American Hospital Association™
Advancing Health in America

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Michael S. Regan
Administrator
U.S. Environmental Protection Agency
EPA Docket Center
Docket ID No. EPA-HQ-OAR-2019-0178
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Dear Administrator Regan:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, the American Society for Health Care Engineering, American Society for Health Care Risk Management, Association for Health Care Resource & Materials Management and our clinician partners, the American Hospital Association (AHA) appreciates the opportunity to comment on the Environmental Protection Agency's (EPA) proposed standards for the use of ethylene oxide (EtO) to sterilize medical devices. **We recognize and support the agency's critical role of protecting the environment but urge caution and thoughtfulness in EPA's approach to avoid disrupting health care delivery through the unintentional fracturing of the already fragile medical device supply chain.** Such fracturing could put patients at risk of serious harm.

In its proposals, the agency sets forth new thresholds to reduce EtO emissions by 80%, new requirements for continuous monitoring of EtO emissions at commercial sterilization facilities and updated standards focused on worker protection. EPA's goal of lowering unnecessary and unsafe levels of EtO in our air is an important and worthwhile endeavor. Not only does this goal reduce waste and cutback excessive emissions, but also it can play an important role in improving public health. However, the nature and scope of this work requires thoughtfulness and coordination to ensure the right balance is established for both near- and long-term solutions. Currently, EtO plays a critical role in the safe and effective delivery of care. EtO is used to sterilize approximately 50% of medical devices used in the U.S., many of which cannot be effectively or efficiently sterilized using other existing methods. We are encouraged by the agency's ongoing collaboration with the Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC) and the Occupational Health and Safety Administration (OSHA).

The AHA and its members remain concerned about the state of the medical supply chain and are worried that if the EPA were to impose these new requirements rapidly, it could further exacerbate current challenges. Given how reliant our members and their patients are on consistent and timely access to safe and sterile medical devices, **we urge the agency to advance efforts to mitigate environmental impact without buckling the supply chain for care delivery. Specifically, we are concerned that moving too quickly to implement and enforce new standards will result in the unexpected consequence of reducing EtO sterilization capacity, ultimately leading to delays in patient care.**

Our specific comments follow.

**Extension of Implementation Deadlines**

In its proposal to reduce EtO emissions by 80%, the agency provides for an expedited 18-month implementation deadline for compliance with the new and updated standards. We understand EPA's interest in moving more quickly than usual on these priorities; however, these proposed standards are highly technical and require in-depth analyses and research on the part of organizations that utilize EtO for sterilization. They likely will require significant financial, time and resource commitments. While neither AHA nor its members operate any commercial sterilization facilities, we are heavily reliant on the products they sterilize to safely treat people who are sick or injured. We are committed to ensuring that commercial sterilization facilities can continue to provide an adequate supply of safe, sterile medical devices. **We are concerned that the proposed 18-month timeline is too aggressive and could result in significant disruption to the supply chain leading to decreased sterilization capacity and supply availability across the country.**

Not all commercial sterilization facilities are in the same operational or financial situations, and, therefore, some may be in a better position than others to comply with the new requirements rapidly. As the agency notes, there only are 86 commercial sterilization facilities in the U.S. using EtO and those 86 facilities are responsible for sterilizing about 20 billion items annually, including various types of tubing, heart valves, surgical kits, pacemakers, syringes and catheters. The temporary or permanent closure of even just a couple of these facilities could have crippling effects on sterilization capacity and supply availability depending on the volume and need for a specific device. To help mitigate those potential challenges, **we urge the agency to extend its proposed implementation deadlines to account for prolonged lead times and to provide organizations a reasonable amount of time to gather the intensive financial and resource investments needed for compliance, as well as the operational changes.**

We understand there are some commercial sterilization facilities that have the resources available and already have made progress on this work; however, that is not the case for all 86 commercial sterilization facilities across the U.S. Some of these

facilities are smaller in size and lack the resources and expertise to have proactively begun making the necessary investments to come into compliance with the agency's proposed standards. Specifically, as we understand it, those facilities that have not yet begun work to reduce EtO emissions and install air monitoring equipment could run into significant construction delays and equipment lead times through no fault of their own. **With device sterilization capabilities already at or near capacity across the country, we strongly encourage the agency to consider employing its traditional three-year implementation timeline to the standards if made final. This will allow these facilities more time to come into compliance prior to enforcement in an effort to help prevent the closure, temporary or permanent, of any of these facilities.**

**Protecting Individuals Working with EtO**

America's hospitals and health systems understand firsthand the importance of protecting the workforce from dangerous and unhealthy airborne contaminants, which is why we appreciate the EPA's efforts to better measure, manage and mitigate EtO inhalation risk for employees. As part of its preliminary interim decision under the Federal Insecticide, Fungicide, and Rodenticide Act, the agency proposes to require that sterilization facilities invest in and enable real-time monitoring of EtO down to 10 parts per billion (ppb). In instances where levels exceed the proposed 10-ppb threshold, certain PPE requirements would then come into effect. There is concern that availability of technology that allows for the successful measurement and subsequent reporting of levels below 10 ppb is very limited and may not yet be available at all to some commercial facilities. Additionally, it is unclear what factors informed the agency's decision to set the threshold at 10 ppb, which currently represents the lowest amount that can accurately be measured. While we find the agency's efforts to best protect employees well-intended, the potential difficulties associated with these new requirements could exacerbate ongoing workforce challenges.

**We urge the EPA to provide additional, scientifically based information that supports the decision to implement a 10-ppb threshold. We encourage the agency to provide information around the availability of technology capable of measuring at or below 10 ppb and the associated costs with such technology to better inform compliance challenges should the proposed standards be made final.**

**Collaboration with Other Federal Agencies**

The EPA's stated mission is to protect human health and the environment. The AHA and its members are aligned with the agency on the need to further this mission, **which is why we ask that the agency to continue to collaborate in a meaningful way with partners across the federal government to limit and mitigate any potential unintended consequences of EPA's proposals on human health.** In particular, we urge the EPA to recognize and take into account the significant risk to human health

and care delivery if sterile critical supplies are not available. While the underlying intent of the proposed standards clearly is to ensure the air we breathe is clean and the environment in which people work is safe, these proposals and their implications stretch far beyond the sole jurisdiction of the EPA. We worry that the standards, without proper input from and collaboration with the FDA and CDC, could put at risk a vital component to protecting human health — delivering health care to those who need it, when they need it. As the agency moves forward, we strongly encourage it to partner with FDA and CDC to better understand potential consequences of these decisions on health care delivery, and to appropriately mitigate the unintended impact of those decisions.

Longer term, we hope the EPA will continue to engage in meaningful collaboration with federal partners and external stakeholders to ensure any future actions by the agency take into consideration impact across the health care sector**. Moving forward, the AHA remains committed to supporting both short-term and long-term solutions that allow for the safe and effective sterilization of vital medical equipment.** In the short term, this means achieving the lowest possible level of EtO emissions while still ensuring that facilities can sterilize essential medical equipment. Longer term, this will require additional options for effective sterilization of equipment and strategies for reducing and ultimately eliminating harmful emissions, as well as the development of new devices that support new, safer methods of sterilization.

We thank you for the opportunity to comment on these important proposals and appreciate your consideration of the key issues we highlighted. Please contact me if you have questions or feel free to have a member of your team contact Mark Howell, AHA's director of policy, at mhowell@aha.org.

Sincerely,

/s/

Stacey Hughes
Executive Vice President