AHIMA
American Health Information
Management Association®

233 N. Michigan Ave., 21st Fl.
Chicago, IL 60601-5800

phone » (312) 233-1100
fax   » (312) 233-1090
web   » www.ahima.org

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Via Submission to URL: https://www.healthit.gov/isa/section-vi-questions-and-requests-stakeholder-feedback

Office of the National Coordinator for Health Information Technology (ONC)
U.S. Department of Health and Human Services
200 Independence Avenue SW
Suite 729-D
Washington, DC 20201

Subject: ONC Proposed 2018 Interoperability Standards Advisory (ISA)

On behalf of the American Health Information Management Association (AHIMA), I am pleased to submit comments related to the ONC Proposed 2018 Interoperability Standards Advisory (ISA).

The American Health Information Management Association (AHIMA) is the national non-profit association of health information management (HIM) professionals. Serving 52 affiliated component state associations including the District of Columbia and Puerto Rico, AHIMA represents more than 103,000 health information management professionals dedicated to effective health information management, information governance, and applied informatics. AHIMA's credentialed and certified HIM members can be found in more than 40 different employer settings in 120 different job functions—consistently ensuring that health information is accurate, timely, complete, and available to patients and providers. AHIMA provides leadership through standardization of HIM practices, education and workforce development, as well as thought leadership in continuing HIM research and applied management for health information analytics.

AHIMA supports ONC's effort to publish annual Interoperability Standards Advisories. AHIMA previously submitted comments for ONC ISA 2015, 2016 and 2017.

Our comments demonstrate that AHIMA is ready to work with ONC and the nation on the public-private approach to achieving information systems interoperability through standards.

AHIMA commented on the following sections below that are related to our current work.

We appreciate the opportunity to submit comments on the Advisory. We hope that you will continue to engage extensively with stakeholders on the Advisories and we look forward to working with you to ensuring its successful implementation. Should you or your staff have any additional questions or comments, please contact me at pamela.lane@ahima.org; or (312) 233-1511 or Diana Warner, Director, Standards at diana.warner@ahima.org, (312) 233-1519 if you have any questions.

Sincerely,

Pamela L. Lane, MS, RHIA
Interim Chief Executive Officer

AHIMA Comments on ONC Interoperability Standards Advisory - 2017

Updated questions for the 2017 Review and Comment Period

As with the previous iterations of the Interoperability Standards Advisory (ISA), posing questions has served as a valuable way to prompt continued dialogue with stakeholders for continuous improvement of the ISA. Your feedback on the questions posed below is critical and we encourage answers to be submitted as part of the current comment process.

General

17-1. In what ways has the ISA been useful for you/your organization as a resource? ONC seeks to better understand how the ISA is being used, by whom, and the type of support it may be providing for implementers and policy-makers.

The ISA is useful within the limitation of the statement below focusing on "inform":

> "*the ISA should serve as the first resource consulted to inform the selection of standards and implementation specifications.*"

It does serve as an informational resource or conduit of health information technology (HIT) standards.

AHIMA does not generally view the ISA as "a coordinated catalog . . .to consistently address specific interoperability need" despite its intent (see statement below):

> "*The ISA is designed to be a coordinated catalog of standards and implementation specifications that can be used by different stakeholders to consistently address a specific interoperability need.*"

This is because:

1. ISA does not include the full spectrum of standards needed for semantic, technical and functional interoperability as it is focuses only on data standards (Section I), content standards (Section II), information exchange standards (Section III) and lists privacy standards in Appendix 1. It is missing functional and business standards for information exchange rules. HL7 Functional profiles cannot be effective in this regard. Please see response regarding the Functional Models section below.

   Please see the full list of HIT standards categories by interoperability components that we consistently suggested for ONC to use in our earlier comments on various ONC documents.[1,2,3,4,5,6,7]

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[1] AHIMA Comments for ONC Proposed Interoperability Standards Measurement Framework. 2017. URL: http://bok.ahima.org/PdfView?oid=302222

[2] AHIMA Comments — ONC Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap DRAFT Version 1.0. 2015. URL: http://bok.ahima.org/PdfView?oid=300817

[3] AHIMA Comments — ONC 2015 Interoperability Standards Advisory. 2015. URL: http://bok.ahima.org/doc?oid=300906

[4] AHIMA Comments — ONC 2015 Interoperability Standards Advisory. 2015. URL: http://bok.ahima.org/doc?oid=300906

2. Sections include various, non-coordinated "interoperability needs" that are not "consistently" addressed across different sections. For example, **I-A: Interoperability Need: Representing Patient Allergic Reactions** is listed in Section 1 but is not listed in any other Sections.

    We would like to suggest that identified interoperability needs, i.e., I-A will be addressed as needed in the other Sections which will enable consistency and coordination.

3. It will be helpful to provide a definition for "interoperability need" and explain how/why they were selected. Is there dependency/coordination/hierarchy between the "interoperability needs?" Do "interoperability needs" across various sections relate to each other, if any, e.g.:

    I-A: Interoperability Need: Representing Patient Allergic Reactions

    II-A Interoperability Need: Sending a Notification of a Patient's Admission, Discharge and/or Transfer Status to Other Providers

    III-A Interoperability Need: An Unsolicited "Push" of Clinical Health Information to a Known Destination and Information System User, etc.

    We would like to suggest that "interoperability need(s)" identified in the Section I should be "consistently" followed/addressed in the other Sections (II-IV) to demonstrate that standards listed in various Sections are "coordinated" with each other to achieve interoperability. Please see comment below in item 4 for examples of coordination needed across "interoperability needs."

4. In various healthcare domains included in ISA, e.g., imaging, laboratory, public health, etc., data, information content and information exchange standards are listed in Sections I-III, respectively. For example, ODH (Occupational Data for Health) interoperability standards include an information model, vocabulary, functional profile, document templates. ODH data can be exchanged via HL7 2.x, IHE RFD, XDS, XDM, XDA, XCA; they also need privacy and security standards (now in Appendix I). Right now all these standards for ODH as well as standards for imaging, laboratory, public health reporting, etc. are scattered throughout the ISA.

    However, the new added Section V: Administrative Standards and Implementation Specifications represents various items (see questions 17-8, 17-10---17-17 below) that are listed under data, information content and information exchange standards (Sections I-III) in the current ISA organization.

    Section V presents example of standards grouping for a specific domain of use - Use Case: Patient Administration Management. We would like to suggest ONC use the concept of Use Case to group standards for other domains as done in Section V. The Use Case needs to incorporate current

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[5] AHIMA Comments — ONC 2016 Interoperability Standards Advisory. 2015. URL: http://bok.ahima.org/PdfView?oid=301305

[6] AHIMA Comments — ONC's Transatlantic eHealth-Health IT Cooperation Roadmap. 2016. URL: http://bok.ahima.org/PdfView?oid=301409

[7] AHIMA Comments — ONC Proposed Interoperability Standards Measurement Framework. 2017. URL: http://bok.ahima.org/PdfView?oid=302222

discrete "interoperability needs" concepts to allow grouping individual standards for a specific domain of use. Please see below publications in the Journal of AHIMA (2017) on the findings of the IHE Use Case Task Force with the coordinated approach for representing user interoperability needs in the Use Case, including examples of standards groupings as well as examples of functional and business standards that are currently missing in the ISA:

1. Bourquard K, Orlova A, Parisot C. Understanding User Needs for Interoperability: Defining Use Cases in eHealth. JAHIMA. 2017. 88(6): 42-45. URL: http://bok.ahima.org/doc?oid=302159
2. Orlova A, Bourquard K, Parisot C. Understanding User Needs for Interoperability: Standards for Business Cases in eHealth. JAHIMA. 2017. 88(7): 34-37. URL: http://bok.ahima.org/doc?oid=302184
3. Orlova A, Bourquard K, Parisot C. Understanding User Needs for Interoperability: Standards for Use Cases in eHealth. JAHIMA. 2017. 88(9): 40-44. URL: http://bok.ahima.org/doc?oid=302252
4. Bourquard K, Orlova A, Parisot C. Understanding User Needs for Interoperability: Collaborative Approach. JAHIMA. 2017. 88(10): 58-61. URL: http://bok.ahima.org/doc?oid=302323

The Use Case approach is in use by the ISO Technical Committee 215 Health Informatics (ISO/TC215) and DICOM to develop a Reference Standards Portfolio (RSP) for Clinical Imaging -- ISO/IS 21860 Reference standards portfolio -- Clinical imaging (RSP-CI)

17-2. Over the course of 2017, various new functionality has been added to the ISA to make it a more interactive and useful resource (e.g., print-friendly pages, change notifications, advanced search functionality, etc). Are there additional features or functionalities that would enhance the overall experience?

AHIMA suggests that the following features require improvement:

1. Develop Instructions for Comment Submission and link it to the announcement to save time communicating with ONC staff and enhance usability experience. This document should include:
   a. Registration at ONC site
      i. Log in button in the upper right edge is covered by the web page and hard to find
      ii. Setting-up password issues – after confirmation that the password is saved, the log-in page should appear automatically; not after closing the browser and opening the https://www.healthit.gov/isa/user
   b. Comment can be submitted only to the questions that contain hyperlinks. Can readers submit comments for questions that do not have hyperlinks? If not, why they are listed in ISA?
   c. When copying questions to a Word document – Word document is needed to solicit feedback on the comments within the organization – hyperlinks do not open. Please add URLs after hyperlinks as follows:
      "17-3. An Appendix II (https://www.healthit.gov/isa/AppendixII) has been added. . ."

2. All sections and items in the tool have separate web pages. Current features - pdf, print - do not allow for aggregated view and comparison. It would be productive if there was a clear and standard way to link related pages/items/products.

   For example, for ODH (Occupational Data for Health) there are: an information model, vocabulary, functional profile, document templates. In addition ODH data can be exchanged via HL7 2.x, IHE

RFD, XDS, XDM, XDA, XCA; they also need privacy and security standards (now in Appendix I). Right now all these ODH standards are scattered throughout the ISA. Please see our comment in question 17-1 regarding the Use Case approach and the need for standards grouping as it was done in the new Section V: Administrative Standards and Implementation Specifications.

17-3. An [Appendix II](https://www.healthit.gov/isa/AppendixII) (https://www.healthit.gov/isa/AppendixII) has been added that includes educational and informational resources as recommended by the Health IT Standards Committee/2017 ISA Task Force. Are there other topics and/or existing resources which would be helpful to include in this area to increase stakeholder understanding of health IT interoperability issues?

Please add the Glossary of Terms for the definitions of the following terms:

1. Standards Categories used in ISA
2. Interoperability
3. Interoperability Need
4. Use Case
5. Specific Terms Used in ISI
   a. *Observations and Observation Values* – In some places, the ISA "Type" identifies a "standard for observations" and a "standard for values", e.g., section I-L: Representing Clinical/Nursing Assessments, but in other places, a "standard" is listed, e.g., section, I-B: Representing Patient Medical Encounter Diagnosis. It is unclear if the latter refers to a standard for observations or values or both.
   b. *Applicable Value Set(s) and Starter Set(s)* – The value and starter sets are not always used to list these items. For example, section I-S, Representing Alcohol Use uses this component to list the LOINC codes for specific, applicable observations. This is valuable information and a new component that specifically lists such LOINC codes would be helpful.
   c. *Models, Profiles, Information Models* – it is not clear why models and profiles are listed as a separate section in the ISA and how these models relate to Sections I-III. Definitions will clarify their role/place in interoperability. Please see additional comments regarding specific models included in question 17-7 below.

We also would like to suggest that a continuing comment process on the definitions of these terms would be welcomed. Soliciting comments on these terms will facilitate national consensus and awareness regarding these terms and concepts to ease ISA adoption.

Suggested AHIMA educational resources to include in Appendix II:

AHIMA Standards. Educational Resources. URL: http://www.ahima.org/about/standards
> **Standards and Systems Interoperability: Definitions**.
> **Functional Interoperability Standards**
> - Functional Standards
> - Business Standards
>
> **Semantic Interoperability Standards**
> - Data Standards
> - Information Content Standards
> - Identifier Standards

> **Technical Interoperability Standards**
> - Information Exchange Standards
> - Privacy and Security Standards
> - HIT Safety Standards

Section I: Vocabulary/Code Set/Terminology Standards

17-4. Are there additional Interoperability Needs (with corresponding standards) that represent specific sociodemographic, psychological, behavioral or environmental domains that should be included in the ISA?

AHIMA is concerned that the way the ISA handles vocabulary is confusing. The existing ISA Section I does not indicate specific observations and related observation values. Stating LOINC for observations and SNOMED for observation values appears overly broad. There is no guarantee those selecting the same codes intend to mean the same thing.

We suggest adding examples of specific datasets/value sets by "interoperability need" to show the context in which specific code(s) can be used. These datasets are usually specified in the Use Cases, HL7 Domain Analysis Models (DAM), IHE Content Profiles and other data requirements standard resources. References to these resources need to be added under Limitations, Dependencies, and Preconditions for Consideration. Please see comments on question 17-1 and 17-2 regarding using the Use Case concepts. Additionally, please see also our comments for Section V as an example of Patient Administration Management Use Case.

I-H Industry and Occupation

Please see edits for the Occupational Data for Health (ODH) table below. The current table shows one "standard" but it really comprises two value sets (see comment above on observation and observation values context). There is no section to provide the LOINC codes for the relevant observations (identifying "LOINC" as the "standard for observations" would not really help interoperability). For now, the LOINC codes could be put in the "Applicable Value Set(s) and Starter Set(s)" (even though they don't fit that title).

Proposed revisions to I-H Industry and Occupation

Type	Standard Implementation/ Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Standard	Occupation CDC Census 2010	~~Final~~ Draft	~~Production~~ Pilot	Feedback Requested	No	Free	N/A
Standard	Industry CDC Census 2010	~~Final~~ Draft	~~Production~~ Pilot	Feedback Requested	No	Free	N/A

- LOINC code for Past or Present Industry: 86188-0 'Occupation Industry'
- LOINC Code for Past or Present Occupation: 11341-5 'History of Occupation'
- LOINC code for Usual Industry: 21844-6 'Usual Industry'
- LOINC code for Usual Occupation: 21843-8 'Usual Occupation'

Section II: Content / Structure Standard and Implementation Specifications

17-5. A new interoperability need, Reporting Birth Defects to Public Health Agencies was added to Section II-R: Public Health Reporting. Please review and provide comment about the accuracy of the attributes.

Content/Structure Standards represent the organization of data sets/value sets in a message or document content structures. Therefore, HL7 2.x, CDA and FHIR are correctly listed in this section. However, "interoperability need" titles include actions such as "sending, sharing, allowing to respond, exchanging, ability to communicate, etc." which points to send-receive transactions not content. Please see in question 17-3 our suggestion to add Glossary of Terms to the ISA with the definitions of standards categories used in Sections I-IV and term "interoperability needs."

We also would to suggest the following revisions to the "interoperability need" titles to reflect that the Section is focusing on information content not send-receive transactions. Please see below suggested revisions to the selected titles in strikethrough and red font:

II-A Interoperability Need: ~~Sending a~~ Notification Content for ~~of~~ a Patient's Admission, Discharge and/or Transfer Status to Other Providers

II-B Interoperability Need: ~~Sending a~~ Notification Content for ~~of~~ a Long Term Care Patient's Admission, Discharge and/or Transfer Status to the Servicing Pharmacy

II-G Interoperability Need: ~~Exchanging~~ Diet and Nutrition Orders Content Across the Continuum of Care

II-H Interoperability Need: ~~The Ability for Pharmacy Benefit Payers to Communicate~~ Formulary and Benefit Information Content for Communication Between Pharmacy Benefit Payers and ~~to~~ Prescribers Systems

II-R: Public Health Report~~ing~~
~~Reporting~~ Antimicrobial Use and Resistance Information Report for ~~to~~ Public Health Agencies

and so on.

II-K: Healthy Weight. Interoperability Need "Sending Health Weight Information"

Proposed additions to the **Limitations, Dependencies, and Preconditions for Consideration**:

a.   The IHE Healthy Weight Content Profile includes the Occupational Data for Health (ODH) template. Public health studies the relationship between obesity and work factors as the prevalence of obesity has been shown to vary substantially by occupation. Source: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4681272/

Add New Item for Section II:

II-O: Occupational Data for Health (ODH):

Type	Standard Implementation/ Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Implementation Specification	IHE Quality, Research and Public Health Technical Framework Supplement: Healthy Weight (HW). Rev. 2.2 – Trial Implementation, section 6.3.3.10.5, Occupational Data for Health Section, 1.3.6.1.4.1.19376.1.5.3.1.3.37, p. 127-128 and section 6.3.4, CDA Entry Content Modules, p. 129-144.	Balloted Draft	Pilot	Feedback Requested	No	Free	Yes
Implementation Specification	HL7 CDA® R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes; Additional Templates, Release 1 - US Realm, Chapter 4, Occupational Data for Health, p. 41-74.	In Development		Feedback Requested	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration
The Occupational Data for Health (ODH) CDA template is being balloted by HL7 as a supplemental template for incorporation in C-CDA

Section IV: Models and Profiles

17-7. Is the existing ISA format used for listing standards and implementation specifications applicable for listing Models and Profiles? Are there additional or different attributes that should be collected for them? Are there additional models and/or profiles that should be listed?

AHIMA suggests there is a need for (a) definitions for the terms "Models and Profiles" in ISA, (b) description about how these artifacts relate to the ISA Sections I-III and (c) "interoperability needs" items listed in Sections I-III. Please see above our comment on the need for the Glossary of Terms in ISA in question 17-3.

The current Section includes (1) HL7 EHR/PHR functional models and profiles; and (2) HL7 domain analysis models (DAMs) for 2 domains - nutrition and behavioral health. Please see below our comments regarding these artifacts:

1. The overall value of HL7 EHR/PHR Functional Models (FM) and Functional Profiles (FP) needs to be further discussed to reference them in the ISA. These artifacts have not been used yet in the HIT implementations. The expectation that they might inform the HIT Certification criteria had not been proven yet by the Certification entities. We believe that further discussions are needed regarding the inclusion of those in the ISA. In the meantime, please see below comments regarding the profiles included in this Section:

    a. Suggested name change and additional information
       Current Name: "HL7 Public Health Functional Profiles (published 2015), suite of nine (9) FPs for specific public health services/domain areas, based on ISO/HL7 10781 EHR-S FM"

       Correct Name: "HL7 EHR-System Public Health Functional Profile, Release 2"
       1) HL7 Electronic Health Record System - Public Health Functional Profile (PHFP) identifies functional requirements and conformance criteria for public health and clinical information collection, management and exchanges for the following public health programs (domains): Vital Records; Early Hearing Detection and Intervention; Chronic Diseases (Cancer Surveillance); Public Health Laboratory Interactions (Orders and Results); Occupational Disease, Injury, and Fatality; Health Statistics; Deep Vein Thrombosis and Pulmonary Embolism; Birth Defects; and Adverse Events. This profile is a U.S. Realm Functional Profile that is aimed to healthcare providers and public health stakeholders at the local, state and federal levels.
       2) Type: Implementation Specification
       3) Maturity: In development
       4) Adoption level: none
       5) Federally required: no
       6) Cost: Free
       7) Test Tool Availability: no

    b. Additional Public Health FP to add:
       1) HL7 EHR-S FM Release 2: Functional Profile: Work and Health, Release 1.
       2) Clinical users of EHR Systems can benefit from a targeted set of the patient's work and/or injury/poisoning causation data to provide care, create reports, and meet other stakeholders' expectations such as public health case reporting, surveillance, and investigative studies.
       3) Type: Implementation Specification
       4) Maturity: In development
       5) Adoption level: none
       6) Federally required: no
       7) Cost: Free
       8) Test Tool Availability: no

2. We believe that HL7 DAMs should be listed under Content Standards (under Section II) because DAMs represent content models (data sets models and their structures). In addition to the 2 HL7 DAMs, the HL7 Vital Record DAM, URL: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=69 should be included in Section II as an information content standard (model) for Public Health: Vital Records

Section V: Administrative Standards and Implementation Specifications

17-8. Please review the contents of the new Section V: Administrative Standards and Implementation Specifications and provide comments about the accuracy of any of the listed standards/specifications and attributes.

This section presents examples of grouping various standards under a specific domain of use (Use Case). In the current ISA structure, it is not clear, why this is a separate section. Items listed in questions 17-8 – 17-17 are data, content and information exchange standards that in other domains (e.g. healthcare, imaging, laboratory, public health) are listed in Sections I-III as appropriate. Creating Section V warrants creation of similar sections for other domains such as healthcare, imaging, laboratory, public health, i.e. organizing standards by domain of use (Use Cases). Please see our comments under question 17-1 regarding grouping standards scattered through Sections I-IV under Use Cases with specific example of Occupational Data for Health (ODH).

17-9. Are there additional administrative-related interoperability needs that should be listed in this section?

IHE ITI Patient Administration Management (PAM) US National Extension standard (https://wiki.ihe.net/index.php/Patient_Administration_Management) is currently under development by the IHE and AHIMA Standards Task Force. Suggested addition:

1) IHE ITI Patient Administration Management (PAM) US National Extension
2) IHE ITI PAM US National Extension enables standardization of patient administration management content and work processes for patient registration, diagnostics and laboratory testing, medication administration, care management and transition of care, and other functions in emergency, inpatient and outpatient care settings. Items listed under interoperability needs Section V 17.8 and 17-10 –17-17 are included in the standard.
3) Type: Implementation Specification
4) Maturity: In development
5) Adoption level: none
6) Federally required: no
7) Cost: Free
8) Test Tool Availability: IHE Connectathon test tools