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October 4, 2024

U.S. Department of Health and Human Services
Assistant Secretary for Technology Policy
Office of the National Coordinator for Health Information Technology
330 C Street SW
Washington, DC 20201

Re: Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule (RIN 0955-AA06)

The Radiological Society of North America (RSNA) appreciates the opportunity to comment on 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) Proposed Rule titled, "Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability."

RSNA is a non-profit organization that represents professionals spanning the full breadth of radiologic subspecialties in more than 150 countries around the world. RSNA promotes excellence in patient care and health care delivery through education, research and technological innovation. RSNA has for many years worked to expand access to medical imaging and health data through initiatives to develop and deploy interoperability standards.

RSNA's comments below focus on the "New Imaging Requirements for Health IT Modules" section of the Proposed Rule. ASTP-ONC proposes to revise its certification criteria requirements at §170.315(b)(1), (e)(1), (g)(9), and (g)(10) to ensure that certified electronic health records (EHR) solutions used by referring providers can incorporate links to images and corresponding data from imaging providers. ASTP-ONC does not propose specific content or exchange standards to correspond with the proposed certification criteria revisions.

RSNA supports the proposed addition of imaging links to the certification criteria at §170.315(b)(1), (e)(1), (g)(9), and (g)(10) as an incremental step toward enabling secure, convenient access to imaging data for patients and providers, a longstanding goal of RSNA and its members. We note, however, that the addition of imaging links to the certification criteria alone will not be sufficient to achieve that goal. Developers, implementers and vendors of imaging systems require regulatory guidance specifying exchange standards and required behaviors to be followed in resolving imaging links.

The interoperability standards needed to support network-based electronic exchange of medical imaging data are well established and widely deployed around the world. Profiles defined by Integrating the Healthcare Enterprise (IHE) for network-based exchange of medical documents are currently in use by health information exchange networks in the USA, including the Qualified Health Information Networks overseen by ASTP-ONC. IHE has defined complementary profiles extending this architecture for exchange of medical images, which again are being used successfully today in numerous health IT

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network domains. RSNA worked with Carequality to publish the *Imaging Data Exchange Implementation Guide* and with its partner organization Sequoia Project to establish the Image Share Validation Testing Program to test the compliance of vendor systems with this specification. Several leading image exchange vendors participated in this program. Incorporating these standards as criteria for certifying EHR modules and adding image exchange into the Trusted Exchange Framework and Cooperative Agreement onboarding program would incentivize rapid deployment of network-based image sharing across the US health ecosystem.

RSNA understands and supports ASTP-ONC's efforts to move the US health IT ecosystem toward adoption of emerging standards based on RESTful services and Application Programming Interfaces (APIs), including HL7 FHIR and DICOMweb, which will be critical to successful deployment of imaging links. These standards can and should be adopted in ways that are compatible with currently deployed systems using older Web Services architectures for data sharing across health information exchange networks (e.g. IHE XDS/XCA). IHE has defined a complementary set of data exchange profiles based on HL7 FHIR and DICOMweb, including the Web-Based Image Access (WIA) profile, designed to integrate with existing health information networks. IHE profiles for Internet User Authorization (IUA) and Cross-Enterprise User Assertion (XUA) address key issues of security, privacy and trust among interoperable systems. These profiles, once again, have been widely tested and are currently deployed in many health jurisdictions. They specify methods for discovery and authorization compatible with those developed and tested as part of the Argonaut Project SMART Imaging Access project.

A clear and thorough set of implementation guidelines and procedures for deploying these capabilities would ensure that the addition of imaging links achieves the goal of enabling secure and convenient access to medical imaging. Achieving that goal would significantly improve the efficiency and safety of patient care, relieving patients from the burden of maintaining and transporting their own imaging studies using obsolete physical media or undergoing duplicate imaging when previous studies are not accessible. Patients deserve the right to expect secure and convenient access to their health data to support optimal care decisions. RSNA looks forward to working with ASTP-ONC and other stakeholders in the health IT ecosystem to fully realize that goal.

Sincerely,

Umar Mahmood, MD, PhD
Chair of the Board, Radiological Society of North America