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*The mission of the American College of Cardiology and the American College of Cardiology Foundation is to transform cardiovascular care and improve heart health.*

March 18, 2020

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  
Mary E. Switzer Building  
330 C Street, S.W.  
Washington, D.C. 20201

Comments Submitted Electronically

**RE: 2020-2025 Federal Health IT Strategic Plan**

Dear Dr. Rucker,

The American College of Cardiology (ACC) appreciates the opportunity to provide input on the draft 2020-2025 Federal Health IT Strategic Plan.

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 54,000 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 next five years will continue to see rapid, technologically driven change in health care. Public and private stakeholders are working together to build the foundation for a truly interoperable health care system through a standards-based approach. The introduction of artificial intelligence (AI) and machine-learning (ML) enhanced systems, powered by access to massive datasets could fundamentally alter the practice of medicine. The development of an application-based, electronic health record (EHR)

agnostic health information ecosystem could empower patients, enhanced shared-decision making, and provide insights that drive down costs and improve outcomes.

The 21<sup>st</sup> Century Cures Act directed the Centers for Medicare & Medicaid services (CMS) and ONC to make meaningful progress in advancing interoperability, improving EHR usability, and providing patients with access to their health information when they want it in an accessible and usable format. The proposed *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program* rule was a step in the right direction. Codifying the use of specific standards for certified electronic health record technology (CEHRT) systems 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.

As ONC works to not only implement provisions in the *21st Century Cures Act* rule, but develops additional approaches to improving interoperability, enhancing the quality of patient care, and ensuring patient information is protected, it is vital that ONC continue to work with stakeholders such as the ACC to mitigate potential burdens and unintended consequences. The ACC stands ready to work with ONC and other regulatory agencies to help ensure these policies are implemented in a stepwise, responsible, yet fundamentally transformative manner.

## **Goals, Objectives and Strategies**

### **1. Promote Health and Wellness**

The ACC agrees with ONC that “health IT should be used to empower individuals, address patients’ full range of health needs, promote healthy behaviors, and facilitate the improvement of health for individuals, families, and communities.” The fundamental goal of any strategic plan should remain focused on promoting health and wellness for patients and the College is pleased to see ONC state this as the number one goal for guiding the development and implementation of policies throughout the agency.

#### **Objective 1a- Improve individual access to health information**

Access to information is fundamental to efforts to promote health and wellness. However, the format and manner of which this information is available is just as important as access to the information itself. Many systems today 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 clinical staff to compile the necessary information through manual transcription or other methods such as third-party software. The proposed ONC and CMS Interoperability and Information Blocking rules both advance progress through the promotion of application programming interfaces (APIs) and the implementation of a standards development process. 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.

#### Objective 1b- Advance Healthy and Safe Practices Through Health IT

ONC's strategies for advancing healthy and safe practices through health IT include leveraging data at the individual and population-levels to advance the use of evidence-based digital therapeutics to help treat patients. The development of a new ecosystem of wearable technologies, patient-facing applications, and other digital tools promises to bring additional insights into the totality of care for a patient. The ACC encourages ONC to work with other federal agencies to ensure these digital therapeutic tools promote wellness and are successfully integrated into the clinician's workflow. Without consideration for the process of integrating this health information into workflow, ONC runs the risk of adding to IT noise rather than contributing to improving care.

## **2. Enhance the Delivery and Experience of Care**

ONC accurately realizes that improved interoperability and advancements in health IT will improve the quality and experience of care for patients. These improvements will also have a direct impact on how health care clinicians practice medicine, improving clinical workflow and patient care. The objectives under this goal specifically seek to address the root causes of increased administrative burdens, improve interoperability, and successfully utilize health IT to drive quality improvement. The ACC thanks ONC for recognizing the direct impact policies can have on working to fulfil the quadruple aim: improving the health of populations, enhancing the patient experience of care, reducing the per capita cost of health care, and improving the work life of clinicians.

#### Objective 2a- Ensure Safe and High-Quality Care through the use of Health IT

The development of personalized medicine and individualized treatment plans using technology such as AI/ML systems, remote monitoring, clinical-decision support (CDS), and other innovations promises to revolutionize care and lead to better outcomes. However, for these promises to be realized, it is essential that ONC and the Department of Health and Human Services (HHS) work with other federal agencies to promote policies where robust clinical evaluation is at the core of the development and implementation processes. Reliability, repeatability, and scientific integrity in both the pre-and post-market settings are essential to the successful deployment of innovative new technologies. It is important for agencies to promote a patient and clinician-focused approach to health IT implementation.

There are several specific policies ONC can work with other federal agencies to help implement which will promote this safe and high-quality health IT ecosystem. First, ONC can work to 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.

Second, ONC can work with CMS to develop methods to improve patient-matching. Actions such as the Patient Matching Algorithm Challenge have led to technological developments that promise improve matching rates. However, if a prohibition on the use of federal funds to promulgate or adopt a national unique patient identifier (UPI) is in place, federal agencies are limited in how much they can do. We encourage ONC to work with CMS to share its views with Congress on the benefits of lifting the ban. We believe that removing the prohibition will provide HHS the ability to evaluate a range of patient identification solutions and enable it to work with the private sector to explore potential challenges and identify a solution that protects patient privacy and is cost-effective, scalable, and secure.

Finally, we encourage ONC to continue to work with stakeholders to develop an environment conducive to the promotion of interoperability and data-sharing. ONC should work to ensure that policies work to promote interoperability while avoiding punitive policies that punish well intentioned actors. Clinicians, vendors, and organizations will need time to successfully prepare for and adopt new technologies and implementation timelines should account for the time it takes to prepare for and train on new systems and technologies.

#### Objective 2c- Reduce Regulatory and Administrative Burden on Providers

The current health IT landscape, driven by policies that did not promote true interoperability, directly promoted the development of the EHR as a billing tool. A lack of consideration for workflow and usability of EHR systems has led to an increased burden on clinicians that has become one of the main drivers of burnout. As ONC notes, "the paperwork and box-checking associated with these third-party-driven activities is a two-fold threat to delivering high quality care. It leaves healthcare clinicians feeling burned out, and it reduces the amount of time they have to interact with patients."

It is imperative that ONC work to draft and implement policies that seek to reduce the regulatory and administrative burdens placed on clinicians by health IT systems. CMS and ONC have taken several initial steps to minimize burdens by reducing reporting requirements for the Quality Payment Program (QPP), changing documentation requirements for evaluation and management (E/M) services, and altering supervision requirements for different services. As ONC works to implement provisions of the 21st Century Cures Act and develops additional regulations dealing

with the certification, implementation, and use of health IT in health care, ONC should continue to utilize a patient- and clinician-focused approach to policy development.

### **3. Build a Secure, Data-Driven Ecosystem to Accelerate Research and Innovation**

The development of a regulatory paradigm that fosters the creation of a secure, standards-based, data-driven health IT ecosystem is key to the advancement of a learning health care system fueled by interoperability and innovation. While the ACC is supportive of the direction ONC and CMS are moving toward realizing true interoperability and access to large data-sets, it is vital that ONC continue to work with stakeholders such as the ACC to mitigate the burdens and unintended consequences regulations place on clinicians, patients, and quality improvement entities. The ACC is currently exploring public/ private collaborations to help develop and implement data standards and common language to better enable electronic health information transmission. ONC should continue to not only encourage these collaborations, but support them. Additionally, it is important that ONC work with other regulatory agencies to ensure applications of health IT for clinical, administrative, and research purposes are safe, clinically validated, secure, and easy to use.

#### Objective 3a: Advance individual- and population-level transfer of health data

The importance of the development of policies that advance individual- and population-level transfers of health data cannot be overstated. The creation of a health ecosystem that develops tools to allow patients to access their data when they want it, how they want it has the potential to revolutionize care. The ability for clinicians to access individual and population-level health data will help improve outcomes and provide more individualized care to patients in settings and methods they are more comfortable with. As ONC rightly states, the creation, testing, and implementation of secure, standardized-based APIs are key to the development of a health care system that achieves these aims. However, it is important that data accessibility and portability do not compromise security and privacy.

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 clinicians. However, the ACC is concerned the proliferation of third-party vendors with access to patient health information that fall outside of current Health Insurance Portability and Accountability Act (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 efforts 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 clinicians, 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.

ONC must also work with other regulatory agencies to ensure there is alignment between different regulations governing the electronic transfer of information such as the information blocking and HIPAA rules. 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 noted the proposed information blocking rules may require that actors provide access, exchange, or use of electronic health information (EHI) in situations that HIPAA does not. This greatly expands not only the demands placed on clinicians but will lead to confusion about what requirements they must legally follow.

Objective 3b: Support research and analysis using health IT and data at the individual and population levels

As technology rapidly integrates into health care and the practice of medicine fuses traditional and digital solutions, it is important that the federal government, in conjunction with patients, clinicians, and industry, work together to foster an ecosystem that provides sufficient regulatory clarity to promote the responsible generation of digital health solutions while not stifling innovation. The ACC believes it is essential that robust clinical evaluation is at the core of the development and implementation processes for the use of AI-enabled health solutions, other new technologies, and analytical approaches to improve outcomes, drive down costs, and improve professional satisfaction for clinicians. Successful technological innovations will require early engagement from clinicians and organizations like the ACC that stand at the nexus of this innovation. The College is engaging with both regulatory agencies and industry to ensure the clinician's voice is incorporated into the development of these AI systems. The ACC encourages ONC to work with all federal regulatory agencies to develop consistent policies that provide sufficient regulatory guidance while remaining flexible enough to allow for necessary innovation, and promote a patient and clinician focused approach to new technologies and analytic approaches in health care.

#### **4. Connect Health Care and Health Data Through an Interoperable Health IT Infrastructure**



Patients, caregivers, and clinicians have the right to accurate, interoperable health information. Access to health information is essential to the delivery of accurate, timely care and the seamless exchange and integration of health information between platforms using shared data standards and common terminologies is necessary for access to important health information. While access to this health information is important, it is equally as important that patients and clinicians trust the accuracy of the information provided and have faith that the stewards of this data are acting in the best interest of the patient. Without trust in the system, all the technological innovations advancing interoperability will be for not. ONC must work to ensure that patients and clinicians can trust that health data stewards sufficiently protect all health information.

Objective 4a: Advance the development and use of health IT capabilities

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 pointed out in the proposed Interoperability and Information Blocking rule and the Congress acknowledged under Cures, intentional information blocking has occurred in the past and should be prohibited.

The Strategic Plan calls for rigorous enforcement of information blocking and privacy and security laws when applicable, and by encouraging consumer reviews and reports on health IT products. The ACC agrees that malicious information blocking should be strictly enforced. However, ONC should work jointly with the Office of the Inspector General (OIG) to ensure that enforcement focuses on education rather than punitive action against non-malicious information blockers. No clinicians 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. Punitive measures should only be considered after a clinician has been flagged, educated, and warned about the actions that violated information blocking provisions.

Objective 4b: Establish transparent expectations for data sharing

As previously noted, educational efforts are essential to the successful implementation of policies that encourage information sharing. ONC, OIG, and the Office of Civil Rights (OCR) must engage clinicians in a substantial campaign to educate on HIPAA, information blocking, and other information sharing requirements. ONC has previously stated that clinicians have used HIPAA as an excuse not to share patient information. However, this does not always stem from malicious intent. Instead, clinicians 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, ONC, OIG, and OCR must provide clear, concise, easy to understand and timely education materials to patients, clinicians and administrative staff to ensure every individual understands 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 clinicians and cultivate an environment that encourages information sharing.

In addition to educational efforts, the ACC encourages CMS and ONC to work with the Congress to create a modern regulatory framework that governs health data privacy and interoperability. The current system of data creation, aggregation, storage, use, and sharing of health information was never contemplated by the authors of federal laws governing privacy and interoperability. The ACC joins a multitude of other organizations in calling for CMS, ONC, and the Congress to modernize the health data framework to enhance the use and protection of data to improve health through comprehensive health information privacy reform.

#### Objective 4c: Enhance technology and communications infrastructure

As ONC acknowledges, smaller practices and rural hospital clinicians are often unable to adopt the same advanced health IT capabilities as counterparts in other parts of the country due to constrained resources and infrastructure deficiencies. Technological advances such as remote monitoring, telehealth, biometric sensors, and AI-enabled CDS tools can help provide access to care for individuals in rural or impoverished areas, where care is harder to deliver. However, it is important for ONC to work with other agencies across the federal government to ensure the development of the necessary infrastructure to deploy these new and innovative technologies. Access to broadband and wireless technologies, 5G deployment, cheap cloud-based services, and other necessary infrastructure developments are key to enhancing access to these new tools and methods of care. The ACC encourages ONC to work to align policies with other agencies that promote the necessary investments, construction, and development of important technology and communications infrastructure.

#### Objective 4d: Promote secure health information that protects patient privacy

The privacy of a patient's electronic health information (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. Coupled with the proposed approach for expanded access to health information by third parties with the consent of patients, the risks for potential health information exposure or non-consented uses increases. To ensure that patients' health information is protected while maintaining the right for patients to freely access and use their health information, the ACC once again calls on CMS, ONC, and the Congress to modernize the health data framework to enhance the use and protection of data to improve health through comprehensive health information privacy reform.



In addition to needed comprehensive health information privacy reform, ONC should continue to emphasize the need for the incorporation of consent management and cybersecurity considerations into the development of health IT systems used by both clinicians and patients. By developing these systems and evaluating them with the capabilities incorporated early in the process, health IT vendors and developers will create safer, more trustworthy systems that require less post-deployment add-on patches and capabilities. Additionally, ONC should work with vendors to ensure educational resources and technical assistance is available to ensure hospitals, practices, and clinicians correctly install, are trained, and utilize health IT systems. By providing these resources up front, ONC can work to ensure that systems are safe and protect patient privacy.

### **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 clinicians 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 clinicians and patients have access to information that helps facilitate coordinated care and improves outcomes.

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](mailto:jcody@acc.org).

**Sincerely,**



Richard J. Kovacs, MD, FACC  
President