PREMIER TRANSFORMING HEALTHCARE TOGETHER®

March 8, 2022

Dawn O'Connell
Assistant Secretary
Office of the Assistant Secretary for Preparedness and Response
Department of Health and Human Services
200 Independence Ave., Washington, DC 20201

Re: Request for Information on the 2023–2026 National Health Security Strategy

Submitted electronically to: NHSS@hhs.gov

Dear Assistant Secretary O'Connell:

Premier appreciates the opportunity to submit comments on the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR)'s Request for Information (RFI) on the 2023–2026 National Health Security Strategy that was published in the Federal Register on February 14, 2022. Premier Inc. applauds ASPR's commitment to developing a strategy that considers lessons learned during the COVID-19 response and aims to improve the nation's medical preparedness, response, and recovery capabilities over the next five years.

In our comments, Premier reflects on the lessons learned during COVID-19 response efforts and provides recommendations to address the most critical national health security threats and public health and medical preparedness, response, and recovery challenges that demand increased attention. Specifically, Premier recommends actions that should be taken over the next five years to mitigate health security challenges by:

- Modernizing the country's data infrastructure;
- Strengthening the Strategic National Stockpile;
- Incentivizing domestic manufacturing;
- Mitigating drug and device shortages;
- Maintaining supply chain integrity; and
- Leveraging technology to prevent infections in nursing homes.

I. Background on Premier Inc.

Premier Inc. is a leading healthcare improvement company and national supply chain leader, uniting an alliance of more than 4,400 U.S. hospitals and health systems and approximately 225,000 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 200,000 ambulatory clinicians. Premier is an agnostic, data-driven organization with a 360-degree 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 is also a leader in identifying, fulfilling, and closing gaps in diverse sources for product categories and working directly with manufacturers to incentivize new manufacturers to enter the marketplace through programs

such as ProvideGx for drug shortages and S2S Global for personal protective equipment (PPE) – a strategy that proved to be critical as the country looked to increase domestic manufacturing and identify new sources of critical supplies. Premier also identified and solved a major gap for alternate site providers to obtain PPE and created an e-commerce platform, Stockd, to ensure alternate site providers could access critical medical supplies.

Premier also has a long history of partnering with the government through initiatives such as managing one of the largest Centers for Medicare and Medicaid Services (CMS) demonstration models that led to the enactment of the hospital value-based purchasing program. As a government contractor, Premier has served as a trusted advisor and has a proven track record of positive results.

A 2006 Malcolm Baldrige National Quality Award recipient, Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with healthcare providers, manufacturers, distributors, government, and other entities to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Headquartered in Charlotte, North Carolina, Premier is passionate about transforming American healthcare and ensuring healthcare providers have access to the right supplies, at the right time, to treat the right patient.

II. 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 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, including new domestic entrants of N95 masks, 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 essential products such as hand sanitizer, face shields, 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 in the nation's largest domestic supplier of PPE, such as masks and N95s, Prestige Ameritech.
- Partnered with 34 health systems to acquire a minority stake in a domestic supplier of isolation gowns, DeRoyal.
- Partnered with 80 health systems to invest in the domestic manufacturing of nitrile gloves alongside Honeywell.
- Partnered with 11 health systems to acquire a minority stake in Exela Pharma Sciences, LLC, to secure vital supply of pharmaceutical products and support domestic production.
- 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.

Premier also played the organizing and leadership 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 served as a single coordination point for the government 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 were to promote public and private sector cooperation, strengthen the healthcare supply chain, and speed answers to urgent supply challenges across hospitals and other U.S. healthcare providers. The coalition shifted its work to a standing organization, with Healthcare Ready serving as the coordinator, at the end of 2020.

Finally, Premier has worked closely with Congress to advance needed reforms to address supply chain issues. This included playing a leadership role in working with healthcare organizations, federal agencies and lawmakers to pass sections 3101, 3111, 3112, and 3121 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act to mitigate drug and device shortages necessary for patient care during the pandemic.

III. 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 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 tax 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 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.

IV. 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.
- 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.
- Develop a real-time national surveillance system that includes supply chain data so that there is a real-time 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.

- Leverage technology to implement comprehensive infection prevention and antimicrobial stewardship programs in nursing homes to provide meaningful assistance with infection control.

V. Developing a Real-Time Inventory Data Management System

A major failure 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, for example, 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 the equivalent of Excel files. 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.

An August 2021 GAO report reviewed this system, pointing to the inadequate and duplicative hospital reporting and data collection system used during the pandemic.[1] The siloed system burdened many public health authorities, practicing physicians and hospitals with time-consuming manual work all the while failing to provide early warnings of supply shortages, putting communities and patients at risk. Compounding these challenges and further splintering the nation's approach is the multitude of data reporting requests from numerous state, local, and private entities, which place a significant burden on health systems and renders data that is not real-time, standardized, reliable, actionable or usable for robust analytics.

The GAO report highlights the limitations and inefficiencies of the system put in place during the pandemic and the need for a better approach to understand the health systems' capacity to provide care and to inform the allocation of resources

- The GAO examined the new data ecosystem HHS launched during the pandemic—HHS Protect—designed to collect and share national and state-level COVID-19 data on hospital capacity and supply of ventilators, PPE and the availability of COVID-19 therapies.

- The GAO found that hospitals' existing workflows often did not align with HHS Protect, requiring them to either create new data workflows or enter and report data manually, which was done via Excel worksheets. Similarly, the way HHS asked hospitals to report on PPE supplies was not consistent with how these data are collected and maintained by hospital systems.

[1] GAO Report: COVID-19 HHS's Collection of Hospital Capacity Data. August 2021. Available at: https://www.gao.gov/assets/gao-21-600.pdf

- The GAO observed that "accurate, complete, consistent, and timely data are essential for monitoring trends at the state and regional level, and making informed comparisons between these areas and assessing the effect of public health response measures." This is a need that will persist beyond the pandemic, GAO noted.

- Instead, the nation's incomplete, inconsistent and opaque line of sight on the quantity, location, and production of critical PPE, drugs and other medical supplies left healthcare providers and government officials largely in the dark as they sought to locate needed products in the supply chain.

In addition, a February 2021 report from the Business Executives for National Security (BENS), a group chaired by Senators Hassan and Cassidy, concluded the following:

> *"Shared awareness of fast-developing crisis metrics is indispensable to an informed, effective national response. Yet, stakeholders described struggling to gain a common operating picture during the COVID-19 response. Reported obstacles included minimal data sharing and the lack of an established method to submit requests for resources and track responses in real-time.*
>
> *Compounding this problem, the national emergency response enterprise is characterized by a patchwork of antiquated, non-standard, and non-interoperable IT systems, further inhibiting coordination. Of note, the after-action report on the Crimson Contagion joint exercise expressly noted that HHS' and DHS/FEMA's use of disparate information management systems "hampered their ability to establish and maintain a national common operating picture." Developing interoperable systems, technologies, and capabilities to facilitate robust, resilient communication and data sharing between all federal, state, and local emergency operations centers will be critical to achieving this goal."*[2]

Furthermore, in recent conversations with ASPR, it was noted that only about 50 percent of state stockpiles are currently reporting into the Supply Chain Control Tower under HHS Protect. It was also noted that a major blind spot continues to be hospital inventory.

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 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.

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.

[2] Findings and Recommendations of the BENS Commission on the National Response Enterprise: A CALL TO ACTION. February 2021. Available at: https://www.bens.org/file/national-response-enterprise/CNRE-Report-February-2021.pdf

- 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, incentives must be established to encourage reporting such as providing two-way visibility into the health of the supply chain to reporting entities. .

Consistent with the findings of the GAO report and Premier's recommendations, the bipartisan *Medical and Health Stockpile Accountability Act of 2022* (H.R. 6520) would require the HHS Secretary to establish an automated supply-chain tracking application that provides near real-time insight into critical supplies available in the Strategic National Stockpile (SNS) and medical and health supply inventories in communities across the country. Specifically, the legislation would:

- Establish a system for internal tracking of supplies within the SNS during a public health emergency, natural disaster, or other unforeseen circumstance that impacts the healthcare supply chain. Tracked supplies would include only those considered critical to addressing the emergency.
- Allow for data access during an emergency by the HHS Secretary to the medical and health stockpiles of State, local, and private partners including suppliers, distributors, and hospitals that choose to participate.
- To incentivize participation, authorize $250 million across FY2022-27 for the HHS Secretary to assist State, local, and private partners in setting up automated reporting systems – preventing these entities from manually reporting via Excel during a future emergency.
- Ensure transparent and efficient mechanisms for health care entities, including hospitals, to voluntarily report data in an emergency, including detailed data regarding all relevant supplies secured and available.
- Ensure that (1) HHS protects any data from hospitals, manufacturers, and distributors shared through the application; and, (2) that Federal data collection is for monitoring and dynamic allocation and will not be used to remove or re-allocate inventory from organizations.

Premier is pressing Congress to pass *The Medical and Health Stockpile Accountability Act* will help ensure that hospitals, doctors, nurses, and others responding to health emergencies have the supplies they need when they need them to provide safe, effective care for patients and not be put in harm's way themselves. Armed with information from this inventory monitoring infrastructure, decision-makers will be better able to plan and allocate PPE, syringes, and rapid testing kits, among other critical items. This will prevent shortfalls and hoarding, move products from the SNS and other stockpiles to points of care, or ramp up production.

Development of *The Medical and Health Stockpile Accountability Act* considered stakeholder feedback from the hospital, distributor, and supplier communities as well as several federal agencies. A bipartisan companion bill will be introduced shortly in the Senate.

VI. Strengthening the Strategic National Stockpile

Regarding the Strategic National Stockpile (SNS), Premier strongly supports the need 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 broader approach than the SNS was originally designed for by 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.

  To accomplish this, statutory changes are required to amend the composition of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), the group responsible for dictating the contents of the SNS. The PHEMCE is currently led by ASPR and includes three primary HHS internal agency partners: the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA) and the National Institutes of Health (NIH), as well as several interagency partners: the Department of Defense (DoD), the U.S. Department of Veterans Affairs (VA), the Department of Homeland Security (DHS) and the U.S. Department of Agriculture (USDA). The PHEMCE currently does not include private sector feedback. This was also highlighted in a recent National Academies of Medicine report, *Ensuring an Effective Public Health Emergency Medical Countermeasures Enterprise*, that provides recommendations from an expert committee for a re-envisioned PHEMCE.

- 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 including product specifications;
  - 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.

- <u>Develop a Network of Stockpiles Throughout the Country</u> - 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.

- <u>Rotate Inventory</u> - 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.

Consistent with Premier's recommendations, the bipartisan *Protecting Providers Everywhere (PPE) in America Act* (S.308/H.R 1436) takes positive steps to create predictable, dedicated funding from the SNS to U.S. manufacturers of medical supplies required during national emergencies. The bill would create and fund a Department of Health and Human Services (HHS) pilot to:

- Create transparent and diverse sourcing for critical medical supplies by requiring the SNS to procure a percentage of applicable supplies from domestic manufacturers, with safeguards for availability and pricing.
- Test the functionality, readiness, and reliability of the SNS at least twice per year and communicate if there is an increased need for supplies.
- Create an efficient and dynamic fulfillment process by leveraging a vendor managed inventory system to promote efficient and predictable operations of the SNS while mitigating the risk of product expiration or shortages.
- Routinely transfer supplies to federal agencies or sell to the commercial healthcare market to mitigate the current risk of product expiration while also funding future replenishments of the SNS.

Premier is recommending that Congress take additional steps to modernize the nation's stockpile and boost domestic manufacturing of critical supplies by improving upon the policies in S.308/H.R 1436. These include:

- In addition to testing supplies and PPE, require a percentage of pharmaceuticals purchased for the SNS to be sourced domestically.
- Require manufacturers or agent of the manufacturer to build and maintain a robust, real-time, automated, and interoperable data collection infrastructure to support the needs of the SNS.
- Assemble a public-private advisory council to identify critical medical supplies and drugs needed to respond to a pandemic that would evolve with advances in technology, medicine and best practices. Including representatives from manufacturers, group purchasing organizations, distributors, physicians, pharmacists, laboratorians, and others would help ensure that stockpiles are built by providers for providers.

Together, these actions will provide a launching pad to:

- Help remove one of the major deterrents for manufacturers moving operations onshore, which is a lack of a predictable demand for longer-term purchasing. Premier has done this by teaming up with U.S. manufacturers to boost domestic production capacity for masks, gowns and other supplies, but we need a commitment by the federal government to scale these types of efforts.
- Allow an efficient means to rotate inventory to ensure the SNS is continuously stocked with in-date products.
- Reduce product waste while providing opportunities for health systems and other providers to purchase at a competitive rate soon-to-expire PPE and testing supplies being rotated out of the SNS.

Premier encourages ASPR to support the policies in S.308 / H.R 1436, and the additional elements outlined.

VII. Incentivizing Domestic Manufacturing

Regarding domestic manufacturing and reducing the dependence on China, 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. In addition, longer-term contracts at least three years in length will help provide ongoing volume commitments and assurance for suppliers entering the marketplace.

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.

VIII. Mitigating Drug Shortages

Premier applauds HHS' implementation of sections 3101, 3111 and 3112 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act to mitigate drug shortages necessary for patient care during the pandemic. Specifically, these provisions:

- Created a priority pathway for the review of drug shortage applications;
- Required a report examining the risk to national security as a result of drug shortages;
- Strengthened FDASIA Title X reporting requirements to include full disclosure of the problems resulting in the shortage, information concerning the extent of the shortage, its expected durations, and other information the Secretary may require;
- Extended FDASIA Title X reporting requirements to Active Pharmaceutical Ingredient (API) manufacturers; and
- Required manufacturers to maintain redundancy and contingency plans to ensure ongoing supply.

While the provisions included in CARES are monumental to continuing the fight against drug shortages, the pandemic highlighted additional vulnerabilities in the pharmaceutical supply chain warranting revisiting drug shortages legislation to strengthen the Food and Drug Administration's (FDA) ability to proactively address and respond to potential shortages. These include:

- Requiring manufacturers, including API manufacturers, to report the volume of product that is manufactured in each FDA registered facility.
    - The FDA currently collects information regarding the number of registered manufacturers in each country, but a blind spot is the actual volume of product that is produced by each facility. For example, FDA data shows that 18% of registered API manufacturers are located in India whereas

Premier data shows that upwards of 30% of the world's API is manufactured in India. On the contrary, FDA data shows that 28% of registered API manufacturers are located in the United States whereas Premier data shows that approximately 15-20% of the world's API is manufactured in the United States. Furthermore, it is estimated that upwards of 80% of the world's raw materials, also known as key starting materials, for pharmaceuticals are manufactured in China. The inability of the FDA to pinpoint the volume of product that is derived in each country results in a lack of transparency in the pharmaceutical supply chain regarding source of raw materials, API, and finished dose forms (FDF) making it difficult to assess the downstream risk to supply disruptions. This lack of transparency makes it difficult to assess the true risk to the pharmaceutical supply chain due to manufacturing delays, export bans, global pandemics, etc.

- Expanding the FDA drug shortage list to include regional shortages as well as shortages based on strength and dosage form.
    - The FDA drug shortage list currently does not account for regional shortages or shortages based on excipient, strength, or dosage form. These limitations created difficulties during the COVID-19 pandemic as drug shortages were rampant in hot spots while the majority of the nation did not experience the same. This resulted in an inability of providers and manufacturers in hot spots to move product to areas of greatest need and leverage other statutory and regulatory flexibilities that would have otherwise been applicable in a shortage situation, such as 503B compounding as an interim solution.

- Temporarily extending expiration dates for drug shortage products if determined to be scientifically sound.
    - Oftentimes during drug shortages, a compounding factor that places further strain on an already vulnerable supply chain is the need to dispose of product as it approaches its expiration date. Historically, FDA has leveraged its regulatory flexibility to extend expiration dates for drugs in shortage such as Epi-Pen, but this authority has been used very infrequently. To help combat shortages, it would be beneficial for FDA to have statutory authority to extend expiration dates when scientific evidence supports doing so. For example, this level of authority could have been very helpful for COVID-19 vaccines with millions of doses set to expire in June 2021. Having authority to extend the expiration date if scientifically sound would have provided an opportunity to vaccinate more of the U.S. population and reduced waste.

Premier urges the Administration to encourage Congress to provide FDA greater authority to further mitigate drug shortages.

IX. Mitigating Device Shortages

Premier applauds HHS' implementation of section 3121 in the Coronavirus Aid, Relief, and Economic Security (CARES) Act to mitigate device shortages necessary for patient care during the pandemic. Specifically, these provisions:

- Required device manufacturers to notify the FDA of a permanent discontinuance in the manufacture of the device or an interruption of the manufacture of the device that is likely to lead to a meaningful disruption in the supply of that device in the United States, and the reasons for such discontinuance or interruption;
- Required FDA to publish a device shortage list with information on the discontinuance or interruption of the manufacture of devices reported; and

- Prioritized and expedited review of applications and inspections for a device that could help mitigate or prevent such shortage.

While these were positive steps in the right direction and created the first ever device shortage reporting requirements, these provisions are temporary and tied to reporting only during a public health emergency. More can be done to make the device shortage program robust and akin to the drug shortage program at the FDA. This includes:

- Making permanent the device shortage requirements;
- Requiring device manufacturers to provide information about production volume for their devices, including for the raw materials;
- Requiring device manufacturers to perform risk assessments, implement risk management plans, and identify alternate suppliers and manufacturing sites; and
- Providing FDA with authority to allow temporary importation of unapproved devices, with appropriate scientific and regulatory controls, when it's in the interest of the public health.

Premier urges the Administration to encourage Congress to provide FDA greater authority to further mitigate device shortages.

X. Expanding Infection Prevention Clinical Surveillance

COVID-19 has brought to the forefront the specific challenges nursing homes face in containing the spread of infectious disease. The virus has accelerated at nursing homes because residents are generally vulnerable to its complications and more susceptible in the contained space of the facilities. While data about infections in nursing homes is limited, the CDC notes that, even prior to the pandemic, a staggering 1 to 3 million serious infections occur every year in these facilities and as many as 380,000 people die of the infections in nursing homes every year.

Infection prevention oversight and training at nursing homes is a challenge in and of itself with limited staffing and several layers or reporting requirements. This challenge is compounded by limited Electronic Health Record (EHR) functionality at the sites. Without a comprehensive infection prevention surveillance workflow, the surveillance, tracking, documenting and reporting of epidemiologically significant organisms and infection is difficult for everyday risks, such as multi-drug resistant organisms, but also when an outbreak like COVID-19 occurs.

Clinical analytics technologies are currently widely leveraged in hospitals and acute setting to detect patient care issues through surveillance, interventions and reporting capabilities that are needed to support antimicrobial stewardship programs. These systems utilize data from EHRs and have significantly helped clinicians and pharmacists in acute settings identify overuse of antibiotics and drug-bug mismatches, reduce time-to-appropriate therapy and enhance therapy for difficult-to-treat pathogens. Those health systems already utilizing clinical surveillance technology were well positioned to respond to COVID-19 before the pandemic hit.

Unfortunately, clinical analytics technologies are currently not widely used in nursing homes and other long-term and post-acute (LTPAC) settings. These settings should have the same access to tools that will help them combat infection spread during any future outbreaks of COVID-19 and during their day-to-day operations, but unfortunately funding remains a significant barrier as all the programs authorized and funded under the Health Information Technology for Economic Clinical Health (HITECH) Act excluded LTPAC providers. These entities are already challenged with meeting their more visible needs, such as testing and securing adequate PPE levels at their sites, but a comprehensive approach is additionally needed to ensure data collection is efficient, non-duplicative and

being analyzed in ways that are helpful for facilities. Furthermore, it is critical that lessons learned from meaningful use are applied forward as we develop cohesive solutions to address the lack of EHRs and clinical surveillance technology in nursing homes and create appropriate incentives for adoption.

Premier encourages the Administration and Congress to consider policies that incentivize nursing homes and other LTPAC providers to implement EHRs and electronic clinical surveillance technology to provide meaningful assistance with infection control.

XI. Maintaining Supply Chain Integrity

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

To combat the gray market and ensure supply chain integrity, Premier offers the following recommendations:

- Establish a national, centralized clearinghouse to vet all gray market offers regarding vaccine availability. A clearinghouse approach would remove the risk and guess work from efforts by healthcare providers, states and other entities to secure a reliable supply of critical medical supplies and drugs. The clearinghouse should:
    1. Hold all payments in escrow until testing is validated;
    2. Test lot samples through a certification process;
    3. Permit the sale of products that are validated; and
    4. Confiscate and take appropriate action against the gray market actor if the product is not validated.
- Require entities associated with the distribution of critical medical supplies and drugs to implement checks and balances systems, similar to suspicious order monitoring requirements for controlled substances, to identify potential diversion of products to the gray market.
- Promote the reporting of gray market offers to the FDA Office of Criminal Investigations and share reported incidents with the Federal Trade Commission (FTC).
- Implement civil monetary penalties (CMPs) for entities selling products to the gray market.
- Establish best practices for security to minimize diversion from sites.
- Broaden FDA's authority to destroy counterfeit devices that are imported into the United States.

Premier encourages the Administration to consider policies that combat the gray market and ensure supply chain integrity.

XII. Conclusion

In closing, Premier applauds ASPR's commitment to identifying both near-term and long-term solutions to bolster the nation's public health and medical preparedness, response, and recovery capabilities. Premier looks forward to working with the ASPR 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, Vice President of Advocacy, at soumi_saha@premierinc.com or 732-266-5472.

Sincerely,

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