

April 23, 2015

Via Submission to URL: <http://www.healthit.gov/policy-researchers-implementers/2015-interopability-standards-advisory-public-comments>

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

Subject: AHIMA Comments on the ONC 2015 Interoperability Standards Advisory

On behalf of the American Health Information Management Association (AHIMA), I am pleased to submit comments related to the 2015 Interoperability Standards Advisory (2015 Advisory or Advisory) developed by the Office of the National Coordinator for Health Information Technology (ONC).

AHIMA is a not-for-profit, membership-based healthcare association representing more than 101,000 health information management (HIM) and informatics professionals who work in more than 40 different types of entities related to our nation's healthcare and public health industry.

The aim of the Advisory is to provide “*a list of standards and implementation specifications for a broad range of clinical health IT interoperability purposes.*”(p. 1)¹ This effort aligns with AHIMA's Strategy, “Drive the Power of Knowledge—Health Information Where and When It's Needed,” in which AHIMA partners with industry allies including other associations, employers, universities, government agencies, and consumer groups to increase the use of health data in professional practice, create standards for interoperability, and advocate for their consistent application across the healthcare domain.²

AHIMA applauds ONC's effort to “*create the 2015 Advisory is an “open draft” designed to begin an interactive process.*”(p.1)

The following comments show that AHIMA is ready to work with ONC to finalize the Advisory enabling standardization of health information technology (HIT) and systems interoperability in healthcare and public health.

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

² American Health Information Management Association (AHIMA). Drive the Power of Knowledge—Health Information Where and When It's Needed. Strategy 2014-2017. URL: <http://www.ahima.org/about/aboutahima?tabid=strategy>

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

The Advisory was developed as a catalog of individual HIT standards and implementation specifications “*grouped into four categories: Vocabulary/code sets/terminology (i.e., “semantics”), Content/structure (i.e., “syntax”), transport (i.e., the method by which information is moved from point A to point B, Services (i.e., the infrastructure components deployed and used to accomplish specific information exchange objectives).* (p. 6)

Though we believe that developing such a catalog is an important effort, the catalog by itself does not make these individual standards interoperability standards.

Interoperability standards are a specific type of technical specification, not just a list of individual specifications. The term “interoperability standards,” however, was not defined in either the ONC Interoperability Roadmap or the Advisory.

As we wrote in our Comments for the ONC Interoperability Roadmap,³ interoperability standards are special products of standards selection and harmonization activities for a specific business need (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 experience of the Health Information Technology Standards Panel (HITSP)⁴ showed that there is a need for additional constraints defined by the meta-standard (interoperability specification) for individual standards to work together for a specific Use Case.

The International Organization of Standardization Technical Committee 215 Health Informatics (ISO/TC215),⁵ with leadership from the US Technical Advisory Group (TAG) for ISO/TC 215 and the active engagement and support of fifty-two (52) TC215 member nations, has been defining an interoperability standards reference portfolio for a specific domain as a grouping of individual standards. (Please note that AHIMA provides secretariat to the ISO TC 215 and ISO/TC215 US TAG.) This work should be taken into account to align national and international efforts towards defining and implementing HIT systems interoperability.

AHIMA is committed to work with ONC to leverage experience of the international standards development community to define interoperability standards as well as the approach for their development.

³ 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. URL: <http://bok.ahima.org/PdfView?oid=300817>

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

⁵ International Organization of Standardization (ISO) Technical Committee (TC) 215 Health Informatics. URL: http://www.iso.org/iso/home/standards_development/list_of_iso_technical_committees/iso_technical_committee.htm?commid=54960

Comment 2: Aligning the Advisory with Federal Regulation and Programs for Health Information Systems Interoperability

Various HIT-related laws, regulations, policy documents, and governmental agencies' reports had been developed in the past few years to address lack of interoperability of electronic health record (EHR) systems adopted under the Meaningful Use of HIT Program. Several of these documents are referenced in the Advisory. Various HIT standards and Use Cases were called in these documents.

AHIMA strongly believes all federal laws, regulations, and programs documentation that refer to or require standards for interoperability should be tied together. This is a necessary step toward enabling various aspects of interoperability (semantic, technical and functions) through standards. The Advisory should serve this need to reach ONC's goal to "*provide clarity, consistency, and predictability for the public regarding ONC's assessment of the "best available" standards and implementation specifications for a given clinical health IT interoperability purpose.*" (p. 4)

Comment 3: Advisory's Purpose

The current Advisory serves two purposes:

"1) To provide the industry with a single, public list of the standards and implementation specifications that can best be used to achieve a specific clinical health information interoperability purpose... <and>

2) To prompt dialogue, debate, and consensus among industry stakeholders when more than one standard or implementation specification could be listed as the best available." (p.2)

Purpose 1 is aimed to produce the catalog of existing standards. As it was stated under Comment 1 above, a catalog of standards is not sufficient to make individual standards interoperability standards. "*Specific clinical health information interoperability purpose*" must be defined before selecting standards for this purpose. In HIT, the "purpose" is called Use Case. There is a need to re-establish the process for defining national Use Cases for interoperability as it was done by the American Health Information Community—a federally chartered advisory committee operated during 2005–2008 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 priority areas (breakthroughs) and developed foundational Use Cases that were then used by HITSP to harmonize standards and develop interoperability specifications—selection of standards for a specific interoperability purpose.

It is interesting to note that while the Advisory describes the activities of Consolidated Health Informatics (CHI) (2001–2007)— a predecessor of AHIC and HITSP—the Advisory does not mention the AHIC that defined 152 national Use Cases and HITSP that produced interoperability specifications for 18 of these Use Cases. CHI produced the list of standards. AHIC/HITSP produced Use Cases/specifications for individual standards (from the CHI list and other sources) to work together. To enable interoperability, the industry expects from the ONC more than an updated CHI-like catalog of standards.

Purpose 2 is aimed at enabling a dialogue. Today, something more than dialogue about standards is needed.

As stated in the AHIMA Comments on the ONC Interoperability Roadmap,⁶ the experience of AHIC, HITSP, the European Union (EU)'s Antilope Project that defined EU Interoperability Framework and EU Use Cases (special purposes)⁷ and ISO/TC 215 have to be leveraged to re-establish the leadership of the United States in enabling interoperability through standards.

AHIMA is ready to work with ONC to transform the Advisory from the catalog (list) of standards into the guidance document for supporting interoperability for selected Use Cases through interoperable (i.e., working together) HIT standards.

Comment 4: Criteria for Selecting Standards for the Advisory

The Advisory provides criteria for selecting standards for the Advisory. In the absence of the nationally recognized Use Cases, it is not clear, however, how selected standards can work together to support specific purpose of interoperability. Standards selection criteria from HITSP process have to be revisited, nationally revalidated and used to select individual standards for interoperable solutions.

The following are the criteria that should be used for selecting standards for the Advisory:

1. Standards maturity (ability to pass testing)
2. Standards adoption (the extent to which a particular standard has been used in HIT products on the market)
3. Standards compatibility (ability for new and old versions of standards to work together), and
4. 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)

For the standard maturity selection criteria, AHIMA supports ONCs statement that *“if a standard or implementation specification is “new” it should not be automatically excluded from consideration as a best available standard or implementation specification”* (p. 8).

AHIMA advocates that all standards (new and existing) be tested prior to inclusion on the Advisory.

AHIMA agrees with ONC's timeline and availability statement that not-mature standards will not be selected for the Advisory (i.e., *“next year’s 2016 Advisory would not include a standard or implementation in the process of being developed and expected to be ready during 2016).*

⁶ 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. URL: <http://bok.ahima.org/PdfView?oid=300817>

⁷ Vincent Van Pelt, Refinement of the eHealth European Interoperability Framework. URL: http://www.antilope-project.eu/wp-content/uploads/2015/01/02-Antilope_Handover_Workshop_WP1.pdf

Instead the 2017 Advisory would be the next available opportunity for that standard or implementation specification to be listed.” (p. 8). We support that standards and implementations guides should be successfully tested prior to inclusion in the Advisory.

Sufficient time has to be given to the HIT vendors to enable the adoption of matured, compatible, and interoperable standards in their systems. Standards-based systems certification process has to be established to ensure the deployment of interoperability standards in HIT products.⁸

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

Comment 5: Advisory Update Process

“ONC expects to annually update the Advisory through a transparent and structured process that includes advice from the HIT Standards Committee (ONC’s federal advisory committee) and the public at large. To the extent possible, updates to future advisories will be done in a manner that seeks to minimize the potential for unnecessary sunk costs and to promote the entry of innovative standards.” (p. 4).

AHIMA strongly supports ONC's commitment to keep the Advisory updated on an annual basis. AHIMA also supports the open, collaborative, and participatory process for reviewing selected standards through the public comments process in order to build national consensus on the standards included in the Advisory in the following years.

AHIMA is committed to participate in the annual review process for the Standards Advisory in the upcoming years.

The following sections present supporting materials for our comments as well as our responses to the ONC questions raised in the Standards Advisory document (p. 6–7).

AHIMA looks forward to working with ONC to enable interoperability of information systems in healthcare through standards.

Please contact me at lynne.thomasgordon@ahima.org; or (312) 233-1165 if you have any questions.

Sincerely,



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

⁸ 45 CFR Part 170. 2014 Edition Release 2 Electronic Health Record (EHR) Certification Criteria and the ONC HIT Certification Program; Regulatory Flexibilities, Improvements, and Enhanced Health Information Exchange; Final Rule URL: <http://www.gpo.gov/fdsys/pkg/FR-2014-09-11/pdf/2014-21633.pdf>.

Attachments: supporting comment materials; responses to ONC questions

5-1. **[General]** What other characteristics should be considered for including best available standards and implementation specifications in this list?

In the AHIMA Comments for the ONC Interoperability Roadmap, we proposed to use Health Level Seven (HL7) definition of interoperability⁹ as follows:

"Interoperability" means the ability to <capture>¹⁰, communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks in various settings, and exchange data such that clinical or operational purpose and meaning of the data are preserved and unaltered."

HL7's approach to interoperability is based on the following three interoperability components (pillars):¹¹

1. **Semantic** interoperability—shared content
2. **Technical** interoperability—shared information exchange infrastructure
3. **Functional** interoperability—shared rules of information exchanges (i.e., business rules and information governance ("*the rules of the road*").¹²

The Advisory has to specify standards to support the three interoperability components.

5-2. **[General]** Besides the four standards categories included in this advisory, are there other overall standards categories that should be included?

An additional three categories of standards have to be included: Functional Standards, Privacy and Security Standards, and Identifier Standards.¹³ A brief description of these standards categories is provided below.

Functional standards (rules of the road) support business processes (e.g., clinical guidelines) and information governance¹⁴ (business rules for data and information availability, integrity, protection, accountability, compliance, retention, and disposition).

AHIMA has worked with Integrating the Healthcare Enterprise (IHE) to develop HIT standards to support information governance and associated HIM practices in healthcare organizations.

⁹Health Level Seven (HL7). Coming to Terms: Scoping Interoperability for Healthcare. White Paper. 2007. URL: <https://www.hln.com/assets/pdf/Coming-to-Terms-February-2007.pdf>

¹⁰ AHIMA proposes to add "capture" to the HL7 definition of interoperability.

¹¹Ibid.

¹² Dimick C. Governance: apples and oranges. Differences exist between information governance, data governance, and IT governance. *JAHIMA*. 2013; 84(11): 60-2.

¹³ Public Health Data Standards Consortium (PHDSC). Web-Resource Center. HIT Standards. URL:

<http://www.phdsc.org/standards/health-information-tech-standards.asp>

¹⁴ AHIMA. Information Governance Principles for Healthcare (IGHCP). URL: [AHIMA's Information Governance \(IG\) resource portal](#) (NOTE: You need to fill out AHIMA brief IG survey to access this document.)

Privacy and Security Standards ensure information is sent securely, disclosed to the authorized users, and shared only with the patient's permission. Analysis of specific HIT standards to enable privacy and security of information has to be conducted to identify these standards. Detailed list of privacy and security of standards for such analysis can be found in the White Paper entitled *Assure Health IT Standards for Public Health*.

Identifier standards provide a universal method to identify and match entities and objects participating in the information exchange. Identifiers are the lexical tokens that name entities in all information systems essential for any kind of symbolic processing.¹⁵ A 2008 RAND study concluded that identifiers are "clearly desirable for reducing errors, amplifying interoperability, increasing efficiency, improving patient confidence, promoting architectural flexibility, and protecting patient privacy."¹⁶ For example, ONC Standards & Interoperability (S&I) Framework Data Provenance initiative¹⁷ is aimed to identify the owner of information.

Identifiers are needed for consumers, providers, healthcare organizations, payers and other participants of health information exchange, as well as information objects (orders, results reports, prescriptions, referrals, etc.) and physical objects (specimens, devices, instrumentation, medication, medical supplies, etc.) involved in the information flow in healthcare.

5-3. **[General]** For sections I through IV, what "purposes" are missing? Please identify the standards or implementations specifications you believe should be identified as the best available for each additional purpose(s) suggested and why.

It is not clear why the Advisory refers to a data element as a "purpose." Please note that valid selection of an individual standard for a data element is not possible without the overall context in which this data element will be used. This context can be only provided by the Use Case (i.e., the purpose of information sharing by users in a specific clinical or public health scenario supported by the interoperability of the participating information systems).

We suggest that ONC will reconsider the term "purpose" at the level of a data element, and focus on the purpose at the level of a Use Case (specific clinical or public health scenario for information sharing).

Specific examples of the Use Cases may include:

- Exchange ambulatory summary or inpatient summary between authorized users
- Exchange transition of care/referral summaries between authorized users
- Exchange information between healthcare and public health on public health reporting (communicable and chronic diseases, maternal and child health, and other programs)

¹⁵ Orlova, Anna. "An Overview of Health IT Standards." *Journal of AHIMA* 86, no.3 (March 2015): 38–40.

¹⁶ Rekindling the patient ID debate, January 29, 2013: <http://www.healthcareitnews.com/news/rekindling-patient-id-debate?page=0>

¹⁷ ONC Standards & Interoperability (S&I) Framework. Data Provenance Initiative. URL: <http://wiki.siframework.org/Data+Provenance+Initiative>

- Exchange information (test orders and results) for laboratory, radiology, and other tests between authorized users in healthcare and public health.¹⁸

As we stated in the AHIMA Comments on the ONC Interoperability Roadmap, examples of Use Cases from the EU Antelope project include¹⁹:

- Medication
- Radiology
- Laboratory
- Patient summary
- Referral and discharge reporting
- Participatory healthcare (chronic diseases)
- Telemonitoring
- Multi-disciplinary consultations

Eighteen HITSP interoperability specifications for the US national Use Cases developed by AHIC in 2005–2009 have to be reviewed to revalidate standards selected in the Advisory.

5-4. **[General]** For sections I through IV, is a standard or implementation specification missing that should either be included alongside another standard or implementation specification already associated with a purpose?

Please see comment regarding “purpose” above. As it was stated in 5-3, 18 HITSP interoperability specifications for the US national Use Cases developed by AHIC in 2005–2009 have to be reviewed to revalidate the selection of individual standards in the Advisory.

5-5. **[General]** For sections I through IV, should any of the standards or implementation specifications listed thus far be removed from this list as the best available, and if so, why?

Please see comment above regarding data element versus Use Case as a “purpose”.

¹⁸ 45 CFR Part 170. 2014 Edition Release 2 Electronic Health Record (EHR) Certification

Criteria and the ONC HIT Certification Program; Regulatory Flexibilities, Improvements, and Enhanced Health Information Exchange; Final Rule URL: <http://www.gpo.gov/fdsys/pkg/FR-2014-09-11/pdf/2014-21633.pdf>.

¹⁹ Vincent Van Pelt, Refinement of the eHealth European Interoperability Framework. URL: http://www.antelope-project.eu/wp-content/uploads/2015/01/02-Antelope_Handover_Workshop_WP1.pdf

5-6. **[Section I]** Should more detailed value sets for race and ethnicity be identified as a standard or implementation specification?

For clinical, public health, and population health data analysis, a greater level of detail than in the high-level OMB standard (five categories) is needed for precision medicine, analysis of the racial and cultural determinants of health and diseases, etc. The National Center for Health Statistics (NCHS), Centers for Disease Control and Preventions (CDC) maintains the broader list of the race and ethnicity codes for vital records that have to be used.²⁰

5-7. **[Section I]** Should more traditionally considered “administrative” standards (e.g., ICD-10) be removed from this list because of its focus on clinical health information interoperability purposes?

AHIMA strongly disagree with removing “*more traditionally considered ‘administrative’ standards (e.g., ICD-10)...from this list...*”

We also believe there is an error in the question itself. We assume “administrative” standards were asked to be removed because of their “*focus on <non> - clinical health information interoperability purposes.*”

As we stated in the AHIMA Comments on the ONC Interoperability Roadmap, “Administrative electronic health information must be included and integrated <into the Roadmap>. By delaying this integration, ONC is potentially creating duplicate efforts in the future when administrative data is included.”

“Terminologies are regarded as input mechanisms using terms arising from the clinical care process; classifications are regarded as outputs, aggregating terms into meaningful classes for counting purposes. Aggregation into meaningful classes, facilitated by ICD-10 code sets, is important for population health data and public health statistics, both used in the clinical process and exchanged with clinical data.”

5-8. **[Section I]** Should “Food allergies” be included as a purpose in this document or is there another approach for allergies that should be represented instead? Are there standards that can be called “best available” for this purpose?

Please see comment above regarding data element versus Use Case as a “purpose”.

In which context (Use Case) “food allergies” data category is expected to be used? The answer to this question will determine “*are there standards that can be called “best available” for this purpose.*”

²⁰ Centers for Disease Control and Preventions (CDC). National Center for Health Statistics (NCHS). Race and Ethnicity Code Set. Version 1. URL: http://www.cdc.gov/nchs/data/dvs/Race_Ethnicity_CodeSet.pdf

5-9. **[Section I]** Should this purpose category be in this document? Should the International Classification of Functioning, Disability and Health (ICF) be included as a standard? Are there similar standards that should be considered for inclusion?

Please see comment above regarding data element versus Use Case as a “purpose”.

In which context (Use Case) is ICF intended to be used?

AHIMA recommends that ICF be included as one of the code sets for interoperability. Functional status is often more related to a person’s health concerns and healthcare goals than his or her diagnosis. Disability status is critical for making essential accommodations in the healthcare setting and ensuring people with disabilities are not discriminated against in the workplace. ICF is an internationally recognized standard, and the only recognized classification for functioning and disability. It is recognized by many clinical professions (physical therapy, occupational therapy, etc.) and is used in their training.

5-10. **[Section I]** Should the MVX code set be included and listed in tandem with CVX codes?
5-11. **[Section I]** Public health stakeholders have noted the utility of NDC codes for inventory management as well as public health reporting when such information is known/recorded during the administration of a vaccine. Should vaccines administered be listed as a separate purpose with NDC as the code set?

For immunization Use Case, AHIMA supports recommendations from the HL7 Public Health and Emergency Response (PHER) Workgroup regarding the use of MVX, CVX (Question 5-10) and NDC (Question 5-11) as follows:

The NPRM identifies two code systems to identify a vaccine administered. For historic records of vaccination, the CVX should be used to identify the vaccine administered. For newly administered immunizations, the NPRM identifies NDC for identifying the vaccine. This guidance is found in the section on immunization messaging and in the Common Clinical Data Set.

It is important to understand the landscape where these codes are used and to understand what they need to support. They need to support product identification, inventory management and clinical decision support, and identification of a vaccine group/family. This means they should be as specific as possible. Any codes to identify a vaccine should be able to record historic doses, where the exact formulation is not known. For instance, for Haemophilus Influenza Type B (HIB) when the source of the record is a vaccination card, the vaccine is recorded as a HIB. There are a number of different formulations for HIB vaccine. CVX have a concept for HIB, unspecified formulation. On the other hand, a newly administered vaccine can be identified to the trade name level (for example, ACTHIB). The CVX (CDC vaccine code) and MVX (vaccine manufacturer code) support identification of either HIB, unspecified formulation (CVX = 137) or ACTHIB (CVX= 48, MVX = PMC). This approach has been in place since 1999 and is widely adopted. It is identified as the preferred code system in C-CDA.

National Drug Codes (NDC) are created by FDA and the drug manufacturers. They encode the packager/manufacturer, the product and the packaging (i.e., syringe). These codes identify the vaccine by the trade name. They are used for ordering vaccines and are a component of GTIN (2-D barcoding). The more detailed information that can be derived from the NDC provides good support for vaccine inventory management systems that many Immunization Information Systems include. CDC maintains a set of tables that map from NDC to CVX and that link unit of use NDC (carton) to unit of sale NDC (syringe).

PHER supports the continued use of CVX for historic doses. It also supports ongoing support for CVX and MVX for newly administered doses. Permitting ongoing use of these codes allows a gradual transition to NDC for newly administered doses. PHER supports NDC for administered doses. In HL7 V2 messages, both codes may be sent for each immunization. Systems that have not yet moved to NDC can still accept and use the CVX/MVX codes.

PHER supports the requirement that senders and receivers SHALL support:

1. Use of CVX for historic doses
2. Use of CVX and MVX for newly administered doses
3. Use of NDC for newly administered doses.

5-12. *[Section I]* Is there a best available standard to represent industry and occupation that should be considered for inclusion in the 2016 Advisory?

The following occupation data elements (“purposes”) must be included in the 2016 Advisory:

- Employment Status,
- Usual Occupation and Industry, and
- History of Occupation.

These data elements were modeled as a new Occupational Data for Health (ODH) template as an optional sub-section in a Social History section of the HL7 Clinical Document Architecture (CDA) standard. Providing the new ODH section as a template to use as sub-section of the CDA-based clinical document makes it possible for the EHR system vendors to begin using the new template to share ODH information in the EHR systems. The template ensures occupation and industry information is consistently represented in an interoperable, standard format.

Establishing a standard representation for exchanging ODH content (a) enables clinicians and patients to use/re-use occupation and industry information in their healthcare communications; (b) allows the use of occupational health data for public health surveillance and occupational risk factor analysis; and (c) could be used within the industry and across various standards development initiatives to achieve a consistent and more complete representation of occupation health data.²¹

²¹ Public Health Data Standards Consortium (PHDSC). Occupational Data for Health Standards Project. URL: <http://phdsc.org/standards/ohd-hit-standards.asp>

5-13. **[Section I]** If a preferred or specific value set exists for a specific purpose and the standard adopted for that purpose, should it be listed in the “implementation specification” column or should a new column be added for value sets?

A separate column should be added for Value Sets. This column may point to the automated web-based resources (tools) for maintaining specific value sets (e.g., CDC PHIN-VADS²² for public health value sets, NLM VSAC²³ for quality measure value sets under Meaningful Use of HIT regulation).

5-14. **[Section II]** Several laboratory related standards for results, ordering, and electronic directory of services (eDOS) are presently being updated within HL7 processes. Should they be considered the best available for next year’s 2016 Advisory once finalized?

Standards and implementation specifications in the “ballot” phase should not automatically be added. As noted on p. 8, *“the 2015 Advisory would not include a standard or implementation in the process of being developed and expected to be ready. Instead the 2017 Advisory would be the next available opportunity for that standard or implementation specification to be listed.”*

Again, AHIMA strongly recommends that all standards and implementation specifications are tested prior to being placed on the Advisory list. In addition, backwards compatibility between standard’s versions to ensure continuing interoperability will be required. Timelines should be determined in which older standards and implementation specifications will be discontinued or sunsetted.

5-15. **[Section III]** Are there best available standards for the purpose of “Patient preference/consent?” Should the NHIN Access Consent Specification v1.0 and/or IHE BPPC be considered?

Both specifications should be included in the Advisory.

5-16. **[Section III]** For the specific purpose of exchanging behavioral health information protected by 42 CFR Part 2, does an alternative standard exist to the DS4P standard?

AHIMA notes that ONC only linked to one of the three DS4P implementation guides:
HL7_IG_DS4P_R1_CH2_DIRECT_N1_2013SEP.pdf

We believe that all three of these implementation guides should have been included:
HL7_V3_IG_DS4P_R1_2014MAY_CH1_CONTENT.pdf
HL7_V3_IG_DS4P_R1_2014MAY_CH2_DIRECT.pdf

²² Centers for Disease Control and Prevention (CDC). Public Health Information Network—Vocabulary Access and Distribution System (PHIN-VADS). URL: <https://phinvads.cdc.gov/vads/SearchVocab.action>

²³ National Library of Medicine (NLM). Value Set Authority Center (VSAC). URL: <https://vsac.nlm.nih.gov/>

HL7_V3_IG_DS4P_R1_2014MAY_CH3_EXCHANGE.pdf

It's the "CONTENT" implementation guide that tells you how, for example, to put a 42 CFR warning in a Continuity Care Document (CCD), or to mark a specific section or entry in a CCD with a privacy annotation like a confidentiality code, purpose of use, obligation, etc.

It also should be noted that implementation of segmentation use cases beyond the stated example of exchanging 42 CFR Part 2 data is still an emerging field of work and consists primarily of pilot or prototype projects, such as

- Consent2Share (URL: <https://github.com/OBHITA/Consent2Share>)
- DS4P Pilot Projects (URL: <http://wiki.siframework.org/Data+Segmentation+for+Privacy+RI+and+Pilots+Sub-Workgroup>) and
- Decision Support for Data Segmentation (URL: <http://sharps.org/resources>).

5-17. **[Section II]** For the 2015 list, should both Consolidated CDA® Release 1.1 and 2.0 be included for the “summary care record” purpose or just Release 2.0?

Assuming there is backwards compatibility, both should be listed now to ensure HIT vendors have time to implement the updated standard. The timeline should be defined when the older standard is sunsetted.

5-18. **[Section IV]** Should specific HL7 message types be listed? Or would they be applicable to other purposes as well? If so, which ones and why?

The Advisory is the list (catalog) of standards. It is not the interoperability specification that defines the standards selected for a specific Use Case.

Therefore, all existing standards have to be listed in the Advisory. Determination about which individual standard to use for which purpose (Use Case) should be done based on the specific Use Case’ requirements analysis in a separate effort of developing interoperability specification (specification of selected standards to enable interoperability for the specific clinical scenario). Based on this, individual standards can be selected from the Advisory.

ONC should re-visit the process used by HITSP (2005-2009), by EU Antelope Project and by ISO TC 215 as described above to develop interoperability standards using individual standards listed in a catalog (Advisory) for a selected Use Case (purpose).

Additional Comment

The Advisory contains acronyms and terms that are not well defined.

AHIMA recommends all acronyms and terms, including the terms “interoperability standards” and “purpose,” will be defined in the Advisory.