

May 29, 2020

Robert Kadlec  
Assistant Secretary of Preparedness and Response  
Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue, SW.  
Washington, DC 20201

Dear Dr. Kadlec:

On behalf of our 40,000 members, the American College of Emergency Physicians (ACEP) appreciates the opportunity to respond to a request for information (RFI) on the Assistant Secretary of Preparedness and Response's (ASPR's) proposed strategy and structure of the Strategic National Stockpile (SNS) and the role of public-private partnerships in achieving this vision. ACEP is a national organization representing emergency medicine, and as such, our members include users of SNS supplies, as well as individuals involved in state, regional, and local planning of responses to disaster events. Our answers therefore will be limited to those questions in Section 1 of the RFI that are pertinent to emergency physicians and the patients we serve.

### **ACEP Responses to Questions in Section 1**

#### ***1. Do you agree with the stated objectives of the SNS? Have we missed anything major in articulating our vision?***

ACEP has some concerns about the proposed vision. Overall, there should be a system in place that contains regional stores of well-rotated stock that is ready for immediate dissemination in the event of weather-related emergencies, earthquakes and tsunamis, and localized biologic or chemical release emergencies. The federal government should be responsible for design, stock rotation, and expense. However, the SNS needs to be integrated into regional and local supply stores, likely those that serve the health care system on a daily basis.

The strategy must be able to account for all types of hazards, keeping in mind that a pandemic is a much higher probability event than a terrorist attack. The process of designing and building the SNS should include the need for identifying the needs of the disaster response system. For example, emergency physicians have identified the need for better mask design since the SARS outbreak in 2003. The design needs should have been integrated into the overall plan for the SNS to develop better tools that will compose the stockpile and allow the efficient design and delivery of materials that will enhance the work of health care professionals. The current design of protective face shields and gowns also needs to be improved to facilitate patient work with agents like Ebola and COVID-19.

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**2. Are there emerging technologies transforming the logistics sector (e.g. 3D printing, block chain, automation in warehouse and delivery operations, etc.) that we should build into our vision now?**

Not applicable to ACEP.

**3. How can your organization contribute to achieving the vision for the SNS?**

ACEP is composed of many physician experts in the design of disaster response systems, but more importantly, of the most efficacious ways that emergency care is provided, and what disaster needs are most likely in a Hazard Vulnerability Analysis (HVA). Those experts should be a defined contributor to the design of the SNS, the ongoing supply updates that will be beneficial, and what equipment is becoming outdated.

**4. Please provide your perspectives on the feasibility, benefits and risks of the below partnership strategies:**

- a. Building inventory and/or capacity at different points in the value chain**
  - i. Raw materials inventory – stockpiled raw material inputs required to manufacture items**
  - ii. Manufacturing capacity – reserved manufacturer capacity to ramp up production when needed (please also indicate what efforts would need to be made to achieve sufficient domestic manufacturing capability for this approach)**
  - iii. Warehoused finished goods – finished goods inventory buffers managed by vendors (VMI) or held in US Government warehouses**
  - iv. Point of care finished goods – finished goods inventory held at the point of care or use**
- b. Utilizing existing distribution infrastructure to enable rapid and more targeted emergency response**
- c. Sharing information with the government to enable real-time visibility across the end-to-end supply chain through a Supply Chain IT Control Tower**

From a clinician perspective, it appears there should be a process of supply design, development, manufacture, prioritization, and distribution that fulfills crisis medical needs. That should very much include a process that begins and ends in the United States, or at least in stable sites in North and Central America.

With respect to building inventory and/or capacity at different points in the value chain, the vendor managed inventory part of the process needs improvement. There is much "just in time inventory" permeating the system with supply lines stretched too far. This results in vulnerabilities depending on the disaster such that what seemed reasonable in general becomes clearly non-functional when actually applied. Again, the capacity to expand inventory has to have a greater component of vendors with their entire business and related suppliers located within the United States.

**5. What other partnership strategies should be considered?**

It is very important that emergency physicians be involved in the stock design and development processes. In particular, emergency physicians must be consulted when designing integrated products that serve current and future patient needs in likely HVA incidents for this country (including chemical and biologic incidents; mass shooting or bombing events; and future pandemics).

Further, it is extremely important to partner with health care facilities, such as hospitals, and help them respond to disaster situations. There seems to be an ongoing unmet need for necessary funding of these partners, which we believe can be addressed through increased federal funding through increased grants to hospitals for disaster preparedness or allowing Medicare to cover institutional charges related to preparedness.

**6. *What can the Government do to improve the feasibility of these strategies, and/or to ensure successful partnerships? What can industry do?***

The federal government should be responsible for organization, design, stock rotation, and funding of the SNS program. Keeping the SNS adequately stocked should always be a federal priority. Public-private partnerships can be very useful, but we do not believe outsourcing all of these functions necessarily serves the best interest of country. Creating competition between states to acquire personal protective equipment (PPE), ventilators, medications, and other supplies is not the most effective or cost-efficient process.

We should always have sufficient supply to face pandemic or other events. One vulnerability that we have experienced in many areas during the COVID-19 pandemic is that items have been available in storage, but that they are expired and non-functional (elastics degraded on masks, etc). This leads to massive waste in the system, as well as supplies not being functional when needed.

The process for requesting SNS assets should be streamlined and be consistent across the country. The methodology for allocating SNS assets should be consistent and transparent and fair across states. The public should have visibility on how, where, and when SNS assets are deployed. The request and allocation processes should include medical technical specialists who can speed the process and ensure information is correctly communicated. The SNS request, tracking, and reporting system should be made into one national electronic system with a consistent portal.

The SNS should not be limited to simply warehousing of supplies. In a modern era, the SNS should include contracts with domestic manufacturers to guarantee immediate increases in production that will meet expected demands for supplies. The most obvious use case for this is PPE, where there is no warehouse system in the US big enough to accommodate our COVID-19 PPE needs. Instead, the ability to instantly increase N95, gown, mask, and other crucial supply production to meet national needs would have been extremely valuable. The same could apply to other key items that could be in short supply for a prolonged incident like a mass burn event (burn rehab takes a long time and has a thin supply chain) and others.

Beyond the federal government, state and local officials and private entities with expertise in manufacturing, warehousing, and distribution need to be integrated into regional and local supply stores. The entities that should have primary roles are those that serve the health care system on a daily basis. Finally, the specifications of all items in the SNS should be known to all who may receive those items so appropriate planning can be performed in advance, not in the crisis of the moment. There must be supplies available for natural disasters such illness secondary to hurricanes, also supplies such as PPE, ventilators for both pandemics and major patient transport from, for example, earthquake requiring a major transport of intubated patients.

We appreciate the opportunity to share our comments, and encourage you to keep in mind the true purpose of the SNS—it is not the end-all response to a disaster, but rather it should be used in the first two to three days of the disaster to augment a specific area until regular assets can be brought to bear. If you have any questions, please contact Jeffrey Davis, ACEP’s Director of Regulatory Affairs at [jdavis@acep.org](mailto:jdavis@acep.org).

Sincerely,



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