

September 25, 2024

U.S. Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Mary E. Switzer Building, Mail Stop: 7033A
330 C Street SW
Washington, DC 20201

Re: (RIN 0955-AA06) Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability; Comments of the American College of Radiology

The American College of Radiology (ACR)—a professional association representing more than 40,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine (NM) physicians and medical physicists—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) Aug. 5, 2024, Notice of Proposed Rulemaking (NPRM) titled, “*Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability*” (RIN 0955-AA06; 89 FR 63498; Document No. 2024-14975). The ACR is an advocate for interoperability and health information exchange in radiology and throughout health care.

ASTP-ONC Proposals and ACR Comments on 45 CFR Part 170, *Health IT Standards, Implementation Specifications, and Certification Criteria and Certification Programs for Health IT*

Proposal – §170.315(b)(1), (e)(1), (g)(9), and (g)(10) “New Imaging Requirements for Health IT Modules”

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 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.

Comments

The ACR supports the proposed addition of imaging links to the certification criteria at §170.315(b)(1), (e)(1), (g)(9), and (g)(10). This proposal is generally aligned with the ACR’s longstanding goal—shared broadly by many radiologists, companies, and organizations in the radiology provider community—for medical images to be electronically exchanged without use of physical media (known on social media as the “#DitchTheDisk” campaign¹). We believe the ASTP-ONC could also promulgate the DICOM standard in Part 170 to ensure the clinical utility of this

¹ <https://www.acr.org/Advocacy-and-Economics/Voice-of-Radiology-Blog/2019/10/10/14/19/Time-to-Ditch-the-Disk>

criterion for certifying EHR modules used by referring providers; although as accurately stated in the NPRM, DICOM is the de facto industry standard regardless of Part 170 certification.

ASTP-ONC Proposals and ACR Comments on 45 CFR Part 171, *Information Blocking*

Proposal – §171.104 “Interferences”

ASTP-ONC proposes to promulgate in regulatory language at §171.104 a list of examples of what the agency understands to be “interferences.”

Comments

The ACR strongly opposes finalization of the proposed §171.104 and its subcomponents, which would create in regulation a noncomprehensive list of example practices considered by ASTP-ONC to be “interferences.” The regulatory purpose of §171.104 is unclear. By law, an interference by a provider-actor without that provider’s explicit knowledge that the interference occurred and that it was “unreasonable” *does not meet the statutory definition of “information blocking”* by a provider. Therefore, §171.104 would not substantially alter actors’ compliance strategies nor improve their understanding of the enforcement priorities of the HHS Office of Inspector General (OIG). More importantly, the noncomprehensive list of “interference” examples in §171.104 is likely to be confusing and counterproductive. Some actors may erroneously perceive this list as a prioritization or limitation of the scope of OIG investigations (e.g., enforcement discretion).

Additionally, the ACR has the following concerns with specific “interference” examples under the proposed §171.104:

- **Proposed §171.104(a)(1) “Delay on new access”** – These scenarios are unlikely to be viewed as “unreasonable” by most physicians or other providers. Often, this interference may be medically necessary for a physician to review, oversee, and/or validate the accuracy of the electronic health information (EHI)—for example, a delay for review of output EHI from medical devices such as AI/ML software devices, in which the radiologist’s review is a fundamental and necessary component of safe and effective on-label use.
- **Proposed §171.104(a)(8) “Medical images”** – The scenario described in the interference example at §171.104(a)(8) misunderstands and misrepresents the instigating factors of physical media-based exchange. Radiology providers generally do not choose physical media, such as optical discs, over other options. In such scenarios, these copies are typically the only available technological means to meet a patient’s request for diagnostic quality images. Rather than focusing on providers, as the §171.104(a)(8) example does, it would be more beneficial for ASTP-ONC to provide guidance to device and IT vendors and networks that facilitate, or can facilitate, electronic exchange of diagnostic quality images.

Proposal - §171.304 “Requestor preferences exception”

The ASTP-ONC proposes to implement a new Information Blocking exception for when an actor’s practice of tailoring the access, exchange, or use of electronic health information to a requestor’s preference(s) is exempted from Information Blocking.

Comments

The ACR generally supports the flexibility of the newly proposed exception at §171.304; however, we believe the proposed regulatory verbiage “without any improper encouragement or *inducement* by the actor” is open to varying interpretations. For this new exception to be accessible and actionable by radiology providers, provider-actors must be allowed to *routinely request* these preferences from patients in some organized, scalable, and documentable manner.

The ACR strongly recommends that ASTP-ONC finalize this exception with further clarification. Specifically, ASTP-ONC should clarify in the preamble that provider-actors using this new §171.304 exception can routinely request this information in writing from patients/patient representatives via standardized form questions—for example, during routine check-in for a medical procedure or other appointment.

Proposal - §171.206 “Protecting care access exception”

The ASTP-ONC proposes to create a new Information Blocking exception for when an actor believes that sharing EHI could risk exposure to legal action for any person(s) sought, received, provided, or facilitated the provision or receipt of reproductive health care that was lawful under the circumstances in which it was provided.

Comment

The ACR supports this exception and recommends finalization. Pursuant to positions established by the ACR Council, the ACR opposes criminalization of the provision of evidence-based medical care within the scope of a given physician/professional’s training, professional judgment, and nationally recognized professional practice guidelines (2024 Resolution 60, “*Supporting Abortion as an Essential Component of Health Care*” and 2023 Resolution 11, “*ACR Opposes Interference in the Physician-Patient Relationship*”).

The ACR appreciates the ASTP-ONC’s consideration of these comments and recommendations. We welcome further discussion with ASTP-ONC on these matters. Please send any questions or requests to Michael Peters, ACR Senior Director, Government Affairs, at mpeters@acr.org.

Sincerely,



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American College of Radiology