



American Society of Echocardiography

October 27, 2025

Office of Science and Technology Policy
Executive Office of the President
1650 Pennsylvania Avenue NW,
Washington, DC 20504

**Re: Request for Information on Regulatory Reform to Support AI Innovation
Docket ID number OSTP-TECH-2025-0067**

Dear OSTP Team,

The American Society of Echocardiography (ASE) appreciates the opportunity to respond to Office of Science and Technology Policy's (OSTP) Request for Information on Regulatory Reform for AI, seeking input on existing regulations, guidance, forms, and administrative processes that may unnecessarily hinder the development, deployment, and adoption of AI technologies in the United States. ASE is the Society for Cardiovascular Ultrasound Professionals™. As the largest global organization for cardiovascular ultrasound imaging serving physicians, sonographers, nurses, veterinarians, and scientists, ASE is the leader and advocate, setting practice standards and guidelines for the field. Since 1975, the Society has been committed to advancing cardiovascular ultrasound to improve lives.

As clinicians and researchers advancing AI in cardiovascular imaging, we recognize AI's potential to improve accuracy, efficiency, and equity in patient care. However, current regulatory frameworks create uncertainty that can impede responsible adoption.

Core Principle: Physician Oversight

ASE supports clear requirements that maintain physician oversight of any AI used in clinical decision-making. These safeguards protect patients, uphold clinical integrity, and maintain accountability. A qualified physician must review and sign off on AI outputs before results enter the medical record or guide care - no auto-finalization. Clinicians need immediate pause/override capabilities and visible uncertainty/quality indicators at the point of care. Initial deployment should follow supervised pilots under formal governance defining physician roles for review, authorization, and incident response. Once live, physician-led monitoring must track performance drift and subgroup outcomes, with periodic re-validation after updates. Every AI-assisted result should include provenance (algorithm/version/inputs), physician attestation, and audit trails. Role-based training must cover model scope, limitations, and appropriate overrides, and systems must degrade safely to manual workflows during outages or low-confidence states. While ASE's expertise is echocardiography, these safeguards are foundational for all AI-enabled services to protect patients, uphold clinical integrity, and keep liability with identifiable human actors and accountable organizations.

Recommended Regulatory Reforms

1. **Standardized Terminology & Classification:** Establish clear, standard definitions for AI healthcare applications to reduce confusion and facilitate appropriate regulatory pathways. We recommend alignment with established clinical taxonomies - including, but not limited to, the AMA taxonomy - to promote consistency, interoperability, and clear provider communication. Common terminology will help patients and clinicians better understand AI capabilities, limitations, and appropriate oversight requirements for each category.
2. **Transparency & Accountability:** Require premarket validation across diverse patient populations, vendors, and care settings. Data collection and use must be transparent, demonstrating how patient variety affects care quality and equity. Explicit disclosure of limitations and "do-not-use" conditions should be embedded in clinical workflows. Required documentation should include:
 - Concise model cards with intended use, inputs, assumptions, and performance metrics with confidence intervals
 - Uncertainty and quality indicators
 - Versioned change logs and safety notices
 - Provenance and audit trails
 - Post-market surveillance with drift detection triggers
 - Role-based training for physicians and sonographers
3. **Shared Liability Frameworks:** Establish balanced accountability among clinicians, institutions, and AI developers. Liability should be distributed across the medical community, avoiding undue burdens on frontline clinicians while promoting safe AI development. Vendors/developers and clinical organizations should jointly bear responsibility, especially when algorithmic transparency is limited.

Physicians must maintain oversight at every stage of clinical decision-making: co-designing and validating premarket studies, supervising pilots, and providing final sign-off before deployment. Post-deployment, vendors and providers should jointly monitor performance using physician-defined triggers, maintain feedback channels that drive Corrective and Preventive Actions (CAPA), and ensure visible override controls.

Shared liability should be proportional to each party's contribution when failures result from inadequate validation, insufficient physician engagement, unclear disclosure, or delayed safety communications.

4. **Ongoing Monitoring:** Require robust post-market surveillance and drift detection to ensure safe, effective, and equitable performance over time. This includes:
 - Physician-approved key performance indicators (accuracy, calibration, failure/override rates, turnaround time) and alert thresholds
 - Subgroup performance tracking across demographic and clinical variables (sex, age, race/ethnicity, vendor, setting) to identify and address disparities
 - Re-validation after updates
 - Provenance, audit trails, and versioned change logs

- Frontline clinician reporting into CAPA processes
- Joint vendor-provider quality reviews with defined remediation/rollback criteria
- Fail-safe degradation to manual workflows during outages or detected drift

Conclusion

We encourage OSTP to advance reforms that balance innovation with patient safety and physician oversight. A regulatory environment fostering transparency, shared responsibility, standardized terminology, and consistent oversight will accelerate safe AI adoption in echocardiography and across the U.S. healthcare system.

Thank you for the opportunity to provide input. We welcome continued engagement as OSTP shapes policy frameworks that enable innovation while protecting patients and supporting clinical decision-making. If you have any questions, please contact Katherine Stark, ASE Director of Advocacy, at kstark@asecho.org.

Sincerely,

A handwritten signature in black ink, appearing to read "D Wiener MD".

David Wiener, MD, FASE
ASE President