March 16, 2026

Thomas Keane, MD, MBA
Assistant Secretary for Technology Policy/
National Coordinator for Health Information Technology
United States Department of Health and Human Services
Mary E. Switzer Building
330 C Street, S.W.
Washington, DC 20201

Re: Request for Information: Diagnostic Imaging Interoperability Standards and Certification, RIN 0955-AA11

Dear Dr. Keane:

The Society of Nuclear Medicine and Molecular Imaging (SNMMI), appreciates the opportunity to submit comments in response to the Assistant Secretary for Technology Policy (ASTP)/Office of the National Coordinator for Health Information Technology (ONC) Request for Information: Diagnostic Imaging Interoperability Standards and Certification.

About SNMMI

SNMMI is an international nonprofit medical society dedicated to advancing nuclear medicine, molecular imaging, and theranostics. Founded in 1954, SNMMI represents more than 15,000 physicians, technologists, scientists, and other healthcare professionals worldwide.

SNMMI members develop and apply advanced imaging technologies and targeted radiopharmaceutical therapies that enable earlier disease detection, more precise treatment planning, and improved patient outcomes. 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.

Because nuclear medicine and molecular imaging are inherently data-intensive and quantitative, SNMMI members rely heavily on interoperable imaging data, including full DICOM datasets and derived quantitative imaging metrics.

General Comment

SNMMI strongly agrees that improving access to the images acquired during diagnostics studies significantly enhances patient care, reduces duplicative imaging, and improves healthcare system efficiency.

Current processes for accessing and exchanging diagnostic images often impose unnecessary administrative burdens on patients, caregivers, and healthcare providers. In many cases, the responsibility for transferring imaging studies still falls on the patient, who must obtain and physically transport imaging data between healthcare institutions.

These limitations contribute to delayed clinical decision-making and patient disease management, repeat imaging examinations, and unnecessary radiation exposure. They also create inequities for patients with limited digital literacy, limited broadband access, or complex care involving multiple healthcare systems.

SNMMI therefore supports ASTP/ONC efforts to strengthen interoperability standards that improve the access, exchange, and use of diagnostic imaging data across healthcare settings.

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Key Recommendations

To advance interoperability for diagnostic imaging and improve patient and provider access to imaging data, SNMMI recommends that ASTP/ONC consider the following policy actions:

1. **Recognize diagnostic images as a core component of interoperable electronic health information.**
   ASTP/ONC should clarify that diagnostic images—including full DICOM datasets and associated imaging metadata—are part of Electronic Health Information (EHI) and should be accessible and exchangeable under interoperability and information-blocking requirements.

2. **Incorporate diagnostic imaging access into the ONC Health IT Certification Program.**
   Certification criteria should include testable capabilities that allow both providers and patients to electronically access diagnostic images—not only imaging reports—through standards-based exchange mechanisms.

3. **Advance imaging elements within the United States Core Data for Interoperability (USCDI).**
   ASTP/ONC should prioritize the maturation of imaging-related data classes, including Diagnostic Imaging Reference elements and related metadata, to enable consistent access to imaging endpoints for clinical systems and patient-facing applications.

4. **Encourage the transition away from physical media for image exchange.**
   ASTP/ONC, in collaboration with the Centers for Medicare & Medicaid Services (CMS), should promote policies and incentives that support standards-based electronic image exchange and reduce reliance on CDs and other physical media that continue to burden patients and providers.

5. **Support interoperability for quantitative imaging data.**
   As medical imaging becomes increasingly quantitative, interoperability frameworks should support the exchange of derived imaging data, including PET quantitative metrics, tumor measurements, radiation dose information, and other structured imaging outputs used in clinical decision-making.

Specific Comments

PM-1

In current clinical practice, patients and caregivers frequently bear the burden of obtaining and transporting diagnostic imaging studies between healthcare providers. While many healthcare systems provide patient portals, several barriers limit effective patient access to imaging data.

These barriers include:

- fragmented access across multiple patient portals
- inconsistent image availability within portal environments
- limited portal-integrated DICOM viewing capability
- authentication and identity-proofing challenges when images are stored outside the primary electronic medical record
- limited internet connectivity and digital literacy barriers

Even today, physical media, primarily CDs, remains widely used for transferring diagnostic imaging studies between institutions. When electronic exchange is unavailable or unreliable, patients are often required to transport imaging data themselves. This practice can be particularly burdensome for patients with serious illnesses or limited resources.

Physical media also presents technical limitations. Modern computing devices frequently lack optical drives, and CDs can only be accessed by one individual at a time. Media may also be lost, corrupted, or incompatible with receiving systems. These barriers frequently result in repeat imaging examinations, which increase costs and may expose patients to avoidable radiation.

SNMMI encourages ASTP/ONC to consider several policy approaches to address these challenges:

- Recognize patient access to diagnostic images as a core interoperability capability, distinct from access to imaging reports.
- Incorporate testable diagnostic image access requirements within the ONC Health IT Certification Program.
- Advance USCDI Diagnostic Imaging Reference elements and related imaging metadata toward required exchange to enable reliable access to imaging endpoints for patient- and provider-facing applications.

Several regional initiatives demonstrate the feasibility and clinical value of coordinated imaging exchange. For example, the **Delaware Health Information Network (DHIN)** provides statewide access to diagnostic information from hospitals, laboratories, and radiology facilities (https://dhin.org/). Similarly, the **Maryland Image Exchange**, operated through CRISP Health, allows clinicians to view diagnostic-quality patient images across participating institutions (https://www.crisphealth.org/).

These initiatives demonstrate that large-scale diagnostic imaging exchange is achievable and can significantly improve clinical workflow.

PM-2

Several policy and operational factors continue to limit diagnostic imaging interoperability. These include:

- institutional policies that restrict image sharing or require manual release workflows
- security and network architecture constraints
- misunderstanding of HIPAA requirements for treatment-related information exchange
- variation in state medical record retention and governance requirements
- operational costs associated with maintaining image exchange infrastructure

To address these barriers, ASTP/ONC could consider the following policy actions:

- Clarify that diagnostic images constitute Electronic Health Information (EHI) and should be subject to access and exchange requirements under interoperability and information-blocking policies.
- Coordinate with the Centers for Medicare & Medicaid Services (CMS) to align payment and quality programs with standards-based electronic image exchange and discourage reliance on physical media.
- Ensure that certification testing includes patient access to diagnostic images, not only imaging reports.

PM-2A

Healthcare providers also face operational challenges when accessing imaging studies from outside institutions.

Handling physical media requires substantial staff time and administrative effort to import imaging data into local systems. Institutions must also verify that imported studies correspond to the correct patient, as mismatched images occasionally occur.

Additional barriers include variation in state definitions of the legal medical record and concerns regarding clinical liability when providers rely on outside imaging that may be incomplete or poorly documented.

These factors may discourage providers from relying on external imaging and contribute to unnecessary repeat imaging.

PM-4

For many specialties, including nuclear medicine, radiology, oncology, cardiology, orthopedics, neurosurgery, and trauma care, access to full DICOM imaging datasets is essential for clinical decision-making.

Clinicians often require access to the complete imaging dataset to:

- evaluate subtle imaging findings
- perform quantitative measurements
- assess multi-series imaging context
- support treatment planning

Patients may also require full-fidelity imaging data for second opinions, referral to specialty centers, or participation in clinical research.

PM-5

As medical imaging becomes increasingly quantitative and computationally driven, clinicians require access not only to images themselves but also to associated quantitative imaging outputs.

Examples include:

- tumor measurements and volumetric metrics
- PET quantitative metrics
- cardiac functional measurements
- radiation dose information
- AI-derived imaging biomarkers and analytic outputs

Ensuring interoperability for these data elements will be increasingly important for precision medicine and data-driven clinical care.

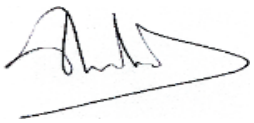
Conclusion

SNMMI appreciates ASTP/ONC's leadership in addressing diagnostic imaging interoperability. Strengthening standards, certification requirements, and policy alignment for imaging data exchange will improve care coordination, reduce unnecessary imaging, and enhance patient access to their health information.

Given SNMMI's expertise in molecular imaging, quantitative imaging biomarkers, and theranostics, the Society would welcome the opportunity to collaborate with ASTP/ONC on future standards development and implementation strategies related to imaging interoperability.

Please contact SNMMI's Director of Health Policy and Regulatory Affairs, **Julia Bellinger, MPP (jbellinger@snmmi.org)**, if we can provide additional information.

Sincerely,



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