American College of Physicians
Leading Internal Medicine, Improving Lives

October 1, 2018

Don Rucker, M.D.
National Coordinator
Office of the National Coordinator for Health Information Technology
330 C Street, SW
Washington, DC 20201

Re: 2018 Interoperability Standards Advisory

Dear National Coordinator 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) 2018 Interoperability Standards Advisory (ISA) in preparation to update the ISA for the 2019 "Reference Edition." 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.

General Comments on Scope, Purpose, and Structure

The College appreciates ONC's ongoing development and maintenance of the ISA as we believe this type of public resource is an important aspect in harmonizing standards and implementation specifications across the industry to support interoperability. ONC clearly states the scope of the ISA focuses on 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. While we understand the ISA is not exhaustive and continues to be updated incrementally, ACP believes it is critical for ONC to begin to address, and incorporate within the ISA, the issues that arise with enhanced interoperability including the overflow of unnecessary data and sharing of potentially inaccurate, incomplete, and out-of-context data.

The ISA, and much of the government's interoperability focus, is based upon an assumption that observations recorded in systems and exchanged among systems are factual and accurate.

Evidence shows that it is more reasonable to expect that there are clinically significant errors in every patient record, and that the primary reason that data errors in patient records are not usually a cause of care delivery errors is because the clinicians have the full context of the patient record available at their fingertips. However, as we foster the rapid spread of potentially inaccurate data to systems and locations that do not have the full patient context, the likelihood of bad data causing care delivery errors rises. Additionally, the rapid spread of data to more and more locations and systems will make it even harder to affect repairs when errors are identified. **As ONC continues to update the ISA, ACP strongly recommends 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.** 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 Fast Healthcare Interoperability Resources (FHIR) standards and can be attached in order to track the original 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 any issues with inaccurate data. **ONC should work with stakeholders to develop industry guidance on best practices for implementing and managing provenance functionality in systems.**

As we are learning when we share seemingly correct patient data outside the bounds of our institutions, we find that, all too often, "meaning" is institution-specific. Every health care facility conducts care delivery processes differently, and they manage their data differently in order to drive their internal processes properly. As "accurate" data move from their native context into a different context, we can no longer assert that we fully understand their meaning. **The College recommends that ONC develop standards to ensure that important clinical and institutional context moves along with the data elements that we believe are needed**

The College agrees that many of the structured data elements specified in the ISA, such as the social, behavioral, and environmental factors, may sometimes have value in treating specific patients. However, there seems to be an assumption among many stakeholder groups that it is the responsibility of clinicians to collect these data in structured forms from all of their patients, and to make them available for free to everyone else who has an interest. **ACP has a general, ongoing concern as to the availability of standards for these types of data elements, the ability to clinically translate these terms, and the implication that every added standard will result in mandated questions that need to be answered by clinicians taking time to enter coded data into structured formats. We agree that these social, behavioral, and environmental factors are extremely important to capture within the EHR but it must not create a new and overly burdensome administrative or data entry tasks for clinicians.**

Moreover, while it is appropriate to address the wider health IT interoperability capabilities in support of clinical use cases, it is not always clear what specific health IT capabilities are applicable for certain interoperability standards. For example, the research focused interoperability standards may give the impression that all electronic health record (EHR) technology should support that. However, we have to be very careful encumbering all interoperability capabilities on all variants of health IT to avoid putting unnecessary burden on the primary users/clinicians of those systems. **To that end, ACP recommends providing categorization of use cases and providing more detail on the intent of the use case to help the reader come to these conclusions (e.g., add a paragraph to each use case beyond a title). Also, rather than requiring EHRs and other clinical health IT to support multiple separate standards for extracting data for quality, public health, research, payment, administrative, and other reporting purposes, ONC should commission development of a single application programming interface (API) for all of the query and data extraction requirements.**

The following sections outline the College's specific comments and recommendations on the interoperability need use cases, standards, and implementation specifications within the 2018 ISA.

I-R: Sex at Birth, Sexual Orientation and Gender Identity

ACP Comment: Clinicians need accurate genotype, phenotype, and declared identity to safely manage patients and it is unclear what is required to be captured within the standards under Sex at Birth, Sexual Orientation, and Gender Identity. For example, if a clinician does not have information on sex at birth, they may miss the patient's need for preventive services such as pap smears. The College is also concerned with what the data entry process will look like and who will be required to enter that data. Additionally, these are sensitive questions that require nuanced clinical expertise to gather accurate information – raising another concern around the validity of the data captured.

- **Interoperability Need: Representing Patient Gender Identity**
    - **ACP Comment:** As noted above, clinicians and their patients would benefit from having these data available in patient records. However, this should not suggest that it is the sole responsibility of clinicians and their staffs to collect these sensitive data.
- **Interoperability Need: Representing Patient-Identified Sexual Orientation**
    - **ACP Comment:** We have a general, ongoing concern as to the availability of standards and the implication that every standard results in mandated questions that need to be answered by clinicians taking time to enter coded data into structured formats.

I-S: Social, Psychological, and Behavioral Data

ACP Comments: While most of the recommended codes for these standards are present in LOINC, many have originated from non-clinical settings and uses such as public health reporting and research uses. There needs to be a process where non-clinically sourced codes are validated for use in clinical settings. As mentioned above in our general comments, the College

has an ongoing concern as to the availability of standards for these types of data elements and the ability to clinically translate these terms. We are also concerned about the implication that every added standard will result in clinicians answering mandated questions and taking additional clinical time to enter coded data into structured formats. We agree that these social, behavioral, and environmental factors are extremely important to capture within the EHR but it must not create a new and overly burdensome administrative or data entry tasks for clinicians. **In addition to the social, psychological, and behavioral interoperability needs listed in the current version of the ISA, ONC should add interoperability needs for food scarcity and housing/homelessness and test these standards and LOINC codes in clinical settings.**

II-H Electronic Prescribing

ACP Comments: The electronic prescribing interoperability needs described in this section are great examples of how there are adequate standards to address the need but the issue lies within their implementation. It is good to have a value set for these processes but it is not useful if the data received is inaccurate or incomplete. The standard alone will not address the interoperability need because there is no requirement for the other participants in the exchange (e.g., Surescripts, pharmacies, pharmacy benefits managers) to implement the standard consistently.

- **Interoperability Need: Prescriber's Ability to Obtain a Patient's Medication History from a PDMP**
    - **ACP Comment:** Even if all PDMPs eventually agree to use the same interoperability standard, variations in state laws and PDMP access procedures will guarantee that the actual experience of clinicians attempting to use these systems will vary significantly. Due to irregularities in funding, laws, and other state-level variations, PDMPs are not capable of implementing an otherwise agreed upon standard. Therefore, these standards cannot be required for use until PDMP systems are accurate and reliable.

II-Q Public Health Reporting

- **Interoperability Need: Case Reporting to Public Health Agencies**
    - **ACP Comment:** There are different standards listed for each type of public health report – making it extremely cumbersome for clinicians to report out to the numerous public health agencies that request or require information. It is not reasonable for clinicians to have to enter duplicative information in different formats to serve the needs of external public health agencies. Those agencies should be extracting the clinical data entered into the EHR and translating that information into whatever they need for their tracking, surveillance, or research.
- **Interoperability Need: Exchanging Immunization Data with Immunization Registries**
    - **ACP Comment:** This interoperability need cannot be met unless clinicians are receiving updated information on the immunizations of their patients. Exchange of immunization data is a great example of how enhanced interoperability can negatively affect care delivery when bad or outdated data are exchanged.

II-R Research

- **Interoperability Need: Integrate Healthcare and Clinical Research by Leveraging EHRs and other Health IT Systems while Preserving FDA's Requirements**
    - **ACP Comment:** The standards listed under the Research Interoperability Needs (e.g., CDISC Operational Data Model and Study Design Models) are leveraging EHRs but they not using or leveraging EHR-based standards. The standards listed within this section that are based on what researchers have developed for their own research purposes and are entirely different from those standards needed in clinical practice.
    - **ACP Comment:** ONC has identified very important research interoperability needs but will now require clinicians to do double work by using both research and clinical standards. The standards for this interoperability need should actually leverage EHRs and EHR standards in order to integrate healthcare and clinical research. Researchers should collect the needed clinical data and then translate that data into a format that is necessary for their research needs.

II-T Summary Care Record

- **Interoperability Need: Support a Transition of Care or Referral to Another Health Care Provider**
    - **ACP Comment:** The implementation of the standards for summary care records, not the standards themselves, are not working for clinicians and the more recent version has not improved. The biggest problem to date has been over-prescriptive definitions of what should be in a "summary;" definitions that have caused note bloat and have made for interoperability of legible information – where nothing useful is communicated. It may be easy for the sender to create – but it is a waste of time for the reader. Thus far, this well-known problem has still not been addressed. The functionality to constrain the information is there but vendors need to develop and implement applications that manage the creation of useful summary care records.

III-F Public Health Exchange

- **Interoperability Need: Transport for Immunization Submission of Query/Response**
    - **ACP Comment:** This interoperability need cannot be met unless clinicians are receiving updated information on the immunizations of their patients. This use case needs to be expanded to include the provision of immunization data to the clinicians – it needs to be a bidirectional process wherein the public health agency is able to provide accurate immunization histories to clinicians.

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

Sincerely,

Patricia L. Hale, MD, PhD, FACP
Chair, Medical Informatics Committee
American College of Physicians