemic influenza plan (1 point).			3 states report that their public health laboratories do NOT meet the expectations of the state's pandemic influenza plan (0 points).
Alabama	Louisiana	North Dakota	California Kansas Ohio
Alaska	Maine	Oklahoma	
Arizona	Maryland	Oregon	
Arkansas	Massachusetts	Pennsylvania	
Colorado	Michigan	Rhode Island	
Connecticut	Minnesota	South Carolina	
Delaware	Mississippi	South Dakota	
D.C.	Missouri	Tennessee	
Florida	Montana	Texas	
Georgia	Nebraska	Utah	
Hawaii	Nevada	Vermont	
Idaho	New Hampshire	Virginia	
Illinois	New Jersey	Washington	
Indiana	New Mexico	West Virginia	
Iowa	New York	Wisconsin	
Kentucky	North Carolina	Wyoming	

Source: APHL 2008 Survey of State Public Health Lab Directors

States submitted revised pandemic influenza plans on July 9, 2008 based on the most recent HHS guidance. As a condition to receive PHEP cooperative agreement funding from CDC in FY 2009, state pandemic plans must meet certain national standards. Specific supporting activities from the state pandemic influenza operating plans were identified to be used as part of the assessment in determining whether a particular jurisdiction's PHEP funding may be subject to a partial withholding in FY2009. These activities (chosen across six operating objectives) were selected because they 1) are

important for a pandemic influenza response, 2) are ones in which the states have received some guidance or had an opportunity to prepare, and 3) could easily be evaluated by reviewers. One of the PHEP-related supporting activities involved the evaluation of a state's ability to collect, handle, ship, test, and report on influenza virus specimens.

According to APHL's survey of state public health laboratory directors, as of October 2008 public health laboratories in 47 states and D.C. reported that their labs met the expectations of their state's pandemic influenza plan.

LABORATORY RESPONSE NETWORK (LRN)

The Laboratory Response Network (LRN) is a network of state, local, and federal public health, military, and international laboratories that provides public health, food, veterinary, and environmental testing capacity to respond to biological and chemical terrorism and other public health emergencies. The LRN provides emergency assistance and support through the pooling of resources and personnel based on cooperative agreements.

Over the past six years CDC has expanded the number of LRN labs from 91 in FY 2001 to 164 in FY 2007.⁴⁷ CDC has also worked with LRN member labs to improve their ability to rapidly and accurately identify biological threat agents, raising the passing rate from 83 percent in FY 2005 to 91 percent in FY 2007. Currently, more than 90 percent of LRN labs can perform tests for bioterror agents such as anthrax, tularemia, and plague, and more than 9,000 clinical lab workers have been trained to detect, diagnose, and report public health emergencies.⁴⁸

LRN labs undergo proficiency testing on a regular basis. CDC evaluates the LRN labs based on their performance in four to six challenges per year that use simulated clinical and environmental samples to mimic real events. If LRN labs fail a challenge, CDC and APHL provide technical assistance to the labs and they are re-tested.

CHEMICAL LABORATORY CAPABILITY

According to CDC, there are over 80 chemical agents that can kill or seriously injure a person that have been identified as likely terrorist agents.⁴⁹ Many of these are common commercial and industrial chemicals that can be easily weaponized.

To help address the critical gaps in chemical laboratory preparedness, CDC has expanded the Laboratory Response Network (LRN), an integrated network of approximately 160 labs encompassing federal, state, local, veterinary, military, environmental, food testing, and international labs, to include a chemical network.⁵⁰ The chemical LRN (LRN-c) is made up of 62 state, territorial and metropolitan public health laboratories. LRN-c labs undergo proficiency testing and are put through three challenges per year per chemical testing method. According to CDC, in FY 2007, the LRN-c labs had a 90 percent passing rate on exercises.

Of the 62 LRN-c labs, only 10 are characterized as Level I laboratories.⁵¹ These 10 Level I labs have “biomonitoring” capabilities, meaning they are equipped to detect an expanded number of chemical agents in human specimens (blood, saliva, urine), plus run analyses for mustard agents, nerve agents, and other toxic chemicals that could be used in chemical warfare.

Of these 10, half are ‘new’ labs that need to be brought “to analytical parity with existing Level I laboratories,” a process that is expected to take two more years.⁵² The five existing Level I labs are in California, Michigan, New Mexico, New York, and Virginia. The five new Level I labs will be located in: Florida, Massachusetts, Minnesota, South Carolina, and Wisconsin.⁵³

In the event of a chemical terrorist attack, labs will not only need to be able to test clinical specimens, but also environmental samples, such as water, air, soil, or food, to determine the source, route, and potential extent of contamination. Very few public health laboratories, however, are able to test for chemical warfare agents in environmental samples. In 2006, the Environmental Protection Agency (EPA) began developing the environmental arm of the LRN (eLRN) which will include equipment standards, testing protocols, and training modules for laboratory workers. Without adequate funding, however, it is unclear how many states will be able to upgrade their public health labs.

RADIOLOGICAL LABORATORY PREPAREDNESS

Under the all-hazards approach to emergency preparedness, the United States must be ready to respond to any number of public health catastrophes, including the detonation of a so-called dirty bomb. A dirty bomb, or radiological dispersal device, releases radioactive material through the use of a conventional explosive. Although the detonation of a dirty bomb is unlikely to cause massive casualties or physical destruction, it could expose thousands of individuals to small traces of radioactive materials, which can require medical treatment and leave the exposed at higher risk of developing cancer.

The National Planning Scenarios put together by the Homeland Security Council for use in national, federal, state, and local homeland security preparedness activities includes a scenario that features the detonation of a dirty bomb in a downtown business district of three U.S. cities. Under National Planning Scenario #11, public health emergency responders will have to screen, monitor, and decontaminate up to 300,000 victims (100,000 at each site).⁵⁴ However, according to a U.S. House of Representatives subcommittee report, "...validated methods to test clinical specimens in a radiological emergency exist for only six of the 13 highest priority radioisotopes most likely to be used in a terrorist scenario."⁵⁵ Additionally, for those isotopes for which validated methods do exist, screening 100,000 victims in the wake of a dirty bomb could take more than four years due to current gaps in laboratory preparedness, including lack of equipment, trained personnel, and facilities.⁵⁶ Testing the environmental samples after a dirty bomb attack could take up to six years given current laboratory capacity. A 2006-2007 APHL survey found that fewer than 25 percent of state public health laboratories can screen or test clinical specimens for radiation.⁵⁷

The weakness of current U.S. radiological laboratory capacity was seen in November 2007 when a former Russian KGB agent was poisoned with the radioisotope Polonium-210 in London. After the agent's death, CDC identified 160 U.S. citizens who were potentially exposed to the radioactive material while staying at the same hotel or eating in the same restaurants. However, CDC was only able to find one U.S.-based laboratory capable and qualified to conduct the necessary clinical tests for potential exposure to Polonium-210.⁵⁸

That there are major gaps in radiological laboratory preparedness is not new information. In fact, a 2005 Department of Homeland Security (DHS) report highlighted the weaknesses in current federal efforts.⁵⁹ More recently, in January 2007, the White House issued HSPD-18 to address "Medical Countermeasures against Weapons of Mass Destruction." HSPD-18 warned of the threats posed by nuclear and radiological devices and called on the United States to improve its radiological clinical laboratory testing capabilities.⁶⁰

Two federal agencies have funded and are establishing surge capacity in several state public health laboratories to close the gap in radiological laboratory preparedness. The EPA has funded three state public health laboratories for surge capacity to build a National Environmental Radioanalytical Laboratory Response Network. Once built, the network would drastically decrease the environmental sampling shortfall by 80 percent.⁶¹ FDA has funded and established five surge capacity state public health laboratories.⁶²

CDC has detailed plans to establish a Radiological Laboratory Response Network (LRN-R) that would include five state radioanalytical labs to expand the federal response. The LRN-R would cost an estimated \$20.6 million over the next five years, but if implemented, would reduce the time to analyze the clinical samples from a dirty-bomb attack from four years to three weeks.⁶³ The president's FY 2009 budget request included \$10 million that would be used to expand the urine radionuclide screen into five states through the creation of the LRN-R.⁶⁴ The screen will be able to test for 22 high priority radionuclides likely to be used in a terrorist attack.

Congress, however, failed to pass a FY 2009 budget, instead enacting a Continuing Resolution holding funding at FY 2008 levels for six months, through March 2009.

Indicator 5: BIOSURVEILLANCE -- NEDSS COMPATIBILITY

FINDING: Six states do not use a disease surveillance system that is compatible with CDC’s National Electronic Disease Surveillance System (NEDSS).

44 states and D.C. report that they use a disease surveillance system that is compatible with CDC’s National Electronic Disease Surveillance System (NEDSS) (1 point)			6 states report that they do NOT use a disease surveillance system that is compatible with CDC’s National Electronic Disease Surveillance System (NEDSS) (0 points)
Alabama	Kentucky	Ohio	Connecticut Kansas Minnesota Mississippi Nevada Utah
Alaska	Louisiana	Oklahoma	
Arizona	Maine	Oregon	
Arkansas	Maryland	Pennsylvania	
California	Massachusetts	Rhode Island	
Colorado	Michigan	South Carolina	
Delaware	Missouri	South Dakota	
D.C.	Montana	Tennessee	
Florida	Nebraska	Texas	
Georgia	New Hampshire	Vermont	
Hawaii	New Jersey	Virginia	
Idaho	New Mexico	Washington	
Illinois	New York	West Virginia	
Indiana	North Carolina	Wisconsin	
Iowa	North Dakota	Wyoming	

Source: CDC National Center for Public Health Informatics, Division of Integrated Surveillance Systems and Services.

“ IF WE WANT TO DO ANYTHING IN REAL TIME, IF WE WANT TO ACTUALLY RESPOND TO AN OUTBREAK IN SOME WAY, WE’RE GOING TO HAVE TO COMPRESS THE TIME FROM THE DATA MOVING FROM THE CLINICAL CARE SYSTEM TO THE STATE AND LOCAL PUBLIC HEALTH DEPARTMENTS TO THE CDC, PARTICULARLY WHEN IT’S A DISEASE OF NATIONAL INTEREST OR IMPORTANCE SUCH AS PANDEMIC INFLUENZA OR A SUSPECTED BIOTERRORISM RELATED CONDITION.”⁶⁵

— DR. LESLIE LENERT, DIRECTOR OF THE NATIONAL CENTER FOR PUBLIC HEALTH INFORMATICS, CDC.

Delivering effective public health services depends on timely and reliable information. Health departments can not protect people from existing or emerging health threats, such as a pandemic flu, or a bioterrorist attack, without correct and pertinent information. The lack of timely and comprehensive data can delay the identification of and response to serious and mass emergency health problems. In addition, federal, state, and local health departments and private health care providers must all work together to effectively track information about and respond to health threats.

The National Electronic Disease Surveillance System (NEDSS) was developed to integrate and standardize the tracking of specific infectious diseases. It promotes standards-based, electronic reporting for more rapid, accurate, and integrated information. In fact, a study published in January 2008 found that automated electronic laboratory results (ELR) identified nearly five times as many cases as traditional, paper-based reporting and identified these cases nearly eight days earlier.⁶⁶ The authors noted, that “Public health monitoring of disease outbreaks, including reports of notifi-

able conditions from laboratories and health care providers to public health authorities, is fundamental to the prevention and control of population-based disease.⁷⁶⁷ NEDSS also has the advantage of producing "...integrated surveillance systems, where the disease issues of reportable conditions in public health are tracked in an environment that allows you to see that patients who have HIV also have hepatitis C and tuberculosis, and you can take integrated public health action."⁷⁶⁸

The tracking of specific (i.e., notifiable) diseases does not, however, address the important need to detect health events of urgent concern due to conditions not already called out for surveillance. Additionally, detection is often necessary before the specific cause has been identified even when due to a reportable condition. Early detection of unusual patterns of disease and health behaviors can provide critical lead-time for unexpected events and unexpected occurrences of common conditions (like diarrheal illness). Therefore, NEDSS is working closely with CDC's BioSense program to identify best practices and explore ways to use the same IT infrastructure for both surveillance systems. In 2008, the two programs began testing the integration of their systems for automated laboratory reporting to state and local public health authorities. Further integration of case-based surveillance systems, like NEDSS, with event-based detection is needed at the state and local levels.

According to CDC, to be considered NEDSS-compatible, states must have systems that meet the following requirements:

1. Disease data entry directly through an Internet browser-based system, thereby creating a database accessible by health investigators and public health professionals.
2. Electronic Laboratory Results (ELR) reporting, which allows labs to report cases to health departments.
3. Integration of multiple health information databases creating a single repository.

A fourth component, electronic messaging capabilities, allowing states to share information efficiently with CDC and other health agencies, is being upgraded system-wide, and is, therefore, not included among the criteria.

In order to determine FY2009 grant allocations, CDC's Division of Integrated Surveillance Systems and Services queried state health departments on the status of their Public Health Information Networks. According to CDC's *2008 Assessment of States NEDSS Status*, 44 states and D.C. are NEDSS-compatible, including seven states that achieved NEDSS-compliance for the first time in 2008: Alaska, Arizona, Arkansas, California, Iowa, New Hampshire, and Wyoming. Six states are identified as non-compatible with NEDSS. The majority of the non-compatible states meet two of the three criteria. These states are making steady progress towards meeting the third requirement.

According to CDC, 2009 is the first year of the new project period for the NEDSS cooperative agreement with the states. As part of the NEDSS strategic planning process, which is currently underway, CDC will develop new criteria for NEDSS-compliance. TFAH will use the new criteria in its 2009 report.

REAL-LIFE PUBLIC HEALTH EMERGENCIES

Respiratory Syncytial Virus Outbreak in Alaska, 2007.

In early 2007, hospitals in Alaska were pushed to their limit during a Respiratory Syncytial Virus (RSV) outbreak. By March, 53 infants and young children were diagnosed at a small, 10-bed hospital in Barrow, Alaska. The surge of patients led to the hospital going through nine months of supplies in just six weeks. The Alaska Department of Health and Social Services activated its Emergency Operations Center (EOC) to support the hospitals affected by the illness and developed and distributed fact

sheets around the state describing the symptoms and warning signs of RSV. Such diligence paid off in September 2007 when an outbreak of enterovirus occurred, as well as during the 2008 RSV season. When four infants were admitted in a single week with an unknown illness the hospital staff immediately notified the Alaska Department of Health and Social Services. The rapid disease monitoring and reporting prevented the health system from encountering the overload it had seen the previous year.

Source: ASTHO⁶⁹

BIOSENSE

BioSense is CDC's early-event detection system that collects clinical information from hospitals, such as patients' symptoms, quantities and types of drug prescriptions, and the number of emergency room visits, among other data. This so-called "system of systems" links data "from large hospital systems, data-aggregating systems, and state/county surveillance systems to provide a unified national view."⁷⁰ This type of surveillance, known as syndromic surveillance, relies on information available well before an official diagnosis or confirmed lab result. Some public health officials believe this type of surveillance can be crucial to alerting them to possible disease outbreaks or bioterrorism, while others are skeptical about the merits of syndromic surveillance in providing outbreak recognition.

According to CDC, as of November 2007, BioSense had more than 1,900 hospitals and health care facilities around the country transmitting data. This includes 423 hospitals transmitting real-time data, covering 38 states and 71 major metropolitan areas, and 1,500 federal military and veterans' outpatient facilities.⁷¹ BioSense officials told TFAH that another 200 hospitals joined the program in 2008, as well as the Georgia State Public Health Department and Quest Diagnostics.⁷²

Over the past year, the BioSense program has undergone major revisions based on serious concerns expressed by Congressional overseers and state and local health departments. BioSense is moving away from the previous model of connecting hospitals directly to CDC, which bypassed state and local health departments. According to one CDC official, "This model is kaput." Instead, the BioSense program is focusing on creating a national system that builds on state and local health departments surveillance systems.

The shift in mission has led to new priorities. Over the next four years (2008-2012) the program plans a rapid expansion that will integrate existing state and local real time surveillance systems to maximize coverage. CDC plans to work with state and local health departments and offer technical and financial support for their real time systems in exchange for data.

CDC is also sponsoring the formation of regional collaboratives for real time surveillance. The first grants for these regional partnerships were awarded in October 2008. The four partnerships that received CDC funding cover the following geographic regions: the National Capital Region (Maryland, Virginia, and D.C.); Ohio and Pennsylvania; the St. Louis area; and a Southern States collaborative (North Carolina, South Carolina, Georgia,

Florida, Alabama, and Tennessee). The grantees will focus on developing procedures to collect and share data; information infrastructure; and legal issues around data sharing agreements.

Another program goal is focused on data stewardship. Currently, states have independent systems that are not connected to one another, and in many cases, local health departments are not connected to state systems. To build trust among federal, state, and local partners, CDC is developing a federated database model that would ease the sharing of data among partners. This technology would underpin the regional collaboratives. Under the federated database model, data is stored in different geographic locations around the country. By storing data locally at state and local health departments, but providing access to CDC and other authorized organizations to access and analyze the data, CDC says this "eliminates the risk of a single point of failure thus creating a robust, safe-fail framework."⁷³ BioSense program officials believe this model will entice the participation of those cities and counties that had been reluctant to share data.

Finally, BioSense will work to improve case-detection capabilities, which will allow the surveillance system to capture data more quickly from health care settings and move the information to public health departments at the federal, state, and local levels. CDC also plans to offer incentives to hospitals and health care providers to join the BioSense network by enhancing the system's ability to share data from the public health departments with clinical care providers, and by allowing data collected via BioSense to be used to support research activities.

The president's FY 2009 budget request included \$49.9 million for BioSense, an increase of \$15.5 million over the previous fiscal year.⁷⁴ The additional funds were to be used to:

- Enhance syndromic surveillance capabilities and develop case-based surveillance ones;
- Support basic and applied research and evaluation;
- Implement connections with the new Regional Health Information Organizations (RHIOs) and Health Information Exchanges (HIEs); and
- Increase BioSense coverage in major metropolitan areas.

Congress, however, failed to pass a FY 2009 budget, instead opting for a six-month Continuing Resolution at FY 2008 levels through March 2009.

Indicator 6: HEALTH CARE VOLUNTEER EMERGENCY LIABILITY PROTECTION

FINDING: Eight states have “low” protections for health care volunteers during times of emergency, meaning that those states have only Good Samaritan or similar laws under which volunteers may be provided with an affirmative defense, but not necessarily immunity from liability.

42 states and D.C. have “high” or “medium” protections for health care volunteers during times of emergency (1 point).			8 states have “low” protections for health care volunteers during times of emergency (0 points).
Alabama	Kentucky ⁶	Oklahoma ³	Alaska
Arizona ¹	Louisiana ³	Oregon ³	Florida ^{2,4}
Arkansas	Maine ^{2,3}	Pennsylvania ³	Maryland ^{3,4}
California ^{2,3}	Michigan ^{2,4}	Rhode Island ²	Massachusetts ⁴
Colorado ⁶	Minnesota ^{3,4}	South Carolina ²	Montana ⁴
Connecticut ¹	Mississippi ^{3,4}	South Dakota ^{4,7}	Ohio ⁴
Delaware ^{1,2}	Missouri ^{2,4}	Tennessee ⁶	Texas ⁴
D.C.	Nebraska ^{4,7}	Utah ⁶	Wyoming ^{2,4}
Georgia ^{2,4}	Nevada	Vermont ³	
Hawaii ^{2,3}	New Hampshire ²	Virginia ²	
Idaho	New Jersey	Washington ²	
Illinois ^{2,3,4,7}	New Mexico ⁶	West Virginia ²	
Indiana ⁶	New York	Wisconsin ²	
Iowa ^{1,4,5}	North Carolina ^{2,5}		
Kansas ^{2,4}	North Dakota		

Notes:

States in bold font have “high” protections for health care volunteers during an emergency.

1 State not only pays for liability coverage, but also handles some aspect of legal representation of emergency workers if necessary.

2 Health practitioners explicitly named as a covered class.

3 Introduced UEVHPA legislation; not yet codified.

4 Statute mandates that care provided be uncompensated.

5 State has not codified the UEVHPA but appears to have covered all bases for full immunity for volunteers.

6 State has adopted the UEVHPA.

7 Based on 2007 TFAH review.

Source: Legal review conducted by the George Washington University School of Public Health and Health Services and School of Medicine and Health Sciences.

“REGARDLESS OF THE FREQUENCY WITH WHICH MALPRACTICE CLAIMS MAY OR MAY NOT BE BROUGHT AGAINST VOLUNTEER PRACTITIONERS, AND THE LIKELY OUTCOME OF ANY CLAIMS THAT MAY ARISE, THE RISK OF EXPOSURE TO LIABILITY GREATLY CONCERNS PRACTITIONERS WHO ARE CONSIDERING VOLUNTEERING THEIR SERVICES, AND MAY CLEARLY DETER SOME SKILLED PERSONNEL FROM VOLUNTEERING DURING EMERGENCIES.”⁷⁵

— MICHEALLE CARPENTER, JAMES G. HODGE, AND RAYMOND P. PEPE,

AMERICAN JOURNAL OF DISASTER MEDICINE

In the event of a catastrophic public health emergency, such as a bioterrorist attack, pandemic influenza, or natural disaster, government officials will depend on volunteer health professionals to treat the surge of patients coming forward to seek care. However, relying on volunteer health professionals presents several

issues including: licensing; permissible scope of practice; the relationship between volunteers, the relief organizations, and local health care, emergency management, and licensing agencies; the eligibility of volunteers for immunities from liability; and volunteer protection laws and workers’ compensation benefits.

In a recent survey conducted by the American Public Health Association, almost 60 percent of clinicians reported that having medical malpractice insurance coverage would be important (24.3%) or essential (35.4%) in their decision to travel out of state to provide assistance during an emergency. At the same time, almost 70 percent of respondents answered that immunity from civil lawsuits would be an important (35.6%) or essential (33.8%) factor in deciding whether to volunteer in an emergency.⁷⁶

While federal laws such as the 1996 Federal Volunteer Protection Act (FVPA), the 2002 Federal Tort Claims Act (FTCA), and the 2006 Public Readiness and Emergency Preparedness (PREP) Act all provide some federal liability coverage, there is no uniform federal law that acts as a shield to liability for health care volunteers during declared public health emergencies.⁷⁷ (Please see Section 2: Federal Preparedness for a further discussion on federal law.)

Good Samaritan laws, which exist in all 50 states and D.C., are narrow in scope and generally provide protection only for emergency aid at the scene of an emergency. Health care volunteers who provide non-emergency care at a facility following the acute phase of an emergency, for example, would likely not be protected by a state's Good Samaritan law.⁷⁸ Furthermore, a Good Samaritan statute offers only an affirmative defense in a liability action; it is not a legal grant of immunity from suit.

In response to this gap in nature and scope of legal liability protection extended to volunteers, the National Conference of Commissioners on Uniform State Laws (NCCUSL), along with a number of health care professional organizations, developed the Uniform Emergency Volunteer Health Practitioners Act (UEVHPA). The Act offers model legislation to facilitate the deployment of health care volunteers during emergencies. The UEVHPA addresses a number of important issues, such as registration, licensing and accreditation of qualified health care volunteers for the purpose of swift and effective deployment.⁷⁹ The UEVHPA also

extends civil liability protections to registered health care volunteers similar to the immunity provided to state employees under the Emergency Management Assistance Compact (EMAC), as well as provision for workers compensation.

Researchers examined the extent to which, as of October 2008, states had either adopted UEVHPA or had legislated its elements in equivalent fashion. Researchers adopted the following three-tier approach to the review:

- 1) States adopting the UEVHPA or enacting its full equivalent, as measured by the terms of state statutory law;
- 2) States whose laws offer some, but not all, of the emergency volunteer protections available under UEVHPA; and
- 3) States offering only minimal protections in the form of Good Samaritan Statutes.

The “minimal protections” or “low” category represents those states with only Good Samaritan or similar laws under which volunteers may be provided with an affirmative defense, but not necessarily immunity from liability. The “some protections” or “medium” group of states extend protections to volunteers during times of emergency, but may not explicitly identify health practitioners, may require affiliation with a regional or local emergency compact, or may not provide coverage to volunteers in the event of injury during rendering of services. Finally, the “UEVHPA” or “high” protection states have adopted the model statute or all of its elements.

Based on the research team's findings, TFAH awarded a full point to “high” and “medium” protection states. Forty-two states and D.C. have “high” or “medium” liability protection for health care volunteers during an emergency, while 8 states have “low” liability protection.

The number of states with “high” or “medium” protection for health care volunteers in an emergency grew from 29 states and D.C. in 2007, and TFAH expects state efforts to increase.

There are also efforts underway in the states to use their legal reforms to incentivize volunteerism. For example, in Arizona, state and local government agencies joined the Arizona Medical Association's Disaster Preparedness Task Force and collaboratively produced the "Disaster Preparedness and Awareness Guide for the Arizona Physician."⁸⁰ Colorado now hosts an annual educational seminar focused on legal issues in emergency management through their Division of Emergency Management during which they address issues of volunteer liability among other topics.⁸¹ Texas has focused on systematically registering and credentialing volunteers through their Disaster Volunteer Registry.

In the two years since the NCCUSL adopted the UEVHPA, six states have adopted the UEVHPA model statute or all of its elements: Colorado, Indiana, Kentucky, New Mexico, Tennessee, and Utah. Another 12 states have introduced UEVHPA legislation although it has not been passed or signed into law: California, Hawaii, Illinois, Louisiana, Maine, Maryland, Minnesota, Mississippi, Oklahoma, Oregon, Pennsylvania, and Vermont.

The UEVHPA offers the most complete immunity protections for volunteer health practitioners.⁸² Because the model act includes a prospective designation process, licensing requirements, worker's compensation, and immunity from liability, the UEVHPA sets forth an ideal set of conditions under which practitioners can render emergency care during disasters. By alleviating immediate concerns about personal safety and liability, the UEVHPA establishes a legal climate in which health care professionals are free to provide emergency care in areas under emergency or disaster declarations.

Whether or not a state has explicitly adopted the UEVHPA, most states now provide some level of protection to disaster relief workers during emergencies. At the same time, it is somewhat surprising that nearly a decade after September 11th, all states have not, at a minimum, incentivized volunteerism among health professionals by extending to such professionals the level of immunity accorded a public official acting in an official capacity.

REAL-LIFE PUBLIC HEALTH EMERGENCIES

Southern California Wildfires, November 2007.

In the fall of 2007, California saw the largest evacuation in state history due to a series of wildfires that caused 10 deaths and 139 injuries. The California Department of Public Health deployed 2,000 alternate care site beds that had been purchased by the state to improve the emergency preparedness capabilities. The department also coordinated evacuations from 23 nursing homes, two acute care facilities and a psychiatric hospital. Because of the fast moving and unpredictable nature of the wildfires, approximately 1,600 patients were moved from long term care facilities and hospitals -- all of which was done safely and effectively. Throughout the entire incident the California Department of Public Health provided important information to local health agencies through the Health Alert Network.

Source: ASTHO⁸³

Indicator 7: ENTITY EMERGENCY LIABILITY PROTECTION

FINDING: Twenty-four states and D.C. have statutes that extend some level of immunity to groups and/or organizations providing charitable, emergency, or disaster relief services, although these laws varied greatly among states.

24 states and D.C. have statutes that extend some level of immunity to groups and/or organizations providing charitable, emergency, or disaster relief services (1 point).		26 states do NOT have statutes that extend some level of immunity to groups and/or organizations providing charitable, emergency, or disaster relief services (0 points).	
Alabama ¹	Nevada ⁷	Alaska	Missouri
Arkansas ^{1,2,3}	New Hampshire	Arizona	Montana
California ^{1,2,3,4}	New Jersey ^{3,4}	Connecticut	Nebraska
Colorado ⁴	North Carolina ^{1,3}	Florida ⁶	New Mexico
Delaware ¹	Ohio ¹	Hawaii	New York
D.C. ⁷	Pennsylvania ^{1,3}	Illinois	North Dakota
Georgia ^{1,3}	Rhode Island ^{2,3,4}	Kansas	Oklahoma ⁶
Idaho ¹	Texas ^{1,3}	Kentucky	Oregon
Indiana ^{2,4,5}	Utah	Maine	South Carolina
Iowa ^{1,3}	Vermont	Maryland	South Dakota
Louisiana ^{3,4}	Virginia ³	Massachusetts	Tennessee
Michigan ^{1,3,4,5}	Washington ^{6,7}	Minnesota	West Virginia
	Wisconsin	Mississippi	Wyoming ⁶

Notes:

- 1 Statute specifies that entity service must come at the request of a political division or state agency.
- 2 Statute limits the role an entity may play in the emergency.
- 3 Statute requires entity to provide service without compensation.
- 4 Statute limits the kind of legal entity that may provide emergency services.
- 5 Statute only extends immunity to health care entities.

6 State provides liability protection to real property owners who voluntarily offer their premises for disaster response purposes.

7 A separate telephone survey of state health attorneys by the UNC Institute of Public Health concluded these states offer entity liability protection, however, a facial read of the plain text of the statute suggests remaining ambiguities regarding the extent to which the statute confers unequivocal entity liability.

Source: Legal review conducted by the George Washington University School of Public Health and Health Services and School of Medicine and Health Sciences.

Just as volunteer health professionals will be called upon to provide treatment in a catastrophic public health emergency, so too will private sector and non-profit organizations. In fact, many state preparedness plans envision the role private companies will play in distributing medical countermeasures in the event of a pandemic or bioterrorist attack. (Please see Indicator 1: Strategic National Stockpile for a discussion of the role of the private sector in the distribution and dispensing of medical countermeasures.)

A 2008 IOM workshop examined the issues surrounding the dispensing of medical countermeasures for public health emergencies, including the need for liability protection for private-sector volunteers and entities.⁸⁴ As

the workshop summary report noted, “few states furnish immunity from liability to corporations and other entities when they act as Good Samaritans.”⁸⁵ This is disconcerting as businesses may not be able to maintain typical quality control standards in their efforts to meet demand for resources. During declared states of emergency, legitimate concerns about liability thus could deter or delay health care professionals and entities from fully participating in relief efforts.

Researchers examined state law to identify states that have enacted “volunteer entity” protections to incentivize emergency response by public and private actors. In assessing state law relevant to entity protections, the research team drew from model language developed

by the Public/Private Legal Preparedness Initiative, a special undertaking of the North Carolina Institute for Public Health.⁸⁶ Key elements of this model law are as follows:

- The establishment of a specific coverage trigger (e.g., a Gubernatorial declaration of a state of emergency);
- Retroactive coverage that reaches pre-planning and training activities; and
- An approach to protection that follows the immunity model used for volunteers rather than the more limited, “affirmative defense” approach.

State statutes that extended to entities what might be thought of as “property” immunity – that is, immunity with respect to injuries involving real or other property owned or controlled by an entity – were not included. Rather, in order to qualify for designation, a state statute must have focused on protecting conduct undertaken by entities during an emergency.

As of October 2008, 24 states and D.C. had extended some level of immunity to groups and/or organizations providing charitable, emergency, or disaster relief services. At the same time, these statutes exhibit a wide degree of variation. For example, 12 state laws specify that the provision of services by a covered entity must come at the official request of a state political division; four states limit the role that a covered entity can play in the emergency (e.g., allowing only the provision of goods in response to a disaster); 12 state laws require that the service provided be without compensation; seven state laws limit the types of legal entities that can provide services (i.e., immunizing specific professional groups, such as architectural and engineering firms, rather than extending immunities to all corporate entities); and two states only extended legal protections to health care entities. Though Florida, Oklahoma, and Wyoming provide liability protection to real property owners who voluntarily offer their premises for disaster response purposes, they did not qualify for the entity liability indicator.

STATE EMERGENCY LIABILITY PROTECTION INDICATORS

Faculty and staff at The George Washington University School of Public Health and Health Services and School of Medicine and Health Sciences conducted the research and analysis for “Indicator 8: Health Care Volunteer Emergency Liability Protection” and “Indicator 9: Entity Emergency Liability Protection.” TFAH thanks:

Jennifer Lee, MD; Assistant Professor, Department of Emergency Medicine,

Orriel L. Richardson, MPH; JD anticipated 2011 (GW Law), Research Associate, Department of Health Policy,

Ross Margulies, JD-MPH anticipated 2012, Research Assistant, Department of Health Policy, and Sara Rosenbaum, JD; Chair and Hirsh Professor, Department of Health Policy.

The full-length write-up and the associated table of “State Liability Protections and Relevant Statutes” are available online at <http://healthyamericans.org/bioterrorism-and-public-health-preparedness/>.

TOOLS FOR PUBLIC HEALTH EMERGENCY LEGAL PREPAREDNESS

In 2007-2008, CDC's Public Health Law Program released a set of tools for policy makers and practitioners to use in assessing and strengthening their state's or locality's legal preparedness for all-hazards public health emergencies. These include, among others, the Forensic Epidemiology 3.0 and Public Health Emergency Law 3.0 training curricula, guides for developing MOUs for improved, cross-sector investigation and response, suggested provisions for mutual aid agreements, the National Action Agenda for Public Health Legal Preparedness, and the Social Distancing Law Assessment Template. The National Action Agenda contains 100 'action options' states, tribes, and localities can consider as they work to improve their legal preparedness. (These and other tools can be found at <http://www.cdc.gov/phlp>).

The Social Distancing Law Assessment Template grew out of a CDC-ASTHO project in which 17 states assessed their legal and operational sufficiency to implement quarantine, school closure, and other non-pharmaceutical measures in an influenza pandemic. Fourteen states conducted multi-sector and multi-jurisdiction exercises. Many of the participating states concluded that their relevant laws were adequate but most identified potential problems in implementing social distancing measures effectively. These findings were reflected also in the National Governors Association's 2008 report on pandemic planning that found that 22 states had experienced problems with school continuity and that 13 had cited legal issues.⁸⁷

EMERGENCY PREPAREDNESS DRILLS

State public health departments are encouraged to carry out a variety of drills and exercises, or to use real-world events, to measure their ability to respond in an emergency. According to a Congressional Research Service report "Exercises and drills test the ability of jurisdictions to execute their plans, and they detect planning gaps. Consequently, assessments of response capability rest not only on assessments of planning, but also on assessments of exercise programs and integration of findings into subsequent rounds of planning."⁸⁸

There are three key reasons to measure public health emergency preparedness by drilling, testing and exercising. First, drills and exercises allow planners and policy makers to focus on the most critical aspects of emergency planning, such as mass countermeasure distribution or vaccination and mass casualty care. Second, drills and exercises performed and evaluated in a transparent manner hold officials accountable to the public. Finally, well-designed exercises allow evaluators to identify and address weaknesses in emergency plans.

CDC categorizes preparedness exercises into three groups: tabletop exercises, functional exercises, and full-scale exercise. Tabletop exercises involve discussing responses to emergency scenarios and focus on training and problem solving. Functional exercises test and evaluate capabilities and functions in responding to a simulated emergency, such as a disease outbreak. Full-scale exercises test and evaluate multi-agency, multi-jurisdictional coordinated response to an actual deployment of resources under crisis conditions as if a real incident had occurred.⁸⁹

Under the 2006 PAHPA legislation, preparedness funding is tied to state and local public health departments' incorporation of drills and exercises to test emergency preparedness. The legislation also calls on HHS to develop evidence-based performance measures and criteria to evaluate state and local health departments' performance in these drills. Nearly two years after the PAHPA legislation was signed into law, however, neither CDC nor ASPR have put forth evidence-based guidelines regarding conduct of an emergency preparedness exercise in terms of what outcomes are expected from each drill.

As CDC and ASPR work to develop federal guidelines for public health emergency preparedness drills and exercises, there are some existing federal programs that may offer guidance.

The first model is the **Homeland Security Exercises and Evaluation Program (HSEEP)**, "a capabilities and performance-based exercise program."⁹⁰ HSEEP provides Homeland Security agencies and grantees with "...a common exercise policy and program guidance capable of constituting a national standard for all exercises."⁹¹ HSEEP uses consistent terminology so that exercise planners from all federal agencies can communicate more easily.

In order to be compliant with HSEEP protocols, there are four distinct performance requirements.⁹² They include:

1. Conducting an annual training and exercise plan workshop and developing and maintaining a multiyear training and exercise plan;
2. Planning and conducting exercises in accordance with the guidelines set forth by HSEEP;
3. Developing and submitting an after-action report; and
4. Tracking and implementing corrective actions identified in the after-action report.

CDC has encouraged states to use HSEEP but has not required it.

A second model is the **Nuclear Regulatory Commission (NRC)**, which has stringent emergency preparedness planning procedures in place for NRC headquarters, regional offices, and individual nuclear power plants. Before the NRC licenses a nuclear power plant, NRC must have "reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency."⁹³ NRC determines whether or not the nuclear power plant has provided reasonable assurance by reviewing plant emergency planning procedures and training. According to NRC, "these reviews include regular drills and exercises that assist licensees in identifying areas for improvement."⁹⁴ Each plant owner is required to exercise its emergency plan with the NRC, the Federal Emergency Management Agency (FEMA), and offsite authorities at least once every two years to ensure state and local officials remain proficient in implementing their emergency plans. Plants also self-test their emergency plans regularly by conducting drills. Perhaps, most importantly to assure accountability and transparency, each plant's performance in drills and exercises can be accessed through the NRC Web site.⁹⁵

CENTERS FOR PUBLIC HEALTH PREPAREDNESS AND PREPAREDNESS AND EMERGENCY RESPONSE RESEARCH CENTERS

The Centers for Public Health Preparedness (CPHP) are a network of 30 academic-based preparedness education and training programs located in 27 accredited schools of public health and three universities. The initial mission of the CPHPs was to link their academic expertise with the needs of states for emergency responders and public health professionals trained in public health emergency skills. However, under PAHPA, CPHPs were reorganized. Now, in addition to focusing on the development, implementation, and dissemination of competency-based programs to train public health practitioners, they are required to focus on public health systems and emergency preparedness research. The change in focus to include public health systems research was deemed necessary because legislators found that there has been “tremendous financial investment made to date for public health preparedness with no evidence-based measures for evaluating progress or preparedness.”⁹⁶

Before establishing these new Preparedness and Emergency Response Research Centers (PERRCs), CDC asked the IOM to produce a report on near-term research priorities for emergency preparedness and response.⁹⁷ IOM held a series of public meetings and workshops in December 2007 on the subject and then identified four priority areas for research into PHEP. They include: enhancing the usefulness of PHEP training; improving timely emergency communications; creating and maintaining sustainable response systems; and generating effective criteria and metrics. The final research area is vital as currently “...it is difficult to measure objectively the progress that has been made and the preparedness gaps.”⁹⁸

In October 2008, CDC awarded \$10.9 million to seven accredited schools of public health for the establishment of the PERRCs. CDC awarded the five-year grants (2008-2013) to Emory University; Harvard School of Public Health; Johns Hopkins University; University of Minnesota, Minneapolis; University of North Carolina, Chapel Hill; University of Pittsburgh, Pennsylvania; and University of Washington, Seattle.

Indicator 8: MEDICAL RESERVE CORPS READINESS

FINDING: Seventeen states do not have State-level Medical Reserve Corps Coordinators.

33 states and D.C. have Medical Reserve Corps (MRC) Coordinators (1 point).			17 states do NOT have Medical Reserve Corps (MRC) Coordinators (0 points).	
Alabama	Louisiana	Ohio	Alaska	Nebraska
California	Maine	Oklahoma	Arizona	Nevada
Colorado	Maryland	Pennsylvania	Arkansas	Oregon
Connecticut	Massachusetts	South Carolina	Delaware	Rhode Island
D.C.	Michigan	Tennessee	Idaho	South Dakota
Florida	Minnesota	Utah	Iowa	Texas
Georgia	New Hampshire	Virginia	Mississippi	Vermont
Hawaii	New Jersey	Washington	Missouri	Wyoming
Illinois	New Mexico	West Virginia	Montana	
Indiana	New York	Wisconsin		
Kansas	North Carolina			
Kentucky	North Dakota			

Note: D.C., Guam, Palau, Puerto Rico, and the U.S. Virgin Islands are not required to have State MRC Coordinators, but they do have unit coordinators.

Source: Office of the Civilian Volunteer Medical Reserve Corps, www.medicalreservecorps.gov.

The Medical Reserve Corps (MRC) is a national network of community-based groups which engage civilian volunteers to strengthen public health, emergency response, and community resilience. MRC volunteers include professionals from fields such as public health, medicine, and nursing, as well as non-health professionals who work on administration, logistics, communications, and other support tasks.

The MRC network is supported by the Office of the Civilian Volunteer Medical Reserve Corps (OCVMRC), which is run out of the Office of the U.S. Surgeon General in coordination with ASPR. As of October 28, 2008 there were 170,413 volunteers enrolled in 791 MRC units in 49 states, D.C., Guam, Palau, Puerto Rico, and the U.S. Virgin Islands.

It is recognized that local governmental services may be quickly overtaxed in a major public health emergency, and that MRC volunteers could help deliver essential medical care and other services. For example, in HSPD-21, the White House emphasized the need for state and local jurisdictions to have a cadre of trained volunteers who can come to the aid of their fellow community members. This presidential directive envisions a country “where local civil leaders, citizens, and families are educated regarding threats and are empowered to mitigate their own risk, where they are practiced in responding to events, where they have social networks to fall back upon, and where they have familiarity with local public health and medical systems.”⁹⁹ Groups such as MRC fulfill this vision and “will significantly attenuate the requirement for additional assistance.”¹⁰⁰

In the *2007 Ready or Not?* report, TFAH looked at the number of MRC volunteers per 100,000 persons in each state. In the absence of federal guidelines and evidence-based best practices, TFAH set the threshold for the 2007 indicator at the 25th percentile, meaning 75 percent of states received a point for having met or exceeded 14 Medical Reserve Corps volunteers per 100,000 persons.

For the 2008 report, TFAH, in coordination with the MRC Program Office, looked at a

number of factors in assessing the MRC units within a state, in addition to having volunteers.

■ **Is there a state-level MRC Coordinator?**

All states have been encouraged to appoint an MRC State Coordinator to provide recommendations to OCVMRC about new (and continued) MRC unit registrations, and to provide technical assistance and support to the local MRC units within a state. The appointment of an MRC State Coordinator shows a level of commitment from the state to the MRC. In some states, the same individual serves a dual role as the MRC State Coordinator as well as coordinator for the Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP).

As of October 28, 2008, 33 states had an MRC Coordinator: Alabama, California, Colorado, Connecticut, Florida, Georgia, Hawaii, Illinois, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Maryland, Maine, Michigan, Minnesota, North Carolina, North Dakota, New Hampshire, New Jersey, New Mexico, New York, Ohio, Oklahoma, Pennsylvania, South Carolina, Tennessee, Utah, Virginia, Washington, Wisconsin, and West Virginia

■ **Are the majority of MRC units (≥ 50 percent) in a state in compliance with the National Incident Management System (NIMS) requirements?**

The National Incident Management System (NIMS) provides a consistent nationwide mechanism for federal, state, tribal, and local governments, and private sector and nongovernmental organizations to effectively work together to prepare for, respond to, and recover from emergency incidents. The federal government requires all volunteers and emergency responders to be NIMS compliant, and an understanding of NIMS is one of the MRC Core Competencies.¹⁰¹

As of October 28, 2008, 16 states and D.C. met this benchmark: Alaska, Colorado, D.C., Florida, Iowa, Kansas, Kentucky, Maine, North Carolina, North Dakota, Nebraska, New Hampshire, Oregon, Pennsylvania, Rhode Island, Utah, and Washington. Most

MRC units indicate that they are working towards NIMS compliance.

■ **Are the majority of MRC units (≥ 50 percent) in a state integrated with state ESAR-VHP systems?** The MRC and ESAR-VHP are national initiatives of HHS to improve the nation's ability to prepare for and respond to public health and medical emergencies. While MRC units are made up of individuals from local communities who support public health activities year-round, and are trained to respond in times of emergency, the ESAR-VHP system is primarily a means of registering and verifying the credentials of volunteer health professionals in advance of an emergency. HHS recommends the two programs integrate so as to strengthen the local-state-federal coordination of volunteers in the event of a public health emergency.¹⁰²

As of October 28, 2008, 16 states and D.C. met this benchmark: Colorado, D.C., Florida,

Hawaii, Kentucky, Louisiana, Michigan, Minnesota, Montana, North Carolina, North Dakota, New Jersey, Oklahoma, Rhode Island, South Carolina, Utah, and West Virginia. Many MRC units indicate that they are working towards integration with ESAR-VHP.

For the 2008 report, TFAH awarded states a point based on the presence of an MRC State Coordinator. Not only does this position enhance the collaboration among MRC units across a state, but it is also a position that demonstrates a state's level of funding and commitment to its MRC programs.

For the 2009 report, TFAH will also evaluate states on the second two criteria: NIMS-compliance and ESAR-VHP integration. Although states usually do not have direct control of the MRC units operating within their borders, state governments can affect community resiliency and other MRC-related outcomes through policy, funding, and coordination.

REAL-LIFE PUBLIC HEALTH EMERGENCIES

Major Flooding in Ohio, August 2007.

The Ohio Department of Health emergency response system was tested when flooding hit nine counties in the summer of 2007. In Allen County, one of the affected counties, the local health department used its recently updated communication equipment to share information with local and state officials regarding the flood damage and needs within their community. Public information staff, who had been trained with funds from a CDC cooperative agreement, worked with the media to get information to the public regarding building clean-up, mold prevention, and the potential need of tetanus and other vaccines. Volunteers from the local MRC unit set up a mass dispensing tetanus vaccine clinic, a plan which had been developed as part of SNS preparations. The Ohio Department of Health's Real-time Outbreak and Disease Surveillance (RODS) System was used to detect an increase in complaints related to insect bites in the flooded region, and personal protective measures after a flood were shared with the public in order to reduce the risk of vector-borne illness outbreaks.

Source: ASTHO¹⁰³

Indicator 9: FOOD SAFETY -- DETECTION AND DIAGNOSIS

FINDING: Twenty states and D.C. were unable to identify the pathogen responsible for reported foodborne disease outbreaks at a rate that met or exceeded the national average of 44 percent (combined data 2004-2006).

30 states were able to identify the pathogen responsible for reported foodborne disease outbreaks at a rate that met or exceeded the national average of 44 percent (combined data 2004-2006) (1 point).		20 states and D.C. were NOT able to identify the pathogen responsible for reported foodborne disease outbreaks at a rate that met or exceeded the national average of 44 percent (combined data 2004-2006) (0 points).	
State	Percent of Confirmed Outbreaks (combined data 2004-2006)	State	Percent of Confirmed Outbreaks (combined data 2004-2006)
Alaska	83%	Alabama	2%
Arkansas	88%	Arizona	40%
Colorado	63%	California	30%
Connecticut	83%	Delaware	25%
Hawaii	94%	D.C.	22%
Idaho	61%	Florida	17%
Indiana	100%	Georgia	38%
Louisiana	58%	Illinois	32%
Massachusetts	55%	Iowa	42%
Minnesota	77%	Kansas	24%
Nebraska	100%	Kentucky	0%
Nevada	50%	Maine	33%
New Hampshire	48%	Maryland	42%
New Mexico	75%	Michigan	28%
North Carolina	66%	Mississippi	33%
North Dakota	57%	Missouri	12%
Ohio	44%	Montana	33%
Oklahoma	71%	New Jersey	30%
Oregon	63%	New York	43%
Pennsylvania	66%	Texas	30%
Rhode Island	100%	Washington	28%
South Carolina	68%		
South Dakota	50%		
Tennessee	65%		
Utah	67%		
Vermont	75%		
Virginia	89%		
West Virginia	100%		
Wisconsin	95%		
Wyoming	54%		

Source: CDC's Summary Statistics for Foodborne Outbreaks, 2004, 2005, and 2006. Available online at http://www.cdc.gov/foodborneoutbreaks/outbreak_data.htm

Approximately 76 million Americans – one in four – are sickened by foodborne disease each year. Many of these cases go unreported although there are an estimated 325,000 individuals who are hospitalized annually due to foodborne illness and 5,000 who die each year.¹⁰⁴

CDC defines a foodborne disease outbreak as the occurrence of two or more cases of a similar illness resulting from the ingestion of a common food. State, local, and territorial health departments report foodborne disease outbreaks to CDC each year via the electronic Foodborne Outbreak Reporting System (eFORS). CDC's goal is for 75 percent of outbreaks to have a preliminary report in eFORS within 60 days of the date the first individual became ill.¹⁰⁵

Between 2004 and 2006, the last year for which CDC data was available at the time of publication, state public health departments reported a total of 3,548 foodborne disease outbreaks that sickened 74,077 individuals. Of the 3,548 reported outbreaks, state public

health departments were only able to confirm the etiology, or causative pathogen, in 1,552 cases, or 44 percent of outbreaks.

Monitoring the public's food supply is a real-world example of public health preparedness as it requires the same skills and technologies needed to detect and mitigate bioterrorism and infectious disease outbreaks: a strong surveillance system and adequate lab capacity. According to Michael Taylor, former Deputy Commissioner for Policy at FDA and former Administrator at USDA's FSIS, "ensuring the safety of the food supply is centrally important to the public's health and underpins the success of the nation's trillion dollar food and agriculture industries."¹⁰⁶

The 30 states that earned a point on this indicator were successful at identifying the bacteria, virus, parasite, or chemical that caused the outbreak at rate that met or exceeded the national average of confirmed foodborne disease outbreaks of 44 percent (combined data 2004-2006).

REAL-LIFE PUBLIC HEALTH EMERGENCIES

Salmonella Outbreak in Southern Colorado, March 2008.

Salmonella was first reported in Alamosa, Colorado on March 6, 2008, and by mid-March the Colorado Department of Public Health and Environment was able to pinpoint the source of the outbreak to the water supply. The department then activated its public information hotline, and issued a mutual aid request to water experts as well as requesting donations of bottled water for the affected area. With CDC cooperative agreement funds, the state health agency placed epidemiologists in each of the state's nine all-hazards regions. These epidemiologists conducted case interviews and phone surveys and tracked cases and hospitalizations. The greatest challenge the state faced was keeping the public informed of the outbreak, specifically when it was safe to use the water. The Colorado Department of Public Health and Environment and the local Joint Information Center issued news releases, kept web sites up to date, and produced and handed out informational fliers. Also, with federal cooperative agreement funding, the department was able to contract with the Rocky Mountain Poison and Drug center to run the Colorado Health Emergency Line for the Public, which proved to be very helpful -- answering 2,544 calls.

Source: ASTHO¹⁰⁷

STATES' ROLE IN FOOD SAFETY

State health departments are on the front lines of food safety. A May 2008 report by the Food Safety Research Consortium (FSRC), a multidisciplinary collaboration among eight research institutions to improve the U.S. food safety system, identified the following as the primary roles of state food safety agencies:¹⁰⁸

- Lead responsibility, in collaboration with local health departments and sometimes CDC, of many major outbreak investigations.
- Frontline responsibility for ongoing foodborne illness surveillance, working both independently and in collaboration with CDC and localities on FoodNet, PulseNet, OutbreakNet, and other surveillance initiatives.
- Responsibility for the great majority of all food-related laboratory testing, including testing for pathogens in clinical isolates and chemical and microbial contaminants in food.
- Carrying out more than 80 percent of all non-retail food establishment inspections, other than in meat and poultry establishments, including the majority of “FDA inspections” conducted by state agencies under contract with FDA.
- Overseeing farm inspections of animal health and other conditions related to food safety, including primary jurisdiction for enforcement of federal pesticide use restrictions, which relate directly to the possibility of unsafe residues in food.
- Informing and educating consumers and commercial participants in the food safety system.

Apart from CDC’s Epidemiology and Laboratory Capacity for Infectious Diseases grants to state public health departments, which includes the program goal of reporting 75 percent of foodborne disease outbreaks to eFORS within 60 days of the first case, quantitative standards to measure state food safety surveillance are lacking. To address this gap, the Council to Improve Foodborne Outbreak Response (CIFOR) is developing a series of performance indicators to measure effective foodborne disease surveillance and outbreak response at the state and local level.

On the regulatory side of food safety, in lieu of official required national standards, FDA has pushed two voluntary efforts to create more uniform standards and practices as well as enhance the efficiency and effectiveness of the nation’s food safety system: FDA’s Food Code and a Voluntary National Retail Food Regulatory Program. Both programs seek to provide local, state, and federal regulatory officials with science-based measures of performance that will lead to more effective and uniform regulation of the food service and food retail sectors by state and local food safety programs.

THE FOODBORNE DISEASES ACTIVE SURVEILLANCE NETWORK

The Foodborne Diseases Active Surveillance Network (FoodNet) is an active surveillance system, which means that FoodNet staff routinely contact all clinical laboratories in the 10 FoodNet sites to collect information on every confirmed case under surveillance of nine foodborne diseases. The nine pathogens are *Campylobacter*, *Cryptosporidium*, *Cyclospora*, *Listeria*, *Salmonella*, Shiga toxin-producing *Escherichia coli* O157, *Shigella*, *Vibrio*, and *Yersinia*. FoodNet is a collaborative project of CDC, 10 states* with a population of 45.5 million persons, or 15 percent of the U.S. population, the U.S. Department of Agriculture (USDA), and the FDA. There are four main FoodNet objectives:¹⁰⁹

1. Determine the burden of foodborne illness in the United States.
2. Monitor trends in the burden of specific foodborne illness over time.
3. Attribute the burden of foodborne illness to specific foods and settings.
4. Develop and assess interventions to reduce the burden of foodborne illness.

Note: * the 10 states that are part of FoodNet are California, Colorado, Connecticut, Georgia, Maryland, Minnesota, New Mexico, New York, Oregon, and Tennessee.

MANDATORY REPORTING ON FOODBORNE DISEASES

In the late spring/early summer of 2008, a nationwide *Salmonella* outbreak sickened more than 1,442 individuals in 43 states and D.C. At least 286 persons were hospitalized, and the infection might have contributed to two deaths.¹¹⁰ Food safety officials initially warned consumers to stay away from fresh tomatoes, although this warning was later rescinded as scientists focused instead on raw jalapeño and Serrano peppers. Some epidemiologists and laboratorians have attributed the delay in identification to gaps in mandatory reporting requirements. For example, although 559 individuals (38.7 percent) were sickened in Texas alone from the outbreak, and although Texas was also where the farm with the contaminated peppers was located, it took officials nearly four months to identify the source of the outbreak. Some epidemiologists have questioned whether this delay was related to the fact that Texas does not require labs to collect all clinical specimens associated with a foodborne disease outbreak.

Identifying foodborne disease outbreaks requires regular submission of clinical isolates and specimens to state public health labs. However, according to APHL, hospital and clinical laboratories are sometimes reluctant to send isolates of foodborne pathogens to a SPHL due to cost and time issues. A May 2008 survey of APHL members revealed that only 26 states have laws or rules on the books requiring nongovernmental (e.g. clinical, hospital-based) laboratories within the state to send clinical isolates or specimens associated with reportable foodborne diseases to the state public health laboratory. According to APHL, “failure by these nongovernmental laboratories to submit isolates, specimens and samples could delay timely identification of an outbreak, prolonging exposure to the contaminated product and leading to increased incidence of disease.”¹¹¹

Among the 26 states that do mandate the collection of clinical specimens to state public health labs, 25 states require the submission of *E. Coli* specimens or isolates, 23 states require *Salmonella*, 22 states require *Shigella*, 21 states require *Listeria monocytogenes*, and 20 states require *Vibrio* samples.

ENHANCING THE ROLES OF STATE AND LOCAL GOVERNMENT IN THE FOOD SAFETY SYSTEM

Much of the food safety debate has been over the reforms needed at FDA and USDA in order to streamline the nation’s food safety system. While a federal restructuring is necessary, a successful food safety system that focuses on preventing foodborne disease must also include coordination and collaboration with food safety regulators and health officials at the state and local level. In order to strengthen the roles of state and local agencies, in both their community-based food safety efforts and as integral parts of the nation’s food safety system, the Robert Wood Johnson Foundation is funding a series of meetings among state and local officials, their federal counterparts, and food industry and consumer groups.

The project brings together members of the Association of Food and Drug Officials (AFDO), ASTHO, and NACCHO. Participants will focus on five goals:

1. Formulate and express a modern vision of the role of state and local government in an integrated, prevention-oriented food safety system;
2. Identify gaps or constraints in current law, policy and practice at the federal, state and local levels that inhibit fulfillment of that vision;
3. Recommend changes in law, policy, and practice that are needed to enhance the effectiveness of state and local agencies in addressing food safety problems at the local, state, and national level;
4. Identify specific opportunities to improve collaboration among state, local, and federal agencies; and
5. Describe current funding patterns and resource needs at the state and local level.

A report is due out in early 2009.

Indicator 10: PUBLIC HEALTH FUNDING COMMITMENT -- STATE PUBLIC HEALTH BUDGETS

FINDING: Eleven states and D.C. cut funding for public health from FY 2006-07 to FY 2007-08.

39 states increased or maintained level funding for public health services from FY 2006-07 to FY 2007-08 (1 point)		11 states and D.C. DECREASED funding for public health services from FY 2006-07 to FY 2007-08 (0 points)
State and percent increase (adjusted for inflation)		State and percent decrease (adjusted for inflation)
Alabama (7.2%)	Montana (47.4%)	Arkansas (-0.2%)
Alaska (0.8%) ²	New Hampshire (6.0%)	Colorado (-0.2%)
Arizona (13.4%)	New Mexico (6.2%)	Connecticut (-0.2) ²
California (8.7%) ⁸	New York (12.3%)	D.C. (-2.8%)
Delaware (4.8%) ²	North Carolina (8.8%) ²	Idaho (-2.2%)
Florida (3.3%) ²	North Dakota (52.7%)⁷	Maryland (-9.5%) ²
Georgia (7.5%) ^{6,8}	Ohio (9.0%) ⁴	Nebraska (-3.5%) ⁴
Hawaii (7.2%) ²	Oregon (29.7%)	Nevada (-6.9%)
Illinois (3.7%)	Rhode Island (4.9%)	New Jersey (-4.3%)
Indiana (50.9%)	South Carolina (1.8%)	Oklahoma (-4.1%) ^{1,8}
Iowa (9.2%)	South Dakota (21.7%)	Pennsylvania (-0.8%) ²
Kansas (9.6%)	Tennessee (10.5%)	West Virginia (-0.7%)
Kentucky (1.5%)	Texas (8.6%) ⁸	
Louisiana (20.0%)	Utah (9.2%) ⁸	
Maine (9.3%) ²	Vermont (1.8%) ³	
Massachusetts (3.1%) ⁴	Virginia (5.5%)⁴	
Michigan (2.8%) ⁴	Washington (20.4%)⁴	
Minnesota (14.9%) ²	Wisconsin (9.0%) ⁴	
Mississippi (3.3%) ^{2,8}	Wyoming (3.9%)	
Missouri (2.9%) ^{5,8}		

NOTES: Biennium budgets are bolded.

1 May contain some social service programs, but not Medicaid or CHIP.

2 General funds only.

3 Includes federal funds.

4 Budget data taken from appropriations legislation.

5 Missouri's percent change based on FY 2006-07 and FY 2007-08 actual expenditures.

6 Georgia's budget data for FY 2006-07 taken from appropriations legislation.

7 North Dakota's budget data for the 2007-2009 biennium taken from appropriations legislation.

8 Excludes one-time funding for anti-virals.

Source: Research by TFAH of publicly available state budget documents and interviews with health and budget officials in the states.

This indicator, adjusted for inflation, illustrates a state's commitment to funding public health programs that support the infrastructure – including workforce – needed to adequately respond to emergencies.

Every state allocates and reports its budget in different ways. States also vary widely in the budget details they provide. This makes comparisons across states difficult. For this analysis, TFAH examined state budgets and appropriations bills for the agency, department, or division in charge of public health services for FY 2007-2008, using a definition as consistent as possible across the two years,

based on how each state reports data. TFAH defined “public health services” broadly, including most state-level health funding.

Based on this analysis, 11 states and D.C. experienced cuts in their public health budgets. With the present economic downturn, states are encountering great economic distress and many states have tried to close shortfalls by increasing taxes and/or cutting spending. Currently, 33 states are facing shortfalls to their 2009 state budgets, and 16 states already project shortfalls to their 2010 budgets. At the current rate of economic deterioration, and based on the course of past recessions, the

Center on Budget and Policy Priorities predicts that 2010 state budget gaps will be about \$100 billion.¹¹² TFAH is deeply concerned about the potential of state budget cuts and the effect they will have a state's ability to be prepared for emergencies over the next years.

Several states that received points for this indicator may not have actually increased their spending on public health programs. The ways some states report their budgets, for instance, by including federal funding in the totals or including public health dollars within health care spending totals, makes it difficult to determine "public health" as a separate item.

Few states allocate funds directly for bioterrorism and public health preparedness as part of their public health budgets. Instead, most rely on federal funds to support these activities. The infrastructure of other public health programs, however, also supports their underlying preparedness capabilities.

The PAHPA legislation states, however, that beginning with FY 2009, public health and hospital preparedness grant awardees must contribute non-federal funds to support the cooperative agreements. States are required to match five percent of the total federal funding for FY 2009, and 10 percent of the total amount thereafter.¹¹³ Non-federal funds may come from state public funding or private donations and may be in cash or in-kind. Those states with stagnant or decreasing state public health budgets may be challenged to identify funds required for the state match.

While this indicator examines whether states' budgets increased or decreased, it does not assess if the funding is adequate to cover public health needs in the states. This also does not take into account ongoing hospital needs and funding.

(For additional information on the methodology of the budget analysis, please see Appendix C: Data and Methodology for State Indicators.)

REAL LIFE PUBLIC HEALTH EMERGENCIES

Killer Tornado in Kansas, May 2007.

An EF5 tornado tore through the town of Greensburg, Kansas on May 4, 2007, leaving 11 dead and \$268 million in damages. In the months following the storm, the Kansas Department of Health and Environment led the effort to protect the health and safety of residents. The Kansas Center for Public Health and Preparedness helped to secure medical supplies; the Kansas National Guard deployed its mobile hospital facility to assure that medical care was accessible; the Kansas Department of Health and Environment reissued 355 birth and marriage certificates; the Food Safety division inspected food vendors and oversaw the destruction of perishable food and over the counter drugs; and the Bureau of Disease Control and Prevention distributed vaccines and helped with administering and registering vaccines. The health agency had been trained in the NIMS ICS and was able to respond to the emergency in a more integrated and informed manner than it would have been capable of in the past.

The all-encompassing response by the Kansas Department of Health and Environment illustrates the importance of a well-funded state public health department, which is why TFAH evaluates states on their ability to increase, or at a minimum, maintain state public health funding.

Source: ASTHO¹¹⁴

UNDER PAHPA STATES MUST MATCH FEDERAL DOLLARS

The 2006 PAHPA legislation included a requirement that states receiving CDC PHEP cooperative agreement funding must match those federal dollars with nonfederal contributions beginning in FY 2009 (CDC PHEP budget period August 10, 2009 -- August 9, 2010). The concept of requiring states to match federal dollars is not new. HRSA's Maternal and Child Health Block Grant includes a required state match, as do other federal programs.

The PHEP grantees will be required to provide nonfederal contributions (match) "directly or through donations from public or private entities and may be in cash or in-kind, fairly evaluated, including plant, equipment, or services."¹¹⁵ For FY 2009 states will be required to match at least five percent of the PHEP grant, or \$1 for each \$20 of federal funds. However, for any subsequent fiscal year, states will be required to match no less than 10 percent of such costs, or \$1 for each \$10 of federal PHEP funds. States must thoroughly document their in-kind match to the level that it can pass a U.S. government audit. If they cannot document their five percent match, then their PHEP grant award will be reduced to the level where they can document a match.

In addition, PAHPA includes language on the maintenance of funding which suggests that while states are required to put hard dollars in their public health budget for emergency preparedness and response, if the states are not contributing hard dollars, there is no penalty. The disparity between the severe penalty for the match and the absence of any penalty for the maintenance of funding requirement has led to serious concerns among state health officials.

SELECT 2009 STATE PREPAREDNESS INDICATORS

Based on feedback from state health departments and federal public health officials, TFAH will, for the first time, give states and the public a preview of select indicators that will be measured in the 2009 Ready or Not? report. By doing so, TFAH expects to incentivize local, state, and federal health officials and policy makers to take action to bolster preparedness in key areas.

The indicators presented on pages 51-53 give readers an overview of current preparedness efforts in the following areas: Medical Reserve Corps readiness and food safety. They are not included in the 2008 overall state preparedness scores, but will be used in the 2009 report.



Future Indicator 1: COMMUNITY RESILIENCY -- MEDICAL RESERVE CORPS

For the 2009 report, TFAH will assess the MRC units within each state on three factors, in addition to having volunteers.

- Is there a state-level MRC Coordinator?
- Are the majority of MRC units (≥ 50 percent) in a state in compliance with the National Incident Management System (NIMS) requirements?
- Are the majority of MRC units (≥ 50 percent) in a state integrated with state ESAR-VHP systems?

Although states usually do not have direct control of the MRC units operating within their borders, state governments can affect community resiliency and other MRC-related outcomes through policy, funding, and coordination.

The results, as of October 2008, are listed below.

6 states and D.C. have: 1) Medical Reserve Corps (MRC) Coordinators, 2) a majority of MRC units in compliance with NIMS, and 3) a majority of MRC units integrated with state ESAR-VHP systems (1 point).	44 states do NOT have: 1) Medical Reserve Corps (MRC) Coordinators, 2) a majority of MRC units in compliance with NIMS, and 3) a majority of MRC units integrated with state ESAR-VHP systems (0 points).	
Colorado D.C.* Florida Kentucky North Carolina North Dakota Utah	Alaska Alabama Arkansas Arizona California Connecticut Delaware Georgia Hawaii Iowa Idaho Illinois Indiana Kansas Louisiana Massachusetts Maryland Maine Michigan Minnesota Missouri Mississippi	Montana Nebraska New Hampshire New Jersey New Mexico Nevada New York Ohio Oklahoma Oregon Pennsylvania Rhode Island South Carolina South Dakota Tennessee Texas Virginia Vermont Washington Wisconsin West Virginia Wyoming

*Note: D.C., Guam, Palau, Puerto Rico, and the Virgin Islands are not required to have State MRC Coordinators, but do have unit coordinators.

Source: Office of the Civilian Volunteer Medical Reserve Corps

Future Indicator 2: FOOD SAFETY -- IMPLEMENTATION OF FOOD SAFETY PROGRAMS

For the 2009 report, TFAH will assess states on their implementation of the Voluntary National Retail Food Regulatory Program.

The FDA -- in collaboration with federal, state, and local regulatory agencies; the academic industry; trade associations; and consumers -- has also established a Voluntary National Retail Food Regulatory Program. The program's goal is to reduce or eliminate the occurrence of illnesses and deaths from food produced or handled at the retail level.¹¹⁶

The program seeks to provide local, state, and federal regulatory officials with science-based measures of performance by state and local food regulatory programs that will lead to more effective and uniform regulation of the food industry.

Participation in the program is voluntary. To be part of the program, the jurisdiction must carry out an initial self-assessment of its retail

food safety program within 12 months of enrollment in the program, conduct self-assessments every 36 months after that, and submit to verification audits by outside parties.

As of July 2008, 40 states had at least one state-wide agency enrolled in the program. Of these 40 states, 33 had completed the initial self-assessment of their program. The self-assessment is used to identify each program's strengths and weaknesses. Programs are assessed in nine areas. If a state meets any of the nine standards, it reports that self-assessment result to FDA. Thirty-two states met at least one of the nine standards based on their self-assessment. Thirteen states had that achievement verified by an external evaluator.

States that have their self-assessments verified by an external evaluator will earn a point on this indicator.



Status of States Enrolled in Voluntary National Retail Regulatory Program

State	State Agency Enrolled	Self-Assessment Completed	Achieved at least 1 of 9 Standards Based on Self-Assessment	Achievement Verified by External Evaluator
Alabama	✓	✓		
Alaska	✓	✓	✓	✓
Arizona*				
Arkansas	✓	✓	✓	
California	✓	✓	✓	
Colorado	✓	✓	✓	
Connecticut	✓	✓	✓	
Delaware	✓			
D.C.	✓			
Florida	✓	✓	✓	✓
Georgia	✓	✓	✓	✓
Hawaii	✓	✓	✓	
Idaho	✓	✓	✓	✓
Illinois	✓	✓	✓	
Indiana				
Iowa	✓	✓	✓	✓
Kansas	✓	✓	✓	✓
Kentucky				
Louisiana				
Maine				
Maryland	✓	✓	✓	
Massachusetts	✓	✓	✓	✓
Michigan	✓	✓	✓	✓
Minnesota	✓	✓	✓	
Mississippi	✓	✓	✓	
Missouri	✓	✓	✓	✓
Montana	✓	✓	✓	
Nebraska	✓	✓	✓	
Nevada	✓	✓	✓	
New Hampshire				
New Jersey	✓			
New Mexico	✓	✓	✓	
New York				
North Carolina	✓	✓	✓	✓
North Dakota				
Ohio	✓	✓	✓	
Oklahoma	✓	✓	✓	
Oregon	✓	✓	✓	✓
Pennsylvania	✓	✓	✓	
Rhode Island	✓	✓	✓	✓
South Carolina				
South Dakota	✓			
Tennessee	✓			
Texas	✓	✓	✓	✓
Utah	✓			
Vermont				
Virginia	✓			
Washington				
West Virginia	✓	✓	✓	
Wisconsin	✓	✓	✓	
Wyoming	✓	✓	✓	

Source: Data as of July 2008 as reported by FDA's Center for Food Safety and Applied Nutrition.¹¹⁷

Note: *No state-wide agency is enrolled in the program. However, 11 of 15 counties in Arizona are enrolled. Of the 11 counties, five have had their achievements verified by an outside auditor.

VOLUNTARY NATIONAL RETAIL FOOD REGULATORY PROGRAM

The nine standards enshrined in the program seek to provide local, state and federal regulatory officials with sound, science-based measures that will lead to a more uniform regulation of the food industry.

The Standards address the following program areas:

1. Regulatory Foundation
2. Trained Regulatory Staff
3. Inspection Program Based on HACCP Principles
4. Uniform Inspection Program
5. Foodborne Illness and Food Security Preparedness and Response
6. Compliance and Enforcement
7. Industry and Community Relations
8. Program Support and Resources
9. Program Assessment

The Program's high standards are not static but ever changing as new problems and new solutions come to light. A built-in framework allows for continuous improvement based on scientifically-sound performance measures.

States and local jurisdictions that choose to participate in the voluntary program must follow a continuous improvement model. First, the jurisdiction carries out an initial self-assessment of its retail food safety program within 12 months of enrollment in the Program, and every 36 months thereafter. The self-assessment is used to determine whether or not the jurisdiction meets the NRFRP's standards. After the self-assessment, the jurisdiction must conduct a verification audit within 36 months of the initial self-assessment. The verification audits are to be performed by an outside party and these results are used to confirm the accuracy of the self-assessment. Once the verification audit is finished, the jurisdiction begins the whole cycle anew by completing another self-assessment. This allows the jurisdiction a chance to meet more of the nine standards, while accounting for changes and updates in food safety regulations.



Federal Preparedness

In this section of the report, TFAH examines federal preparedness activities.

December 2008 marks the two-year anniversary of the signing of PAHPA and the one-year anniversary of HSPD-21: Public Health and Medical Preparedness. Both the PAHPA legislation and the Presidential Directive represent significant advances in the nation's preparedness as they set out key deliverables and benchmarks for government agencies. While much progress has been made in meeting these deliverables, TFAH finds that the federal government continues to lag in several key areas:

- Congress has failed to deliver a sustained financial commitment towards preparedness – especially at the state and local level – where many of the essential preparedness and response activities occur.
- The federal government has failed to align its own policies with the recommendations

and guidance it set forth for individual and household preparedness.

- The current federal emergency preparedness structure is complex and overlapping; the Obama administration will need to untangle this.

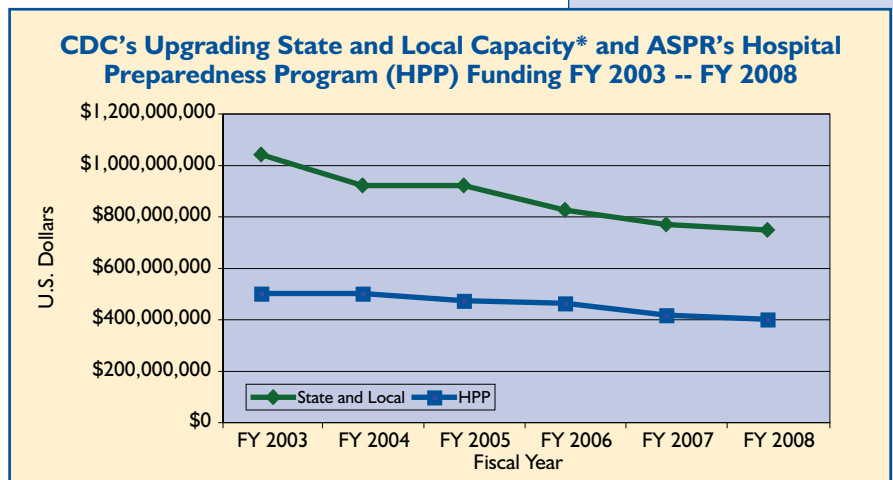
Issues addressed in this section include:

1. Funding for pandemic and all-hazards preparedness;
2. The state of federal preparedness;
3. Implementation of the PAHPA of 2006; and
4. Additional federal issues, including the lack of an emergency health benefit and deficiencies in sick leave policies, liability protection for federal health care workers, and the shelf-life extension program for medications and vaccines.

I. Funding for Pandemic and All-Hazards Preparedness

Over the past six years, the federal government has invested more than \$6.3 billion in state and local preparedness, and provided an additional \$600 million for state and local pandemic preparedness. Federal funding, however, has been inconsistent and has declined over the past several years. A report from the Center for Studying Health System Change noted that “federal funding is fragmented ...coming from several sources with varied requirements, making it difficult for communities to pursue a comprehensive strategy.”¹¹⁸

Federal funding also has declined steadily over the past four fiscal years. Congress failed to pass the FY 2009 budget and instead, passed a continuing resolution that funded programs at the FY 2008 level through March 2009. This flat funding represents a 25 percent cut from the public health preparedness funding level in FY 2005.



*Note: Upgrading State and Local Capacity includes funds for: PHEP Cooperative Agreements, Centers for Public Health Preparedness, Advanced Practice Centers, and all other state and local capacity. HPP line represents actual grant awards to states and does not include non-grant program funds used to support HPP evaluation activities or federal administration costs.

Source: 1) Upgrading State and Local Capacity funding from CDC's FY 2009 Budget Justification document.¹¹⁹ 2) Hospital Preparedness Program (HPP) funding from HHS's FY 2009 Budget Justification document.¹²⁰

A. UPGRADING STATE AND LOCAL CAPACITY

State and local preparedness funds have remained relatively stagnant since FY 2003. Congress failed to pass the FY 2009 budget, instead opting for a six-month continuing resolution until March 2009, so funding will remain at the FY 2008 level unless Congress strengthens the program in March.

According to ASTHO, steep cuts in the preparedness grants “will seriously hinder the ability of state and local health agencies to plan and carry out future activities.”¹²¹ Cutting the budget will affect the ability of state

public health agencies to carry out the following activities:¹²²

- Recruitment and training of a highly skilled, professional workforce;
- Improvement in state response plans;
- Expansion of laboratory capacity for biological, chemical, and radiological agents of terrorism;
- Enhancement of surge capacity for mass casualties; and
- Improvements in disease detection and surveillance technologies and programs.

B. HOSPITAL PREPAREDNESS PROGRAM (HPP)

Inconsistent and decreasing funding also has plagued the HPP grants. For instance, in FY 2007, ASPR competitively awarded \$18.1 million to Health care Facilities Partnerships “for the purpose of improving surge capacity and enhancing community and hospital preparedness for public health emergencies in defined geographic areas.”¹²³ Another \$25 million was awarded to Health care Facilities Emergency Care Partnerships to help integrate emergency care systems into overall preparedness strategies and plans.¹²⁴ Both programs were zeroed out in the FY 2009 budget. Although Congress failed to pass the FY 2009 budget and instead, passed a six-

month Continuing Resolution that funds programs at FY 2008 levels through March, it is unclear if these programs will receive funding.

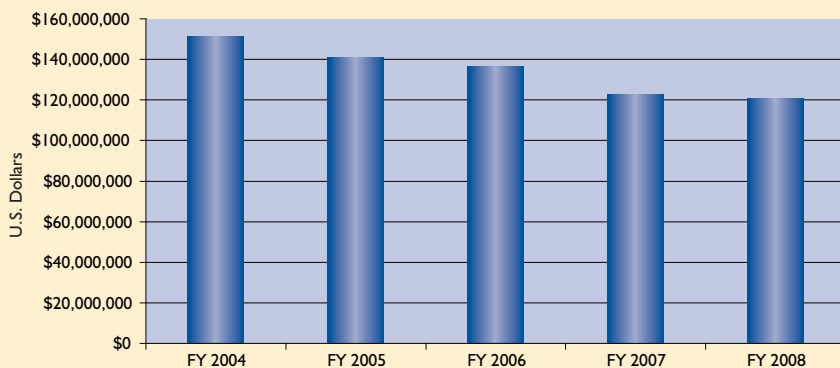
According to a 2008 GAO report, state health officials have expressed concern that “federal funding for ASPR’s HPP decreased while program requirements increased, making it difficult for states to plan for maintenance of emergency preparedness systems, meet new requirements, and replace expired supplies.”¹²⁵ State officials have argued that a three-year funding cycle would allow for long-term planning and more realistic work plans.¹²⁶ ASPR officials are said to be aware of these concerns and considering a change beginning in FY 2009.

C. UPGRADING CDC CAPACITY

In FY 2008, Congress appropriated \$120 million to CDC’s Coordinating Office for Terrorism Preparedness and Emergency Response to upgrade CDC capacity in the area of public health emergency preparedness initiatives. This funding supported a variety of programs including:

- Laboratory Response Network (LRN),
- Radiological Laboratory Response Network (LRN-R);
- Select Agents Program;
- Epidemic Intelligence Service (EIS);¹²⁷

Upgrading CDC Capacity Funding Levels FY 2004 -- FY 2008



Source: CDC’s FY 2009 Budget Justification document.¹²⁸

- CDC Director's Emergency Operations Center (DEOC); and
- Monitoring and evaluation of COTPER-funded programs, including the state and local grants.

As with other CDC programs, funding has declined significantly over the past five years,

yet PAHPA and HSPD-21 require programs to meet higher benchmarks and deliverables. Policy directives without the adequate funding to support them are rhetoric and do not show a serious commitment on the part of the administration and Congress towards emergency preparedness and response.

D. BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY (BARDA)

The president's FY 2009 budget proposal included \$250 million for BARDA, an increase of \$148 million over FY 2008. An August 1, 2008 White House amendment to the FY 2009 budget proposed to increase BARDA funding by about \$500 million. The additional funds would have been used to support the advancement of medical countermeasures for 12 biological threat agents, volatile nerve agents, and radiological and nuclear threats. In addition to these funds for advanced research and development, \$25 million was included to support the advanced development of next generation ventilators to help patients

in acute respiratory distress in a pandemic or other public health emergency. The request also included \$22 million to manage Project BioShield, slightly more than FY 2008.

Given the passage of the continuing resolution that funded programs at FY 2008 levels through March 2009, it is unclear if BARDA will be able to meet its development goals.

BARDA Funding FY 2007 - 2009	
FY 2007 actual	\$103,921,000
FY 2008 enacted	\$101,544,000

Source: U.S. Department of Health and Human Services¹²⁹

E. PANDEMIC INFLUENZA PREPAREDNESS

Congress passed a continuing resolution that funded programs at FY 2008 levels through March 2009. In FY 2008, Congress funded \$322 million for ongoing pandemic preparedness activities at CDC, FDA, NIH, and the Office of the Secretary of HHS.

In September 2008, CDC announced it had awarded \$24 million to fund 55 programs in 29 state and local public health departments that could serve as innovative approaches for influenza pandemic preparedness.¹³⁰ The \$24 million for the new projects is part of the \$600 million allocated toward state and local pandemic influenza preparedness back in FY 2006.

The \$600 million for state and local pandemic preparedness was supplemental funding that has been exhausted, although states will continue to work on pandemic influenza planning through the all-hazards PHEP cooperative agreement. However, CDC estimates that \$20 million of the \$600 million went to hire qualified personnel for specific pandemic planning positions. When this money is exhausted, these employees will be let go. Meanwhile, at the same time the federal government has cut all state pandemic influenza preparedness funding, the PAHPA legislation links the quality of state pandemic plans to their eligibility for future PHEP grants.

2. Pandemic Influenza Preparedness

In the three years since the White House issued the National Strategy for Pandemic Influenza, much progress has been made to ready the nation for a future pandemic influenza outbreak. The federal government has:¹³¹

- Stockpiled pre-pandemic vaccines and antivirals;
- Created a domestic vaccine production capacity commensurate with the expected requirements of a pandemic;
- Sponsored advanced development projects toward the next generation of vaccines, therapeutics, and diagnostics; and
- Provided financial and technical assistance to states to help them, among other things, create complementary stockpiles of antiviral drugs and develop and test various mitigation strategies.

Pandemic preparedness, to date, has focused on the low-hanging fruit. Now that the easier to solve problems have been addressed, HHS Secretary Michael Leavitt notes that, “We have entered a new phase in our preparations. The

milestones are farther apart but no less significant. We are now tackling some challenging issues that can only be resolved with the collaboration of the full range of stakeholders – state and local officials, public health and medical professionals, religious leaders and ethicists, the business community, organized labor, non-governmental organizations, and individuals from all walks of life.”¹³²

Among these challenging issues are four areas of crucial importance to pandemic preparedness:

- Real-time disease detection and clinical surveillance;
- Mass casualty care / Surge capacity;
- Swift distribution of medical countermeasures; and
- Legal and feasibility issues associated with community mitigation strategies.

If unaddressed, these could significantly limit the effectiveness of the national pandemic response.

FEDERAL - STATE PANDEMIC PREPAREDNESS COLLABORATION

The National Pandemic Implementation Plan includes 324 action items; 17 of these call for states and local governments to lead national and sub-national efforts; 64 of these require state involvement. The 2006 PAHPA legislation requires states to develop pandemic influenza plans that meet national standards.¹³³ HHS collected the first round of state plans in April 2007; however, an initial review of these plans by HHS and other federal agencies found the plans to be lacking. According to a separate GAO report published in September 2008, the HHS-led review of state pandemic influenza response plans found “many major gaps” in state pandemic planning in 16 out of 22 priority areas.¹³⁴ The GAO report faulted HHS and other federal agencies, noting that “while the federal government has provided some support to states in their planning efforts, states and localities have had little involvement in national planning for an influenza pandemic....even though the Na-

tional Pandemic Implementation Plan relies on these stakeholders efforts.”¹³⁵

In between the initial submission of state pandemic plans and the publication of the GAO report, HHS revised its set of pandemic planning criteria to remedy gaps in state plans and address state and local officials’ concerns. In July 2008, states re-submitted their revised plans to HHS. These plans are currently under review.

The quality of state pandemic plans takes on additional significance beginning in FY 2009 (CDC PHEP budget period August 10, 2009 – August 9, 2010), as the PAHPA legislation mandates that CDC link the quality of state plans to public health emergency preparedness (PHEP) funding. To evaluate the quality of state plans, experts from HHS, CDC and the states developed grading criteria. State plans must demonstrate the state’s ability to accomplish the following objectives:¹³⁶

- Ensure public health continuity of operations during each phase of a pandemic;
- Ensure surveillance and laboratory capability during each phase of a pandemic;
- Implement community mitigation interventions;
- Acquire and distribute medical countermeasures;

- Ensure mass vaccination capability during each phase of a pandemic; and
- Ensure communication capability during each phase of a pandemic.

HHS has indicated that they will release the results of the state pandemic influenza operational plan review in December 2008, although the transition of administrations may result in changes to how or when the results are released.¹³⁷

3. The State of Federal Preparedness: What the Obama Administration Needs to Know

Although there have been many achievements over the past seven years, including the development of medical countermeasures for use in a pandemic flu or bioterrorist attack, the creation and implementation of a National Strategy for Pandemic Influenza, and the creation of volunteer med-

ical and public health emergency response teams, among others, there are many crucial areas where much remains to be done. In addition, the current system has many redundancies that need to be addressed and streamlined. This should be a top priority of the Obama administration.

A. DEFINING PUBLIC HEALTH PREPAREDNESS ROLES AND RESPONSIBILITIES

The Obama administration must address how public health emergency preparedness and response can be better organized. Many experts have called for more clarity around the roles and responsibilities of federal agencies involved in public health emergency preparedness – both among cabinet agencies – HHS, DHS, VA, and DOD – and for offices within HHS – ASPR, CDC, and HRSA.

HHS is the lead cabinet agency for determining policy and planning for health emergen-

cies. There is broad consensus among experts that HHS should remain as the lead agency. However, other cabinet agencies have different types of expertise that are needed during emergencies, for example, the VA can manage large health systems and the VA and DOD can effectively and rapidly move people, equipment, and supplies. The Obama administration should ensure that these agencies are well-integrated in the nation’s public health emergency response system.

B. Biosurveillance Coordination

A 2008 GAO report highlighted the importance of a robust national biosurveillance system. In testimony before the U.S. House of Representatives, the lead author of the GAO report noted that “Infectious diseases have the potential to develop into widespread outbreaks and could have significant consequences, such as causing hundreds of thousands of casualties, disrupting transportation and weakening our economy, damaging public morale and confidence, and threatening our national security.”¹³⁸ While

these infectious disease outbreaks could occur naturally, the United States faces the possibility that terrorists will use biological agents as weapons of mass destruction.

It is, therefore, no surprise that the administration and Congress have emphasized the need to improve biosurveillance. While HHS is considered the lead agency for public health response – including human biosurveillance – some critical health functions operate out of the DHS Office of Health, which has devel-

oped three major initiatives to provide early detection and warning of biological threats: the National Biosurveillance Integration Center (NBIC), the National Biosurveillance Integration System (NBIS), and BioWatch.

Meanwhile, CDC, consistent with HSPD-21, has set up the Biosurveillance Coordination Unit (BCU). The BCU is leading the development of the National Biosurveillance Strategy for Human Health and its implementation in collaboration with public and private stakeholders. The development of this strategy is necessary to leverage current nationwide capabilities and target new investments where the greatest improvement can occur. The specific goal of this effort is to generate timely and comprehensive information that is accessible to decision-makers in government, business, and the public in a usable and appropriate context; thereby, saving lives through improved recognition of and response to urgent health threats. BCU released an updated draft on October 31, 2008.

HSPD-21 also requires the establishment of a federal advisory committee, including representatives from state and local government public health authorities and appropriate private sector health care entities, in order to ensure that the federal government is enhancing state and local government public health surveillance capability. The National Biosurveillance Advisory Subcommittee (NBAS), which is comprised of prominent public and private biosurveillance stakeholders and contributors, was developed to meet this mandate. The

NBAS will provide independent advice on biosurveillance for human health which will be incorporated into the National Biosurveillance Strategy for Human Health.

In addition to systems at DHS and CDC, there are biosurveillance systems at many other federal agencies, including USDA, FDA, EPA, VA, DOD, and the Office of the Director of National Intelligence (ODNI). The mission of DHS's NBIC is to bring all these disparate biosurveillance feeds together by developing, operating, and maintaining an integrated network. This network, the NBIS, will be used to detect a biological event that presents a risk to the United States or its infrastructure or key assets.

Given the confusion surrounding the existing national biosurveillance structure, Congress has commissioned two reports on the subject. First, IOM and the National Research Council are evaluating national biosurveillance systems to detect biological threats in order to determine the relative strengths and weaknesses of the existing programs in detecting and responding to biological attacks. This report is scheduled to be released in the late spring/early summer of 2009. Second, GAO is studying the integration of U.S. biosurveillance systems as mandated by the 9/11 Commission Act of 2007 (P.L. 110-53). This report is due out in the spring of 2009.

The Obama administration should review the recommendations in these two major reports as well as the recommendations from the NBAS.

NATIONAL BIOSURVEILLANCE INTEGRATION CENTER (NBIC)

DHS was required to establish a fully operational NBIC by September 30, 2008 as part of the Implementing Recommendations of the 9/11 Commission Act of 2007 (P.L. 110-53). NBIC's mission, as spelled out by the 9/11 Commission Act is to:

- Rapidly identify, characterize, localize, and track a biological event of national concern;
- Integrate and analyze data relating to human health, animal, plant, food, and environmental monitoring systems; and
- Disseminate alerts to member agencies, and state, local, and tribal governments.

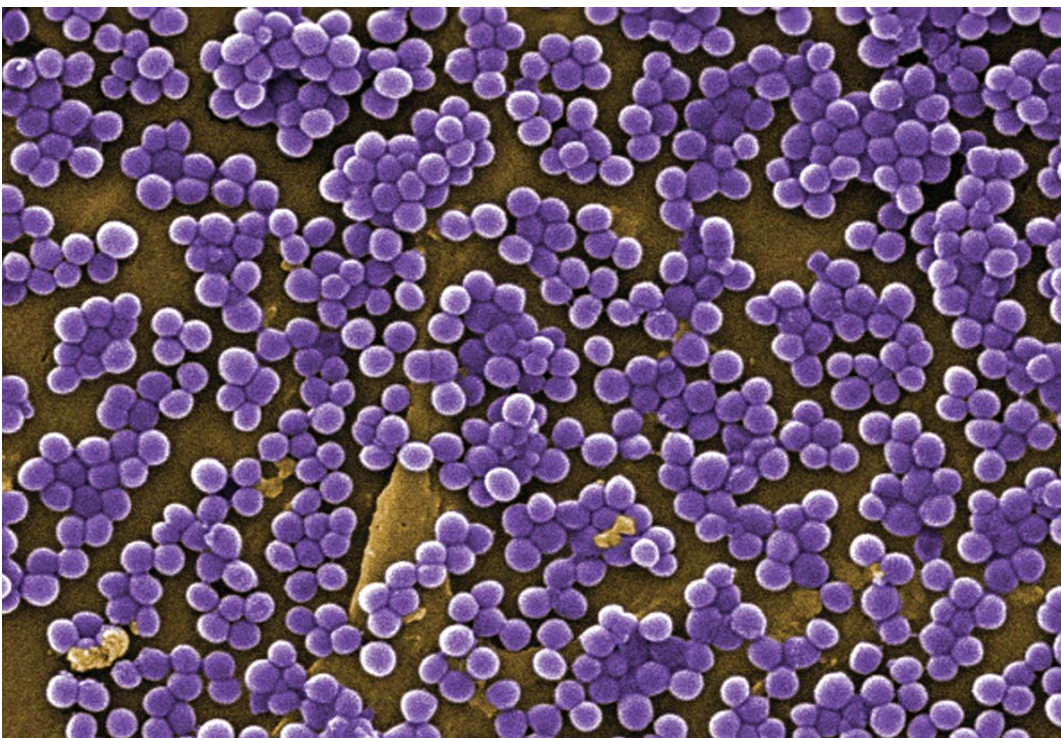
NBIC is developing a so-called "system of systems", the NBIS, that will pull together and integrate surveillance data from all federal agencies, including CDC. The NBIC, it is important to note, has no routine information exchange with the states. Considering that state and local governments are the first to respond to public health emergencies, that appears to be a major gap.

Although there is some indication that NBIC intends to move into primary data collection, public health experts worry that this could lead to duplication. Especially in an era of declining resources, they argue that it would be better for NBIC to focus on the integration of data.

According to a 2008 GAO report, there have been numerous difficulties in bringing the NBIC online, including: defining what capabilities the center will provide once fully operational; formalizing interagency cooperation agreements; and, installing a new information technology (IT) system.

NBIC continues to negotiate agreements with member agencies on the data they are to provide for the IT system. There is an inter-agency working group and MOUs have been finalized with six of the 11 agencies that NBIC officials deemed important to center operations. DHS has signed MOUs with DOD, USDA, HHS, the Department of Interior, State, and Transportation. NBIC has MOUs pending with five other agencies: the Department of Commerce, the EPA, Department of Justice, the U.S. Postal Service, and the VA.¹³⁹

In FY 2008, DHS received \$8 million to establish the NBIC and has requested an additional \$4.2 million in reprogrammed funds.¹⁴⁰



BIOWATCH

BioWatch is DHS's environmental monitoring system, which is designed to serve as an early warning system in the event of the release of biological agents by monitoring and testing air samples. BioWatch sensors were first deployed in 2003 and there are currently some 500 sensors located in some 30 U.S. cities.¹⁴¹

The goals of BioWatch are to:

- Deliver early warning of a biological attack by identifying the biological toxin to minimize casualties;
- Assist in providing evidence on the source, nature, and extent of an attack to aid law enforcement and public health officials; and
- Determine where the biological attack occurred and what populations were exposed.

The latest generation of BioWatch detectors is in development. These sensors will be fully automated and monitor five biological agents. Samples are collected on a 24/7/365 basis.

Critics of BioWatch point to its high cost -- the annual maintenance and operating budget is \$77 million -- and have suggested that the money would be better spent on enhancing hospital-based rapid diagnostic capabilities. BioWatch has also suffered from sensors picking up bioagents occurring naturally in the environment that were not related to any sort of terrorist attack. In fact, most of BioWatch detections have been environmental detection events of indigenous organisms, while a few were related to lab cross contamination.

State public health laboratories have also faced significant problems related to the BioWatch program. There are 24 state public health laboratories that host the BioWatch program and provide dedicated office and lab space for the BioWatch program free of charge.¹⁴² In July 2008 testimony before the U.S. House of Representatives Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Dr. Frances Pouch Downes, President of APHL, outlined her association's major concerns with the BioWatch program.¹⁴³ These included:

- The lack of a contractual relationship between DHS and public health laboratories;
- Uncompensated laboratory costs;
- Unclear rules for the management and oversight of BioWatch contract employees by state public health lab employees;
- Gaps in performance data necessary for state and local labs to assess BioWatch responses, or possible false positives; and
- Security clearance concerns.

To address these concerns, APHL recommends that DHS fund BioWatch program partners through a cooperative agreement so that contractors become employees of state and local jurisdictions and more easily integrated into the public health labs. APHL also calls on CDC to direct more funding from the public health emergency preparedness program grants to labs with BioWatch programs.

Given the controversy surrounding BioWatch, several organizations are preparing reports on its effectiveness and place within the broader U.S. biosurveillance system. First, at the request of Congress, the IOM and the National Research Council are evaluating national biosurveillance systems to detect biological threats in order to determine the relative strengths and weaknesses of the BioWatch system and the U.S. hospital and public health system in detecting and responding to biological attacks. The final report will be released in the late spring/early summer of 2009.

A second group, the National Biosurveillance Advisory Subcommittee (NBAS), which was created under HSPD-21, is also evaluating BioWatch and other biosurveillance systems to develop a series of recommendations for the Obama administration. That report is due in February/March 2009.

Finally, GAO is working on its own report on the integration of U.S. biosurveillance systems as mandated by the 9/11 Commission Act of 2007 (P.L. 110-53). This report is due out in the spring of 2009.

CDC BIOSURVEILLANCE INITIATIVES

In the past year CDC has worked with federal, state, and local stakeholders to organize current biosurveillance capability for human health and identify priorities to achieve the capability we need as a nation to detect acute health emergencies early and respond effectively. Two important entities have been stood up to meet the HSPD-21 mandate: the Biosurveillance Coordination Unit (BCU) and the National Biosurveillance Advisory Subcommittee (NBAS).

The Biosurveillance Coordination Unit (BCU)

The BCU is responsible for developing the strategy and implementation plan for an integrated biosurveillance system to safeguard human health. In early June 2008, the BCU developed a draft *National Biosurveillance Strategy for Human Health* that was sent to the CDC Director and over 425 stakeholders. Based on feedback from this initial review, BCU released an updated draft on October 31, 2008. As was done with the *National Strategy for Pandemic Influenza*, BCU will lead the drafting of an implementation plan for the *National Biosurveillance Strategy for Human Health*, which will describe specific tasks and responsibilities of different agencies and programs at the federal, state, and local level.

In addition, the BCU has developed a conceptual framework of how CDC plans to integrate all human biosurveillance activities at the agency.

The newest element in the conceptual framework, is CDC's BioPHusion program which will integrate information from across CDC experts and programs, as well external sources to produce timely and actionable reports. Multiple information products will be produced for various audiences, from state and local public health practitioners to the NBAS.

The National Biosurveillance Advisory Subcommittee (NBAS)

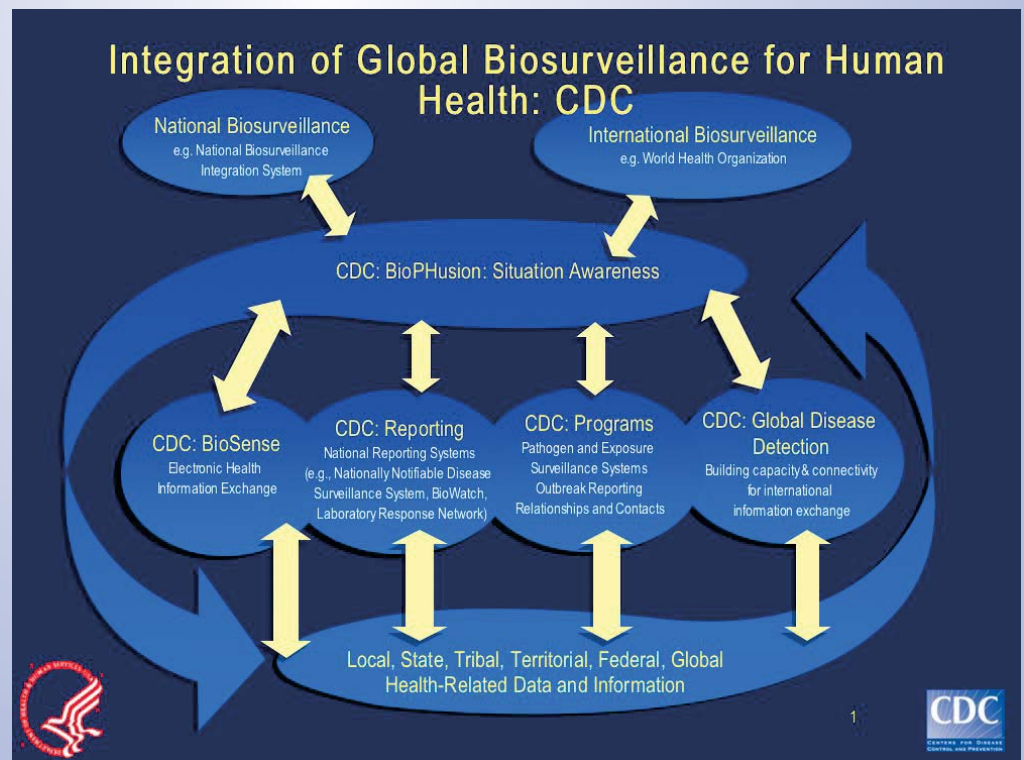
The NBAS, which is a subcommittee to CDC's Advisory Committee to the Director (ACD), held its first meeting in August 2008. The NBAS includes representatives from state and local public health departments and private sector health care entities. Its mission is to serve as independent advisors

for the development of the next generation biosurveillance capability. After carrying out an initial survey of national and international biosurveillance programs, the NBAS will provide a series of priority recommendations to the federal government through the ACD. NBAS recommendations will also be addressed through future versions of the *National Biosurveillance Strategy for Human Health*.

The NBAS has set up eight task forces to address key priorities:

- Integrating Clinical and Public Health Reporting;
- Animal, Food, and Vectors;
- Genomic Epidemiology and Digital Technologies;
- Environmental Monitoring;
- Diagnostics and Laboratory Information Exchange;
- Global Disease Detection and Collaboration;
- Biosurveillance Workforce of the Future; and
- Cross-Sector Collaborations for Biosurveillance Strategies.

The subcommittee's first set of recommendations is due out in March 2009. The NBAS will also produce an annual assessment on the state of biosurveillance.



Source: CDC Biosurveillance Coordination Unit

C. ADVANCED RESEARCH AND DEVELOPMENT OF COUNTERMEASURES

In June 2007, HHS Secretary Michael Leavitt published a *Draft BARDA Strategic Plan for Countermeasure Research, Development and Procurement* to guide and facilitate the research, development, innovation, and procurement of medical countermeasures and build upon

established national strategies and directives. There are still, however, major challenges facing BARDA, the Biomedical Advanced Research and Development Authority. Several of these challenges are detailed below.

Funding

The major obstacle facing BARDA is sufficient annual funding for advanced development of medical countermeasures (MCM). According to an analysis by the Center for Biosecurity, while BARDA's current level of funding has allowed ASPR to set up the infrastructure necessary to support advanced research and development of MCM, it has been insufficient to support the successful development of a whole range of MCM. The Center for Biosecurity estimates that BARDA needs \$817 million in FY 2009 alone "to support one year of advanced development for the candidate medical countermeasures against biological threats that

are currently in development."¹⁴⁴ However, to achieve the goals identified by the Public Health Emergency Medical Countermeasures Enterprise, whose mission is to identify high threat areas and the appropriate MCMs, BARDA would need a staggering \$3.39 billion in FY2009 alone to have a 90 percent chance of ultimately developing successful MCMs for each biodefense requirement set forth in HHS's Public Health Emergency Countermeasures Enterprise (PHEMCE) Implementation Plan. This funding would have to be sustained for many years, given the risks and costs associated with MCM development.

Completion of pre-pandemic influenza vaccine stockpile

A key element for U.S. pandemic preparedness is the establishment of a pre-pandemic influenza vaccine stockpile that provides protection against possible pandemic virus threats, including the avian influenza virus H5N1. BARDA is working with manufacturers to facil-

itate research and development on adjuvants for use with the pre-pandemic vaccine, while also trying to build a vaccine manufacturing infrastructure capable of producing and distributing the vaccine at pandemic onset.

The inherent risk of medical countermeasures development

According to ASPR, "analyses of the pharmaceutical industry cost models show the development of vaccines, drugs and other biological products is \$500 to \$700 million per product over eight to 12 years, with a low probability of success (12 to 15 percent by

the end of Phase II clinical studies)."¹⁴⁵ BARDA must find ways to mitigate and control risk, including shared cost responsibilities for early and advanced development and focused advanced development of products with highest benefit-to-risk profiles.

Product line sustainability

Once a company delivers its initial stockpile to the U.S. government, it is in the best interest of the federal government to maintain the infrastructure required to provide additional product upon expiration and/or surge

capacity in the event of an outbreak. This requires federal investment not only in the development of the product, but also in the sustainability of its investment.

Prioritization of MCM development

Considering the diverse and dynamic nature of public health threats, and the expense and time required to develop MCM, strategies must prioritize investment and optimize our ability to protect the nation. Numerous CBRN threats have been identified, and any number of emerging infectious diseases may

endanger public health in the future. It is important to address the most significant threats while at the same time retaining sufficient flexibility to respond to changes in priorities due to events, given the time and investment required to develop medical countermeasures for these threats.

D. MEDICAL AND PUBLIC HEALTH EMERGENCY FEDERAL ADVISORY COMMITTEES

Over the past seven years, the White House and Congress have convened a series of federal advisory committees. In most cases, the committee members include representatives from government, business, academia, community organizations, and professional associations. Many of the members serve on multiple federal preparedness groups. These committees or boards are tasked with providing advice and counsel to federal government agencies on matters related to public health emergency preparedness. The reports and documents these committees produce are often non-binding. In addition, it does not appear that these committees regularly or routinely communicate with each other. As such, there is much duplication of effort. Although TFAH believes it is very use-

ful for federal agencies to hear from such civilian advisory boards, the Obama administration should conduct a thorough review of the existing federal advisory committees and their work. The administration should pay close attention to the reports and recommendations developed by these bodies and, when appropriate, implement the recommendations to improve public health emergency preparedness. If there are duplicative committees, the administration should evaluate their usefulness.

[A summary of the federal public health preparedness advisory committees that TFAH was able to identify can be found in Appendix D: Federal Preparedness Advisory Groups, Panels, and Committees.](#)

E. MEDICAL AND PUBLIC HEALTH EMERGENCY RESPONSE TEAMS

Currently, the federal government has a three-tiered level of medical and public health emergency response teams. Level I responders are full-time federal employees, including members of the U.S. Public Health Service Commissioned Corps (Commissioned Corps), the VA, and DOD. The Level I responders are the equivalent of the full-time professional military and handle national disasters and emergencies. Level II responders are part-time or intermittent federal employees, such as members of the National Disaster Medical System (NDMS). Level II responders are the equivalent of the military reserves and are activated when there is a national disaster or emergency. Level III responders are community-based volunteer health care professionals and non-health care professionals, such as members of the MRC, Community Emergency

Response Teams (CERT), and ESAR-VHP. Level III responders are the equivalent of the state national guard. They are the first responders when an emergency strikes in their communities, although in a federally-declared disaster or emergency, they can be mobilized to respond at the national level.

The administration should review the national strategy to respond to catastrophic public health emergencies and address any issues that may impede a successful deployment of this three-tiered structure, including issues pertaining to liability protection, licensing and accreditation, and workers' compensation. In addition, the administration should examine the legal issues relating to when and how DOD and VA can engage in the response, and issues pertaining to cross-agency reimbursement.

4. The Implementation of the 2006 Pandemic and All-Hazards Preparedness Act (PAHPA)

The 2006 PAHPA legislation further strengthened the nation's preparedness and response planning. The legislation included a series of benchmarks for federal agencies to meet over the five-year span of the Act. Seven of these deliverables were due no later than 180 days after the enactment of PAHPA, or by the end of June 2007. Another set of four deliverables were due no later than December 2007, or 12 months after enactment. Three more deliverables are due between October 1, 2008 and January 2009. Funding, however, was not provided for the implementation of the PAHPA benchmarks. In spite of this, as of November 2008, eight of the 14 benchmarks have been met, which is commendable, given staffing and funding constraints at the federal level.

5. Additional Federal Issues

A. EMERGENCY HEALTH BENEFIT

In the event of a public health crisis such as a bioterrorist attack, natural disaster, or pandemic flu, the expected demand on the U.S. health care system would be extraordinary. The HHS Pandemic Influenza Plan projects that a pandemic could result in 45 million additional outpatient visits, with 865,000-9,900,000 individuals requiring hospitalization, depending on the severity of the pandemic. Such a major disaster would cross state lines and quickly overwhelm health care systems. A public health crisis of less magnitude, for example, a major hurricane or terrorist attack, could also severely test the U.S. health care system. According to a 2008 report from the Congressional Research Service (CRS), "recent incidents – the September 11th and anthrax attacks of 2001, and several Gulf Coast hurricanes in 2005 – have shown the limitations of existing funding mechanisms in support of public health and medical incident responses."¹⁴⁶

With more than 15 percent of Americans lacking health insurance coverage, the financial impact on the country's public health

However, some of the unmet or partially completed deliverables are crucial to the nation's preparedness, including:

- Development of new, outcome-oriented performance measures;
- Enhanced real-time disease detection and surveillance;
- Review of the medical and public health emergency response; and
- Advanced research and development of countermeasures.

Congress should hold regular oversight hearings to monitor the progress and implementation of PAHPA.

For more details, see Appendix E: Key Deliverables and Due Dates under PAHPA.

and health care systems could be disastrous if hospitals, community health centers, and primary care facilities treat large numbers of uninsured.¹⁴⁷ Likewise, if uninsured or underinsured patients hesitate to seek treatment because of fears of out-of-pocket costs, treating and containing the further spread of a pandemic would be nearly impossible.

To save lives, contain any pandemic to the degree possible, and ensure a functioning health care system throughout and after such a catastrophic emergency, the federal government should act now to create a framework for emergency health coverage and reimbursement.

A public health emergency benefit would have to address two separate concerns for providers and patients. It would have to guarantee providers some level of compensation for the services they provide during a pandemic, while encouraging individuals to come forward for diagnosis or treatment.

In fact, such legislation was introduced in the 110th Congress by Senator Richard Durbin

(D-IL) and Representative Lois Capps (D-CA). The bill, the Public Health Emergency Response Act (PHERA), would establish a temporary emergency health benefit for uninsured individuals and individuals whose health insurance coverage is not actuarially equivalent to benchmark coverage. The benefit could only be triggered if the secretary of HHS declared that a public health emergency existed under section 319 of the Public Health Service Act and chose to activate the benefit. The benefit would last for up to 90 days; the HHS secretary could extend it once for another 90 days. The funding mechanism in the legislation is the Public Health Emergency Fund; the bill would clarify that using the Fund for uncompensated care is permissible. The legislation authorizes \$7 million each year for

the administration of this fund and for a public education campaign about the program, and Congress would need to appropriate money to the Fund only after the HHS secretary activated the benefit. It would also ensure that coverage would be provided for individuals displaced by a public health emergency and would clarify the scope of coverage.

It is best to create these mechanisms prior to an emergency, rather than in the heat of the moment when any delay would be counted in lives lost. In addition, prior planning may enable the government to be more cost-effective in using scarce resources. Planning ahead for a catastrophic public health emergency is the best way to avoid needless loss of life or wasted resources.

B. EMERGENCY SICK LEAVE

Controlling the spread of a pandemic flu will depend on keeping infected persons away from the uninfected as much as possible. Doing so includes getting the infected and their families to stay home from work. CDC guidance issued in February 2007 includes the recommendation that sick people stay home from work for seven to 10 days and that family or household members of those sick remain at home for seven days.¹⁴⁸ This stay-at-home policy will limit the contact of sick people, and their potentially infected families, with others when they are contagious. These recommendations raise a troubling issue, however, because 48 percent of private-sector workers in the United States lack paid sick leave benefits and 94 million Americans do not have a single paid sick day they can use to care for a sick child.¹⁴⁹

TFAH encourages Congress to require paid sick leave to ensure economic stability and minimize health risks during a pandemic or infectious disease outbreak. Although existing law, the Family and Medical Leave Act, allows employees to take unpaid sick time due to a serious illness, the law exempts 40 percent of the workforce who work at small and mid-size businesses, does not cover less severe communicable diseases, and does not mitigate the fear of lost income among many workers.

These deficiencies in the law indicate that a federal paid sick day law is necessary. Proposed legislation that seeks to address this need includes the Healthy Families Act. This legislation would require employers with 15 or more employees to offer seven paid sick days each year, to be used to deal with individual medical needs or to care for sick family members. Although the bill garnered over 100 House cosponsors and 24 Senate Cosponsors in the 110th Congress, the Healthy Families Act was not taken up in either Chamber. The legislation is expected to be reintroduced early in 2009. While some argue that this legislation is good for public health in general, because sick individuals should not attend work and risk infecting coworkers and the public, others point out that seven days of paid sick leave may not be enough to minimize the spread of disease during a public health emergency such as a pandemic flu outbreak. Nor is the legislation expansive enough to conform with the CDC recommendation for possible self-quarantine for up to 10 days. However, given the political realities surrounding the legislation, such as opposition to any paid sick day requirements by some employer groups, the existing language is a positive step toward addressing shortcomings in existing law.

C. FEDERAL LIABILITY PROTECTIONS FOR VOLUNTEER HEALTH PROFESSIONALS AND PRIVATE SECTOR ENTITIES

The following analyses were carried out by the research team at HealthPolicy R&D in affiliation with Powell Goldstein LLP. The analysis in these sections does not constitute legal advice.

I. Federal Liability Protections For Volunteer Health Professionals

Liability protection for those health care volunteers who serve in a public health emergency has proved to be a serious issue as state and local governments seek to build community-based volunteer medical and public health teams to respond to public health emergencies. Although 42 states and D.C. have enacted legislation that offers liability protection to health care volunteers who serve during a public health emergency, there are concerns that not all states have adequate legal authority to extend liability protection to volunteer health professionals. [\(Please see Section 1, Indicator 8 for a detailed discussion of state liability laws.\)](#)

This patchwork of state laws raises concerns about gaps in liability protection for health professionals seeking to volunteer in a public health emergency and for emergency planners seeking to organize volunteer health professionals in advance of an emergency.

Existing federal statutes and regulations related to volunteer health professionals' liability during public health emergencies include:

The Federal Tort Claims Act: In the aftermath of Hurricane Katrina, the federal government recruited volunteer health professionals for potential deployment to the impacted region.¹⁵⁰ These volunteer health professionals were recognized as non-paid, temporary federal employees (travel and per diem were paid) and made eligible for Federal Tort Claims Act (FTCA) liability protection.^{151,152} The FTCA, with some exceptions, makes the U.S. government legally liable “for injury or loss of property, or personal injury or death caused by the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or

employment.”¹⁵³ For purposes of FTCA protection, a federal employee can include anyone acting in an official capacity on behalf of a federal agency, whether that person is a temporary or permanent employee and whether or not he or she is compensated.¹⁵⁴

The Public Health Services Act: The Public Health Services Act authorizes FTCA protection for certain volunteer health professionals, such as members of the federal NDMS. The NDMS recruits citizens with medical, behavioral, and public health expertise to serve on federal response teams that provide medical and ancillary services to those affected by a public health emergency. NDMS personnel are considered intermittent federal disaster-response employees and, when deployed, are paid by the federal government on a part-time basis.^{155,156} For the purposes of liability protection, when they are acting within the scope of their NDMS appointments, these individuals are considered to be employees of the federal government's Public Health Service and are given equivalent FTCA protection.¹⁵⁷ To help coordinate state and local emergency response, in 2006, the PAHPA Act authorized the HHS secretary to extend similar protections to select members of the MRC during a public health emergency.¹⁵⁸

The Volunteer Protection Act: The federal Volunteer Protection Act (VPA) was enacted in 1997 in response to concerns that liability issues were affecting people's willingness to volunteer for a broad range of community activities, not limited to medical volunteerism or emergency situations. Under the VPA, volunteers acting on behalf of a nonprofit organization or government entity are not liable for causing harm if they were performing services without compensation and certain conditions were met. The conditions require that the vol-

unteer was: acting within the scope of his or her responsibilities; properly licensed or certified if required in the state in which harm occurred; not engaged in willful or criminal misconduct, gross negligence, reckless misconduct or a conscious flagrant indifference to the rights or safety of the individual harmed; and not operating a motor or other vehicle.¹⁵⁹ The VPA does not apply to the nonprofit organization itself, and volunteers remain potentially liable for certain non-economic losses.¹⁶⁰ The VPA preempts weaker state laws; however, states can provide additional liability protection beyond the VPA.¹⁶¹ States also retain the option of opting out of the VPA.¹⁶²

The Public Readiness and Emergency Preparedness Act: The Public Readiness and Emergency Preparedness Act of 2005, also

Limitations of Current Federal Laws and Regulations

Volunteer health professionals who are “federalized” during public health emergencies have the benefit of liability protection that is equivalent to federal employees’ protection. Through the EMAC states can provide liability protection to state employees who deploy from one state to another in an emergency.¹⁶⁴ Other volunteer health professionals have protection, to varying degrees, through state laws and the federal VPA. However, confusion and gaps remain, particularly for health professionals seeking to volunteer across state lines during a public health emergency.

For example, a significant number of volunteer health professionals are private sector and local government employees. The state-to-state agreements under EMAC apply to state employees and do not expressly cover other volunteers.¹⁶⁵ The federal VPA requires licensure in the state in which harm occurs, yet many health professionals are only licensed in the state in which they regularly practice. Some states attempted to provide a “work-around” for volunteer health professionals during Hurricane Katrina by temporarily declaring them to be state employees.¹⁶⁶ At the same time, the federal government rushed to

known as the PREP Act, offers liability protection to manufacturers willing to sell countermeasures during a national emergency. The law protects manufacturers when selling pandemic products, security countermeasures, drugs, devices, and biological products. It also extends immunity to distributors and program planners, as well as to health care professionals who dispense medical countermeasures.¹⁶³ The only medical countermeasures that currently have protection under PREP are those for which the HHS Secretary has issued declarations. While the PREP Act would seem to offer liability protection for volunteer health professionals and private sector entities that dispense medical countermeasures during a public health emergency, it does not offer protection for other services rendered.

register volunteer health professionals as temporary federal employees and provide them FTCA protection.

These federal and state stopgap liability efforts in the aftermath of Hurricane Katrina demonstrate the limitations of the current patchwork of volunteer health professional liability protections.

Removing barriers to well-organized and timely response to critical public health emergencies is an issue of national interest. Rather than rely on an incomplete, complex array of federal and state liability provisions and the use of stopgap measures after an event, Congress should establish clear statutory authority under the Public Health Service Act¹⁶⁷ for FTCA protection to be provided to qualified ESAR-VHP participants activated by the federal government in response to a public health emergency.¹⁶⁸ A federal liability standard need not preempt states’ management of their individual registries as part of the ESAR-VHP network. Instead, it can help limit confusion on the ground during a public health emergency and expedite health expertise to areas in critical need.

2. Public Health Emergencies and Entity Liability

The federal government's National Response Framework for disasters and emergencies clearly articulates the important role of public-private partnerships in emergency preparedness. The Framework outlines a comprehensive, national approach to emergency response and affirms that the government cannot work alone in responding to events such as public health emergencies.¹⁶⁹ Private-sector partners include hospitals and other critical health care facilities, as well as businesses and non-profit organizations that can help supply and deliver vital services and maintain community functions before, during, and after an event.

Although individual volunteer responders working with private-sector entities can secure

varying degrees of liability protection through a number of different existing federal and state mechanisms, many organizational entities that are key partners in emergency response do not typically qualify for immunity protections.¹⁷⁰ This lack of liability protection and the exposure it creates can limit or delay organizations' willingness to join in an emergency response and can hinder the timely action required to address a public health emergency.

This section reviews public health emergency-related liability issues for two different groups of entities: 1) hospitals; and 2) businesses and non-profit organizations.

Hospitals

Hospitals are not often included in public health emergency-related immunity coverage.¹⁷¹ Instead, hospitals can potentially be held liable for their own actions or as a result of the actions of health care professionals and staff that are imputed to the hospital.¹⁷² In certain public health emergency situations, hospitals' liability exposure may increase when circumstances make it difficult for hospitals and their personnel to follow standard protocols and when the scope of the emergency response compels hospitals to take on new and unfamiliar medical staff.

During a public health emergency, hospitals may urgently need additional professional staff to meet their obligations to provide health care services.¹⁷³ One tool for addressing capacity needs in large-scale events is volunteer health professionals, although the use of volunteer health professionals has the potential to increase a hospital's liability risk.¹⁷⁴

Some have suggested that risk management policies can help mitigate these concerns.¹⁷⁵ Good policies could include, for example, well-defined processes and practices for selecting and managing volunteer health professionals during a public health emergency.¹⁷⁶ However, these processes and practices can be thwarted by events. For example, some hospital administrators in New York City reported that they were unable to use health profes-

sionals who volunteered in response to the 9/11 tragedy because the hospitals could not confirm basic information about the volunteers' licensing and credentials due to communications system breakdowns.¹⁷⁷

To address the need for rapid verification of volunteers' credentials during an emergency, in 2006 PAHPA required the HHS secretary to establish a national interoperable network that links state systems for verifying volunteer health care professionals' credentials and licenses (ESAR-VHP).¹⁷⁸ The network does not specifically address hospitals' potential liability exposure, but it is an attempt to create a readily available resource to expedite hospitals' credential verification processes, which may have the potential to improve hospitals' risk management. Nonetheless, systems failures and other events are real threats to this and other mechanisms designed to pre-certify the credentials of volunteers, leaving hospitals with continued concerns about meeting emergency-related surge demand while managing their facilities' liability exposure.

To address hospital liability issues, Congress may wish to consider providing hospitals and health care organizations with liability protection for the actions of qualified ESAR-VHP participants accepted into hospital facilities during a federal public health emergency.

Congress established ESAR-VHP under federal law to help states develop registry systems for identifying and verifying the credentials of volunteer health professionals who could respond during a public health emergency.¹⁷⁹ Additional federal actions have encouraged ESAR-VHP's growth and development.¹⁸⁰ However, under existing law, hospitals and health care organizations may assume liability risk when accepting volunteers.¹⁸¹

If federal and state governments are engaged in actively building a network of health care

Businesses and Non-Profit Organizations

In a public health emergency, a network of community entities may be needed to expedite goods and services to individuals and critical infrastructure sites, to provide shelter and basic necessities, and to help maintain and restore other vital community functions. Although Good Samaritan laws at the state level are likely to protect individual volunteers, these laws, with some exceptions, generally leave significant gaps in liability protection for businesses and non-profit organizations that voluntarily assist during a public health emergency.¹⁸²

In a large-scale event, sizable numbers of volunteers, facilities and other private-sector resources are necessary to augment government resources. Advocates have pointed to the magnitude of Hurricane Katrina and the various needs it created for volunteers to: 1) support law enforcement, emergency medical and fire response; 2) assist with preserving and repairing infrastructure, including schools; and 3) provide social support services such as counseling and sheltering.¹⁸³ Businesses and non-profit organizations not only have the capacity to organize large numbers of people, they also can provide other resources, such as hotels, stadiums, and other facilities that can be vital tools in emergency response.¹⁸⁴

Although many groups face liability issues in a public health emergency, there are certain entities that may already have liability protection under federal law for specific response-related actions. Under the federal PREP Act enacted in 2005, if the HHS secretary declares that a countermeasure is necessary to confront a disease or other threat, immunity from tort claims is established for, among other things, the develop-

ment, distribution, dispensing, prescribing and administration of the countermeasure. The limited immunity applies only to covered countermeasures for which declarations have been issued, and may be subject to other limitations that the Secretary specifies in the declaration. There is an exception to this liability protection for willful misconduct.¹⁸⁵ The PREP Act created a federally supported emergency fund to compensate individuals for injuries caused directly by a countermeasure initiated under the Secretary's declaration, but funds have not yet been appropriated for this compensation fund.¹⁸⁶ The first declaration under this provision of the PREP Act was for the H5N1 vaccine to protect against the avian influenza virus.¹⁸⁷

volunteers that can be deployed in response to emergencies, the government also has a stake in removing barriers to health care facilities accepting qualified volunteers. One mechanism to advance this goal would be to alleviate the actual and perceived liability concerns attached to accepting volunteers by protecting hospitals when the volunteers are vetted through this established federal-state partnership program for recruiting and certifying volunteer health professionals.

A variety of leading public health and disaster preparedness organizations, including the American Red Cross, the American College of Emergency Physicians, APHA, and TFAH support the expansion of Good Samaritan laws to protect a wide range of volunteers and their sponsoring entities during a public health emergency.¹⁸⁸

To address liability issues for businesses and non-profit organizations, Congress may wish to create a federal floor for the minimum protection that should be available to these emergency response partners when working in concert with government agencies. For example, a federal liability "gap-filling" bill could recognize states that have acted on this issue already and create protections in those states without coverage. This approach would be consistent with the approach taken by Congress in the VPA. The VPA preempts weaker state laws, but allows states to exceed

the VPA's protections. A distinction would be that a federal provision providing businesses and non-profit organizations with Good Samaritan protections would be lim-

D. SHELF-LIFE EXTENSION PROGRAM

DOD and SNS both maintain large stockpiles of medications and vaccines in order to ensure that both military and civilian populations have access to needed antidotes and treatments in the event of a medical emergency. In order to save federal dollars, FDA and DOD developed a system of extending the shelf-life of these drugs and vaccines beyond the manufacturer's expiration date. The Shelf-Life Extension Program (SLEP) is administered jointly by the FDA and DOD. The SNS also participates in the program.¹⁸⁹

The program has resulted in substantial savings. According to CDC's analysis, the return on investment for SNS participation in the SLEP is that for each dollar (\$1.00) spent on SLEP costs, which includes testing, shipping, and re-labeling, SNS saved \$13.00.¹⁹⁰

Despite the substantial savings at the federal level, states' stockpiles of antivirals – purchased through an HHS-subsidized program as part of states pandemic preparedness – are not eligible.

HHS designated \$170 million to subsidize states' purchases of up to 31 million treatment courses of Tamiflu® (oseltamivir) and

ited to actions occurring during a public health emergency, whereas the VPA provides protections that are broader in scope.

Relenza® (zanamivir). HHS will subsidize 25 percent of the cost, and states will pay the other 75 percent. As of September 30, 2008 state and local jurisdictions have stockpiled nearly 22 million treatment courses of antivirals, of which almost 21 million were purchased using the federal government subsidy.

In 2006, ASTHO surveyed its members regarding the stockpiling of antivirals. At the time, states indicated that inventory management, including the storage, rotation, and shelf-life extension strategies, were of critical concern.¹⁹¹ State public health budgets are stretched thin already. Without a federal compromise on the SLEP, many states will be unwilling to commit scarce dollars to buy antivirals that will expire in only seven years. Although the May 2006 *National Strategy for Pandemic Influenza Implementation Plan* asked HHS, DOD, and the VA to explore the possibility of extending SLEP to state and privately-held stockpiles, according to a 2008 IOM report, "nothing has been released about the feasibility, cost, and other barriers of extending the program to properly maintained non-federal stockpiles."¹⁹²

E. FEDERAL FOOD SAFETY REFORMS

Prompted by recent nationwide *Salmonella* and *E. Coli* outbreaks, Congress held nearly 30 hearings on food safety in the 110th Congress and introduced over 100 pieces of legislation designed to improve the nation's food safety net. However, no new food safety laws were enacted in 2007 or 2008. In November 2007, FDA released its Food Protection Plan, a modernization strategy designed to enhance FDA's ability to prevent and detect foodborne disease and contamination. In June 2008, Congress increased FDA's FY2008 funding by \$150 million, \$66 million of which was designated for food safety. However, as of September 2008, FDA had not yet told Congress how much money was required to fully implement the Food Protection Plan.

As FDA and Congress seek to strengthen the nation's food supply, they face a number of obstacles, including:

- Inadequate federal leadership, coordination, and resources;
- Outdated laws and policies; and
- Limited federal, state, and local coordination.

(For a detailed discussion of food safety, please see our April 2008 report [Fixing Food Safety: Protecting America's Food Supply from Farm-to-Fork](#) and the October 2008 report [Blueprint for a Healthier America: Modernizing the Federal Public Health System to Focus on Prevention and Preparedness](#), both available online at: www.healthyamericans.org.)

Hospital Emergency Preparedness

SECTION 3

“SURGE CAPACITY IS A HEALTH CARE SYSTEM’S ABILITY TO EXPAND QUICKLY BEYOND NORMAL SERVICES TO MEET AN INCREASED DEMAND FOR MEDICAL CARE IN THE EVENT OF BIOTERRORISM OR OTHER LARGE-SCALE PUBLIC HEALTH EMERGENCIES.”¹⁹³

— AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (AHRQ)

In a public health emergency, such as a bioterror attack or catastrophic natural disaster, U.S. hospitals and health care facilities will be on the front lines providing triage and medical treatment to individuals. In the best of times, however, most emergency departments must confront bed shortages and staffing issues; in a mass casualty event, the situation could quickly spiral out of control.

For the past five years, the U.S. government has worked to improve hospitals’ overall surge capacity, which the Agency for Healthcare Research and Quality (AHRQ) defines as the ability to of a health care system to expand quickly beyond normal services to meet an increased demand for medical care in the event of bioterrorism or other large-scale public health emergencies.¹⁹⁴

The challenge of how to equip hospitals and train health care staff to handle the large influx of critically injured or ill patients who show up for treatment after or during a public health emergency remains the single, most challenging issue for public health and medical preparedness.

The following section outlines the steps that have been taken and highlights some crucial gaps in medical preparedness, including information on:

1. The Hospital Preparedness Program;
2. Mass casualty care;
3. Financing hospital preparedness; and
4. Preparedness and health reform.



I. Hospital Preparedness Program

The Hospital Preparedness Program (HPP) focuses on improving the clinical response to a large-scale health emergency. Initially run by HRSA, HPP is now run by ASPR as mandated by PAHPA. ASPR awards one-year funding grants to hospitals and other health care facilities to improve surge capacity and enhance community and hospital preparedness for all-hazards, including bioterrorism and pandemic influenza.

HPP activities are to focus on the following five core goals:¹⁹⁵

1. **Integration:** Integration of public and private medical capabilities with public health and other first responder systems;
2. **Medical Preparedness:** Increasing the preparedness, response capabilities, and surge capacities of hospitals, other health care facilities (including mental health facilities), and trauma care and emergency medical service systems with respect to public health emergencies;
3. **At-risk Populations:** Taking into account the public health and medical needs of at-risk individuals in the event of a public health emergency;
4. **Coordination:** Minimizing duplication of, and ensuring coordination among all levels of planning, preparedness, response, and recovery activities; and
5. **Continuity of Operations:** Maintaining vital public health and medical services in the event of a public health emergency.

Grantees are expected to be compliant with NIMS, provide education and preparedness training to staff and hospital personnel, exercise and drill according to HSEEP guidance, and clearly articulate which at-risk populations with medical needs are being served by the health care facility.

In addition, grantees are required to address the following capabilities:

- Interoperable Communication Systems;
- Tracking of Bed Availability via the National Hospital Available Beds for Emergency and Disasters (HAvBED);
- ESAR-VHP;
- Fatality Management;

- Medical Evacuation / Shelter in Place; and
- Partnership/Coalition Development.

If these capabilities are being adequately addressed, HPP grantees can work on these additional activities:

- Alternate Care Sites;
- Mobile Medical Assets;
- Pharmaceutical Caches;
- Personal Protective Equipment; and
- Decontamination.

In FY 2008, HPP awarded \$398 million to 50 states and Washington, D.C., for an average of \$82,500 a year per hospital. An article in the *Journal of Law, Medicine and Ethics* notes that “this barely permits the hiring of a preparedness coordinator, leaving nothing for the infrastructure development and maintenance that would be required.”¹⁹⁶ In fact, a 2006 study by the Center for Biosecurity estimated that true hospital preparedness for a severe pandemic influenza would require a one-time investment of at least \$1 million per hospital plus an additional \$200,000 per year in maintenance costs, for a total of \$5 billion for the 5,000 general hospitals in the United States.

Beginning in FY 2008, HPP grantees, for the first time, were subject to maintenance of funding requirements and had to meet specific evidence-based benchmarks. Grantees are expected to maintain their health care preparedness expenditures at a level not less than the average of expenditures during the previous two-year period. The maintenance of funds refers to state or local contributions to health care preparedness and not federal dollars.

As mandated by the 2006 PAHPA legislation, HPP grantees that fail to meet the evidence-based benchmarks will have funds withheld from their FY 2009 awards.¹⁹⁷ There is no penalty for states who fail to meet maintenance of funding requirements.

Some public health experts have questioned whether reducing HPP funding to certain hospitals or states that fail to meet the evidence-based benchmarks is the correct approach. They argue that these are the places that might need the money most to reach benchmarks.

2. Mass Casualty Care

According to GAO, as of 2005, there were approximately 950,000 staffed hospital beds in the United States, meaning that health care staff was available to attend to the patient occupying the bed. However, in a mass casualty event, such as a severe pandemic influenza, HHS expects that demand would far exceed capacity.¹⁹⁸

Altered Standards of Care

There is growing recognition in the United States that a mass casualty event, particularly a pandemic influenza, will result in the need to alter and adapt the traditional standards of care appropriate to the situation. Unfortunately, as an article in the *New England Journal of Medicine* notes, under current federal and state law, governors can declare a state of emergency during disasters, “suspending some of the normal standards without giving any idea of what the alternative standards ought to be.”¹⁹⁹

According to the federal government, “states in conjunction with professional societies will

The question for hospitals, health care facilities, clinicians, and hospital administrators is how to handle the surge of patients. Not only in terms of space for the critically injured and sick, but in allocating scarce resources such as ventilators and pharmaceuticals, and finding enough trained, licensed health care workers to care for the patients.

determine the appropriate standards of care for the situation – not HHS or the federal government.”²⁰⁰ Although AHRQ has published two documents on mass casualty care – *Altered Standards of Care in Mass Casualty Events (2005)* and *Mass Medical Care with Scarce Resources (2007)* – these are intended merely to serve as planning guidance for states and professional associations as they develop “definitive guidance.”²⁰¹ Several states, including New York²⁰² and California,²⁰³ and professional associations, such as the American Nurse Association²⁰⁴ and the American Health Lawyers Association,²⁰⁵ have taken the lead in this arena.

Hospital Planning Considerations

Despite the release of guidance documents, many disaster plans fail to account for the reality a mass casualty event will present. To help develop comprehensive guidance for managing mass casualty events, leading public health and medical preparedness officials convened a Task Force of Mass Casualty Critical Care. The Task Force is composed of 37 experts from various fields, such as bioethics, critical care, emergency medicine, infectious diseases, law, nursing, and government planning and response, including HHS, DHS, DOD, and the VA. According to a write-up from the Task Force’s January 2007 meeting in Chicago, “disaster plans have assumed that critical care resources will be available when needed, and generally this assumption has been correct. However, with the anticipation of large volumes of critically ill patients in fu-

ture disasters, some believe that hospital capacity, and in particular critical care capability, will be a major limiting factor for survival.”²⁰⁶

Not only will emergency departments be overwhelmed in an emergency, but so would critical care units and rehabilitation beds. For instance, following the 2003 Rhode Island nightclub fire, the emergency department response lasted several hours while the intensive care unit (ICU) admitted 47 critically injured patients with an average length of stay of 21 days.²⁰⁷

Any sort of mass casualty event with prolonged hospitalizations will put a strain on hospitals and health care workers. To help hospitals prepare for such an event, much of the current guidance focuses on the three S’s – supplies, staff, and space.

Supplies/Equipment

Today's hospitals and health care facilities function with a "just-in-time supply chain," meaning very limited supplies, including pharmaceuticals, are stored on-site and instead, are replenished on an as-needed basis. While the use of a just-in-time supply chain keeps hospital storage costs down, it also "creates a significant threat to successful disaster response."²⁰⁸ Hospital administrators argue that it is not feasible for hospitals to stockpile large quantities of supplies as they lack both the space to do so and the resources to pay for these extra supplies.

In addition to the supplies, hospitals are likely to run short of needed technologies, such as ventilators and decontamination units.

Ventilators are especially crucial in the event of a pandemic influenza. The write-up from the 2007 meeting on mass critical care in Chicago noted that ventilators in particular are "unique to the critical care environment, and they are essential equipment for the management of respiratory failure." The task force went on to note that in a pandemic in-

fluenza there will be a shortage and "scarce mechanical ventilators will need to be allocated to those patients who are prioritized."²⁰⁹

The president's FY 2009 budget request included \$25 million to support the advanced development of next generation ventilators. The new ventilators are to be portable, inexpensive, and equipped with universal parts. HHS has specified that the ventilators should be easy enough to use so that "inexperienced health care providers with no respiratory support training could safely use the device."²¹⁰ Congress, however, failed to pass the FY 2009 budget and instead, adopted a six-month continuing resolution. Although there is no funding for the project in the current budget, ASPR continues to insist that the development of these next generation ventilators is a priority. HHS envisions their FDA approval over a two to three year span. However, even if hospitals were to stockpile additional easy-to-use ventilators, they would likely still not be able to treat all the patients seeking care in a pandemic influenza.

Staff

Workforce shortages plague hospitals and health care facilities even in the best of times. It is no wonder then that workforce shortages are a serious concern for mass casualty event planning. According to a June 2008 report from the Center for Studying Health System Change, "the day-to-day shortages of key health personnel – such as nurses, physi-

cians, pharmacists, laboratory technicians, and respiratory therapists – exacerbate the challenge of having sufficient numbers of health workers in an emergency."²¹¹ The report goes on to note that until elected officials and policy makers address these challenges, "the ability to have adequate personnel for an emergency will be limited."²¹²

Space

During a mass casualty event, hospitals will be pressed to treat a sudden influx of injured and sick patients. In order to make room for the surge of patients, the California Department of Public Health surge capacity guidelines recommend that hospitals take the following actions:²¹³

- Rapid discharge of emergency department and other patients who can continue their care safely at home;
- Cancel elective surgeries and procedures and reassign surgical staff and space;
- Reduce use of imaging, laboratory testing, and other ancillary services;

- Group like-patient types together to maximize efficient delivery of patient care;
- Convert single rooms to double rooms and double rooms to triple rooms if possible;
- Use cots and beds in flat space areas such as classrooms and lobbies within the hospital; and
- Identify wings, areas, and spaces that can be opened or converted for use as patient treatment areas, including outpatient clinics, waiting rooms, conference rooms, physical therapy gyms, and medical office buildings.

Other mechanisms to expand surge capacity include:

- Encouraging home care for less severely ill patients;
- Telemedicine, which allows health care providers in hospitals to care for and moni-

tor patients at home with the use of electronic information and telecommunications technologies; and

- Call centers, which will allow patients at home to contact health care providers in hospitals to obtain medical advice for home care.

3. Financing Hospital Preparedness

A 2001 study by the American Hospital Association found that a typical metropolitan hospital needed an estimated \$3 million in upgrades just to achieve baseline disaster preparedness. This figure does not include the money for additional staff, support personnel, or medical supplies and equipment. A 2006 study by the Center for Biosecurity suggested that a 164-bed hospital would need \$1 million just to be minimally prepared for pandemic influenza. However, a 2006 IOM report found that average federal grant to hospitals is far below that. “Of significance, current policy dictates that the source of funding for hospital preparedness originates from general tax revenues. Medical payers (e.g., Medicare,

Medicaid, and private insurance) directly fund little, if any, of the preparedness bill.”²¹⁴

Hospitals and health care associations have argued that the easiest way to address this problem is to boost hospital preparedness program grants from general revenue taxes. The American Hospital Association has said that \$11 billion is needed to achieve basic hospital preparedness. A top White House official has suggested that funding for the Hospital Preparedness Program be more than doubled to a steady, sustained \$1 billion a year. However, the worsening economic situation in the United States and around the world may prevent the Obama administration from seriously increasing hospital preparedness funding.

4. Preparedness And Health Reform

President-Elect Obama, his administration, and the 111th Congress are likely to re-visit the notion of health reform. Any discussion of expanding access to quality health care should include a commitment to a strong public health system and public policies focused on prevention of disease and injury and public health emergency preparedness. In order to strengthen public health and preparedness, the nation must ensure that any health care financing system that is developed includes stable and reliable funding for core public health functions and clinical and preventive services. The nation must adequately fund federal, state, and local public health departments and programs to be able to fulfill their responsibility of protecting the public’s health, and, at the same time, public health needs a sustainable funding stream. Building healthy, prepared communities requires a financial commitment.

The health reform debate is likely to include a conversation about the role of information technology in health care delivery and public health. The federal, state, and local public health agencies need to have the near real-time capacity to monitor the delivery of health care to the population in order to identify unusual illnesses or health events, whether natural or man-made. Health care providers are interested in electronic health records (EHRs) to improve patient care and efficiency. The needs of both clinicians and public health officials should be considered when discussing the role of health information technology.

For a thorough discussion of what a reformed health system would like and what it will take to build one, please see TFAH’s October 2008 report *Blueprint for a Healthier America: Modernizing the Federal Public Health System to Focus on Prevention and Preparedness*. The full report is available online at www.healthymamericans.org.



Additional Issues and Concerns

I. TRANSITION TERROR: ARE WE PREPARED?

Evidence shows that acts of terror often take place in the weeks and months before or after elections and political transitions.²¹⁵ Terrorists seek opportunities to exploit weaknesses in national security, whether real or made-up, and a presidential election and transition is seen as a period of increased vulnerability.²¹⁶

During a transition period, the outgoing administration has the ability to implement policy affecting national or international security, and the next day, the new administration and leadership may have a completely different strategy. The changing of policies coupled with the perceived lack of experience of a new administration may create a target of opportunity to those wanting to injure the security of the nation in transition.

Some documented events that have occurred during national as well as international transitions include:²¹⁷

- March 2004: Terrorists bombed commuter trains in Madrid, Spain just three days before the country's general election.
- December 2003: A suicide bomber detonated explosives aboard a commuter train near Yessentuki, Russia two days before the national elections.
- September 2001: Nine months after President George W. Bush's transition, terrorists attacked New York City and the Pentagon, killing nearly 3,000 people.
- February 1993: Terrorists detonated a car bomb underneath the World Trade Center in New York City, killing at least five people and injuring scores more, just a month after President Bill Clinton was sworn into office.
- March 1992: Irish Republican Army conducted a bombing campaign in Britain aimed at influencing the upcoming election.

- November 1989: President Rene Moawad of Lebanon was killed by a bomb – he had been in office for only 17 days.
- October-December 1982: An outbreak of violence, causing more than 30 deaths, occurred in Northern Ireland in opposition to elections to form a Provincial Assembly.

History shows the increased vulnerability of new administrations, and although it may be impossible to prevent an attack or crisis during the transition, steps can be taken to lessen the risks to national security. Some recommendations include:

- Select and confirm quickly senior executive branch leaders who have significant national security responsibilities;²¹⁸
- Put in place an accelerated screening and confirmation for the main members of the new president's national security team;²¹⁹
- President-Elect Obama should provide the names of those whom he intends to nominate as soon as possible so that investigations can begin;²²⁰
- The outgoing president should be cautious of any activity taken in the last few days of the administration that could interfere with the incoming administration's transition efforts, such as:²²¹
 - ▲ Establishing or revising national security organizations, policies, or programs that are clearly counter to the positions of the incoming president;
 - ▲ Interacting with foreign leaders that may have the perception of attempting to portray future U.S. foreign policy desires; and
 - ▲ Undertaking any steps that would have a negative effect or produce unintended national security consequences.

- The new president may want to have prior administration officials maintain their security clearances and receive briefings regarding previous, current and emerging threats and to learn of the prior administration's national security policy and program successes and failures.²²²

- Congress should work with the new administration to understand its national security priorities and where applicable, have the changes in policies and programs reflected in the 2009 budget and pass FY 2009 appropriations without unnecessary delay.²²³

2. AT-RISK POPULATIONS AND COMMUNITY RESILIENCE

Before, during, and after an incident, members of at-risk populations may have additional needs in one or more of the following functional areas:

- Maintaining independence;
- Communication;
- Transportation;
- Supervision; and
- Medical care.

In addition to those individuals specifically recognized as at-risk in PAHPA (i.e., children, senior citizens, and pregnant women) individuals who may need additional response assistance should include people who:

- Have disabilities;
- Live in institutionalized settings;
- Are from diverse cultures;
- Have limited English proficiency or are non-English speaking;
- Are transportation disadvantaged;
- Have chronic medical disorders; and
- Have pharmacological dependency.

The 2006 PAHPA legislation directed the nation's public health agencies to take the needs of "at-risk individuals" into consideration when managing preparedness programs, such as the SNS and federal grants to states and hospitals.

The Center for Biosecurity convened a roundtable discussion in April 2008 on community resiliency and the implementation of HSPD-21. According to a draft meeting report, the roundtable meeting discussed the meaning of "community resilience" and came up with an illustrative definition:²²⁴

"Community resilience is the ability of a community to rebound from a disaster with a new focus on recovery and mitigation and a renewed sense of trust in government and other community leadership. Community resilience is achieved when a community has forged meaningful social networks with the goal of emergency preparedness among community members, leaders, government, and private industry."

Overall the meeting attendees agreed that the concept of community resilience is beneficial because it shifts the conversation away from fear and toward the collective attitudes and actions necessary to build strong communities and ensure a swift recovery from major tragedy. The report finds that it is important for federal, state, local, tribal, and territorial governments to include community-based groups and faith-based organizations in the response and preparedness activities, specifically for "at-risk" groups. The group agreed that community resilience is a positive turn for national policy and in order to build community resilience, the following issues should be considered:

- Cross-sector partnership;
- The critical role of community- and faith-based organizations, especially as intermediaries with vulnerable populations;
- Strong social networks and robust communication linkages;
- Active engagement of the public in preparedness policy decisions;
- Vital, interconnected public health, safety, and medical institutions; and
- Strong diversified economic base with broadly distributed opportunity.

3. CHILDREN AND PREPAREDNESS

Children under the age of 18 represent one quarter of the U.S. population. Planning to care for the nation's 73.6 million children and adolescents during a public health emergency presents complex considerations and challenges. Children are not "small adults" and special consideration needs to be given to complicated issues ranging from child-appropriate doses of medications and vaccines, to caring for children if schools and childcare facilities are closed for extended periods. Parents and other caregivers may also become sick or injured during a disaster, complicating their ability to care for children.

Columbia University's National Center for Disaster Preparedness has identified the following issues of concern for biological, chemical and nuclear attacks:²²⁵

- Children are more vulnerable to chemical agents that are absorbed through the skin or inhaled;
- Children have special susceptibilities to dehydration and shock from biological agents;
- Children can not be decontaminated in adult decontamination units;

Limited pediatric care facilities

Children, particularly children under the age of five, exhibit significantly higher mortality rates in disasters when compared with adults.²²⁶ Because children have unique vulnerabilities – physiological, developmental and psychological – it is crucial that their needs be incorporated into all stages of disaster

Unprepared emergency shelters

According to a recent *Newsweek* article, shortly after Hurricane Ike hit Texas, San Antonio officials compiled a list of statistics about evacuees in their city. City officials counted a total of 5,303 persons who had been forced to leave their homes, including 561 individuals with special medical needs,

- Children require different dosages or different antibiotics and antidotes to many agents;
- Children are more susceptible to the effects of radiation exposure and require different responses than adults;
- Children have unique psychological vulnerabilities, and special management plans are needed in the event of mass casualties and evacuation;
- Emergency responders, medical professionals, and children's health care institutions require special expertise and training to ensure optimal care of those exposed to chemical, biological, or nuclear agents;
- Children's developmental ability and cognitive levels may impede their ability to escape danger; and
- EMS, medical, and hospital staff may not have pediatric training, equipment, or facilities available.

Other concerns related to children and preparedness include the following:

ter planning to improve the response system for children in emergencies.²²⁷ Currently, the United States has fewer than 300 pediatric hospitals, a fraction of all hospitals (five percent), and only 40 percent of emergency department hospitals have specific procedures regarding pediatric transfers.²²⁸

but there was no separate tally for children.²²⁹ According to disaster-relief experts, this is not uncommon as kids are rarely counted in evacuations. Like hospitals, emergency shelters are often unprepared to handle children in emergencies, with essentials such as baby wipes and diapers nowhere to be found.²³⁰

Schools and daycare emergency plans

In the United States, there are approximately 13 million children (63 percent) under the age of five in some type of child care arrangement during the day.²³¹ As of 2004, approximately 59 million students were enrolled in prekindergarten through grade 12.²³² At school, children rely on adults to protect them, therefore teachers and staff must be prepared to help students through a crisis and get them home safely.²³³ There are thousands of fires in schools each year, yet there is minimal harm to students because staff and students are prepared and have regular drills.

More plans need to be in place for the event of other emergencies such as floods, earthquakes, tornadoes, infectious disease outbreaks, and acts of terrorism.²³⁴ The time for childcare facilities and schools to plan and practice is now, before an emergency occurs.

The good news is that many states do have specific emergency plans for child care facilities and schools.²³⁵ For example, the Office of Child Care and Head Start in Maine put together an emergency response plan that serves as a planning tool for child care programs across the state.²³⁶

OBESITY, CHRONIC DISEASES AND PREPAREDNESS

According to CDC, the states and federal agencies are having serious problems evacuating and sheltering obese and chronically ill people. At a 2008 CDC conference on emergency preparedness, the agency reported that 40 percent of evacuees during Hurricanes Gustav and Ike were obese, and many of those individuals were unable to stay in local shelters because of their condition.²³⁷ Also, earlier this year, during the flooding in Iowa, a similar problem occurred and many people who were obese or on oxygen were unable to stay at local shelters and instead, these individuals had to stay in hospitals -- taking up a bed that might be needed for an actual emergency case.²³⁸

Evidence from Hurricane Katrina also suggests that a large proportion of the evacuee population displaced to shelters had a significant burden of disease.²³⁹ Among those who arrived at shelters (in the sample study), 55.6 percent had a chronic disease, with hypertension, hypercholesterolemia, diabetes, and pulmonary disease as the most common chronic conditions.²⁴⁰

Caring for evacuees who are obese or afflicted with one or more chronic disease increases the resources needed at each shelter to prevent further morbidity and mortality.

4. BEHAVIORAL HEALTH CONSIDERATIONS

A catastrophic disaster, whether man-made or naturally occurring, can lead to a variety of psychological consequences, including depression, post-traumatic stress disorder (PTSD), increased substance use, as well as a rise in pain intensity.²⁴¹ At the same time, the disaster can severely limit a community's ability to provide mental health and substance abuse services, also referred to as behavioral health. It is important for communities to have a behavioral health emergency preparedness plan in place, not only for the benefit of the individual, but also in order to have a productive workforce. In distressed populations, mental health issues may be manifested by a rise in work-related injuries, excessive absenteeism, and lower productivity.²⁴²

Addressing mental health issues following a disaster requires planning and coordination among federal, state, and local governments and private sector groups to effectively deliver mental health and substance abuse services. It is also important to have a plan regarding how to handle those already mentally ill or dealing with substance abuse prior to a disaster, such as the importance of ongoing access to medications and support services. Research on past disasters and public health emergencies shows that psychological casualties (e.g. multiple unexplained physical symptoms, acute anxiety, etc.) can vastly outnumber medical casualties and place a large and rapid expanding burden on emergency medical care organizations and providers. Therefore, effective behavioral health preparedness and response is also an important consideration for medical surge capacity planning.

The Substance Abuse and Mental Health Services Administration (SAMHSA) works to integrate mental health and substance abuse services into the federal public health emergency response. To provide short-term crisis counseling after a disaster, the federal government offers grants to states and localities through the FEMA Crisis Counseling Assistance and Training Program (CCP), which is

administered by SAMHSA. To qualify for a CCP grant, a state must demonstrate that the need for crisis counseling in the affected area is beyond the capacity of state and local resources. In a 2008 report on federal efforts to help states prepare for the mental health consequences of disasters, however, GAO argued that it is difficult to determine whether program funds are used efficiently and effectively to help alleviate psychological distress.²⁴³

In FY 2003 and FY 2004 SAMHSA awarded \$6.8 million in preparedness grants to mental health and substance abuse agencies in 35 states for disaster planning.²⁴⁴ The total amount awarded to each state ranged from \$105,000 to \$200,000. Since then, SAMHSA has not allocated any additional funds to the states for mental health preparedness. Instead, according to the 2008 GAO report, funding in more recent years has come from CDC and HRSA/ASPR. These preparedness funds may be used for mental health and substance abuse preparedness, "but the agencies' data-reporting requirements do not produce information on the extent to which states used funds for this purpose."²⁴⁵

At the federal level, HHS directed the U.S. Public Health Service Commissioned Corps to organize into five Rapid Deployment Force teams, which each include four mental health providers, and five Mental Health teams made up of about 20 mental health providers.²⁴⁶

HHS has also increased the number of antidepressants and antipsychotics in the Federal Medical Stations' cache of drugs, and added five new classes of drugs, including those to treat sleeping disorders.²⁴⁷

In June 2008, HHS's National Biodefense Science Board (NBSB) convened a group of experts to study the mental health consequences of disasters and study how to protect, preserve, and restore individual and community mental health in catastrophic events.²⁴⁸ Recommendations from the Disaster Mental Health Subcommittee were presented before the NBSB on November 18, 2008.

5. PUBLIC HEALTH WORKFORCE

According to a 2007 survey by ASTHO, over 100,000 workers are employed in state public health, in addition to the 160,000 workers NACCHO estimates are employed in local health departments.²⁴⁹ However, by 2020, the Association of Schools of Public Health estimates that state and local health departments will need an additional 250,000 public health workers.²⁵⁰

Public health workers are the backbone of the U.S. public health system and carry out a range of duties including epidemiologic surveillance, laboratory testing and analysis, prevention and

treatment of infectious and chronic diseases, and emergency preparedness.

The public health workforce, however, is seriously strained, according to the 2007 ASTHO survey. Twenty-four states have 25 percent or more of their state public health workforce eligible to retire within in the next five years, while 10 states have 35 percent or more of their state public health workforce eligible. Only seven states have less than 25 percent of their state public health workforce eligible to retire within the next five years.

Public Health Workforce Eligible to Retire within the Next Five Years	
States with < 25% of workforce eligible for retirement.	States with ≥ 25% of workforce eligible for retirement.
Connecticut (19%) North Carolina (23%) Ohio (14%) South Carolina (15%) Tennessee (16%) Texas (23%) Utah (22%)	Alabama (32%) Alaska (27%) Colorado (37%) Delaware (25%) Georgia (25%) Illinois (39%) Indiana (25%) Iowa (30%) Maryland (31%) Michigan (39%) Minnesota (27%) Missouri (37%) Montana (34%) Nebraska (56%) New Hampshire (50%) New Jersey (49%) North Dakota (27%) Oklahoma (29%) Oregon (32%) Pennsylvania (29%) Virginia (60%) West Virginia (30%) Wisconsin (54%) Wyoming (32%)

Source: ASTHO's 2007 State Public Health Workforce Survey Results. Note: Twenty states did not respond to this question on ASTHO's survey (AR, AZ, CA, DC, FL, HI, ID, KS, KY, LA, MA, ME, MI, NV, NM, NY, RI, SD, VT, and WA).

The state public health workforce has continued to age since ASTHO's last survey in 2003 and the average age of a state public health employee is now 47. According to ASTHO, "Despite ongoing efforts, the state public health agency workforce is graying at a higher rate than the rest of the American workforce and state health agencies continue to be affected by workforce shortages."²⁵¹

A 2006 survey by CSTE reported a current total of 2,502 epidemiologists working in state and territorial health departments. The survey, however, also reported an estimated need for 3,361 epidemiologists to reach ideal capacity, a 34 percent increase.²⁵² In the field of bioterrorism/emergency preparedness the gap between current and needed capacity was even larger at 37 percent.

As state health departments struggle with the inevitable "exodus of highly skilled older workers," they face numerous challenges to recruit-

ing and retaining qualified, trained personnel, including the following:²⁵³

- Budget constraints;
- Lack of competitive wages for public health careers;
- Lack of interest by recent graduates in public health careers;
- Lack of visibility of public health careers; and
- Red-tape that hampers the recruitment and hiring of qualified candidates.

For a more detailed discussion on the challenges in recruiting and retaining a well-trained public health workforce, including recommendations for the Obama administration and the 111th Congress, please see TFAH's report *Blueprint for a Healthier America: Modernizing the Federal Public Health System to Focus on Prevention and Preparedness*, available online at www.healthyamericans.org.

Recommendations

Overall, this report finds that significant progress has been made in the nation's preparedness to respond to public health emergencies based on state-by-state measures and available data. Yet much work remains on critical issues of preparedness, including: surge capacity, legal protections for health care volunteers, and eliminating geographic disparities in preparedness planning. Above all, preparedness requires a sustained effort and ongoing investment of funds. The progress we have seen is threatened by diminishing federal support to states and localities for their preparedness activities, and it is unlikely that these states and localities can make up the funding shortfalls, given the current nationwide financial crisis. Our country is only as secure as the least prepared state; there is a federal interest and responsibility to assure a minimum level of preparedness throughout the country.

Important progress has been made since September 11, 2001 and the ensuing anthrax tragedies. Passage of PAHPA and updated federal directives have been important milestones in the effort to protect the American people from major health disasters. The passage of the legislation, however, does not mean the changes called for have been achieved. In fact, without increased and sustained funding and political prioritization, many of the gains that have been made will be jeopardized and new objectives and outcomes for public health preparedness will unlikely be realized. Americans deserve basic protections in the event of health emergencies, and right now, many of these protections are lacking, leaving Americans vulnerable to unacceptable levels of risk.

At the state level, there has been significant progress in some areas of preparedness, including enhancing critical laboratory capacity and the development of pandemic

preparedness plans. However, significant work remains in areas such as medical countermeasures distribution and dispensing, surge capacity, and legal protections for volunteers working during emergencies.

To further strengthen emergency preparedness, TFAH recommends action across the following key areas:

1. Funding;
2. Restructuring of federal health agencies;
3. Transparency, accountability, and oversight;
4. Surge capacity;
5. Preparedness and health reform;
6. Public health workforce;
7. Research and development;
8. Legal preparedness;
9. Health and sick leave benefits;
10. Food safety reforms; and
11. Community resiliency.

I. FUNDING

Public health preparedness requires a well-trained public health workforce, a sustained effort at research and development, the building and maintenance of stockpiles of countermeasures, and hospital surge capacity. When funding declines – whether at the federal, state, or local level – the immediate impact on public health preparedness may not be evident. Funding cuts frequently result in workforce reductions or hiring freezes. Without a trained public health workforce, preparedness suffers. Preparedness requires that we have enough qualified laboratory scientists who analyze lab specimens and transmit those results to federal, state, and local health officials; epidemiologists and health information specialists who develop and run biosurveillance systems to monitor disease rates and warn of bioterror or foodborne disease out-

breaks; stockpile managers who receive, store, and dispense medical countermeasures; and public health nurses and doctors who vaccinate populations against infectious diseases such as pandemic flu. The federal government should provide increased and sustained funding for preparedness activities to state and local health departments. It is a shared responsibility between the federal government and the states. State-generated revenues invested in public health should, therefore, increase as well. As demonstrated in this report, federal funding has fluctuated – limiting the ability of states to build the kind of response capacity that is needed to prepare for everything from a pandemic to a natural disaster to a terrorist attack. The variation in critical state investment in public health also reflects a significant variation in geographic capacity.

Recommendations for Funding	
Fully fund and stabilize funding for state public health emergency preparedness activities	FY 2008 funding for programs dedicated to bioterrorism and public health emergency preparedness capabilities, specifically programs intended to support upgrading state and local capabilities and hospital readiness, was \$704 million. The PHEP Cooperative Agreement should be funded at \$1.03 billion, which is the FY 2005 level adjusted for inflation. These funds are used to develop core boots-on-the-ground support for disaster response and any reduction in funding leaves the country at unnecessary levels of risk. Inconsistencies in funding from year to year means that states cannot predict how much money they will receive and this affects their ability to hire and train staff, expand capacity, and implement new programs.
End the practice of “reprogramming” and redirecting money from the state preparedness grants for special projects	In recent years, the PHEP Cooperative Agreement not only has seen its base funding decline, but further reductions as portions are carved out for special projects. For example, in FY 2007 HHS took \$35 million from the PHEP to fund a Poison Control Partnership Program (PCPP) to enhance real-time disease detection program. HHS did not renew this funding in FY 2008. It is not clear how HHS expects to maintain any gains in enhanced collaboration among state health departments and poison control centers without additional funding. HHS should refrain from one-year-carve outs that waste taxpayers’ money. Instead, PHEP base funding should be increased and maintained so these relationships and workforces can be built and sustained.

Recommendations for Funding

Fully fund hospital preparedness	<p>The HPP focuses on improving the clinical response to a large-scale health emergency, which includes both developing surge capacity and continuity of operations planning. On average, hospitals receive about \$100,000 per year, with some as low as \$10,000 per year. In FY 2008, the HPP was funded at \$398 million. In the short-term, this crucial program should be funded at \$596 million, which is the FY 2004 level adjusted for inflation. In the long-term, the administration and Congress should examine ways to build hospital preparedness into the federal health care financing system, by providing, for example, enhanced reimbursement rates under Medicare to those facilities that are willing to enhance and maintain their emergency response capacity. This would remove the funding of hospital preparedness from the unpredictability of the annual appropriations cycle.</p>
Increase pandemic influenza funding	<p>The Obama administration should provide a detailed assessment of long-term funding needs for pandemic preparedness. In the short-term, Congress should appropriate \$870 million in no-year FY 2009 pandemic preparedness funding, \$363 million above the recommended level of \$507 million, providing additional resources for the development and purchase of vaccine, antivirals, necessary medical supplies, diagnostics and other surveillance tools. Additionally, an appropriation of \$662 million is recommended for ongoing annual pandemic preparedness activities at HHS, \$350 million above the recommended level of \$312 million, providing additional resources for state and local preparedness.</p>
Increase funding for BARDA	<p>In FY 2008, BARDA received \$101 million, which is nowhere near the amount needed for advanced research and development of medical countermeasures. Congress should appropriate \$1.29 billion over multiple years for BARDA's Pandemic and Emerging Disease Program for the advanced development of pandemic influenza vaccine and pre-pandemic vaccine and antiviral stockpiles. Another \$850 million for biological countermeasures and diagnostics should be appropriated, and made available over multiple years in the Public Health and Social Services Emergency Fund (PHSSEF) for BARDA's Advanced Research and Development Fund.</p>
Funding should be appropriated for the replenishment and maintenance of national stockpiles as many parts of the stockpile are set to expire in the coming years	<p>The next secretary of HHS should give the president and Congress a professional judgment budget that includes the cost of replenishing and maintaining stockpiles. Funding to buy new medical countermeasures may require a new Act of Congress as the 2004 Project BioShield does not allow for replenishment and maintenance costs.</p>
Funding should be appropriated for the development of new evidence-based benchmarks and objective standards	<p>PAHPA required HHS to work in coordination with the research community and evaluation specialists and develop new objectives to measure how well states respond to major public health emergencies. PAHPA specifically required CDC's CPHP to focus on systems research, but overall CPHP funding was not increased to account for the program. CDC should provide Congress with a professional judgment budget that includes the cost of fully funding the CPHPs and the PERRCs to carry out their important work on public health workforce preparedness and public health emergency preparedness research and evaluation.</p>
Provide a transparent accounting of pandemic influenza funding	<p>Nearly \$5 billion of FY 2006 pandemic influenza funding was designated as 'no-year funding,' meaning HHS was able to spend that money as needed over the next several years. This approach enables HHS to contract with pharmaceutical manufacturers to advance the development of new-line vaccines and medications and bolster production capacity over several years. HHS should provide a clear plan for how the remaining funds will be spent.</p>

2. RESTRUCTURING OF FEDERAL HEALTH AGENCIES

Prevention, preparedness, and public health are vital to the well-being of families, communities, workplace productivity, U.S. competitiveness, and national security. The incoming Obama administration and the 111th Congress should make protecting the health of all Americans a priority. However, the nation's public health structure is broken and needs to be fixed. The current federal structure for public health emergency preparedness has several specific problems. Major limitations include:

- Lack of clear, strong leadership;
- Understaffing; and

- Limited coordination within health agencies and poor coordination across agencies in the federal government.

The following recommendations represent a set of options that could be addressed together as a whole or individually by the Obama administration and Congress. They are drawn from TFAH's October 2008 transition paper *Blueprint for a Healthier America: Modernizing the Federal Public Health System to Focus on Prevention and Preparedness*. The full report is available online at www.healthyamericans.org.

Recommendations for Restructuring of Federal Health Agencies	
Ensure a broad understanding of health security issues within the Executive Office of the President	The Obama administration should appoint a Deputy Assistant to the President for Health Security Affairs who can coordinate domestic and global health security issues across the National Security Council, Homeland Security Council, Domestic Policy Council, and National Economic Council.
Clarify roles and responsibilities among federal agencies	HHS is the lead cabinet agency for determining policy and planning for emergencies. There is broad consensus among experts that HHS should remain as the lead agency. However, other cabinet agencies have different types of expertise that are needed during emergencies. For example, the VA can manage large health systems, and the VA and DOD can effectively and rapidly move people, equipment, and supplies. The White House Homeland Security Council should review Emergency Support Function-8 to determine whether any changes in protocol are needed, and if any new authorities are needed to permit larger contributions by VA and DOD during emergencies.
Clarify the role of the Office of Health Affairs in DHS	While HHS is considered the lead agency for public health response, some critical health functions operate out of the DHS Office of Health Affairs (OHA), including bio-monitoring activities such as BioWatch, a bio-aerosol environmental monitoring system for early detection of biological events. OHA is also responsible for integrating emergency management and medical response at all levels of government. The White House Homeland Security Council should review the health-related functions of DHS and establish a structure to make sure these systems are well-coordinated and housed in the most appropriate agencies.

Recommendations for Restructuring of Federal Health Agencies

<p>Elevate the current Assistant Secretary for Health position to be an Undersecretary for Health (USH)</p>	<p>This office should oversee a strategic approach to prevention, preparedness, and public health to increase coordination and accountability among agencies, including all Public Health Service agencies, ASRP, and the Centers for Medicare and Medicaid Services reporting to this official. The USH is not meant to disempower agencies or add another bureaucratic layer, but to help coordinate and provide leadership.</p>
<p>Ensure appropriate division of labor within HHS</p>	<p>Under the current structure, ASPR functions as both a policy arm and operating division. As a policy office, it recommends and oversees policy and coordination for all HHS agencies and interacts with other cabinet agencies and the White House on preparedness issues. As an operating division, it manages some programs including hospital preparedness grants and medical response (ESF-8). Some officials have suggested that all preparedness grants should be managed by ASPR rather than CDC, even though CDC has traditionally functioned as an operating division and has expertise in managing grants. Roles must be clarified. With support from a new Undersecretary of Health (USH), ASPR should focus on consistency in policy and coordination among programs, to ensure that all HHS agencies follow the policy guidance of ASPR. CDC should continue to be responsible for the public health emergency response, which includes serving as the main operating division for preparedness grants, to avoid adding more bureaucracy and confusion for state and local government grantees.</p>
<p>Leadership and accountability</p>	<p>Designate a single official within HHS to be responsible, accountable, and fully empowered to plan and coordinate implementation of the National Health Security Strategy called for in PAHPA. This official should either perform or oversee all the preparedness-related activities of the new Assistant Secretary for Preparedness and Response, the Assistant Secretary for Health, and all other components of HHS. Further, he or she must ensure the needed coordination and integration across all the agencies that have a role to play.</p>
<p>Appoint a strong, independent Surgeon General</p>	<p>The Surgeon General must be given the independence to speak directly to the public on matters of public health emergency preparedness and personal preparedness, and be given the resources needed to ensure those messages are heard.</p>

3. TRANSPARENCY, ACCOUNTABILITY, AND OVERSIGHT

PAHPA not only demonstrated the resolve of Congress and the Bush administration to continue to address public health emergency preparedness, but gave the federal agencies, namely HHS, a series of deliverables and deadlines to produce and meet. While much progress has been made on the implementation of PAHPA, which is notable in light of

personnel and funding constraints, much remains to be done. To ensure HHS fully complies with PAHPA and does so in an open and transparent manner, pursuant to the provisions of the statute, Congress should use its oversight powers to ensure full implementation and execution of PAHPA.

Recommendations for Strengthening Transparency, Accountability and Oversight

Publish regular progress reports on the implementation of PAHPA	HHS should regularly provide publicly available updates on the progress made on benchmarks and deliverables under the PAHPA statute. The first progress report was released in November 2007. An update is planned for late 2009.
Develop new evidence-based benchmarks and objective standards	CDC's Division of State and Local Readiness' Outcome Monitoring and Evaluation Branch is working closely with PHEP program and evaluation specialists to develop a new set of performance based metrics to measure organizational readiness and response to public health emergencies. The objectives should focus on outcome results from real-life drills and exercises. Benchmarks currently in use are more process-oriented and not clear predictors of how well a state will respond to an emergency.
Develop and implement the use of standardized preparedness exercises	CDC, in coordination with other government agencies, state and local health departments, research organizations, and universities, should develop and implement the use of standardized public health preparedness exercises. The exercises should include a thorough evaluation and after-action report that is made publicly available. Any weaknesses or gaps identified in the evaluation should be addressed within a specific amount of time.
Incorporate lessons learned into future planning	The use of real-life exercises and drills, in addition to table-top exercises, gives states the ability to accurately gauge how well they would perform in a public health emergency. The lessons learned from these evaluations, however, are only useful if they are demonstrably incorporated into revised and updated preparedness plans.
Collect performance data; assess the results; and, annually release the findings publicly on a state-by-state basis	As required by PAHPA, HHS is in the process of developing a standardized reporting form for all states and hospital grantees. The use of this form will allow HHS to rate the performance of the grantees and to assure the proper expenditure of funds. Data from this form and other evaluations of states' emergency preparedness should be reported yearly on a state-by-state basis. This allows Americans to appropriately assess their states' progress and document how states have used taxpayer-supported preparedness funds.
Transparency	The federal government, in collaboration with the states, should share states' pandemic preparedness plans and performance grades with the public to increase transparency and build community resiliency. CDC, which published its first report on the PHEP Cooperative Agreement in February 2008, should continue to share evaluation results on a state-by-state basis, in addition to releasing the specific criteria it uses for evaluating states, and providing the public a basis for interpreting these scores. The more people know about state and local preparedness, the better equipped they are to make their own family and household plans. CDC's next report will be released in early 2009 and will provide an evaluation of the agency's preparedness programs and activities.
Continuous revision and strengthening of preparedness plans	Federal and state agencies need to keep preparedness plans updated to account for changes in the environment and advancements in scientific knowledge.

4. SURGE CAPACITY

Surge capacity remains the largest threat to the nation’s ability to respond to a major catastrophe such as a pandemic influenza. Much remains to be done to ensure that the

U.S. health care system is able to function in a mass-casualty event. In addition to the funding recommendations discussed above, TFAH suggests the following:

Recommendations for Surge Capacity	
Altered standards of care	Legal issues are a major barrier for many states (and hospitals) in their planning for scenarios that would involve altered standards of care and the allocation of scarce resources. The federal government should take steps to address the legal issues associated with shifting to a different paradigm of providing health care when the need for care overwhelms available resources (i.e., staff, supplies, space) during catastrophic public health emergencies.
Regional coordination of health care facilities, including alternative care sites, with public health and emergency management	Hospitals, local health departments, and emergency management agencies should build regional consortiums to organize and plan for public health emergencies. Such regional collaboration can lead to more efficient use of resources among hospitals and health departments, including personnel, and facilitate the sharing of promising practices. This coordination should include all federal resources active in the region, including VA and DOD facilities. (Regional efforts could be within a locality or across county and/or state lines depending on the size of the communities involved.)
Alternate care sites	Despite the clear need for alternative care sites following a mass casualty event, there are several barriers to their successful roll-outs. To address these barriers, TFAH recommends the following measures: 1) Increase local, state, and regional planning with clear delineation of responsibilities and authority; 2) Foster public-private partnerships among health care practitioners; 3) Employ operational drills to test the deployment of mobile units and the creation of alternative care sites; and, 4) Address licensing and liability concerns for health care workers, behavioral health professionals, and volunteers and liability concerns for non-health care volunteers and third-party entities that play host to alternative care sites. In addition, emergency planners will need to obtain, stockpile, and store supplies, equipment and medicines for use in the alternative care sites.
Enhance communication systems	Hospitals must develop communication systems that allow health care facilities and public health departments to talk to each other and collectively manage an emergency response.
Designation of a disaster coordinator for each hospital	Strong leadership is essential to mounting and sustaining a successful public health emergency response at the national, state, and local levels. This applies to hospitals as well, which should designate a strong leader, respected and trusted by staff, to serve as a disaster coordinator. The person who fills this role will be required to assure that many difficult decisions are made, including the use of altered standards of care, alternate care sites, limited resources, and the call-up of volunteer medical personnel.
Surge workforce	Public and private health care organizations should develop means to boost staff during a public health emergency, either through the use of incentives for current staff or through the use of volunteers or non-traditional staff, such as emergency medical technicians and medical and nursing students. The surge workforce should be recruited in advance in order to ensure licensing and accreditation issues are resolved before an emergency strikes.

5. PREPAREDNESS AND HEALTH REFORM

America must provide quality, affordable health care to all. A strong public health system and public policies focused on prevention of disease and injury, and preparedness for public health emergencies, should be a cornerstone of a health reform plan. A strong public health system is necessary to help promote better health,

monitor the health of the country, and protect people from health threats that are beyond individual control, including bioterrorism, food-borne illness, and natural disasters. The nation must ensure that a reformed health care system will be prepared to react to and mitigate the consequences of a public health emergency.

Recommendations for Preparedness and Health Reform

Build preparedness and prevention into health reform	Past health reform discussions have focused on how best to care for people after they become sick or harmed. As the next president, administration, and Congress debate 21st century health reform, an emphasis should be placed on prevention of disease and preparedness against public health emergencies. A reformed health care system should assure stable funding for a strong public health infrastructure and finance the preparedness role of the health care system.
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6. PUBLIC HEALTH WORKFORCE

The growing workforce shortage in the health care and public health fields threatens U.S. emergency preparedness. America's response will be severely limited, unless the workforce challenges the public health system faces are

addressed. PAPHA contained two key provisions related to workforce development, whose implementation TFAH supports. But much more remains to be done to address the public health workforce crisis.

Recommendations for Public Health Workforce

Fund and implement PAHPA workforce provisions	Congress should appropriate and allocate the necessary funds to implement the HHS workforce demonstration project. This student loan repayment project is intended for individuals who: 1) are eligible for the National Health Service Corps loan repayment program and 2) also agree to serve in a state health department that provides service to a significant number of health professional shortage areas or has areas that are at risk of a public health emergency. Congress should also appropriate and allocate monies necessary to execute the second PAHPA workforce provision, which allocates grants to states to assist in operating state loan repayment programs.
Enact and fund comprehensive public health workforce scholarship initiatives	Institute a grant and/or loan repayment program to college juniors and seniors and graduate students (in their final years of training) who commit to entering governmental public health. Students would have to meet certain academic requirements, such as achieving a B average, to qualify for the program.
Federal match for state and local workforce	The federal government should provide federal matching funds to state and local governments to invest in recruitment, retention, training, and retraining for public health workers.
Allow federal funding to support more public health education programs	Currently, only the nation's 40 schools of public health can compete for certain CDC and other funding to support governmental public health professionals. Universities that offer master's programs in public health (outside the schools of public health) and other related master's programs should be allowed to compete for funding.
Strengthen the U.S. Public Health Service Commissioned Corps	Congress should strengthen the U.S. Public Health Service Commissioned Corps by increasing the number of active duty personnel, creating a "Ready Reserve," and establishing a dedicated funding stream for all Corps activities under the management and fiscal control of the Surgeon General.
Streamline the registration and accreditation of emergency health care volunteers	The expansion of ESAR-VHP and the mandatory participation in the program in order to receive preparedness funds is a major step in the right direction. HHS should integrate other health care volunteer systems such as the MRC and the NDMS into ESAR-VHP in order to eliminate confusion among participants and avoid double-counting potential health care volunteers. Health care volunteers enrolled in these systems should participate in federal, state, and local emergency drills.

7. RESEARCH AND DEVELOPMENT

The basic technology and tools of public health need to be modernized. Too often front-line health care professionals are relying on outdated diagnostic tests and med-

ications. As new tests and therapies are developed and as older ones become obsolete, the SNS should be replenished.

Recommendations for Research and Development	
Enhance research and development of vaccines and public health technologies	Basic technology and tools of public health must be modernized to adequately protect the American people. This includes research and development of vaccines and new technologies; and improved chemical laboratory testing capabilities. Collaboration with the private sector, as envisioned under BARDA and Project BioShield, will be essential.
Clarify requirements and deliverables under Project BioShield contracts	ASPR should coordinate with NIH, FDA and CDC to ensure future BioShield requests for proposals and procurement contracts for new countermeasures have clearly articulated requirements, expectations, and deliverables.
Replenish and augment the SNS	Ensure the SNS contains enough supplies and dosage recommendations for adults and children. In addition, future federal appropriations cycles must take into account the need to replenish currently stockpiled countermeasures that pass their expiration dates. Currently, the bulk of SNS medications were purchased under the 2004 BioShield Act. Many of these vaccines and drugs are beginning to expire -- even within the Shelf Life Extension Program -- which leaves a huge gap in our nation's preparedness.
Complete purchases of antiviral medications	The federal government has met its goal of stockpiling 50 million treatment courses of antivirals. States have collectively stockpiled 22.5 million treatment courses towards the 31 million goal. The 26 states that have not yet purchased 100 percent of their subsidized antivirals should do so. Meanwhile, the federal government should re-examine this shared responsibility in light of major gaps in antiviral stockpiling in certain states. Additionally, if federal guidance on the use of antivirals shifts from treatment to prophylaxis, stockpiling goals will change and more purchases will be needed.
Expand the Shelf Life Extension Program	Congress should extend the Shelf Life Extension Program (or establish a new, parallel, SLEP-like program within FDA) to include state and local antiviral and antibiotic stockpiles. Currently, state and local stockpiles could have shorter shelf lives even though the nation is depending on state and local stockpiles to meet national goals.
Modernize disease surveillance systems	Every health department and health agency should be part of a 21st century surveillance system that meets national standards and is interoperable between jurisdictions and agencies to ensure rapid information sharing. Surveillance systems should be able to detect infectious disease outbreaks or a bioterrorist attack. Plans should ensure adequate laboratory surveillance of influenza and other infectious diseases, as well as testing for pathogens such as E. Coli, Methicillin-resistant Staphylococcus aureus (MRSA), and extensively drug-resistant Tuberculosis (XDR-TB).
Public health should be a central part of the design and implementation of health information technology systems	Current health information technology is concentrated on electronic health records (EHRs), which are used to improve patient care and efficiency. As the use of EHRs grows, public health officials' need for near real-time data on disease surveillance should be factored into their design and implementation. Public health can use data from EHRs to monitor the health of the population and the demand for care, invaluable tools to help detect and mitigate public health emergencies.

8. LEGAL PREPAREDNESS

This report has underscored the critical need for states to develop full legal preparedness for all-hazards public health emergencies. All four core elements of public health legal preparedness should be addressed: laws and

legal authorities; competency in using law; coordination across sectors and jurisdictions in implementing law-based interventions; and legal best practices.

Recommendations for Legal Preparedness	
State legal preparedness for all-hazards public health emergencies	States should review and apply tools that have been developed for their use in assessing and making needed improvements in their legal preparedness for public health emergencies. These tools include, for example, model legislation (e.g., the Draft Model State Emergency Health Powers Act) and draft memoranda of understanding (e.g., between public health and law enforcement agencies), such training curricula as “Forensic Epidemiology 3.0” and “Public Health Emergency Law 3.0”, the Menu of Suggested Provisions for Mutual Aid Agreements, The Social Distancing Law Assessment Template, and the National Action Agenda for Public Health Legal Preparedness. (These and additional tools are accessible at http://www.cdc.gov/phlp)
State liability protections for volunteer health professionals	Liability concerns are a growing challenge to emergency preparedness officials. Volunteers and private entities have expressed reluctance to participate in response and recovery efforts for fear that their actions may make them liable. State legislatures should adopt the UEVHPA which has been approved by both the National Conference of Commissioners on Uniform State Laws and the American Bar Association, or enact similar legislation that extends liability protection to volunteer health professionals in a public health emergency.
Federal volunteer health professional liability protection	Congress should amend the Public Health Service Act to provide Federal Tort Claims Act protection to qualified ESAR-VHP participants when they are activated by the federal government to respond to a public health emergency. The federal Public Health Security and Bioterrorism Preparedness and Response Act of 2002 authorized the ESAR-VHP to help states develop registry systems for the timely identification, verification and use of volunteer health professionals during public health emergencies. ²⁵⁴ In 2006, PAHPA required the federal Secretary of Health and Human Services to link the state systems into a single national network of systems. ²⁵⁵ The state systems continue to be maintained by the individual states, with guidance from the federal government. Despite ongoing efforts to build this national network, the liability issues that can arise from activating the ESAR-VHP remain an area of concern. ²⁵⁶
State entity liability protection	State legislatures should consider extending Good Samaritan liability protections to those non-health care volunteers and business and non-profit entities that provide emergency assistance.
Federal entity liability protection	To address liability issues for businesses and non-profit organizations, Congress may wish to create a federal floor for the minimum protection that should be available to these emergency response partners when working in concert with government agencies.

9. HEALTH AND SICK LEAVE BENEFITS

A public health emergency will create financial hardships for individuals and the health care system. Because compliance with recommendations to seek immediate care and/or self-isolate or quarantine may be critical to containing the spread of influenza or

a terrorist-introduced organism, TFAH believes the federal government should take steps to assure that lack of health insurance or sick leave do not prevent compliance with public health recommendations.

Recommendations for Health and Sick Leave Benefits

<p>Establish an emergency health benefit</p>	<p>Congress should establish a short-term emergency health benefit, which would allow hospitals and health care centers to keep functioning during a prolonged public health emergency, while ensuring care to uninsured and underinsured individuals affected by the crisis. Legislation currently under consideration in Congress, the Public Health Emergency Response Act (PHERA), would help ensure that victims of catastrophic public health emergencies have meaningful and immediate access to medically necessary health care services.</p>
<p>Set up emergency sick leave policies and procedures</p>	<p>The federal government should clarify whether the Department of Labor’s Disaster Unemployment Assistance Program, as currently established, would cover workers without sick leave who self-quarantine in the event of a pandemic flu. Congress should pass legislation that would require employers with 15 or more employees to offer a minimum of seven paid sick days each year, to be used to deal with individual medical needs or to care for sick family members. Having paid leave may be critical to assuring compliance with public health recognitions for voluntary quarantine by individuals in a pandemic influenza.</p>

10. FOOD SAFETY REFORMS

Reforms are needed to make the U.S. food safety system preventive, instead of reactive.

Recommendations for Food Safety Reforms

<p>Unified and prevention-oriented statutory mandate and organizational structures</p>	<p>In the short-term, HHS should split the FDA into two separate entities: one that handles drugs, cosmetics, and medical devices and one that handles food. By splitting the agency, HHS will ensure that food safety gets the attention, resources, and priority it deserves and does not take a back seat to the more profitable drug and medical regulation. In the long-term, Congress should enact legislation that paves the way for a single, unified food safety agency to carry out a prevention-focused, integrated food safety strategy, including mandatory implementation of preventive controls by producers and processors. The single food safety agency should include: FSIS; the food regulatory functions of FDA, including CFSAN, the Center for Veterinary Medicine, and the food portion of FDA’s field resource; and the food safety aspects of EPA’s pesticide program.</p>
<p>Increased resources for research, standard-setting, inspection, enforcement, and education</p>	<p>A modernized food safety system will require additional resources for (1) research and data collection on the incidence and causes of foodborne disease, new food safety technologies and prevention strategies, and consumer behavior; (2) setting food safety performance standards and establishing a mandatory standard of care for preventing food safety problems; (3) inspection and enforcement to ensure standards are consistently met by both domestic and foreign producers and processors; and (4) food safety education of commercial food handlers and consumers.</p>
<p>Risk-based resource allocation</p>	<p>The federal government should direct its resources for food safety research, regulation, and education in the manner most likely to maximize reduction in foodborne disease. This would require repealing the current FSIS inspection mandate and substituting a modernized mandate for the entire farm-to-table food safety system that would ensure an adequate resource base for inspection, but require the inspection and other resources be applied in the manner most likely to contribute to disease reduction.</p>

II. COMMUNITY RESILIENCY

HSPD-21 identifies community resilience as one of “the four most critical components of public health and medical preparedness,” along with mass casualty care, mass distribution, and biosurveillance. The U.S. government defines “community resiliency” as the ability of a community to cope and recover from a disaster or public health emergency. A CDC-funded study states that in order “for a community to be resilient, its members must put into practice early and effective ac-

tions, so that they can respond to adversity in a healthy manner.”²⁵⁷

Taking this into account, preparedness plans need to consider the diverse needs of the U.S. population, in particular, “at-risk,” “special needs,” and “vulnerable” populations. Only by effectively reaching out to all segments of the U.S. population can the country appropriately be prepared to survive and overcome crises.

Recommendations for Strengthening Community Resiliency	
Guard against complacency	One of the biggest challenges facing public health emergency preparedness is complacency. Federal, state, local, tribal, and territorial governments must maintain a sense of urgency regarding preparedness. Officials should communicate the importance of preparedness to the public while not resorting to scare tactics. Engagement with media is the key to building a heightened sense of awareness around the issues of emergency preparedness, especially at the community level.
Engage communities in planning	Federal, state, local, tribal, and territorial governments must engage communities in local emergency and pandemic planning. Too often emergency planners just look to their grantees and ignore other key stakeholders, such as volunteer organizations, religious institutions, and schools and universities. Planners must proactively approach these diverse groups and bring them to the table.
Focus on disease prevention and health promotion	The president and Congress should invest strategically in community-based disease prevention programs. Americans cannot be prepared if they are unhealthy, yet chronic disease rates are spiraling out of control in this nation. More than two-thirds of American adults are overweight or obese. One in four has heart disease; and one in three has high blood pressure. Twenty-four million Americans have type 2 diabetes and another 54 million are pre-diabetic. These underlying health conditions pose a challenge when residents are asked to evacuate due to a public health emergency. Persons dependent on prescription drugs also face challenges when asked to shelter-in-place as they may run out of their medicines.

Recommendations for Strengthening Community Resiliency

<p>Communicating effectively with at-risk individuals</p>	<p>Federal, state, local, tribal, and territorial officials must design culturally competent risk communication campaigns that use respected, trusted, and culturally competent messengers. Current research and best-practices regarding emergency preparedness communication strategies for at-risk populations should direct the creation and dissemination of these messages.</p>
<p>Children are not small adults</p>	<p>Children are inherently vulnerable as they depend upon adults for food, shelter, supervision and guidance. As such, their needs should be taken into account in all public health emergency and pandemic preparedness efforts. Because disease susceptibility, outcome, and transmission will likely differ for children when compared to adults, recommendations for child social distancing during a pandemic, will likely differ from social distancing recommendations for adults. Evacuation and reunification planning should reflect the fact that children are often separated from their parents for much of the day. Child advocates, such as teachers and pediatricians, should be consulted as plans are made. Preparedness plans should be clearly communicated to parents, schools, and daycare facilities.</p>
<p>The president and Congress should carefully consider the recommendations from the National Commission on Children and Disasters, which are due out in 2010.</p>	<p>The National Commission on Children and Disasters, a bi-partisan panel appointed by the president and Congressional leaders, held its first meeting in October 2008. Over a period of two years, the Commission will examine and assess the needs of children independently, and in relation to the preparation, response and recovery from all emergencies, hazards and disasters. Following its investigation, the Commission will issue a final report, complete with findings and recommendations, to the next president and Congress. These recommendations should be acted upon with utmost urgency.</p>
<p>Behavioral health considerations</p>	<p>Disasters have far reaching behavioral health consequences.²⁵⁸ Federal and state emergency planners should, therefore, coordinate with mental health and substance abuse agencies to ensure effective and ongoing response to all-hazard emergencies.</p>

APPENDIX A: CDC AND ASPR PREPAREDNESS GRANTS BY STATE

BIOTERRORISM FUNDING BY SOURCE AND YEAR								
State	FY 2007			State	FY 2008			% Change FY 07-FY 08
	CDC	ASPR	Total		CDC	ASPR	Total	
Alabama	\$10,228,439	\$6,330,289	\$16,558,728	Alabama	\$10,241,093	\$6,073,401	\$16,314,494	-1.5%
Alaska	\$5,015,000	\$1,349,441	\$6,364,441	Alaska	\$5,015,000	\$1,312,013	\$6,327,013	-0.6%
Arizona	\$14,284,449	\$8,317,173	\$22,601,622	Arizona	\$14,227,671	\$7,972,742	\$22,200,413	-1.8%
Arkansas	\$7,533,981	\$4,063,403	\$11,597,384	Arkansas	\$7,435,489	\$3,906,396	\$11,341,885	-2.2%
California	\$52,023,574	\$34,106,620	\$86,130,194	California	\$50,161,370	\$32,625,884	\$82,787,254	-3.9%
Colorado	\$11,234,142	\$6,525,958	\$17,760,100	Colorado	\$11,141,885	\$6,260,449	\$17,402,334	-2.0%
Connecticut	\$9,112,072	\$4,943,121	\$14,055,193	Connecticut	\$8,927,705	\$4,747,354	\$13,675,059	-2.7%
Delaware	\$5,000,000	\$1,581,970	\$6,581,970	Delaware	\$5,000,000	\$1,534,297	\$6,534,297	-0.7%
D.C.	\$9,129,492	\$1,737,218	\$10,866,710	D.C.	\$6,698,743	\$1,707,585	\$8,406,328	-22.6%
Florida	\$33,289,391	\$23,432,938	\$56,722,329	Florida	\$32,940,501	\$22,422,494	\$55,362,995	-2.4%
Georgia	\$18,230,415	\$12,370,869	\$30,601,284	Georgia	\$18,689,009	\$11,847,828	\$30,536,837	-0.2%
Hawaii	\$5,296,353	\$2,129,653	\$7,426,006	Hawaii	\$5,228,184	\$2,057,849	\$7,286,033	-1.9%
Idaho	\$5,439,853	\$2,359,069	\$7,798,922	Idaho	\$5,405,739	\$2,277,157	\$7,682,896	-1.5%
Illinois	\$19,245,542	\$13,163,842	\$32,409,384	Illinois	\$19,912,211	\$12,605,863	\$32,518,074	0.3%
Indiana	\$13,406,349	\$8,503,785	\$21,910,134	Indiana	\$13,335,867	\$8,151,131	\$21,486,998	-1.9%
Iowa	\$7,832,164	\$4,280,453	\$12,112,617	Iowa	\$7,702,063	\$4,113,883	\$11,815,946	-2.4%
Kansas	\$7,709,812	\$4,004,077	\$11,713,889	Kansas	\$7,598,339	\$3,849,684	\$11,448,023	-2.3%
Kentucky	\$9,905,373	\$5,832,130	\$15,737,503	Kentucky	\$9,750,535	\$5,597,192	\$15,347,727	-2.5%
Louisiana	\$10,536,471	\$5,935,695	\$16,472,166	Louisiana	\$9,998,186	\$5,696,194	\$15,694,380	-4.7%
Maine	\$5,381,949	\$2,175,388	\$7,557,337	Maine	\$5,271,144	\$2,102,569	\$7,373,713	-2.4%
Maryland	\$12,815,412	\$7,619,177	\$20,434,589	Maryland	\$13,038,391	\$7,305,500	\$20,343,891	-0.4%
Massachusetts	\$14,418,081	\$8,660,567	\$23,078,648	Massachusetts	\$14,805,770	\$8,301,006	\$23,106,776	0.1%
Michigan	\$21,555,319	\$13,298,463	\$34,853,782	Michigan	\$20,453,241	\$12,734,552	\$33,187,793	-4.8%
Minnesota	\$12,587,653	\$7,050,445	\$19,638,098	Minnesota	\$12,616,406	\$6,761,826	\$19,378,232	-1.3%
Mississippi	\$7,797,260	\$4,189,754	\$11,987,014	Mississippi	\$7,629,747	\$4,027,180	\$11,656,927	-2.8%
Missouri	\$13,236,793	\$7,906,932	\$21,143,725	Missouri	\$13,029,088	\$7,580,577	\$20,609,665	-2.5%
Montana	\$5,026,488	\$1,697,530	\$6,724,018	Montana	\$5,022,876	\$1,644,766	\$6,667,642	-0.8%
Nebraska	\$5,966,406	\$2,741,751	\$8,708,157	Nebraska	\$5,877,064	\$2,642,978	\$8,520,042	-2.2%
Nevada	\$7,662,442	\$3,663,636	\$11,326,078	Nevada	\$7,652,253	\$3,524,243	\$11,176,496	-1.3%
New Hampshire	\$5,308,479	\$2,166,921	\$7,475,400	New Hampshire	\$5,317,054	\$2,093,475	\$7,410,529	-0.9%
New Jersey	\$17,584,884	\$11,560,312	\$29,145,196	New Jersey	\$18,788,803	\$11,072,985	\$29,861,788	2.5%
New Mexico	\$7,249,926	\$2,977,887	\$10,227,813	New Mexico	\$7,054,780	\$2,868,709	\$9,923,489	-3.0%
New York	\$22,935,076	\$14,561,258	\$37,496,334	New York	\$22,518,790	\$13,941,707	\$36,460,497	-2.8%
North Carolina	\$16,570,173	\$11,727,581	\$28,297,754	North Carolina	\$16,696,497	\$11,232,884	\$27,929,381	-1.3%
North Dakota	\$5,028,972	\$1,306,102	\$6,335,074	North Dakota	\$5,023,132	\$1,270,585	\$6,293,717	-0.7%
Ohio	\$22,745,252	\$15,050,914	\$37,796,166	Ohio	\$21,838,104	\$14,409,789	\$36,247,893	-4.1%
Oklahoma	\$8,871,195	\$5,037,444	\$13,908,639	Oklahoma	\$8,740,269	\$4,837,520	\$13,577,789	-2.4%
Oregon	\$9,192,614	\$5,191,530	\$14,384,144	Oregon	\$9,100,217	\$4,984,817	\$14,085,034	-2.1%
Pennsylvania	\$24,743,362	\$16,271,242	\$41,014,604	Pennsylvania	\$23,758,643	\$15,576,347	\$39,334,990	-4.1%
Rhode Island	\$5,048,931	\$1,853,432	\$6,902,363	Rhode Island	\$5,012,619	\$1,793,799	\$6,806,418	-1.4%
South Carolina	\$9,972,754	\$5,978,140	\$15,950,894	South Carolina	\$9,968,869	\$5,736,768	\$15,705,637	-1.5%
South Dakota	\$5,000,000	\$1,491,255	\$6,491,255	South Dakota	\$5,000,000	\$1,447,580	\$6,447,580	-0.7%
Tennessee	\$13,009,292	\$8,155,520	\$21,164,812	Tennessee	\$12,844,807	\$7,818,211	\$20,663,018	-2.4%
Texas	\$44,570,881	\$30,301,320	\$74,872,201	Texas	\$43,355,376	\$28,988,249	\$72,343,625	-3.4%
Utah	\$7,174,066	\$3,732,769	\$10,906,835	Utah	\$7,162,839	\$3,590,331	\$10,753,170	-1.4%
Vermont	\$5,039,717	\$1,290,942	\$6,330,659	Vermont	\$5,041,316	\$1,256,092	\$6,297,408	-0.5%
Virginia	\$17,109,122	\$10,189,048	\$27,298,170	Virginia	\$17,222,047	\$9,762,140	\$26,984,187	-1.2%
Washington	\$14,168,202	\$8,608,090	\$22,776,292	Washington	\$14,012,182	\$8,250,841	\$22,263,023	-2.3%
West Virginia	\$6,026,051	\$2,805,313	\$8,831,364	West Virginia	\$5,933,288	\$2,703,739	\$8,637,027	-2.2%
Wisconsin	\$12,667,934	\$7,544,102	\$20,212,036	Wisconsin	\$12,188,297	\$7,233,733	\$19,422,030	-3.9%
Wyoming	\$5,000,000	\$1,152,882	\$6,152,882	Wyoming	\$5,000,000	\$1,124,115	\$6,124,115	-0.5%
	CDC Total FY 07*	ASPR Total FY 07*	Grand Total FY 07*		CDC Total FY 08*	ASPR* Total FY 08*	Grand Total FY 08*	Grand Total Percent Change FY 07 - FY 08
	\$645,917,558	\$378,925,351	\$1,024,842,909		\$636,383,499	\$363,379,009	\$999,762,508	-2.4%

*Note that CDC total funding for FY 2007 includes CRI, Level 1 chemical lab capacity, real-time disease detection, and EWIDS funding. It does NOT include pandemic influenza funding. FY 2008 CDC total funding includes CRI, Level 1 chemical lab capacity, and EWIDS funding. **Note that totals do not include funds for 3 major U.S. metropolitan areas, Chicago, L.A. County, and New York City, U.S. Territories, such as Puerto Rico and Guam, and Freely Associated States of the Pacific, such as the Marshall Islands. **Source:** 1) HHS. HHS Provides More Than \$1 Billion to Improve All Hazards Public Health. News Release, June, 3, 2008. <<http://www.hhs.gov/news/press/2008pres/06/20080603a.html>> (accessed June 6, 2008). 2) CDC. Cooperative Agreement Guidance for Public Health Emergency Preparedness Program Announcement AA154 - FY 2008 (Budget Period 9). Atlanta, GA: U.S. Department of Health and Human Services, 2008, p. 22-24. <http://emergency.cdc.gov/cotper/coopagreement/08/pdf/fy08announcement.pdf> (accessed September 16, 2008). 3) HHS. HHS Provides \$430 Million to States to Enhance Hospital and Other Health Care Facilities Preparedness for Public Health Emergencies. News Release, June 28, 2007 <<http://www.hhs.gov/news/press/2007pres/06/pr20070628a.html>> (4) CDC. Guidance Document for Continuation of the Public Health Emergency Preparedness (PHEP) Cooperative Agreements (Budget Period 8). Atlanta, GA: U.S. Department of Health and Human Services, 2007, p. 22-24. <http://www.bt.cdc.gov/planning/coopagreement/pdf/fy07announcement.pdf> (accessed September 16, 2008).

APPENDIX B: INFLUENZA ANTIVIRAL DRUG PURCHASES BY STATES, TERRITORIES, AND SELECT CITIES

PANDEMIC INFLUENZA ANTIVIRAL DRUGS STOCKPILE PURCHASES -- STATES, LOCALITIES, AND TERRITORIES				
State	Population	Initial Allocation* (06/30/06)	All Antivirals Purchased by State (09/30/08)	Percent of Allocation Purchased
Alabama	4,503,726	472,860	533,553	112.84%
Alaska	648,280	68,065	77,030	113.17%
Arizona	5,579,222	585,780	67,717	11.56%
Arkansas	2,727,774	286,397	382,398	133.52%
California**	25,591,206	2,686,899	2,752,151	102.43%
Colorado	4,547,633	477,470	215	0.05%
Connecticut	3,486,960	366,107	22,829	6.24%
Delaware	818,166	85,902	121,164	141.05%
District of Columbia	557,620	58,546	45,000	76.86%
Florida	16,999,181	1,784,796	66,000	3.70%
Georgia	8,676,460	910,968	474,022	52.03%
Hawaii	1,248,755	131,111	172,487	131.56%
Idaho	1,367,034	143,529	8,567	5.97%
Illinois**	9,779,966	1,026,829	516,018	50.25%
Indiana	6,199,571	650,912	650,912	100.00%
Iowa	2,941,976	308,887	312,631	101.21%
Kansas	2,724,786	286,084	286,084	100.00%
Kentucky	4,118,189	432,381	216,224	50.01%
Louisiana	4,493,665	471,804	471,804	100.00%
Maine	1,309,205	137,457	0	0.00%
Maryland	5,512,310	578,754	210,727	36.41%
Massachusetts	6,420,357	674,093	50,662	7.52%
Michigan	10,082,364	1,058,578	1,076,950	101.74%
Minnesota	5,064,172	531,703	340,640	64.07%
Mississippi	2,882,594	302,652	338,648	111.89%
Missouri	5,719,204	600,477	600,477	100.00%
Montana	918,157	96,400	8,174	8.48%
Nebraska	1,737,475	182,423	71,952	39.44%
Nevada	2,242,207	235,416	135,514	57.56%
New Hampshire	1,288,705	135,305	68,000	50.26%
New Jersey	8,642,412	907,393	880,293	97.01%
New Mexico	1,878,562	197,236	77,409	39.25%
New York (includes NYC)	19,212,425	2,017,172	2,444,836	121.20%
North Carolina	8,421,190	884,167	677,882	76.67%
North Dakota	633,400	66,503	57,000	85.71%
Ohio	11,437,680	1,200,877	1,388,858	115.65%
Oklahoma	3,506,469	368,155	54,015	14.67%
Oregon	3,564,330	374,230	26,523	7.09%
Pennsylvania	12,370,761	1,298,844	1,298,792	100.00%
Rhode Island	1,076,084	112,981	11,900	10.53%
South Carolina	4,148,744	435,589	459,960	105.59%
South Dakota	764,905	80,310	80,310	100.00%
Tennessee	5,845,208	613,706	613,706	100.00%
Texas	22,103,374	2,320,701	1,023,141	44.09%
Utah	2,352,119	246,956	52,033	21.07%
Vermont	619,343	65,027	71,036	109.24%
Virginia	7,365,284	773,304	827,661	107.03%
Washington	6,131,298	643,744	417,902	64.92%
West Virginia	1,811,440	190,189	227,561	119.65%
Wisconsin	5,474,290	574,763	363,729	63.28%
Wyoming	502,111	52,718	52,718	100.00%
State Subtotal:	278,048,349	29,193,150	21,185,815	72.57%
Other Entity				
American Samoa	57,884	6,077	0	0.00%
Chicago	2,869,121	301,238	200,545	66.57%
Fed States of Micronesia	108,143	11,354	0	0.00%
Guam	163,593	17,176	0	0.00%
LA County	9,871,506	1,036,440	1,036,440	100.00%
Marshall Islands	56,429	5,925	0	0.00%
Northern Marianas Islands	76,129	7,993	0	0.00%
Palau	19,717	2,070	0	0.00%
Puerto Rico	3,877,881	407,151	407,151	100.00%
Virgin Islands	108,814	11,425	0	0.00%
Entity Subtotal	17,209,217	1,806,849	1,644,136	90.99%
TOTAL	295,257,566	30,999,999	22,829,951	73.65%

Source: ASPR, information as of September 30, 2008. * Initial allocation is for subsidized treatment courses only; 25% federal subsidy per treatment course. Many states have purchased additional antivirals at unsubsidized prices. ** The population count for California and Illinois does not include residents of Los Angeles County or Chicago, respectively. These two localities, along with the District of Columbia, received their own allocation of federally-subsidized antivirals based on their populations.

APPENDIX C: DATA AND METHODOLOGY FOR STATE INDICATORS

The data for the state indicators come from a variety of publicly available sources.

Methodology for Mass Distribution – Strategic National Stockpile

Source: CDC, Coordinating Office for Terrorism Preparedness and Response, Division of the Strategic National Stockpile.

TFAH used the states' 2007 – 2008 scores on the CDC technical assistance review (TAR) of state SNS plans. According to CDC, states must score 69 or higher out of 100 to satisfactorily document their SNS planning efforts. States were given an opportunity to verify the SNS TAR scores CDC provided to TFAH in coordination with ASTHO.

Methodology for Mass Distribution – Antiviral Stockpiling

Source: ASPR.

ASPR provided TFAH with the pandemic influenza antiviral drugs stockpile purchases for states, localities, and territories as of September 30, 2008.

Methodology for Flu Vaccination Rates

Data for this analysis was obtained from the Behavioral Risk Factor Surveillance System (BRFSS) dataset (publicly available on the web at cdc.gov/brfss).²⁵⁹ BRFSS is an annual cross-sectional survey that measures behavioral risk factors in the adult population (18 years of age or older) living in households. Data are collected from a random sample of adults (one per household) through a telephone survey. The BRFSS currently includes data from 50 states, D.C., Puerto Rico, Guam, and the Virgin Islands. The 2007 statistics are the most recent data available.

To conduct the analyses, TFAH contracted with Daniel Eisenberg, Ph.D., assistant professor, and Edward N. Okeke, MBBS, Health Service Organization and Policy Doctoral Student, at the Department of Health Management and Policy of the University of Michigan School of Public Health. Re-

searchers weighted the data using sample weights provided by CDC in the dataset and then merged data on the FLUSHOT variable from 2004-2007.²⁶⁰ Researchers dropped observations where either the survey participant answered “don't know” or refused to answer. These accounted for less than 0.4 percent of the data. Researchers then calculated three-year rolling averages for each state restricting the sample to only individuals aged 65 and older, and then carried out hypothesis testing to determine if there were statistically significant changes in the percentage of adults 65 and over who reported receiving vaccination for the flu.

Researchers reported three-year averages for 2004-2006 and 2005-2007 as well as standard errors and 95 percent Confidence Intervals. They also reported which states experienced a statistically significant change from 2004-2006 to 2005-2007. Sample sizes were 246,773 and 300,530 respectively.

Methodology for Public Health Laboratories – Lab Pickup and Delivery Services

Source: APHL

APHL surveyed state public health lab directors between September and October 2008. All 50 states and D.C. responded to the survey.

Respondents were asked:

Does your State Public Health Lab currently have an intra-state courier system (non-mail) that operates 24 hours per day for specimen pickup and delivery? For the purposes of this assessment, intra-state courier service refers to a system that is state owned and operated or contracted to a designated carrier.

Yes

No. Please explain what system is in place:

Decline to respond

Methodology for Public Health Laboratories – Pandemic Influenza Planning

Source: APHL

APHL surveyed state public health lab directors between September and October 2008. All 50 states and D.C. responded to the survey.

Respondents were asked:

1) Are you familiar with the expectations for your laboratory’s capabilities described in your state’s pandemic influenza plan?

Yes

No

Decline to respond

2) Can your laboratory meet the expectations of your state’s pandemic influenza plan?

Yes

No

Decline to respond

Methodology for Biosurveillance - NEDSS

Source: CDC, National Center for Public Health Informatics, Division of Integrated Surveillance Systems and Services.

In order to determine FY 2009 grant allocations, CDC’s Division of Integrated Surveillance Systems and Services queried state health departments on their NEDSS status. According to CDC, for a state to be considered NEDSS-compatible, the state health department must have systems that meet three basic requirements:

- 1) An internet browser-based system;
- 2) Electronic laboratory results (ELR) reporting; and
- 3) An integrated data repository.

States were given an opportunity to verify CDC’s NEDSS-compatibility assessment in coordination with ASTHO.

Methodology for Health Care Volunteer Emergency Liability Protection

TFAH contracted with the George Washington University School of Public Health and Health Services. A research team consisting of an experienced lawyer and team members with experience in reading and interpreting statutory text assembled all relevant statutes and then assessed the statutes using methods of plain text analysis. Because of growth in the adoption of UEVHPA and the comprehensiveness of the statute, researchers adopted the following three-tier approach to the review:

1) States adopting the UEVHPA or enacting its full equivalent, as measured by the terms of state statutory law;

2) States whose laws offer some, but not all, of the emergency volunteer protections available under UEVHPA; and

3) States offering only minimal protections in the form of Good Samaritan Statutes.

The “minimal protections” or “low” category represents those states with only Good Samaritan or similar laws under which volunteers may be provided with an affirmative defense, but not necessarily immunity from liability. The “some protections” or “medium” group of states extend protections to volunteers during times of emergency, but may not explicitly identify health practitioners, may require affiliation with a regional or local emergency compact, or may not provide coverage to volunteers in the event of injury during rendering of services. Finally, the “UEVHPA” or “high” protection states have adopted the model statute or all of its elements.

Methodology for Entity Emergency Liability Protection

TFAH contracted with the George Washington University School of Public Health and Health Services. A research team consisting of an experienced lawyer and team members with experience in reading and interpreting statutory text assembled all relevant statutes and then assessed the statutes using methods of plain text analysis. Researchers examined state law to identify states that have enacted “volunteer entity” protections to incentivize emergency response by public and private actors.

In assessing state law relevant to entity protections, researchers drew from model language developed by the Public/Private Legal Preparedness Initiative, a special undertaking of the North Carolina Institute for Public Health.²⁶¹ Key elements of this model law are as follows:

- 1) The establishment of a specific coverage trigger (e.g., a Gubernatorial declaration of a state of emergency);
- 2) Retroactive coverage that reaches pre-planning and training activities; and
- 3) An approach to protection that follows the immunity model used for volunteers rather than the more limited, “affirmative defense” approach.

State statutes that extended to entities what might be thought of as “property” immunity – that is, immunity with respect to injuries involving real or other property owned or controlled by an entity – were not included. Rather, in order to qualify for designation, a state statute must have focused on protecting conduct undertaken by entities during an emergency.

Methodology for Community Resiliency – Medical Reserve Corps

Source: OCVMRC

The OCVMRC provided TFAH with the raw data on 791 MRC units nationwide as of October 28, 2008. Variables included: state; region; date established; volunteer count total; sponsoring organization type; jurisdiction type; unit focus; Is your MRC unit compliant with NIMS requirements? (Y/N); If no, is your MRC unit working towards NIMS com-

pliance? (Y/N); Are your MRC members included in the State volunteer registry (ESAR-VHP)? (Y/N); If no, do you plan to include your members in the State volunteer registry (ESAR-VHP)? (Y/N); Is there a State MRC Coordinator? (Y/N).

In consultation with OCVMRC, TFAH limited the analysis of MRC units to those 716 units that were more than six months old.

Methodology for Food Safety – Detection and Diagnosis

Source: CDC. Summary Statistics for Foodborne Outbreaks, 2004, 2005, and 2006. Atlanta, GA: U.S. Department of Health and Human Services, 2005, 2006, and 2007. Available online at http://www.cdc.gov/foodborne-outbreaks/outbreak_data.htm

Data for this indicator were obtained from CDC’s Foodborne Disease Outbreak Surveillance System (publicly available at http://www.cdc.gov/foodborne-outbreaks/outbreak_data.htm.) State health department are responsible for reporting foodborne disease outbreaks to CDC through the Electronic Foodborne Disease Outbreak Reporting System (eFORS).

TFAH analyzed data from 2004 through 2006 (the most recent year for which data were available at the time of publication). For each year, TFAH calculated the total number of reported outbreaks per state and the total number of reported outbreaks with confirmed etiology (bacterial, chemical, parasitic, viral, or multiple) per state. TFAH also calculated the national total number of reported outbreaks and national proportion of confirmed outbreaks. TFAH combined the 2004 to 2006 data and calculated the three year average for each state and the nation. States that met or exceeded the national average of confirmed outbreaks (44 percent) achieved a point on this indicator; states that fell below the national average of confirmed outbreaks earned zero points.

All data for 2004 - 2006 were collected electronically through eFORS without confirmation of etiology by CDC staff; all etiologies are as reported by the state.

Methodology for Funding Commitment – State Public Health Budgets

TFAH conducted an analysis of state spending on public health for the last budget cycle, fiscal year 2007-2008. For those states that only report their budgets in biennium cycles, the 2007-2009 period (or the 2008-2010 and 2009-2010 for Virginia and Wyoming respectively) was used, and the percent change was calculated from the last biennium, 2005-2007 (or 2006-2008 and 2007-2008 for Virginia and Wyoming respectively).

This analysis was conducted from August to October of 2008 using publicly available budget documents through state government web sites. Based on what was made publicly available, budget documents used included either executive budget document that listed actual expenditures, estimated expenditures, or final appropriations; appropriations bills enacted by the state's legislature; or documents from legislative analysis offices.

“Public health” is defined to broadly include all health spending with the exception of Medicaid, CHIP, or comparable health coverage programs for low-income residents. Federal funds, mental health funds, addiction or substance abuse-related funds, WIC funds, services related to developmental disabilities or severely disabled persons, and state-sponsored pharmaceutical programs also were not

included in order to make the state-by-state comparison more accurate since many states receive federal money for these particular programs. In a few cases, state budget documents did not allow these programs, or other similar human services, to be disaggregated; these exceptions are noted. For most states, all state funding, regardless of general revenue or other state funds (e.g. dedicated revenue, fee revenue, etc.), was used. In some cases, only general revenue funds were used in order to separate out federal funds; these exceptions are also noted.

Because each state allocates and reports its budget in a unique way, comparisons across states are difficult. This methodology may include programs that, in some cases, the state may consider a public health function, but the methodology used was selected to maximize the ability to be consistent across states. As a result, there may be programs or items states may wish to be considered “public health” that may not be included in order to maintain the comparative value of the data.

Finally, to improve the comparability of the budget data between FY 2006-2007 and FY 2007-2008 (or between biennium), TFAH adjusted the FY 2007-2008 numbers for inflation (using a 0.95 conversion factor based on the U.S. Dept. of Labor Bureau of Labor Statistics; Consumer Price Index Inflation Calculator at <http://www.bls.gov/cpi/>).

APPENDIX D: FEDERAL PREPAREDNESS ADVISORY GROUPS, PANELS AND COMMITTEES

TITLE	MISSION
The Department of Homeland Security Homeland Security Advisory Council	The Department of Homeland Security Homeland Security Advisory Council provides advice and recommendations to the secretary of DHS on a variety of homeland security issues, including public health and health care. ²⁶² The Committee is the secretary's primary advisory body and its 21 members are experts from state and local governments, terrorism prevention and response communities, academia and the private sector, including health care.
The Department of Homeland Security National Advisory Council (NAC)	The Department of Homeland Security National Advisory Council (NAC) was born post-Katrina and has 30 members across the country. The NAC's work has focused on the National Response Framework (NRF), National Incident Management System (NIMS), and special needs populations. The NAC reports to the administrator of FEMA, which has started to place a heavy emphasis on regional coordination. NAC members are appointed by the FEMA administrator and are drawn from a wide cross-section of society, both in terms of geographic location and professional experience. The initial NAC charter expires in February 2009 and must be renewed in accordance with the law. ²⁶³
The Healthcare Sector Coordinating Council (HSCC)	The Healthcare Sector Coordinating Council (HSCC) was self-established by the health care sector, as a part of the DHS-led Critical Infrastructure Protection Program as part of HSPD-7, Critical Infrastructure Identification, Prioritization, and Protection. Per HSPD-7 and the National Infrastructure Protection Plan, HHS serves as the Sector Specific Agency for the health care and public health sector. HSPD-7 also encouraged the creation of an independent self-governed sector coordinating council for 17 critical sectors of the U.S. economy, including health care. The HSCC is to coordinate with a wide variety of health care components including direct health care delivery systems (hospitals, clinicians/personnel, etc), insurers/payors, health information technology, laboratories and blood services, mass fatality/mortuary services, medical materials management (manufacturers/distributors/suppliers), occupational health, and the pharmaceutical/biotech industry and share this sector's concerns with HHS. The HSCC includes over 100 representatives of the companies, organizations, trade associations, and professional societies that either own and operate or play a critical role in ensuring the continuity of the nation's healthcare system. HSCC has responsibility for activities such as communicating potential risks, threats, and vulnerabilities to private health care organizations. ²⁶⁴ The HSCC and the HPH GCC work closely together to better protect the nation's critical infrastructure and key resources.
The Healthcare and Public Health Sector Government Coordinating Council (HPH GCC)	As a partner to the HSCC, the HPH GCC is led by HHS and consists of representatives from a wide-variety of federal agencies, national associations representing state, local, tribal, and territorial public health entities, and members from various state and local jurisdictions. The HPH GCC was also established in response to HSPD-7 and the National Infrastructure Protection Plan. The HPH GCC is tasked with the same mission as the HSCC but to represent the federal, state, local, tribal, and territorial public health and health care entities. The HSCC and the HPH GCC work closely together to better protect the nation's critical infrastructure and key resources.
The Homeland Security Science and Technology Advisory Committee (HSSTAC)	The Homeland Security Science and Technology Advisory Committee (HSSTAC) serves as a source of independent, scientific and technical planning advice for the Under Secretary for Science and Technology. The Committee's primary focus is the use of science and technology to prevent or mitigate the effects of catastrophic emergencies -- both terrorist attacks and natural disasters. ²⁶⁵

TITLE	MISSION
<p>The Interagency Coordinating Council on Emergency Preparedness and Individuals with Disabilities</p>	<p>The Interagency Coordinating Council on Emergency Preparedness and Individuals with Disabilities was established in 2004 to ensure that the federal government appropriately supports safety and security for individuals with disabilities in disaster situations.²⁶⁶ Housed within DHS, the Council has three priorities. First, the Council is to consider the unique needs of federal agency employees with disabilities and individuals with disabilities whom the agency serves. Second, the Council is to encourage state, local, and tribal governments to consider the unique needs of employees and individuals with disabilities in emergency preparedness planning. Finally, the Council is to facilitate cooperation among federal, state, local, and tribal governments and private organizations and individuals in the implementation of emergency preparedness plans as they relate to individuals with disabilities. Council members include the heads of executive departments, the Administrator of the Environmental Protection Agency, the Administrator of General Services, the Director of the Office of Personnel Management, and the Commissioner of Social Security.</p>
<p>The IOM Forum on Medical and Public Health Preparedness for Catastrophic Events</p>	<p>The IOM Forum on Medical and Public Health Preparedness for Catastrophic Events serves to bring together leaders from government, academic, and private sectors to openly discuss issues of concern. The Forum members identify topics of interest for meetings and workshops. Initially, the Forum has focused on: medical surge capacity, disaster preparedness training, communication and distribution, psychological and community resilience, and research and evaluation. The Forum is sponsored by federal agencies, state and local associations, health professional associations, and private sector business associations. There are 32 members and a staff of four.</p>
<p>The National Advisory Committee on At-Risk Individuals and Public Health Emergencies</p>	<p>The National Advisory Committee on At-Risk Individuals and Public Health Emergencies, formerly the National Advisory Committee on Children and Terrorism, was created under the 2006 PAHPA legislation to focus on public health emergencies as they relate to at-risk individuals. According to the Office for At Risk Individuals, Behavioral Health, and Human Services Coordination at ASPR, the charge for the Advisory Committee on At-Risk Individuals and Public Health Emergencies has significantly evolved since its previous iteration and steps must be taken to determine how best to reconstitute the group and reestablish it. In the meantime, HHS is currently working on related at-risk issues through existing relevant advisory committees, such as the National Biodefense Science Board (NBSB) and the Commission on Children and Disasters.²⁶⁷</p>
<p>The National Biodefense Science Board (NBSB)</p>	<p>The National Biodefense Science Board (NBSB) was created under PAHPA and has a five-year mandate (2007 -- 2012).²⁶⁸ The NBSB was established to provide expert advice and guidance to the secretary of the HHS (HHS) on scientific, technical, and other matters of special interest to HHS regarding activities to prevent, prepare for, and respond to adverse health effects of public health emergencies resulting from chemical, biological, nuclear, and radiological events, whether naturally occurring, accidental, or deliberate. On March 4, 2008, the charter of the NBSB was amended to allow the NBSB to provide advice and guidance to the secretary on other matters related to public health emergency preparedness and response.²⁶⁹ There are 13 voting members of the NBSB in addition to non-voting, ex officio members. There are five working groups under NBSB that focus on: pandemic influenza, disaster medicine, medical countermeasures R&D, medical countermeasures sustainability and market development, and personal preparedness; and one subcommittee on disaster mental health. NBSB planned to issue a series of recommendations from each working group in the summer and fall of 2008</p>

TITLE	MISSION
<p>The National Biosurveillance Advisory Subcommittee (NBAS)</p>	<p>The National Biosurveillance Advisory Subcommittee (NBAS) was created as part of HSPD-21, which mandated that the secretary of HHS, in collaboration with other federal agencies, create an “Epidemiologic Surveillance Federal Advisory Committee” that includes representatives from state and local government public health authorities and appropriate private sector health care entities. The Committee’s role is “to ensure that the federal government is meeting the goal of enabling state and local government public health surveillance capabilities.”²⁷⁰ The National Biosurveillance Advisory Subcommittee is a subcommittee of the Advisory Committee to the Director of CDC.²⁷¹</p>
<p>The National Commission on Children and Disasters</p>	<p>The National Commission on Children and Disasters was established in December 2007. The commission chair and nine members are appointed by the president and bipartisan members of Congress. The panel of experts will recommend changes that federal, state, and local governments need to make to meet the needs of children in emergencies, including planning, response and recovery efforts. The Commission held its first meeting October 14, 2008, more than 10 months after its creation, and well into the 2008 hurricane season, which saw devastating storms Gustav and Ike tear across the Gulf states.²⁷²</p>
<p>The National Science Advisory Board for Biosecurity</p>	<p>The National Science Advisory Board for Biosecurity was developed by HHS to help confront the so-called “dual-use dilemma” -- that the research in biology, chemistry, and radiology can be used inappropriately for the purposes of bioterrorism or biowarfare. NASBB offers advice and recommendations on how to further biotechnological research while minimizing the risk of harm. NASBB is housed in the Office of Biotechnology Activities (OBA) within the Office of the Director, NIH.²⁷³</p>

APPENDIX E: KEY DELIVERABLES AND DUE DATES UNDER PAHPA

KEY DELIVERABLES AND DUE DATES UNDER P.L. 109-417			
Deliverable	Why the Deliverable is Important	Due Date	Met?
<p>Section 201 (g) (1) -- Achievement of measurable evidence-based benchmarks and objective standards. Not later than 180 days after the date of enactment of the Pandemic and All-Hazards Preparedness Act, the HHS secretary shall develop or where appropriate adopt, and require the application of, measurable evidence-based benchmarks and objective standards that measure levels of preparedness. In developing such benchmarks and standards, the secretary shall consult with and seek comments from state, local and tribal officials and private entities, as appropriate. Where appropriate, the HHS secretary shall incorporate existing objective standards.</p>	<p>This demonstrates the federal government's ability to develop clear, evidence-based performance metrics to evaluate federal and state emergency preparedness.</p>	<p>June 2007</p>	<p>Yes. HHS is using new capability-based performance measures for the PHEP grantees.²⁷⁴ As CDC and the research community build a stronger research base on preparedness, CDC expects to roll out new objectives.</p>
<p>Section 201 (g) (2) -- Criteria for pandemic influenza plans. Not later than 180 days after the date of enactment of the Pandemic and All-Hazards Preparedness Act, the HHS secretary shall develop and disseminate to the chief executive officer of each state criteria for an effective state plan for responding to pandemic influenza.</p>	<p>This demonstrates the federal government's ability to provide clear direction and guidance to state emergency planners and keep variation among states pandemic plans to a minimum.</p>	<p>June 2007</p>	<p>Yes. HHS sent a letter with criteria and guidance to states on January 26, 2007.²⁷⁵</p> <p>Revised guidance was sent out in March 2008 and revised plans were submitted in June 2008. ASPR expects to release the results of the review in December 2008, although delays in the review and the presidential transition may postpone the release.²⁷⁶</p>
<p>Section 202 (d) (2) -- Public Health Situational Awareness. Not later than 180 days after the date of enactment the Pandemic and All- Hazards Preparedness Act, the HHS Secretary shall submit to the appropriate committees of the Congress a strategic plan demonstrating the steps the HHS secretary will undertake to develop, implement, and evaluate the interoperable network of systems for real-time disease detection and surveillance.</p>	<p>This reflects federal commitment to a near real-time electronic surveillance system, which is necessary to quickly identify and track disease outbreaks and biological and chemical incidents (accidental or intentional).</p>	<p>June 2007</p>	<p>Yes. On October 31, 2008 CDC's Biosurveillance Coordination Unit (BCU) released the latest draft version of the <i>National Biosurveillance Strategy for Human Health</i>.</p>

KEY DELIVERABLES AND DUE DATES UNDER PL. 109-417

Deliverable	Why the Deliverable is Important	Due Date	Met?
Section 301(a) (C) (2) -- Joint review and medical surge capacity strategic plan. Not later than 180 days after date of enactment of the Pandemic and All-Hazards Preparedness Act, the HHS secretary, in coordination with the secretary of Homeland Security, secretary of Defense, and secretary of Veterans Affairs, shall conduct a joint review of the National Disaster Medical System. Such review shall include an evaluation of medical surge capacity.	This demonstrates the ability of HHS to lead and coordinate with other key federal agencies on issues of concern for public health preparedness, such as medical surge capacity.	June 2007	Yes. The Department has completed a joint review with the Departments of homeland security, defense, and veterans affairs of the National Disaster Medical System (NDMS), although the final report has not yet been released.
Section 201(j) (1) -- Annual reporting requirements. Each entity shall prepare and submit to the HHS secretary annual reports on its activities under this section and section 319C-2 of the Public Health Service Act. Each such report shall be prepared by, or in consultation with, the health department. In order to properly evaluate and compare the performance of different entities assisted under this section and section 319C-2 and to assure the proper expenditure of funds under this section and section 319C-2, such reports shall be in such standardized form and contain such information as the HHS secretary determines and describes within 180 days of the date of enactment of the Pandemic and All-Hazards Preparedness Act.	This demonstrates the federal government's commitment to tracking the use of federal preparedness dollars.	June 2007	Yes. ASPR receives annual health-department prepared, standardized progress reports on HPP grantee program activities. ASPR uses these reports to properly evaluate HPP grant-related performance and assure the expenditure of funds requirements are met for HPP. ²⁷⁷
Section 303(a) -- Not later than 180 days after the date of enactment of the Pandemic and All-Hazards Preparedness Act, the HHS secretary, in collaboration with state, local, and tribal officials, shall build on state, local, and tribal programs in existence on the date of enactment of such Act to establish and maintain a Medical Reserve Corps to provide for an adequate supply of volunteers in the case of a Federal, State, local, or tribal public health emergency. The corps shall be headed by a director who shall be appointed by the HHS secretary and shall oversee the activities of the corps chapters that exist at the state, local, and tribal levels.	This reflects the federal government's ability to set forth a nationally recognized certification process for health care volunteers who serve in emergency public health events and recruit said volunteers.	June 2007	Yes. The department expanded the Medical Reserve Corps (MRC) to provide for an adequate supply of volunteers in the case of a federal, state, tribal, territorial, or local public health emergency.

KEY DELIVERABLES AND DUE DATES UNDER PL. 109-417

Deliverable	Why the Deliverable is Important	Due Date	Met?
Section 401 -- Not later than six months after the date of enactment of the Pandemic and All-Hazards Preparedness Act, the HHS secretary shall develop and make public a strategic plan to integrate biodefense and emerging infectious disease requirements with the advanced research and development , strategic initiatives for innovation, and the procurement of qualified countermeasures and qualified pandemic or epidemic products.	This illustrates the federal government's ability to set a national strategy for research and development, innovation support, and procurement of countermeasures to chemical, biological, radiological, and nuclear (CBRN) agents and emerging infectious diseases.	June 2007	Yes. On July 7, 2007, Secretary Michael Leavitt published a <i>Draft BARDA Strategic Plan for Countermeasure Research, Development and Procurement</i> , to guide and facilitate the research, development, innovation, and procurement of medical countermeasures and build upon established national strategies and directives.
Section 303(b) -- Not later than 12 months after the date of enactment of the Pandemic and All-Hazards Preparedness Act, the HHS secretary shall link existing state verification systems to maintain a single national interoperable network of systems , each system being maintained by a state or group of states, for the purpose of verifying the credentials and licenses of health care professionals who volunteer to provide health services during a public health emergency.	This reflects the federal government's ability to set forth a nationally recognized certification process for health care volunteers who serve in emergency public health events.	December 2007	Yes. The department has written compliance requirements for state participation in the ESAR-VHP program. As of October 1, 2008 (FY 2009) participation in ESAR-VHP will be a mandatory requirement to receive future grant dollars from the PHEP.
Section 402 -- The HHS secretary shall establish the National Biodefense Science Board to provide expert advice and guidance to the HHS secretary on scientific, technical and other matters of special interest to the Department of Health and Human Services regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate.	This illustrates the federal government's ability to convene leading experts from government, private sector and research institutions to come together to guide the national strategy for research and development, innovation support, and procurement of countermeasures to chemical, biological, radiological, and nuclear (CBRN) agents and emerging infectious diseases.	December 2007	Yes. On May 24, 2007, Secretary Leavitt established and issued a call for nominations to the National Biodefense Science Board (NBSB). On December 17, 2007 Secretary Leavitt announced the 13 members of the NBSB. ²⁷⁸
Section 402(A) -- Not later than one year after the date of enactment of the Pandemic and All-Hazards Preparedness Act, the HHS secretary shall hold the first meeting of the National Biodefense Science Board.	This illustrates the federal government's ability to convene leading experts in government, private sector and research institutions to come together to guide the national strategy for research and development, innovation support, and procurement of countermeasures to chemical, biological, radiological, and nuclear (CBRN) agents and emerging infectious diseases.	December 2007	Yes. Secretary Leavitt held the inaugural meeting of the NBSB December 17 -18, 2007. ²⁷⁹

KEY DELIVERABLES AND DUE DATES UNDER PL. 109-417

Deliverable	Why the Deliverable is Important	Due Date	Met?
<p>Section 102(d) -- Amends the Public Health Service Act by inserting Section 2814(1). The HHS secretary shall oversee the implementation of the national preparedness goal of taking into account the public health and medical needs of at-risk individuals in the event of a public health emergency. Not later than one year after the date of enactment of the Pandemic and All-Hazards Preparedness Act, the HHS secretary shall prepare and submit to the U.S. Congress a report describing the progress made on implementing the duties described in this section.</p>	<p>This benchmark reflects how well the federal government is implementing plans to reach at-risk populations, including the elderly and other special needs individuals.</p>	<p>December 2007</p>	<p>Yes. The Pandemic and All-Hazards Preparedness Act Progress Report released in November 2007 describes the progress made toward implementing duties related to at-risk individuals.</p>
<p>Section 201(g) (5) -- Withholding of amounts from entities that fail to achieve benchmarks or submit influenza plans.</p>	<p>This component of the bill links funding with accountability, which motivates states to meet preparedness benchmarks.</p>	<p>October 2008 (FY 2009)</p>	<p>Yes. CDC established 10 benchmarks that state and local grantees are required to meet in order to receive their full PHEP base funding. States that fail to meet these benchmarks can lose up to 10 percent of their FY 2009 base PHEP funding.²⁸⁰ This funding will be distributed in August 2009.</p> <p>ASPR established five state-level and seven hospital-level performance measures that HPP grantees must achieve. Those that fail to substantially meet the benchmarks will have funds withheld from FY 2009 awards.^{281,282} This funding will be distributed in August 2009.</p>

KEY DELIVERABLES AND DUE DATES UNDER P.L. 109-417

Deliverable	Why the Deliverable is Important	Due Date	Met?
<p>Section 202 (d) (1) -- Public Health Situational Awareness. Not later than two years after the date of enactment of the Pandemic and All-Hazards Preparedness Act, the HHS secretary, in collaboration with state, local, and tribal public health officials, shall establish a near real-time electronic nationwide public situational awareness capability through an interoperable network to share data and information to enhance early detection of rapid response to, and management of, potentially catastrophic infectious disease outbreaks and other public health emergencies that originate domestically or abroad. Such network shall be built on existing state situational awareness systems or enhanced systems that enable such connectivity.</p>	<p>This reflects federal commitment to a near real-time electronic surveillance system, which is necessary to quickly identify and track disease outbreaks and biological and chemical incidents (accidental or intentional).</p>	<p>January 2009</p>	<p>In progress. In early 2008, CDC established the Biosurveillance Coordination Unit (BCU) to lead the development of a strategy and implementation plan for integrated human biosurveillance. However, a DHS entity, the NBIC, will integrate all biosurveillance, including data from CDC, USDA, FDA, DOD, EPA, VA, and ODNI.</p>
<p>Section 103 -- Amends the Public Health Service Act and adds Section 2802(a) (1). Preparedness and response regarding public health emergencies. Beginning in 2009 and every four years thereafter, the HHS secretary shall prepare and submit to the relevant committees of the congress a coordinated strategy (to be known as the National Health Security Strategy) and any revisions thereof, and an accompanying implementation plan for public health emergency preparedness and response.</p>	<p>This quadrennial review of public health emergency preparedness illustrates the importance of the issues and the need to keep continually updating and revising preparedness plans.</p>	<p>2009</p>	<p>In progress. HHS has completed the preliminary work of defining key terms and creating a framework to guide development of the National Health Security Strategy. HHS is now being supported by the RAND Corporation to carry out a broad community engagement plan and finalize the strategy and accompanying implementation plan and evaluation framework. HHS anticipates meeting the 2009 legislative deadline in delivering the strategy to Congress.²⁸³</p>

Source: Office of the Assistant Secretary for Preparedness and Response. Pandemic and All-Hazards Preparedness Act Progress Report. Washington, DC: U.S. Department of Health and Human Services, November 2007. <http://www.hhs.gov/aspr/conference/pahpa/2007/pahpa-progress-report-102907.pdf> (accessed October 31, 2007), except where noted.

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