June 3, 2019

Submitted via Regulations.gov

Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Attention: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule
Mary E. Switzer Building
Mail Stop: 7033A
330 C Street SW
Washington, DC 20201

Re: (RIN 0955-AA01; 84 FR 7424) 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule; Comments of the American College of Radiology

The American College of Radiology (ACR)—a professional association representing over 38,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians, and medical physicists—appreciates the opportunity to comment on the notice of proposed rulemaking (NPRM) from the U.S. Department of Health and Human Services (HHS) Office of the National Coordinator for Health IT (ONC) titled, "21st Century Cures Act (Cures): Interoperability, Information Blocking, and the ONC Health IT Certification Program" (RIN 0955-AA01). ACR strongly supports the federal government's efforts to promote trusted exchange, advance interoperability, and reduce information blocking.

Recognition of FDA Processes

References to the FDA Software Pre-Certification (Pre-Cert) Pilot Program (84 FR 7438-39)
ONC proposed to establish processes to allow developers certified under the Pre-Cert program to have their certified health IT modules exempted from the 2015 Edition "quality management systems" criterion and "safety-enhanced design" criterion.

ACR recommends that ONC only apply this proposal to FDA-regulated Software as a Medical Device (SaMD) products. Certain companies develop both SaMD solutions and other health IT solutions that do not meet the legal "medical device" definition. Individual components of FDA's Pre-Cert paradigm are intended to inform the others. For example, SaMD from precertified companies submitted through expedited Pre-Cert pathways, such as Streamlined Review, are then subject to real world performance assessment and monitoring in perpetuity. A company's precertification status does not provide reasonable assurance of safety and effectiveness of all products manufactured by that company—it merely enables SaMD submissions from that company to leverage expedited FDA pathways to market. Therefore, it would be inadequate for ONC to leverage only a company's precertification status to eliminate specific health IT certification requirements, and to ignore whether or not the certified health IT is also FDA-regulated SaMD subject to the various safeguards of the Pre-Cert Program.

Additionally, a company's precertification status is intended to be actively maintained or else revocable. If ONC were to base flexibility in the health IT certification program on FDA's Pre-Cert Program, ONC would need to plan for situations in which precertified companies intentionally or unintentionally lose their precertification so as not to penalize providers who rely on certified heath IT modules for regulatory compliance with assorted payment programs.

USCDI Version 1.0

§ 170.213 United States Core Data for Interoperability (USCDI) - clinical notes - imaging narrative (84 FR 7441)

ONC proposed to add the "clinical notes" data class—including a new "imaging narrative" data element—to the USCDI, which represents the minimum baseline of data classes and elements that must be commonly available for interoperable exchange.

ACR supports ONC's proposed inclusion of the clinical notes data class and imaging narrative data element in the USCDI Version 1. However, we recommend that ONC work with the radiology informatics community and imaging standards development organizations toward future inclusion of imaging studies in the USCDI. The imaging-related exchange capabilities of health information networks (HINs) currently vary due to a lack of federal incentives. It is important for HINs participating in the future Trusted Exchange Framework and Common Agreement to invite the meaningful participation of imaging providers and work with the imaging IT community toward enabling access by network participants to radiology-related information.

Proposed Adoption of FHIR DSTU2

§ 170.215 - Application programming interface standards (84 FR 7479-80)

§ 170.315(g)(10) - Standardized API for patient and population services (84 FR 7481-84)

ONC proposed HL7 Fast Healthcare Interoperability Resources (FHIR) Draft Standard for Trial Use (DSTU) 2 (v1.0.2-7202), OpenID Connect Core 1.0 incorporating errata set 1 for application authentication, and HL7 Fast Healthcare Interoperability Resources (FHIR) Release 3 Standard for Trial Use (STU) 3 (v3.0.1). ONC requested comment on implementation of more recent FHIR releases, suggesting four possible options for finalization including the proposed "Option 1."

ACR recommends that ONC implement "Option 4" to minimally require FHIR Release 4. Many EHR technology vendors that have adopted FHIR-enabled APIs are using Release 2 with proprietary implementation variations that impede interoperability. Requiring that certified health IT use Release 4 instead of Release 2 after the proposed effective date in January 2022 would help minimize proprietary interfaces. Moreover, ONC should consider the flexibility afforded to developers of the proposed January 2022 deadline for (g)(10) API technology certification, and the additional time it would take the agency beyond 2022 to update § 170.215 via rulemaking.

ACR supports incorporation by reference in § 170.215(a)(2) of the API Resource Collection in Health (ARCH) Version 1 implementation specification. The proposed adoption of ARCH by reference instead of naming the individual supported FHIR resources in regulation would provide ONC the necessary flexibility to expeditiously update the minimum resource list over time.

Finally, ACR urges ONC to consider adding the "ImagingStudy" FHIR resource to the ARCH specification to support representation of content produced in DICOM imaging studies. Doing so would help push

developers and providers forward toward image exchange without physical media. This would minimize unnecessary duplicative imaging, improve the quality and safety of care, facilitate earlier diagnoses, and reduce costs.

Conditions of Certification

§ 170.404 - Application programming interfaces (Condition and Maintenance of Certification) (84 FR 7485-95)

ONC proposed various requirements applying to developers of Health IT Modules certified to any of the certification criteria adopted in § 170.315(g)(7) through (11), including assorted transparency conditions.

ACR supports ONC's proposal that the API Technology Supplier must publish all terms and conditions for its API technology, including any fees, restrictions, limitations, obligations, registration process requirements, or other similar requirements that would be needed. Vendors should be required to explicitly document their implementations of standards.

In that same spirit, ACR recommends that ONC clarify that suppliers are not permitted to require interested parties to create accounts, sign license agreements, or agree to monetization/tracking to merely access this material information. Doing so would reduce barriers for a larger group of individuals and organizations to make use of the interoperability implementations.

EHI Export

§ 170.315(b)(10) - EHI Export Certification Criterion (84 FR 7446-49)

ONC requested information regarding the types of imaging elements of EHI that must be exportable by certified health IT as part of the proposed "EHI export" certification criterion.

ACR recommends that ONC require certified health IT to enable the exportation of available links to imaging studies and other externally hosted imaging data. We recognize the intent of the proposed 2015 Edition "EHI export" certification criterion is to set a minimum floor of the data that must be exportable when providers are switching EHR products or providing records to patients of any EHI maintained directly in the certified health IT. Diagnostic images may or may not be locally accessible within certified health IT; however, imaging providers often provide referring physicians and patients with electronic access (e.g., secure links, etc.) to imaging studies and corresponding data stored in radiology IT/web-based solutions. Available links to that externally hosted imaging data should be exportable when referring physicians migrate patient data to their new EHR solutions.

Information Blocking

§ 170.102 – Definitions – "Electronic Heath Information (EHI)" (84 FR 7509-15)

ONC proposed that EHI be defined as (1) Electronic protected health information; and (2) Any other information that identifies the individual, or with respect to which there is a reasonable basis to believe the information can be used to identify the individual and is transmitted by or maintained in electronic media, as defined in 45 CFR 160.103, that relates to the past, present, or future health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual. De-identified data would not be covered.

ACR supports ONC's proposal of an expansive EHI definition that goes beyond the limited data types maintained by traditional certified health IT/EHR technology. We strongly disagree with the suggestion by some stakeholders of limiting the EHI definition to the USCDI dataset or other information

maintained in certified health IT, as those limitations would fail to address the anticompetitive behaviors that motivated Congressional action via Cures Section 4004.

To that end, ACR also recommends that ONC explicitly clarify that orders/referrals for imaging services are indeed part of the EHI definition and thus are covered by the information blocking provision. We believe this is currently ONC's intent; however, explicit clarification in the preamble of the final rule would be helpful for sending the appropriate message. ACR has regularly heard from members regarding hospitals and health systems discouraging or preventing electronic orders for imaging provided by unaffiliated radiology practices. Additionally, some EHR vendors have employed exploitative schemes to require imaging providers to pay excessive "partnership" fees and "pay-per-referral" fees for the ability to connect or be listed in the CPOE directory of referring clinicians' EHRs. These relatively commonplace information blocking behaviors are to the detriment of patients and cost-conscious care, and addressing these specific situations was one of the primary objectives of the legislative policy that evolved into Cures Section 4004.

Likewise, ACR supports the inclusion of all other imaging-related clinical data that meets the proposed EHI definition, including images and reports. We strongly believe in the importance of moving toward electronic exchange of images and corresponding data without physical media. As mentioned previously, this would minimize unnecessary duplicative imaging, improve the quality and safety of care, facilitate earlier diagnoses, and reduce costs.

Finally, ACR supports the proposed exclusion of de-identified data from the EHI definition. De-identified information is typically for secondary uses (e.g., registries, benchmarking, performance monitoring and clinical validation, research, etc.) and rarely for providing care to an individual patient. Moreover, given the proposed overly broad definition of "heath information exchanges and health information networks" (discussed with concern below), it would be critical for ONC to preserve the exclusion of de-identified data from the EHI definition to avoid unduly penalizing specialty registries and other organizations.

§ 170.102 – Definitions – "Health Information Exchange" and "Health Information Network" (*84 FR 7509-15*)

ONC proposed separate definitions for "Health Information Exchange or HIE" and "Health Information Network or HIN," notably including clinical data registries in the HIE proposed definition.

ACR recommends that ONC consolidate and narrow the definition of HIE/HIN to avoid covering clinical data registries and other organizations that are unrelated to traditional HIE networks and that do not engage in provider-to-provider EHI sharing for direct patient care purposes. Congress intended for HIEs and HINs to be synonymous labels for the same type of entity—essentially, health information exchange networks. This is evidenced by the fact that both terms were included in a single "entity" reference at Section 4004(b)(1)(C), and both terms were used interchangeably throughout the remainder of Section 4004. HIE networks often refer to themselves using different terms (e.g., exchanges, networks, collaboratives, forums, etc.), so the use of two labels within the single entity description at 4004(b)(1)(C) was intended to cover these variations. Moreover, clinical data registries were defined elsewhere in Cures and would have been explicitly called out in Section 4004(b)(1)(C)—and mentioned to stakeholders by Members and staff during the compilation of the Cures legislative package in 2016—if Congress intended for clinical data registries to be categorized as HIEs. Therefore, Section 4004(b)(1)(C) should be implemented as a single regulatory definition for HIE/HIN entities encompassing only traditional health information exchange networks.

§ 171.201 Exception 1 – Preventing harm (84 FR 7523-26)
ONC proposed that practices reasonable and necessary to prevent harm to a patient or another person are permissible, provided certain conditions are met.

ACR recommends elimination or clarification of the permissible harm risk described in the NPRM preamble of "corrupt or inaccurate data being recorded or incorporated into the patient's record" to ensure hospitals, developers, and networks do not implement exploitative, unnecessarily broad policies. Organizations should be required to work with requesting actors to resolve any corrupt/inaccurate data concerns before being able to invoke the "preventing harm" exception.

§ 171.202 Exception 2 – Promoting the privacy of electronic health information (84 FR 7526-35)
ONC proposed that practices reasonable and necessary to protect the privacy of an individual's EHI are permissible, provided certain conditions are met. Exception 2 includes specific "sub-exceptions" with corresponding conditions.

ACR recommends hospitals using certified EHR technology (CEHRT) for participation in the Medicare/Medicaid "Promoting Interoperability" Program that receive exchange requests from providers using certified health IT or FDA-regulated software not be allowed to invoke the proposed privacy exception at § 171.202. The regulated and/or certified security features of the technology involved in the exchange should forgo any reasonable need for this exception.

§ 171.203 Exception 3 – Promoting the security of electronic health information (84 FR 7535-38)
ONC proposed that practices reasonable and necessary to promote the security of EHI are permissible, subject to certain conditions.

ACR recommends that ONC consolidate the proposed "security" exception under § 171.203 with the proposed "privacy" exception under § 171.202 as a single exception. The justifications and concerns underlying both exceptions are similar.

§ 171.204 Exception 4 – Recovering costs reasonably incurred (84 FR 7538-41)
ONC proposed that actors be permitted to the recovery of certain costs reasonably incurred to provide access to, exchange, or use of EHI. ONC's proposals do not prevent a profit provided that all applicable conditions are met. Access to EHI that is provisioned by supplying some form of physical media (e.g., copies of EHI on printouts, discs, flash drives, etc.) would not be subject to the provision, provided fees for that level of access complied with HIPAA. The method for recovering costs must be reasonable and nondiscriminatory, and be based on objective and verifiable criteria that are uniformly applied for all similar classes of persons and requests.

ACR recommends that ONC provide additional clarity around the concept of "reasonable cost recovery" to ensure that small providers and small developers are not disproportionately discouraged from connectivity. Costs that are ostensibly "reasonable" for medium- and larger-sided actors may prove financially burdensome if flatly applied to smaller actors, which could generate a loophole for hospitals and developers seeking to price out competition.

ACR is also concerned about ONC's preamble discussion on permissible profits from cost recovery under the proposed exception at § 171.204, and we recommend this vague discussion be eliminated in the final rule. The notion of the consumer market deciding "reasonableness" related to profits made from

cost recovery would introduce unnecessary subjectivity to OIG investigations. Moreover, information sharing within a given market is typically dominated by a single hospital, health system, or regional network, so OIG investigators would presumably need to develop and maintain national reference levels to ensure a given market's profits are comparable to profits in other markets. Thus, ensuring that cost recovery profits are "reasonable" appears to be complex and likely unenforceable by OIG.

Finally, ACR recommends further clarification around the concept of "similar classes of persons and requests" to explicitly mean regardless of affiliation. There must not be separate classes differentiating affiliated from unaffiliated providers as that would lead to discrimination. ONC may also consider guidance, or an explanation in the preamble of the final rule, about how different classes of persons and requests may be appropriately categorized for cost recovery purposes.

§ 171.205 Exception 5 – Responding to requests that are infeasible (84 FR 7542-44)
ONC proposed that actors be permitted to decline access/exchange/use of EHI in a manner that is plainly unreasonable, provided certain conditions are met.

Due to the high potential for loopholes under the proposed § 171.205, ACR recommends that HHS require hospitals, developers, and networks to report "infeasible" requests to ONC or OIG for evaluation and prior authorization. The terminology used by ONC of "plainly unreasonable" is vague, subjective, and likely unenforceable via retrospective OIG investigations. We also note that physicians and ambulatory providers should not need this added step of a prior evaluation/authorization given their relatively minor influence on regional health information exchange.

§ 171.206 Exception 6 – Licensing of interoperability elements on RAND terms (84 FR 7544-50)
ONC proposed that actors be permitted to license interoperability elements on reasonable and non-discriminatory (RAND) terms, provided certain conditions are met. To comply with the RAND condition, actors must respond within 10 business days from receipt of the request, negotiate in a RAND fashion to identify interoperability elements needed; and offer an appropriate license with RAND terms. The royalty base and rate must be reasonable, and cannot be based on strategic value. The proposed factors HHS would consider in determining royalty reasonableness are based on court decisions on royalties charged by standard development organizations to license standard-essential technologies on RAND terms. The nondiscriminatory requirement would apply to both price and other terms of the license, and must be uniformly applied to all similar classes of persons and requests.

ACR strongly supports the proposed applicability of RAND to actor responsiveness, pricing, and terms. ACR agrees with ONC that an explicit response deadline of ten business days from the request is appropriate and enforceable.

While implied by the RAND concept and other exceptions in the proposed rule, ACR urges that ONC explicitly clarify in the final rule that "similar classes of persons and requests" also mean regardless of affiliation. There must not be separate classes differentiating affiliated from unaffiliated providers as that would lead to discrimination.

Information Blocking - Disincentives for Health Care Providers—Request for Information
ONC requested information on implementation of PHSA section 3022(d)(4), which directs OIG to refer information blocking providers to the appropriate agency to be subject to appropriate disincentives using authorities under applicable law. Developers and HIEs/HINs would be subject to penalties of up to $1 million per violation.

ACR recommends a higher tier or range of penalties for information blocking violations by hospitals and health systems due to the commanding influence of these entities on regional exchange. Penalties for hospitals and health systems should minimally involve significant negative Medicare/Medicaid payment adjustments. More egregious, repeat violations could potentially result in civil monetary penalties or barring from federal programs. The circumstances of the reported incident(s) and other variables—e.g., the severity of the report, the impact of the reported behavior on patient care, regional influence of the provider, and history of anticompetitive practices or policies—should influence OIG's penalty decisions.

Unlike hospitals/health systems, individual physicians and ambulatory providers do not broadly dictate the terms of regional health information exchange. Disincentives for such providers should be commensurate with their comparatively low level of influence on data-sharing by others. Therefore, penalties for physicians and non-hospital providers could involve the public reporting of violations on Physician Compare for minor incidents and/or score reductions in the Quality Payment Program (QPP) for major incidents. Repeated violations could possibly result in failure of Promoting Interoperability or other requirements in the QPP for the performance year(s) in which the information blocking violation(s) occurred.

Registries

Registries—Request for Information (84 FR 7553-54)

ONC requested information on Cures Section 4005(a) and (b) implementation, which is focused on interoperability and exchange between EHRs and registries.

ACR recommends that ONC adopt FHIR Release 4 given the benefits of the update, such as inclusion of designated normative resources and new standard operations on obtaining data from multiple patients via FHIR. ACR discussed our community's concerns with finalizing the effectively outdated FHIR Release 2 in the API standard and certification criterion subsection section of this comment letter. Enthusiasm for FHIR Release 4 notwithstanding, many entities currently lack standardized and codified data elements, and development of these resources is often costly and requires technical support. As a result, the ACR joins our colleagues in the Physician Clinical Registry Coalition to urge ONC to develop a mechanism to provide technical assistance to organizations in need.

As always, the American College of Radiology welcomes continued dialog with ONC on issues of shared interest. Please contact Gloria Romanelli, JD, ACR Senior Director of Legislative and Regulatory Relations, and Michael Peters, ACR Director of Legislative and Regulatory Affairs, at (202) 223-1670 or mpeters@acr.org with questions or concerns.

Sincerely,

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