PREMIER TRANSFORMING HEALTHCARE TOGETHER®

October 18, 2023

The Honorable Bill Johnson
Chairman
House Energy and Commerce Committee
Subcommittee on Environment, Manufacturing, and Critical Materials
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Paul Tonko
Ranking Member
House Energy and Commerce Committee
Subcommittee on Environment, Manufacturing, and Critical Materials
2125 Rayburn House Office Building
Washington, D.C. 20515

Re: Exposing EPA Efforts to Limit Chemicals Needed for Life-Saving Medical Devices and Other Essential Products

Dear Chairman Johnson and Ranking Member Tonko:

Premier Inc. appreciates the opportunity to submit comments to the Environment, Manufacturing, and Critical Materials Subcommittee in connection with its hearing entitled "Exposing EPA Efforts to Limit Chemicals Needed for Life-Saving Medical Devices and Other Essential Products" on October 18, 2023. We applaud the Subcommittee for examining this critical issue.

Premier is equally dedicated to weighing environmental responsibilities with our ability to sustain patient care across the country. Earlier this year, the Environmental Protection Agency (EPA) issued a proposed rule entitled "National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review [Docket Number EPA-HQ-OAR-2019-0178]" which was published in the April 13, 2023, Federal Register. Premier submitted comments on the EPA proposal, which would amend the National Emission Standards for Hazardous Air Pollutants (NESHAP) and aims to strengthen and update Clean Air Act standards for ethylene oxide (EtO) emissions from commercial sterilizing facilities.

For years, Premier has called for the EPA to expeditiously define clear and workable standards in this space and also provide a sufficient timeframe for medical device sterilizers to meet those standards. Development of national standards is critical to provide certainty, ensure rational decision-making that is in the best interest of potentially impacted communities, and ensure critical medical supplies are available for patient care. Given the intense supply chain pressures our nation has faced during the pandemic, building towards true domestic resiliency requires us to think cohesively about how national standards and regulations support that goal. Today, EtO sterilization capacity for medical devices is extremely limited, particularly in the U.S., and any disruption creates risk of significant shortages of essential medical devices.

Premier has concerns that the proposed rule issued by EPA does not adequately balance the need to protect and enhance environmental stewardship in the communities we serve with preventing medical device shortages and downstream impact to patient care. Premier believes there are opportunities to balance these needs and proactively mitigate potential medical device shortages through public-private collaboration.

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I. BACKGROUND ON PREMIER INC.

Premier is a leading healthcare improvement company and national supply chain leader, uniting an alliance of 4,350 hospitals and approximately 300,000 continuum of care providers to transform healthcare. With integrated data and analytics, collaboratives, supply chain solutions, consulting and other services, Premier enables better care and outcomes at a lower cost. Premier's sophisticated technology systems contain robust data gleaned from nearly half of U.S. hospital discharges, 812 million hospital outpatient and clinic encounters, and 131 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 drive the product and service contracting decisions using a data driven approach to remove biases in product sourcing and contracting and assure access to the highest quality products.

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 stakeholders 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. PROPOSED IMPLEMENTATION TIMELINE AND IMPACT TO MEDICAL DEVICE SHORTAGES

Under EPA's proposed rule, facilities would have 18 months to comply with the revised requirements upon finalization of the rule and the establishment of an effective date. ***While Premier believes that 18 months is an aggressive, yet feasible, timeline for compliance for an individual facility, Premier is concerned that the proposed timeline is not adequate when accounting for facilities in the aggregate***. Premier's view regarding the inadequate timeline stem from two main concerns:

- First, Premier recognizes that facilities will have to be offline for a period of time to upgrade their machinery and systems to the new standards. When multiple facilities are offline at the same time, production slowdowns or stoppages can create downstream impacts for providers and patients where medical device shortages are imminent. In 2019, Premier analyzed sterilization capacity across the nation and concluded that most third-party EtO sterilization facilities operate at 90 percent capacity, which equates to approximately 1 billion units of excess sterilization capacity in the U.S. In other words, based on Premier's calculations, the U.S. would exceed its excess sterilization capacity if four or more medium-sized facilities were offline at the same time – resulting in shortages of medical devices and impacts to patient care. ***To avoid exceeding the United States' sterilization capacity and inadvertently triggering medical device shortages, Premier has strongly urged the EPA to ensure an adequate implementation timeline that permits facilities to stagger when they are offline for upgrades.***

- Second, Premier recognizes that a handful of companies produce the equipment required to meet the proposed EPA guidelines, and therefore, a rate-limiting step in compliance for sterilization facilities may be the availability of the necessary equipment and skilled labor needed to install and test it. ***Premier has strongly urged the EPA to ensure an adequate implementation timeline that accounts for potential supply chain shortages for the equipment, materials and labor necessary to meet new emissions requirements***. Sterilization facilities should not be penalized for their inability to comply with the 18-month timeline if due to shortages or backorders of necessary equipment.

III. RECOMMENDED REVISED IMPLEMENTATION TIMELINE TO MITIGATE MEDICAL DEVICE SHORTAGES

To meet the end goal of addressing EtO concerns while also addressing the unintended negative consequences that facility closures may have on medical device shortages and patient care, Premier recommended the following revised implementation timeline in conjunction with a public-private collaborative approach:

1. Premier recommended that EPA amend the overall implementation timeline to 36 months from the date of finalization and establishment of an effective date. The goal in extending the implementation timeline would be to allow facilities to stagger their implementation and minimize the number of facilities that are offline at the same time, thereby minimizing the impacts to production, and therefore, medical device shortages. While the overall implementation timeline should be 36 months, each individual facility should be granted 18 months within the broader window to complete their upgrades and come into compliance with the new requirements.

2. Premier recommended that the EPA include in the final rule a strong recommendation that device manufacturers and sterilizers work together to voluntarily notify the U.S. Food and Drug Administration (FDA) of anticipated supply disruptions, per Section 2514 of the Consolidated Appropriations Act, 2023 (P.L. 117-328), to their medical devices because of upgrading sterilization facilities. A disruption analysis and notification to the FDA should occur within 60 days of finalization of the EPA rule.

3. Premier recommended that upon receipt of supply disruption notifications, the FDA work in coordination with the EPA and private sector entities to understand the downstream impacts to patient care. The public-private entities should work together to determine a staggered implementation timeline for sterilization facilities such that medical device shortages are minimized, and ideally eliminated. For example, two facilities that both sterilize a critical medical device should have their implementation timelines staggered such that the nation is never in a situation where all sterilizers of a critical product are offline at the same time. In addition, the public-private entity should work across sterilizers to understand the ability to leverage excess sterilization capacity in the most efficient manner to further minimize medical device shortages and impact to patient care.

4. To accommodate items number 2 and 3 above, Premier recommended that the effective date be at least 120 days after publication of the final rule. The first 60 days after publication of the final rule will be necessary to collect information on anticipated supply disruptions and the second 60 days will be necessary for the public-private entities to review the information and develop an appropriate staggering strategy.

5. Premier recommended that the public-private entities continually reevaluate the staggering strategy to ensure it remains flexible and nimble, as needed, to address any sudden needs or changing dynamics.

Patients and families need to be top of mind, meaning the industry's charge is to find a path forward that addresses EtO concerns while carefully weighing the unintended consequences that facility closures have on patient care and caregivers. The FDA, EPA and private industry must unite to cohesively designate a reasonable timeframe for sterilization facilities to achieve the mark while minimizing medical device shortages. ***Premier strongly urges the EPA to extend the overall implementation timeline to 36 months to permit for a staggered approach to compliance, and to work with public-private entities to minimize impacts to the healthcare supply chain and patient care***.

IV. CONCLUSION

In closing, Premier appreciates the opportunity to share comments with the Subcommittee. We look forward to working with the Administration and lawmakers to achieve policies that balance the need to protect the communities we serve with preventing medical device shortages and downstream impact to patient care.

If you have any questions regarding our comments, or if Premier can serve as a resource on these issues, 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.