AdvaMed
The Medtech Association

Membership has its Privileges

Overview

Every day in Washington, AdvaMed's advocacy and policy teams champion the priorities and objectives of our member companies, yielding bottom-line results that directly benefit the patients and families you serve, every day. Below are just a few highlights of the tangible benefits of membership in 2025, and how grateful we are to be part of your team.

2025 Federal and State Legislative and Regulatory Wins:

Formulated and implemented a workable medtech sterilization rule with the EPA

Potential savings/costs avoided: $3.24-$9.07 million per facility

Background: In 2024, faced with an Environmental Protection Agency draft rule on sterilizing medical equipment and technologies that threatened to limit 35-50 percent capacity, AdvaMed led the industry in helping to formulate and later implement a final rule that allowed every sterilizer to remain operational at full capacity and not threaten critical supply lines. The successful advocacy initiative – finalized this year – yielded a range of $3.24-$9.07 million per member facility in avoided costs, necessary capital improvements, environmental engineer expertise, and unsterilized medtech that would have been otherwise sidelined with potential cost increases per device of 28-55 percent, according to EPA's even most conservative estimates. To further illustrate the impact of effort, this does not account for upwards of $200,000 per cycle that would have been incurred for revalidation of the sterilization cycle of millions of products if the rule had proceeded as proposed, with savings further increased by 50 percent for member facilities.

Neutralized all PFAS policies in more than 19 statehouses

Background: Given the ubiquitous presence of PFAS in major medtech products across the device spectrum – and the growing pursuit by states across the country to regulate the "forever chemical" – AdvaMed was instrumental in 2025 in neutralizing poorly drafted and unworkable legislative text that threatened to remove the scientifically sound substance manufacturers use. In each of the 19 statehouses where legislation was pending in 2025, AdvaMed was able to either secure critical language to exempt medical technologies and equipment, or prevent the harmful legislation from advancing, a potential average impact of at least $250,000 to $500,000 per company utilizing the chemistry.

Secured Congressional enactment of R&D expensing provisions.
Tax relief for AdvaMed members: $3.1b or approx. $344k-$3.25m per member

Background: In 2025, as Congress advanced the nearly 900-page "Big Beautiful Bill," AdvaMed led a targeted advocacy effort to secure permanent restoration of full, immediate expensing for domestic research and development, restoring the R&D expensing provisions that were removed under the TCJA during the first Trump term. Without restoration of immediate 100 percent expensing, businesses were only allowed to expense 40 percent of the cost for 2025 before it was scheduled to fall to 20 percent in 2026. The final law makes full expensing permanent and includes a retroactive provision for small companies with gross receipts under $31 million, allowing them to expense R&D investments from 2022 through 2025. AdvaMed is proud to have joined dozens of other industries to push for this important tax measure, relief that could mean a range from $344 thousand for small manufacturers up to $3.25 million for large medtech companies investing in future R&D projects.

Advanced Access to Alzheimer's Neuro-Biomarker Diagnostic Tests: A Win for Patients and Access
Reimbursement impact: $6.9–$15.5 million per year

Background: Science and medtech have revolutionized the ability to measure key biomarkers that signal Alzheimer's pathology years before symptoms become severe. By enabling earlier and more accurate diagnosis, patients can access emerging treatments sooner and plan care proactively. After initially proposing a reimbursement rate of $17 for Alzheimer's neuro-biomarker blood tests, AdvaMed pushed CMS to reconsider the amount – a move that led to a new rate of $128.92, effective January 2026. This change ensures that these tests are not only clinically valuable but also financially viable for providers and patients. Today, millions of Americans live with Alzheimer's, and by 2030, that number is projected to reach 8.5 million. With sustainable reimbursement, biomarker testing can become a standard tool for risk assessment and diagnosis–potentially benefiting millions of individuals who might otherwise face delayed or missed diagnoses. With AdvaMed's advocacy, this new rate means greater reimbursement for our member diagnostic companies in the range of $6.9–$15.5 million per year beyond the initial amount set by CMS.

AdvaMed-Led Actions on the Continuing Resolution:

Secured Extension of Medicare Telehealth Services

Potential reimbursement impact: $2 billion

Background: There were several provisions in the recently enacted continuing resolution (CR) that AdvaMed helped secure, which benefit our member companies. One measure averts a telehealth "cliff" by extending key Medicare telehealth flexibilities through January 30, 2026. These provisions allow beneficiaries to receive care from home without geographic restrictions, including audio-only options, and expand eligible providers such as physical and occupational therapists. In early 2025, 4.3 million beneficiaries – approximately 15 percent – had at least one telehealth visit, totaling over 11 million encounters.

PAMA Cuts Suspended: Protecting Access to Clinical Lab Testing

Potential cuts avoided (through Jan 30, 2026): $1-$1.5 billion

Background: The recently enacted continuing resolution delayed up to 15 percent Medicare reimbursement cuts for roughly 800 clinical laboratory tests, averting billions in reductions that would have strained diagnostic access nationwide. Clinical lab payments cover essential diagnostics – such as blood counts, metabolic panels, and advanced molecular tests – that inform nearly 70 percent of medical decisions, from routine care to cancer screening.

Medicare's 65 million beneficiaries rely on these services, and clinical labs perform more than 14 billion tests annually across the U.S., supporting preventive care, chronic disease management, and timely treatment decisions. By suspending cuts, Congress preserved patient access and stabilized a sector critical to public health. Without this relief, labs faced unsustainable payment reductions, threatening innovation and care delivery. Advocacy continues for permanent reform to ensure predictable reimbursement and protect the infrastructure behind America's diagnostic backbone. If the 15 percent cuts had resumed in 2025, projections suggest $1.0-$1.5 billion per year in additional reductions – meaning the one – year suspension likely saved over $1 billion in Medicare spending for 2025 alone.

Secured Extension of CISA (Sec. 149)
Potential cuts avoided: $491 million, or 17 percent, reduction in its budget averted; 1,000 staff

Background: AdvaMed helped ensure the continuation of a federal program that allows medtech companies and government agencies to share cybersecurity threat information safely through January 30, 2026. Without it, hospitals and medical devices could have been more vulnerable to cyberattacks, putting patients' personal and health data at risk.

The new continuing resolution averts the steep cuts once proposed for CISA – including a proposed $491 million, or 17 percent, reduction in its budget and potential loss of more than 1,000 staff. By extending, the legislation restores liability shields, antitrust protections, and confidentiality safeguards that enable private-sector medtech companies – and other firms – to securely share cybersecurity threat data with federal agencies. The extension helps reverse a post-expiration collapse in cooperation: formal sharing of threat indicators dropped by more than 70 percent in the weeks following the lapse. That decline translated into delayed alerts and slower response times, raising vulnerability in sectors including healthcare, energy, and critical infrastructure.

Transparency in FDA User Fee Funding – MDUFA (Sec. 773)
Potential savings: an estimated $2.3–$6.8 million annually from increased transparency and reduced inefficiencies in how FDA allocates medical device user-fee resources.

Background: This provision requires the FDA to provide an Ombudsman-certified report detailing how user-fee agreements are being fully maintained and implemented, including current staffing and resource levels dedicated to user-fee commitments. By increasing transparency, the report can help prevent unnecessary spending overlaps, reduce inefficiencies, and give Congress and stakeholders clearer insight into where savings may be found as the agency allocates staff and resources.

In FY 2022, medical device user fees (MDUFA) fees totaled about $228 million; better clarity could yield millions in savings while preserving program performance. By improving oversight and resource allocation, the measure supports more efficient regulatory reviews and may help avert delays in product approvals or safety reviews tied to funding uncertainty.

AdvaMed led funding fight for additional FDA dollars

Potential savings: $8.12 million

Background: Thanks to AdvaMed's advocacy for a strong user fee program, the Center for Devices and Radiological Health (CDRH) is the only FDA division to receive a budget increase for FY 2026. Congress boosted CDRH funding by $8.21 million, reinforcing FDA's capacity to review medical devices efficiently. This increase – combined with new user fee transparency requirements, also championed by AdvaMed – helps ensure funds are used as intended and reduces risk of misallocation and regulatory bottlenecks.

AdvaMed secured additional provisions outlined in the Agriculture/FDA Appropriations Joint Explanatory Statement:

- **AdvaMed advocated for the inclusion of point of care testing:** This agreement amends the Over-the-Counter Tests language from S.Rpt. 119-37 and H.Rpt. 119-172 to also include point of care tests. Without this change, patients could have faced delays in access to rapid diagnostic tests used in clinics. Particularly to address infections for which there is no OTC diagnostic currently authorized.

- **Strengthened FDA oversight of medical device manufacturing in Asia:** The agreement supports FDA prioritizing funds to build a permanent presence in East Asia, including locations in Tokyo, Japan, and Hanoi, Vietnam, to conduct inspections, including unannounced inspections, and strengthen regulatory control and oversight for products being produced in that region, including medical devices.

- **AdvaMed advocated for expanded FDA transparency and reporting:** The agreement directs FDA to provide quarterly briefings to the House and Senate Appropriations Committees to discuss funding obligations and user fee agreements (referring to Sec. 773). FDA is directed to establish a regular cadence for these quarterly briefings within 60 days of the enactment of this act.