June 20, 2023

Submitted via regulations.gov

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–AA03; 88 FR 23746) Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule; Comments of the American College of Radiology and Radiological Society of North America

The American College of Radiology (ACR)[1] and Radiological Society of North America (RSNA)[2] appreciate the opportunity to comment on the United States' Department of Health and Human Services (HHS) Office of the National Coordinator for Health Information Technology (ONC) proposed rule addressing *Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing* (RIN 0955–AA03). The ACR and RSNA are staunch proponents of interoperability and health information exchange in the radiology specialty and throughout health care.

45 CFR 170 – Certification Criteria Naming Convention Changes

ONC Proposal: ONC proposes to remove year-themed "editions" from the certification criteria, and to instead rename the in-effect certification criteria as "ONC Certification Criteria for Health IT." ONC proposes to differentiate any revised certification criteria and revised standards references from unchanged criteria.

ACR-RSNA Comment: The ACR and RSNA support this proposal and recommend timely updates to corresponding regulations, sub-regulatory guidance documents, and educational resources provided by ONC and any regulatory agencies that incorporate health IT certification criteria into their respective programs.

Changing the naming convention of the certification criteria as proposed would reduce confusion regarding certification criteria incorporated by reference into other agencies' regulatory programs (e.g., the Centers for Medicare and Medicaid Services (CMS) Quality Payment Program). Typically, federal and state programs require new editions several years after the edition's namesake year, which is

[1] **ACR** is a professional association representing over 41,000 diagnostic radiologists, interventional radiologists, nuclear medicine physicians, radiation oncologists, and medical physicists.
[2] **RSNA** is a professional organization representing approximately 50,000 radiologists, radiation oncologists, medical physicists, and related scientists.

counterintuitive and adds to the educational burden. For example, the "2015 Edition" was first mandatory during the Quality Payment Program's 2020 reporting period.

§170.213 and §170.299 – United States Core Data for Interoperability (USCDI)

ONC Proposal: ONC proposes to update the in-effect version of the USCDI in the regulation and standards list from version 1 (V1) to V3.

ACR-RSNA Comment: The ACR and RSNA support this proposal and recommend an expeditious update of the in-effect USCDI version to V4 via the future HTI-2 rulemaking.

ONC should plan to codify the latest USCDI version into the regulatory language at §170.213 and §170.299 during future HTI rulemaking cycles. This will advance the capabilities of the Trusted Exchange Framework and Common Agreement (TEFCA) and related programs in a timely manner.

V3 includes the "Diagnostic Imaging" data class with the "Diagnostic Imaging Test" and "Diagnostic Imaging Report" data elements first implemented in V2. We anticipate the future V4 may incorporate additional data elements of relevance to radiology patient care, and we look forward to its regulatory adoption.

§170.102, §170.315(a)(9), and §170.315(b)(11) – Decision Support Interventions (DSI) and Predictive DSI Models

ONC Proposal: ONC proposes to define "decision support intervention" and "predictive DSI" and to revise its clinical decision support certification criterion with a corresponding transition period between §170.315(a)(9) and the new §170.315(b)(11). The new §170.315(b)(11) is meant to provide information transparency to address uncertainty regarding the quality of predictive DSIs that certified health IT modules enable or interface with, so that potential users have sufficient information about how a predictive DSI was designed, developed, trained, and evaluated to determine whether it is trustworthy.

ACR-RSNA Comment: The ACR and RSNA generally support algorithm transparency to ensure that end-users can identify and implement the predictive DSI of maximum benefit to their patients. We recommend that ONC coordinate with the Food and Drug Administration (FDA) to ensure consistent application of transparency expectations for AI across HHS regulatory agencies and jurisdictions. We also recommend that ONC identify "identification of intended user qualifications" as a risk mitigation.

Although ONC's certification criteria regulations in Part 170 are architecture agnostic in principle, health IT modules submitted for voluntary certification are almost always electronic health record (EHR) solutions that fall outside the statutory "medical device" definition pursuant to the limitations added by the 21st Century Cures Act Sec. 3060. Therefore, most/all health IT modules submitted for testing and certification are not FDA-regulated device software functions. ONC's proposals for predictive DSI under §170.315(b)(11) should help better align unregulated EHR technology and regulated device software functions; however, a key differentiator remains that ONC certification is voluntary whereas FDA oversight is not. Rather, EHR developers generally view certification as a business necessity to ensure their products meet their customers' compliance needs for CMS regulatory programs. Still, consistency between HHS oversight expectations for unregulated and regulated AI will help broadly advance transparency and promote innovation.

The ACR filed comments in Nov. 2021 for the public record of the Oct. 14, 2021, FDA workshop on transparency of AI-enabled medical devices. That comment submission provides a descriptive list of radiology provider data needs related to AI-enabled software medical devices that would be most useful for informing acquisition, implementation, and medical use decision-making.[3] The attributes in ONC's proposed §170.315(b)(11)(vi)(C) are aligned with ACR's AI transparency recommendations.

Additionally, the explanatory text for the proposed §170.315(b)(11)(vii)(A)(2) describes different "risk mitigations" to identify and address impacts of predictive DSI on patients and populations. Users with sufficient expertise to independently evaluate input and output data are key for identifying performance changes and closing the feedback loop with developers. This is also viewed as an important mitigation by FDA for many AI software medical devices. To that end, qualified intended users should be identified by ONC as a risk mitigation for predictive DSI.

45 CFR 171 – Information Blocking – "Offer" Health IT

ONC Proposal: ONC proposes to modify the Information Blocking actor definition for "health IT developer of certified health IT" to clarify what it means to "offer" certified health IT to a provider. Specifically, ONC proposes to exclude certain activities that promote EHR subsidies and certain EHR functionalities.

ACR-RSNA Comment: The ACR and RSNA oppose exclusions for subsidies from the definition of "offering" health IT if those subsidies are tied to a specific product, or if those subsidies would promote or prioritize imaging referrals of patients to the subsidizing entity or its partners. If ONC finalizes this concept, we recommend the agency seek to preempt exploitation by stating in the final rule preamble that promotion or prioritization of the subsidizing entity's services over those of unaffiliated, competing providers would not be exempted from the "offer health IT" definition.

The primary objective of the legislative policy later included as Sec. 4004 in the 21st Century Cures Act was to deter anticompetitive behaviors enabled, in part, by the self-referral/anti-kickback exception and safe harbor for donations of EHR technology. EHR technology could be "donated" to local referring providers by regionally dominant health systems, who could use the donated technology to influence the flow of referrals for patient care services, such as imaging. For example, donated order entry modules could deprioritize or leave competing imaging providers off the list of options, thereby making it comparatively more burdensome for a physician end-user to refer their patient to an unaffiliated imaging provider. Donated EHR technology could also enable bidirectional information sharing with affiliated imaging providers while making such capabilities comparatively less intuitive when communicating with unaffiliated imaging providers, thereby making one provider more attractive than the other simply due to ease of connectivity.

While IT donations and subsidies can provide benefits to safety net providers as described in the preamble for ONC's proposal, there is no valid reason for why such donations/subsidies should not be held to the higher developer/network-specific Information Blocking knowledge requirements and corresponding civil monetary penalties for Part 171 violations.

§171.204 – Information Blocking – Infeasibility Exception

[3] ACR's recommendations to FDA for enhanced AI transparency. https://www.acr.org/-/media/ACR/Files/Advocacy/Regulatory-Issues/acr-comments_fda-ai-transparency.pdf. Nov. 15, 2021.

ONC Proposal: ONC proposes to modify the Infeasibility Exception, including the addition of two conditions for §171.204(a)(3) "Third party seeking modification use" and §171.204(a)(4) "Manner exception exhausted."

ACR-RSNA Comment: The ACR and RSNA recommend ONC reevaluate the complexity of §171 Subparts B and C and implement least burdensome regulatory principles. We also recommend ONC consider establishing separate, simplified exceptions for provider actors. For example, ONC could use the HTI rulemaking to simplify requirements for providers using the "infeasible under the circumstances" condition at §171.204(a)(3) (proposed to be changed to §171.204(a)(5)).

The requirements of the exceptions/conditions in §171 Subparts B and C are unnecessarily complex for small providers. The proposals in the HTI-1 rulemaking could exacerbate the prevailing problem of incomprehensibility. The confusion derives from ONC's use of a single set of interwoven exceptions/conditions universally applicable to all three actor types and all EHI exchange scenarios. The proposed new conditions §171.204(a)(3) and (4) are unlikely to provide further clarity.

ONC could alleviate provider confusion by implementing separate, simplified exceptions/conditions for provider actors under Subparts B and C. Cures Act Sec. 4004 does not mandate that "reasonable and necessary activities" (i.e., implemented by ONC as Information Blocking exceptions) be universally applied across all actor categories. For §171.204, small providers incapable of supporting a request should be able to invoke the Infeasibility Exception without needing to navigate complex decision trees more suitable for EHR developers and networks.

§171.301 – Information Blocking – Manner Exception

ONC Proposal: ONC proposes to rename and modify the Manner Exception to add a "TEFCA manner" under §171.301(c) that would allow TEFCA participating entities to ignore EHI access preferences when exchanging with other TEFCA participating entities.

ACR-RSNA Comment: As with our comments on the proposals for §171.204, the ACR and RSNA recommend that ONC broadly seek simplification of §171 Subparts B and C for provider actors. This should ideally take the form of separate exceptions/conditions for providers different from those for developers and networks. ONC should also explore additional provider-targeted exception options not tied to certified health IT module use or TEFCA participation.

We refer ONC to the justification provided above for the §171.204 proposed additions. Similarly, the procedure exceptions outlined in §171 Subpart C could benefit from delineation and tailoring based on actor type, with simplification of provider-focused exceptions/conditions.

Additionally, the proposed TEFCA manner is of questionable utility to most providers due to the limited EHI subset and network coverage currently enabled by TEFCA exchange. The proposed new manner is primarily useful to networks fluent in Part 171 and other ONC programs. These networks can already expeditiously follow existing Subpart C procedures without leveraging the proposed §171.301(c).

The ACR and RSNA appreciate ONC's time and consideration of these comments, and we welcome further dialog with agency staff about these issues. Please contact Michael Peters, ACR Senior

Government Affairs Director, at mpeters@acr.org; or Richard Martin, RSNA Director: Government Relations at rmartin@rsna.org, with questions.

Sincerely,

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