



PUBLIC HEALTH PREPAREDNESS

HHS Should Address Strategic National Stockpile Coordination Challenges

Report to Congressional Committees

May 2024
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GAO Highlights

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Why GAO Did This Study

Recent public health emergencies have highlighted the importance of coordination across all levels of government. One key component of the nation's medical response is the SNS. In January 2022, GAO placed HHS's leadership and coordination of public health emergencies on its High Risk List, in part due to coordination issues with the SNS.

The CARES Act includes a provision for GAO to report on the federal response to the COVID-19 pandemic.

This report examines (1) SNS resources provided to jurisdictions; (2) challenges jurisdictions faced in accessing SNS assets during two recent emergencies; and (3) jurisdictional and tribal SNS coordination issues that might affect future responses.

For this work, GAO surveyed public health officials from all 62 jurisdictions nationwide and received a 100 percent response rate. GAO also interviewed officials in nine jurisdictions which were selected to obtain variation in governance structure and tribal presence, among other criteria. GAO also reviewed guidance, presentations, strategic plans, and other documentation; compared HHS actions to leading practices for collaboration and federal internal controls; and interviewed HHS and tribal officials.

What GAO Recommends

GAO is making three recommendations: HHS should define and share SNS roles, develop procedures for updating guidance, and assess unique tribal issues. HHS concurred with our recommendations.

What GAO Found

The Strategic National Stockpile (SNS) is a multibillion dollar inventory of drugs, vaccines, supplies, and other medical countermeasures that can be provided to jurisdictions—states, localities, territories—and Tribes during emergencies. The Department of Health and Human Services (HHS) provided four primary types of resources ahead of recent public health emergencies—COVID-19 and mpox—to help jurisdictions access and use SNS assets. This included guidance, recurring communication, trainings and exercises, and an inventory management system.

The 62 jurisdictions we surveyed reported challenges during the COVID-19 and mpox responses related to understanding the SNS inventory and coordinating on requesting and receiving SNS assets. HHS has taken steps to address some of these challenges by creating a new office focused on external coordination and developing a new system to track SNS requests. Jurisdictions also reported challenges related to understanding federal agencies' roles and navigating outdated guidance. These challenges led to jurisdictional confusion during response efforts. While HHS has taken some actions, challenges still exist regarding the lack of (1) clearly defined roles for HHS agencies that work with SNS assets; and (2) procedures for updating SNS's main guidance document. For example, the main guidance document for SNS assets has not been updated since 2014 and does not reflect the agency

currently responsible for the SNS. By defining and sharing SNS roles and developing procedures for updating guidance, HHS would help jurisdictions navigate SNS processes improving response efforts.

GAO Survey Results About Strategic National Stockpile Written Guidance



Source: GAO analysis of survey data (text); Line-Art/stock.adobe.com (icons). | GAO-24-106260

Jurisdiction and tribal officials identified other coordination issues that may affect future responses. This included jurisdiction officials not seeing, or being unaware of, HHS response plans including those specific to the SNS, and federal efforts needed to help jurisdictions manage stockpiles that expanded after the COVID-19 pandemic. HHS officials said they plan to coordinate with jurisdictions on these issues by creating and sharing information about response planning and stockpile management. Also, GAO found that Tribes experienced various concerns with requesting and receiving SNS assets. In response, an HHS working group is focused on clarifying the ways Tribes can request SNS assets. However, HHS has not assessed the unique challenges—such as geography and infrastructure—that could affect Tribes’ ability to receive SNS assets. By engaging with Tribes to do such an assessment, HHS and Tribes would be better equipped to deliver and receive assets, respectively, collectively strengthening preparedness and response efforts to future incidents.

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Abbreviations

ASPR	Administration for Strategic Preparedness and Response
CDC	Centers for Disease Control and Prevention
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
NIOSH	National Institute for Occupational Safety and Health
PHEP	Public Health Emergency Preparedness
PPE	personal protective equipment
SNS	Strategic National Stockpile

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May 2, 2024

Congressional Committees

Recent emergencies—including natural disasters and infectious disease outbreaks—have highlighted the importance of coordination between the federal government and state, local, tribal, and territorial governments. The ability of all these levels of government to seamlessly work together is the foundation of national preparedness and an important element in ensuring an effective response to public health emergencies.

This coordination is especially critical when it comes to life-saving medicines and supplies. One key component of the nation’s medical response infrastructure is the Strategic National Stockpile (SNS), which is overseen by the Administration for Strategic Preparedness and Response (ASPR) within the Department of Health and Human Services (HHS).¹ First established in 1999 to respond to biological or chemical attacks, the SNS is a multibillion dollar federal inventory of medical countermeasures—drugs, vaccines, medical supplies, medical equipment and other medical materials—that can be used to respond to a broad range of public health emergencies.²

The contents of the stockpile—referred to in this report as assets—may be deployed to federal agencies and state, local, and territorial governments (hereafter referred to as jurisdictions) and tribal governments when their supplies are depleted or when the necessary medical countermeasures are not commercially available.³ For example, jurisdictions and Tribes requested and received a variety of medicines, medical supplies, and personal protective equipment (PPE), to respond to Hurricane Katrina (2005), the H1N1 influenza pandemic (2009), the COVID-19 pandemic (2020-2023), and the mpox outbreak (2022-2023), among other public health emergencies.

Our previous work has found significant challenges related to the management and contents of the SNS.⁴ These include determining the appropriate role of the SNS during a pandemic, allocating scarce inventory during an emergency, developing procedures to ensure that reviews of its inventory are conducted in

¹ In July 2022, the Secretary of Health and Human Services removed ASPR from the HHS Office of the Secretary and created a new operating division in the department, known as the Administration for Strategic Preparedness and Response. Previously, ASPR was known as the Office of the Assistant Secretary for Preparedness and Response.

² The Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999 provided \$51 million “for pharmaceutical and vaccine stockpiling activities.” Pub. L. No. 105-277, § 705, 112 Stat. 2681, 2681-358 (1998). This effort was sometimes referred to as the “National Pharmaceutical Stockpile” in annual appropriations acts, until the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 created the “Strategic National Stockpile.” Pub. L. No. 107-188, § 121, 116 Stat. 594, 611-13 (codified, as amended, at 42 U.S.C. § 247d-6b).

³ Federally recognized Tribes may request assets from the SNS. As such, when we refer to Tribes or tribal governments throughout the report, we are referring to federally recognized Tribes. The United States has a unique trust responsibility to protect and support Tribes and their members through treaties, statutes, and historical relations with Tribes. See Pub. L. No. 114-178, § 101(3), 130 Stat. 432 (2016) (codified at 25 U.S.C. § 5601(3)). Federal recognition of a Tribe establishes a government-to-government relationship between the recognized Tribe and the federal government, and various laws require federal agencies to provide a range of services and benefits to Tribes and their members because of their unique political status. As of January 8, 2024, there were 574 federally recognized Tribes. 89 Fed. Reg. 944 (Jan. 8, 2024).

⁴ See Appendix III for a list of previous recommendations related to the Strategic National Stockpile.

accordance with statutory requirements, and ensuring stockpiling decisions involve technical experts.⁵ Additionally, our previous work on the COVID-19 pandemic and other public health emergencies has raised questions about the effectiveness of coordination and communication between federal agencies, jurisdictions, and Tribes including around roles and responsibilities of response partners.⁶ For example, in our March 2021 report, we found that states faced a long-standing set of challenges related to the SNS that included state-federal coordination around supply allocation, requests, and delivery. Additionally, we have previously reported on the need to understand and manage challenges ahead of emergencies, before they become systemic, intractable problems.⁷

The CARES Act includes a provision for us to report on the federal response to the COVID-19 pandemic.⁸ This report is also part of our body of work on HHS's leadership and coordination of public health emergencies, which we identified as an area of high risk in part due to persistent deficiencies in HHS's management of medical countermeasures, including through the SNS. We added this area to our High Risk List in 2022, citing the critical need for the nation to be prepared for, and effectively respond to, future public health threats and emergencies.⁹

In this report, we specifically:

1. describe the resources HHS provided to jurisdictions prior to recent public health emergencies to help them access and use SNS assets;
2. examine the challenges jurisdictions faced in accessing and using SNS assets during recent public health emergencies and HHS efforts to address those challenges; and
3. examine additional SNS coordination issues identified by jurisdictions, Tribes, and HHS officials that may affect responses to future public health emergencies and HHS efforts to address those issues.

To describe the resources HHS provided to jurisdictions to help them access and use SNS assets, we analyzed relevant documentation from ASPR and the Centers for Disease Control and Prevention (CDC). CDC administers the Public Health Emergency Preparedness (PHEP) cooperative agreement program and

⁵ For example, see GAO, *COVID-19: Sustained Federal Action Is Crucial as Pandemic Enters Its Second Year*, [GAO-21-387](#) (Washington, D.C.: Mar. 31, 2021); GAO, *COVID-19: Continued Attention Needed to Enhance Federal Preparedness, Response, Service Delivery, and Program Integrity*, [GAO-21-551](#) (Washington, D.C.: July 19, 2021); and GAO, *Public Health Preparedness: HHS Should Address Strategic National Stockpile Requirements and Inventory Risks*, [GAO-23-106210](#) (Washington, D.C.: Oct. 17, 2022).

⁶ [GAO-21-387](#).

⁷ GAO, *Biodefense: After-Action Findings and COVID-19 Response Revealed Opportunities to Strengthen Preparedness*, [GAO-21-513](#) (Washington, D.C.: Aug. 4, 2021).

⁸ Specifically, the act requires us to monitor and oversee the federal government's efforts to prepare for, respond to, and recover from the COVID-19 pandemic. Pub. L. No. 116-136, § 19010(b), 134 Stat. 281, 580 (2020). The American Rescue Plan Act of 2021 also includes a provision for us to conduct oversight of the COVID-19 response. Pub. L. No. 117-2, § 4002, 135 Stat. 4, 78. All of GAO's reports related to the COVID-19 pandemic are available on GAO's website at <https://www.gao.gov/coronavirus>.

⁹ GAO, *High-Risk Series: Efforts Made to Achieve Progress Need to Be Maintained and Expanded to Fully Address All Areas*, [GAO-23-106203](#) (Washington, D.C.: Apr. 20, 2023) and the *New High-Risk Designation: HHS and Public Health Emergencies* appendix in *COVID-19: Significant Improvements Are Needed for Overseeing Relief Funds and Leading Responses to Public Health Emergencies*, [GAO-22-105291](#) (Washington, D.C.: Jan. 27, 2022).

oversees related preparedness activities, among other things.¹⁰ ASPR and CDC documentation we reviewed included guidance documents and training resources, among other documents. For this objective, we chose to review resources provided by ASPR and CDC from 2018 to 2020, as these were resources available to jurisdictions after the transfer of the SNS to ASPR, but before the start of the COVID-19 pandemic response.¹¹ Additionally, we interviewed officials from HHS, ASPR, SNS, and CDC to obtain information about these resources.

To examine challenges jurisdictions faced accessing and using SNS assets during recent public health emergencies and HHS efforts to address those challenges, we surveyed public health emergency preparedness officials. We surveyed officials from all 62 jurisdictions (50 states, four localities, and eight U.S. territories and freely associated states) that receive PHEP funding. We used PHEP jurisdictional designations because both CDC and ASPR interact closely with officials within that program to prepare for and respond to emergencies, including requesting and receiving SNS assets. Our survey asked jurisdictions about their experiences between 2019 and early 2023 interacting with federal agencies, requesting and receiving SNS assets during emergencies, and planning for future emergencies at the jurisdictional level. All 62 jurisdictions responded to the survey. Please see appendix II for the full survey results.

Additionally, we interviewed public health department officials in six states, two localities, and one territory to provide additional context on interacting with the federal government regarding SNS assets. We selected jurisdictions to obtain variation in the following characteristics: health department governance structure (i.e., the relationship between state health agencies and local health departments), presence of federally recognized Tribes, involvement in recent emergencies, and ASPR region, among other criteria. We interviewed or received written responses from public health department officials in the following jurisdictions: Georgia, Guam, Maine, New Mexico, New York, New York City, South Carolina, Washington, and Washington, D.C.¹² Additionally, we reviewed HHS documentation, such as a presentation on SNS's new coordination office, a memorandum of understanding between SNS and CDC, available guidance on requesting SNS assets, and a presentation on SNS's request tracking system. We also interviewed officials from ASPR, SNS, and CDC to discuss resources provided to jurisdictions to help them access and use SNS assets, among other things. Finally, we assessed HHS actions to address challenges noted by jurisdictions against a goal and milestone in ASPR's 2022-2026 strategic plan, GAO's leading practices for interagency collaboration, and federal standards for internal control.¹³

To examine any additional coordination issues identified by jurisdictions, Tribes, and HHS officials that may affect responses to future public health emergencies and HHS efforts to address those issues, we reviewed

¹⁰ A cooperative agreement is a federal award to a non-federal entity to carry out a public purpose. Unlike grants, cooperative agreements generally provide for substantial involvement between the federal awarding agency and the non-federal entity in carrying out the activity contemplated by the award.

¹¹ The Secretary of Health and Human Services transferred responsibility for the SNS from CDC to ASPR in 2018. As a result, this report looks at HHS efforts since 2018 to focus on the SNS operating environment and resources available after the transfer.

¹² For the purposes of this report, when referring to what public health officials in these jurisdictions told us, "most" represents seven to eight jurisdictions, "many" represents five to six jurisdictions, "some" represents three to four jurisdictions, and "few" represents two jurisdictions.

¹³ GAO, *Government Performance Management: Leading Practices to Enhance Interagency Collaboration and Address Crosscutting Challenges*. [GAO-23-105520](#) (Washington, D.C.: May 24, 2023) and GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#) (Washington, D.C.: September 10, 2014). Internal control is a process effected by an entity's management, oversight body, and other personnel that provides reasonable assurance that the objectives of an entity will be achieved.

HHS documentation such as ASPR's National Health Security Strategy, ASPR's 2022-2026 strategic plan, an assessment of PPE viability, and a presentation on the tribal access working group. In addition to the survey results and jurisdictional interviews, we also selected and interviewed current officials from the Seminole Tribe of Florida, the Poarch Band of Creek Indians, the Pueblo of Pojoaque, the National Indian Health Board, and the American Indian Health Commission as well as a former tribal health official from the Navajo Nation. We selected these Tribes and tribal organizations based on a recommendation from a jurisdiction, interaction with regional HHS officials during the COVID-19 or mpox response, and tribal efforts to access SNS assets during the COVID-19 or mpox response. Our findings from these interviews are not generalizable to other jurisdictions and Tribes.

Additionally, we interviewed officials from ASPR, SNS, CDC, the Food and Drug Administration (FDA), and the National Institute for Occupational Safety and Health (NIOSH) to obtain information on internal policies and practices regarding exercises, guidance, and communications with jurisdictions and other federal agencies, among other things. Finally, we assessed HHS actions to address issues noted by jurisdictions and Tribes against the objectives in ASPR's 2022-2026 strategic plan and GAO's leading practices for interagency collaboration.¹⁴

Please see appendix I for a more detailed discussion of our objectives, scope, and methodologies.

We conducted this performance audit from September 2022 to May 2024, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

National Response Framework

The SNS is a key component of HHS's response capabilities under the National Response Framework. The framework, which establishes an all-hazards response structure to coordinate federal resources during emergencies and disasters, is divided into 15 emergency support functions assigned to various federal agencies, including HHS. Within HHS, ASPR is the lead agency for emergency support function #8—the public health and medical services response—and is responsible for coordinating a variety of activities, including assessment of public health and medical needs, patient evacuation, patient care, the provision of medical equipment and supplies, and public health communication. The National Response Framework designates state, local, tribal, and territorial agencies as primarily responsible for response activities in their jurisdictions, including those related to public health and medical services. However, when effective emergency response is beyond the capabilities of the state, tribal, or territorial government, those governments can request federal

¹⁴ [GAO-23-105520](#).

assistance. For example, during the COVID-19 pandemic, jurisdictions requested SNS assets to help manage the response.

Requesting and Receiving SNS Assets - Jurisdictions

In the face of a public health threat, jurisdictional officials such as a governor, governor's designee, or senior health official may request medical countermeasures from the SNS. The request may occur when local supplies have been or may be depleted. Depending on the type of emergency, requests are typically made by contacting the HHS Secretary's Operations Center, the CDC Emergency Operations Center, or by working through ASPR's Regional Emergency Coordinators (ASPR Coordinators).

Generally, jurisdictions make a request for SNS assets in conjunction with a presidential disaster declaration or an HHS public health emergency declaration, such as during the COVID-19 pandemic and the mpox outbreak. Currently, 50 states, four localities (Chicago, Los Angeles County, New York City, and Washington, D.C.), and eight U.S territories and freely associated states are eligible to receive SNS assets.¹⁵ However, there does not need to be a disaster declaration or public health emergency declaration to request assets. For example, a jurisdiction may request SNS assets to manage an isolated, minor, or time-critical incident (e.g., a single patient with botulism) without a formal declaration.

According to ASPR's website, requests are considered by a group of federal stakeholders that, depending on the emergency, may include ASPR, SNS, and CDC staff, other federal agency staff, and subject matter experts. These stakeholders consider a variety of factors before deploying any assets, including available jurisdictional assets, commercial availability, and SNS inventory, among other things. After considering these factors, a decision is made on whether to completely, partially, or not fulfill the request. Needed assets may be available directly from the SNS inventory, through commercial suppliers that manage certain SNS assets, or from other federal agencies.

Assets that are deployed from the SNS may be sent to the jurisdiction's receive, stage, and store facility which, depending on the jurisdiction, may be an aircraft hangar or similar facility due to the large floor space. Jurisdictions are required to identify and operate these facilities as a condition of receiving SNS assets. Generally, this facility will act as the hub of a jurisdiction-wide distribution system. Depending on the size of the jurisdiction, more than one facility may be available. Receive, stage, and store facilities must meet certain standards including security measures, climate control, and square footage requirements, among other things. Jurisdictions are required to maintain plans that outline how to receive, store, manage, and distribute SNS assets.

Requesting and Receiving SNS Assets – Tribal Governments

There are 574 ethnically, culturally, and linguistically diverse federally recognized Tribes in the United States.¹⁶ These Tribes are distinct political entities whose inherent sovereignty predates the United States, and federal recognition establishes a government-to-government relationship between the recognized Tribe and the

¹⁵ The eight U.S. territories and freely associated states are American Samoa, Guam, Puerto Rico, U.S. Virgin Islands, Commonwealth of Northern Mariana Islands, Federated States of Micronesia, Republic of Palau, and Republic of the Marshall Islands.

¹⁶ 89 Fed. Reg. 944 (Jan. 8, 2024).

federal government. Through treaties, statutes, and historical relations, the United States has undertaken a unique trust responsibility to protect and support Tribes and their members.¹⁷

According to ASPR guidance, the manner in which Tribes request, receive, and store SNS assets may differ from the manner in which jurisdictions request and receive assets. In contrast to jurisdictions, Tribes can request SNS assets through the Indian Health Service or work with jurisdictions to have them request and receive assets on their behalf.¹⁸ Historically, while Tribes have had the ability to request assets directly from the SNS, they have accessed assets through state or local health departments rather than directly from the SNS, as SNS guidance focused on these pathways.

Recent federal actions have focused on improving access to the SNS for tribal governments. In January 2021, President Biden issued Executive Order 14001 that directed HHS to take steps to facilitate access to the SNS for federally recognized tribal governments and certain other tribal entities.¹⁹ Additionally, the Consolidated Appropriations Act, 2023 requires the Secretary of Health and Human Services to make SNS contents available directly to Tribes and tribal organizations during public health emergencies.²⁰

Centers for Disease Control and Prevention

Since its inception, the SNS has generally been the responsibility of HHS.²¹ In 2018, the Secretary of Health and Human Services transferred management of the SNS from CDC to ASPR.²² As we have previously reported, senior SNS officials stated that the SNS moved wholesale with policies, procedures, and staff generally remaining the same. However, these same officials noted that they still rely on CDC for several support functions related to the SNS, including human resources, certain information technology systems for the SNS such as an inventory management system available to jurisdictions, and providing guidance and procedures to ensure the safe use of SNS assets during emergencies.²³

CDC continues to play a key role related to the SNS through the PHEP cooperative agreement program as well as by providing clinical expertise on medical countermeasure administration. CDC's PHEP program was established with the goal of preparing the nation for all public health threats, including infectious diseases,

¹⁷ See 25 U.S.C. § 5601(3).

¹⁸ The Indian Health Service, an agency in HHS, is responsible for providing health care for over 2.8 million American Indians and Alaska Natives who are citizens or descendants of federally recognized Tribes. Beyond federally recognized Tribes, other indigenous communities may have different pathways for receiving federal support for health care services. For example, the Native Hawaiian Health Care Systems Program supports the provision of health care and other services to Native Hawaiians living in Hawaii. For more information on the Native Hawaiian Health Care Systems, see [GAO-24-106407](#).

¹⁹ Exec. Order No. 14001, 86 Fed. Reg. 7219, 7221 (Jan. 26, 2021). In the executive order, other tribal entities include tribal health authorities and Urban Indian Organizations. An Urban Indian Organization is a nonprofit corporate body that provides health care services to American Indian/Alaska Native populations residing in urban centers.

²⁰ See Pub. L. No. 117-328, div. FF, tit. II, § 2408, 136 Stat. 4459, 5789 (2022). Tribal organizations are the recognized governing body of any Indian Tribe.

²¹ During a brief period from 2002 to 2004, the SNS was transferred to the Department of Homeland Security.

²² Under 42 U.S.C. § 300hh-10(c)(3)(B), the Assistant Secretary for Preparedness and Response is to exercise the Secretary's responsibilities with respect to coordination of the SNS.

²³ [GAO-23-106210](#).

natural disasters, and terrorist incidents. The PHEP program awards funding to jurisdictions' health departments, which may be used to conduct exercises to test response capabilities, maintain preparedness plans, and purchase equipment and supplies, among other things. While Tribes are not eligible recipients of PHEP funding per statute, PHEP recipients may subaward PHEP funding to federally recognized Tribes within their jurisdictions.²⁴

Additionally, CDC officials serve as subject matter experts on clinical guidance for SNS assets including usage and target populations for treatment. For example, CDC officials communicate directly with clinicians to provide guidance on specific medical countermeasures and emerging public health threats, including how threats may affect special populations. As we have previously reported, CDC officials play a key role in providing guidance around regulatory issues related to SNS assets.²⁵ For example, CDC officials work with jurisdictions and clinicians around appropriate procedures if an SNS medical countermeasure is being distributed under an emergency use authorization or expanded access investigational new drug protocol.²⁶

HHS Provided Jurisdictions with Multiple Resources to Help Access and Use SNS Assets Prior to the COVID-19 and Mpox Emergencies

From 2018 to 2020, HHS provided four primary types of resources to help jurisdictions access and use SNS assets: guidance, recurring communications, trainings and exercises, and an inventory management system. While HHS provided some enhanced resources after the transfer—such as expanding the role of ASPR coordinators to include providing SNS information—several of these resources had already been in place when the SNS was at CDC prior to 2018.

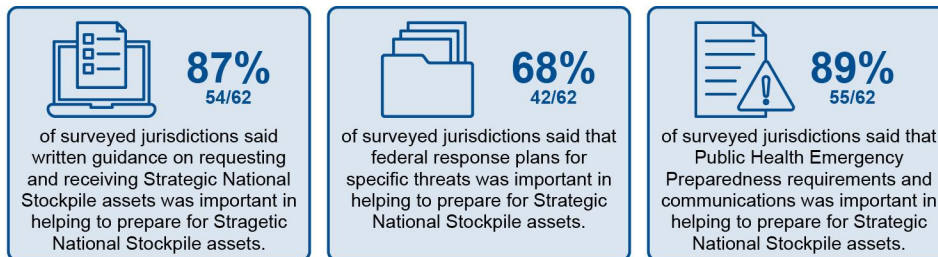
Guidance. HHS provided several types of documents to jurisdictions related to accessing and using SNS assets including specific guidance on (1) requesting SNS assets; (2) planning for and using SNS assets in specific emergencies; and (3) implementing broader jurisdictional preparedness. Jurisdictions we surveyed found this guidance important for helping them prepare for emergencies in which SNS assets might be needed (see fig. 1)

²⁴ 42 U.S.C. § 247d-3a.

²⁵ [GAO-23-106210](#).

²⁶ During an emergency, as declared by the Secretary of Health and Human Services under 21 U.S.C. § 360bbb-3(b), FDA may temporarily authorize the use of unapproved medical products or the unapproved use of approved medical products, through an emergency use authorization, provided certain statutory criteria are met. See 21 U.S.C. § 360bbb-3. Through FDA's expanded access program, patients with serious or immediately life-threatening ailments and no other FDA-approved therapeutic options may potentially obtain investigational drugs or biologics as a last resort for treatment if certain criteria are met. See 21 U.S.C. § 360bbb(c) and 21 C.F.R. Part 312, Subpart I (2023).

Figure 1: Importance of Federal Guidance in Helping Jurisdictions Prepare for Strategic National Stockpile Assets



Source: GAO analysis of survey data (text); keenan/stock.adobe.com (icons). | GAO-24-106260

Note: The percentages reported in figure 1 represent the number and percentage of jurisdictions that responded that a particular federal effort was either "very important" or "somewhat important" in helping them to prepare for an emergency. See appendix II, question 4.

- Requesting SNS assets.** The main guidance document for requesting SNS assets—*Receiving, Distribution, and Dispensing Strategic National Stockpile Assets: A Guide to Preparedness, Version 11* (Version 11)—is designed to provide information to jurisdictional officials on key aspects of SNS medical countermeasures.²⁷ Version 11 outlines how to request SNS assets during various emergency declarations as well as how to make effective use of medical countermeasures to prevent, mitigate, and treat adverse health effects during public health emergencies. As such, it contains chapters on requesting SNS assets; receiving, staging, and storing medical countermeasures; managing medical countermeasure inventory; and distributing medical countermeasures, among other information. Version 11 was last updated in 2014, which was prior to the transfer of responsibility for the SNS to ASPR; however, ASPR officials noted that it remained the primary guidance document for jurisdictions prior to recent emergencies. Eighty-seven percent (54/62) of jurisdictions we surveyed said that written guidance on requesting and receiving assets was important in helping to prepare for SNS assets.
- Planning for SNS assets.** In addition to Version 11, CDC, in conjunction with the SNS, published a guidance document outlining how SNS medical countermeasures would be distributed in the event of an inhalational anthrax incident.²⁸ Finalized in 2017, the guidance was intended to help jurisdictional public health and health care planners coordinate efforts around receipt, distribution, and dispensing of medical countermeasures to exposed populations. For example, the guidance outlines what medical countermeasures jurisdictions can expect to receive, in what amount, and the time frames for administration. SNS officials noted that this was the only threat-specific guidance document shared with jurisdictions specifically related to SNS assets. Sixty-eight percent (42/62) of jurisdictions we surveyed said that federal response plans for specific threats were important in helping to prepare for SNS assets.
- Implementing broader preparedness.** In 2018, CDC updated its preparedness capability standards and published them in a guidance document for jurisdictions.²⁹ The guidance includes 15 capabilities that are designed to advance the emergency preparedness and response capabilities of jurisdictions. Two of the 15 capabilities—medical countermeasure dispensing and administration, and medical material management and distribution—provide guidance to jurisdictions on how to receive, distribute, dispense, administer, and

²⁷ Centers for Disease Control and Prevention, *Receiving, Distributing, and Dispensing Strategic National Stockpile Assets: A Guide to Preparedness, Version 11* (2014).

²⁸ Centers for Disease Control and Prevention, *Receiving 60-day Anthrax Medical Countermeasures from CDC's Strategic National Stockpile* (June 2017).

²⁹ Centers for Disease Control and Prevention, *Public Health Emergency Preparedness and Response Capabilities: National Standards for State, Local, Tribal, and Territorial Public Health* (Oct. 2018, updated January 2019).

manage medical countermeasures, including SNS assets. Additionally, as part of CDC’s PHEP program, jurisdictions receive awards and guidance on PHEP requirements that align with the capability standards. Eighty-nine percent (55/62) of jurisdictions we surveyed said that PHEP requirements and communications were important in helping to prepare for SNS assets.

Recurring Communications. HHS provided several opportunities for jurisdictions to communicate with the federal government regarding accessing and using SNS assets. ASPR expanded one of these opportunities—working with ASPR coordinators and staff—after the transfer of the SNS from CDC to ASPR. This is in addition to CDC’s already established regular PHEP emails and meetings. Specifically, HHS provided the following opportunities:

- *ASPR regional coordinators and staff.* ASPR coordinators, located in each of ASPR’s 10 regions, serve as ASPR’s primary representatives throughout the country. According to ASPR officials, after the SNS transfer in 2018, ASPR coordinator responsibilities were expanded to include helping jurisdictions navigate the SNS. Officials we interviewed from ASPR headquarters and two regional offices said their role is to act as a liaison, or “front door,” to the federal government for jurisdictions with questions about SNS assets including how to operationalize jurisdictional response plans.

Survey Result: Importance of Meetings and Communications in Preparing for Strategic National Stockpile Assets



Source: GAO analysis of survey results (text); keenan/stock.adobe.com (icons). | GAO-24-106260

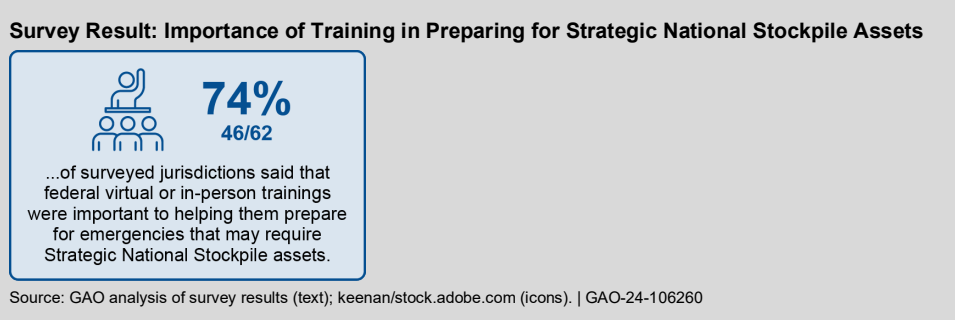
In addition to the expanded role of the ASPR coordinators, ASPR officials noted Regional Medical Countermeasure Advisors were also added to regional offices to help address jurisdictions’ technical questions about medical countermeasures, including SNS assets. For example, one advisor noted that they have had discussions with jurisdictions about accessing SNS assets during weather incidents and how to manage expiring medical countermeasures. According to ASPR officials, the Regional Medical Countermeasure Advisors were transferred to ASPR from CDC in 2019 and are funded through SNS appropriations. Ninety-seven percent (60/62) of jurisdictions we surveyed said that ASPR regional meetings and communication were important in helping to prepare for SNS assets.³⁰ For example, officials from one jurisdiction noted that they relied on communication with the ASPR coordinator to understand how to request SNS assets and to discuss statewide needs for assets.

- *CDC e-mails and meetings.* CDC officials noted that the PHEP program regularly communicates with jurisdictions through weekly e-mails and monthly meetings. When relevant, these communications included updates or time-sensitive information on the SNS. For example, in 2019 CDC’s Friday e-mail updates included information about SNS trainings related to the formulary, request process, and storage temperature conditions for certain medical countermeasures. Jurisdictions have pointed to the PHEP

³⁰ The percentages reported here, and in the sidebar, represent the number and percentage of jurisdictions that responded that a particular federal effort was either “very important” or “somewhat important.” See appendix II, question 4.

program as a key source of information about the SNS. As noted above, 89 percent (55/62) of jurisdictions we surveyed said that PHEP requirements and communications were important in helping to prepare for emergencies that may require SNS assets.

Trainings and Exercises. From 2018 to 2020, SNS and CDC officials provided virtual trainings, as well as formal and ad-hoc in-person trainings. SNS officials told us that these trainings covered topics such as the management and distribution of SNS assets. For example, in 2019 SNS officials posted a webinar to CDC’s training website about temperature considerations for medical countermeasures.



In addition to virtual trainings, SNS officials also provided in-person trainings. For example, they hosted a 5-day in-person SNS operations course at the Center for Domestic Preparedness for jurisdiction medical countermeasure planners. The course—scheduled to resume in 2024 after being paused at the onset of the COVID-19 pandemic—discussed planning considerations and capabilities related to requesting, receiving, distributing, dispensing, and administering SNS assets. SNS officials stated that they also worked with ASPR coordinators and jurisdictions to select and participate in trainings when requested by jurisdictions. Overall, jurisdictions noted that these training opportunities were important. According to our survey, 74 percent (46/62) of jurisdictions said that federal virtual or in-person trainings were important to helping them prepare for emergencies that may require SNS assets.³¹

Similar to trainings, SNS officials told us that they designed or participated in exercises with jurisdictions upon request.³² Exercises simulate an emergency response and thus help jurisdictions prepare for real life incidents. For example, the Crimson Contagion Exercise, conducted in 2019, in which 12 states, 74 local health departments, and 15 Tribal Nations and pueblos participated, simulated conditions much like the COVID-19 pandemic.³³ If a jurisdiction was interested in an exercise, SNS officials stated that they would work with the jurisdiction and associated ASPR coordinator to design or participate in an exercise that would meet the jurisdiction’s needs. For example, SNS officials said that they participated in anthrax and plague exercises with jurisdictions in 2018 and 2019. While SNS officials noted that they do not provide funding to jurisdictions to develop and hold exercises, jurisdictions can use PHEP funding to cover exercise costs.

³¹ The percentages reported here, and in the sidebar, represent the number and percentage of jurisdictions that responded that a particular federal effort was either “very important” or “somewhat important.” See appendix II, question 4.

³² ASPR officials noted that responsibility for designing and developing exercises generally falls to the Exercise, Evaluation, and After Action Division. Depending on available resources, division officials said that they either execute the exercise or give jurisdictions guidance on how to execute the exercises.

³³ The Crimson Contagion 2019 Functional Exercise conducted August 13–16, 2019, exercised the nation’s ability to respond to a large-scale outbreak of a novel avian influenza virus (H7N9) strain, which quickly spreads via human-to-human transmission around the world and across the continental United States with high rates of morbidity and mortality.

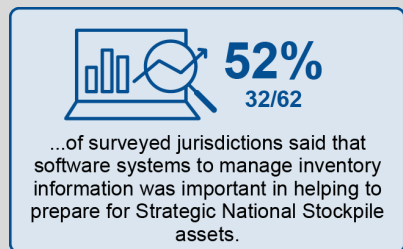
Survey Result: Importance of Exercises in Preparing for Strategic National Stockpile Assets



Source: GAO analysis of survey results (text); keenan/stock.adobe.com (icons). | GAO-24-106260

CDC officials mentioned that they also conducted PHEP-funded exercises with jurisdictions on topics such as using and distributing medical countermeasures during emergency responses. For example, CDC officials said that they conducted pandemic influenza exercises in 2018 and 2019 that included the distribution of pharmaceuticals (e.g., vaccines, antivirals) and medical countermeasures, such as masks. According to our survey, 47 percent (26/62) of jurisdictions said that federal-led exercises that incorporate the SNS were important in helping prepare for SNS assets.³⁴ One survey respondent noted that the jurisdiction exercised with the SNS prior to the COVID-19 pandemic and that the exercises were crucial to the success of its COVID-19 response. The respondent noted that the relationships the jurisdiction built in addition to the planning efforts provided a strong foundation at the beginning of the response.

Survey Result: Importance of Inventory Management Systems in Preparing for Strategic National Stockpile Assets



Source: GAO analysis of survey results (text); keenan/stock.adobe.com (icons). | GAO-24-106260

Inventory Management System. Since 2011, SNS officials have provided a free inventory management and tracking system to jurisdictions to help them manage their medical countermeasures, including SNS assets.³⁵ The system also was intended to give federal agencies more information on jurisdictional stockpiles, according to SNS officials. The inventory system tracks when materials have been received from the SNS or other entity, the location where the materials are stored, and when they ship from one location to another or are moved within a location. SNS officials noted that they provide trainings and technical assistance, in addition to participating in exercises to help jurisdictions use the system.

³⁴ The percentages reported here, and in the sidebar, represent the number and percentage of jurisdictions that responded that a particular federal effort was either “very important” or “somewhat important.” See appendix II, question 4.

³⁵ SNS’s free inventory management system is the Inventory Management and Tracking System (IMATS) and, as of August 2023, is used by 38 state and 52 local governments to manage inventory day-to-day and during emergency responses, according to SNS officials.

According to our survey, 52 percent (32/62) of jurisdictions said that software systems to manage inventory information was important in helping prepare for SNS assets.³⁶ For example, according to a demonstration provided by SNS officials, jurisdictions can use the inventory management system to monitor storage locations within multiple warehouses—where SNS assets might be stored—to help jurisdictions assess the feasibility of storing assets at a given location. A few jurisdictions we surveyed and interviewed said that they wanted more functionality from the inventory management system. SNS officials stated that the inventory system is currently housed on CDC’s network systems, which limits some software upgrades due to security considerations. SNS officials added that they are in the process of moving the inventory management system to ASPR’s network, which they said should help make it more accessible.

Jurisdictions Faced Challenges Coordinating with the Federal Government During the COVID-19 and Mpox Emergencies That HHS Has Not Completely Addressed

Analysis of our survey data and interviews shows that jurisdictions faced several challenges coordinating with the federal government around SNS assets during the responses to the COVID-19 pandemic and mpox outbreak. HHS has taken actions to address some of these coordination challenges, including developing a system and office to increase coordination, but has not fully addressed these challenges.

HHS Has Not Fully Addressed Federal-Jurisdictional Coordination Challenges

Coordination challenges between jurisdictions and the federal government noted by jurisdictions included: transparency of the SNS inventory; requesting assets; receiving assets; and understanding federal agency roles during a response.

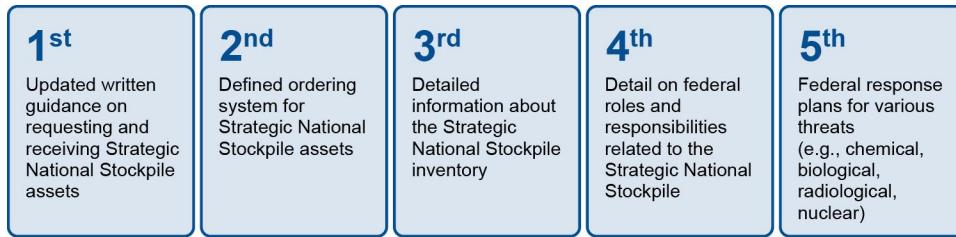
Transparency of inventory. According to our survey, 16 percent (10/62) of jurisdictions said they did not understand enough about what assets were in the SNS inventory to plan response efforts.³⁷ One survey respondent noted that federal partners struggled to provide insight into what was in the SNS during the COVID-19 response. Additionally, most public health officials from selected jurisdictions we interviewed stated that they would have liked more information about the SNS inventory, including information about specific products and quantities. For example, according to officials from one jurisdiction, at the beginning of the COVID-19 pandemic, the jurisdiction requested assets from SNS officials and discovered they had requested the entire inventory of that specific asset. They added that they had to play a “guessing game” to figure out what was in the SNS. Officials from another jurisdiction noted that having more insight into the SNS inventory would facilitate coordination with the federal government because it would help jurisdictions better prepare to request and receive assets.

³⁶ The percentages reported here, and in the sidebar, represent the number and percentage of jurisdictions that responded that a particular federal effort was either “very important” or “somewhat important.” See appendix II, question 4.

³⁷ In our survey, we asked respondents to rate their agreement with various statements about their understanding of the SNS inventory and processes on a scale of strongly agree, somewhat agree, neither agree nor disagree, somewhat disagree, strongly disagree, and no basis to judge. The percentage reported here combines “somewhat disagree” and “strongly disagree” responses into “did not understand.” See appendix II, question 5.

As such, jurisdictions we surveyed listed detailed information about the SNS inventory as the third most useful federal resource to help prepare for SNS assets before the next emergency (see fig. 2).

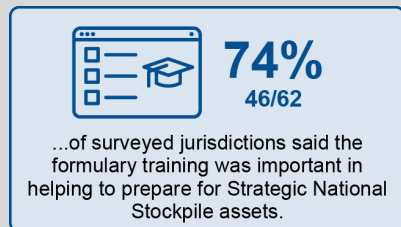
Figure 2: Jurisdictions' Top Five Federal Resources Seen as Most Useful to Prepare for Strategic National Stockpile Assets Ahead of the Next Emergency



Source: GAO analysis of survey data. | GAO-24-106260

Note: In our survey, we asked respondents to rank order the usefulness of 12 different federal resources. For each resource, we multiplied the number of responses per rank by the rank. For example, if 10 jurisdictions ranked updated written guidance as the most useful resource, we multiplied 10 responses by the rank of one. We then totaled all the sums per resource. We ranked resources by ascending totals. The ranked order in figure 2 summarizes these top five resources. See appendix II, question 10.

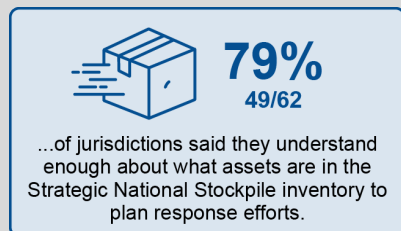
Survey Result: Importance of Formulary Training in Preparing for Strategic National Stockpile Assets



Source: GAO analysis of survey results (text); keenan/stock.adobe.com (icons). | GAO-24-106260

SNS officials said that they received similar comments from jurisdictions during their outreach meetings in the ASPR regions. SNS officials said that they already communicate inventory information to jurisdictions through a quarterly online formulary training. The online formulary training covers planning considerations and regulatory mechanisms used by SNS officials when distributing and storing SNS assets during different emergencies, focusing on chemical, biological, radiological, and nuclear threats. The training includes information, by threat, on types of assets the SNS contains, including ancillary supplies. According to our survey, this information has been helpful, with 74 percent (46/62) of jurisdictions saying that the formulary training is important in helping them prepare for emergencies.³⁸ Additionally, in response to the feedback they received during their outreach meetings, SNS officials posted a list of SNS products by threat and type to CDC’s secure web platform in May 2023.

Survey Result: Understanding Strategic National Stockpile Inventory



Source: GAO analysis of survey results (text); keenan/stock.adobe.com (icons). | GAO-24-106260

SNS officials said they are trying to balance sharing inventory information with security concerns and need to weigh the desire to help jurisdictions prepare for emergencies while protecting sensitive information that might point to national preparedness vulnerabilities. Providing inventory levels could get into the hands of adversaries and threaten the security of the United States, according to SNS officials.

SNS officials are considering ways of sharing additional information, such as increasing the use of secure information sharing platforms to do so, according to officials. Additionally, while jurisdictions indicated more

³⁸ The percentages reported here, and in the sidebar, represent the number and percentage of jurisdictions that responded that a particular federal effort was either “very important” or “somewhat important.” See appendix II, question 4.

detailed information would help with planning in the future, 79 percent (49/62) of jurisdictions said they currently understand enough about what assets are in the SNS inventory to plan response efforts.³⁹

Survey Result: Understanding Who to Contact to Request Assets During the COVID-19 Pandemic



Source: GAO analysis of survey results (text); keenan/stock.adobe.com (icons). | GAO-24-106260

Requesting assets. According to our survey, 24 percent (15/62) of jurisdictions did not know whom to contact during the COVID-19 pandemic to request SNS assets.⁴⁰ This was primarily because the COVID-19 response was managed by the Federal Emergency Management Agency rather than HHS, which would have normally led the response to a public health emergency. As such, some jurisdictions were unfamiliar with its request process. As one survey respondent noted, although the jurisdiction had a plan that outlined the SNS request process, the involvement of other federal stakeholders in the response added uncertainty and confusion to the process.

As we have previously reported, HHS was designated as the lead federal agency to address the public health and medical portion of the COVID-19 response as outlined in the National Response Framework. Due to a finite amount of supplies and overwhelming requests for SNS assets, ASPR distributed SNS supplies to states primarily using a pro-rata allocation strategy, which provided supplies to jurisdictions in proportion to their population. This strategy had been used in the past, including during the H1N1 pandemic, so jurisdictions were familiar with the process and had trained for it.

However, as the needs of the pandemic increased nationwide, the Federal Emergency Management Agency was designated as the lead agency for coordinating the overall federal COVID-19 response.⁴¹ As such, responsibility for responding to requests and allocating SNS assets shifted away from HHS—and request processes familiar to jurisdictions—to federal task forces led by the Federal Emergency Management Agency. As one survey respondent noted, the movement of request and distribution processes to the Federal Emergency Management Agency during the COVID-19 response led to a lot of confusion and in-fighting for

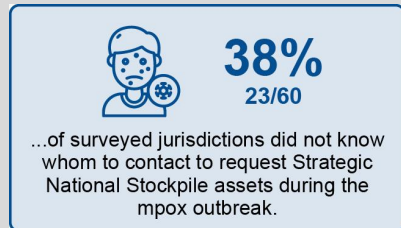
³⁹ In our survey, we asked respondents to rate their agreement with various statements about their understanding of the SNS inventory and processes on a scale of strongly agree, somewhat agree, neither agree nor disagree, somewhat disagree, strongly disagree, and no basis to judge. For the percentage reported here, and in the sidebar, we combined “somewhat agree” and “strongly agree” responses into “did understand.” See appendix II, question 5.

⁴⁰ In our survey, we asked respondents to rate their agreement with various statements about their understanding of the SNS inventory and processes on a scale of strongly agree, somewhat agree, neither agree nor disagree, somewhat disagree, strongly disagree, and no basis to judge. For the percentage reported here, and in the sidebar, we combined “somewhat disagree” and “strongly disagree” responses into “did not know.” See appendix II, question 7A.

⁴¹ [GAO-20-625](#).

control at the state level. We previously made recommendations related to federal supply coordination during the COVID-19 pandemic that have been closed as implemented.⁴²

Survey Result: Understanding Who to Contact to Request Assets During the Mpox Outbreak



Source: GAO analysis of survey results (text); Line-Art/stock.adobe.com (icons). | GAO-24-106260

For example, we recommended that HHS, in coordination with the Federal Emergency Management Agency, document roles and responsibilities for supply chain management functions transitioning to HHS. In September 2021, the National Strategy for a Resilient Public Health Supply Chain was released with a goal of transforming the federal government’s ability to monitor and manage the public health supply chain through stockpiles, visibility, and engagement with partners. HHS is the lead agency for implementation and the strategy required HHS, in conjunction with interagency partners, to develop plans including providing information on organizational roles and responsibilities and resource needs.

Despite efforts to resolve jurisdictional confusion around requesting SNS assets during the COVID-19 pandemic, confusion remained during the mpox response. According to our survey, 38 percent (23/60) of jurisdictions did not know whom to contact to request SNS assets during the mpox response.⁴³

Available guidance about requesting SNS assets states that jurisdictions should make requests through the HHS Secretary’s Operations Center, the CDC Emergency Operations Center, or through ASPR coordinators.

However, some jurisdiction officials we interviewed and surveyed said that they were required to make requests through various email addresses, with some email addresses changing without notice. For example, one survey respondent listed six different e-mail addresses that they were instructed to use for ordering SNS assets during the mpox response. Officials from one jurisdiction stated they worked with ASPR coordinators to find the correct email address to contact.

CDC officials noted that the reason for a dedicated email address was that some mpox countermeasures were limited in quantity and could only be administered under an expanded access investigational new drug protocol. These protocols were held by CDC to alleviate the burden on health care providers to establish and seek authorization from FDA. As such, all requests for therapeutics were routed via e-mail to CDC’s Poxvirus

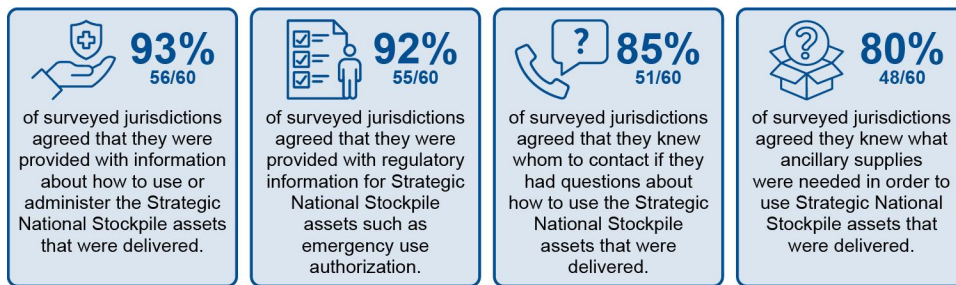
⁴² GAO, *COVID-19: Federal Efforts Could Be Strengthened by Timely and Concerted Actions*, [GAO-20-701](#) (Washington, D.C.: Sept. 21, 2020).

⁴³ In our survey, we asked respondents to rate their agreement with various statements about their experience with SNS assets during various public health emergencies on a scale of strongly agree, somewhat agree, neither agree nor disagree somewhat disagree, strongly disagree, and no basis to judge. For the percentage reported here, and in the sidebar, we combined “somewhat disagree” and “strongly disagree” responses into “did not know.” See appendix II, question 6A.

Consultation Team which provided clinical consultation, ensured that the patient met specific criteria, and provided recommendations for patient care, among other services.

According to CDC officials, if the Poxvirus Consultation Team determined that all criteria had been met, they would place an order to SNS officials with state health department awareness. Additionally, CDC officials provided instructions for obtaining mpox therapeutics through email and held weekly webinars where they answered questions about obtaining mpox therapeutics. Despite confusion with the request process, jurisdictions we surveyed agreed that they were provided with information about using SNS assets during the mpox outbreak (see fig. 3).

Figure 3: Jurisdictions’ Experiences Receiving Information About Using Strategic National Stockpile Assets During the Mpox Outbreak



Source: GAO analysis of survey data (text); keenan/stock.adobe.com (icons). | GAO-24-106260

Note: The percentages and numbers reported in figure 3 represent the proportion of jurisdictions that responded that they either “strongly agreed” or “somewhat agreed” with a particular statement. See appendix II, question 6C.

Additionally, some jurisdictions we surveyed and interviewed noted confusion around ordering the mpox vaccine when ASPR switched to a system called the Health Partner Order Portal—an online portal that was used to order and track medical countermeasures. For example, one survey respondent noted that staff responsible for vaccine ordering were unfamiliar with the portal, especially since it did not connect with the state’s vaccine tracking system. Additionally, some of the public health officials from selected jurisdictions we interviewed noted that the switch to the portal was unexpected since a vaccine ordering system already existed. As officials from some jurisdictions noted, they assumed vaccines would be ordered through the existing Vaccine Tracking System—CDC’s on-line vaccine ordering system—and some other officials expressed confusion as to why ASPR had decided to switch to the portal during the mpox outbreak.

ASPR officials noted that the Health Partner Ordering Portal system was designed during the COVID-19 pandemic to support public health partners with ordering, distributing, and tracking inventory of COVID-19 assets. They added that because the system was being used by public health officials for COVID-19, it was identified as the system to best support the distribution of mpox vaccine and therapeutics because of familiarity. However, as one survey respondent noted, while the portal was used during the COVID-19 response, it was not used by state immunization staff who were unfamiliar with it for mpox vaccine ordering. ASPR officials told us they helped address jurisdiction officials’ questions about the portal as well as any other issues through scheduled office hours, weekly calls, guidance documents on utilizing the portal, and other technical assistance efforts.

To address some of the coordination challenges related to requesting SNS assets, SNS officials stated they established an Office of State, Local, Tribal, and Territorial (SLTT) Preparedness in 2022. The Office of SLTT Preparedness is tasked with strengthening communication and relationships with jurisdictions regarding SNS

assets, according to SNS officials. Specifically, the mission of this office is to assist partners with medical countermeasure logistics planning and coordinate access to SNS training and exercise support to enhance jurisdictions' and tribal communities' readiness to respond to public health threats.

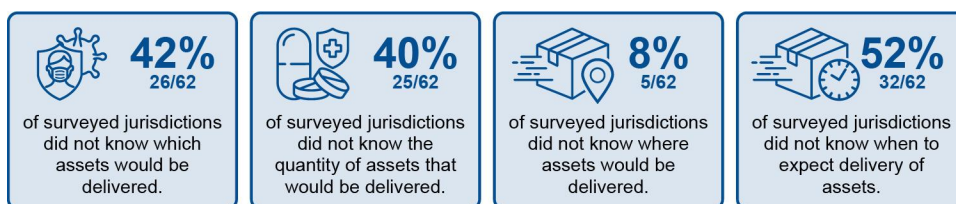
The new office comprises two divisions: (1) the Division of Technical Assistance, focused on providing direct technical assistance to jurisdictions and providing support for inventory management and medical countermeasure preparedness activities, among other things; and (2) the Division of Stakeholder Engagement, focused on promoting partnerships with jurisdiction and tribal partners.

The creation of the Office of SLTT Preparedness has provided jurisdictions with additional pathways to coordinate and communicate about requesting SNS assets with ASPR. For example, officials from the new office have been holding meetings with jurisdictions in each ASPR region throughout 2023 to understand the current state of planning at the jurisdiction and what they can do to help. As noted earlier, 97 percent (60/62) of survey respondents agreed that ASPR regional meetings and communications are important in helping them prepare for emergencies for which SNS assets might be needed.

SNS officials noted, however, that, as of January 2024, they had filled less than half the vacancies in the office, including some vacancies for key leadership positions. Also, SNS officials said while some operating procedures for the office have been developed, additional procedures are dependent on filling these vacancies to build up the office's divisions.

Receiving assets. Jurisdictions we surveyed and interviewed reported confusion around the delivery of SNS assets, much more so during the COVID-19 pandemic than the mpox outbreak. During the COVID-19 response, some jurisdictions experienced challenges understanding what and how many assets they were receiving, where those assets would be delivered and when jurisdictions would receive them (see fig. 4). As one survey respondent noted, the randomness of arrivals and lack of shipping information hindered the process of unloading the assets that arrived, due to uncertainty about when the assets would be delivered. Another survey respondent noted that SNS e-mails that listed quantities to be delivered did not match what was actually received. Additionally, most of the public health officials from selected jurisdictions we interviewed noted similar challenges. As one jurisdiction official noted, missing paperwork made it difficult to know what was arriving or even if it was something they asked for. Similar issues were raised during the H1N1 response, when jurisdictions mentioned challenges about the timing and contents of SNS shipments.⁴⁴

Figure 4: Jurisdictional Understanding of Strategic National Stockpile Asset Delivery During the COVID-19 Pandemic



Source: GAO analysis of survey data (text); keenan/stock.adobe.com (icons). | GAO-24-106260

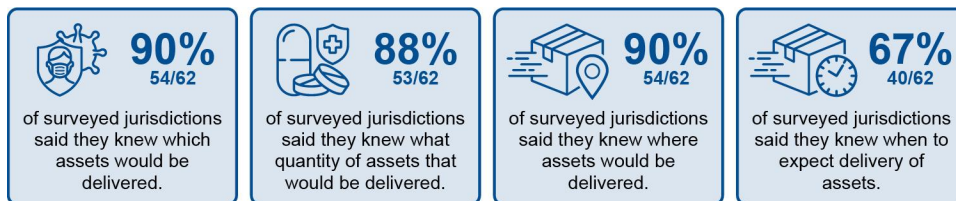
⁴⁴ GAO, *Influenza Pandemic: Lessons from the H1N1 Pandemic Should Be Incorporated into Future Planning*, GAO-11-632 (Washington, D.C.: June 27, 2011).

Note: The percentages and numbers reported in figure 4 represent the proportion of jurisdictions that responded that they either “somewhat disagreed” or “strongly disagreed” with a particular statement. We combined these responses into “did not know” for the purpose of the figure. See appendix II, question 7B.

Both SNS and some jurisdictional officials acknowledged that the COVID-19 response was unlike previous emergencies due to the national scale, which contributed to some of the delivery confusion. SNS officials attributed the confusion to the volume of assets distributed, the expediency in which they attempted to deliver assets, and the involvement of the Federal Emergency Management Agency in supply distribution.

Delivery of SNS assets significantly improved during the mpox response, as jurisdictions we surveyed reported having a better understanding of the assets they were receiving (see fig. 5).

Figure 5: Jurisdictional Understanding of Strategic National Stockpile Asset Delivery During the Mpox Outbreak



Source: GAO analysis of survey data (text); keenan/stock.adobe.com (icons). | GAO-24-106260

Note: The percentages and numbers reported in figure 5 represent the proportion of jurisdictions that responded that they either “somewhat agree” or “strongly agree” with a particular statement. We combined these responses into “they knew” for the purpose of the figure. See appendix II, question 6B.

Although improved, jurisdictions we surveyed and interviewed pointed to delivery challenges. For example, some jurisdictional officials we surveyed and interviewed said that the limitation on the number of delivery sites for the mpox vaccine created challenges. To illustrate, one survey respondent noted that the limited amount of delivery sites was burdensome and compromised cold chain storage since vaccines would need to be redistributed. Additionally, officials from a jurisdiction we interviewed stated that distribution of the mpox vaccine to a limited number of sites did not align with best practices for chain of custody and cold chain management. After receiving this feedback, ASPR allowed additional delivery sites to help with mpox vaccine distribution, according to ASPR regional officials.

Additionally, some jurisdictions we surveyed and interviewed said CDC interacted with their jurisdictions’ epidemiology departments around receiving SNS assets instead of through public health preparedness departments, which are typically the points of contact for SNS assets. As a result, some public health preparedness officials experienced issues when communicating about SNS assets. As one survey respondent noted, “The State SNS coordinator was left out of the mpox response altogether while the bureau of epidemiology was the main contact...State SNS coordinator were unaware of allotments...and where medications were being stored and being sent to...Typical processes were not followed.” Another survey respondent noted that the federal government did not follow established SNS plans, and the involvement of infectious disease subject matter experts rather than SNS subject matter experts caused confusion around asset delivery.

CDC officials told us that once a decision was made by the Poxvirus Consultation Team to provide mpox assets, jurisdiction officials were included on any correspondence related to delivering SNS mpox therapeutic requests. CDC officials said that they contacted states using health department contact lists, which contained information for jurisdictional epidemiologists and infectious diseases points of contact. However, as stated above, these types of jurisdictional officials are not normally involved in SNS requests and maintaining jurisdictional medical countermeasures.

SNS officials acknowledged that improved internal and external coordination around supplies was needed. Following a GAO recommendation from September 2020 that HHS work to devise interim solutions to help states enhance their ability to track the status of supplies during the COVID-19 pandemic, the department took several actions.⁴⁵ These actions included, among other things, scheduling monthly calls with states to discuss medical countermeasure distribution and dispensing and hosting twice a week stakeholder calls—which shifted to once a week in May 2022—with health officials and health care and hospital associations to provide the latest information on COVID-19 therapeutics, including changes to distribution processes. In April 2023, we closed this recommendation as implemented.

In addition to the Office of SLTT Preparedness mentioned earlier—which will also provide more avenues for jurisdictions to communicate about receiving assets—SNS officials also updated the internal task order system in 2022 to better coordinate and track orders and deliveries with jurisdictions. According to SNS officials, these updates sought to improve coordination and communication by standardizing shipment and tracking information via e-mail to jurisdictions. For example, SNS officials told us that during the COVID-19 pandemic, the jurisdiction officials who requested assets were not always the officials who received the assets at the jurisdiction’s warehouse. As a result, the tracking information provided did not always make it to the receiving official, which caused some of the delivery issues. Through the updated task order system, SNS officials said they now collect contact information for both the requesting official and delivery site. Also, SNS officials stated they use the system to follow-up with jurisdictions to confirm information and to coordinate internal communications between SNS groups managing fulfillment and delivery.

While SNS officials have taken some steps to improve coordination and communication around receiving assets, jurisdictions described wanting additional visibility and information into the process. For example, many of the jurisdictions we interviewed stated they wanted more information about their SNS requests—such as how their requests are moving through the approval process and delivery and tracking information—in real time. As officials from one jurisdiction noted, they would like more visibility into the process where one can track asset approvals or denials, and when it is shipped or delivered. Additionally, jurisdictions we surveyed noted that having such a defined ordering system was one of the top federal resources for preparing for SNS assets ahead of future emergencies (see fig. 2).

However, such a system would be costly and require more advanced and integrated technology systems than what the SNS currently has, according to SNS officials. Additionally, SNS officials stated that a system like this would take already limited resources away from asset procurement. Similarly, our previous work has shown that the SNS’s resource constraints limit its ability to meet its expanding responsibilities, according to ASPR officials.⁴⁶

Understanding of federal agency roles. Jurisdictions we surveyed and interviewed reported challenges understanding the roles and responsibilities of federal agencies. For example, 38 percent (23/60) of surveyed jurisdictions did not know whom to contact to request SNS assets during the mpox outbreak, as noted earlier. One survey respondent noted that the SNS transition from CDC to ASPR affected understanding of SNS processes. They added that clearer connections around how CDC and ASPR would work collaboratively would help to avoid confusion during responses. Another survey respondent noted that the roles of CDC and ASPR

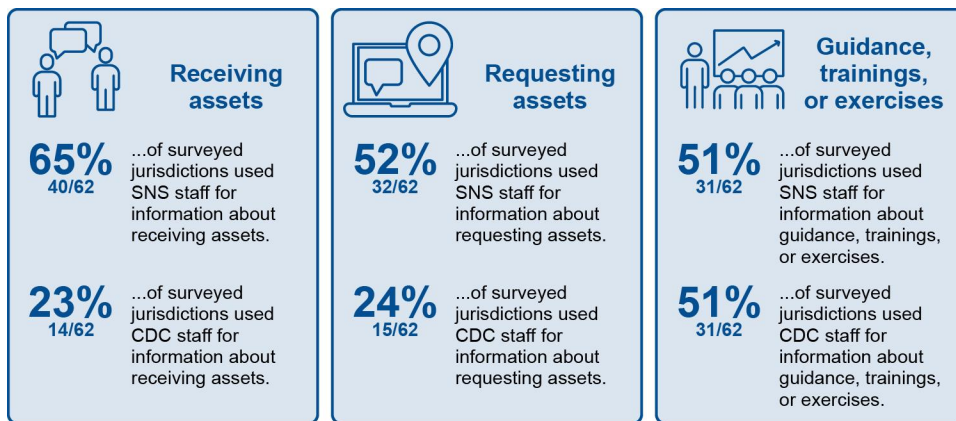
⁴⁵ [GAO-20-701](#).

⁴⁶ GAO, *COVID-19: Critical Vaccine Distribution, Supply Chain, Program Integrity, and Other Challenges Require Focused Federal Attention*, [GAO-21-265](#) (Washington, D.C.: January 28, 2021).

during the mpox outbreak were unclear. Additionally, some public health officials from selected jurisdictions we interviewed said that they were not clear about roles or the extent to which there was communication between ASPR and CDC regarding SNS operations after the transfer. One survey respondent said that moving SNS asset requests to CDC during the mpox response created confusion and delays in their response efforts. As mentioned above, jurisdictions we surveyed listed having more detail on federal roles and responsibilities related to the SNS as the fourth most useful effort for helping to prepare for SNS assets ahead of the next emergency (see fig. 2). Additionally, some of those surveyed and interviewed noted wanting closer coordination between CDC and ASPR—the agencies with the most direct responsibility for SNS assets.

Jurisdictions we surveyed reported they rely on both agencies for information regarding SNS assets (see fig. 6). While SNS has made internal changes to better coordinate and communicate with jurisdictions around SNS assets—particularly by establishing the Office of SLTT Preparedness— there is no formal documented agreement between ASPR and CDC that details each agency’s roles and responsibilities related to SNS operations, according to SNS officials.

Figure 6: Jurisdictions’ Use of Strategic National Stockpile (SNS) and Centers for Disease Control and Prevention (CDC) Staff for Information About SNS Assets



Source: GAO analysis of survey data (text); keenan/stock.adobe.com (icons). | GAO-24-106260

Note: The percentages and numbers reported in figure 6 represent the proportion of jurisdictions that responded that they used SNS and CDC staff for particular information about the SNS. See appendix II, question 3.

CDC and SNS officials both noted a strong, long-standing working relationship and mentioned informal coordination processes between the two agencies that have not been documented. SNS officials also said that the transfer of the SNS from CDC to ASPR affected coordination with CDC and they have worked to re-establish those connections. Particularly, the transfer of the SNS to ASPR spread the expertise and responsibilities related to the SNS across two HHS agencies. For example, CDC officials have noted that SNS staff are considered experts in medical logistics and warehousing operations, while CDC staff have a deep expertise on medical countermeasure clinical guidance. Jurisdictions need the expertise from both agencies to receive and use SNS assets.

SNS and CDC officials noted recent efforts to improve coordination. For example, in April 2022, SNS and CDC’s Center for Preparedness and Response officials finalized a memorandum of understanding on procedures for sharing non-public emergency management information. CDC officials also stated that they have developed an informal framework for coordination between ASPR and CDC regional teams regarding communication to jurisdictional partners related to public health emergency responses. According to CDC

officials, the framework is intended to improve coordination between ASPR and CDC related to information sharing with jurisdictions during public health emergency responses requiring the distribution, dispensing, and administration of medical countermeasures, such as SNS assets. Additionally, SNS's new Office of SLTT Preparedness has established a resource liaison branch that is responsible for federal coordination between SNS, ASPR coordinators, and CDC. However, none of these efforts formally outline the specific roles and responsibilities of ASPR and CDC related to the SNS, according to SNS officials.

It is critically important that ASPR and CDC work together to formally define their respective roles and responsibilities related to the assets in the SNS and how they will coordinate in the event of an emergency. Doing so is consistent with ASPR's current strategic plan.⁴⁷ Specifically, strategic goal 2—managing the federal response to and recovery from public health emergencies and other disasters—has a milestone to enhance coordination with intra-agency and interagency partners.

Further, GAO's leading practices for interagency collaboration state that collaborating agencies should work together to define and agree on their respective roles and responsibilities, including how the collaborative effort will be led.⁴⁸ By defining and agreeing on roles and responsibilities, agencies can clarify who will do what, organize their joint and individual efforts, and facilitate decision-making. Additionally, defined and agreed upon roles can help overcome barriers when working across agency boundaries. Finally, *Standards for Internal Control in the Federal Government* state that quality information should be communicated internally and externally to achieve an entity's objectives.⁴⁹

We have reported that improving coordination of public health emergencies is essential to saving lives and preparing the nation to respond to multiple simultaneous threats.⁵⁰ By clearly and fully articulating ASPR's and CDC's roles and responsibilities related to the SNS in a formal document—and sharing the resulting document with jurisdictions—ASPR will help jurisdictions better navigate the SNS and respond quickly to public health crises.

Jurisdictions Noted Challenges with Outdated Guidance, Which SNS Has Not Addressed

Most jurisdictions we interviewed reported that outdated guidance was a challenge because, as some noted, it made it difficult to understand current SNS processes during recent emergencies. Jurisdictions ranked updated guidance as the most useful resource for helping to prepare for SNS assets ahead of the next emergency (see fig. 2). Further, some jurisdictional officials we interviewed stated that up-to-date guidance on requesting and receiving assets is useful to ensuring access to SNS assets. However, some jurisdictions we surveyed reported that they did not agree that the process for requesting and receiving SNS assets during the COVID-19

⁴⁷ Department of Health and Human Services, Administration for Strategic Preparedness and Response, *ASPR Strategic Plan for 2022-2026* (2022).

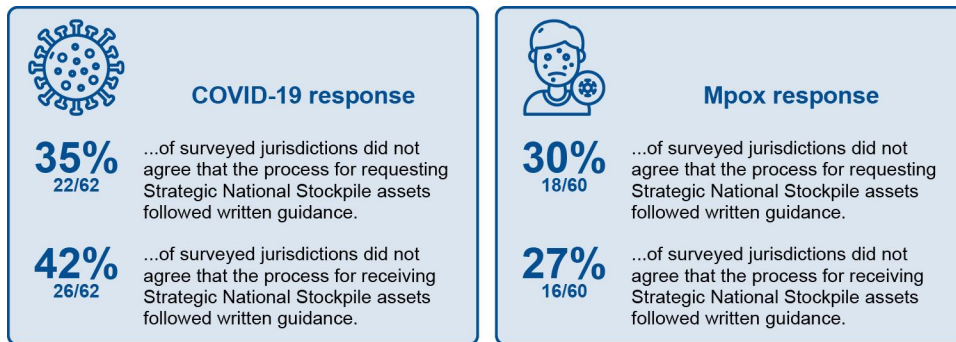
⁴⁸ GAO. *Government Performance Management: Leading Practices to Enhance Interagency Collaboration and Address Crosscutting Challenges*. [GAO-23-105520](#). (Washington, D.C.: May 24, 2023).

⁴⁹ GAO. *Standards for Internal Control in the Federal Government*. [GAO-14-704G](#). (Washington, D.C.: September 10, 2014).

⁵⁰ GAO, *COVID-19: Significant Improvements Are Needed for Overseeing Relief Funds and Leading Responses to Public Health Emergencies*, [GAO-22-105291](#) (Washington, D.C.: Jan. 27 2022).

and mpox responses followed guidance (see fig. 7). As officials from one jurisdiction noted, the main guidance document—Version 11—is not sufficient because it is outdated and does not reflect reality.

Figure 7: Survey Results Related to Whether Written Guidance Was Followed During the COVID-19 and Mpox Responses



Source: GAO analysis of survey data (text); Line-Art/stock.adobe.com (icons). | GAO-24-106260

Note: The percentages and numbers reported in figure 7 represent the proportion of jurisdictions that responded that they either “somewhat disagreed” or “strongly disagreed” with a particular statement. We combined these responses into “did not agree” for the purpose of the figure. See appendix II, questions 6A, 6B, 7A, 7B.

Our review found that the current SNS guidance for requesting and receiving SNS assets, Version 11, is out of date and does not reflect the transfer of responsibility for the SNS from CDC to ASPR. For example, the guidance states that SNS operations—including the requesting and distribution process—are under CDC authority, rather than under ASPR authority. Further, the guidance does not mention the role of ASPR Regional Medical Countermeasure Advisors or ASPR’s role in reviewing jurisdictions’ receiving, staging, and storing sites and plans. SNS officials noted that the transfer of the SNS followed by the COVID-19 pandemic did not afford them an opportunity to update Version 11 or develop procedures. They added that they are working on updating and streamlining Version 11 and plan to release an updated version in 2024.

However, SNS officials stated they have not developed procedures to consistently update the key external SNS guidance document, which has resulted in outdated guidance that has affected jurisdictions’ understanding of how to request and receive SNS assets, among other things. Even if ASPR updates Version 11 in 2024, a more fundamental and longstanding issue would still exist in that, according to ASPR officials, ASPR lacks procedures for updating SNS guidance more broadly. We have previously made recommendations to address ASPR’s lack of documented procedures for other organizational efforts related to the SNS including the Public Health Emergency Medical Countermeasures Enterprise.⁵¹ We recommended in 2021 that ASPR document procedures for the restructured enterprise and its records management practices. ASPR has noted that it is developing procedures, among other actions, but these recommendations have not been implemented as of January 2024.

Congress has taken action to ensure more current guidance related to the SNS is available. The Consolidated Appropriations Act, 2023 required that the Secretary of Health and Human Services issue guidance “related to

⁵¹ See [GAO-21-551](#). The Public Health Emergency Medical Countermeasures Enterprise is an interagency group that includes ASPR. The group is tasked with making recommendations to the Secretary of Health and Human Services regarding research, procurement, and stockpiling of medical countermeasures as well as developing strategies for logistics, deployment, distribution, dispensing, and use of medical countermeasures from the SNS. See 42 U.S.C. § 300hh-10a and [GAO-23-106210](#) for more information.

processes by which to request access to the contents of the Strategic National Stockpile” to states, territories, Tribes, and tribal organizations, and other applicable entities.⁵²

To address the requirement, SNS officials published guidance on requesting SNS assets on the ASPR website in March 2023. However, Version 11 has not yet been updated, according to SNS officials, and the website guidance lacks the level of detail provided by Version 11. For example, while the website guidance provides a summary of how to request assets, Version 11 discusses the difference in the request process under different emergency declarations. Version 11 also provides guidance on receiving, staging, storing, managing, distributing, and dispensing medical countermeasures, among other things. The guidance published on ASPR’s website in March 2023 does not cover these other aspects of jurisdictions’ access to and use of SNS assets.

Without procedures establishing how and when to update its guidance, ASPR increases the risk that its SNS guidance will not be updated in a timely manner and, therefore, will become outdated again. This in turn could lead to continued confusion among jurisdictions about how SNS processes, including requesting and receiving SNS assets, are supposed to work. Developing standard operating procedures for updating guidance would help ASPR ensure that it is consistently updating key external guidance and articulating the most current procedures for accessing SNS assets to jurisdictions and Tribes.

Developing standard operating procedures for updating guidance is consistent with ASPR’s current strategic plan. Specifically, strategic goal 3— improving and leveraging partnerships with health care and public health stakeholders—has a milestone to provide clear guidance on coordinated medical countermeasure distribution to ensure stakeholder expectations and needs are met.

Additionally, *Standards for Internal Control in the Federal Government* state that there should be control activities, including policies, procedures, and mechanisms that are effective and efficient in accomplishing the agency’s goals as well as activities designed to ensure ongoing monitoring occurs during normal operations.⁵³

Adhering to these standards when developing procedures for updating its guidance documents would help ensure that ASPR has written procedures that articulate how it will consistently refine guidance, identify, and rectify issues, and build a feedback system that meets the needs of users at all levels of government. Further, developing procedures that incorporate internal control standards could enhance overall communication, improve the likelihood that the guidance will meet stakeholder needs, and strengthen efforts to address any challenges that have been identified.

Finally, consistent with ASPR’s strategic plan and GAO’s *Standards for Internal Control*, these standard operating procedures should include internal review processes, opportunities for stakeholder feedback, and time frames for updating to ensure that SNS officials provide guidance that reflects the current operating environments. With these procedures in place, jurisdictions will be more likely to have access to updated guidance that reflects current processes, in turn, improving response efforts.

⁵² Pub. L. No. 117-328, div. FF, tit. II, § 2404, 136 Stat. at 5785.

⁵³ [GAO-14-704G](#).

HHS Has Taken Steps to Address Additional Coordination Issues Identified by Jurisdictions and Tribes but Has Not Fully Assessed SNS Challenges Faced by Tribes

Our analysis of survey data and interviews shows several issue areas where jurisdictions and Tribes identified the need for additional coordination from the federal government—particularly around response plans and stockpiling information—to help better prepare for future emergencies that may require SNS assets. HHS is taking, or plans to take, steps to address issue areas identified by jurisdictions by (1) sharing updated HHS response plans, including plans that outline SNS asset deployment during specific kinds of emergencies, and (2) providing guidance to help jurisdictions manage their jurisdictional stockpiles that may include SNS assets. While HHS has taken steps to coordinate with Tribes on issues related to requesting SNS assets, HHS has not assessed how it will accommodate unique challenges, such as infrastructure and geography, that will affect SNS asset delivery to Tribes.

HHS Plans to Share Updated Federal Response Planning with Jurisdictions

Many of the selected jurisdictions we interviewed said that they have not seen, or are not aware of, any existing HHS response plans. Officials from one jurisdiction told us that they wanted to see more documents about federal planning assumptions and responsibilities to help the jurisdiction plan for, and direct, their own activities during responses. Additionally, jurisdictions we surveyed said that having federal response plans for various threats was the fifth most useful resource for helping to prepare for SNS assets ahead of the next emergency (see fig. 2).

HHS officials told us that their All-Hazards Plan is the department's operational document designed to guide responses to a full range of threats and emergencies as outlined in ASPR's National Health Security Strategy.⁵⁴ This plan outlines how HHS divisions will provide public health and medical support to jurisdictional and tribal governments in response to emerging infectious diseases, chemical, biological, radiological, and nuclear threats, and concurrent public health emergencies, among other emergencies. HHS is in the process of updating this document and plans to share the document with jurisdictions and Tribes, according to agency officials. HHS officials noted the current plan is from 2012, and they have been working on an updated version since 2019 and plan to issue the document by the second quarter of 2024. The updated plan will include new and expanded sections on how HHS divisions will be involved in responses, as well as coordination guidance for responses that involve three or more HHS divisions, according to HHS officials.

HHS officials said the updated All-Hazards Plan will also include threat-specific response plans as annexes that may help jurisdictions and tribal partners plan for certain incidents. For example, previous ASPR threat specific annexes have addressed nuclear threats, hurricanes, chemical releases, and earthquakes, according to HHS officials. ASPR and SNS officials are working together to ensure that the updated annexes outline how and what SNS assets will be deployed in response to these incidents, according to ASPR officials. HHS

⁵⁴ The National Health Security Strategy, developed by ASPR every 4 years, promotes capability-based improvements to strengthen and adapt health care, public health, and emergency preparedness no matter the threat.

officials said that they plan to complete the pandemic and infectious disease and cyber threats annexes in fiscal year 2025.

HHS officials acknowledged that sharing the updated All-Hazards Plan and annexes, once they are finalized, could be useful for jurisdictions and tribal partners who may want to use the document to inform their own response planning including around SNS assets. Specifically, HHS officials said that they will share the updated finalized All-Hazards Plan and annexes with jurisdictions and tribal partners through various outreach initiatives including via an ASPR online portal. As seen with recent nationwide emergencies, a whole of nation approach is needed to respond to all types of emergencies. To ensure more effective coordination during responses, federal agencies, jurisdictions, and Tribes need to have a better understanding of each other's capabilities and planning assumptions prior to emergencies, according to the National Response Framework. Sharing this plan and annexes will be an important step to helping HHS, jurisdictions, and Tribes understand each other's capabilities and align actions in preparation for emergency responses including those that require SNS assets.

HHS Is Taking Some Steps to Support Jurisdictional Stockpiles, while Jurisdiction and SNS Officials Identified Funding Limitations

HHS is taking some steps to help jurisdictions manage and maintain the large amounts of medical supplies in jurisdictional stockpiles by providing guidance and information. Particularly, in response to recent legislation, HHS plans to develop and share guidance in fiscal year 2024 with jurisdictions on what medical countermeasures to stockpile and how to maintain them.⁵⁵ Also, HHS is taking steps to share information on how to manage expiring supplies and plans to develop guidance specifically on PPE in response to requests from jurisdictions. These steps could help improve jurisdiction-federal coordination on aligning stockpiling inventories and managing expiring supplies. However, both jurisdiction and SNS officials noted that limited funding could affect their abilities to maintain the supplies acquired during the COVID-19 pandemic.

During the COVID-19 pandemic, jurisdictions focused on purchasing and holding PPE—such as masks, gowns, and gloves—needed to combat the pandemic. (See fig. 8 for an example of a jurisdictional stockpile). According to our survey, 92 percent (57/62) of surveyed jurisdictions stated they started or expanded an existing stockpile during the COVID-19 pandemic. In addition to purchasing PPE in the commercial market, jurisdictions received supplies from the federal government, including ASPR and the SNS. During fiscal years 2020 and 2021, ASPR obligated \$1.4 billion dollars for direct shipment of products, including PPE, to jurisdictions.

⁵⁵ See Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, div. FF, tit. II, § 2409, 136 Stat. at 5791.

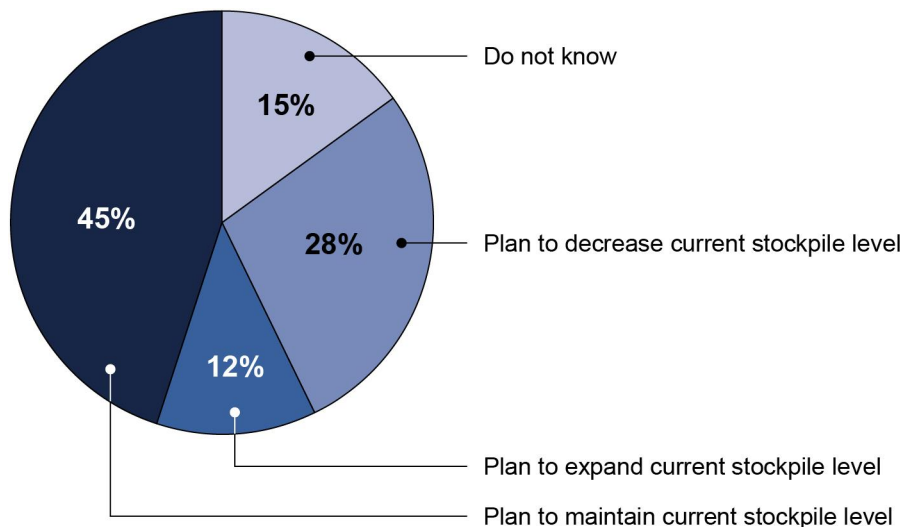
Figure 8: Example of a Jurisdictional Medical Countermeasure Stockpile



Source: GAO. | GAO-24-106260

However, with the end of the COVID-19 public health emergency, jurisdictions we surveyed identified additional resources and information from the federal government that could help them manage the assets acquired from both the commercial market and federal government. Without some of this additional support, 43 percent (26/60) of surveyed jurisdictions reported that they plan to decrease their stockpiles or do not know what will happen to their stockpiles. (See fig. 9). For example, one survey respondent that replied “do not know” about their stockpiling future, noted that stockpiling efforts will depend on funding levels and a better understanding of SNS plans and capabilities.

Figure 9: Survey Results Related to Expanding, Maintaining, or Decreasing Jurisdictional Stockpiles



Total = 60

Source: GAO analysis of survey data. | GAO-24-106260

Accessible Data for Figure 9: Survey Results Related to Expanding, Maintaining, or Decreasing Jurisdictional Stockpiles

Category	Percentage
Do not know	15%
Plan to decrease current stockpile level	28%
Plan to expand current stockpile level	12%
Plan to maintain current stockpile level	45%

Source: GAO analysis of survey data. | GAO-24-106260

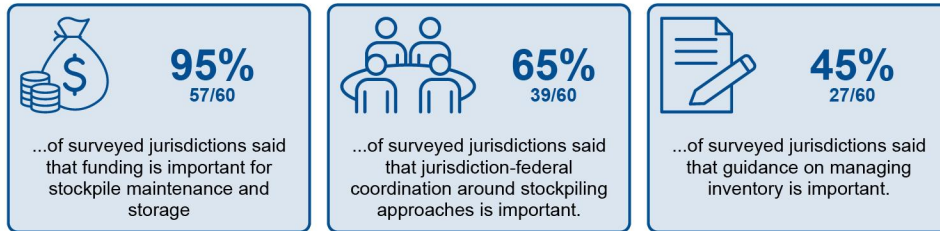
Note: Two of the 62 jurisdictions that responded to our survey stated that they did not have a stockpile prior to recent public health emergencies, nor started a stockpile during recent emergencies. As a result, these two jurisdictions did not respond to questions specifically for jurisdictions with stockpiles such as challenges with managing stockpiled materials or future planning.

Jurisdictions we surveyed ranked what specific federal efforts would most help them maintain their stockpile (see fig. 10). Congress and HHS agencies—including ASPR, FDA, and CDC’s NIOSH—have taken steps to provide support in these areas.⁵⁶

⁵⁶ NIOSH is part of CDC and is a research agency focused on the study of worker safety and health. As part of its work, NIOSH has conducted assessments on PPE, including respirators and surgical gowns. Additionally, NIOSH has provided information and guidance regarding PPE, including guidance for federal, state, and local public health officials on how to conserve limited supplies.

Figure 10: Top Ranked Federal Efforts to Help Maintain Jurisdictional Stockpiles

Top ranked federal efforts



Source: GAO analysis of survey data (text); keenan/stock.adobe.com (icons). | GAO-24-106260

Note: The percentages and numbers reported in figure 10 represent the proportion of jurisdictions that ranked a particular federal effort as either the first, second, or third most important effort. See appendix II, question 15.

Funding for stockpile maintenance and storage. According to our survey, 95 percent (57/60) of jurisdictions ranked funding as one of the top three federal efforts to help them maintain a stockpile. Officials we interviewed from some of the selected jurisdictions stated that securing funding to cover the costs of storing and maintaining the supplies in their stockpiles is a primary concern. Particularly, funding challenges are due in part to the limited amount of jurisdictional funds that are directed toward the high costs of maintaining supplies. For example, one jurisdiction official said that there is no money to pay for storage, maintenance, or disposal of the large amounts of PPE purchased during the COVID-19 pandemic. Also, officials we interviewed from a few of the selected jurisdictions said they are uncertain if they can replace PPE once it expires, which could affect their future preparedness. Officials we interviewed from some of the selected jurisdictions discussed facing similar funding challenges after the H1N1 response. Officials said that they lacked the funding to maintain and store supplies acquired during the H1N1 pandemic, which one jurisdiction official noted contributed to issues in being prepared to respond to the COVID-19 pandemic.

In terms of available funding from the federal government, CDC officials told us that jurisdictions can use PHEP funds to maintain and store medical countermeasures, although jurisdictions may have other budget priorities for these funds, such as personnel salaries. In addition, the Consolidated Appropriations Act, 2023 included a provision that HHS should create a pilot program and award grants or cooperative agreements to at least five states to establish, expand, or maintain stockpiles in the case of emergencies.⁵⁷

According to ASPR and SNS officials, this pilot program was not specifically funded under the Consolidated Appropriations Act, 2023, and ASPR’s current funding levels are not enough to support all of ASPR’s current programmatic goals and requirements. Particularly, ASPR officials said that the agency decided to use its funds to focus on certain budget priorities, specifically meeting Public Health Emergency Medical Countermeasures Enterprise requirements that include maintaining and replacing medical countermeasures in the SNS. Also, ASPR officials told us the agency has not requested additional funds to implement the pilot program.

Additionally, SNS officials discussed their own challenges with maintaining large quantities of PPE acquired during the COVID-19 pandemic due to funding challenges. Similar to the PPE acquired by jurisdictions, the SNS purchased PPE with COVID-19 relief funds, according to SNS officials. With the end of COVID-19-related funding, SNS officials discussed that the SNS does not have sufficient base funding to sustain its current portfolio of medical countermeasures—including for chemical, biological, radiological, and nuclear threats—

⁵⁷ Pub. L. No. 117-328, div. FF, tit. II, § 2409, 136 Stat. at 5789.

and cannot allocate any of its limited base funding to hold large quantities of PPE. Particularly, ASPR obligated \$6.1 billion for critical COVID-19 supplies delivered directly to the SNS, including \$2.4 billion for PPE during fiscal years 2020 and 2021 using COVID-19 relief funds.⁵⁸ By contrast, during fiscal year 2015 through fiscal year 2019, HHS made no obligations over \$1 million for PPE for the SNS.⁵⁹ These current funding issues are similar to funding issues the SNS faced after the H1N1 pandemic, according to our previous work.⁶⁰ Specifically, according to ASPR officials, HHS was unable to replenish PPE levels acquired during the H1N1 response due to funding challenges.⁶¹

Coordinating jurisdiction and federal stockpiling capabilities. According to our survey, 65 percent (39/60) of jurisdictions ranked jurisdiction-federal coordination as one of the top three federal efforts to help maintain a stockpile. Officials from some of the jurisdictions we interviewed discussed wanting to coordinate with the federal government to align stockpiling inventories and planning. For example, officials from one jurisdiction said that stockpiles at different governmental levels can help absorb the effect of future emergency needs. However, the officials said that there needs to be more visibility into the federal government’s stockpiling plans to inform the jurisdiction’s inventory. Also, when asked about the main challenges jurisdictions face related to the SNS, one ASPR regional official said that jurisdictions want information on what to stockpile to align with the SNS inventory. As officials from one surveyed jurisdiction said, improved communication about federal stockpiling strategy can help jurisdictions to better plan and prepare local stockpiling strategies.

The Consolidated Appropriations Act, 2023 included a provision that HHS should develop and issue guidance for jurisdictions related to maintaining their own medical countermeasures stockpiles.⁶² This guidance should include information on how to maintain and replenish stockpiles, what medical supplies may be appropriate for states to stockpile, and how to manage contents of stockpiles including disposal, as well as how to procure medical products. HHS was required to issue the guidance by June 27, 2023. According to HHS officials, HHS plans to release and share this guidance in fiscal year 2024. ASPR officials told us that they are planning to use information from their 10 regional engagement meetings—which concluded in October 2023—to develop this guidance. ASPR officials noted that they used these meetings to better understand jurisdictions’ current capabilities and outstanding needs, including their intent to maintain their own stockpiles.

Developing guidance for managing expiring inventory. According to our survey, 45 percent (27/60) of jurisdictions ranked guidance on managing inventory as one of the top three federal efforts to help maintain a stockpile. Particularly, officials we interviewed from some of the selected jurisdictions said that they lack federal guidance on how to manage expiring assets and would like more information from the federal government on how, if at all, they may extend expiration dates for stockpiled assets, including PPE. Officials from one jurisdiction said that without guidance on how to extend PPE expiration dates, jurisdictions have had to throw away significant quantities of expired N95 masks after the H1N1 pandemic and now face the same issue with

⁵⁸ [GAO-23-106210](#).

⁵⁹ [GAO-23-106210](#).

⁶⁰ GAO, *COVID-19: Opportunities to Improve Federal Response and Recovery Efforts*, [GAO-20-625](#) (Washington, D.C.: Jun 25, 2020).

⁶¹ SNS officials also mentioned that the end of COVID-19-related funding may also affect their ability to staff the Supply Chain Control Tower—a program set up during the COVID-19 pandemic to monitor commercial sector inventory, capacity, and distribution of medical supplies to increase understanding of supply problems. According to SNS officials, a similar supply chain monitoring program was set up after the H1N1 pandemic and was dissolved due to a lack of funding.

⁶² Pub. L. No. 117-328, div. FF, tit. II, § 2409, 136 Stat. at 5791.

the end of the COVID-19 pandemic. Officials from another jurisdiction had a similar concern and told us that guidance would be helpful as they do not want to dispose of large quantities of medical countermeasures that could be tested for usability and maintained for future emergencies.

ASPR, FDA, and NIOSH have taken steps to provide jurisdictions with information on how to manage expiring medical countermeasures, although these agencies have a limited role in extending expiration dates for assets—particularly for PPE—in jurisdiction stockpiles. For example, SNS officials said that they try to share information with jurisdictions about shelf-life extensions. Also, FDA and NIOSH officials noted steps their agencies have taken to provide jurisdictions with guidance on managing expiring medical countermeasures, including:

- FDA has developed expiration extension guidance for specific medical countermeasures in jurisdictional stockpiles. In 2019, FDA published doxycycline expiration extension guidance.⁶³ The guidance outlines how states can identify labs to conduct testing to see if the drug is still potent, as well as the process for requesting and receiving an expiration date extension from FDA. FDA officials said that they considered creating similar guidance for another medical countermeasure but ultimately decided against it since few jurisdictions used the doxycycline guidance. Also, during the 2022 influenza season, FDA officials worked with the SNS to evaluate the usability of Tamiflu and Relenza in jurisdictional stockpiles to extend the expiration date for these products. FDA officials told us that they also provide and share other product-specific information, including through FDA’s website.

The Shelf-Life Extension Program

The Shelf-Life Extension Program was established in 1986. The program offers fee-for-service testing of federal stockpiled pharmaceuticals to receive a shelf-life extension. The Department of Defense administers the program for participating federal agencies, while Food and Drug Administration officials are responsible for testing the material.

Participants in the program include the Strategic National Stockpile, Department of Defense, Federal Bureau of Investigation, Department of State, Department of Homeland Security, and Department of Veterans Affairs.

Source: GAO summary of Food and Drug Administration documents and interviews. | GAO-24-106260

- FDA officials told us they have received questions from jurisdictions about the possibility of testing jurisdictions’ medical countermeasures through the federal Shelf-Life Extension Program. The federal Shelf-Life Extension Program determines the effectiveness and safety of medical countermeasures that are past the stated expiration date, and FDA is responsible for testing the material (see sidebar for more information). FDA officials said that requests for the program have been limited to prescription drug products, and the program does not include PPE nor vaccines. FDA officials told us that between 2006 and 2007, the federal government considered expanding the program to test supplies in jurisdictional stockpiles. However, an interdepartmental working group found that it would be challenging to implement as it would require additional resources and costs.
- NIOSH is drafting guidance about stockpiled PPE that can be used by jurisdictions, according to NIOSH officials. The guidance will include information about different types of PPE, including how to select, store, and purchase PPE. Also, the guidance may include suggestions for jurisdictions on how to manage

⁶³ See FDA, *Extending Expiration Dates for Doxycycline Tablets and Capsules in Strategic Stockpiles* (April 2019), available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, accessed on November 15, 2023. Doxycycline is an antibiotic that is approved by FDA to treat several kinds of bacteria, including anthrax. Anthrax is a naturally occurring disease that could be used intentionally to harm the public, according to CDC. Federal and jurisdiction stockpiles may include drugs that are stored under controlled conditions as part of preparedness for chemical, biological, radiological, and nuclear emergencies, according to FDA officials. Doxycycline is an example of a prescription drug product that may be stockpiled.

products near expiration, according to NIOSH officials. NIOSH officials said they plan to develop the guidance based on concerns they heard from jurisdictions during NIOSH's past work on PPE. In this past work, NIOSH has conducted performance testing on PPE, but this testing cannot be used to issue extensions on products as it only evaluates PPE at the moment of testing, NIOSH officials stated. NIOSH officials have discussed the guidance with ASPR and SNS, and both have expressed interest in working with NIOSH. NIOSH officials said they may have a draft in the summer of 2024.

HHS Has Not Assessed Tribes' Unique Challenges with Receiving SNS Assets

HHS documentation and our interviews with selected Tribes and tribal organizations revealed various concerns Tribes had with accessing—requesting and receiving, specifically—SNS assets during recent emergencies. These concerns include Tribes' issues with requesting SNS assets through states or directly from the SNS and issues with receiving assets due, in part, to infrastructure or geography. SNS officials have taken steps to address tribal request challenges by leading an HHS-wide working group whose efforts focused on clarifying request pathways for Tribes. However, SNS officials told us they have not assessed the unique challenges that may affect SNS asset delivery to Tribes, nor have considered how these challenges will be managed.

Senate hearings on the COVID-19 response in Native communities

The Senate Committee on Indian Affairs held two hearings in 2020 and 2021 that focused on the COVID-19 response in Native communities. During these hearings, tribal organization officials, as well as Native Hawaiian health organization officials, discussed how relationships with states impacted Tribes' access to federal assets, among other topics. During the 2021 hearing, tribal and Native Hawaiian health organization officials provided the following comments:

"Tribal health organizations across Alaska have long established relationships with each other, as well as with State and federal officials, so throughout this pandemic our response has been coordinated and cooperative with good communication channels."

Dr. Robert Onders, Administrator, Alaska Native Medical Center

"The first year of [the] pandemic response demonstrated the health needs of Native Hawaiians are not among the standing emergency priorities of either the state or counties."

Dr. Sheri-Ann Daniels, Executive Director of Papa Ola Lōkahi.

Source: Senate Committee on Indian Affairs | GAO-24-106260

Relationships with states dictated Tribes' experiences with requesting and receiving SNS assets.

Tribes' experiences in requesting and receiving SNS assets during the COVID-19 pandemic varied, causing confusion and delays. Although Tribes may make direct requests to the SNS, our review of HHS documents and interviews with tribal and tribal organization officials revealed that Tribes generally worked with other entities—state agencies or Indian Health Service—to request and receive assets. Although SNS officials did accept direct requests from Tribes during the COVID-19 response, SNS officials said they encouraged Tribes to work with state and other entities to request and receive SNS assets.⁶⁴ As a result, Tribes' experiences in requesting and receiving SNS assets varied in part due to the strength of their existing relationships with states.

Specifically, Tribes that lacked strong relationships with states had issues with requesting SNS assets and communicating with state officials. For example, one former tribal official discussed how their Tribe was unsure which state agency would assist the Tribe to request and receive SNS assets during the COVID-19 pandemic, as the state had not created nor shared plans detailing procedures for state-tribal coordination. According to

⁶⁴ For example, Version 11 states that the SNS "has been working to foster a relationship in which tribal governments partner with state and local health departments to obtain the needed medications and assistance during a medical countermeasures response."

the former tribal official, state officials recommended that the Tribe try to request assets through a federal agency instead. Additionally, officials from one tribal organization we interviewed discussed facilitating two listening sessions in 2022 with Tribes across the United States to get information on Tribes' experiences with requesting and receiving assets, including SNS assets. Officials from the tribal organization told us that Tribes reported that state governments did not make agreements with Tribes ahead of emergencies on how SNS assets would be distributed, which officials said contributed to Tribes' uncertainty on what support they could expect from states. ASPR officials said that they also heard from Tribes that they did not always receive the support they needed from states to access federal resources.

In contrast, according to the Tribe and tribal organizational officials we interviewed, Tribes and states with strong relationships worked together to facilitate how Tribes could request and receive SNS assets during the COVID-19 pandemic. For example, officials from two Tribes told us they requested SNS assets from states and communicated with state-appointed tribal liaison officers to receive key information during the COVID-19 response. Also, officials from one tribal organization discussed how state health officials attended weekly meetings with tribal officials to discuss tribal resource needs, including SNS assets.

Further, officials from one Tribe that requested and received SNS supplies directly rather than through other entities described the process as unclear and told us they experienced delays working with SNS officials. For example, a tribal official who directly requested SNS assets stated that SNS officials told the Tribe to first work with Indian Health Service, the state, and counties for medical countermeasures rather than accepting the Tribe's direct request. Tribal officials said that they had already tried that route with limited success. After providing additional information and explaining their needs, this Tribe was able to receive assets directly from the SNS. Tribal officials told us that it took about 2 weeks to resolve this issue. During an emergency, it is important that response efforts remain nimble, adaptable, and resilient, according to the National Response Framework. Instead, situations like this can delay the delivery of important assets. These tribal officials told us they felt that the process for how Tribes work with SNS officials was not clear nor streamlined, particularly compared to the process for how states work with SNS officials.

HHS established an agency-wide working group to take steps to address Tribes' concerns with requesting SNS assets. Federal actions were taken in response to Tribes' concerns with requesting SNS assets. In 2021, President Biden signed Executive Order 14001, which directed HHS to consult with tribal authorities to facilitate tribal access to the SNS.⁶⁵ Additionally, the Consolidated Appropriations Act, 2023 requires HHS to make SNS assets directly available to Tribes and tribal organizations.⁶⁶

Beginning in 2021, in response to Executive Order 14001, SNS officials led an HHS-wide tribal access working group focused on defining the different ways Tribes could request SNS assets, including directly from the federal government. According to HHS officials, the working group's focus was determined by discussions between HHS and White House officials in 2021. The working group included officials from ASPR, SNS, Indian

⁶⁵ Exec. Order No. 14001, 86 Fed. Reg. 7219, 7221 (Jan. 26, 2021).

⁶⁶ Pub. L. No. 117-328, div. FF, tit. II, § 2408, 136 Stat. at 5789.

Health Service, CDC, among other HHS agencies, as well as input from the Federal Emergency Management Agency and the Department of the Interior's Bureau of Indian Affairs.⁶⁷

To address Tribes' concerns about request processes, in December 2022 the HHS-working group developed a draft strategy to outline the different ways that Tribes and other tribal entities can request SNS assets, including directly from federal agencies. According to an ASPR presentation given at a national conference on public health preparedness in April 2023, the draft strategy is designed to present streamlined pathways for Tribes to request assistance from the Federal Emergency Management Agency or HHS, depending on the emergency. Additionally, according to the presentation, the draft strategy will also maintain pathways for Tribes to coordinate with states and Indian Health Service on requests for SNS assets. This draft strategy may provide Tribes with clearer options for requesting SNS assets. For example, tribal officials can determine what other request pathways may work better for them if they do not want to coordinate with state agencies. In December 2023, SNS officials told us that the draft strategy is being finalized by the working group but could not provide a release date.

In addition to the draft strategy, the working group plans to develop other guidance documents for Tribes and state health agencies. According to SNS officials, the group has begun developing a communications plan on how the draft strategy will be shared with Tribes. The working group also plans to develop technical assistance guidance for state health agencies on how to support Tribes with medical countermeasure dispensing and administration. However, SNS officials said that funding and resources have not yet been established for this initiative. SNS officials told us that funding for this initiative may come from a funding opportunity announcement or another federal entity, such as CDC, rather than from the SNS.

SNS officials have not engaged with Tribes to assess unique challenges that may impact delivery of SNS assets. Although SNS officials have taken steps to address Tribes' concerns related to requesting SNS assets through the working group, SNS officials do not have plans to address other challenges identified by the working group, particularly related to receiving assets. As part of its efforts, the working group received feedback from Tribes on issues beyond the request process, including that assets received did not align with requests.

In addition, our interviews with selected Tribes and tribal organizations found that Tribes faced unique challenges related to receiving assets beyond those experienced by jurisdictions. For example, officials from one Tribe as well as a former official from another Tribe reported challenges with having the equipment and infrastructure needed to receive and store delivered assets. Officials from two tribal organizations heard similar issues from the Tribes they work with. Unlike jurisdictions that receive PHEP funding—which have specialized receive, stage, and store sites to manage the delivery of a variety of SNS assets, including those requiring cold storage—Tribes have used hotel rooms, offices, or casinos for storage, according to officials from one Tribe and one tribal organization. These sites are not traditionally used for the receipt of emergency supplies. Additionally, Tribes may be in geographically remote areas or be spread out across multiple states requiring close coordination to determine where assets should be delivered, according to officials from one tribal organization.

⁶⁷ The Federal Emergency Management Agency's Tribal Affairs Program is led by the National Tribal Affairs Advisor, who advises the Federal Emergency Management Agency leadership on issues related to Tribal Nations and tribal communities. Additionally, the Tribal Affairs Team collaborates with the agency's regional tribal liaisons that serve as the primary contacts for tribal governments regarding disaster preparedness and response.

SNS officials told us that they can coordinate with tribal officials to send assets to a desired delivery location. Specifically, SNS officials referred to the SNS request guidance published on ASPR's website in 2023. This guidance states that tribal health officials can request SNS assets during a public health threat and outlines what information SNS officials will collect to coordinate asset delivery, including information on delivery locations and potential transportation challenges.

However, in written comments provided to GAO in August 2023, SNS officials told us they are only beginning to grapple with the significant operational challenges if even a sub-set of 574 federally recognized Tribes decide to request and receive assets directly from the SNS. SNS officials initially told us that these challenges could potentially be addressed by the working group's planned efforts, including the communication and technical assistance plans, in addition to ongoing planning with Tribes and jurisdictions. However, according to an ASPR presentation and discussion with SNS officials, the working group's efforts are related to the draft strategy that focuses solely on the request process rather than challenges related to receiving assets. Additionally, in written comments provided to GAO in August 2023, SNS officials said that issues outside of the request process are beyond the scope of the working group. In terms of ongoing planning, SNS officials told us in January 2024 that they are trying to determine what steps they need to take to assess and approach challenges related to delivering assets to Tribes but have not yet done so.

HHS's initial steps to address Tribes' concerns with accessing SNS assets are promising. Clearly defining the SNS request process will help Tribes more efficiently request critical SNS assets during emergencies. However, due to the unique challenges that Tribes face in receiving SNS assets—and the fact that SNS officials have not widely distributed SNS assets directly to Tribes—it will be important for ASPR to coordinate internally and externally prior to the next emergency. Specifically, ASPR would benefit from designating an office—such as the Office of SLTT Preparedness—to regularly engage with tribal officials and other relevant stakeholders to assess the unique challenges that could affect the delivery of SNS assets to Tribes during future emergencies and develop options for addressing those challenges. Such an effort could help ASPR and Tribes better prepare for future emergencies.

Engaging with Tribes and relevant stakeholders to assess these issues would align with GAO's leading practices for collaboration that state that, among other things, solving complex problems is more successful when the participants have full knowledge of the relevant resources and capabilities that each can bring.

Additionally, assessing and considering options to address challenges that will affect delivery of SNS assets to Tribes ahead of future emergencies would align with objectives in ASPR's strategic plan. These objectives include:

- Strengthen state, local, tribal, and territorial partner resilience to adapt to and recover from incidents. This includes coordinating with partners to identify critical gaps in public health support.
- Engage in ongoing communication with partners—particularly with underserved communities such as Indigenous and Native American communities—to identify sources of inequity and potential remedies.
- Provide clear guidance on how the agency plans to coordinate the distribution of medical countermeasures—including SNS assets—to ensure partners' expectations and needs are met.

If ASPR regularly engages with Tribes and relevant stakeholders to assess the unique challenges that might affect the delivery of SNS assets to Tribes and develop options for addressing those challenges, SNS officials will be better prepared to deliver resources to Tribes with varied infrastructure and geography, particularly

during large-scale emergencies. As a result, Tribes will be better positioned to receive critical supplies, which will strengthen their ability to prepare for and respond to incidents.

Conclusions

The SNS continues to be a key resource for jurisdictions and Tribes. Its inventory of life-saving medical countermeasures is critical to ensuring the nation's ability to respond to public health emergencies, such as COVID-19 and mpox. However, our current review of ASPR's coordination with jurisdictions, Tribes, and the federal government, raises concerns about its efforts to ensure an efficient and effective system for providing SNS assets.

Specifically, jurisdictions lacked clarity on the specific roles and responsibilities of ASPR and CDC regarding the SNS, resulting in confusion among jurisdictions during recent public health responses. The transfer of the SNS from CDC to ASPR resulted in SNS medical countermeasure expertise spread across two HHS agencies and makes it imperative that roles and responsibilities are defined. By clearly and fully articulating ASPR's and CDC's roles and responsibilities related to the SNS in a formal document—and sharing the resulting document with jurisdictions—ASPR will help jurisdictions better navigate the SNS and respond quickly to public health crises. In addition, ASPR can improve coordination by developing standard operating procedures that outline how and when guidance documents, such as those for requesting and receiving SNS assets, are updated. Consistent with GAO's *Standards for Internal Control*, these standard operating procedures should include internal review processes, opportunities for stakeholder feedback, and time frames for updating. By developing these standard operating procedures, jurisdictions will be more likely to have access to updated guidance that reflects current processes, in turn, improving response efforts.

Furthermore, while ASPR has made progress in defining pathways for how Tribes can request SNS assets, it has not identified how it will address unique tribal challenges related to receiving assets. Specifically, officials from Tribes and tribal organizations discussed challenges with having the infrastructure to receive assets as well as living in geographically remote locations. ASPR would benefit from formally designating an office—such as the Office of SLTT Preparedness—to regularly engage with Tribes and relevant stakeholders to assess unique tribal challenges that could affect the delivery of SNS assets and develop options for addressing those challenges. Such steps would allow SNS officials to be better prepared to deliver assets to Tribes. In addition, Tribes would also be better positioned to receive critical supplies, which will strengthen their ability to prepare for and respond to incidents.

By improving coordination related to the SNS—both internally and externally—ahead of the next emergency, HHS will be better positioned to understand and manage challenges that might otherwise derail future responses.

Recommendations for Executive Action

We are making the following three recommendations to the Assistant Secretary for Preparedness and Response:

The Assistant Secretary for Preparedness and Response should work with CDC to clearly define ASPR's and CDC's roles and responsibilities related to the SNS in a formal document and share that document with jurisdictions. (Recommendation 1)

The Assistant Secretary for Preparedness and Response should develop standard operating procedures, outlining how and when guidance documents, such as those for requesting and receiving SNS assets, are updated. Consistent with GAO's *Standards for Internal Control*, these standard operating procedures should include internal review processes, opportunities for stakeholder feedback, and timeframes for updating. (Recommendation 2)

The Assistant Secretary for Preparedness and Response should formally designate an entity—such as the Office of SLTT Preparedness—to regularly engage with Tribes and relevant stakeholders to (1) assess the unique challenges, such as infrastructure and geography, that could affect the delivery of SNS assets to Tribes during future emergencies and (2) develop options for how to address those challenges. (Recommendation 3)

Agency Comments and Our Evaluation

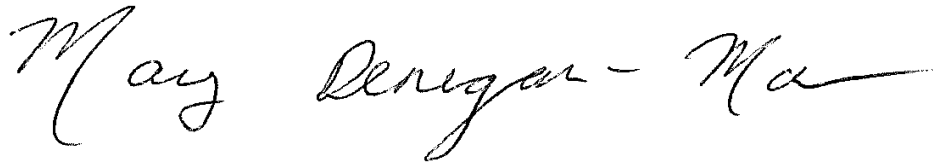
We provided a draft of the report to HHS for review and comment. HHS concurred with our recommendations and provided technical comments, which we incorporated as appropriate. The department's comments are reprinted in appendix IV.

With respect to our third recommendation to designate an entity to regularly assess—and provide options for addressing—tribal challenges that could affect the delivery of SNS assets, while they agreed, HHS officials stated that they consider this recommendation closed. Specifically, they stated that they had already taken steps to implement it by designating the Office of SLTT Preparedness as the central entity for SNS tribal engagement along with other initiatives such as holding regional meetings with stakeholders and finalizing and releasing the Tribal Access Strategy. These steps to increase coordination and communication among external stakeholders, including Tribes, are promising. However, the information that HHS provided does not outline a process by which the office will ensure regular engagement with Tribes moving forward. Further, while HHS has increased its communication with a variety of stakeholders, it is unclear from its comments how it has assessed, and developed options for, the challenges that might affect the delivery of assets to Tribes. As our report notes, SNS officials have focused on clearly defining the SNS request process and are still determining how to manage operational challenges of delivering SNS assets directly to Tribes. By engaging with Tribes to do an assessment, HHS and Tribes would be better equipped to deliver and receive assets, respectively.

We are sending copies of this report to the appropriate congressional committees and the Secretary of Health and Human Services. In addition, the report will be available at no charge on the GAO website at <http://www.gao.gov>

If you or your staffs have any questions about this report, please contact me at (202) 512-7114 or DeniganMacauleyM@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Major contributors to this report are listed in appendix V.

Letter

A handwritten signature in black ink that reads "Mary Denigan-Macauley". The signature is written in a cursive style with a long horizontal flourish at the end.

Mary Denigan-Macauley
Director, Health Care

List of Committees

The Honorable Patty Murray
Chair
The Honorable Susan Collins
Vice Chair
Committee on Appropriations
United States Senate

The Honorable Ron Wyden
Chairman
The Honorable Mike Crapo
Ranking Member
Committee on Finance
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The Honorable Mark E. Green, M.D.
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The Honorable Bennie G. Thompson

Letter

Ranking Member
Committee on Homeland Security
House of Representatives

The Honorable James Comer
Chairman
The Honorable Jamie Raskin
Ranking Member
Committee on Oversight and Accountability
House of Representatives

The Honorable Jason Smith
Chairman
The Honorable Richard Neal
Ranking Member
Committee on Ways and Means
House of Representatives

Appendix I: Scope and Methodology

The objectives of this report were to 1) describe resources the Department of Health and Human Services (HHS) provided jurisdictions prior to recent public health emergencies to help them access and use Strategic National Stockpile (SNS) assets, 2) examine challenges jurisdictions faced accessing and using SNS assets during recent public health emergencies, and 3) examine additional SNS coordination issues identified by jurisdictions, Tribes, and HHS officials that may affect responses to future public health emergencies and HHS efforts to address those issues.

To describe the resources HHS provided jurisdictions (state, local, and territorial governments) prior to recent public health emergencies to help them access and use SNS assets, we reviewed documentation related to the SNS. Our review focused on resources that were available to jurisdictions in 2018, after the transfer of the SNS to the Administration for Strategic Preparedness and Response (ASPR), but before the start of the COVID-19 pandemic response. This documentation included external guidance for requesting and receiving SNS assets; a threat-specific plan for SNS asset distribution; available trainings including those related to the SNS formulary; an after-action report; and a demonstration of the inventory management system. We also interviewed SNS and Centers for Disease Control and Prevention (CDC) officials about the resources that they provided to jurisdictions.

To address objectives two and three—we administered a web-based survey to public health emergency preparedness officials in the following 62 jurisdictions: the 50 states, the District of Columbia, eight territories, and three localities (Chicago, Los Angeles, and New York City) that receive awards from CDC’s Public Health Emergency Preparedness (PHEP) cooperative agreement program.

We surveyed these officials because, in addition to their jurisdictions receiving PHEP funding, they are, generally, the main points of contact for the SNS and other federal agencies involved in emergency preparedness and response. Therefore, they are most likely to know about their jurisdictions’ experiences with requesting and using SNS assets. We obtained contact information for these jurisdictional officials from CDC. We tested the survey by conducting three pretests of draft versions with public health emergency preparedness officials from three of the surveyed jurisdictions.

We administered our survey in May 2023, with the last responses received in September 2023. We collected information from survey respondents on the usefulness and importance of resources provided by federal agencies in preparing for emergencies, experiences requesting, receiving, and using SNS assets during recent emergencies, and plans for their jurisdictional stockpiles, among other things.

We had a survey response rate of 100 percent. Two of the jurisdictions did not complete part of the survey. Only responses for questions they did answer are included in our survey analyses. Our results are representative of the entire target population—jurisdictions that receive PHEP funding—due to the 100 percent response rate.

We analyzed the survey responses and conducted follow up with respondents, as needed, to clarify certain survey responses or obtain additional information. We conducted data checks on the survey responses, including checking for skip patterns and invalid responses, to ensure the completeness of the data.

To further address these two reporting objectives, we interviewed or received written responses from public health emergency preparedness officials from South Carolina, Maine, Georgia, New York, Washington, New Mexico, New York City, Guam, and Washington, D.C. We selected these jurisdictions to ensure a mix of characteristics, such as, geographic diversity, health department governance structure (i.e., the relationship between state health agencies and local health departments), and participation in recent federal emergency response exercises, among other criteria.

In addition to the survey results and jurisdictional interviews, we also selected and interviewed current officials from the Seminole Tribe of Florida, the Poarch Band of Creek Indians, the Pueblo of Pojoaque, the National Indian Health Board, and the American Indian Health Commission as well as a former tribal health official from the Navajo Nation. These Tribes and tribal organizations were selected based on a recommendation from a jurisdiction, interaction with regional HHS officials during the COVID-19 or mpox response, and tribal efforts to access SNS assets during the COVID-19 or mpox response.

We interviewed these jurisdictional and tribal officials to discuss their experiences accessing and using SNS assets, navigating federal resources, and preparing for future emergencies, among other topics. We reviewed relevant documents and resources provided by these jurisdictions and tribal organizations, including an after-action report and a medical countermeasure coordination plan, among other things. As part of these interviews, we conducted site visits to three states' and two localities' medical countermeasure warehouses to obtain information on medical countermeasure logistics, including asset receiving processes and plans for future storage of medical countermeasures.

We also interviewed federal officials for these two reporting objectives. We interviewed officials from HHS, ASPR, SNS, CDC, the Food and Drug Administration, and the National Institute for Occupational Safety and Health. Through these interviews we obtained information on coordination and communication with jurisdictions, internal policies regarding external guidance, federal response planning, and communications with jurisdictions, Tribes, and other federal agencies, among other things. Additionally, we conducted a site visit to SNS headquarters and visited an SNS warehouse located in the United States to obtain information and better understand SNS assets and logistic processes.

Finally, for these two reporting objectives, we also examined documentation gathered from federal, jurisdictional, and tribal officials. This included *A Guide for Receiving, Distribution, and Dispensing SNS Assets Version 11*; presentations related to SNS's internal task order system and Office of State, Local, Tribal, and Territorial Preparedness; ASPR strategic plans; an internal policy, a procedure, and a memorandum of understanding; quarterly on-line formulary training; a presentation related to HHS's tribal access working group; and a tribal COVID-19 after-action report, among other documents. We assessed all our collected evidence against our previous work, GAO's leading practices for interagency collaboration, and *Standards for Internal Control*.¹

We conducted this performance audit from September 2022 to May 2024, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our

¹ GAO. *Standards for Internal Control in the Federal Government*. [GAO-14-704G](#). (Washington, D.C.: September 10, 2014).

audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix II: Results of GAO Survey with Public Health Emergency Preparedness Departments

We administered a web-based survey to public health emergency preparedness officials in 62 jurisdictions (50 states, the District of Columbia, eight territories, and three localities (Chicago, Los Angeles, and New York City)) that receive Centers for Diseases Control and Prevention (CDC) Public Health Emergency Preparedness cooperative agreement funding. We surveyed these officials because they are the main points of contact within a jurisdiction for the Administration for Strategic Preparedness and Response's (ASPR) Strategic National Stockpile (SNS) assets. The survey was administered in May 2023, with the last responses received in September 2023.

Q1) Since January 1, 2019, has your jurisdiction received assets from the SNS?

Yes\No	Number	Percent
Yes	62	100
No	0	0
Total	62	100

Q2) Please select the emergencies for which your jurisdiction received SNS assets from January 1, 2019 to present day.

Emergency	Number	Percent
COVID-19 public health emergency	62	100.0
Mpox (initially known as monkeypox) public health emergency*	60	96.8
Natural disaster	0	0.0
Other emergency	6	9.7

*Our review of ASPR data shows that all 62 surveyed jurisdictions received SNS assets during the mpox public health emergency. However, two jurisdictions did not select mpox as an emergency for which they received SNS assets. These two jurisdictions did not respond to GAO's follow up questions regarding mpox assets and did not respond to mpox-related survey questions. As such, we only have 60 responses for questions related to the mpox response.

Q3) Since January 1, 2019, which federal information source(s) did your jurisdiction use to access the following information about the SNS?

Type of information	ASPR Regional Emergency Coordinator	Division of Strategic National Stockpile	CDC's Division of State and Local Readiness	Other Federal Information Source	No Federal Resource Used.	Total
Information about the contents of the inventory	52 (83.9)	43 (69.4)	24 (38.7)	5 (8.1)	0 (0.0)	62 (100.0)
Information about requesting SNS assets	56 (90.3)	32 (51.6)	15 (24.2)	3 (4.8)	0 (0.0)	62 (100.0)
Information about receiving SNS assets	53 (85.5)	40 (64.5)	14 (22.6)	4 (6.5)	0 (0.0)	62 (100.0)
Information about storing SNS assets	38 (61.3)	36 (58.1)	15 (24.2)	7 (11.3)	2 (3.2)	62 (100.0)
Information about using SNS assets	41 (66.1)	37 (59.7)	26 (41.9)	7 (11.3)	2 (3.2)	62 (100.0)
Information about disposal or return of SNS assets	39 (62.9)	45 (72.6)	17 (27.4)	4 (6.5)	0 (0.0)	62 (100.0)
Information about SNS guidance, trainings, or exercises*	46 (75.4)	31 (50.8)	31 (50.8)	2 (3.3)	2 (3.3)	61 (98.4)

*One jurisdiction did not respond to this specific part of the question.

Appendix II: Results of GAO Survey with Public Health Emergency Preparedness Departments

4) Since January 1, 2019, to what extent have the following efforts by the federal government been important in helping your jurisdiction prepare for emergencies for which SNS assets might be needed?

Federal efforts	Very important	Somewhat important	Not very important	Not at all important	Not applicable	Total
Federal response plans for specific threats (e.g., chemical, biological, radiological, or nuclear, etc.)	21 (33.9%)	21 (33.9%)	7 (11.3%)	2 (3.2%)	11 (17.7%)	62 (100.0%)
SNS formulary information on CDC's TRAIN website	24 (38.7%)	22 (35.5%)	7 (11.3%)	3 (4.8%)	6 (9.7%)	62 (100.0%)
Written guidance on requesting and receiving SNS assets	37 (59.7%)	17 (27.4%)	3 (4.8%)	2 (3.2%)	3 (4.8%)	62 (100.0%)
Federal led exercises that incorporate the SNS	15 (24.2%)	14 (22.6%)	5 (8.1%)	1 (1.6%)	27 (43.5%)	62 (100.0%)
Federal virtual or in-person trainings about the SNS	24 (38.7%)	22 (35.5%)	1 (1.6%)	1 (1.6%)	14 (22.6%)	62 (100.0%)
ASPR regional meetings and communications	37 (59.7%)	23 (37.1%)	2 (3.2%)	0 (0.0%)	0 (0.0%)	62 (100.0%)
Software systems to manage and share inventory information (e.g., IMATS)	17 (27.4%)	15 (24.2%)	15 (24.2%)	10 (16.1%)	5 (8.1%)	62 (100.0%)
Public Health Emergency Preparedness requirements and communications	38 (61.3%)	17 (27.4%)	5 (8.1%)	1 (1.6%)	1 (1.6%)	62 (100.0%)
Other federal efforts*	8 (12.9%)	0 (0.0%)	1 (1.6%)	0 (0.0%)	48 (77.4%)	57 (91.9%)

*Five jurisdictions did not respond to the part of 'Other federal efforts' for this question. As a result, the total number of jurisdictions that responded to this part of the question was 57 jurisdictions.

Appendix II: Results of GAO Survey with Public Health Emergency Preparedness
Departments

Q5) To what extent do you agree or disagree with the following statements about the SNS inventory?

Federal efforts	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree	I do not know	Total
My jurisdiction understands enough about what assets are in the SNS inventory to plan response efforts.	20 (32.3%)	29 (46.8%)	3 (4.8%)	5 (8.1%)	5 (8.1%)	0 (0.0%)	62 (100.0%)
My jurisdiction understands who to contact with questions about the SNS inventory.	35 (56.5%)	20 (32.3%)	2 (3.2%)	4 (6.5%)	1 (1.6%)	0 (0.0%)	62 (100.0%)
My jurisdiction receives the answers it needs about the SNS inventory.	17 (27.4%)	25 (40.3%)	8 (12.9%)	6 (9.7%)	5 (8.1%)	1 (1.6%)	62 (100.0%)
My jurisdiction is able to provide input about what goes into the SNS inventory	5 (8.1%)	14 (22.6%)	9 (14.5%)	11 (17.7%)	18 (29.0%)	5 (8.1%)	62 (100.0%)

Q6A) Based on your jurisdiction’s experience during the response to the mpox public health emergency, please indicate the extent to which you agree or disagree with the following statements about requesting assets from the SNS.

Statements on requesting SNS assets	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree	I do not know	Total*
My jurisdiction had written guidance that clearly outlined the process for requesting SNS assets.	13 (21.7%)	23 (38.3%)	7 (11.7%)	4 (6.7%)	11 (18.3%)	2 (3.3%)	60 (100.0%)
The process for requesting SNS assets followed the written guidance.	10 (16.7%)	22 (36.7%)	6 (10.0%)	11 (18.3%)	7 (11.7%)	4 (6.7%)	60 (100.0%)
My jurisdiction relied on others (Regional Emergency Coordinators, etc.) to provide information about the request process.	18 (30.0%)	19 (31.7%)	11 (18.3%)	4 (6.7%)	5 (8.3%)	3 (5.0%)	60 (100.0%)
It was clear throughout the response who to contact to request SNS assets.	11 (18.3%)	17 (28.3%)	6 (10.0%)	12 (20.0%)	11 (18.3%)	3 (5.0%)	60 (100.0%)
My jurisdiction understood how SNS assets were allocated to my jurisdiction.	17 (28.3%)	25 (41.7%)	5 (8.3%)	4 (6.7%)	6 (10.0%)	3 (5.0%)	60 (100.0%)

*Our review of ASPR data shows that all 62 surveyed jurisdictions received SNS assets during the mpox public health emergency. However, two jurisdictions did not select mpox as an emergency for which they received SNS assets. These two jurisdictions did not respond to GAO’s follow up questions regarding mpox assets and did not respond to mpox-related survey questions. As such, we only have 60 responses for questions related to the mpox response.

Q6B) Based on your jurisdiction’s experience during the response to the mpox public health emergency, please indicate the extent to which you agree or disagree with each of the following statements about receiving SNS assets.

Statements on receiving SNS assets	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree	I do not know	Total*
My jurisdiction had written guidance that clearly outlined the process for receiving SNS assets.	19 (31.7%)	20 (33.3%)	6 (10.0%)	6 (10.0%)	7 (11.7%)	2 (3.3%)	60 (100.0%)
The process for receiving SNS assets followed the written guidance.	14 (23.3%)	19 (31.7%)	7 (11.7%)	8 (13.3%)	8 (13.3%)	4 (6.7%)	60 (100.0%)
My jurisdiction relied on others (Regional Emergency Coordinators, etc.) to provide information about the process for receiving assets.	12 (20.0%)	23 (38.3%)	9 (15.0%)	7 (11.7%)	4 (6.7%)	5 (8.3%)	60 (100.0%)
My jurisdiction knew which SNS assets would be delivered.	27 (45.0%)	27 (45.0%)	1 (1.7%)	3 (5.0%)	1 (1.7%)	1 (1.7%)	60 (100.0%)
My jurisdiction knew what quantity of SNS assets would be delivered.	23 (38.3%)	30 (50.0%)	1 (1.7%)	4 (6.7%)	1 (1.7%)	1 (1.7%)	60 (100.0%)
My jurisdiction knew where SNS assets would be delivered.	32 (53.3%)	22 (36.7%)	1 (1.7%)	4 (6.7%)	0 (0.0%)	1 (1.7%)	60 (100.0%)
My jurisdiction knew when to expect delivery of SNS assets.	18 (30.0%)	22 (36.7%)	9 (15.0%)	5 (8.3%)	5 (8.3%)	1 (1.7%)	60 (100.0%)
My jurisdiction was provided with information about how to properly store SNS assets.	31 (51.7%)	20 (33.3%)	6 (10.0%)	1 (1.7%)	0 (0.0%)	2 (3.3%)	60 (100.0%)

Appendix II: Results of GAO Survey with Public Health Emergency Preparedness Departments

Statements on receiving SNS assets	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree	I do not know	Total*
My jurisdiction knew who to contact if it had difficulty receiving SNS assets.	23 (38.3%)	21 (35.0%)	6 (10.0%)	6 (10.0%)	1 (1.7%)	3 (5.0%)	60 (100.0%)
My jurisdiction knew who to contact if something was wrong with the SNS assets that were received.	26 (43.3%)	18 (30.0%)	4 (6.7%)	6 (10.0%)	3 (5.0%)	3 (5.0%)	60 (100.0%)

*Our review of ASPR data shows that all 62 surveyed jurisdictions received SNS assets during the mpox public health emergency. However, two jurisdictions did not select mpox as an emergency for which they received SNS assets. These two jurisdictions did not respond to GAO's follow up questions regarding mpox assets and did not respond to mpox-related survey questions. As such, we only have 60 responses for questions related to the mpox response.

Q6C) Based on your jurisdiction’s experience during the response to the mpox public health emergency, please indicate the extent to which you agree or disagree with the following statements about using assets from the SNS.

Statements on using SNS assets	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree	I do not know	Total*
My jurisdiction was provided with information about how to use or administer the SNS assets that were delivered.	27 (45.0%)	29 (48.3%)	2 (3.3%)	1 (1.7%)	0 (0.0%)	1 (1.7%)	60 (100.0%)
My jurisdiction was provided with regulatory information for SNS assets such as Emergency Use Authorization.	34 (56.7%)	21 (35.0%)	4 (6.7%)	0 (0.0%)	0 (0.0%)	1 (1.7%)	60 (100.0%)
My jurisdiction knew who to contact if it had questions about how to use the SNS assets that were delivered.	29 (48.3%)	22 (36.7%)	2 (3.3%)	4 (6.7%)	1 (1.7%)	2 (3.3%)	60 (100.0%)
My jurisdiction knew what ancillary supplies were needed (tubing, syringes, etc.) in order to use SNS assets that were delivered.	23 (38.3%)	25 (41.7%)	4 (6.7%)	4 (6.7%)	2 (3.3%)	2 (3.3%)	60 (100.0%)

*Our review of ASPR data shows that all 62 surveyed jurisdictions received SNS assets during the mpox public health emergency. However, two jurisdictions did not select mpox as an emergency for which they received SNS assets. These two jurisdictions did not respond to GAO’s follow up questions regarding mpox assets and did not respond to mpox-related survey questions. As such, we only have 60 responses for questions related to the mpox response.

Q7A) Based on your jurisdiction’s experience during the response to the COVID-19 public health emergency, please indicate the extent to which you agree or disagree with the following statements about requesting assets from the SNS.

Statements on requesting SNS assets	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree	I do not know	Total
My jurisdiction had written guidance that clearly outlined the process for requesting SNS assets.	21 (33.9%)	18 (29.0%)	9 (14.5%)	6 (9.7%)	6 (9.7%)	2 (3.2%)	62 (100.0%)
The process for requesting SNS assets followed the written guidance.	13 (21.0%)	15 (24.2%)	9 (14.5%)	6 (9.7%)	16 (25.8%)	3 (4.8%)	62 (100.0%)
My jurisdiction relied on others (Regional Emergency Coordinators, etc.) to provide information about the request process.	23 (37.1%)	28 (45.2%)	5 (8.1%)	4 (6.5%)	2 (3.2%)	0 (0.0%)	62 (100.0%)
It was clear throughout the response who to contact to request SNS assets.	16 (25.8%)	23 (37.1%)	8 (12.9%)	9 (14.5%)	6 (9.7%)	0 (0.0%)	62 (100.0%)
My jurisdiction understood how SNS assets were allocated to my jurisdiction.	14 (22.6%)	20 (32.3%)	12 (19.4%)	4 (6.5%)	12 (19.4%)	0 (0.0%)	62 (100.0%)

Q7B) Based on your jurisdiction’s experience during the response to the COVID-19 public health emergency, please indicate the extent to which you agree or disagree with each of the following statements about receiving SNS assets.

Statements on receiving SNS assets	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree	I do not know	Total
My jurisdiction had written guidance that clearly outlined the process for receiving SNS assets.	19 (30.6%)	18 (29.0%)	8 (12.9%)	10 (16.1%)	6 (9.7%)	1 (1.6%)	62 (100.0%)
The process for receiving SNS assets followed the written guidance.	9 (14.5%)	14 (22.6%)	9 (14.5%)	13 (21.0%)	13 (21.0%)	4 (6.5%)	62 (100.0%)
My jurisdiction relied on others (Regional Emergency Coordinators, etc.) to provide information about the process for receiving assets.	18 (29.0%)	22 (35.5%)	10 (16.1%)	7 (11.3%)	3 (4.8%)	2 (3.2%)	62 (100.0%)
My jurisdiction knew which SNS assets would be delivered.	7 (11.3%)	18 (29.0%)	10 (16.1%)	12 (19.4%)	14 (22.6%)	1 (1.6%)	62 (100.0%)
My jurisdiction knew what quantity of SNS assets would be delivered.	4 (6.5%)	22 (35.5%)	10 (16.1%)	12 (19.4%)	13 (21.0%)	1 (1.6%)	62 (100.0%)
My jurisdiction knew where SNS assets would be delivered.	28 (45.2%)	26 (41.9%)	3 (4.8%)	3 (4.8%)	2 (3.2%)	0 (0.0%)	62 (100.0%)
My jurisdiction knew when to expect delivery of SNS assets.	6 (9.7%)	16 (25.8%)	7 (11.3%)	19 (30.6%)	13 (21.0%)	1 (1.6%)	62 (100.0%)
My jurisdiction was provided with information about how to properly store SNS assets.	16 (25.8%)	23 (37.1%)	14 (22.6%)	4 (6.5%)	4 (6.5%)	1 (1.6%)	62 (100.0%)

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Statements on receiving SNS assets	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree	I do not know	Total
My jurisdiction knew who to contact if it had difficulty receiving SNS assets.	20 (32.3%)	24 (38.7%)	9 (14.5%)	7 (11.3%)	2 (3.2%)	0 (0.0%)	62 (100.0%)
My jurisdiction knew who to contact if something was wrong with the SNS assets that were received.	20 (32.3%)	22 (35.5%)	8 (12.9%)	7 (11.3%)	4 (6.5%)	1 (1.6%)	62 (100.0%)

Q7C) Based on your jurisdiction’s experience during the response to the COVID-19 public health emergency, please indicate the extent to which you agree or disagree with the following statements about using assets from the SNS.

Statements on using SNS assets	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree	I do not know	Total
My jurisdiction was provided with information about how to use or administer the SNS assets that were delivered.	17 (27.4%)	28 (45.2%)	13 (21.0%)	1 (1.6%)	2 (3.2%)	1 (1.6%)	62 (100.0%)
My jurisdiction was provided with regulatory information for SNS assets such as Emergency Use Authorization.	30 (48.4%)	16 (25.8%)	8 (12.9%)	3 (4.8%)	3 (4.8%)	2 (3.2%)	62 (100.0%)
My jurisdiction knew who to contact if it had questions about how to use the SNS assets that were delivered.	21 (33.9%)	26 (41.9%)	8 (12.9%)	5 (8.1%)	2 (3.2%)	0 (0.0%)	62 (100.0%)
My jurisdiction knew what ancillary supplies were needed (tubing, syringes, etc.) in order to use SNS assets that were delivered.	16 (25.8%)	23 (37.1%)	13 (21.0%)	7 (11.3%)	2 (3.2%)	1 (1.6%)	62 (100.0%)

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Q9A) Based on your jurisdiction’s experience during the response to the other public health emergency, please indicate the extent to which you agree or disagree with the following statements about requesting assets from the SNS.

Statements on requesting SNS assets	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree	I do not know	Total*
My jurisdiction had written guidance that clearly outlined the process for requesting SNS assets.	2 (33.3%)	3 (50.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	6 (100.0%)
The process for requesting SNS assets followed the written guidance.	2 (33.3%)	2 (33.3%)	1 (16.7%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	6 (100.0%)
My jurisdiction relied on others (Regional Emergency Coordinators, etc.) to provide information about the request process.	3 (50.0%)	2 (33.3%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (100.0%)
It was clear throughout the response who to contact to request SNS assets.	2 (33.3%)	2 (33.3%)	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	6 (100.0%)
My jurisdiction understood how SNS assets were allocated to my jurisdiction.	3 (50.0%)	2 (33.3%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	6 (100.0%)

*Six jurisdictions selected 'other public health emergency' as an emergency for which they received SNS assets. As a result, these six jurisdictions responded to survey questions specific to this 'other public health emergency.'

Q9B) Based on your jurisdiction’s experience during the response to the other public health emergency, please indicate the extent to which you agree or disagree with each of the following statements about receiving SNS assets.

Statements on receiving SNS assets	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree	I do not know	Total*
My jurisdiction had written guidance that clearly outlined the process for receiving SNS assets.	1 (16.7%)	2 (33.3%)	2 (33.3%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	6 (100.0%)
The process for receiving SNS assets followed the written guidance.	1 (16.7%)	3 (50.0%)	1 (16.7%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	6 (100.0%)
My jurisdiction relied on others (Regional Emergency Coordinators, etc.) to provide information about the process for receiving assets.	3 (50.0%)	1 (16.7%)	2 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (100.0%)
My jurisdiction knew which SNS assets would be delivered.	6 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (100.0%)
My jurisdiction knew what quantity of SNS assets would be delivered.	5 (83.3%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	6 (100.0%)
My jurisdiction knew where SNS assets would be delivered.	5 (83.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	6 (100.0%)
My jurisdiction knew when to expect delivery of SNS assets.	4 (66.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	6 (100.0%)
My jurisdiction was provided with information about how to properly store SNS assets.	4 (66.7%)	2 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (100.0%)

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Statements on receiving SNS assets	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree	I do not know	Total*
My jurisdiction knew who to contact if it had difficulty receiving SNS assets.	4 (66.7%)	2 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (100.0%)
My jurisdiction knew who to contact if something was wrong with the SNS assets that were received.	4 (66.7%)	2 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (100.0%)

*Six jurisdictions selected 'other public health emergency' as an emergency for which they received SNS assets. As a result, these six jurisdictions responded to survey questions specific to this 'other public health emergency.'

Q9C) Based on your jurisdiction’s experience during the response to the other public health emergency, please indicate the extent to which you agree or disagree with the following statements about using assets from the SNS.

Statements on using SNS assets	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree	I do not know	Total*
My jurisdiction was provided with information about how to use or administer the SNS assets that were delivered.	4 (66.7%)	1 (16.7%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	6 (100.0%)
My jurisdiction was provided with regulatory information for SNS assets such as Emergency Use Authorization.	4 (66.7%)	0 (0.0%)	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	6 (100.0%)
My jurisdiction knew who to contact if it had questions about how to use the SNS assets that were delivered.	4 (66.7%)	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (100.0%)
My jurisdiction knew what ancillary supplies were needed (tubing, syringes, etc.) in order to use SNS assets that were delivered.	3 (50.0%)	1 (16.7%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	1 (16.7%)	6 (100.0%)

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*Six jurisdictions selected 'other public health emergency' as an emergency for which they received SNS assets. As a result, these six jurisdictions responded to survey questions specific to this 'other public health emergency.'

Q10) For this question we want you to think about the next pandemic, natural disaster, or other public health emergency. Thinking about these future emergencies, please rank the following resources from most useful to least useful for helping your jurisdiction prepare to request, receive, and use SNS assets.

Type of information)	Total points = most useful)**	Number of jurisdictions ranked #1	Number of jurisdictions ranked #2	Number of jurisdictions ranked #3	Number of jurisdictions ranked #4	Number of jurisdictions ranked #5	Number of jurisdictions ranked #6	Number of jurisdictions ranked #7	Number of jurisdictions ranked #8	Number of jurisdictions ranked #9	Number of jurisdictions ranked #10	Number of jurisdictions ranked #11	Number of jurisdictions ranked #12	Total*
Updated written guidance on requesting and receiving SNS assets.	222	15 (25.0%)	6 (10.0%)	12 (20.0%)	10 (16.7%)	3 (5.0%)	5 (8.3%)	4 (6.7%)	2 (3.3%)	0 (0.0%)	3 (5.0%)	0 (0.0%)	0 (0.0%)	60 (100.0%)
Defined ordering system for SNS assets.	265	4 (6.7%)	14 (23.3%)	8 (13.3%)	6 (10.0%)	8 (13.3%)	6 (10.0%)	5 (8.3%)	8 (13.3%)	0 (0.0%)	1 (1.7%)	0 (0.0%)	0 (0.0%)	60 (100.0%)

Appendix II: Results of GAO Survey with Public Health Emergency Preparedness Departments

Type of information	Total points (lowest = most useful)**	Number of jurisdictions ranked #1	Number of jurisdictions ranked #2	Number of jurisdictions ranked #3	Number of jurisdictions ranked #4	Number of jurisdictions ranked #5	Number of jurisdictions ranked #6	Number of jurisdictions ranked #7	Number of jurisdictions ranked #8	Number of jurisdictions ranked #9	Number of jurisdictions ranked #10	Number of jurisdictions ranked #11	Number of jurisdictions ranked #12	Total*
Detailed information about the SNS inventory	271	10 (16.7%)	7 (11.7%)	10 (16.7%)	3 (5.0%)	11 (18.3%)	3 (5.0%)	6 (10.0%)	3 (5.0%)	5 (8.3%)	1 (1.7%)	1 (1.7%)	0 (0.0%)	60 (100.0%)
Detail on federal roles and responsibilities related to the SNS	327	10 (16.7%)	9 (15.0%)	2 (3.3%)	8 (13.3%)	2 (3.3%)	4 (6.7%)	7 (11.7%)	1 (1.7%)	5 (8.3%)	8 (13.3%)	3 (5.0%)	1 (1.7%)	60 (100.0%)

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Type of information	Total points (lowest = most useful)**	Number of jurisdictions ranked #1	Number of jurisdictions ranked #2	Number of jurisdictions ranked #3	Number of jurisdictions ranked #4	Number of jurisdictions ranked #5	Number of jurisdictions ranked #6	Number of jurisdictions ranked #7	Number of jurisdictions ranked #8	Number of jurisdictions ranked #9	Number of jurisdictions ranked #10	Number of jurisdictions ranked #11	Number of jurisdictions ranked #12	Total*
Federal response plans for various threats (e.g., chemical, biological, radiological, nuclear, etc.)	356	13 (21.7%)	6 (10.0%)	2 (3.3%)	1 (1.7%)	3 (5.0%)	4 (6.7%)	6 (10.0%)	8 (13.3%)	4 (6.7%)	4 (6.7%)	8 (13.3%)	1 (1.7%)	60 (100.0%)
Written guidance on how SNS assets will be allocated	359	0 (0.0%)	2 (3.3%)	10 (16.7%)	8 (13.3%)	8 (13.3%)	8 (13.3%)	7 (11.7%)	6 (10.0%)	4 (6.7%)	5 (8.3%)	2 (3.3%)	0 (0.0%)	60 (100.0%)

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Type of information	Total points (lowest = most useful)**	Number of jurisdictions ranked #1	Number of jurisdictions ranked #2	Number of jurisdictions ranked #3	Number of jurisdictions ranked #4	Number of jurisdictions ranked #5	Number of jurisdictions ranked #6	Number of jurisdictions ranked #7	Number of jurisdictions ranked #8	Number of jurisdictions ranked #9	Number of jurisdictions ranked #10	Number of jurisdictions ranked #11	Number of jurisdictions ranked #12	Total*
Enhanced tracking systems for delivery of SNS assets	380	1 (1.7%)	4 (6.7%)	5 (8.3%)	8 (13.3%)	6 (10.0%)	5 (8.3%)	8 (13.3%)	9 (15.0%)	6 (10.0%)	6 (10.0%)	2 (3.3%)	0 (0.0%)	60 (100.0%)
Virtual or in-person trainings about the SNS	394	3 (5.0%)	5 (8.3%)	2 (3.3%)	5 (8.3%)	5 (8.3%)	7 (11.7%)	6 (10.0%)	8 (13.3%)	10 (16.7%)	7 (11.7%)	2 (3.3%)	0 (0.0%)	60 (100.0%)
Federally led exercises that incorporate the SNS	450	1 (1.7%)	1 (1.7%)	3 (5.0%)	3 (5.0%)	7 (11.7%)	6 (10.0%)	2 (3.3%)	10 (16.7%)	14 (23.3%)	8 (13.3%)	5 (8.3%)	0 (0.0%)	60 (100.0%)

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Type of information	Total points (lowest = most useful)**	Number of jurisdictions ranked #1	Number of jurisdictions ranked #2	Number of jurisdictions ranked #3	Number of jurisdictions ranked #4	Number of jurisdictions ranked #5	Number of jurisdictions ranked #6	Number of jurisdictions ranked #7	Number of jurisdictions ranked #8	Number of jurisdictions ranked #9	Number of jurisdictions ranked #10	Number of jurisdictions ranked #11	Number of jurisdictions ranked #12	Total*
Ability to provide input on what is contained in the SNS inventory	485	0 (0.0%)	2 (3.3%)	4 (6.7%)	5 (8.3%)	3 (5.0%)	6 (10.0%)	4 (6.7%)	2 (3.3%)	6 (10.0%)	10 (16.7%)	16 (26.7%)	2 (3.3%)	60 (100.0%)

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Type of information	Total points (lowest = most useful)**	Number of jurisdictions ranked #1	Number of jurisdictions ranked #2	Number of jurisdictions ranked #3	Number of jurisdictions ranked #4	Number of jurisdictions ranked #5	Number of jurisdictions ranked #6	Number of jurisdictions ranked #7	Number of jurisdictions ranked #8	Number of jurisdictions ranked #9	Number of jurisdictions ranked #10	Number of jurisdictions ranked #11	Number of jurisdictions ranked #12	Total*
Updated software systems to manage and share inventory information (e.g., IMATS).	488	1 (1.7%)	4 (6.7%)	2 (3.3%)	2 (3.3%)	4 (6.7%)	5 (8.3%)	5 (8.3%)	3 (5.0%)	6 (10.0%)	7 (11.7%)	20 (33.3%)	1 (1.7%)	60 (100.0%)
Other (please specify)	683	2 (3.3%)	0 (0.0%)	0 (0.0%)	1 (1.7%)	0 (0.0%)	1 (1.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.7%)	55 (91.7%)	60 (100.0%)

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*The total number of jurisdictions for this question is 60 as two jurisdictions did not respond to this question.

** To get the "Total points" column, we asked respondents to rank order the usefulness of 12 different federal resources. For each resource, we multiplied the number of responses per rank by the rank. For example, if 10 jurisdictions ranked updated written guidance as the most useful resource, we multiplied 10 responses by the rank of one. We then totaled all the sums per resource. We ranked resources by ascending totals.

Q11) Did your jurisdiction start a medical countermeasure stockpile (e.g., personal protective equipment, pharmaceuticals, ventilators, etc.) or expand a stockpile due to the recent public health emergencies?

Yes\No	Number	Percent
Yes, we started a stockpile	16	25.8%
Yes, we expanded an existing stockpile	41	66.1%
Yes, we had a stockpile but it remained the same	3	4.8%
No, we did not have a stockpile	2	3.2%
Other (please explain)	0	0.0%
Total	62	100.0%

The following questions are answered only when Q11 is answered “No, we did not have a stockpile.”

Q12) Does your jurisdiction plan to create a stockpile in the next year?

Yes\No	Number	Percent
Yes, we plan to create a stockpile	0	0.0%
No, we have no plans to create a stockpile	1	50.0%
I do not know (please explain)	1	50.0%
Total	2	100.0%

The following questions are answered only when Q11 is answered “No, we did not have a stockpile.”

Q15) From the list below, please rank the three biggest challenges to your jurisdiction creating a medical countermeasure stockpile (e.g., personal protective equipment, pharmaceuticals, ventilators, etc.) for future emergencies.

Federal efforts	Number (percent) of jurisdictions ranking federal efforts: #1	Number (percent) of jurisdictions ranking federal efforts: #2	Number (percent) of jurisdictions ranking federal efforts: #3	Number (percent) of jurisdictions ranking federal efforts: Not selected	Total
Funding for stockpile maintenance and storage	2 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (100.0%)
Guidance on what medical countermeasures to stockpile	0 (0.0%)	1 (50.0%)	0 (0.0%)	1 (50.0%)	2 (100.0%)
Guidance on managing inventory (such as shelf-life extension)	0 (0.0%)	0 (0.0%)	1 (50.0%)	1 (50.0%)	2 (100.0%)
Guidance on federal strategy for medical countermeasure usage	0 (0.0%)	0 (0.0%)	1 (50.0%)	1 (50.0%)	2 (100.0%)
Comprehensive inventory management software	0 (0.0%)	1 (50.0%)	0 (0.0%)	1 (50.0%)	2 (100.0%)

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Federal efforts	Number (percent) of jurisdictions ranking federal efforts: #1	Number (percent) of jurisdictions ranking federal efforts: #2	Number (percent) of jurisdictions ranking federal efforts: #3	Number (percent) of jurisdictions ranking federal efforts: Not selected	Total
State and federal coordination around stockpiling approaches	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (100.0%)	2 (100.0%)
Other	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (100.0%)	2 (100.0%)

The following question is only answered when Q11 is answered either "Yes, started a stockpile", "Yes, expanded an existing stockpile", or "Yes, we had a stockpile but it remained the same."

Q12) What is your jurisdiction's stockpiling goal for your selected target population (e.g., hospitals, nursing homes, general population, etc.)?

Stockpiling goals	Count	Percent
30 days or less	17	28.3
31-60 days	16	26.7
61-90 days	15	25.0
91-180 days	3	5.0
More than 180 days	2	3.3
I do not know	7	11.7
	60	100.0

The following question is only answered when Q11 is answered either “Yes, started a stockpile”, “Yes, expanded an existing stockpile”, or “Yes, we had a stockpile but it remained the same.”

Q13) Does your jurisdiction plan to continue to maintain, expand or decrease its stockpile in the next year?

Future plans	Count	Percent
We plan to expand the current stockpile levels.	7	11.7
We plan to maintain current stockpile levels.	27	45.0
We plan to decrease the current stockpile levels.	17	28.3
We do not know (please explain)	9	15.0
	60	100.0

The following question is only answered when Q11 is answered either “Yes, started a stockpile”, “Yes, expanded an existing stockpile”, or “Yes, we had a stockpile but it remained the same.”

Q15) From the list below, please rank the three federal efforts that are the most important for helping your jurisdiction maintain a medical countermeasure stockpile (e.g., personal protective equipment, pharmaceuticals, ventilators, etc.) for future emergencies.

Federal efforts	Number (percent) of jurisdictions ranking federal efforts: #1	Number (percent) of jurisdictions ranking federal efforts: #2	Number (percent) of jurisdictions ranking federal efforts: #3	Number (percent) of jurisdictions ranking federal efforts: Not selected	Number of jurisdictions
Funding for stockpile maintenance and storage	51 (85.0%)	6 (10.0%)	0 (0.0%)	3 (5.0%)	60 (100.0%)
Guidance on what medical countermeasures to stockpile	1 (1.7%)	14 (23.3%)	7 (11.7%)	38 (63.3%)	60 (100.0%)
Guidance on managing inventory (such as shelf-life extension)	0 (0.0%)	10 (16.7%)	17 (28.3%)	33 (55.0%)	60 (100.0%)
Guidance on federal strategy for medical countermeasure usage	1 (1.7%)	3 (5.0%)	7 (11.7%)	49 (81.7%)	60 (100.0%)
Comprehensive inventory management software	0 (0.0%)	8 (13.3%)	10 (16.7%)	42 (70.0%)	60 (100.0%)
State and federal coordination around stockpiling approaches	6 (10.0%)	17 (28.3%)	16 (26.7%)	21 (35.0%)	60 (100.0%)
Other	1 (1.7%)	2 (3.3%)	3 (5.0%)	54 (90.0%)	60 (100.0%)

Appendix III: Previous Recommendations Related to the Strategic National Stockpile (SNS)

Table 1: Previous Recommendations Related to the Strategic National Stockpile (SNS)

Report Title	Recommendation	Status
<i>Public Health Preparedness: HHS Should Address Strategic National Stockpile Requirements and Inventory Risks (GAO-23-106210)</i>	The Assistant Secretary for Preparedness and Response should update procedures for how SNS reviews will be conducted in accordance with statutory requirements, including a description of the roles and responsibilities of its interagency partners in the development of the SNS reviews.	Open
<i>Public Health Preparedness: HHS Should Address Strategic National Stockpile Requirements and Inventory Risks (GAO-23-106210)</i>	The Assistant Secretary for Preparedness and Response should develop and document an approach—whether through the standard operating procedures for the SNS reviews or some other mechanism—for ensuring that MCMs under consideration for SNS procurement receive the same consideration regardless of whether they received development funding from BARDA, in accordance with statutory requirements.	Open
<i>Public Health Preparedness: HHS Should Address Strategic National Stockpile Requirements and Inventory Risks (GAO-23-106210)</i>	The Assistant Secretary for Preparedness and Response should develop and document an approach for regularly managing the risks associated with the gaps between SNS MCM inventory levels and recommended quantities. Such an approach, which could occur as part of the SNS reviews, should clearly prioritize risks, track progress made in addressing the risks, and estimate resources needed to address risks. This approach should involve communicating this information to key decision makers, including Congress.	Open – Partially Addressed
<i>COVID-19: Continued Attention Needed to Enhance Federal Preparedness, Response, Service Delivery, and Program Integrity (GAO-21-551)</i>	To improve the nation’s preparedness for a wide range of threats, including pandemics, the Office of the Assistant Secretary for Preparedness and Response should develop and document plans for restructuring the Public Health Emergency Medical Countermeasures Enterprise. These plans should describe how the Assistant Secretary will ensure a transparent and deliberative process that engages interagency partners in the full range of responsibilities for the Public Health Emergency Medical Countermeasures Enterprise outlined in the Pandemic and All-Hazards Preparedness and Innovation Act of 2019, including the annual Strategic National Stockpile Threat-Based Reviews. These plans should also incorporate GAO’s leading practices to foster more effective collaboration, while ensuring that sensitive information is appropriately protected.	Open – Partially Addressed
<i>COVID-19: Continued Attention Needed to Enhance Federal Preparedness, Response, Service Delivery, and Program Integrity (GAO-21-551)</i>	To improve organizational accountability, the Office of the Assistant Secretary for Preparedness and Response should implement records management practices that include developing and maintaining, and securing documentation related to Public Health Emergency Medical Countermeasures Enterprise activities and deliberations, including those related to the Strategic National Stockpile. Documentation should include information such as the factors considered, the rationale for the action or decision, and the final outcomes of the Public Health Emergency Medical Countermeasures Enterprise processes.	Open

Appendix III: Previous Recommendations Related to the Strategic National Stockpile (SNS)

Report Title	Recommendation	Status
<p><i>COVID-19: Critical Vaccine Distribution, Supply Chain, Program Integrity, and Other Challenges Require Focused Federal Attention (GAO-21-265)</i></p>	<p>To improve the nation’s response to and preparedness for pandemics, the Assistant Secretary for Preparedness and Response should establish a process for regularly engaging with Congress and nonfederal stakeholders—including state, local, tribal, and territorial governments, and private industry—as the Department of Health and Human Services refines and implements a supply chain strategy for pandemic preparedness, to include the role of the Strategic National Stockpile.</p>	<p>Open – Partially Addressed</p>
<p><i>COVID-19: Federal Efforts Could Be Strengthened by Timely and Concerted Actions (GAO-20-701)</i></p>	<p>The Secretary of Health and Human Services in coordination with the Administrator of the Federal Emergency Management Agency—who head agencies leading the COVID-19 response through the Unified Coordination Group—should immediately document roles and responsibilities for supply chain management functions transitioning to the Department of Health and Human Services, including continued support from other federal partners, to ensure sufficient resources exist to sustain and make the necessary progress in stabilizing the supply chain, and address emergent supply issues for the duration of the COVID-19 pandemic.</p>	<p>Closed – Implemented</p>
<p><i>COVID-19: Federal Efforts Could Be Strengthened by Timely and Concerted Actions (GAO-20-701)</i></p>	<p>The Secretary of Health and Human Services in coordination with the Administrator of the Federal Emergency Management Agency—who head agencies leading the COVID-19 response through the Unified Coordination Group—should further develop and communicate to stakeholders plans outlining specific actions the federal government will take to help mitigate remaining medical supply gaps necessary to respond to the remainder of the pandemic, including through the use of Defense Production Act authorities.</p>	<p>Closed – Implemented</p>
<p><i>COVID-19: Federal Efforts Could Be Strengthened by Timely and Concerted Actions (GAO-20-701)</i></p>	<p>The Secretary of Health and Human Services—who heads one of the agencies leading the COVID-19 response through the Unified Coordination Group—consistent with their roles and responsibilities, should work with relevant federal, state, territorial, and tribal stakeholders to devise interim solutions, such as systems and guidance and dissemination of best practices, to help states enhance their ability to track the status of supply requests and plan for supply needs for the remainder of the COVID-19 pandemic response.</p>	<p>Closed – Implemented</p>

Source: Analysis of GAO recommendations | GAO-24-106260

Appendix IV: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

April 10, 2024

Mary Denigan-Macauley
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Denigan-Macauley:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "**PUBLIC HEALTH PREPAREDNESS: HHS Should Address Strategic National Stockpile Coordination Challenges**" (GAO-24-106260).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Melanie Anne Egorin

Melanie Anne Egorin, PhD
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED – PUBLIC HEALTH PREPAREDNESS: HHS SHOULD ADDRESS STRATEGIC NATIONAL STOCKPILE COORDINATION CHALLENGES (GAO-24-106260)

The U.S. Department of Health and Human Services (HHS) appreciates the opportunity to review and provide comments on the Government Accountability Office's (GAO) draft report.

GAO Recommendation 1

The Assistant Secretary for Preparedness and Response should work with CDC to clearly define its roles and responsibilities related to the SNS in a formal document and share that document with jurisdictions.

HHS Response

HHS concurs with the recommendation.

ASPR will work with CDC to clearly define its roles and responsibilities related to the SNS in a formal document and share that document with jurisdictions.

GAO Recommendation 2

The Assistant Secretary for Preparedness and Response should develop standard operating procedures, outlining how and when guidance documents, such as those for requesting and receiving SNS assets, are updated. Consistent with GAO's Standards for Internal Control, these standard operating procedures should include internal review processes, opportunities for stakeholder feedback, and timeframes for updating.

HHS Response

HHS concurs with the recommendation.

An updated draft of the SNS guidance document is in clearance and it is anticipated it will be disseminated to State, Local, Territorial, Tribal stakeholders in the near-term.

Also, SNS is updating its Policy Management System Operational Policy and it is anticipated the updates to the policy will be finalized by the end of fiscal year 2024. This operational policy will define different types of SNS policy documents, including guidance documents; explain the process for development and issuance of documents; outline the timetable to periodically review documents; and, describe SNS staff responsibilities for development; review and approval; dissemination and publication and maintenance and retention of these documents.

GAO Recommendation 3

The Assistant Secretary for Preparedness and Response should formally designate an entity—such as the Office of STLT Preparedness—to regularly engage with Tribes and relevant stakeholders to (1) assess the unique challenges, such as infrastructure and geography, that could affect the delivery of SNS assets to Tribes during future emergencies and (2) develop options for how to address those challenges.

HHS Response

HHS concurs with GAO’s recommendation and considers this recommendation closed based on actions detailed below.

In 2022, the SNS established the Office of State, Local, Tribal, and Territorial Preparedness (OSLTTP). OSLTTP supports continued engagement with critical partners, to include Tribes, on medical countermeasure (MCM) logistics planning and opportunities for SNS training and exercises that enhance readiness to respond to public health threats. OSLTTP achieves the objective of this recommendation and serves as the designated, central entity for SNS tribal engagement and coordination.

Throughout 2023 and into 2024, SNS’ OSLTTP led a series of ten Regional Engagement Meetings (REMs) to discuss changes to SNS operational capabilities, distribution models and overall structure directly with SLTTs. These 1–2-day sessions focused on information sharing and facilitated discussions on shared experiences during the COVID-19 response. REM sessions included more than 480 (non-federal) attendees across all 10 HHS regions. Attendees represented multiple stakeholders in medical countermeasures planning, including local, state, and territorial public health departments, emergency management groups, healthcare coalitions and facilities, tribal partners, and emergency medical services.

In addition to the REM sessions, the SNS supported other efforts to directly engage and promote awareness of capabilities to aid a response with Tribes over the last year.

- In March 2023, the SNS-led working group on Executive Order 14001 Tribal Access conducted two targeted feedback sessions to collect and discuss input on the strategy to guide how tribal nations and Urban Indian Organization (UIOs) access to public health emergency response supplies held in the SNS (as well as accessing other relevant federal medical supply stockpiles). More than 230 participants from tribal governments and UIOs provided verbal and written comments, feedback, and recommendations for strategy refinement that the working group was able to incorporate into the final draft document.
- In December 2023, OSLTTP launched the SNS Technical Assistance and Resources SharePoint site. This SharePoint site is a limited-access technical assistance resource to enhance SLTT MCM planning and preparedness efforts. This site serves as a communication resource and information repository for SNS to provide SNS MCM planning guidance and resources intended for target audiences in SLTT public health and hospital preparedness programs. The site is improving information sharing between SNS, SLTT planners, and other external stakeholders. There is also a portal on the home page labeled “Request for Assistance” for requesting assistance for the various services offered on the site. Users also have the option to send requests to the SLTT mailbox (SNS-SLTT@hhs.gov). It should be noted that the request for assistance referenced on the site is not to request assets from the SNS in response to a public health emergency.
- In February 2024, SNS finalized and released the Tribal Access Strategy labeled, “Strategy for Improving Access to Federal Resources During a Public Health Emergency Response for Federally Recognized Tribal Governments, Indian Health Service Health

Care Providers, Tribal Health Authorities, and Urban Indian Organizations,” in response to Executive Order (EO) 14001. The document provides analysis which outlines current request processes for federally recognized tribes and UIOs to access SNS and other federal public health response supplies under a different legal instruments and emergency response authorities. The document also describes the factors driving both the request processes themselves and the methods through which SNS deploys MCMs during a response. The document recommends pathways through which tribal nations and UIOs can directly access lifesaving federal public health emergency response supplies when needed during a public health emergency to support native communities, prevent supply shortages, and reduce health disparities. The Tribal Access Working Group hosted a webinar in March 2024 to brief tribal stakeholders regarding the strategy, and ASPR has posted online a summary and the actual strategy document: [Tribal Pathways for Accessing Emergency Medical Countermeasures \(hhs.gov\)](#). Furthermore, SNS presented information about the Tribal Access Strategy at the National Association of County and City Health Officials’ conference in March 2024.

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Accessible Text for Appendix IV: Comments from the Department of Health and Human Services

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Appendix V: GAO Contact and Staff Acknowledgments

GAO Contact

Mary Denigan-Macauley, (202) 512-7114 or DeniganMacauleyM@gao.gov

Staff Acknowledgments

In addition to the individual named above, Jennel Lockley (Assistant Director), Dan Klabunde (Analyst-in-Charge), Jack Knauer, Elizabeth Marin, and Sam Flom made key contributions to this report. Also contributing were Sam Amrhein, Julie Flowers, Kaitlin Farquharson, Emily Wilson Schwark, and David Jones.

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