State-Managed Medication Stockpiling

Landscape assessment of medication stockpiling practices and efforts across the U.S.

June 2024

Executive Summary

The COVID-19 pandemic and growing concerns over drug shortages have heightened attention on state-managed stockpiles and their potential role in safeguarding patient access to medications, particularly during crisis events. This research aims to provide a landscape review of state-managed medication stockpiles (also known as buffers or caches), defined here as strategic reserves of medications controlled by state authorities outside of traditional reserves for medical counter measures.

Data collection from October 15, 2023, to February 15, 2024, focused on the following factors as potential progress indicators for the development of medication stockpiles: past experiences with stockpiling; identification of lead stakeholders; proposed, current, or unsuccessful policies; publicly shared descriptions on the intended function or management of the stockpile; and established funding mechanisms. Based on research for this white paper including discussions held with public sector participants (public health and emergency management), it appears that most states are not currently prioritizing state-managed medication stockpiling.

However, drawn to action because of negative experiences from the pandemic and other recent public health emergencies, including drug shortages, some states are taking proactive measures to explore stockpiling of essential medicines. Other states are closely monitoring these efforts in order to inform their own strategies. This white paper highlights key factors influencing decisions towards developing state-managed medication stockpiles, including unclear statutory authority, equity concerns, as well as private industry perspectives and considerations.

Key Findings

1. **Unclear Statutory Authority for Drug Shortages Responsibility and Lack of Resources**
    - Supply-side drug shortages are not uniformly regarded as public health emergencies, therefore responsibility for addressing shortages can be murky and slow or complicate response.
    - Sustainable funding mechanisms essential for the development and implementation of state-managed stockpiles are severely lacking or non-existent.
    - Public health leaders have significant concerns if limited resources from vital public health programs are to be diverted to develop and manage stockpiles.
2. **Equity as a Driving Factor for States to Develop Stockpiles**
    - Public and private sector participants share significant concerns surrounding current and future impacts of drug shortages on patient care, especially during emergencies.
    - State-managed stockpiles can be a factor in helping ensure there is an equitable approach for vulnerable regions, communities, and facilities serving underserved populations to have access to medications in case of an emergency event, including during critical drug shortages.
3. **Private Sector Stakeholder Concerns**
    - Private industry stakeholders voice reservations about state-managed medication stockpiles, highlighting potential ramifications on the broader medical supply chain. Concerns include

the perceived risk of creating unwanted surpluses or shortages and inefficiency or slowness observed when collaborating with government entities.

- Hospitals and healthcare providers exhibit reluctance to solely depend on state-managed stockpile resources for shortages, instead preferring to rely on existing internal supply chain capabilities.
- Several private sector participants expressed potential concerns about state stockpiling initiatives lacking effective communication and appropriate engagement with the private sector, particularly based on experiences working with government-managed stockpiles during the COVID-19 pandemic.

Amid ongoing public health emergencies and persistent drug shortages, applying learnings from the evolving landscape can help improve coordination among states, jurisdictions, and the federal government, and mitigate potentially adverse effects on the healthcare supply chain.

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About Us

Healthcare Ready is a nonprofit organization that serves as a public-private nexus to prevent patient care disruptions amid crises. We do this by forging partnerships and serving as the linkage point between the healthcare supply chain and government. By working with supply chain stakeholders, emergency management, patient advocacy groups, and community-based organizations, we help safeguard patients before, during, and after crises by leveraging our core capabilities.

Healthcare Ready leverages our three pillars of core capabilities of **crisis response** which provides a range of support in response to emergencies, such as natural disasters, disease outbreaks, medication and healthcare supply shortages, and other events that pose a wide-scale threat to public health or healthcare operations/access. **Research and policy** leverage a team of analysts and network of subject matter experts to monitor for shifts in public opinion and policy, particularly in the areas of healthcare supply chains, preparedness and response capabilities of public health and healthcare systems, and the implications of policy/funding decisions on access to medications and healthcare services. Finally, **resilience** is by conducting programmatic activities year-round in areas that promote community and individual resilience.

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Staff Contributors

Angie Im, MSPPM

Julie Abrams, MBA

Lily Scheindlin, MPP

Sean Brzozowski

Tom Cotter, MPH

Terms

ASPR	U.S. Administration for Strategic Preparedness and Response
DOH	Department of Health
DPH	Department of Public Health
HPP	Hospital Preparedness Program
Stockpile	Also referred to as reserve or cache
MCM	Medical countermeasure
OTC	Over the counter
PHEP	Public Health Emergency Preparedness
PPE	Personal Protective Equipment
RSV	Respiratory Syncytial Virus
SNS	Strategic National Stockpile

Introduction

The COVID-19 pandemic and heightened discussions surrounding drug shortages have renewed attention on the topic of state-managed medication stockpiles and their potential for safeguarding access to medications during disasters. Though drug shortages are not a new issue, recent events combined with surges in patient care caused by public health emergencies (e.g., COVID-19, mpox, respiratory syncytial virus [RSV]), have led states and healthcare providers to proactively explore various strategies for responding to drug shortages. Delays in federal intervention—often initiated long after shortages have adversely affected patient care for prolonged periods—underscores the pressing need for broader industry discussions across healthcare supply chain stakeholders to ensure the availability of healthcare supplies and services amidst disasters.

Throughout the pandemic, significant pressures were placed on public health—federal and state—to ensure equitable access to healthcare services. These pressures persist, despite the absence of adequate funding for public health systems, and, lack of statutory authority designating entities responsible for addressing related challenges arising from supply-side drug shortages. A small number of states, however, are advancing efforts to explore or develop their own stockpile of essential medicines, hoping to address concerns raised by patients, providers, and other stakeholders.

This white paper provides a landscape review of state-managed medication stockpiles and associated state-level policies and efforts. While the focus of this white paper is around medication stockpiles, there are references to personal protective equipment (PPE) and traditional medical countermeasure (MCM) stockpiles, as they provide useful learning opportunities. References are also made to Strategic National Stockpile (SNS) caches that are managed by some states and jurisdictions. The varied terminology surrounding stockpiling, such as cache, reserve, buffer stock, and storage, reflects the nuanced language used by different entities to describe stockpiling practices, acknowledging the diverse approaches and contexts in different jurisdictions.

By broadly sharing the findings of this research, we hope to enhance coordination necessary to advance regional and national preparedness capabilities, and to mitigate future adverse risks to the supply chain.

Scope

- **Data Collection:** October 15, 2023, to February 15, 2024
- **Focus:** Medication stockpiles, state-managed medication stockpiles, and related policies and legislation (implemented, not fully implemented, or failed)
- **Out-of-Scope:** Federal policies/legislation, PPE-only stockpiles, Strategic National Stockpile (SNS) and other regional stockpiles

Methodology

Data collection took place from October 15, 2023, to February 15, 2024. The scope of this white paper focuses on medication stockpiles and state-managed medication stockpiles, as well as programs, policies and legislation pertaining to state-managed medication stockpiles. The following related topics were out of scope, though referenced where applicable: PPE-only stockpiles, SNS, federal and national level stockpiles, and national or federal policies and/or legislation.

A. Review of Publicly Available Information

Research began with a literature review of open-source information, including a review of all 50 states for current or proposed policies and/or legislation related to state-managed medication stockpiles, and current or proposed state-managed medication stockpiles.[1] Data were sought from publicly available literature as well as various state and governmental websites, including departments of health, departments of public health, and offices of emergency management and preparedness. Follow up research was conducted if a state website shared information about a state-managed medication stockpile or other references to state-managed medication stockpiles were found.

B. Discussions and Focus Groups

In total, **twelve discussions** were held with public sector representatives (state departments of public health, departments of health, offices of emergency management and preparedness, etc.) and **nine private sector discussions** were held (health systems, hospital associations, healthcare supply chain stakeholders, etc.). Discussions ranged from 30-60 minutes, and all responses have been anonymized and aggregated with key themes subsequently identified based on the number of instances and time spent in discussions on a particular sub-topic or area. Specific or private information from discussions are excluded from this white paper.

Public sector discussions involved PHEP directors and deputy directors, MCM coordinators, emergency management and preparedness specialists, and others with information and experience relevant to state-managed medication stockpiles. A more complete list of participant titles can be found in Appendix 1.1.

Private sector discussions were held with industry partners, coalitions, and private hospitals and health systems. In addition, this research was presented during a meeting of employees of state, regional, and metro hospital associations responsible for emergency preparedness and response. The associations span the US, representing each state, several cities, and several in-state regions. Data were collected based on questions raised during the call (also shared via electronic survey). Two participants responded to the electronic survey. See Appendix 1.3 for survey questions.

Figure 1. Data Collection

Literature Review
Academic journals, public health & emergency management websites, policy/legislative review

Discussions
Private & public sector stakeholders (e.g., hospital associations, public health)

State-Level Assessment
Snapshot of recent state-level efforts in PPE or medication stockpiling

[1] Search terms included: State medication stockpile + [state]; Medication cache + [state]; Medication reserve + [state]; Medication + buffer stock + [state]; State medication stockpile + legislation + [state]; State medication reserves + policy + [state]

Landscape Review

State-managed medication stockpiles are strategic reserves of pharmaceuticals maintained and controlled by state level government authorities. This white paper focuses on medications and related pharmaceutical products, excluding PPE and other medical supplies. Additionally, state-managed medication stockpiles are separate from the SNS, which is managed by the federal government.

State-managed medication stockpiles can be a critical component of public health preparedness, helping to safeguard the well-being of communities during crises. The strategic planning, comprehensive inventories, and collaborative efforts with various stakeholders can aid an equitable, proactive, and effective response to emerging health threats. The primary objective of state-managed medication stockpiles is to provide a rapid and effective response to health crises by ensuring the availability of essential medications. State-managed medication stockpiles typically include a diverse range of pharmaceuticals, vaccines, and antidotes, that may be used to address a variety of health threats.

Key features of state-managed medication stockpiles

1. **Strategic Placement:** Stockpiles should be strategically located across the state (i.e., not centralized in one location) to facilitate quick and equitable distribution in the event of an emergency. Placement considerations should include proximity to population centers and potential risk factors.
2. **Comprehensive Inventory:** Authorities should maintain a comprehensive inventory of medications within the stockpile. This inventory needs to be regularly updated, rotated, and tailored to address specific populations and health threats that the state may face.
3. **Regulatory Compliance:** The management of state-managed medication stockpiles must adhere to strict regulatory standards. Quality control measures ensure the safety and efficacy of stored medications, and close monitoring of compliance with relevant laws and guidelines.
4. **Collaboration with Stakeholders:** State health agencies often collaborate with various stakeholders, including pharmaceutical companies, distributors, healthcare providers, and emergency response agencies, to enhance the efficiency of stockpile management. Partnerships may involve procurement agreements, information sharing, and coordinated response planning.
5. **Emergency Distribution Protocols:** Robust distribution protocols need to be in place to ensure the swift deployment of medications and medical supplies to affected areas. These protocols may involve coordination with local health authorities, emergency responders, and healthcare facilities.
6. **Continuous Evaluation and Improvement:** State-managed medication stockpiles should undergo regular evaluations to assess their readiness and effectiveness. Lessons learned from previous emergencies should be used to refine and improve stockpile management strategies.

A. State Stockpiling Landscape

This research centered on several key indicators to assess states' progress towards developing and implementing state-managed medication stockpiles, considering a variety of aspects that underscore the diversity of functions stockpiles are intended to serve (e.g., to mitigate supply shortages; mitigate shortages caused by medical surge events; provide a market for otherwise unmarketable drugs, much like MCMs for the smallpox vaccine). Sourced from publicly available information, data gathered was related to: Current or past experience with state-managed medication stockpiles (non-SNS stockpiles); lead stakeholders that manage or have managed existing stockpiles; relevant policies, programs, or proposed legislation; intended functions (or specific medications housed in the stockpile); access mechanisms; and known funding structures for procurement and maintenance. See Appendix 2.0 for further details on domain areas and measures associated with each criterion.

Snapshot of State-Managed Stockpiling Efforts – Stockpile Types

At the outset of this research, we initially relied on past stockpiling experience as a key potential indicator of states that might exhibit a robust need or interest in future stockpiling. However, following discussions with public and private sector stakeholders, it became clear that past experiences only provide a partial narrative. Findings showed that although a majority of states have attempted stockpiling in at least one way—including creating a limited stockpile for event- or disease-specific purposes (e.g., mifepristone stockpiling, or PPE stockpile in response to the COVID-19 pandemic)—most are not currently positioned to develop or prioritizing development of state-managed medication stockpiles.

Figure 2. Overview of Stockpile Landscape

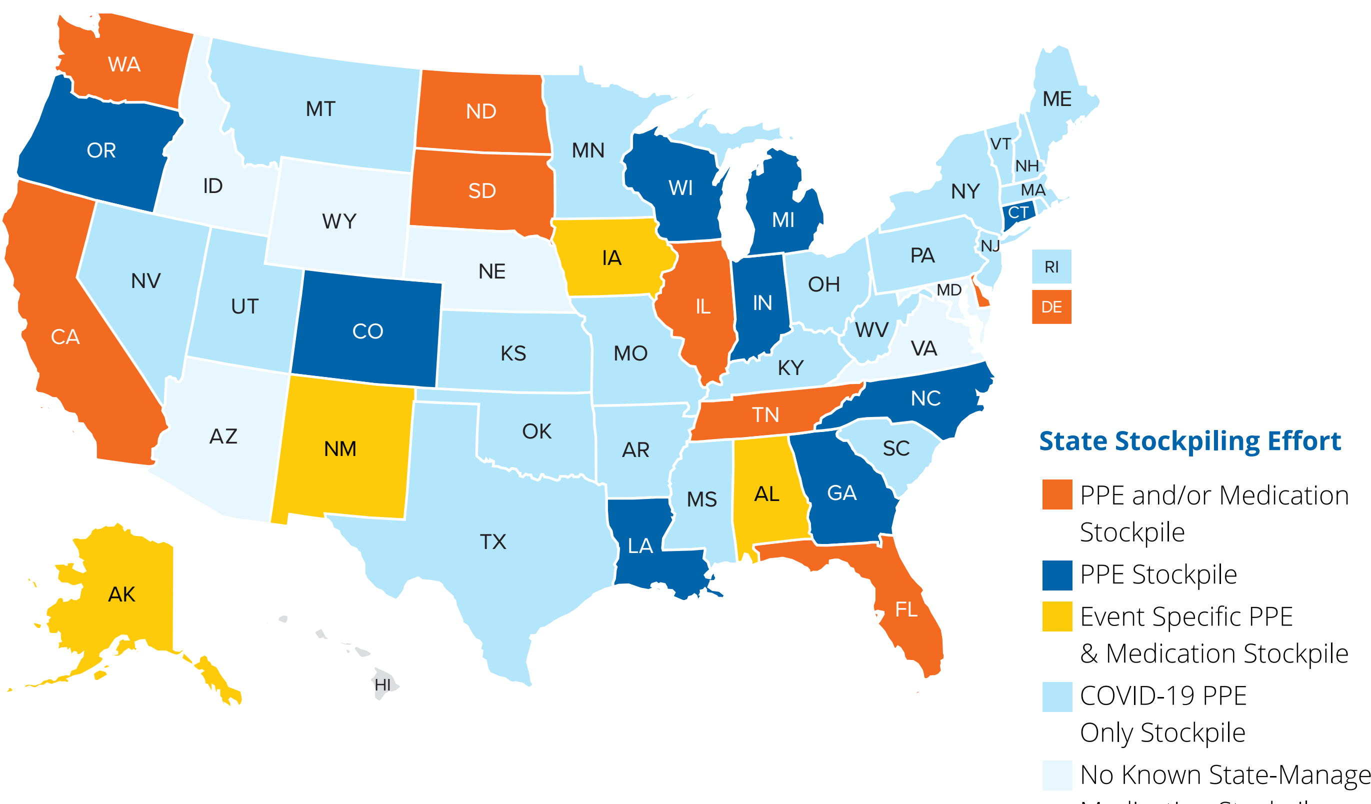

Figure 3. Summary Past and Current Stockpile Efforts at the State-Level*

PPE and/or Medication Stockpile	PPE Stockpile	Event-Specific PPE & Medication Stockpile	COVID-19 PPE Only Stockpile	No Known State-Managed Stockpile
8 States	**9 States**	**4 States**	**22 States**	**7 States**
State-managed stockpiles consist of PPE and some medications (sometimes MCMs)	Have an established PPE stockpile program managed by the state	Have a PPE and/or medication stockpile in response a specific event (e.g., H1N1, COVID-19), including caches of abortion medications	Developed a PPE stockpile in response to COVID-19 (no publicly available information on further updates)	Based on publicly available sources, there is no evidence that a state-managed stockpile exists

* From publicly available sources only.

Snapshot of State-Managed Medication Stockpiling Efforts – Programs and Policies

A small number of states have existing programs that support medication stockpiling beyond MCMs, and increasingly other states also appear to be working towards medication stockpiling. A review of programs, legislation, and policies related to medication stockpiling revealed several existing state-managed medication stockpiles established in the past through programs managed by state agencies, including Departments of Health or Emergency Management Divisions. Some states have proposed, existing, or failed legislation related to stockpiling, demonstrating that medication stockpiling was or is of some level of interest to the state. Other states have advanced policies outlining planning, development and/or management of the stockpile. Figure 4 demonstrates how state efforts were categorized to provide a high-level snapshot of state stockpiling efforts, including insight into states that are seriously considering stockpiling as a preparedness and response mechanism.

Figure 4. Summary of Policies, Programs, Legislation Efforts at the State-Level*

13 states have programs, legislation, and/or policy related to medication stockpiling[a]		
Program Previously established or currently operational under the management of a state agency	**Legislation** Existing, proposed, or failed	**Policy** Documented policy apart from legislative measures or existing programs (e.g., strategic plan, executive order)
Alabama ** Alaska ** Arkansas Florida Illinois Iowa ** New Mexico ** North Dakota Tennessee Washington	California Delaware	South Dakota

[a] Mention of medication stockpiling through programs (typically managed by public health departments); legislative bills proposed, enacted, or failed; and other policies (e.g., executive order).

* From publicly available sources only.

** Indicates medications may be part of H1N1 stockpile and may not be indicative of other pharmaceutical reserve.

B. Key Drivers and Obstacles to State-Managed Medication Stockpiling

Unclear Statutory Authority for Drug Shortages Responsibility and Lack of Resources

A majority of participants cited the lack of clear responsibility for addressing drug shortages as a major obstacle preventing effective coordination and response. While certain states have established medical supply or PPE stockpiles, many public sector participants expressed concern with, or disagreed with the idea that supplementing medication during shortages is the responsibility of public health departments. Four public sector participants mentioned that drug shortages are a supply chain issue, likely to be solved through existing mechanisms within the supply chain, rather than the responsibility of the state. Most public sector participants also voiced concerns about allocating limited resources—particularly skilled staff—to establish and manage state-managed medication stockpiles, fearing potential adverse effects on other critical public health functions.

Sustainable funding mechanisms for utilizing stockpile inventories beyond public health emergencies are lacking. A handful of states fund some stockpiling capabilities through federal preparedness cooperative agreement grants (i.e., ASPR's Hospital Preparedness Program [HPP] or CDC's Public Health Emergency Preparedness [PHEP] cooperative agreements). However, funding via those programs is severely limited, as well as restricted to usage for planning and response to emergencies and disasters and as noted earlier, supply shortages are not uniformly regarded as public health emergencies. Overall, the prevailing sentiment among state public health leaders who participated in this research, was that there are more immediate and crucial public health priorities to address, especially in the absence of necessary resources and authority to respond to drug shortages.

> *"The grants have stayed the same and inflation is wildly different than it was. I think our staffing costs increased 15%--more, maybe. The warehousing costs went up like 50%; it was something crazy post-COVID. Funding and resources to manage whatever you're going to do—whether it's just masks or vents—it's a real challenge."*
>
> — Public Sector Participant, Emergency Management Agency

Private Sector Stakeholders Concerns Surrounding State-Managed Medication Stockpiles

Private industry stakeholder participants expressed reservations about state-managed medication stockpiles, citing concerns from previous experiences that led to impacts on the overall healthcare supply chain, such as creating unintended surpluses or shortages. Concerns also arose from perceived inefficiency and slowness when collaborating with government entities, especially those focused on public health rather than direct patient care.

Several private sector participants, including representatives from major health systems or state hospital associations, expressed unease regarding state stockpiling initiatives without additional support to ensure effective communication and appropriate engagement with the private sector. Health systems reported a preference for leveraging internal supply chain capabilities over state-managed medication stockpiling, emphasizing their expertise in supply chain management (over that of state public health resources). Overall, hospitals and providers prioritizing patient care, seem reluctant to depend on state-

managed stockpiling efforts, also suggesting that the responsibility for equitable distribution during drug shortages or emergencies should rest with public health rather than healthcare entities.

Experiences during the COVID-19 pandemic underscore the necessity of collaboration to mitigate further disparities from the pandemic across historically medically underserved communities. Addressing these concerns will require substantial investment in strengthening public-private partnerships to foster trust between hospitals and stakeholders that develop, manage, and maintain medication stockpiles. While some private health entities benefited from federal government support in acquiring and distributing medical resources, others faced challenges, including competition from other healthcare providers, and prolonged wait times for supplies, sometimes also receiving expired products.

> *"The biggest takeaway in my mind [regarding stockpiling efforts] is transparency and communication and clear messaging."*
>
> —Chief Pharmacy Officer, Major Health System

Equity as a Driving Factor for States to Develop Stockpiles

Despite the absence of clear responsibility or authorities to address drug shortages, a handful of states are striving to proactively protect patient access to medications and combat drug shortages by establishing medication reserves. Six public sector participants expressed an interest in bolstering their own preparedness endeavors, such as establishing a stockpile, due to uncertainty regarding the deployment process and allocation of resources from the SNS during past emergencies. Another participant highlighted that past disaster experiences have shown federal assistance to be often delayed, necessitating reliance on their own state resources.

In reflecting on their public health COVID-19 response and contemplating future response, one public sector participant noted, "If we have stockpiles, we should approach the distribution in a way that helps reduce inequitable access to resources, I think [it] is a public health imperative and should be driving our strategy…I think that is part of the rationale to have a stockpile, to help ensure from a public health perspective that we are trying to reduce the disparities to access our healthcare system."

Participants in two states shared that they have established a state-managed stockpile due to their large, rural geography. Another public sector participant shared that during COVID-19 their jurisdiction convened an advisory group of stakeholders and experts to determine stockpile related processes that prioritized equitable distribution of resources. The advisory group emphasized the importance of supplying product to non-major hospitals, which typically have necessary staffing and resources to manage supply chain issues with internal processes.

> *"The safety net hospitals were operating in some of these areas where we knew they were [historically underserved and in areas of higher risk] …In that initial phase we were increasing the percentage of product going to [safety-net] hospitals because a lot of the major hospital chains were just fine…We were still distributing to them, but they were not our priority."*
>
> —Public Sector Participant, Emergency Management Agency

Considerations for Future Development or Management of State-Managed Medication Stockpiles

Various recommendations and leading practices emerged during discussions for this research. These themes are encompassed in the following resource, and framed as questions for states to consider as they explore the development of a state-managed medication stockpile. Consideration for these questions can help shape strategies, functions, and resource requirements for future preparedness endeavors.

RESOURCE: Planning Considerations for State-Managed Medication Stockpiles

Consider the questions and feedback in Figure 5 during your discussions on state-managed medication stockpiling efforts.

Figure 5. Planning Considerations for State-Managed Medication Stockpiles

Planning Considerations	Research Participant Feedback	Discussion Prompts
Stockpile Access	Defining the designated recipients for stockpile products can influence the formulary and/or the processes guiding to the selection of products to be included. Public sector participants noted the importance of identifying end-consumers and involving relevant communities or representatives in the discussion as part of the design and implementation of a stockpile. They also raised the importance of considering how facilities in rural areas, safety-net hospitals, and other facility types that lack the resources to manage excess inventories, might access product from a stockpile.	"End-consumers" may include hospitals, specific facility types, specific prioritized communities, etc. • Who will be able to receive/request products from the stockpile? • What does the request process look like?
Improving Equity	When determining the intended recipients, understanding equitable access to ensure that underserved populations are reached is one of the biggest opportunities for a state-managed stockpile. Both public and private sector participants shared that a state-managed stockpile has a strong chance of ensuring equitable access, compared to provider-managed stockpiles, because they can incorporate the appropriate equity plans into distribution processes vs a hospital's focus serving its patients.	Work with local health departments, community-based organizations, and other entities to determine population health needs. • How can community-based organizations be involved in stockpile development from the outset? • How will community-based organizations and community-based healthcare providers, such as safety-net hospitals, have access to supplies from the stockpile? • How can the stockpile development process center and prioritize patients in medically underserved areas?

 Stakeholder Involvement	Consider other stakeholders (including healthcare organizations, community-based organizations, professional associations, other government agencies, etc.) that would benefit from being a part of planning discussions. Participants emphasized the need for strong communication across all stakeholders to effectively develop and implement a stockpile.[2]	Examples include: • Interdepartmental coordination within state public health • State boards of pharmacy • Healthcare coalitions • Regional coalitions • Hospital associations • Major hospitals or hospital systems within the state • Rural hospitals or other healthcare facilities with low-purchasing power • Representatives of non-hospital facilities, including long-term care, nursing homes, or other ancillary care facilities • Local public health departments • Safety net hospitals • Providers/provider groups
Funding and Resources	Consider alternative sources for sustainable funding. Some participants described leveraging a third-party vendor to develop and manage stockpiling inventory. This has helped some states avoid the financial risk and burden associated managing their own stockpiles, and alleviated the pressure of ensuring there are downstream buyers of product.[3] For these particular states, managing the intricacies of a stockpile – developing the formulary, handling rotation management, etc. – was beyond the capacity of the public health department/state entity, so using a third-party vendor was the best solution to build up this aspect of preparedness.	• Are there other sources of state/local/other funding to explore? • Vendor-managed stockpiles are one strategy states can employ to invest in preparedness yet not bear financial risk for purchasing or holding inventory. • What third-party vendors can be leveraged to support elements of warehouse design, implementation, management (tracking, inventory replenishment, distribution, rotation) to reduce risk and capital investment from the state?[4]

[2] 9/12 public sector participants.

[3] 5/12 public sector participants.

[4] https://www.lslog.com/who-we-serve/hospitals-provider-networks/

Other Barriers and Challenges to Pursuing Medication Stockpiles

The following tables provide an overview of the key barriers and challenges cited by public sector participants through discussions held over the course of this research. They offer valuable insights into the multifaceted landscape surrounding the development of state-managed medication stockpiles and primary barriers or challenges states are grappling with in navigating this aspect of healthcare readiness.

- Table 1 describes themes of barriers and challenges that public sector participants discussed specifically about the *physical aspects* of standing up and maintaining a state-managed medication stockpile, including warehouse and staffing, rotation management, etc.
- Table 2 reviews themes that public sector participants reported as *general and overall* barriers and challenges to standing up and maintaining a medication stockpile.

Table 1. Barriers and Challenges Related to Physical Stockpile Maintenance

Barriers and Challenges for Physical Stockpile Maintenance	
Barriers/challenges to managing physical stockpiles	**Examples**
Rotation Management Resources including time, effort, expertise, and funding required to establish a stockpile is immense; managing pharmaceuticals with a short shelf-life adds an additional logistical challenge. It can be difficult for a public health department to manage expired medications and deal with waste management. Rotation management is a complex enough endeavor to warrant its own department or specialists, making public health department officials hesitant to manage the processes.[5]	"Rotation management is pretty much impossible with the current staffing and funding available." "Once we purchase something, there's not much we can do with it other than keep it and get rid of it. We can't sell it. It's a waste. We [recently] shipped eight truckloads of Relenza to...be destroyed. We don't want to replicate that again."
Lack Of Resources To Build And Maintain Some participants described a lack of a warehouse, skilled staff/workforce, and a lack of funding specifically designated to build and maintain a state-managed stockpile an impasse to stockpiling efforts.[6]	"But we don't have the staff or time to [stockpile medications], so we need money from the legislature to figure out what we need and to be able to do that and prep...the more important part, is that once we get the medications in warehouses, we don't have any sort of funding or ability to actually rotate the medications or deal with rotation management – let the [distributors] of the world deal with that."

[5] 10/12 public sector participants.

[6] 5/12 public sector participants.

Concerns Surrounding Financial Risk/Burden	
Some participants noted concerns around end-consumers of the products in a potential stockpile. Without clarity around who will buy the product or how products in the stockpile will be paid for when they are used, states are unwilling to take on the financial risk involved in building and maintaining a stockpile.[7]	"From our perspective, our stakeholders are our public health and our healthcare partners." Others reported a lack of clear consumer of products in a potential stockpile, indicating that a process is needed to define how the state would allocate or prioritize product distribution in the case of a widespread emergency.

Table 2. General Barriers and Challenges Related to State-Managed Medication Stockpiling Efforts

Barriers and Challenges Related to Overall Stockpiling Efforts		
General Barriers/ Challenges to Medication Stockpiling	**Description**	**Examples**
Lack of funding and skilled staff	Participants reported that budgets are already stretched thin, so it is infeasible to devote any funding to stockpiling efforts. Specifically, states without a stockpile reported that a lack of funding specifically designated for building and maintaining a stockpile makes it difficult to prioritize stockpiling efforts.[8]	"Cooperative agreement and HPP programs – legally it fits, but it's not well-funded." "PHEP and HPP budgets have decreased. It's not so easy to do that anymore. Those budgets have gotten a lot tighter."
Lack of stakeholder alignment and resources to navigate development of a formulary	Stakeholders across various areas of a state do not always align as to what a stockpile would look like or mean for the state, making it difficult to move towards building and maintaining stockpiles. Some participants reported that a lack of a pharmacist, or pharmacist-group, to develop or determine a formulary is a barrier to stockpiling efforts. Public sector participants noted that it is difficult to predict what medications will be necessary in an emergency without an appropriate formulary.[9] Note: Stakeholders involved include hospitals, healthcare coalitions, public health departments, etc.	"[Hospitals] were specific about what brand…they wanted of gloves and supplies, etc. and that's not necessarily going to work. [Public health was] not stocking name brand, but generic. And [hospitals] might not want to take our generic. If you're using a coalition of hospitals, you need to agree on the generic brand. And then it's the dispensing of medication, some only want a specific type or manufacturer." "There's been no formal guidance developed at the federal level to determine how much [to stockpile], what to stockpile, and the rotation issue."

[7] 4/12 public sector participants.

[8] 9/12 public sector participants.

[9] 6/12 public sector participants.

Lack of resources and processes to support federal and/or SNS coordination	Participants shared that it is difficult to anticipate the details of the federal government response to an emergency, making it a challenge to develop their own complementary response. Participants reported a lack of coordination with the SNS, meaning that without knowing what they will receive in an event, states are unable to project their own needs and build a supply. This can deter states from building their own stockpile and has contributed to a lack of trust in the federal government to provide sufficient support in an emergency for some states.[10]	"We need to know how many PPE [or supplies] in a global emergency would be allocated to [state] and we can look at our burn rate and know how many days we need to stockpile to fill in the days that SNS can't cover."
Lack of pre-existing infrastructure to support coordination and logistics planning	There is a lack of federal guidance or clear mandate outlining how states might best approach stockpiling efforts. Some participants further noted that the challenge of how best to coordinate across entities including hospitals, healthcare coalitions, long-term care facilities, etc. is a deterrent to building a stockpile. In some states it can be unclear whose responsibility it is to build up and manage a stockpile (i.e., public health, hospital systems, healthcare coalitions, etc.), meaning that it does not get built at all.[11]	"We don't have guidance. We don't want to spend limited grant dollars on something that we don't know how to approach. We don't want to stockpile what's already in the SNS. In an emergency, it would be better if the feds just supplied what we would need rather than us trying to build up and anticipate what the feds won't do or send us. So, there is no clear answer as to how this would work between the feds and the state." "We're not funded as if we're [neighboring states], but the largest outbreaks, they happen to [us] simultaneously. We're treated as a small state...We're not funded based on the risk to our region." The state noted that if there is an outbreak in their region, people from their state might be working in neighboring states and impacted by the outbreak, "But we're not funded to enable us to stockpile."

[10] 6/12 public sector participants.

[11] 7/12 public sector participants.

SPOTLIGHT: Recent Federal Policy Efforts Related to State-Managed Medication Stockpiles

Recent Federal Policies (Introduced or Passed)

Policy	Status	Legislative Body	Year
State Strategic Stockpile Act of 2023 Introduced by Senators Maggie Hassan (D-NH) and John Cornyn (R-TX). The purpose of which is to expand bipartisan efforts to create state medical stockpiles and promote coordination between regions and states. The intention of this bill is to "empower states to build and maintain their own medical stockpiles so they can respond quickly to emerging infectious diseases in the future."	**Introduced**	Senate	2023
Essential Medicines Strategic Stockpile Act of 2023 Introduced by Representative Buddy Carter (R-GA). Would require the Department of Health and Human Services to initiate a pilot program testing the effectiveness of establishing and managing a state stockpile.	**Introduced**	House of Represent-atives	2023
PREVENT Pandemics Act Introduced by Senator Patty Murray (D-WA), includes Sec.409. Grants for State Strategic Stockpiles, that outlines a pilot program to support state-managed medication stockpiles. This stipulation describes a requirement that states must adhere to; however, it includes no designated funding to stand up this pilot program.	**Passed**	Senate	2023
Pharmaceutical Supply Chain Risk Assessment Act of 2023 Introduced by Senator Gary Peters (D-MI), intends to mitigate health and national security risks. If passed, this would require an interagency risk assessment of the pharmaceutical supply chain to identify and mitigate health and national security risks. This risk assessment would occur 18 months after the date of enactment and be updated annually thereafter. This is relevant as it relates to building state-managed medication stockpiles and the impact they have on overall pharmaceutical supply chain.	**Introduced**	Senate	2023
Drug Shortage Prevention Act of 2023 Introduced by Representative Sara Jacobs (D-CA). If passed, would amend the Federal Food, Drug, and Cosmetic Act to provide notification by manufacturers of critical essential medicines of increased demand for such pharmaceuticals.	**Introduced**	House of Represent-atives	2023
Mapping America's Pharmaceutical Supply Act (MAPS) Introduced by Senator Gary Peters (D-MI), if passed, would require an interagency effort to map the United States pharmaceutical supply chain and use data analytics to identify supply chain vulnerabilities and other national security threats.	**Introduced**	Senate	2023

Conclusion

There is a growing awareness that stockpiling efforts have the potential to help address gaps in healthcare access, but without adequate coordination and resource investments, these strategies can inadvertently create more harm than good. This white paper seeks to contribute to an ongoing dialogue on effective strategies for constructing and managing state-managed medication stockpiles, as states explore innovative strategies to safeguard patient access to healthcare services amidst disasters, including drug shortages.

The data presented underscores the need for greater investments across the public sector to enable more coordination, and address shortcomings in existing emergency management systems, such as the SNS, which was neither intended to, nor is capable of, operating as a standalone solution to all emerging threats in the healthcare supply chain. This research also raises questions and presents perspectives from private and public stakeholders on coordination with manufacturers, distributors, and end-consumers (e.g., hospitals) to prevent unintended adverse consequences in the healthcare supply chain.

Questions prompted by these insights for future research include:

- What scenarios are state-managed medication stockpiles best suited (or not suited) to address?
- How can we prevent new risks in the healthcare supply chain while continuing to innovate and evolve?
- What existing emergency management and public health coordination mechanisms can be leveraged, and what needs to be developed for state-managed stockpiles?

Looking to the future, it's crucial that we continue to explore collaboration opportunities across sectors, and convene stakeholders from healthcare organizations and government to jointly develop supply chain management initiatives. Navigating these complexities underscores the importance of a practical approach to enhance preparedness and response capabilities, addressing the needs of stakeholders in regions facing disparities in resource accessibility during crises. This research aims to deepen understanding and reinforce coordination, with the goal of enhancing state and jurisdictional capacities in responding to future public health emergencies.

Appendix

Appendices can be found on our website at HealthcareReady.org.

1. Discussions and Focus Groups
2. Process for Assessing States

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