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Submitted via the Federal eRulemaking Portal: http://www.regulations.gov

The Honorable Michael S. Regan
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20460

Re: National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review (EPA-HQ-OAR-2019- 0178)

Dear Administrator Regan,

Vizient, Inc. appreciates the opportunity to comment on the Environmental Protection Agency (EPA) proposed rule, "National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review" (hereinafter, "Proposed Rule"). The Proposed Rule provides amendments to the National Emission Standards for Hazardous Air Pollutants (NESHAP) for the Commercial Sterilization Facilities source category to address ethylene oxide (EtO) emissions. Vizient emphasizes the critical importance of policies that protect public health, and we appreciate EPA's efforts to gain stakeholder input regarding the Proposed Rule. Similarly, Vizient is aware of the essential role EtO plays in medical device sterilization. Therefore, we urge EPA to exercise caution as it considers finalizing the Proposed Rule, as disruptions of sterilization facilities' operations could upend healthcare delivery given the need for sterilized medical devices.

Background

Vizient, Inc. provides solutions and services that improve the delivery of high-value care by aligning cost, quality, and market performance for more than 60% of the nation's acute care providers, which includes 97% of the nation's academic medical centers, and more than 20% of ambulatory providers. Vizient provides expertise, analytics, and advisory services, as well as a contract portfolio that represents more than $130 billion in annual purchasing volume, to improve patient outcomes and lower costs. Headquartered in Irving, Texas, Vizient has offices throughout the United States.

Recommendations

Vizient recognizes the critical importance of policies that protect public health, and we appreciate EPA's efforts to gain stakeholder input regarding the Proposed Rule. However, we are concerned that the healthcare industry may be inadvertently, negatively impacted by the Proposed Rule given the scope of medical devices which are sterilized by EtO and for which no other sterilization

methods are currently available.[1] Also, more than 20 billion devices sold in the U.S. every year are sterilized with EtO which is approximately half of all devices that require sterilization.[2] In addition, regarding EPA's recent regulatory activity related to EtO, FDA Commissioner Califf expressed concern, indicating "I'm very worried."[3] Vizient's comments to EPA urge the agency to ensure that any policy finalized related to EtO not disrupt the medical supply chain as this would negatively impact patients.

Impact to Medical Device Supply Chains

As noted above, EPA proposes several policies for commercial sterilizers that would significantly impact sterilization of medical devices using EtO, and therefore, patient care more broadly. For example, EPA acknowledges that requiring facilities to follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach[4] to achieve sterility assurance may reduce the number of products that can be sterilized simultaneously, causing bottlenecks in the medical device supply chain. Further, EPA acknowledges that revalidation of sterilization cycles is a time-intensive process that could worsen potential bottlenecks in the medical device supply chain. While EPA seeks comment on this requirement and others, we urge EPA to clarify how the agency is weighing the potential impacts of the Proposed Rule on patients who rely on sterilized medical devices with the agency's goal to reduce EtO emissions. Vizient urges EPA to finalize policies only if the agency, and FDA, can assure stakeholders that patient access to sterilized medical devices will not be disrupted as a result of the policies proposed.

EPA also notes in the Proposed Rule that there is a lack of alternatives to EtO for medical device sterilization and that it identified nearly 90 commercial sterilizers that would need to comply with the additional requirements. Given the small number of commercial sterilizers, any disruptions or slowdowns to their operations would have far reaching consequences on the overall availability of medical devices, and will therefore impact patients. As proposed, Vizient is concerned that some commercial sterilizers will exit the market or slow sterilization, on both a short and long-term basis. In addition, a potential unintended consequence to the medical device supply chain could be an increase of products being sterilized outside of the United States, including countries overseas. Not only would these changes increase costs to sterilize, but it would also create additional logistical issues, creating a more vulnerable supply chain. Further, the lack of alternative sterilization options to EtO heightens patient access concerns since no other options could be promptly implemented in the United States to replace EtO. Again, given these issues have not been addressed in the Proposed Rule, Vizient urges EPA to only finalize policies in the Proposed Rule that would not jeopardize patient access to sterilized medical devices.

Implementation Period

In addition, EPA proposes a relatively short implementation period for several policies (e.g., 18-months). Vizient is concerned that this may not be enough time for commercial sterilizers to both implement new operations and install new systems while also being able to maintain current output. Although EPA acknowledges that supply chain challenges such as bottlenecks may occur, Vizient is concerned EPA has not done more to better estimate the impact.

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[1] https://www.fda.gov/news-events/press-announcements/fda-continues-efforts-support-innovation-medical-device-sterilization

[2] https://www.fda.gov/news-events/press-announcements/fda-continues-efforts-support-innovation-medical-device-sterilization

[3] https://www.politico.com/newsletters/prescription-pulse/2023/04/28/device-makers-await-cms-redo-00094345, FDA Commissioner Robert Califf stated at the Medial Device Manufacturers Association conference, "Make your voice heard... This issue is very much on the forefront for us. We are highly aware of it and we're engaged in the discussions. I'm very worried."

[4] In accordance with ISO 11135:2014 and ISO 11138-1:2017.

Impact to Hospitals and Other Providers
Further, in the Proposed Rule and Regulatory Impact Analysis[5], EPA does not address how patients, hospitals and other providers will be affected if the Proposed Rule is finalized. For example, the Regulatory Impact Analysis notes that "the price of EtO sterilization services may increase", "cost increases may be passed from sterilizers to medical device manufacturers to hospitals and end-use consumers" and "any price effects transmitted to end-use consumers are likely to be small". Based on this information, hospitals, patients, and the government are particularly vulnerable to bearing the additional costs to comply with the proposed policies. In addition, reimbursement rates often take several years to adjust for the increased costs of supplies, meaning providers will face both greater cost outlays and inadequate reimbursement. Again, Vizient is concerned that failing to account for consequences to providers and patients is a significant oversight on EPA's part, as there could also be additional public health implications. Vizient recommends EPA work closely with providers to better understand how the proposed changes would impact patient care. Should EPA finalize the Proposed Rule, extensive mitigation plans will need to be developed to prepare for disruptions and efforts must be made, including potential collaboration with the Centers for Medicare and Medicaid Services, to address reimbursement challenges. Without critical attention and consideration to these issues, providers may be placed in the untenable position of having to reduce services based on which sterilized products are available.

Conclusion

Vizient welcomes the opportunity to comment on the EPA's Proposed Rule regarding EtO for commercial sterilizers. On behalf of Vizient, I would like to thank EPA for advancing rulemaking that aims to address public health challenges, however, we urge EPA to ensure that medical device supply chain disruptions will not occur due to this rulemaking. Please feel free to contact me at (202) 354-2600 or Jenna Stern, AVP, Regulatory Affairs and Government Relations (Jenna.Stern@vizientinc.com), if you have any questions or if Vizient can provide any assistance as you consider these issues.

Respectfully submitted,

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Vizient, Inc

[5] https://www.epa.gov/system/files/documents/2023-04/RIA_EtO_Commercial_Sterilizers_NESHAP_Proposal.pdf