



# 2010 Sector CIKR Protection Annual Report for the Healthcare and Public Health Sector

June 2010



Homeland  
Security

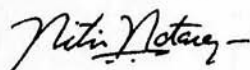


Department of  
Health and Human  
Services

2010 Sector CIKR Protection Annual Report for the  
Healthcare and Public Health Sector

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Released by:



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## Executive Summary

In the past year the Healthcare and Public Health (HPH)<sup>1</sup> Sector has been impacted by major events including the 2009 H1N1 influenza outbreak, the tsunami in American Samoa, and the earthquake in Haiti. The sector has responded to protect HPH infrastructure and the public's health while continuing to plan for future threats. The 2010 HPH Sector Annual Report summarizes the numerous activities that have taken place between May 1, 2009, and April 30, 2010, to improve the preparedness of the HPH Sector. This report was written through a collaborative process between the HPH Sector Coordinating Council (SCC) and Government Coordinating Council (GCC), with the U.S. Department of Health and Human Services (HHS), which coordinated the process as the Sector-Specific Agency (SSA).

### ES.1 Sector Risks, Goals, Objectives, Risk Mitigation Activities, and Research Priorities

Following the National Infrastructure Protection Plan (NIPP) Risk Management Framework, this report is structured around the primary risks to the sector. These risks are categorized as threats to continuity of services, workforce, physical assets, and cyber systems. The report articulates four goals and twelve objectives related to these risk categories. Elements of the sector have engaged in risk mitigation activities (RMA) to advance these goals and objectives. This report prioritizes ten of these as key RMAs and links them to specific sector goals. The goals are also supported by research and development (R&D) activities undertaken and priorities identified by the sector's R&D/Modeling, Simulation, and Analysis (MS&A) Joint Advisory Work Group (JAWG).

#### ES.1.1 Continuity of Services

The HPH Sector is highly reliant on its workforce and on its increasingly interdependent supply chain in order to deliver services. During emergencies, the sector must not only sustain but also increase its capacity. All other critical infrastructure sectors rely on the HPH Sector to protect the overall workforce by continuing to provide healthcare and public health services during emergencies. The sector's goal for service continuity is to maintain the ability to provide essential health services during and after disasters and/or disruptions in the availability of supplies or supporting services (e.g., water, power). It advances this goal through objectives related to Health Care Continuity, Supply Chain Continuity, Supporting Services Continuity, and Workforce Family Member Protection. Among the sector's key RMAs addressing these objectives are the HHS Hospital Preparedness Program; The Joint Commission's (TJC) Accreditation Programs; RxResponse; preparedness and response activities of the Centers for Disease Control and Prevention (CDC) Public Health Emergency Preparedness (PHEP) Cooperative Agreement; and Project Public Health Ready (PPHR). JAWG activities in this area include hosting an all-day meeting of thought leaders within the sector to discuss approaches for building operational sustainability into the overall physical structure of facilities.

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<sup>1</sup> Attachment A provides a list of acronyms used in this report.

## ES.1.2 Workforce

The sector is highly reliant on its workforce for response, and that workforce faces a high likelihood of being exposed to disease agents during an emergency. The sector's goal for workforce protection is to protect members of the sector's workforce from the harmful consequences of all hazards that may compromise their health and safety and limit their ability to carry out their responsibilities. It advances this goal through its Mass Prophylaxis and Health Surveillance objectives. Among the sector's key RMAs addressing these objectives are the CDC PHEP Cooperative Agreement (Disease Detection, Investigation Activities, and Mass Prophylaxis objectives) and the Cities Readiness Initiative (CRI).

## ES.1.3 Physical Assets

Internationally, the sector has faced threats to physical assets in recent years. Sector facilities are often vulnerable to physical attack because they are "open access" facilities, and some contain Select Agents<sup>2</sup> that make them potential targets for theft. The sector's goal for physical asset protection is to mitigate the risks posed by all hazards to the sector's physical assets. It advances this goal through its Biosafety Level (BSL)-3 and BSL-4 Facility Protection, Countermeasure Facility Security, HPH Protection, and Research Facility Protection objectives. Among the sector's key RMAs addressing these objectives are the CDC Select Agent Program, the HHS Biomedical Advanced Research and Development Authority (BARDA) Program Office, and hospital protection activities. JAWG activities in this area include the development of a tool to assist healthcare facility owners and operators in identifying consequence-mitigation strategies that can be integrated into the design of their facilities based on the facilities' unique circumstances.

## ES.1.4 Cyber Systems

The rapid expansion of health information technology (IT) and the high reliance on these systems for sensitive health and claims data make the sector increasingly vulnerable to the consequences of cyber incidents. The sector's goal for cybersecurity is to mitigate the risks to its cyber assets that may result in disruption to or denial of health services. It advances this goal through its Cyber Network, System, and Data Protection objective. To address this objective, the sector formed a Cyber Security Work Group (CSWG) and began development of a cybersecurity strategy that speaks to unique aspects of the sector. JAWG activities in this area include the submission of capability gap statements (CGSs) pertaining to cyber disruptions, interdependencies, and cascading consequences within the sector.

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<sup>2</sup> Select Agents are defined by CDC as biological agents and toxins that pose a severe threat to public health and safety.



## ES.2 Past Year's Priorities and Accomplishments

The sector established three cross-cutting priorities for the past year: information sharing, response coordination, and expansion of partner awareness of and participation in critical infrastructure protection (CIP) activities. A key to advancing all three priorities was to increase membership and participation in the sector's portal on the Homeland Security Information Network (HSIN). Through outreach to various HPH-related associations, the SSA was successful in expanding the sector's user base on its HSIN portal from less than 300 users to more than 1,000 users.

The sector had several significant accomplishments in information sharing. The SSA developed and implemented a robust alerts-and-warnings process and supporting infrastructure to ensure that all sector partners can receive timely and urgent information should an incident occur. The SSA also began providing regular classified briefings to sector stakeholders having the appropriate security clearances to share knowledge of feasible threats facing the sector.

To improve its response coordination, the SSA established its Private Sector Liaison Officer (LNO) Program. Participants in this program represent the private sector within the HHS Emergency Management Group during events and assist in disseminating disaster response information to other sector partners.

Through presentations at various conferences, the SSA raises awareness of the CIP program within the HPH Sector. Over the course of the prior year, the SSA gave presentations at several conferences, including the conference of the Association for Healthcare Resource and Materials Management (AHRMM), the International Association for Healthcare Security and Safety (IAHSS) Annual General Meeting, the State Public Health Preparedness Director's Annual Meeting, and the Public Health Preparedness Summit.

Over the past year, the HPH Sector has made progress against the metrics outlined for key RMAs. For example, the medical supply chain program, RxResponse, increased the number of participating jurisdictions from 21 States in 2008 to all 50 States by the end of 2009. Also, over the past year, the number of metropolitan statistical areas (MSAs) that meet CRI criteria for distributing medical countermeasures increased by 20 percent.

## ES.3 Sector Challenges and Path Forward for Coming Year

The past year has seen many changes for the HPH Sector. Although most of these changes have been positive, adapting to some of them may create challenges for the coming year. The large and expanding user community of the sector's HSIN portal will expect accurate and relevant information to be disseminated in a timely manner. The SSA and its private sector partners must invest resources in conducting analysis and developing information products that are useful to HSIN portal users and that maintain their interest in the CIP program.

The prioritization of assets has always been a challenge to the sector because of its diversity and dispersion across a wide geographic area. Through its pilot projects related to critical foreign



dependencies and theft/diversion of radiologic materials, and its evaluation and selection of a new risk assessment methodology for sector assets, the sector will improve its ability to identify and prioritize critical assets.

The expansion of HPH preparedness activities across all levels of government and the private sector over the past decade has yielded significant progress. A challenge of the coming year will be identifying the best way to sustain this progress in the face of mounting pressure on private sector profit margins and government budgets. Sector leadership must continue to communicate the value proposition of CIP activities to sector members.

## Section 1: Introduction

The Healthcare and Public Health (HPH) Sector is pleased to provide the U.S. Department of Homeland Security (DHS) with the 2010 HPH Sector Annual Report. The sector has continued to make progress over the current reporting period of May 1, 2009, through April 30, 2010, both within the sector and across sectors as a result of its partnerships. This report reflects the state of the HPH Sector, highlighting the recent activities and accomplishments that support the sector's vision, mission, and goals. In addition, the report details sector priorities and identifies activities that the sector anticipates initiating or accomplishing in the coming year.

### Highlights of the 2010 HPH SAR

- *Expanded the Homeland Security Information Network (HSIN)-HPH user base to 1,000+ users*
- *Implemented the Private Sector Liaison Officer (LNO) Program*
- *Established a Cyber Security Work Group (CSWG) and began developing a sector-wide cybersecurity strategy*

### 1.1 Sector Overview

The HPH Sector provides a diverse array of goods and services that are distributed widely across the country. It includes not only acute care hospitals and ambulatory healthcare, but also the vast and complex public-private systems that finance that care. It includes population-based care provided by health agencies at the local, State, and Federal levels, as well as other public health and disease surveillance functions. It incorporates a large system of private sector enterprises that manufacture, distribute, and sell drugs, biologics, and medical devices, as well as a network of small businesses that provide mortuary services. All these goods and services are provided within and by means of a complex environment of research, regulation, finance, and public policy.

For the HPH Sector, critical infrastructure protection (CIP) is ultimately defined by the extent to which the sector has been able to mitigate interruptions in public health services and healthcare services to the individual. The sector faced continuous CIP challenges, including the breadth and diversity of the sector and the overlap between the sector's CIP role and its emergency response role. The scope of the sector's reach described in the 2010 Sector-Specific Plan (SSP) included approximately 13 million healthcare personnel<sup>3</sup> from many professions. Included are approximately 5 million first-responders with at least some emergency medical training, 3 million registered nurses, and more than 800,000 physicians.

Preventing HPH service interruptions requires coordination with a wide range of public and private sector partners with unique areas of expertise, influence, and authority. For example, while most services in the area of clinical care are provided by the private sector, the public sector also provides many clinical services and finances many of the services provided by the private sector. In the area of public health, most programs are financed and operated by Federal, State, local, territorial, and tribal health agencies, but such functions as disease surveillance are

<sup>3</sup> See U.S. Department of Health and Human Services (HHS), National Center for Health Workforce Analysis Reports, Health Resources and Services Administration, available at <http://bhpr.hrsa.gov/healthworkforce/reports> (accessed June 28, 2010).

performed in conjunction with private sector healthcare providers. Medical products, including drugs, biologics, and medical devices, are produced almost entirely by the private sector, but are regulated by government agencies. In addition, medical products produced by the private sector are a shared resource across both the public and private sectors. Thus, the sector must focus infrastructure protection efforts on service continuity across the full range of HPH services within the private sector and multiple levels of government.

Another characteristic that the HPH Sector shares with a few other sectors is that its efforts to protect critical infrastructure often overlap with its emergency response functions. The most important component of HPH critical infrastructure is its workforce. From healthcare professionals to public health workers, people are the most important element for delivering HPH services. The HPH workforce faces a high likelihood of being exposed to disease threats during health emergencies and must be protected. The tools that the sector uses to protect its own workers during a public health emergency – including disease surveillance, isolation and quarantine, drug and vaccine delivery, and risk communication – are the same tools that are used to protect the population at large.

## 1.2 Report Development Process

This report was developed through the collaboration of the Sector Coordinating Council (SCC) and the Government Coordinating Council (GCC) of the HPH Sector. The U.S. Department of Health and Human Services (HHS), serving as the Sector-Specific Agency (SSA) for the HPH Sector, coordinated this effort. HHS assembled a work group comprised of SCC and GCC members to guide the development of this report and produced draft sections based on comments and discussion provided by the work group. Using the 2009 Sector Annual Report as a starting point, the SSA determined what activities were still applicable, updated sections to account for progress throughout the reporting period, and added new activities in which the sector became involved.

Over a period of six weeks, work group members reviewed drafts of each Sector Annual Report section and provided their comments, edits, and guidance through weekly conference calls. Work group members had the opportunity to review each section on two occasions – first the initial draft and then a revised draft that incorporated their comments – prior to reviewing the draft Sector Annual Report in its entirety. The SSA believed that this approach would ensure that all work group members had ample opportunity to provide their input, resulting in a report that justly represents the sector's accomplishments.

## 1.3 Sector Developments over the 2010 Reporting Cycle

During the 2010 reporting cycle, the HPH Sector achieved many milestones and continued defining a path forward to improve risk and vulnerability analyses with regard to the medical supply chain and cyber threats. The year was marked by the 2009 H1N1 influenza pandemic, which demonstrated the sector's ability to provide a national public health response while highlighting the importance of the sector's workforce and supply chain as critical infrastructure.

The SSA continued to focus on and improve information-sharing capabilities and was successful in expanding the user base of the Homeland Security Information Network Healthcare and Public Health (HSIN-HPH) portal to more than 1,000 users. This was accomplished by reaching out to various HPH-related associations. Emergency responses to the 2009 H1N1 influenza outbreak and the Haiti earthquake furthered the development of the sector's information-sharing processes. During both events, the SSA held regular calls with sector partners to keep them informed of the response efforts. The SSA established a dedicated page within the HSIN-HPH portal during the H1N1 influenza outbreak to provide stakeholders with the most up-to-date information.

To further enhance information-sharing capabilities, the SSA, with guidance from the HPH Information Sharing Work Group (ISWG), developed and implemented a robust alerts-and-warnings process and supporting infrastructure to ensure that all sector partners can receive timely and urgent information in the event of an incident. The SSA also began providing regular classified briefings to sector stakeholders holding the appropriate security clearances to share knowledge of feasible threats facing the sector.

This year, the SSA was successful in establishing its Private Sector Liaison Officer (LNO) Program. LNO Program participants are required to complete a set curriculum, after which they are eligible to be called upon during events to represent the private sector within the HHS Emergency Management Group. Five LNO participants have completed the program requirements and are available to provide expertise that informs the Federal response. In their role, the LNOs also assist in disseminating disaster response information to other sector partners.

On a regular basis, the SSA gives presentations at various sector conferences to inform attendees about the CIP program and a variety of CIP-related topics. Within the 2010 reporting cycle, some of the conferences at which the SSA made presentations include the Security Analysis and Risk Management Association (SARMA) conference, the Association for Healthcare Resource and Materials Management (AHRMM) conference, the International Association for Healthcare Security and Safety (IAHSS) Annual General Meeting, the Emergency Support Function (ESF) 8 Integrated Training Summit, the 2009 Directors of Public Health Preparedness Annual Meeting, and the 2010 Public Health Preparedness Summit. Participation in a variety of conferences is beneficial not only in terms of sharing information about the HPH Sector's CIP programs, but also for expanding the engagement of sector partners in CIP activities and forging relationships that provide the SSA with valuable knowledge and new perspectives.

A major focus of the SSA is the medical supply chain and the understanding of its vulnerabilities and the consequences to the sector of its disruption. The HPH Risk Assessment Work Group (RAWG) continued identifying and defining the functions of the medical supply chain to gain better insight into the sector's risk landscape. Based on this understanding, the work group modified the sector's functional model to facilitate an assessment of sector interdependencies, external dependencies, and critical nodes.

As information technology (IT) is gaining importance within the sector, the sector's vulnerability to both intentional and unintentional cyber threats is increasing. To help mitigate this issue, the sector established a Cyber Security Work Group (CSWG) that was tasked with developing a

sector-wide cybersecurity strategy. The CSWG was successful in creating a framework that categorizes cyber risks and that can be used to examine areas where improved security would reduce an organization's vulnerability to cyber threats.

The sector's research and development (R&D) Joint Advisory Work Group (JAWG) continued to make progress on its focus areas of healthcare facility security, biosurveillance, and continuity of operations (COOP). The JAWG initiated development of a tool that will provide healthcare facility owners and operators with a series of consequence mitigation strategies that can be integrated into the design of healthcare facilities. The JAWG started development of a white paper that examines the current state of public health education in biosurveillance and identifies methods to achieve a sustainable cadre of biosurveillance workers. As part of its efforts to share COOP best practices across the sector, the JAWG hosted an all-day meeting that brought together sector thought leaders to discuss the legal challenges, patient issues, methodologies for improved planning, regional programs, security, and approaches for building operational sustainability into the overall physical structure of facilities. The findings from this meeting were presented at the 2010 Public Health Preparedness Conference and will be published in a white paper.

This report provides details for these and many other accomplishments that support the HPH Sector's vision, mission, and goals.

## Section 2: Sector Risk Considerations

The HPH Sector is vast and diverse, encompassing a wide range of organizations exposed to a broad range of risks. Shared characteristics across these organizations that contribute to the sector's risk profile include the sector's high reliance on the workforce for sustained operations, its dependence on domestic and international manufacturers for critical resources and raw materials, the close proximity of workforce members to disease agents during events, and the importance of the sector's assets for human health and safety. This section describes the sector's risk landscape as it pertains to continuity of services, workforce, physical assets, and cyber systems.

### 2.1 Continuity of Services

The HPH Sector faces continuity-of-service challenges resulting from a wide range of all-hazards scenarios. Many of these challenges are the result of interdependencies with other critical infrastructure and key resources (CIKR) Sectors that provide supporting products and services, such as Food and Agriculture, Emergency Services, Nuclear, Transportation, Energy, and Water. In addition, interdependencies between government agencies and private sector organizations complicate the delivery of services and require close collaboration and a clear understanding of roles and responsibilities, logistics, and operational processes. The 2009 H1N1 pandemic highlighted the importance of the medical supply chain in providing drugs, vaccines, medical devices, and personal protective equipment (PPE) for patient treatment and workforce protection.

### 2.2 Workforce

The sector's emergency response role has the potential to expose workforce members to threat agents resulting from pandemics and chemical, biological, radiological, nuclear, and explosive (CBRNE) events. Sickness and death within the workforce resulting from threat agent exposure reduces the capacity of the healthcare system at a time when the volume of patients surges. It is critical that the sector protect its workforce from threat agents to limit illness and death and to maintain its capacity to care for patients.

### 2.3 Physical Assets

Direct threats to physical assets include terrorist attacks and natural disasters that can impact facilities and cyber systems. Some HPH facilities located in other countries have experienced direct threats in recent years from small arms attacks, improvised explosive devices (IEDs), and vehicle-borne improvised explosive devices (VBIEDs).



## 2.4 Cyber Systems

Cyber infrastructure across all sectors is increasingly being targeted by nation-state and nefarious actors. As members of the HPH Sector expand their reliance on technology, the sector's exposure to unintentional incidents as well as direct and indirect attacks will increase. To date, the consequences of cyber threats have largely resulted in identity theft, fraud, and data loss. As the technology landscape increases in complexity and sophistication, so too will the cyber-threat landscape. In order to ensure operational sustainability, the HPH Sector will need to be vigilant in its security posturing, working closely with the vendor community, international and domestic standards bodies, cross-sector partners, and R&D programs that are focused on cybersecurity challenges.

## Section 3: Sector Goals and Objectives

HPH is a services-based sector. Its capabilities are reliant upon specialized personnel, dedicated treatment environments, unique supplies and equipment, and resources from outside the sector. The sector must be prepared for the direct impact of an event as well as the simultaneous surge in demand for its goods and services resulting from an event. To fulfill its mission, the sector must meet its goals of maintaining service continuity, protecting its workforce, and mitigating risks to its physical and cyber assets (Table 3-1).

Table 3-1: Healthcare and Public Health Sector CIKR Vision and Mission Statements and Goals

Sector Vision and Mission Statements	
<p><b>Vision:</b> <i>The HPH sector will achieve overall resilience against all hazards. It will prevent or minimize damage to, or destruction of, the Nation’s healthcare and public health infrastructure. It will strive to protect its workforce and preserve its ability to mount timely and effective responses, without disruption to services in non-impacted areas, and its ability to recover from both routine and emergency situations.</i></p> <p><b>Mission:</b> <i>The mission of the HPH sector is to sustain the essential functions of the Nation’s healthcare and public health delivery system and to support effective emergency preparedness and response to nationally significant hazards by implementing strategies, evaluating risks, coordinating plans and policy advice, and providing guidance to prepare, protect, prevent, and, when necessary, respond to attacks on the Nation’s infrastructure and ensure the necessary resilience in infrastructure to recover and reconstitute healthcare and public health.</i></p>	
Sector Goals	
<b>Goal 1</b>	<b>Service Continuity:</b> Maintain the ability to provide essential health services during and after disasters or disruptions in the availability of supplies or supporting services (e.g., water, power).
<b>Goal 2</b>	<b>Workforce Protection:</b> Protect the sector’s workforce from the harmful consequences of all hazards that may compromise their health and safety and limit their ability to carry out their responsibilities.
<b>Goal 3</b>	<b>Physical Asset Protection:</b> Mitigate the risks posed by all hazards to the sector’s physical assets.
<b>Goal 4</b>	<b>Cyber security:</b> Mitigate risks to the sector’s cyber assets that may result in disruption to or denial of health services.

### 3.1 Objectives

The HPH Sector has identified a series of objectives that support its service continuity, workforce protection, physical asset protection, and cybersecurity goals. These objectives (shown in Table 3-2) serve to direct efforts within the sector to improve CIKR protection.

Table 3-2: Healthcare and Public Health Sector CIKR Objectives

Service Continuity	
<b>Objective 1</b>	<b>Health Care Continuity:</b> Enhance the ability of healthcare facilities to provide care during all-hazards incidents.
<b>Objective 2</b>	<b>Supply Chain Continuity:</b> Mitigate the threat of disruptions in the supply of drugs, biological products, medical devices, personal protective equipment, and other critical supplies.
<b>Objective 3</b>	<b>Supporting Services Continuity:</b> Mitigate risks to the sector of disruptions in supporting services including water, power, transportation, telecommunications, and waste management.
<b>Objective 4</b>	<b>Workforce Family Member Protection:</b> Plan for the protection of the sector's workforce family members to increase the availability of the workforce for emergency response.
<b>Objective 5</b>	<b>CIKR Essential Personnel Protection:</b> Assist other CIKR sectors in the protection of their essential personnel through public health measures.
Workforce Protection	
<b>Objective 6</b>	<b>Mass Prophylaxis:</b> Enhance protection of the sector's workforce through the availability and rapid delivery of countermeasures and protective equipment.
<b>Objective 7</b>	<b>Health Surveillance:</b> Improve and maintain health surveillance systems to enable the rapid and accurate detection of all-hazards events and monitoring of the associated health consequences.
Physical Asset Protection	
<b>Objective 8</b>	<b>Biosafety Level (BSL) 3 and 4 Facility Protection:</b> Mitigate risks posed to BSL 3 and 4 facilities that utilize select agents so that harmful biological agents and toxins are secured and laboratory services are available for response.
<b>Objective 9</b>	<b>Countermeasure Facility Security:</b> Enhance the security of facilities involved in the development and stockpiling of medical countermeasures.
<b>Objective 10</b>	<b>Healthcare and Public Health Facility Protection:</b> Improve the sector's ability to protect against direct threats to healthcare and public health facilities posed by all hazards.
<b>Objective 11</b>	<b>Research Facility Protection:</b> Mitigate risks posed by all hazards to the sector's critical research facilities.
Cyber security	
<b>Objective 12</b>	<b>Cyber Network, System, and Data Protection:</b> Protect against cyber incidents that disrupt or compromise critical information technology networks, systems, and data supporting the sector.

### 3.2 Priorities

The HPH Sector continues to focus on its 2009 priorities of information sharing and response coordination. This year, in addition to these priorities, the sector will focus on improving its asset identification process and extending it beyond national priority levels 1 and 2 to include a third priority level of assets that are critical to the sector.

### 3.2.1 Information Sharing

Information sharing is a critical process, ensuring that partners at all levels of government and the private sector work together to achieve shared objectives. The HPH Sector continues to invest significant resources to continually expand its information-sharing capabilities among Federal, State, local, tribal, and territorial governments and the private sector.

The sector maintains an ISWG, a partnership of government agencies and private sector entities that collaborate to address the information-sharing needs of the sector. The ISWG meets on a periodic basis to develop communications and information-sharing strategies for the sector and to promote information exchange. Over the course of the 2010 reporting period, the ISWG oversaw and provided input into multiple information-sharing initiatives. These initiatives included: (1) the enhancement, restructuring, and rollout of the HSIN-HPH portal, which is the sector's primary information-sharing platform, and (2) the implementation of an alert-and-notification process and supporting technology.

The HPH Sector is continuing to expand content on the HSIN-HPH portal in order to provide sector partners with timely and relevant information, and is conducting ongoing efforts to increase the user base of the portal. The SSA continues to coordinate with sector professional and industry associations to distribute invitations to the HSIN-HPH to its members describing the value of the portal and providing instructions on how to request an account. This approach resulted in the addition of more than 700 new HSIN-HPH users, bringing the total user base to more than 1,000. Users include members of the private sector (62 percent); Federal government (23 percent); and State, local, tribal, and territorial governments (15 percent).

In response to all-hazards events, such as the 2009 H1N1 influenza outbreak and the Haiti earthquake, the SSA initiates conference calls open to the entire sector to accelerate communications. These information-sharing initiatives deliver considerable value to sector members and have significantly increased engagement in the CIP program. The sector has also expanded the availability of both classified and unclassified threat briefings, as appropriate, to non-Federal partners to assist them in their preparedness planning. These briefings are typically held in conjunction with national meetings at which key partners are present.

The sector will continue to invest in information-sharing activities in the coming year, with a focus on increasing the quality and quantity of relevant content made available to sector partners.

### 3.2.2 Emergency Response

Over the past year the SSA developed new capacities for responding to emergencies within the CIP partnership framework. New methods were developed for mapping assets and sharing information during emergencies. The sector demonstrated its capabilities by participating in the 2010 National Level Exercise (NLE) and by responding to emergencies, including the 2009 H1N1 influenza outbreak, the tsunami in American Samoa, and the earthquake in Haiti.

The sector launched a new Private Sector LNO Program to increase the connection between Government and private sector entities during response. The SSA has worked with the SCC chairpersons to select a representative group of SCC members to take part in this program. The participants have received training and are called upon when needed to represent the private sector within the HHS Emergency Management Group during events. Private Sector LNOs provide their expertise to inform the Federal response and assist in disseminating information to the rest of the sector. General SCC and GCC members are kept informed of relevant response information through e-mail and the HSIN Portal. The LNOs were first activated in the early days of the 2009 H1N1 influenza response.

### 3.2.3 Asset Identification and Prioritization

The HPH Sector participates annually in the DHS National Critical Infrastructure Prioritization Program (NCIPP) through its RAWG. Comprised of experts from across the sector, this work group is responsible for developing and refining the sector's critical infrastructure identification criteria. The RAWG analyzes critical functions within the sector that, if disrupted, could lead to overall mission degradation and cascading consequences. The group then identifies asset types that support these critical functions and their associated attributes. This information forms the basis for developing the criteria. Using this approach for the 2009 NCIPP data call, the HPH Sector defined criteria for eight asset types that provide critical steady-state and emergency response capabilities.

The HPH Sector continues to mature in its ability to effectively identify its critical assets, systems, and networks. The sector will continue to conduct functional analyses to support the identification of critical sector assets. The sector will also explore other methodologies that can be used to identify critical assets.

## Section 4: Activity Progress

The HPH Sector conducts numerous activities to improve its ability to maintain service continuity and to mitigate risks to its workforce, physical assets, and cyber systems. The majority of the sector's risk mitigation activities (RMAs) are focused on service continuity. The sector has made significant investments in programs that improve its ability to continue delivering healthcare during and immediately following all-hazards events. These investments have considerably improved the ability of hospitals and other healthcare facilities to communicate during all-hazards events, manage surges in the number of patients, and evacuate when necessary. These investments have also improved the sector's ability to continue delivering medicines through public and private partnerships to people who need them after an all-hazards event has occurred.

### Key Accomplishments

- *Established a dashboard that provides a national view of aggregate inventory data for available supply, timeliness to fill orders, and production levels of critical H1N1 countermeasures.*
- *Increased participation in RxResponse from 21 states to all 50 states.*
- *Increased the number of Metropolitan Statistical Areas (MSAs) that meet Cities Readiness Initiative criteria for effectively distributing medical countermeasures by 20 percent.*

The sector has invested heavily in programs that better prepare the Nation's public health system for handling all-hazards events. As a result of these investments, public health departments at the State, local, tribal, and territorial levels have emergency preparedness plans and improved communications infrastructure. The public health departments exercise their plans and test their communications infrastructure on a regular basis to enable continuous improvement.

The sector has continued to devote resources to programs that protect its workforce by improving health surveillance and mass prophylaxis capabilities. As a result, the sector has improved its ability to more rapidly detect chemical and biological agents that threaten the workforce and the population at large. The sector has also forged partnerships and developed processes to quickly deliver antivirals, vaccines, and other medical countermeasures to its workforce and the general population when needed.

The sector has increased its emphasis on protecting critical physical assets, with a focus on bio-safety laboratories, hospitals, and sites where medical countermeasures are stockpiled. Over the past year, the sector conducted frequent site visits to identify vulnerabilities and provide guidance to the owners and operators of these sites to help them improve the security posture of their facilities.

Cyber assets within the sector are becoming increasingly vulnerable as a result of increased systems interconnectivity. This past year, the sector formed a work group to discuss cybersecurity and develop a strategy for increasing the sector's cybersecurity posture. The strategy is nearing completion and will be posted to the HSIN-HPH portal when completed.



## 4.1 Overview of Key Risk Mitigation Activities

Key RMAs were selected based on a number of considerations, including alignment with the sector's CIP goals and objectives, resources dedicated to the activity, involvement of a representative group of public and private sector organizations across the sector, and demonstration of measurable outcomes. Descriptions and progress indicators for the sector's key RMAs are provided in the sections that follow. The key RMAs are organized by sector goal. Other activities that contribute to infrastructure protection in the sector are described in Section 4.5.

### 4.1.1 Goal 1: Service Continuity

#### 4.1.1.1 HHS Hospital Preparedness Program

- **Description of Activity.** The Hospital Preparedness Program (HPP), administered under the HSS Assistant Secretary for Preparedness and Response (ASPR) of HHS, is a Federal cooperative agreement program operated by HHS and administered through State, local, tribal, and territorial health agencies. HPP enhances the ability of hospitals and healthcare systems to prepare for and respond to bioterrorism and other public health emergencies. Program priority areas include interoperable communication systems, bed tracking, personnel management, fatality management planning, and hospital evacuation planning. HPP funds have also improved bed and personnel surge capacity, decontamination capabilities, isolation capacity, pharmaceutical supplies, training, education, drills, and exercises.<sup>4</sup>
- **Progress Indicators.** As of August 2009, 60 of the 62 participating States, localities, and territories report that 4,958 hospitals within their borders participate in the HPP Program. States and hospitals continued to exercise emergency response plans throughout 2009. Several States made progress in standardizing and consolidating their exercises under the Homeland Security Exercise and Evaluation Program (HSEEP). Many hospitals also used the 2009 H1N1 pandemic as an opportunity to exercise and evaluate their plans. Metrics related to hospital capability remained consistent between 2008 and 2009:
  - 90 percent having demonstrated the ability to report available beds to their State, locality, or territory within 60 minutes during an exercise or event;
  - 90 percent having demonstrated dedicated, redundant communications capability during an exercise or incident;
  - 81 percent having evacuation plans; and
  - 59 percent having fatality management plans.

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<sup>4</sup> The report, *Hospitals Rising to the Challenge: The First Five Years of the U.S. Hospital Preparedness Program and Priorities Going Forward*, was written by the Center for Biosecurity at the University of Pittsburgh Medical Center with support from HHS. It discusses progress in healthcare preparedness and is available at <http://www.upmc-biosecurity.org/HPPreport> (accessed June 29, 2010).

#### 4.1.1.2 *The Joint Commission Healthcare Facility Accreditation Programs*

- **Description of Activity.** The Joint Commission (TJC) offers hospital, ambulatory care, behavioral healthcare, home care, long-term care, and laboratory accreditation programs. These programs include standards that require healthcare facilities to plan for all hazards. While accreditation is voluntary, TJC accredits 80 percent of the Nation's hospitals, comprising 90 percent of the Nation's hospital beds. TJC requires healthcare organizations to have emergency operations plans based on hazard vulnerability assessments that identify potential emergencies affecting the ability to provide services. Within the plans, healthcare organizations need to consider how they will manage the six key capabilities – communications, resources and assets, security and safety, staff, utilities, and patient care – during an emergency. The hospital accreditation program in particular requires hospitals (including critical-access hospitals) to establish response procedures and contingency plans for patient care to be used when they cannot be supported by the local community for at least 96 hours.
- **Progress Indicators.** TJC created a new standards chapter dedicated to emergency management (EM), effective January 2009, for the hospital, critical-access hospital, home care, ambulatory care, and office-based surgery accreditation programs. In 2010, the EM chapter became effective for the long-term care, behavioral health, and laboratory accreditation programs. The EM chapter restructures two lengthy and complex standards from the Environment of Care chapter and incorporates two standards which previously resided in the Medical Staff and Human Resources chapters for some programs. The EM chapter is composed of a set of 12 EM standards and 111 corresponding elements of performance, providing clearer guidance to institutions seeking accreditation. This change highlights an all-hazards approach that supports key organizational capabilities (such as communications, resources, and patient care) regardless of the type of emergency faced by the organization. The new chapter also requires collaborative emergency planning throughout the organization and with other healthcare and response partners in the community. In addition, TJC introduced updates to its 2010 on-site survey process for hospitals and critical access hospitals to better align the process with key concepts in the EM chapter. EM now has its own stand-alone survey session independent of the Environment of Care session, giving surveyors more space in the on-site survey for exploring issues specific to EM. Emergency preparedness and planning are explored in survey activities throughout the organization, addressing leadership, individual patients, and organization systems. This approach takes EM from the narrow purview of one department or discipline to a higher degree of integration within the organization. The survey process is expanded from a narrow focus on a specific-event scenario to broader emphasis on all-hazards planning to sustain the six critical areas of capabilities; actual preparedness (and not merely documentation of a plan); situational awareness and contingency planning; and collaboration with community partners.

#### 4.1.1.3 *RxResponse*

- **Description of Activity.** RxResponse is a not-for-profit, private sector initiative to support the medical supply chain during emergencies. RxResponse partners work together with Federal, State, and local officials as well as volunteer organizations to help support the continued delivery of medicines in the event of an emergency – whether it is caused by a natural disaster, terrorist incident, or health emergency (such as a pandemic) – to the people who need them. RxResponse is a single point of contact for the entire pharmaceutical supply system and relies on a robust network that allows Federal and State EM officials to communicate with RxResponse regarding pharmaceutical needs and other issues that may impact the supply system. The communications are actively monitored by all segments of the pharmaceutical supply system to ensure the fastest possible resolution. Partners include the American Hospital Association (AHA), American Red Cross, Biotechnology Industry Organization (BIO), Generic Pharmaceutical Association, Healthcare Distribution Management Association, National Association of Chain Drug Stores, National Community Pharmacists Association, and Pharmaceutical Research and Manufacturers of America.
- **Progress Indicators.** Due to the ongoing response to the H1N1 pandemic and the critical role that pharmaceutical manufacturing and supply played in that response, RxResponse was in communication with every State in the Nation, up from 21 States and two Metropolitan Statistical Areas (MSAs) by the end of 2008. Activities in that response included: situation reports and information sharing in regard to availability of antivirals and vaccines; participation in the development of and active support for the Centers for Disease Control and Prevention (CDC) antiviral dashboard effort; development of the Association of State and Territorial Health Officials (ASTHO) guidance for state health officials in collaboration with the professional pharmacy and public health communities to engage pharmacies as vaccination sites for 2009 H1N1 influenza; and a manufacturer-distributor summit that allowed for a free exchange of response and resiliency strategies and observations among the pharmaceutical supply companies.

RxResponse also has expanded the reach of the Pharmacy Status Reporting Tool by partnering with 2-1-1, a United Way/Alliance for Information and Referral Systems (AIRS) service providing information to persons after disasters. This tool leverages normal business operations to enhance the continued provision of healthcare to the public by making information on open pharmacies available to them, as well as providing valuable situational awareness to public health, EM, and clinical care providers.

#### 4.1.1.4 *CDC Public Health Emergency Preparedness Cooperative Agreement – Preparedness and Response Activities*

- **Description of Activity.** The Public Health Emergency Preparedness (PHEP) Program is a Federal cooperative agreement program operated by HHS and administered through State, local, tribal, and territorial health agencies. The PHEP cooperative agreement provides funding to enable public health departments to have the capacity and capability

to effectively respond to the public health consequences of all hazards. These emergency preparedness and response efforts are designed to support the National Response Framework (NRF) and the National Incident Management System (NIMS) and are targeted specifically for the development of emergency-ready public health departments.

- Within the PHEP program, some funds are dedicated to initiatives that enhance disease surveillance and mass prophylaxis capabilities. These initiatives are described in more detail as key RMAs within the workforce protection section for Goal 2.
- **Progress Indicators.** The most recent performance data for the preparedness and response activities funded by PHEP indicate significant accomplishments since its inception:
  - All State public health departments now can receive and evaluate reports of urgent health threats 24/7/365, whereas in 1999 only 12 could do so. Previously, it was often difficult for clinicians to reach a public health professional after normal work hours.
  - All States have plans to receive, store, and distribute from the Strategic National Stockpile (SNS), a national repository of antibiotics, other life-saving medications, and medical supplies.
  - The number of States performing within an acceptable range in their plans to receive, stage, distribute, and dispense medical assets received from the SNS or other sources increased from 37 to 50 between 2006 and 2009.
  - In 2009, 48 of 50 States (96 percent) responded within 30 minutes to a test message from the Health Alert Network (HAN), which allows for the rapid exchange of critical public health information. In 2007, only 78 percent responded to the HAN test message within 30 minutes.
  - In 2008, 47 of 51 State and District of Columbia (D.C.) public health laboratories used HAN or another rapid method (e.g., blast e-mail or facsimile) to communicate with sentinel laboratories and other partners for outbreaks, routine updates, training events, and other applications.

### **4.1.1.5 Project Public Health Ready**

- **Description of Activity.** Project Public Health Ready (PPHR) is a competency-based training and recognition program that assesses preparedness and assists local health departments or groups of local health departments in working collaboratively as a region to respond to emergencies. The program is funded by CDC and administered by the National Association of County and City Health Officials (NACCHO). It builds preparedness capacity and capability through a continuous-quality-improvement model. Each of the three PPHR project goals – all-hazards preparedness planning, workforce capacity development, and demonstration of readiness through exercises or real events – has a comprehensive list of standards that must be met in order to achieve PPHR recognition.

- **Progress Indicators.** Since 2005, 164 local health departments in 25 different States have been recognized as meeting all the PPHR requirements. The State-supported model of PPHR is currently being implemented in Arizona, Colorado, Florida, and Virginia. The States of Oregon, Pennsylvania, and Texas will be beginning the process in 2010. Several others are interested in the program as well. There are many steps being taken to streamline and simplify the PPHR process, including electronic submission, an online review system, and improvements in technical assistance and training provided by NACCHO staff.

#### 4.1.2 Goal 2: Workforce Protection

##### 4.1.2.1 CDC Public Health Emergency Preparedness Cooperative Agreement – Disease Detection and Investigation Activities

- **Description of Activity.** Within the PHEP program, funds are set aside to improve the ability of public health departments to detect and investigate diseases and increase their laboratory testing capacity for bioterrorism agents. Through these funds, public health departments have increased the number of epidemiologists working in emergency response, the number of public health professionals using health surveillance systems, and the number of laboratories capable of testing for biological and chemical agents.
- **Progress Indicators.** The most recent performance data for the disease detection and investigation activities funded by PHEP indicate significant accomplishments since the program's inception:
  - In 2008, 48 percent of approximately 5,500 active users in 50 States of CDC's Epidemic Information Exchange (Epi-X) responded to a system-wide notification test that entailed logging into the system and viewing a report within a three-hour targeted time frame.
  - The number of State and local public health laboratories able to detect biological agents has increased to 151 in 2008, from 110 in 2007.
  - The number of State and local public health laboratories able to detect chemical agents has increased to 56 in 2009, from 47 in 2007.

##### 4.1.2.2 Strategic National Stockpile

- **Description of Activity.** SNS is a national repository of antibiotics, chemical antidotes, antitoxins, life-support medications, intravenous (IV) administration supplies, airway maintenance supplies, and medical/surgical items. The SNS is designed to supplement and resupply State and local public health agencies in the event of a national emergency within the United States or its territories. The SNS is organized for flexible response. The first line of support is the provision of 12-hour push packages. These are caches of pharmaceuticals, antidotes, and medical supplies designed to provide rapid delivery of a

broad spectrum of assets for an ill-defined threat in the early hours of an event. The push packages are positioned in strategically located, secure warehouses and are ready for immediate deployment to a designated site within 12 hours. If an incident requires additional pharmaceuticals and/or medical supplies, follow-on managed-inventory supplies will be shipped to arrive within 24 to 36 hours. If the agent is well-defined, managed inventories can be tailored to provide pharmaceuticals, supplies, and/or products specific to the suspected or confirmed agent(s).

- **Progress Indicators.** To improve visibility into the commercial supply chain and public sector stockpiles of H1N1 medical countermeasures, the Division of Strategic National Stockpile (DSNS) established a Supply Chain Dashboard. The primary goal of the DSNS Dashboard is to assist Federal and State officials in the process and decision to release stockpiled assets. It provides a national view of aggregate inventory data for available supply, timeliness to fill orders, and production levels of critical H1N1 countermeasures. These data provide key information on available or anticipated assets to meet demand in the near future and in the long term. Reports of order fill status are received as green, yellow, or red indicators, with the time to fill orders and inventory replenishment delays serving as gauges. The DSNS Dashboard tracks certain doses of the Tamiflu and Relenza antivirals, N-95 respirators, and surgical masks. The DSNS Dashboard is currently undergoing expansion to further refine data collection elements, improve utility of information to State and Federal decisionmakers, and collect local-level dispensing data.

### 4.1.2.3 CDC Cities Readiness Initiative

- **Description of Activity.** The Cities Readiness Initiative (CRI) is funded through CDC's PHEP Program. The goal of CRI is to prepare major U.S. MSAs to effectively respond to a large-scale bioterrorist event by dispensing countermeasures to the affected population within 48 hours. By providing technical assistance to grant recipients, CRI has strengthened points of dispensing (PODs) infrastructures; increased planning that includes alternate modalities for dispensing; enhanced communication and engagement with partners from all levels of government, private sector, military installations, academia, and community-based organizations; and improved the ability to identify capabilities, strengths, and shortcomings through preparedness planning, exercises, modeling, and assessments.
- **Progress Indicators.** In 2004, 21 U.S. MSAs participated in CRI. As of 2009, 72 CRI MSAs are participating, representing 57 percent of the U.S. population.<sup>5</sup> CDC and State SNS Program personnel conduct reviews in each of the local jurisdictions within the CRI MSAs each year. These reviews measure capability for twelve functions considered critical to planning for countermeasure distribution and dispensing. CDC also reviews training on and exercising of these plans. Each of the 12 functions receives a weighted score. The sum of these weighted scores results in an overall score for the CRI area reviewed. The review scores from each area within a CRI MSA are aggregated to arrive

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<sup>5</sup> Based on CDC analysis of 2008 U.S. Bureau of the Census data.



at a single CRI MSA score. Over the past year, the percentage of CRI MSAs operating within the acceptable range (those receiving a score of 69 or higher on the technical assistance review) increased by 20 percent. Additionally, improved scores were observed within each of the 12 functions (a range from 3 to 14 percent).

The greatest overall increases during the past year were related to security; hospital and alternate care facilities coordination; and training, exercise, and evaluation functions. Examples include coordination at all levels of law enforcement for security of medical countermeasures and PODs; working with hospitals and alternate care facilities and those companies, agencies, or individuals assisting with distribution and inventory control activities; and training and exercise plans developed for the local jurisdictions that are specific to mass prophylaxis.

The CDC, in conjunction with its Federal, State, tribal, territorial, and local partners, continues to forge new partnerships, explore innovative venues, and seek alternate methods to continue to reduce the time it takes to deliver life-saving countermeasures to affected populations in the effort to reduce mortality and morbidity during a public health emergency.

The use of closed PODs is a method of dispensing to supplement the traditional community POD. A closed POD is a private location where medications are dispensed to a specific group of people such as businesses, universities, community organizations, and military installations (Table 4-1 shows types and numbers of closed PODs). Closed PODs help to reach specific portions of the community more quickly. As a result, long lines and public anxiety at traditional community PODs can be reduced, and resources can be used more efficiently. Closed PODs also enhance continuity of operations among entities that provide critical infrastructure during a declared emergency. A majority of the CRI MSAs have added closed PODs as an alternate modality to their medical countermeasure distribution and dispensing plans.

Table 4-1: Type and Number of Closed POD Units among 72 MSAs

Type of POD	No. of MSAs	POD Units
Business PODs	48	229
Government PODs (non-Military)	52	729
Military PODs	47	46
Academic PODs	46	670
Community Organization PODs	45	167

### 4.1.3 Goal 3: Physical Asset Protection

#### 4.1.3.1 CDC Select Agent Program

- Description of Activity.** The CDC Select Agent Program regulates the possession, use, and transfer of biological agents and toxins that could pose a severe threat to public

health and safety (known as select agents). This program has enhanced the Nation's oversight of the safety and security of select agents. The Select Agent Program promotes laboratory safety and security by developing, implementing, and enforcing the select agent regulations; providing guidance to the regulated community; and inspecting facilities working with select agents. CDC works closely with the Criminal Justice Information Services Division (CJIS) of the U.S. Department of Justice (DOJ) to conduct security risk assessments of non-governmental entities and personnel needing access to select agents.

- **Progress Indicators.** CDC works proactively with registered entities in advance of natural disasters and national events to ensure that all select agents and toxins are properly secured to protect them from theft, loss, or release. CDC took such actions for flooding, hurricanes, wildfires, and earthquakes that occurred in the United States in 2009. To aid States in emergency preparedness planning, CDC established a policy by which State officials can receive information about CDC-registered select agent entities in their States. On August 12, 2009, CDC hosted a workshop series themed "Management Oversight" for all of its registered entities and partners to inform individuals of their legal responsibilities for implementing the Select Agent Regulations.

In fiscal year (FY) 2009, CDC had the following operational accomplishments:

- Responded to 2,392 inquiries from the public as part of outreach efforts regarding the Select Agent Regulations (of which ninety-five percent of the inquiries received a response within one business day); and
- Processed 3,059 reports of identifications of select agents and toxins.

#### **4.1.3.2 HHS Biomedical Advanced Research and Development Authority Program Protection Office**

- **Description of Activity.** The HHS Biomedical Advanced Research and Development Authority (BARDA) Program Protection Office (PPO) establishes security standards, provides guidance, and ensures compliance throughout the complete life-cycle acquisition process of critical vaccines, diagnostics, and drugs acquired under Project BioShield (PBS) and the Pandemic Influenza and Emerging Infectious Diseases (PIEID) Program. BARDA PPO administers and ensures compliance with comprehensive security practices relating to physical, operations, personnel, information, and transportation security and conducts security awareness programs at all contractor facilities supporting PBS and PIEID. It participates in DHS-conducted Enhanced Critical Infrastructure Protection (ECIP) visits and the Regional Resiliency Assessment Program (RRAP). It also conducts security assistance visits at critical domestic and international contractor facilities. BARDA PPO is actively involved in coordinating on behalf of BARDA with Federal, State, local, and foreign law enforcement agencies to share appropriate information, including ways to minimize the potential impact of an emergency situation on contracted acquisition operations.

- **Progress Indicators.** BARDA PPO significantly increased its activities and impact in 2009. PPO security professionals partnered with DHS Protective Security Advisors (PSAs) to conduct joint security assessments at four major distribution centers responsible for securing and distributing the H1N1 vaccine to the U.S. population and eight other designated critical infrastructure facilities providing crucial operations in support of manufacturing, storing, and distributing the H1N1 vaccine and antiviral drugs. It also conducted follow-up security assessments at seven additional critical infrastructure facilities in support of both PIEID and PBS programs and 20 other security assessments in support of the healthcare sector at both U.S. and overseas locations.

BARDA PPO actively participated in the DHS-led RRAP in the Raleigh Research Triangle area, which assessed the physical security, vulnerabilities, interdependencies, and resiliency of critical infrastructure.

The BARDA PPO co-hosted the first multi-agency security-related tabletop exercise (TTX) at the sole U.S. domestic influenza manufacturer and DHS-designated critical infrastructure facility. The TTX involved more than 20 local, State, Federal, and private industry officials. The in-depth TTX included response actions at all levels and captured essential lessons learned in preparation for a potential pandemic influenza event.

BARDA PPO assisted in the facilitation of Buffer Zone Protection Program (BZPP) grant submissions at BARDA-nominated critical infrastructure sites. The BZPP is a DHS-sponsored infrastructure protection grant program focused on providing funding to local law enforcement for equipment and planning activities to address gaps and enhance security capabilities in protecting the highest-risk critical infrastructure sites.

#### 4.1.4 Goal 4: Cybersecurity

##### 4.1.4.1 Cybersecurity Strategic Plan

- **Description of Activity.** The HPH Sector has embarked on an effort to develop a cybersecurity strategic plan that considers the unique aspects of cybersecurity within the sector. More detail on this RMA is provided in Section 4.3 of this document.
- **Progress Indicators.** In October 2009, the sector established a CSWG. The work group has met several times and is nearing completion of the development of the sector's cybersecurity strategy. More detail on the sector's progress is provided in Section 4.3 of this document.

## 4.2 Implementation of the NIPP Risk Management Framework

This year, the HPH Sector has made significant progress implementing the National Infrastructure Protection Program (NIPP) risk management framework (Figure 4-1). The

framework considers all-hazards threats that it systematically evaluates with a process that sets goals and objectives; identifies assets, systems, and networks; assesses risks; prioritizes risks; implements programs; and measures effectiveness. The following subsections discuss progress in each of these areas.

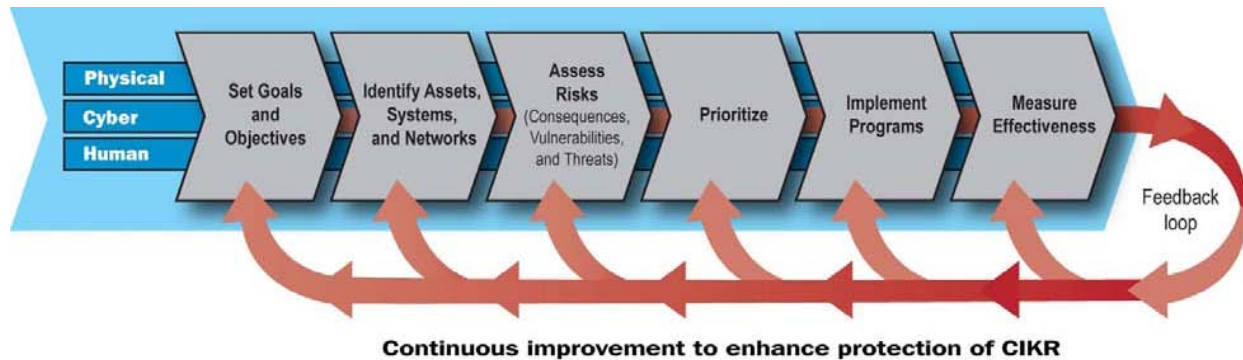


Figure 4-1: NIPP Risk Management Framework

#### 4.2.1 Sector Annual Report Development and Setting Goals and Objectives

In developing the 2010 HPH Sector Annual Report, the SSA adopted the same approach it took for writing its 2009 report. The SSA established a Critical Infrastructure Partnership Advisory Council (CIPAC) Sector Annual Report Writing Group (SAR WG) composed of representatives from the SCC and GCC. The work group provided input into each section of the report and also offered feedback on draft sections as they were completed. The iterative review process with the SAR WG enabled the SSA to create a document that is representative of the sector and its accomplishments over the course of the reporting period.

In 2009, the HPH Sector drew upon the expertise of the SAR WG to refine its goals and objectives. This effort resulted in the establishment of four overarching goals and twelve supporting objectives, all of which are critical in support of the sector’s vision and mission. The goals and objectives, which remain largely unchanged from 2009, are described in Section 3 of this document.

#### Significant NIPP Risk Management Framework Accomplishments

- Expanded the functional model that defines a framework for identifying assets, systems, and networks to include medical supply chain activities.
- Created a framework to categorize cyber risks.
- Continued development of a healthcare facility security and design analysis tool to analyze security risks.

#### 4.2.2 Identify Assets, Systems, and Networks

The HPH Sector continues to participate in the NCIPP. The criteria defined by the sector’s RAWG in 2009 will remain unchanged this year. The sector will use these criteria during the 2010 NCIPP data call to identify critical assets, systems, and networks.

Members of the RAWG and other subject matter experts (SMEs) continue to work on the sector's functional model. This model provides a framework for identifying and depicting sector infrastructure, detecting interdependencies, and identifying risks to sector capabilities. The functional model can be further leveraged at the local and regional levels to identify and examine the vulnerabilities associated with specific assets and systems.

#### 4.2.3 Assess Risks

The HPH Sector has traditionally struggled with assessing risks across the sector because it is services-based, not physical assets-based; however, through the efforts of various work groups, the SSA has made considerable progress in developing an approach to assessing risks and has defined a path forward to continue improving the approach.

In the fall of 2009, the RAWG identified and defined the functions of the medical supply chain to obtain a more in-depth understanding of the sector's risk landscape. The work group updated the sector's functional model based on this effort. The functional model supports a network analysis approach that facilitates the assessment of sector interdependencies, external dependencies, and critical nodes to identify potential vulnerabilities and single points of failure. This particular approach also allows for an analysis of cascading consequences that may result from a disruption to or failure of a function.

The HPH Sector continues developing a healthcare facility security and design analysis tool. The tool is intended to be used by building owners and designers to analyze the security risks of a facility based on geographic location, natural hazards, and service types to facilitate optimal design options for security and medical surge events. Currently, the tool synthesizes the responses to a series of questions related to facility attributes, threat characteristics, past risk assessments, and safety and security features to provide a facility risk score. Future plans include expanding the tool to provide specific risk-mitigation strategies based on responses to certain questions.

Cybersecurity has become a primary area of focus within the HPH Sector. To address issues related to cybersecurity, the SSA formed the CSWG in the summer of 2009. The purpose of this work group is to develop a strategy for improving cybersecurity within the sector. The CSWG has created a framework to categorize cyber risks based on the loss of availability, loss of data integrity, loss of confidentiality, or loss of privacy. The framework has been used to examine specific areas where improved security would greatly reduce an organization's overall risk from cyber threats. When it is complete, the sector's cyber strategy will provide a discussion on risk management, identify the fundamentals of security, and provide recommendations for cyber R&D.

In light of the 2009 H1N1 influenza, an HPH-affiliated association evaluated and conducted a lessons-learned study on the supply chain problems encountered during the outbreak. The study provided insights into what materials were in short supply and how long it took for the supply chain to stabilize. The study then offered an explanation of the cascading effects the shortages

created. This information helped the sector to better understand certain aspects of the supply chain and its associated risks.

#### 4.2.4 Prioritize

The HPH Sector prioritizes critical infrastructure and assets through the DHS NCIPP. The SSA, in collaboration with DHS, conducts a consequence-based risk assessment annually to identify assets that are of national significance.

The RAWG conducted an analysis of critical functions within the sector that, if disrupted, would lead to overall mission degradation and cascading consequences. The work group then identified asset types that support these critical functions and their associated attributes. This information formed the basis for developing the criteria that play a role in the prioritization of assets within the NCIPP. Using this approach, the HPH Sector defined criteria for eight asset types that provide critical steady-state and emergency-response capabilities.

#### 4.2.5 Implement Programs

Section 4.1 and the remaining sections in Section 4 provide a detailed summary of the various CIKR protection and resiliency programs implemented by the HPH Sector. Please refer to these sections for a description of these efforts.

#### 4.2.6 Measure Effectiveness

The HPH sector relies upon performance measurement conducted at the program level to indicate progress toward achieving its CIP goals and objectives. Most federally funded programs require grant awardees to report their progress on an annual basis. The agencies that manage these programs provide the SSA with this performance data for use in determining and reporting on progress.

The sector also measures engagement in its CIP Program. Metrics based on participation in CIP meetings, use of the sector's information-sharing portal, and participation in work groups provide meaningful information about the progress of the sector's CIP Program. The sector will continue to monitor program engagement, with a focus on measuring information-sharing activities. For example, the SSA tracks usage metrics for the HSIN-HPH portal, as the portal is central to the sector's information-sharing priority. At the beginning of the Sector Annual Report reporting period, there were approximately 280 HSIN-HPH users. As a result of the SSA's outreach to many of the sector-related associations, the HSIN-HPH user base expanded to more than 1,000 users by the end of the reporting period.

Moving forward, the SSA will continue to leverage performance management data provided by organizations that fund large CIP programs to gauge the sector's progress in protecting its critical



infrastructure. The program office will also work with these organizations to add measures to their performance management systems that are CIP-focused.

### 4.3 Cybersecurity

Over the past 24 months, the Federal government has undertaken several initiatives that highlight the Nation's economic dependence on the Internet and cyber infrastructure. As a result, a number of strategies have been put into place to address a growing cyber-threat environment, including:

- The 2009 Cyberspace Policy review;
- The establishment of the U.S. Cyber Command, to be headed by the Director of the National Security Agency (NSA);
- A White House-designated "Cyber Czar";
- Funding for DHS to hire 1,000 new cybersecurity specialists over the next three years; and
- Proposed cybersecurity legislation: House Report (H.R.) 4061, the Cybersecurity Enhancement Act of 2009.

#### Significant Cyber Security Accomplishments and Initiatives

- *Established Sector Cyber Security Work Group.*
- *Developed draft Sector Cyber Security Strategy that supports the sector's overall goal for improving the sector's cyber-security posture.*
- *Provided education and outreach to the sector to address cyber threats and vulnerabilities.*
- *Presented HPH Physical Cyber Security issues and recommendations for R&D.*
- *Engaged in an international effort to develop standardized security guidelines for Health Information Technology (HIT) that facilitate confidentiality, availability, and integrity of health information systems and the data residing on those systems.*

For the HPH Sector, the focus on cybersecurity has resulted in new legislative mandates over the security of health IT and additional funding streams for security through the Health Information Technology and Economic Clinical Health (HITECH) Act of 2009. HITECH Act acknowledges the concern over the security and privacy controls of electronic health records as the United States moves forward on the implementation of a nationwide health information network for sharing clinical data on a national scale.

In 2008, through the Strategic Homeland Infrastructure Risk Assessment (SHIRA) process, sector specialists developed a number of threat scenarios directed at health IT infrastructure. The scenarios demonstrated a cyber-threat environment capable of bringing some public health services to a halt, diverting large sums of financial transactions out of the health system, conducting denial-of-service attacks across the medical supply chain, and committing fraud worth hundreds of millions of dollars. The analysis has resulted in an

#### Sector Cyber Domain

*HPH cyber domain is "the integrated systems, networks, and applications, including the Internet and telecommunications, which move, translate, manipulate, share or otherwise process data." The domain has no physical or logical boundaries, spanning international borders and geopolitical influences.*

increased emphasis on improving the cybersecurity posture across HPH Sector owners and operators.

In October 2009, the sector established a CSWG to develop a sector-wide cybersecurity strategy. The strategy gives recognition to the significant and growing presence of IT in the HPH Sector. IT systems are used across nearly every dimension of operations from laboratory analysis and pharmaceutical inventory management to security monitoring and automated heating, ventilation, and air conditioning (HVAC) systems. While the sector has achieved economies of scale through the broad adoption of IT, the growing dependence on cyber infrastructure cannot be overstated.

Numerous initiatives exist today outside of the sector CSWG that are focused on securing medical devices and network infrastructure. From activities sponsored by the Health Information Management and Systems Society (HIMSS) to efforts under the Medical Device Security Center (MDSC), the HPH Sector is driving toward sustainable, interoperable, and secure mechanisms to deliver care and manage disease prevention. Some examples include the following:

- The HIMSS Privacy and Security Work Group developed the Privacy and Security Toolkit.
- The HIMSS Patient Identity Integrity Work Group examined and drafted a white paper to address the critical business processes that must be in place to support and maintain the integrity of the data for quality of care, patient safety, and cost management.
- The HIMSS Medical Device Security Work Group identifies both the security issues associated with medical devices and systems and the best practices available to address those issues; evaluates the issues of security threats and vulnerabilities that affect medical devices; and coordinates with similar groups and committees, in HIMSS and other organizations, to capitalize on existing efforts.
- The MDSC assesses the security of medical devices and addresses vulnerabilities. MDSC works to further the understanding of and balance between security, privacy, safety, and effectiveness for next-generation medical and pervasive healthcare devices.
- The International Electrotechnical Commission (IEC) Medical Device Security Initiative develops common security standards for medical device technology that can be applied across the international community.

Today, the HPH Sector is committed to IT and cybersecurity efforts. Research agendas, grants, and security spending all indicate that significant attention is being directed to the protection of sector resources and safety at the point of care; nevertheless, technology is advancing at a pace that is not synchronized with security. The threat environment has evolved. In the beginning, threats came from curious and resourceful hackers; now hacking is a modern-day business that by all accounts generates more money than drug trafficking. Boundary protections, such as firewalls, have been a staple for information security professionals, and now research indicates that assailants easily defuse these preventive measures using sophisticated malware. As the complexity of attacks evolves, business owners must be prepared to adjust their networks

rapidly. Security must be dynamic, it must reside at the data and application levels, and it must have continuous monitoring capabilities to address persistent threats.

## 4.4 Partnership

The NIPP partnership model provides a foundation of processes, procedures, and policies for sector collaboration. HHS serves as the SSA responsible for coordinating CIKR activities within the sector. The SSA works closely with the SCC and GCC to set goals and objectives, identify priorities, and implement activities to protect the sector's CIKR.

### 4.4.1 HPH Sector Coordinating Council and Government Coordinating Council

The HPH SCC and GCC continued to meet over the course of the last year. They have each supported the SSA in reaching sector goals and meeting sector requirements.

The sector held a joint SCC/GCC meeting in October 2009. At that meeting, the SCC selected one new co-chair and maintained the other two co-chairs. Since the joint SCC/GCC meeting, SCC and sub-council chairs have held conference calls every two months, and the full SCC has met by conference call in the intervening months. The three SCC co-chairs have also attended monthly HPH CIP team meetings with staff from HHS and DHS. These meetings actively involve SCC representatives in the programmatic planning of sector activities.

The SCC and GCC continue to maintain work groups to identify R&D/modeling, simulation, and analysis (R&D/MS&A) needs and direct information-sharing activities. This past year, the sector formed a new work group to develop a cybersecurity strategy. In addition to its support of sector work groups, the SCC co-chairs have facilitated cross-sector planning and information sharing through participation in Partnership for Critical Infrastructure Security (PCIS) and Information Sharing and Analysis Center (ISAC) Council meetings. The sector has also participated in several other cross-sector CIP initiatives, including the State, local, tribal, and territorial GCCs and cross-sector work groups on cybersecurity and R&D/MS&A.

#### Significant Partnership Accomplishments

- *Increased information sharing during the 2009 H1N1 influenza pandemic.*
- *Expanded HSIN portal user community to more than 1,000 members.*
- *Developed and distributed a white paper describing sector procedures for handling supply chain shortages.*

This past year SCC and GCC members collaborated to produce both the 2010 Sector Annual Report and the 2010 revision to the HPH SSP. The 2010 SSP updates the framework established in the 2007 SSP by incorporating the revised goals and objectives that were adopted during the development of the 2009 Sector Annual Report. It also includes new sections to assist State, local, tribal, territorial, and private sector partners in implementing HPH Sector infrastructure protection within their own organizations or jurisdictions.

#### 4.4.2 Information Sharing

Information sharing continues to be one of the top priorities for the sector and is the SSA's primary activity for building and maintaining partnerships. Over the course of the past year, the sector demonstrated enhanced information sharing during natural disasters and other events. During the H1N1 influenza pandemic, the SSA maintained regular contact with SCC and GCC members to share information related to the pandemic. Situation reports and other materials kept SCC and GCC members informed. Based on interactions among SCC and GCC members, the SCC Medical Materials sub-council developed a white paper to inform the government on the procedures that the private sector implements during shortages. The white paper was shared widely across the government.

The SSA has made progress on its Private Sector LNO program and has expanded the number of participants from three to seven. During a national emergency, National Security Special Event (NSSE), or other significant event, the SSA asks one or more of the non-Federal LNOs from the SCC and GCC to support the HHS Emergency Management Group response. The SSA selects participants based on the needs of the specific event and expects them to provide guidance to the Federal response and outreach to other non-Federal partners. The SSA activated this program in response to the 2009 H1N1 influenza outbreak. Two private sector LNOs and two LNOs representing State and local public health agencies participated with HHS in the response. The SSA will continue to implement improvements to the program as they are identified by after-action analysis.

The sector's information-sharing efforts are directed by the ISWG, which continues to hold regular meetings. The ISWG has improved information-sharing processes based on the sector's experience responding to events, including the 2008 hurricanes and the 2009 H1N1 influenza outbreak. The ISWG is in the process of identifying information needs and processes for steady-state operations.

The sector has increased outreach to partners and has taken steps to eliminate barriers to information sharing among Federal and non-Federal entities. The sector has enabled access to information deemed FOUO through HSIN. The SSA updated and expanded the sector's HSIN portal in order to provide new sources of information relevant to the sector's CIP efforts. The portal user community has grown to more than 1,000 members.

The sector has also increased the number of SCC and GCC members with security clearances to enable the sharing of classified information. The SSA has provided three classified briefings to cleared SCC and GCC members during the first year of this initiative. The briefings highlight threats against the sector for which members should prepare in their efforts to protect critical infrastructure. The SSA plans to continue providing these briefings four times per year.

The SSA has established a Protected Critical Infrastructure Information (PCII) Office within HHS and became PCII accredited in 2010. The PCII designation allows secure handling of infrastructure information voluntarily provided by the private sector.

## 4.5 Other Risk Mitigation Activities

In addition to the key RMAs described in Section 4.1, there are many CIP-related RMAs at all levels of government, within academic and not-for-profit organizations, and in the private sector. These activities support the sector's goals of maintaining service continuity, protecting the workforce, protecting physical assets, and enhancing cybersecurity. These activities exist in addition to the ongoing work of the HPH Sector in protecting lives and health both every day and on an emergency basis. This section discusses activities at the Federal and owner/operator levels that mitigate risks.

### 4.5.1 Federal Activities

Federal activities to mitigate risks are undertaken in many areas of government, including public health, emergency preparedness, defense, and others. This section discusses the following activities: Food and Drug Administration (FDA) Drug, Biologic, and Medical Device Shortage Programs; Public Health Information Network (PHIN); Emergency Prescription Assistance Program (EPAP); U.S. Department of Defense (DoD) Defense Critical Infrastructure Program (DCIP); CDC Preparedness and Emergency Response Research Centers (PERRC); National Disaster Medical System (NDMS); Federal and State Antiviral Stockpiling Program; CDC CHEMPACK Program; Federal Emergency Management Agency (FEMA) Emergency Management Institute (EMI); U.S. Department of Veterans Affairs (VA) Comprehensive Emergency Management Program (CEMP) Analysis; VA Accreditation in the Emergency Management Accreditation Program (EMAP); and VA Biosurveillance.

#### Significant Accomplishments

- *Responded to multiple requests from several states for information related to shortages of devices in response to the H1N1 influenza outbreak.*
- *Coordinated efforts to provide numerous shipments of needed blood to Haiti following its devastating January 2010 earthquake.*

#### **4.5.1.1 FDA Drug, Biologic, and Medical Device Shortage Programs**

The Drug, Biological Product, and Medical Device Shortage Programs of the FDA address potential or actual shortages that have a significant impact on public health. Through communication, facilitation, and negotiation, these programs work with medical manufacturers to plan for and manage shortages.

The Drug Shortage Program (DSP) addresses potential or actual shortages of prescription and over-the-counter medications on the U.S. market and works with pharmaceutical manufacturers, other government agencies, and professional organizations to plan for and manage drug shortages. DSP prioritizes drug products needed for serious diseases or medical conditions for which there are no alternatives. DSP maintains the Critical Products database, which includes information collected for drug products needed for emergency preparedness, counterterrorism activities, and life-threatening diseases and medical conditions. These products are continually monitored for inventory, surge capacity, sources of raw material, and locations of manufacturing facilities in order to ensure the ability to respond to federally declared disasters or emergencies and potential shortages. The manufacturers provide data voluntarily with the understanding that the information is considered confidential in nature. The manufacturers agree to report any potential shortage issues involving these products so that they can be addressed expeditiously by DSP.

The FDA's Center for Biologics Evaluation and Research (CBER) manages the Biological Product Shortage Program. The goal of this program is to help prevent or alleviate shortages of biological products. CBER works with all parties involved to ensure that medically necessary products are available within the United States. During emergency operations (e.g., natural disasters), the CBER Biological Product Shortage Program works with the CBER Emergency Operations Coordinator (EOC) and other Federal entities such as the CDC, as needed. The program will continue to address shortages that occur and will continue to monitor all products listed as current shortages.

The FDA's Center for Devices and Radiological Health (CDRH) acquires and maintains detailed data on domestic inventory, manufacturing capabilities, distribution plans, and raw material constraints for medically necessary medical devices. CDRH works with medical device manufacturers and distributors to plan for and manage shortages. CDRH is in the process of developing a new shortages database that will have the ability to access data critical to assessing the potential for and prevention of shortages of diagnostic and therapeutic medical devices that may result from federally declared disasters or emergencies or regulatory actions taken by CDRH.

Over the past year, CDRH has conducted the following CIP-related activities:

- Coordinated with CDC to create a dashboard to identify potential critical device shortages;
- Responded to multiple requests from CDC and several States for information related to shortages of devices in response to the H1N1 influenza outbreak;



- Assisted foreign countries that requested support in developing strategies to avoid shortages of devices critical to their healthcare systems;
- Worked with BARDA to identify strategies to avoid shortages of accessories to ventilators in the SNS;
- Initiated dialogue with CDC in order to better understand the supply chain of SNS devices to avoid shortages of those devices; and
- Initiated dialogue with representatives of the U.S. Department of Energy's (DOE) Oak Ridge National Laboratory to address potential security issues related to medical devices with wireless capabilities.

The FDA uses the information collected by these programs to support risk assessment, help inform risk mitigation strategies, and support real-time decision-making by HHS during actual emergencies or emergency preparedness exercises.

#### ***4.5.1.2 Public Health Information Network***

The CDC PHIN is a national initiative to improve the capacity of public health programs to use and exchange information electronically by promoting the use of standards that define functional and technical requirements. PHIN strives to improve public health by enhancing research and practice through best practices related to efficient, effective, and interoperable public health information systems.

#### ***4.5.1.3 Emergency Prescription Assistance Program***

The HHS EPAP leverages private sector resources for efficient prescription drug distribution. EPAP provides access to necessary prescription drugs and limited durable medical equipment (DME) at any enrolled pharmacy in the United States or its territories for designated eligible individuals in a federally identified disaster area. EPAP strengthens the pharmaceutical supply chain by eliminating barriers to the access of medical products to those affected by disasters.

#### ***4.5.1.4 DoD Defense Critical Infrastructure Program***

The purpose of the DoD DCIP is to ensure that the Military Health System (MHS) has identified the major threats to its critical assets and mitigated those threats to the greatest extent possible through a risk management program. The DCIP Health Sector integrates activities within the broader activities of the HPH Sector.

The DCIP Health Sector has three elements. It:



1. Develops and maintains a database of assets. The DCIP Health Sector has developed a Web-based characterization tool, the Primary Health Assets Staging Tool (PHAST), which allows users to search for assets by ten functional areas and geographic parameters;
2. Identifies, analyzes, and assesses sector's critical assets. The DCIP Health Sector has identified single-source or mission-degrading assets deemed vital to meet mission requirements; and
3. Implements a risk management program for task-critical assets. The DCIP Health Sector is developing a risk management program for critical assets. The intent is to protect these assets to the maximum extent possible and to present a prioritized list of mitigating actions to the senior leadership for direction, resolution, and/or resourcing.

#### **4.5.1.5 Public Health Emergency Response Grant**

Congress appropriated funding in June 2009 through the 2009 Supplemental Appropriations Act for the Public Health and Social Services Emergency Fund to prepare for and respond to an influenza pandemic. This funding provides HHS and other Federal and State agencies with resources to respond to ongoing and emerging outbreaks of novel H1N1 influenza in the United States. To date, CDC is administering \$1.35 billion through the Public Health Emergency Response (PHER) grant program to upgrade State and local pandemic influenza preparedness and response capacity.

#### **4.5.1.6 Healthcare and Public Health Surge Capacity and Workforce Augmentation Programs**

The HPH Sector operates several programs to recruit, train, register, credential, and deploy public health and medical professionals for emergency response. A primary purpose of these programs is to provide workforce augmentation at the time of an emergency. Although these programs do not relate specifically to the sector's workforce protection goal, they do support the sector's workforce infrastructure and ability to respond to emergencies.

The NDMS is a federally coordinated system that supplements an integrated national medical response capability to assist State and local entities in dealing with the medical impacts of major disasters and to provide support to the military and the VA medical systems in caring for casualties evacuated to the United States from overseas armed conventional conflicts.

The NRF uses the NDMS, as part of HHS, under ESF #8, Public Health and Medical Services, to support Federal agencies in the management and coordination of the Federal medical response to major emergencies and federally declared disasters.

The Emergency System for the Advance Registration of Volunteer Health Professionals (ESAR-VHP) is a national program intended to help health professionals volunteer in emergencies. Each

system is maintained by a State or group of States, for the purpose of verifying the credentials, certifications, licenses, accreditations, and hospital privileges of healthcare professionals who volunteer to provide health services during a public health emergency. In 2009, HHS awarded 53 project grants for ESAR-VHP implementation.

The Medical Reserve Corps (MRC) is a national network of local groups of volunteers committed to improving the health, safety, and resilience of their communities. MRC volunteers include medical and public health professionals, as well as others interested in strengthening the public health infrastructure and improving the preparedness and response capabilities of their local jurisdiction. MRC units identify, screen, train, and organize the volunteers and utilize them to support routine public health activities and augment preparedness and response efforts. The MRC is coordinated at the Federal level within the Office of the Surgeon General.

#### ***4.5.1.7 Federal and State Antiviral Stockpiling Program***

HHS established the Federal and State antiviral stockpiling program several years ago. States have stockpiled in excess of 20 million courses of antivirals through a combination of Federal and State funds. Medical stockpiles are essential not only to the treating of patients, but also to ensuring protection of the sector's workforce during emergencies.

#### ***4.5.1.8 CDC CHEMPACK Program***

The CHEMPACK pilot program began in September 2002 with three volunteer project areas. In March 2008, the program reached a major milestone and had successfully placed CHEMPACK containers in every State and large city in the Nation.

#### ***4.5.1.9 FEMA Emergency Management Institute***

FEMA's EMI serves to develop and deliver EM training to enhance the capabilities of Federal, State, local, and tribal government officials, volunteer organizations, and the public and private sectors to minimize the impact of disasters. Instruction focuses on the four phases of EM: mitigation, preparedness, response, and recovery. Approximately 5,500 participants attend resident courses each year, while 100,000 individuals participate in non-resident programs sponsored by EMI and conducted by State EM agencies under cooperative agreements with FEMA.

#### ***4.5.1.10 VA Comprehensive Emergency Management Program Analysis***

The VA is currently engaged in continuous quality improvement for emergency preparedness after having embraced the need to establish a more systematic strategy for proactively identifying and addressing system weaknesses. Such a strategy allows the VA to consistently

meet National Fire Protection Association (NFPA) 1600®,<sup>6</sup> TJC, and FEMA standards and also will position the VA to ensure the safety of its employees and better serve veterans and every community with a VA presence.

The mission of the VA's Veterans Health Administration (VHA) Comprehensive Emergency Management Program (CEMP) is to ensure the continued delivery of vital healthcare services to veterans and to support the Nation's communities in times of national or local emergency. This is accomplished by utilizing sound EM principles to mitigate against, prepare for, respond to, and recover from any and all types of emergencies in accordance with national, VA, State, and local laws and authorities.

Through the ongoing effort to further assess and enhance the VHA EM program with emphasis on all-hazards preparedness, the VHA initiated a project for VHA facilities to focus and shape their EM program. The VHA assessment teams are composed of clinical, engineering, EM, and healthcare operations experts. Using the 69 CEMP capability assessment variables, the objective of the assessment teams is to gather information and make recommendations on local, regional, and system-wide issues and opportunities for improvement that should be elevated to national attention.

#### **4.5.1.11 VHA Emergency Management Accreditation Program**

VHA is working toward becoming the first Federal agency accredited by the EMAP. The EMAP is a standards-based voluntary assessment and accreditation process for government programs having responsibility for coordinating prevention, mitigation, preparedness, response, and recovery activities for natural and human-caused disasters. Accreditation is based on compliance with collaboratively developed national standards. EMAP's Emergency Management Standard establishes a common set of criteria for disaster management, EM, and business continuity programs. The standard intends to be fair and equitable for EM programs seeking accreditation and choosing to adopt it. Accreditation is open to Federal, State, territorial, and local government EM programs.

As part of the pre-assessment, an EMAP-trained group of EM professionals from various organizations reviewed and evaluated the VHA EM program using the self-assessment process. The assessment team used the documentation provided by VHA to ascertain its compliance with each of the 63 EMAP standards. The primary purpose of these meetings was to make program personnel aware of any potential areas of non-compliance as far in advance of the exit interview as practicable to allow VHA to provide additional documentation if warranted. VHA will work through corrective actions prior to undergoing an actual full EMAP on-site assessment. The on-site assessment should be accomplished by the end of FY 2010.

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<sup>6</sup> NFPA, NFPA 1600®: Standard on Disaster/Emergency Management and Business Continuity Programs, 2010 Edition, available at <http://www.nfpa.org/aboutthecodes/AboutTheCodes.asp?DocNum=1600> (accessed June 29, 2010).

#### **4.5.1.12 VA Biosurveillance**

The VA is currently engaged in active biosurveillance utilizing the Electronic Surveillance System for the Early Notification of Community-Based Epidemics (ESSENCE) component of its Healthcare Associated Infection and Influenza Surveillance System (HAISS). VA ESSENCE was successfully employed in 2009–2010 to track novel H1N1 pandemic influenza cases, hospitalizations, and deaths within the VA. In support of Homeland Security Presidential Directive (HSPD)-21, the VA, along with DoD, transmits data daily to the CDC BioSense program to provide ongoing situational awareness of influenza activity and other syndromic outbreaks or potential bioterrorism events. VA staff is currently deployed at the CDC in Atlanta, Georgia, to assist and advise CDC staff on VA biosurveillance events and activities. The VA has also partnered with DoD whereby both agencies are creating a joint failover ESSENCE for ongoing, complementary biosurveillance in locations where medical facilities of both agencies co-exist. A pilot study of this combined program was completed in 2009 at the North Chicago Federal Health Care Center and has demonstrated enhanced situational awareness for biosurveillance events using combined agency data streams.

#### **4.5.2 Activities of Private Sector and Non-governmental Organizations**

Private and non-governmental organizations conduct activities to mitigate risks. The activities discussed in this section include: the American Association of Blood Banks (AABB) Inter-organizational Task Force on Domestic Disasters and Acts of Terrorism; the Blood Availability and Safety Information System (BASIS); Project ER *One*; the National Retail Data Monitor (NRDM); Business Executives for National Security (BENS); The Aidmatrix Foundation; and Electronic Mass Casualty Assessment and Planning Scenarios (EMCAPS).

##### **4.5.2.1 AABB Inter-organizational Task Force on Domestic Disasters and Acts of Terrorism**

The AABB is a professional association with approximately 8,000 individual members and 1,700 institutional members, including community blood centers, hospital-based blood banks and laboratories, and transfusion services. Its Inter-organizational Task Force on Domestic Disasters and Acts of Terrorism (Task Force) helps coordinate efforts to facilitate blood collection and distribution in preparation for and resulting from disasters affecting the blood supply. AABB serves as the designated coordinating entity for the Task Force. The Task Force is composed of representatives from all of the national blood organizations and other interested professional and commercial entities, as well as liaisons from governmental agencies, including HHS, FDA, CDC, and the Armed Services Blood Program. In the event of a disaster, the Task Force helps ensure that blood needs can be met and that the public receives clear and consistent messages about the need for blood collections.

Blood products are collected and stored primarily in centralized facilities and are delivered to hospitals on a just-in-time (JIT) basis to ensure maximum efficiency and to reduce outdating. During an emergency, there is a critical public health imperative that local and national blood

organizations work together to ensure that blood is quickly available for victims while controlling related impacts on the blood supply, such as a donor surge. The Task Force fulfills this role by coordinating national efforts and providing support to local organizations.

Since 2002, the Task Force has played a critical role in coordinating the blood-related activities in all major domestic disasters, as well as planning for national special security events and national exercises, and is specifically referenced in the National Response Framework. Most recently, the Task Force coordinated efforts to provide numerous shipments of needed blood to Haiti following its devastating January 2010 earthquake. The Task Force also provides blood centers and hospitals with substantial educational resources regarding disaster (including pandemic) preparedness.

#### ***4.5.2.2 Blood Availability and Safety Information System***

BASIS is a secure Web-based data collection, analysis, and reporting platform designed to collect preparedness and response-capabilities information from owners and operators within the U.S. blood industry. The program is managed and funded by HHS. The BASIS platform can produce a host of graphical analyses, including geospatial information system (GIS)-enabled mapping. The data are secured under a categorical inclusion accreditation from the DHS PCII program.

Since 2008, more than 100 hospital centers have been volunteering daily data of their blood supply inventories, and greater than 95 percent of the 130 U.S. blood collection centers have been participating in BASIS. The BASIS program has enjoyed 100 percent availability and use during HHS participation in all-hazards preparedness and response. Weekly BASIS reports are compiled and submitted to several HHS staff and operating division heads. In late 2009, the BASIS program partnered with the U.S. Army's Telemedicine and Advanced Technology Research Center program under a combined HHS/DoD Small Business Innovative Research phase II proposal.

#### ***4.5.2.3 National Retail Data Monitor***

The NRDM monitors sales of over-the-counter (OTC) healthcare products to identify disease outbreaks as early as possible. Since its beginning in December 2002, NRDM has grown to more than 21,000 participating retail pharmacy, grocery, and mass merchandise stores.

#### ***4.5.2.4 Business Executives for National Security***

BENS helps create public and private partnerships to aid in dealing with catastrophic events. BENS has successfully organized partnerships to mitigate risks, respond to disasters and public health emergencies, and help communities recover from disasters through the joint efforts of government and private organizations.

#### 4.5.2.5 *The Aidmatrix Foundation, Inc.*

The Aidmatrix Foundation, Inc., is a 501(c)3 not-for-profit organization that collaborates with more than 35,000 business, non-profit, and government partners to mobilize more than \$1.5 billion in aid on an annual basis worldwide. The donated goods, money, and services impact the lives of more than 65 million people. The Aidmatrix Foundation has played a critical role in organizing donations for disaster relief in Haiti following the 2010 earthquake.

#### 4.5.2.6 *Electronic Mass Casualty Assessment and Planning Scenarios*

The Johns Hopkins Office of Critical Event Preparedness and Response has developed EMCAPS, a free Web-based tool. EMCAPS can be used to predict the impact of an influenza epidemic, bioterrorist attack, flood, or plane crash on individual hospitals. The tool accounts for such elements as number of victims, pathogen-carrying wind patterns, available medical resources, bacterial incubation periods, and bomb size and generates the anticipated outcomes of disaster-planning scenarios developed by DHS.

### 4.6 Education, Training, and Outreach

Education, training, and outreach are essential to ensuring engagement in CIP activities by HPH Sector partners at all levels of government and the private sector. The SSA routinely reaches out to sector partners through association engagement and direct outreach at the State, local, tribal, territorial, and private sector levels. Education, training, and outreach activities include meeting and conference participation, exercise participation, and targeted briefings.

#### Significant Education, Training, and Outreach Accomplishments

- *Conducted three classified briefings to inform key partners of threats to the sector.*
- *Assisted FEMA with the development of a course on critical infrastructure protection for the HPH Sector.*

#### 4.6.1 Education and Training

The SSA invests significant time and resources reaching out to educate and inform sector members of the CIP Program. These outreach and educational activities include presenting at industry conferences, hosting knowledge-sharing sessions with SMEs, conducting webinars, and presenting classified briefings.

The SSA hosts meetings that enable experts within the sector to share knowledge with each other about specific CIP-related topics. On the basis of an examination of best practices and new approaches to operational planning processes by the Joint Advisory Work Group (JAWG), it became apparent that the sector needed an integrated approach to business continuity planning (BCP) and operational planning that included a focus on medical surge needs, patient needs, interdependencies, local and regional cooperation, and other factors. In October 2009, JAWG



convened SMEs for a full-day COOP/BCP meeting to discuss a number of COOP topics, including legal challenges, patient issues, and methodologies for improved planning, regional programs, security, and facility design. The sector intends to form communities of practice when there is an interest in continuing the dialogue from these sessions.

As part of the Private Sector LNO Program, participants have a training curriculum they must complete. The briefings and courses are as follows:

- HHS CIP LNO Briefing;
- FEMA Independent Study (IS):
  - IS-100.HC: Introduction to Incident Command System (ICS) for Healthcare/Hospitals;
  - IS-200.HC: ICS for Single-Resources and Initial-Action Incidents;
  - IS-700.a: NIMS – An Introduction;
  - IS-800.b: NRF – An Introduction;
  - IS-808: ESF #8 – Public Health and Medical Services;
  - IS-821: CIKR Support Annex;
  - IS-860.a: Introduction to the NIPP;
- HHS WebEOC Training;
- InSIGHT System Training;
- HHS Secretary's Operations Center Operations Briefing; and
- ICS 300/400 (Recommended).

The courses ensure that the LNOs are able to be effective when providing their expertise to inform the Federal response and when assisting in the dissemination of information to the rest of the sector.

Because of the expanding user base and the organizational changes that have been made to the HSIN-HPH portal, the SSA periodically conducts online webinars to provide a demonstration of the portal as well as an overview of recent changes and basic functionality. Throughout the reporting period, three HSIN-HPH webinars were conducted and were attended by both new and experienced HSIN-HPH users. The webinars received positive feedback as being a helpful way to explain the objectives and benefits of the portal. SSA representatives also performed in-person HSIN training sessions at the 2009 Public Health Preparedness Summit and during visits to ASTHO, NACCHO, the Association of Public Health Laboratories, and the Council of State and Territorial Epidemiologists.

The SSA collaborates with the HHS Office of Security and Strategic Information (OSSI), the DHS Homeland Infrastructure Threat and Risk Analysis Center (HITRAC), and the Federal Bureau of Investigation (FBI) in preparing and delivering these briefings. Briefings include a presentation by each agency, followed by an open discussion of potential threat impacts and response actions. In addition to classified briefings, the SSA conducts unclassified briefings based on redacted information with larger audiences to share information with all sector partners. Three briefings were conducted during this first year of this initiative, and the SSA plans to conduct four annual briefings in coming years. In addition, the SSA provided an unclassified



threat briefing during an SCC monthly teleconference and will continue to do so as requested by the SCC.

To educate partners on various CIP-related topics and ongoing activities within the SSA, members of the CIP Program Office often publish articles in various healthcare and public health publications. During the reporting period, staff published the following articles:

- *Safety in Numbers: Your Group's Emergency Preparedness Should Mesh with the Community's.* Published by Medical Group Management Association, September 2009.
- *"Information Sharing in the Healthcare and Public Health Sector: Current Efforts and the Path Forward."* Published in the NIPP Newsletter, October 2009.

#### 4.6.2 Association, State, and Local Outreach Activities

The SSA regularly attends and presents at sector industry conferences to inform attendees about the CIP Program and to provide subject matter expertise concerning a variety of CIP-related topics. Staff from the CIP Program Office present each year at the Public Health Preparedness Summit, which is attended by more than 1,500 partners from State, local, tribal, and territorial health agencies; the Federal government; and the private sector. They also present at the annual State and Territorial Directors of Public Health Preparedness Meeting as well as several industry conferences, including the SARMA conference, the AHRMM conference, the IAHS Annual General Meeting, the Physical Cyber Security Conference, the PHIN conference, and the ESF #8 Integrated Training Summit, to name a few. At these conferences, the SSA describes the unique opportunities and challenges of enacting CIP activities within the HPH Sector and provides information on how to engage in national CIP efforts, including the HSIN portal.

The SSA realizes the need to enhance State- and local-level partnerships and continues to take steps to strengthen those partnerships by raising awareness, sharing information, and providing support for State and local CIP efforts. The SSA presented on CIP at the 2009 State Public Health Preparedness Director's Annual Meeting and at the 2010 Public Health Preparedness Summit, the two key events for State and local preparedness directors. The goal of these presentations was to demonstrate the value of the national HPH CIP program to State and local health agencies.

The SSA works with several State health agencies that have initiated their own CIP programs. These States recognize the value of CIP at the state level, and are working with other State agencies and the private sector to implement programs that mirror Federal CIP efforts. The SSA shares information, lessons learned, and various governance documents from Federal CIP programs to assist States with their CIP efforts.

After the SSA relaunched the HSIN-HPH portal in March 2009, the focus shifted to increasing the user base. The SSA coordinated with and reached out to sector professional and industry associations to distribute invitations to their members describing the value of the portal and providing instructions for requesting an account. Some of the associations the SSA reached out to were the AHA, IAHS, ASTHO, NACCHO, National Funeral Directors Association (NFDA),

AHRMM, and Association for Professionals in Infection Control (APIC). This approach resulted in the successful addition of hundreds of HSIN-HPH portal account holders.

### 4.6.3 Emergency Response Outreach Activities

Because the HSIN-HPH portal is central to the sector's information-sharing strategy, the SSA leverages the portal as the primary information-sharing mechanism with sector partners during an incident or emergency.

At the onset of an event, an incident-specific site is created within the HSIN-HPH portal to house incident-related documents, such as situation reports, guidance, and maps, as well as discussion threads and announcements. This approach ensures that sector partners and stakeholders have timely information during these events, as was the case during the 2009 H1N1 influenza outbreak. Usage statistics demonstrated the benefit of initiating the 2009 H1N1 incident site as it typically had higher usage volumes during the peak of the outbreak than the main HSIN-HPH portal did.

The HPH Sector uses conference calls during incidents as another way to share information. To ensure sector stakeholders and partners had timely information about the 2009 H1N1 influenza outbreak and the January 2010 earthquake in Haiti, the SSA held weekly or biweekly conference calls with members of the sector to provide updates and gather pertinent information from owner-operators. The calls enabled valuable information exchange that was helpful in assisting in the response to and recovery from both incidents.

The SSA recently finalized an alerts, warnings, and notifications standard operating procedure that defines the management and distribution of alerts and notifications to and within the HPH Sector during both steady-state operations and incidents. The SSA leverages listserv technology and is in the process of implementing social media tools to provide urgent incident-related alerts to sector partners.

### 4.6.4 Exercises

The HPH Sector participated in the 2009 NLE in several ways, including testing its ability to quickly notify sector partners of a teleconference to discuss the exercise scenario. During the teleconference, the SSA explained to sector partners what was currently known about the scenario and what actions the Federal government was taking to respond within the exercise. This call also provided an opportunity to question sector partners about their information needs during an incident similar to the one being tested in the exercise.

The sector looks forward to continuing to expand its education, training, and outreach activities to enhance awareness of the HPH CIP Program and increase participation in its activities.

## 4.7 International Coordination

International coordination is of special importance to the HPH Sector. Diseases travel easily across international borders, and many of the products and services upon which the sector relies are supplied by foreign countries.

In addition to disease threats, there are also significant infrastructure dependencies across international borders. In many Canadian border states, healthcare personnel travel across the border daily for work. In the event of an emergency, the sustainability of the HPH Sector would depend in part on ensuring that these workers are able to cross the border freely. State and local governments and the private sector have found that they must work closely with authorities at the border to address this issue. All elements of the sector have worked with international partners over the past year to address this and similar concerns.

### 4.7.1 Disease Surveillance and Containment

Protection of the workforce is a key goal of CIP for the sector. The sector achieves this through public health measures that include disease surveillance, isolation and quarantine, sanitation, risk communication, and mass prophylaxis.

The Federal government continues to operate and provide funding for international disease surveillance efforts through a variety of initiatives. The Security and Prosperity Partnership provides a platform for coordinating these efforts among the United States, Canada, and Mexico. In 2007, the three parties signed a Trilateral Declaration of Cooperation for Public Health Emergencies. As an extension of these efforts, in 2008 HHS assigned its first liaison in Canada for public health emergencies. During the 2009 H1N1 influenza response, strong trilateral relationships facilitated the sharing of information and clinical samples to support the epidemiological investigation of the outbreak.

Additional activities are taking place along the northern and southern U.S. borders. The U.S.-Mexico Border Health Commission provides a platform for coordination of disease control efforts. Along the Canadian border, a number of interstate regional initiatives link State public health departments with their Canadian counterparts. These initiatives include the Eastern Border Health Initiative, the Great Lakes Border Health Initiative, and the Pacific Northwest Emergency Management Agreement. The Early Warning Infectious Disease Surveillance (EWIDS) project provides funds for disease detection along the U.S. borders with Canada and Mexico. EWIDS is administered by HHS and provides funding for State activities through the PHEP cooperative agreement program.

At the same time, the United States is working with international partners to develop systems to track the spread of potential pandemic strains overseas. The Federal government has assisted in the development of laboratory capacity in key foreign countries and is collaborating with the World Health Organization on international disease surveillance. HHS and the Government of Panama are developing a joint program for disease surveillance and workforce protection in the critical Panama Canal Zone.

The sector has been especially focused this past year on cross-border infectious disease threats, particularly pandemic influenza. The CDC Division of Global Migration and Quarantine (DGMQ) operates quarantine stations at U.S. ports of entry to limit the introduction of infectious diseases to the United States and to prevent their spread. Over the past year, DGMQ and other Federal agencies have continued a series of planning activities with State and local health agencies to develop and refine strategies for screening passengers at U.S. ports of entry during the early stages of a pandemic. In the event of a pandemic originating overseas, an augmentation of the routine border screening currently performed by quarantine stations and the establishment of processes to handle large numbers of potentially infected or exposed individuals would be required.

### 4.7.2 Foreign Dependencies

The sector is increasing efforts to identify critical infrastructure overseas. As a result of the 2009 Critical Foreign Dependencies Initiative (CFDI), in partnership with DHS and the U.S. Department of Commerce (DOC), the sector is exploring a pilot project that will enhance its understanding of critical foreign dependencies. Foreign dependencies are often extremely complex due to the globalization of industry and the international supply chain. For a single product, its bulk materials, product assembly, and packaging may each be provided by a separate country. The pilot program will leverage the expertise gained by the DOC in studying dependencies in other industries under the Defense Production Act to address the unique challenges of the HPH Sector. The pilot program will be conducted on a voluntary basis with private sector partners to identify key vulnerabilities in the sector's international supply chain.

The shift in the manufacturing of certain medical devices from domestic to international manufacturers leaves certain segments of the sector's medical supply chain vulnerable to risks outside of U.S. control. In 2008, the sector identified and developed requirements to address the need for research in this area. To date, the proposed research project has not yielded funding; however, there has been renewed interest in the international medical supply chain resulting from the April 2009 H1N1 influenza outbreak. This event highlighted the dependency on international manufacturers and demonstrated firsthand that the combination of JIT business models coupled with the Nation's reliance on international resources could result in negative health consequences to the population of the United States and its territories.

The FDA Drug, Biological Product, and Medical Device Shortage Programs continue to examine both domestic and international threats to the availability of medically necessary products. Many private sector organizations in the HPH Sector are undertaking similar initiatives on a company-by-company basis.

### 4.7.3 International Lessons Learned

The HPH Sector has learned about the vulnerability of healthcare facilities to terrorism from the experiences of international partners in responding to sector threats. The sector has interacted with counterparts in Israel, the United Kingdom, and other countries to learn more about the risks to the HPH Sector from direct attacks. In future years, further coordination with

international partners may assist the sector in identifying best practices in preparing for these threats.

## Section 5: R&D and Other CIKR Protection and Resilience Mission Needs

The HPH Sector R&D/MS&A JAWG has been in existence since September 2007. It is composed of SCC and GCC members as well as other SMEs from both the public and private sector. The work group continues to focus on efforts that contribute to consequence reduction and overall operational sustainability of sector services during an event.

### 5.1 Work Group Update

Over the past year, the JAWG sub-workgroups for healthcare facility security, biosurveillance, and COOP have made significant progress. Each of these sub-workgroups pursues initiatives that strive to improve the sector's ability to respond to and recover from significant events and reduce the negative consequences associated with these events, including the loss of lives, economic impacts, psychological impacts, and mission degradation. The following bullet points reflect the current status of each initiative.

- **HPH JAWG Facility Security Sub-Workgroup.** Following a detailed examination of current healthcare facility design and renovation approaches, it became evident to sector members that a basic risk assessment process was needed to inform design requirements related to security, safety, and sustainability. The resulting effort focused on development of a security and design analysis tool to assist owners and operators in understanding the contribution of security and protective measures to reduce the negative effects of an event. The tool provides a series of questions regarding facility attributes, threats, and security features that combine to present the user with an overall risk characterization. Once complete, the tool will offer a series of consequence-mitigation strategies that can be integrated into the design in order to help achieve a more resilient physical structure, enhanced security features that can be augmented to manage surge, and improved patient safety at the point of care. The workgroup anticipated finalizing the tool in the spring of 2010 and plans to release a white paper to introduce the tool to sector owners and operators.
- **HPH JAWG Biosurveillance Sub-Workgroup.** Biosurveillance is a rapidly growing field that seeks to enhance the detection of outbreaks through the analysis of both new and existing data sources. The 2008 draft National Biosurveillance Strategy for Human Health (NBSHH) highlighted, as part of the overall gap analysis, a lack of capacity and skill sets in the workforce available to manage a significant bioterrorist attack or disease outbreak. The strategy highlights the need to focus on developing “a workforce that is available, prepared, and collaborating to adapt to evolving threats and crises.”<sup>7</sup>

Following a review of the NBSHH, the JAWG determined that addressing this priority was a natural extension of its initiatives. The HPH Sector formed a Biosurveillance Sub-

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<sup>7</sup> HSS, CDC, *National Biosurveillance Strategy for Human Health*, Ver. 2, February 2010, p. 26, available at [http://www.cdc.gov/osels/pdf/NBSHH\\_V2\\_FINAL.PDF](http://www.cdc.gov/osels/pdf/NBSHH_V2_FINAL.PDF) (accessed June 30, 2010).

Workgroup to develop a white paper that examines the current state of public health education in the area of biosurveillance. The work group focused its efforts on identifying gaps in education and providing recommendations for strategies to increase biosurveillance capacity and enhance the capabilities of workforce members working in the field of biosurveillance. This research will result in a paper intended to discuss the lack of adequate biosurveillance capacity that results from gaps in the biosurveillance workforce. The paper defines the discipline of biosurveillance, a term which until now has only been used to refer to someone in public health that would be called to respond to a bio-event. The document is intended to inform Federal leadership, university programs, and public health organizations on the criticality of the biosurveillance specialty and methods to achieve a sustainable cadre of workers as the Nation moves into the 21st century.

- **HPH COOP Sub-Workgroup.** Over the past year, the JAWG COOP Sub-Workgroup has focused its efforts on identifying critical components of operational sustainability that are central to HPH. The complexity of sector operations, coupled with the multiple dimensions of response and recovery, necessitated that the work group examine best practices and new approaches to inform the operational planning processes in HPH. The result of these efforts revealed that the sector needed to take an integrated approach to BCP and operational planning that included a focus on medical surge needs, patient needs, interdependencies, local and regional cooperation, and other factors. To begin to define and address these challenges, the work group held an all day meeting that brought together thought leaders from across the sector to discuss the legal challenges, patient issues, methodologies for improved planning, regional programs, security, and approaches for building operational sustainability into the overall physical structure of facilities. The findings from this meeting were presented at the 2010 Public Health Preparedness Conference and will be published in a white paper. Continued efforts will be supported through an HPH COOP Community of Interest of sector partners.

## 5.2 New R&D and MS&A Capability Gaps/Mission Needs

This section addresses R&D and MS&A capability gaps/mission needs in three areas: healthcare facility security capability gaps, cyber capability gaps, and additional capability gaps not addressed in the previous two areas.

### 5.2.1 Healthcare Facility Security Capability Gaps

Healthcare facility security is reliant on a number of intersecting components, including design guidelines, technology, security controls, soundness of infrastructure, personnel, and policies and procedures, yet most assessments and standards narrowly focus on just a few of these areas. As a result, there are vast disparities across the sector in the robustness and effectiveness of facility security. For many, these disparities go unobserved because the delivery of healthcare is not intrinsically tied to security.



There are a number of other reasons for designing physical and technical security into buildings. Each component has its role in reducing the consequences of all hazards, and more importantly, protecting patients and workforce from the impacts of negative events. As an example, numerous hospitals have experienced violence against their employees from angry or unstable patients. Some healthcare facilities, in the path of disasters, have become the victim of looters or insider attacks attempting to access pharmacies and drug caches. Still others have been impacted by hurricanes powerful enough to destroy them in whole or in part, rendering them unable to fulfill their mission. Designing security into structures will reduce the impacts of these events and provide mechanisms to proactively respond to the changing dynamics of both high-impact and seemingly mundane events.

Tables 5-1 and 5-2 identify capability gaps in design guidelines and healthcare facility security.

Table 5-1: Design Guidelines: Security and Design Decision Support Tool

Question	Response
Statement Tracking Number	2010-002-Healthcare and Public Health
Proposed Title of Mission Need	Decision Support Tool: Healthcare Facility Security and Design Analysis
2010 Priority Number	1
Is this Submission a Modeling, Simulation, and Analysis (MS&A) Mission Need?	Yes
Goal/Objective/Driver to which Mission Need Responds	Physical Asset Protection; Service Continuity; Workforce Protection
Theme	Advanced Infrastructure Architectures; Analysis and Decision Support Systems; Response, Recovery, and Reconstitution Tools
Description of Operational Requirement	<p>The HPH Sector JAWG Facility Security Sub-workgroup has developed a survey-based tool to assess security and design requirements for new and renovated structures. The current version of the tool allows users to identify risks to their facility, assess design needs, and make informed decisions regarding security technologies. In its current state, however, the tool does not provide an automated assessment and intuitive reporting capability, which will likely have a negative impact on usability. As an automated capability, this tool will have improved functionality increasing adoption rates by both architects and healthcare organizations.</p> <p>It is believed that as this tool is adopted, the result will be more robust facilities that are able to maintain the provision of care and public health services during disasters while improving the overall safety of the environment. The added benefit of this tool is that it will save organizations time and money and increase the likelihood of identifying and addressing security and medical surge needs. The required capability</p>

Table 5-1: (Cont.)

Question	Response
	should: <ul style="list-style-type: none"> <li>▪ Have web-based software capability;</li> <li>▪ Have underlying analysis capability that links threat, vulnerability, and consequence reduction data;</li> <li>▪ Have a small download footprint;</li> <li>▪ Have automated report capability;</li> <li>▪ Be agile and easy to update as design standards and security requirements evolve, or as the threat environment changes;</li> <li>▪ Be cost effective;</li> <li>▪ Be broadly available and easily accessible; and</li> <li>▪ Be easy for the user to update as plans/designs change.</li> </ul>
Identification of the End User	<ol style="list-style-type: none"> <li>1. Architects;</li> <li>2. Security and safety professionals;</li> <li>3. Healthcare facility Chief Executive Officers (CEOs) and/or decision-making management;</li> <li>4. Emergency planners;</li> <li>5. Community planners, to ensure integration of hospital/healthcare facility emergency preparedness; and</li> <li>6. Other (non-healthcare) facility managers wishing to address all-hazards consequence reduction, emergency preparedness, and response planning (direct cross-sector implications).</li> </ol>
Identification of Existing Related Capabilities or Technology	No current capability exists.

Table 5-2: Healthcare Facility Security: Scenario-Based Security Assessment Tool

Question	Response
Statement Tracking Number	2010-003-Healthcare and Public Health
Proposed Title of Mission Need	Healthcare Facility Security: Scenario-Based Security Assessment Tool
2010 Priority Number	2
Is this Submission a Modeling, Simulation, and Analysis (MS&A) Mission Need?	Yes
Goal/Objective/Driver to which Mission Need Responds	Physical Asset Protection; Service Continuity; Workforce Protection
Theme	Advanced Infrastructure Architectures; Analysis and Decision Support Systems; Response, Recovery, and Reconstitution Tools

Table 5-2: (Cont.)

Question	Response
Description of Operational Requirement	<p>Research is necessary to determine the core data elements of facility security and design in order to create a modeling capability suitable to healthcare and public health.</p> <p>The MS&amp;A tool should:</p> <ol style="list-style-type: none"> <li>1. Test security features to determine which aspects of the facility need improvement and assist management in developing plans for future security design features;</li> <li>2. Apply risk scenarios simulating a disaster or an emergency specific to a healthcare facility in order to predict the consequences based upon previously populated data elements;</li> <li>3. Provide a detailed analysis of vulnerabilities highlighted through the simulated event;</li> <li>4. Provide healthcare facility managers with sufficient information to help institute an effective plan for implementation of security measures; and</li> <li>5. Test retrofitting implementation (adjust features/data input based on improvements); this requires building into the tool the capability to re-simulate each scenario with varying inputs .               <ol style="list-style-type: none"> <li>a. This feature would be used to demonstrate the value of implementing (as well as the costs of not implementing) safety measures/design changes prior to the onset of an event.</li> <li>b. This feature would allow for a cost-benefit analysis of implementing safety/design changes in a healthcare facility.</li> </ol> </li> </ol>
Identification of the End User	<ol style="list-style-type: none"> <li>1. Architects;</li> <li>2. Healthcare facility CEOs and/or decision-making management;</li> <li>3. Owners and operators;</li> <li>4. Emergency managers;</li> <li>5. Community planners, to ensure integration of hospital/healthcare facility emergency preparedness and response plans with those of the community; and</li> <li>6. Other (non-healthcare) facility managers wishing to address all-hazards consequence reduction, emergency preparedness, and response planning (direct cross-sector implications).</li> </ol>
Identification of Existing Related Capabilities or Technology	<p>Leverage Infrastructure Survey Tool (IST) and Healthcare and Public Health Security and Design Analysis tool (in development).</p>

### 5.2.2 Cyber Capability Gaps

As the HPH Sector increases its reliance on cyber infrastructure in response to legislation mandating the adoption of electronic health records (EHRs), coupled with the proliferation of health information exchanges, issues relating to security will rise in national significance. Botnets, malware, and other Web-based vulnerabilities exist across the sector due to a number of factors, not the least of which includes lax security measures in the design of technologies and at the network boundary. The potential consequences of an attack on critical IT systems, as well as the magnitude of such consequences, remain generally unknown and unanalyzed. The

importance of modeling cyber disruptions cannot be understated, as it will play a significant role in addressing mitigation strategies and validating the effectiveness of current security controls. Disruptions to cyber infrastructure will continue to increase as the sector’s reliance on the internet and IT assets increases. The sector must, therefore, develop robust tools to assess the potential consequences before a significant event occurs.

Tables 5-3 and 5-4 identify capability gaps in cyber disruptions and in cross-sector cyber interdependencies and cascading consequences.

Table 5-3: Cyber Disruptions

Question	Response
Statement Tracking Number	2010–004–Healthcare and Public Health
Proposed Title of Mission Need	Cyber Disruptions to Healthcare and Public Health
2010 Priority Number	1
Is this Submission a Modeling, Simulation, and Analysis (MS&A) Mission Need?	Yes
Goal/Objective/Driver to which Mission Need Responds	Service Continuity Goals: Continue the provision of essential services (e.g., patient care, public health) and facilitate essential response and recovery functions both during and following an event.
Theme	Advanced Infrastructure Architecture; Response, Recovery, and Reconstitution Tools
Description of Operational Requirement	The desired outcome is analysis that: <ol style="list-style-type: none"> <li>1. Provides key attributes of systems or infrastructure likely to be targets of cyber attacks;</li> <li>2. Provides scientific data that details the potential vulnerabilities in HPH systems that are likely to be exploited for purposes of infiltrating health systems;</li> <li>3. Supports planning for IT investments and security;</li> <li>4. Offers recommendations for improvements to medical systems or information management processes; and</li> <li>5. Supports situational awareness and incident response requirements.</li> </ol>
Identification of Existing Related Capabilities or Technology	Unknown

Table 5-4: Cyber: Cross-Sector Cascading Consequences

Question	Response
Statement Tracking Number	2010-005-Healthcare and Public Health
Proposed Title of Mission Need	Cyber Interdependencies: Cascading Consequences
2010 Priority Number	2
Is this Submission a Modeling, Simulation, and Analysis (MS&A) Mission Need?	Yes
Goal/Objective/Driver to which Mission Need Responds	HPH Sector Cyber Goals; Federal Information Security Management Act (FISMA), HSPD-7, HSPD-23
Theme	Analysis and Decision Support Systems; Protection and Prevention Systems.
Description of Operational Requirement	The sector requires the operational capability to simulate and examine the potential effects of both cascading consequences and direct attacks on sector systems and infrastructures in order to: <ul style="list-style-type: none"> <li>▪ Identify weaknesses/vulnerabilities in current technologies and practices;</li> <li>▪ Estimate consequences to HPH services, programs, and individuals resulting from disruptions;</li> <li>▪ Quantify impacts to sector assets resulting from the loss of data, service capabilities, identity theft, etc.;</li> <li>▪ Provide public agencies and the private sector with scientific data to support IT investment dollars related to technical security;</li> <li>▪ Develop strategies to mitigate infrastructure vulnerabilities;</li> <li>▪ Develop/recommend guidelines to improve mission assurance; and</li> <li>▪ Work with appropriate standards boards and technologists to identify mitigation strategies to improve system security.</li> </ul>
Identification of the End User	<ol style="list-style-type: none"> <li>1. Chief Executive Officers (CEOs)</li> <li>2. Chief Information Officers (CIOs)</li> <li>3. Chief Technology Officers (CTOs)</li> <li>4. Chief Information Security Officers (CISOs)</li> <li>5. Information Security Officers/Professionals</li> </ol>
Identification of Existing Related Capabilities or Technology	Pending follow-up with DHS Science and Technology Directorate (S&T) National Cyber Security Division (NCSD).

### 5.2.3 Additional Capability Gap Statements

The HPH Sector has identified capability gaps that lie outside the areas of physical and cybersecurity. These capability gaps are addressed in Tables 5-5, 5-6, and 5-7.

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**Table 5-5: Emergency Response Team Disaster Site Environment Reporting Database and Environment Data for Medical Countermeasures**

<b>Question</b>	<b>Response</b>
Statement Tracking Number	2010-001-Healthcare and Public Health
Proposed Title of Mission Need	Emergency Response Team Disaster Site Environment Reporting Database & Environment Data for Medical Countermeasures.
2010 Priority Number	1
Is this Submission a Modeling, Simulation, and Analysis (MS&A) Mission Need?	<p>Yes.</p> <p>In recent years, progress has been made in design and use of electronic documentation and sensor technologies. The City of Portland, Maine, for example has established an electronic database of as-built plans for critical infrastructure buildings that can be downloaded to the laptop computers of first responders as they arrive at a disaster site. This database informs the first responders about the environment they are about to enter in response to a man-made or natural disaster. At the same time, building sensors for fire, smoke, and structural integrity have been designed and tested, and scanners are available for recovering those data.</p> <p>Lacking is an integration of these two technologies into a secure, electronic, as-built design database and sensor data retrieval system that first responders can access as they arrive at a disaster site. Electronic, as-built 3-dimension plans provided from a secure database to the first responders can facilitate informed decision making of search and rescue within the building, while sensors can inform first responders and medical personnel of the building's structural integrity, presence or absence of smoke, fire, toxins, or biological-chemical-radiological contaminants and the location of occupants. These technologies need to be integrated, modeled, and simulated, and a data delivery system or decision support tool needs to be established.</p> <p>This technology system is valuable across multiple sectors including the Emergency Services, Defense Industry Industrial Base, Healthcare and Public Health, and Commercial Facilities Sectors.</p>
Goal/Objective/Driver to which Mission Need Responds	HSPD-7, HSPD-21, ESF #8, ESF #15, and NIPP SSP identified requirements and sector risk goals and objectives.
Theme	Detection and Sensor Systems; Protection and Prevention Systems; Analysis and Decision Support Systems; Response and Recovery Tools
Description of Operational Requirement	<ul style="list-style-type: none"> <li>▪ The system will provide first responders and medical personnel with accurate up-to-the-minute data on the environment inside a disaster site and provide current building layout (as-builts) to facilitate search, rescue, and evaluation of the structure for continued or partial occupancy and application of medical countermeasures. This will speed effective search, rescue, and application of medical countermeasures while simultaneously reducing risk to first responders and medical personnel.</li> <li>▪ This technical capability will be used in all man-made and natural disasters, including routine fire, and in terrorism and police activity such as hostage situations where the buildings have been included</li> </ul>

Table 5-5: (Cont.)

Question	Response
	<ul style="list-style-type: none"> <li>▪ within the secure database of electronic as-builts and sensors have been put in place.</li> <li>▪ The interface will be with existing mobile laptop and scanner technologies and with secure electronic databases of building as-builts and diverse building sensors.</li> <li>▪ The key characteristics/attributes of this solution are: the ability to provide accurate and timely data on the actual conditions inside a building; the security of the database through encryption, the interoperability of the data, and the ability to use diverse hardware to download and access building as-builts and sensor data; and the ability of those data to be readily understandable and used by first responders and other emergency response personnel.</li> </ul>
Description of Secure Implementation	<ul style="list-style-type: none"> <li>▪ The database would need to be encrypted to assure its security and prevent intrusion by outsiders. This is especially true for the electronic as-builts that first responders would download as they arrived at disaster event.</li> <li>▪ Examples of conditions that would result from the successful, secure implementation of this technology include:               <ul style="list-style-type: none"> <li>▪ Significant reduction in rescue and evacuation timeframes; Increased speed and accuracy of building damage assessment;</li> <li>▪ Greater predictability of a structure's ability to withstand subsequent damage from aftershocks in an earthquake event; and</li> <li>▪ Reduction of potential injury and loss of life to the first responders themselves.</li> </ul> <p>In addition, the owners of buildings (hospitals, schools, public assembly structures, etc.) will have accurate and detailed information necessary for them to determine if they should continue to occupy the building or sections of the building. It will also help them determine the condition of other buildings to which they may have planned to relocate their operations and if those operations can be safely moved there.</p> </li> <li>▪ Key aspects that characterize a successful, secure implementation of this new technology include:               <ul style="list-style-type: none"> <li>▪ More rapid and effective response to disasters in buildings;</li> <li>▪ Reduced timeframes to rescue those trapped in buildings;</li> <li>▪ More accurate assessment of damage done to buildings;</li> <li>▪ Reduced injuries and loss of life to both first responders and those trapped in buildings; and</li> <li>▪ More rapid and accurate assessment of other buildings to which critical functions (hospitals) or operations can be safely relocated.</li> </ul> </li> </ul>
Identification of the End User(s)	<ol style="list-style-type: none"> <li>1. First responders from fire, police, Emergency Medical Services (EMS), and building and public works departments in a jurisdiction</li> <li>2. Building owners, building operations managers, and those staff in charge of building functions</li> <li>3. EOC in terms of gaining accurate assessment of damage done to critical structures in a disaster</li> </ol>



Table 5-5: (Cont.)

<p>Identification of Existing Related Capabilities or Technology</p>	<p>Preliminary work in the development of secure databases of electronic as-builts has been done by the Alliance for Building Regulatory Reform in the Digital Age through Robert Wible &amp; Associates and by the City of Portland, Maine.</p> <p>Sensor work has been performed by the FIATECH Consortium and several universities affiliated with FIATECH and by the National Institute of Standards and Technology (NIST).</p>
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Table 5-6: Cross-Sector Interdependency Analysis

<p>Statement Tracking Number</p>	<p>2010-006-Healthcare and Public Health</p>
<p>Proposed Title of Mission Need</p>	<p>Cross-Sector Interdependency Analysis</p>
<p>2010 Priority Number</p>	<p>2</p>
<p>Is this submission a Modeling, Simulation, and Analysis (MS&amp;A) Mission Need?</p>	<p>Yes</p>
<p>Goal/Objective/Driver to which Mission Need Responds</p>	<p>Service Continuity Goals: Continue the provision of essential services (e.g., patient care, public health) and facilitate essential response and recovery functions both during and following an event.</p>
<p>Theme</p>	<p>Advanced Infrastructure Architecture; Response, Recovery, and Reconstitution Tools</p>
<p>Description of Operational Requirement</p>	<p>The desired outcome is an MS&amp;A tool that:</p> <ol style="list-style-type: none"> <li>1. Prioritizes interdependencies based on importance to the sector;</li> <li>2. Identifies alternate strategies for service continuity in the event that a key resource is lost or degraded;</li> <li>3. Provides quantitative data of crisis scenarios to be leveraged for planning, preparedness, and response activities; and</li> <li>4. Leverages exercise data to aid in the development of mitigation and alternate resource strategies in support of preparedness and response.</li> </ol>
<p>Identification of Existing Related Capabilities or Technology</p>	<p>Unknown</p>

Table 5-7: Cascading Consequence Analysis

Statement Tracking Number	2010-007-Healthcare and Public Health
Proposed Title of Mission Need	Compound Threat: Cascading Consequence Analysis
2010 Priority Number	3
Is this submission a Modeling, Simulation, and Analysis (MS&A) Mission Need?	Yes
Goal/Objective/Driver to which Mission Need Responds	Service Continuity Goals: Continue the provision of essential services (e.g., patient care, public health) and facilitate essential response and recovery functions both during and following an event.
Theme	Advanced Infrastructure Architecture; Response, Recovery, and Reconstitution Tools
Description of Operational Requirement	<ol style="list-style-type: none"> <li>1. Empirical data on economic or loss of life impacts resulting from cascading effects of all hazards;</li> <li>2. Scientific analysis that can be integrated into a decision-support tool for purposes of situational awareness and incident command and control; and</li> <li>3. Development of a decision-support tool that can be leveraged at the local level and regional level from planning, response, and recovery operations.</li> </ol>
Identification of Existing Related Capabilities or Technology	Unknown

### 5.3 Progress on Prior Capability Gaps/Mission Needs

Over the past two years, The National Institute for Hometown Security (NIHS) has selected eight HPH Sector capability gap statements (CGSs) for project proposal. NIHS is a DHS-funded program that accomplishes research projects through the Kentucky Homeland Security University Consortium, which consists of all public universities in Kentucky and the private universities and colleges affiliated with the Association of Independent Kentucky Colleges and Universities.<sup>8</sup> The CGSs selected by NIHS are in various stages of R&D from proposal development to funding to project initiation. Table 5-8 provides an update on these CGSs and describes the sector capabilities that will result from the projects when they are completed.

Table 5-8: Progress on Prior Capability Gap Statements

Statement Tracking Number	2008-HPH-003
Requirement Title	Incident Command Decision Support Tool
Action	In March 2010, the NIHS awarded a \$1.7 million contract to Murray State University to develop an incident command decision-support tool for HPH. The project addresses the need for real-time situational awareness during disruptive events. Existing decision support systems tend not to be focused on the medical community. Thus, data elements, data aggregation, and analysis capabilities do not support incident management in the context of HPH. Further, the types of decisions that must be made, such as how to use scarce resources, alternative management strategies during surge, escalation triggers, and other requirements that are necessarily informed by situational awareness, are not tailored to the sector.
Status	The objective of this project is to develop a decision-support system that will assist a local community in the provision of essential healthcare services and to facilitate response and recovery operations both during and after a disruptive event. Completion of the project is expected in 2012.
Statement Tracking Number	Based on DHS/Office of Infrastructure Protection (IP) Capability Gap Statements 2008-001-HPH, 2008-002-HPH, 2008-004-HPH, 2008-005-HPH, and 2008-002-ESS
Requirement Title	Decision Support Tool (DST) and Mental Health Training
Action	In February 2010, the National Institute for Hometown Security awarded a \$3.3 million contract to the University of Louisville to develop a decision support tool and mental health training capability for the HPH and Emergency Services Sectors. The objective of this project is to develop both an informed decision-making capability that is supported by real-time situational awareness, and innovative mental health training solutions to assist the sectors in continuing the provision of medical services during a disaster. Networks and tools must be interoperable, based on established standards and terminology, and be able to respond effectively and efficiently during and after an unpredictable, dynamic event.

<sup>8</sup> The National Institute for Hometown Security, Kentucky Critical Infrastructure Protection Program; available at <http://www.thenihs.org/news>.

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Table 5-8: (Cont.)

Status	Preliminary work began in late 2009 when the university's principal investigator held a series of discussions with SMEs in HPH to develop requirements for the DST. The discussion was open to the members of the SCC and GCC of the HPH and Emergency Services Sectors. Completion of the project is expected in 2013. The principal investigator continues to work closely with the sectors in this effort.
Statement Tracking Number	2008-011-HPH
Requirement Title	Identifying Sole or Limited Source Dependencies in the HPH Sector
Action	<p>A number of the raw materials or sub-components of medical devices upon which the sector is dependent (e.g., latex for PPE and microprocessor subcomponents for physiological monitoring devices) originate from single or limited sources, often based in foreign countries. Dependencies on these single or limited sources put the sector at great risk should the supply of critically necessary resources they provide be interrupted, even for short durations. This is further complicated by the JIT nature of manufacturing and distribution, which limits the product supplies to what is necessary during steady-state operations. The purpose of this research project is to:</p> <ul style="list-style-type: none"> <li>▪ Identify, analyze, and monitor current single- or primary-source dependencies;</li> <li>▪ Scientifically address vulnerabilities in manufacturing and other supply processes;</li> <li>▪ Track the supply and locations of certain raw materials and sub-components of medical devices;</li> <li>▪ Anticipate new single or primary source dependencies; and</li> <li>▪ Apply scenario-based analysis to examine the consequences of disruptions on the ability of the HPH Sector to provide essential medical services and propose countermeasures to minimize these consequences</li> </ul>
Status	The Request for Proposals (RFP) for this CGS has been prepared by NIHs and is currently awaiting approval from DHS S&T to move into proposal stage. When that occurs, the RFP will be released to the NIHs universities for proposal preparation. Funds for fiscal year 2010 for the Kentucky Critical Infrastructure Protection (KCIP) program have been expended. Thus, it is unlikely that this RFP will be issued prior to the fiscal year 2011 funding cycle. The possibility also exists that the RFP will not move into formal proposals and project initiation due to a highly competitive environment for fiscal year 2011 funds.
Statement Tracking Number	2008-013-HPH
Requirement Title	Just-in-Time (JIT) Inventory Production
Action	<p>The HPH Sector needs to develop strategies that can address underutilized production capabilities and identify requirements for expanded capacity in the production and distribution of medical supplies to plan for increased resource needs associated with significant events.</p> <p>In many facilities, buffer inventories exist in anticipation of surge demands. However, when demand is at steady-state, these buffer inventories can be negatively impacted due to insufficient inventory turnover, leading to expired resources. A more agile, robust supply chain that can respond to capacity increases would reduce the need</p>

Table 5-8: (Cont.)

	<p>for high-volume storage at HPH facilities and improve time to delivery during an event. The purpose of this research project is to:</p> <ul style="list-style-type: none"> <li>▪ Examine scientific data on the immediate and long-term impacts resulting from a loss of select medical materials that are essential to the provision of care (e.g., gloves, masks, syringes);</li> <li>▪ Provide the sector with empirical data on the cost to expand production of select resources beyond JIT inventory to develop production, distribution, and storage standards;</li> <li>▪ Identify the framework necessary to increase JIT production and distribution capacity to meet anticipated resource demands in real time; and</li> <li>▪ Develop a set of recommended incentives for private sector manufacturers and distributors to plan for and increased demand for essential medical supplies.</li> </ul>
Status	<p>The RFP for this CGS has been prepared by NIHS and is currently awaiting approval from DHS S&amp;T to move into proposal stage. When that occurs, the RFP will be released to the NIHS universities for proposal preparation. Funds for fiscal year 2010 for the KCIP program have been expended. Thus, it is unlikely that this RFP will be issued prior to the fiscal year 2011 funding cycle. The possibility also exists that the RFP will not move into formal proposals and project initiation due to a highly competitive environment for fiscal year 2011 funds.</p>
Statement Tracking Number	2008-015-HPH
Requirement Title	Medical Supply Chain Transportation and Distribution
Action	<p>The HPH Sector is heavily reliant on the transportation network for the distribution of supplies. During a crisis, the transportation network is at risk of degradation in its ability to move supplies in a timely manner. The sector needs to improve its ability to distribute medical supplies during a crisis to ensure that it can continue to function effectively. The scope of this project is limited to those supplies that have been identified as critical during a disaster. After critical supplies have been identified, the analysis will:</p> <ul style="list-style-type: none"> <li>▪ Identify all nodes and links in the distribution and transport of critical medical supplies;</li> <li>▪ Create the ability to transport, track, distribute, and manage medical supplies during a crisis in an efficient and standardized manner;</li> <li>▪ Develop alternative distribution processes in the event of a disaster;</li> <li>▪ Build a Federal solution to aggregate, identify, and inform the effective distribution of medical supplies during and after a disruptive event; and</li> <li>▪ Create a mechanism for fostering collaboration among all security partners.</li> </ul>
Status	<p>The RFP for this CGS has been prepared by NIHS and is currently awaiting approval from DHS S&amp;T to move into proposal stage. Once that occurs, the RFP will be released to the NIHS universities for proposal preparation. Funds for fiscal year 2010 for the KCIP program have been expended. Thus, it is unlikely that this RFP will be issued prior to the fiscal year 2011 funding cycle. The possibility also exists that the RFP will not move into formal proposals and project initiation due to a highly competitive environment for fiscal year 2011 funds.</p>

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Table 5-8: (Cont.)

Statement Tracking Number	2008-017-HPH
Requirement Title	Information Sharing
Action	<p>The sector is faced with the inability to rapidly and accurately disseminate threat or situational awareness data and other real-time information in the event of a disaster or other major sector disruption. The inability to rapidly communicate across the sector exacerbates consequences and prolongs recovery time. The HPH Sector currently shares information across multiple media, including e-mail and teleconferencing.</p> <p>This project will assess the following core areas:</p> <ul style="list-style-type: none"> <li>▪ The ability to share classified data;</li> <li>▪ The interoperability of the network with other systems and hand-held technologies such as smartphone devices;</li> <li>▪ The capacity and throughput of the network; and</li> <li>▪ Integration with other applications and technologies.</li> </ul> <p>The resulting analysis will form the basis for defining the technological requirements necessary to achieve optimal sector information-sharing capabilities for both steady-state and incident communications.</p>
Status	<p>The RFP for this CGS has been prepared by NIHS and is currently awaiting approval from DHS S&amp;T to move into proposal stage. Once that occurs, the RFP will be released to the NIHS universities for proposal preparation. Funds for fiscal year 2010 for the KCIP program have been expended. Thus, it is unlikely that this RFP will be issued prior to the fiscal year 2011 funding cycle. The possibility also exists that the RFP will not move into formal proposals and project initiation due to a highly competitive environment for fiscal 2011 funds.</p>

## Section 6: Funding of CIKR Programs and Activities

Funding information in this section has been redacted.



## Section 7: Sector CIKR Challenges and Path Forward

This section of the Sector Annual Report describes the challenges faced by the sector and a path forward for addressing these challenges.

### 7.1 Summary of Sector Challenges

The past year has seen the persistence of some sector challenges and the emergence of new ones. Three significant challenges that are currently being addressed by the sector relate to information sharing, asset prioritization, and resource allocation.

#### 7.1.1 Information Sharing

Information sharing continues to be a top priority for the sector. This presents both opportunities and challenges. Some of the information that is helpful to non-Federal agency partners in their CIP efforts is sensitive or proprietary. It may relate to sector vulnerabilities or intelligence gathering and must therefore be kept secure. Much of this information is controlled under the FOUO designation, while other information is PCII or classified information. Some information relevant to the HPH Sector is also protected under the Health Insurance Portability and Accountability Act (HIPAA).

The sector must share information efficiently and effectively while keeping it secure. Valuable information should be easily accessible to individuals who need it. However, not all information is valuable to all individuals; its dissemination must be targeted to reduce information overload. When information is shared through mechanisms such as HSIN, it must be categorized in a way that makes it easy to retrieve. During an emergency response, this becomes especially critical due to the urgency of the situation and time sensitivity of incident-related information. The sector must ensure that it shares targeted information without imposing an overly burdensome information-collection process that slows information sharing.

The sector has been very successful in enrolling its members on its HSIN portal and has been conducting classified briefings on a routine basis of four per year. The next challenge is to ensure that shared information is current and relevant.

#### 7.1.2 Asset Prioritization

The sector has encountered challenges related to the prioritization of assets through the NCIPP and CFDI processes. These challenges are primarily due to the unique characteristics of the sector. Although the sector as a whole is critically important to protecting the life and health of every American, it is distributed geographically and across functional areas in such a way that it is rare for any one component to rise to the level of national criticality. For example, a large urban hospital might be critically important for a specific large city, but its criticality as part of the national healthcare infrastructure is much less clear. Any impact on a particular hospital

would have a negligible effect on the delivery of healthcare in other parts of the country, and local impacts could be mitigated through mutual aid.

Some HPH infrastructure assets are critical because of the secondary consequences they prevent. Vaccine manufacturers, for example, are critical in the prevention of death and disease from seasonal influenza as well as providing military personnel with protection from tropical diseases and biological weapons. The criticality of other assets also varies depending on circumstances. As another example, the destruction of a sole-source manufacturer of a countermeasure to pandemic influenza would not in itself have a catastrophic, immediate impact on lives and health; however, the national impacts would be catastrophic if this were to happen in conjunction with an actual pandemic. Assets of this type require an additional – and not yet fully developed – level of analysis to establish priorities accurately.

### 7.1.3 Resource Allocation

The government and private sector partners within the HPH Sector face a number of competing demands on resources. The healthcare industry must find ways to serve patients in an increasingly challenging business environment. State, local, tribal, and territorial health agencies must continue to develop preparedness and response capabilities in an environment of diminishing resources. While some sector partners embrace the value of the sector's CIP efforts, priorities for these efforts must be established and weighed against important patient service and emergency response missions that continue to demand more time and resources.

## 7.2 Path Forward to Address Challenges

The HPH Sector continues to work toward addressing many of the challenges outlined above. These are complex challenges and are likely to remain with the sector in some form in the future. The sector is using the NIPP partnership model as a framework for addressing these issues in a collaborative manner across Federal, State, local, and private sector stakeholders.

To address the challenge of ensuring the relevance of shared information, the sector will be investing additional resources to analyze available information and providing this analysis to sector members to assist them in determining the relevance and value of the information to them. The sector will also look to identify tailored threat/risk information products for the sector.

To address the challenges of establishing priorities to sector assets, the sector will continue its work to better understand supply chain vulnerabilities. The sector has launched two new pilot projects related to critical foreign dependencies and the theft/diversion of radiologic materials. The sector will also begin applying a new risk assessment methodology for sector assets.

The sharp increase in HSIN enrollment over the prior year indicates an active interest in the CIP Program; sector leadership must continue to improve its ability to communicate the value proposition of CIP activities to sector members.

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## Acronym List

AABB	American Association of Blood Banks
AHA	American Hospital Association
AHRMM	Association for Healthcare Resource and Materials Management
AIRS	Alliance for Information and Referral Systems
APIC	Association for Professionals in Infection Control
ASPR	Assistant Secretary for Preparedness and Response (HHS)
ASTHO	Association of State and Territorial Health Officials
BARDA	Biomedical Advanced Research and Development Authority (HHS-ASPR)
BASIS	Blood Availability and Safety Information System (HHS)
BCP	business continuity planning
BENS	Business Executives for National Security
BIO	Biotechnology Industry Organization
BSL	biosafety level
BZPP	Buffer Zone Protection Program (DHS)
CAT	computerized axial tomography
CBER	Center for Biologics Evaluation and Research (FDA)
CBRNE	chemical, biological, radiological, nuclear, and explosive
CDC	Centers for Disease Control and Prevention
CDRH	Center for Devices and Radiological Health
CEMP	Comprehensive Emergency Management Program
CEO	chief executive officer
CFDI	Critical Foreign Dependencies Initiative (DHS)
CGS	capability gap statement
CIKR	critical infrastructure and key resources
CIO	chief information officer
CIP	critical infrastructure protection
CIPAC	Critical Infrastructure Partnership Advisory Council
CISO	chief information security officer
CJIS	Criminal Justice Information Services
COOP	continuity of operations
CRI	Cities Readiness Initiative (CDC)
CSWG	Cyber Security Working Group
CT	CAT, or computerized axial tomography
CTO	chief technology officer
D.C.	District of Columbia
DCIP	Defense Critical Infrastructure Program (DoD)
DGMQ	Division of Global Migration and Quarantine (CDC)
DHS	U.S. Department of Homeland Security
DME	durable medical equipment
DOC	U.S. Department of Commerce
DoD	U.S. Department of Defense

DOE	U.S. Department of Energy
DOJ	U.S. Department of Justice
DST	Decision Support Tool
DSNS	Division of Strategic National Stockpile (CDC)
DSP	Drug Shortage Program (FDA)
ECIP	Enhanced Critical Infrastructure Protection (DHS)
EHR	electronic health record
EM	emergency management
EMAP	Emergency Management Accreditation Program (TJC)
EMCAPS	Electronic Mass Casualty Assessment & Planning Scenarios
EMI	Emergency Management Institute (DHS-FEMA)
EMS	emergency medical services
EOC	Emergency Operations Coordinator
EPAP	Emergency Prescription Assistance Program (HHS)
Epi-X	Epidemic Information Exchange (CDC)
ESAR-VHP	Emergency System for the Advance Registration of Volunteer Health Professionals
ESF	emergency support function
ESSENCE	Electronic Surveillance System for the Early Notification of Community-Based Epidemics (DoD)
EWIDS	Early Warning Infectious Disease Surveillance (HHS)
FBI	Federal Bureau of Investigation
FDA	U.S. Food and Drug Administration (HHS)
FEMA	Federal Emergency Management Agency (DHS)
FISMA	Federal Information Security Management Act
FOUO	for official use only
FY	fiscal year
GCC	Government Coordinating Council
GIS	geospatial information system
HAISS	Healthcare Associated Infection and Influenza Surveillance System (VA)
HAN	Health Alert Network
HHS	U.S. Department of Health and Human Services
HIMSS	Health Information Management and Systems Society
HIPAA	Health Insurance Portability and Accountability Act
HIT	Health Information Technology
HITECH	Health Information Technology and Economic Clinical Health
HITRAC	Homeland Infrastructure Threat and Risk Analysis Center (DHS)
HPH	healthcare and public health
HPP	Hospital Preparedness Program (HHS)
H.R.	House Report (U.S. Congress)
HSA	Homeland Security Advisor (DHS)
HSDB	Homeland Security Database

HSEEP	Homeland Security Exercise and Evaluation Program (DHS)
HSIN	Homeland Security Information Network (DHS)
HSPD	Homeland Security Presidential Directive
HVAC	heating, ventilation, and air conditioning
IAHSS	International Association for Healthcare Security and Safety
ICS	incident command system
IEC	International Electrotechnical Commission
IED	improvised explosive device
IP	Office of Infrastructure Protection (DHS)
ISAC	Information Sharing and Analysis Center
ISWG	Information Sharing Work Group
IS	independent study
IST	Infrastructure Survey Tool
IT	information technology
IV	intravenous
JAWG	Joint Advisory Work Group
JIT	just-in-time
KCIP	Kentucky Critical Infrastructure Protection
LRN	Laboratory Response Network
LNO	Liaison Officer (HHS)
MDSC	Medical Device Security Center
MHS	Military Health System (DoD)
MRC	Medical Reserve Corps
MRI	magnetic resonance imaging
MS&A	modeling, simulation, and analysis
MSA	metropolitan statistical area
NACCHO	National Association of County and City Health Officials
NBSHH	National Biosurveillance Strategy for Human Health
NCIPP	National Critical Infrastructure Prioritization Program (DHS)
NCSD	National Cyber Security Division (DHS)
NDMS	National Disaster Medical System
NFDA	National Funeral Directors Association
NFPA	National Fire Protection Association
NIHS	National Institute for Hometown Security
NIMS	National Incident Management System
NIPP	National Infrastructure Protection Plan
NIST	National Institute of Standards and Technology
NLE	National Level Exercise
NRDM	National Retail Data Monitor
NRF	National Response Framework
NSA	National Security Agency

NSSE	National Special Security Event
OMB	Office of Management and Budget
OSSI	Office of Security and Strategic Information (HHS)
OTC	over-the-counter
PBS	Project BioShield
PCII	protected critical infrastructure information
PCIS	Partnership for Critical Infrastructure Security
PERRC	Preparedness and Emergency Response Research Centers (CDC)
PHAST	Primary Health Assets Staging Tool (DoD)
PHEP	Public Health Emergency Preparedness (CDC)
PHER	Public Health Emergency Response
PHIN	Public Health Information Network
PIEID	Pandemic Influenza and Emerging Infectious Diseases
POD	point of dispensing
PPE	personal protective equipment
PPHR	Project Public Health Ready (CDC)
PPO	Program Protection Office
PSA	Protective Security Advisor (DHS)
R&D	research and development
RAWG	Risk Assessment Work Group
RDD	radiological dispersal device
RFP	Request for Proposal
RMA	risk mitigation activity
RRAP	Regional Resiliency Assessment Program (DHS)
S&T	Science and Technology Directorate (DHS)
SARMA	Security Analysis and Risk Management Association
SAR WG	Sector Annual Report Writing Group
SCC	Sector Coordinating Council
SHIRA	Strategic Homeland Infrastructure Risk Assessment (DHS)
SNS	Strategic National Stockpile
SME	subject matter expert
SSA	Sector-Specific Agency
SSP	Sector-Specific Plan
Task Force	Inter-organizational Task Force on Domestic Disasters and Acts of Terrorism (AABB)
TJC	The Joint Commission
TTX	tabletop exercise
VA	U.S. Department of Veterans Affairs
VBIED	vehicle-borne improvised explosive device
VHA	Veterans Health Administration (VA)



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## Attachment A: RMA Information for the Healthcare and Public Health Sector

A complete list of the Healthcare and Public Health Sector’s 2010 risk mitigation activities (RMAs) is provided in this attachment. Table A-1 lists the sector’s RMAs and associated descriptive data, output data, and outcome metrics, if available. This information was downloaded from the NIPP Metrics Portal and is current as of August 2, 2010.

**Table A-1: RMAs and Progress Indicators**

CDC Cities Readiness Initiative (CRI)
<p><b>Overview</b></p> <p><b>Description:</b>                      The Cities Readiness Initiative (CRI) is funded through CDC’s PHEP Program. The goal of CRI is to prepare major U.S. MSAs to effectively respond to a large-scale bioterrorist event by dispensing countermeasures to the affected population within 48 hours. By providing technical assistance to grant recipients, CRI has strengthened points of dispensing (PODs) infrastructures; increased planning that includes alternate modalities for dispensing; enhanced communication and engagement with partners from all levels of government, private sector, military installations, academia, and community-based organizations; and improved the ability to identify capabilities, strengths, and shortcomings through preparedness planning, exercises, modeling, and assessments.</p> <p><b>Key:</b> Yes</p>
<p><b>Data and Metrics</b></p> <p><b>Descriptive Data:</b>                      CDC and State SNS Program personnel conduct reviews in each of the local jurisdictions within the CRI MSAs each year. These reviews measure capability for twelve functions considered critical to planning for countermeasure distribution and dispensing. CDC also reviews training on and exercising of these plans. Each of the 12 functions receives a weighted score. The sum of these weighted scores results in an overall score for the CRI area reviewed. The review scores from each area within a CRI MSA are aggregated to arrive at a single CRI MSA score.</p> <p>Over the past year, the percentage of CRI MSAs operating within the acceptable range (those receiving a score of 69 or higher on the technical assistance review) increased by 20 percent. Additionally, improved scores were observed within each of the 12 functions (range 3 – 14 percent).</p> <p>The greatest overall increases during the past year were related to security, hospital and alternate care facilities coordination, and training, exercise, and evaluation functions. Examples include coordination at all levels of law enforcement for security of medical countermeasures and PODs, working with hospitals and alternate care facilities and those companies, agencies, or individuals assisting with distribution and inventory control activities, and training and exercise plans developed for the local jurisdictions that are specific to mass prophylaxis.</p> <p>The CDC, in conjunction with its federal, state, tribal, territorial, and local partners, continues to forge new partnerships, explore innovative venues, and seek alternate methods to continue to reduce the time it</p>

Table A-1: (Cont.)

takes to deliver life-saving countermeasures to affected populations in the effort to reduce mortality and morbidity during a public health emergency.

**Output Data:**

In 2004, there were 21 U.S. MSAs participating in CRI. As of 2009, there are 72 CRI MSAs, representing 57 percent of the U.S. population (2008 Census).

**Outcome Metrics:** The largest aggregate percent increase over the past year has been in those areas involving engagement of external partners. Examples include working with hospitals and alternate care facilities and those companies, agencies, or individuals assisting with distribution and inventory control activities. Over the past year, the percentage of CRI MSAs operating within the acceptable range (those receiving a score of 69 or higher on the technical assistance review) increased by 30%.

The use of “Closed” PODs is a method of dispensing to supplement the traditional community POD. A closed POD is a private location where medications are dispensed to a specific group of people such as businesses, universities, community organizations, and military installations. Closed PODs help to reach specific portions of the community more quickly. As a result, long lines and public anxiety at traditional community PODs can be reduced and resources can be used more efficiently. Closed PODs also enhance continuity of operations among entities that provide critical infrastructure during a declared emergency. A majority of the CRI MSAs have added closed PODs as an alternate modality to their medical countermeasure distribution and dispensing plans.

- Business PODs - 48 MSAs, 229 POD units
- Government PODs (non military) - 52 MSAs, 729 POD units
- Military PODs - 47 MSAs, 46 POD units
- Academic PODs - 46 MSAs, 670 POD units
- Community Organization PODs - 45 MSAs, 167 POD units

CDC Public Health Emergency Preparedness Cooperative Agreement – Disease Detection and Investigation Activities

Overview

**Description:**

Within the PHEP program, funds are set aside to improve the ability for public health departments to detect and investigate diseases and increase their laboratory testing capacity for bioterrorism agents. Through these funds, public health departments have increased the number of epidemiologists working in emergency response, the number of public health professionals using health surveillance systems, and the number of laboratories capable of testing for biological and chemical agents.

**Category:**

**Key:** Yes

Data and Metrics

**Outcome Metrics:**

The most recent performance data for the disease detection and investigation activities funded by PHEP indicates significant accomplishments since the program’s inception: The number of epidemiologists in public health departments working in emergency response has doubled from 115 in 2001 to 232 in 2006. Epidemiologists detect and investigate health threats and disease patterns and work to minimize the negative effects of a health threat in a community.

Table A-1: (Cont.)

The number of users for the Epidemic Information Exchange (Epi-X), a secure CDC-based communications system that helps track disease outbreaks, has increased to 4,646 in 2006, up from 890 in 2001. Users are primarily from state and local health departments (75 percent).

The number of state and local public health laboratories able to detect biological agents has increased to 110 in 2007, from 83 in 2002.

The number of state and local public health laboratories able to detect chemical agents has increased to 47, from none in 2001.

More than twice the number of state public health laboratories are conducting exercises to test their ability to handle, confirm, and report results for chemical agents (from 16 in 2003 to 38 in 2006).

CDC Public Health Emergency Preparedness Cooperative Agreement – Preparedness and Response Activities

Overview

**Description:**

The Public Health Emergency Preparedness (PHEP) Program is a Federal cooperative agreement program operated by HHS and administered through state, local, tribal, and territorial health agencies. The PHEP cooperative agreement provides funding to enable public health departments to have the capacity and capability to effectively respond to the public health consequences of all hazards. These emergency preparedness and response efforts are designed to support the National Response Framework (NRF) and the National Incident Management System (NIMS) and are targeted specifically for the development of emergency-ready public health departments.

Within the PHEP program, some funds are dedicated to initiatives that enhance disease surveillance and mass prophylaxis capabilities. These initiatives are described in more detail as key RMAs within the workforce protection section for Goal 2.

**Key:** Yes

Data and Metrics

**Outcome Metrics:**

The most recent performance data for the preparedness and response activities funded by PHEP indicates significant accomplishments since its inception:

All state public health departments now can receive and evaluate reports of urgent health threats 24/7/365, whereas in 1999 only 12 could do so. Previously, it was often difficult for clinicians to reach a public health professional after normal work hours.

All states now have plans to receive, store, and distribute from the Strategic National Stockpile (SNS), a national repository of antibiotics, other life-saving medications, and medical supplies.

Seventy-three percent of states reviewed have satisfactorily documented their SNS planning efforts.

In 2005, public health departments in 50 states and Washington, DC trained public health professionals about their roles and responsibilities during an emergency as outlined by the Incident Command System, while in 1999 public health departments in only 14 states did so.

All states now participate in the Health Alert Network, which allows for the rapid exchange of critical public health information.

Table A-1: (Cont.)

CDC Select Agent Program

Overview

**Description:**

The CDC Select Agent Program regulates the possession, use, and transfer of biological agents and toxins that could pose a severe threat to public health and safety (known as select agents). This program has enhanced the Nation’s oversight of the safety and security of select agents. The Select Agent Program promotes laboratory safety and security by developing, implementing, and enforcing the select agent regulations; providing guidance to the regulated community; and inspecting facilities working with select agents. CDC works closely with the Criminal Justice Information Services Division (CJIS) of the U.S. Department of Justice (DOJ) to conduct security risk assessments of non-governmental entities and personnel needing access to select agents.

**Key:** Yes

Data and Metrics

**Descriptive Data:**

CDC works proactively with registered entities in advance of natural disasters and national events to ensure that all select agents and toxins are properly secured to protect them from theft, loss, or release. CDC took such actions for flooding, hurricanes, wildfires, and earthquakes that occurred in the United States in 2009. To aid States in emergency preparedness planning, CDC established a policy by which State officials can receive information about CDC-registered select agent entities in their States. On August 12, 2009, CDC hosted a workshop series themed “Management Oversight” for all of its registered entities and partners to inform individuals of their legal responsibilities for implementing the Select Agent Regulations.

**Output Data:**

In fiscal year (FY) 2009, CDC had the following operational accomplishments:

- Responded to 2,392 inquiries from the public as part of outreach efforts regarding the Select Agent Regulations (of which ninety-five percent of the inquiries received a response within one business day); and
- Processed 3,059 reports of identifications of select agents and toxins.

Cybersecurity Strategic Plan

Overview

**Description:**

The HPH sector has embarked on an effort to develop a cyber security strategic plan that considers the unique aspects of cyber security within the sector.

**Key:** Yes

Data and Metrics

**Descriptive Data:**

In October 2009, the sector established a Cyber Security Work Group (CSWG). The work group has met several times and is nearing completion of the development of the sector’s cyber security strategy.

Table A-1: (Cont.)

### FDA Drug, Biologic, and Medical Device Shortage Programs

#### Overview

#### **Description:**

Federal activities to mitigate risks are undertaken in many areas of government, including public health, emergency preparedness, defense, and others. This section discusses the following activities: Food and Drug Administration (FDA) Drug, Biologic, and Medical Device Shortage Programs, Public Health Information Network, Emergency Prescription Assistance Program, Department of Defense (DoD) Defense Critical Infrastructure Program, CDC Preparedness and Emergency Response Research Centers, National Disaster Medical System, Federal and State Antiviral Stockpiling Program, CDC CHEMPACK Program, Federal Emergency Management Agency (FEMA) Emergency Management Institute, Department of Veterans Affairs (VA) Comprehensive Emergency Management Program (CEMP) Analysis, VA Accreditation in the Emergency Management Accreditation Program (EMAP), and VA Biosurveillance.

#### ***FDA Drug, Biologic, and Medical Device Shortage Programs***

The Drug, Biological Product, and Medical Device Shortage Programs of the FDA address potential or actual shortages that have a significant impact on public health. Through communication, facilitation, and negotiation, these programs work with medical manufacturers to plan for and manage shortages.

The Drug Shortage Program (DSP) addresses potential or actual shortages of prescription and over-the-counter medications on the U.S. market and works with pharmaceutical manufacturers, other government agencies, and professional organizations to plan for and manage drug shortages. DSP prioritizes drug products needed for serious diseases or medical conditions for which there are no alternatives. DSP maintains the Critical Products Database, which includes information collected for drug products needed for emergency preparedness, counterterrorism activities, and life-threatening diseases and medical conditions. These products are continually monitored for inventory, surge capacity, sources of raw material, and locations of manufacturing facilities in order to ensure the ability to respond to Federally declared disasters/emergencies and potential shortages. The manufacturers provide data voluntarily with the understanding that the information is considered confidential in nature. The manufacturers agree to report any potential shortage issues involving these products so that they can be addressed expeditiously by DSP.

The FDA's Center for Biologics Evaluation and Research (CBER) manages the Biological Product Shortage Program. The goal of this program is to help prevent or alleviate shortages of biological products. CBER works with all parties involved to ensure that medically necessary products are available within the United States. During emergency operations (e.g., natural disasters) the CBER Biological Product Shortage Program works with the CBER Emergency Operations Coordinator (EOC) and other Federal entities such as the CDC as needed. The program will continue to address shortages that occur and will continue to monitor all products listed as current shortages.

The FDA's Center for Devices and Radiological Health (CDRH) acquires and maintains detailed data on domestic inventory, manufacturing capabilities, distribution plans, and raw material constraints for medically necessary medical devices. CDRH works with medical device manufacturers and distributors to plan for and manage shortages. CDRH is in the process of developing a new shortages database that will have the ability to access data critical to assessing the potential for and prevention of shortages of diagnostic and therapeutic medical devices that may result from Federally declared disasters/emergencies or regulatory actions taken by CDRH.

**Key:** Yes

Table A-1: (Cont.)

Data and Metrics

**Descriptive Data:**

The FDA uses the information collected by these programs to support risk assessment, help inform risk mitigation strategies, and support real-time decision-making by HHS during actual emergencies or emergency preparedness exercises.

**Outcome Metrics:**

Over the past year, CDRH has conducted the following CIP-related activities:

Coordinated with CDC to create a dashboard to identify potential critical device shortages.

Responded to multiple requests from CDC and several states for information related to shortages of devices in response to the H1N1 flu outbreak.

Assisted foreign countries that requested support in developing strategies to avoid shortages of devices critical to their healthcare systems.

Worked with BARDA to identify strategies to avoid shortages of accessories to ventilators in the SNS.

Initiated dialogue with CDC in order to better understand the supply chain of SNS devices in order to avoid shortages of those devices.

Initiated dialogue with representatives of the Oak Ridge National Laboratory in order to address potential security issues related to medical devices with wireless capabilities.

HHS Biomedical Advanced Research and Development Authority Program Protection Office

Overview

**Description:**

The HHS Biomedical Advanced Research and Development Authority (BARDA) Program Protection Office (PPO) establishes security standards, provides guidance, and ensures compliance throughout the complete life-cycle acquisition process of critical vaccines, diagnostics, and drugs acquired under Project BioShield (PBS) and the Pandemic Influenza and Emerging Infectious Diseases (PIEID) Program. PPO administers and ensures compliance with comprehensive security practices relating to physical security, operations security, personnel security, information security, and transportation security, and conducts security awareness programs at all contractor facilities supporting PBS and PIEID. PPO participates in Department of Homeland Security (DHS) sponsored Enhanced Critical Infrastructure Protection (ECIP) visits and Regional Resiliency Assessment Tool (RRAT) evaluations. PPO also conducts security assistance visits at critical domestic and international contractor facilities. PPO is also actively involved in coordinating on behalf of BARDA with federal, state, local, and foreign law enforcement agencies to share appropriate information, including ways to minimize the potential impact of an emergency situation on contracted acquisition operations.

**Key:** Yes

Data and Metrics

**Output Data:**

BARDA PPO significantly increased its activities and impact in 2009. PPO security professionals partnered with DHS Protective Security Advisors (PSA) to conduct joint security assessments at four major distribution centers responsible for securing and distributing the H1N1 vaccine to the U.S. population and eight other designated critical infrastructure facilities providing crucial operations in support of manufacturing, storing and distributing the H1N1 vaccine and anti-viral drugs. The BARDA



Table A-1: (Cont.)

PPO also co-hosted the first multi-agency security related table top exercise at the sole U.S. domestic influenza manufacturer and DHS designated critical infrastructure facility which involved over 20 local, state, federal, and private industry officials. The in-depth table top exercise included response actions at all levels and captured essential lessons learned in preparation for a potential pandemic influenza event. PPO assisted in the facilitation of Buffer Zone Protection Program grant submissions at three BARDA nominated critical infrastructure sites.

HHS Hospital Preparedness Program

Overview

**Description:**

The Hospital Preparedness Program (HPP), administered under the Assistant Secretary for Preparedness and Response (ASPR) of Health and Human Services (HHS), is a Federal cooperative agreement program operated by HHS and administered through state, local, tribal, and territorial health agencies. HPP enhances the ability of hospitals and health care systems to prepare for and respond to bioterrorism and other public health emergencies. Program priority areas include interoperable communication systems, bed tracking, personnel management, fatality management planning, and hospital evacuation planning. HPP funds have also improved bed and personnel surge capacity, decontamination capabilities, isolation capacity, pharmaceutical supplies, training, education, drills and exercises.

**Key:** Yes

Data and Metrics

**Descriptive Data:**

As of August 2009, 60 of the 62 participating States, localities, and territories report that 4,958 hospitals within their borders participate in the HPP Program. States and hospitals continued to exercise emergency response plans throughout 2009. Several States made progress in standardizing and consolidating their exercises under the Homeland Security Exercise and Evaluation Program (HSEEP). Many hospitals also used the 2009 H1N1 pandemic as an opportunity to exercise and evaluate their plans. Metrics related to hospital capability remained consistent between 2008 and 2009.

**Output Data:**

- 90 percent having demonstrated the ability to report available beds to their State, locality, or territory within 60 minutes during an exercise or event;
- 90 percent having demonstrated dedicated, redundant communications capability during an exercise or incident;
- 81 percent having evacuation plans; and
- 59 percent having fatality management plans.

Project Public Health Ready

Overview

**Description:**

Project Public Health Ready (PPHR) is a competency-based training and recognition program that assesses preparedness and assists local health departments or groups of local health departments working collaboratively as a region to respond to emergencies. The program is funded by CDC and administered by the National Association of County and City Health Officials (NACCHO). It builds preparedness capacity and capability through a continuous quality improvement model. Each of the three PPHR project goals – all-hazards preparedness planning, workforce capacity development, and demonstration of readiness through exercises or real events – has a comprehensive list of standards that must be met in order to achieve PPHR recognition.

Table A-1: (Cont.)

<p><b>Key:</b> Yes</p>
<p>Data and Metrics</p> <p><b>Output Data:</b>                  Since 2005, 164 local health departments in 25 different states have been recognized as meeting all the PPHR requirements. The state supported model of PPHR is currently being implemented in Arizona, Colorado, Florida, and Virginia. The states of Oregon, Pennsylvania, and Texas will be beginning the process in 2010. Several others are interested in the program as well. There are many steps being taken to streamline and simplify the PPHR process including electronic submission, an online review system, and improvements in technical assistance and training provided by NACCHO staff.</p>
<p><b>RxResponse</b></p>
<p>Overview</p> <p><b>Description:</b>                  RxResponse is a non-profit, private sector initiative to support the medical supply chain during emergencies. RxResponse partners work together with Federal, state, and local officials as well as volunteer organizations to help support the continued delivery of medicines to people who need them in the event of an emergency – whether it is caused by a natural disaster, terrorist incident, or health emergency (such as a pandemic). RxResponse is a single point of contact for the entire pharmaceutical supply system and relies on a robust network that allows Federal and state emergency management officials to communicate with RxResponse regarding pharmaceutical needs and other issues that may impact the supply system. The communications are actively monitored by all segments of the pharmaceutical supply system to ensure the fastest possible resolution. Partners include the American Hospital Association, American Red Cross, Biotechnology Industry Organization, Generic Pharmaceutical Association, Healthcare Distribution Management Association, National Association of Chain Drug Stores, National Community Pharmacists Association, and Pharmaceutical Research and Manufacturers of America.</p> <p><b>Key:</b> Yes</p>
<p>Data and Metrics</p> <p><b>Descriptive Data:</b>                  Rx Response also has expanded the reach of the Pharmacy Status Reporting tool by partnering with 2-1-1, a United Way / Alliance for Information and Referral Systems (AIRS) service providing information to persons needing information after disasters. This status reporting tool leverages normal business operations to enhance the continued provision of healthcare to the public by making information on open pharmacies available to them, as well as providing valuable situational awareness to public health, emergency management, and clinical care providers..</p> <p><b>Output Data:</b>                  Due to the ongoing response to H1N1 and the critical role that pharmaceutical manufacturing and supply played in that response, Rx Response was in communication with every state in the U.S., up from 21 states and two Metropolitan Statistical Areas (MSAs) by the end of 2008. Activities in that response included: situation reports and information-sharing in regards to availability of antivirals and vaccine; participation in the development of and active support for the Centers for Disease Control and Prevention (CDC) antiviral dashboard effort; development of the Association of State and Territorial Health Officials (ASTHO) guidance for State Health officials in collaboration with the professional pharmacy and public health communities to engage pharmacies as vaccination sites for H1N1 ; and a manufacturer-distributor summit that allowed for a free exchange of response and resiliency strategies and observations among the pharmaceutical supply companies.</p>

Table A-1: (Cont.)

Strategic National Stockpile
<p data-bbox="180 306 310 338">Overview</p> <p data-bbox="180 369 347 401"><b>Description:</b></p> <p data-bbox="180 401 1422 768">SNS is a national repository of antibiotics, chemical antidotes, antitoxins, life-support medications, intravenous (IV) administration supplies, airway maintenance supplies, and medical/surgical items. The SNS is designed to supplement and re-supply state and local public health agencies in the event of a national emergency within the U.S. or its territories. The SNS is organized for flexible response. The first line of support is the provision of 12-hour push packages – caches of pharmaceuticals, antidotes, and medical supplies designed to provide rapid delivery of a broad spectrum of assets for an ill-defined threat in the early hours of an event. These push packages are positioned in strategically located, secure warehouses, and are ready for immediate deployment to a designated site within 12 hours. If an incident requires additional pharmaceuticals and/or medical supplies, follow-on managed inventory supplies will be shipped to arrive within 24 to 36 hours. If the agent is well-defined, managed inventories can be tailored to provide pharmaceuticals, supplies, and/or products specific to the suspected or confirmed agent(s).</p> <p data-bbox="180 789 302 821"><b>Key:</b> Yes</p>
<p data-bbox="180 846 399 877">Data and Metrics</p> <p data-bbox="180 909 352 940"><b>Output Data:</b></p> <p data-bbox="180 940 1430 1272">To improve visibility into the commercial supply chain and public sector stockpiles of H1N1 medical countermeasures, the Division of Strategic National Stockpile (DSNS) established a Supply Chain Dashboard. The primary goal of the DSNS Dashboard is to assist federal and state officials in the process and decision to release stockpiled assets. The dashboard provides a national view of aggregate inventory data for available supply, timeliness to fill orders and production levels of critical H1N1 countermeasures. This data provides key information on available (or anticipated) assets to meet demand in the near future and in the long term. Reports of order fill status are received as Green, Yellow, or Red indicators, with the time to fill orders and inventory replenishment delays serving as gauges. The DSNS Dashboard tracks certain doses of the tamiflu and rezenza antivirals, N-95 respirators, and surgical masks. The DSNS Dashboard is currently undergoing expansion to further refine data collection elements, improve utility of information to state and federal decisions makers and collect local level dispensing data.</p>
The Joint Commission Healthcare Facility Accreditation Programs
<p data-bbox="180 1346 310 1377">Overview</p> <p data-bbox="180 1409 347 1440"><b>Description:</b></p> <p data-bbox="180 1440 1422 1776">The Joint Commission offers hospital, ambulatory care, behavioral health care, home care, long-term care, and laboratory accreditation programs. These programs include standards that require healthcare facilities to plan for all hazards. While accreditation is voluntary, The Joint Commission accredits 80 percent of the nation’s hospitals, comprising 90 percent of the nation’s hospital beds. The Joint Commission requires health care organizations to have emergency operations plans based on hazard vulnerability assessments that identify potential emergencies affecting the ability to provide services. Within the plans, health care organizations need to consider how they will manage key capabilities – communications, resources and assets, security and safety, staff, utilities, and patient care – during an emergency. The hospital accreditation program in particular requires hospitals (including critical access hospitals) to establish response procedures and contingency plans for patient care for when they cannot be supported by the local community for at least 96 hours.</p> <p data-bbox="180 1797 302 1829"><b>Key:</b> Yes</p>

Table A-1: (Cont.)

Data and Metrics

**Descriptive Data:**

The Joint Commission created a new standards chapter dedicated to Emergency Management (EM) that became effective in January, 2009 for the hospital, critical-access hospital, home care, ambulatory care, and office-based surgery accreditation programs. In 2010, the EM chapter became effective for the long-term care, behavioral health, and laboratory accreditation programs. The EM chapter restructures two lengthy and complex standards from the Environment of Care chapter and incorporates two standards which previously resided in the Medical Staff and Human Resources chapters for some programs. The EM chapter is composed of a set of 12 EM standards and 111 corresponding elements of performance, providing clearer guidance to institutions seeking accreditation. This change highlights an all-hazards approach that supports key organizational capabilities (such as communications, resources, and patient care) regardless of the type of emergency faced by the organization. The new chapter also requires collaborative emergency planning throughout the organization and with other healthcare and response partners in the community.

In addition, The Joint Commission introduced updates to its 2010 on-site survey process for hospitals and critical access hospitals to better align the process with key concepts in the EM chapter. EM now has its own stand-alone survey session independent from the Environment of Care session, giving surveyors more space in the on-site survey for exploring issues specific to emergency management. Emergency preparedness and planning are explored in survey activities throughout the organization, addressing leadership, individual patients, and organization systems. This approach takes emergency management from the narrow purview of one department or discipline to a higher degree of integration within the organization. The survey process is expanded from a narrow focus on a specific event scenario to broader emphasis on all hazards planning to sustain the six critical capabilities; actual preparedness, not just documentation of a plan; situational awareness and contingency planning; and collaboration with community partners.

ER One

Overview

**Description:**

Launched in 1999 by Washington Hospital Center (WHC), ER One is an initiative to design and demonstrate the concepts, features, and specifications for a new type of all-risks ready emergency care facility that has been optimized to manage the medical consequences of terrorism and emerging illness. ER One will provide emergency medical care during a crisis situation (e.g., terrorist attacks or epidemics) and will function as the hospital's emergency department during daily operations.

**Key:** No

National Retail Data Monitor

Overview

**Description:**

The National Retail Data Monitor (NRDM) monitors sales of over-the-counter (OTC) healthcare products to identify disease outbreaks as early as possible.

**Key:** No

Table A-1: (Cont.)

Public Health Information Network (PHIN)

Overview

**Description:**

The CDC Public Health Information Network (PHIN) is a national initiative to improve the capacity of public health to use and exchange information electronically by promoting the use of standards that define functional and technical requirements. PHIN strives to improve public health by enhancing research and practice through best practices related to efficient, effective, and interoperable public health information systems.

**Key:** No