

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
OPTN Membership Application for Transplant Hospitals	2	1	2	3	6
OPTN Certificate of Assessment and Program Coverage Plan Membership Application	2	1	2	3	6
OPTN Membership Application for Kidney Transplant Programs	189	2	378	3	1,134
OPTN Membership Application for Liver Transplant Programs	110	2	220	3	660
OPTN Membership Application for Pancreas Transplant Programs	120	2	240	3	720
OPTN Membership Application for Heart Transplant Programs	142	2	284	3	852
OPTN Membership Application for Lung Transplant Programs	60	2	120	3	360
OPTN Membership Application for Islet Transplant Programs	4	2	8	2	16
OPTN Membership Application for Vascularized Composite Allograft (VCA) Transplant Programs	53	2	106	2	212
OPTN Membership Application for Intestine Transplant Programs	90	2	180	3	540
OPTN Membership Application for Organ Procurement Organizations (OPOs)	10	1	10	3	30
OPTN Membership Application for Histocompatibility Laboratories	27	2	54	3	162
OPTN Representative Form	20	2	40	1	40
OPTN Medical/Scientific Membership Application	7	1	7	1	7
OPTN Public Organization Membership Application	4	1	4	1	4
OPTN Business Membership Application	2	1	2	1	2
OPTN Individual Membership Application	4	1	4	1	4
OPTN Membership Application Surgeon or Physician Log*	.....	.....	.....	.....	.....
Total = 18 forms	846	.....	1,661	.....	4,755

\* The OPTN Membership Application Surgeon or Physician Log accompanies every individual organ application. The burden to complete is built into the organ application data.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**Maria G. Button,**

*Director, Executive Secretariat.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Office of the Secretary**

**Office of the Assistant Secretary for Preparedness and Response; Statement of Organization, Functions and Delegations of Authority**

Part A, Office of the Secretary, Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (HHS) is being amended at Chapter AN, Office of the Assistant Secretary for Preparedness and Response (ASPR), as last amended at 83 FR 33941 (July 2018), 79 FR 70.535 (Nov. 26, 2014), 78 FR 25277 (April 30, 2013), 78 FR 7784 (Feb. 4, 2013), 75 FR 35.035 (June 21, 2010) to add the Strategic National Stockpile (SNS). This

notice transfers the Office of the Director, Strategic National Stockpile, to the Office of the Principal Deputy Assistant Secretary (ANC), Division of Resource Management (ANC3) pursuant to 5 U.S.C. Appendix (the Reorganization Plan No. 1 of 1953 and the Reorganization Plan No. 3 of 1966) and 31 U.S.C. 1531, and effective October 1, 2018 the functions, personnel, assets, and liabilities of the SNS to the Office of the Secretary, Office of the Assistant Secretary for Preparedness and Response (ASPR).

The changes are as follows.

I. Delete AR.20 Functions in its entirety and replace with the following: Section AN.20 Functions.

A. Immediate Office of the Assistant Secretary for Preparedness and Response: The Immediate Office of the Assistant Secretary for Preparedness and Response (IO/ASPR) is headed by

the Assistant Secretary, who provides leadership and executive and strategic direction for the ASPR organization. The Assistant Secretary is the principal advisor to the Secretary on all matters related to Federal public health and medical preparedness and response for public health emergencies. The Assistant Secretary is responsible for carrying out ASPR's mission and implementing the functions of ASPR. The IO/ASPR (1) ensures development and maintenance of liaison relationships with HHS operating and staff divisions and represents HHS at interagency meetings, as required; (2) establishes and maintains effective communications and outreach guidance and support for all external communications, including legislative and executive branch questions and inquiries, and serves as the principal advisor to the ASPR on all legislative strategies to fulfill the Office of the ASPR and the HHS mission under section 2811 and other relevant sections of the Public Health Service Act, as amended; (3) oversees advanced research, development and procurement of qualified countermeasures, security countermeasures and qualified pandemic or epidemic products; (4) coordinates with relevant federal officials to ensure integration of federal preparedness and response activities for public health emergencies; (5) manages correspondence control for the Assistant Secretary; and (6) coordinates the strategic and operational activities for public health preparedness response and recovery.

B. Office of Biomedical Advance Research and Development Authority (ANB). The Office of Biomedical Advanced Research and Development Authority (BARDA), established in April 2007 in response to the Pandemic and All-Hazards Preparedness Act of 2006, serves preparedness and response roles to provide medical countermeasures (MCM) in order to mitigate the medical consequences of chemical, biological, radiological, and nuclear (CBRN) threats and agents and emerging infectious diseases, including pandemic influenza. BARDA executes this mission by facilitating research, development, innovation, and acquisition of MCM and expanding domestic manufacturing infrastructure and surge capacity of these MCM.

BARDA is headed by a Deputy Assistant Secretary, and includes the following components:

- Office of Medical Countermeasures Program Support Services (ANB1)
- Division of Regulatory Science and Quality Affairs (ANB12)

- Division of Clinical Development (ANB13)
  - Division of Non-Clinical Development (ANB14)
  - Office of Medical Countermeasures Program (ANB2)
  - Division of Chemical, Biological, Radiological and Nuclear Program (ANB21)
  - Division of Influenza, Emerging & Infectious Diseases (ANB22)
  - Division of Detection, Diagnostics, Device Infrastructure (ANB23)
  - Division of Pharmaceutical Countermeasure Infrastructure (ANB24)
  - Division of Research, Innovation and Ventures (ANB25)
  - Division of Contracting Management & Acquisitions (ANBA1)
- C. Office of the Principal Deputy Assistant Secretary (ANC). The Office of the Principal Deputy Assistant Secretary (OPDAS) is responsible for providing a well-integrated infrastructure that supports the Department's capabilities to prevent, prepare for, respond to and recover from natural public health and medical threats and emergencies. OPDAS leads the preparedness and response activities required to coordinate public health and healthcare response systems and activities with relevant federal, state, tribal, territorial, local, and international communities under the National Response Framework and Emergency Support Annexes #8, #6 and #14. OPDAS is responsible for the execution of business management operations and managing coordination. OPDAS provides for the facility, logistics, information technology and infrastructure support services necessary to maintain day-to-day operations of ASPR, including functions of Human Resources, Organization and Employee Development, Ethics, United States Public Health Service (USPHS) liaison, acquisitions management, contracts, grants, and all financial planning and analysis.

The Office of the Principal Deputy Assistant Secretary is headed by the Principal Deputy Assistant Secretary, and includes the following components:

- Office of Management Finance and Human Capital (ANC1)
- Office of Emergency Management and Medical Operations (ANC2)
- Office of Resource Management (ANC3)

*Division of the Strategic National Stockpile (ANC34).* The Office of the Director, Division of the Strategic National Stockpile, (1) Leads executive planning and management of the Division of Strategic National Stockpile (DSNS); (2) protects U.S. health security by collaborating with, and recruiting for,

partners to enhance international medical supply chain planning, coordination, and management in coordination with operating components of HHS; and (3) supports the U.S. government's Global Health Security Agenda to improve the capabilities of emerging nations' medical countermeasure (MCM) supply chain to combat communicable diseases and other health threats in coordination with operating components of HHS.

*Information and Planning Branch. (ANC341)* The Information and Planning Branch (1) Coordinates and integrates information and preparedness activities for DSNS and partners to build, sustain, and improve alternative emergency supply chain capabilities and readiness during a response; (2) captures, develops, and shares information and knowledge to facilitate preparedness; (3) designs and delivers learning activities to DSNS staff and partners to enhance knowledge base for alternative emergency medical supply chain capabilities; (4) supports partner exercises and plans, coordinates, and conducts DSNS exercises to enhance and validate alternative emergency medical supply chain preparedness; (5) maintains day-to-day situational awareness, connectivity, and readiness to ensure rapid transition to SNS response operations; (6) supervises the preparation and readiness of all SNS on-site and off-site response coordination facilities to maintain each in a ready state; (7) manages the development, coordination, and maintenance of DSNS response plans; (8) manages the staffing, preparation, and readiness of DSNS staff to respond to emergencies as part of the DSNS incident management structure and on DSNS deployable teams; (9) coordinates staffing for the DSNS incident management structure during exercises or upon a federal deployment of the strategic national stockpile (SNS) to accompany SNS medical countermeasures and provide technical assistance; (10) manages the DSNS Corrective Action Program for exercises and responses to actual emergencies; and (11) manages DSNS personal and program response communications devices and systems.

*Operational Logistics Branch. (ANC342)* The Operational Logistics Branch (1) Develops logistical requirements for DSNS formulary MCMs established by HHS and the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE); (2) maintains inventory accountability for all DSNS MCMs utilizing an inventory management system; (3) manages the procurement of medical materiel to meet formulary

requirements; (4) manages and tracks expenditure of DSNS funds for the procurement, storage, and transport of medical materiel; (5) manages the development and oversight of contracts for Stockpile Managed Inventory (SMI) and Vendor Managed Inventory (VMI); (6) establishes and manages third party logistics contracts for the storage and maintenance of DSNS MCMs; (7) manages the rotation and programmed replacement of DSNS MCMs; (8) coordinates safety of DSNS MCMs; (9) provides logistics staff for deployable teams that accompany SNS MCMs deployed in response to a public health emergency or full scale exercise; (10) provides emergency operations support to the DSNS Emergency Operations Center (EOC); (11) coordinates transportation contracts needed to deploy DSNS MCMs; (12) manages cold chain storage and deployment capabilities; (13) manages the forward deployment and sustainment of CHEMPACK chemical countermeasures in project areas; (14) manages and maintains calibration and maintenance of DSNS equipment; (15) manages the Shelf Life Extension Program in coordination with the Food and Drug Administration and the Department of Defense (DoD); (16) serves as a storage and distribution partner to the DoD for biologic products; (17) coordinates quality assurance and quality control; (18) in coordination with Centers for Disease Control and Prevention (CDC) will provide support for small scale releases; and (19) conducts physical inventories for stored DSNS materiel.

*Management and Business Operations Branch. (ANC343)* The Management and Business Operations Branch (1) Provides leadership of all management and operations aspects for the division; (2) manages the development of program policies and procedures; (3) procures, maintains, and supports division information technology systems; (4) monitors and manages reporting of DSNS performance measures; (5) provides leadership in issue and risk management, business transformation, and change management; (6) maintains contract management responsibility within DSNS; (7) provides guidance and other support for all division acquisitions; (8) plans, manages, and coordinates all aspects of program business services and resource management operations; (9) provides editing and writing services and coordinates and clears internal and external communications; (10) acts as the Division's liaison for internal/external audits and reviews; (11) directs and monitors a comprehensive strategy

for managing and executing the critical systems in operating a successful commercial good manufacturing practice compliance program; (12) develops and leverages systems to manage, track and report the disposition of deployed SNS MCMs; (13) in coordination with CDC, manages and coordinates SNS tasks from Congress, Office of Management and Budget, and other federal agencies; (14) manages the development and oversight of DSNS-wide annual budget and spend plans and handles all aspects of DSNS budget execution; (15) executes the opening and closing of Stockpile Resource Planning (SRP) accounting periods, oversees SRP financial reconciliation (e.g., inventory procurement and finance modules), and coordinates SRP accounting and reporting; and (16) manages budget formulation and produces 7-year budget requirement projections to support procurement planning and strategic decision making.

*Science Branch. (ANC344)* The Science Branch (1) In collaboration with CDC, guides scientific and medical integration for MCM planning and response with Federal, state, local, and non-government partners; (2) in collaboration with CDC and PHEMCE partners, steers SNS medical countermeasure acquisition, sustainment, and deployment; (3) manages administrative, medical, pharmaceutical, and scientific oversight of the SNS formulary; (4) ASPR and CDC will work together to engage federal officials and subject matter experts in reviewing and disseminating the best available guidance for use of stockpiled MCMs; (5) engages public and private sector partners to develop and deliver information and training on SNS assets to specialized healthcare delivery audiences to increase nationwide knowledge base and preparedness for MCM response; (6) ASPR and CDC will coordinate medical surveillance program for all SNS deployable teams; (7) responds to inquiries regarding the SNS formulary and program from local, state, and federal agencies; and (8) collaborates with academic institutions, governmental and nongovernmental agencies on research, regulatory, licensing and compliance issues surrounding stockpiling of MCMs.

*Strategic Logistics Branch (ANC45).* The Strategic Logistics Branch (1) In collaboration with CDC, provides technical assistance to State, Local, Tribal, and Territorial (SLTT) partners to improve their medical countermeasure response capabilities; (2) performs analysis and assessment of public health supply chain functions to

enhance operational efficiencies; (3) educates partners on Strategic National Stockpile activities and capabilities; (4) evaluates, analyzes, and develops supply chain processes or procedures and recommends enhancements or new procedures, as necessary; (5) plans, manages, coordinates, and evaluates DSNS functions associated with commercial supply chain collaboration and distribution; (6) analyzes manufacturer and commercial supply chain data to identify trends and obstacles to achieve MCM goals and operational requirements; (7) in collaboration with CDC and non-government experts, conducts analysis to evaluate medical countermeasure supply chain characteristics to determine supply chain capacity and probable areas of vulnerability; and (8) develops partnerships with associations, for-profit business, professional organizations and private groups to improve public access to medical countermeasures during a public health emergency.

D. Deputy Assistant Secretary Incident Command and Control (ANG): The Deputy Assistant Secretary (DAS/ICC) is responsible for the policy development, planning analysis, requirements and strategic planning. DAS/ICC manages and operates the HHS Secretary's Operation Center (SOC), intelligence, security, information management and is also responsible for the HHS Continuity of Operations (COOP) and the development of the ASPR COOP Plan. The Office of the Assistant Secretary Incident Command and Control (DAS/ICC) is headed by the Deputy Assistant Secretary Incident Command and Control, and includes the following components:

- Office of Security Intelligence and Information Management
- Office of Strategy, Policy, Planning and Requirements

III. Delegations of Authority. Delegations of authority made to officials and employees of affected organizational components will be established in them or their successors to be consistent with this reorganization.

Dated: February 7, 2020.

**Alex M. Azar II,**

Secretary.

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