



May 31, 2019

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
PO 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 [CMS-9115-P]

Dear Administrator Verma,

On behalf of the American College of Physicians (ACP), I am pleased to share our comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding improving patient access to data and interoperability. The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 154,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

ACP applauds CMS for working alongside the Office of the National Coordinator for Health Information Technology (ONC) to issue two proposed rules that seek to improve the state of interoperability of electronic health information (EHI). Effective interoperability is crucial to improving the patient experience, reducing burden on physicians, and in turn improving the quality of care. Through the adoption of standards-based Application Programming Interfaces (APIs), amongst other proposals further discussed below, this proposed rule is a step in the right direction in empowering patients to take control and access their personal health information in a manner that better facilitates the coordination of care throughout the health care continuum. However, it is important that these interoperability efforts prioritize the transfer of and access to secure, *meaningful* data in order to avoid confusing patients, who are lacking context, and overburdening physicians with irrelevant information. Given the long-

standing impediments for seamless data exchange within health IT, it is crucial the federal government promote the use of and hold private health care stakeholders responsible for adherence to nationally-endorsed standards. The College appreciates CMS' efforts in bringing key payer, physician, hospital, and patient players to the table to address this important issue and offers more detailed comments and recommendations on key provisions in the following section.

Interoperability Definition and Focus

ACP is troubled by the volume-centric focus in the definition of interoperability currently used by the federal government as defined in the *21st Century Cures Act*. The College believes the current definition inappropriately focuses on high volumes of data transferred or access to every piece of health information ever collected. A health care system in which health IT is judged on its ability to reliably, securely, and electronically transfer and accept an abundance of clinical information at one point in time does not meet what is necessary for practical interoperability. Rather, interoperability efforts should prioritize the breadth, depth, and relevance of information and its usefulness in clinical management of patients throughout the health care system; the secure exchange of practicable, meaningful data at the point of care; the ability to incorporate clinical perspective; and query health IT systems for up-to-date information related to specific and pertinent clinical questions. To maximize the potential of health IT in enhancing high-value patient care and improving the patient-physician relationship, it must be useful and help reduce the administrative burdens of practice rather than add to the burden of care delivery.

Patient and Clinician Access to Data through APIs

ACP is supportive of efforts to place pertinent health information directly in the hands of patients and make it more easily accessible. Doing so can enhance patient-physician collaboration, empower patients to participate in healthcare decision-making and the self-management of their well-being, and result in more safe, efficient, and effective care being provided. Central to any serious effort to increase patient access to data and quality of care must be an emphasis on achieving interoperability – without an uninhibited exchange of information, patients and physicians are not properly equipped to realize the full potential benefits of medical decision-making informed by a more complete picture of one's health data. In this rule, CMS proposes requiring covered payers to adopt and implement an openly published API that allows third-party software applications to access claims data and clinical data that the payer manages, including lab results, within one business day of the claim being processed. Covered payers include Medicare Advantage (MA) organizations, Medicaid state agencies, Children's Health Insurance Program (CHIP) state agencies, qualified health plans (QHPs) in a federally facilitated exchange (FFE), Medicaid managed care plans, and CHIP managed care entities. These same covered payers, aside from QHP issuers in FFEs, would be required to make their clinician networks and drug benefit data available to enrollees and prospective enrollees through an API.

The College agrees that standards-based APIs are an important component in advancing patients' access to their health data and have long advocated for their use to help promote EHI exchange. However, we have some concerns about the API proposals related to patient privacy, security, and cost. The College is concerned that a number of patient privacy issues will arise when allowing third-party app developers to access EHI on behalf of the patient when the patient is unaware of who they are actually allowing to access their data. While CMS is allowing covered entities to cut access to their API if they determine an unacceptable risk is posed to patient data, the Agency is not requiring the API technology to include privacy controls, despite the existing technological capability. There have been multiple reports of app developers selling patient data to third parties, not sharing their privacy policies with patients, or failing to adhere to their published privacy policies. Personal health information is some of the most sensitive and private information for an individual. Patients have a right to access their personal health information; however, without the necessary privacy and security controls, it is critical to acknowledge the very real risk present that may ultimately impact the patient's inclination to share information with their physician.

Additionally, as the ever expanding ecosystem of personal health and wellness apps that track, store, and share patient health information advances, it will become all the more crucial that patients be adequately informed and counselled around what they are agreeing to when signing up for and using an app, including any personal EHI risks. **ACP recommends CMS include a provision that vendors supplying API technology require the API user, or the app developer, to have in place a model privacy notice, possibly resembling that of ONC's Model Privacy Notice.** This will provide a uniform and plain language description to the patient about how the information is sold so that both the app developer and the payer can accurately reflect what is being shared. It is crucial that privacy notices are accessible to patients and using a uniform and plain language description will facilitate patient education and understanding. Further, there needs to be some mechanism to report bad actors or app developers that consistently share data inappropriately.

From the physician perspective, the College believes there is a misconception underlying the conversation on interoperability that indiscriminately sending data is promoting or enhancing interoperability and improving patient care. Accessing every aspect of a patient's information can sometimes actually hinder a clinician's ability to find useful and actionable information in a timely manner. As the payer claims-based data are made available to patients via APIs, the College has concerns with data quality issues within the claims data that may contradict the clinical information maintained by the patient's physician and other health care professionals. Moreover, the claims data itself may be difficult for patients to interpret and understand. As proposed, it is not determined who patients should contact to have their questions answered or incorrect claims-based data remedied and updated. The College is concerned that the responsibility to examine and correct such data—potentially out of context, which is problematic in and of itself—could fall to a patient's primary care physician, adding to existing administrative burden that is increasingly interfering with the patient-physician relationship. **In making such data available directly to patients, CMS must make it clear that it is the duty of payers to correct and update any inaccurate information and should require a mechanism that allows for patients' concerns regarding inaccurate information to be addressed.**

To better serve the interests of patients and promote high-value patient-centered care, interoperability policy must be developed and implemented iteratively, so that its effects on patient care are adequately demonstrated and the risks of data overload and data without context are mitigated. Simply opening the floodgates to additional data does not necessarily correlate with better care; physicians operating while inundated with data that lacks appropriate context could result in diagnostic or treatment errors. ACP contends that CMS should prioritize facilitating access to meaningful patient health information by targeting the high-yield clinical data that have shown to be the most useful in current health information exchange practices and that the Agency should take into consideration the potential negative externalities excessive information could have on both patients and physicians.

While useful in facilitating the access of information by patients, ACP also emphasizes that APIs are not the sole solution to solving interoperability inadequacies and there is room for improvement in this space. As the College pointed out in its comments to ONC, the lack of a standard API means that payers and clinicians interacting with various EHR systems are engaging with various APIs and hence can lead to numerous versions of clinical data output in various forms, lending to the previous information overload discussion.

Health Information Exchange Across Payers

The College strongly supports the intent of CMS' proposal in facilitating the continuity of patient health information even when they switch payers. In the proposed rule, CMS seeks to require that covered payers must forward patient information, such as diagnoses, procedures, tests, and clinicians seen, to new plans or other entities for a requesting beneficiary up to 5 years after they have disenrolled in the plan. This exchanged data must include, at a minimum, US Core Data for Interoperability (USCDI) data. Included under covered payers are MA plans, Medicaid managed care plans, CHIP managed care plans, and QHPs in FFEs. ACP believes that patient access to progress notes, as well as the rest of their medical records, may offer a way to improve patient engagement, resource utilization, quality measurement, continuity of care, and care outcomes. Creating well-informed patients by removing barriers to accessing their personal health information can arm patients with the tools they need to play an active role in managing their health and contribute towards improved outcomes. ACP supports CMS' efforts to utilize the US Core Data for Interoperability (USCDI) data elements in the exchange of information between payers—rather than ONC's overly broad, unstructured approach to EHI. However, as USCDI is clinical data maintained by clinicians' health IT, a payer may not have a beneficiary's complete USCDI. We are uncertain how CMS expects payers to satisfy these USCDI requirements, and are concerned that some payers may institute contractually mandated access to clinicians' EHRs as a condition for clinician participation in a plan. This could negatively affect small, independent, and rural practices that are unable to afford EHRs that payers determine share adequate clinical information with them.

Moreover, we are concerned about payer's increased access to clinical information impacting coverage decision-making. While historically physicians have controlled the patient's clinical data in determining what to submit to obtain reimbursement for care provided, payers would

now have access to information outside of the scope of the specific service being billed. It's possible that payers could impose barriers or restrictions on coverage for medically necessary care that a patient may have received previously. **ACP strongly contends that payer access to patient clinical data should not disadvantage beneficiaries in any way and should never be a determining factor for coverage. CMS should require payers attest that USCDI information exchanged between payers cannot be used to limit access to care in any manner.**

Public Reporting of Information Blocking

Beginning with the 2019 performance period data made available in late 2020, CMS proposes creating an indicator to include on a physician's Physician Compare page that reports whether or not they attested positively to the Promoting Interoperability (PI) program prevention of information blocking statements. A similar indicator would be created to publicly report information blocking engaged in by hospitals on a future yet-to-be-created CMS website. ACP appreciates the steps the Agency has taken towards acknowledging and preventing unwarranted and disruptive information blocking. When vendors engage in information blocking and prevent or make it cumbersome to access a patient's complete medical history, physicians are not able to make a fully informed determination of the best course of action for a specific patient. We are also supportive of the prospect of utilizing a public reporting system to hold those that engage in information blocking accountable, so long as there adequate mechanisms in place for physicians to review before publishing, appeal, and request reconsideration of any publicly reported measure to ensure accurate information is being provided. Patients' health is best served when clinicians, payers, vendors, and others involved in the continuum of care work together to coordinate care by sharing pertinent health information. **CMS should adopt similar public reporting mechanisms for other non-clinician and non-hospital entities that engage in information blocking, including vendors and health information exchanges and networks.**

While we support CMS' proposal—so long as there are proper mechanisms for physicians to review and contest publicly reported information and vendors who are information blockers are subject to public reporting as well—we are concerned about the effectiveness of this approach due to the complexity of ONC's information blocking provisions and exceptions, concerns around ONC's definition and scope of EHI, and the lack of understanding by physicians whether they are engaging in information blocking or not, as expressed in our [previous comments](#) to the Agency on the Promoting Interoperability (PI) information blocking attestation statements. We are further worried that this publicly reported information may potentially be used against physicians by private payers in their contracting matters.

Clinician Digital Contact Information

CMS proposes publicly reporting the national provider identifier (NPI) of those who have not provided digital contact information in the National Plan and Provider Enumeration System (NPPES). Digital contact information could include a direct address, FHIR server URL, or query endpoint associated with a health information exchange.

Ensuring permanent digital health contact information is updated and published is vital for achieving interoperability and improving care coordination by facilitating the efficient exchange of digital records, as opposed to more burdensome paper records. As mentioned previously in our comments, ACP supports the idea of publicly reporting information with the intention of holding bad actors accountable, so long as the measures being used are accurate and there are mechanisms to review, appeal, and request for reconsideration if the information reported is incorrect. **However, we feel that in order to maximize physician participation to the benefit of patients, it may be more effective for CMS to utilize positive incentives rather than public shaming and other punitive measures. It is also important that physician participation is sought and communicated through multiple channels and that engaging with the NPPES system isn't overly burdensome or complex.**

Revisions to Conditions of Participation for Hospitals

The conditions required of hospitals, including critical access and other designation of hospitals, to participate in the Medicare or Medicaid program would be altered by this proposed rule. Participating hospitals that currently possess EHR systems with adequate technical capabilities must send electronic patient event notifications upon a patient's admission, discharge, or transition that includes basic personal information and diagnosis, amongst other information. Hospitals must demonstrate that the notification be sent to licensed and qualified practitioners, other care team members, and post-acute care (PAC) services clinicians and suppliers that: (1) receive the notification for treatment, care coordination, or quality improvement purposes; (2) have an established care relationship with the patient relevant to his or her care; and for (3) whom the hospital has a reasonable certainty of receipt of notifications.

The College appreciates CMS taking the initiative to propose measures that promote the coordination of care between the hospital and physician practice settings. EHRs are crucial to the facilitation of longitudinal care delivery as well as care that involves teams of clinicians and patients that are managed over time. However, as written, the proposal is vaguely worded and has the potential to cause unintended consequences and overwhelm physicians with excessive information and unnecessary burden. In implementing any electronic patient event notification requirement, **CMS must ensure that these notifications are being presented to physicians in a helpful and useful way and only contain information that is necessary and pertinent.** ACP further requests clarification regarding the criteria of those who are required to receive the patient event notification, as well as the liability and responsibility of physicians to act upon those notifications. Central to this clarified definition should be the inclusion of all care team members, and not just clinicians, social workers, care coordinators, etc. While those central to a patient's care should be included, it is important to keep in mind that not everyone needs to receive the information—nor is it always only the physician who is best suited to receive the information—and the oversharing of information could actually be detrimental to providing the patient with the best care. Notifications should only go to those physicians and care team members that are relevant to the episode of care; while the internist providing comprehensive primary care should always be kept in the loop, it may not be necessary for a patient's subspecialist or other clinicians to be informed of every patient activity. **We also are concerned**

around the requirement of these notifications as a condition of participation and believe that CMS should offer the option to opt-in or opt-out.

Interoperability Data Standards

CMS proposes to align the API standard in this rule with the API technical standard that was proposed by ONC for Department of Health and Human Services (HHS) adoption at 45 CFR 170.215, which requires use of the Health Level 7® (HL7) Fast Healthcare Interoperability Resources® (FHIR). The Agency also proposes required use of the content and vocabulary standard ONC proposes for HHS adoption at 45 CFR 170.213, which requires use of USCDI.

ACP applauds CMS and ONC for proposing FHIR® standards as alignment in health IT standards and implementation of standards is critical to improving interoperability and allowing disparate health IT systems to communicate effectively. **The College recommends CMS and ONC require the use of FHIR Release 4 (R4) immediately instead of focusing on FHIR Release 2 (R2) in these initial development stages.** Given that the certification updates will not happen for at least two and a half years, it is likely that FHIR R2 will no longer be in use. Moreover, FHIR R2 was a draft standard, while FHIR R4 is a normative standard and has many important elements that are not present in FHIR R2 and are necessary to promote interoperability.

ACP also supports the move to USCDI v1, however much clarification is needed to make the USCDI implementable. There is a significant leap from specifying data classes in the USCDI to fully implementing those data classes in standards that are ready for use. Also, we have learned the hard way that implementation of data structures in standards does not result in successful interoperability. Each standard requires one or more companion implementation guides that explain to developers how to use the standards properly.

Implementation Timeline

As proposed, MA organizations and QHP issuers in FFEs would be required to implement the API provisions by January 1, 2020 while Medicaid and CHIP FFS and managed care programs by July 1, 2020. With these dates coming up in less than six months, ACP strongly believes that these proposed timelines are moving too fast and are unreasonably aggressive. To have an effective implementation, adequate time must be allowed to develop and refine the standards and technology, implement and test the technology, adjust workflow, and train users. With the complex nature of both the ONC and CMS proposed rules, there are a number of overlapping timelines that are not fully aligned and do not seem entirely feasible. For example, the CMS proposal has more aggressive timelines for API deployment and proposes to require some health plans to support the updated functionality by January 1, 2020 – while other plans are required to do so by July 1, 2020. These compressed timeframes could result in problems in software being deployed that is not up to the right standards – and could have implications on patient care.


Moreover, as touched on in our comments for ONC's proposed rule, there are a number of significant updates being made to the 2015 Edition of Certified EHR Technology (CEHRT). While

CMS' proposed rule does not address Quality Payment Program (QPP) participation or clinician CEHRT adoption policies, it is imperative that CMS take ONC's proposals into consideration as they develop future policies around clinical adoption of CEHRT. There are enormous costs associated with implementing and rolling out these types of system upgrades and while moving to more up-to-date standards and functions is important, it is also important physicians have adequate time to train clinical staff and test and implement the upgrades once the new versions of 2015 CEHRT are available from their vendors to help ensure patient safety and a smooth transition to the new technology. **ACP recommends that physicians be given at least six months, if not a full year, for implementation of upgraded health IT systems before they are regulated on the use of their new technology. To that end, the College urged ONC to focus on the development timelines and allow other HHS agencies, such as CMS, to determine policies regarding physician adoption and use.**

Conclusion

Thank you for considering our comments on this extremely important set of policies and regulations. Please contact Brooke Rockwern, MPH, Associate, Health IT Policy at brockwern@acponline.org if you have any questions or need additional information.

Sincerely,

A handwritten signature in blue ink, appearing to read 'ZAR', with a long horizontal line extending to the right.

Zeshan A. Rajput, MD, MS
Chair, Medical Informatics Committee
American College of Physicians