33 West Monroe, Suite 1700
Chicago, IL 60603-5616
Phone: (312) 664-4467
Fax: (312) 664-6143
www.iheusa.org

March 21, 2016

Karen DeSalvo, MD, MPH, MSc
National Coordinator
Office of the National Coordinator for Health IT
Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

Dear Dr. DeSalvo,

On behalf of Integrating the Healthcare Enterprise USA (IHE USA), we are pleased to provide written comments to the Office of the National Coordinator for Health Information Technology (ONC) in response to the 2016 Interoperability Standards Advisory. IHE appreciates the opportunity to leverage our members' expertise in commenting on the Standards Advisory, and we look forward to continuing our dialogue with ONC on identifying, assessing, and determining the best available interoperability standards and implementation specifications. We feel that this effort will provide the necessary foundation for more rapidly advancing interoperability in our country.

IHE USA is a 501.c.3 not for profit organization founded in 2010. Its vision is to improve the quality, value, and safety of healthcare by enabling rapid, scalable, and secure access to health information at the point of care. IHE USA operates as a national deployment committee of IHE International in order to advance its mission to improve U.S. healthcare by promoting the adoption and use of IHE and other world-class standards, tools, and services for interoperability. IHE USA engages all levels of public and private sector participants to test, implement and use standards-based solutions for all health information needs. Since 1998, IHE has achieved global consensus on a common framework for applying health IT standards in the real world.

IHE USA's primary observations focus on the following issues:

1. **IHE USA appreciates that ONC has included Value Sets in Section I of the 2016 Interoperability Standards Advisory (ISA) to advance the achievement of nationwide interoperability.**
   - IHE USA would like to suggest a centralized repository be provided for all value sets (code subsets) used in the 2015 Edition Health IT Certification Criteria Rule. Some value sets are mentioned in the 2015 Edition Health IT Certification Criteria Rule but are not available for download and other value sets are "concealed" within implementation specification (e.g. C-CDA®). The industry needs a centralized repository of all value sets that is filterable (at the least) by the Health IT

Certification Criteria Rule version and implementation specification name.

- IHE USA would also note that a centralized repository would be a valuable tool to ensure consistent development of value sets by all participating authors. These repositories are efficient for search and retrieval of value sets, specifically in cases where value sets are similar in their naming convention or the code sets they contain.

2. **IHE USA applauds ONC on the six new informative characteristics that have been included for best available standards, implementation specifications and the addition of a section for security patterns.**
   - ONC's inclusion of the six new informative characteristics and security patterns are helpful to the healthcare IT community; specifically to the developers and implementers which enable them to make better informed decisions about a standards maturity and adoptability.
   - Specific to the adoption level characteristic, IHE USA would like clarification on how the adoption level is calculated. What is the denominator for each standard? Adoption levels may be high or lower depending on the denominator. We also observe that the adoption level of base standards like CDA® R2 does not seem relevant and is misleading, since CDA® R2 is the basis of many different implementation specifications which are at different levels of adoption.
   - IHE USA also recommends the implementation specifications and adoption levels that are listed should be paired up more consistently. Implementation specifications are based on the foundational standards. As you know, if implementation specifications are not utilized then associated standards are not utilized. In order to address possible underuse of the standard and accompanying implementation specification, IHE USA recommends publishing a slope of the adoption curve. Please also clarify if adoption of the standard is increasing rapidly or is the adoption in fact declining as a standard is replaced by one that is more interoperable?

3. **IHE USA commends ONC for separating out some of the Interoperability Needs where LOINC represents the question vs. where SNOMED-CT represents the answer, where applicable.**
   - IHE USA recommends that when data elements are separated into questions and answers they should be spelled-out for readers not familiar with the questions. Questions are typically encoded using LOINC and Values can be encoded using other systems. We encourage ONC to consistently clarify how the data elements are articulated and the distinction between the question and answer in each of these sections.

In the attached Excel template are the detailed comments to the 2016 Interoperability Standards Advisory, which are submitted in collaboration with HIMSS.

We appreciate the opportunity to submit comments on the 2016 Interoperability Standards Advisory. Our comments are intended to recognize the importance of each stakeholder's role in advancing standards-based interoperability and health information exchange, and ensuring that each domain is invested in overcoming the inherent challenges, while further enhancing health IT's pivotal role in enabling healthcare transformation.

We welcome the opportunity to meet with you and your team to discuss our comments in more depth. Please feel free to contact Joyce Sensmeier, President, IHE USA at 312-915-9281, or Celina Roth, IHE Liaison, at 312-915-9213, with questions or for more information. Thank you for your consideration.

Sincerely,

Joyce Sensmeier, MS, RN-BC, CPHIMS, FHIMSS, FAAN
President, IHE USA

Attachment: Excel template response to ONC's 2016 Interoperability Standards Advisory

Commenter Name/Title: HIMSS Standards Advisory Task Force
Organization: HIMSS and IHE-USA
Email: efleet@himss.org and jhout@himss.org

Comment Template Instructions: Please select a topic and section from the dropdown list for each comment provided. Where more than one interoperability need or standard/implementation specification exists, please identify the applicable interoperability needs or standard/implementation specification. If your comment has a specific request for action, please include it in the "Comment (Request for Action)" column. Where no action is required (e.g., comments in support of currently listed standrds, etc), please use the "Comment (No Action)" column. Where possible, use of a new row for individual recommendations is preferred. The deadline for comment submissions is at 5 p.m. on Monday, March 21, 2016. If more time is needed, please contact Chris Muir at Christopher.Muir@hhs.gov to request an extension. Comments can be submitted at https://www.healthit.gov/standards-advisory/2016. Please **do not convert this template to a PDF file** for submission. Thank you for your ongoing participation and engagement with the ISA process.

Topic	Section	Interoperability Need	Standard/Implementation Specification	Comment (No Action)	Comment (Request for Action)
"Best Available" Characteristics					HIMSS suggests adding a definition of what an emerging standard is to distinguish between the terms final, balloted draft, production and pilot. How does ONC distinguish between pilots and emerging standards?
"Best Available" Characteristics					IHE would like to recommend adding a characteristic for who owns the standard.
Section I: Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specifications	Section I-A: Allergies	Representing patient allergic reactions	SNOMED-CT		HIMSS urges ONC to incorporate generic names. Allergies should be able to be viewed, using either the Generic Name or the Trade (Brand) Name.
Section I: Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specifications	Section I-A: Allergies	Representing patient allergies: food substances	SNOMED-CT	HIMSS would like to note that this could be included in future CMS Regulations such as changes to MU3 or a MACRA rule.	
Section I: Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specifications	Section I-A: Allergies	Representing patient allergies: environmental substances	SNOMED-CT	HIMSS would like to note that this could be included in future CMS Regulations such as changes to MU3 or a MACRA rule. Use SNOMED CT substance codes, consistent with C-CDA.	
Section I: Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specifications	Section I-B: Health Care Provider	Representing care team member (healthcare provider)	National Provider Identifier (NPI)	HIMSS would like note that when the use of the NPI for non-billable providers becomes of higher value, there will likely be more adoption.	
Section I: Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specifications	Section I-C: Encounter Diagnosis	Representing patient medical encounter diagnosis	SNOMED-CT ICD-10 - CM	Both SNOMED-CT and ICD-10-CM are listed, “Final”, in “Production”, “Federally Required”, with high adoption. There should be some constraints put on this; such as SNOMED-CT being used for clinical records and ICD-10-CM for claims submission. HIMSS cautions the ISA on suggesting that they are interchangeable. The discussion could be more focused be on Diagnosis, not on Problems. Use equivalent code system as the one used for patient problems - SNOMED CT. Providers may, if they choose so, supply codes from ICD-10; however SNOMED CT code must always be supplied.	
Section I: Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specifications	Section I-D: Race and Ethnicity	Representing patient race and ethnicity	OMB Standards for Maintaining, Collecting and Presenting Federal Data on Race and Ethnicity		HIMSS suggests using the race and ethnicity code systems and value sets that are consistent with C-CDA. Also consider defining standards for capturing proteomics and genomics data, which may ultimately supersede OMB and CDC race and ethnicity categories due to higher level of precision. See next section(Family Health History) for recommended genomic data standards.
Section I: Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specifications	Section I-E: Family Health History	Representing patient family history	SNOMED-CT	HIMSS agrees with the comments listed. However, there is a need to augment clinician workflow related to Family History to include Genomics and genomic data.	
Section I: Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specifications	Section I-F: Functional Status/Disability	Representing patient functional status and/or disability		HIMSS agrees that functional status is very important to patient care (specifically hard of hearing, limited visibility, prone to falls) and should be included in the ISA.	HIMSS recommend adding the following applicable Value Sets: Functional Status Identifier: LOINC For symptoms/problems. Value Set: Problem urn:oid:2.16.840.1.113883.3.88.12.3221.7.4 (SNOMED-CT code system) Self-care: Value Set: Ability 2.16.840.1.113883.11.20.9.46 Value Set: ADL Result Type 2.16.840.1.113883.11.20.9.47
Section I: Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specifications	Section I-H: Immunizations	Representing immunizations - historical	HL7 Standard Code Set - Clinical Vaccines Administered (CVX) HL7 Standard Code Set - Manufacturing Vaccine Fomrulation (MVX)	HIMSS agress that both CVX and MVX standards should be listed. This is a good example where “Limitations…” lists the conditions under which MVX should be considered, and should be the model for other items that list multiple standards. CVX is the more important code, regarding the vaccine administered.	

Commenter Name/Title: HIMSS Standards Advisory Task Force
Organization: HIMSS and IHE-USA
Email: efleet@himss.org and jhout@himss.org

Comment Template Instructions: Please select a topic and section from the dropdown list for each comment provided. Where more than one interoperability need or standard/implementation specification exists, please identify the applicable interoperability needs or standard/implementation specification. If your comment has a specific request for action, please include it in the "Comment (Request for Action)" column. Where no action is required (e.g., comments in support of currently listed standrds, etc), please use the "Comment (No Action)" column. Where possible, use of a new row for individual recommendations is preferred. The deadline for comment submissions is at 5 p.m. on Monday, March 21, 2016. If more time is needed, please contact Chris Muir at Christopher.Muir@hhs.gov to request an extension. Comments can be submitted at https://www.healthit.gov/standards-advisory/2016. Please **do not convert this template to a PDF file** for submission. Thank you for your ongoing participation and engagement with the ISA process.

Topic	Section	Interoperability Need	Standard/Implementation Specification	Comment (No Action)	Comment (Request for Action)
Section I: Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specifications	Section I-H: Immunizations	Representing immunizations - administered	HL7 Standard Code Set - Clinical Vaccines Administered (CVX) National Drug Code (NDC)		HIMSS proposes using two code systems: RxNorm and CVX We suggest using RxNorm code system (over CVX) to capture patient-specific immunization information because RxNorm is also used in allergic reactions in C-CDA. CVX can be used for statistical (aggregate) purposes. Both CVX and NDC are listed, “final”, in “production”, with high adoption. However, both appear to be insufficient. Perhaps this one is best as stated – two “best available” standards, neither sufficient, and therefore identifying a gap in the standards. However, no gap is evident on first inspection. Perhaps there needs to be a way to indicate that a gap exists – something the current structure does not allow. The current approach lists “Standard” and “Emerging Alternative Standard” as alternatives in the first column. Perhaps a third option – “Standard with Identified Gap” – should be added, and used for both terminologies in this section.
Section I: Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specifications	Section I-H: Immunizations	Representing immunizations - administered	HL7 Standard Code Set - Clinical Vaccines Administered (CVX) National Drug Code (NDC)		Adoption level is set to 5 but we see many vendors not sending this data or they only send administer but not historical. One vendor recently told us they would only send this data if we were an immunization registry. HIMSS would suggest lowering this to a 4. The table beneath the standards and implementation specifications includes limitations, dependencies, and preconditions. Given the enhancements made, please comment on accuracy and completeness and where information gaps remain, forward applicable content.
Section I: Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specifications	Section I-I: Industry and Occupation	Representing patient and industry occupation	*See Question #4 - Questions and requests for stakeholder feedback*		At this time HIMSS does not endorse this standard for inclusion, it can be clinically relevant but not enough to be included. Suggest using value sets defined by CDC (CDC_REC). Applicable Value Sets: “PHVS_Industry_CDC_Census2010” (urn:oid:2.16.840.1.114222.4.11.7187) “PHVS_Occupation_CDC_Census2010” (urn:oid:2.16.840.1.114222.4.11.7186)
Section I: Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specifications	Section I-J: Lab Tests	Representing numerical laboratory test results (observations	LOINC	Regarding LOINC Codes, HIMSS encourages ONC to look at the work from the ONC S&I Framework regarding Laboratory Orders and Laboratory Results.	
Section I: Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specifications	Section I-K: Medications	Representing patient medications	RxNorm National Drug Code (NDC) National Drug File - Reference Terminology (NDF-RT)		Three terminologies are listed, with comments on the limitations of each one. However, what is not obvious is an “advised” course of action if a vendor is implementing a product. That would seem to be valuable. HIMSS would like clarification on what the recommendation should be.
Section I: Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specifications	Section I-N: Preferred Language	Representing patient preferred language	RFC 5646		HIMSS would like ONC to consider having language of (at) birth. Also, add present (preferable) language. ONC may also want to add dialect. In some regions, the dialect is very important. Some speaking the same language with a different dialect may not be able to easily verbally communicate.
Section I: Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specifications	Section I-O: Procedures	Representing medical procedures performed	SNOMED-CT ICD-10-PCS the combination of CPT-4/HCPCS		HIMSS encourages ONC to explore the development of value sets for observational (X-ray, labs), interventional and other procedures. We would also like to note that ICD-10-PCS is only for Inpatient Procedures. Outpatient Procedures are not coded in ICD-10-PCs.
Section I: Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specifications	Section I-O: Procedures	Representing dental procedures performed	Code on Dental Procedures and Nomenclature (CDT)	HIMSS agress that CDT should remain the standard for procedures throughout the dental sphere in the United States. In addition, it is the recognized terminology for dental claims submission, much like CPT and ICD10 for medical claims.	
Section I: Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specifications	Section I-P: Imaging (Diagnostics, interventions and procedures)	Representing imaging diagnotics, interventions and procedures	LOINC		HIMSS urges ONC to consider adding the LOINC Value Set for Radiology procedures. Also please provide clarification on why DICOM, the standard for PACS Images is not included here.
Section I: Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specifications	Section I-Q: Tobacco Use (Smoking Status)	Representing patient tobacco use (smoking status) observation result values or assertions (answers)	SNOMED-CT		The informational value of the values (8 SNOMED CT codes) within the existing "Smoking Status" value set has extremely limited clinical and epidemiological value. HIMSS proposes an addition of several new DEs to capture mora granularly smoking habits such as tobacco type, frequency, duration and quantity. Also please consider adding the type of inhalant, pack-years for cigarettes. Tobacco: smoked or chewed? Age started, aged stopped? There is also a need to capture secondary (second hand) smoking. For example, the patient does not smoke; however, others at the home currently smoke.

Commenter Name/Title: HIMSS Standards Advisory Task Force
Organization: HIMSS and IHE-USA
Email: efleet@himss.org and jhout@himss.org

Comment Template Instructions: Please select a topic and section from the dropdown list for each comment provided. Where more than one interoperability need or standard/implementation specification exists, please identify the applicable interoperability needs or standard/implementation specification. If your comment has a specific request for action, please include it in the "Comment (Request for Action)" column. Where no action is required (e.g., comments in support of currently listed standrds, etc), please use the "Comment (No Action)" column. Where possible, use of a new row for individual recommendations is preferred. The deadline for comment submissions is at 5 p.m. on Monday, March 21, 2016. If more time is needed, please contact Chris Muir at Christopher.Muir@hhs.gov to request an extension. Comments can be submitted at https://www.healthit.gov/standards-advisory/2016. Please **do not convert this template to a PDF file** for submission. Thank you for your ongoing participation and engagement with the ISA process.

Topic	Section	Interoperability Need	Standard/Implementation Specification	Comment (No Action)	Comment (Request for Action)
Section II: Best Available Content/Structure Standards and Implementation Specifications	Section II-A: Admission, Discharge, and Transfer	Sending a notification of a patient's admission, discharge and/or transfer status to other providers	HL7 2.5.1 (or later) ADT message		HIMSS notes the need to add concept of sending ADT to a regional Health Information Exchange. There is also a need to have a concept of registration at the point of entry: eliminate duplicate medical record numbers. Issues of patient data matching, false positive and false negatives continue to increase in volume.
Section II: Best Available Content/Structure Standards and Implementation Specifications	Section II-B: Care Plan	Documenting patient care plans	HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Release 2.1		HIMSS suggests a more succinct and complete explanation of where the standard is and what it represents. Consider including the care plan in release 2.1 where there are 30 new section templates for C-CDA and thusthe newness listed as pilot, but the truth is it hasn't really thoroughly piloted. Adoption level 'unknown' could be changed to near zero in order to make sure the document structures have the right data fields to support those workflows and uses like shared decision making. Intended to be that but very much untested. Please also provide more information on the newness of the section templates that are part of this standard to more informative.
Section II: Best Available Content/Structure Standards and Implementation Specifications	Section II-B: Care Plan	Documenting patient care plans	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition		HIMSS advocates for the need to incorporate Care Plans into Clinician workflows. Patients need to be part of "their" care plan and shared decision making.
Section II: Best Available Content/Structure Standards and Implementation Specifications	Section II-F: Family Health History (clinical genomics)	Representing family history for clinical genomics	HL7 Version 3 Standard: Clinical Genomics; Pedigree		For genomic data, HIMSS encourages ONC to consider the following value sets: • Gene Identifier: HGNC Value Set • Transcript Reference Sequence Identifier: NCBI vocabulary • DNA Sequence Variation Identifier: NCBI vocabulary • DNA Sequence Variation: HGVS nomenclature
Section II: Best Available Content/Structure Standards and Implementation Specifications	Section II-G: Images	Medical image formats for data exchange and distribution	Digital Imaging and Communiations in Medicine (DICOM)	HIMSS agrees with DICOM standard since it is very well accepted in the industry. One issue faced, however, is sharing DICOM images externally.	
Section II: Best Available Content/Structure Standards and Implementation Specifications	Section II-G: Images	Medical image formats for data exchange and distribution	Digital Imaging and Communiations in Medicine (DICOM)		IHE encourages ONC to consider adding XDS-I which provides a CDA document manifest. A test tool will be available in 2016 from the IHE CAsC program. The most widely used approach is open text in an HL7 ORU message – but we need to push for further standardization in CDA. DICOM structured reports are best within the institution, CDA works best outside as it fits with EMRs.
Section II: Best Available Content/Structure Standards and Implementation Specifications	Section II-H: Laboratory	Receive electronic labroratory test results	HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Results Interface Implementation Guide, Release 1 DSTU Release 2 - US Realm		HIMSS supports and encourages that the emerging alternative is preferable to the current implementation specification listed.
Section II: Best Available Content/Structure Standards and Implementation Specifications	Section II-H: Laboratory	Receive electronic labroratory test results	HL7 2.5.1		IHE encourages the use of XDS-Lab CDA document for lab reports. Not used in the US but used in Europe.
Section II: Best Available Content/Structure Standards and Implementation Specifications	Section II-K: Public Health Reporting	Reporting antimicrobial use and resistance information to public health agencies	HL7 Implementation Guide for CDA Release 2 – Level 3: NHSN Healthcare Associated Infection (HAI) Reports Release 2, DSTU Release 2.1		HIMSS supports the Public Health systems' need to be able to "consume" the data from the Providers (EH and EP) EMR. Encourage move to HL7 IG for CDA release 2 –Level3: NHSN Healthcare Associated Infection (HAI) Reports Release 2. DSTU Release 2.1. There is also a need to bring in data which is super-protected. For example, 42 CFR Part II data, abuse reporting, data on legal-hold, HIV, STDs, and more.
Section II: Best Available Content/Structure Standards and Implementation Specifications	Section II-K: Public Health Reporting	Reporting cancer cases to public health agencies	HL7 Implementation Guide for CDA® Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1 - US Realm		HIMSS requests clarification on how the adoption level of 3 was calculated on this implementation specification.
Section II: Best Available Content/Structure Standards and Implementation Specifications	Section II-K: Public Health Reporting	Reporting cancer cases to public health agencies	HL7 CDA ® Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1, DSTU Release 1.1 – US Realm		HIMSS recommends using the emerging implementation specification DTSU Release 1.1 as the production implementation specification.
Section II: Best Available Content/Structure Standards and Implementation Specifications	Section II-K: Public Health Reporting	Case reporting to public health agencies	HL7 FHIR DSTU 2, Structured Data Capture (SDC) Implementation Guide		HIMSS advises changing the adoption level to zero on this emerging alternative implementation specification.
Section II: Best Available Content/Structure Standards and Implementation Specifications	Section II-L: Quality Reporting	Reporting aggregate quality data to federal quality reporting initiatives		HIMSS advocates for the need to preserve semantic equivalence in the cCQM and in the clinical data and to be able to export quality data, QRDA Category I and QRDA Category III.	

Commenter Name/Title: HIMSS Standards Advisory Task Force
Organization: HIMSS and IHE-USA
Email: efleet@himss.org and jhout@himss.org

Comment Template Instructions: Please select a topic and section from the dropdown list for each comment provided. Where more than one interoperability need or standard/implementation specification exists, please identify the applicable interoperability needs or standard/implementation specification. If your comment has a specific request for action, please include it in the "Comment (Request for Action)" column. Where no action is required (e.g., comments in support of currently listed standrds, etc), please use the "Comment (No Action)" column. Where possible, use of a new row for individual recommendations is preferred. The deadline for comment submissions is at 5 p.m. on Monday, March 21, 2016. If more time is needed, please contact Chris Muir at Christopher.Muir@hhs.gov to request an extension. Comments can be submitted at https://www.healthit.gov/standards-advisory/2016. Please **do not convert this template to a PDF file** for submission. Thank you for your ongoing participation and engagement with the ISA process.

Topic	Section	Interoperability Need	Standard/Implementation Specification	Comment (No Action)	Comment (Request for Action)
Section II: Best Available Content/Structure Standards and Implementation Specifications	Section II-M: Representing clinical health information as a "resource"	Representing clinical health information as a "resource"	Fast Healthcare Interoperability Resources (FHIR), DSTU 2		HIMSS suggests listing an implementation specification with the standard. Also, as part of release 2 of FHIR there is a FHIR maturity model which assigns a maturity level objectively to each resource as opposed to the idea of trying to apply maturity to the entire standard or the FHIR framework.
Section II: Best Available Content/Structure Standards and Implementation Specifications	Section II-M: Representing clinical health information as a "resource"	Representing clinical health information as a "resource"	Fast Healthcare Interoperability Resources (FHIR), DSTU 2		It appears that FHIR's granular data approach will become a fast, flexible, and effective way to retrieve a specific piece of data, but there are two constraints that IHE suggests is worth noting: 1) unless the retrieval is correctly specified, the context of the retrieved data may be incorrect (e.g., if we ask for the latest blood gas, we may get this morning's lab tests but not the critically important pulse oximeter data from 10 minutes ago, nor the suggestions that heart rate has been rapidly trending upward while blood pressure has been dropping); 2) sending and writing granular data may be inefficient if/when large amounts of data must be written and/or if multiple parties attempt to update fragments of a patient's record simultaneously.
Section II: Best Available Content/Structure Standards and Implementation Specifications	Section II-N: Segmentation of sensistive information	Document-level segmentation of sensitive information	Consolidated HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1		HIMSS reommends that the implementation maturity be updated from pilot to production. This has been in production with at least one company and is very patient centered. Humanitrix. http://www.humetrix.com/ http://www.humetrix.com/#panel_ibb http://www.humetrix.com/#panel_news EMRs need to be able to segment data and data types. Whene one looks at the initial beginning of the DSFP (S & I Framework Initiative) the patient would have the ability to state which of their data goes to whom; and which are of their data does not go to whom.
Section III: Best Available Standards and Implementation Specifications for Services	Section III-B: Clinical Decision Support Services	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	HL7 Version 3 Standard: Context Aware Knowledge Retrieval Application. (“Info button”) , Knowledge Request, Release		The adoption level listed here is a level 3 while the adoption level for the same standard listed under section II-I: Patient Education Materials is listed with a level 4 adoption. HIMSS encourages consistency when applying adoption levels to standards across the entire ISA.
Section III: Best Available Standards and Implementation Specifications for Services	Section III-C: Image Exchange	Exchanging imaging documents within a specific health information exchange domain	IHE Cross Enterprise Document Sharing for Images (XDS-I.b)		IHE would like to suggest that the adoption level is perhaps higher than 1/5, based on the IHE Connectathon. Many vendors used XDS scan document which has image imbedded in CDA doc. If the other two implementation specifications (IHE-PQD and IHE-PIX) receive a 4/5, then this should be perhaps IHE-XDS-I.b should be listed as level 2 or 3/5. IHE also recommends the implementation maturity should also be changed from pilot to production.
Section IV: Projected Additions to the ISA	Section IV: Family Health History (Projected)	Representing patient family health history observations (questions)	LOINC		HIMSS recommneds changing the standard to SNOMED-CT as well as the problem value set to reflect SNOMED-CT. Please also re-asses the adoption level (3/5) as this may be a little high.
Section IV: Projected Additions to the ISA	Section IV: Gender Identity, Sex and, Sexual Orientation (Projected)	Representing patient gender identity observations (questions)	LOINC		For people not familiar with standards issues HIMSS encourages ONC to mention the difference between gender identity/sexual orientation and the very ubiquitous administrative gender data element that may not consider a more granular value set.
Section IV: Projected Additions to the ISA	Section IV: Gender Identity, Sex and, Sexual Orientation (Projected)	Representing patient sex (at birth) observations (questions)	LOINC		HIMSS would like to make a suggestion where the data elements that are separated into questions and answers throughout the entire document should be spelled out for readers not familiar with the word questions. Questions are typically encoded using LOINC and Values can be encoded using other systems.
Section IV: Projected Additions to the ISA	Section IV: Health Care Provider (Projected)	Provider role in care setting	SNOMED-CT	HIMSS would like to mention that the NPI where many health care providers self-attribute their role is not aligned with SNOMED nor with the provider taxonomy in HIPAA or CMS classification of providers. Different systems may include those different code systems and their capture of the providers in their organization and their roles.	
Section IV: Projected Additions to the ISA	Section IV: Lab Tests (Projected)	Representing numerical laboratory test order observations (questions/what will be tested)	LOINC		HIMSS recommends adding the frequency based ordering from the Regenstrief Institure for ordering and results. (Consistent with suggesting S&I framework)
Section IV: Projected Additions to the ISA	Section IV: Lab Tests (Projected)	Representing categorical laboratory test result observation values (answers)	SNOMED-CT		HIMSS recommends a value set created by the Value Set Authority Center specifically for laboratory test results such as positive, negative, detected, not detected, etc.
Section IV: Projected Additions to the ISA	Section IV: Nursing (Projected)	Representing nursing assessments	LOINC SNOMED-CT		HIMSS concurs that observations are assessment questions and the questions should be coded using LOINC. However, when a validated scale is in LOINC (such as the Morse Fall Scale), LOINC codes for observations should be used for the questions and LOINC codes for answers should be used for the values. We would also like direction as to how to facilitate interoperability of instruments that are proprietary and cannot be put into any standard terminologiy. This issue is a barrier to interoperability and subsequent downstream impacts.

Commenter Name/Title: HIMSS Standards Advisory Task Force
Organization: HIMSS and IHE-USA
Email: efleet@himss.org and jhout@himss.org

Comment Template Instructions: Please select a topic and section from the dropdown list for each comment provided. Where more than one interoperability need or standard/implementation specification exists, please identify the applicable interoperability needs or standard/implementation specification. If your comment has a specific request for action, please include it in the "Comment (Request for Action)" column. Where no action is required (e.g., comments in support of currently listed standrds, etc), please use the "Comment (No Action)" column. Where possible, use of a new row for individual recommendations is preferred. The deadline for comment submissions is at 5 p.m. on Monday, March 21, 2016. If more time is needed, please contact Chris Muir at Christopher.Muir@hhs.gov to request an extension. Comments can be submitted at https://www.healthit.gov/standards-advisory/2016. Please **do not convert this template to a PDF file** for submission. Thank you for your ongoing participation and engagement with the ISA process.

Topic	Section	Interoperability Need	Standard/Implementation Specification	Comment (No Action)	Comment (Request for Action)
Section IV: Projected Additions to the ISA	Section IV: Nursing (Projected)	Representing patient problems for nursing	SNOMED-CT		Since SNOMED-CT is the current MU standard for representing patient problems it is logical and HIMSS recommends that all disciplines use this standard. There is a need for recommended value sets for representing the "answers" in SNOMED CT (such as skin colors, breath sounds) as standard value sets and will require standardization as core/recommended value set answer choices for a particular clinical observation. In addition, we suggest creating and maintaining these value sets in the NLM value set authority center. We agree that all ANA-recognized terminologies should be "mapped" to (not "converted" to and messaged using SNOMED-CT. Finally, HIMSS recommends that all nursing diagnoses mapped from ANA-recognized terminologies to SNOMED CT should be available to users to implement.
Section IV: Projected Additions to the ISA	Section IV: Nursing (Projected)	Representing nursing interventions and observations (observations are assessment items)	SNOMED-CT		Nursing Interventions should be an independent category, not grouped with other nursing concepts. HIMSS recommends the categories/groupings should be: Nursing Observations and Assessments (observations can be an assessment) and Nursing Interventions.
Section IV: Projected Additions to the ISA	Section IV: Research (Projected)	Representing analytic data for research purposes	CDISC Controlled Terminology for Medical Devices Hosted by NCI-EVS		HIMSS would like clarification on the alignment between the CDISC terminology for medical devices and that issued by the FDA for unique device identifier. We recommend creating a table of some sort that shows the overlap in the device area maybe both for FDA and CDISC and any other terminology that may exist.
Section IV: Projected Additions to the ISA	Section IV: Tobacco Use (Smoking Status) (Projected)	Representing patient tobacco use (smoking status) observations (questions)	LOINC	HIMSS would like to note that there is some misalignment of smoking status from a medical history standpoint and from a clinical trials standpoint. The ways of capturing status and history of smoking does not provide informational value – "sometimes" "occasional" does not give information on what or how is being smoked/chewed/how or exactly how often.	HIMSS suggest to fundamentally change the structure of how we ask for and collect smoking status. There is a need to capture use of other things other than tobacco. Chewing vs. smoking is important, and well as nuance for e-cigarrettes and other non-tobacco nicotine use.
Section IV: Projected Additions to the ISA	Section IV: Care Plans (Projected)	Documenting, planning and summarizing care plans for patients with cancer	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition		IHE recommends using role based access control (RBAC) for the security pattern, since this is for cancer.
Section IV: Projected Additions to the ISA	Section IV: Medical Device Communication to Other Information Systems/Technologies (Projected)	Transmitting patient vital signs from medical devices to other information systems/technologies	IHE-PCD (Patient Care Device Profiles)		IHE recommends updating the Test Tool Availability column to say 'Yes'. Please note the NIST test tool for IHE-PCD link (http://ihe-pcd-con.nist.gov/PCD-HL7WebCon/#home.htm).
Section IV: Projected Additions to the ISA	Section IV: Research (Projected)	Complete disease registry forms and submit to reporting authority (ACC)			The role that domain analysis models play in development and harmonization of standards is not well known to most – IHE suggests that this could be useful to add as an appendix or a line item in dependencies for consideration for future versions.
Section IV: Projected Additions to the ISA	Section IV: Data Provenance (Projected)	Establishing the authenticity, reliability, and trustworthiness of content between trading partners.	HL7 CDA® Release 2 Implementation Guide Data Provenance, Release 1 - US Realm		IHE suggests there be a section/appendix around data provenance and the meaning of that. This topics has also come up with respect to patient generated data, needs to be metadata that goes with the data to provide a record of its provenance
Section IV: Projected Additions to the ISA	Section IV: "Push" Exchange (Projected)	Push communication of vital signs from medical devices	ISO/IEEE 11073 Health informatics - Medical/ health device communication standards		IHE recommends including the IHE-PCD profile here as an implementation specification. Please note the NIST test tool for IHE-PCD link (http://ihe-pcd-con.nist.gov/PCD-HL7WebCon/#home.htm). IHE would like to suggest adding a separate section for mobile devices, wearables in future ISAs. Please also consider adding guidance around the precision medicine topic.
Section V: Questions and Requests for Stakeholder Feedback	Section V: Questions and Requests for Stakeholder Feedback	1. For each standard and implementation specification there are six assessment characteristics, and with the 2016 Advisory a noteworthy amount of detail has been received and integrated. However, there are still some gaps. Please help complete any missing or "unknown" information. Additionally, assessing the adoption and maturity of standards is an ongoing process, so please continue to provide feedback if you believe something has changed or is not correct.			HIMSS would like clarification on how the adoption level is calculated. What is the denominator for each standard? Adoption levels may be high or lower depending on the denominator. Adoption level of base standards like CDA® R2 does not seem relevant and is misleading, since CDA® R2 is the basis of many different implementation guides which are in different levels of adoption. HIMSS also recommends the implementation specifications and adoption levels that are listed pair up more equivalently. Implementation specifications are based on the standards. If the implementation specification is not used, then the standard is not used. If the implementation specification is used, then the standard is used. A useful concept, which admittedly would be difficult to calculate, would be the slope of the adoption curve. Please clarify if adoption of the standard is increasing rapidly or is the adoption in fact declining as a standard is replaced by one that is more interoperable?

Commenter Name/Title: HIMSS Standards Advisory Task Force
Organization: HIMSS and IHE-USA
Email: efleet@himss.org and jhout@himss.org

Comment Template Instructions: Please select a topic and section from the dropdown list for each comment provided. Where more than one interoperability need or standard/implementation specification exists, please identify the applicable interoperability needs or standard/implementation specification. If your comment has a specific request for action, please include it in the "Comment (Request for Action)" column. Where no action is required (e.g., comments in support of currently listed standrds, etc), please use the "Comment (No Action)" column. Where possible, use of a new row for individual recommendations is preferred. The deadline for comment submissions is at 5 p.m. on Monday, March 21, 2016. If more time is needed, please contact Chris Muir at Christopher.Muir@hhs.gov to request an extension. Comments can be submitted at https://www.healthit.gov/standards-advisory/2016. Please **do not convert this template to a PDF file** for submission. Thank you for your ongoing participation and engagement with the ISA process.

Topic	Section	Interoperability Need	Standard/Implementation Specification	Comment (No Action)	Comment (Request for Action)
Section V: Questions and Requests for Stakeholder Feedback	Section V: Questions and Requests for Stakeholder Feedback	2. The table beneath the standards and implementation specifications includes limitations, dependencies, and preconditions. Given the enhancements made, please comment on accuracy and completeness and where information gaps remain, forward applicable content.			HIMSS has identified information gaps in the following areas: We recommend including the role of domain models where they exist and the need for some where they don't exist – as in disease registries. We suggest including cross-references in the ISA where there might be the same standards in the advisory in different sections. It is also important to consider the terms of gaps in standards around care team and care coordination workflows. There is a great deal of work going on around care teams and in both HL7 and IHE around care coordination. We suggest that those should be included in the next iteration of the standards advisory. Finally, please consider adding who owns the standard within the limitations or value set.
Section V: Questions and Requests for Stakeholder Feedback	Section V: Questions and Requests for Stakeholder Feedback	3. Within the Section I tables, Value Sets have been selected to substitute for what otherwise references Security Patterns in Sections II and III. Please review and provide feedback on placement, accuracy and the completeness of the selected value sets.			HIMSS would like to suggest providing centralized repository for all value sets (code subsets) used in 2014 and 2015 E-certification Rule. Some value sets are mentioned in 2015 Rule but are not available anywhere for download and other value sets are "buried" within implementation guides (e.g. C-CDA®). The industry needs a centralized repository of all value sets filterable (at the least) by E-certification version and implementation guide name. We would like to also recognize that a centralized repository would provide tools that ensure consistent development of a value sets by all participating authors. These tools are efficient for searching and retrieval of value sets, specifically in cases where value sets appear similar in their naming or code sets they contain.
Section V: Questions and Requests for Stakeholder Feedback	Section V: Questions and Requests for Stakeholder Feedback	4. Public Comments surrounding I-F: Functional Status/Disability and I-I: Industry and Occupation continue to be varied on the "best available" standards or implementation specifications in these areas. Please review and provide feedback on what should be included and/or whether these areas should be removed.			HIMSS agrees that Functional Status/Disability should be included. Functional Status/Disability is important in care coordination. There is an ongoing effort in the international domain to develop a new value set in the realm of Functional Status/Disability.
Section V: Questions and Requests for Stakeholder Feedback	Section V: Questions and Requests for Stakeholder Feedback	5. Opinions vary in the way (messaging vs. transport) the Advisory should represent FHIR. Please review and provide feedback on the manner FHIR should be represented.			HIMSS would like to note that FHIR is not messaging vs. transport, but is actually both. The concept of messaging and transport is morphed into a couple of other terms. FHIR exchanges use RESTful transport and suggest leveraging Oauth protocols for security. We suggest that FHIR should be represented appropriately in the different sections (vocabulary, transport; all the different levels) of the ISA. Profiles are still not at the level of what you would call implementation guides so they would just be standards at an earlier phase of development. Finally, we recommend representing FHIR for mobile applications as well.
Section V: Questions and Requests for Stakeholder Feedback	Section V: Questions and Requests for Stakeholder Feedback	5. Opinions vary in the way (messaging vs. transport) the Advisory should represent FHIR. Please review and provide feedback on the manner FHIR should be represented.			IHE would like to note that FHIR is often paired with SOA frameworks, which enhances potential benefits. However, it is important to identify clearly that SOA requires its own, separate design, governance, and operation for stable and secure implementation. In particular, SOA segregates data, functions, and services using a pre-orchestrated SOA services system. When the FHIR and SOA tools are correctly designed and integrated, secure and functional benefits must be properly maintained and authorized. i.e., reliable access to data by FHIR will depend on the selected SOA functionality and performance.
Section V: Questions and Requests for Stakeholder Feedback	Section V: Questions and Requests for Stakeholder Feedback	7. Public comments on the Draft 2016 Advisory highlighted an interest in including "interoperability needs" associated with communication between certain types of personal health devices and other information technology systems. Specifically, the health informatics standards under IEEE 11073 that have been recognized by the FDA2 and referenced by Continua and Personal Connected Health Alliance. What particular interoperability needs would be best to include in the Advisory to reflect this work by the industry?			HIMSS would like to recommend that PCHA and Continua not be separately referenced. 11073 and the rest of the PCHA and Continua framework stress not just interconnectivity but "medical-grade" interoperability. Meaning that the underlying 11073 standards ensure that sufficient information is collected along with physiological measurements to make the resulting data more clinically trustworthy and relevant. Any standards for interoperability should stress this semantic base in addition to simple interconnectivity. Device standards in an increasingly complicated world need to address more than simple data exchange. For example, the emergence of artificial pancreas technologies and the endorsement of continuous glucose monitoring (CGM) by endocrinologists have brought issues of device command and control to the forefront (i.e. control of an insulin pump from company A by a CGM from company B. 11073 and the PCHA and Continua framework strive to ensure that these needs are being met in order for individual devices to contribute to a greater result than their individual functions.

Commenter Name/Title: HIMSS Standards Advisory Task Force
Organization: HIMSS and IHE-USA
Email: efleet@himss.org and jhout@himss.org

Comment Template Instructions: Please select a topic and section from the dropdown list for each comment provided. Where more than one interoperability need or standard/implementation specification exists, please identify the applicable interoperability needs or standard/implementation specification. If your comment has a specific request for action, please include it in the "Comment (Request for Action)" column. Where no action is required (e.g., comments in support of currently listed standrds, etc), please use the "Comment (No Action)" column. Where possible, use of a new row for individual recommendations is preferred. The deadline for comment submissions is at 5 p.m. on Monday, March 21, 2016. If more time is needed, please contact Chris Muir at Christopher.Muir@hhs.gov to request an extension. Comments can be submitted at https://www.healthit.gov/standards-advisory/2016. Please **do not convert this template to a PDF file** for submission. Thank you for your ongoing participation and engagement with the ISA process.

Topic	Section	Interoperability Need	Standard/Implementation Specification	Comment (No Action)	Comment (Request for Action)
Section V: Questions and Requests for Stakeholder Feedback	Section V: Questions and Requests for Stakeholder Feedback	7. Public comments on the Draft 2016 Advisory highlighted an interest in including "interoperability needs" associated with communication between certain types of personal health devices and other information technology systems. Specifically, the health informatics standards under IEEE 11073 that have been recognized by the FDA2 and referenced by Continua and Personal Connected Health Alliance. What particular interoperability needs would be best to include in the Advisory to reflect this work by the industry?			**IHE-DEC (Device Enterprise Communication)** is the correct Implementation Specifications for Vital Signs recording either by itself or with the Continua/WAN interface. Also, when applied to Personal Health Device data, a flag is needed to allow clinicians to know such data may be collected in home or other uncontrolled environments, and may be coarser or inaccurate compared to hospital or practice settings. e.g., a hospital can measure blood pressure very accurately via a catheter inserted into an artery or aorta, but a personal health device may likely report systolic and diastolic blood pressure from a consumer-bought cuff-based device that has been applied over one or two layers of clothing! It is important, for patient safety and care, to capture such personal health data, but it should be clearly and properly flagged for clinical context. Through recent collaboration with IEEE 11073 and IHE PCD, LOINC now has more viable utility for manually entered patient vital signs, but that is only a small fraction of the vital signs available in patient care settings. LOINC and ISO/IEEE 11073 will need to meet on a regular basis to just keep the subsets of the two nomenclature systems synch for manual, hand-keyed vital signs reporting. Further, LOINC is not the copyright owner of the necessary Vital Signs nomenclature. Copyright is owned by IEEE and ISO. LOINC and NIST were provided IEEE's 11073 Vital Signs nomenclature under a limited use MOU which allows A) NIST to continue supporting its well-developed Patient Care Device testing tools, B) Allows IHE's Rosetta Terminology Mapping project to have more complete crosswalk mapping between ISO/IEEE 11073 and LOINC, and C) allows all clinical and provider users fee-free use of the nomenclature. **IHE's DEC** uses HL7 structure and IEEE 11073 nomenclature to provide a mature, NIST validated, Vital Sign vocabulary that covers all patient physiologic data, including time-stamped raw and computed numeric vital signs and metadata, waveforms, events and alarms, annotations, device location and device management information. Also, PCHA/Continua uses DEC for near real-time transmission of personal health and home monitoring data in its Continua/WAN interface, allowing collection of both hospital and personal health data for a patient. **IHE and PCHA/Continua**, have collaborated with NIST for many years to define, test and validate IHE DEC Vital Signs message content, ensuring complete and correct data essential for safe and effective patient care and Health IT integration. **The correct DEC Standards Process Maturity / Implementation Maturity / Adoption Level / Regulated / Cost / Test Tool Availability in Industry applications is** : Final / Production / Adoption 4 out of 5 internationally / No / Free / NIST testing tool set.
Section V: Questions and Requests for Stakeholder Feedback	Section V: Questions and Requests for Stakeholder Feedback	8. Based on comments received, some of the Interoperability Needs were split to point out where LOINC (questions) vs. SNOMED-CT (answers) applies. Please review and provide feedback on this approach. Also, provide feedback on whether the Interoperability Needs describe this separation properly.			HIMSS would like to make a recommendation where the data elements that are separated into questions and answers throughout the entire document should be spelled out for readers not familiar with the word questions. Questions are typically encoded using LOINC and Values can be encoded using other systems. We encourage ONC to consistently clarify how the data elements are articulated and the distinction between the question and answer in each of these sections, as this would be beneficial.
Section V: Questions and Requests for Stakeholder Feedback	Section V: Questions and Requests for Stakeholder Feedback	9. Are there other authoritative sources for Security Standards that should be included in Appendix II?			**HIMSS would like to suggest adding the following authoritative sources for security standards:** NIST Special Publication 800-30, rev 1: http://csrc.nist.gov/publications/nistpubs/800-30-rev1/sp800_30_r1.pdf Authentication: OpenID Connect, version 2.0 Authorization: OAUTH 2 Patient Choice (Privacy): UMA (User Managed Access) Cybersecurity Standards: https://www.us-cert.gov/Information-Sharing-Specifications-Cybersecurity
Section V: Questions and Requests for Stakeholder Feedback	Section V: Questions and Requests for Stakeholder Feedback	9. Are there other authoritative sources for Security Standards that should be included in Appendix II?			**IHE recommends adding the following authoritative sources for security standards:** Consistent Time Audit Trail and Node Authentication Enterprise User Authentication Cross-Enterprise User Assertion Document Digital Signature Basic Patient Privacy Consents Document Encryption Access Control