

April 12, 2024

The Honorable Katherine Tai
U.S. Trade Representative
Office of the U.S. Trade Representative
600 17th Street NW
Washington, DC 20508

Submitted electronically via www.regulations.gov

Re: Request for Comments on Promoting Supply Chain Resilience [Docket Number: USTR-2024-0002]

Dear Ambassador Tai:

Premier Inc. appreciates the opportunity to submit comments in response to the questions posed by the Office of the United States Trade Representative (USTR) regarding the promotion of supply chain resilience. Premier is dedicated to advancing supply chain resiliency at home and abroad through our domestic manufacturing initiatives, direct sourcing capabilities and constant monitoring of the level of critical medical supplies in the United States. In response to the questions posed in the request, Premier has identified several trade and investment policy initiatives that promote supply chain resilience and create a stable supply chain that is more resilient to shocks. Premier has been actively collaborating with our member hospitals and suppliers to enhance supply chain resiliency for years and our extensive experience in this space has given us key insights into effective practices and procedures.

Premier's comments focus on several key questions and include recommendations for:

- Establishing trusted trade partnerships to better support growth and investment in domestic manufacturing and services;
- Leveraging tax credits to incentivize domestic manufacturing;
- Committing to environmental standards;
- Collaborating across government and prioritizing healthcare products during public health emergencies;
- Requiring manufacturers to report shortages and raw materials data;
- Measuring supply chain resilience and the cost of inefficient resilience; and
- Promoting disadvantaged and underserved businesses.

I. BACKGROUND ON PREMIER INC.

Premier Inc. is a leading healthcare improvement company and national supply chain leader, uniting an alliance of more than 4,350 U.S. hospitals and approximately 300,000 continuum of care providers to transform healthcare. Premier's sophisticated technology systems contain robust standardized data gleaned from 45 percent of U.S. hospital discharges, 2.7 billion hospital outpatient and clinic encounters and 177 million physician office visits. 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's work is closely aligned with healthcare providers, who use a data-driven approach to remove biases in product sourcing and contracting and assure access to the highest quality products.

Premier is also a leader in identifying, fulfilling and closing gaps in diverse sources for critical product categories – working directly with manufacturers to incentivize new manufacturers to enter the marketplace

through programs such as ProvideGx for at-risk drugs and S2S Global for personal protective equipment (PPE) – a strategy that proved to be critical as the country looked to increase domestic manufacturing and identify new sources of critical supplies.

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

Finally, Premier's leadership in COVID-19 response efforts and expertise in supply chain issues was recognized by the appointment of Premier to the executive committee of the [Joint Supply Chain Resiliency Working Group](#) which is charged with ensuring that the path to a more resilient healthcare and public health supply chain is jointly established by the federal government and industry partners.

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. RESPONSE TO USTR QUESTIONS

i. How can U.S. trade and investment policy, in conjunction with relevant domestic incentive measures, better support growth and investment in domestic manufacturing and services?

Premier has been a long-standing leader and advocate for appropriate geographic diversity to mitigate risk, reduce overreliance, and help create a more sustainable and secure healthcare supply chain for U.S. providers and patients. While there is a need to incentivize domestic manufacturing, global diversity is also vitally important; moving all manufacturing onshore – if it were even possible in some instances - would create a similar overreliance on a single geographical region. Ideally, Premier recommends that there be at least three global suppliers of the final form, ancillary products and raw materials for critical medical supplies – with at least one supplier being domestic.

U.S. trade and investment policy can better support growth and investment in domestic manufacturing and services by creating opportunities to collaborate with other countries that adhere to our environmental and labor standards. Premier supports existing legislation that would accomplish this goal. *The Medical Supply Chain Resiliency Act* ([S.2115/H.R. 4307](#)), introduced by Senators Carper and Tillis and Representatives Steel and Schneider, authorizes the President to enter into trade agreements for the reciprocal elimination of duties and import restrictions on medical goods. It would establish trusted trade partners that would enable the diverse sourcing of medical devices and pharmaceuticals while also enabling timely access to the vital supplies providers need to care for patients during a public health crisis or national security threat.

Recently, the Department of Defense (DoD) released a [report](#) on the pharmaceutical supply chain risks for the agency that confirms ongoing challenges in this respect. The DoD's report showed that 54 percent of the DoD pharmaceutical supply chain of active pharmaceutical ingredients (APIs) is sourced from either high or very high-risk suppliers. Of the very high-risk suppliers, 5 percent of the APIs came from China and 22 percent came from an unknown source. Additionally, for the high-risk suppliers, 27 percent came from non-Trade Agreements Act (TAA) compliant suppliers, with India being the most predominant country, supplying 26 percent of the APIs. Furthermore, the report indicated that somewhere between 17 percent and 32 percent of the drugs from the Food and Drug Administration (FDA) Essential Medicine List were having availability issues as of August 2023.

The volatility of these supply chains, and lack of redundancy, affects the wider U.S. healthcare system beyond DoD. According to PINC AI™ [data](#), healthcare providers are 2.5 times more likely to experience shortages on products in unhealthy markets – when a category has two or fewer manufacturers representing 80+ percent of market share. A trusted trade partnership would not only create new trade and investment opportunities abroad but generate growth and investment in domestic manufacturing and services, insulating some of our most critical supply chains from shocks.

ii. What existing or new tools could help ensure that growth in domestic manufacturing and services does not undergo the same offshoring that we have experienced over the past few decades?

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

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 expand domestic capacity, manufacturers need assurances of longer-term purchasing and a recognition of the required capital investments. Targeted tax incentives can stimulate investments in domestic manufacturing while also ensuring that domestically manufactured goods are priced competitively with globally sourced products. Premier has been working closely with Rep. Wenstrup on [legislation](#) that would leverage tax credits as a mechanism for achieving these goals. The bill, which is currently in [draft format](#), includes:

- A 30 percent tax incentive for investments in advanced manufacturing equipment or machinery to support the domestic manufacturing of critical medical supplies and drugs.
- A 30 percent tax incentive for investments to upgrade facilities to meet Environmental Protection Agency (EPA) to support the domestic manufacturing of critical medical supplies and drugs.
- To reward entities that have already invested in domestic manufacturing, a 10 percent tax credit on the income generated from the sale of domestically manufactured goods. This would also help lower the cost of goods manufactured domestically and make them price competitive with globally sourced products. Guardrails would help ensure companies aren't artificially increasing their prices.
- To underscore the intersection between supply chain resilience and national security, only the production of certain supplies would qualify for incentives. The bill identifies those critical drugs and devices, focused on products that are on the FDA and DoD lists of Essential Medicines, Medical Countermeasures, and Critical Inputs, the FDA List of Critical Medical Devices, and the DoD Joint Deployment List.

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 in new trade agreements the USTR work with government purchasers to contract for critical medical supplies and pharmaceuticals with 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, to support domestic manufacturing, the FDA regulatory framework 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.

iii. How can U.S. trade and investment policy promote a virtuous cycle and “race to the top” through stronger coordination and alignment on labor and environmental protections within trusted networks among regional and like-minded trading partners and allies?

Premier believes that leveraging tax credits and committing to environmental protections will promote a virtuous cycle and “race to the top.”

The aforementioned legislation Rep. Wenstrup is expected to introduce would provide a 30 percent tax incentive so manufacturing facilities can make investments in upgrades to meet EPA requirements and adhere to environmental protections. For example, the EPA recently released the final ethylene oxide sterilization rule, and sterilizers and manufacturers of devices could utilize the tax credit, once implemented, to meet the new standards.

In addition, there is existing legislation that implements environmental tax credits as part of the Inflation Reduction Act (IRA), which many healthcare providers are beginning to take advantage of. The tax credits from the IRA apply to non-profit organizations and include:

- Production Tax Credit for Electricity from Renewables
- Clean Electricity Production Tax Credit
- Investment Tax Credit for Energy Property
- Clean Electricity Investment Tax Credit

Entities need to take advantage of tax credits, but also must commit to tackling climate change. As part of our efforts to improve the health of our nation’s communities, Premier pursues our mission as prudent stewards of the environment. We strive to identify products and services that not only help our members protect the environment but also seek to integrate environmentally friendly practices into our own operations. Premier’s Environmental Policy, affirmed by Premier’s Board and senior management, continues to serve as the base for our environmental initiatives. In addition to our own environmental policy, Premier is a signatory to the Office of Climate Change and Health Equity (OCCHE) [pledge](#) from the U.S. Department of Health and Human Services. Organizations pledged to:

- Reduce their emissions by 50 percent by 2030 and to net zero by 2050;
- Complete an inventory of supply chain emissions by 2024;
- Develop a climate resilience plan for facilities and communities; and
- Designate an executive lead for this work.

Premier believes that Congress and the Administration can help create incentives to drive greener choices for the safety and health of patients, workers and the environment by:

- Giving healthcare providers a seat at the table in setting emissions goals and other climate-related targets. It is critical that, once climate-related targets are identified, healthcare entities are given a reasonable runway to implement such targets.
- Considering incentives for healthcare providers to purchase greener medical supplies and pharmaceuticals.
- Creating incentives for manufacturers of critical medical supplies and pharmaceuticals to manufacture products using more environmentally sustainable processes and materials.

iv. What are examples of trade and investment policy tools that potentially could be deployed in the following sectors to enhance supply chain resilience? In these sectors, what features of the current policy landscape are working well, or less well, to advance resilience?

COVID-19 exposed weaknesses in the U.S. supply chain and the country's overdependence on medical goods and pharmaceuticals imported from overseas. 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 (HIDA). The pilot was successful in testing the ability of ports to prioritize and expedite the offloading of healthcare supplies and legislation has since been introduced to codify the program known as the FAST PASS Act ([H.R.6140](#)). Premier recommends USTR implement stipulations into trade agreements that prioritize and expedite the delivery of healthcare supplies during public health emergencies.

In addition, Premier urges USTR to review legislation such as The Medical and Health Stockpile Accountability Act ([H.R.3577](#)) which would require the Administration for Strategic Preparedness and Response (ASPR) to establish an automated supply chain tracking application that provides insight into critical medical supplies across the country. The Medical and Health Stockpile Accountability Act is designed to ensure the nation's healthcare providers and the patients they care for never again face the widespread supply shortages and uncertainty that plagued the U.S. during the pandemic. One of the most vexing problems that presented during the pandemic was the lack of visibility into the quantity and location of critical medical supplies and pharmaceuticals on U.S. soil. As highlighted by the [GAO](#), the opaqueness of the healthcare supply chain failed to provide us with early warnings of supply shortages and the information necessary to overcome them.

Specifically for medical products, one aspect of the current policy landscape that is working well is provisions from the CARES Act that bolster supply chain resilience, including:

- Requiring device manufacturers to notify the FDA during a public health emergency 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;
- Requiring FDA to publish a device shortage list with information on the discontinuance or interruption of the manufacture of devices reported; and
- Prioritizing 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. To enhance supply chain resilience, Premier recommends the USTR include medical supply shortage requirements into trade agreements to aid the FDA in making the device shortage program robust, which would include:

- Permanent reporting of device shortages
 - The FDA's new authority 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.
- 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. Premier recommends that USTR work with trade partners to ensure manufacturers of goods critical to national security, such as medical supplies and pharmaceuticals, have risk management plans.

Regardless of what specific provisions, USTR deems appropriate for future trade agreements, Premier urges USTR to collaborate across government, and particularly with FDA to further mitigate device shortages and increase supply chain resiliency.

vii. How can the development of technical standards and regulations support supply chain resilience?

There is currently a lack of consistent and reliable data for government agencies on the specifics of where and what healthcare products are produced. For example, the FDA currently collects information regarding the number of registered manufacturers in each country, but a blind spot is the actual volume of products produced by each facility. [FDA data](#) shows that 18 percent of registered API manufacturers are in India whereas Premier data shows that upwards of 30 percent of the world's actual API is manufactured in India. Similarly, FDA data shows that 28 percent of registered API manufacturers are in the United States whereas Premier data shows that only 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 (KSMs), 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 the 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, and decreases supply chain resiliency.

Premier recommends that in future trade agreements and initiatives, USTR require that manufacturers, including API manufactures, report the volume of product that is being manufactured in an FDA-registered facility.

viii. There is concern that preferential rules of origin in free trade agreements can operate as a “backdoor” benefiting goods and/or firms from countries that are not party to the agreements and are not bound by labor and environmental commitments. What actions could be taken to mitigate these risks and maximize production in the parties? What policies could support strong rules of origin and adherence to rules of origin?

Establishing a transparent, diverse and reliable supply chain is essential for ensuring the U.S. is prepared to respond to future global pandemics and public health crises. Those supply chains also must adhere to international law and the stipulations around preferential rules of origin set forth in trade agreements like the United States Mexico Canada Agreement (USMCA). However, areas of the healthcare supply chain are susceptible to being used as a “backdoor,” such as the KSMs and APIs used in the production of pharmaceuticals, the raw materials used in the production of PPE and the critical minerals used in medical devices.

To mitigate the risk of inputs and raw materials as a “backdoor,” there needs to be transparent & diverse sourcing of critical medical supplies & drugs, that will in turn establish a transparent, diverse and reliable supply chain. In order to do this, it is essential that the U.S. have upstream visibility into our medical supply chains and understand vulnerabilities. Premier recommends USTR utilize stipulations in trade agreements to:

- Establish transparency guidelines so that government agencies can obtain upstream visibility into the supply chain to determine the source of raw materials, ancillary products, and finished goods. All manufacturers contracted with the Strategic National Stockpile (SNS), DoD, or other government agency should be given upstream visibility into the sourcing for their products to provide a holistic view.

- Create stipulations within government contracting that identify the primary and secondary manufacturer for each critical input for PPE, drugs, and devices. Contracts 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.
- ix. What factors are driving supply chain and sourcing decisions, and how does trade and investment policy impact them? How do companies factor geopolitical risk into their global and domestic manufacturing and sourcing decisions? How do companies take into account traceability and transparency considerations in supply chain and sourcing decisions?**

Global healthcare supply chains are a complex labyrinth of manufacturers, raw material suppliers, subcontractors and more. In many cases, companies selling finished goods know their immediate suppliers, but have limited knowledge of the locations where finished products and their components are manufactured – and in what quantities. Supply chain sourcing requires building in redundancies and diversifying production and sourcing to mitigate risk and reduce overreliance on any single supplier, country or region.

One of the most critical lessons Premier learned during the COVID-19 pandemic is that when the United States outsources too much of our manufacturing and sourcing capabilities overseas, we create vulnerabilities for providers and patients here at home. For instance, after learning that 90% of all face masks were produced in China and highly susceptible to shortages, Premier and 15 leading health systems pooled resources to secure a minority stake in [Prestige Ameritech](#), one of the nation's only domestic producers of face masks and other PPE. In exchange for the cash infusion and long-term purchase commitment, the company is now making 5 million masks per month that it ordinarily would have little incentive to make.

In the past, economics pushed many manufacturers of healthcare supplies and drugs to source their products from overseas where tax incentives and lower-cost labor enabled cheaper production. One of the most staggering examples is that over time, this led to a dynamic where 80 percent of all PPE was sourced from East Asia, primarily China. However, new policy initiatives have led to the nearshoring effort we see today, with [96 percent](#) of manufacturing CEOs evaluating reshoring their operations, deciding to reshore or have already reshored – an increase from 78 percent in 2022.

Additionally, Premier believes in diverse – not just domestic – sourcing for critical supplies, including raw materials, pharmaceutical ingredients and finished drugs. As noted earlier, Premier believes there should be three or more global suppliers and at least one U.S.-based source readily available to serve the American people. This diverse and balanced approach is not just a better contingency plan for emergencies, but it also recognizes the need for global sourcing to keep costs in check and help alleviate U.S. national security concerns. It is also crucial to have upstream visibility and traceability into where each component of a finished product is made, and in what quantities. Premier requires all contracted suppliers to disclose API sources and finished-drug manufacturing locations, as well as the inputs for other medical supplies.

Geographically diverse and U.S.-based manufacturing will help reduce overreliance on any single country or region for healthcare supplies and medications, including our own. Premier is continuously adding diversity into our portfolio and taking advantage of domestic investments to ensure greater preparedness, protect patients and healthcare workers and insulate our supply chains from shortages in the future.

xi. How can supply chain resilience be measured, including the costs of insufficient resilience, and the impacts of trade and investment policy on resilience? What are appropriate quantitative or qualitative data to consider?

Supply chain resilience can be measured by how affected supply chains are during public health crises, geopolitical threats, natural disasters and transportation delays. In order to be resilient to these shocks, supply chains must diversify across domestic and offshore markets for healthcare products and drugs. By this definition and based upon data from [Premier's 2023 supply chain resiliency survey](#), our healthcare supply chains are not as resilient as they need to be, but we are making progress.

Hundreds of U.S. healthcare leaders in operations and clinical roles were surveyed, and 75 percent of respondents expected supply chain challenges to worsen or remain the same over the next year. They cited increased labor costs and availability, inflationary pressures, and ongoing disruptions and product shortages. Additionally, 39 percent of leaders surveyed anticipated that the largest operational and financial challenges for their organization would be supply chain disruptions, backorders and product shortages. However, supply chain resiliency does not just mean having product availability, but it also entails financial stability. PINC AI™ data shows \$1.1 billion in increased hospital spend in 2022 tied to purchases of substitute products when the original product was unavailable due to shortage.

Moreover, in the post-pandemic environment, healthcare providers are still experiencing shortages of hundreds of various products. On average, PINC AI™ data shows larger health systems are experiencing shortages for upwards of 600 unique products and 200-300 drugs per month. The rate of product backorders is currently double the rate prior to the pandemic in early 2020. Additionally, these shortages have arguably become more challenging to manage. PINC AI™ data indicates that shortages are largely shifting from multi-year, pervasive issues to an unpredictable set of new products/categories every month.

Furthermore, the reality of tracking down equivalents to shortage items – and managing their downstream clinical and operational impacts – further burdens healthcare supply chain teams already struggling with inflationary pressures and workforce challenges. More than 75 percent of U.S. healthcare leaders said their teams are spending 10+ hours per week mitigating supply chain challenges and shortages, according to Premier's survey. Thirty seven percent said they are spending more than 20 hours, and some organizations are reporting 80+ hours spent weekly managing product availability concerns.

Premier's belief is that a successful supply chain strategy includes domestic and diverse manufacturing. To that end, our contract portfolio includes ~3450 active contracts with 1460 distinct supplier partners in 590+ categories that manufacture in diverse locations, including the United States, North America, South America, Europe, Africa and Asia. Overall, future trade and investment policy is crucial towards achieving manufacturing resiliency, redundancy and quality investments.

xii. How can U.S. trade and investment policy support supply chains that are inclusive of small, disadvantaged businesses and underserved businesses, including minority owned and women-owned businesses, veteran-owned businesses, service-disabled veteran owned small businesses, and HUBZone businesses, and promote trade opportunities in underserved communities?

Premier believes that trade and investment policy should incorporate diversity, equity, inclusion and belonging (DEI&B) strategies that are inclusive of minority, women, veteran, service-disabled and small businesses. Diverse and local suppliers and small businesses can be key to helping prevent shortages and increase supply chain resiliency. Premier incorporates our DEI&B strategy into our member-facing solutions to move the industry toward more diverse and resilient sourcing.

Together with our members, Premier created a Supplier Diversity Pledge, codifying commitments to equitable business opportunities that result in the inclusion, growth and increased spend with diverse suppliers. Alongside 400+ contracts with diverse suppliers (minority, veteran, women and LGBTQ+-owned and small businesses), Premier is fostering an environment rich in diversity where our members bring equity and distinct perspectives to their supply chains. This is a natural progression of [Premier's Sourcing Education and Enrichment for Diverse and Small Suppliers \(SEEDS™\) program](#), which provides resources and tools to help suppliers contract with members and build long-term relationships.

Additionally, Premier recognized that our industry has historically lacked a standardized system to measure and benchmark DEI&B spend even though accrediting organizations and certification types exist. To address these gaps, Premier expanded its innovative technology solution set to allow providers to easily identify and engage with diverse and local suppliers and small businesses – and monitor progress on an ongoing basis. Alongside the data and critical benchmarks, providers today are advancing DEI&B efforts within the supply chain, supporting an enterprise-wide strategy and commitment, and with ongoing goal setting and metrics evaluation.

Promoting diverse business and trade opportunities in underserved communities is just as important as being able to track what is going on. Premier recommends that USTR reach agreements that increase these opportunities and dedicate resources to tracking them.

III. CONCLUSION

In closing, Premier appreciates the opportunity to submit comments in response to the request for comments on promoting supply chain resiliency. Premier looks forward to continuing our work in this space and collaborating with the Office of the United States Trade Representative to address these critical supply chain issues.

If you have any questions regarding our comments, or if Premier can serve as a resource on these issues, please do not hesitate 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.