American College of Radiology™

June 16, 2025

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0042-NC
PO Box 8013
Baltimore, MD 21244-8013

Re: (CMS-0042-NC) Request for Information; Health Technology Ecosystem; 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 provide comments to the U.S. Department of Health and Human Services (HHS) Centers for Medicare and Medicaid Services (CMS) and Assistant Secretary for Technology Policy (ASTP/ONC) addressing the May 16, 2025, request for information (RFI), "Health Technology Ecosystem" (CMS-0042-NC; 2025-08701; 90 FR 21034). The ACR is previously on-record with HHS agencies, including CMS, ASTP/ONC, and the Food and Drug Administration (FDA), regarding the digital health policy recommendations discussed below.

General Recommendations

Revisit and implement imaging PAMA AUC consultation requirements. The ACR supports the appropriate ordering of radiology studies by ordering providers, a practice which has been shown to significantly reduce costs for patients and the healthcare system-at-large. In doing so, the ACR has long advocated for implementation of a CMS program requiring ordering providers to use appropriate use criteria (AUC)-based clinical decision support mechanisms to inform radiology order entry. Section 218(b) of the Protecting Access to Medicare Act of 2014 (PAMA) mandated such a program but it has yet to be fully implemented by CMS.

The ACR proposes that CMS revisit the PAMA AUC program and make necessary changes to address the challenges associated with its implementation. These changes include self-attestation by ordering providers instead of the requirement to report AUC consultation information on each claim enabling audits only on an "as-needed" basis. The ACR also supports new exemptions for small/rural practices and those participating in clinical trials. Our comments in response to CMS' proposed rule regarding the 2026 rates for the Hospital Inpatient Prospective Payment System provide additional details about this issue.

Advance image exchange. The ACR supports appropriate access, exchange, and use of electronic health information (EHI) by providers and patients. For example, we continue to advocate that imaging IT and exchange service vendors move to electronic sharing capabilities for diagnostic quality images without the use of compact discs or other physical storage media. HHS should partner with radiology societies and others to develop and implement a national strategy to

modernize image-sharing using existing radiology standards, federal regulatory levers, and programs.

Improve "Information Blocking" regulatory implementation. The ACR endorsed the original legislation in the mid-2010s that later became Sec. 4004 of the 21st Century Cures Act of 2016 (or the "Information Blocking" provision). We have since advocated improvements to HHS' implementation of Information Blocking regulations and guidance that would prioritize the law's original goal of deterring anticompetitive nontechnical barriers to exchange. Several of these recommendations are addressed in the relevant subsection below, as well as within separate comments filed by the Physician Clinical Registry Coalition (of which ACR is a member organization).

Advance safe, effective, and useful AI innovations used by qualified end-users. The ACR Data Science Institute® (DSI) was established in 2017 to advance safe, effective, and responsible use of data and AI in radiology practices. The ACR DSI collaborates with radiology professionals, industry, government (including FDA), patients, and other stakeholders in developing programs and tools in support of the implementation of AI applications in clinical practice. We welcome collaboration with CMS, ASTP/ONC, and all other HHS agencies. The ACR DSI's AI monitoring portfolio includes:

- ***AI-Central:*** The most complete and up-to-date online, searchable directory of commercially available imaging AI products in the United States with more than 200 FDA-cleared products from over 100 vendors.
- ***The ACR Recognized Center for Healthcare-AI (ARCH-AI):*** A recognition program that outlines expert consensus-based building blocks for the infrastructure, processes, and governance necessary for AI implementation in real-world practice.
- ***Assess-AI:*** The first AI quality registry to monitor and track the performance of AI by capturing real-world data during clinical use over time.

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.

ACR Responses to RFI Questions

C. Providers

PR-1. What can CMS and its partners do to encourage providers, including those in rural areas, to leverage approved digital health products for their patients?

PR-1 Response. The goal of federal policy should be to advance safe and effective patient care. This includes ensuring appropriate, high quality medical use of digital health products and other innovations by qualified end-users. CMS could assist in this assurance by requiring providers to have processes and mechanisms for governance, model selection, acceptance testing, monitoring, etc. The ACR's ARCH-AI recognition program, for example, requires radiology providers using AI to attest to these capabilities, and the ACR is working toward establishment of a practice

accreditation program for radiology AI (See: "The Road Map for ACR Practice Accreditation for Radiology Artificial Intelligence." Larson, David B. et al. *Journal of the American College of Radiology*, Volume 22, Issue 5, 586 - 592).

Additionally, CMS and its partners should provide new appropriate payment outside of the current physician payment system for high clinical value digital health products, with clinical value determined by physicians with expertise in the relevant specialties.

PR-6. Is TEFCA currently helping to advance provider access to health information?

PR-6 Response. The Trusted Exchange Framework and Common Agreement (TEFCA) is limited in its applicability to radiology data exchange due to its current focus on basic data classes/elements collected and shared via EHR-centric IT systems. Participation options and mechanisms are unclear for radiology practices and other specialist providers. HHS could expand the relevance and public benefit of the TEFCA program by requiring participating networks to enable electronic exchange of images and imaging data. This should include a focused effort by the ASTP/ONC to partner with radiologist societies to incorporate expanded radiology data classes/elements into the U.S. Core Data for Interoperability (USCDI) standard.

PR-7. What strategies can CMS implement to support providers in making high-quality, timely, and comprehensive healthcare data available for interoperability in the digital product ecosystem? How can the burden of increasing data availability and sharing be mitigated for providers?

PR-7 Response. Image exchange service vendors are subject to 45 CFR Part 171 (Information Blocking) regulatory requirements as "health information network/exchange (HIE/HIN)" actors. CMS, ASTP/ONC, and OIG could help these actors comply by providing informational resources to move the health IT industry and image exchange service vendors toward policies that advance interoperability and data sharing between disparate products/systems and customers.

PR-12. Should ASTP/ONC consider removing or revising any of the information blocking exceptions or conditions within the exceptions (45 CFR part 171, subparts B through D) to further the access, exchange, and use of EHI and to promote market competition?

PR-12 Response. The regulations under 45 CFR 171 Subparts B through D are extensive, complex, and nebulous for many healthcare providers with limited legal/compliance resources. Yet, Congress intended for the Information Blocking "exceptions" to provide compliance clarity to actors making good faith attempts to comply. The ACR recommends that ASTP/ONC make the following revisions/additions to Subparts B through D:

- ***Implement flexible and simplified provider-specific exceptions.*** ASTP/ONC should establish a separate set of provider-only exceptions to eliminate complications that arise from applying exceptions across multiple provider, developer, and network actor types. Provider-specific exceptions should be clear, flexible, and useable by various clinical settings and provider types. These exceptions should ensure that HHS compliance requirements carefully avoid HHS impositions on physician-patient communications and medical decision-making autonomy.

- ***Implement a new exception for providers who withhold as-of-yet-unreviewed and unverified EHI, including EHI generated by medical devices.*** Medical device labelling and/or instructions for safe and effective use typically assume intended user review of the output EHI as a key risk mitigation. Therefore, sending medical device data directly and/or immediately to a patient is usually an "off-label" use of the device in unintended ways not considered during FDA's vetting of that device for its safety and effectiveness. Additionally, providers occasionally send EHI to subspecialists during the medical decision-making process, and academic centers also require review by attending physicians of residents' and fellows' work with certain EHI. As patients increasingly use AI-enabled digital health technologies to inform their own decision-making, the quality and accuracy of any patient-accessible EHI is critical. Therefore, withholding access to certain EHI until it can be appropriately reviewed by a qualified provider is often reasonable and necessary.
- ***Improve and finalize the previously proposed exception in the HTI-2 proposed rule under §171.304 ("Requestor preferences").*** This proposal should be finalized by ASTP/ONC in a manner that continues to enable provider-actors to routinely request patient preferences about EHI access during the check-in process (for example, via a question on patient intake forms). This is critical to ensure the applicability and scalability of this exception by many radiology practices and other providers.

PR-13. For any category of healthcare provider (as defined in 42 U.S.C. 300jj(3)), without a current information blocking disincentive established by CMS, what would be the most effective disincentive for that category of provider?

PR-13 Response. CMS and OIG should focus Information Blocking investigations and application of provider disincentives on clearly intentional, repetitive, and objectively anticompetitive behaviors by major actors rather than by individuals. Large systems and major institutions typically influence EHI access, exchange, and use within a given region or facility more than individual physicians, physician practices/departments, or smaller provider facilities.

PR-14. How can CMS encourage providers to submit information blocking complaints to ASTP/ONC's Information Blocking Portal? What would be the impact? Would it advance or negatively impact data exchange?

PR-14 Response. CMS and ASTP/ONC can increase the quality and quantity of provider-submitted information blocking complaints by refocusing and improving educational resources, guidance, and other messaging about Information Blocking rules and their importance for ensuring provider- and vendor-level competition and fairness.

The legislative policy inserted as Sec. 4004 (the "Information Blocking Provision") into the 21st Century Cures Act of 2016 was originally intended by Congress and advocates to deter anticompetitive, artificial, nontechnical barriers to exchange by IT vendors, networks, and major institutions. At the time, nontechnical exchange barriers encountered by radiology providers and others were common due to referring providers' need for, and reliance on, certified EHR technology for compliance with the Medicare/Medicaid EHR Incentive Program (or "Meaningful Use"). Examples of those barriers included data silos, unfair or predatory fees, subsidized technology donations and other policies to control order entry software and connections between providers (i.e., to influence the flow of referrals and orders), and other policies that adversely impacted many providers and limited the care choices of their patients.

To date, ASTP/ONC has ineffectively communicated how Information Blocking regulations also protect ***provider-level*** access, use, and exchange of EHI. Most stakeholders misunderstand these rules to be limited to, or focused on, patient-level access. As a result, many physicians, practices, and small providers seem unaware that they too can report dubious behaviors, fees, and policies they experience from certain competitors, networks, and vendors.

The ACR appreciates consideration of these comments and recommendations by CMS and ASTP/ONC staff. We welcome further discussion with HHS agencies on these matters. Please send any questions or requests to Michael Peters, ACR Senior Director, Government Affairs, at mpeters@acr.org.

Sincerely,

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Chief Executive Officer
American College of Radiology