June 27, 2023

The Honorable Michael S. Regan
Administrator
Environmental Protection Agency
Mail Code 1101A
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Submitted electronically via www.regulations.gov

Re: 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]

Dear Administrator Regan:

Premier Inc. appreciates the opportunity to submit comments to the Environmental Protection Agency (EPA) on the 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. The EPA is soliciting public comment on a proposed rule amending the National Emission Standards for Hazardous Air Pollutants (NESHAP) which aims to strengthen and update Clean Air Act standards for ethylene oxide (EtO) emissions from commercial sterilizing facilities.

Premier is equally dedicated to weighing environmental responsibilities with our ability to sustain patient care across the country. For years, Premier has called for the EPA to expeditiously define what "good" looks like in this space and 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. Therefore, ***Premier has significant concerns that the EPA's proposed rule 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's comments focus on opportunities to better balance these needs and proactively mitigate potential medical device shortages through public-private collaboration.

I. Background on Premier Inc.

Premier is a leading healthcare improvement company and national supply chain leader, uniting an alliance of 4,400 hospitals and approximately 250,000 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. In addition, Premier operates the nation's largest population health collaborative, having worked with more than 200 ACOs.

Premier is a long-standing national leader in addressing disruptions and strengthening the U.S. healthcare supply chain. For example:

- Premier worked closely with the Administration to provide data on surge demand, clinical utilization, and barriers to providing care and improving healthcare delivery during the pandemic. This work resulted in numerous waivers, regulatory flexibilities and guidance documents that were critical during the public health emergency to prevent infection, avoid unnecessary hospitalizations for ambulatory conditions, increase availability of personal protective equipment (PPE) and medical supplies, and more.
- Premier also played the organizing and leadership role in the creation of the COVID-19 Private Sector Supply Chain Coalition, which was established to coordinate an integrated, public-private supply chain response to the challenges created by the COVID-19 pandemic. The Coalition served as a single coordination point for the government to share non-competitive, non-pricing information, best practices and strategies among key parties in the healthcare supply chain to promote the efficient management of supply and distribution during the COVID-19 pandemic. The Coalition's primary goals were to promote public and private sector cooperation, strengthen the healthcare supply chain, and speed answers to urgent supply challenges across hospitals and other U.S. healthcare providers. The coalition shifted its work to a standing organization, with Healthcare Ready serving as the coordinator, at the end of 2020.
- Premier has worked closely with Congress to advance needed reforms to address public health and supply chain issues. This included playing a leadership role in working with healthcare organizations, federal agencies and lawmakers to pass sections 3101, 3111, 3112, and 3121 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act to mitigate drug and device shortages necessary for patient care during the pandemic.
- 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 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 the 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 strongly urges 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 strongly urges 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 recommends the following revised implementation timeline in conjunction with a public-private collaborative approach:

1. Premier recommends that the 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 recommends 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 recommends that upon receipt of supply disruption notifications, the FDA work in coordination with the EPA and private sector entities, such as Premier, 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 who 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 recommends 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 recommends 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 submit comments on the proposed rule "*National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review.*" Premier looks forward to working with the EPA to finalize the rule in a manner that balances 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 need more information, 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.