Statement for the Record

Submitted by Premier Inc.

"Preparing for and Responding to Future Public Health Security Threats"

House Energy and Commerce Subcommittee on Health

May 11, 2023

Premier Inc. appreciates the opportunity to submit a statement for the record on the House Energy and Commerce Subcommittee on Health hearing titled "Preparing for and Responding to Future Public Health Security Threats" on May 11, 2023. Premier applauds Chairman Guthrie and Ranking Member Eshoo for holding this hearing and their bipartisan leadership. It is vital that we as a nation consider lessons learned during the COVID-19 response and improve the nation's public health infrastructure and preparedness to respond to the next public health threat. Premier further appreciates the Committee's thoughtful approach to seeking stakeholder input as part of the process of developing consensus policy proposals and the acknowledgement that collaboration across the public and private sectors is essential to ensuring the nation's readiness and ability to proactively address future public health threats. Premier previously submitted detailed comments to the Committee's request for information on PAHPA reauthorization.

The existence of PAHPA during the COVID-19 pandemic was instrumental in supporting the nation's rapid response. As a nation we would have been in a much worse situation had PAHPA's infrastructure not been in place. However, lessons learned during the COVID-19 pandemic, and subsequently the Mpox public health emergency, demonstrate that there are opportunities to strengthen PAHPA to be better responsive to public health needs during unprecedented times.

Specifically, Premier recommends revisions to PAHPA to mitigate national 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;
- Leveraging technology to prevent infections in nursing homes;
- Finding sustainable solutions to environmental issues impacting patient care;
- Identifying and bundling waivers and flexibilities for expeditious implementation during a future public health emergency;
- Broadening and better organizing lab networks;
- Ensuring emergency efforts account for the needs of disabled individuals and their families; and
- Holding manufacturers accountable for the cybersecurity of their devices.

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 250,000 continuum of care providers to transform healthcare. Premier's sophisticated technology systems contain robust data from nearly half of U.S. hospitals and 200,000 ambulatory clinicians. Premier is a data-driven organization with a 360-degree view of the supply chain, working with more than 1,460 manufacturers to source the highest quality and most cost-effective products and services.

Premier is also a leader in identifying, fulfilling and closing gaps in diverse sources for critical product categories – working directly with manufacturers to incentivize new manufacturers to enter the marketplace – 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 continuum of care providers to obtain PPE and created an e-commerce platform to ensure continuum of care providers could access critical medical supplies.

A 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.

II. ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE (ASPR)

Since the onset of the COVID-19 pandemic, the Assistant Secretary for Preparedness and Response was elevated to an operating division within HHS in 2022 and is now known as the Administration for Strategic Preparedness and Response (ASPR). With the elevation to an operating division, it was noted that ASPR "leads the nation's medical and public health preparedness for, response to, and recovery from disasters and other public health emergencies." Seemingly, this indicated the ASPR would take point on future pandemic response and alleviate much of the confusion that existed during the early days of the COVID-19 pandemic regarding which federal agency was leading response efforts.

However, shortly after ASPR's elevation a public health emergency for Mpox was declared. While many anticipated that ASPR would be named to lead response efforts given its newly elevated role and mission, it surprised many when officials from FEMA and CDC were named as the primary and secondary leads for the Mpox response.

Furthermore, the CAA of 2023 establishes within the Executive Office of the President an Office of Pandemic Preparedness and Response Policy creating further confusion regarding the role of this new office versus ASPR.

Therefore, ***Premier recommends that PAHPA reauthorization help clarify the roles and responsibilities of the various federal agencies during a pandemic response and articulate which agency, or agencies, should lead response efforts during a pandemic***.

III. NATIONAL HEALTH SECURITY STRATEGY (NHSS)

One of the three primary objectives of the NHSS is to leverage the capabilities of the private sector by:

- Developing and sustaining robust public-private partnerships for MCM development and production;
- Fostering the creation of a resilient medical product supply chain; and
- Incentivizing and sustaining private sector healthcare surge capacity for large-scale incidents.

Premier's comments in this section focus on creating a sustainable medical product supply chain.

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 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 was the multitude of data reporting requests from numerous state, local, and private entities, which placed a significant burden on health systems and rendered data that was not real-time, standardized, reliable, actionable or usable for robust analytics.

The GAO report highlighted 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. Specifically:

- 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.
- The GAO observed that "accurate, complete, consistent and timely data are essential for monitoring trends at the state and regional level, and for 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.*

[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

> *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 allow for powerful and accurate prediction, enabling the nation to manage supplies during a crisis.

This data infrastructure would also strengthen the Strategic National Stockpile (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, incentives must be established to encourage reporting such as providing two-way visibility into the medical 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, 117th Congress) 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 SNS and medical and health supply inventories in communities across the country. 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.

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.

[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

- 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 – creating efficiencies and easing burden associated with manual reporting 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 leveraged for monitoring and dynamic allocation and will not be used to remove or re-allocate inventory from organizations.

Premier supports reintroduction of this legislation in the 118th Congress to 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.

Incentivizing Domestic Manufacturing

Regarding domestic manufacturing and reducing the dependence on overseas 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 production 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 percent 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 include, but are not limited to:
    - 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 percent tax credit on the income generated from the sale of domestically manufactured goods to reward manufacturers who have already invested in domestic manufacturing. 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 with 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 on 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 consider incentives for healthcare providers to purchase domestically 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. For example, CMS recently finalized a Premier-supported payment adjustment to compensate hospitals for the increased cost of domestically produced N95 masks, however, absent Congressional action – the payment policy was implemented in a budget-neutral manner, impacting its ability to be applied broadly to additional domestically manufactured critical medical supplies. Therefore, ***Premier recommends that Congress provide CMS with statutory authority to implement payment adjustments for domestically manufactured critical medical supplies and pharmaceuticals in a non-budget neutral manner***.

Finally, ***to truly support domestic manufacturing, the FDA regulatory framework for approval must be adapted to expedite review of applications and inspections of manufacturing facilities for new domestic entrants***. As manufacturers seek to invest in onshoring the manufacturing of critical medical supplies and pharmaceuticals, it is essential that our nation's regulatory framework support, and not inhibit or deter, repatriation. As such, Congress should consider policies that expedite FDA review for domestically manufactured critical medical supplies and pharmaceuticals.

Mitigating Drug Shortages

Premier applauds Congressional action to pass 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 national security risks as a result of drug shortages;
- Strengthened FDASIA Title X reporting requirements to include full disclosure of the problems resulting in a shortage, information concerning the extent of a 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 the CARES Act are monumental to continuing the fight against drug shortages, the pandemic highlighted additional vulnerabilities in the pharmaceutical supply chain warranting a revisit of drug shortages legislation to strengthen the FDA's 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 percent of registered API manufacturers are located in India whereas Premier data shows that upwards of 30 percent of the world's API is manufactured in India. On the contrary, FDA data shows that 28 percent of registered API manufacturers are located in the United States whereas Premier data shows that approximately 15-20 percent of the world's API is manufactured domestically. Furthermore, it is estimated that upwards of 80 percent 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 creates challenges 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 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.

- ***Modernizing the FDA's data infrastructure to collect shortage signals from the private sector.***
    - Oftentimes, the warning signals of an impending shortage can be seen weeks to months in advance due to discrepancies in demand vs supply data. For example, during the COVID-19 pandemic, Premier shared weekly demand signals with the FDA for approximately 250 critical medications to help the FDA understand what medications were at risk for shortage due to increased demand. Premier's 360-degree view into the demand vs supply signals from a broad swath of our membership across multiple suppliers provided an accurate and predictive model for determining which drug products were at risk of disruption. While individual suppliers could report increases in demand to FDA, as requested in the President's FY 2024 budget, in practice individual demand signals are not telling of a potential disruption and create unnecessary and undue reporting burden on the supplier. Instead, it is critical to work with larger data sets and predictive modeling with artificial intelligence to truly understand medications at risk for disruption. Therefore, to better help the FDA predict shortages before they occur, Premier recommends that Congress provide FDA with funding to modernize its data infrastructure and work with existing private sector data sets to collect and analyze market demand signals.
- ***Leveling the playing field for all FDA inspections.***
    - Currently, the FDA assesses whether a facility is in a state of control through periodic inspections that provide an evaluation of manufacturing operations, including their system

for quality management. However, not all facilities are treated the same as domestic manufacturers are inspected regularly via unannounced inspections whereas many foreign facilities are inspected less regularly via announced inspections. This dichotomy in inspection authority creates an undue burden for domestic manufacturers and can create an incentive for manufacturers to build their facilities overseas. It is welcome news that the Fiscal Year (FY) 2023 Omnibus Appropriations Bill contains a provision requiring the FDA to establish a pilot program for unannounced foreign inspections, but the quality standard should focus on FDA approval and inspection, with all FDA-registered global manufacturers inspected equitably and consistently via unannounced inspections at the same time intervals. Both domestic and overseas manufacturers of FDFs and APIs should be held to the same standard. To level the playing field, the FDA will require the appropriate resources in highly trained and experienced inspectors and may also need additional statutory authority. Once a level playing field is adopted as policy, the FDA should provide Congress with a five-year plan, with metrics and annual targets to achieve the desired parity.

- ***Expanding drug shortage authorities to vaccines.***
    - While the FDA has statutory authority to mitigate drug shortages, vaccines are currently excluded from those authorities. Therefore, if shortages of COVID, Mpox or other vaccines needed to address and treat a public health emergency were to go into shortage in the future, FDA would have limited authority to mitigate the shortage. Therefore, Premier recommends that Congress expand FDA's statutory authority to address shortages to include vaccines.

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

Mitigating Device Shortages

Premier applauds Congressional action to pass section 3121 in the 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 U.S., 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.***
    - Currently, device manufacturers are only required to report supply disruptions to the FDA for the duration of the public health emergency. COVID-19 exposed weaknesses in the U.S. supply chain and the country's overdependence on medical supplies, devices and components imported from overseas. Shortages persist today and span a variety of categories, including supplies essential for patient care such as blood collection tubes, contrast media, tourniquets, and more. Thanks to the authority granted to FDA in the CARES act, the FDA has been able to better understand and monitor the complex web of

supply chains that feed the medical device industry and to solve problems more proactively before they occur. As a result, the FDA has recommended actions that have helped industry, providers and the nation mitigate potential damage and further disruption. But while the FDA's new authority has been important, it does not cover all situations that can lead to shortages. These can and will arise outside of public health emergencies, such as during natural disasters, device recalls, geopolitical issues, and other unforeseen circumstances impacting the supply chain. Therefore, it is critical that this authority be made permanent so that the FDA can continue this important work and proactively mitigate device shortages before they occur.

- ***Requiring device manufacturers to implement risk management plans.***
    - A key component of a resilient supply chain is having a backup plan to ensure redundancy in manufacturing and minimize supply disruptions. Therefore, Premier supports Congress extending FDA's authority to requiring risk management plans on device manufacturers. Congress provided similar statutory authority to the FDA to require risk management plans for drug manufacturers in the CARES Act.

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

Maintaining Supply Chain Integrity

During the pandemic, unfortunately a lack of clear visibility of distributor fulfillment led 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.

In the CAA 2023, Congress included the INFORM Consumers Act which establishes a national standard, enforced by the Federal Trade Commission (FTC) and State Attorneys General, that requires online platforms that allow for third party sellers of consumer products (including PPE and other medical goods) to verify the identity of high-volume third-party sellers. The CAA 2023 also strengthened FDA enforcement authority against, and increased the penalties for, selling counterfeit medical devices, including PPE, in the United States.

While the CAA 2023 made great strides, to further 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 for critical medical supplies, pharmaceuticals and vaccines. 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).
- 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 Congress to consider policies that combat the gray market and ensure supply chain integrity.

IV. NATIONAL ADVISORY COMMITTEE (NAC) ON INDIVIDUALS WITH DISABILITIES AND DISASTERS

Recently during recovery efforts for Hurricane Ian, Premier became aware of a lack of emergency services and shelters that can accommodate the specialized needs for individuals with disabilities. For example, many disabled individuals and their families that were in the path of the hurricane were unable to evacuate their homes as shelters did not have the necessary infrastructure and support services needed to care for disabled individuals. This unfortunately resulted in these individuals having to shelter in place and hope for the best. ***Premier encourages Congress to work with federal agencies such as FEMA, and relief organizations such as the American Red Cross, to provide appropriate funding to ensure that emergency efforts during a public health emergency, natural disaster, or other unforeseen circumstance account for the needs of disabled individuals and their families.***

V. 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, continuum of care 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:

- <u>Establish a Public-Private Advisory Council</u> – As outlined in section VI below, Premier urges Congress to amend PHEMCE to create a public-private advisory council.

- <u>Identify A List of Critical Medical Supplies, Drugs & Other Supplies Necessary to Manage a Surge</u> – 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. This includes broadening the scope of products maintained in the SNS beyond countermeasures to include lifesaving and protective equipment and medications, such as ventilators, PAPRs and medical gas cylinders, and the corresponding consumables, such as breathing circuits, filters and hoses that sustain life or protect front line staff. The list should be inclusive of all products

necessary to treat a potential global pandemic, including potential comorbidities, and take into account special patient populations such as pediatrics and geriatrics.
    - 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. The list should be dynamic and regularly updated.

- 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, overseas reliance on manufacturing, and the 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.

- 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, continuum of care, 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 offering a full array of services that is complemented by state and local stockpiles to optimize supply and ensure coordination. 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 a minimum.

  Better coordination amongst stockpiles would also permit a national infrastructure to absorb excess inventory that exists in state or health system stockpiles versus purchasing net new products.

- Rotate Inventory – The SNS should rotate soon-to-expire product out of the SNS. This can be accomplished either by 1) contracting with a third party vendor to rotate inventory; or 2) selling short-dated products to health systems and alternate site providers at a discounted rate, a newly created authority under the CAA 2023; or 3) maintaining a virtual inventory by working with manufacturers or private sector partners to maintain and rotate inventory on behalf of the SNS, akin the Vaccine for Children program that leverages vaccine manufacturers to maintain and rotate inventory. Critical to establishing, maintaining and rotating inventory is to avoid huge bulk purchases as they can create noise and distortion in market demand signaling. In addition, bulk purchases can result in downstream shortages as manufacturers prioritize government fulfillment over standard distribution thereby impacting the availability of products for frontline patient care. Finally, rotation of product should also occur as products are discontinued or removed from the SNS as the list of critical medical supplies and pharmaceuticals is updated annually.

- 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 submitting requests to 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, versus relying on a historical allocation process as was leveraged during the pandemic. 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.

Premier urges Congress to take additional steps to modernize the nation's stockpile.

VI. BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY (BARDA)

Throughout the pandemic, the Industrial Base Management & Supply Chain (IBMSC) Program Office within BARDA invested billions of taxpayer dollars in over 50 manufacturers to "expand, secure, and build resiliency across the entire public health and medical industrial base." In many cases, it appears that these investments were made without a formal request for proposals (RFP) process and bypassed traditional government contracting requirements, potentially cherry-picking award recipients and not providing a fair opportunity for eligible entities to compete. Furthermore, little to no information has been made available publicly regarding the ability of these manufacturers to meet their manufacturing goals and the impact to the supply chain. Therefore, ***Premier urges Congress to request an OIG report regarding the distribution of IBMSC funds, the progress to date of award recipients in meeting their contractual obligations and the impact to supply chain resiliency. Furthermore, Premier urges Congress to leverage the OIG findings to develop a process for awarding future IBMSC funds in a transparent manner and for regular public reporting of progress by award recipients.***

VII. PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISES (PHEMCE)

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. Therefore, ***Premier recommends that Congress amend the composition of PHEMCE to include private sector representation and create a true public-private advisory council.***

VIII. MEDICAL RESERVE CORPS (MRC)

During the pandemic, to help alleviate staffing challenges throughout the country, several federal resources from HHS, DOD, FEMA, the Public Health Service and other agencies were deployed to provide on-the-ground support to hospitals and health systems. In some situations, this help was welcome and beneficial. However, in certain cases, hospitals have reported that the help may have been duplicative or not geared towards the specific areas where assistance was needed the most. ***Premier recommends that Congress direct the GAO to study the effectiveness of federally deployed resources to hospitals and health systems***. The study should look at lessons learned, efficiencies created, opportunities for improvement and recommendations for how to optimize federal resources during future public health emergencies.

IX. PLAYBOOK OF REGULATORY FLEXIBILITIES FOR FUTURE NATIONAL PUBLIC EMERGENCIES

Throughout the COVID-19 pandemic, federal agencies provided a host of regulatory waivers and flexibilities that were critical to hospital operations and permitted providers to focus on patient care. While the various waivers and flexibilities were extremely helpful, they were also released in a piecemeal fashion and it was often difficult for providers to keep track of what requirements were being waived. In addition, while some waivers came expeditiously, others took time to establish such as the hospital-at-home waiver that was not established until November 2020. For future pandemics, a recent Premier survey found that the expeditious establishment of waivers and flexibilities would be essential to ensuring a prompt response from hospitals. Specifically, respondents noted that it would be beneficial if a bundle of waivers or flexibilities could be pre-identified as essential to operations during a future pandemic such that they could be immediately

implemented, and hospitals would know exactly what to expect. Therefore, ***Premier recommends that Congress direct federal agencies to identify and bundle waivers and flexibilities that would be automatically invoked and could be expeditiously implemented during a future public health emergency to improve patient care and reduce burden on hospitals and other healthcare providers.***

X. EPIDEMIOLOGY AND LABORATORY CAPACITY GRANT PROGRAM

Early COVID-19 testing was plagued by a lack of testing locations, a shortage of specimen collection swabs, inadequate lab capacity to process tests and sporadic genomic sequencing to monitor for variants. With Mpox, efforts to speed access to testing were swifter as the CDC effectively onboarded commercial labs to expand testing for Mpox within one month. While an improvement, that one month delay did have consequences creating testing bottlenecks.

As we learned during COVID-19, delays of even a day can have dire effects on limiting transmission. Instead, ***the government should broaden and better organize the lab network to include hospitals, academic medical centers, and regional testing laboratories that have the ability and capacity to perform these tests in their communities.*** Broadening the lab network will help ensure that regionally based testing can produce more timely results, empowering immediate and effective public health action. It is also critical for the nation to develop a genomic sequencing strategy for Monkeypox to stay ahead of potential variants.

XI. PUBLIC HEALTH SITUATIONAL AWARENESS AND BIOSURVEILLANCE NETWORK PROGRAMS

Syndromic Surveillance to Predict Community Outbreaks

In the early days of the pandemic, Premier leveraged clinical decision support, powered by machine-learning, artificial intelligence and natural language processing, to effectively predict COVID-19 surges and regional flare ups well before patients started showing up at the hospital for treatment. Armed with positive results, Premier advocated for federal agencies to adopt a national system for syndromic surveillance to better track and predict outbreaks – and quicken response times.

Symptoms are the earliest and most reliable indicator of the emergence of infectious diseases that threaten our nation's public health. Identifying suspected cases early is the best signal of the need to take action. However, a recent Government Accountability Office (GAO) report notes how a lack of federal action to modernize the public health data infrastructure seriously undercut efforts to combat the COVID-19 virus. This is a situation that was unfortunately replayed with the Mpox public health emergency.

America needs an automated, near real-time means to collect symptoms and confirmed case information consistently and comprehensively so that it can be shared between and among multiple public and private stakeholders, including federal, state, local, Territorial and tribal public health authorities as well as on-the-ground providers. Such a system can pull in information on symptoms, comorbidities and other vital information, allowing for targeted tracing and interventions to proactively prevent outbreaks. Earlier recognition of new hot spots speeds quarantining of potentially infected persons, reduces the spread of the virus and saves the nation money on contact tracing and testing. This reality is possible today and Congress should push federal agencies to explain how a system that was required under PAHPA in 2006 in still not operational today.

Automated Tracking and Reporting the Spread of Disease

During the COVID-19 pandemic, virtually all reporting was done using paper-based forms that were then faxed back to the state and local public health departments for recording and follow up. Reporting was limited to hospitals providing treatment for the most severe cases and labs that encountered a positive COVID-19 test. This meant public health agencies received no information from milder cases diagnosed in a physician office, or from patients self-diagnosed via at-home tests.

Fast forward to Mpox and some improvements in reporting were made. Any labs performing a Mpox test were required to report all results directly to public health departments and are strongly encouraged to submit this data electronically, as opposed to via paper forms.

However, electronic reporting is still not a requirement and public health case investigation forms used to track the source of transmission are still paper based and very lengthy (e.g. more than six pages long for Mpox). ***The federal government should require and prioritize efforts for automated, streamlined nationwide public health data collection, exchange and sharing using data and interoperability standards.***

XII. ADDITIONAL AREAS FOR CONSIDERATION

Presidential Advisory Council on Combating Antibiotic-resistance Bacteria (PACCARB)

COVID-19 has brought to the forefront the specific challenges nursing homes face in containing the spread of infectious disease. The virus accelerated at nursing homes because residents are generally vulnerable to its complications and more susceptible in the contained space of 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 annually in these facilities and as many as 380,000 people die of 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 disease outbreaks and during their day-to-day operations, but unfortunately funding remains a significant barrier as 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 more comprehensive approach is 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 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.

Strategy for Public Health Preparedness Response to Address Cybersecurity Threats

Alongside technology innovations and the frequent electronic exchange of health information, cybersecurity for medical devices and equipment has become a top priority for healthcare providers. These cyberattacks not only threaten patient privacy and clinical safety and outcomes, but also a hospital's financial resources. Alongside direct costs related to a breach, providers may see added costs in hardware, software, firmware and labor.

In the CAA of 2023, Congress required manufacturers of cyber devices to develop processes to ensure their devices are secure, have plans to identify and address cybersecurity vulnerabilities, provide a software bill of materials in their labeling, and submit this information to FDA in any premarket submissions. However, these provisions are only applicable to devices going through a traditional 510(k) pathway and it is unclear how devices and other products granted an emergency use authorization during a public health emergency would be required to comply with these provisions. Given heightened cybersecurity concerns during pandemics, ***Premier urges Congress to clarify the roles and responsibilities of manufacturers granted an emergency use authorization as it relates to cybersecurity of their devices. In addition, Premier urgers Congress to decrease fines and other civil monetary penalties for healthcare providers if they experience a cybersecurity breach due to a device granted an emergency use authorization that did not comply with FDA cybersecurity requirements.***

Port Congestion and Transportation Delays

During the pandemic, port congestion and delays in global logistics nearly doubled and tripled product lead times. This resulted in supply shortages due to an inability to prioritize cargo ships carrying healthcare supplies. These delays and shortages were further exacerbated due to shortages of drivers and impending discussions of a rail strike.

To help combat this, the private sector piloted a "fast pass" system led by the Health Industry Distributors Association. The pilot was successful in testing the ability of ports to prioritize and expedite the offloading of healthcare supplies. ***Premier urges Congress to prioritize and expedite the delivery of healthcare supplies during public health emergencies.***

Contracting and Hiring Authority

Throughout the pandemic, a rate limiting step in federal agency response was contracting and hiring authority. While some agencies had more flexibility to increase resources to meet the task at hand, other agencies did not have the same authority or flexibility to increase their staff. To better respond to future pandemics, ***Premier urges Congress to ensure all federal agencies with a potential role in response to a future pandemic have similar contracting and hiring authority to expeditiously obtain the resources necessary to adequately carry out their duties.***