March 16, 2026

Assistant Secretary for Technology Policy/ONC
U.S. Department of Health and Human Services
Attn: RFI, Diagnostic Imaging Interoperability Standards and Certification
Mary E. Switzer Building, Mail Stop: 7033A
330 C Street SW, Washington, DC 20201

Subject: (RIN 0955-AA11) Request for Information: Diagnostic Imaging Interoperability Standards and Certification; Comments of the American College of Radiology, Radiological Society of North America, American Association of Physicists in Medicine, American Society of Radiologic Technologists, and Society of Nuclear Medicine and Molecular Imaging

The American College of Radiology (ACR),[1] Radiological Society of North America (RSNA),[2] American Association of Physicists in Medicine (AAPM),[3] American Society of Radiologic Technologists (ASRT),[4] and Society of Nuclear Medicine and Molecular Imaging (SNMMI)[5] appreciate the opportunity to comment on the request for information (RFI) published in the January 30, 2026, *Federal Register*, titled, "RFI: Diagnostic Imaging Interoperability Standards and Certification" (RIN 0955-AA11; 91 FR 4054). Our organizations strongly support electronic access, exchange, and use of diagnostic quality medical images and we applaud the U.S. Department of Health and Human Services (HHS) Assistant Secretary for Technology Policy/Office of the National Coordinator for Health IT (ASTP/ONC) for exploring this important topic.

General Comments

Radiology and nuclear medicine have historically been at the forefront of technological innovation in healthcare, including standardization of diagnostic quality medical images. In the 1980s, radiology and nuclear medicine providers and imaging device manufacturers jointly created what became DICOM—a standard for communication of digital image information which has subsequently expanded from radiology to include medical imaging needs in other domains, including digital pathology. In the late 1990s, the Integrating the Healthcare Enterprise (IHE) initiative was created with a radiology focus, then this also subsequently branched out to other areas in medicine. IT systems that support medical use of diagnostic quality image data, such as

[1] The **American College of Radiology (ACR)** is professional association representing more than 40,000 physicians practicing diagnostic radiology, interventional radiology, radiation oncology, and nuclear medicine, as well as medical physicists. (*ACR.org*)

[2] The **Radiological Society of North America (RSNA)** is a global organization representing over 52,000 radiologists and medical imaging professionals and is dedicated to advancing excellence in patient care and healthcare delivery by fostering education, driving research, and spearheading technological innovation. (*RSNA.org*).

[3] The **American Association of Physicists in Medicine (AAPM)** is a professional organization representing more than 10,000 medical physicists globally. Its mission is to advance medicine through the science, education, and professional practice of medical physics, ensuring safety in radiation therapy and imaging. (*AAPM.org*).

[4] The **American Society of Radiologic Technologists (ASRT)** is the professional association representing more than 155,000 medical imaging and radiation therapy professionals across the nation. It's mission is to advance and elevate the medical imaging and radiation therapy profession and enhance quality, safe patient care. (*ASRT.org*)

[5] The **Society of Nuclear Medicine and Molecular Imaging (SNMMI)** is an international nonprofit medical society dedicated to advancing nuclear medicine, molecular imaging, and theranostics. The Society establishes clinical practice guidelines, publishes leading scientific journals, convenes scientific meetings, and advocates for policies that support innovation and patient access in molecular imaging and precision medicine (*SNMMI.org*).

Picture Archiving and Communication Systems (PACS), have been universally adopted by radiology practices for well over two decades.

Accordingly, the undersigned organizations have led multiple efforts over many years—including via the radiology and nuclear medicine community-wide "Ditch the Disk" initiative—to push the radiology IT ecosystem toward exchange of medical images without legacy physical storage media such as compact discs. We have also long advocated for policy improvements, including via programs within HHS agencies, such as ASTP/ONC regulations and U.S. Core Data for Interoperability (USCDI) standards. Radiology organizations met over time with HHS leaders and consistently supported the pro-exchange developments listed in "Supplementary Information" Sec. II of the ASTP/ONC's RFI.

However, despite widespread adoption, variability in the implementation of technical standards has impeded interoperability and exchange across disparate products and settings. While radiologists, nuclear medicine physicians, medical physicists, radiologic technologists, nuclear medicine technologists, and others overwhelmingly want physical media-free image exchange, these functions are often unavailable in imaging IT systems implemented in their workplaces, with physical storage media remaining a common feature for sharing diagnostic quality images, metadata, supporting files, and DICOM viewer applications.

There is a need for the federal government to partner with radiologists, nuclear medicine physicians, medical physicists, radiologic technologists, nuclear medicine technologists, and industry on this issue and signal that true interoperability and image-sharing for patient care purposes is a national priority, akin to similar policy priorities in the EHR and prior authorization/billing software domains. At the same time, any federal policy initiative to advance electronic exchange must account for the wide variation in resources and capabilities across providers. Therefore, any future action should promote interoperability and move standards forward within the industry while avoiding system acquisition mandates or other new compliance burdens for resource-constrained providers or the patients they serve.

Specific Responses

A. Transition From Physical Media to Electronic Access, Exchange, and Use

PM-1. What barriers do patients experience with electronic access to diagnostic images? Are there examples today where patients can successfully access, exchange, and use diagnostic images outside of a particular hospital or network system without use of physical media?

Physical media remains a frequent method for transport of diagnostic imaging for patients whose care involves care teams spanning multiple provider sites. Patients are often forced to act as the steward and courier of their imaging records. After the imaging procedure is performed, they may be given physical media containing their diagnostic images, a viewing application, and sometimes the radiologist's report and other supporting files or data, which they are expected to preserve and transport to other providers on the care team. Subsequent care providers may face considerable barriers to accessing and using this information and provider sites may be required to maintain pathways for ingesting externally generated data with dedicated systems and staff. The data may be lost or inaccessible when it could provide value during future episodes of care, often leading to additional redundant imaging. This situation is especially difficult for private practice radiologists,

who often encounter considerable obstacles when reviewing imaging studies from small community imaging centers lacking electronic image sharing systems. Consequently, providers are frequently unable to obtain critical comparison images or pertinent patient history, which hinders their ability to make precise diagnoses and may result in significant adverse outcomes for patients. Reliance on this approach to data sharing imposes burdens on patients and care providers, increases costs, and impacts the quality and efficiency of care by delaying or impeding care decisions.

Increasingly, providers within the operating environment of a given health care organization's network/system are able to access diagnostic quality imaging acquired and stored throughout that network. Patients may also be able to access their imaging records through patient portals associated with the organization's electronic health record (EHR) system (though often not in full diagnostic quality DICOM format). However, once again, patients moving across networks are often forced to find ways to transfer their diagnostic images when necessary, often by obtaining and transporting physical media.

In certain states and regions in the US (as well as in many other countries), imaging-enabled health information exchange (HIE) networks allow care providers at any participating site to view and/or download diagnostic imaging acquired at any other participating site. Patients from these sites are spared from the burden of actively maintaining and transporting their records—at least within the broader boundaries of the HIE network—and providers using these HIEs are able to access prior imaging records more conveniently for diagnosis and care. These benefits could be extended nationwide through ubiquitous adoption of standardized methods of electronic access to diagnostic imaging.

PM-2. What existing policies do you believe limit or interfere with diagnostic image access, exchange, and use? What policies would you introduce to accelerate the transition to electronic, standards-based diagnostic image access and exchange and to reduce the practice of imaging silos that impede electronic access, exchange, or use of diagnostic images?

Certain existing federal policies may unintentionally limit or complicate diagnostic image access, exchange, and use. For example, exceedingly cautious interpretations of HIPAA and related privacy requirements often lead organizations to adopt restrictive data-sharing practices, particularly when exchanging diagnostic imaging data with external entities. Similarly, federal and state regulatory programs can influence internal IT investment decisions, resulting in prioritization of EHR-centric upgrades while imaging interoperability capabilities remain underdeveloped or siloed.

ASTP/ONC efforts to foster interoperability that could otherwise advance diagnostic image access are instead hampered by a limited, intentional focus on EHR software capabilities. While ASTP/ONC has implemented various regulatory and nonregulatory programs to broaden access to health information—including the USCDI, the Health IT Certification Program, and the Trusted Exchange Framework and Common Agreement (TEFCA) for Qualified Health Information Networks (QHINs), among others—these programs have pertained primarily to EHR technologies and the data these systems are designed to collect and store. Diagnostic imaging systems, including PACS and vendor-neutral archives (VNA), are generally unrelated to most ASTP/ONC programs, with the exceptions of 45 CFR Part 171 "Information Blocking" regulations and certain data standards-related efforts.

To accelerate the transition to standards-based imaging exchange, ASTP/ONC and other HHS agencies could clarify data-sharing privacy/security issues, advance API-based image exchange methods, and create alignment across federal programs so that imaging systems and EHR platforms are interoperable. Policies encouraging adoption of standardized authorization and authentication frameworks, expanded support for widely accepted imaging standards (such as DICOM, IHE, HL7 FHIR), and clearer guidance on liability considerations when using externally sourced imaging, would further reduce institutional barriers and incentivize vendors and organizations to discontinue use of physical media and proprietary workflows.

PM-2A. What other policy or financial barriers do providers face in accessing diagnostic images from outside facilities? For example, are there concerns about compliance with health care facility policies or procedures (e.g., security or overall policies on data sharing outside the facility), state laws, or malpractice liability?

Radiologists and others encounter various nontechnical barriers when attempting to access diagnostic images generated outside their own institutions/practices, vendor systems, or networks. Many facilities maintain stringent security, privacy, and data sharing policies that can impede exchange of/access to external imaging. Differences in state-level regulatory requirements and institutional interpretations of compliance obligations further complicate this. Additionally, support for external image access frequently requires dedicated staff/resources, manual processes, or investment in new IT services and solutions—all of which may not be fully reimbursed or prioritized within existing institutional/department budget frameworks compared to revenue-generating or efficiency-improving tools. In addition, there may be concerns regarding malpractice liability when access to outside images is incomplete, inconsistent, or unreliable, with providers feeling compelled to mitigate risk through additional redundant imaging.

PM-2B. What technical/interoperability concerns exist, such as compatibility between systems, authorization issues from external sources, or issues with the provenance of diagnostic images?

While technical standards are well established and widely adopted internationally, proprietary imaging systems often implement them inconsistently, resulting in incompatibilities that impede exchange between systems, such as varying implementation of transaction and security protocols, limited support for imaging-related FHIR resources and other interoperability challenges. These issues can lead to failed retrievals, partial studies, or loss of important contextual information. Patient identity-matching challenges further complicate exchange when demographic or identifier data do not align. External systems may also use incompatible token-based authorization approaches, causing validation issues.

PM-3. What technical, operational, and policy approaches can best support health care providers in transitioning from physical media (e.g., CDs and DVDs) to secure, electronic exchange-based methods for sharing diagnostic images outside of their operating environment/health care organization system? If possible, please be detailed in your response.

From a technical perspective, radiology care would benefit from consistent adoption of contemporary, standards-based exchange mechanisms—e.g., FHIR-based APIs, DICOMweb

services, and standardized authorization frameworks such as OAuth 2.0—that enable imaging systems, EHRs, and external applications to communicate reliably. Ensuring that PACS and VNA systems implement these standards uniformly is essential to ensuring seamless access when exchanging studies across organizational boundaries.

Operationally, providers need convenient workflows for accessing and integrating outside imaging and related clinical data without substantial additional effort. Diagnostic imaging records should be made accessible using the same mechanisms for subject and record discovery and retrieval (view and download) as other elements of the electronic patient record so that external images can be viewed and (when needed) downloaded seamlessly within existing user interfaces. Investments in staff training, IT support, and ongoing maintenance of interoperability endpoints can help ensure that electronic image exchange functions consistently. Additionally, institutions and departments could benefit from governance structures to address system/service adoptions, monitoring, and problem resolution.

From a government policy perspective, HHS agencies responsible for various health IT and software devices—such as FDA, ASTP/ONC, and the Office for Civil Rights—could collectively promote consistent use of existing technical standards, including those governing authorization and authentication, while also reducing uncertainty around liability when clinicians use externally sourced imaging. ASTP/ONC guidance and coordination could further accelerate universal adoption of standard image exchange methods through several targeted approaches:

- Advancing imaging-related data elements into USCDI and the HL7 US Core Implementation Guide.
- Supporting incorporation of DICOM-based imaging requirements within 45 CFR Part 170 regulatory language to promote alignment between imaging IT systems and certified EHR technologies.
- Leveraging TEFCA participation criteria so that qualified health information networks (QHINs) consistently facilitate access to diagnostic imaging data as part of nationwide exchange priorities.
- Partnering with standards development organizations to refine and test emerging imaging-exchange standards—such as the Carequality Imaging Data Exchange Implementation Guide, SMART Imaging Access, and IHE's Manifest-based Access to DICOM Objects (MADO) profile.
- Publishing guidance clarifying how image exchange-enabling service vendors should assess their compliance obligations under 45 CFR Part 171 as health information network/exchange actors.

PM-4. Do health care providers and/or patients (including patient-facing apps) need access to the full resolution diagnostic images stored in PACS or is a reference image (e.g., a DICOM image rendered as a JPEG) sufficient for clinical decision-making and use by health care providers and patients? Does this vary by clinician specialty or by type(s) of care provided to the patient? Please feel free to elaborate with rationale.

For radiology and nuclear medicine care use cases, and for many other imaging-reliant specialties (examples include but are not limited to surgical and orthopedic specialties), diagnostic quality DICOM images and metadata—including high-fidelity pixel data and acquisition parameters—are critical. The imaging IT systems radiologists use are designed to work exclusively with DICOM-

formatted imaging data, and radiologists need the image quality and associated DICOM imaging data to accurately identify and differentiate abnormalities, dependably compare current and prior studies, and provide accurate measurements that guide treatment.

Lower fidelity reference images in JPEG format, often in combination with radiology report data, may be useful for patient-facing communications and limited types of coordination. However, these are informational only and generally unusable for diagnostic purposes. Non-DICOM images are also generally not used in quality management/assurance, equipment performance evaluation, third-party accreditation of imaging facilities, algorithm training/testing/validation, or many other clinically adjacent purposes.

PM-5. Do health care providers and/or patients need access to quantitative parameters derived from images for clinical decision-making and use by providers and patients? Please feel free to elaborate with rationale.

In radiology and nuclear medicine imaging, quantitative information derived from images is often essential for medical decision-making. Physician interpretations and many treatment planning use cases depend not only on the pixel data and on metadata in the DICOM header including slice thickness, orientation, voxel dimensions, and acquisition parameters, but also on annotations sent as separate DICOM objects for correct measurements and comparisons. Conversely, the clinical utility of non-DICOM, consumer-grade reference image files is comparatively limited, and reference copy images can typically be produced from DICOM images if desired (whereas the reverse is not true). Accordingly, HHS should prioritize true DICOM-based, diagnostic quality image/imaging data exchange.

B. Standards and Certified Health IT Functionality

SC-1. What technical approaches are currently in use to enable access and/or exchange of diagnostic images between health care systems and health information networks? To what extent are these methods based on standards (e.g., DICOM, DICOMwebTM, FHIR®, IHE® XDS-I, IHE® XCA-I) versus proprietary or custom integrations?

Several technical approaches are currently in use to exchange diagnostic images across systems and networks, and the variability in approaches remains an unnecessary barrier. The most common methods rely on long-established imaging standards, particularly DICOM protocols and DICOMweb, which supports API-driven access for cloud-based workflows. Some cross-enterprise exchanges also use IHE integration profiles, including XDS-I and XCA-I, to specify how authorized systems can discover, query for and retrieve imaging records. Certain vendor networks may use proprietary variations on these standards to enable image access.

Other vendors and organizations have begun to introduce FHIR-based mechanisms for access to imaging, using FHIR resources to support metadata exchange and discovery of relevant imaging studies, while relying on DICOM or DICOMweb for the image content. These approaches are gaining interest as part of API modernization efforts.

SC-2. What metadata and other information is currently associated with diagnostic images for purposes of access and exchange, including images exchanged using different standards and

custom integrations? Please feel free to elaborate on the use of artificial intelligence tools in adding metadata to images and additional information to accompany an image.

The metadata and associated information used in the access and exchange of diagnostic imaging falls into several categories, each with different current and potential uses:

The DICOM header information associated with imaging studies, study series and image instances is an inherent part of the imaging dataset, which is generated during the process of acquiring images. This imaging dataset is used by radiology systems to organize, retrieve, display and analyze imaging studies.

For access and exchange of diagnostic imaging data, imaging systems generate a manifest, based on the DICOM header information, that describes key properties of the contents of the imaging study (or a selected subset of images from the study). The manifest is made available to facilitate discovery and access to the relevant data. The manifest may be formatted as a DICOM Key Object Selection (KOS) structured document. In imaging-enabled HIEs, KOS documents are registered with network gateways (using the architecture defined in the IHE XDS-I.b and XCA-I profiles) and made available for search and retrieval by authorized systems. Alternatively, the HL7 FHIR Imaging Study resource can be used as a manifest for discovery of available diagnostic imaging in emerging approaches for exchange via FHIR-based APIs. SMART Imaging Access uses the same authentication and authorization techniques to exchange both the FHIR ImagingStudy resource as well as the images themselves as first class objects of the medical record.

The Diagnostic Imaging Report is also a key piece of information associated with diagnostic imaging data (and a required element enumerated under USCDI). Currently, this report, which may or may not be included, is often an unstructured block of text used to communicate the radiologist's findings to the care team. Work is currently in progress to add more rigorous structure and greater semantic consistency to the report. The IHE Imaging Diagnostic Report profile provides implementation guidance for use of the HL7 FHIR Diagnostic Report resource in radiology. Additionally, ACR and RSNA are currently developing a catalog of common data elements (CDEs), based on a structured data schema, to communicate observations and impressions in a radiology report.

AI tools have the potential to enhance the utility of metadata and other information associated with diagnostic imaging for access and exchange. For example, the DICOM Study Description field is currently an unstructured string that is populated inconsistently and heterogeneously across care sites. AI could hypothetically be used to harmonize Study Description values to standard names and codes, like the LOINC-RSNA Radiology Playbook, to facilitate pre-fetching of relevant prior studies and streamlining of diagnostic workflows. AI can also be used to improve structure and maintain consistency in the radiology report, and to extract concepts from report text for curation as CDEs that can help guide the outputs of AI models used in diagnosis.

SC-3. What technical barriers, such as proprietary interfaces or ambiguous standards, limit the access, exchange, and use of diagnostic images across health IT systems (including by patient-facing apps), and should existing technical standards be further modified (please identify the standard)?

Technical standards to enable access to diagnostic imaging are well established and implemented in certain HIEs and many proprietary networks in the US and other countries. Building on the foundation of DICOM and HL7 standards, IHE has published implementation guides (XCA, XC-WADO) defining a network architecture for access to diagnostic imaging that parallels and reuses components of the network architecture for sharing other care records formatted using the HL7 Clinical Document Architecture. IHE profiles for document sharing underpin data exchange networks around the world, including both the Carequality "network of networks" and their emerging successors, the QHINS. In the Carequality network alone, these profiles enable the successful exchange of billions of patient records each year.

RSNA partnered with the Sequoia Project and Carequality to develop the Imaging Data Exchange Implementation Guide and the Image Share Validation Program to facilitate implementation of these standards. While the program drew engagement from a broad segment of imaging vendors, the lack of advancement via TEFCA participation requirements for QHINs impeded final implementation. Expanding the capacity of existing networks to enable access to diagnostic imaging could be achieved quickly by requiring these well-defined standards and capabilities in existing programs such as the Health IT Certification Program and TEFCA guidance for QHINs.

The undersigned organizations understand that the direction of technological advancement outlined by ASTP/ONC and its federal partners is toward a "FHIR-forward future," and we are collectively engaged to ensure that diagnostic imaging is included in that progression. We support and participate in the work of the HL7 Imaging Integration Work Group/DICOM Working Group 20 and IHE to fully develop the standards and implementation guidance needed to enable FHIR-based API access to diagnostic imaging. We also support the work under the Argonaut/SMART on FHIR project to bring imaging systems under a common set of authentication and launch protocols within EHR systems.

Our understanding is that FHIR-based access to health information is currently limited to specific point-to-point connections and to "facilitated FHIR" exchange within existing HIE networks (such as Carequality and QHINs). We are aware of ongoing work under the UDAP/ Security for Scalable Registration, Authentication, and Authorization project to facilitate formation of FHIR-based network exchange. Our understanding is that readiness for broad adoption of that work will require additional time. We strongly recommend that development of these protocols, along with implementation guidance and testing, continue in order to enable implementation as soon as feasible.

We thus recommend that ASTP/ONC take immediate steps to enable diagnostic imaging access within established health information exchange networks and accelerate progress toward a FHIR API-based approach. The undersigned organizations can continue to support this approach through communication with the imaging professional and vendor communities and active engagement in the testing and implementation process.

Many IT systems still rely on proprietary integrations, vendor-specific gateways, or customized interfaces/bridges to handle differences in standards implementations. This variability leads to inconsistent interoperability, requiring point-to-point connections, custom mappings, and/or additional coordination to achieve functional image exchange.

SC-4. How do certified health IT and/or EHRs enable or facilitate access, exchange, and use of diagnostic images today? Specifically, do EHRs play an active role in diagnostic image exchange, or is the functionality primarily driven by imaging systems such as PACS and VNAs?

Currently, certified health IT/ EHRs do not commonly play a role in facilitating access to diagnostic imaging. In image-enabled HIEs, imaging IT systems (PACS, VNA) typically connect directly to network infrastructure using gateways that may also provide access to non-imaging EHR-based data. As they are the repository and source of diagnostic imaging data, it seems likely imaging IT systems will continue to play an essential role in access, exchange and use of that data.

ASTP/ONC's health IT certification program and certification criteria regulations under 45 CFR Part 170 are centered around modular functions and features of conventional EHR technologies and do not currently address access to diagnostic imaging, although ASTP/ONC rules and proposals have changed over time regarding this issue with transient periods of agency interest in imaging data access. Moreover, due to the structure and provisions of relevant Medicare/Medicaid quality incentive programs that rely on ASTP/ONC certification regulations—e.g., the hospital Promoting Interoperability (PI) Program and Merit-based Incentive Payment System PI performance category—there is no clear business case for radiology IT vendors to seek certification for their products. I.e., market demand for imaging IT is strong without voluntary certification, whereas EHR technologies have a de facto mandate from customers for the certification.

Due to the paradigm of 45 CFR Part 171, many non-EHR health IT vendors are actively disincentivized from seeking ASTP/ONC certification for any IT products in their catalog to avoid exposing them to Information Blocking civil monetary penalties within all areas of their product lines. However, many specialty IT vendors may be unaware of their existing exposures under the actor definition in 45 CFR 171.102 for "health information network or health information exchange," and ASTP/ONC guidance for those specific vendors could raise awareness.

Certified health IT/EHRs may play a greater role in access to diagnostic imaging under the emerging FHIR API model for data access. Under this model an API exposing FHIR Imaging Study resources in the EHR would facilitate discovery of imaging records. The EHR would maintain registrations for authorized systems and pass requests to imaging systems, which provide access to records, following Smart on FHIR protocols. EHRs can enable secondary access for referring provider and patient access via secure links to imaging data. EHRs can also enable other functions that inform or document radiology care, including clinical decision support for informing the appropriateness of referring providers' imaging orders, computerized physician order entry, imaging history curation, provider directories access, and summarization features.

SC-5. Should ASTP/ONC update the Certification Program to support the access, exchange, and use of diagnostic images? For example, an image access requirement could be added to the existing VDT certification criterion or additional imaging data elements could be included in the United States Core Data for Interoperability (USCDI).

The undersigned organizations recommend that the ASTP/ONC Health IT Certification be updated to support EHR-enabled access, exchange and use of diagnostic images. Additionally, level 2 USCDI elements for "Diagnostic Imaging" have broad support from the radiology community and the imaging IT industry, but without a clear federal requirement they have not been widely implemented in EHR-type systems. Incorporation of the Diagnostic Imaging Reference into draft

USCDI v7 is an important step toward future imaging interoperability with EHRs as well as TEFCA-participating networks. Adding an image-access requirement to the Health IT Certification Program would help advance EHRs' capabilities to interoperate with imaging IT systems.

SC-6. Should there be a focus on particular, individual diagnosis and treatment use cases (e.g., ocular imaging)? Are there specific requirements that need to be considered for use cases in other fields?

We urge ASTP to encourage the use of native DICOM images for medical specialties that employ imaging to facilitate the exchange of images throughout the healthcare ecosystem. DICOM is the internationally recognized standard for handling, storing, and transmission medical imaging information. By encouraging the consistent use of native DICOM formats rather than proprietary or converted formats, ASTP can help ensure interoperability, seamless exchange, and accurate interpretation of images across diverse health IT platforms and clinical settings.

SC-7. Could image management systems, such as PACS and VNAs, be certified to specific certification criteria that would improve interoperability between these systems and EHRs and make access to diagnostic images available to "outside" providers and patients (including patient-facing apps)? What standards and capabilities should these certification criteria include?

Conceptually, imaging IT systems (PACS and VNAs) could be certified to existing, revised, and/or newly created certification criteria in 45 CFR Part 170 to improve interoperability with EHRs and enable access to diagnostic images to "outside" providers and patients. Certification criteria changes may also help make the addition of Diagnostic Imaging Reference to USCDI operationally effective. The certification criteria could include the capability for imaging IT systems to generate valid Diagnostic Imaging References and provide them to an EHR system. They would also need to be able to receive and interpret authorization tokens for outside systems provided by the EHR and respond appropriately to requests for access. The SMART on FHIR Imaging Access protocols, along with DICOM WADO-RS transactions could provide the foundation for this criterion, as they have in testing, focusing on the availability of standardized access to imaging data rather than prescribing specific internal system architectures. Enabling direct external access to internal imaging systems could introduce cybersecurity and performance risks if not implemented thoughtfully—policy should prioritize standards-based API access to needed information while preserving institutional flexibility in how that access is technically implemented.

While the certification criteria in 45 CFR Part 170 could be revised as discussed above, realistically, there would be major practical barriers to the success of any ASTP/ONC certification paradigm targeted at non-EHR modules, including imaging IT systems. Unlike conventional EHR technologies that fundamentally need ASTP/ONC certification for marketability, there is no business rationale for vendors to obtain voluntary certification for PACS/VNA solutions, and there may be perceived deterrents. For example, becoming a "health IT developer of certified health IT" under information blocking rules at 45 CFR 171.102 is widely viewed by most non-EHR specialized IT vendors as nonviable from a regulatory risk standpoint, even though many are already regulatorily subject to Part 171 as health information network/exchange actors.

SC-8. Beyond or absent the certification of health IT to specific technical standards, what diagnostic image-related standards should ASTP/ONC adopt on behalf of HHS to improve interoperability and health IT alignment?

Beyond certification criteria, ASTP/ONC could improve interoperability and health IT alignment by generally promoting adoption of DICOM, HL7 FHIR and IHE profiles.

DICOM standards provide the foundational metadata necessary for the discovery, access, and use of diagnostic imaging data. Consistent ASTP/ONC recognition of DICOM—including incorporation into the USCDI, integration within 45 CFR Part 170 requirements, and inclusion in the Trusted Exchange Framework and Common Agreement (TEFCA) as a QHIN support expectation—would help incentivize coordinated adoption and ensure effective access to imaging data across the ecosystem.

Additionally, ASTP/ONC should recognize and elevate imaging-related FHIR resources—specifically ImagingStudy and ImagingSelection—as core, first-class components of interoperability infrastructure. In parallel, PACS and VNA vendors could be encouraged to support OAuth 2.0 token introspection and the SMART App Launch framework, enabling standardized authorization and authentication workflows between imaging systems and EHRs.

IHE provides consensus-driven implementation guidance for interoperability standards, including DICOM and HL7 FHIR, as well as voluntary testing to drive adoption of these standards. IHE profiles have long provided the foundation for interoperability between imaging IT and EHR systems, they have defined the architecture for HIEs, including image-enabled HIEs, in many jurisdictions and they include a growing body of FHIR-based implementation guides, including profiles for providing access to diagnostic imaging using RESTful services and FHIR.

SC-9. Are there unique privacy and security concerns related to the access, exchange, and use of diagnostic images that may not exist with other types of health information?

From a regulatory perspective, diagnostic images require similar privacy and security protections as access to other sensitive health information.

However, there are some potential privacy/security concerns with medical imaging and the increasingly advanced capabilities of AI-enabled technologies. For example, while individual images of a CT or MR exam may not reveal a patient's identity, when put together and reconstructed, may lead to the ability for AI/facial recognition technologies to identify the patient.

Finally, a complicating factor for privacy/security is that while the current DICOM standard and IHE implementation profile have defined secure transaction implementations, current use of these in real-world practice is limited as most communication happens between systems behind an institution's firewall.

SC-10. Would further development and adoption of the SMART® Imaging Access draft specification help address the access, exchange, and use of diagnostic images, as well as any specific privacy and security concerns related to such access, exchange, and use?

Further development and adoption of the SMART® Imaging Access draft specification would meaningfully advance the access, exchange, and use of diagnostic imaging by providing a standardized, FHIR-native mechanism for authorized applications to retrieve imaging studies from PACS and VNA systems. The specification builds upon the mature SMART on FHIR and OAuth 2.0 ecosystem, enabling consistent authorization workflows that reduce variation and security risks.

SMART Imaging Access can also serve as the implementation framework for any future 45 CFR Part 170 certification criterion to ensure that imaging systems, EHRs, and third-party applications all utilize the same secure, standards-based methods for querying, retrieving, and presenting diagnostic images.

The undersigned organizations welcome continued dialog with ASTP/ONC and other HHS agencies on diagnostic image access, exchange, and use topics. For more information, please contact Michael Peters, ACR Senior Director, Government Affairs at mpeters@acr.org, and Libby O'Hare, RSNA Director of Government Relations at eohare@rsna.org.

Sincerely,

American College of Radiology (ACR)
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