

February 27, 2026

Re: [RIN 0955-AA09] Health Data, Technology, and Interoperability: Deregulatory Actions to Unleash Prosperity (HTI-5)

The Radiological Society of North America (RSNA) is a leading global organization representing over 52,000 radiologists and medical imaging professionals across 150 countries. RSNA is dedicated to advancing excellence in patient care and healthcare delivery by fostering education, driving research, and spearheading technological innovation. For years, the Society has been committed to expanding access to and exchange of medical imaging and health information, leading initiatives to create and implement robust interoperability standards that enhance connectivity across the healthcare ecosystem and ultimately improve patient outcomes.

Radiology is among the most data-intensive fields in medicine, and the specialty has pioneered advancements in medical informatics, including the adoption of digital imaging, complex data management systems, and interoperability standards that facilitate seamless exchange of information across healthcare settings. The field generates vast volumes of imaging data daily, necessitating advanced tools for storage, retrieval, and analysis. Radiologists have long leveraged informatics solutions such as Picture Archiving and Communication Systems (PACS), Radiology Information Systems (RIS), and integration with electronic health records (EHRs) to optimize workflow and improve patient outcomes. Furthermore, radiology has been at the forefront of developing and implementing artificial intelligence (AI) and machine learning algorithms to enhance diagnostic accuracy, automate image interpretation, and support clinical decision-making. This leadership in data and informatics positions radiology as a critical driver of innovation in health IT, setting benchmarks for other medical specialties in harnessing technology to improve care delivery.

RSNA appreciates this 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, *Health Data, Technology, and Interoperability: Deregulatory Actions to Unleash Prosperity (HTI-5)* [RIN 0955-AA09]. RSNA broadly supports the changes proposed by ASTP/ONC in HTI-5 toward reducing regulatory burden and thereby removing unnecessary costs and encouraging innovation.

Certification Criteria for Decision Support Interventions

Regarding section 2.e., proposed changes to Care Coordination Certification Criteria for Decision Support Interventions (DSIs), RSNA agrees with the proposal to remove the requirements for source data transparency as originally defined in HTI-1. The prescriptive formats specified in that regulation impose a burden on developers of AI-based DSIs without providing users of these systems with information necessary to understand their functionality or assess their effectiveness. Based on the experience of implementers and users of AI-based DSIs

in radiology, however, we would assert the benefit of having access to a standardized set of clinically actionable disclosures for such systems, including:

- Intended role (e.g., triage, decision support, prioritization, quantification)
- Intended clinical users and workflows
- Intended patient population and exclusions
- Disclosure of known failure modes and common false-negative contexts

Model cards that present this information in a standardized and easily accessible way can help inform the appropriate selection and use of AI-based Decision Support Interventions (DSIs). RSNA strongly encourages ASTP/ONC, when considering requirements for model cards, to recognize that providing clinically relevant disclosures through these cards improves transparency and builds trust in AI technologies. This transparency is essential for physicians to use AI responsibly, and reassures patients who expect clear information when AI is involved in their care.

To support that goal, RSNA has developed a schema and ontology for model cards in imaging AI and a website where AI developers can voluntarily publish cards describing their tools and resources (<https://atlas.rsna.org/>). As noted in the proposed rule, "...developers of certified health IT have reported an inconsistent approach to oversight of other parties producing similar, health-based AI systems. Developers note that "[t]he current model of imposing rigorous requirements [(i.e., algorithmic transparency and risk management)] on certified health IT but not the many other tech companies working in this space is simply unacceptable and needs to be remedied." We agree with this observation that transparency should apply equally to AI systems used across healthcare and encourage ASTP/ONC to continue its work with its federal partners to align policies toward this goal.

HL7 FHIR, APIs, and Diagnostic Imaging

RSNA applauds the changes ASTP/ONC proposes in HTI-5 to expand and consolidate the use of HL7 FHIR as a standard language for electronic health information (EHI) exchange and to mandate that health information technology implements a universal set of FHIR-based APIs for access to EHI. We also support expanding the definitions of "access" and "use" of EHI to explicitly include automated, agentic, and autonomous AI systems and appreciate the necessity and benefits of providing access to EHI for these tools.

We strongly urge that diagnostic images be recognized as a fundamental part of electronic health information (EHI). Excluding medical imaging from these initiatives would significantly limit their effectiveness, especially considering that over 75 percent of FDA-cleared AI-based medical devices are used in diagnostic imaging. RSNA encourages ASTP/ONC, in coordination with its federal partners, to take steps to expand the USCDI and Health IT Certification Program to include requirements to enable access, exchange, and use of medical images. Because medical images adhere to DICOM standards, effectively integrating diagnostic images into these programs requires not only the adoption of DICOM-based specifications but also clear guidance on using FHIR-based APIs to access diagnostic images. RSNA has a long history of support for interoperability standards in medical imaging and looks forward to working with ASTP/ONC and its federal partners, other stakeholder organizations, and industry to help define and implement the necessary standards to facilitate access to medical images for innovation and improved patient care.

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RSNA values the opportunity to provide comments on the HTI-5 Proposed Rule. For additional information or questions, please contact RSNA's Director of Government Relations, Libby O'Hare (eo hare@rsna.org).

Sincerely,

A handwritten signature in black ink, appearing to read 'Carolyn C. Meltzer', with a long horizontal flourish extending to the right.

Carolyn C. Meltzer, MD
Chair of the Board
Radiological Society of North America