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May 31, 2019

The Honorable Donald Rucker, M.D.
National Coordinator for Health Information Technology
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, S.W.
Washington, D.C. 20201

Comments Submitted Electronically

RE: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program

Dear Dr. Rucker,

The American College of Cardiology (ACC) appreciates the opportunity to provide input on the Office of the National Coordinator for Health IT (ONC) proposed rule on 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program.

The ACC envisions a world where innovation and knowledge optimize cardiovascular care and outcomes. As the professional home for the entire cardiovascular care team, the mission of the College and its more than 52,000 members is to transform cardiovascular care and to improve heart health. The ACC bestows credentials upon cardiovascular professionals who meet stringent qualifications and leads in the formation of health policy, standards and guidelines. The College also provides professional medical education, disseminates cardiovascular research through its world-renowned JACC journals, operates national registries to measure and improve care, and offers cardiovascular accreditation to hospitals and institutions.

Introduction

The passage and implementation of the 21st Century Cures Act provides the Centers for Medicare & Medicaid Services (CMS) and ONC with the opportunity to make substantial progress in addressing the issues providers

and patients have with Electronic Health Records (EHRs). Among the most cited issues with EHRs are the lack of true interoperability between different EHR systems and poor EHR usability. Provisions in the Cures Act empower CMS and ONC with the tools to make meaningful progress in advancing interoperability and improving EHR usability. By taking these steps, CMS and ONC can improve clinician workflows, provide patients with access to their health information when they want it in an accessible and usable format, and allow providers to access previously siloed information to help improve care coordination and improve the quality of care.

The ACC agrees with the fundamental idea that patients own their data and should have access to it when they want it, how they want it. **The creation of a health ecosystem that develops tools to allow patients to own and access their data has the potential to revolutionize care. The ACC applauds the efforts of CMS and ONC to start down this path.** Additionally, by codifying the use of specific standards for certified health information technology (IT) systems, ONC ensures vendors help advance semantic interoperability. EHR interoperability remains a cornerstone of effective and efficient patient care. The difficulties and additional costs of not having easy access to patient information is antithetical to the ACC's aim to provide patient-centered care.

While the ACC is supportive of the direction ONC and CMS are moving toward realizing true interoperability, it is vital that ONC continue to work with stakeholders such as the ACC to mitigate the burdens and unintended consequences health IT interoperability and information blocking requirements place on providers, patients, and quality improvement entities such as clinical data registries. ONC can work to strengthen the implementation of these interoperability and information blocking proposed rules by:

- Minimizing or eliminating barriers to efficient, high-quality cardiovascular care in all practice settings by addressing and minimizing administrative burdens and costs imposed on providers by new interoperability and information blocking requirements
- Providing opportunity for continued stakeholder input through an interim final rule making period and delaying implementation of provisions within the rule to allow providers, vendors, and organizations sufficient time to prepare for the changes accordingly. These include but are not limited to the required dates for certified health IT development and implementation, the effective date for responses to data requests to avoid information blocking, and the timeline for updating contracts
- Limiting the scope of electronic health information (EHI) to ensure only the classes of individuals defined in the 21st Century Cures Act are regulated and providing clear guidance on the EHI export regulations to these classes of individuals
- Providing additional clarity on definitions used in the rule, including health information exchanges (HIEs) and health information networks (HINs), and offering specific examples of actors ONC believes the information blocking provisions regulate

- Aligning Health Insurance Portability and Accountability Act (HIPAA) and EHI sharing requirements and providing sufficient regulatory clarity to ensure actors are aware of their responsibilities and of patients' rights to their information
- Working jointly with CMS and the Office of the Inspector General (OIG) to ensure that information blocking enforcement focuses on education rather than punitive action against non-malicious information blockers
- Ensuring patients are afforded every opportunity to clearly consent to the sharing of the health information and third parties protect information stored on behalf of an individual

Implementing these and other ACC recommendations will allow CMS and ONC to avoid repeating the failures of the Meaningful Use program and instead lead to the development of a comprehensive, truly interoperable health system where providers and patients have access to information that helps facilitate coordinated care and improves outcomes while working to reduce administrative burdens associated with health IT systems.

Health IT Interoperability

A lack of true interoperability is one of the main drivers for clinician discontent with health IT and Electronic Health Record (EHR) systems. The ACC believes interoperability requires more than the ability of two or more health information systems or components to exchange clinical and other information; it also requires that information be exchanged using common data standards to facilitate coordinated care and improved outcomes. Many systems can open and share different documents and files, such as a PDF, with relative ease. However, it is often difficult for clinicians to extract any information from the resulting document. Under current systems, a patient's care team receiving a transition of care summary and accompanying test results and images often must sort through hundreds of pages to find relevant medical information. This results in the risk that important health information will be inadvertently overlooked, as well as significant cognitive overload that directly leads to clinician burnout. The burden is placed on clinicians and staff to compile the necessary information through manual transcription or other methods such as third-party software. **Solely having the ability to transfer medically necessary information to another facility does not constitute true interoperability.**

The ACC has continuously called for the development of a nationwide strategy to further the exchange of electronic health information to improve interoperability and reduce health IT burdens through the creation and enforcement of information blocking provisions, promotion of application programming interfaces (APIs), and standards development process. Under the proposed rule, ONC requires certified electronic health record technology (CEHRT) and certified health IT systems to adhere to codified standards and implement API technology while not blocking information. **The ACC thanks ONC for taking this much-needed step and putting into place the regulations necessary to advance interoperability.**

However, interoperability extends to all facets of care delivery in the modern health system and extends beyond CEHRT and certified health IT. **Cardiologists and members of the cardiovascular team rely on the ability to take, interpret and transfer images.** Cardiac catheterization and echocardiogram images are essential to modern cardiology and it is vital that ONC foster the development of an ecosystem that allows for the seamless and easy transfer of these images to both certified and non-certified systems. Allowing providers and patients equal and easy access to these images will help facilitate shared decision-making processes. While the ACC appreciates these rules are a starting point, it is important that ONC continue to work with stakeholders to ensure the entire health care system benefits from true interoperability. A fragmented IT ecosystem composed of certified and non-certified systems will not achieve ONC's stated goal of true interoperability.

To ensure ONC and CMS develop the necessary regulatory framework that facilitates open data exchange, ends information blocking, and achieves true interoperability, it is important to slow down implementation and provide additional avenues for continued stakeholder input. **The first step to this would be issuing an interim final rule following this proposed rule.** By issuing an interim final rule, ONC and CMS would allow all stakeholders additional time to process changes to the proposed rule, provide additional substantive feedback, and coordinate efforts to ensure the mistakes of previous programs like Meaningful Use are not repeated.

Revised and New 2015 Edition Criteria

As part of its efforts to foster interoperability, ONC proposes multiple updates to the 2015 Edition criteria for CEHRT. **The ACC supports ONC's efforts to update 2015 edition certification criteria through the United States Core Data for Interoperability (USCDI), updated eRx SCRIPT, CMS QRDA Implementation Guide (IGs), and Health Level 7 International (HL7®) Fast Healthcare Interoperability Resources (FHIR®) standards.** By laying out new criteria and updating standards, ONC provides vendors and health IT users necessary clarity to ensure they take appropriate steps to prepare, develop and implement updated health IT systems. Additionally, by codifying the use of specific standards for certified health IT systems, ONC ensures vendors will help advance interoperability and free previously siloed data.

For vendors and providers to clearly understand and implement the proposed revisions and additional certification criteria, ONC should create a new edition title (such as 2019 or 2020 edition criteria) to reflect the changes to the criteria rather than simply naming it updated 2015 criteria. When making health IT procurement decisions, offices may inadvertently purchase a health IT that is not certified to the correct standards, only seeing the 2015 edition and thinking it meets the necessary criteria. **Instead, ONC should clearly delineate the difference between the editions by creating a new naming convention for the updated criteria.**

Additionally, it is vital that ONC work with HL7 and health IT vendors to provide educational resources and technical assistance to ensure hospitals, practices, and

providers implement FHIR standards in a secure method, reducing the chances of cyberattacks. A recent study by the University of California system found that unsure implementation of HL7 standards lead to "unauthenticated, unvalidated, and plaintext transmission of sensitive data across networks."[1] To protect patient information, correct and secure implementation of updated standards are required and it is important that ONC work to provide the tools necessary for providers to correctly adhere to standards requirements.

Recognition of Food and Drug Administration Processes

The ACC appreciates the complexity of both the digital health software and certified health IT regulatory processes necessary for approval under the Food and Drug Administration (FDA) and ONC. Both agencies require manufacturers to meet specific and rigorous criteria for approval. **The College has supported efforts by both the FDA and the ONC to evaluate methods to reduce the regulatory burdens manufacturers face to promote needed innovation. However, burden reduction must not come at the expense of patient safety.** Protecting public health should remain the number one priority of both the FDA and ONC.

As ONC contemplates methods for streamlining approval processes for certified health IT, including modeling the Conditions and Maintenance of Certification for health IT after the proposed FDA Software Pre-Certification Pilot Program and developing a similar independent program process, it is important for ONC to consider public safety when developing certification programs. While health IT and EHRs have greatly improved providers ability to deliver the highest quality of care to patients, there are still many medical errors directly attributable to EHRs, such as those caused by poor usability. According to the MedStar Health National Center for Human Factors in Healthcare, a recent study indicated poor EHR usability contributed to a third of nine thousand identified health IT and medication safety events[2]. Kaiser Health News and Fortune Magazine also recently published a joint investigation documenting medical errors caused by EHRs, detailing specific cases where patients were harmed due to EHR software errors[3].

The College is hopeful many of the proposals put forth by ONC, including required real-word testing and improved interoperability, will help to reduce safety issues attributed to EHRs. **However, until the impact of these proposed changes can be accurately measured and the impact on both patient safety and interoperability measured, ONC should not implement any certification processes that reduce Conditions and Maintenance of Certification requirements.**

[1] https://hitinfrastructure.com/news/hl7-standards-could-open-health-it-infrastructure-to-cyberattacks
[2] https://ehrseewhatwemean.org/letter-to-congress/
[3] Schulte, Fred and Fortune, Erika Fry, *Death by 1,000 Clicks: Where Electronic Health Records Went Wrong*, Kaiser Health News, March 18, 2019, https://khn.org/news/death-by-a-thousand-clicks/

Scope of EHI

Under the proposed rule, patients and providers will have access to vital electronic health information (EHI) to support the goal of data liquidity. The ACC supports ONC's effort to ensure patients and their providers have access to this information and agrees with the fundamental idea that patients own their data. The creation of a health system that moves beyond foundational interoperability and provides the infrastructure for true, semantic interoperability will help facilitate the exchange of EHI.

However, as ONC and CMS jointly work to set the stage for semantic and organizational interoperability, it is important that both agencies align existing and proposed definitions and limit the reach of the regulations to align with Congressional intent. **As currently defined, ONC's proposed definition and the scope of EHI is too broad, will unintentionally expose a vast number of entities to information blocking enforcement, and is contrary to Congressional intent.** Under the current proposed definition and contextual examples provided by ONC, the ACC is concerned entities beyond the point of care and those that are not originating sources of data will be subject to undue burdens through information blocking provisions.

By stating EHI includes any data that may be stored in separate data warehouses that the system "has access to, can produce, and electronically manages," the ACC is concerned entities that physically store EHI on behalf of a provider, registry, or other health organization could be subject to possible information blocking enforcement and would need to comply with any EHI data requests from authorized individuals. While the ACC supports the concept of data liquidity and believes entities that capture and store patient EHI should comply with all EHI requests, ONC should limit the scope of EHI to more accurately capture Congressional intent for information blocking prohibitions and limit unintended consequences by regulating entities beyond the scope of care of patients.

To more clearly define the scope of EHI and information blocking provisions, ONC should limit the scope of EHI to defined elements, ensure only the classes of individuals defined in the 21st Century Cures Act are regulated, and provide clear guidance on the EHI export requirements to these classes of individuals. ONC should ensure all regulated entities are involved in the development of standards, their EHI export responsibilities are clear, and explicitly draft requirements for all regulated classes of individuals so they can ensure they comply with information blocking rules.

Finally, ONC must remain cognizant of the administrative burdens placed on providers through EHI information sharing requirements. Until a truly automated and intuitive digital system is available to all providers, there are associated administrative and financial costs associated with information sharing requests. Clinical or administrative staff will need to take time to ensure the correct data is safe to be shared with the correct, authorized entity, which can be a time-consuming process. While the creation of trusted exchange networks and other

interoperability innovations promise to help facilitate these processes, these capabilities do not exist in their final form and CMS should ensure any requirements do not add to the administrative or financial burdens placed on entities.

Conditions and Maintenance of Certification

ONC proposes updating the Conditions of Certification and Maintenance of Certification requirements for certified Health IT vendors. **The ACC applauds ONC's proposal to include requirements concerning information blocking; appropriate exchange, access, and use of electronic health information; communications regarding health IT; APIs; real world testing for interoperability; attestations regarding certain Conditions and Maintenance of Certification requirements; and submission of reporting criteria under the EHR reporting program.** By including these requirements as part of the certification process, ONC is developing the infrastructure and rules necessary to achieve true semantic interoperability. In addition, the ACC thanks ONC for requiring developers to not prohibit or restrict communication regarding health IT usability, interoperability, security, user experiences, business practices of developers of health IT related to health information exchange, and how users use health IT. As recent studies have shown, improving EHR and health IT usability can greatly contribute to improved viability and safety. The promotion of transparency will allow providers and researchers to work with vendors to continually improve EHR and health IT usability, interoperability, security, user experiences, and business practices.

Under the proposed rule, existing certified health IT developers will have up to 24 months to provide customers of certified health IT with systems that meet the new requirements and new developers will have 12 months. While the ACC appreciates the need for expediency to ensure updated systems with the new interoperability requirements are deployed in clinical settings, the proposed timeline does not account for the considerable time providers and procurement and health IT staff will need to learn, understand, and train on the new system requirements. Studies have shown that health systems that provide staff with adequate training and time to learn on newly installed EHR systems have greater confidence in the systems and feel they enable high-quality care[4]. **To ensure the process is not rushed and both health IT developers and users have adequate time to prepare for the new systems, ONC should develop separate timelines for health IT developers and health IT users.** While health IT developers will have up to 24 months to provide customers of certified health IT with systems that meet the new requirements, sites of service and practitioners will need additional time once systems are rolled out to ensure they are properly trained on the new system capabilities to ensure they are maximizing the technological utility of health IT systems.

[4] Stanford Medicine, September 2018, http://med.stanford.edu/content/dam/sm/ehr/documents/SM-EHR-White-Papers_v12.pdf

Under the proposed Conditions and Maintenance of Conditions, ONC requires the updating of contracts in an unrealistically short period of time. **While the ACC understands the need to update contracts and agreements to become compliant with updated conditions of certification, requiring health IT developers to update all contracts and agreements within six months of the effective date of the final rule will place a substantial financial and administrative burden on hospitals and providers.** Instead, ONC should require health IT developers to begin updating agreements as soon as the rule is effective and extend the effective date to at least one year for updated agreements, providing more time for providers to understand the complexity of new agreements.

Application Programming Interfaces

As part of the updated 2015 Edition Criteria, ONC proposes utilizing FHIR-based APIs to allow patients to access their EHI and help ensure interoperability. APIs are the foundation of the modern internet and the ACC supports ONC's proposal to require APIs that are standardized, transparent, and pro-competitive. The development of a rich API-based ecosystem will allow patients and providers to gain access to important health information in easy to use, standardized applications. The College is encouraged by the possibilities that this proposal brings to the health IT landscape.

While APIs have been utilized in EHRs and health IT, they have not been standardized, transparent, pro-competitive, or widely accessible across different platforms. The development of open API tools will bring needed data liquidity and improve health IT usability through easier interfacing. **However, to ensure the promise of API utilization is fulfilled, ONC should work with HL7 and health IT vendors to provide educational resources and technical assistance to ensure hospitals, practices, and providers properly implement APIs in a secure method.** The introduction of APIs to an increasingly connected health system introduces additional points of entry for hackers and bad actors. Correct and secure implementation of updated standards are required to reduce the changes of cyberattacks and protect data privacy and patient information. It is important that ONC work to provide the tools necessary for providers to correctly adhere to standards requirements, especially for those that have not widely utilized API technology in the past.

The development of open APIs and a transparent health information ecosystem will also allow third-parties to develop tools that provide utility to patients and much needed competition to the health IT system. Third-parties will imagine ways to store and make patient data accessible in easy to understand ways and provide valuable insights to patients and providers. However, the ACC is concerned the proliferation of third-party vendors with access to patient health information that fall outside of current HIPAA regulations presents a threat to the privacy and consent protection patients deserve. **It is vital that ONC work with CMS, the Federal Trade Commission (FTC) and other agencies to develop a third-party system that allows verified**

and trusted vendors to access patient data and ensures patient health information is sufficiently protected.

One way ONC can ensure patients can trust how their health information is used by non-HIPAA covered entities is through clear, easy to understand, plain text terms and conditions coupled with stringent consent requirements. **The ACC supports ONC's proposal to require API Technology Suppliers to publish all terms and conditions for use of its API technology including fees, restrictions, limitations, obligations, registration process requirements, and other terms or condition and encourages ONC to stack strong consumer protections into the API verification process.** Patients will place their trust in providers, vendors and third-parties that they will be good stewards of their health information. It is important ONC cultivate a regulatory structure that rewards this faith with equal protections.

Permitted Fees Conditions

Under the proposed rule, ONC establishes a general prohibition on API Technology Suppliers imposing fees associated with API technology and may not impose fees to facilitate a patient's ability to access, exchange, or use their EHI. This leads to the creation of an environment where API technology suppliers can charge API data providers (often health care providers) fees for the underlying API technology as well fees based on the usage activities of API users (patients and those that stand to benefit from the introduction of API technology). This will inevitably lead to the creation of contracts and fees like cell phone bills where data overages are charged at a high level, increasing the cost of use.

While the ACC is understanding of the need for API technology suppliers to recoup costs incurred for developing API technology and appreciates the requirement that fees must be based on objective and verifiable criteria that are uniformly applied for all substantially similar or similarly situated classes of persons and requests, the College is concerned the proposed permitted fees conditions will leave providers as the only entity unable to recoup any costs associated with implementing API technology.

Patients have the fundamental right to accessing their information and the ACC believes API technology can unlock previously siloed data and lead to important clinical and administrative advances. **However, this technology is not free and it is unfair to expect providers and hospitals to serve as the only entities that must pay for this technology without the ability to recoup any costs.** Despite the substantial investments and monies provided by the federal government to Health IT vendors through the Meaningful Use, Advancing Care Information, and Promoting Interoperability programs, Health IT vendors have failed to achieve meaningful interoperability which has come at a high cost to patients and the healthcare system alike. **While technological capabilities for increased interoperability have existed for years, vendors have failed to provide necessary investment and resources into developing these solutions at the point of care.**

It is important that ONC and CMS ensure vendors minimize increases in pricing and take the leading role in the responsibility to develop, pay for, and implement the proposed interoperability requirements. ONC must work to ensure patients and providers are not stuck with the bill for the implementation of required technology. Additionally, to help offset the high costs for upgrading technology, ONC should allow API Data Providers the ability to recoup the costs for upgrading technology like any other business is allowed so long as they are reasonable and non-discriminatory.

Real World Testing

The Cures Act requires, as a Condition and Maintenance of Certification under the Program, that health IT developers have successfully tested the real-world use of the technology for interoperability in the type of setting the technology will be used. This requirement provides ONC the opportunity to ensure health IT developers develop technology that meets the needs of unique practice settings and clinical scenarios rather than relying on vague test cases. The ACC encourages ONC to set rigorous real-world testing requirements that ensure usability and patient-safety concerns are sufficiently mitigated before deployment into clinical settings where patients can be harmed.

As part of the certification process and real-world testing, it is vital that ONC include functionality-based criteria such as usability and user-centered design as these have direct impacts on the real-world applications of health IT systems. Numerous studies, including research published by the MedStar Health's National Center for Human Factors in Healthcare, have shown medical errors and patient harm is directly attributable to poorly designed EHR systems. Including user-reported data in the EHR certification and maintenance process will assist in shifting user-centered design to the focus of the EHR design and implementation process. Factoring these components into the initial design will assist in keeping the total cost of ownership for EHR systems down, enabling practices and health systems to more accurately plan for the resources required for EHR system purchase, installation, training and maintenance.

When undergoing real-world testing in clinical settings, it is also important for ONC to consider the inclusion of user-reported criteria. Practitioners can provide unique insights into the real-world applications of EHR and health IT systems and ONC should incorporate this input into the certification process. The inclusion of user-reported data into the real-world testing and certification process for health IT promises to provide additional pressure for continued progress in addressing the concerns of the clinical community. **Usability and interoperability will only improve when clinicians can provide feedback to ONC and Health IT Vendors that will directly contribute to the certification and maintenance of an EHR system.**

Finally, it is important that ONC and developers are transparent regarding real-world testing performed on certified health IT systems. Making real-world testing data available will provide

needed context to ensure health IT acquisition personnel make informed decisions when upgrading or purchasing a new system. **ONC should incorporate real-world testing data into any EHR comparison reports and should emphasize development of a marketing strategy and educational resources to increase awareness of and access to such important comparison tools.** Development of interactive online and application-based resources that allow for side-by-side comparisons and real-time user input and reviews would provide much-needed accessibility and context to the decision-making process.

Standard Version Advancement Process

The ACC thanks CMS for proposing a process to continuously update health IT standards. The creation of more nimble process with stakeholder input will accelerate industry and standard development organization (SDO) processes and allow for rapid innovation and the expansion of additional use cases for standards-based data exchange. As interoperability efforts continue to grow, more stakeholders will participate in these groups, providing additional time, effort, and resources to help develop future standards.

As new standards are developed using this proposed advancement process, it is important that ONC and SDOs clearly outline the requirements for participation, timelines, resource necessities, and other important components of the process. Additionally, ONC and SDOs should regularly communicate updates to all affected stakeholders and hold regular, open meetings to provide necessary transparency to the process. By creating a transparent standard version advancement process, ONC will earn stakeholder buy-in and make implementation of updated standards easier.

Finally, it is important that any standard advancement include updated and detailed implementation guides to ensure API developers can properly install updated versions. The creation of new standards alone is not sufficient to ensure proper implementation at the site of use. Instead, any process should also develop appropriate educational materials and user guides along with realistic implementation timelines to ensure ONC provides all stakeholders sufficient time and resources.

EHR Reporting Criteria Submission

Under the 21st Century Cures Act, Congress asked ONC to reevaluate the reporting criteria for the EHR reporting program, including certification standards and reporting criteria for several categories including interoperability and incorporation of user-reported data. The development of relevant health IT and EHR comparison tools would help clinicians make informed choices during the acquisition process, while incorporating user-reported criteria would allow EHR vendors and ONC to gather valuable input in real world settings and drive usability and workflow enhancements.

While the inclusion of real-world testing has the potential to greatly improve EHR usability and functionality, the ACC believes ONC should take the time to re-evaluate EHR reporting criteria and

the submission process and focus on improving security, usability, and interoperability through the inclusion of data sources such as user-reported criteria and additional data reported by health IT developers.

The ACC believes that data reported by health IT developers to ONC under the certification process must complement the needs of end users and serve the purpose of driving informed decision-making for health IT acquisition. It is important that developer-reported data to be easy to read, providing necessary technical specifications for IT personnel and plain language information useful for end users. Examples of developer-reported data that would be useful for end users include:

- Manufacturer's expected full-time equivalent (FTE) IT and end user installation and support staff
- Data standard and version adherence
- Availability of app stores to allow for customization and tool development

It is important that ONC report this data in a uniform and comparable format, allowing for the side-by-side comparison of different system capabilities. Data reported by Health IT developers as part of the certification process should specifically work to advance improvements in usability, user-centered design, security, and interoperability.

Additionally, including user-reported data in the EHR certification and maintenance process will assist in shifting user-centered design to the focus of the EHR design and implementation process. **Rather than strictly being designed to address billing and data capture processes, vendors must account for different users, tasks, care settings, and other unique circumstances when designing EHR systems.** In addition to user-reported data and market forces, it is important that ONC account for usability and user-centered design criteria in the certification process. Incorporating usability and user-centered design criteria will ensure EHR vendors consider these elements during the design phase. Factoring these components into the initial design will assist in keeping the EHR total cost of ownership down, enabling practices and health systems to more accurately plan for the resources required for EHR system purchase, installation, training and maintenance.

There are several human-computer interface evaluation methods[5] that ONC can incorporate into the certification and maintenance process that would benefit clinicians and health IT decision makers. These include but are not limited to:

- Heuristic techniques to evaluate a user interface

[5] C.M. Johnson et al. *Journal of Biomedical Informatics*, 38 (2005) pp. 75-87.

- Keystroke level models that sum up the time taken for keystrokes, pointing, clicking, thinking, waiting, and deciding
- Comparative analysis between similarly commercially available systems

There are also several user-reported criteria that ONC should consider for inclusion in the EHR certification and maintenance process and published comparison reports:

- Work-after-work (WOW) time per provider (time spent on an EHR following conclusion of the work day)
- Measurements of time spent logged into an EHR versus the number of patients seen
- Ease of displaying user-defined report formats
- Total time extracting and manipulating health information transferred from external data source

These listed usability and user-centered design criteria are not an exhaustive list of criteria available for incorporation into the EHR certification, maintenance and reporting process. The College encourages ONC to work with end users to include these and other criteria in the certification and maintenance process. Increasing the availability of this data, those measured by ONC and those reported by end users, to clinicians and health IT decision makers would greatly expand the number of variables to be factored into the EHR procurement process and enable group practices and healthcare systems to make better informed decisions. In turn, EHR vendors would be forced to consider the needs of the end-user when developing EHRs, leading to improved products, decreased frustration and burden for clinicians and patients, and increased time for discussions between clinicians and patient.

Information Blocking

The ACC has long supported efforts to prohibit information blocking and thanks ONC for implementing the information blocking prohibition passed in the 21st Century Cures Act. Information blocking has been one of the main contributors to a lack of true interoperability, along with technological and other limitations put into place by EHR vendors. As ONC rightly points out in the proposed rule and the Congress acknowledged under Cures, intentional information blocking has occurred in the past and should be prohibited.

The Public Health Service Act (PHSA) as modified by Cures, in defining information blocking, refers to four classes of individuals and entities that may engage in information blocking and which include: health care providers, health IT developers of certified health IT, HINs, and HIEs. Clinical data registries such as National Cardiovascular Data Registry (NCDR®) are likely included under the broad HIE and HIN definitions in the proposed rule and therefore may be implicated under information blocking provisions. **While the ACC understands the need for ONC to provide broad definitions to fit the four classes of individuals defined under the 21st**

Century Cures Act, it is essential that ONC provide necessary context and clarification to the HIN and HIE definitions so actors which may be regulated clearly understand information sharing requirements. Explicitly defining entities that are regulated under the provisions will provide necessary regulatory clarity and help advance the shared goal of ending information blocking.

Furthermore, when shaping these definitions, ONC should understand nuances exist between different clinical data registries, including administration and extraction processes developed for distinct clinical purposes. ONC should develop policies that differentiate between registries rather than issue blanket information blocking policies. Registries have innovated in a way that moved health care forward, improving patient care and expanding access to data. For example, the NCDR® suite of registries currently includes registries in both the inpatient and outpatient setting. These registries include the PINNACLE Registry® and Diabetes Collaborative Registry® for the outpatient care in the ambulatory care setting and a suite of hospital registries for the inpatient setting including the STS/ACC TVT Registry™, CathPCI Registry® and ICD Registry™, to name a few. While each of these registries collect important clinical information, each has developed their own data processes and are not uniform. The inpatient and outpatient registries in NCDR® have separate data extraction processes. The outpatient registries currently work with an external vendor to extract data while the inpatient registries handle data extraction processes in-house. **Any information blocking provisions which require HINs and HIEs to respond to and fulfill EHI requests must account for individual variances in extraction processes and provide sufficient time and guidance for actors to respond to and fulfill these requests.**

In the proposed rule, ONC states information blocking may occur if an actor does not utilize broadly adopted standards when an identified standard does not exist. Registries have developed standards and definitions to meet the needs of the practitioners and customers they serve and have not been required to utilize broadly adopted or identified standards. **Any efforts to unfairly punish clinical data registries or other actors for information blocking without sufficient time to address deeply entrenched processes for information collection and extraction could constitute punitive action that threatens the viability of registries going forward. Instead, ONC should adopt policies that allow registries sufficient time to test and migrate to common data models and broadly adopted standards.**

Additionally, to promote additional transparency and ensure the continued viability of clinical data registries, **registries should publicly publish data elements and definitions to facilitate data liquidity and ONC should allow the licensing of mechanism coding systems and standards to interface with registries.** Most registries do not publish their data elements and definitions. By making elements and definitions accessible, registries would demonstrate their commitment to transparency and interoperability. The ability to license standards and coding systems to facilitate data exchange would allow registries to continue to operate and provide

patients, providers, payers, and drug and device manufacturers with valuable clinical information by recouping expensive and time consuming technologic and standards development costs.

Finally, the Office of the Inspector General (OIG) is tasked with information blocking enforcement under the 21st Century Cures Act. **However, ONC and CMS should work jointly with the OIG to ensure that enforcement focuses on education rather than punitive action against non-malicious information blockers.** No health care providers should be punished for violating information blocking provisions unless there is clear evidence of malicious intent to block the sharing of EHI. The implementation of information blocking prohibitions and regulations represents a substantial change to the health information landscape, and while prohibitions on information blocking are welcomed, OIG should work to ensure all actors are aware of their responsibilities and provided sufficient time to make necessary administrative and technological changes to comply with the new requirements. By rushing implementation and enforcement, OIG threatens to stifle information and counterintuitively prevent information from being accessible. Punitive measures should only be considered after a provider has been flagged, educated, and warned about the actions that violated information blocking provisions.

Electronic Health Information

As previously stated, ONC's proposed definition and the scope of EHI is too broad, will unintentionally expose a vast number of entities to information blocking enforcement, and is contrary to Congressional intent. ONC should ensure that the definition of EHI clearly limits the scope of provisions to classes of individuals defined in the 21st Century Cures Act and does not unintentionally subject entities further removed from the point of care to unnecessary regulations.

In addition to considering the scope of EHI definitions, ONC should consider processes entities must adopt to comply with EHI requests. Clinical data registries such as NCDR® are not originating sources of data but instead aggregate data collected at the point of care. Many registries do not provide direct access to personal health information (PHI) and rely on business agreements to provide HIPAA limited data sets to requestors. By expanding the definition of EHI beyond HIPAA regulations, ONC greatly increases the export requirements placed on entities that may hold EHI. **ONC should account for the types of data stored in clinical data registries and other entities when drafting EHI export guidance by allowing non-originating sources of data entities such as clinical data registries to develop clear, documented processes for routing EHI export requests back to originating sources to allow for identity authentication and data quality control.** By doing so, ONC will ensure entities such as NCDR® are not exposing PHI or EHI to unnecessary exposure or data breach risks while providing clarity to the information blocking prohibition requirements.

Finally, in a request for information, ONC seeks comment on the technical, operational, legal, cultural, environmental and other challenges to creating price transparency within health care. The ACC has called for greater transparency in pricing, especially in drugs, and appreciates CMS

and ONC efforts to develop tools that create price transparency. **However, ONC and CMS need to be cognizant of the burden placed on providers if they are responsible for including negotiated rates or price comparison tools and making them accessible on demand.** Current billing practices are complex and are often payer specific, making it nearly impossible for providers to be responsible for providing individual pricing information alone. Instead, ONC and CMS should work with payers to develop real time, personalized pricing tools that balance HIPAA and privacy concerns with the need for greater price transparency.

Proposed Exceptions to the Information Blocking Provision

The 21st Century Cures Act charged the Secretary and ONC with developing exceptions to information blocking provisions. The proposed exceptions laid out by ONC are a good faith effort to understand situations where providers and vendors may need to withhold EHI in real-world settings. While the ACC believes patients deserve access to their data, as these exceptions show, there will be times where withholding information is necessary. **The ACC thanks ONC for providing these exceptions and encourages ONC to remain open to further exceptions based on scenarios that have not been considered. ONC should retain a process for adding exceptions when appropriate through future rulemaking and explicitly lay out a process for developing additional exceptions as needed.**

The ACC has provided comments on specific proposed exceptions below:

Preventing Harm

The ACC supports the inclusion of an exception that would prevent sharing of information that could bring harm to a patient or another person. Adding a preventing harm exception will help to reduce provider liability and protect patients from inadvertent exposure to or release of potentially harmful information. One component of the preventing harm exception is the discovery of corrupt or inaccurate data in a patient's health record. The ACC thanks ONC for preventing providers from being forced to share incorrect data. However, it is not clear from the exception who is responsible for the corrupt or incorrect information in a health record and who is responsible for ensuring the information is corrected. **If a clinician discovers corrupt or inaccurate data in a patient's electronic health record, the ACC is concerned the discovering clinician could be exposed to liability risks if they do not take actions to correct the information, even if it was data or tests they did not order or put into the record.** ONC should provide clarity on the process for correcting information in a health record to ensure patients have access to correct information.

Promoting the Privacy of EHI

The privacy of patient EHI is one of the most important components that needs constant consideration through the push for interoperability. As API technology allows for the electronic transfer of sensitive and personal information, it is vital that ONC do everything

in its power to ensure privacy is the number one priority. Currently, HIPAA governs patient health information privacy and has provided patients with the tools to ensure their information is as protected as possible. However, under the proposed information blocking rules, ONC notes the information blocking provision may require that actors provide access, exchange, or use of EHI in situations that HIPAA does not. This greatly expands not only the demands placed on providers but will lead to confusion about what requirements they must legally follow. **The ACC strongly opposes placing clinicians in a situation where, due to regulatory ambiguity, they feel they must choose between potentially violating HIPAA privacy requirements or information blocking provisions.**

HHS must work with the Office of Civil Rights (OCR), ONC, and CMS to ensure there is clarity and alignment between information sharing requirements under HIPAA and information blocking. As currently drafted, information sharing requirements are not clear and promote an environment of uncertainty and potential liability. One specific example where clarity is needed includes information that is protected from HIPAA privacy rules or clinical trial/ patient information used in internal safety intelligence reporting for quality purposes. **The ACC seeks clarification on the necessity to share information that may be protected from HIPAA Privacy rules and patient access, such as health information created or obtained by a covered health care provider/researcher for a clinical trial or patient information used in internal safety intelligence reporting for quality purposes that is legally non-discoverable.**

In addition to needed regulatory clarity and alignment, OCR must engage providers in a substantial campaign to educate on HIPAA, information blocking, and other information sharing requirements. ONC states that providers have used HIPAA as an excuse not to share patient information. However, this does not stem from malicious intent. Instead, providers may not be aware of all HIPAA sharing requirements and, instead of opening themselves up to potential liability and HIPAA violations, they err on the side of caution and do not share information. **To counter this, OCR must provide clear, concise, easy to understand and timely education materials to patients, providers and administrative staff to ensure every individual understands new information sharing requirements.** The complex nature of privacy rules and regulations and the potential for substantial fines and punishment create an environment that does not encourage information sharing. ONC and OCR must educate patients and providers and cultivate an environment that encourages information sharing.

ONC provides an exception for not providing access, exchange, or use of EHI pursuant to an individual's request. However, consent management software is in its technological infancy and incredibly expensive or burdensome to operate. Until consent management technology is widely available and allows for patients and providers to choose which information can and should be shared, providers will expose themselves to potential liability by potentially

sharing information a patient does not want shared to avoid violating information blocking regulations. ONC should ensure providers are not unfairly punished due to technological limitations and provide sufficient leniency for actors that choose to under share information due to liability concerns.

Recovering Costs Reasonably Incurred

While the ACC is understanding of the need for API technology suppliers to recoup costs incurred for developing API technology and appreciate the requirement that fees must be based on objective and verifiable criteria that are uniformly applied for all substantially similar or similarly situated classes of persons and requests, the College is concerned the proposed permitted fees conditions will leave providers as the only entity unable to recoup any costs associated with implementing API technology.

Patients have the fundamental right to accessing their information and the ACC believes API technology can unlock previously siloed data and lead to important clinical and administrative advances. **However, this technology is not free, and it is unfair to expect providers and hospitals, which often operate with small margins, to serve as the only entities that must pay for this technology without the ability to recoup any costs.** Despite the substantial investments and monies provided by the federal government to Health IT vendors through the Meaningful Use, Advancing Care Information, and Promoting Interoperability programs, Health IT vendors have failed to achieve meaningful interoperability which has come at a high cost to patients and the healthcare system alike. While technological capabilities for increased interoperability have existed for years, vendors have failed to provide necessary investment and resources into developing these solutions at the point of care.

It is important that ONC and CMS ensure vendors minimize increases in pricing and take the leading role in the responsibility to develop, pay for, and implement the proposed interoperability requirements. ONC must work to ensure patients and providers are not stuck with the bill for the implementation of required technology. Additionally, to help offset the high costs for upgrading technology, ONC should allow API Data Providers the ability to recoup the cost like any other business is allowed so long as they are reasonable and non-discriminatory.

Responding to requests that are infeasible

Under the proposed rule, ONC requires actors to respond to requests in a timely manner. **ACC seeks clarification on the timeline ONC requires for responses to EHI requests to ensure actors do not violate information blocking provisions.** Timely response is a highly subjective term and can vary depending on specific situations. Specific response requirements are necessary for actors to develop clear policies for responding to information requests and determining if the request is infeasible.

ONC states information blocking maybe invoked if a health care provider has the capability to provide same-day access to EHI in a form and format requested by a patient or a patient's health care provider, but takes several days to respond. Current technological capabilities, privacy concerns, workflow, and administrative staffing often do not allow for same-day responses for providers or other entities such as clinical data registries. **Until technology that allows for safe, secure, automated information extraction is widely available and no longer cost prohibitive, ONC should not place undue administrative burdens on providers, their clinical staff, clinical data registries or other entities by requiring infeasible timelines for responses to inquiries.** ONC should allow actors to develop clear policies that provide specific, feasible timelines for responses that allow requestors to know when they should expect a response.

Registries Request for Information

The ACC appreciates ONC's inclusion of a request for information on methods for improving the bi-directional exchange of information with clinical data registries. Registries are an essential component of quality improvement activity and are vital to continued progress in helping to improve outcomes. As previously mentioned, it is important for ONC to work with CMS to understand differences between clinical data registries, as they are used in a diverse number of ways in different care settings. Each registry is developed to address a specific need. Registries are used for federal quality reporting, real-world data collection, and mandatory data collection required for payment under coverage decisions. In addition to having a diverse number of uses, clinical data registries have developed data collection methods and standards to fit these uses and often collect many elements. For example, the STS/ACC TVT Registry™ data collection form contains over 300 data fields.

The development of standards to aid in bi-directional exchange with clinical data registries offers a promising way to ensure clinical data collected at the point of care is recorded correctly and uniformly and provides the basis for automated data entry process, helping to reduce registry reporting burdens. **However, any transition to standards for registries needs to be measured and in coordination with registries. ONC, CMS, SDOs and registries should work in concert to develop solutions for the collection of detailed, standardized data.** The unique nature and use cases for individual registries requires a high degree of coordination and understanding between all stakeholders. **An abrupt, forced transition to standards-based bidirectional exchange would severely disrupt important clinical data collection and threaten current registry viability.** The ACC and the NCDR® stand ready to help ONC, CMS and other stakeholders improve bi-directional exchange and improve health IT interoperability.

Patient Matching Request for Information

CMS, ONC, the Congress, and numerous studies have indicated accurate patient matching solutions are essential to the goal of achieving true interoperability and the development of automated and

seamless data transmissions. Inaccurate, incorrect, or inconsistent patient demographic or identifying information can enter a patient's record at any point during an encounter and it is crucial that patients and providers have confidence in the accuracy and integrity of the health record. Patient matching errors can be costly and dangerous, as a 2012 College of Healthcare Information Management Executives (CHIME) report showed, 1 in 5 hospital chief information officers indicated that patients had been harmed in the previous year due to patient record mismatches[6].

The ONC and CMS proposed rules will help to improve patient matching through defined standardized data elements, the creation of a standard version advancement process, requiring real world testing for certified health IT and the mandated use of API technology. **The College thanks CMS and ONC for taking these steps and encourages the continued emphasis of the importance of patient matching solutions as technological advances continue.**

So long as HHS is prohibited from using funds to promulgate or adopt any final standard providing for the assignment of a unique health identifier for an individual, **CMS and ONC should continue to work to adopt methods that provide patient matching solutions through technological innovation and collaboration with external stakeholders.** As a recent report from the Government Accountability Office (GAO) indicates[7], stakeholders across the country are developing patient matching applications that utilize algorithms to patch records across care settings and organizations. While these applications show promise, it is important that ONC and CMS work with standards development organizations (SDOs) and health IT vendors to ensure these programs operate with a very high degree of certainty before they are deployed into the care setting. ONC and CMS should work with SDOs and health IT vendors to set an ambitious, yet attainable match rate for all patient matching algorithms to ensure patients are not exposed to undue harm caused in part by matching errors.

In addition to this needed high degree of certainty, it is vital that SDOs and health IT vendors develop patient matching applications in an open and accessible process. Much like the development of health IT standards put forth in these proposed rules, transparency will provide all stakeholders both the ability to provide input in the developmental stages to ensure unique use-cases are properly considered as well as the needed confidence in both the process and the product created. A transparent and open process led by SDOs and health IT vendors will also ensure technological advances are incorporated into patient matching solutions. For example, as biometric authenticators continue to advance at a rapid pace and are widely accepted across industries, SDOs and vendors should account for the proliferation of this technology.

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[6] The Pew Charitable Trusts, *Enhanced Patient Matching is Critical to Achieving Full Promise of Digital Health Records*, October 2018. https://www.pewtrusts.org/-/media/assets/2018/09/healthit_enhancedpatientmatching_report_final.pdf

[7] GAO, *Heath Information Technology: Approaches and Challenges to Electronically Matching Patients' Records Across Providers*, January 2019. https://www.gao.gov/assets/700/696426.pdf

Patient matching solutions will only serve their intended purpose and successfully protect patients from unintended harm if they are trusted by the vendors, health systems and providers that install and utilize them. As ONC and CMS continue to work on patient matching solutions, the ACC encourages a transparent process which incorporates stakeholder feedback throughout development and deployment.

Conclusion

The ACC is committed to working with CMS and ONC on realizing the goal of true interoperability, preventing information blocking and ensuring patients and providers have access to their data through easily accessible, standardized methods. The College thanks ONC for beginning the process of developing a comprehensive, truly interoperable, 21st Century health system where providers and patients have access to information that helps facilitate coordinated care and improves outcomes.

The proposed rules by CMS and ONC represent a seismic shift in the Health IT landscape and patients and providers will need time to adjust. Implementing new Health IT systems with additional capabilities, including expanded information sharing, will require substantial resources in both time and money expended by providers, practices, and health systems. Providers will be subject to new liabilities and penalties under the new EHI and information blocking regulations. Patients will have access to their health information through third-party entities that may not fall under HIPAA protections. To protect patients and providers alike, it is essential CMS and ONC work jointly to slow down implementation, focus on education, and ensure the proper execution of these proposed rules.

If you have any questions or would like additional information regarding any recommendations in this letter, please contact Joseph Cody, Associate Director, Research and Innovation Policy, at (202) 375-6251 or jcody@acc.org.

Sincerely,

Richard J. Kovacs, MD, FACC
President