DEPARTM

Office of the Secretary

45 CFR Part 170

RIN 0955-AA11

Request for Information: Diagnostic Imaging Interoperability Standards and Certification

AGENCY: Assistant Secretary for Technology Policy (ASTP)/Office of the National Coordinator for Health Information Technology (ONC) (collectively, ASTP/ONC), Department of Health and Human Services (HHS).

ACTION: Request for Information.

SUMMARY: This request for information (RFI) seeks input from the public regarding the potential adoption of diagnostic imaging technical standards and certification criteria for health information technology (IT) under the ONC Health IT Certification Program (Certification Program) to better enable the access, exchange, and use of diagnostic images by health care providers and patients. Responses to this RFI will be used to inform potential future rulemaking.

DATES: To be assured consideration, written or electronic comments must be received at one of the addresses provided below, by [Insert date 45 days after the date of publication in the **Federal Register**].

ADDRESSES: You may submit comments, identified by **RIN 0955-AA11**, by any of the following methods (please do not submit duplicate comments). Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

- *Federal eRulemaking Portal*: Follow the instructions for submitting comments. Attachments should be in Microsoft Word, Microsoft Excel, or Adobe PDF; however, we prefer Microsoft Word. http://www.regulations.gov.
- *Regular, Express, or Overnight Mail:* Department of Health and Human Services, Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology, Attention: Request for Information: Diagnostic Imaging

Interoperability Standards and Certification, Mary E. Switzer Building, Mail Stop: 7033A, 330 C Street SW, Washington, DC 20201. Please submit one original and two copies.

- *Hand Delivery or Courier:* Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology, Attention: Request for Information: Diagnostic Imaging Interoperability Standards and Certification, Mary E. Switzer Building, Mail Stop: 7033A, 330 C Street SW, Washington, DC 20201. Please submit one original and two copies. (Because access to the interior of the Mary E. Switzer Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the mail drop slots located in the main lobby of the building.)

Inspection of Public Comments: All comments received before the close of the comment period will be available for public inspection, including any personally identifiable or confidential business information that is included in a comment. Please do not include anything in your comment submission that you do not wish to share with the general public. Such information includes, but is not limited to: a person's social security number; date of birth; driver's license number; state identification number or foreign country equivalent; passport number; financial account number; credit or debit card number; any personal health information; or any business information that could be considered proprietary. We will post comments that are received before the close of the comment period at http://www.regulations.gov.

Docket: For access to the docket to read background documents or comments received, go to http://www.regulations.gov or the Department of Health and Human Services, Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology, Mary E. Switzer Building, Mail Stop: 7033A, 330 C Street S.W., Washington, DC 20201 (call ahead to the contact listed below to arrange for inspection).

FOR FURTHER INFORMATION CONTACT: Michael Lipinski, Office of Policy, Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology, 202-690-7151.

SUPPLEMENTARY INFORMATION:

I. Purpose

Diagnostic images, including, but not limited to, radiographic, photographic, and video images produced by light, radiation, sound waves, or magnetic resonance, are critical to supporting care in a variety of health care settings and are routinely used by health care providers to help determine a patient's course of treatment.[1] Diagnostic images are often stored in systems external to an electronic health record (EHR),[2] such as picture archiving and communication systems (PACS), vendor neutral archives (VNAs), and other imaging platforms. While health care providers (e.g., radiologists, ophthalmologists, dermatologists, and pathologists) who work within the same organization generally have direct access to the diagnostic images obtained by the organization, access to such images by health care providers from outside the organization can be nonexistent, inconsistent, and highly dependent on several technical, operational, and organizational factors. In some cases, organizations' vendors use proprietary formats that impede exchange and external access by "outside" providers. In other cases, outside providers are denied access to full-resolution Digital Imaging and Communications in Medicine® (DICOM®) files, and are instead given access to low resolution, incomplete, or inferior (e.g., encapsulated PDF) images through web-based viewers. They may also be denied access to prior imaging studies. In addition, originating organizations frequently refuse to securely electronically transmit diagnostic images despite the source organization's technical capability to do so. Ultimately, the burden to "exchange" these images is placed on the patient or their caregiver. In such instances,

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[1] For purposes of this RFI, "treatment" generally means the provision, coordination, or management of health care and related services among health care providers or by a health care provider with a third party, consultation between health care providers regarding a patient, or the referral of a patient from one health care provider to another. See 45 CFR 164.501.

[2] For purposes of this RFI, an electronic health record (EHR) generally means health IT certified under the Certification Program that would meet the criteria of the Qualified EHR definition (42 USC 300jj).

patients too are often unable to access their own imaging directly or with a patient-facing application (app). Consequently, patients and their caregivers are left to carry around physical media (e.g., CDs and DVDs), or printed images and reports, from provider to provider. These outcomes are far from ideal, particularly due to the quality of the images and even sometimes due to the lack of provider hardware to view the images stored on CDs and DVDs.

Enhanced access to diagnostic images can improve care and health outcomes, decrease the need for duplicative imaging tests, and reduce costs within the United States (U.S.) health care system. Therefore, we seek comments on whether the adoption of technical standards and/or certification criteria for health IT would improve the access, exchange, and use of diagnostic images for both providers and patients.

II. Regulatory Background

On March 7, 2012, the Secretary of HHS issued a proposed rule with request for comments titled "Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology" (77 FR 13832) (2014 Edition Proposed Rule), which proposed new and revised standards, implementation specifications, and certification criteria. In the 2014 Edition Proposed Rule, we proposed certification to the 2014 Edition "imaging" certification criterion (§ 170.314(a)(12)) without use of the DICOM standard but requested comments on using the standard (77 FR 13838). We also proposed to require EHR technology that would be certified to the 2014 Edition "view, download, and transmit to 3rd party" (VDT) certification criterion (§ 170.314(e)(1)) to be capable of enabling images formatted according to the DICOM standard to be downloaded and transmitted to a third party (77 FR 13839 and 13840).

On September 4, 2012, the Secretary published a final rule titled "Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for

Health Information Technology" (77 FR 54163) (2014 Edition Final Rule). In the 2014 Edition Final Rule, we adopted an "image results" certification criterion (without the DICOM standard) to support the Medicare and Medicaid EHR Incentive Programs (now referred to as the Medicare Promoting Interoperability Program and the Merit-based Incentive Payment System Promoting Interoperability performance category) requirement, also known as the Meaningful Use or "MU Stage 2 Objective" requirement. The MU Stage 2 Objective required eligible clinicians, hospitals, and critical access hospitals to have access to imaging results and information through Certified EHR Technology (77 FR 54172 and 54173). The associated MU Stage 2 Objective certification criterion required a Health IT Module to be capable of indicating the availability of a patient's images and narrative interpretations and enable access to those images and narrative interpretations. We stated that the requirements of the certification criterion could be met via the capability to directly link to images stored in the EHR system or by providing a context-sensitive link to an external application which provided access to images and their related narrative. We also stated in the 2014 Edition Final Rule that the use of the DICOM standard (or any other imaging standards) was unnecessary to meet the functional requirement expressed in the image results certification criterion (77 FR 54172 and 54173). Instead, we reiterated our understanding, stated in the 2014 Edition Proposed Rule, that the adoption of standards was unnecessary to enable users to electronically access images and their narrative interpretations, as required by this certification criterion (77 FR 13838). Further, in the 2014 Edition Final Rule, after considering the comments received and the complexity and potential burden identified by commenters, we removed the requirement that images be made available for download and transmission to a third party as part of the VDT certification criterion (77 FR 54183).

On February 26, 2014, the Secretary published a proposed rule titled "Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements" (79 FR 10880) (Voluntary Edition Proposed Rule). The proposed rule proposed a voluntary edition of certification criteria that was designed to enhance

interoperability, promote innovation, and incorporate "bug fixes" to improve upon the 2014 Edition (79 FR 10880). In the proposed rule, we contemplated improvements that could be made to the VDT certification criterion in § 170.314(e)(1) for the "2017 Edition" (79 FR 10907). We requested public comments on whether we should again propose (in the future) to require that images be part of this certification criterion. More specifically, we requested comment on: (1) whether images for patients need to be of diagnostic quality; (2) whether they should be viewable and downloadable, but not required to be transmitted; and (3) whether cloud-based technology could allow for a link to the image to be made accessible (79 FR 10907). On September 11, 2014, a final rule was published titled "2014 Edition Release 2 Electronic Health Record (EHR) Certification Criteria and the ONC HIT Certification Program; Regulatory Flexibilities, Improvements, and Enhanced Health Information Exchange" (79 FR 54430) (2014 Edition Release 2 Final Rule), which did not include any updates to the VDT certification criterion related to diagnostic imaging (79 FR 54439 and 54465).

On March 30, 2015, the Secretary of HHS published a proposed rule titled "2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications" (80 FR 16804) (2015 Edition Proposed Rule). In the 2015 Edition Proposed Rule, we proposed to maintain the image results certification criterion (80 FR 16822). While some commenters supported this proposal, we ultimately removed the image results certification criterion in the 2015 Edition Final Rule (80 FR 62602), published October 16, 2015, because the associated CMS EHR Incentive Programs objective (now referred to as Promoting Interoperability objectives) was removed and no longer required technological support (80 FR 62683).

On August 5, 2024, we published a proposed rule titled "Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability" (89 FR 63498) (HTI-2 Proposed Rule) to revise the certification criteria adopted in § 170.315(b)(1), (e)(1), (g)(9), and (g)(10) to include new certification requirements to support

access, exchange, and use of diagnostic images via imaging links. On December 29, 2025, the Secretary published a withdrawal notice titled "Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability; Withdrawal" (90 FR 60602) (HTI-2 Proposed Rule Withdrawal Notice) to withdraw the remaining proposals that were not finalized from the HTI-2 Proposed Rule, including our proposed revisions to the certification criteria adopted in § 170.315(b)(1), (e)(1), (g)(9), and (g)(10).

ASTP/ONC's joint Request for Information (RFI) with the Centers for Medicare & Medicaid Services (CMS) (90 FR 21034), published May 16, 2025, sought input from the public regarding the market of digital health products for Medicare beneficiaries as well as the state of data interoperability and broader health technology infrastructure. Responses to the RFI covered a broad range of topics, including ways to increase patient access to effective digital capabilities needed to inform health decisions and increase data availability for health care providers and patients. Among these comments were the identification of challenges specific to the access, exchange, and use of diagnostic images, including: (1) a fragmented ecosystem where diagnostic image exchange is manual, burdensome, and unreliable; (2) continued reliance on physical media (such as CDs and DVDs), which is generally inefficient, not secure, and presents barriers to timely care; and (3) lack of patient access to their own diagnostic images through modern, application programming interface (API)-driven tools.

III. Solicitation of Public Comments

The access, exchange, and use of diagnostic images is crucial for timely and accurate diagnosis, leading to better patient outcomes and lower treatment costs. As we evaluate the best and least burdensome ways to support the access, exchange, and use of electronic health information (EHI), including diagnostic images, through the adoption of standards and the certification of health IT under the Certification Program, we invite public comment to help us further explore how we can achieve these goals for the purpose of accessing, exchanging, and using diagnostic images.

We encourage interested parties to share their responses for as many of the questions below as possible. The questions are not intended for a specific audience but are meant to solicit feedback from multiple individuals and groups. To aid in our understanding of submitted responses, please prioritize clarity and conciseness and annotate your responses with question label(s) (for example, PM-1).

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

We acknowledge there are certain outlying use cases and circumstances where access via physical media may be more appropriate than internet-based access to diagnostic images (e.g., locations with inadequate internet capabilities). However, we believe the health care ecosystem's continued default to physical media and the slow shift from this practice is due to a combination of limited investment in image exchange standards, business practices that silo images within systems, and a lack of policy drivers to reinforce a shift to electronic access and exchange of diagnostic images.

Ultimately, the status quo creates a perfect storm of administrative burden, unnecessary costs, and uncoordinated care for providers and patients alike. For example, health care providers often rely on imaging to evaluate how well treatments are working. When a health care provider assumes the care of a new patient, access to prior imaging from outside facilities is a key component for accurate treatment planning. However, patients may not always have physical media (e.g., CDs and DVDs) or access to online diagnostic images to share with their providers. In time-sensitive situations, this lack of access may result in delayed or inappropriate treatment or unnecessary health care costs through duplicative testing.

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?

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?

- 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?
- 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?

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.

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.

PM-5. Do health care providers and/or patients need access to quantitative parameters[3] derived from images for clinical decision-making and use by providers and patients? Please feel free to elaborate with rationale.

[3] Quantitative parameters are numerical measurements that describe specific (e.g., physical, anatomical, or functional) properties. We have received information that quantitative image parameters are being manually entered into EHRs due to the lack of standards adoption.

B. Standards and Certified Health IT Functionality

The Certification Program[4] is a voluntary program under which health IT developers can obtain ONC certification for their health IT products that meet certain requirements. Requirements for certification are established by standards, implementation specifications, and certification criteria adopted through rulemaking by the Secretary of HHS. The Certification Program supports the availability of certified health IT for use by health care providers under other federal, state, and private programs.

Health IT developers often rely on custom interfaces and connections for individual customer (e.g., health care provider) systems resulting in incompatibilities between different health IT developers' technology platforms. For example, survey findings suggest that although many U.S. children's hospitals have electronic image-sharing platforms, substantial challenges in radiologic image sharing persist, primarily due to ongoing reliance on CDs and the lack of interoperability between existing image-sharing platforms.[5]

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, DICOMweb™, FHIR®, IHE® XDS-I, IHE® XCA-I) versus proprietary or custom integrations?

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.

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-

[4] For more information, see https://www.healthit.gov/topic/certification-ehrs/certification-health-it.
[5] https://link.springer.com/article/10.1007/s00247-022-05474-9.

facing apps), and should existing technical standards be further modified (please identify the standard)?

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?

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).[6]

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?

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?

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?[7]

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?

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[6] https://www.healthit.gov/isp/united-states-core-data-interoperability-uscdi.
[7] https://www.healthit.gov/topic/hhs-health-it-alignment-program.

SC-10. Would further development and adoption of the SMART® Imaging Access draft specification[8] 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?

IV. Collection of Information Requirements

In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), and OMB guidance, we believe this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

Robert F. Kennedy, Jr.,

Secretary,

Department of Health and Human Services.

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[8] https://github.com/sync-for-science/imaging.