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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.

May 31, 2019

The Honorable Seema Verma
Administrator - Centers for Medicare and Medicaid Services
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-9115-P,
P.O. Box 8016,
Baltimore, MD 21244-8016

Re: Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-facilitated Exchanges and Health Care Providers

Comments Submitted Electronically

Dear Administrator Verma,

The American College of Cardiology (ACC) appreciates the opportunity to provide input on the Centers for Medicare & Medicaid Services (CMS) proposed rule on Interoperability and Patient Access for Medicare Advantage (MA) Organization and Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans (QHPs) in the Federally-facilitated Exchanges (FFE) and Health Care Providers.

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 CMS and the Office of the National Coordinator for Health Information Technology (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 systems and poor usability. Provisions in the Cures Act allow CMS and ONC to make meaningful progress in advancing interoperability and improving EHR usability. By taking these steps, CMS and ONC can provide patients with access to their health information when they want it in an accessible and usable format, improve clinician workflows, allow providers to access previously siloed information to help improve the quality of care and care coordination, reduce the cost of unnecessary repeat testing for the entire healthcare system, and improve patient satisfaction.

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 and payers, ONC and CMS ensure 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 CMS considers these and future changes to address interoperability and patient access, it is important that CMS consider the related administrative and financial burdens development of such a system places on providers and other care givers. While the ACC encourages continued development of policies and technical standards that allow health information accessibility and transparency, the real costs and time needed to properly develop, install, and implement these systems should not be ignored. The ACC stands ready to continue work with CMS and ONC to foster the creation of a health ecosystem that encourages true interoperability and allows patients and providers to have access to vital health information.

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.

Technical Standards Related to Interoperability

CMS proposes requiring MA organizations, Medicaid state agencies, state CHIP agencies, Medicaid managed care plans, CHIP managed care entities, and QHP issuers in FFEs make a variety of information accessible to patients via “openly published” application programming interfaces (APIs). APIs are the foundation of the modern internet and the ACC supports CMS’s proposal to require information be accessible via open APIs. The development of a rich API-based ecosystem will allow patients and providers to gain access to important health information whenever they want it 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, CMS should work with ONC, Health Level 7 International (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 increasing 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 chances of cyberattacks and protect 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 protections patients deserve. **It is vital that CMS work with ONC, the Federal Trade Commission (FTC) and other agencies to develop a third-party system that allows only verified and trusted vendors to access patient data and ensures patient health information is sufficiently protected.**

One way CMS can ensure patients trust use of their health information is through clear, easy to understand, plain text terms and conditions coupled with stringent consent requirements. **CMS should follow 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 conditions. CMS needs to work with**

ONC to stack strong consumer protections into the API verification process. Patients trust that providers, vendors and third-parties will be good stewards of their health information and it is important CMS cultivate a regulatory structure that rewards this faith with equal protections.

Request for Information on Information Sharing Between Payers and Providers through APIs

As CMS considers the profound implications on patient privacy and data accessibility with the implementation of widely-deployed open APIs, **it is essential that CMS work with the Office of Civil Right (OCR) and ONC to ensure harmonization among privacy policies.** A complex regulatory framework without harmonization will not only inhibit information sharing and create an environment where breaches and violations are more likely.

CMS should work with payers to develop and deploy consent management software to allow providers to work with patients to manage health information access. Consent management software is in its technological infancy and incredibly expensive or burdensome to operate, but payers have the resources and responsibility to ensure patients' rights are protected and can help facilitate the expansion of this technology at the point of care. It is important that CMS ensure payers and vendors minimize increases in pricing and take the leading role in the responsibility to develop, pay for, and implement the proposed interoperability requirements. CMS must work to ensure patients and providers are not stuck with the bill for the implementation of required technology.

In line with the development and deploying of consent management software, it is important that CMS develop appropriate regulatory safeguards to ensure that information collected by payers is limited to information necessary for the administration of the patient's health plan only. Unfettered access to the health record through an API would expose patient's health information to unauthorized export, violating a patient's trust in their provider. Additionally, any information shared between a payer and provider should be limited to the payer's beneficiaries and defined elements the patient has explicitly consented to being shared.

Finally, CMS must remain cognizant of the administrative burdens placed on providers through 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 shared with the correct, authorized entity, which is 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 providers.

Public Reporting and Prevention of Information Blocking on Physician Compare

CMS proposes public reporting and posting an indicator on Physician Compare for eligible clinicians (ECs) and groups showing how they attested to the information blocking statements required under the Promoting Interoperability (PI) performance category of the Quality Payment Program (QPP). ECs and groups that do not attest to the information blocking statements would not have an indicator on Physician Compare. However, if an EC or group is granted an exclusion from the PI performance category and does not need to complete an attestation, Physician Compare would not list an indicator. This may unfairly insinuate to patients that ECs or groups are not actively working to prevent information blocking from occurring. **When an EC or group is granted an exclusion, it is important for CMS to clearly indicate an exception was granted and the absence of an indicator does not mean the EC or group provides lower quality care.**

Provider Digital Contact Information

The 21st Century Cures Act required the Department of Health and Human Services (HHS) to create a digital contact information index to facilitate a comprehensive and open exchange of patient health information. As CMS notes in the proposed rule, the creation and availability of an accurate, easily accessible digital index with secure contact information can help improve interoperability by facilitating efficient exchange of patient records electronically, help to eliminate existing burdens of working with scanned paper documents or locating provider contact information, and ultimately enhance care coordination.

CMS notes it has updated the National Plan & Provider Enumeration System (NPPES) to capture digital contact information necessary for electronic exchange. CMS proposes publicly reporting the name and national provider identifier (NPI) of providers who do not have digital contact information included in the NPPES system. **While the College appreciates the need for providers to include their digital contact information, it is important for CMS to make every effort to contact these providers to request the needed information.** Additionally, CMS should note providers that have received exclusions from the PI program and may not have digital contact information readily available and provide additional information to facilitate information exchange in these situations.

A digital contact information index is intended to reduce the administrative burdens providers face, not increase them. **CMS should not impose administratively burdensome reporting requirements that only increase required data entry by providers and their staff and instead work to streamline digital gathering by incorporating digital contact information into the Medicare enrollment or revalidation process.** By integrating this information capture into an accepted process, CMS will reduce the burden placed on providers and increase contact information entry adherence.

Request for Stakeholder Input on Interoperability in Innovation Models

Alternative payment models (APMs) tested through the Center for Medicare and Medicaid Innovation (CMMI) rely heavily on quality and cost data to provide high value and patient-centered care. The ACC strongly supports CMS efforts and principles to promote interoperability in CMMI models. The College encourages CMS to promulgate APMs that incentivize the interoperability of patient records and data across settings of care and clinicians. Trusted data exchange between sites of care is integral to the successful participation of clinicians in APMs that incorporate total cost of care, such as Bundled Payments for Care Improvement Advanced. The College also encourages CMS to incentivize data exchange between entities operating different APMs in which a patient may be attributed to both, such as an accountable care organization (ACO) and bundled payment model. **Any effort to promote interoperability should also seek to reduce administrative burden, particularly in Certified Electronic Health Record Technology (CEHRT) usage and quality reporting.**

Interoperability should facilitate collaboration between clinicians, especially between cardiology and primary care. The lessons learned from the Comprehensive Primary Care Plus model regarding health IT implementation and usage could be applied to future APMs that encourage primary care and specialty collaboration. **To this end, ACC recommends that CMS review the November 2017 JAMA Cardiology article entitled “Payment Reform to Enhance Collaboration of Primary Care and Cardiology: A Review.”**¹ This article resulted from an in-person meeting held in January 2016 where ACC members participated along with representatives from primary care organizations, payers, CMMI, health system leaders, and others. Table 1 of the article outlines five models of care under a collaborative management framework between cardiology and primary care.

Request for Information on Policies to Improve Patient Matching

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 mismatches².

¹ Farmer, SA et al. “Payment Reform to Enhance Collaboration of Primary Care and Cardiology: A Review.” *JAMA Cardiology*. 2018;3(1):77-83.

² 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

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) indicates³, stakeholders across the country are developing patient matching applications that utilize algorithms to match 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.

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.

³ GAO, *Health Information Technology: Approaches and Challenges to Electronically Matching Patients' Records Across Providers*, January 2019.
<https://www.gao.gov/assets/700/696426.pdf>

Conclusion

The ACC is committed to working with CMS and ONC on realizing the goal of true interoperability and ensuring patients and providers have access to their data through easily accessible, standardized methods. The College thanks CMS 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 electronic health information (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