THE WHITE HOUSE
PRESIDENT
GEORGE W. BUSH

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Homeland Security Presidential Directive

HOMELAND SECURITY PRESIDENTIAL DIRECTIVE/HSPD-21

Subject: Public Health and Medical Preparedness

Purpose

(1) This directive establishes a National Strategy for Public Health and Medical Preparedness (Strategy), which builds upon principles set forth in *Biodefense for the 21st Century* (April 2004) and will transform our national approach to protecting the health of the American people against all disasters.

Definitions

(2) In this directive:

(a) The term "biosurveillance" means the process of active data-gathering with appropriate analysis and interpretation of biosphere data that might relate to disease activity and threats to human or animal health – whether infectious, toxic, metabolic, or otherwise, and regardless of intentional or natural origin – in order to achieve early warning of health threats, early detection of health events, and overall situational awareness of disease activity;

(b) The term "catastrophic health event" means any natural or manmade incident, including terrorism, that results in a number of ill or injured persons sufficient to overwhelm the capabilities of immediate local and regional emergency response and health care systems;

(c) The term "epidemiologic surveillance" means the process of actively gathering and analyzing data related to human health and disease in a population in order to obtain early warning of human health events, rapid characterization of human disease events, and overall situational awareness of disease activity in the human population;

(d) The term "medical" means the science and practice of maintenance of health and prevention, diagnosis, treatment, and alleviation of disease or injury and the provision of those services to individuals;

(e) The term "public health" means the science and practice of protecting and improving the overall health of the community through disease prevention and early diagnosis, control of communicable diseases, health education, injury prevention, sanitation, and protection from environmental hazards;

(f) The term "public health and medical preparedness" means the existence of plans, procedures, policies, training, and equipment necessary to maximize the ability to prevent, respond to, and recover from major events, including efforts that result in the capability to render an appropriate public health and medical response that will mitigate the effects of illness and injury, limit morbidity and mortality to the maximum extent possible, and sustain societal, economic, and political infrastructure; and

(g) The terms "State" and "local government," when used in a geographical sense, have the meanings ascribed to such terms respectively in section 2 of the Homeland Security Act of 2002 (6 U.S.C. 101).

Background

(3) A catastrophic health event, such as a terrorist attack with a weapon of mass destruction (WMD), a naturally-occurring pandemic, or a calamitous meteorological or geological event, could cause tens or hundreds of thousands of casualties or more, weaken our economy, damage public morale and confidence, and threaten our national security. It is therefore critical that we establish a strategic vision that will enable a level of public health and medical preparedness sufficient to address a range of possible disasters.

(4) The United States has made significant progress in public health and medical preparedness since 2001, but we remain vulnerable to events that threaten the health of large populations. The attacks of September 11 and Hurricane Katrina were the most significant recent disasters faced by the United States, yet casualty numbers were small in comparison to the 1995 Kobe earthquake; the 2003 Bam, Iran, earthquake; the 2004 Sumatra tsunami; and what we would expect from a 1918-like influenza pandemic or large-scale WMD attack. Such events could immediately overwhelm our public health and medical systems.

(5) This Strategy draws key principles from the *National Strategy for Homeland Security* (October 2007), the *National Strategy to Combat Weapons of Mass Destruction* (December 2002), and *Biodefense for the 21st Century* (April 2004) that can be generally applied to public health and medical preparedness. Those key principles are the following: (1) preparedness for all potential catastrophic health events; (2) vertical and horizontal coordination across levels of government, jurisdictions, and disciplines; (3) a regional approach to health preparedness; (4) engagement of the private sector, academia, and other nongovernmental entities in preparedness and response efforts; and (5) the important roles of individuals, families, and communities.

(6) Present public health and medical preparedness plans incorporate the concept of "surging" existing medical and public health capabilities in response to an event that threatens a large number of lives. The assumption that conventional public health and medical systems can function effectively in catastrophic health events has, however, proved to be incorrect in real-world situations. Therefore, it is necessary to transform the national approach to health care in the context of a catastrophic health event in order to enable U.S. public health and medical systems to respond effectively to a broad range of incidents.

(7) The most effective complex service delivery systems result from rigorous end-to-end system design. A critical and formal process by which the functions of public health and medical preparedness and response are designed to integrate all vertical (through all levels of government) and horizontal (across all sectors in communities) components can achieve a much greater capability than we currently have.

(8) The United States has tremendous resources in both public and private sectors that could be used to prepare for and respond to a catastrophic health event. To exploit those resources fully, they must be organized in a rationally designed system that is incorporated into pre-event planning, deployed in a coordinated manner in response to an event, and guided by a constant and timely flow of relevant information during an event. This Strategy establishes principles and objectives to improve our ability to respond comprehensively to catastrophic health events. It also identifies critical antecedent components of this capability and directs the development of an implementation plan that will delineate further specific actions and guide the process to fruition.

(9) This Strategy focuses on human public health and medical systems; it does not address other areas critical to overall public health and medical preparedness, such as animal health systems, food and agriculture defense, global partnerships in public health, health threat intelligence activities, domestic and international biosecurity, and basic and applied research in threat diseases and countermeasures. Efforts in those areas are addressed in other policy documents.

(10) It is not possible to prevent all casualties in catastrophic events, but strategic improvements in our Federal, State, and local planning can prepare our Nation to deliver appropriate care to the largest possible number of people, lessen the impact on limited health care resources, and support the continuity of society and government.

Policy

(11) It is the policy of the United States to plan and enable provision for the public health and medical needs of

the American people in the case of a catastrophic health event through continual and timely flow of information during such an event and rapid public health and medical response that marshals all available national capabilities and capacities in a rapid and coordinated manner.

Implementation Actions

(12) *Biodefense for the 21st Century* provides a foundation for the transformation of our catastrophic health event response and preparedness efforts. Although the four pillars of that framework – Threat Awareness, Prevention and Protection, Surveillance and Detection, and Response and Recovery – were developed to guide our efforts to defend against a bioterrorist attack, they are applicable to a broad array of natural and manmade public health and medical challenges and are appropriate to serve as the core functions of the Strategy for Public Health and Medical Preparedness.

(13) To accomplish our objectives, we must create a firm foundation for community medical preparedness. We will increase our efforts to inform citizens and empower communities, buttress our public health infrastructure, and explore options to relieve current pressures on our emergency departments and emergency medical systems so that they retain the flexibility to prepare for and respond to events.

(14) Ultimately, the Nation must collectively support and facilitate the establishment of a discipline of disaster health. The specialty of emergency medicine evolved as a result of the recognition of the special considerations in emergency patient care, and similarly the recognition of the unique principles in disaster-related public health and medicine merit the establishment of their own formal discipline. Such a discipline will provide a foundation for doctrine, education, training, and research and will integrate preparedness into the public health and medical communities.

Critical Components of Public Health and Medical Preparedness

(15) Currently, the four most critical components of public health and medical preparedness are biosurveillance, countermeasure distribution, mass casualty care, and community resilience. Although those capabilities do not address all public health and medical preparedness requirements, they currently hold the greatest potential for mitigating illness and death and therefore will receive the highest priority in our public health and medical preparedness efforts. Those capabilities constitute the focus and major objectives of this Strategy.

(16) *Biosurveillance*: The United States must develop a nationwide, robust, and integrated biosurveillance capability, with connections to international disease surveillance systems, in order to provide early warning and ongoing characterization of disease outbreaks in near real-time. Surveillance must use multiple modalities and an in-depth architecture. We must enhance clinician awareness and participation and strengthen laboratory diagnostic capabilities and capacity in order to recognize potential threats as early as possible. Integration of biosurveillance elements and other data (including human health, animal health, agricultural, meteorological, environmental, intelligence, and other data) will provide a comprehensive picture of the health of communities and the associated threat environment for incorporation into the national "common operating picture." A central element of biosurveillance must be an epidemiologic surveillance system to monitor human disease activity across populations. That system must be sufficiently enabled to identify specific disease incidence and prevalence in heterogeneous populations and environments and must possess sufficient flexibility to tailor analyses to new syndromes and emerging diseases. State and local government health officials, public and private sector health care institutions, and practicing clinicians must be involved in system design, and the overall system must be constructed with the principal objective of establishing or enhancing the capabilities of State and local government entities.

(17) *Countermeasure Stockpiling and Distribution*: In the context of a catastrophic health event, rapid distribution of medical countermeasures (vaccines, drugs, and therapeutics) to a large population requires significant resources within individual communities. Few if any cities are presently able to meet the objective of dispensing countermeasures to their entire population within 48 hours after the decision to do so. Recognizing that State and local government authorities have the primary responsibility to protect their citizens, the Federal Government will create the appropriate framework and policies for sharing information on best practices and mechanisms to address the logistical challenges associated with this requirement. The Federal Government must work with nonfederal stakeholders to create effective templates for countermeasure distribution and dispensing that State and local government authorities can use to build their own capabilities.

(18) *Mass Casualty Care*: The structure and operating principles of our day-to-day public health and medical systems cannot meet the needs created by a catastrophic health event. Collectively, our Nation must develop a disaster medical capability that can immediately re-orient and coordinate existing resources within all sectors to satisfy the needs of the population during a catastrophic health event. Mass casualty care response must be (1) rapid, (2) flexible, (3) scalable, (4) sustainable, (5) exhaustive (drawing upon all national resources), (6) comprehensive (addressing needs from acute to chronic care and including mental health and special needs populations), (7) integrated and coordinated, and (8) appropriate (delivering the correct treatment in the most ethical manner with available capabilities). We must enhance our capability to protect the physical and mental health of survivors; protect responders and health care providers; properly and respectfully dispose of the deceased; ensure continuity of society, economy, and government; and facilitate long-term recovery of affected citizens.

(19) The establishment of a robust disaster health capability requires us to develop an operational concept for the medical response to catastrophic health events that is substantively distinct from and broader than that which guides day-to-day operations. In order to achieve that transformation, the Federal Government will facilitate and provide leadership for key stakeholders to establish the following four foundational elements: Doctrine, System Design, Capacity, and Education and Training. The establishment of those foundational elements must result from efforts within the relevant professional communities and will require many years, but the Federal Government can serve as an important catalyst for this process.

(20) *Community Resilience*: The above components address the supply side of the preparedness function, ultimately providing enhanced services to our citizens. The demand side is of equal importance. Where local civic leaders, citizens, and families are educated regarding threats and are empowered to mitigate their own risk, where they are practiced in responding to events, where they have social networks to fall back upon, and where they have familiarity with local public health and medical systems, there will be community resilience that will significantly attenuate the requirement for additional assistance. The Federal Government must formulate a comprehensive plan for promoting community public health and medical preparedness to assist State and local authorities in building resilient communities in the face of potential catastrophic health events.

Biosurveillance

(21) The Secretary of Health and Human Services shall establish an operational national epidemiologic surveillance system for human health, with international connectivity where appropriate, that is predicated on State, regional, and community-level capabilities and creates a networked system to allow for two-way information flow between and among Federal, State, and local government public health authorities and clinical health care providers. The system shall build upon existing Federal, State, and local surveillance systems where they exist and shall enable and provide incentive for public health agencies to implement local surveillance systems where they do not exist. To the extent feasible, the system shall be built using electronic health information systems. It shall incorporate flexibility and depth of data necessary to respond to previously unknown or emerging threats to public health and integrate its data into the national biosurveillance common operating picture as appropriate. The system shall protect patient privacy by restricting access to identifying information to the greatest extent possible and only to public health officials with a need to know. The Implementation Plan to be developed pursuant to section 43 of this directive shall specify milestones for this system.

(22) Within 180 days after the date of this directive, the Secretary of Health and Human Services, in coordination with the Secretaries of Defense, Veterans Affairs, and Homeland Security, shall establish an Epidemiologic Surveillance Federal Advisory Committee, including representatives from State and local government public health authorities and appropriate private sector health care entities, in order to ensure that the Federal Government is meeting the goal of enabling State and local government public health surveillance capabilities.

Countermeasure Stockpiling and Distribution

(23) In accordance with the schedule set forth below, the Secretary of Health and Human Services, in coordination with the Secretary of Homeland Security, shall develop templates, using a variety of tools and including private sector resources when necessary, that provide minimum operational plans to enable communities to distribute and dispense countermeasures to their populations within 48 hours after a decision to do so. The Secretary of Health and Human Services shall ensure that this process utilizes current cooperative programs and engages Federal, State, local government, and private sector entities in template development, modeling, testing, and evaluation. The Secretary shall also assist State, local government, and regional entities in

tailoring templates to fit differing geographic sizes, population densities, and demographics, and other unique or specific local needs. In carrying out such actions, the Secretary shall:

(a) within 270 days after the date of this directive, (i) publish an initial template or templates meeting the requirements above, including basic testing of component distribution mechanisms and modeling of template systems to predict performance in large-scale implementation, (ii) establish standards and performance measures for State and local government countermeasure distribution systems, including demonstration of specific capabilities in tactical exercises in accordance with the National Exercise Program, and (iii) establish a process to gather performance data from State and local participants on a regular basis to assess readiness; and

(b) within 180 days after the completion of the tasks set forth in (a), and with appropriate notice, commence collecting and using performance data and metrics as conditions for future public health preparedness grant funding.

(24) Within 270 days after the date of this directive, the Secretary of Health and Human Services, in coordination with the Secretaries of Defense, Veterans Affairs, and Homeland Security and the Attorney General, shall develop Federal Government capabilities and plans to complement or supplement State and local government distribution capacity, as appropriate and feasible, if such entities' resources are deemed insufficient to provide access to countermeasures in a timely manner in the event of a catastrophic health event.

(25) The Secretary of Health and Human Services shall ensure that the priority-setting process for the acquisition of medical countermeasures and other critical medical materiel for the Strategic National Stockpile (SNS) is transparent and risk-informed with respect to the scope, quantities, and forms of the various products. Within 180 days after the date of this directive, the Secretary, in coordination with the Secretaries of Defense, Homeland Security, and Veterans Affairs, shall establish a formal mechanism for the annual review of SNS composition and development of recommendations that utilizes input from accepted national risk assessments and threat assessments, national planning scenarios, national modeling resources, and subject matter experts. The results of each such annual review shall be provided to the Director of the Office of Management and Budget and the Assistant to the President for Homeland Security and Counterterrorism at the time of the Department of Health and Human Services' next budget submission.

(26) Within 90 days after the date of this directive, the Secretary of Health and Human Services shall establish a process to share relevant information regarding the contents of the SNS with Federal, State, and local government health officers with appropriate clearances and a need to know.

(27) Within 180 days after the date of this directive, the Secretary of Health and Human Services, in coordination with the Secretaries of State, Defense, Agriculture, Veterans Affairs, and Homeland Security, shall develop protocols for sharing countermeasures and medical goods between the SNS and other Federal stockpiles and shall explore appropriate reciprocal arrangements with foreign and international stockpiles of medical countermeasures to ensure the availability of necessary supplies for use in the United States.

Mass Casualty Care

(28) The Secretary of Health and Human Services, in coordination with the Secretaries of Defense, Veterans Affairs, and Homeland Security, shall directly engage relevant State and local government, academic, professional, and private sector entities and experts to provide feedback on the review of the National Disaster Medical System and national medical surge capacity required by the Pandemic and All-Hazards Preparedness Act (PAHPA) (Public Law 109-417). Within 270 days after the completion of such review, the Secretary shall identify, through a systems-based approach involving expertise from such entities and experts, high-priority gaps in mass casualty care capabilities, and shall submit to the Assistant to the President for Homeland Security and Counterterrorism a concept plan that identifies and coordinates all Federal, State, and local government and private sector public health and medical disaster response resources, and identifies options for addressing critical deficits, in order to achieve the system attributes described in this Strategy.

(29) Within 180 days after the date of this directive, the Secretary of Health and Human Services, in coordination with the Secretaries of Defense, Veterans Affairs, and Homeland Security, shall:

(a) build upon the analysis of Federal facility use to provide enhanced medical surge capacity in disasters required by section 302 of PAHPA to analyze the use of Federal medical facilities as a foundational element of public health and medical preparedness; and

(b) develop and implement plans and enter into agreements to integrate such facilities more effectively into national and regional education, training, and exercise preparedness activities.

(30) The Secretary of Health and Human Services shall lead an interagency process, in coordination with the Secretaries of Defense, Veterans Affairs, and Homeland Security and the Attorney General, to identify any legal, regulatory, or other barriers to public health and medical preparedness and response from Federal, State, or local government or private sector sources that can be eliminated by appropriate regulatory or legislative action and shall, within 120 days after the date of this directive, submit a report on such barriers to the Assistant to the President for Homeland Security and Counterterrorism.

(31) The impact of the "worried well" in past disasters is well documented, and it is evident that mitigating the mental health consequences of disasters can facilitate effective response. Recognizing that maintaining and restoring mental health in disasters has not received sufficient attention to date, within 180 days after the date of this directive, the Secretary of Health and Human Services, in coordination with the Secretaries of Defense, Veterans Affairs, and Homeland Security, shall establish a Federal Advisory Committee for Disaster Mental Health. The committee shall consist of appropriate subject matter experts and, within 180 days after its establishment, shall submit to the Secretary of Health and Human Services recommendations for protecting, preserving, and restoring individual and community mental health in catastrophic health event settings, including pre-event, intra-event, and post-event education, messaging, and interventions.

Community Resilience

(32) The Secretary of Health and Human Services, in coordination with the Secretaries of Defense, Veterans Affairs, and Homeland Security, shall ensure that core public health and medical curricula and training developed pursuant to PAHPA address the needs to improve individual, family, and institutional public health and medical preparedness, enhance private citizen opportunities for contributions to local, regional, and national preparedness and response, and build resilient communities.

(33) Within 270 days after the date of this directive, the Secretary of Health and Human Services, in coordination with the Secretaries of Defense, Commerce, Labor, Education, Veterans Affairs, and Homeland Security and the Attorney General, shall submit to the President for approval, through the Assistant to the President for Homeland Security and Counterterrorism, a plan to promote comprehensive community medical preparedness.

Risk Awareness

(34) The Secretary of Homeland Security, in coordination with the Secretary of Health and Human Services, shall prepare an unclassified briefing for non-health professionals that clearly outlines the scope of the risks to public health posed by relevant threats and catastrophic health events (including attacks involving weapons of mass destruction), shall coordinate such briefing with the heads of other relevant executive departments and agencies, shall ensure that full use is made of Department of Defense expertise and resources, and shall ensure that all State governors and the mayors and senior county officials from the 50 largest metropolitan statistical areas in the United States receive such briefing, unless specifically declined, within 150 days after the date of this directive.

(35) Within 180 days after the date of this directive, the Secretary of Homeland Security, in coordination with the Attorney General, the Secretary of Health and Human Services, and the Director of National Intelligence, shall establish a mechanism by which up-to-date and specific public health threat information shall be relayed, to the greatest extent possible and not inconsistent with the established guidance relating to the Information Sharing Environment, to relevant public health officials at the State and local government levels and shall initiate a process to ensure that qualified heads of State and local government entities have the opportunity to obtain appropriate security clearances so that they may receive classified threat information when applicable.

Education and Training

(36) Within 180 days after the date of this directive, the Secretary of Health and Human Services, in coordination

with the Secretary of Homeland Security, shall develop and thereafter maintain processes for coordinating Federal grant programs for public health and medical preparedness using grant application guidance, investment justifications, reporting, program performance measures, and accountability for future funding in order to promote cross-sector, regional, and capability-based coordination, consistent with section 201 of PAHPA and the National Preparedness Guidelines developed pursuant to Homeland Security Presidential Directive-8 of December 17, 2003 ("National Preparedness").

(37) Within 1 year after the date of this directive, the Secretary of Health and Human Services, in coordination with the Secretaries of Defense, Transportation, Veterans Affairs, and Homeland Security, and consistent with section 304 of PAHPA, shall develop a mechanism to coordinate public health and medical disaster preparedness and response core curricula and training across executive departments and agencies, to ensure standardization and commonality of knowledge, procedures, and terms of reference within the Federal Government that also can be communicated to State and local government entities, as well as academia and the private sector.

(38) Within 1 year after the date of this directive, the Secretaries of Health and Human Services and Defense, in coordination with the Secretaries of Veterans Affairs and Homeland Security, shall establish an academic Joint Program for Disaster Medicine and Public Health housed at a National Center for Disaster Medicine and Public Health at the Uniformed Services University of the Health Sciences. The Program shall lead Federal efforts to develop and propagate core curricula, training, and research related to medicine and public health in disasters. The Center will be an academic center of excellence in disaster medicine and public health, co-locating education and research in the related specialties of domestic medical preparedness and response, international health, international disaster and humanitarian medical assistance, and military medicine. Department of Health and Human Services and Department of Defense authorities will be used to carry out respective civilian and military missions within this joint program.

Disaster Health System

(39) Within 180 days after the date of this directive, the Secretary of Health and Human Services shall commission the Institute of Medicine to lead a forum engaging Federal, State, and local governments, the private sector, academia, and appropriate professional societies in a process to facilitate the development of national disaster public health and medicine doctrine and system design and to develop a strategy for long-term enhancement of disaster public health and medical capacity and the propagation of disaster public health and medicine education and training.

(40) Within 120 days after the date of this directive, the Secretary of Health and Human Services shall submit to the President through the Assistant to the President for Homeland Security and Counterterrorism, and shall commence the implementation of, a plan to use current grant funding programs, private payer incentives, market forces, Center for Medicare and Medicaid Services requirements, and other means to create financial incentives to enhance private sector health care facility preparedness in such a manner as to not increase health care costs.

(41) Within 180 days after the date of this directive, the Secretary of Health and Human Services, in coordination with the Secretaries of Transportation and Homeland Security, shall establish within the Department of Health and Human Services an Office for Emergency Medical Care. Under the direction of the Secretary, such Office shall lead an enterprise to promote and fund research in emergency medicine and trauma health care; promote regional partnerships and more effective emergency medical systems in order to enhance appropriate triage, distribution, and care of routine community patients; promote local, regional, and State emergency medical systems' preparedness for and response to public health events. The Office shall address the full spectrum of issues that have an impact on care in hospital emergency departments, including the entire continuum of patient care from pre-hospital to disposition from emergency or trauma care. The Office shall coordinate with existing executive departments and agencies that perform functions relating to emergency medical systems in order to ensure unified strategy, policy, and implementation.

National Health Security Strategy

(42) The PAHPA requires that the Secretary of Health and Human Services submit in 2009, and quadrennially afterward, a National Health Security Strategy (NHSS) to the Congress. The principles and actions in this directive, and in the Implementation Plan required by section 43, shall be incorporated into the initial NHSS, as appropriate, and shall serve as a foundation for the preparedness goals contained therein.

Task Force and Implementation Plan

(43) In order to facilitate the implementation of the policy outlined in this Strategy, there is established the Public Health and Medical Preparedness Task Force (Task Force). Within 120 days after the date of this directive, the Task Force shall submit to the President for approval, through the Assistant to the President for Homeland Security and Counterterrorism, an Implementation Plan (Plan) for this Strategy, and annually thereafter shall submit to the Assistant to the President for Homeland Security and Counterterrorism a status report on the implementation of the Plan and any recommendations for changes to this Strategy.

(a) The Task Force shall consist exclusively of the following members (or their designees who shall be full-time officers or employees of the members' respective agencies):

(i) The Secretary of Health and Human Services, who shall serve as Chair;

(ii) The Secretary of State;

(ii) The Secretary of Defense;

(iii) The Attorney General;

(iv) The Secretary of Agriculture;

(v) The Secretary of Commerce;

(vi) The Secretary of Labor;

(vii) The Secretary of Transportation;

(viii) The Secretary of Veterans Affairs

(ix) The Secretary of Homeland Security;

(x) The Director of the Office of Management and Budget;

(xi) The Director of National Intelligence; and

(xii) such other officers of the United States as the Chair of the Task Force may designate from time to time.

(b) The Chair of the Task Force shall, as appropriate to deal with particular subject matters, establish subcommittees of the Task Force that shall consist exclusively of members of the Task Force (or their designees under subsection (a) of this section), and such other full-time or permanent part-time officers or employees of the Federal Government as the Chair may designate.

(c) The Plan shall:

(i) provide additional detailed roles and responsibilities of heads of executive departments and agencies relating to and consistent with the Strategy and actions set forth in this directive;

(ii) provide additional guidance on public health and medical directives in *Biodefense for the 21st Century*; and

(iii) direct the full examination of resource requirements.

(d) The Plan and all Task Force reports shall be developed in coordination with the Biodefense Policy Coordination Committee of the Homeland Security Council and shall then be prepared for consideration by and submitted to the more senior committees of the Homeland Security Council, as deemed appropriate by the Assistant to the President for Homeland Security and Counterterrorism.

General Provisions

(44) This directive:

(a) shall be implemented consistent with applicable law and the authorities of executive departments and agencies, or heads of such departments and agencies, vested by law, and subject to the availability of appropriations and within the current projected spending levels for Federal health entitlement programs;

(b) shall not be construed to impair or otherwise affect the functions of the Director of the Office of Management and Budget relating to budget, administrative, and legislative proposals; and

(c) is not intended, and does not, create any rights or benefits, substantive or procedural, enforceable at law or in equity by a party against the United States, its departments, agencies, instrumentalities, or entities, its officers, employees, or agents, or any other person.

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