American College of Radiology™

October 27, 2025

Attn Docket ID: OSTP-TECH-2025-0067
Office of Science and Technology Policy
Eisenhower Executive Office Building
1650 Pennsylvania Avenue NW
Washington, D.C. 20504

Re: (OSTP-TECH-2025-0067; 90 FR 46422; 2025-18737) Notice of Request for Information; Regulatory Reform on Artificial Intelligence; Comments of the American College of Radiology

The American College of Radiology (ACR)—a professional association representing more than 40,000 physicians practicing diagnostic radiology, interventional radiology, radiation oncology, and nuclear medicine, as well as medical physicists—appreciates the opportunity to comment on the White House Office of Science and Technology Policy (OSTP) request for information (RFI), "Regulatory Reform on Artificial Intelligence" (OSTP-TECH-2025-0067) published in the September 26, 2025, *Federal Register*.

ACR Data Science Institute
ACR established its Data Science Institute (DSI) in 2017 to advance safe, effective, and clinically useful radiology AI innovations. DSI collaborates with radiology professionals, industry, government, patients, and other stakeholders to develop programs and tools in support of the implementation of AI applications that will help improve patient care. Initiatives include:

- Defining clinically relevant use cases intended to guide the development of useful imaging AI (ACR Define-AI).
- Establishing and making broadly available the first national recognition program for safe and effective implementation of AI in imaging practices (ACR ARCH-AI), which is now used in many different sites across the U.S.
- Creating opportunities to monitor the effectiveness of AI models in real-world clinical practice, including the first large-scale quality registry for AI performance monitoring (ACR Assess-AI).
- Participating in the Healthcare AI Challenge, a multi-institution collaborative effort dedicated to crowdsourced evaluation of generative AI solutions.
- Sharing information about training and characteristics of radiology AI models (including model cards) with radiologists to help them choose what works for their practices and patients (ACR AI Central).
- Organizing thought leadership activities regarding the regulatory, legal, and ethical issues associated with radiology AI.

Responses to OSTP Questions I–VI
ACR offers the following integrated responses to OSTP's questions:

FDA Oversight Enhancement
The Food and Drug Administration (FDA) has authorized more than 1,200 AI-enabled software devices to date. These authorizations have primarily involved locked, narrowly defined task-specific functions (e.g., triage/quantification), especially in radiology. FDA recently enabled manufacturers' use of predetermined change control plans (PCCPs) to review planned software modifications in advance, including the required circumstances for a manufacturer to implement these modifications.

Moving forward, the FDA will need to enhance its oversight mechanisms to address adaptive/continuously learning systems, multi-function device products, foundation model-based devices for broader tasks, and other AI with novel safety and effectiveness considerations. In doing so, the FDA should consider:

- Focused oversight on continuous, real-world monitoring and post-market performance assessment of AI models, to ensure safety and reliability in clinical settings while also enabling pre-market flexibility. AI model performance can vary by site, population, and imaging equipment, frequently necessitating local validation. Proper acceptance testing and real-world post-deployment monitoring on local data provides early insights into the lack of generalizability of commercial models. Acceptance testing and ongoing monitoring in practice also enable data/performance-driven selection of optimal technology (instead of reliance on marketing material or anecdotal insights from other sites).
- Recognition of *qualified* national registries, such as ACR's Assess-AI, which can assist clinical sites with tracking of model performance and drift across various practice settings and offer developers and clinical sites nonregulatory mechanisms for continuous monitoring.
- Recognition that clinical sites and qualified end-users (licensed practitioners) play a significant role in risk mitigation.
- Acknowledgement that licensed and credentialed end-users should take responsibility for the hybrid medical practice of human medical professionals and AI technology. This concept would also extend to future implementation of hypothetical autonomous AI systems, deployment of which should only occur under the oversight of such qualified end-users.

HHS OCR, HIPAA Data Sharing Clarity
Unclear requirements regarding the sharing of data with clinical data registries can be counterproductive to advancing nonregulatory methods of continuous monitoring of AI models. Clinical sites may be reluctant to share data they perceive as requiring additional authorizations.

To ease concerns, ACR recommends the HHS Office of Civil Rights (OCR) and/or the Administration for a Healthy America (AHA) clarify that AI performance monitoring via national registries is a recognized "healthcare operations" activity under the Health Insurance Portability and Accountability Act (HIPAA) when conducted with compliant safeguards. This would:

- Enable continuous monitoring at scale by supporting registry participation.
- Support future regulatory flexibility by generating reliable post-market performance data that adds to regulators' understanding of safety, effectiveness, and value.

CMS Reimbursement for Clinically Meaningful AI

The Centers for Medicare and Medicaid Services (CMS) should support payments for clinician work when using clinically meaningful AI. Many of the current and future AI tools require clinician validation and/or incorporation of findings into the patient's care plan. Without a funding mechanism, there is a lack of incentives for widespread adoption. Because of the budget neutral structure of this fee schedule (which requires downward to reimbursement adjustments for other critical physician services when new services are added), these payments for AI cannot come from the current Medicare Physician Fee Schedule allocation.

Adequate technical reimbursement for AI-informed care is also necessary to support practice investment in other necessary activities to maintain a robust and high-quality digital medicine program. These payments should cover direct and indirect costs such as AI governance, infrastructure, and other payments like continuous monitoring, end user training, and quality and safety initiatives, all of which are necessary for safe and effective use of clinically meaningful AI.

Harmonization of HHS AI Transparency Requirements

HHS administers a voluntary "health IT certification program" focused on electronic health record (EHR) solutions. The HHS certification criteria regulations include transparency requirements for certain types of EHR-integrated "decision support interventions," such as AI functions. This is the only area of the Code of Federal Regulations that explicitly defines the healthcare AI transparency obligations of developers/manufacturers. However, most healthcare AI tools, including nearly all FDA-regulated AI software devices and unregulated practice management AI, are not EHR-integrated.

ACR recommends that HHS harmonize its transparency standards across regulatory agencies that oversee healthcare AI or AI medical uses, including FDA, CMS, and OCR. Such requirements should:

- Assist providers seeking to identify and deploy AI tools that safely and effectively meet their patients' needs.

- Ensure interoperable transparency requirements for AI developers who must meet the requirements of multiple agencies within HHS and may need to enable providers' compliance with OCR's nondiscrimination rules.

Other/Organizational Considerations to Support AI Innovation and Adoption
Healthcare providers are generally eager to adopt AI that improves patient care and reduces administrative burden. Concerns around liability and data sharing, as well as confusion surrounding HIPAA requirements for AI persist, however. Federal agencies can help by:

- Addressing relevant medical liability considerations wherever feasible.
- Recognizing consensus-based governance programs, such as ACR's ARCH-AI, as best practices for procurement, grants, or quality programs.
- Recognizing *qualified* national registries, such as ACR's Assess-AI and other similar programs.
- Enhancing community trust and adoption via risk-appropriate oversight as regulatory recissions may be counterproductive to real-world adoption in certain cases.

Conclusion
ACR welcomes the opportunity for continued communications with OSTP and other healthcare regulatory agencies. For questions, please contact Michael Peters, ACR Senior Director, Government Affairs, at mpeters@acr.org.

Sincerely,

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Dana H. Smetherman, MD, MPH, MBA, FACR
Chief Executive Officer
American College of Radiology