

November 6, 2015

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

Re: AHIMA Comments on the ONC 2016 Interoperability Standards Advisory
(Electronically submitted at <http://www.healthit.gov/standards-advisory>)

Dear Dr. DeSalvo,

On behalf of the American Health Information Management Association (AHIMA), I am pleased to submit comments related to the 2016 Interoperability Standards Advisory developed by the Office of the National Coordinator for Health Information Technology (ONC).

AHIMA is the national, non-profit association of health information management (HIM) professionals. With component state associations in all 50 states, the District of Columbia, and Puerto Rico, AHIMA has more than 101,000 members dedicated to effective health information management, information governance, and health data analytics. HIM professionals work for more than 40 different employer types in 120 different job functions, including hospitals, physician offices, long term care organizations, clinics, health information technology vendors and developers, consulting firms, life science companies, and government and education systems. AHIMA's members can be found in numerous and diverse roles with a wide range of responsibilities. Individual members are hospital administrators; deans of universities; lawyers; privacy and compliance officers; government officials; coders and data analysts; and consultants and industry professionals.

AHIMA is ready to continue working with ONC on its approach to “*coordinate the identification, assessment and determination of the “best available” interoperability standards and implementation specifications for industry use to fulfill specific clinical health IT interoperability needs*” (p. 4).¹

As you know, on April 23, 2015, AHIMA commented on the 2015 Advisory (please find our response at URL: <http://bok.ahima.org/PdfView?oid=300906>). We see important changes in the 2016 Advisory compared to the 2015 Advisory. Specifically, these changes relate to defining the “interoperability need/purpose” and standards selection characteristics (standards maturity, adoption, testing, etc.) --- the need for which we described in our comments on the 2015 Advisory. However, we believe that several comments we made in April have not yet been addressed in the

¹ *Italicized text* represents direct quotes from the Advisory.

2016 Advisory to the full extent. There are three important issues that need further attention. They are: 1) defining interoperability standards; 2) defining “interoperability need/purpose”; and 3) defining selection criteria for the Advisory’s metric. We describe our views about these comments in the sections that follow.

Comment 1: Defining Interoperability Standards and Approach for Developing Interoperability Standards

Like the 2015 Advisory, the 2016 Advisory still represents a catalog of individual HIT standards and implementation specifications. Selected standards are grouped into three sections: *Vocabulary/code sets/terminology standards, Content/structure standards, and Services.*

As we wrote in our comments on the 2015 Advisory, though we believe that developing such a catalog is an important effort, the catalog by itself does not make these individual standards interoperability standards.

The term “interoperability standard,” was not defined in either the 2015 or the 2016 Advisories. An interoperability standard is a specific type of technical specification (not a list or a catalog) of individual standards or implementation specifications. In our comments on the ONC Interoperability Roadmap² and the 2015 Advisory, we wrote that interoperability standards are special products of standards selection, harmonization, and testing activities for a specific business need/purpose (use case). This product is a meta-standard (a standard about standards)—an assembly of standards in an interoperability specification or reference standards portfolio—that defines how individual standards (e.g., those in the Advisory) have to work together to enable interoperability for a specific use case such as care coordination, radiology, laboratory, pharmacy, data reporting, population health, etc.

The International Organization for Standardization’s Technical Committee 215 for Health Informatics (ISO/TC 215),³ with leadership from the US Technical Advisory Group (TAG) for ISO/TC 215 and the active engagement and support of 52 TC 215 member nations, has been defining interoperability standards as a grouping (an assembly or “a bundle”) of individual standards in a normative reference document or a reference standards portfolio (RSP) for a specific interoperability purpose (i.e., clinical use). In collaboration with Digital Imaging and Communications in Medicine (DICOM), ISO TC 215 has been developing an RSP for clinical imaging that names individual standards needed to enable interoperability in the clinical imaging domain, addressing various use cases where clinical imaging is used, i.e., cardiology, oncology, prenatal care, etc. This work should be taken into account to align national and international efforts toward defining and implementing HIT systems interoperability.

² American Health Information Management Association (AHIMA) Comments on the Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap DRAFT Version 1.0 (ONC Interoperability Roadmap), April 3, 2015. <http://bok.ahima.org/PdfView?oid=300817>

³ International Organization for Standardization (ISO) Technical Committee (TC) 215 for Health Informatics. http://www.iso.org/iso/home/standards_development/list_of_iso_technical_committees/iso_technical_committee.htm?commid=54960

Please note that AHIMA is the secretariat to the ISO TC 215 and ISO/TC 215 US TAG. We will be happy to engage ONC in the development of interoperability standards (reference standards portfolio) at ISO/TC 215.

Comment 2: Improving Definition of “Interoperability Need” (Purpose)

The 2016 Advisory’s standards catalog is organized within the three sections mentioned above by a specific “interoperability need.” We appreciate this change, as it is consistent with our comments on the 2015 Advisory. However, the interoperability needs are expressed at various levels of granularity, such as:

- a. a single data element (e.g., *race and ethnicity* (p.10), *gender* (p.11), *preferred language* (p.16), *UDI* (p.17), etc.)
- b. a whole clinical domain (e.g., *immunization* (p.13), *radiology (interventions and procedures)* (p.17), *electronic prescribing* (p. 20), *public health reporting* (p. 25), etc.) and
- c. a specific “service” (e.g., *clinical decision support* (p. 32), *query* (p. 35), etc.).

It will be difficult to achieve interoperability when it is left to the implementer to assemble individual standards to address various levels of granularity of the “need” (data element, report document, query message, etc.). The same “need” may be achieved differently at various facilities; the same standards may be used inconsistently to achieving the same “need.”

In addition, the main purpose of interoperability is data re-use (“collect once, use many times”). Different vocabulary and terminology standards (SNOMED, LOINC, ICD, etc.) are used to enable data representation for a specific use (use case), i.e., SNOMED for clinical care, CPT codes for medical procedures, ICD for public health statistics, and so on. The choice of vocabulary and terminology standards to code a data element (allergies, gender, race and ethnicity, and other examples of “interoperability needs” under Sections I and II) depends on the context in which this data element is used, i.e., why allergy data is being collected. Selecting a standard for only a data element out of the context of specific data use is not meaningful.

As we wrote in our 2015 Advisory comments, in HIT, the “need/purpose” is called a use case. **There is a need to re-establish the process of defining national use cases for interoperability (i.e. interoperability purpose documents)** as done by the American Health Information Community(AHIC)—a federally chartered advisory committee operated between 2005–09 to make recommendations to the Secretary of the US Department of Health and Human Services on how to accelerate the development and adoption of HIT. AHIC defined 152 priority areas (i.e., interoperability purposes) and developed national use cases that were further used by the Healthcare Information Technology Standards Panel (HITSP)⁴ to enable standards selection (cataloging), harmonization (addressing individual standards gaps and overlap), testing, and publishing an interoperability specification for a specific interoperability purpose.

⁴ Healthcare Information Technology Standards Panel (HITSP). <http://www.hitsp.org/>

As stated in the AHIMA Comments on the ONC Interoperability Roadmap,⁵ the experience of AHIC, HITSP, the European Union (EU)'s Antilope Project (which defined an EU Interoperability Framework and EU use cases [special purposes]),⁶ and ISO/TC 215 Health Informatics on developing reference standards portfolios described above must be leveraged in enabling interoperability through standards in the US.

AHIMA is ready to work with ONC to transform the Advisory from a catalog (list) of standards into a guidance document for supporting interoperability for selected national use cases through interoperable HIT standards.

Comment 3: Scope

The Advisory states that its “*scope includes electronic health information created in the context of treatment and subsequently used to accomplish a purpose for which interoperability is needed (e.g., a referral to another care provider, public health reporting). The advisory does **not** include within its scope administrative/payment oriented interoperability purposes or administrative transaction requirements that are governed by HIPAA and administered by the Centers for Medicare & Medicaid Services (CMS).*”(p. 4)

We do not see how clinical and administrative interoperability needs can be separated, i.e. one is interoperable and another is not. For example, “the referral” is also an administrative/payment oriented purpose (e.g., an insurance plan is determining who to refer to). Administrative interoperability needs should be included in the Advisory. AHIMA believes that for quality reporting initiatives, administrative interoperability is required. The implementation specification from HL7 that is listed on p. 28 is used by quality reporting agencies such as the Agency for Healthcare Research and Quality (AHRQ). AHRQ's Healthcare Cost and Utilization Project databases are derived from administrative data and contain encounter-level clinical and nonclinical information, including all-listed diagnoses and procedures, discharge status, patient demographics, and charges for all patients, regardless of payer (e.g., Medicare, Medicaid, private insurance, uninsured), beginning in 1988.⁷

Comment 4: Criteria for Selecting Standards for the Advisory

We support the new approach for standards selection outlined in the 2016 Advisory. It is consistent with examples of criteria that we included in our comments to the 2015 Advisory. The 2016 Advisory selection criteria include:

1. *Standards process maturity (standards status)*
2. *Implementation maturity*
3. *Adoption level*
4. *Regulated*
5. *Cost*

⁵ American Health Information Management Association (AHIMA) Comments on the Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap DRAFT Version 1.0 (ONC Interoperability Roadmap), April 3, 2015. <http://bok.ahima.org/PdfView?oid=300817>

⁶ Vincent Van Pelt, Refinement of the eHealth European Interoperability Framework. http://www.antilope-project.eu/wp-content/uploads/2015/01/02-Antilope_Handover_Workshop_WP1.pdf

⁷ AHRQ. "Healthcare Cost and Utilization Project (HCUP)." <http://www.ahrq.gov/research/data/hcup/index.html>

6. *Test Tool availability*

We hope that ONC will establish a mechanism/capabilities/ infrastructure that will allow tracking of the status of individual standards over time to define the level of readiness of such standards to be included in the interoperability standard (e.g., ISO reference standards portfolio, see Comment 1 above).

We believe that in the context of standards usability, there is a need to better define several terms used in the selection criteria. They include “draft” and “trial implementation” under *Standards process maturity* and “pilot” under *Implementation maturity* criteria. A number of questions arise: How does this immature level of standards maturity (draft, pilot, trial implementation) impact interoperability? Should an implementer use or not use these standards? When standards reach a mature status (i.e., its status changes to “final” and “production”), what indication do we have that standards in the final/production state actually met the interoperability need?

We are also interested to know what data ONC used to develop the *adoption level* metrics and how information on adoption was collected.

It is stated on p. 4 that the scope of the Advisory does not include administrative/payment-oriented interoperability purposes or requirements governed by HIPAA and administered by CMS. However, the selection criteria include the “*Regulated*” category. If HIPAA and CMS administrative regulation is out of scope, what does “adopted in regulation” refer to? As we commented on the 2015 Advisory, we believe that administrative and clinical purposes should not be separated. (Please see our response on this matter to the ONC question regarding additional interoperability purposes in the Appendix below.)

We also believe that in addition to the 2016 Advisory’s selection criteria (1-6) above, it is important to address the following two criteria as well (listed in our 2015 comments):

1. Standards compatibility (ability for new and old versions of standards to work together), and
2. Standards interoperability (ability of a standard to work together with other standards when grouped in an interoperability specification, integration profile, etc. for a specific use case)

AHIMA is ready to work with ONC and the HIT community to further refine ONC criteria for selecting standards for the Advisory.

The following Appendix includes our additional responses to the ONC questions raised in the 2016 Advisory document (pp. 38-39).

AHIMA is committed to participating in the annual review process for the Standards Advisory and looks forward to working with ONC to enable interoperability of information systems in healthcare through standards.

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AHIMA Comments

Please feel free to contact Pamela Lane, AHIMA's vice president, policy and government relations directly at (202) 659-9440 or Pamela.lane@ahima.org if we can provide any further information or address questions regarding this letter and its recommendations.

Sincerely,



Cassi Birnbaum, MS, RHIA, CPHQ, FAHIMA
President/Chair



Lynne Thomas Gordon, MBA, RHIA, CAE, FACHE, FAHIMA
Chief Executive Officer

Appendix: Responses to ONC Questions Listed in Advisory's *Section IV: Questions and Requests for Stakeholder Feedback* (pp. 38-39)

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Please note that ONC questions are in italics.

General

4-1. In the 2015 Advisory, each standard and implementation specification was listed under a "purpose." Prior public comments and HIT Standards Committee recommendations suggested that the Advisory should convey a clearer link to the ways in which standards need to support business and functional requirements. This draft attempts to do so and lists standards and implementation specifications under more descriptive "interoperability needs." Please provide feedback on whether revision from "purpose" to "interoperability need" provides the additional requested context and suggestions for how to continue to improve this portion.

See comment 2 above.

4-2. For each standard and implementation specification there are six assessment characteristics. Please review the information provided in each of these tables and check for accuracy. Also, please help complete any missing or "unknown" information.

See comment 4 above.

4-3. For each standard and implementation specifications, there is a table that lists security patterns. This draft only includes select examples for how this section would be populated in the future. Please review examples found in Sections III-A and III-F and provide feedback as to the usefulness of this approach and any information you know for a specific interoperability need.

Please see our answer below to the ONC question in *Appendix II: Sources of Security Standards: Are there other authoritative sources for Security Standards that should be included in Appendix II?*

4-4. For each interoperability need, there is a table beneath the standards and implementation specifications that includes limitations, dependencies, and preconditions. This draft only includes select examples for how this section would be populated in the future. Please review populated sections and provide feedback as to the usefulness of this approach and any specific information you know for a specific interoperability need.

This cell in the table will not be necessary if a data element, a document, a domain, or a service (called "interoperability needs" in the Advisory; see comment 2 above) were presented in the context of a use case. The constraints to be imposed on the use of specific standards (i.e., *limitations, dependencies and preconditions*) may be meaningful only in a context of a use case. The current approach is not useful.

Section I: Vocabulary/Code Set

Based on public feedback and HIT Standards Committee review, there does not appear to be a best available standard for several "interoperability needs" expressed in this section of the draft

Advisory. Please provide feedback on whether this is correct or recommend a standard (and your accompanying rationale).

See comments 1 and 2 above. The mixed levels of granularity (data element, document, domain, service) in which the “interoperability need” is currently expressed does not allow the selection of a specific standard that will serve needed content, context, and purpose (need). Please revisit the AHIC, HITSP, EU, and ISO/TC 215 comprehensive approach for defining “interoperability need.”

Examples of specific issues with individual standards included in the Advisory are:

1. SNOMED-CT challenges: data quality (ambiguity, hierarchical relationships, and content coverage), implementation, data retrieval, etc. See Lee, Dennis, et al., "A Survey of SNOMED CT Implementations," *Journal of Biomedical Informatics*, 2012, DOI: <http://dx.doi.org/10.1016/j.jbi.2012.09.006>.
2. A study was done on the usefulness of using RxNorm and NDF-RT to classify medication data extracted from the EHR. See Pathak, J., Murphy, S.P., Willaert, B.N., et al., “Using RxNorm and NDF-RT to Classify Medication Data Extracted from Electronic Health Records: Experiences from the Rochester Epidemiology Project,” *AMIA Annual Symposium Proceedings*. 2011:1089-1098.

p. 9 *Care team member*. The NPI is listed as “non-regulated standards.” We disagree. The NPI is required for all healthcare providers covered under HIPAA. Some public sector accounts include providers, classified as “atypical,” who do not provide healthcare (e.g., transportation providers or non-licensed case management providers), as defined under HIPAA in federal regulations at 45 CFR section 160.103; these providers are not eligible to receive NPIs.

p. 15. *Representing patient medication*. The NDC standard is selected. We disagree. The NDC would not allow for detailed patient-centric information. RxNorm, on the other hand, represents drugs in a way that corresponds directly to a prescriber's view of a drug, i.e., ingredient + strength + dose. (Please see comment 2 above regarding the context of data use/reuse in selecting standards for an “interoperability need.”)

p.15. *Representing patient “problems.”* SNOMED is selected. It is not clear which problems this interoperability need refers to, i.e., clinical, psychological, social, or environmental. See comment above about the limitations of SNOMED.

p. 29. *Reporting patient-level data to quality reporting initiative*. What are specific examples of these reports? All listed standards have to be constrained by the specific data set defined by the data use (use case). See comment 2 above regarding the definition of “interoperability need.”

Section II: Content / Structure

Should more generalized survey instruments such as the IHE Profile Retrieve Form for Data Capture be considered?

It is unclear why the IHE RFD is defined as a survey instrument standard. This is a standard to pre-populate a Clinical Document Architecture (CDA)-based form from the Continuity of Care Document (CCD) standard, e.g., clinical research forms (could be a survey), public health reports, etc.

It is not clear what is meant by “generalized.” Survey instruments are very specific to the context of the specific need (i.e., use case/domain).

Survey instruments are usually content documents, so they should be defined in the content profiles developed by Integrating the Healthcare Enterprise (IHE), implementation guides developed by Health Level Seven (HL7), or international efforts, such as the Trillium Bridge Project. When content is defined in the IHE, HL7, and/or other specifications, the IHE RFD can be used to pre-populate data into the survey instrument.

In addition to the two interoperability needs already listed, are there others that should be included related to imaging? If so, what would the best available standard and/or implementation specifications be?

See comment 1 above which described that, in collaboration with DICOM, ISO TC 215 has been developing a reference standards portfolio (RSP) for clinical imaging. This interoperability standard defines individual standards needed to enable interoperability in clinical imaging, addressing various clinical specialties where clinical imaging is used, i.e., cardiology, oncology, OB/GYN, orthopedics, surgery, radiation therapy, dentistry, and eye care. The RSP for clinical imaging includes 23 use cases describing “interoperability needs” in these clinical specialties. AHIMA invites ONC to join the US TAG at ISO TC 215 to develop an interoperability standard for clinical imaging and other health domains.

Should a more specific/precise aspect of DICOM be referenced for the implementation specification for this interoperability need?

See answer to the question above.

The HIT Standards Committee recommended to ONC that clearer implementation guidance is required. Are there additional implementation specifications that should be considered for this interoperability need?

We agree. Interoperability specification, not a simple catalog of standards, is needed. Please see comment 1 above which refers to the examples of work conducted by AHIC, HITSP, EU, and currently ISO/TC 215. Specifically, see description of the ISO/TC 215 Reference Standards Portfolio above.

Section III: Services

The 2015 Advisory’s Section III, Transport has since been removed with content representation migrated as applicable within Section IV Services. What is your view of this approach?

We believe the transport section must be reinstated. Transport mechanisms (message-based HL7 V2.x, V3, structured documents using IHE XDS for CDA, secure e-mail, etc.) must be specified for specific content representation options (messages [strings of data]; structured documents; PDFs; images; device reading; etc.). Please see the IHE white paper “Health Information Exchange: Enabling Document Sharing Using IHE Profiles” (http://www.ihe.net/Technical_Framework/upload/IHE_ITI_White-Paper_Enabling-doc-sharing-through-IHE-Profiles_Rev1-0_2012-01-24.pdf), on five possible transport mechanisms for data exchange.

Appendix II: Sources of Security Standards

Are there other authoritative sources for Security Standards that should be included in Appendix II?

In 2012, the Public Health Data Standards Consortium, in collaboration with the Association of Public Health Laboratories and with the support from the Centers for Disease Control and Prevention, published the white paper “Assure Health IT Standards for Public Health: Part I: Health IT Standards in Public Health Laboratory Domain” (http://www.phdsc.org/standards/pdfs/PHDSC-APHL_PHL_Standards_White-Paper_Part-1FINAL_v1.pdf). This paper contains a comprehensive list of security standards (pp. 41-48), including ISO standards.

AHIMA will be happy to work with ONC to establish an authoritative source for security standards.