

## **Statement for the Record**

**Submitted by**

**The Premier Inc. healthcare alliance**

***“COVID-19 Part II: Evaluating the Medical Supply Chain and Pandemic Response Gaps”***

**Senate Homeland Security Committee**

**May 19, 2021**

The Premier healthcare alliance appreciates the opportunity to submit a statement for the record on the Senate Homeland Security Committee hearing titled “COVID-19 Part II: Evaluating the Medical Supply Chain and Pandemic Response Gaps,” scheduled for May 19, 2021. We applaud Chairman Peters, Ranking Member Portman and members of the Committee for holding this hearing to examine lessons learned from the COVID-19 pandemic and ways to strengthen the nation’s medical supply chain.

Premier Inc. is a leading healthcare improvement company and national supply chain leader, uniting an alliance of more than 4,100 U.S. hospitals and health systems and approximately 200,000 alternate site providers to transform healthcare. With integrated healthcare quality, cost and supply chain data and analytics, supply chain solutions, consulting and other services, Premier enables better care and outcomes at a lower cost. Premier’s sophisticated technology systems contain robust data from nearly half of U.S. hospitals and 300,000 ambulatory clinicians. Premier is an agnostic, data-driven organization with a 360° view of the supply chain, working with more than 1,300 manufacturers to source the highest quality and most cost-effective products and services. Premier’s work is closely aligned with healthcare providers, who drive the product and service contracting decisions using a data-driven approach to remove biases in product sourcing and contracting and assure access to the highest quality products.

### **Premier’s Reflections & Learnings From COVID-19 Response Efforts**

From the beginning of the COVID-19 pandemic, Premier has been at the forefront of response efforts working around the clock to ensure hospitals, health systems, and alternate site providers across the country had access to the necessary PPE, medical supplies and pharmaceuticals to treat COVID-19 patients. Premier has spent significant time reflecting on the experience of the healthcare industry during COVID-19 response efforts to determine elements that worked well as well as areas for improvement for the future. Premier’s reflections have found that:

- **Elements that Have Worked Well:**
  - Nimbleness and ingenuity of the private sector to anticipate and identify needs as well as respond quickly to fill gaps
  - Formation of the Private Sector Supply Chain Coalition to provide a coordinated and collaborative response to the government and in the market
  - Sharing of supply chain data that accounted for both supply and demand from neutral, vendor agnostic, and value orientated entities
  - Regulatory flexibilities and waivers from FDA, CMS, HRSA, and CDC that were delivered rapidly

- Timely and regular access to government leaders and openness to input
- Elements that Led to the Current Situation and Points of Failure.
  - In spite of efforts by Premier and others to counter the trend, a focus for the past 20+ years to move manufacturing offshore as a means to reduce costs to offset decreasing healthcare reimbursement. This is because emerging economies:
    - Are more willing to take greater environmental regulatory risks
    - Have large populations of low-cost labor
    - Have incentives to move manufacturing to their markets
  - Lack of centralized upstream visibility into supply chain to determine source of raw materials and finished goods. This resulted in a lack of understanding of vulnerabilities, foreign reliance on manufacturing, and impact as export bans and manufacturing shutdowns were announced.
  - Unprecedented demand both globally and nationally that led to an imbalance in the supply vs demand, e.g., 17X increase in surge demand for N95 masks.
  - Export bans and manufacturing shutdowns globally.
  - Insufficient supplies in the Strategic National Stockpile (SNS) and cumbersome process for accessing supplies in the stockpile.
  - More reactive approach vs a proactive approach by the government at the outset. Product was not allocated to the “hot spots” because there was not clear identification of them until late.
  - Fragmented approach to securing supply (private sector vs federal vs states) led to increase in prices as multiple entities competed for the same inventory and out-bid one another.
  - Lack of clear visibility of distributor fulfillment lead to uncertainty on where products were delivered. This continued uncertainty left providers with dwindling confidence in the normal supply chain and proliferated more maverick and forward buying, as well as hoarding. This also led to a rampant gray market and many entities purchasing counterfeit products.
  - Insufficient national strategy and plan for addressing global pandemics, including confusion regarding which federal agency was responsible.
  - Existence of patent restrictions that impeded access to ancillary products needed for care such as viral swabs.

### **Strengthening the Healthcare Supply Chain to Address Future Pandemics**

To strengthen the supply chain to address future global pandemics, Premier has robust recommendations on how the existing private sector supply chain can be further enabled and augmented. Premier’s guiding principles include:

- Augment the existing private sector supply chain to better respond to global pandemics through diversification and transparency. The private sector supply chain is highly functioning and should be further enabled, not disrupted.
- Develop a cohesive and holistic national strategy for addressing global pandemics and stabilizing the U.S. supply chain to respond to surge demand for critical medical supplies and drugs.
- Identify critical medical supplies and drugs needed to treat a global pandemic and associated comorbidities. This identification should occur via a public-private advisory council that includes representatives from manufacturers, GPOs, distributors, physicians, pharmacists, laboratorians, and others. This list must be dynamic and regularly updated as technology advances, best practices are identified, and the practice of medicine evolves.

- Create upstream visibility into the supply chain to understand sources of raw materials and manufacturing facilities. This information is critical to assess vulnerabilities and prioritize what critical medical supplies and drugs should be focused on initially to assure adequate diversification of the supply chain.
- Develop a nimble, automated supply chain data infrastructure so that there is a real-time mechanism to track supplies and predict shortages.
- Advance payment and delivery system reforms that hold providers accountable for the health of a population, budgets and transparent outcomes. This will incent improving the health of a population, which will both improve patients' comorbidities and attention to care management to sick patients. Acting within a budget helps reduce long-term financial pressure from rising healthcare costs.
- Leverage technology to implement comprehensive infection prevention and antimicrobial stewardship programs in nursing homes to provide meaningful assistance with infection control.
- Design stockpiles to create coordination rather than competition between state, local and national stockpiles.
- Leverage supply and demand data from GPOs, who serve as neutral, vendor-agnostic, and value- orientated entities to drive transparency in the supply chain and forecast demand needs.

### **Incentivizing Domestic Manufacturing**

Regarding domestic manufacturing, there are five major barriers that policy proposals must address. These barriers include: 1) capacity; 2) environmental regulations; 3) labor costs; 4) availability of raw materials; and 5) historical policy decisions that advantaged offshoring.

While Premier recognizes a need to incentivize domestic manufacturing, we also recognize a need to ensure global diversity in manufacturing. For example, moving all manufacturing onshore would create a similar overreliance on a single geographical region. Therefore, Premier recommends that there be at least three global suppliers of the final form, ancillary products and raw materials for critical medical supplies and drugs. Global suppliers should be from geographically diverse regions including at least one domestic supplier.

To stimulate domestic manufacturing, Premier has thought critically about how to incentivize manufacturers to invest in domestic manufacturing while also ensuring that domestically manufactured goods are price competitive with globally sourced products. To that end, Premier recommends a two-part approach that leverages tax credits as a mechanism for achieving these goals.

#### Part I:

- A 30% tax incentive for investments to support the domestic manufacturing of critical medical supplies and drugs, including their raw materials. Examples of how the tax incentive could be applied (not intended to be all inclusive – examples only):
  - Investments in advanced manufacturing equipment or machinery
  - Investments to repurpose existing abandoned facilities
  - Investments to build new facilities
  - Investments to expand existing facilities
  - Investments to relocate foreign facilities back to the U.S.
  - Investments to upgrade facilities to meet EPA requirements
  - Regulatory filing fees for new domestic entrants to the market (e.g. FDA, NIOSH, etc.)

- The tax incentive should be reevaluated in five years to determine its ongoing necessity and whether the incentive level can be lowered or eliminated.

#### Part II:

- A 10% tax credit on the income generated from the sale of domestically manufactured goods. This would also help lower the cost of goods manufactured domestically and make them price competitive with globally sourced products.
- To be prudent, companies found to be price gouging or selling counterfeit products by the Department of Justice, Federal Trade Commission, or other agency should not be eligible for the tax credit. Guardrails would help ensure companies aren't artificially increasing their prices to take advantage of the tax credit from higher sales prices and support the integrity of the supply chain.

To truly create a long-term domestic manufacturing infrastructure that is sustainable, incentives for onshoring manufacturing must be coupled to committed purchasing volumes so new entrants to the market have a guaranteed sales channel. To accomplish this goal while cultivating global diversity, Premier recommends that government purchasers be required to contract for critical medical supplies and pharmaceuticals from a mixture of onshore, near-shore (such as Central and South American countries) and off-shore countries. Purchase thresholds based upon a geographical region can help prioritize domestic manufacturers while ensuring global diversity and sustainability of the supply chain.

Finally, Premier recommends that Congress and the Administration consider incentives for healthcare providers to purchase domestic manufactured critical medical supplies and drugs through programs such as tax incentives, CMS bonus payments, etc. to create committed purchasing volume for domestic suppliers and offset higher acquisition costs.

### **Developing a Real-Time Inventory Data Management System**

A major barrier during the pandemic was the lack of downstream visibility into the exact quantities of critical medical supplies and drugs that were on US soil at any given time. As a result, there was a surplus of products in many parts of the nation while communities in the New York City area were operating in crisis mode and leveraging household products such as garbage bags to protect frontline workers. Moreover, because of the lack of understanding of what product availability risks existed, there was excessive purchasing of products, the emergence of unscrupulous and fraudulent vendors, and hoarding which created shortages for others.

In response to the urgent need to understand product availability and risks, the federal government stood up a health information collection process to determine these factors across the supply chain. However, this system was antiquated and created substantial additional work for healthcare providers, with hospitals being asked to report inventory on hand via Excel files. Hospitals and other providers were also being asked to report to state and local officials with similar, and sometimes different, data which created redundancies and further confusion. Furthermore, the system proved to be of little use as inconsistent data nomenclature meant hospitals were reporting "boxes" and "units" differently from one another, and in many cases, many hospitals opted to cease reporting inventory levels due to the administrative burden and fear that available products would be confiscated by the government.

A key component to an end-to-end supply chain solution is an on-call, nimble automated data collection infrastructure that the nation can call upon in any future crises similar in magnitude to COVID-19. Rather

than standing up an inadequate and duplicative system as we experienced during the pandemic, the nation needs a system that can track critical product availability - from the raw materials, to manufacturer, to distribution, to state and national stockpiles, to hospital inventory. This system would exist behind the scenes and be ready to be "turned on" in a moment's notice. It would provide visibility of supplies in hospital inventories with detailed information that would enable accurate and intelligent decisions about supply allocation and needs at the local, state, regional and national levels. This information would inform dynamic and appropriate product allocation and distribution strategies, minimize hoarding, and enable powerful and accurate prediction, enabling the nation to manage supplies during the crisis. Moreover, this data could be made available to providers in a metropolitan statistical area to help them understand community risks and enable intelligent purchasing.

This data infrastructure would also strengthen the SNS by:

- Creating visibility into inventory via a standardized data nomenclature and automated acquisition of data across the SNS, manufacturers, distributors, and within healthcare systems that is tied to real-time resource demand data.
- Providing inventory monitoring and advanced alerts of critical supply inventory levels warranting movement of product from the SNS to points of care, ramping up production of certain supplies, etc.

To accomplish these goals, policy changes are needed to provide data rights to create predictive algorithms and to acquire and utilize data for surveillance. In addition, rules must be established to provide assurances that government will not seize inventory and to ensure confidentiality around supplies held by different competitors. To encourage reporting, the policy might require that providers report the data as a condition of eligibility for receiving supplies from the SNS during pandemics.

### **Strengthening the Strategic National Stockpile**

Regarding the Strategic National Stockpile (SNS), Premier strongly supports the vision of the Administration to augment the SNS to better respond to global pandemics by enabling public-private partnerships. However, to develop a truly cohesive and holistic national strategy for addressing future global pandemics and stabilizing the U.S. supply chain to respond to surge demand for essential medical supplies and drugs, Premier believes that it is critical to take a slightly broader approach to creating a true end-to-end supply chain solution that is transparent, diverse, and reliable. In addition, it is critical to not only focus on the quantity on hand for critical supplies, but also focus on the time to inventory and ensuring the U.S. has contractual relationships established, including contingency and redundancy plans, to ramp up production expeditiously and efficiently upon identification of need.

The SNS is the supply chain of last resort for health systems, alternate site providers, and first responders. Therefore, the SNS must be built by providers for providers. The SNS must also leverage analytics and insights to assist providers in the delivery of care during global pandemics that is in the best interest of patients and ensure access to the right supplies at the right time.

Premier's vision for the next generation SNS includes the following elements that can be accomplished via a public-private partnership:

- Establish a Public-Private Advisory Council - The SNS should establish a Public-Private Advisory Council that includes representatives from the private sector such as manufacturers, group purchasing organizations, distributors, physicians, pharmacists, nurses, laboratorians, non-acute providers, patients, professional associations, and others as well as representatives from the public sector such as federal agencies (HHS, FEMA, ASPR, CDC, CMS, FDA, SAMHSA, the Veterans Health Administration, Indian Health Services, etc.), prisons, first responders, state and local representatives, and others. The advisory council should leverage a multi-committee structure to ensure the appropriate expertise is represented for specific product categories such as pharmacy, lab, nursing homes, pediatrics, etc. The advisory council will be critical to ensuring the SNS is soliciting feedback from a broad range of entities to augment its operations through a data-driven approach, remain unbiased and vendor agnostic, support a collaborative decision-making process, identify innovative products, and continuously refine the vision of the SNS. Essentially, the advisory council structure helps ensure the SNS is built by providers for providers.
- Identify A List of Critical Medical Supplies, Drugs & Other Supplies Necessary to Manage a Surge - The Public-Private Advisory Council should be tasked with:
  - Identifying the list of critical medical supplies, drugs, medical foods, and other supplies needed to treat a global pandemic and associated comorbidities that should be included in the SNS, including determining the most cost-effective product where multiple options may exist within a single product category or therapeutic category; and
  - Annually, at minimum, assessing, refining, and revising the list of critical medical supplies, drugs, medical foods, and other supplies contained in the SNS to account for product discontinuations, emerging technologies, changes in clinical guidelines, and identification of best practices.
- Create Transparent & Diverse Sourcing for Critical Medical Supplies & Drugs - Establishing a transparent, diverse, and reliable supply chain is essential for ensuring the U.S. is prepared to respond to future global pandemics. This is critical information to understand vulnerabilities, foreign reliance on manufacturing, and impact of geopolitical issues such as export bans and manufacturing shutdowns. A robust sourcing strategy for the SNS should:
  - Create transparency by obtaining upstream visibility into the supply chain to determine source of raw materials, ancillary products, and finished goods. All manufacturers contracted with the SNS should commit to providing upstream visibility into the sourcing for their products to provide a holistic view.
  - Assure diversity by ensuring there are several suppliers of raw materials, ancillary products, and finished goods from geographically diverse regions.
  - Leverage multiple sourcing options including contracting directly with manufacturers, contracting with group purchasing organizations to help aggregate purchasing volume and keep prices competitive, and recruiting and incentivizing the entry of new manufacturers for product categories that lack diversification. Policy changes may be needed to 1) permit the SNS to pursue innovative contracting methodologies to meet the vision of the next generation SNS; and 2) amend the Federal Supply Schedule to incentivize domestic manufacturing and ensure a stable supply at a sustainable price.
  - Identify and contract with at least a primary and secondary manufacturer for each critical medical supply and drug. The contract should stipulate the ability of the manufacturer to meet certain supply requirements within a specified period during surge demand,

redundancy and contingency plans for manufacturing, requirements for safety stock and warehousing of the product, and quality standards that must be ensured.

- The Public-Private Advisory Council should be tasked with:
  - Developing criteria for awarding SNS contracts to manufacturers;
  - Vetting and approving all SNS contracts to manufacturers to provide an agnostic and unbiased voting process;
  - Providing recommendations for warehousing at the product level; and
  - Prioritizing product categories for domestic manufacturing.
- Develop a Network of Stockpiles Throughout the Country - Stockpiles should be designed to create coordination, rather than competition. Stockpiles should also be curated to meet specific needs such as acute, alternate site, first responders, etc. as each segment of healthcare will have varying needs. Therefore, the SNS should develop a network of stockpiles that creates a hub-and-spoke model with the SNS as an anchor that offers a full array of services that is complemented by state and local stockpiles to optimize supply. To further optimize the availability of supplies as close to the point of care as possible, the SNS should explore opportunities to leverage health system and alternate site provider warehouses in major metropolitan areas or in rural areas. Finally, to ensure the network of stockpiles are interoperable and complementary to one another, the Public-Private Advisory Council should be tasked with developing national standards that all stockpiles must meet at minimum.
- Rotate Inventory - The SNS should rotate soon-to-expire product out of the SNS. This can be accomplished either by 1) contracting with manufacturers to rotate inventory; or 2) selling short-dated products to health systems and alternate site providers at a discounted rate. The second option would allow the SNS to recoup some expenses associated with managing the SNS and reinvest those dollars while also assisting healthcare providers with decreasing their acquisition costs. Any sale of covered outpatient drugs from the SNS should be exempted from Medicaid Best Price calculations. Rotation of inventory should also occur as products are discontinued or removed from the SNS.
- Create an Efficient & Dynamic Fulfillment Process - The current process for accessing the SNS is cumbersome and state specific. Therefore, the SNS should create a single, streamlined, and efficient electronic process for making requests of the SNS along with a standardized process for responding to requests. It is also critical for the SNS to develop a dynamic distribution methodology that leverages a data-driven approach to ensure products are available in the right place at the right time. Finally, a nimble and flexible distribution method is also needed to move supplies amongst health systems from areas with excess product or declining need to hot spots or areas with increasing needs.
- Test the Functionality, Readiness & Reliability of the SNS - To ensure the next generation SNS can deliver during future global pandemics, it is critical to periodically pressure test the system. Annually, without prior notice, the SNS should require all contracted manufacturers to provide the SNS with a specified quantity of product. An annual test allows the SNS to ensure all contracted manufacturers can expeditiously and efficiently ramp up production to meet surge demand, as well as ensure production lines remain operational and are maintained.
- Analyze & Report - Transparency regarding the efficiency and utilization of the SNS is critical to understanding its purpose and continued need. The SNS should be transparent regarding

distribution of supplies and drugs from the SNS and therefore should provide, at minimum, a detailed monthly report of what supplies were requested versus distributed to where and in what quantities. During a public health emergency, reporting should occur weekly.

## **Conclusion**

In closing, Premier appreciates the opportunity to submit a statement for the record on the Senate Homeland Security Committee hearing focusing on the gaps in the medical supply chain and nation's response to the COVID-19 pandemic. Premier looks forward to working with Congress and other stakeholders to develop a cohesive and holistic national strategy for addressing global pandemics and stabilizing the U.S. supply chain to respond to surge demand for critical medical supplies and drugs.

If you have any questions regarding our comments or need more information, please contact Soumi Saha, PharmD, JD, Vice President of Advocacy, at [soumi\\_saha@premierinc.com](mailto:soumi_saha@premierinc.com) or 732-266-5472.