U.S. Department of Health and Human Services

Concept of Operations Plan (CONOPS) for Public Health and Medical Emergencies

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Foreword

The Department of Health and Human Services (HHS) is the United States Government's principal agency for protecting the health of all Americans. HHS provides essential human services, especially for those who are least able to help themselves. Through the activities of the Department, HHS touches the lives of every American.

While HHS is one of the largest organizations in the Government, our over-arching goal is to function as a single entity – as One HHS. To ensure this "One Department" approach, I have taken a number of steps to enhance the coordination between our many operational entities. The HHS Concept of Operations Plan for Public Health and Medical Emergencies, or HHS CONOPS, represents another major step in this process to assure that we respond as a coordinated and unified Department to public health and medical threats and emergencies.

The HHS CONOPS outlines how HHS implements its emergency preparedness and response authorities and establishes the Department's policies for emergency preparedness and response. While the CONOPS will continue to evolve, reflecting the lessons learned from actual experience in disasters, emergency planning, training, and exercises, I am confident that this document will serve as a basis for improving the coordination within HHS, with other Federal Agencies and with our State and local partners.

Tommy G. Thompson
Secretary

I. Introduction

A. Purpose

The Department of Health and Human Services (HHS) Concept of Operations Plan for Public Health and Medical Emergencies, or HHS CONOPS, establishes a framework for the management of public health and medical emergencies and events that require assistance from HHS. This concept of operations plan covers all events and activities (e.g. preparedness, response, recovery, etc.) deemed by the Secretary, or his / her designee, to require a coordinated Departmental response.

The HHS CONOPS will continue to evolve throughout the planning process and will be coordinated with other intra- and inter-agency planning efforts (e.g., National Response Plan, National Incident Management System).

B. Overview

HHS is the primary Federal Agency responsible for public health and medical emergency planning, preparations, response, and recovery in which one or more of the following apply:

- Local, State, or Tribal resources are insufficient to address all of the public health needs.
- The resources of State, local or Tribal public health and / or medical authorities are overwhelmed and HHS assistance has been requested by the appropriate authorities.
- The Federal Government has the lead responsibility under public health authorities.
- A Federal Department or agency acting under its own authority has requested the assistance of HHS.

HHS manages its resources, in support of an affected State, jurisdiction, or Tribe during the response to a variety of hazards and events with implications for public health and medical emergencies. Such emergencies or events include:

- Natural and man-made disasters and public health and medical emergencies;
- Terrorist threats or incidents using chemical, biological, nuclear / radiological or large explosive devices;
- Infectious disease outbreaks and pandemics;
- National Security Special Events (e.g. G8 Summits, Presidential Inaugurations, Olympics, National Party Conventions);
- Animal health emergencies (e.g. Bovine Spongiform Encephalopathy, Foot and Mouth Disease, etc.); or

- Any other circumstance that creates an actual or potential public health or medical emergency where Federal assistance may be necessary.

This plan provides the concept that HHS uses to manage Federal public health and medical personnel and response assets, whether HHS is leading the response under public health authorities, acting in support of another Federal Department (e.g., Department of Homeland Security, Department of State, Department of Defense), or acting in support of the requesting State, Tribal government, Territory, or affected jurisdiction. This document will be reviewed on an annual basis under the oversight of the Assistant Secretary for Public Health Emergency Preparedness (ASPHEP) to ensure that current emergency plans reflect lessons learned from response experiences (both exercises and actual responses).

II. Assumptions

This plan provides the framework for the transition from normal HHS operations to a coordinated Departmental response in support of a public health and medical emergency. It is consistent with Homeland Security Presidential Directive #5 (HSPD-5) and the Department of Homeland Security's Initial National Response Plan (INRP). This plan explains how the Secretary, through the ASPHEP, coordinates HHS-wide preparedness, response and recovery actions, but does not change the specific authorities and responsibilities of HHS Operating Divisions (OPDIVs) such as the Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), etc. HHS will coordinate all its response activities with the appropriate Federal, State, local, Territorial, and Tribal public health and medical officials, as appropriate.

The following assumptions apply:

- The phrase "public health and medical emergencies" includes emergencies related to public health, mental health, substance abuse, food safety and other domains under the jurisdiction of HHS and its operating divisions.

- Lifesaving and health protecting actions, including responder health and safety, take precedence over all other response activities.

- One of the primary consequences of any disaster is its adverse impact on human health and welfare. Therefore, public health and medical officials at all levels of government must be prepared to address sudden and unexpected demands for services that may exceed readily available resources.

- Normally, State, local or Tribal emergency responders and health officials will respond to the incident and lead the response efforts at the scene. HHS will provide support to an affected State after the Governor or other appropriate official has requested assistance.

- HHS may take independent response actions under its own authorities[1] or respond as part of a larger Federal Government response as authorized for specific types of emergencies or disasters.

- Operations involving sensitive or classified information will follow additional procedures to meet security requirements.

- Private industry and non-governmental organizations may play an important role in the response to a public health and medical emergency and will be engaged as deemed appropriate to the specific crisis or emergency.

III. Authorities, Responsibilities and Funding

A. Legal Authorities

The **Public Health Service Act** (as amended by the US Patriot Act, The Homeland Security Act and The Public Health Security and Bioterrorism Preparedness and Response Act) forms the foundation of HHS' responsibility for responding to public health and medical emergencies. Among other things, it authorizes the Secretary of HHS to:

- Declare a public health emergency.

- Make and enforce regulations to prevent the introduction, transmission or spread of communicable diseases into the United States or from one State or possession into another, including isolation and quarantine.

- Conduct and support research and investigations into the cause, treatment, or prevention of a disease or disorder.

- Direct the deployment of officers of the Public Health Service in support of public health and medical operations.

- Provide public health and medical services.

- Provide for the licensure of biological products.

The Homeland Security Act of 2002 transferred ownership of the Strategic National Stockpile (SNS) to the Department of Homeland Security so that it could respond effectively to terrorist acts and other national emergencies. It also gave HHS responsibility for managing parts of the SNS to ensure that these assets would be available and consistent with anticipated threats. Subsequently, both departments delineated specific responsibilities in a Memorandum of Understanding (MOU).Under the Public Health Service Act and delegation of authority from the Secretary, the ASPHEP is authorized, on behalf of the Secretary, to direct and coordinate HHS-

[1] Appendix A lists and describes HHS' primary emergency response authorities.

wide efforts with respect to preparedness for, and response to, bioterrorism and other public health and medical emergencies.

The Federal Food, Drug and Cosmetic Act has the foundation of the FDA's responsibility for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. Among other things, it authorizes the Secretary to: approve drugs and devices; and to make and enforce regulations to implement the law. It also prohibits the introduction into interstate commerce of human or animal food, drugs, devices, or cosmetics that are adulterated or misbranded.

A detailed discussion of HHS legal authorities is included in the appendix. HHS may also carry out emergency response activities in conjunction with other Federal agencies, under Federal government wide authorities such as the Stafford Act and the Economy Act.

B. Responsibilities

The overall goal of the HHS preparedness and response programs is to ensure sustained public health and medical readiness for our communities and our nation against bioterrorism, infectious disease outbreaks, other public health threats and medical emergencies. The following officials and organizations have critical responsibilities within HHS to meet the Secretary's preparedness, response, and recovery objectives:

- The **Secretary of HHS** is responsible for the overall response to public health and medical emergencies. The Secretary or his / her designee determines the nature and scope of the HHS response to a public health or medical emergency

- The **Assistant Secretary for Public Health Emergency Preparedness** (ASPHEP), on behalf of the Secretary, directs and coordinates the Department's efforts to prevent, prepare for, respond to, and recover from, the public health and medical consequences of disaster or emergency. In particular, as directed by the Secretary, the ASPHEP establishes and deploys the Secretary's Emergency Response Teams (SERT) to be the Secretary's agent on scene at emergency sites. The SERT directs and coordinates the activities of all HHS personnel deployed to the emergency site to assist local, State, and other Federal and government agencies as applicable. This includes teams deployed through the OPDIVs (through the OPDIV team leader) as well as persons deployed from Headquarters. Unless designated otherwise by the Secretary, the Regional Health Administrator (RHA) will serve as the SERT leader. In this role, the SERT Leader reports to the Secretary through the ASPHEP.

  The ASPHEP acts as the Department's liaison with the Department of Homeland Security and other Federal agencies and serves as the Secretary's principal advisor on issues relating to intelligence matters, bioterrorism, and other public health and medical emergencies. The ASPHEP, on behalf of the Secretary, is responsible for evaluating HHS response operations.

- The **Regional Directors** (RDs) are the Secretary's Regional Representatives and primary spokespersons for the Department in the Regional Offices, except for the activities of any SERT deployed to their region. During normal operations, the RDs report pertinent information on regional issues and implications to the Director of the Office of Intergovernmental Affairs, who reports directly to the Secretary and Deputy Secretary. The RDs develop close working relationships with key State, local, and Tribal government officials to facilitate communication regarding HHS initiatives and policies. Additionally, the RDs work directly with local media, constituent groups of the Department, and the regional representatives of other Federal agencies.

  During an emergency, the RD assumes a slightly different role. The RDs, or their designees, are automatically members of any SERT deployed to their respective regions, and may under some circumstance be appointed to serve as the SERT Leader. During an emergency, all field communications to the Secretary are directed through the SERT Leader with a view to ensuring a coordinated response.

- The **Assistant Secretary for Health** (ASH), within the Office of Public Health and Science (OPHS), directs the Office of the Surgeon General in its management of deployed active duty and reserve corps officers. The ASH approves missions, determines the size of deployments, and exercises policy direction under normal operating conditions. The ASH directs the activities of the Regional Health Administrators (RHAs), who are responsible for building relationships with State and local public health and medical officials, as well as other Federal Departments within their region.

  - The **Office of the Surgeon General (OSG)** is responsible for operating the Commissioned Corps Readiness Force (CCRF) and officers who are called to duty in the Inactive Reserve Corps during deployment. Upon mission approval, the OSG coordinates the utilization of active duty and reserve Corps officers with the ASPHEP and their assigned agencies, under the policies established by the ASH. The OSG is responsible for developing a cadre of highly trained officers who can deploy to all-hazard responses and urgent public health needs. Members of the CCRF currently number 6,200 physicians, nurses, pharmacists, engineers, environmental health officers, dentists, mental health providers, scientists, therapists, dieticians, epidemiologists, health educators, food safety inspectors, and other public health professionals.

  - The **Regional Health Administrators** (RHAs) oversee HHS public health programs at the regional level and coordinate with State and local health officials. The RHAs are responsible for building relationships with State and local public health officials as well as other Federal Departments within their region. In a public health or medical emergency, the respective RHA serves as the SERT Leader, unless directed otherwise by the Secretary. During an emergency, all communications to HHS are directed through the SERT Leader with a view to ensuring a coordinated response.

- The **Assistant Secretary for Public Affairs** (ASPA), on behalf of the Secretary, coordinates and directs the Department's emergency public information and

communications efforts. The ASPA's mission is to disseminate accurate, consistent, timely, and easy-to-understand information to the public and ensure the Department, in coordination with the White House and other Federal agencies, speaks with "one voice" in order to help protect lives when the nation is threatened or experiences a major public health emergency.

- HHS **OPDIVs** play key roles in the HHS response.

  - The **Director of the Centers for Disease Control and Prevention** (CDC) is responsible for conducting disease surveillance activities, detecting and investigating disease outbreaks and other health problems, and developing strategies for dealing with the public health aspects of an emergency. Components within CDC have roles in evaluating chemical spills and environmental contamination and providing safety and health recommendations to responders (e.g. personal protective equipment).

  - The **Commissioner for Food and Drugs at the Food and Drug Administration** (FDA) is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and by helping the public get the accurate, science-based information they need to use medicines and food to improve their health.

  - The **Health Resources and Services Administration** (HRSA) is charged with increasing access to basic health care for those who are medically underserved. As the access Agency of the Department, HRSA works to assure the availability of quality health care to low income, uninsured, isolated and special needs populations and meets their unique health needs. With regard to emergency preparedness, HRSA manages the National Bioterrorism Hospital Preparedness Program, as well as the Bioterrorism Training and Curriculum Development Program. HRSA also has developed an Emergency Response Center capability, which is activated in emergency situations.

  - The **Indian Health Service** (IHS) provides a comprehensive health service delivery system to include personal and public health care, mental health issues, environmental health, engineering, dental, pharmaceutical, nursing, laboratory, community health and varied surveillance activities that involve disease outbreaks and other health problems that deal with American Indians and Alaska Natives. IHS personnel provide these services during national and international disasters and emergencies.

  - The **Substance Abuse and Mental Health Services Administration** (SAMHSA) is responsible for addressing the psychosocial factors in preparedness, response and recovery for natural and manmade disasters. Psychosocial factors include mental health, substance abuse, and related concerns. SAMHSA activities may include

staffing interagency emergency operations centers, deploying personnel, and providing grants, services, and technical assistance to States and local jurisdictions.

- The **National Institutes of Health (NIH)** is the steward of medical and behavioral research for the Nation. Its mission is science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability. The goals of the agency are as follows: 1) foster fundamental creative discoveries, innovative research strategies, and their applications as a basis to advance significantly the Nation's capacity to protect and improve health; 2) develop, maintain, and renew scientific human and physical resources that will assure the Nation's capability to prevent disease; 3) expand the knowledge base in medical and associated sciences in order to enhance the Nation's economic well-being and ensure a continued high return on the public investment in research; and 4) exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science.

- The **Agency for Healthcare Research and Quality (AHRQ)** is responsible for supporting research preparing models and practices that enhances the preparedness efforts of national, State and local jurisdiction through the development and assessment of alternative approaches that ensure health surge capacity for mass casualty events, alternative uses of information technology and electronic communication networks, protocols and technologies to enhance interoperability among healthcare systems, the public health systems, and other organizational participants in the emergency response network and training and information needs of healthcare providers for enhanced emergency response.

- The **Administration on Aging (AoA)** is responsible for assisting a nationwide network of aging organization in emergency preparedness and response to disaster events related to weather, bioterrorism and other catastrophes that adversely affect the lives and service delivery system for older persons. The AoA works with State and Area Agencies on Aging, Tribal Organizations and aging services providers in partnering with emergency preparedness systems to assure that the special needs of the elderly are included in emergency planning and response management.

- The **Administration for Children and Families (ACF)** is responsible for Federal programs that promote the economic and social well being of families, children, individuals, and communities. Within ACF, the Office of Refugee Resettlement is responsible for helping refugees, Cuban / Haitian entrants, asylees, and other beneficiaries establish a new life that is founded on the dignity of economic self-support and encompasses full participation in opportunities which Americans enjoy.

C. Funding

The funds for activities described in this plan are provided through direct and supplemental appropriations and reimbursements. Reimbursements include funds associated with emergency

response missions and task assignments from other Agencies, as well as fund transfers, in accordance with the authority of the Economy Act. Reimbursements from the States may be received for funding activities authorized under Section 311 of the Public Health Service Act.

IV. Operational Framework

Public health threats and medical emergencies can ensue from a myriad of causes - natural epidemics of infectious disease; terrorist acts involving explosives, biological agents, toxic chemicals, radiological or nuclear devices; industrial or transportation accidents; and weather-related catastrophes. In order to effectively and efficiently prepare for and respond to possible incidents, HHS has adopted a comprehensive operational framework that involves a continuous cycle of prevention, preparedness, evaluation, response (through exercises and actual responses), containment and recovery.

A. Prevention & Preparedness

On an annual basis, HHS updates its Strategic Plan to Combat Bioterrorism and other public health threats and medical emergencies. This work is completed by the HHS Bioterrorism Council and serves as the annual guide of the Department for prevention and preparedness activities.

The Secretary of HHS created the Bioterrorism Council in January 2003 to foster a "One Department" approach to combat bioterrorism and other public health threats and medical emergencies. The Strategic Plan explicates HHS priorities and focus areas, articulates goals associated with each focus area, and outlines relevant activities being conducted by HHS Operating and Staff Divisions. The continuous review and update of the Strategic Plan will be an instrument for promoting results-oriented management and for appraising contributions toward ensuring public health emergency preparedness.

Examples of some of the prevention goals in the current Strategic Plan are: safe and secure handling of potential bioterrorism agents; safe and secure laboratories for research and testing involving potential terrorism agents; ensuring that food and medical products are secure from potential terrorism agents; and engaging in productive partnership with other federal agencies, State / local / territorial / Tribal governments, private sector, non-governmental agencies, and other Nations in combating bioterrorism and other public health threats and emergencies.

Preparedness efforts are designed to enhance Federal, State, Territorial, local, and Tribal government preparedness for public health and medical emergencies. HHS has improved Departmental preparedness by enhancing national capability for infectious disease surveillance and response, fostering the development of medical countermeasures, and the analysis of potential chemical or biological terrorism agents in food and food processing mitigation strategies.

HHS is also actively engaged in the development and implementation of public health and medical emergency exercises and training. Various OPDIVs in the Department provide technical assistance to State, Territorial, local, and Tribal governments aimed at enhancing

preparedness through the development of all-hazards planning. HHS has also partnered with universities and professional organizations to encourage curriculum development, as well as continuing education opportunities in the area of public health and medical emergency preparedness and response. The Department seeks to ensure that the nation has an emergency-ready public health and health care system, along with a secure information technology and physical infrastructure for health care delivery.

HHS, through CDC and HRSA, has funded Cooperative Agreements to support State and local public health and health care system preparedness efforts. The Cooperative Agreement guidance emphasizes the development of regional plans for integrated, coordinated public health and hospital / health care system preparedness and response at the State and local levels. The CDC funds are strengthening public health preparedness to address bioterrorism, outbreaks of infectious diseases and public health emergencies. The HRSA funding provides funds to States and other awardees to develop surge capacity to deal with mass casualty events through regional health care system planning.

Normal Response Operations

Normal response operations are the day-to-day activities that support ongoing preparedness and planning activities. Normal response operations can include operational responses that are a part of the agencies day-to-day mission (e.g. food safety inspections, outbreak investigations, etc.), both domestically and abroad. HHS OPDIVs notify the SCC of any routine deployments, but manage their assets according to internal policies and procedures.

HHS has many assets involved in day-to-day response planning, preparedness and response:

- The **Secretary's Command Center** (SCC) serves as an information and operations center that provides a single focal point for information sharing, command and control, communications, specialized technologies and information collection, assessment, analysis and sharing for all HHS components under emergency and non-emergency conditions.

- OPDIV **Emergency Operations Centers** (EOCs) can be activated separately from the SCC when involved in an OPDIV-specific response that does not require HHS agency-wide coordination. During such a response, the OPDIV serves as the focal point for coordinating OPDIV response activities. The OPDIV must notify the SCC that the OPDIV EOC is activated and provide status updates of activities. During a Departmental response, if an OPDIV is not activated and that agency's support is need for the response, the SCC may request that an OPDIV activate its EOC. Under Departmental responses each EOC coordinates its operational information with the SCC to develop a single Departmental response picture.

- On a daily basis, HHS provides **liaisons** to the Department of Homeland Security's Homeland Security Operations Center (HSOC) and the Federal Bureau of Investigation's (FBI) National Joint Terrorism Task Force (NJTTF). These liaisons support the

respective host organizations by providing public health and medical input to non-health focused operations centers. Critical public health and medical requirements are transmitted to the SCC and brought to the ASPHEP for dissemination within HHS.

- The **Emergency Preparedness and Response Group** convenes as needed to discuss emergency preparedness and response issues and to make policy recommendations to the Secretary, through the ASPHEP. The SCC coordinates the scheduling and implementation of the Emergency Preparedness and Response Group meetings through face-to-face meetings and video and audio teleconferences. The Deputy Assistant Secretary for Public Health Emergency Preparedness normally chairs the group on behalf of the ASPHEP. Emergency coordinators from the following OPDIVs and STAFFDIVs participate:

  - Centers for Disease Control and Prevention;
  - Food and Drug Administration;
  - National Institutes of Health;
  - Substance Abuse and Mental Health Services Administration;
  - Health Resources and Services Administration;
  - Indian Health Service;
  - Administration on Aging;
  - Administration for Children and Families;
  - Office of Public Health and Science;
  - Office of the Assistant Secretary for Public Affairs; and
  - Office of the General Counsel.

The SCC and CDC EOC maintain 24-hour operations during baseline operations. Other OPDIV EOCs are activated based on the needs of the threat or emergency as indicated by the Secretary through the ASPHEP. The SCC and OPDIV EOCs maintain rosters of their respective on-call response personnel and make periodic tests of the communications systems and recall procedures. Each Agency should assure that the responders on their roster meet basic health and safety requirements.

Once activated, on-call personnel are ready to deploy within four (4) hours of the notification. This includes deploying personnel both domestically and abroad in response to a threat or emergency when a Departmental level response is required. Timelines may be adjusted based on national threat levels (such as the Homeland Security Advisory System) or internal policies and procedures. Through the respective OPDIVs, HHS maintains adequate equipment and supplies to support Departmental response teams and personnel.

B. Emergency Response Operations

The mobilization of a Departmental emergency response begins with an identification of a credible threat, a potential emergency or notification of an actual event of national significance. With any of these situations, the ASPHEP consults with senior management within OPHEP and the relevant OPDIVs and recommends to the Secretary whether to transition from "normal" operations to a coordinated Departmental emergency response operation. At the direction of the

Secretary, the ASPHEP will notify OPDIVs that the situation requires a Departmental emergency response.

As a situation is developing the ASPHEP, on behalf of the Secretary, will coordinate a process of evaluation to determine the extent, scope, breadth, and severity of the incident. This evaluation may be prior to the actual event occurring, such as a hurricane, or it may be based on information received through one or multiple operations centers. The analysis of the situation will determine the extent of the HHS response in coordination with other agencies and their roles and responsibilities.

The HHS emergency response framework includes two general stages (1) notification and alert, and (2) deployment and field management. More detailed stages, or risk levels, are sometimes used in national or Departmental operational plans to expand upon this framework.

Notification and Alert

Information about threats to the public's health come to the attention of HHS components through a variety of sources: public health and emergency management authorities at all levels of Government; disease surveillance systems; law enforcement agencies; intelligence channels; agricultural, industrial, and environmental agencies; and media sources.

For the Secretary to maintain constant situational awareness, the SCC has been established as the notification point within the Department for public health threats and emergencies. Any information regarding a threat or public health emergency received within the Department should be transmitted immediately to the SCC. The SCC immediately notifies the ASPHEP who personally notifies the Secretary and / or the Chief of Staff. The ASPHEP will direct the SCC regarding further notifications to the HSOC, senior Departmental officials (e.g. ASH, etc.), OPDIV EOCs, the relevant RHA, RD and other pertinent Agencies and Departments depending on the nature of the threat. Actions that may occur during such an alert include, but are not limited to:

- Activating or enhancing the staffing of the SCC and / or OPDIV EOCs;
- Providing HHS liaisons to other Federal EOCs (e.g. FBI Strategic Information and Operations Center, etc.); or
- Alerting or pre-deploying specific teams or personnel to speed the time to deployment should that order be given.

The ASPHEP will provide direction to organizational components regarding the appropriate staffing based on the event information. An HHS liaison will be provided to other Federal operations centers only after that Department or Agency (e.g. Department of Homeland Security, FBI, etc.) has made a request to the Department through the ASPHEP. The decision to pre-deploy HHS personnel will be made by the Secretary, through the ASPHEP.

Deployment and Management

The Secretary directs the deployment of HHS assets in response to a potential or actual public health and medical emergency, which requires a Department level response.

The Secretary, through the ASPHEP, will activate a SERT as required. Each SERT includes the Team Leader and other appropriate personnel such as the pertinent RD or her / his designee, and OPDIV liaisons for those components with deployed or deploying personnel, including HHS personnel deployed to multi-agency response entities, such as Regional Operations Centers and Joint Field Offices. The SERT Leader will be the respective RHA, unless designated otherwise by the Secretary. Once on scene, the SERT directs and coordinates the activities of all deployed HHS teams and individuals and represents HHS in interactions with the regional response structure. The SERT Leader maintains contact with the ASPHEP and receives direction from the Secretary, through the ASPHEP.

Headquarters Management

The ASPHEP directs and coordinates the HHS response on behalf of the Secretary. The SCC is the focal point for coordinating information related to the overall response operation. OPDIVs will provide liaisons to the SCC, at the request of the ASPHEP, to facilitate this coordination. HHS may be asked to provide liaisons to other Federal operations centers. All requests for HHS assistance will be made to the Secretary through the ASPHEP. If HHS requires assistance from other Federal Agencies, the ASPHEP will make those requests on behalf of the Secretary.

Video and / or audio conferences will be scheduled at regular intervals by the SCC to facilitate communications between the different components of the Department, affected States, Tribes and other relevant Federal and public health and medical officials.

Field Management

Based on the initial assessment by the SERT, additional personnel may be deployed to meet certain mission requirements. On behalf of the Secretary, the ASPHEP will provide specific mission assignments, priorities and objectives to the SERT. These mission assignments will be coordinated, and may be at the request of, other Federal entities, particularly DHS. Once in the field, the SERT:

- Directs and coordinates HHS response assets.
- Represents HHS in interactions with local, State, Territorial and Tribal government public health and medical incident management authorities, as well as the regional response structure.
- Assesses the requirements or potential needs for additional HHS assistance.
- Facilitates the transmission of incident information from incident authorities to the ASPHEP through the SCC.

- Provides continuous assessment of the adequacy of the HHS response to the Secretary through the ASPHEP.

The SERT directs and coordinates all Departmental support activities with the appropriate local, State, Territorial, or Tribal incident management authorities having jurisdiction for the activities. The SERT shares information and coordinates closely with other federally deployed management structures (e.g., DHS, FBI, etc.).

Public Information

The HHS Assistant Secretary for Public Affairs works with the Department of Homeland Security Public Affairs Office to ensure that public affairs aspects of the response are coordinated across the Department and assembles a variety of public affairs response teams based on the needs of the emergency. These teams handle media inquiries, develop public information materials, and provide public information liaison officers to the SERT and other operations centers.

Containment

Once a determination has been made, plans should be quickly developed to establish procedures for containing the incident from further spread which would increase the quantity of resources needed for response. The containment measures will vary depending on the situation.

C. Recovery

Demobilization

The decision to demobilize the SERT is made by the Secretary, through the ASPHEP, based on the successful completion of mission assignments and assessments of the response. The demobilization of other HHS-deployed assets is coordinated with the SERT.

With the demobilization of the SERT, full responsibility for coordination with incident authorities transitions to the OPDIVs. All deployed assets continue to report their status to the SCC through their respective agencies as long as they remain deployed for the incident.

Each OPDIV should assure there are medical and mental health services available to agency workers after deployment.

Acronym List

ACF	Administration for Children and Families
AHRQ	Agency for Healthcare Research and Quality
AOA	Administration on Aging
ASH	Assistant Secretary for Health
ASPA	Assistant Secretary for Public Affairs
ASPHEP	Assistant Secretary for Public Health Emergency Preparedness
CCRF	Commissioned Corp Readiness Force
CDC	Centers for Disease Control and Prevention
DHS	Department of Homeland Security
DOS	Department of State
EOC	Emergency Operations Center
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
HSOC	Homeland Security Operations Center
HSPD-5	Homeland Security Presidential Directive #5
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
IIMG	Interagency Incident Management Group
INRP	Initial National Response Plan
LRN	Laboratory Response Network
NIH	National Institutes of Health
NJTTF	National Joint Terrorism Task Force
NSSE	National Security Special Events
OPDIV	Operating Division
OPHS	Office of Public Health and Science
OSG	Office of the Surgeon General
RD	Regional Director
RHA	Regional Health Administrator
SAMHSA	Substance Abuse and Mental Health Services Administration
SCC	Secretary's Command Center
SERT	Secretary's Emergency Response Team
SNS	Strategic National Stockpile

Appendix A – Legal Authorities

The following summarizes significant emergency response authorities of the Department of Health and Human Services (HHS) under the Public Health Service Act, the Social Security Act, and the Federal Food, Drug and Cosmetic Act. These are the principal emergency response authorities. The Department may exercise any of its legal authorities as needed to respond to public health and medical emergencies.

I. Public Health Service Act[2]

The Public Health Service (PHS) Act authorizes the Secretary, acting both at the Departmental level and through agencies of the PHS (e.g., the Centers for Disease Control and Prevention, the Food and Drug Administration, the National Institutes of Health, the Health Resources and Services Administration, the Substance Abuse and Mental Health Services Administration, and the Indian Health Service, Food and Drug Administration, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Drug Reactions to protect the public health and provide public health and medical services during emergencies. Under the PHS Act, 42 U.S.C. 241 et. seq., the Secretary is authorized to, among other things, declare a public health emergency and take appropriate discretionary actions to respond to the emergency, take actions to prevent the introduction, transmission, and spread of communicable diseases, deploy the Public Health Service Commissioned Corps, and develop and stockpile countermeasures to agents that could be used in a bioterrorist event.

42 USC 247d: Declaration of a Public Health Emergency

The Secretary may declare a public health emergency under section 319(a) of the PHS Act, and take appropriate actions in response to that emergency. Prior to a declaration, the Secretary must determine, after consultation with such public health officials as may be necessary, that: (1) a disease or disorder presents a public health emergency; or (2) a public health emergency, including significant outbreaks of infectious disease or bioterrorist attacks, otherwise exists. The Secretary may then take action appropriate to respond to the public heath emergency, including making grants, providing awards for expenses, and entering into contracts and conducting and supporting investigations into the cause, treatment, or prevention of the disease or disorder that presents the emergency, and may use resources from the Public Health Emergency Fund. Funds may be appropriated as necessary to the emergency fund, and supplement, rather than supplant, other Federal, State, and local public funds provided for such activities. These funds generally remain available until expended.

The Secretary's declaration lasts for 90 days, but may be extended by the Secretary based on the same or additional facts. The Secretary's declaration terminates when the

[2] Summarized sections include amendments made by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and the Homeland Security Act of 2002.

Secretary declares that the emergency no longer exists, or after 90 days, which ever occurs first. Congress must be notified of the Secretary's determinations within 48 hours.

Section 887 of the Department of Homeland Security Act states that the annual Federal Response Plan developed by the Department of Homeland Security shall be consistent with section 319 of the PHS Act and provides that, during the period in which the Secretary has declared a public health emergency pursuant to Section 319(a) of the PHS Act, he shall keep relevant agencies, including the Department of Homeland Security, the Department of Justice, and the Federal Bureau of Investigation, fully and currently informed. In cases involving, or potentially involving, a public health emergency in which the Secretary has not made a determination under Section 319(a) of the PHS Act, all relevant agencies, including the Department of Homeland Security, the Department of Justice, and the Federal Bureau of Investigation, are to keep the Secretary and the Director of the Centers for Disease Control and Prevention fully and currently informed.

42 U.S.C. 214 - 216: Commissioned Corps and PHS Personnel

Section 203 of the PHS Act establishes Commissioned Regular Corps and a Commissioned Reserve Corps for duty in time of emergency. 42 U.S.C. 204. Commissioned Corps officers must be citizens and are appointed and compensated under a separate personnel system without regard to civil service laws. Commissioned Officers of the Regular Corps are appointed by the President with the advice and consent of the Senate. Reserve Corps officers are appointed by the President.

Commissioned officers of the Reserve Corps are at all times subject to call to active duty by the Secretary[3], for training or for determining their fitness for appointment in the regular Corps. Warrant officers may be appointed to the Service to provide support to the health and delivery systems maintained by the Service and are considered to be officers within the Commissioned Corps. Section 216 of the PHS Act allows the President to use the Commissioned Corps in times of war or an emergency proclaimed by the President, and allows the President to declare personnel of the Corps to be part of the military during such time.

Under section 214 of the PHS Act, the Secretary is authorized to detail personnel of the U.S. Public Health Service to other Federal departments to cooperate in, or conduct work related to, the function of that department or of the Service, upon request of the head of that department. Personnel of the Service may also be detailed to State health and mental health authorities, upon request, to assist the State or political subdivision thereof to conduct work related to functions of the Service, and to committees of Congress, or to nonprofit educational research or other institutions engaged in health activities for special studies of scientific problems and for the dissemination of information relating to public health.

[3] Although these and several other cited provisions of the PHS Act refer to authorities of the Surgeion General, under Reorganization Plan No.3 of 1966, functions of the Public Health Service and the Surgeon General of the Public Health Service were transferred to the Secretary of the Department. This summary describes authorities of the Secretary consistent with Reorganization Plan No. 3.

42 U.S.C. 233, Defense of Certain Malpractice and Negligence Suits, Smallpox Compensation

Section 224 of the PHS Act provides that remedies under the Federal Tort Claims Act are the exclusive remedy for malpractice and negligence claims against Commissioned Corps officers and employees of the Public Health Service for performance of their official duties. Section 304 of the Department of Homeland Security Act amended section 224 of the Public Health Service Act to provide an exclusive remedy under the Federal Tort Claims Act for injury or death attributable to smallpox countermeasures, meaning those substances that the Secretary specifies in a declaration that are used to prevent or treat smallpox (including the smallpox vaccine) or that are used to control or treat the adverse effects of vaccinia inoculation or another covered countermeasure. The Secretary issued such a declaration on January 24, 2003 for the period of one year. 68 Fed. Reg. 4212. The Smallpox Emergency Personnel Protection Act of 2003, P.L. 108-20, established a compensation program to provide benefits and/or compensation to eligible persons injured as a result of exposure to a smallpox countermeasure while the January 24 Declaration is in effect. Individuals must first file a claim under section 224 of the PHS Act, as amended by section 304 of the Homeland Security Act.

42 U.S.C. 241: Research and Development

Under Section 301 of the PHS Act, the Secretary is authorized to conduct and support research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man, including water purification, sewage treatment, and pollution of lakes and streams. These authorities are further carried out under Title IV of the PHS Act.

42 U.S.C. 247d-6(h): Accelerated Research and Development on Priority Pathogens and Countermeasures

Section 319F(h) of the PHS Act permits the Secretary to give priority funding to research and studies related to countermeasures to pathogens of potential use in a bioterrorist attack and other agents that may cause a public health emergency. In addition, the Secretary may designate medical products for counterterrorism for priority review 42 U.S.C. 247d-6(h). In addition, the Secretary may designate medical products for counterterrorism for priority review under the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. 356, 356-1, 360e(d)(5).

The term "priority countermeasure" means a drug, biological product, device, vaccine, antiviral, or diagnostic test that the Secretary determines to be a priority: 1) to treat, identify, or prevent infection by a biological agent or toxin listed as a select agent under Section 351A of the PHS Act or harm from any other agent that may cause a public health emergency; or 2) to diagnose conditions that may result in adverse health consequences or death and may be caused by the administering of a drug, biological product, device, vaccine, antiviral, or diagnostic test that is a priority under item (1).

Section 304 of the Department of Homeland Security Act directs the Secretary, HHS to coordinate with the Department of Homeland Security in research and development activities related to countermeasures for emerging agents of terrorism and in developing specific benchmarks and outcome measurements for evaluating progress toward achieving research goals.

42 U.S.C. 264: Prevention of Communicable Diseases

Under Section 361 of the PHS Act, the Secretary may quarantine individuals: (1) arriving into the United States; (2) moving from one State or possession into another; or (3) when such individuals are a probable source of infection to other individuals moving between States. Section 361 authorizes the "apprehension, detention, or conditional release" of individuals to prevent the spread of communicable diseases that are specified in Executive Orders of the President that are based on a recommendation of the Secretary in consultation with the Secretary. The most recent Executive Order, 13295, issued April 4, 2003, permits apprehension, detention, or conditional release of individuals to prevent transmission of cholera, diphtheria, infectious tuberculosis, plague, smallpox, yellow fever, viral hemorrhagic fevers, and severe acute respiratory syndrome.

Implementing regulations at 42 C.F.R. Part71 permit the Department to detain, isolate, put into isolation, or place under surveillance any arriving person reasonably believed to be infected with or exposed to the diseases listed under the most recent Executive Order. Implementing regulations at 42 CFR Part 70 also allows the Department to take such measures as are necessary to prevent the interstate spread of diseases whenever the measures taken by a State or local health authority are inadequate. See, also, FDA regulations at 21 C.F.R. Part 1240. Customs and Coast Guard Officers are authorized to aid in the enforcement of Federal quarantine rules and regulations, 42 U.S.C. 268, and the Secretary may request assistance from Customs, Coast Guard, and military officers in the execution of State quarantine actions. 42 U.S.C. 97.

42 U.S.C. 243: Quarantine Enforcement and Temporary Assistance to States

Under section 311(a) of the PHS Act, the Secretary is authorized to accept from State and local authorities any assistance in the enforcement of quarantine Federal regulations, to assist States and their political subdivisions in the prevention and suppression of communicable diseases, to cooperate with and aid State and local authorities in the enforcement of their quarantine and other health regulations, and to advise the States on matters relating to the preservation and improvement of the public health. Section 311(c) of the PHS Act allows the Secretary to cooperate with public and private entities to control epidemics and meet other health emergencies and problems, and render temporary assistance to States and localities to meet health emergencies. 42 U.S.C. 243.

42 U.S.C. 265: Prohibition of Entry and Imports

Under Section 362 of the PHS Act, whenever the Secretary determines that by reason of the existence of any communicable disease in a foreign country there is a serious danger of the introduction of such disease into the United States, and that this danger is so increased by the introduction of persons or property from such country that a suspension of the right to introduce such persons and property is required in the interest of the public health, the Secretary, in accordance with regulations approved by the President, can prohibit, in whole or in part, the introduction of persons and property from such countries or places as he shall designate in order to avert such danger, and for such period of time as he may deem necessary for such purpose. Separate regulations specifically implementing this section have not been promulgated. Under Executive Order 13295, the functions of the President under Section 362 of the PHS Act have been assigned to the Secretary.

42 U.S.C. 266: War-Time Quarantine

Under Section 363 of the PHS Act, to protect the military and naval forces and war workers of the United States in time of war against any communicable disease specified in Executive Orders and provided in section 361(b) of the PHS Act, the Secretary, in consultation with the Surgeon General, is authorized to provide by regulations for the apprehension and examination, in time of war, of any individual reasonably believed (1) to be infected with such disease and (2) to be a probable source of infection to members of the armed forces of the United States or to individuals engaged in the production or transportation of arms, munitions, ships, food, clothing, or other supplies for the armed forces. Such regulations may provide that if upon examination any such individual is found to be so infected, he may be detained for such time and such manner as may be reasonably necessary. Separate regulations specifically implementing this section have not been promulgated.

42 U.S.C. 267(a): Quarantine Stations

Under Section 364(a) of the PHS Act, the Secretary shall control, direct, and manage all United States quarantine stations, grounds, and anchorages, designate their boundaries, and designate the quarantine officers to be in charge thereof, except as provided in 50 U.S.C. §§191, 192, 194, and 195 (which establish Presidential and Transportation authorities to govern anchorage and movement of any vessel in the territorial waters of the United States in response to actual or threatened war, insurrection, invasion or disturbance of international relations or mass migration.) Section 364(a) of the PHS Act further states that, with approval of the President, the Secretary shall from time to time select suitable sites for and establish such additional stations, grounds, and anchorages in the States and possessions of the United States as in his judgment are necessary to prevent the introduction of a communicable disease into the States and possessions of the United States. 42 U.S.C. 267(a). Under Executive Order 13295, the functions of the President under Section 364(a) of the PHS Act have been assigned to the Secretary.

42 U.S.C. 249: Care and Treatment for Persons Under Quarantine:

Sections 322(a) and (c) of the PHS Act provide for care and treatment by the Public Health Service for persons under quarantine, or care and treatment at the expense of the Public Health Service from public or private medical or hospital facilities when authorized by the officer in charge of the quarantine station. Section 322(b) also provides for temporary treatment and care of individuals at Public Health Service hospitals and stations in the event of an emergency. Implementing regulations are provided at 42 C.F.R. 32.111.

42 U.S.C. 248: Establishment of Hospitals

Section 321 of the PHS Act enables the Secretary to operate Public Health Service hospitals, including management of the hospitals and treatment of patients, transfer patients between hospitals, dispose of articles produced by patients in the course of treatment, dispose of money and effects of deceased patients, and, to the extent the Secretary determines that other public or private funds are not available, pay expenses of preparing and transporting remains of, or payment of reasonable burial expenses for, any patient dying in a public health service hospital or station. Implementing regulations may be found at 42 C.F.R. Part 35.

42 U.S.C. 290aa: Crisis Counseling

Under Section 501(m) of the PHS Act, the Secretary may make awards to public entities to address emergency substance abuse or mental health needs. Under implementing regulations, 42 C.F.R. 51d, an emergency must be the direct consequence of a clear precipitating event that has a sudden, rapid onset and a definite conclusion, such as a natural disaster, technological disaster or criminal act that results in significant death, injury, exposure to life-threatening circumstances, hardship, suffering, loss of property, or loss of community infrastructure.

42 U.S.C. 300hh-12: Pharmaceutical Stockpile

The Secretary of Homeland Security, in coordination with the Secretary of HHS and the Secretary of Veterans Affairs, may maintain a stockpile of drugs, vaccines, and other biological products, medical devices, and other supplies in such numbers, types, and amounts as are determined by the Secretary of HHS to be appropriate and practicable, taking into account other available sources, to provide for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations. 42 U.S.C. 300hh-12(a)(1). "Stockpile" is defined as: 1) physical accumulation (at one or more locations) of the described supplies, or 2) a contractual agreement between the Secretary and a vendor or vendors under which each vendor agrees to provide the described supplies to the Secretary. 42 U.S.C. 300hh-12(d).

According to Section 1705 of the Homeland Security Act of 2002, the Secretary of HHS continues to be responsible for some aspects of the stockpile. Under Section 121 of the Public Health Security and Bioterrorism Preparedness and Response Act, the Secretary,

HHS, is directed to: 1) work with the Working Group on Bioterrorism and Other Public Health Emergencies established under Section 108 of the Public Health Security and Bioterrorism Preparedness and Response Act; 2) ensure that adequate procedures are followed for inventory management and accounting and physical security; 3) in consultation with Federal, State, and local officials, take into consideration the timing and location of special events; 4) review and revise, as appropriate, the contents of the stockpile on a regular basis to ensure that emerging threats, advanced technologies, and new countermeasures are adequately considered; 5) devise plans for the effective and timely supply-chain management of the stockpile, in consultation with appropriate Federal, State and local agencies, and the public and private health care infrastructure; and 6) ensure the adequate physical security of the stockpile. 42 U.S.C. 300hh-12(a)(2).

42 U.S.C. 262: Regulation of Biological Products

Section 351 of the PHS Act states that no person may introduce or deliver for introduction into interstate commerce any biological product unless it is licensed and plainly marked with the name, identity of manufacturer, and expiration date. The Secretary is authorized to establish, by regulation, requirements for approval, suspension, and revocation of licenses. See 21 C.F.R. Part 601. Such licenses are approved on the basis of a demonstration of safety, purity and potency; assurance the manufacturing, processing, or packaging was done to standards that ensure the continued safety, purity and potency of the biological; and consent by the manufacturer to FDA inspections. The FDA may also conduct inspections of facilities that manufacture and prepare biological products. Upon a determination that a batch, lot, or other quantity of a product licensed under the Section presents an imminent or substantial hazard to the public health, the Secretary shall issue an order immediately ordering the recall of such batch, lot, or other quantity of such product. As used in this section, "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative arsphenamine (or any other trivalent organic arsenic compound) applicable to the prevention, treatment, or cure of a disease or condition of human beings.

42 U.S.C. 242p: National Disease Prevention Data Profile

The Secretary must compile and disseminate a national disease prevention data profile to provide a database for use in an emergency situation. This database includes such items as morbidity rates for diseases and health profiles on segments of the population.

42 U.S.C. 247d-1: National Needs to Combat Threats to Public Health

The Secretary authorized to establish reasonable capacities to improve, enhance, or expand the abilities of national, State, and local public health agencies to detect and respond to public health threats. This authority extends to detection and identification of infectious disease, and developing and implementing plans to provide medical care for infected people and those likely to be infected, as well as communicating this information to local, State and national health care agencies.

42 UCS 247d-2: Assessment of Public Health Needs

The Secretary is authorized to award grants to perform evaluations of the capabilities of local and State public health agencies to respond to public health threats.

42 U.S.C. 300hh: Public Health Response and Recovery Preparations

The Secretary is authorized to develop and implement a coordinated strategy for carrying out health-related preparations, response and recovery to public health emergencies. The Secretary is authorized to coordinate and collaborate with States to achieve this goal. The Secretary is also authorized to develop and implement a preparedness and response plan and to provide effective assistance to State and local governments in ensuring that they have the appropriate capabilities, including public health surveillance, laboratory readiness, trained and equipped emergency response, public health, and medical personnel, health and safety of emergency response workers, public health agencies to coordinate emergency response, participation in communication networks, maintenance of medical stockpiles and the preparation and maintenance of hospital readiness.

42 U.S.C. 300ff-81: Protection of Emergency Response Workers

The Secretary is authorized to complete a detailed list of potentially life-threatening infectious diseases to which emergency response workers may be exposed in responding to emergencies. The authority is also granted to transmit the list to State, Tribal, territory and local health officials.

42 U.S.C. 247-7c: Supplies and Equipment

Under Section 319J of the PHS Act, the Secretary may provide supplies, equipment, and services and detail HHS officers or employees to recipients of awards made under Sections 319 through 319I and 319K of the PHS Act, which deal with, among other things, action in response to public health emergencies; capacity building of State and local public health systems to detect and respond to public health threats; assessment of State and local public health needs; grants to improve State, Tribal and local public health agencies; improving capabilities of the CDC; antimicrobial resistance; education of personnel; grants to address shortages of personnel; credentialing of health professionals; and priority countermeasures.

42 U.S.C. 247d-6(g)(1): Emergency Response Personnel Training

Section 319F(g) of the PHS Act authorizes the Secretary to develop teaching materials and core curricula: 1) to be given to public health officials, medical professionals, emergency physicians and emergency department staff, laboratory personnel and other personnel working in health care facilities, including poison control centers, for recognition and identification of potential bioweapons and other agents that may create a public health emergency, and care of victims of such an emergency, recognizing the

special needs of children and other vulnerable populations; 2) for community-wide planning by State and local governments, hospitals and other health care facilities, emergency response units and appropriate public and private sector entities to respond to a bioterrorist attack or other public health emergency; and 3) for proficiency testing of laboratory and other public health personnel for the recognition and identification of potential bioweapons and other agents that may create a public health emergency.

42 U.S.C. 247d-7b: Credentialing of Health Professionals

Section 319I of the PHS Act authorizes the Secretary to establish and maintain a system for advance registration of health professionals to verify credentials, licenses, accreditations, and hospital privileges when such professionals volunteer to provide services during public health emergencies. This verification system may be carried out directly, or through a grant, contract, or cooperative agreement. In establishing the system, Secretary is directed to provide for an electronic database, and to establish provisions for promptness and efficiency of the system in collecting, storing, updating, and disseminating information on the credentials, licenses, accreditations, and hospital privileges of the volunteers.

The Secretary may award grants and provide technical assistance to States and other public or nonprofit private entities for activities relating to the verification system, and may encourage each State to provide legal authority during a public health emergency for health professionals authorized in another State to provide such services in the State. However, the Secretary is not authorized under this section to issue requirements regarding provision by States of credentials, licenses, accreditations, or hospital privileges.

42 U.S.C. 300aa-10: National Vaccine Injury Compensation Program

Section 2110 of the PHS Act establishes the National Vaccine Injury Compensation Program, administered by the Secretary, under which compensation may be paid for a vaccine-related injury or death from covered childhood vaccines. Sections 2111-23 of the PHS Act address the process for filing claims under the program with the U.S. Court of Federal Claims, eligibility for filing such claims, limits on civil actions brought in regard to such claims, jurisdiction, and compensation. Section 2114 of the PHS Act and regulations at 42 C.F.R. Part 100, provide the Vaccine Injury Table, which lists vaccines and describes, including required timing of onset, injuries, disabilities, illnesses and conditions and deaths which may be presumed to be caused by those vaccines for purposes of receiving compensation under the program. Only vaccines, which are recommended for routine administration to children are eligible for compensation.

II. Social Security Act

42 U.S.C. 1320b-5 Waiver of Medicare, Medicaid, or SCHIP Requirements

Section 143 of the Public Health Security and Bioterrorism Preparedness and Response Act amends section 1135 of the Social Security Act (SSA) to enable the Secretary to ensure in an emergency, to the maximum extent feasible, that health care services are available to meet the needs of individuals enrolled in the Medicare, Medicaid, and SCHIP programs. Health care personnel who provide services in good faith, but are unable to comply with specific program requirements are reimbursed and exempted from sanctions for noncompliance, save for fraud or abuse. 42 U.S.C. 1320b-5. Further, the Secretary may temporarily waive or modify specified statutory or regulatory requirements of Medicare, Medicaid, or SCHIP, or any related statutes and regulations for health care services rendered during an emergency.

III. The Federal Food, Drug, and Cosmetic Act

The Food and Drug Administration (FDA) is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer and more affordable; and by helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

21 U.S.C. 334: Detention of Food; Seizure of Food

FDA may, by Administrative Order, detain food (which includes live food animals) for up to 30 days if it has credible evidence or other information that the food presents a threat of serious adverse health consequences or death to humans or other animals. The United States may seize any adulterated article of food that has been introduced into interstate commerce. This authority is valid at all interstate commerce points, departure areas, and receiving areas, retail or wholesale. Both of these authorities apply to domestically produced articles of food and can be used while imported articles of food are still in the custody of Customs and Border Protection (sometimes referred to as 'import status').

21 U.S.C. 342: Adulterated Food

Food is adulterated if, inter alia, it bears or contains any added poisonous or deleterious substance that may render it injurious to health; is unfit for food; or has been prepared, packed or held under insanitary conditions whereby it may have been rendered injurious to health.

21 U.S.C. 350c, 372, 374: Inspections and Investigations

FDA is authorized to inspect any location or vehicle where foods are manufactured, processed, packed or held, for introduction into interstate commerce or after such introduction, and this inspection extends to records of such persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, hold, or import food when FDA has a reasonable belief that the food is adulterated and presents a threat of serious adverse health consequences or death to humans or other animals (21 U.S.C. 374(a)(1)). FDA is authorized to collect samples (21 U.S.C. 372)), and is authorized to inspect and copy certain records of persons (excluding farms and restaurants) who manufacture, process, pack, distribute, receive, hold, or import an article of food if FDA has a reasonable belief that the article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals (21 U.S.C. 350C).

21 U.S.C. 381: Imports and Exports

Imports of food or cosmetics that appear to be adulterated are subject to refusal of admission to the United States (21 U.S.C. 381(a)(3)). In addition, if FDA has credible evidence or information that an imported food presents a threat of serious adverse health consequences or death to humans or other animals and FDA needs more time to inspect, examine, or investigate, FDA can request the Bureau of Customs and Border Protection to hold the product at the border for 24 hours.