May 1, 2015

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

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 Healtheway, we are pleased to provide written comments to ONC in response to the 2015 Interoperability Standards Advisory (2015 Advisory) developed by the Office of the National Coordinator for Health Information Technology (ONC).

Healtheway commends ONC's effort to broadly coordinate with health IT industry stakeholders throughout 2015 to improve the 2015 Advisory's depth and breadth in order to publish a more complete 2016 Advisory. The careful thought and consideration that ONC has given to the current advisory and plans for future updates is apparent.

We appreciate the opportunity to share comments based on our extensive real-world implementation experience supporting two, large-scale interoperability initiatives (the eHealth Exchange and Carequality); and we look forward to maintaining an open dialogue with ONC as future advisories are published.

Healtheway is a 501 (c) 3 organization operating with a public mission that convenes industry and government working to achieve secure, interoperable health information exchange nationwide. Healtheway's oversight and public-private governance process insures transparent oversight of this work. We have assembled, through our initiatives, and our engagement with government and industry, acknowledged experts who are able to identify the critical barriers to interoperability and design new processes to make HIE work on a national level.

We are a neutral body, inclusive of diverse stakeholders, which allows us to create workable solutions to overcome real-world data exchange problems.

The practical application of Healtheway's endeavors:

- Enables consensus agreement on the policies and standards required to reduce barriers to data exchange
- Advances development and continued support for HIE governance frameworks
- Provides services that enable HIE networks to interoperate

Healtheway's work takes the form of two independent initiatives, each having its own mission, governance, membership and structure. Healtheway currently supports:

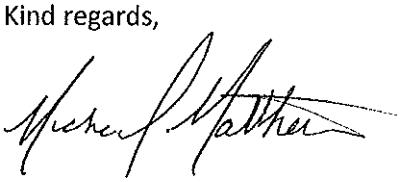
The eHealth Exchange is the country's largest and fastest-growing nationwide data sharing network. Today, the eHealth Exchange connects more than 30% of the US hospitals, 4 federal agencies, including Veterans Administration, Social Security Administration, Department of Defense, Centers for Medicare and Medicaid Management, and more than 10,000 medical groups who provide care and services to more than 100 million patients. The eHealth Exchange is a prime example of a public-private endeavor that has an open, transparent, inclusive, nimble and responsive governance process, and has thrived in a rapidly changing health IT environment.
Carequality is a public-private collaborative that provides a framework to enable widespread interoperability in healthcare by connecting different data sharing networks. Carequality brings together a large, diverse group of stakeholders to build consensus on the different elements comprising this framework, including rules of the road and technical specifications for inter-network exchange. Carequality has developed a standards-based use case that enables the query for documents among networks. In addition, the Carequality efforts are under way to roll out this framework nationwide, which will address many of the issues contemplated in the 2015 Advisory. More than seventy different organizations across the health IT ecosystem are involved in Carequality's work.

The attachment provides supporting information for our comments as well as our responses to the ONC questions identified in the Standards Advisory document (p. 6–7).

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

Please contact us at mmatthews@cvhn.com or myeager@healthewayinc.org if you have any questions.

Kind regards,



Michael Matthews, Board Chair

Healtheway, Inc.

Mariann Yeager CEO

Healtheway, Inc.

Attachment 1: supporting comments and responses to ONC questions

ATTACHMENT 1

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

Comment 1: General Comments

Over the past several weeks, Healtheway has been working closely with healthcare community colleagues to respond to ONC's 2015 Standards Advisory for health IT stakeholders to leverage for nationwide interoperability. The group included more than a dozen organizations, such as AHIMA, DirectTrust, EHRA, HIMSS, IHE International, IHE USA, RSNA and other industry stakeholders from vendor organizations, government agencies, and membership from SDOs such as HL7. Multiple organizations are essential to socialize and orchestrate all the components needed to enable secure health information exchange.

We, therefore, urge ONC to continue to work with stakeholders to establish a lightweight coordination of the best available standards for deployment with a focused approach to support a small set of high-value use cases that can substantially benefit from improved interoperability. In addition, the Standards Advisory is proposed as a "point-in-time" assessment that is updated yearly. The value of a snapshot is closely linked to future predictability. In healthcare, the deployment of connected IT solutions frequently takes several years across a wide range of distinct organizations to not only introduce and provide education on the technology, but also align and update systems and processes.

We recommend that the annual advisory process encourage continuity while not stifling innovation. The standards chosen for inclusion should enable incremental change. When implementing best available standards, a period of stability is essential to remain interoperable for many years in the future to ensure the adherence to the Standards Advisory is worthy of investment.

We pledge our support to advancing interoperability that engages the patient through coordinated, collaborative, and complementary actions by the public and private sector efforts. A coordinated approach that takes advantage of the efforts already underway will provide the level of sophistication needed to meet the data sharing and health information exchange requirements of a 'Learning Health System".

Comment 2: Industry Collaboration/Coordination

We believe that the broader health IT community should identify the specific capabilities including use cases that require uniformity at the national-level and coordinate and build consensus around those interoperability issues at hand. Consensus needs to be built on where there are both strong need and potential disagreement, and then focus coordination on resolving that disagreement.

Secondarily, there is a need to look ahead at use cases that need to be addressed for which there is not an obvious standard, and coordinate efforts to meet that need. The actual standards published in future advisories should be based upon the issues that warrant national-level coordination.

Collaboration is necessary among various standards to enable exchange of health information such as HL7 FHIR ®, Consolidated CDA (C-CDA), HL7 v2 and v3 messages. These base standards as well as implementation guides from HL7 and IHE depend on the same data elements within HIT systems. Standards and Implementation Guides usually constrain these data elements with vocabularies and value sets. For instance, in HL7 there are v2 message standards for public health, within IHE there are content based implementation guides that depend on the same data elements packaged differently but that should utilize the same vocabularies and value sets to allow HIT systems be interoperable when transporting messages leveraging those same data elements in different ways. The standards that associate that data need to be carefully coordinated and visible to all workgroups in various SDOs working with various ways to slice and dice this data so the published works will enable interoperable HIT systems and allow for backwards and forwards compatibility.

To that end, we recommend that ONC maximize its unique role to encourage the coordination across existing standards development organizations (SDOs) and interoperability initiatives to foster consensus on the specific standards that need to be addressed at a national-level. HL7 and IHE recently established a joint workgroup with representatives from each SDO called the Healthcare Standards Integration Workgroup. This workgroup is open to all SDOs that will required coordination of efforts and there is already a long listing of topics to coordinate from the four IHE domains addressing some of its growing backlog of HL7 FHIR® ballot comments. We encourage ONC to leverage this joint workgroup for standards coordination.

Comment 3: Criteria for Standards Advisory Inclusion of Standard(s)/Implementation Specification(s)

A clear set of criteria associated with any recommendation for a standard / implementation specification is required for the recommendations to be credible. Healtheway has learned from its operations that the following are necessary:

- Standards and implementation specifications need to be stable with reference to mature standards that have passed some piloting of implementations for validation to ensure the standards and specifications are unambiguous and can be clearly interpreted by implementers.
- An active maintenance process to allow a feedback loop from various deployments and implementations must be in place. Change proposals to the standards and specifications should be expected. This process is necessary to ensure successful

deployments and implementation within HIT systems is maintained as systems are upgraded and new innovations are added.
    - For instance, many different standard publications including the newest HL7 FHIR ® standards reference the published work by the Healthcare Integration Technology Standards Panel (HITSP) known as C-80 – Clinical Document and Message Terminology Component. This C-80 document defines the vocabularies and terminology utilized by HITSP specifications for Clinical Document and Messages used to support the interoperable transmission of information. This body of work has no current home for ongoing maintenance needs. This is one example of a project on the HL7/IHE HSI Workgroup previously referenced above.
- Robust testing tools are necessary and should have some production/piloting performed to ensure tooling readiness. These tools may exist among various testing bodies and therefore, should be piloted among vendors or other stakeholders who have adopted the standards in their HIT products to ensure consistency of results and proper operation of the tools and procedures with no conflicts.
- Standards forward and backward compatibility (ability for new and old versions of standards to work together
- 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)

Comment 4: Defining Interoperability Standards with Versioning and Use Cases

The Advisory was developed as a catalog of individual Health Information Technology (HIT) standards and implementation specifications "grouped into four categories:

1. Vocabulary/code sets/terminology (i.e., "semantics")
2. Content/structure (i.e., "syntax")
3. Transport (i.e., the method by which information is moved from point A to point B),
4. Services (i.e., the infrastructure components deployed and used to accomplish specific information exchange objectives). (p. 6)

Healtheway believes that developing such a catalog is an important effort, but the catalog by itself does not make these individual standards interoperable. Interoperability standards are a specific type of technical specification many times grouping standards from these various categories, not just a list of individual specifications.

Interoperability standards are well-defined implementation specifications or guides of standards selection with constraints and harmonization activities for a specific business need (Use Case). These implementation specifications or guides provide a product that assembles required standards in a portfolio—that defines how individual standards (e.g., those in the 2015 Advisory) have to work together to enable interoperability for a specific

Use Case such as patient care coordination, radiology image exchange, laboratory results delivery, laboratory reporting to public health, prescription drug monitoring, etc.

We suggest that the 56 use cases proposed for consideration in Appendix H of the previously published ONC Interoperability Roadmap can be grouped and prioritized to be more achievable, reduce redundancy, and align with use cases that are showing deployment efforts where others have identified as high-value. For example, many of the use cases would rely on underlying core functionality (e.g. request/receive, transmit, publish or subscribe) that could be used for a multitude of purposes, users and types of data. It may be helpful to group the use cases by function since multiple use cases could be enabled by a common set of underlying capabilities.

We suggest that versioning, where applicable, be added to the Standards Advisory to help avoid mismatches and drive harmonization industry wide. In addition, it would be beneficial to establish an explicit process to measure actual deployments and use of standards and implementation specifications with links to case studies, and evaluations where possible.

Healtheway is committed to work with ONC to leverage experience gained over the years of deployment activities to define interoperability standards and drive their adoption and continued development.

Comment 5: 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 use cases and specific purposes of interoperability. Standards selection criteria from the HITSP process should be revisited, nationally revalidated and used to select individual standards for interoperable solutions. The criteria used for standards inclusion within the advisory as mentioned in comment #4 above should go hand-in-hand with this selection criteria.

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

For the standard maturity selection criteria, Healtheway 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). However, Healtheway advocates that all standards (new and existing) be implemented within HIT systems to validate that the standards are clearly documented before encouraging wide scale adoption. In addition, these various HIT systems should pilot or test the standard among each other in a peer-to-peer fashion minimally or against tooling prior to inclusion on the 2015 Advisory.

The Standards Advisory is proposed as a "point-in-time" assessment that is updated yearly. The value of a snapshot is closely linked to its predictability. Healtheway has found through experience with deployment of interoperable data sharing, that the deployment of connected IT solutions frequently takes several years across a wide range of distinct organizations to not only introduce the technology, but also align and update processes. When implementing best available standards, a period of stability is essential to remain interoperable for many years in the future to ensure that adherence to the Standards Advisory is a worthy investment.

Healtheway agrees with ONC's timeline and availability statement that immature 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). 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 future Advisories.

Sufficient time has to be given to the HIT vendors to enable the adoption of mature, compatible, and interoperable standards in their systems. Standards-based systems and testing processes have to be established to ensure the deployment of interoperability standards in HIT products. [1]

Healtheway would further advise that the future standards advisories have more than one classification of standards for "current" and "emerging" standards to allow implementers some forward looking guidance for their development timelines and roadmaps.

Healtheway looks forward to working with ONC and the HIT community to refine criteria for selecting standards for the Advisory.

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 should be included: Operational Standards, Privacy and Security Standards, and Identifier Standards. A brief description of these standards categories is provided below.

[1] 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.

Operational standards (rules of the road) support business processes (e.g., clinical guidelines) and information governance[2] (business rules for data and information availability, integrity, protection, accountability, compliance, retention, and disposition).

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.[3] 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."[4] For example, ONC Standards & Interoperability (S&I) Framework Data Provenance initiative[5] 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.

We also encourage ONC to leverage work developed by industry for a minimally acceptable set of identity attributes that should be used for matching purposes. Healtheway has been working collaboratively with the Care Connectivity Consortium and across our diverse stakeholders to develop and vet such a set of attributes; and, we believe that referencing additional guidance or best practices in the Advisory would be beneficial.

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[2] http://healthewayinc.org/ehealth-exchange/onboarding/dursa/ Healtheway utilizes this agreement to enforce the governance for the eHealth Exchange. Separate principles of trust are being developed for the Carequality initiative and can be found here: http://healthewayinc.org/carequality-news/carequality-introduces-trust-principles-for-secure-interoperability-among-u-s-data-sharing-networks/

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

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

[5] ONC Standards & Interoperability (S&I) Framework. Data Provenance Initiative. URL: http://wiki.siframework.org/Data+Provenance+Initiative

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.

IV. Services

- Expansion of Services into a Foundational Service Components category. This will include the "security" components discussed in "The Structure of Sections I through IV". This expanded category would include basic component standards and implementation specifications necessary as building blocks for the Services infrastructure components. Purposes to be added to the Transport Category should include:
    - Audit logging of transactional activity
    - Consistent date and time stamps throughout a sequence of health events
    - User access authorizations and assertions
    - Terminology/nomenclature mapping services as well as workflows required to bring non-EHR data into EHRs as well as PHRs
    - Simple way for known, trusted participants to "pull" health information directly from other known trusted participants (existing)
    - Purposes moved from II. Content/Structure Standards
        - Segmentation of sensitive information
        - Patient preference/consent

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?

a. **For Section I: Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specifications**, the column "Implementation Specification" should contain the value set (and a specific version, if desired), while the standard is the terminology standard from which the value set is derived. For example:

Allergy reactions	**SNOMED-CT**	**Value set is all entries from the Concept "Allergy Reaction"**

Or if the value set is fixed:

Allergy reactions	**SNOMED-CT (version/date)**	**Value set is all entries from the Concept "Allergy Reaction"**

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?

a. **For Section II: Best Available Content/Structure Standards and Implementation Specifications** - the following additions are recommended:

Purpose (listed alphabetically)	**Standard(s)**	**Implementation Specification(s)**
Admission, discharge, and transfer	HL7 2.x ADT message[6]	
Healtheway, Inc. Comments	**Rationale:** Recognize use of HL7v3; Add Implementation Specs for specific ADT implementations and additional profiles suitable for inclusion as follows: **Standard(s):** Add HL7 3.x ADT message **Implementation Spec(s) :** Add Patient Administration Management (PAM) Profile Add IHE Quality, Research and Public Health Technical Framework Supplement – Trial Implementation - Newborn Admission Notification Information (NANI)	
Cancer registry reporting	HL7 Clinical Document Architecture (CDA®), Release 2.0, Normative Edition	HL7 Implementation Guide for CDA® Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1 (US Realm), Draft Standard for Trial Use
Healtheway, Inc. Comments	**Rationale:** Additional IHE profile that was written prior to the above listed HL7 Implementation Guide for CDA ® Release 2 should be added as this work has also been implemented by states and other countries. The IHE profile aligns with the HL7 Implementation Guide. **Standard(s):** n/a **Standard(s):** No changes to base underlying standard from what is listed **Implementation Spec(s):** Add IHE Quality, Research and Public Health Technical Framework Supplement for Trial Implementation - Physician Reporting to a Public Health Repository-Cancer Registry (PRPH-Ca)	

[6] Any HL7 2.x version-messaging standard associated with ADT is acceptable.

Purpose (listed alphabetically)	Standard(s)	Implementation Specification(s)
Electronic transmission of lab results to public health agencies	[R] HL7 2.5.1	HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Draft Standard for Trial Use, Release 2 (US Realm), DSTU Release 1.1
Healtheway, Inc. Comments	Please note: The older version is currently named in MU 2014: HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) link: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=98	
Immunization registry reporting	[R] HL7 2.5.1	HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5
Healtheway Inc. Comments	The HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5 should be changed to release 1.4	
Lab - results (receipt)	***[See Question #5-14]*** [R] HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1—US Realm [HL7 Version 2.5.1: ORU_R01] Draft Standard for Trial Use, July 2012	
Healtheway, Inc. Comments	**Rationale:** The current listing under the standard(s) column should be moved to the implementation specification(s) column and the base HL7 v2.5.1 should be listed as the standard but this is the best available. **Standard(s)** Add HL7 Version 2.5.1 and move the current listed guide to Implementation Specs **Implementation Spec(s)** Add from above: Implementation Specs - [R] HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1—US Realm [HL7 Version 2.5.1: ORU_R01] Draft Standard for Trial Use, July 2012	
Lab - orders	***[See Question #5-14]***	
Healtheway, Inc. Comments	**Rationale:** The current listing under the standard(s) column should be moved to the implementation specification(s) column and the base HL7 v2.5.1 should be listed as the standard but this is the best available. **Standard(s)** Add: HL7 Version 2.5.1 **Implementation Spec(s)** Add: HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, Release 1 - US Realm (link:	

Purpose (listed alphabetically)	Standard(s)	Implementation Specification(s)
	http://www.hl7.org/implement/standards/product_brief.cfm?product_id=152)	
Patient preference/consent	*[See Question #5-15]*	
Healtheway, Inc. Comments	**Rationale:** Healtheway suggests that the IHE IT Infrastructure Technical Framework profile - Basic Patient Privacy Consent (BPPC) is perhaps the best electronic patient privacy consent we have today. However, it provides a solid foundation that is in wide use in the US and internationally. For example the Social Security Administration (SSA) uses the IHE BPPC for the eHealth Exchange Access Consent Policy profile for eligibility determination for disability. Healtheway just completed a pilot testing program to automate testing for this profile to support the SSA with their on boarding efforts. The open source OpenEMR product uses BPPC in markets worldwide.	
Segmentation of sensitive information (e.g., 42 CFR Part 2 requirements)	*[See Question #5-16]* HL7 Clinical Document Architecture (CDA®), Release 2.0, Normative Edition	❖ Consolidated HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1
Healtheway, Inc. Comments	**Rationale:** The full power of DS4P is unnecessary for behavioral health information. The only component that is necessary is the subset of DS4P that was accepted by IHE ITI into the US National Extension (IHE IT Infrastructure Technical Framework Volume 4 – National Extensions – Section 3.1 Data Segmentation for Privacy (DS4P), http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol4.pdf). This allows for the tagging of this sensitive information in a way that is appropriate to the use. Specific guidance on exactly what tags must be used, and exactly what behaviors are expected, would be very helpful to the community to assure accurate and proper handling of this data. Healtheway suggests **a**dopting the US Realm subset of DS4P from IHE: IHE IT Infrastructure Technical Framework Volume 4 – National Extensions – Section 3.1 Data Segmentation for Privacy (DS4P) (http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol4.pdf). **Standard:** CDA Rel 2.0 **In Implementation Specification:** IHE IT Infrastructure Technical Framework Volume 4 – National Extensions – Section 3.1 Data Segmentation for Privacy (DS4P) (http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol4.pdf	

Purpose (listed alphabetically)	Standard(s)	Implementation Specification(s)
Summary care record	*[See Question #5-17]* HL7 Clinical Document Architecture (CDA®), Release 2.0, Normative Edition	• [R] Consolidated CDA® Release 1.1 (HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, Release 1.1 - US Realm) • Consolidated CDA® Release 2.0[7]
Healtheway, Inc. Comments	**Rationale:** Consolidated-CDA R 2.0 is a newer version than C-CDA R1.1. It intentionally updates and reconciles issues reported from the use of R1.1. C-CDA R1.1 includes 9 document templates and about 70 section templates. C-CDA R2.0 includes 3 new document templates and some 30 new section templates. Both are Implementation Guides for use of the CDA R2 Standard to implement the document types included (also referred to as clinical notes). Consolidated-CDA R2.0 must be considered the best available standard, as it is an update of a previous standard. ONC's transformer utility suggestion would be a good solution to the problem of interoperability issues during a transition phase. 2.0 should be removed from advisory until backward compatibility is achieved. There needs to be allowance for market adoption that includes a glide path. Should have mechanisms to maintain interoperability between the two versions and should not be a responsibility of the vendors.	
Syndromic surveillance to public health (emergency department, inpatient, and urgent care settings)	[R] HL7 2.5.1,	PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent, Ambulatory Care, and Inpatient Settings, Release 2.0
Healtheway, Inc. Comments	**Rationale:** n/a **Standard(s):** n/a **Implementation Specs(s):** Add eHealth Exchange/NHIN Document Submission, Administrative Distribution, and Health Information Event Messaging specifications	

b. <u>For Section III: Best Available Transport Standards and Implementation Specifications</u> - the following additions and edits are recommended:

[7] Link will be updated once publicly available.

Purpose (listed alphabetically)	Standard(s)	Implementation Specification(s)
	Hypertext Transfer Protocol (HTTP) 1.1, RFC 723X (to support RESTful transport approaches)	
	[R] SOAP-Based Secure Transport Requirements Traceability Matrix (RTM) version 1.0 specification.	eHealth Exchange Messaging Platform v3.0
	Healtheway, Inc. Comments Added implement specification based on SOAP used by eHealth Exchange	
	Simple Object Access Protocol (SOAP) 1.2	
Data sharing through Service Oriented Architecture (SOA) - that enables two systems to interoperate together	**Healtheway, Inc. Comments** **Rationale:** Need to add specific row for the transport to support XDR which is slightly different than the SOAP-based RTM Only the transport of XDR is referenced **Standard(s):** Add IHE IT Infrastructure Technical Framework : IHE-XDR (Cross-Enterprise Document Reliable Interchange) **Implementation Spec(s) :** Document Submission Production Specification v2.0	
	For security, Transport Layer Security (TLS) Protocol Version 1.2, RFC 5246	
	Healtheway, Inc. Comments **Rationale:** Need to include node authentication **Standard(s):** n/a **Implementation Spec(s) :** IHE ATNA (node authentication part)	

c. **For Section IV: Best Available Standards and Implementation Specifications for Services** - the following additions and edits are recommended:

Purpose (listed alphabetically)	Standard(s)	Implementation Specification(s)
An unsolicited "push" of clinical health information to a known destination	[R] Applicability Statement for Secure Health Transport ("Direct")	• [R] XDR and XDM for Direct Messaging Specification • [R] IG for Direct Edge Protocols • IG for Delivery Notification in Direct
	[R] SOAP-Based Secure Transport Requirements Traceability Matrix (RTM) version 1.0 specification.	
	IHE-XDR (Cross-Enterprise Document Reliable Interchange)	
	NwHIN Specification: Authorization Framework	
	NwHIN Specification: Messaging Platform	
Healtheway, Inc. Comments	**Rationale:** Healtheway, Inc. recommends this more inclusive listing as shown above in the individual comments per line and would like to note that the two NwHIN Specifications: Authorization Framework and Messaging Platform should not be listed under the standards column, but under the implementation specification column as they are implementation guides of the base standard for IHE profiles XCA and XCPD. The standard should be the IHE profiles not the NwHIN implementation guides. **Standard(s): The following should be added under the Standard(s) column:** IHE IT Infrastructure (ITI) Technical Framework • Cross-Enterprise User Assertion (EUA) • Consistent Time (CT) **Implementation Guide(s) – the following should be added under this column** • eHealth Exchange/NwHIN Document Submission • Administrative Distribution • Health Information Event Messaging specification • NwHIN Specification: Authorization Framework • NwHIN Specification: Messaging Platform	
Query for documents within a specific health information exchange domain	IHE-XDS (Cross-enterprise document sharing)	
	No changes required	

Purpose (listed alphabetically)	Standard(s)	Implementation Specification(s)
	IHE-PIX (Patient Identity Cross-Reference)	
	Healtheway, Inc. suggests moving IHE-PIX (Patient Identity Cross Reference to the Implementation Specification(s) and adding IHE PIX v3 row. In addition, HL7 v2.x and HL7 v3.x need to be added under the standard(s) column.	
	IHE-PDQ (Patient Demographic Query)	
	Healtheway, Inc. suggests moving IHE-PDQ (Patient Demographic Query Specification(s) column and adding PDQ v3. In addition, HL7 v2.x and HL7 v3.x need to be added under the standard(s) column.	

Purpose (listed alphabetically)	Standard(s)	Implementation Specification(s)
Query for documents outside a specific health information exchange domain	IHE-XCA (Cross-Community Access)	

Purpose (listed alphabetically)	Standard(s)	Implementation Specification(s)
	Healtheway, Inc. recommends moving the eHealth Exchange Query for Documents v2.0 and the Retrieve Document v3.0 specifications under the Implementation Specification(s) column associated to the XCA IHE profile.	
	IHE-XCPD (Cross-Community Patient Discovery)	
	Healtheway, Inc. recommends adding the eHealth Exchange Patient Discovery v2.0 under the Implementation Specification(s) column associated to the XCPD IHE Profile	
	NwHIN Specification: Patient Discovery	
	Healtheway, Inc. recommends removing the separate row and listing this specification as referenced above.	
	NwHIN Specification: Query for Documents	
	Healtheway, Inc. recommends removing the separate row and listing this specification as referenced above.	
	NwHIN Specification: Retrieve Documents	
	Healtheway, Inc. recommends removing the separate row and listing this specification as referenced above.	

Purpose (listed alphabetically)	Standard(s)	Implementation Specification(s)
Healtheway, Inc. Comments	**Rationale:** Healtheway, Inc. agrees with your listing in general but feels the placement of some of the listings may be better served in the headings as listed above. In addition, Healtheway recommends adding the following standards and specifications as separate rows under this topic category as shown below: **#1 Row to add:** **Standard(s):** Oasis: • Assertions and Protocols for Security Assertion Markup Language (SAML) v2.0 • Cross-Enterprise Security and Privacy Authorization (XSPA) Profile of Security Assertion Markup Language (SAML) for Healthcare v1.0 • Authentication Context for Security Assertion Markup Language (SAML) v2.0 • Web Services Security: SOAP Message Security V1.1 • Web Services Security: SAML Token Profile v1.1 WSI: • Security Profile v1.1 **Implementation Specification(s):** eHealth Exchange Specifications • Authorization Framework v3.0 **#2 Row to add:** **Standard(s):** WS-I v2.0 • Simple Object Access Protocol (SOAP) v1.2 • SOAP Message Encoding Style • SOAP Faults • Hypertext Transfer Protocol (HTTP) v1.1 • WS-Addressing v1.0 • WS-Base Notification v1.3 • Message Transmission Optimization Mechanism (MTOM) binding for SOAP v1.0 • Web Services Description Language (WSDL) v1.1 • XML Schema v1.0 • Universal Discovery and Description Interface (UDDI) v3.0.2 WS-I v1.1 • Transport Layer Security v1.0 • XML Signature v1.0 • Web Services Description Language (WSDL) v1.1 • Symmetric Encryption Algorithm and Key Length AES 128-bit • X.509 Token Profile v1.0 • Attachment Security v1.0 **Implementation Specification(s):** eHealth Exchange Specifications • Messaging Platform v3.0	

Purpose (listed alphabetically)	Standard(s)	Implementation Specification(s)
Data element based query for clinical health information	Fast Healthcare Interoperability Resources (FHIR)	
Healtheway, Inc. Comments	Healtheway, Inc. acknowledges the potential use of HL7 FHIR® to enable data element query and retrieval for clinical health information; and, we will remain actively engaged in testing and piloting its use. We question, however, whether FHIR meets the maturity criteria outlined in the Advisory.	
Image exchange	Digital Imaging and Communications in Medicine (DICOM)	
Healtheway, Inc. Comments	**Rationale:** Healtheway would like to expand the above listing by adding adding the following row as follows: **ROW #1 addition** **Standard(s):** IHE IT Infrastructure (ITI) Technical Framework • Cross Community Access (XCA) **Implementation Specification(s):** IHE Radiology Technical Framework • Cross-Community Access for Imaging (XCA-I) **ROW #2 addition:** **Standard(s):** IHE IT Infrastructure (ITI) Technical Framework • Cross-Enterprise Document Sharing (XDS) **Implementation Specification(s):** IHE Radiology Technical Framework • Cross-Enterprise Document Sharing for Imaging (XDS-I.b) **ROW #3 addition:** **Standard(s):** IHE IT Infrastructure (ITI) Technical Framework • Patient Demographic Query (PDQ) • Patient Demographic Query v3 (PDQv3) • Patient Cross Reference Manager (PIX) • Patient Cross Reference Manager V3 (PIXv3) **Implementation Specification(s):** IHE Radiology Technical Framework • Cross-Enterprise Patient Discovery (XCPD) **ROW #4 addition:** **Standard(s):** Digital Imaging and Communications in Medicine (DICOM) DICOM Manifest	

Purpose (listed alphabetically)	Standard(s)	Implementation Specification(s)
	Implementation Guide(s): Nothing listed for this row	
Resource location	IHE IT Infrastructure Technical Framework Supplement, Care Services Discovery (CSD), Trial Implementation	
Healtheway, Inc. Comments	**Rationale:** Healtheway, Inc. would suggest reclassifying listing for the CSD profile to Implementation Specification(s) and adding standards as follows: **Standard(s):** HTTP 1.1, XQuery 1.0, XForms 1.1 SOAP 1.2, IETF RFC 4791 **Implementation Guide(s):** IHE IT Infrastructure Technical Framework Supplement, Care Services Discovery (CSD), Trial Implementation	
Provider directory	IHE IT Infrastructure Technical Framework Supplement, Healthcare Provider Directory (HPD), Trial Implementation	
Healtheway, Inc. Comments	**Rationale:** Healtheway would suggest reclassifying listing for HPD to Implementation Specification(s) and adding standards as follows: **Standard(s):** ISO 21091, IETF LDAP, OASIS DSML v2.0 **Implementation Guide(s):** IHE IT Infrastructure Technical Framework Supplement, Healthcare Provider Directory (HPD), Trial Implementation	
Publish and subscribe	NwHIN Specification: Health Information Event Messaging Production Specification	
Healtheway, Inc. Comments	**Rationale:** Healtheway, Inc. would suggest reclassifying listing for Document Subscription and adding standards as follows: **Standard(s):** WS-BaseNotification 1.3 OASIS Standard 620 WS-BrokeredNotification 1.3 OASIS Standard WS-Topic 1.3 OASIS Standard **Implementation Guide(s):** NwHIN Specification: Health Information Event Messaging Production Specification IHE IT Infrastructure Technical Framework • Document Subscription Profile – Trial Implementation	

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.[8]

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?

Healtheway disagrees with removing "*more traditionally considered 'administrative' standards (e.g., ICD-10)…from this list…"*

Providers do not consider diagnosis codes as administrative codes. Administrative code sets that are related to demographics do have clinical relevance. From a provider standpoint these should not be removed. Not considering the administrative codes would result in loss of the historical data. 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. Administrative standards are relevant to value based care.

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?

Healtheway feels food allergies should be included. As stated above, use case inclusion would help eliminate confusion 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."*

[8] 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?

Healtheway supports AHIMA's recommendation 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?
Healtheway supports the American Immunization Registry Association (AIRA) position on this question:

AIRA supports the inclusion of CVX as the primary method for reporting historical doses, and MVX as an additional data element when it is available, noting that MVX is not always known for a historical dose. When it is known, however, it provides helpful additional data to infer the brand of vaccine administered.

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?

Healtheway supports the AIRA position on this question.

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?

Healtheway has no response for this question.

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-VADS[9] for public health value sets, NLM VSAC[10] 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."*

Healtheway has found through experience that standards must be tested before wide scale use is encouraged and prior to being placed on the Advisory list. In addition, backwards compatibility between standard's versions to ensure continuing interoperability should be required. Timelines should be determined in which older standards and implementation specifications should be discontinued or sunset.

5-15. ***[Section II]*** 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.

[9] 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
[10] National Library of Medicine (NLM). Value Set Authority Center (VSAC). URL: https://vsac.nlm.nih.gov/

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

Healtheway supports AHIMA's response that notes ONC only linked to one of the three DS4P implementation guides: HL7_IG_DS4P_R1_CH2_DIRECT_N1_2013SEP.pdf

We feel that all three of these implementation guides should be considered and have been included after additional piloting is completed:
HL7_V3_IG_DS4P_R1_2014MAY_CH1_CONTENT.pdf
HL7_V3_IG_DS4P_R1_2014MAY_CH2_DIRECT.pdf
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).

We also feel that OASIS XACML should be included as it provides for a rules-based method of expressing 42 CFR Part 2 point- to- point authorizations.

Finally, we feel that the ability to convey patient's authorizations is important, and would like the ONC to add two standards for conveying patient consent and authorization documents: IHE IT Infrastructure Technical Framework Supplement – Cross-Enterprise User Assertion (XUA) (for SOAP using the OASIS SAML 2.0 standard) and IHE IT Infrastructure Technical Framework Supplement – Internet User Authorization (IUA)- (for FHIR/REST using the OAuth standard). We would like the ONC to also add one Implementation Guide based on these standards: the NHIN/eHealth Exchange Access Consent Policies specification.

In addition, Healtheway supports the IHE response as follows:
The full power of DS4P is unnecessary for behavioral health information. The only component that is necessary is the subset of DS4P that was accepted by IHE ITI into the US National Extension (IHE IT Infrastructure Technical Framework Volume 4 – National Extensions – Section 3.1 Data Segmentation for Privacy

(DS4P), http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol4.pdf). This allows for the tagging of this sensitive information in a way that is appropriate to the use. Specific guidance on exactly what tags must be used, and exactly what behaviors are expected, would be very helpful to the community to assure accurate and proper handling of this data. The EHRA suggests **a**dopting the US Realm subset of DS4P from IHE: IHE IT Infrastructure Technical Framework Volume 4 – National Extensions – Section 3.1 Data Segmentation for Privacy (DS4P) (http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol4.pdf).

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?

Existing and potentially valuable care summary documents have already been generated using older standards. Thus, in order to continue to be able to leverage them, receiving systems should be required to consumption HITSP C32 (as per Meaningful Use 1), and both Consolidated CDA 1.1 and 2.0. All three of these standards should be listed in the ONC Standards Advisory. Regarding systems that generate documents, the ONC should list the most recent version of Consolidated CDA. This will be an on-going moving target as the industry improves Consolidated CDA. And the ONC should continue to encourage adoption of newer versions of Consolidated CDA while supporting historical information in prior versions. Healtheway acknowledges that this is a complex issue in part due to change management considerations. In the transition to Release 2.0, consideration should be given to allow an extended period of time when sending systems are required to migrate to Release 2.0. In the interim, systems will be exchanging data with other systems that are still on Release 1.1 and C32. The three are very similar but normally require different computer logic to generate or consume them. Release 2.0 has significant improvements over Release 1.1 and C32. The ONC should list all versions currently in use, including those specified by prior MU versions.

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 should be listed in the Advisory. A process should be developed to determine which individual standard to use for which purpose (Use Case) 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), to develop interoperability standards using individual standards listed in a catalog (Advisory) for a selected Use Case (purpose).

Summary Recommendations

Healtheway makes the following specific recommendations to ONC as we work collaboratively toward achieving the nation's interoperability objectives - safer, more efficient healthcare services in an environment where care delivery and payment models are evolving:

- Leverage the market, and engage in existing public/private, multi-stakeholder processes working on different aspects of interoperability and the standards required for specific use cases.
- ONC should convene and coordinate among stakeholders to accelerate standards development efforts, as well as efforts to develop and maintain implementation guides. Properly coordinated, the collaborative and complementary actions of the public and private sector efforts will achieve a sophisticated level of interoperability.
- Federal involvement is welcomed and encouraged. Federal oversight should be limited to a thin layer of coordination, participation in standards development, and recognition of collectively developed solutions.

We strongly value the ability to share data across the care continuum. Working together with ONC and other federal partners, we can make great strides toward achieving interoperability.