American College of Radiology

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Assistant Secretary for Technology Policy
Department of Health and Human Services
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Subject: Docket ID: (HHS-ONC-2026-0001; 90 FR 60108) "HHS Health Sector AI RFI"—Request for Information: Accelerating the Adoption and Use of Artificial Intelligence as Part of Clinical Care; Comments of the American College of Radiology

The American College of Radiology (ACR)—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 Assistant Secretary for Technology Policy's (ASTP, or ASTP/ONC) request for information (RFI), "Accelerating the Adoption and Use of Artificial Intelligence as part of Clinical Care" (HHS-ONC-2026-0001) published Dec. 23, 2025.

The ACR established its Data Science Institute (DSI) in 2017 to advance safe, effective, and clinically useful AI innovations for use by radiologists. 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 regulatory, legal, and ethical issues associated with radiology AI.

HHS General Questions

HHS seeks to establish a regulatory posture on AI that is well understood, predictable, and proportionate to any risks presented to enable rapid innovation while protecting patients and

the confidentiality of their identifiable health information. We seek feedback on how current HHS regulations impact AI adoption and use for clinical care.

HHS regulation provides an essential foundation for the safe and effective clinical adoption of AI technologies. For example, FDA oversight of AI-enabled medical devices gives deployers and end-users added confidence in adopting these tools for radiology and other patient-care applications. However, FDA's authority covers only a subset of clinical AI, and many AI-enabled software functions used in care delivery are either entirely unregulated by HHS agencies or operate as non-device features embedded within voluntarily ASTP/ONC-certified health IT systems, such as EHRs.

HHS should enhance its regulations to address other aspects of AI adoption and use. There remains a significant unmet need for federal support, incentives, or regulatory expectations that promote good AI governance; standardize AI model transparency; ensure that primary clinical AI end-users are qualified to perform the patient-care service at issue and empowered to mitigate risk; and require sites to implement risk-appropriate post-deployment monitoring and related processes to help ensure patients are well served and protected.

Given the inherent flaws in legacy payment systems, we seek to ensure such payment systems are modernized to meet the needs of a changing healthcare system. We seek feedback on payment policy changes that ensure payers have the incentive and ability to promote access to high value AI clinical interventions, foster competition among clinical care AI tool builders, and accelerate access to and affordability of AI tools for clinical care.

While we appreciate HHS's recognition that legacy payment systems must evolve, there is no clear or consistent federal payment policy that supports the clinical use of AI tools. This gap limits provider adoption, stifles innovation, and ultimately restricts patient access to high value AI-enabled care. The ACR will continue working with HHS, CMS, industry partners, and other stakeholders to develop a modern, robust payment framework that promotes access to clinically valuable AI tools, encourages fair competition, and ensures sustainable, value-based integration of AI into patient care. Under current rules, AI tools are typically treated as practice expense inputs or bundled into existing CPT/HCPCS codes, regardless of whether they materially enhance diagnostic accuracy, reduce variation, or support improved clinical outcomes. This approach effectively treats AI the same as commodity software, even when the technology performs clinically meaningful tasks and requires physicians, particularly radiologists, to invest additional time to interpret, validate, and incorporate AI outputs into clinical decision-making.

Without a payment structure that recognizes this work, clinicians have limited incentives to use AI tools, and health systems face a financial disincentive to adopt innovations that could otherwise improve care delivery. A payment policy that ties reimbursement for AI-enabled services to demonstrated improvements in quality, efficiency, or clinical outcomes would more effectively incentivize best practices. Such an approach would allow Medicare to capture the true value of AI tools, support responsible clinical adoption, and ensure that radiologists and other clinicians are appropriately recognized for the work associated with integrating AI into patient care.

We seek input on ways in which HHS may invest in research & development (including public-private partnerships and cooperative research and development agreements (CRADAs)) to

integrate AI in care delivery and create new, long-term market opportunities that improve the health and wellbeing of all Americans.

ACR supports expanded federal investment in AI innovation, including targeted research and development (R&D) activities that advance high-value clinical use cases for radiologist end-users. HHS agencies should work closely with professional associations, such as the ACR, to ensure that federally funded R&D efforts are aligned with the practical needs of clinicians and the care environments in which AI will be deployed. Strategic public-private partnerships and CRADAs focused on clinically meaningful radiology applications would help accelerate development, strengthen real-world evaluation, and create durable market opportunities that improve patient care and long-term health outcomes.

HHS Specific Questions

1. ***What are the biggest barriers to private sector innovation in AI for health care and its adoption and use in clinical care?***

Unsustainable Payment—Clinical AI adoption is not currently supported by sustainable and appropriate Medicare payment policies that promote clinically useful innovation, reward safe and effective deployment/governance practices, and advance appropriate/responsible use of AI by qualified end-users.

Challenges Meeting Use Cases of Practical Value—Private sector innovators often pursue AI tools optimized for regulatory success, academic recognition, or investor appeal rather than solutions that meet high-value, real-world needs in current clinical environments. AI solutions that deliver genuine clinical value are frequently obscured by a crowded landscape of tools that may not meaningfully support real-world practice improvements and efficiencies.

Lack of AI Model Transparency/Resources—There are few model transparency requirements and trusted government or third-party resources available to support AI investment and adoption decision-making. AI innovations must be financially and clinically justifiable to those making adoption decisions, and deployers need information to ensure their investments are likely to yield return on investment via patient care improvements and full cost recovery. This was a driver behind ACR's establishment of the AI Central repository of AI-enabled software medical devices; however, this tool is limited to the radiology domain.

Interoperability/Integration Problems—Insufficient interoperability between AI functions and disparate, fragmented systems within clinical settings create significant adoption and usability barriers. For example, a lack of standardized API access poses a challenge for integrating AI innovations into legacy platforms, including picture archiving and communication systems (PACS) and EHR systems. This lack of interoperability between AI systems and EHR/PACS makes performance monitoring cumbersome and costly.

Privacy/Security Compliance Uncertainty—Hesitancy about privacy/security compliance requirements, such as requirements under the Health Insurance Portability and Accountability Act (HIPAA), can also pose a barrier to AI adoption. Participation in clinical data registries, such as Assess-AI, encourage AI adoption by providing real-world monitoring capabilities to qualified end-users. However, due to unclear requirements or overly cautious compliance strategies regarding

data sharing, clinical sites may be reluctant to share data with clinical data registries that they perceive as requiring additional authorizations.

2. ***What regulatory, payment policy, or programmatic design changes should HHS prioritize to incentivize the effective use of AI in clinical care and why? What HHS regulations, policies, or programs could be revisited to augment your ability to develop or use AI in clinical care? Please provide specific changes and applicable Code of Federal Regulations citations.***

Through its agencies' regulatory authorities and programmatic activities, HHS should promote or reinforce appropriate and sustainable payment, AI model transparency, good governance practices among deployers—such as post-deployment monitoring via national registries and, where appropriate, practice accreditation—and also ensure that primary clinical end-users possess the qualifications necessary to deliver the associated patient-care services and effectively mitigate risk.

Performance Monitoring—Post-deployment performance monitoring is crucial for detecting model drift, sub-population effectiveness gaps, and site-specific failures. ACR's Assess-AI is a national registry for radiology AI models that captures real-world data to provide qualified end-users with technology for continuous automated monitoring of model inputs and outputs, versioning, and concordance with radiologist reports. As a result, Assess-AI allows users to capture data during clinical use to ensure safe and effective performance of AI medical devices in real world settings. In addition, Assess-AI compares performance of local model-based inference with aggregated national data (processed by same or different commercial models on identical clinical use cases) to uncover performance variation and identify improvement opportunities.

To better enable AI performance monitoring via national registries and other mechanisms, HHS regulations, guidance, and other initiatives should advance standardized exchange of AI outputs, model/version identifiers, and device meta data to allow such comparisons on a broad scale. This infrastructure could further serve as the basis for a structured "AI Product Facts" schema that standardizes how model attributes and outputs are communicated and consistently interpreted during performance monitoring. Additionally, HHS could address privacy/security concerns of participation by clarifying via sub-regulatory guidance or other informational resources that AI performance monitoring via national registries is a recognized "healthcare operations" activity under HIPAA.

Good Governance—HHS' regulatory framework should scale organizational readiness via accreditation, attestation, and governance playbooks. Encouraging adoption of low-burden, auditable building blocks, such as AI governance groups, algorithm inventories, workflow documentation and training, and ongoing monitoring can help ensure organizations have capacity for AI adoption. For example, ACR's AI quality assurance program (ARCH-AI) supports organizational readiness by recognizing adherence to best practices for AI governance.

Appropriate Payment—With respect to reimbursement, one of the central challenges in establishing appropriate payment for AI tools lies in determining how these technologies should be incorporated into the Medicare Physician Fee Schedule. AI applications span a wide range of clinical workflows and are often developed for specific imaging modalities (e.g., CT, MRI, ultrasound) and anatomical regions. As a result, creating distinct CPT codes for each AI solution risks substantial fragmentation of the existing imaging code set. This fragmentation could

undermine coding consistency, complicate billing, and create administrative burden for providers and payers.

An alternative reimbursement approach may involve aligning payment for AI deployment and use with the measurable value these tools contribute to clinical care. Although there are frequent suggestions that AI tools could reduce radiologist workload, the current reality is quite different. In practice, radiologists often invest additional time to review, validate, and interpret AI outputs, particularly as they integrate these technologies into routine practice with appropriate clinical caution. Radiologists continue to adopt AI because of its strong long-term value proposition, but the short-term effect is often an increase, not a decrease, in cognitive and workflow demands.

3. ***For non-medical devices, we understand that use of AI in clinical care may raise novel legal and implementation issues that challenge existing governance and accountability structures (e.g., relating to liability, indemnification, privacy, and security). What novel legal and implementation issues exist and what role, if any, should HHS play to help address them?***

   For **non-device** clinical AI—which is by definition "unregulated" by HHS agencies but may be in voluntarily ASTP/ONC-certified health IT systems—there is a lack of clarity regarding where the responsibility lies when errors occur. There are no established standards designating responsibilities and expectations for handling model updates, data logging, and incidence response sharing amongst HHS, the developer, the platform, and the clinical site.

   ASTP/ONC should strive to help fill this gap via federal standards or recommendations for shared safety, effectiveness, risk-appropriate monitoring, and privacy/security responsibilities for non-device clinical AI use.

4. ***For non-medical devices, what are the most promising AI evaluation methods (pre- and post deployment), metrics, robustness testing, and other workflow and human-centered evaluation methods for clinical care? Should HHS further support these processes? If so, which mechanisms would be most impactful (e.g., contracts, grants, cooperative agreements, and/or prize competitions)?***

   Evaluation methods should be applied in a consistent and risk-appropriate manner for all AI utilized in patient care, including unregulated **non-device** AI. AI tools should undergo pre-deployment testing as well as post-deployment monitoring.

   Pre-deployment testing should include external validation, subgroup analyses to confirm that no patient population is disproportionately impacted by differences in model performance, stress/robustness testing, and usability/workflow impact testing.

   Post-deployment monitoring should involve continuously gathering AI output in real-world clinical settings to detect model drift and ensure safe and effective use. ACR's Assess-AI national registry—which is currently limited in applicability to AI medical devices used in radiology—exemplifies how such post-deployment monitoring could be applied more broadly via tracking algorithm versions, inputs, and concordance between AI outputs and radiology reports over time and across sub-cohorts. Local clinical governance committees can use the resulting dashboards to benchmark performance against national peer organizations, investigate outliers, and detect drift early.

5. ***How can HHS best support private sector activities (e.g., accreditation, certification, industry driven testing, and credentialing) to promote innovative and effective AI use in clinical care?***

   HHS should encourage site readiness programs to standardize governance and monitoring expectations across clinical sites, which could include future practice accreditation akin to mammography and advanced diagnostic imaging provider accreditation programs at FDA and CMS.

   ACR, as an experienced accreditor of various imaging and treatment modalities, is working toward development of an AI practice accreditation program. In making progress toward that objective, ACR established an attestation-based AI quality assurance program (ARCH-AI) that promotes and recognizes adherence to best practices for AI governance in imaging interpretation while facilitating gap analysis and quality and process improvement. Participants in that program also must promise to participate if feasible in ACR's Assess-AI registry. Additionally, ACR is using lessons learned from these programs to help develop a "Practice Parameter", which will form the basis for ACR's future accreditation program design, for radiology AI in 2026.

6. ***Where have AI tools deployed in clinical care met or exceeded performance and cost expectations and where have they fallen short? What kinds of novel AI tools would have the greatest potential to improve health care outcomes, give new insights on quality, and help reduce costs?***

   Currently available AI tools in clinical care have demonstrated meaningful promise in several targeted, task-specific applications, particularly those that support clinician workflows rather than replace clinical judgment. For example, in radiology, CAD detection and diagnostic devices typically perform well when narrowly focused on a defined task and when integrated into clinical workflows of a qualified end-user (i.e., an end-user qualified to perform the same patient care service without the AI and therefore able to help mitigate safety/effectiveness risks).

   In many other areas, however, AI tools have not yet met cost or performance expectations, particularly where vendor pricing structures remain prohibitively high. In some cases, AI vendors may capture a disproportionate share of the technical fee associated with a medical procedure, creating substantial financial burdens for facilities and limiting broader adoption. As a result, while the underlying technology may perform to expectation, real-world deployment may be unsustainable and impractical due to cost recovery problems.

   Looking forward, several categories of newer, more advanced AI tools have significant potential to improve outcomes and enhance value. Tools capable of real-time, context-aware integration of the patient's longitudinal medical record, powered by large language models (LLMs), could markedly enhance diagnostic precision. These types of intelligent, interactive systems go beyond traditional pattern-recognition algorithms. They have the potential to improve care quality, reduce diagnostic error, and generate substantial efficiencies, especially if implemented at a price point commensurate with the value delivered. For example, a radiologist may identify an indeterminate liver lesion while interpreting a CT abdomen and pelvis study. A hypothetical AI system that simultaneously reviews relevant prior imaging, pathology, clinical notes, and laboratory data, and then proposes a contextually informed differential diagnosis with estimated likelihoods could meaningfully improve diagnostic accuracy and clinical decision-making.

7. ***Which role(s), decision maker(s), or governing bodies within health care organizations have the most influence on the adoption of AI for clinical care? What are the primary administrative hurdles to the adoption of AI in clinical care?***

   Departmental governance, enterprise IT/security, legal and compliance teams, and procurement and finance teams hold significant administrative influence over the adoption of AI within healthcare organizations. These are generally important for handling quality assurance, legal, and privacy/security compliance considerations.

   However, administrators can encounter hurdles such as IT/infrastructure interoperability issues and competition for limited resources within a given institution. Many AI tools designed for healthcare settings are priced on a per patient/use basis, which significantly impacts financial considerations and administrative decisions around acquisition, deployment, and use. Other challenges include vendor contracts/agreements, security review complications, staffing/resource limitations on quality assurance capabilities, and model/product transparency shortfalls.

   There is currently a large, unmet need to organize and prioritize AI requests. There is a role for professional/trade associations and others to help inform this type of administrative decision-making. HHS could explore mechanisms for supporting this work through funding opportunities or other collaborations.

8. ***Where would enhanced interoperability widen market opportunities, fuel research, and accelerate the development of AI for clinical care? Please consider specific data types, data standards, and benchmarking tools.***

   Enhanced interoperability would significantly broaden market opportunities, strengthen research, and accelerate AI development for clinical care. Today, fragmentation in data types, standards, and benchmarking across disparate systems creates barriers to both effective R&D and seamless clinical integration. Improving interoperability would make it easier to aggregate datasets, evaluate AI performance across diverse settings, and integrate AI outputs into existing IT infrastructure and clinical workflows. To address these challenges, HHS should support and promote interoperability of AI results and outputs across systems by advancing the use of criteria developed by appropriate standards, professional, and trade organizations. This would empower R&D operations, reduce AI integration burdens, improve consistency in evaluating model performance, and help ensure clinically useful AI innovations can be adopted more readily and safely.

9. ***What challenges within health care do patients and caregivers wish to see addressed by the adoption and use of AI in clinical care? Equally, what concerns do patients and caregivers have related to the adoption and use of AI in clinical care?***

   Radiology providers have observed patients' frustrations with procedure scheduling and follow-up delays, repeat/duplicative testing, and rising healthcare costs. Patients are generally interested in ensuring that appropriate guardrails are in place to ensure safety, effectiveness, privacy, and security (e.g., FDA's reasonable assurance of safety and effectiveness is important to patients for establishing trust in AI medical devices). Patients seem to be wary of an overly automated care experience and may be more receptive to clinical AI when a physician with the appropriate qualifications is managing AI-enhanced care. Establishing patient-facing disclosure standards

(where risk-appropriate) and setting clear expectations for incident reporting can also help establish or enhance patients' trust in AI tool-empowered care by their physicians.

10. ***Are there specific areas of AI research that HHS should prioritize to accelerate the adoption of AI as part of clinical care?***

HHS should prioritize research into implementation science for real-world deployment of AI. These efforts should include research into methods for detecting and addressing model drift and implementing AI into clinical workflows. Monitoring and benchmarking of AI devices is critical for safe and effective implementation; HHS should utilize public-private partnerships and cooperative agreements to build shared infrastructure for developers and qualified users to monitor AI output.

Additionally, HHS should also encourage more research into AI for pediatrics and rare diseases—with prioritized funding opportunities from NIH/ARPA-H/other research agencies and incentives for developers to invest in these innovations (e.g., continued prioritization in FDA's Breakthrough Device Program)—to ensure AI has broad applicability and clinical impact. Pediatrics and rare disease care are relatively small markets with limited data, which results in less commercial AI development for these fields. A pediatric disease can have impacts that span the child's entire life, however.

The ACR welcomes further communication and collaboration with ASTP on AI safety and effectiveness. For questions, please do not hesitate to contact Mike Peters, ACR Senior Director, Government Affairs, at mpeters@acr.org, Lindsay Robbins, ACR Regulatory Policy Specialist, at lmrobbins@acr.org, or Christina Berry, Manager, Economic Policy, at cberry@acr.org.

Sincerely,

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