American College of Physicians
Leading Internal Medicine, Improving Lives

November 5, 2015

Karen DeSalvo, MD, MPH, MSc
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: 2016 Interoperability Standards Advisory, Draft for Comment

Dear Dr. DeSalvo,

The American College of Physicians (ACP), the largest medical specialty organization and second-largest physician group in the United States, representing 143,000 internal medicine specialists (internists), related subspecialists, and medical students, applauds ONC's efforts to identify and coordinate the best available interoperability standards for the health IT industry. We appreciate the invitation to comment, and thank you for the opportunity to provide input on these very important issues. We hope that you will find value in our responses. Attached to this letter are comments from the College's Medical Informatics Committee members on specific interoperability standards relevant to practicing Internists. Some of the key themes from the Committee's comments include:

Poorly Defined Interoperability Need

Throughout the Advisory document there is a pattern in which the interoperability need is not adequately defined. The College believes the success of interoperable health IT is not obtained by a data liquidity "flow meter," but rather by improving the health and safety of the American public through sharing meaningful, usable, and actionable information. For example, the current system for sharing partial information about medication allergies (as well as medications and problems) has led to a mandated permanent state of allergic fatigue. Improving the liquidity of poorly usable information is not helpful and the issues with interoperability will not be solved until we eliminate the concept that more data moved is more virtuous.

Clinical Effectiveness

Many of ACP's concerns with the Advisory document are centered on the mandated structured data fields that have interfered with the effectiveness of clinical medicine. For example, a requirement for additional occupational history taking and structured field completion will make the process much more burdensome and timely. This will be another example of electronic health records adding cost and leading to misuse of codes to compensate for the additional time spent completing the required fields.

The College does not agree with creating a structured field without absolute clarity on the rules and guidance for collection and use of that data. Furthermore, having patients fill out the mandated fields does not provide clarity or reduce clinician workload. The resulting documentation must then be attested to and signed by the clinician, which leads to the clinician then "owning" the implications of that documentation, whether the information contained is accurate, or relevant, or not. The Interoperability Standards Advisory should start with an explanation of the clinical value of collecting and transmitting each data element. The data must serve a clinical need and be actionable. If there is no clinical problem to be solved, then an alternative method for collecting the data would better serve the need. For example, much of the data of interest to public health are routinely collected and managed by other government agencies such as IRS, DoD, VA, and the Census Bureau.

Clinical Relevance

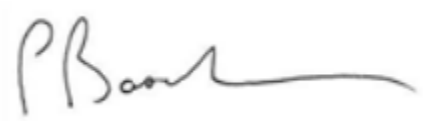
Given the result of several rollouts of immature standards, such as HL7 Continuity of Care Document and Health Quality Measures Format, the entire health IT community widely accepts that proposed standards must be tested sufficiently prior to selection. The problem now is the definition of the term sufficiently does not include clinical relevance, utility, and value as fundamental considerations. Standards & Interoperability Framework projects require pilot testing of proposed standards; however, the pilots do not include clinicians. Data elements must be evaluated against appropriate clinical needs to make sure that they are delivering better advice or alerting with increased sensitivity and specificity compared to what is already in use.

Issues with Public Reporting

It cannot be up to the individual doctor or other healthcare professional to seek out jurisdictional specifications and somehow deal with necessary modifications to reporting systems. All public reporting for all purposes should flow from the practice system to a single hub using a single set of standards. After that, it is up to the receivers of data to figure out how to ingest the data. Additionally, it is imperative that every public agency that requires submission of healthcare data must provide useful feedback to the reporting practice based on the data that practice submitted.

We thank you for seeking our input on these important issues, and hope that you will find value in our response. Should you have any questions, please contact Thomson Kuhn, Sr. Systems Architect, at tkuhn@acponline.org.

Sincerely,



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

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

I-A: Allergies

Interoperability Need: Representing patient allergic reactions

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	SNOMED-CT	Final	Production	●●●●○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• **ACP Comments:** The issue with interoperability of allergy information is a lack of standardization as to what is meant by an allergy or adverse reaction, or what the severity is. Selecting SNOMED is not sufficient to address the need. In this case, a subset of the vocabulary should be defined. Wherever available, appropriate HL7 value sets should be specified.	•

Interoperability Need: Representing patient allergens: medications

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	RxNorm	Final	Production	●●●●○	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• When a medication allergy necessitates capture by medication class, NDF-RT is best available (as recommended by the HIT Standards Committee)	• Feedback requested
• **ACP Comments:** Is this a question of vocabulary – or its impact on preventing errors of omission and commission? As with other standards described here, how will we determine if we are moving forward using health IT efficiently and effectively to better the health and healthcare of people?	•

I-B: Care Team Member

Interoperability Need: Representing care team member (health care provider)

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	National Provider Identifier (NPI)	Final	Production	●●○○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• For the purpose of recording a care team member, it should be noted that NPI permits, but does not require, non-billable care team members to apply for an NPI number to capture the concept of 'person'. • There is a SNOMED-CT value set for a "subjects role in the care setting" that could also be used in addition to NPI for care team members.	• Feedback requested
• **ACP Comments**: Is there a standard definition of what a "care team" member means (see ACP's position paper on Clinical Care Teams- http://annals.org/article.aspx?articleid=1737233), and is there any evidence of how its liquidity improves the care of people? This is an example where the drive towards satisfying a requirement has led to putting anything in a mandated field before there is clarity in how it is used.	•

I-C: Encounter Diagnosis

Interoperability Need: Documenting patient encounter diagnosis

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	SNOMED-CT	Final	Production	●●●●○	Yes	Free	N/A
Standard	ICD-10-CM	Final	Production	●●●●○	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• **ACP Comments:** Have both SNOMED-CT and ICD10 been evaluated against condition – medication interaction databases to make sure that they are leading to better alerting with increased sensitivity and specificity?	•

I-D: Race and Ethnicity

Interoperability Need: Representing patient race and ethnicity

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	OMB standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, Oct 30, 1997	Final	Production	●●●●●	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The CDC Race and Ethnicity Code Set Version 1.0, which expands upon the OMB standards may help to further define race and ethnicity for this interoperability need as it allows for multiple races and ethnicities to be chosen for the same patient. • The HIT Standards Committee noted that the high-level race/ethnicity categories in the OMB Standard may be suitable for statistical or epidemiologic purposes but may not be adequate in the pursuit of precision medicine and enhancing therapy or clinical decisions.	• Feedback requested
• **ACP Comments:** This is an example where much of what is filled out in the field reflects expediency and staff members' assumptions of patients' race and ethnicity. ACP agrees with the HIT Standards Committee's concerns that mandated race and ethnicity fields may not be adequate in the pursuit of precision medicine and enhancing therapy or clinical decisions. Once race and ethnicity became mandated fields, questions among practicing clinicians began. One point was clarified early on, at least for race, which for some it is objectionable that clinicians would even ask someone. This was clarified as "self-perception of race" – whose purpose is to collect data for purposes of studying, reducing, eliminating health disparities, otherwise known as public health research, not clinical care. It was clear from 2010, when this was first released, that the data collected could only be useful for self-identification for these non-clinical purposes. And even then, the categories that OMB set in 1997 were based on politics and lobbying by certain groups, and this categorization has not kept up with current immigration patterns. No one has yet explained to clinicians what purpose is served by having millions of people categorized as Hispanic or non-Hispanic?	•

Another problem is the lack of guidance in collecting data such as these. When and how often should these data elements be collected? The result of the current lack of guidance is conflicting data in different records.	

I-F: Functional Status/Disability

Interoperability Need: Representing patient functional status and/or disability

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	***[See Question 4-5]***						

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:

• **ACP Comments:** Is there a standard to functional status and disability, such that once that information is entered it can be mobilized downstream? ACP believes that fields should not be included without absolute clarity on the rules for collection and use. Additionally, having patients fill out the mandated fields does not provide clarity or reduce clinician workload as the resulting documentation is then attested and signed by the clinician – and the clinician then "owns" the implications of that documentation.
• ACP's Suggestions for the Field include:
  ○ 1 – If a patient has a % disability rating either from the military OR Social Security – then we have a field to capture % and reason;
  ○ 2 – There are fields to capture standard functional assessment and there is NO expectation that functional assessments are done, except where the service code pays for such assessments; or
  ○ 3 – There are fields to contain and faithfully transmit the functional assessments last done by a clinician – and the standard captures that information and date completed
	•

I-G: Gender Identity, Sex, and Sexual Orientation

Interoperability Need: Representing patient gender identity

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	SNOMED-CT	Final	Unknown	Unknown	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The HIT Standards Committee recommended collecting discrete structured data on patient gender identity, sex, and sexual orientation following recommendations issued in a report by The Fenway Institute and the Institute of Medicine.	• Feedback requested
• **ACP Comments:** These fields would work well when we have health IT tools that routinely capture patient entered data supplied by validated sources, that the questions posed are created by a body such that clinicians could reasonably implement what amounts to questions in a US Census, and that the answers are collected using trained staff and appropriate methodology – not by clinicians during a busy encounter. Otherwise, we are adding fields for data collection by clinicians that are likely to generate confusion, discomfort, and misunderstanding. At an absolute minimum, the corresponding billing definitions for cognitive services need to be adjusted. This process could take significant time with each patient. There will be an expectation that these fields will be populated by clinicians, confirmed on a regular basis, and required by CMS and by other payers.	•

Interoperability Need: Representing patient sexual orientation

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	SNOMED-CT	Final	Unknown	Unknown	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:

• The HIT Standards Committee recommended collecting discrete structured data on patient gender identity, sex, and sexual orientation following recommendations issued in a report by The Fenway Institute and the Institute of Medicine.	• Feedback requested
• ACP Comments: These fields would work well when we have health IT tools that routinely capture patient entered data supplied by validated sources, that the questions posed are created by a body such that clinicians could reasonably implement what amounts to questions in a US Census, and that the answers are collected using trained staff and appropriate methodology – not by clinicians during a busy encounter. Otherwise, we are adding fields for data collection by clinicians that are likely to generate confusion, discomfort, and misunderstanding. At an absolute minimum, the corresponding billing definitions for cognitive services need to be adjusted. This process could take significant time with each patient. There will be an expectation that these fields will be populated by clinicians, confirmed on a regular basis, and required by CMS and by other payers.	•

I-I: Industry and Occupation

Interoperability Need: Representing patient industry and occupation

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	***[See Question 4-5]***						

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• **ACP Comments:** Is this describing current occupation or complete occupational history? CDC clearly intends that clinicians gather a complete, life-long, structured employment history, and they are attempting to push a standard through HL7 that is clinically inappropriate. This is a case where clinicians should benefit from the availability of structured employment data collected by an authoritative source and delivered in the form of recommendations supplied by a CDS system. EHRs should not be cluttered with what CDC is proposing. Assume that everything proposed becomes required – and that there is now a requirement for additional history taking and structured field completion – and to what end? As we make patient history taking and documentation more burdensome, how will this	•

be compensated? When doctors raise their billing code level of service to reflect more time spent – why should we not expect another "shocking revelation" from the OIG that EHR use adds cost and leads to code creep?	

I-K: Medications

Interoperability Need: Representing patient medications

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	RxNorm	Final	Production	●●●●●	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• **ACP Comments:** Is there sufficient specificity to represent what is needed to know about medications in RxNorm? With medications as well as with other data elements, there is a giant uncertainty gap between standards work and the purpose it serves. For example, in the 5 years since the start of MU, do we not have a better understanding of what a med list represents and what uncertainty still exists (who is the prescriber, is the prescriber the person attributed with the med for cost purposes, is the prescribed the only person who may renew the med, etc.) Further – we have a host of new problems with mandated medication reconciliation by all specialties, such that patients who took none of their chronic meds at the time of a visit to a specialist find that their medication list has been deleted by clerical staff who are honestly documenting what they believe to be the relevant question of what medications are you currently taking?	•

I-M: Patient "problems" (i.e. conditions)

Interoperability Need: Representing patient "problems" (i.e., conditions)

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	SNOMED-CT	Final	Production	●●●●●	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• **ACP Comments:** Comments as to problem list coding already raised in I-K	•

Medications section. Selection of a large vocabulary without constraint and without usage guidance is unhelpful. In such cases, a subset should be defined and pointed to.	

I-N: Preferred Language

Interoperability Need: Representing patient preferred language

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	RFC 5646	Final	Production	Unknown	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• RFC 5646 encompasses ISO 639-1, ISO 639-2, ISO 639-3 and other standards related to identifying preferred language.	• Feedback requested
• **ACP Comments:** This is another example of a data element that requires specific collection guidance if it is to have any value in care delivery. Should this be more specific and capture whether the patient can clearly communicate and understand health and healthcare issues in one of the predominant languages of this country? Even more specifically, should this capture whether a translator is necessary and not whether someone who is fluent in English prefers to speak French?	•

I-Q: Smoking Status

Interoperability Need: Representing patient smoking status

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	SNOMED-CT	Final	Production	●●●●●	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• According to the HIT Standards Committee, there are limitations in SNOMED-CT for this interoperability need, which include not being able to capture severity of dependency, quit attempts, lifetime exposure, and use of e-Cigarettes.	• Feedback requested
• **ACP Comments:** What is mandated to be collected represents a forced lexicon that is not clinically helpful, and does not help with existing science	•

of tobacco cessation, nor decision making as to if CT scanning is appropriate for screening for lung cancer. This is another example of how mandated structured data collection has interfered with the effectiveness of clinical medicine. We agree with HITSC's concerns, however, their concerns only scratch the surface. The MU smoking status requirement is the poster child for forcing useless structure on clinicians.	

I-S: Vital Signs

Interoperability Need: Recording patient vital signs

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	LOINC	Final	Production	●●●●●	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• **ACP Comments:** This is another area where specific guidance regarding data collection is required if the resulting data are to be clinically useful. As described by a member working in a system that is a partner with Million Hearts, a health system that is committed to improving blood pressure control - they have discovered how interoperability is making the perception of blood pressure control worse. Resting blood pressure that is deemed accurate and reliable and suitable to submit as a measure of BP control is not kept separate from BPs taken during acute trauma or illness – even though the measure definition clearly states that this nuance should be taken into consideration. Mobilizing vital signs without context or meta-tags does not serve patients and does not serve legitimate efforts to improve quality.	•

Section II: Best Available Content/Structure Standards and Implementation Specifications

II-B: Care Plan

Interoperability Need: Documenting patient care plans

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	No	Free	No
Implementation Specification	HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Release 2.1	Draft	Pilot	Unknown	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• **ACP Comments:** Is it accurate that the standards are final and the adoption level is 100 percent? Is available standard serving the goal of using health IT effectively and efficiently to make care better and safer?	•

II-D: Drug Formulary & Benefits

Interoperability Need: The ability for pharmacy benefit payers to communicate formulary and benefit information to prescribers systems

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	NCPDP Formulary and Benefits v3.0	Final	Production	●●●●●	Yes	$	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The HIT Standards Committee noted that the NCPDP Real Time Prescription Benefit Inquiry (RTPBI) is an alternative in development that should be monitored as a potential emerging alternative.	• Feedback requested
• **ACP Comments:** The HIT Standards Committee note is correct as far as it goes. There is a large gap now between what has been made interoperable, and what has been done toward making the correct information timely and usable. RTPBI would be a nice addition, but only if it works as we all intend. Unfortunately, many of the functions of the current e-prescribing system do not work properly and/or cause additional work that was not intended. To make matters worse, ONC and many of the major stakeholders in health IT have declared victory on e-prescribing and moved on – leaving clinicians alone in their struggle to serve their patients	•

with a system that seems to fight them at every turn. ○ Currently, SureScripts has enabled plan level, or sub-plan level information, that has no quality control. The only QC process in effect now is that if the format is wrong, it gets rejected. SureScripts only knows if content is wrong or corrupted when customers complain. ○ The current information is not easy to understand, even when it is present and correct. ○ The mandated display from SureScripts – of all alternatives – is not helpful, as no reasonable person would ever look for more costly alternatives. ○ Where prior authorization exists, there is no explanation as to why, and no ability to select a covered alternative. ○ Copay information is not available. ○ Doctors do not know if a patient can get 30 or 90 day coverage at the pharmacy, so they often write the same prescription multiple times to see which format gets accepted. ○ A common problem with e-prescribing and structured electronic medication lists is that you cannot easily tell the difference between ophthalmic, otic, and IV solutions. Further, dermatology products as well as eye and ear products (where liquid or creams are prescribed) do not readily show what sizes they come in. Doctors used to write such things as "small tube." That doesn't work anymore. This same unintended consequence occurs with inhalers, where the pharmacist expects doctors to know how many grams come in the inhaler, instead of prescribing "#1." ○ Overall – how can we expect prescribers and patients to work together on reasonably lowering costs when the information made available at the point of prescribing is not accurate, transparent, or useable?	

II-E: Electronic Prescribing

Interoperability Need: A prescriber's ability to create a new prescription to electronically send to a pharmacy

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	NCPDP SCRIPT Standard, Implementation Guide, Version 10.6	Final	Production	●●●●●	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The "New Prescription" transaction is best suited for this interoperability need. • Both the prescriber and the receiving pharmacy must have their systems configured for the transaction in order to facilitate successful exchange.	• Feedback requested
• **ACP Comments:** Is there a character limit to the instructions field? For many doctors who often use tapering instructions, the existing standard often got in the way - either because they couldn't enter it, or because of a character limit.	•

Interoperability Need: Prescription refill request

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	NCPDP SCRIPT Standard, Implementation Guide, Version 10.6	Final	Production	●●●●○	No	$	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The "Refill Request" transaction is best suited for this interoperability need. • Both the prescriber and the receiving pharmacy must have their systems configured for the transaction in order to facilitate successful exchange.	• Feedback requested
• **ACP Comments:** This works, but not as well as it could. The existing standard for a renewal request is for # of pills and total fill #. Doctors use dispense # and refill #. The problem is that with Rx renewal requests, when they think they are renewing a 12 month prescription, it is really only 11 months. Further, the renewal request comes to the last prescriber – who may be a covering doctor at night or on the weekend. The existing standard does not acknowledge that renewing on behalf of someone else should not result in any involvement later on.	•

Interoperability Need: Cancellation of a prescription

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	NCPDP SCRIPT Standard, Implementation Guide, Version 10.6	Final	Production	Unknown	No	$	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The "Cancel" transaction is best suited for this interoperability need.	• Feedback requested

• Both the prescriber and the receiving pharmacy must have their systems configured for the transaction in order to facilitate successful exchange.	
• **ACP Comments:** Does this also remove a medication from the patient's profile? This standard may require some clinician scrutiny in order to determine usability/usefulness.	•

Interoperability Need: Pharmacy notifies prescriber of prescription fill status

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	NCPDP SCRIPT Standard, Implementation Guide, Version 10.6	Final	Production	Unknown	No	$	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The "Fill Status" transaction is best suited for this interoperability need. • Both the prescriber and the receiving pharmacy must have their systems configured for the transaction in order to facilitate successful exchange.	• Feedback requested
• **ACP Comments:** Does this capture clinically useful information such as timely fill of an antibiotic vs. regular fill of an ongoing medication?	•

Interoperability Need: A prescriber's ability to obtain a patient's medication history

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	NCPDP SCRIPT Standard, Implementation Guide, Version 10.6	Final	Production	●●●○○	No	$	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The "Medication History" transaction is best suited for this interoperability need. • Both the prescriber and the receiving pharmacy must have their systems configured for the transaction in order to facilitate successful exchange.	• Feedback requested
• **ACP Comments:** Most electronic medication histories are not particularly useful – except as conversation starters. The current standard should address the need for sharing meaningful, usable, and actionable information.	•

II-F: Family health history (clinical genomics)

Interoperability Need: Representing family health history for clinical genomics

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	HL7 Version 3 Standard: Clinical Genomics; Pedigree	Final	Production	●○○○○	Yes	Free	No
Implementation Specification	HL7 Version 3 Implementation Guide: Family History/Pedigree Interoperability, Release 1	Final	Production	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• According to the HIT Standards Committee, there is no available vocabulary to capture family genomic health history. • According to the HIT Standards Committee, further constraint of this standard and implementation specification may be required to support this interoperability need.	• Feedback requested
• **ACP Comments:** What are the implications of this standard regarding obligation for data collection and use? If there is no available vocabulary, and with the exception of certain cancers and perhaps other genetic diseases, there is not even a concept of a family genomic pedigree.	•

II-H: Laboratory

Interoperability Need: Receive electronic laboratory test results

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	HL7 2.5.1	Final	Production	●●●●●	No	Free	No
Implementation Specification	HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1—US Realm [HL7 Version 2.5.1: ORU_R01] Draft Standard for Trial Use, July 2012	Final	Production	●●●●○	Yes	Free	Yes
Emerging Alternative Implementation Specification	*HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Results Interface Implementation Guide, Release 1 DSTU Release 2 - US Realm* *[no hyperlink available yet]*	*Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• HL7 Laboratory US Realm Value Set Companion Guide, Release 1, September 2015, provides cross-implementation guide value set definitions and harmonized requirements.	• Feedback requested
• **ACP Comments:** Will the result be to make electronic ordering and resulting more plug and play? While we are trying to invent use cases that force interoperability in unneeded areas, the ability for clinicians to send orders and receive results still requires expensive one-off interfaces. Until the need for separate lab interfaces is banished, we cannot declare victory in this area.	•

II-I: Patient Education Materials

Interoperability Need: A standard mechanism for clinical information systems to request context-specific clinical knowledge form online resources

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	HL7 Version 3 Standard: Context Aware Knowledge Retrieval Application. ("Infobutton"), Knowledge Request, Release 2.	Final	Production	●●●●○	Yes	Free	No
Implementation Specification	HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1.	Final	Production	●●●○○	No	Free	No
Implementation Specification	HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton), Release 4.	Final	Production	●●●○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• **ACP Comments:** The existing standard is fine, but the companion MU requirement is concerning, where measurement of the provision of educational material is based on a prescriptive process measure that was built from this specification. It always takes more time to click an Infobutton and select a handout, and then select language – than to have this function more embedded into EHR workflow. Use of a standard should not be required where there are simpler ways to perform the function, and interoperability is not hampered.	•

II-J: Patient Preference/Consent

[See Question 4-9]

Interoperability Need: Recording patient preferences for electronic consent to access and/or share their health information with other care providers

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Implementation Specification	IHE Basic Patient Privacy Consents (BPPC)	Final	Production	●●●●○	No	Free	No
Implementation Specification	IHE Cross Enterprise User Authorization (XUA)	Final	Production	●●●●○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• **ACP Comments:** How do these specifications relate to the process of managing patient preferences regarding data sharing? These specifications are insufficient by themselves to meet the use case of managing patient preferences. Doctors assume that these specifications are not applicable where information is shared for purposes of TPO. If the intention is to include use of preferences in TPO exchanges, then doctors and other healthcare professionals must be made aware of this intention and given opportunities to participate in any discussions of this topic.	•

II-K: Public Health Reporting

Interoperability Need: Reporting antimicrobial use and resistance information to public health agencies

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	No	Free	No
Implementation Specification	HL7 Implementation Guide for CDA® Release 2 – Level 3: Healthcare Associated Infection Reports, Release 1, U.S. Realm.	Final	Production	●●○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• This is a national reporting system to CDC. Stakeholders should refer to	• Feedback requested

implementation guide for additional details and contract information for enrolling in the program.	
• **ACP Comments:** ACP was not aware that antimicrobial reporting was at the production level; nor that CDC or other agencies were equipped to receive these reports. Requirements for interoperability at the provider end should only go forward in tandem with similar requirements on the receiver end.	•

Interoperability Need: Reporting cancer cases to public health agencies

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	No	Free	No
Implementation Specification	HL7 Implementation Guide for CDA® Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1 - US Realm	Draft	Production	●●●○○	Yes	Free	Yes
Emerging Alternative Implementation Specification	*HL7 CDA ® Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1, DSTU Release 1.1 – US Realm*	*Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Stakeholders should refer to the health department in their state or local jurisdiction to determine onboarding procedures, obtain a jurisdictional implementation guide if applicable, and determine which transport methods are acceptable for submitting cancer reporting data as there may be jurisdictional variation or requirements.	• Feedback requested
• **ACP Comments:** It is concerning that there is an effort to create interoperability standards which could be meaningless depending on the jurisdiction. It cannot be up to the individual doctor or other healthcare professional to seek out jurisdictional specifications and somehow deal with necessary modifications to reporting systems. All public reporting for all purposes should flow from the practice system to a single hub using a single set of standards. After that, it is up to the receivers of data to figure out how to ingest the data. Also it is imperative that every public agency that requires submission of healthcare data must supply useful responses based on the data supplied back to the reporting practice.	•

Interoperability Need: Case reporting to public health agencies

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
(1) Implementation Specification	IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation, HL7 Consolidated CDA® Release 2.0	Draft	Pilot	●○○○○	No	Free	No
(2) Standard	Fast Healthcare Interoperability Resources (FHIR)	Draft	Pilot	●○○○○	No	Free	No
(2) Implementation Specification	Structured Data Capture Implementation Guide	Draft	Pilot	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Electronic case reporting is not wide spread and is determined at the state or local jurisdiction.	• Feedback requested`
• **ACP Comments:** Same as comments from II-K "Reporting cancer cases to public health agencies"	•

Interoperability Need: Electronic transmission of reportable lab results to public health agencies

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	HL7 2.5.1	Final	Production	●●●●●	Yes	Free	No
Implementation specification	HL7 Version 2.5.1: Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm), Release 1 with Errata and Clarifications and ELR 2.5.1 Clarification Document for EHR Technology Certification	Final	Production	●●●●●	Yes	Free	Yes
Emerging Alternative Implementation Specification	*HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 2 (US Realm), Draft Standard for Trial Use, Release 1.1*	*Draft*	*Pilot*	*Unknown*	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Stakeholders should refer to the health department in their state or local jurisdiction to determine onboarding procedures, obtain a jurisdictional implementation guide if applicable, and determine which transport methods are acceptable for submitting ELR as there may be jurisdictional variation or requirements.	• Feedback requested

• ACP Comments: Same as comments from II-K "Reporting cancer cases to public health agencies"	•

Interoperability Need: Sending health care survey information to public health agencies

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	No	Free	No
Implementation Specification	HL7 Implementation Guide for CDA® R2: National Health Care Surveys (NHCS), Release 1 - US Realm ***[See Question 4-6]***	Draft	Pilot	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• This is a national reporting system to CDC. Stakeholders should refer to the National Health Care Survey Program at: http://www.cdc.gov/nchs/nhcs/how_to_participate.htm for information on participation.	• Feedback requested
• **ACP Comments:** Same as comments from II-K "Reporting cancer cases to public health agencies"	•

Interoperability Need: Reporting administered immunizations to immunization registry

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	HL7 2.5.1	Final	Production	●●●●●	Yes	Free	No
Implementation Specification	HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.4	Final	Production	●●●●●	Yes	Free	Yes
Emerging Alternative Implementation Specification	*HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5*	*Final*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Stakeholders should refer to the health department in their state or local	• Feedback requested

jurisdiction to determine onboarding procedures, obtain a jurisdictional implementation guide if applicable, and determine which transport methods are acceptable for submitting immunization registry data as there may be jurisdictional variation or requirements.	
• **ACP Comments:** Same as comments from II-K" Reporting cancer cases to public health agencies"	•

Interoperability Need: Reporting syndromic surveillance to public health (emergency department, inpatient, and urgent care settings)

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	HL7 2.5.1	Final	Production	●●●●●	Yes	Free	No
Implementation Specification	PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data Release 1.1	Final	Production	●●●●○	Yes	Free	Yes
Emerging Alternative Implementation Specification	*PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings, Release 2.0*	*Final*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Stakeholders should refer to the health department in their state or local jurisdiction to determine onboarding procedures, obtain a jurisdictional implementation guide if applicable, and determine which transport methods are acceptable for submitting syndromic surveillance data as there may be jurisdictional variation or requirements.	• Feedback requested
• **ACP Comments:** Same as comments from II-K "Reporting cancer cases to public health agencies"	•

II-N: Segmentation of sensitive information

Interoperability Need: Document-level segmentation of sensitive information

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	No	Free	No
Implementation Specification	Consolidated HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1	Final	Pilot	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• **ACP Comments:** Physicians and other clinicians must have a voice in the development of the test plan for this standard. We are concerned about the likelihood of unintended consequences, and whether this segmentation may result in changed meaning to the recipient.	•

II-O: Summary care record

Interoperability Need: Support a transition of care or referral to another provider

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	No	Free	No
Implementation Specification	Consolidated CDA® Release 1.1 (HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 - US Realm)	Draft	Production	●●●●●	Yes	Free	Yes
Emerging Alternative Implementation Specification	*HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Release 2.1*	*Draft*	*Pilot*	*Unknown*	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• There are several specific document templates within the C-CDA implementation specification. Trading partners will need to ensure that their systems are capable of supporting specific document templates.	• Feedback requested
• **ACP Comments**: The required components of the ToC referral make this document often unreadable and difficult to use. Improving liquidity of poorly usable information is not helpful.	•

Section III: Best Available Standards and Implementation Specifications for Services

III-D: Provider Directory

Interoperability Need: Listing of providers for access by potential exchange partners

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Implementation Specification	IHE IT Infrastructure Technical Framework Supplement, Healthcare Provider Directory (HPD), Trial Implementation	Draft	Pilot	●○○○○	No	Free	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• **ACP Comments:** Has this been tested for usability? Is the specification such that you can readily tell who you are sending something to (e.g., specialty, phone number, address, NPI, etc.)?	•

III-F: Query

Interoperability Need: Query for documents within a specific health information exchange domain

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Implementation Specification	IHE-XDS (Cross-enterprise document sharing)	Final	Production	●●●●○	No	Free	No
Implementation Specification	IHE-PDQ (Patient Demographic Query)	Final	Production	●●●●○	No	Free	No
Implementation Specification	IHE-PIX (Patient Identifier Cross-Reference)	Final	Production	●●●●○	No	Free	No
Emerging Alternative Implementation Specification	*IHE – MHD (Mobile Access to Health Documents)*	*Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• IHE-PIX and IHE-PDQ are used for the purposes of patient matching and to support this interoperability need.	• Feedback requested

• **ACP Comments:** Similar question to one posed above in III-D "Listing of providers for access by potential exchange partners" - Has any clinician tested the implications of this standard working – and thus has been able to confirm that the vocabulary / subject lines make this query useful and usable?	•

Interoperability Need: Query for documents outside a specific health information exchange domain

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Implementation Specifications	the combination of IHE-XCPD (Cross-Community Patient Discovery) and IHE-PIX (Patient Identifier Cross-Reference)	Final	Production	●●●●○	No	Free	No
Implementation Specification	NwHIN Specification: Patient Discovery	Final	Production	●●●○○	No	Free	No
Implementation Specifications	IHE-XCA (Cross-Community Access) further constrained by eHealth Exchange Query for Documents v 3.0	Final	Production	●●●●○	No	Free	No
Implementation Specification	NwHIN Specification: Query for Documents	Final	Production	●●●○○	No	Free	No
Implementation Specification	NwHIN Specification: Retrieve Documents	Final	Production	●●●○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• IHE-PIX and IHE-XCPD are used for the purposes of patient matching and to support this interoperability need.	• **System Authentication** - The information and process necessary to authenticate the systems involved • **User Details** - identifies the end user who is accessing the data • **User Role** - identifies the role asserted by the individual initiating the transaction • **Purpose of Use** - Identifies the purpose for the transaction • **Patient Consent Information** - Identifies the patient consent information that may be required before data can be accessed. • **Query Request ID** - Query requesting application assigns a unique identifier for each query request in order to match the response to the original query.

• **ACP Comments:** Similar question to one posed above in III-D "Listing of providers for access by potential exchange partners" - Has any clinician tested the implications of this standard working – and thus has been able to confirm that the vocabulary / subject lines make this query useful and usable? The standards labeled "NwHIN Specification" seem to be under the control of an organization that has reorganized twice since these standards were created. ONC should acknowledge the risk presented by recommending standards that are not maintained by an SDO.	•