HEALTHCARE SUPPLY CHAIN ASSOCIATION
Innovators In Evidence-Based Sourcing

**June 26, 2023**

**Submitted Electronically via https://www.regulations.gov/document/**

U.S. Environmental Protection Agency
EPA Docket Center
1200 Pennsylvania Avenue NW
Washington, DC 20460

**Re: Request for Comments on the Proposal to Reduce Ethylene Oxide Emissions from Commercial Sterilization Facilities [Docket No. EPA-HQ-OAR-2019-0178-0154]**

On behalf of the Healthcare Supply Chain Association (HSCA), we appreciate the opportunity to provide comments to the U.S. Environmental Protection Agency (EPA) regarding the proposed amendments to the National Emission Standards for Hazardous Air Pollutants (NESHAP) for the Commercial Sterilization Facilities source category.

HSCA represents the nation's leading healthcare group purchasing organizations (GPOs), the sourcing and purchasing partners of virtually all of America's 7,000+ hospitals, as well as the vast majority of the 68,000+ long-term care facilities, surgery centers, clinics, and other healthcare providers. GPOs lower costs for patients, providers, payers, Medicare and Medicaid, and taxpayers. A recent analysis found that GPOs save the U.S. healthcare system $34.1 billion annually, go up to $456.6 billion over ten years, and up to $116.3 billion in Medicare savings and $90.2 billion in Medicaid savings over the same period. The value and services that GPOs provide allow healthcare providers and physicians to focus on their core mission: providing first-class patient care.

HSCA and its member GPOs are committed to ensuring patient and provider safety. HSCA recognizes the importance of transparency and communication when determining the best course of action to reduce emissions of hazardous air pollutants, including ethylene oxide (EtO), used in commercial sterilization facilities.

Ethylene oxide is used to sterilize approximately 50% of all medical devices annually. Many medical devices – including pacemakers, heart valves, and breathing tubes – can only be sterilized using EtO and would be deemed unsafe for use if sterilized through other mechanisms. Additionally, EtO is the only disinfectant that can penetrate multiple layers of packaging without degrading certain materials such as plastic or resin that are used in catheters and tubes. It is also the preferred sterilant for many devices made from certain plastics, resin, metals, or glass due to its ability to kill microorganisms at low temperatures and penetrate multiple layers of packaging or hard-to-reach crevices. These are important factors that must be considered in the process of finalizing the Agency's Proposed Rule.

HSCA understands the Agency's concerns related to EtO and supports efforts to protect the environment and public health, while also reinforcing the importance of patient safety and effective, uninterrupted medical care. Section 112 of the Clean Air Act (CAA) currently requires the EPA to establish emission standards that require the maximum degree of reduction in emissions of hazardous air pollutants.

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The EPA's recommendations revise the current NESHAP for commercial sterilization facilities by amending and expanding Section 112. The Proposed Rule requires that all current or new sources of hazardous air pollutants meet the maximum degree of reduction in emissions; that the EPA administrator take into consideration the cost of achieving emission reduction; that all standards be required to provide a margin of safety in emission reduction; and that the EPA consider adverse environmental factors when producing a margin of safety to reducing emission standards. We are concerned that the proposed changes in emissions standards could lead to severe delays in sterilizing healthcare facilities, medical devices, and equipment, and could delay treatments for providers and patients across the country.

**Given the unique line of sight of GPOs across the entire healthcare delivery system, HSCA and its members respectfully make the following recommendations**:

**Provide at Least Three Years' Notice of Changes to Emission Standards**

The Proposed Rule would affect the 86 commercial sterilization facilities under this source category and could have unintended consequences on the supply of safely sterilized essential products and materials. Currently, all EtO sterilizers are at maximum capacity, and changes in sterilization processes could result in shortages. HSCA recommends that EPA provide a minimum of three years' notice for new emission standards, based on labor, cost, and supply chain considerations.

**Allow Additional Time for Impacted Companies to Comply with Regulations**

The language put forth in the Proposed Rule acknowledges the possible impact of EtO regulation on the supply of medical devices and products and suggests that the largest impacts would be limited to a handful of companies already involved in sterilization. These impacts include any costs associated with changing sterilization methods and testing to ensure sterilization facilities are achieving the maximum degree of emissions reductions. HSCA recommends EPA allow more time than the 18 months allotted in the Proposed Rule for impacted companies to comply with new regulations, which will require them to integrate new sterilization and monitoring equipment that may not be readily available.

**Increase Transparency and Communication with Supply Chain Stakeholders**

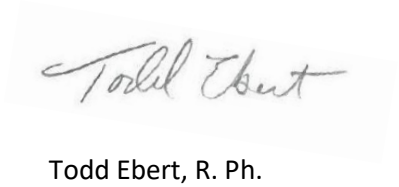
The recommendations in the Proposed Rule recognize that the new sterilization equipment and standards "must reflect the maximum degree of emissions reductions." To ensure all facilities are adequately reducing emissions standards, HSCA recommends greater transparency and communication between EPA and supply chain stakeholders, including GPOs, to ensure sufficient notice of any plans to use new sterilizers and control systems.

HSCA encourages EPA to work with GPOs and other supply chain stakeholders to evaluate potential device shortages that may occur as a result of closures of affected sterilization facilities. GPOs can also help identify sterilization facilities that are serving medical device manufacturers, monitor sterilization capacity levels, and actively assess risks of specific device shortages in the supply chain. Gathering and sharing information on possible device shortages will allow GPOs and other stakeholders to proactively develop strategies to mitigate national device shortages.

We appreciate the opportunity to provide you with our perspective and we look forward to continuing to serve as a resource to our federal partners to maintain a healthy supply chain and protect access to

essential drugs and products. Please do not hesitate to contact me directly if HSCA can be a resource on this issue moving forward. I can be reached at (202) 629-5833 and tebert@supplychainassociation.org.

Sincerely,



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