American College of Physicians
Leading Internal Medicine, Improving Lives

September 23, 2019

Donald Rucker, MD
National Coordinator
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
Hubert Humphrey Building, Suite 729
200 Independence Avenue SW
Washington, DC 20201

Re: 2019 Interoperability Standards Advisory

Dear Dr. Rucker,

On behalf of the American College of Physicians (ACP), I am pleased to share our comments on the Office of the National Coordinator for Health Information Technology's (ONC's) 2019 Interoperability Standards Advisory (ISA) in preparation to update the ISA for the 2020 "Reference Edition." The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 159,000 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.

General Comments on Scope, Purpose, Process, and Structure

ACP commends ONC for their efforts in developing a public resource like the ISA. Resources like the ISA are essential in aligning standards and implementation specifications throughout the healthcare system. We believe interoperability efforts must be focused on the adoption and consistent implementation of health IT standards. As outlined in its scope, ONC seeks to address the interoperability needs associated with the creation of electronic health information during treatment and subsequent use of that information for purposes of referrals, reporting to public health agencies, and research. This can in turn help guarantee physicians have the necessary data to provide patients with the best care. However, in the review and updating process, the College contends that it is crucial for ONC to ensure that efforts towards

interoperability do not facilitate the transmission of unnecessary, inaccurate, incomplete, and out-of-context data.

ACP has ongoing concerns regarding the federal government's definition of interoperability, and as a result the ISA's interoperability focus. There remains a fundamental misconception that indiscriminately sending data is improving interoperability and patient care. Specifically, the College asserts that the definition and measurement of interoperability should not focus solely on volumes of data transferred or access to every single piece of data. Rather, it should focus on the high-yield clinical data involved in the management of patients as they transition through the healthcare system, the exchange of useful, 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 relevant clinical questions.

Further, much of the federal government's focus on interoperability operates under the assumption that the data exchanged is accurate and correct. Existing research finds that while clinically significant errors are present in almost every patient record, physicians' access to complete and contextual information prevents these record errors from manifesting into care delivery errors more frequently. Interoperability efforts that focus on the rapid exchange on all information, but neglect to consider the quality and relevance of information, may potentially lead to the widespread exchange of inaccurate or out-of-context information and subsequently risk patient care, and make it harder to affect repairs when errors are identified. **In updating the ISA, ACP strongly suggests adding a section or element to this catalog that focuses on identifying, repairing, and mitigating the negative effects of rapidly spreading incorrect and incomplete data. Additionally, ONC should develop processes for propagating corrected data as well establish consistent guidelines for how the corrected data are represented within the system. This will not only help to correct bad information but also ensure that the clinical team responsible for treatment identifies critical issues.** Similarly, as different institutions have different processes and "meanings," and the exchange of data increasingly transcends any one single institution**, it is important that ONC develop standards to ensure the vital clinical and institutional context moves along with the needed data elements.**

Data provenance is another important concept to consider as health data become more available and shareable. Provenance data are included in Clinical Document Architecture (CDA) and FHIR standards and can be attached in order to track the source of each observation. Any data received or sent has a marker of the origin associated with the data that would be evident to subsequent users of that information – providing great clinical value when exchanging health information and helping to mitigate challenges with reconciliation as well as any issues with inaccurate data. **ONC should work with industry stakeholders to develop industry guidance on best practices for implementing and managing provenance functionality in systems as a strategy to improve practical interoperability.**

Moreover, the standards development process has prioritized efforts to structure clinical data, when in some cases there are certain components that should not be structured. In the push to structure and exchange everything, the value of the narrative text has been lost. The College recommends that the patient's story and the clinician's assessment must be maintained and

exchanged as full text no matter what gets structured. While ACP acknowledges the usefulness of ISA-specified data elements like social, behavioral, and environmental factors in treating certain patients, we remain concerned around others' assumption that physicians would be responsible for collecting this data and distributing it freely. The College is uncertain as to the availability of standards for these types of data elements, the ability to clinically translate these terms, and the implications on physician workload and burden from taking the time to enter coded data into structured formats for mandated questions. **ONC must prioritize balancing the need to capture this extremely important data within the EHR in a way that is not a new and overly burdensome administrative or data entry task for physicians, and pursue further study before requiring the capture of these data elements.**

Before health IT standards and interoperability rules are adopted, testing and subsequent implementation must be conducted in a way to avoid and/or mitigate any adverse effects on patient care, privacy, security and clinical team workflow, and burden. ACP is concerned that by the time that standards reach the front line clinician, there is no one examining the actual impact. Additionally, multiple use cases add complexity for implementers and users. It would be better to make the first version of a standard as simple as possible and add functionality in future versions. Further, the College believes there is a lack of a review process for approved standards. For example, e-prescribing has been with us for years; however, there are a host of problems that have never been addressed. Interest seems to be lost in a standard once it is initially implemented. Rarely are those standards reviewed to see if the first thoughts about how to do something were accurate. Several recent JAMIA articles demonstrate that we are struggling to get something as simple as race and ethnicity data right. **ONC should implement an annual review cycle that examines how specific standards are working in practice and how their use impacts desirable outcomes.** The points above reflect the minimum ACP feels necessary for an annual review and would encourage multi-stakeholder discussion on what an effective, impactful, and streamlined annual review process might look like.

The following sections outline the College's specific comments and recommendations on the interoperability need use cases, standards, and implementation specifications within the 2019 ISA.

Specific Interoperability Needs

Public Health Standards

Given the current trend of a new, distinct standard being proposed for each public health reporting interoperability need, **ACP recommends that ONC work with public health agencies to reduce the number of different standards for reporting to public health agencies.** When the CDA-based quality reporting standards were being developed, public health stakeholders insisted that that standards be broadened to encompass the needs of public health reporting. The public health requirements were incorporated into the quality standards; however, no public health agency ever chose to use these broadly adopted standards. Public health stakeholders are now calling for FHIR-based reporting standards under development by quality and payer reporting groups to be expanded to encompass public health reporting needs. **The**

College recommends that ONC promote efforts for public health agencies to convene and agree to use common reporting standards with their specific public health needs in mind.

Prescription Drug Monitoring Program (PDMP) Standards

The Federal government should take the lead in insisting that state agencies promote interoperability through the use of common standards. **The College believes that all PDMP agencies should be required to use the same interoperability approach across all states. It is more common than not for clinical practices to use more than one state PDMP agency – and most practices routinely have needs to query multiple state registries. It is a shortcoming by all levels of government that clinicians are forced to use different tools and techniques to perform this routine task. ONC must take the lead in moving all PDMP agencies in a common direction, and it should not tolerate excuses and delays.**

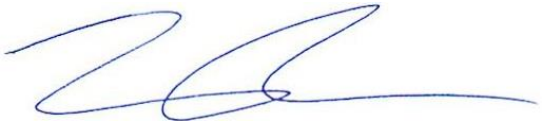
Care Plans, Care Teams, Social Determinants of Health (SDOH), Payer Data Exchange, and Others

Clinical requirements should drive standards development – not the reverse. ACP is concerned that data standards will be imposed on clinicians without sufficient needs assessments and real-world testing. Experience has shown that some standards are being developed well in advance of current clinical practice, and in some cases, have imposed clinical practice changes to adhere to the standard. In some cases, it appears that advocates are trying to use emerging data standards to impose practice changes. Over ten years ago, many health IT advocates stated with certainty that personal health records were about to spread rapidly throughout healthcare, without fully considering the practical implications and challenges involved at the clinical level. Government and industry must learn from these past shortcomings and realize that in order for health IT standards to successfully improve interoperability, they must be developed based on the clinical need, and clinicians should be involved throughout the standards development process. The College has been active in various standards development organizations and processes and looks forward to further engagement with both the private and public sectors to help provide that real-world, clinical insight necessary to improve interoperability.

Conclusion

We thank you for the opportunity to provide input on these important issues and hope that you will find value in our response. Please contact Brooke Rockwern, MPH, Associate, Health IT Policy at brockwern@acponline.org if you have any questions or need additional information.

Sincerely,



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