

Statement for the Record

Submitted by

The Premier Inc. healthcare alliance

***Part 2: Protecting the Reliability of the U.S. Medical Supply Chain During the COVID-19
Pandemic***

Senate Finance Committee

July 30, 2020

The Premier healthcare alliance appreciates the opportunity to submit a statement for the record on the Senate Finance Committee’s hearing titled “*Part 2: Protecting the Reliability of the U.S. Medical Supply Chain During the COVID-19 Pandemic*” scheduled for July 30, 2020. We applaud the leadership of Chairman Grassley, Ranking Member Wyden and members of the Committee for holding this hearing to examine the integrity of our nation’s medical supply chain.

Background on Premier

Premier Inc. is a leading healthcare improvement company, uniting an alliance of more than 4,000 U.S. hospitals and health systems and approximately 175,000 non-acute providers to transform healthcare. With integrated data and analytics, collaboratives, supply chain solutions, and consulting and other services, Premier enables better care and outcomes at a lower cost.

Premier works around the clock with the nation’s hospitals and other healthcare providers, suppliers, distributors and federal and state agencies to ensure products get into the right hands so every patient gets the care they need. Given Premier’s unique position in the supply chain as an extension of America’s healthcare providers, we understand firsthand the impact to patient care when hospitals and health systems do not have access to the drugs and medical supplies needed to treat patients. The coronavirus outbreak underscores what Premier has been advocating for the better part of a decade – that the U.S. must be more forward-looking and strategic about our supply chain. When the system works, no one thinks about it, but in an outbreak, vulnerabilities are on display.

Premier has been a longstanding advocate for supply chain diversity and resiliency, taking lessons learned from disasters and past outbreaks such as Ebola and H1N1. Creating permanent solutions to ensure a reliable supply of critical medical supplies and drugs has been the mission of Premier since day one. We need, however, policy changes for us to continue to succeed in our work. It is critical that Congress act now to proactively address known supply chain vulnerabilities.

Premier's Leadership in 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 identify and implement innovative solutions that 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. To meet the unprecedented demand, Premier

- Used our global sourcing arm, S2S Global, to identify new sourcing of manufacturing capacity, ultimately contracting with seven different PPE factories across the globe to secure 36 million masks and respirators and 16 million gowns.
- Arranged cargo carriers and major airlines to expedite transportation of products so they could be onshore in hours, rather than months.
- Coordinated and allocated 2 million donated masks.
- Added 40 new manufacturers of COVID-19 related supplies to our national contracts using an expedited review process to rapidly increase options.
- Worked with non-traditional and adjacent industries such as distilleries, textile manufacturers, and automobile manufacturers to fill supply gaps for essentials such as hand sanitizer, isolation gowns and surgical caps.
- Created an online exchange for health systems, Resilinc, to trade PPE supplies among one another, dynamically moving specific supplies to the neediest hot spots.
- Partnered with 15 health systems to acquire a minority stake the nation's largest domestic supplier of PPE, Prestige Ameritech, such as masks and N95s.
- Leveraged our existing drug shortage program, ProvideGx, to secure additional safety stock and dedicated supplies, thereby avoiding shortages for many critical products.

In addition, Premier also worked closely with the Administration to provide data on surge demand, clinical utilization, and barriers to providing care and improving healthcare delivery during the pandemic. This work resulted in numerous waivers, regulatory flexibilities, and guidance documents that were critical during the public health emergency to prevent infection, avoid unnecessary hospitalizations for ambulatory conditions, increase availability of PPE and medical supplies, and more.

Finally, Premier played the leading role in the creation of the COVID-19 Private Sector Supply Chain Coalition, which was established to coordinate an integrated, public/private supply chain response to the challenges created by the COVID-19 pandemic. The Coalition serves as a single coordination point to share non-competitive, non-pricing information, best practices and strategies among key parties in the healthcare supply chain to promote the efficient management of supply and distribution during the COVID-19 pandemic. The Coalition's primary goals are to promote public and private sector cooperation, strengthen the healthcare supply chain, and speed answers to urgent supply challenges across hospitals and other US healthcare providers.

Premier's Reflections & Learnings From COVID-19 Response Efforts

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:
 - 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 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 where 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 US 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, nursing homes, and others.
- 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.
- Design stockpiles to create coordination rather than competition between state, local and national stockpiles. Stockpiles should be customized to meet the unique needs of various healthcare sectors, such as nursing homes.
- 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.
- Develop a real-time national syndromic surveillance system that also includes real-time supply chain demand data so that there is a means to identify a disease threat as early as possible as well as its implications on healthcare resources.
- 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.

Maintaining Supply Chain Integrity

During the pandemic, unfortunately a 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 thereby challenging the integrity of the medical supply chain.

Premier divides the gray market into two categories:

- Alternative suppliers → Legitimate product but not acquired through traditional entity in the supply chain at an elevated price. For example, N95 masks being sold at \$3-\$5 per piece whereas they normally cost \$0.30-\$0.40 per piece.
- Black market → Fraudulent, adulterated or counterfeit products at an elevated price. For example, quantities of product being offered that are physically unable to be legitimate such as an offer for 2 billion medical grade N95 masks that would normally require 10+ years to manufacture.

The emergence and continued presence of the gray market is directly related to supply chain stresses adding complexity and confusion for supply chain experts and clinicians questioning if their PPE is adequate to protect

them, their patients, and their families. In the past month, Premier has noted an increase in gray market actors with increasingly sophisticated plans rendering themselves nearly undetectable.

Throughout the pandemic response, Premier has been diligent in warning healthcare providers of the risks associated with gray market purchases and has been prudent in our response which includes vetting over 2000 gray market solicitations through 1) review of submitted documentation to evaluate business and clinical certifications; 2) clinical evaluation of the product including raw materials, production facilities, and documented integrity of their supply chain; and 3) evaluation of the business itself. To date, less than 15% of gray market solicitations have passed Premier's stringent vetting process and were considered legitimate alternate suppliers.

To help strengthen and maintain the integrity of the supply chain during this and future pandemics, Premier recommends the creation of a centralized clearing house to vet gray market offers and test products to ensure integrity. The clearing house should:

- Hold all payments in escrow until testing is validated;
- Test lot samples through a certification process;
- If the product is validated, it should be permitted for sale;
- If the product is not validated; it should be confiscated, and appropriate action be taken against the gray market actor.

Revamping 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:

- The SNS should maintain a minimum of a 90-day supply of critical medical supplies and drugs based upon surge demand from hot spots such as New York, Washington, Detroit, etc.
- The current process for accessing the SNS is cumbersome and state specific. Working alongside private sector partners, the Administration should create a streamlined and efficient process for accessing drugs from the SNS.

- The SNS should work proactively with GPOs to forecast demand and increase capacity/supply to avoid shortages.
- The SNS should work with GPOs to rotate soon-to-expire stock out of the SNS and into health systems at a discounted rate. This rotation is supposed to occur, but GPOs can make this happen and will ensure the SNS is continuously stocked with in-date products and allow the SNS to recoup some of their expenses associated with purchase of these products.
- The SNS should be transparent regarding distribution of supplies and drugs from the SNS. The SNS should provide, at minimum, a detailed monthly report of what supplies were distributed to where and in what quantities. During a public health emergency, reporting should occur weekly.
- The SNS, as well as state and local stockpiles, should be encouraged to purchase off GPO contracts to help aggregate purchasing volume and keep prices competitive.
- The SNS should work to ensure that critical medical supplies and drugs are located as close to the delivery of care as possible. This includes exploring opportunities to leverage health system warehouses in major metropolitan areas or in rural areas.
- Create a customized stockpile for nursing homes with appropriate supplies, drugs and other needs.
- Include health systems or regional buying groups as potential stockpile operators. These organizations would be responsible for managing the stockpile for the providers in a region. This would allow an efficient means to rotate inventory and assure accountability for the stockpile.

Incentivizing Domestic Manufacturing

To increase domestic manufacturing of critical medical supplies and drugs, 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. To incentivize domestic manufacturing, Premier recommends Congress consider the following policy proposals:

- Section 3101 of the CARES Act requires a report by the National Academies of Medicine (NAM) on the foreign reliance on manufacturing for critical healthcare supplies, the risk to national security, and recommendations for improving the resiliency of the supply chain. However, these recommendations are not expected to be available in the near future and, therefore, Congress should accelerate the development of this report to strengthen domestic manufacturing in the long-term.
- Offer 0% interest loans to manufacturers of critical medical supplies and drugs to incentivize increasing domestic manufacturing capacity. (for example – investing in automation to offset labor costs)
- Offer tax incentives to manufacturers of critical medical supplies and drugs to incentivize increasing domestic manufacturing capacity, similar to incentives provided during the 1980's and 1990's to incentivize manufacturing in Puerto Rico.
- Ensure there is at least:
 - One domestic supplier of the final form, ancillary products and raw materials for critical medical supplies and drugs.
 - 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.
- Incentivize the domestic farming/cultivation of raw materials needed for critical medical supplies and drugs
 - For example: cotton for PPE and swabs, pigs for Heparin, poppy for sedatives, etc.

Expanding Disease Surveillance to Detect, Identify, Model, and Track Emerging Infectious Diseases

COVID-19 has exposed one of healthcare's fundamental weaknesses: the fragmented and siloed nature of care delivery and the lack of centralized coordination when it comes to managing and preventing disease spread. The public health system continues to rely on flawed data and obsolete technology that consistently fails to accurately identify and track current cases, monitor disease progression, or predict future surges. Not only do these blind spots create opportunities for the disease to spread, they also undermine the ability to safely plan for economic recovery and re-opening of the country. Unfortunately, issues related to underfunding of and improvements to the public health infrastructure are not new.^{1 2 3}

There is a limited ability to nationally track symptoms of the pandemic, which would provide lifesaving insights as many as seven days before a patient is hospitalized with COVID-19. This inability to detect and respond is a critical missing "gating step" called for in the "Opening of America" to re-starting the economy and keeping it open. Instead, the preference has been to rely on testing, which has significant limitations. Americans need confidence that there is a means to identify a new COVID-19 surge as early as possible to allow effective containment and mitigation without adding billions in costs to national, state, and local budgets. The COVID-19 emergency underscores the need for real-time syndromic surveillance, providing an upstream alternative to identifying cases before tests can detect them or patients are hospitalized.

Conclusion

In closing, the Premier healthcare alliance appreciates the opportunity to submit a statement for the record on the Senate Finance Committee hearing on the integrity of the medical supply chain. As an established leader in the healthcare supply chain, Premier is available as a resource and looks forward to working with Congress as it considers policy options to continue to address this very important issue.

If you have any questions regarding our comments or need more information, please contact Soumi Saha, Senior Director of Advocacy, at soumi_saha@premierinc.com or 732-266-5472.

¹ Institute of Medicine 2012. For the Public's Health: Investing in a Healthier Future. Washington, DC: The National Academies Press. <https://doi.org/10.17226/13268>.

² DeSalvo KB, Wang YC, Harris A, Auerbach J, Koo D, O'Carroll P. Public Health 3.0: A Call to Action for Public Health to Meet the Challenges of the 21st Century. *Prev Chronic Dis* 2017;14:170017. DOI: <http://dx.doi.org/10.5888/pcd14.170017>

³ <https://www.astho.org/Programs/Preparedness/Public-Health-Emergency-Law/Public-Health-and-Information-Sharing-Toolkit/Collection-Use-Sharing-and-Protection-Issue-Brief/>