



Charles N. Kahn III  
President and CEO

June 27, 2023

The Honorable Michael S. Regan  
Administrator  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Mail Code: 4607M  
Washington, D.C. 20460

**RE: Notice of Proposed Rulemaking, Environmental Protection Agency; NESHAP Ethylene Oxide Emission Standards for Sterilization Facilities; Docket ID No. EPA-HQ-OAR-2019-0178; 88 Fed. Reg. 22,790 (April 13, 2023)**

Dear Administrator Regan:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable health care in both urban and rural areas across 46 States, Washington DC, and Puerto Rico. These members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals, and together they provide a wide range of inpatient, ambulatory, post-acute, emergency, children's, and cancer services to patients in diverse communities across the country.

On behalf of its members, the FAH appreciates this opportunity to submit comments to the U.S. Environmental Protection Agency (EPA or Agency) regarding the National Emission Standards for Hazardous Air Pollutants (NESHAP) for the Commercial Sterilization Facilities Source Category Rulemaking to address emissions of ethylene oxide (EtO) (Docket ID No. EPA-HQ-OAR-2019-0178, proposed in the Notice of Proposed Rulemaking published in the *Federal Register* on April 13, 2023 (Proposed Rule).<sup>1</sup> The FAH applauds EPA's efforts to protect workers, the public, and the environment from harmful emissions associated with the use of EtO in commercial sterilization facilities. However, the FAH is concerned with the immediate implications that this rule may have on the healthcare sector if implemented as proposed, which could have detrimental effects on patient care and safety.

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<sup>1</sup> 88 Fed. Reg. 22,790 (Apr. 13, 2023).

Our member hospitals and healthcare systems rely heavily on a steady and uninterrupted supply of essential supplies, including medical equipment, devices, and other critical technologies necessary to deliver effective and timely healthcare services. Reliance on these resources being unquestionably sterile is a vital part of our members' ability to deliver quality and life-saving healthcare. Approximately 50% of all medical devices in the United States, including an estimated 95% of all surgical kits, are sterilized using EtO sterilization – ranging from surgical gowns and dressings to specialized devices such as stents and catheters.<sup>2</sup> Sterilization of medical devices using EtO is a “well-established and scientifically-proven method of preventing harmful microorganisms from reproducing and causing infections.”<sup>3</sup> For many medical devices, EtO sterilization may be the only method that completely sterilizes the device without damaging its structural integrity. While the industry is working on developing additional technology to replace EtO sterilization or to dramatically reduce emissions associated with current sterilization processes, which the FAH supports, this technology does not yet exist on a market-wide basis. Without a sufficient number of operable EtO sterilization facilities, there may be some medical devices that can no longer be used in healthcare. Such devices could include surgical kits used in emergency procedures or feeding tube devices often used in neonatal intensive care units. This is a very practical concern that we urge EPA to consider during this rulemaking process. While FAH members understand and support the need to reduce exposure to EtO emissions in the long-term, our members are concerned about the immediate short-term consequences of working toward this laudable long-term goal too rapidly – a balance is needed to ensure hospital patient safety.

The Proposed Rule, as it currently stands, poses several challenges that threaten the stability of the hospital supply chain and could impede hospitals' ability to provide adequate care to their patients. First, the Proposed Rule will almost certainly cause disruptions in the supply chain due to altered product formations and increased testing and reporting requirements – any one of which may force sterilization facility closures. Secondly, disruptions in product supply caused by the Proposed Rule could impair hospitals' ability to provide access to all patient needs and high quality care to patients. Finally, the Proposed Rule will likely introduce additional complexities and coordination challenges for already burdened hospitals and healthcare systems. These challenges will be felt most acutely by rural hospitals and clinics that are already resource constrained and may be the only healthcare option serving vulnerable populations.

## **I. Disruptions in Supply Chain and Unintended Consequences**

### **A. The Proposed Rule Will Likely Result in Closures of EtO Sterilization Facilities**

Implementation of the emission standards in the Proposed Rule will likely result in closure of certain EtO sterilization facilities because many may not be able to timely outfit their

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<sup>2</sup> FDA Continues Efforts to Support Innovation in Medical Device Sterilization (Aug. 3, 2022), <https://www.fda.gov/news-events/press-announcements/fda-continues-efforts-support-innovation-medical-device-sterilization>.

<sup>3</sup> FDA Statement on Concerns with Medical Device Availability Due to Certain Sterilization Facility Closures (Oct. 25, 2019), <https://www.fda.gov/news-events/press-announcements/statement-concerns-medical-device-availability-due-certain-sterilization-facility-closures>.

facilities with the emissions controls necessary to meet the Proposed Rule's standards and timeframes. Whether permanent or temporary, closures will contribute to a medical device shortage nationwide that will directly impact patient care if closures are not coordinated and managed properly. To ensure minimal disruptions caused as a result of facility closures, the FAH urges additional time in order to comply with the NESHAP. The Proposed Rule's 18-month compliance timeframe is simply too short. Existing facilities that need to retrofit their operations will need to order abatement equipment and other controls – all of which will take significant amounts of time, in addition to the time needed for installing the equipment and controls. We ask the EPA to consider the serious impacts of EtO sterilization facility closures on the medical device supply chain – and the resulting impact on the US healthcare system – when finalizing its Proposed Rule.

The closure of the Sterigenics facility in Willowbrook, Illinois, serves as a prime example of the potential impact of regulatory actions on the healthcare supply chain. The Willowbrook facility, which utilized EtO to sterilize medical equipment and supplies critical to patient care, was abruptly closed after the EPA issued an order for Sterigenics to cease sterilization processes due to concerns over higher EtO emissions than EPA found to be acceptable. This shut down caused a temporary shortage of medical devices, including pediatric breathing tubes, which left hospitals and the Food and Drug Administration (FDA) scrambling to find adequate replacements.<sup>4</sup> In addition, the FDA has expressed concerns about the limited availability of sterilization facilities that use EtO sterilization processes across the country.<sup>5</sup> These concerns extend beyond the Willowbrook facility closure and highlight the broader implications of regulatory actions on the availability of crucial healthcare supplies in the U.S.

## **B. The Proposed Rule Will Cause Supply Chain Delays Due to Increased Time to Sterilize Medical Devices**

For those facilities that are able to meet the NESHAP, the Proposed Rule's stricter regulations and compliance measures may extend the time in which medical devices are sterilized, causing delays in the availability of equipment necessary for medical procedures. The lengthened sterilization process would not only impact the timely delivery of patient care but also poses challenges in managing surgical schedules and emergency care. Surgeries often require careful coordination and planning on already taxed healthcare professionals. These professionals must be able to rely on readily available sterilized equipment in order to treat their patients. Any delay or shortage of sterilized equipment could lead to increased wait times or complete stoppage for patients with certain technology/supply needs and added strain on healthcare staff.

The Proposed Rule could result in increased demand for limited sterilization facilities that are able to meet the proposed NESHAP standards. This surge in demand, combined with

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<sup>4</sup> FDA Statement on Agency Efforts to Mitigate Temporary Shortage of Pediatric Breathing Tubes Due to Recent Closure of Illinois Sterilization Facility (Apr. 12, 2019), <https://www.fda.gov/news-events/press-announcements/statement-jeff-shuren-md-director-center-devices-and-radiological-health-agency-efforts-mitigate>.

<sup>5</sup> FDA Ethylene Oxide Sterilization Facility Updates (Jun. 2, 2021), <https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/ethylene-oxide-sterilization-facility-updates>.

potential facility closures or retrofitting of existing facilities to meet the standards, could lead to capacity limitations and insufficient resources to accommodate the needs of hospitals and healthcare systems.

The Agency should also consider the impact its Pesticide Registration Review: Proposed Interim Decision and Draft Risk Assessment Addendum for Ethylene Oxide, published in the *Federal Register* on April 13, 2023 (Proposed Interim Decision) will have on EtO sterilization facility closures. The Proposed Interim Decision will almost certainly result in altered product formations to sterilize medical devices as sterilization processes will have to be revalidated by the FDA. The Proposed Interim Decision will also increase testing and reporting requirements associated with EtO sterilization. Sterilization facilities will need to factor into their sterilization processes additional time to account for off-gassing and ensure products leaving their possession will not have emission rates that violate the Proposed Rule's standards.<sup>6</sup> Facilities need adequate time to comply with all of these new requirements in order to minimize or prevent EtO sterilization facility closures.

### **C. Unintended Consequences of Off-Shoring Medical Device Sterilization**

As noted above, the Proposed Rule will require many existing EtO sterilization facilities to retrofit their operations with new technology and emissions controls in order to comply with the rule. It is also likely that some existing EtO sterilization facilities will not be able to afford such retrofits or that the resulting increased costs they will pass along to hospitals cannot be absorbed by the healthcare industry. The Proposed Rule's potential to increase costs and create supply chain disruptions may force hospitals to seek alternative suppliers or products. This could lead to medical device sterilization using EtO being outsourced overseas. This shift in procurement practices could introduce new risks and challenges for maintaining consistent quality and an adequate supply chain for healthcare systems, as the US recently experienced with the supply chain shortages surrounding infant formula.

## **II. The Proposed Rule Will Impair Hospitals Ability to Provide Patient Care**

Inadequate access to vital medical equipment and supplies can compromise patient's ability to receive care and on a timely basis. Hospitals rely heavily on a diverse range of products that meet strict quality standards and regulatory requirements to ensure optimal patient outcomes. Any disruption or delay in the availability of these supplies may hinder hospitals' ability to perform vital and timely medical procedures, conduct accurate diagnoses, and manage emergencies effectively

Many EtO sterilization facilities sterilize a variety of medical devices, while other sterilization facilities may specialize in sterilizing only one or two types of medical devices and they may be the only facility that sterilizes such devices. The closure of even one of these

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<sup>6</sup> The Proposed Rule also raises the question of whether recipients of medical devices sterilized by EtO (e.g., a hospital) will be responsible for any EtO emissions associated with products that have not fully off-gassed prior to entering the hospital's chain of command. The FAH urges clarification that EtO emissions regulated under the NESHAP will remain the responsibility of the commercial sterilization facility and will not be passed along to end-users of the medical devices.

specialty sterilization facilities could have disastrous consequences in vital healthcare supply chains, with adverse results in hospitals' ability to treat their patients. Given the critical importance of timely and reliable access to high-quality medical equipment and supplies, it is essential that the Agency consider the potential consequences of the Proposed Rule on hospitals ability to treat patients .

**III. The Proposed Rule May Introduce Additional Complexities and Coordination Challenges for Hospitals and Healthcare Facilities**

The Proposed Rule will require hospital and healthcare systems to adapt in a relatively short period of time to potentially new products, new procurement processes, reevaluation of contracts from suppliers, and other coordination challenges, all of which represent significant investments in time, training, and resources. Further, hospitals and healthcare facilities that rely on medical devices sterilized with EtO will find it difficult to prepare for these coordination challenges until they know which EtO sterilization facilities will be able to continue operations and what types of medical devices will no longer be available to them as a result of closures that will likely result from the Proposed Rule's implementation. Larger hospitals and systems will have the staff and resources to best manage these challenges; however, smaller, rural medical facilities may not be able to timely adapt to the coordination challenges presented by the Proposed Rule's implementation. Thus, the Proposed Rule may have a disproportionate impact on rural and remote hospitals that already face logistical challenges obtaining necessary resources in order to meet the needs of their communities.

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The FAH is concerned that without coordinated efforts among the EPA, FDA, and manufacturers and sterilizers, the Proposed Rule could cause a domino effect of EtO sterilization facility closures that will have dramatic consequences for the healthcare industry nationwide. FAH encourages the EPA to consider the impact of facility closures by allowing sterilization facilities more time to comply with the Proposed Rule as it currently standards, and gradually increasing the stringency of the emissions standards over a period of time to avoid existing facilities not being able to meet the proposed NESHAP. With greater coordination and implementation time, EPA can ensure a sustainable healthcare system that prioritizes patient safety and care while simultaneously protecting the public and the environment.

The FAH appreciates this opportunity to submit these comments. If you have any questions, or if there is any other way that we can assist the EPA as it considers the Proposed Rule, please contact me or any member of my staff at (202) 624-1534.

Sincerely,

