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January 28, 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

Comments Submitted Electronically

Re: Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs

Dear Dr. Rucker,

The American College of Cardiology (ACC) appreciates the opportunity to provide input on the Office of the National Coordinator for Health Information Technology (ONC) Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health Information Technology (IT) and Electronic Health Records (EHRs).

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.

ACC Policy Principles on Reducing Administrative Burden

Excessive administrative tasks that are not central to direct patient care can lead to delayed or missed patient care, clinician dissatisfaction and workplace burnout. The ACC understands that administrative burdens facing clinicians can be both externally driven by other stakeholders and internally initiated by the medical practice or healthcare system.

Recognizing the compounding effect increased administrative burdens have on clinicians and the care delivered to patients, the College approved policy principles on reducing administrative burdens in 2018. ACC is pleased to share

below the principles from that document highlighting priorities concerning the reduction of the administrative burdens EHRs place on clinicians. If ONC has any questions regarding these policy principles, ACC would appreciate the opportunity to discuss this work further with ONC.

Reducing Administrative Burden Principles: Electronic Health Records

To increase effective, high-quality patient care and reduce clinician administrative burden, the ACC advocates for stakeholders to:

- Optimize EHR workflow designs to increase operational efficiency and productivity while continuing to improve quality care.
- Advocate for and adopt consensus methods and standards that allow effortless data transmission, extraction, interpretation and manipulation to ensure interoperability on all medical devices and platforms.

Strategy on Reducing EHR Regulatory and Administrative Burdens

Under the strategy to reduce the regulatory and administrative burdens caused by EHRs, ONC identified three primary goals: reducing the effort and time required to record information in EHRs for health care providers during care delivery; reducing the effort and time required to meet regulatory reporting requirements for clinicians, hospitals, and health care organizations; and improving the functionality and intuitiveness (ease of use) of EHRs. An array of factors contributes to EHR burdens including poor usability, a lack of true interoperability, and increased reporting requirements and the Strategy includes recommendations to address these factors.

The Department of Health and Human Services (HHS), through work by ONC and the Centers for Medicare & Medicaid Services (CMS), has already taken steps to address aspects of these goals through actions such as the Promoting Interoperability reporting program, Patients over Paperwork, MyHealthEData Initiative, Blue Button 2.0, and issuing a request for information (RFIs) on EHR reporting criteria. **The College thanks HHS, ONC, and CMS for their efforts to reduce the burdens EHRs place on clinicians through these initiatives and encourages continued action to address health IT related burdens.**

The ACC has participated in workgroups and meetings as well as provided written comments and recommendations to HHS, CMS, and ONC on ways to reduce the increased regulatory and administrative burdens associated with health IT systems. The College is pleased to continue providing input through comments below on the findings and recommendations from the established workgroups on Clinical Documentation, Health IT Usability and the User Experience, and EHR Reporting.

Clinical Documentation

A lack of automation and standardization in clinical and administrative processes, coupled with regulatory requirements, has exacerbated documentation burdens, leading to an increase in non-clinical work and increased clinician dissatisfaction. Patients have seen the impact of documentation requirements and poor EHR usability through decreased time directly interacting with clinicians during visits. It is important the HHS, CMS, and ONC work to reverse these trends, increase automation and standardization in administrative processes and continue to reduce clinical documentation requirements.

Documentation Requirements

The findings and recommendations from the Clinical Documentation workgroup focus on methods of reducing the regulatory burden around documentation requirements, partnering with stakeholders to encourage best practice adoption, and standardizing data and processes around prior authorization and ordering services processes. Through the CY 2019 Medicare Physician Fee Schedule comment process and meetings with CMS officials, the College has provided CMS with input on proposals to reduce documentation requirement related burdens such as the modification of evaluation and management (E/M) codes and reduced medical record review requirements. **The College will continue to work with partners such as the American Medical Association (AMA), other stakeholders, and CMS to create a documentation process that reduces associated burdens without also making dramatic, comprehensive and disruptive payment policy changes.**

Standardize Data and Processes

Leveraging health IT to standardize data and processes around ordering services and related prior authorization processes is an important mechanism for reducing clinical documentation requirements. The College encourages HHS, CMS, and ONC to use the EHR certification process as a method for developing these standardized processes. The College is encouraged by steps to integrate newly proposed tools such as real-time benefit tools (RTBTs) in to health IT systems and believes further development can help reduce administrative burdens. However, it is important that these tools augment and enhance the usability of the systems, not hinder it. Automated and standardized administrative processes should fit into the clinician's workflow and vendors should design systems that work accordingly.

A specific area on which CMS and ONC should work to standardize data and process is through retrieval capabilities from medical devices. Providing clinicians and patients with the ability to retrieve information from medical devices is a high priority for the ACC, and the College believes that ONC should use the workgroups recommendations to ensure the EHR certification process requires retrieval capabilities, along with consensus standards to assist with this process. For example, providing the ability to access data from implantable cardioverter defibrillator (ICD) systems allows for access to information essential for proper patient management. **The extraction and importation of vital health information from these and other medical devices into the EHR system in a usable, standardized format is a prime example of how a fully interoperable system will benefit patients and clinicians and reduce associated burdens.**

The 21st Century Cures Act included provisions supporting the use of real-world evidence to bolster regulatory decision-making processes. Real-world evidence can include data collected through a clinical data registry or patient-generated data. Clinical data registries such as the ACC's National Cardiovascular Registry® (NCDR®) provide clinicians and regulatory agencies with standardized terminology and access to data that can supplement traditional sources. It is important to harness the power of real-world data collection through the implementation of policies that promote seamless data transfer processes between clinical data registries such as NCDR®, patient-generated data sources, and EHR systems. The College encourages CMS and ONC to ensure real-world evidence generation processes are included in any future policy recommendations regarding the generation and exchange of standardized data.

Health IT Usability and the User Experience

Clinicians report high click counts, note bloat due to documentation requirements, poor EHR usability, and a lack of interoperability as significant contributing factors to the health IT associated burden increases. Clinicians are now spending less time directly interacting with patients during visits and more time performing administrative functions because of the need to input data into EHRs. The Usability and User Experience workgroup provided findings and recommendations that seek to address how improvements in design and use of health IT systems can reduce EHR usability-related burdens. The ACC strongly supports efforts by ONC to work with health IT vendors to improve the usability and interoperability of health IT systems and encourages the incorporation of recommendations below.

Usability

Improving usability through the development, scoring, and reporting of user-centered designs and improved interoperability for all health IT systems, including EHRs, can significantly improve satisfaction among both patients and clinicians. Under the Strategy, ONC recommends improving usability through better alignment of EHRs with clinical workflow, improving decisions making and documentation tools, promoting user interface optimization, and harmonizing clinical content contained in health IT. The ACC is encouraged by ONC's identification of solutions that can drastically increase health IT usability. In comments previously submitted to ONC in response to an RFI, the ACC recommended ONC take the opportunity afforded by provisions in the 21st Century Cures Act to improve EHR usability, interoperability, design, and security. By doing so, ONC would enable EHR systems to become trusted tools that assist with patient care and reverse clinician dissatisfaction.

The ACC recommended ONC account for usability and user-centered design criteria in the certification process, including the capture of user-reported criteria on usability, user-centered design, and EHR system interoperability. 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. Specific human-computer interface evaluations methods include but are not limited to heuristic techniques, keystroke level models that sum up the time taken to perform tasks in a system, and comparative analysis between similarly commercially available systems. **The ACC supports the**

implementation of specific usability and user-centered design criteria into the EHR certification process as one specific method for increasing health IT usability.

Interoperability

The Strategy recommends the continued promotion of nationwide policies to further the exchange of electronic health information to improve interoperability and reduce health IT burdens. The ACC believes HHS, CMS, and ONC all play an important role and need to continue to engage stakeholders in the promotion of strategies, guidance, and policies that encourage true interoperability.

A lack of true interoperability is one of the main drivers for clinician discontent with 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 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.

Instead, interoperability must include the seamless transmission and receipt of data using consensus methods and standards that allow for effortless extraction, interpretation, and manipulation of data. Common data standards must exist to address challenges clinicians continually face when exchanging the simplest elements of data between EHRs. As ONC indicated in a recent report regarding the adoption of the Fast Healthcare Interoperability Resources (FHIR) standard, increased adoption of consensus standards by multiple vendors across the care spectrum can help to improve interoperability.

HHS, CMS, and ONC can promote nationwide strategies to further the exchange of electronic health information to improve interoperability and reduce health IT burdens through the publication of useful interoperability metrics and reports, successful creation and implementation of the Trusted Exchange Framework and Common Agreement (TEFCA), continued promotion of application programming interface (API) usage, and the creation of specific data-blocking definitions and enforcement actions. As HHS, CMS, and ONC further implement interoperability strategies, the ACC will continue to serve as an actively engaged stakeholder by providing input to ensure these policies further the goal of true interoperability.

EHR Reporting

The Strategy acknowledges specific requirements in federal programs have contributed to increased health IT administrative burdens. In recent years, ONC and CMS have recognized these increased burdens and modified reporting requirements, including efforts to simplify and streamline the Meaningful Use and Advancing Care Information (ACI) programs through the Promoting Interoperability (PI) program. By acknowledging the shortcomings of previous efforts to encourage EHR adoption through prescriptive rulemaking, CMS is making significant strides towards reducing EHR reporting burden.

While heartened by the steps taken, the ACC once again encourages CMS to use PI and other programs to promote the appropriate, purposeful and accurate use of health IT solutions, rather than mandate completion of tasks. There are objectives and measures that aim to appropriately promote interoperability. However, CMS should also use PI objectives and measures to focus on the exchange of health information, increased usability of EHRs, and the appropriate realignment of clinical workflows to leverage health IT most effectively to achieve the intention of the PI program and improve patient care. The College believes now is the time to take advantage of technological advances and leverage reporting requirements to reduce EHR reporting burdens.

Conclusion:

ACC is committed to working with HHS, CMS, and ONC to ensure there is a meaningful reduction of regulatory and administrative burdens relating to the use of health IT system. The College looks forward to ongoing discussion and collaboration with HHS, CMS, and ONC on burden reduction initiatives.

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,

C. Michael Valentine, MD, FACC
President