



October 21, 2016

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National Coordinator for Health Information Technology  
Acting Assistant Secretary for Health  
U.S. Department of Health and Human Services  
200 Independence Avenue SW  
Washington, D.C. 20201

**Re: 2017 Interoperability Standards Advisory, Draft for Comment**

Dear Dr. Washington,

On behalf of the American College of Physicians (ACP), I would like to share our comments on The Office of the National Coordinator for Health Information Technology's (ONC's) Draft 2017 Interoperability Standards Advisory (ISA). The College is the largest medical specialty organization. ACP members include 148,000 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 Comments on the ISA Scope:**

While the draft ISA scope is clear, it limits itself to the capability of clinical health information technology (health IT) systems to exchange data. There is no recognition of the need for checks and balances if improved machine interoperability applied within clinical reality leads to errors and miscommunications. In general, as clinical health IT systems are used to care for patients, and interoperability of information may have huge implications for errors of commission and omission – there needs to be a clear understanding of how enhanced interoperability is adjusted based on what changes in care delivery it leads to.

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 clearly shows that this is not true. It is more reasonable to expect that there are clinically significant errors in every patient record. 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 bad data to systems and locations that do not have the full patient context, the

likelihood of bad data causing care delivery errors rises. Also, the rapid spread of bad data to more and more locations and systems will make it even harder to affect repairs when errors are identified. The real challenge of interoperability is to share data in ways that will not increase the likelihood of care delivery errors. **The College recommends that ONC focus their efforts to identify, repair, and mitigate the negative effects of rapidly spreading bad data.**

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 introduction of 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, and other reporting purposes, ONC should commission development of a single application programming interface (API) for all of the query and data extraction requirements.**

#### **ACP Comments on the ISA Purpose:**

The College agrees that many of the structured data elements specified in the draft 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 Comments on the ISA Structure:**

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. Additionally, the College seeks clarification regarding what establishes a standard as “final,” and whether a final standard can be revisited.**

The following sections outline the College’s specific comments and recommendations on the draft standards and implementation specifications within the draft ISA.

## Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications

- **I-A: Allergies**
  - **Interoperability Need: Representing Patient Allergic Reactions**
    - As practicing clinicians, we understand that information about an allergy/adverse reaction is not helpful without qualifiers such as type and severity of reaction – and that failure to include that information along with mobilization of medication allergy is generally not useful.
    - The Systematized Nomenclature of Medicine (SNOMED) is listed with a maturity level of Production and a high Adoption Level. This may be true in general or in specific other interoperability needs, but it is not accurate for this particular need. Maturity and adoption levels should always be set to the particular interoperability need being discussed.
  - **Interoperability Need: Representing Patient Allergens: Medications**
    - There are concerns that overly broad definitions in National Drug File - Reference Terminology (NDFRT) drug classes, coupled with differing interpretations and use of allergy/adverse reaction and severity scales could trigger improper interpretations by systems, clinicians, and patients. For example, if a clinician or patient entered into the Allergy/Adverse Reaction field “Augmentin – severe diarrhea” – would the mobilized information be clear enough such that downstream users of the information would not see “PENICILLIN – SEVERE” – which would make that downstream user avoid any penicillin or possibly cephalosporin as well. Without knowing how what we mobilize is viewed by downstream users – it could be more likely that patients will be denied access to appropriate medications.
  - **Interoperability Need: Representing Patient Allergens: Food Substances**
    - Does this category include food intolerances as well as food allergies? A classic example is lactose intolerance, which is technically not a food allergy. A more recent example is gluten sensitivity, which may be very common (or at least imagined to be common) – whereas celiac disease is much less common.
  - **Interoperability Need: Representing Patient Allergens: Environmental Substances**
    - Is this suggesting that allergic responses to dust, for example, would go in the allergy/adverse reaction field – as opposed to the active medication field? If so, ACP questions its usefulness. If the purpose of the allergy/adverse reaction field is to present useful information that could prevent serious or life-threatening reaction to prescribed or administered medications – how does the entry of “cats, dogs, ragweed, grasses, etc.” do anything but make a terse list into a verbose one. One could say the same about food allergies and intolerances – but in the inpatient setting,

this information is important for diet orders. The same cannot be said for environment allergies.

- Verbosity in an allergy list is not just annoying on general principle but could also be somewhat dangerous if the most critical medication allergies are off the screen (because this list is alphabetical or chronological) requiring the end-user to scroll to see what is important.

- **I-B: Encounter Diagnosis**

- **Interoperability Need: Representing Patient Medical Encounter Diagnosis**

- Is there also a standard for communicating encounter diagnosis position – which is important for billing purposes? Payers typically like to see for any given encounter the ranking of diagnostic codes – showing the principle diagnosis for the visit, as well as others. Payment for a visit may be withheld, adjusted, or delayed if the order of diagnoses for any given encounter is not preserved when mobilized.
- When ONC states that, “Systems should be able to handle older code sets,” what is the implementable, testable meaning of the word “handle?”

- **I-C: Family Health History**

- **Interoperability Need: Representing Patient Family Health History**

- The College recommends that not all family history have to be entered as structured data, and/or mapped into a family tree. The patient may not know that level of detail – and a requirement to enter information as structured data and at a high level of detail inappropriately forces the end-user to change a vague answer into one of false certainty.
- Further, a requirement to enter family history as structured data can add significant time to history taking and data entry – which would lengthen history taking but not the existing payment model for how doctors are paid for conducting a history.

- **Interoperability Need: Representing Patient Family Health History Observations**

- What is the distinction here between Family Health History and Family Health History Observations? Please provide examples of each.
- The College is not entirely clear on this standard – but assumes it would include observations connected to an event. For example, myocardial infarction (MI) in father – observation would be “at age 55.”

- **I-D: Functional Status/Disability**

- **Interoperability Need: Representing Patient Functional Status and/or Disability**

- ACP has concerns about how these standards are used, and the implication of a data entry responsibility for doctors and staff members.

For example, would a text-based disability evaluation by Social Security, the military, or by an orthopedist have to then be re-entered as structured data elements by the primary care doctor? Or, is the implication that disability and functional status examinations would have to be created as structured documents; and that these structured evaluations create both the document and the data elements that are then to be mobilized?

- As with the promulgation of other standards (i.e., Family History) – will the creation of standards that include structured data create an obligation to collect those data?
  
- **I-E: Health Care Provider**
  - **Interoperability Need: Representing Provider Role in Care Setting**
    - Is it correct to assume that this standard identifies a provider by specialty or by status – or is this attempting to establish a connection to a patient – such as the primary care doctor of the patient? There is a strong need to establish and use standards for clinician-patient attribution, including a more detailed attribution model – such as “primary” and “collaborator” for problems or conditions; and “owner” and co-owner for medications. These are the problems in multi-provider care that need work – not identifying the generic who and what. Both interoperability needs should be met.
  
- **I-G: Immunizations**
  - **Interoperability Need: Representing Immunizations – Historical**
    - Does the adoption of a historical and administration standard mean that there is a set of operating rules as to how these are reconciled to create an immunization history for patients?
  
- **I-H: Industry and Occupation**
  - **Interoperability Need: Representing Patient Industry and Occupation**
    - Similar to the comments on functional status, is the implication of a standard a corresponding duty on the treating clinician to input industry and occupation as structured data? Every federal requirement to collect and maintain such structured data should include guidance to industry on alternative methods for data collection and validation. Further, considering the general negative tone of the physician community towards EHRs, which is at least in part due to conflating regulatory requirements for data entry and submission with poor EHR usability – the College again wishes to clarify that the introduction of standards for communicating certain information does not convey an obligation on the part of clinicians for information collection and data entry.

- **I-I: Lab tests**
  - **Interoperability Need: Representing Laboratory Tests**
    - How does this address the need to disambiguate similar lab tests that use different methodologies?
  
- **I-J: Medications**
  - **Interoperability Need: Representing Patient Medications**
    - What are the implications of these standards in regards to mandating over-the-counters (OTCs) and herbals as structured medications?
    - What are the implications of these standards for generic and biosimilar substitution by pharmacists – will they unnecessarily add to medication reconciliation burden with each pharmacy fill?
    - What is the intended meaning of the presence of a medication on the medication list? Does presence of a medication mean that: a prescription has been written; a prescription has been sent for fulfillment; the prescribed medication has been dispensed; a similar medication has been dispensed; the prescribed medication has been or is being taken by the patient; a similar medication is being taken by the patient; or there is a likely history of one or more of the previous actions? Accurate reconciliation is impossible without these contextual distinctions.
  
- **I-L: Nursing**
  - **All Interoperability Needs under Nursing**
    - ACP supports the use of broad and mature industry standards, instead of nursing-specific terminologies, to represent nursing needs.
  
- **I-M: Patient Clinical “Problems” (i.e., conditions)**
  - **Interoperability Need: Representing Patient Clinical “Problems” (i.e., Conditions)**
    - While problem lists are helpful – problem list meta-data can be more useful. Will this standard prohibit problem list comments? Will it mean that problem list comments will be stripped off the problem when the problem list is mobilized as structured data?
  
- **I-N: Preferred Language**
  - **Interoperability Need: Representing Patient Preferred Language (Presently)**
    - We see two separate interoperability needs here, but this proposal only represents one. The concept of preferred language does not clearly ask the more relevant question – which is in what language can a patient best understand and communicate health concerns and information? The patient’s preferred language for conversation may be an entirely different choice.

- **I-O: Procedures**
  - **Interoperability Need: Representing Dental Procedures Performed**
    - Code on Dental Procedures and Nomenclature (CDT) is listed with a maturity level of Production and a high Adoption Level. This may be true in general or in specific other dental interoperability needs, but it is not accurate for this particular need – representation of dental procedures in an EHR. CDT is little used outside of dental systems. Maturity and adoption levels should always be set to the particular interoperability need being discussed.
  - **Interoperability Need: Representing Medical Procedures Performed**
    - Is this procedure list a data entry point for surgical history? If so, there is a difference between recording appendectomy and central line placement. Procedure data collection can be thought of similar to encounter diagnoses and problem list.
    - Is there a need to have four terminologies to represent procedures? At this point, there is no movement toward eliminating any of these terminologies and they are all very separate and distinctly maintained with no true crosswalk. AMA is contracted by CMS for many years to create and maintain Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) is a Medicare only coding system which the agency self maintains. It may be possible in the long-range that Procedure Coding System (PCS) could become the universal system that could be used in the way SNOMED envisions. However for now they all do have separate reporting purposes. ONC should work with its federal partners to eliminate the need for at least one of these terminologies.
  
- **I-P: Race and Ethnicity**
  - **Interoperability Need: Representing Patient Race and Ethnicity**
    - Our concern is that this is defined for one important purpose (health disparities/health equity); but completely misses precision medicine. Will this mean that we will end up with two sets of questions for race and ethnicity? Again, there are two distinct interoperability needs, but only one is addressed.
  
- **I-Q: Research**
  - **Interoperability Need: Representing Analytic Data for Research Purposes**
    - Are all clinical systems expected to support the full range of research standards specified in this ISA? It would be incredibly costly and burdensome to require clinical systems to support all research needs. It would be far better for separate research-focused systems to

interoperate with clinical systems to push and pull data for all non-clinical purposes, including research.

- **I-R: Sexual Orientation and Gender Identity**
  - **Interoperability Need: Representing Patient Gender Identity**
    - 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**
    - We have a general, ongoing concern as to the availability of standards and the implication that every standard results in a mandated question that needs to be answered by clinicians taking time to enter coded data into structured formats.
  
- **I-S: Social Determinants [See Questions 10 and 11, Section IV]**
  - **Interoperability Need: Representing Financial Resource Strain**
    - The College has a general, ongoing concern as to the availability of standards and the implication that every standard results in a mandated question that needs to be answered by clinicians taking time to enter coded data into structured formats.
    - These are very important – but collecting this information every patient every year will add significant time to history-taking.
    - Logical Observation Identifiers Names and Codes (LOINC) is listed with a maturity level of Production and a high Adoption Level. This may be true in general or in specific other interoperability needs, but it is not accurate for this particular need. Maturity and adoption levels should always be set to the particular interoperability need being discussed.
    - We note that depending on clinical use cases different assessment scales may be used making it challenging to arrive at one single, national assessment scale at this time. What efforts are in place to harmonize across these assessments?
  - **Interoperability Need: Representing Level of Education**
    - LOINC is listed with a maturity level of Production and a high Adoption Level. This may be true in general or in specific other interoperability needs, but it is not accurate for this particular need. Maturity and adoption levels should always be set to the particular interoperability need being discussed.
    - The College has a general, ongoing concern as to the availability of standards and the implication that every standard results in a mandated question that needs to be answered by clinicians taking time to enter coded data into structured formats.



- We note that depending on clinical use cases different assessment scales may be used making it challenging to arrive at one single, national assessment scale at this time. What efforts are in place to harmonize across these assessments?
  - **Interoperability Need: Representing Stress**
    - What is recorded and where? How frequently is it supposed to be updated?
    - LOINC is listed with a maturity level of Production and a high Adoption Level. This may be true in general or in specific other interoperability needs, but it is not accurate for this particular need. Maturity and adoption levels should always be set to the particular interoperability need being discussed.
    - The College has a general, ongoing concern as to the availability of standards and the implication that every standard results in a mandated question that needs to be answered by clinicians taking time to enter coded data into structured formats.
    - We note that depending on clinical use cases different assessment scales may be used making it challenging to arrive at one single, national assessment scale at this time. What efforts are in place to harmonize across these assessments?
  - **Interoperability Need: Representing Depression**
    - Is this referring to diagnosis or Patient Health Questionnaire (PQH) score?
    - LOINC is listed with a maturity level of Production and a high Adoption Level. This may be true in general or in specific other interoperability needs, but it is not accurate for this particular need. Maturity and adoption levels should always be set to the particular interoperability need being discussed.
    - The College has a general, ongoing concern as to the availability of standards and the implication that every standard results in a mandated question that needs to be answered by clinicians taking time to enter coded data into structured formats.
    - We note that depending on clinical use cases different assessment scales may be used making it challenging to arrive at one single, national assessment scale at this time. What efforts are in place to harmonize across these assessments?
  - **Interoperability Need: Representing Physical Activity**
    - LOINC is listed with a maturity level of “Production” and a high “Adoption” Level. This may be true in general or in specific other interoperability needs, but it is not accurate for this particular need. Maturity and adoption levels should always be set to the particular interoperability need being discussed.

- The College has a general, ongoing concern as to the availability of standards and the implication that every standard results in a mandated question that needs to be answered by clinicians taking time to enter coded data into structured formats.
  - We note that depending on clinical use cases different assessment scales may be used making it challenging to arrive at one single, national assessment scale at this time. What efforts are in place to harmonize across these assessments?
- **Interoperability Need: Representing Alcohol Use**
  - LOINC is listed with a maturity level of Production and a high Adoption Level. This may be true in general or in specific other interoperability needs, but it is not accurate for this particular need. Maturity and adoption levels should always be set to the particular interoperability need being discussed.
  - The College has a general, ongoing concern as to the availability of standards and the implication that every standard results in a mandated question that needs to be answered by clinicians taking time to enter coded data into structured formats.
  - We note that depending on clinical use cases different assessment scales may be used making it challenging to arrive at one single, national assessment scale at this time. What efforts are in place to harmonize across these assessments?
- **Interoperability Need: Representing Social Connection and Isolation**
  - This standard has the potential to add significant time to history collection/validation.
  - LOINC is listed with a maturity level of Production and a high Adoption Level. This may be true in general or in specific other interoperability needs, but it is not accurate for this particular need. Maturity and adoption levels should always be set to the particular interoperability need being discussed.
  - The College has a general, ongoing concern as to the availability of standards and the implication that every standard results in a mandated question that needs to be answered by clinicians taking time to enter coded data into structured formats.
  - We note that depending on clinical use cases different assessment scales may be used making it challenging to arrive at one single, national assessment scale at this time. What efforts are in place to harmonize across these assessments?
- **Interoperability Need: Representing Exposure to Violence (Intimate Partner Violence)**
  - LOINC is listed with a maturity level of Production and a high Adoption Level. This may be true in general or in specific other interoperability

needs, but it is not accurate for this particular need. Maturity and adoption levels should always be set to the particular interoperability need being discussed.

- The College has a general, ongoing concern as to the availability of standards and the implication that every standard results in a mandated question that needs to be answered by clinicians taking time to enter coded data into structured formats.
  - We note that depending on clinical use cases different assessment scales may be used making it challenging to arrive at one single, national assessment scale at this time. What efforts are in place to harmonize across these assessments?
- **I-T: Tobacco Use (Smoking Status) [See Question 12, Section IV]**
    - **Interoperability Need: Representing Patient Tobacco Use (Smoking Status) Observation Result Values or Assertions**
      - ACP is concerned that what we used to collect about smoking before Meaningful Use was more useful clinically than simply, “current,” “former,” or “never.”
      - We do not want to add documentation burden, but for current and former smokers – we need more information regarding helping them to quit, what has been tried before, etc. as well as cumulative pack years (for triggering decision support for lung cancer screening).
- **I-U: Unique Device Identification**
    - **Interoperability Need: Representing Unique Implantable Device Identifiers**
      - There is ongoing confusion about how and when to communicate Unique Device Identifiers (UDI), and we are concerned that there is a rush to implement UDI without full consideration of all relevant uses and requirements. At a minimum, all care related and downstream-related uses need to be considered together to ensure appropriate data capture and communication can occur. Will the standard imply a need to use by those clinicians who have not implanted the devices? If so, this is a documentation burden placed on the wrong people. Who has a duty to collect this information, and what is the ongoing duty to validate the information? Before requiring the communication of UDI we need to agree on the details of the intended use cases.
- **I-V: Vital Signs**
    - **Interoperability Need: Representing Patient Vital Signs**
      - There is one very important addition – which is the concept of resting or decision point blood pressure. Currently, blood pressure is considered a measurement, where setting and circumstance are not considered. This

would be like having a construct for blood sugar, and ignoring setting (fasting, post-prandial, after a sugar bolus, etc.) And this is creating havoc in the use of blood pressure readings for determining success with blood pressure control measures.

- Further, there is no construct at this time for mean or median blood pressure – or more precisely, mean or median resting/decision point blood pressure – which may end up being critical for determining blood pressure control and necessary actions

## **Section II: Content/Structure Standards and Implementation Specifications ACP Comments/Suggestions**

- **II-A: Admission, Discharge, and Transfer**
  - **Interoperability Need: Sending a Notification of a Patient’s Admission, Discharge and/or Transfer Status to Other Providers**
    - The industry needs specific guidance regarding mobilizing these data and who should get what information and when. This should not be left to trading partners to negotiate on a case-by-case basis – but instead should be a federal requirement.
  
- **II-B: Care Plan**
  - **Interoperability Need: Documenting Patient Care Plans**
    - This standard has been developed based upon expert opinion of what future use might look like. The drafting discussion has – at times – been more political than clinical. The standard has been selected as a federal requirement despite a total lack of implementation, even at a pilot level. Very few clinicians have had any exposure to this standard. Serious concerns are likely to emerge as this rolls out. Standards should not be selected until they have had significant actual use in practice. Where have the pilots occurred, and what was tested? There is no adoption.
  - **Interoperability Need: Documenting, Planning and Summarizing Care Plans for Patients with Cancer**
    - Does the care plan for oncology include the patient? Does the patient know the diagnosis and prognosis? Has the patient been offered – where appropriate – hospice or home hospice services?
    - Very few clinicians have had any exposure to this standard. Serious concerns are likely to emerge as this rolls out. Standards should not be selected until they have had significant actual use in practice. Where have the pilots occurred, and what was tested? There is no adoption.

- **II-C: Clinical Decision Support**
  - **Interoperability Need: Shareable Clinical Decision Support (CDS)**
    - Beyond what is specified to facilitate the triggering and delivery of CDS, we need standard methods for capturing and mobilizing reasons a CDS recommendation was not carried out – medical reasons, patient reasons, disagreement with recommendation, etc. Recalling that the vast majority of alerts are now ignored or dismissed – what are we gaining with mobilizing CDS without addressing the value of CDS?
  - **Interoperability Need: Provide Access to Appropriate Use Criteria (AUC)**
    - While the scope of this project does not include administrative or payment interoperability – it seems pointless to work through only one side of this information loop. Thus, will access to and use of AUC lead to fewer prior authorizations, or will data serve as answers to these prior authorization scenarios? Or will the data serve no needs – and the need to create duplicative documentation for prior authorization remain?
  - **Interoperability Need: Communicate AUC with the Order and Charge to the Filling Provider and Billing System for Inclusion on Claims.**
    - While the scope of this project does not include administrative or payment interoperability – it seems pointless to work through only one side of this information loop. Thus, will access to and use of appropriate use information lead to fewer prior authorizations, or will data serve as answers to these prior authorization scenarios.
    - Consider IHE/HL7 Guideline Appropriate Ordering (Government Accountability Office)
  
- **II- D: Clinical Quality Measurement**
  - **Interoperability Need: Sharing Quality Measure Artifacts for Quality Reporting Initiatives**
    - Adoption levels for Health Quality Measure Format (HQMF) and Quality Data Model (QDM)-based HQMF are not as high as represented. Perhaps two bullets would be more accurate. It is hard to judge adoption for these standards because we do not know the extent of automated use by developers.
  
- **II-E: Clinical Quality Reporting**
  - **Interoperability Need: Reporting Aggregate Quality Data to Federal Quality Reporting Initiatives**
    - This is another instance where we should be seeing a positive impact of standardization of quality reporting – such as reporting once in this format satisfies reporting needs for all requestors. ONC has a responsibility to encourage, if not to require all receivers of quality data to accept data formatted with these standards.

- **Interoperability Need: Reporting Patient-level Quality Data to Federal Quality Reporting Initiatives**
  - Here is another instance where we should be seeing a positive impact of standardization of quality reporting – such as reporting once in this format satisfies reporting needs for all requestors. ONC has a responsibility to encourage, if not to require all receivers of quality data to accept data formatted with these standards.
  - There is a typo in Emerging Implementation Specification – “Release 43.”
  
- **II-G: Drug Formulary & Benefits**
  - **Interoperability Need: The Ability for Pharmacy Benefit Payers to Communicate Formulary and Benefit Information to Prescribers Systems**
    - Not all functions in the standard have the same adoption level. The current formulary is not accurate, transparent, nor actionable. For this to be useful to patient/consumer and prescriber – it needs to be populated with accurate and transparent information at the patient level. It also needs to feed electronic prescription (eRx) systems such that “alternatives available” either is changed to mean “lower cost alternative” or adds a standard for “lower cost alternative.” The current implementation of “alternative available” is useless, but it co-mingles similarly expensive and more expensive options.
    - Further – where drugs require prior authorization – there is no standard for display of similar drugs that don’t require prior authorization, reason for prior authorization, etc. Information transparency and the ability to be actionable at the time of purchase (prescribing) is a 21st century sensibility.
  
- **II-H: Electronic Prescribing**
  - **Interoperability Need: A Prescriber’s Ability to Create a New Prescription to Electronically Send to a Pharmacy**
    - Not all functions in the standard have the same adoption level. In many instances an ePrescription from a prescriber has to be manually re-entered into the dispensing system. Will this standard address those situations?
    - Does this standard permit transmission of long or tapering instructions?
    - Does this standard permit prescriber attribution to the prescription?
    - Another issue that has been made worse with ePrescribing is that medication lists are not helpful in differentially topical, optic, or optic preparations. Further, new prescriptions of liquids, creams, ointments, inhalers, are complicated by the fact that as prescribers, we do not know how to write the dispense amount (are the tubes or bottles 5ml, 15ml, or

tubes of 15g, 30g, 60g) as we don't know how the medications come from the manufacturer. This should be fixed within this standard.

- **Interoperability Need: A Prescriber's Ability to Grant a Refill Request to the Pharmacy**
  - Does this standard permit prescriber attribution to the prescription?
  - When a prescriber is on-call and refills a prescription for a colleague, or when a doctor, as a courtesy, orders a refill of a prescription for another doctor, the prescription is now forever assigned to the doctor who authorized the refill; not the "owner" of the prescription.
  - In this instance, having a standard gets in the way of prescription clarity, unless it permits a renewal by prescriber A on behalf of prescriber B
  - Additionally, and this may just be a defect in particular systems, refill messages are not aggregated – and thus a patient with multiple prescriptions to renew has separate messages to respond to – making it more work and burden on the prescriber. Does this standard support an EHR or ePrescribing application that allows for "accept all?"
- **Interoperability Need: Allows the Pharmacy to Respond to Prescriber with a Change on a New Prescription**
  - This would be a helpful addition.
- **Interoperability Need: Cancellation of a Prescription**
  - This would also be helpful – but prescribers need to understand that a prescription cancellation is transactional, and not the same as removing a medication from a problem list. Thus, a patient may be switched from blood pressure (BP) medication A to BP medication B – and medication A may be cancelled by a prescriber. However, if an additional prescription is still in effect for the same medication, a cancel does not cancel that additional prescription.
  - Within implementation of this standard – is it assumed that pharmacists know where there are multiple prescriptions for the same medication to cancel them all. Does this standard also enable the removal of a prescription from a medication list to automatically send a cancel notice to the pharmacy that the prescription went to (via SureScripts)?
- **Interoperability Need: Pharmacy Notifies Prescriber of Prescription Fill Status**
  - What are the implications of this standard for prescriber responsibility to take action on non-filled prescriptions? This is a long-standing concern on information capabilities coming too far ahead of workflow and standard practices.
  - Also, how will this be implemented? Thus, it is easier when patients are with prescribers for the prescriber to ask the patient, "while you are here, are there prescriptions you need updating?" If the patient says, "no, not yet, but I will need a new one in a month or so" – we typically send in a renewal – to avoid a phone call or missed calls later on. Will

this common workflow trigger non-dispense messages – when in fact we are not expecting a dispense for several weeks?

- Further, does the standard permit notification for certain key medications and/or chronic medications – or is it all or none?
- **Interoperability Need: A Prescriber’s Ability to Obtain a Patient’s Medication History**
  - SureScripts requires authorization from the patient to obtain medication fill history, and in at least one major EHR system, this requirement is implemented such that authorization is set one-by-one. The implication of this implementation is that medication history is not routinely used; unlike benefit and eligibility checking, which is consistently used, as it is typically run as a batch of scheduled patients – medication history. It is not clear if this one-by-one authorization is an EHR issue or a SureScripts requirement – but if it is a general requirement – this is an example where just addressing the technical interoperability need is not really addressing the problem.
- **Interoperability Need: Allows Prescriber to Respond to a Prior Authorization for a Medication Electronically to the Payer/Processor.**
  - This might be useful sometimes, but what is far more important is the provision of accurate and actionable information at the time of prescribing – including alternatives that do not require prior authorization. This could obviate the need for many prior authorizations. Also, having a standard for data fields does not deal with a common situation where the prior authorization request is only asking for the diagnosis and diagnosis code for the medication – which is already on the prescription – but is not necessarily transmitted to the pharmacy benefits manager (PBM).
  - Further – where information for prior authorization is more than diagnosis and diagnosis code – and might include diagnostic results or prior medications used – the effort should be on pulling relevant information that already exists in the EHR, rather than enabling duplicative documentation by already overburdened doctors and staff.
- **Interoperability Need: Prior Authorization Cancel Request**
  - The title of this need does not make clear what this means. We assume it refers to cancelling a prescription that required prior authorization, where it is decided not to pursue prior authorization. If that is the case, then this makes sense. But it makes more sense when paired with the prior authorization process described above in previous comments; where the messaging would reflect “after viewing coverage information, prescribe A, and cancel B.”



- **II-I: Family health history (clinical genomics)**
  - **Interoperability Need: Representing Family Health History for Clinical Genomics**
    - We are not sure of the value of creating interoperability standards for an area of medicine without a defined vocabulary.
  - **Interoperability Need: Representing Patient Family Health History Observations**
    - How is this need different from the one in the vocabulary section? LOINC does not specify structure.
  
- **II-J: Images**
  - **Interoperability Need: Format of Medical Imaging Reports for Exchange and Distribution**
    - Will this standard lead to the ability for EHRs to automatically pull certain sections of the report into a structured data field? If so, critically important – and helpful to reduce manual documentation. The clearest need now is for pulling standardized interpretations of BIRADS readings on mammogram reports.
  
- **II-K: Laboratory**
  - **Interoperability Need: Ordering Labs for a Patient**
    - Will this standard support future lab orders as well? This is very important if we wish to have health IT systems serve as a tool that promotes effective and efficient use of ordering as a way to decrease unwarranted variation in care.
  
- **II-M: Patient Education Materials**
  - **Interoperability Need: A Standard Mechanism for Clinical Information Systems to Request Context-Specific Clinical Knowledge Form Online Resources**
    - Assuming that Meaningful Use (MU) or Advancing Care Information (ACI) requirements are still in effect, will this standard take into account satisfaction of those requirements – if not it solves only one problem – where it should solve two.
  
- **II-O: Public Health Reporting**
  - **Interoperability Need: Reporting Antimicrobial Use and Resistance Information to Public Health Agencies**
    - We assume that this standard is not permissive of duplicative manual documentation – but rather enabling of automating reporting of what is already captured in the EHR as structured information.
    - We urge ONC to work with appropriate federal health-related organizations to ensure that all appropriate standards are implemented

broadly consistently, and rapidly. The government should take the lead in implementing health IT standards.

- **Interoperability Need: Reporting Cancer Cases to Public Health Agencies**
  - We assume that this standard is not permissive of duplicative manual documentation – but rather enabling of automating reporting of what is already captured in the EHR as structured information.
  - We urge ONC to work with appropriate federal health-related organizations to ensure that all appropriate standards are implemented broadly consistently, and rapidly. The government should take the lead in implementing health IT standards.
  - When the quality reporting standards were initially developed, enormous time and effort were devoted to ensure that the standards would meet all of the requirements of public health reporting. Rather than use these customized standards, public health agencies have chosen to develop customized clinical documentation architecture (CDA) Implementation Guides. These require far more effort and cost to implement than HQMF and Quality Reporting Document Architecture (QRDA) guides would take. We need ONC to lead a strategic effort to move all of Public Health reporting to a common set of structural and data standards. Different agencies and departments should not have the flexibility to choose their own direction.
  - Currently, doctors fill out manual reports on cancer patients where they state the date the patient was last seen, and whether or not cancer has recurred, patient alive, patient deceased, etc. This should be automated from the EHR.
- **Interoperability Need: Case Reporting to Public Health Agencies**
  - We assume that this standard is not permissive of duplicative manual documentation – but rather enabling of automating reporting of what is already captured in the EHR as structured information.
  - We urge ONC to work with appropriate federal health-related organizations to ensure that all appropriate standards are implemented broadly consistently, and rapidly. The government should take the lead in implementing health IT standards.
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- **Interoperability Need: Electronic Transmission of Reportable Lab Results to Public Health Agencies**
  - We assume that this standard is not permissive of duplicative manual documentation – but rather enabling of automating reporting of what is already captured in the EHR as structured information.
- **Interoperability Need: Sending Health Care Survey Information to Public Health Agencies**
  - We assume that this standard is not permissive of duplicative manual documentation – but rather enabling of automating reporting of what is already captured in the EHR as structured information.
  - We urge ONC to work with appropriate federal health-related organizations to ensure that all appropriate standards are implemented broadly consistently, and rapidly. The government should take the lead in implementing health IT standards.
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- **Interoperability Need: Reporting Syndromic Surveillance to Public Health (Emergency Department, Inpatient, and Urgent Care Settings)**
  - We assume that this standard is not permissive of duplicative manual documentation – but rather enabling of automating reporting of what is already captured in the EHR as structured information.
  - We urge ONC to work with appropriate federal health-related organizations to ensure that all appropriate standards are implemented broadly consistently, and rapidly. The government should take the lead in implementing health IT standards.
  - When the quality reporting standards were initially developed, enormous time and effort were devoted to ensure that the standards would meet all of the requirements of public health reporting. Rather than use these customized standards, public health agencies have chosen to develop customized CDA Implementation Guides. These require far more effort and cost to implement than HQMF and QRDA guides would take. We need ONC to lead a strategic effort to move all of Public Health reporting to a common set of structural and data standards. Different agencies and departments should not have the flexibility to choose their own direction.

- **II-Q: Research**
  - **Interoperability Need: Submission of Analytic Data to FDA for Research Purposes**
    - ONC is proposing that clinical systems implement an enormous number of standards to support research, but that are not relevant for care delivery. It is reasonable to expect research systems to support research standards, but it is not reasonable to expect clinical systems to absorb the cost of implementing all of these standards. Instead, ACP recommends ONC propose a single Application Programming Interface (API) that allows research systems to query and extract data from clinical systems.
  - **Interoperability Need: Pre-population of Research Forms from Electronic Health Records**
    - ONC is proposing that clinical systems implement an enormous number of standards to support research, but that are not relevant for care delivery. It is reasonable to expect research systems to support research standards, but it is not reasonable to expect clinical systems to absorb the cost of implementing all of these standards. Instead, ACP recommends ONC propose a single API that allows research systems to query and extract data from clinical systems.
  - **Interoperability Need: Integrate Healthcare and Clinical Research by Leveraging EHRs and other Health IT Systems while Preserving FDA's Requirements**
    - ONC is proposing that clinical systems implement an enormous number of standards to support research, but that are not relevant for care delivery. It is reasonable to expect research systems to support research standards, but it is not reasonable to expect clinical systems to absorb the cost of implementing all of these standards. Instead, ACP recommends ONC propose a single API that allows research systems to query and extract data from clinical systems.
  - **Interoperability Need: Complete Disease Registry Forms and Submit to Reporting Authority (ACC)**
    - ONC is proposing that clinical systems implement an enormous number of standards to support research, but that are not relevant for care delivery. It is reasonable to expect research systems to support research standards, but it is not reasonable to expect clinical systems to absorb the cost of implementing all of these standards. Instead, ACP recommends ONC propose a single API that allows research systems to query and extract data from clinical systems.

- **Interoperability Need: Registering a Clinical Trial**
  - We assume that this standard is not permissive of duplicative manual documentation – but rather enabling of automating reporting of what is already captured in the EHR as structured information.
  - ONC is proposing that clinical systems implement an enormous number of standards to support research, but that are not relevant for care delivery. It is reasonable to expect research systems to support research standards, but it is not reasonable to expect clinical systems to absorb the cost of implementing all of these standards. Instead, ACP recommends ONC propose a single API that allows research systems to query and extract data from clinical systems.
  
- **II-R: Segmentation of sensitive information**
  - **Interoperability Need: Document-Level Segmentation of Sensitive Information**
    - Some defined elements can be segmented, but as a general practice, this approach may lead to errors of omission and/or commission. The College looks forward to reviewing more details on what exactly is being proposed for this standard.
    - Is there a standard to label a record as being redacted when such information is removed?
    - This standard should not move forward until its safety has been evaluated thoroughly in many different settings.
  
- **II-S: Summary care record**
  - **Interoperability Need: Support a Transition of Care or Referral to Another Health Care Provider**
    - The biggest problem with this standard 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 not been addressed. ONC needs to address and fix these issues before proceeding.

### **Section III: Standards and Implementation Specifications for Services**

- **III-A: “Push” Exchange**
  - **Interoperability Need: An Unsolicited “Push” of Clinical Health Information to a Known Destination Between Individuals and Systems**
    - Direct and related standards are not supported, maintained, and updated by a formal Standards Developing Organization (SDO). This places our interoperability strategy in jeopardy. ONC should insist that these

- standards be properly supported before suggesting that their use be spread any further.
- **Interoperability Need: An Unsolicited “Push” of Clinical Health Information to a Known Destination Between Systems**
    - Nationwide Health Information Network (NwHIN) specifications and related standards are not supported, maintained, and updated by a formal SDO. This places our interoperability strategy in jeopardy. ONC should insist that these standards be properly supported before suggesting that their use be spread any further.
  - **III-B: Clinical Decision Support Services**
    - **Interoperability Need: Retrieval of Contextually Relevant, Patient-Specific Knowledge Resources from Within Clinical Information Systems to Answer Clinical Questions Raised by Patients in the Course of Care**
      - Will the standard be permissive of machine learning and/or pre-specified workflows – or just manual inquiries? Will the standard permit broader searches than what the clinician is looking for (e.g., finding an MRI result when only a CT result was requested)?
  - **III-D: Healthcare Directory, Provider Directory**
    - **Interoperability Need: Listing of Providers for Access by Potential Exchange Partners**
      - We support this proposal. However, the provider directory needs to include enough information about the provider so that a sender can identify who the provider is. The Provider directory should include a higher-level providers’ practice directory.
  - **III-G: Query**
    - **Interoperability Need: Query for Documents Outside a Specific Health Information Exchange Domain**
      - How feasible is this without a universal identifier?
      - NwHIN specifications are not supported, maintained, and updated by a formal SDO. This places our interoperability strategy in jeopardy. ONC should insist that these standards be properly supported before suggesting that their use be spread any further.
    - **Interoperability Need: Data Element Based Query for Clinical Health Information**
      - The College is not sure how feasible this is without a universal identifier.

## Section IV: Questions and Requests for Stakeholder Feedback

### Content/Structure

1. **Question:** For the existing interoperability need, “representing clinical health information as a resource,” public comments expressed this may not be the best language to describe this area. Please provide feedback on whether or not this is correct or recommend alternative language that better describes this interoperability need.

**Answer:** Instead of listing “Resource” as an interoperability need, the ISA should list Fast Healthcare Interoperability Resources (FHIR) as an emerging standard for each interoperability need where FHIR may apply.

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 Blair Hedgepeth, Senior Associate, Health IT Policy at [bhedgepeth@acponline.org](mailto:bhedgepeth@acponline.org).

Sincerely,

A handwritten signature in black ink, appearing to read 'P Basch', with a long horizontal flourish extending to the right.

Peter Basch, MD, MACP  
Chair, Medical Informatics Committee  
American College of Physicians