



March 24, 2026

Co-Chair Heintzeman, Co-Chair Fischer, and members of the House Environment and Natural Resources Finance and Policy Committee,

Medical Alley represents a global network of more than 800 leading health technology and care organizations with representation from all corners of the state of Minnesota. With access, affordability, and quality as top priorities, Medical Alley and our partners are committed to developing solutions that drive meaningful change and save lives.

Guided by these principles, Medical Alley supports HF4257, legislation which would delay PFAS reporting requirements to allow additional time to ensure the state's reporting framework is accurate, secure, and workable for all stakeholders.

In 2023, the legislature passed Amara's Law and exempted medical devices and drugs regulated by the FDA, recognizing the rigorous federal oversight of these products and their critical role in patient care. However, manufacturers are still subject to the law's reporting requirements.

First, we acknowledge and appreciate the Minnesota Pollution Control Agency's willingness to engage with manufacturers and industry organizations as it has developed the PRISM platform. However, based on direct feedback from these groups, PRISM in its current form is not equipped to handle the scope and technical complexity required under state statute.

Medical device and pharmaceutical manufacturers have consistently identified technical challenges, including incomplete data fields, unclear product descriptions, missing component categories, unresolved system errors, data loss during updates, and functionality gaps that create uncertainty around compliance.

These challenges are compounded by timing constraints. The PRISM system and reporting template were updated as recently as March, leaving companies with limited time to operationalize compliance. Because manufacturers rely on structured, multi-step processes that require a stable reporting framework before collecting data across business units and suppliers, many are only now able to gather the required information.

Together, these factors create significant risk of either delayed reporting, or of incomplete or inaccurate data submission. This is particularly concerning given the statute's enforcement provision (Minn. Stat. § 116.943, subd. 2(d)):

*(d) A person may not sell, offer for sale, or distribute for sale in the state a product containing intentionally added PFAS if the manufacturer has failed to provide the information required under this subdivision and the person has received notification under subdivision 4.*



There are also unresolved questions regarding how proprietary data will be classified and protected. Under current law, submitted data is presumed public unless otherwise designated, raising concerns about how information is handled during review, the timeline for classification decisions, and whether sufficient expertise exists to evaluate highly technical data. The MPCA retains sole discretion to determine whether information qualifies as trade secret. While we appreciate the Agency's explanation of an appeals process, uncertainty remains around how consistently and efficiently these determinations will be made. For companies submitting highly specialized and proprietary data, these risks are significant and warrant additional clarity and safeguards before full implementation.

Finally, there is concern regarding how complex technical data may be interpreted by patients once made public. Medical devices are highly specialized technologies used within specific clinical contexts, and data presented without appropriate context can be misunderstood or mischaracterized. Importantly, medical devices and drugs subject to these reporting requirements have been reviewed and certified by the FDA under rigorous safety and efficacy standards. Public disclosure of incomplete or decontextualized information risks creating confusion about the safety of these products, potentially undermining patient trust and informed decision-making.

Given these concerns, a one-year delay would provide the necessary time for the MPCA to address system functionality, clarify reporting expectations, and ensure a reliable and workable compliance process. Without these improvements, technical limitations, not product safety, could unintentionally disrupt access to essential, FDA-regulated medical technologies.

Medical Alley and our partners remain committed to being constructive partners in this process and support a thoughtful, transparent approach to PFAS reporting that achieves our shared goals of protecting public health while preserving innovation and patient access to care.

Thank you for your consideration.

Sincerely,

**Ben Wagner**

*Interim Director of Government Affairs*

Medical Alley Association