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The Strategic National Stockpile: Overview and Issues for Congress

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The Strategic National Stockpile (SNS) consists of drugs, vaccines, medical products, and ancillary supplies that can be deployed at the request of state, local, tribal, and territorial (SLTT) health jurisdictions at the discretion of the Secretary of the Department of Health and Human Services (HHS) in response to a threat to public health. SNS assets have been deployed in response to various disasters and emergencies, including hurricanes, flooding, bioterror events, and infectious disease outbreaks, including the COVID-19 pandemic. The establishing statute states that the SNS is to “provide for the emergency health security of the United States ... in the event of a bioterrorist attack or other public health emergency.” It provides the HHS Secretary authority to decide which threats to prepare for and which medical countermeasures to stockpile. Those decisions are to be informed by the Public Health and Emergency Medical Countermeasure Enterprise (PHEMCE), an interagency working group. Historically, the SNS has devoted most of its resources to just two threats, smallpox and anthrax. Between FY2015 and FY2021, HHS allocated three-quarters of its non-COVID-19 medical countermeasure obligations to supplies to respond to those two threats.

The performance of SNS before and during the COVID-19 pandemic may raise issues of congressional interest. As Congress considers future support for the SNS, it may consider other issues as well, including

- the scope and purpose of the stockpile,
- its long-term sustainability,
- the appropriate role of the PHEMCE,
- whether lessons can be learned from similar federal programs,
- whether to clarify the process by which tribal authorities can request supplies,
- how the stockpile inventory is managed, and
- the appropriate role for subfederal stockpiles.

This report provides background information on the SNS, including the authorities, structure, and appropriations history associated with the stockpile, as well as a review of select issues for Congress.

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Overview

History, Structure, and Scope of the Strategic National Stockpile (SNS)

In 1999, Congress directed the Centers for Disease Control and Prevention (CDC) to create a pharmaceutical and vaccine stockpile.¹ The purpose of the stockpile, originally named the National Pharmaceutical Stockpile (NPS), was to help counter “potential biological, disease and chemical threats to civilian populations.”² In response to the 2001 September 11 terrorist and anthrax attacks, Congress enacted the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188), which, among other actions, changed the name of the stockpile from the NPS to the Strategic National Stockpile (SNS). The act also further defined and expanded the contents of the stockpile to include drugs, vaccines, and other biological products, medical devices, and supplies in such numbers, types, and amounts as are determined by the Secretary of the Department of Health and Human Services (HHS). In addition, the act explicitly defined the mission of the SNS to “provide for the emergency health security of the United States ... in the event of a bioterrorist attack or other public health emergency.”³

The SNS has moved between U.S. departments and agencies. The Homeland Security Act of 2002 (P.L. 107-296) transferred the SNS from the CDC to the Department of Homeland Security (DHS). The Project BioShield Act of 2004 (P.L. 108-276) transferred the SNS back to HHS, within the CDC Office of Public Health Preparedness, Division of the Strategic National Stockpile (DSNS).⁴ The Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (P.L. 113-5) provided the HHS Assistant Secretary for Preparedness and Response (ASPR) with authority and responsibility for the coordination of the SNS, and the ASPR assumed operational control of the SNS in 2018.⁵

Since the establishment of the SNS, agency administrators have deployed the stockpile in a variety of emergency scenarios, including the 2001 September 11 and anthrax attacks, the H1N1 influenza pandemic, the Ebola outbreak, the Zika Virus crisis, multiple hurricane and flooding responses, and the COVID-19 pandemic response.⁶ Statute does not require either the declaration of a public health emergency by the HHS Secretary or a presidential emergency declaration for deployment of the stockpile. The SNS may be deployed in incidents of varying scope and size, at

¹ P.L. 105-277, Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999; H.Rept. 105-825, to accompany P.L. 105-277.

² P.L. 105-277.

³ P.L. 107-188, Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

⁴ CDC, “Strategic National Stockpile,” https://www.cdc.gov/cpr/documents/dsns_fact_sheet.pdf.

⁵ In July 2022, the Office of the Assistant Secretary for Preparedness and Response was renamed to the Administration for Strategic Preparedness and Response. Throughout this report, both names may be used interchangeably, depending on the context. The title Assistant Secretary for Preparedness and Response remains in place for the position that heads the Office of the Administration for Strategic Preparedness and Response. See the following for more details about this change: HHS, “HHS Strengthens Country’s Preparedness for Health Emergencies, Announces Administration for Strategic Preparedness and Response (ASPR), July 22, 2022, <https://www.hhs.gov/about/news/2022/07/22/hhs-strengthens-countrys-preparedness-health-emergencies-announces-administration-for-strategic-preparedness-response.html>.

⁶ HHS ASPR, *Stockpile Responses*, last reviewed July 25, 2022, <https://www.phe.gov/about/sns/Pages/responses.aspx>.

the request of state, local, tribal, and territorial (SLTT) health jurisdictions, or may be pre-positioned for events of national security significance at the discretion of the HHS Secretary.

Currently, SLTT governments work with ASPR Regional Emergency Coordinators (RECs)⁷ to determine the most effective route of obtaining necessary medical and ancillary supplies, and to submit a request to the HHS Secretary's Operations Center (SOC) for an SNS deployment if appropriate.⁸ Tribal governments can request SNS assets through a state health office or via the Indian Health Service (IHS), depending on the type of request.⁹ In general, upon receipt of a request for SNS assets, the Office of the ASPR evaluates the request, often in collaboration with other relevant federal agencies, to determine if the request can be completely fulfilled, partially fulfilled, or cannot be fulfilled. Individual SLTT jurisdictions are required to maintain plans to receive, store, manage, and distribute SNS supplies once they are received and are responsible for associated costs while the supplies are in their possession. SLTT governments may use grant and cooperative agreement funding—primarily from the CDC Public Health Emergency Preparedness Cooperative Agreement (PHEP CoAg),¹⁰ the Cities Readiness Initiative (CRI) program,¹¹ and the ASPR Hospital Preparedness Program¹²—to train and prepare for receiving, staging, and storing SNS supplies, as well as for managing and distributing them during an event. Furthermore, ASPR provides training opportunities for SLTT jurisdictions to improve their capacity and capability related to SNS deployments.¹³

Contents of the Stockpile

The Secretary of HHS is required to

maintain a stockpile or stockpiles of drugs, vaccines and other biological products, medical devices, and other supplies (including personal protective equipment, ancillary medical supplies, and other applicable supplies required for the administration of drugs, vaccines and other biological products, medical devices, and diagnostic tests in the stockpile) in such numbers, types, and amounts as are determined ... to be appropriate and practicable, taking into account other available sources, to provide for and optimize the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health

⁷ HHS ASPR, *ASPR Regional Emergency Coordinators*, last reviewed June 24, 2022, <https://www.phe.gov/Preparedness/responders/rec/Pages/default.aspx>.

⁸ HHS ASPR, *Requesting SNS Assets*, last reviewed August 12, 2021, <https://www.phe.gov/about/sns/COVID/Pages/requesting.aspx>.

⁹ *Ibid.*

¹⁰ CDC, State and Local Readiness, *Public Health Emergency Preparedness (PHEP) Cooperative Agreement*, last reviewed July 1, 2022, <https://www.cdc.gov/cpr/readiness/phep.htm>.

¹¹ CDC, State and Local Readiness, *Cities Readiness Initiative*, last reviewed April 4, 2022, <https://www.cdc.gov/cpr/readiness/mcm/cr.html>.

¹² HHS ASPR, *Hospital Preparedness Program (HPP)*, <https://aspr.hhs.gov/HealthCareReadiness/HPP/Pages/default.aspx>; see also HHS ASPR, *2019-2023 Hospital Preparedness Program Performance Measures Implementation Guidance*, Performance Measure 6, September 2020, https://www.phe.gov/Preparedness/planning/hpp/reports/pmi-guidance-2019-2023/Documents/2019-2023-HPP-PMI-Guidance_508.

¹³ HHS ASPR, *Strategic National Stockpile Course Listing*, <https://aspr.hhs.gov/MCM/SNS/Pages/Course-Listings.aspx>. Personal protective equipment includes masks, gowns, gloves, N-95 respirators, face shields, and other supplies. See HHS ASPR, *Personal Protective Equipment*, <https://aspr.hhs.gov/SNS/Pages/Personal-Protective-Equipment.aspx>.

emergency and ... make necessary additions or modifications to the contents of such stockpile or stockpiles.¹⁴

Given the diverse types of situations described in this requirement, the Secretary defines *practicable* in the context of the finite resources provided. Current law does not require the publication of the contents of the SNS. Generally, the SNS maintains a broad range of medications (including antibiotics, antidotes, and antitoxins), equipment, and ancillary supplies (such as personal protective equipment¹⁵ and surgical items)¹⁶ that can be deployed in any event that may affect human health in such a severe manner that local supplies are not sufficient for the response. These supplies also include predetermined deployable packages such CHEMPACKs,¹⁷ Federal Medical Stations (FMS),¹⁸ and packs that contain pre-identified supplies to address specific hazards and response needs. Medical countermeasures against smallpox and anthrax accounted for approximately 75% of funds obligated for non-COVID-19 supplies in FY2015 through FY2021.¹⁹

Role of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE)

The HHS Secretary is required to review the stockpile contents annually to ensure they are consistent with current threats to health security.²⁰ To assist in this review, the Secretary works “in consultation with the Public Health Emergency Medical Countermeasure Enterprise [PHEMCE].”²¹ The PHEMCE is an interagency group tasked with identifying national health security needs and making recommendations to the Secretary “regarding research, advanced research, development, procurement, stockpiling, deployment, distribution, and utilization” of medical countermeasures, including the contents and use of the SNS.²² By statute, PHEMCE is chaired by the HHS ASPR and the White House Director of the Office of Pandemic Preparedness and Response Policy,²³ and includes the Director of the CDC, the Director of the National Institutes of Health (NIH), the Commissioner of Food and Drugs (FDA), the Director of National

¹⁴ 42 U.S.C. §247d-6b.

¹⁵ HHS ASPR, *Personal Protective Equipment*, last reviewed August 12, 2021, <https://www.phe.gov/about/sns/COVID/Pages/personal-protective-equipment.aspx>.

¹⁶ HHS, Radiation Emergency Medical Management, *Strategic National Stockpile*, last updated February 17, 2022, <https://remm.hhs.gov/sns.htm>.

¹⁷ CHEMPACKs are containers of nerve agent antidotes strategically placed in more than 1,340 locations across the United States. For more information, see HHS ASPR, *CHEMPACK*, last reviewed August 9, 2021, <https://www.phe.gov/about/sns/COVID/Pages/personal-protective-equipment.aspx>.

¹⁸ Federal Medical Stations (FMS) are caches that can help responders transform a pre-identified location into a temporary medical shelter, and include medical-surgical equipment, ancillary medical supplies, and pharmaceuticals to care for between 50 and 250 patients. For more information, see HHS ASPR, *Federal Medical Stations*, last reviewed August 9, 2021, <https://www.phe.gov/about/sns/COVID/Pages/personal-protective-equipment.aspx>.

¹⁹ U.S. Government Accountability Office (GAO), *Public Health Preparedness: HHS Should Address Strategic National Stockpile Requirements and Inventory Risks*, GAO-23-106210, October 2022, <https://www.gao.gov/assets/gao-23-106210.pdf>.

²⁰ 42 U.S.C. §247d-6b(a)(2).

²¹ *Ibid.*

²² 42 U.S.C. §300hh-10a.

²³ The Office of Pandemic Preparedness and Response Policy was established by the Consolidated Appropriations Act, 2023 (P.L. 117-328).

Intelligence, and the Secretaries of the Departments of Agriculture, Defense, Homeland Security, and Veterans Affairs, and other representatives as deemed appropriate by the HHS Secretary.²⁴

In 2017, ASPR began restructuring the PHEMCE and limiting the scope of its deliberations.²⁵ PHEMCE failed to perform its statutorily required annual SNS reviews in FY2017, FY2018, and FY2019. According to the Government Accountability Office (GAO), these reviews would have informed inventory decisions for fiscal years 2020 through 2022. For those years, SNS purchases were guided by previous reviews and HHS discretion.²⁶

Physical Structure of Stockpile

The SNS employs several methods to manage stockpile assets, including but not limited to SNS-managed inventory, vendor-managed inventory, and user-managed inventory.

SNS-Managed Inventory

SNS-managed inventory accounts for the majority of the stockpile's supplies. Assets are stored in multiple warehouses across the United States.²⁷ The locations of these warehouses are not publically available, but HHS reports that the agency strategically distributes them throughout the country to ensure a timely response to an emergency.²⁸ In general, these supplies are packaged and stored to allow authorities to request specific items tailored to respond to the needs of a defined emergency.

Some of the stockpile is stored in prepackaged, transport-ready containers known as “push packages.” Although the push packages account for less than 5% of the contents of the SNS, they contain the supplies that can be delivered the fastest for most emergencies.²⁹ The ASPR plans and conducts exercises to ensure that push packages can be delivered to an affected area anywhere in the United States or its territories within 12 hours of the decision to deploy.

Push packages allow for relatively rapid delivery, but not flexibility in supply choice. The entire contents of push packages are delivered, even if some are not required for a particular response. They contain supplies to address a wide range of potential public health emergencies, such as several types of antibiotics, intravenous fluids, bandages, and other medical supplies.³⁰

²⁴ 42 U.S.C. §300hh-10a.

²⁵ According to the Government Accountability Office (GAO), the Assistant Secretary for Preparedness and Response felt that the consensus driven decisionmaking process was too slow. For more on the PHEMCE restructuring, see U.S. Government Accountability Office, *COVID-19: Continued Attention Needed to Enhance Federal Preparedness, Response, Service Delivery, and Program Integrity*, GAO-210-551, July 2021, pp. 126-134.

²⁶ GAO, *Public Health Preparedness: HHS Should Address Strategic National Stockpile Requirements*, GAO-23-106210, October 2022, p. 11, <https://www.gao.gov/assets/gao-23-106210.pdf>.

²⁷ The National Biodefense Science Board and the Office of Public Health Preparedness and Response Board of Scientific Counselors, *Anticipated Responsibilities of the Strategic National Stockpile (SNS) in the Year 2020 An Examination with Recommendations*, Appendix D, <https://www.phe.gov/Preparedness/legal/boards/nbsb/recommendations/Documents/nbsb-bsc-sns-2020-final.pdf>.

²⁸ HHS, Radiation Emergency Medical Management, *Strategic National Stockpile*, last updated February 17, 2022, <https://remm.hhs.gov/sns.htm>.

²⁹ Todd Piester, Branch Chief, Division of Strategic National Stockpile, CDC, “Strategic National Stockpile Overview,” CDC Clinician Outreach and Communication Activity conference call, July 1, 2008, hereinafter “CDC SNS conference call.”

³⁰ *Ibid.*

Some supplies are managed through vendor-managed inventory and user-managed inventory, otherwise known as pre-positioned caches.³¹

Vendor-Managed Inventory (VMI)

Replacing expiring SNS supplies incurs a significant cost. To reduce this cost, the SNS has developed the VMI process to have vendors store and manage some SNS supplies, called the vendor-managed inventory program. Under this program, the SNS pays vendors to store and manage a specified amount of the product intended for SNS deployment.³² This arrangement allows the vendor to rotate its product through this inventory on its way to other commercial markets. Thus, fresh product remains available to the SNS and the government need not pay for replacing expired supplies. Delivery of supplies from vendor-managed inventory takes between 24 and 36 hours.

One of the limitations of the VMI program is the need for a commercial market sufficient to support selling the products before they expire. The size of the SNS requirement for some supplies complicates this issue. For example, according to HHS, the SNS requires too much of some oral antibiotics for the vendors to rely on commercial marketplace demands to sell them before SNS deployment or expiration.³³ According to GAO, HHS terminated all of its VMI contracts in 2017, citing that they were not cost-effective or were insufficiently meeting other preparedness goals.³⁴ As part of its COVID-19 response, the SNS began reissuing VMI contracts. According to HHS, VMI contracts account for about 10% of current SNS contracts.³⁵

User-Managed Inventory: Pre-positioned Caches

A portion of the SNS is considered user-managed inventory (UMI), wherein a cache of SNS materials that would need to be deployed very quickly after an incident is stored at medical, emergency management, and public health facilities at the local level across the United States.³⁶ These are for emergency scenarios when the 12-hour push packs would arrive too late for an effective response. For example, people exposed to certain chemical warfare agents require treatment within minutes rather than hours. To address this concern, SNS developed a network of pre-positioned caches of chemical warfare treatments and antidotes. The SNS provides these “CHEMPACKs” to states and local communities, which determine where best to store them.³⁷

³¹ The National Biodefense Science Board and the Office of Public Health Preparedness and Response Board of Scientific Counselors, *Anticipated Responsibilities of the Strategic National Stockpile (SNS) in the Year 2020: An Examination with Recommendations*, Appendix D, <https://www.phe.gov/Preparedness/legal/boards/nbsb/recommendations/Documents/nbsb-bsc-sns-2020-final.pdf>.

³² U.S. Government Accountability Office, *Public Health Preparedness: HHS Should Address Strategic National Stockpile Requirements and Inventory Risks*, GAO-23-106210, October 2022, pp. 33-34, <https://www.gao.gov/assets/gao-23-106210.pdf>.

³³ Todd Piester, Branch Chief, Division of Strategic National Stockpile, CDC, “Strategic National Stockpile Overview,” CDC Clinician Outreach and Communication Activity conference call, July 1, 2008.

³⁴ U.S. Government Accountability Office, *Public Health Preparedness: HHS Should Address Strategic National Stockpile Requirements and Inventory Risks*, GAO-23-106210, October 2022, pp. 33-34, <https://www.gao.gov/assets/gao-23-106210.pdf>.

³⁵ Email to CRS from HHS Office of the Assistant Secretary for Legislation, June 24, 2022.

³⁶ C. Norman Coleman, Chad Hrdina, Rocco Casagrande, et al., “User-Managed Inventory: An Approach to Forward-Deployment of Urgency Needed Medical Countermeasures for Mass-Casualty and Terrorism Incidents,” *Disaster Medicine and Public Health Preparedness*, vol. 6, no. 4 (April 3, 2013).

³⁷ CHEMPACKs are strategically placed in more than 1,340 locations across the United States. For more information,

Appropriations

Two separate funding streams exist to fund new purchases for the SNS. First, Congress appropriates money to the SNS through the Public Health and Social Services Emergency Fund (PHSSEF) to acquire, store, manage, and replace supplies available through the normal commercial marketplace. Such products include medical supplies (e.g., syringes, bandages, and respirators) and medicines (e.g., the antibiotic ciprofloxacin).

Alternatively, countermeasures that cannot be purchased through commercial markets may be acquired through the Project BioShield acquisition mechanism and funding. The Project BioShield Act of 2004 (P.L. 108-276) provides a mechanism for the government to procure certain drugs for the SNS while they are still under development.³⁸ Drugs acquired using this funding stream can be added to the SNS before FDA approval, while the developers are still testing the drug’s efficacy.³⁹ In 2004, Congress advance appropriated \$5.6 billion to acquire SNS supplies through Project BioShield for FY2004-FY2013. Congress subsequently rescinded and transferred some of those advance appropriations (see the negative figures in **Table 1**). Since FY2014, Congress has chosen to appropriate Project BioShield funds annually, rather than through advance appropriations.

Emergency supplemental appropriations have been made to the SNS during disasters and public health emergencies in response to specific threats. For example, in response to the COVID-19 pandemic, “HHS reported it had obligated about \$10.5 billion of the \$13.9 billion it planned to use for the SNS, as of February 2022.”⁴⁰ The table below includes only regular appropriations and Project BioShield funding and does not include emergency supplemental appropriations.

After relatively low funding for the stockpile’s first three years, Congress increased annual appropriations for the stockpile following the 2001 September 11 and anthrax attacks. Subsequent annual funding dropped and leveled off for several years before increasing again following the COVID-19 pandemic. After the expiration of the 10-year advance funding for Project BioShield, its average annual appropriations dropped for two years. This decrease was followed by a steep increase and then a plateau of roughly the same amount of money in constant dollars since 2018.

Table 1. Strategic National Stockpile Appropriations, by Year
(\$ in millions)

Fiscal Year	SNS (Nominal \$)	Project BioShield (Nominal \$)	SNS (Constant 2021 \$)	Project BioShield (Constant 2021 \$)
1999	51.0		78.4	
2000	51.8		78.0	
2001	52.0		76.5	
2002	645.0		933.9	
2003	298.1		423.5	

see HHS ASPR, CHEMPACK, last reviewed August 1, 2022, <https://www.phe.gov/about/sns/Pages/CHEMPACK.aspx>.

³⁸ For more on Project BioShield, see CRS Report R41033, *Project BioShield: Authorities, Appropriations, Acquisitions, and Issues for Congress*, by Frank Gottron.

³⁹ Unapproved drugs can be dispensed from the stockpile under an emergency use authorization. 21 U.S.C. 360bbb-3.

⁴⁰ U.S. Government Accountability Office, *Public Health Preparedness: HHS Should Address Strategic National Stockpile Requirements and Inventory Risks*, GAO-23-106210, October 2022, p. 8, <https://www.gao.gov/assets/gao-23-106210.pdf>.

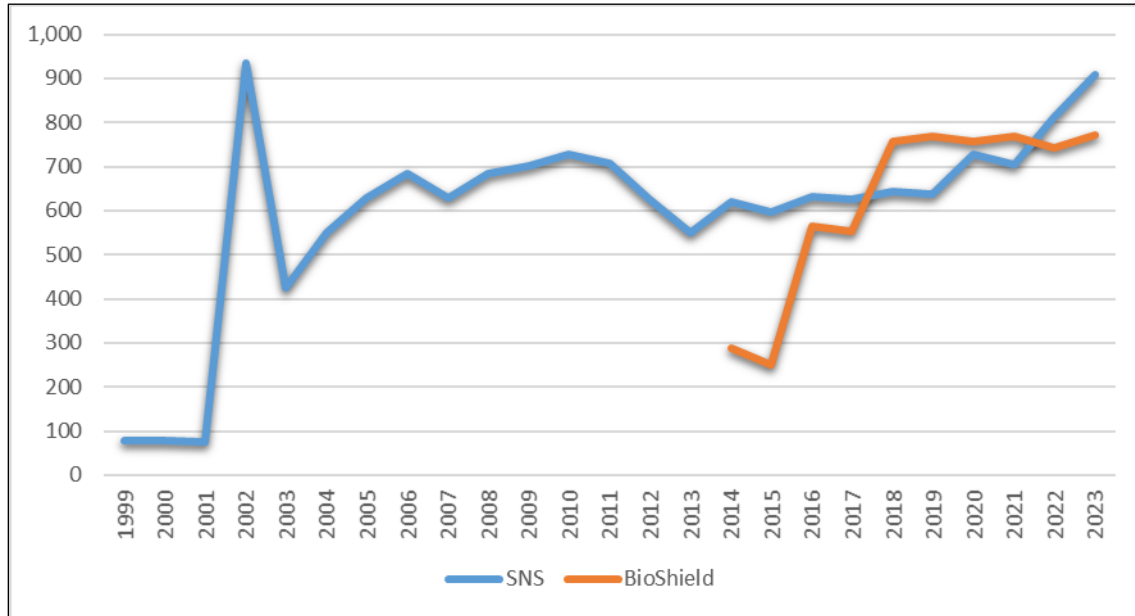
Fiscal Year	SNS (Nominal \$)	Project BioShield (Nominal \$)	SNS (Constant 2021 \$)	Project BioShield (Constant 2021 \$)
2004	397.6	885.0 ^a	551.4	1,227.4
2005	466.7	2,503.0 ^a	628.2	3,369.0
2006	524.3	0	683.4	0
2007	496.3	0	629.7	0
2008	551.5	0	685.4	0
2009	570.3	1,763.0 ^a	701.7	2,169.1
2010	595.7	-609.0 ^b	726.6	-742.8
2011	591.0	-415.0	706.6	-496.2
2012	533.8	-415.0	626.7	-487.3
2013	477.6	-415.0	550.7	-478.5
2014	549.3	254.6	621.3	288.0
2015	534.3	225.0	597.5	251.6
2016	569.3	510.0	631.4	565.6
2017	573.7	508.8	625.1	554.4
2018	603.9	710.0	643.1	756.0
2019 ^c	610.0	735.0	637.1	767.7
2020	705.0	735.0	726.7	757.6
2021	705.0	770.0	705.0	770.0
2022	845.0	770.0	813.2	741.0
2023	965.0	820.0	908.9	772.3

Source: FY1999: P.L. 105-277; FY2000: CDC, *Justification of Estimates for Appropriation Committees, FY2002*, p. 256; FY2001: CDC *Justification of Estimates for Appropriation Committees, FY2003*, p. 229; FY2002-FY2003: CDC, *Justification of Estimates for Appropriation Committees, FY2012*, p. 247; *Estimates for Appropriation Committees, FY2008*, p. 215; FY2007: CDC, *Justification of Estimates for Appropriation Committees, FY2009*, p. 403; FY2008-FY2016: CDC, *Justification of Estimates for Appropriation Committees, FY2018*, p. 176; FY2017: Public Health and Social Services Emergency Fund, *Justification of Estimates for Appropriations Committee, FY2019*, p. 92; FY2018: Public Health and Social Services Emergency Fund, *Justification of Estimates for Appropriations Committee, FY2020*, p. 96; FY2019: Public Health and Social Services Emergency Fund, *Justification of Estimates for Appropriations Committee, FY2021*, p. 103; FY2020: Public Health and Social Services Emergency Fund, *Justification of Estimates for Appropriations Committee, FY2022*, p. 132; FY2021: Public Health and Social Services Emergency Fund, *Justification of Estimates for Appropriations Committee, FY2023*, p. 111; FY2022: https://docs.house.gov/bills/thisweek/20220307/BILLS-117RCP35-JES-DIVISION-H_Part2.pdf#page=143; FY2023: P.L. 117-328.

Notes: CRS converted nominal dollars to estimated 2021 dollars using the OMB, *Budget of the United States Government FY2023*, GDP Chained Price Index from Table 10.1 *Gross Domestic Product and Deflators Used in the Historical Tables*.

- a. Portion of the 10-year \$5.6 billion advance appropriation that became available for obligation that year.
- b. Negative figures indicate rescissions or transfers to other accounts from the unobligated amounts of the advance appropriations.
- c. In FY2019, the SNS transferred to ASPR.

Figure I. SNS and Project BioShield Annual Appropriations
In constant \$ 2021



Source: Table I, CRS.

Note: Between FY2004 and FY2013 Congress appropriated to Project BioShield a net of \$4,561 million (2021 constant dollars) through a combination of advance appropriations, rescissions and transfers. Annual appropriations for Project BioShield began in FY2014 (see Table I).

Issues for Congress

The performance of the SNS before and during the COVID-19 pandemic highlighted several issues that may be of congressional interest. Congress may address these and other issues as it considers the future of the stockpile.

Mission Definition

The establishing statute does not explicitly define the mission of the stockpile, which may have contributed to the apparent mismatch between stakeholders’ expectations and SNS capabilities during the COVID-19 response. The statute states that the SNS is to “provide for and optimize the emergency health security of the United States ... in the event of a bioterrorist attack or other public health emergency.”⁴¹ The types of emergencies and amounts of supplies are left to the discretion of the HHS Secretary, who determines which are “appropriate and practicable.”⁴² The stockpile is known to have enough smallpox vaccine for a nationwide vaccination campaign, but it was less prepared at the beginning of the COVID-19 pandemic for universal infectious disease countermeasures such as N95 respirators and other personal protective equipment (PPE).⁴³ The

⁴¹ 42 U.S.C. §247d-6b.

⁴² Ibid.

⁴³ House Committee on Oversight and Reform, “New Document Shows Inadequate Distribution of Personal Protective Equipment and Critical Medical Supplies to States,” press release, April 8, 2020, <https://oversight.house.gov/news/press-releases/new-document-shows-inadequate-distribution-of-personal-protective-equipment-and->

SNS response to the 2009 H1N1 influenza outbreak had depleted these supplies, yet HHS repeatedly prioritized the stockpiling of other SNS supplies over the replenishment of PPE and respirators. Nevertheless, had the SNS been replenished to prior levels, demand from requesting authorities during the COVID-19 pandemic response would likely have still outstripped supply, since the SNS had not planned on being able to provide sufficient supplies for a sustained nationwide emergency.⁴⁴ The SNS has clarified that it interprets its mission to be a “short-term, stopgap buffer when the immediate supply of these materials may not be available or sufficient.”⁴⁵ GAO has recommended that HHS develop “a formal process for engaging with key stakeholders on a supply strategy for pandemic preparedness,” which may help better match expectations to capacity.⁴⁶

Furthermore, the materials included in the stockpile may provide perspective into the program’s priorities. HHS devoted three-quarters of non-COVID-19-related medical countermeasure obligations between FY2015 and FY2021 to respond to an event involving smallpox or anthrax.⁴⁷ Although the statute includes “other public health emergencies,” HHS has prioritized preparing the SNS to respond to low-probability but high-consequence bioterrorism attacks. Congress may consider whether it deems this prioritization of spending appropriate.

Congress may choose to amend the establishing statute to make explicit the role it intends the SNS to play. For example, Congress could specify the stockpile is to maintain supplies sufficient to provide during a nationwide emergency that lasts for a pre-identified number of days. Alternatively, Congress may determine that continuing to allow the HHS Secretary discretion to make such decisions is preferable and choose to maintain the status quo.

Sustainability of the Stockpile

The long-term sustainability of the SNS will require balancing the scope and purpose of the stockpile with the provided resources. According to HHS, “[t]he primary challenge faced by the PHEMCE is the sustainability of the MCM [medical countermeasures] response capabilities and capacities of the SNS built through [Project BioShield].”⁴⁸ HHS has used Project BioShield to add 22 products to the SNS, including vaccines against anthrax and smallpox and treatments for anthrax, botulism, nerve agents, radiation, and thermal burns.⁴⁹ Each new product added through Project BioShield increases the stockpile’s maintenance costs, because the products need to be stored and eventually replenished when they expire. Typically, SNS appropriations are used to procure or replenish expiring countermeasures that are FDA-approved, and Project BioShield funds are used to procure or replenish expiring countermeasures that lack FDA approval. However, BioShield funds have been used to replenish some expiring FDA- approved

⁴⁴ U.S. Government Accountability Office, *COVID-19: Opportunities to Improve Federal Response and Recovery Efforts*, GAO-20-625, June 2020, p. 109, <https://www.gao.gov/assets/gao-20-625.pdf>.

⁴⁵ HHS, “Strategic National Stockpile,” <https://www.phe.gov/about/sns/Pages/default.aspx>.

⁴⁶ U.S. Government Accountability Office, *COVID-19: Significant Improvements Are Needed for Overseeing Relief Funds and Leading Responses to Public Health Emergencies*, GAO-22-105291, January 27, 2022, p. 193, <https://files.gao.gov/assets/gao-22-105291.pdf>.

⁴⁷ U.S. Government Accountability Office (GAO), *Public Health Preparedness: HHS Should Address Strategic National Stockpile Requirements and Inventory Risks*, GAO-23-106210, October 2022, <https://www.gao.gov/assets/gao-23-106210.pdf>.

⁴⁸ HHS, Public Health Emergency Medical Countermeasure Enterprise, *Multiyear Budget Fiscal Years 2018-2022*, December 2019, p. 10.

⁴⁹ HHS, *Public Health and Social Services Emergency Fund Justification of Estimates for Appropriations Committee FY 2023*, p. 106.

countermeasures, including anthrax vaccine and anthrax antitoxin.⁵⁰ Increasing costs associated with expanding the stockpile may require additional annual SNS appropriations or savings realized through other measures, such as reducing countermeasure holdings. Indeed, according to GAO, ASPR officials have stated that “annual appropriations have not been sufficient to cover the costs associated with responding to the increase in the threats for which the SNS may be needed.”⁵¹ Further, HHS officials have noted a misalignment between the types and quantities of assets recommended for purchase by the PHEMCE and the available SNS budget.⁵²

A related complication is

the challenge of maintaining a stockpile of MCMs against a plethora of low-probability, high-consequence threats, while continuing to develop important countermeasures against other threats, and maintaining the capacity to rapidly respond to novel threats like emerging or re-emerging infectious diseases.⁵³

For example, in December 2019, HHS projected it would spend \$1.04 billion in FY2022 on countermeasures against just two threats, anthrax and smallpox.⁵⁴ This exceeds both the requested and appropriated amount for the entire SNS for FY2022 (\$905 million and \$845 million, respectively).

The long-term sustainability of the SNS will depend on balancing the life-cycle costs of countermeasures (i.e. costs of acquisition, storage, and replenishment) with preparedness goals.

Congress may choose to take these considerations into account when determining funding levels for regular SNS and Project BioShield appropriations.

Shelf Life Extension Program

Various materials maintained in the stockpile—such as medications, vaccines, and some PPE—have expiration dates. Acknowledging that many medical products may be effective and safe after their stated expiration date, depending on storage conditions, the U.S. Department of Defense (DOD) and the FDA established the federal Shelf Life Extension Program (SLEP) in 1986.⁵⁵ This fee-for-service program allows for the deferment of replacement costs of specific stockpile items if they pass periodic FDA stability testing.⁵⁶ If granted, a Shelf-Life Extension applies only to products under the same lot number kept in identical storage conditions.

⁵⁰ HHS, *Public Health and Social Services Emergency Fund Justification of Estimates for Appropriations Committee FY 2023*, p. 105.

⁵¹ U.S. Government Accountability Office, *COVID-19: Critical Vaccine Distribution, Supply Chain, Program Integrity, and Other Challenges Require Focused Federal Attention*, GAO-21-265, January 2021, p. 71, <https://gao.gov/reports/GAO-21-265/>.

⁵² U.S. Government Accountability Office, *Public Health Preparedness: HHS Should Address Strategic National Stockpile Requirements and Inventory Risks*, GAO-23-106210, October 2022, p. 27, <https://www.gao.gov/assets/gao-23-106210.pdf>.

⁵³ HHS, Public Health Emergency Medical Countermeasure Enterprise, *Multiyear Budget Fiscal Years 2018-2022*, December 2019, p. 12.

⁵⁴ HHS, Public Health Emergency Medical Countermeasure Enterprise, *Multiyear Budget Fiscal Years 2018-2022*, December 2019, pp. 18-20.

⁵⁵ Association of State and Territorial Health Officials (ASTHO), “Federal Shelf Life Extension Program Fact Sheet,” 2012, https://legacy.astho.org/uploadedFiles/Programs/Preparedness/Public_Health_Emergency_Law/Emergency_Authority_and_Immunity_Legal_Toolkit/05-EUA%20SLEP%20FS%204-12%20final.pdf.

⁵⁶ FDA, *Expiration Dating Extension*, content current as of July 26, 2022, <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/expiration-dating-extension>.

Additional methods may be used to extend the shelf life of a product. For example, the “manufacturer of an approved drug product may extend the expiration date for the drug product” based on long-term stability and testing data. Additionally, FDA can use existing authorities, such as the Emergency Use Authorization and expiration-dating extension authorities, to extend shelf life under certain circumstances.⁵⁷

As of July 2022, only federal stockpiles are eligible for SLEP. As SLTT jurisdictions, health care systems, and other response entities continue to expand their capacity to maintain local stockpiles, Congress may consider expanding the eligibility requirements to include nonfederal actors.

Role and Effectiveness of the PHEMCE

Statute defines the members of the PHEMCE and the enterprise’s role to help determine the contents of the stockpile.⁵⁸ However, its structure and decisionmaking processes are determined by HHS. Prior to the COVID-19 pandemic, ASPR began reorganizing PHEMCE “to streamline and strategically drive deliberative processes, enabling a quicker and more efficient response to emerging threats.”⁵⁹ According to GAO, ASPR officials acknowledge that the changes made to the PHEMCE from 2018 to 2020 did not fully achieve the desired aims and created other challenges.⁶⁰ Both GAO and the National Academies of Sciences, Engineering, and Medicine (NASEM) have recommended how PHEMCE might be restructured and how the new structure should support its mission.⁶¹ Another group of analysts, pointing out PHEMCE’s insufficient “visibility and clout,” has suggested changing the current ASPR-led management structure to respond effectively to emergent situations. Citing what they consider effective analogous structures in DOD, the analysts recommend the SNS

be guided by a board of governors representing such federal government organizations as the Department of Defense, the Biomedical Advanced Research and Development Authority, the National Institute for Occupational Safety and Health, the Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC).⁶²

HHS released the 2022 PHEMCE Strategy and Implementation Plan in October 2022.⁶³ Although HHS is required by statute to update this plan biennially, it had not done so since 2017.⁶⁴ Congress may be interested in determining the extent to which the new plan incorporates the recommendations from GAO and NASEM. Congress could endorse the new PHEMCE Strategy and Implementation Plan and structure and maintain the course set by HHS. Alternatively, Congress might choose to impose a different decisionmaking structure, by either modifying the

⁵⁷ Ibid.

⁵⁸ 42 U.S.C. §247d-6b.

⁵⁹ Office of the Assistant Secretary for Preparedness and Response, *Strategic Plan 2020-2023*, 2020, p. 39, <https://www.medicalcountermeasures.gov/media/37185/2020-aspr-strategic-plan.pdf>.

⁶⁰ U.S. Government Accountability Office, *COVID-19: Continued Attention Needed to Enhance Federal Preparedness, Response, Service Delivery, and Program Integrity*, GAO-210-551, July 2021.

⁶¹ National Academies of Sciences, Engineering, and Medicine, 2021, *Ensuring an Effective Public Health Emergency Medical Countermeasures Enterprise*, Washington, DC: The National Academies Press.

⁶² Daniel Joseph Finkenstadt, Robert Handfield, and Peter Guinto, “Why the U.S. Still Has a Severe Shortage of Medical Supplies,” *Harvard Business Review*, September 17, 2020.

⁶³ ASPR, *Public Health Emergency Medical Countermeasure Enterprise Strategy and Implementation Plan 2022*, <https://aspr.hhs.gov/PHEMCE/2022-SIP/Pages/default.aspx>.

⁶⁴ 42 U.S.C. §300hh-10(d).

current PHEMCE or replacing it with a new structure. In December 2022, Congress added the White House Director of the Office of Pandemic Preparedness and Response Policy as the co-chair of the PHEMCE through the Consolidated Appropriations Act, 2023 (P.L. 117-328), but did not otherwise alter the structure or decisionmaking process.

Lessons from Other Federal Stockpiling Programs

As Congress considers issues related to the SNS, it may look to other federal stockpiling programs for lessons learned. Both DOD and DHS have somewhat analogous stockpiling needs and have incorporated unique approaches to meeting them.

Each military service stockpiles some critical supplies in War Reserve Material Stocks. In addition, the Defense Logistics Agency (DLA) uses the Warstopper program to maintain an industrial surge capacity for supplies with low-peacetime but high-wartime demands and that have limited shelf-life or long production lead times.⁶⁵ The DLA has contracts with vendors to provide personal protective equipment, ventilators, and other medical supplies on request.⁶⁶ Following market and supply-chain analysis, the DLA uses various methods to ensure item availability, including vendor-managed inventory, purchasing and pre-positioning raw materials or parts, adding vendor manufacturing capacity, and minimum sustaining-rate contracts.⁶⁷

The Federal Emergency Management Agency (FEMA) in DHS uses advance or contingent contracts as an alternative to stockpiling everything it might need for disaster response.⁶⁸ These contracts are typically for an indefinite quantity and cover multiple years. Such contracts obligate the government to purchase a minimum amount of product (or service) up to a defined maximum depending on need.⁶⁹ FEMA uses these contracts for goods such as bottled water and premade meals.

Tribal Access to the Stockpile

Tribal access to the SNS has become a significant issue throughout the COVID-19 pandemic response, because tribes, tribal organizations, and urban Indian organizations have reportedly had difficulties accessing PPE and other materials, including through the SNS.⁷⁰ According to the National Response Framework (NRF), tribal chief executives have the authority to, among other activities, request federal assistance in an emergency.⁷¹ Subsequently, and according to the most recently available guidance, “federally recognized tribal governments can request SNS assets

⁶⁵ Department of Defense Inspector General, *Defense Logistics Agency’s Warstopper Program*, Report No. D-2007-116, August 15, 2007.

⁶⁶ Other Warstopper items include specialty steel, ready-to-eat meals, helicopter windshields, and uniform materials. Luis Villarreal, “Industrial Capabilities and the Warstopper Program,” presentation at the National Defense Industrial Association, June 27, 2011.

⁶⁷ Defense Logistics Agency, *Press Release*, “DLA’s Warstopper Program Makes Medical Supplies Available for COVID-19 Response,” April 1, 2020; and Defense Logistics Agency, *Press Release*, “DLA Industrial Base Planning Team/ Warstopper Program,” November 18, 2021.

⁶⁸ FEMA uses these contracts for goods and services. See FEMA, “Advance Contracts of Goods and Services,” <https://www.fema.gov/businesses-organizations/doing-business/advanced-contracts>.

⁶⁹ Federal Acquisition Regulations 16.504 Indefinite-quantity Contracts.

⁷⁰ “Senate Indian Affairs Committee Holds Hearing on Native American Health During the New Coronavirus,” July 1, 2020, <https://plus.cq.com/doc/congressionaltranscripts-5947593?0&searchId=DNWVg7bB>.

⁷¹ Federal Emergency Management Agency (FEMA), *National Response Framework, Fourth Edition*, October 28, 2019, p. 33, https://www.fema.gov/sites/default/files/2020-04/NRF_FINALApproved_2011028.pdf.

directly.”⁷² However, ASPR has indicated that, in the case of COVID-19, tribes can access SNS assets through one of two strategies: (1) coordinating a request for assets through an associated state health office, or (2) coordinating a request for assets through a tribe’s Indian Health Organization emergency management point of contact (EMPOC).⁷³

HHS and ASPR policy, not federal statute, dictate the mechanisms for deploying and distributing SNS assets. The authorizing statute for the SNS requires in the annual threat-based review that the HHS Secretary shall provide “appropriate protocols and processes for the deployment, distribution, or dispensing of the countermeasure at the State and local level” for each new or modified countermeasure procurement or replenishment.⁷⁴ Further, preparedness guides indicate that state or territorial health officials and/or governors can request SNS deployment through their respective emergency management agencies in the case of a presidentially declared disaster, or through the appropriate federal emergency operations center in absence of such a declaration, but the guides do not specifically and explicitly indicate how tribal organizations would request SNS deployment.⁷⁵

The Consolidated Appropriations Act, 2023,⁷⁶ clarified that the HHS Secretary must consult with and provide assistance to tribal officials, as the Secretary does with state and local officials, related to SNS management and deployment. Further, the act established a new section in the Public Health Service Act (PHSA) that requires the HHS Secretary to make SNS contents available directly to Indian tribes and tribal organizations. Congress may continue to evaluate the SNS’s ability to meet the needs of Indian tribes and tribal organizations during public health emergencies and other emergency situations where SNS contents are requested and deployed.

Inventory Management

Effective inventory management systems are critical for the SNS to function properly. CDC⁷⁷ developed a suite of tools known as the Countermeasure Tracking Systems (CTS) programs to inform deployment of SNS resources.⁷⁸ In light of gaps identified during the 2009 H1N1 influenza pandemic, the CDC CTS program further developed the Inventory Management and Tracking System (IMATS), which was released in September 2011.⁷⁹ SNS continues to utilize IMATS to support state and local public health agencies in their efforts to manage stockpile goods. IMATS and associated training and technical assistance are provided to state and local

⁷² Centers for Disease Control and Prevention (CDC), *Receiving, Distributing, and Dispensing Strategic National Stockpile Assets: A Guide to Preparedness, Version 11*, 2014, chapter 4, p. 9. According to an email to CRS from HHS ASPR Office of External Affairs on October 4, 2022, a formal update to this guidance is pending.

⁷³ ASPR, *Requesting SNS Assets*, <https://www.phe.gov/about/sns/COVID/Pages/requesting.aspx>.

⁷⁴ 42 U.S.C. §247d-6b(a)(2)(B)(i)(VIII).

⁷⁵ Centers for Disease Control and Prevention (CDC), *Receiving, Distributing, and Dispensing Strategic National Stockpile Assets: A Guide to Preparedness, Version 11*, 2014, chapter 4, pp. 4-6.

⁷⁶ P.L. 117-328, Division FF, Title II, Section 2408.

⁷⁷ SNS officials have confirmed that they still rely on CDC for inventory management systems, despite the operational transfer of SNS to ASPR in 2018. See U.S. Government Accountability Office, *Public Health Preparedness: HHS Should Address Strategic National Stockpile Requirements and Inventory Risks*, GAO-23-106210, October 2022, p. 58, <https://www.gao.gov/assets/gao-23-106210.pdf>.

⁷⁸ CDC, *CDC Countermeasure Tracking Systems, Inventory Management and Tracking System*, June 18, 2018, <https://stacks.cdc.gov/view/cdc/59707>.

⁷⁹ HHS ASPR, *Inventory Management and Tracking System (IMATS)*, last reviewed August 9, 2021, <https://www.phe.gov/about/sns/Pages/imats.aspx>.

jurisdictions free of cost; however, jurisdictions receiving SNS assets are not required to use IMATS.

Additional components of CTS allow for nationwide situational awareness of inventory supply. For example, the Countermeasure Inventory Tracking (CIT) Dashboard provides graphic visualizations of the supply chain and key information on countermeasure availability, which may assist federal and state officials with asset deployment decisions.⁸⁰ Further, the Countermeasure and Response Administration (CRA) asset allows for the tracking of vaccine administration, pharmaceutical dispensing, and social distancing measure implementation.⁸¹

The extent to which the components of CTS other than IMATS are still being utilized by CDC and ASPR is unclear. Further, in 2017, an HHS Office of Inspector General (OIG) report recommended that CDC “improve its automated inventory system so that it can accurately identify inventory movements and locations at all times.”⁸² The extent to which improvements have been made to these systems is also unclear.

Congress may choose to more explicitly direct HHS to assign operational control of inventory management systems; it may also choose to exercise more control over how inventory data are collected, reported, and shared among jurisdictions.

State and Local Stockpile Programs

Currently, there is no requirement for state, local, tribal, or territorial governments to maintain their own stockpile of medical and ancillary equipment to prepare for and respond to a health emergency. State, local, and territorial health jurisdictions may choose to use emergency preparedness funding from grant programs such as the Public Health Emergency Preparedness Cooperative Agreement and the Cities Readiness Initiative to stockpile goods and prepare for substate distribution of stockpile materials.⁸³

The Consolidated Appropriations Act, 2023 (P.L. 117-328), established a pilot program administered by the HHS Secretary to support at least five states or consortia of states in establishing, expanding, or maintaining a stockpile of drugs, vaccines, biological products, medical devices, and other medical materials as determined by the grantee to be necessary to respond to a public health emergency, major disaster, or emergency.⁸⁴ Allowable uses of funds under this program include, but are not limited to, the purchase, store, and maintenance of relevant supplies and products; the deployment of such stockpiled products to respond to an actual or potential emergency or disaster; the replenishment, addition, or modification of

⁸⁰ Barb Nichols, Michele D. Renshaw, Sanjeeb Sapkota, et al., “Distributing Countermeasures and Reporting their Utilizations through an Integrated Informatics Approach: Countermeasure Tracking Systems,” Centers for Disease Control and Prevention Office of Surveillance, Epidemiology, and Laboratory Services.

⁸¹ Ibid.

⁸² HHS Office of the Inspector General (OIG), *Readiness of CDC’s Strategic National Stockpile Could Be at Risk in Case of a Public Health Emergency* (A-04-16-03554), June 26, 2017, <https://oig.hhs.gov/oas/reports/region4/41603554.asp>.

⁸³ For more information about the Public Health Emergency Preparedness Cooperative Agreement, see CDC, *Public Health Emergency Preparedness (PHEP) Cooperative Agreement*, last reviewed October 17, 2022, <https://www.cdc.gov/cpr/readiness/phep/index.htm>. For more information about the Cities Readiness Initiative, see CDC, *Cities Readiness Initiative*, last reviewed April 4, 2022, <https://www.cdc.gov/cpr/readiness/mcm/cr.html>.

⁸⁴ P.L. 117-328, Division FF, Title II, Section 2409.

stockpiled products; inventory management of such products; and exercises, drills, and other trainings for deploying, dispensing, and administering stockpiled products.⁸⁵

This new pilot program requires grantees to report activities to Congress and subsequently requires the HHS Secretary to submit an annual report to Congress on the program. Further, this statute requires a GAO report assessment of the program no later than three years after initial funding is administered to grantees.⁸⁶ Congress may choose to evaluate the efficacy of such a program. In addition, Congress may determine the extent to which such a model meets the medical material needs of states and localities during emergencies, and whether and how to expand, maintain, or amend such a program.

Cities Readiness Initiative

CDC's Cities Readiness Initiative (CRI) is a federally funded program designed to enhance preparedness in the nation's largest cities and metropolitan statistical areas (MSAs), where more than 50% of the U.S. population resides.⁸⁷ Through CRI, state and large metropolitan public health departments have developed plans to respond to a large-scale bioterrorist event by dispensing antibiotics to the entire population of an identified MSA with 48 hours. Currently, every state has at least one CRI recipient jurisdiction.

CRI funding is part of the larger Public Health Emergency Preparedness Cooperative Agreement (PHEP CoAg) administered by CDC. CDC determines on a formula basis how much funding will be distributed to each CRI recipient. CRI funding is generally distributed to states and then subdistributed to appropriate substate jurisdictions, except in select cities and counties where funds are directly distributed. The current scope of activities supported by CRI funding does not specifically allow for the creation of a state or local stockpile. Congress could consider directing CDC to expand such allowable use of funds for state and local stockpiling activities.

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⁸⁵ Ibid.

⁸⁶ Ibid.

⁸⁷ CDC, *Cities Readiness Initiative*, last reviewed April 4, 2022, <https://www.cdc.gov/cpr/readiness/mcm/cri.html>.

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