



March 14, 2025

AI Action Plan
Attn: Faisal D'Souza, NITRD NCO
2415 Eisenhower Avenue
Alexandria, VA 22314

Re: (90 FR 9088; 2025-02305) AI Action Plan; Comments of the American College of Radiology

The American College of Radiology (ACR)—a professional association representing more than 40,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians, and medical physicists—appreciates the opportunity to file comments with the White House Office of Science and Technology Policy (OSTP) and the Networking and Information Technology Research and Development (NITRD) National Coordination Office (NCO) to inform the future “AI Action Plan.” The following comments are a response to the Request for Information (RFI) published February 6, 2025 (90 FR 9088; 2025-02305).

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Background

The radiology physician specialty has long been the vanguard of healthcare AI, with over 1,000 AI-enabled software medical devices authorized by the U.S. Food and Drug Administration (FDA) to date. AI-enabled tools provide a wide range of augmentative functions for radiologists as they review and interpret medical imaging studies. These functions include prioritizing cases, detecting and highlighting abnormalities in imaging studies for radiologists to review, characterizing disease progression, assisting with image analysis to create data for inclusion by radiologists in their reports, and more.

Recognizing AI’s promise to enhance patient care, the ACR established its Data Science Institute (DSI) in 2017 to advance safe, effective, and clinically useful radiology AI innovations. The ACR DSI collaborates with radiology professionals, industry, government, patients, and other stakeholders in developing programs and tools in support of 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 ([Define-AI](#)).
- Establishing the first national recognition program for safe and effective implementation of AI in imaging practices ([ARCH-AI](#)), and making it broadly available in 2024.
- Creating opportunities for monitoring the effectiveness of AI algorithms, including via America’s first large-scale quality registry for AI performance monitoring in real-world clinical practice ([Assess-AI](#)).
- Making imaging AI information readily available to radiologists to enable providers to find AI solutions that best support their patients and workflows ([AI Central](#)).
- Addressing the regulatory, legal, and ethical issues associated with radiology AI.

Priorities for the AI Action Plan

The ACR recommends the AI Action Plan includes the following priorities specific to healthcare AI:

I. Enable FDA to continue to regulate AI-enabled software medical devices, and to enhance or modify oversight as needed. The ACR supports the critical role of the FDA as the primary federal agency for overseeing the safety and effectiveness of AI-enabled medical devices. The public would benefit from expanded FDA authorities to enable the agency to implement the following:

- ***Require AI device compatibility with balanced, risk appropriate, post-deployment monitoring mechanisms.*** Healthcare providers should be able to monitor AI performance with suitable and recognized tools. Monitoring could include collaboration with trusted third parties, such as ACR and other organizations with AI registry programs. The additive safety and effectiveness assurance of post-deployment performance monitoring programs for certain software devices could also enable pre-market regulatory flexibility.
- ***Improve AI transparency,*** including consideration of “AI nutrition labels” that enable end-users to readily understand product-specific safety and effectiveness considerations. An example of this would be information on pediatric testing/training and medical use considerations.
- ***Require more specificity about the qualifications of intended end-users*** of a given AI-enabled software medical device to ensure those providing patient care services with the AI can do so safely and effectively with the expertise and autonomy to identify and resolve AI performance concerns.

II. Provide new, physician-informed payment for high clinical value AI. The Centers for Medicare and Medicaid Services (CMS) and other payers should provide fair valuation of

new and existing imaging services, including appropriate recognition of physicians and their practice expenses.

For AI innovations that provide valuable data and additive information unavailable to physicians and their patients without the use of the tools, new funding must come from outside of the current physician payment system. CMS should collaborate with radiologists and other physicians to define clinical value and identify innovations worthy of new payment.

III. Ensure healthcare AI is appropriately, safely, and effectively implemented and used by providers. The AI Action Plan should consider the quality and safety of AI implementations and appropriate medical use, such as via accreditation by FDA- or CMS-recognized accreditation bodies. These programs should ensure AI end-users within accredited facilities are qualified, adhere to standards of care and best practices, and have appropriate AI governance infrastructures and monitoring programs in place.

Accreditation programs are demonstrably successful at improving the quality and safety of healthcare services. For example, ACR has partnered with FDA and CMS on mandatory accreditation for mammography and advanced diagnostic imaging.

Thank you for your consideration of these healthcare-specific priorities for inclusion in the future AI Action Plan. The ACR invites collaboration with OSTP and NITRD NCO staff. Please contact Michael Peters, Senior Director, Government Affairs, at mpeters@acr.org, with questions.

Sincerely,



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Chief Executive Officer
American College of Radiology