PREMIER TRANSFORMING HEALTHCARE TOGETHER®

July 10, 2023

The Honorable Bernie Sanders
Chairman, Senate HELP Committee
U.S. Senate
332 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Bill Cassidy
Ranking Member, Senate HELP Committee
U.S. Senate
455 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Bob Casey
U.S. Senate
393 Russell Senate Office Building
Washington, DC 20510

The Honorable Mitt Romney
U.S. Senate
354 Russell Senate Office Building
Washington, DC 20510

Submitted electronically to: PAHPA2023Comments@help.senate.gov

Re: Feedback on Bipartisan Discussion Draft to Reauthorize the Pandemic and All-Hazards Preparedness Act (PAHPA)

Dear Chairman Sanders, Ranking Member Cassidy, Senator Casey, and Senator Romney:

Premier Inc. applauds your leadership and ongoing commitment to improving our nation's biosecurity and preparedness infrastructure through the release of a bipartisan discussion draft to reauthorize the Pandemic and All-Hazards Preparedness Act (PAHPA). Premier further appreciates your thoughtful approach to seeking stakeholder input in the development of policy proposals to ensure the nation's readiness and ability to proactively address future public health threats.

Premier supports themes within the discussion draft related to public-private collaboration, bidirectional data sharing, the need to standardize and modernize data collection, and focus on individuals with disabilities. However, while Premier believes that the discussion draft is a solid start, Premier is concerned that the draft does not sufficiently heed the lessons learned from the COVID-19 pandemic and apply them in a manner that will fundamentally alter our nation's response to future pandemics or emergency responses. Therefore, Premier urges the Senate HELP Committee to reconsider bolder, bigger, and more impactful policies for inclusion in a revised discussion draft prior to markup. Now is the opportunity for Congress to act and change the trajectory of our nation's response for future pandemics and emergency responses – and Congress must seize this opportunity to protect the communities we serve.

Premier's comments on the discussion draft focus on areas of support and additional areas for consideration in alignment with our statement for the record in connection with the Committee's May 4, 2023 hearing on PAHPA reauthorization and our March 17, 2023 letter in response to the Committee's PAHPA request for information.[1] [2]

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 approximately 250,000 continuum of care providers to transform healthcare. Premier's sophisticated technology systems contain robust data from nearly half of

[1] https://premierinc.com/downloads/Premier-Statement_HELP-Committee-Hearing_PAHPA.pdf

[2] https://premierinc.com/downloads/Premier-Comments_HELP-PAHPA-RFI_FINAL.pdf

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, a strategy that proved to be critical as the country looked to increase domestic manufacturing and identify new sources of critical supplies.

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 patients.

II. COMMENTS ON PROVISIONS INCLUDED IN THE DISCUSSION DRAFT

- SEC. 102 - HOSPITAL PREPAREDNESS PROGRAM (HPP)

  Premier appreciates inclusion of Section 102 that would enhance participation of emergency medical service (EMS) organizations in the Hospital Preparedness Program (HPP).

  Additionally, 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. 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 also amend the Hospital Preparedness Program to direct federal agencies to identify and bundle waivers and flexibilities that could be expeditiously implemented during a future public health emergency to improve patient care and reduce burden on hospitals and other healthcare providers.***

- SEC. 202 – STRATEGIC NATIONAL STOCKPILE ACCOUNTABILITY

  Premier appreciates Section 202 which requires ASPR to "utilize tools to enable the timely and accurate tracking, including the location and geographic distribution, of the contents of the stockpile throughout the deployment of such contents." However, ***Premier believes that this provision should go further than the contents of the Strategic National Stockpile and focus more broadly on the quantity and location of critical medical supplies and pharmaceuticals on U.S. soil during an emergency response.***

  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, known as TeleTracking, 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.[3] 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 nation's 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.*
>
> *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*

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

> *facilitate robust, resilient communication and data sharing between all federal, state, and local emergency operations centers will be critical to achieving this goal."*[4]

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 augment the existing Supply Chain Control Tower, 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* (H.R. 3577) 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. Specifically, the legislation would:

- Augment the Supply Chain Control Tower to establish an automated supply chain tracking application that provides near real-time insight into the amount of critical medical supplies and pharmaceuticals located on U.S. soil, from both the public and private sector, during an emergency response.
- 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.

[4] 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

- 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.

The Medical and Health Stockpile Accountability Act helps 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. Therefore, ***Premier urges Congress to include the Medical and Health Stockpile Accountability Act as part of PAHPA reauthorization.***

- SEC. 204 - PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISES (PHEMCE)

  Section 204 of the discussion draft directs the Secretary to share information related to recommendations made and strategies developed by the Public Health Emergency Medical Countermeasures Enterprises (PHEMCE) with relevant stakeholders, including industry and public health departments at various levels of government. Premier supports the inclusion of this provision which recognizes the key role of public-private partnership in supporting our national preparedness posture.

  Premier recommends that Congress go one step further in amending the composition of PHEMCE to be a public-private advisory council itself. The PHEMCE is currently led by ASPR and includes three primary HHS internal agency partners: the CDC, FDA, and NIH, as well as several interagency partners. 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***. While Section 204 shares information from PHEMCE with the private sector, and that is a step in the right direction, to create a truly robust and resilient public health response, PHEMCE should include private sector representation. Therefore, Premier recommends that Congress amend the composition of PHEMCE to include private sector representation and create a true public-private advisory council.***

- SEC. 205 - PUBLIC HEALTH AND DATA SHARING

  Section 205 would establish a pilot program for a situational awareness system that facilitates bidirectional communication between HHS and State, local and tribal public health officials. Furthermore, the system would maintain a near real-time, open-source, and publicly available website to provide deidentified, aggregated data on disease outbreak. Additional provisions of this section call for the establishment of National Public Health Data Board including members from both the federal government as well as non-federal healthcare experts and organizations.

  Premier is disappointed that Congress is seeking a pilot program of this nature, especially since Congress required HHS to better integrate U.S. data management systems to allow

stakeholders to better share information in 2006 – but HHS has yet to implement said system per a recent GAO report. In lieu of focusing on a pilot, Congress should mandate that HHS implement the system that it envisioned in 2006 – 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 should 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 reduces the spread of the virus and saves the nation money on contract 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.

Additionally, 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. Therefore, ***Premier urges Congress to add a provision requiring the federal government to prioritize efforts for automated, streamlined nationwide public health data collection, exchange and sharing using data and interoperability standards.***

- SEC. 304 and 305 - SUPPORTING INDIVIDUALS WITH DISABILITIES, CHILDREN, AND SENIORS

  Premier encouraged 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. Premier is pleased that the discussion draft addresses this ask through the establishment of grants, contracts, or cooperative agreements to train eligible entities to address the unique needs of at-risk individuals during emergency responses. Additionally, Premier appreciates the extension of funding for the National Advisory Committees on Children and Disasters (NACCD), the National Advisory Committee on Seniors and Disasters (NACSD), and the National Advisory Committee on Individuals with Disabilities and Disasters (NACIDD).

- SEC. 510 - VOLUNTEER MEDICAL RESERVE CORPS (MRC)

  Premier appreciates an additional 5 years of funding for the Volunteer Medical Reserve Corps because 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.

  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. Therefore, ***Premier recommends that Congress additionally direct the GAO to study the effectiveness of federally deployed resources to hospitals, including both the Volunteer Medical Reserve Corps and the Commissioned Corps of the U.S. Public Health Service. 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***.

- SEC. 511 - EPIDEMIOLOGY AND LABORATORY CAPACITY GRANT PROGRAM

  Premier appreciates Section 511 which provides continued funding for the Epidemiology and Laboratory Capacity Grant Program.

  Premier further recommends that Congress require the government to 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. Strengthening our national lab network will help ensure that regionally based testing can produce more timely results, empowering immediate and effective public health action.

III. ADDITIONAL AREAS FOR CONSIDERATION

- 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***. Premier recommends that ASPR serve as the lead agency during a public health emergency response.

- SUPPORTING DOMESTIC MANUFACTURING AND SUPPLY CHAIN RESILIENCY

  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***.

  In addition, ***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.

- STRATEGIC NATIONAL STOCKPILE

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:

- Establish a Public-Private Advisory Council – As outlined above, Premier urges Congress to amend PHEMCE to create a public-private advisory council.

- 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. 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.

- 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.***

- 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.

- <u>STRATEGY FOR PUBLIC HEALTH PREPAREDNESS RESPONSE TO ADDRESS CYBERSECURITY THREATS</u>

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.*** A system of this nature, and prioritization of healthcare supplies, will also help alleviate supply chain pressures during strikes and labor negotiation delays.

- 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.***

IV. CONCLUSION

In closing, Premier applauds your bipartisan commitment to improve the nation's public health response capabilities for emergencies. Premier looks forward to working with the Senate, under your leadership, to further refine PAHPA and develop a cohesive and holistic national strategy for addressing global pandemics.

If you have any questions regarding our comments, or if Premier can serve as a resource on these issues to the Committee, please feel free to contact me at soumi_saha@premierinc.com or 732-266-5472.

Sincerely,

Soumi Saha, PharmD, JD
Senior Vice President of Government Affairs
Premier Inc.