Section V: Questions Regarding the Interoperability Standards Advisory

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

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**Sent**: Wednesday, July 15, 2015 03:08 PM  
**To**: HILLS, CHRISTOPHER J (Chris) CIV USN SPAWARSYSCEN LANT SC (US); Hall, Nona G CIV DHA CMD GRP (US)   
**Subject**: Recommendations for "Standards MATURITY" for ISA   
As per our ONC Town Hall discussion (and HITSC comments), the ISA “best available” listings can be helpful, or even “dangerous", depending on how people interpret this list.  The discussions typically center around “maturity”.

I would like to make the following recommendations for "Standards Maturity” parameters for a given standard listed in the ISA:

* **ONC Recommendation Status** - In Regulation / Recommended / Emerging / Consider / Declining
* **Development Status** - Planning / Initial Development / DSTU / Approved
* **Adoption Status** - None / Pilots / Few Production Instances / Increasing Adoption / Widely Adopted

**SA16** 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 “i*f 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). 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

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>.

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

**SA18 NCPDP Comment**: In addition to the reasoning outlined, standards, transactions, implementation specifications, etc. need to be considered in a broad view, to ensure they support the needed function without constraints regarding “administrative” or “clinical” or based on provider type or care setting.

NCPDP agrees with the statements regarding stability and adoptability; however maturity needs to be considered in regards to the amount of substantive changes or modifications a standard may be undergoing before it is recommended for widespread use.

**A19 NCPDP Comment**: In addition to the reasoning outlined, standards, transactions, implementation specifications, etc. need to be considered in a broad view, to ensure they support the needed function without constraints regarding “administrative” or “clinical” or based on provider type or care setting.

NCPDP agrees with the statements regarding stability and adoptability; however maturity needs to be considered in regards to the amount of substantive changes or modifications a standard may be undergoing before it is recommended for widespread use.

**A21** State specific requirements for Public Health Agencies. While Public Health follows the CMS IG’s, they do vary depending on state requirements.

**SA27** In addition to the five “best available” characteristics listed, we have identified the following additional characteristics for ONC’s consideration:

* The standard or implementation specification is compatible with other selected standards and implementation guides as well as with the roadmap and strategic framework or architecture. Without this compatibility, we will continue to have stove pipe exchanges, requiring health IT systems to support multiple data capture and data exchange capabilities, rather than leveraging and reusing data.
* The standards or implementation specifications go through a validation process where it is determined if the standards are capable of being used together. It should be clear as part of the communication as to how widespread adoption of the standard is. For example, the selection of an HL7 v2 message where the domain require a post coordinated vocabulary, presents a mismatch because the coded data type cannot carry such a vocabulary element.
* The standard or implementation specification is published and publically accessible.
* The standard or implementation specification is confluent with the most rigorous state reporting and compliance and regulatory requirements (e.g., 10D-3 in Florida).
* The standard or implementation specification aligns with the best IT practices across industries.
* Consideration should be given to the standard or implementation specification being able to be adopted internationally.

We suggest adding the following factor to the list of “Additional Factors Affecting Best Available Determinations”:

* **Usability & Visibility to Cost** – usability relates to enabling people to make better decisions on healthcare purchases and reduce how much they spend on those purchases. Greater visibility relates to helping them compare apples to apples as they make their healthcare purchases based on outcomes.

SA30 **1A.** The Advisory makes no reference to primary or secondary use nor their specific distinction as “a given interoperability purpose”.

Please revise the Advisory to include advice for “best available” standards for both primary and secondary use, making the reference to each designated standard explicit as to whether it supports one or both.

**2. Interoperability is Based on Fitness for Use**

*Interoperability ensures fitness for use (purpose) at each ultimate point of health data/record access/use. The following table shows the challenging paradigm of data/record exchange between heterogeneous systems and the risk to fitness (for use/purpose) posed by data transformations. Double transformations often occur during the course of exchange when health data/record content is transformed to/from exchange artifacts (e.g., HL7 messages and documents) – once by the source/sending system and once again by the receiving system.*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| *Use* | *Purpose* | *Health Record Content Exchange* | | | *Post Exchange*  *Fit for Use?* |
| *Source* |  | *Receiver* |
| *Primary* | *Clinical Care, Interventions and Decision Making* | *Without Transformation (maintains/ensures fidelity to source)* | | | ***YES*** |
| *With Transformation(s)* | | | ***Often NO*** |
| *Secondary* | *Most Everything Else* | *With Transformation(s)* | | | ***Typically YES*** |

**2A.** The Advisory makes no mention of “fitness for use” but one would assume this to be a minimum threshold of achievement to support both primary and secondary use.

Per our Comment 1A, the Advisory should be explicit regarding “fitness for use” in cases of

primary and/or secondary use – and note this as post-exchange achievement of

interoperability.

**2B.** Most all of what is offered in Advisory recommendations for “best available” standards – vocabulary/terminology, code sets, exchange artifacts – presume you must transform to/from these standard artifacts to achieve interoperability. While singly/doubly transformed health data/record content may be sufficient for certain secondary use it often falls short of competence and a proper level of trust assurance – as required for primary use.

The Advisory should make explicit which of the enumerated “best available” standards

effectively require single or double transformations and thus aren’t designed to deliver

unaltered (authentic) source health data/record content across points of exchange.

**3. Interoperability is Based on Truth and Trust**

*Truth = factual, authentic = Facts are evident*

*Trust = assurance, reliance = I am assured, I trust, I rely on*

*The achievement of interoperability is primarily about truth and trust – as evidenced at each downstream point of access/use – to the ultimate primary or secondary user of health data/records.*

|  |  |  |
| --- | --- | --- |
| *Truth* | *as evidence for* | *Trust* |
| ✔ *Identity is verified* |  | * *Belief (believability)* * *Certainty* * *Reliance* * *Traceable to a “source of truth”* * *Based on – and manifest in – evidence presented* |
| ✔ *Source, origination and provenance is evident* |
| ✔ *Signature is evident* |
| ✔ *Signature/content binding is evident* |
| ✔ *Content is un-altered* |
| ✔ *Context is evident* |
| ✔ *Completeness (or not) is evident* |
| ✔ *Update(s) to original content are evident* |
| ✔ *Chain of Trust (from source to use) is evident* |
| ✔ *From origination to use* |
| ✔ *Transformation(s) are evident (e.g., to/from exchange artifacts)* |
| ✔ *Original “Source of Truth” is evident* |

**3A.** The Advisory makes no mention of truth or trust or their unique predicate relationship (trust relies on truth) however this objective is unavoidable and should be made an explicit statement in the front matter. There can be no claim to interoperability without basis in truth (evidence of authenticity) and trust (assurance). [See further discussion in Comment 8A.]

**4. Interoperability has a Source of Truth and Anchor Point**

*The source of truth is content captured at the point of health data/record origination. This is the anchor point for the chain of trust and is crucial to the achievement of interoperability. There can be no dispute there. For primary use – clinical care, interventions and decision making – the source of truth is unaltered source health data/record content. The receiving provider will first and always trust (rely on) this direct evidence of clinical facts, findings and observations. Data integrity (including fidelity to source) is fundamental to all aspects of clinical integrity and most importantly, patient safety. From the perspective of the end user, the chain of trust starts at the point of health data/record origination/capture and continues to each point of access/use, traceably and without interruption.*

**4A.** [See Comment 16A.]

**5. A Person-Centered (Individual) Health Record**

**…**

**6. Interoperability is Manifest by Integration**

**…**

Interoperability Roadmap, page 108: “Measuring perceived accuracy, reliability, trustworthiness and utility of information exchanged will help understand variation in use of data. Additionally, information from the end user perspective on barriers to exchange and interoperability may ensure early identification of issues and addressing of concerns.”

**7. Interoperability is in the Eye of the Beholder**

*As described above and as the essential satisfaction premise of the IEEE “interoperability” definition, the affirmative decision to trust and use health data/records received is one ultimate signal of achievement (of interoperability). Each ultimate end user takes responsibility as an individual or organization to make a “trust decision” regarding the veracity of health data/record received and whether/when to use such information as the basis for subsequent clinical care, interventions and decision making (in primary use) or for other purposes.*

**7A.** The Advisory makes no mention of the affirmative trust decision but clearly the end user of health data/record content subject to the constraints of “best available” standards must be able to make that trust decision every time before electing to use such content.

Please revise the Advisory to make this explicit.

**8. Properties/Qualities of Interoperability**

*What are key properties or qualities of health data/records that demonstrate (achievement of)*

*interoperability to the end user? Consider what we we’ve learned from our experience with*

*enterprise integration…*

|  |  |  |
| --- | --- | --- |
| *Enterprise integration enables interoperable health data/record content…* | | *Qualities Manifest to End User* |
| *A* | *Known and verified as to identity:*   * *Subject: patient* * *Provider: individual and organization* | *Identified, Attributable* |
| *B* | *Captured, consolidated from multiple sources within the enterprise* | *Unified, Integrated* |
| *C* | *Oriented to support real-time care delivery* | *Timely, Ready* |
| *D* | *Oriented to what has happened (past), what is now in progress (present), what is anticipated (future)* | *Chronological, Longitudinal* |
| *E* | *Oriented to who did what when* | *Accountable* |
| *F* | *Tuned for consistency: e.g., data types, common units of measure, codes and value sets* | *Uniform* |
| *G* | *Tied to the “source of truth”, showing provenance at point of data/record origination and thereafter* | *Factual, Authentic, Traceable* |
| *H* | *Bound to source, author’s signature* | *Authenticated* |
| *I* | *With known context: clinical, administrative, operational* | *Contextual* |
| *J* | *Known to be unaltered since origination* | *Immutable* |
| *K* | *Known to be complete – or known to have missing elements* | *Whole or Partial* |
| *L* | *Known to be original – or known to be updated from original instance* | *Original/Revision Progression* |
| *M* | *Associated with like information* | *Correlated, Comparable* |

**8A.** This is where the Advisory seems a disconnected universe. First, the Interoperability Roadmap failed to specify key properties (qualities) of interoperability – as noted above. Then Advisory takes this one step further and fails to enumerate “best available” standards which are designed and capable to deliver these (or any other selected set of) key properties.

Please revise the Advisory to make explicit which “best available” standards are built to deliver/evidence vital properties (qualities) to each ultimate end user once (after the point when) exchanged health data/records are subject to the constraints of those standards.

**9. Transition to Interoperability**

**...**

**10. Interoperability Within and Without**

**…**

**11. Interoperability Access/Exchange Methods, Initiators and Limitations**

*Let’s look at three possible methods of achieving health data/record access (if not interoperability) – as beheld by the end user. Each method has a specific type of initiation and each method has limitations in terms of scope of data availability. Methods B & C rely on system-to-system exchange to convey data/records to the end user, whereas Method A takes the end user to the source system where data/records are already likely integrated and thus interoperable (but only within that domain).*

|  |  |  |  |
| --- | --- | --- | --- |
|  | *Method* | *Initiated by…* | *Limitations* |
| *A* | *Allow End User Direct Access to Source Domain* | * *Login to initiate user session* | * *Limited to health data/records available in source domain* |
| *B* | *Push Source Data to End User Domain* | * *Source trigger event* | * *Limited to data pushed* * *May be missing full context* |
| *C* | *Pull Source Data to End User Domain* | * *Receiver trigger event or* * *User inquiry* | * *Limited to data pulled* * *May be missing full context* |

*For each method (A-C), the following shows the end user and their domain of access to health*

*data/records.*

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**11A.** Presuming the scope of the Advisory’s recommendations are limited to the interoperability space, it would seem that the Source (if not Receiver) Domain(s) are themselves out of scope. It is obvious that recommended vocabularies, terminologies and code sets, if implemented natively (in the Source and Receiver systems), would make interoperability much easier to achieve. Please revise the Advisory to make this explicit.

**12. Interoperability Takes Leadership, Planning and Concise Implementation**

**…**

**13. Interoperability that Isn’t**

**…**

**14. Evidence of Interoperability and the Affirmative Trust Decision**

*[Reference Comment #3 above.] Establishing truth and trust as a key foundation for interoperability leads us to consider the current repertoire of standards-based exchange artifacts (messages and documents) and to examine their capability to convey key elements of truth (upon which end user trust can be based). The following table poses key questions/ challenges in our quest to substantiate the end user trust decision.*

|  |  |  |
| --- | --- | --- |
| *Truth (at source)* | *Exchange Artifact* | *Receiver* |
| ✔ *Identity is verified* | *Is identity conveyed?* | *Within common identity domain?*  *Is identity manifest?* |
| ✔ *Source, origination and provenance is evident* | *Is it conveyed?* | *Is it manifest?* |
| ✔ *Signature is evident* | *Is signature conveyed?* | *Is signature manifest?* |
| ✔ *Signature/content binding is* | *Is signature/content binding* | *Is signature/content binding* |

|  |  |  |
| --- | --- | --- |
| *Truth (at source)* | *Exchange Artifact* | *Receiver* |
| *evident* | *conveyed?* | *manifest?* |
| ✔ *Content is un-altered* | *Is non-alteration conveyed?* | *Is non-alteration manifest?* |
| ✔ *Context is evident* | *Is context conveyed?* | *Is context manifest?* |
| ✔ *Completeness (or not) is evident* | *Is completeness/ incompleteness conveyed?* | *Is completeness/ incompleteness manifest?* |
| ✔ *Update(s) to original content are evident* | *Are updates conveyed?* | *Are updates manifest?* |
| ✔ *Chain of Trust is evident* | *Is Chain of Trust conveyed?* | *Is Chain of Trust manifest?* |
| ✔ *From origination to use* |
| ✔ *Transformation(s) are evident (e.g., to/from exchange artifacts)* | *Are transformations conveyed?* | *Are transformations manifest?* |
| ✔ *Original “Source of Truth” is evident* | *Is original “source of truth” conveyed?* | *Is original “source of truth” manifest?* |

*Most objective observers agree that the current set of Standards-based exchange artifacts fall far short of conveying necessary truth attributes – to say nothing of the limitations of receiving systems to manifest those attributes – to the end user who must make a trust decision.*

**14A.** [See Comment 8A.] Please revise the Advisory to make explicit which “best available” standards are built to deliver these vital truth attributes to each ultimate end user once (after the point when) conveyed/received health data/records are subject to the constraints of those standards.

**15. Interoperability via Transformation and Fragmentation?**

*As described in previous comments, substantial amounts of health data/record content are now captured – at the point of service or point of care – and retained in integrated provider EHR systems. This data is immediately available and seamlessly interoperable with a broad range of other information within that domain. The essential qualities of truth are established and the trust decision is most always affirmative. This is the case BEFORE exchange occurs.*

*We then take that same information and rend it from its integrated and interoperable habitat – slicing, dicing, fragmenting and transforming source health data/record content into the form and format required for the standards-based exchange artifact. Structured content becomes unstructured and vice-versa, data types are transformed, coded values are mapped (often incorrectly, or even if correctly, losing important context) into the classification conventions of various external code/value sets and vocabularies. Data is mapped one to many and many to one. Some source data attributes lack corresponding attributes in the exchange artifact and must be dropped. Some codes have no equivalent value and are not included.*

*In patient summary oriented exchange artifacts, data relationships are often sundered. For example, chronologies, trends and relationships between encounters, problems, diagnoses, orders, medications, results, diagnostics, interventions, observations, therapies and care plans are lost or become unrecognizable.*

*And so far we’ve only described what happens on the source/sending side of exchange. On the receiving side, all of the above slicing, dicing, fragmentation and transformation occurs once again.*

**15A.** Before revising and publishing the 2015 Advisory, there should be careful consideration of the extent to which the recommended “best available” standards actually require/promote slicing,dicing, fragmenting and transforming health data/record content from its source representation – as opposed to leaving source content in its original unaltered form – or at least carrying the original content alongside the transformed content.

*It is a simple fact that transformations to/from exchange artifacts often create (introduce) alterations, omissions and errors in health data/record content. Data items that were integrated and seamlessly interoperable in the source system are no longer so. Data once fit for primary (clinical) use may now only be fit for secondary use (or not).*

*As an industry we’ve also demonstrated that in practice, standards-based exchange artifacts mostly yield to the lowest common denominator benchmark. This has proven sufficient to support some very, very limited health data/record secondary uses but not primary use (clinical care, interventions and decision making). Health data/record fragmentation, transformation and loss of context are real barriers to interoperability…*

**15B.** As a vital patient safety and clinical integrity issue, it is critical that key health data/record content and context relationships remain intact and that “best available” standards are built to include/convey these context/context relationships to each ultimate end user once (after the point when) conveyed/received health data/records are subject to the constraints of those standards.

Please revise the Advisory to make explicit which “best available” standards are designed and capable to deliver intact vital clinical context/content relationships from source health data/records (especially for primary uses and users).

**16. IEEE Interoperability is not Sufficient**

*As described in previous Comments, it is self-evident that the IEEE “interoperability” definition*

*falls far short of what is needed for trusted exchange and use of health data/records.*

|  |  |  |
| --- | --- | --- |
| ***IEEE 1990*** | ***IEEE 2014*** | *Interoperability Claim* |
| *Exchange* | *Exchange* | *(Technical)* |
| *Use* | *Use* | *(Semantic)* |
|  | *Without user intervention* | *(Plug and Play)* |

*Interoperability is not something that finally comes into play once data is transformed to exchange artifacts and queued for transmission to an external system (at point of exchange). As described in Comment #8, key qualities of health data/records are essential and must be in place before exchange artifacts are created or exchange itself occurs. Most of these qualities (e.g., source/authorship, provenance, attestation, non-alteration) are either captured at the data/record source or are intrinsic to data/record management up to the point of exchange. In addition, the transformative processes essential to take many disparate sources and transform that information, while maintaining the relevant trust attributes, into a multi-source, useable and useful integrated representation around each individual are fundamental to effective interoperability.*

*It is clear that a valid interoperability Roadmap for health data/records must invariably start at the source – point of data/record origination – and continue uninterrupted to each ultimate point of access/use, potentially traversing one or more points of exchange along the way and resolving itself in the final outcome to an integrated individual health record.*

*Deficiencies of the IEEE “interoperability” definition should be made findings/lessons for the Learning Health System and the Roadmap should expand its definition sufficient for true end to- end health data/record interoperability.*

**16A.** Here again, strongly suggest ONC expand the scope of its “interoperability” definition to start at the point of health data/record origination. This is the key anchor point (source of truth) for health data/record interoperability. Encompassing the source of truth may be without risk or otherwise ignored in other industries, but we cannot take that stance in support of individual health and provision of healthcare (while ensuring patient safety and clinical integrity).

**17. Interoperability Enabled by the Chain of Trust**

*In previous Comments we have described the convergence of integration, truth and trust as vital pillars to support/achieve health data/record interoperability. The following table offers an end-to-end perspective from point of data/record origination to each ultimate point of data/record access/use. Information flow is traceable via a “chain of trust”, itself enabled by the succession of audit and provenance events that capture related metadata. In this example, health data/record flow is top to bottom.*



*The Chain of Trust is shown as successive Events (2nd/3rd column) in health data/record management – starting at the point of origination (the “source of truth”) – with AuditEvent (4th column) captured at each Event. With this metadata the Chain of Trust traces source health data/record content and its path to each ultimate end user/use. Data Provenance (DPROV) Events (5th column) capture related metadata at Events when health data/record content is new or updated. Primary Use requires original data/record content to be evident at each ultimate point of data/record access use (6th column) and is a paramount success factor to achieving health data/record interoperability. The Chain of Trust provides evidence for the Trust Decision by each ultimate end user…*

*[*

*AuditEvent and Provenance are two HL7 Fast Health Interoperability Resources (FHIR), currently on ballot at HL7 as part of FHIR DSTU 2 and profiled together in the HL7 FHIR Record Lifecycle Event Implementation Guide, also on ballot.]*

**17A.** Adding a new category to “best available” standards, please revise the Advisory to include end-to-end chain of trust, health data/record management from point of origination to each ultimate point of access/use or deletion/destruction (lifespan) including events likely to occur within that lifespan (lifecycle). The following standards are directly applicable and should be included:

• ISO 21089, Trusted End-to-End Information Flows (first published 2004, currently in

revision)

• ISO/HL7 10781, Electronic Health Record System Functional Model, Release 2 (2015)

• ISO/HL7 16527, Personal Health Record System Functional Model, Release 1 (2015)

• HL7 EHR Lifecycle Model DSTU (2008)

• HL7 Fast Health Interoperability Resources (FHIR) – Record Lifecycle Event

Implementation Guide (FHIR DSTU-2 ballot now underway) – including FHIR resources for:

• AuditEvent

• Provenance

**18. Interoperability Relies on Audit, Provenance and Traceability**

*As noted in previous Comments, much of what makes interoperability evident is audit logs,*

*provenance and traceability…*

*Since May 2014, an HL7 Project Team has focused on health data/record lifespan – and lifecycle events occurring within that lifespan – in context of implementations using HL7 Fast Healthcare Interoperability Resources (FHIR). Record lifecycle events include: originate, retain/maintain, update/amend, verify, attest, translate/transform, disclose, transmit, receive, archive, delete/destroy and more. The Team started with Standards-based requirements (for audit, provenance, traceability and more) and profiled FHIR AuditEvent and Provenance resources to capture applicable metadata at each lifecycle event. Resulting from this effort is a new Record Lifecycle Event Implementation Guide (RLE IG) for HL7 FHIR. The RLE IG is currently in HL7 ballot as part of FHIR Draft Standard for Trial Use Release 2, opening 3 April and closing 4 May 2015.*

*Consistent, broad-based adoption of fundamental audit, provenance and traceability for health data/records is essential to any interoperability solution.*

**18A.** As referenced in Comment 17A, please use this new category to include Advisory “best available” standards recommendations for audit, provenance and traceability. Include the standards listed in Comment 17A.

**19. Interoperability Relies on End-to-End Standards**

*Reference: ISO 21089, Trusted End-to-End Information Flows*

*Interoperability relies on trusted end-to-end management of health data/records from the point of origination to each ultimate point of data/record access/use, encompassing data at rest and data in motion. This Standard is agnostic as to the type of system (EHR, PHR, HIS, Ancillary or other system), but rather as to its system role in end-to-end information flow. This Standard provides guidance for US and international communities, promoting a common infrastructure and uniformity in management of end-to-end information flow implementations worldwide. International Standards for trusted end-to-end information flows focus on universal solutions for health data/record interoperability.*

**19A.** As noted in Comment 17A, please include ISO 21089 in the list of “best available” standards for health record capture, retention, end-to-end record lifespan and lifecycle management, audit, provenance and traceability.

**20. Interoperability Relies on EHR, PHR (and other) System Functionality Standards**

*Reference: ISO/HL7 10781 Electronic Health Record System Functional Model (EHR-S FM),*

*Release 2, and ISO/HL7 16527 Personal Health Record System Functional Model (PHR-S*

*FM), Release 1.*

*Interoperability relies on common constructs and functional support for health data/record capture, update, retention, management and exchange. The ISO/HL7 Functional Model Standards provide guidance for US and international communities, promoting common functionality between and across EHR and PHR systems. For example, the EHR-S FM*

*Record Infrastructure Section describes basic record management functions for EHR record entries, including functions to support record entry lifespan and lifecycle.*

*Key international Standards for EHR/PHR system functionality provide a common framework for interoperability, both US and worldwide.*

**20A.** The Advisory is silent on EHR, PHR and other system functions necessary to support interoperability and in fact utilize the enumerated “best available” standards. Please include both ISO/HL7 system functional models and the HL7 Meaningful Use functional profile in the Advisory’s enumeration of “best available” standards:

• ISO/HL7 10781, Electronic Health Record System Functional Model, Release 2 (2015)

• ISO/HL7 16527, Personal Health Record System Functional Model, Release 1 (2015)

• HL7 Meaningful Use Functional Profile Release 1, a profile of ISO/HL7 10781 for the US

Realm (2015)

**21. Interoperability is an International Objective which Requires Collaboration**

**…**

**22. Interoperability From/To Provider Business/Legal Records**

*With the advent of enterprise-wide EHR Systems, most all of the provider health data/record is there committed. This record serves:*

*A. Business purposes – as a an account of operations, processes and services provided;*

*B. Legal purposes – as evidence of who did what when, which may be attested for purposes of accountability and substantiation (e.g., of claims for payment) and as the legal record for reporting, administrative and court proceedings;*

*C. Professional purposes – as an account of actions taken by providers in support of individual health and provision of healthcare.*

*Most providers take great care to ensure their business/legal record is precise, accurate, complete and properly maintained. The business/legal record is a chronicle and key asset of every health provider enterprise.*

*In April 2013, the HIT Policy Committee offered a set of recommendations for ONC consideration of “legal health record”. The recommendations offered the basis for a “legal health record” framework as (in part) an underpinning for nationwide interoperability of health data/records from/to enterprises with established business/legal record systems.*

*Provider business/legal records are the foundation for trusted and interoperable end-to-end information flow. Included are all parties engaged in, and accountability for, enterprise operations, processes and services provided.*

**22A.** The Advisory makes no mention regarding if/how the recommended “best available” standards serve to support the provider health record as a business/legal record. Please revise the Advisory to make this explicit and reference the standard set offered in Comment 17A for this “given interoperability purpose”.

**23. Interoperability Doesn’t Require Manual Interception before Committal**

*A basic challenge for most providers capturing exchange artifacts from external sources is acceptance (acceptability) criteria including what to accept automatically – algorithmically verified but without human review. They maintain meticulous control within their enterprise and must ensure their pristine, carefully curated business/legal record is safeguarded and not contaminated by invalid/incomplete/disjoint data/record content from external sources. The following shows a typical pattern of exchange:*

*In most cases, algorithmic verification always precedes human verification. Competent human review is costly, increasing in time/cost as more inbound data/records are received. Human review may still be inconclusive (e.g., often the human has no access or ability to compare inbound content to original source content). The Roadmap is silent on the current challenge of inbound data quality and the need for human review.*

*Data quality and integrity issues include accuracy, consistency, context, completeness and more.*

*Lack of inbound data quality and limitations of software algorithms and even human review stand as barriers to interoperability.*

**23A.** Before the 2015 Advisory is published, careful consideration should be given as to whether the set of recommended “best available” standards overcomes or instead increases/aggravates the challenge(s) of inbound data quality/integrity to receiving entities. Standards lacking basic data quality protections (e.g., carrying original content alongside transformed content) might be “available” but may not be “best” in this context.

**24. Interoperability Relies on Common Constructs**

*One of the best paths to interoperability is to open the breadth of common constructs between source and receiver systems. In 2011, the S&I Simplification Work Group was formed as an all-volunteer Initiative under the Standards and Interoperability Framework (S&I). This WG has taken 20 mostly heterogeneous S&I Use Cases, with 44 different Scenarios, and analyzed each for elemental and common constructs, including:*

*• Requirements: incl. Assumptions, Pre/Post Conditions, System Functional Requirements*

*• Actors and Roles*

*• Scenarios, Events and Actions*

*• Data Objects and Elements*

*A substantial set of common constructs were identified and are now catalogued in the S&I*

*Simplification Core Matrix v3.3, in the AHRQ-hosted US Health Information Knowledgebase*

*(USHIK) and in the Federal Health Information Model (FHIM).*

**24A.** Work of the S&I Simplification Work Group shows the serious advantages of exploiting commonalties across use cases, building on basic/common constructs and facilitating interoperability of health data/records. Please revise the Advisory to include a new category for use case development and the management of patient, work (process) and information flows, referencing:

• S&I Simplification Core Matrix, Version 3.3 (S&I Framework consensus document)

• ISO 19669, Re-Usable Component Strategy for Use Case Development (ISO TC215

Working Draft)

**25. Interoperability Leveraged across Heterogeneous Use Cases**

**…**

**26. Superstructure without First Infrastructure for Interoperability?**

**…**

**27. Interoperability as a Destination**

**…**

[End of reference to previously submitted CentriHealth comments on the ONC Interoperability

Roadmap.]

Additional Comments on the Standards Advisory

**28A. Interoperability Relies on Identity Matching**

Although identity matching is a key barrier to achieving full interoperability, the Advisory is silent on “best available” standards for this “given interoperability purpose”. Identity matching includes: patients (including all health data/record subjects) and providers (both individuals and organizations).

Please revise the Advisory to offer a new category for identity matching and at least include the ASTM healthcare identifier standard:

• ASTM E1714 - 07(2013) Standard Guide for Properties of a Universal Healthcare Identifier

(UHID)

**29A. “Best Available” and “Best Practice”**

Although the Advisory is silent on “best practice”, does ONC suggest that the “best available” qualification carries equivalence to “best practice” guidance?

.1 Starting with clinical “best practice”:

• Is this guidance to clinical professionals regarding their actions to support individual

health and provide healthcare? At the point of service/point of care?

• Does this offer guidance as to what is permissible, acceptable and/or recommended

for purposes of their actual clinical practice?

.2 Also, how is it relevant to “best practice” for documentation of health and healthcare: i.e.,

creation/update of entries in an EHR/PHR health record?

• Is this guidance for clinical professionals and others who author, scribe, update or

amend clinical content in EHR/PHR record entries? Including entries considered part

of a provider’s business/legal health record?

• Does this offer guidance as to what is permissible, acceptable and/or recommended

for purposes of health data/record origination or update? Including entries attested

(signed) for legal or payment purposes?

• Is this guidance as to what is permissible, acceptable and/or recommended for EHR,

PHR or other systems originating, updating and/or retaining health record entries?

.3 And/or is this “best practice” for health data/record exchange?

• Is this guidance for HIT professionals who design, develop, install, implement and

support health data/record exchange, including points of transmittal and/or receipt?

• Does this offer guidance as to what is permissible, acceptable and/or recommended

for purposes of health data/record exchange between software applications?

The Advisory seems conflicted in terms regarding applicability of its guidance: a) to clinical practice; b) to clinical documentation; and/or c) to health data/record exchange. Is it one, two or all of the above? Please revise the Advisory to make explicit the relationship of “best available” and “best practice” for each of these vital areas of focus.

**30A. Qualities of “Best Available”**

Any enumeration of “best available” begs substantiation, particularly when applied to clinical care, interventions and decision making. It is essential to first consider the qualities/ qualifications for “best available” clinical vocabularies, code sets and terminologies with regard to:

• How well do proposed vocabs, code sets and terms fit the specific case(s) of clinical practice? Are they sufficiently descriptive? Are they comprehensive (rich) or meager (sparse) enumerations?

• Do the proposed vocabs, code sets and terms promote or rather compromise clinical practice, substituting “best available” guidance (from ONC) for other, more proper, complete and specific descriptions otherwise applicable and preferred by clinical professionals?

• Have the proposed vocabs, code sets and terms been vetted by medical societies, including both generalists and specialists? And thus published and citable in their “best practice” guidelines?

• Are the proposed vocabs, code sets and terms vetted, recommended and citable as “best practice” by medical journals or other literature?

• Are there citable surveys of live data exchange experience which quantifies the likelihood of

source data/record content matching the proposed vocabs, code sets and terms?

• With regard to the proposed vocabs, code sets and terms, are there citable surveys of EHR,

PHR or other clinical system usage patterns to demonstrate current adoption (proof in

practice)?

• At the front-end point of service/point of care, by clinical practitioners?

• And separately, at the back-end point of health data/record exchange (between

health/healthcare applications?

• Are the proposed vocabs, code sets and terms intended for exclusive use in the US realm?

If not, is there evidence of adoption by the international community?

The Advisory lacks any of these key qualifications for “best available” standards in clinical practice yet offers an extensive enumeration anyway. Please revise the Advisory to be explicit (and include citations) regarding how these recommendations might qualify for inclusion in the “best available” standards for vocabs, code sets and terms.

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**SA32**

does not describe the methodology for how each of the identified standards was measured against the “Best Available” and “Additional Factors” characteristics or the metrics used to assess each of the standards against each of the characteristics and factors noted in this section. It will be critical for ONC to include this information, not only for full transparency, completeness, and trustworthiness of the process, but also to ensure the validity and reliability of the assessments performed for each identified standard and implementation specification.

The Advisory does not distinguish between standards from American National Standards Institute (“ANSI”) recognized SDOs, or similarly recognized international standards (e.g., International Standards Organization (“ISO”)), versus “standards” from unaccredited sources.

We recommend that ONC prioritize standards from accredited SDOs when both accredited and unaccredited sources exist.

**Additional Factors**

*Stability & Adoptability*

ONC should determine what parameters will govern initial consideration of standards. For instance, whether, for the sake of stability, to consider standards in certain phases of development. ONC should explain what it means regarding standards “… not undergoing substantive changes or corrections.”

*Adding “Maturity” as a factor*

An important factor to be considered in the determination of best available standards is maturity, the degree to which the identified standards has matured enough to be adopted.

*Distinguishing between a Standard and an Implementation Specification*

The distinction between a “standard” and an “implementation specification” is still ambiguous, and full distinction may not be possible. For example, Integrating the Healthcare Enterprise (“IHE”) products are always “specifications,” in that they always build on (constrain) one or more existing standards. Often, they are referred to as “standards” and the parent standards (e.g., HL7, XACML, etc.) are merely implied. In such cases, the identified specification should be in the “specification column;” However, regarding whether to include all of the referenced standards in the “standards” column, we suggest only including the parent standards for the sake of clarity.

*Omitting a stand-alone category for Security Standards*

The 2015 Advisory generally directs readers to the National Institute of Standards and Technology (“NIST”) for purposes of security standards. The range of security standards addressed by NIST is very broad and diverse. Identifying and directing readers to the most relevant security-related NIST documentation (e.g., cybersecurity framework, risk management framework, mobile security standards, and encryption standards) would be most helpful in the context of the 2015 Advisory.

5-1 ONC should consider including standards that are in Draft Standard for Trial Use (“DSTU”) status, so long as it also takes into account level of maturity, stability and adoptability of these DSTU standards, and ultimately of all standards identified and being assessed and prioritized.

We do not recommend any other standards to be considered alongside the ones already identified. However, for each of the standards and implementation specifications identified in this 2015 Advisory, information and documentation should be provided in the tables regarding the clearly defined metrics assessed and documented that define their level of maturity

**SA33**

We recommend that ONC consider another “Best Available” important characteristics besides those listed on pages 4-5. Omitted from this list, and very important considerations are Completeness and Track Record. These are particularly important in the Terminology/Vocabulary standards. For example, a primary reason why SNOMED CT is used and recommended by many is that this standard has been developed and refined over decades. In addition, organizations that support these types of standards have shown the capability to be responsive in adding to the lexicon as new clinical scenarios present themselves.

Simply testing the exchange of XML blobs may not be a suitable test of true interoperability. We recommend testing of such things as: round-trip EHR integration, with recreation of identical CDAs, coding standards and consistency, user-interface support for data entry and reporting, support for CDEs, and the some basic concept of data integrity with preservation of contextual semantics (e.g., - what tree of questions and answers led the author to provide a value to each data element.) We provide the following reference as a resource to this paragraph:

D’Amore, J. D., Mandel, J. C., Kreda, D. a, Swain, A., Koromia, G. a, Sundareswaran, S., … Ramoni, R. B. (2014). Are Meaningful Use Stage 2 certified EHRs ready for interoperability? Findings from the SMART C-CDA Collaborative. Journal of the American Medical Informatics Association: JAMIA. doi:101136/amiajnl-2014-002883

We think that standards must be able to support round trip interoperability, from Point-A Data Entry Form (DEF) through message creation, transmission, parsing, display, storage, data-set integration, aggregated data analysis at Point-B. Point B must then be able to recreate the same data from its parsed data set, and send the same data to Point C. Point C must process the same data in the same way as Point-B, and return it to Point-A with 100% integrity. This must be achievable with any sender/receivers, and any arbitrary number of hops. This has been discussed in the ONC S&I Laboratory Reporting TIGER Team.

We are not referring to a static C-CDA document or raw text or pdfs. We think it is important to ensure that data can be decomposed and integrated into each node's host database system, and be able to regenerate the identical record for sending to another node, with no inconsistencies or errors. We think this can be achieved using SDC.

**SA35**  Include a column that indicates the level of adoption and maturity (as discussed in the JAMIA article published on May 2014 by Dixie Baker, et al) of the specified standard. The ability to identify implementation issues, barriers and impacts to the end user workflow and/or use cases would make this document more valuable.

 Include a column for emerging standards that may potentially supplant the existing best available standard(s).

 Include a separate column specifically for value sets that would allow for more guidance on which value sets should be used.

 List more specific versions of the HL7 v2 messages in alignment with specific use cases to promote harmonization between organizations and enhance interoperability.

**SA38** The Purpose of the Advisory is not entirely clear. The Executive Summary states two purposes:

*“…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.”*

• **EHRA Comment:** The judgment for “best” is ultimately that of ONC at a point in time (with input from a public consultation and review by the HIT Standards Committee). Nowhere is there a consideration for the expected stability/sustainability of the selection made over time. This consideration is critical as interoperability progresses

only if stability and backward compatibility are ensured. We suggest that such a “policy commitment” should be added.

*“…prompts dialogue, debate, and consensus among industry stakeholders when more than one standard or implementation specification could be listed as the best available.”*

• **EHRA Comment:** The dialogue is needed not only to arbitrate cases where alternative standards or implementation specifications exist, but equally about the criteria for introduction/removal from the Advisory (maturity, availability of test tools, piloting use, etc.). This second statement needs to be broadened with this point.

• **EHRA Comment:** Although not in the executive summary, as stated in the body of the document, the present ONC intent is that the judgment for “best” be ultimately that of (1) ONC with input from and (2) a review by the HIT Standards Committee, and two (3) public consultations. (1) and (3) are appropriate, but EHRA believes that the “HIT Standards Committee or one of its sub-groups” is not the right body to conduct the comment resolution. We believe that a dedicated committee for this task would be more effective and provide more technical rigor.

o A broader and more expert representation is needed, as it is not a regulatory action.

o Avoid confusion with the regulatory process

o It is important to get input from the standards development organizations (SDOs) as sources of standards and implementation specifications.

o Establish an explicit process to measure actual use.

o Include other key stakeholders, including NCVHS for administrative standards and associations representing developers and providers.

The relationship with the regulatory process is not entirely clear. It is stated on page 4:

*“While the standards and implementation specifications included in an advisory may also be adopted in regulation (already or in the future), required as part of a testing or certification program, or included as procurement conditions, an advisory is non-regulatory and non-binding in nature. Overall, an advisory is intended 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.”*

• **EHRA Comment:** Non-regulatory and Non-Binding -- We understand that the Advisory is not intended to be an early heads-up about what standards and implementation specifications are intended to be included in certification in the future (although this action may happen, but is in no way assured or required). We suggest clarifications on the potential inferences that could be made or not made about the presence of a standard or implementation specification in relation to the regulatory process would be very helpful to set appropriate expectations.

• **EHRA Comment:** The linking of the Interoperability Roadmap evolution process and the Standards Advisory evolution process is not described. It is quite important to decide if the Roadmap drives only the regulatory process and/or also the Standards Advisory. If it is the latter, the annual revision of the Standards Advisory may be out of synch with the Interoperability Roadmap for a given time period.

The Standards Advisory is proposed as a “point-in-time” assessment that is updated yearly.

**EHRA Comment:** The value of a snapshot is closely linked to its predictability. In healthcare, 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.

• **EHRA Comment:** We support the concept of an ONC statement expressing its perception of the current state of the “industry” or “market” for the best available standards/implementation specifications evaluated during the year prior to publication of the Standards Advisory. An annual update is appropriate, but many elements should remain unchanged if we collectively expect to improve interoperability and avoid constant change and churn.

• **EHRA Comment:** A clear set of criteria associated with any recommendation for a standard/implementation specification is lacking in this document but required for its recommendations to be as credible as possible:

o Standards and implementation specifications need to be stable and DSTUs should be avoided.

o An active maintenance process must be in place.

o Robust testing tools need to be available.

o Some production piloting / early deployments need to have been performed.

• **EHRA Comment:** In the tradeoff between the widest adopted standard and the better standard, one should generally prefer the widest adopted. This consideration should be part of the criteria.

• **EHRA Comment:** Statements in the Standards Advisory about intent to consider adoption of a standard/implementation specification in a future Standards Advisory release may not be of significant value for the implementers. We recommend that the Standards Advisory use such statements mainly when the standard or implementation guide cannot demonstrate sufficient piloting. Such statements, if made, should have an automatic expiration date of one or two years.

• **EHRA Comment:** A standard or implementation specification should have a version number unless the standard or profiling body policy is explicit on ensuring backward compatibility during maintenance (e.g., IHE Profiles in final text status).

• **EHRA Comment:** Delayed or non-adoption of a new version of a standard or implementation specification may often be appropriate, for example, to ensure longer term stability of the Standards Advisory. The rationale to adopt new versions of standards should be weighed against the usage impact in terms of upgrade and non-backward/forward compatibility

• **EHRA Comment:** EHRA suggests that the role of federal agencies and their choice of standards and implementation guides should not be given priority over other uses. Furthermore, DSTU or similar specifications should only be allowed and versioned for a temporary period with a one year expiration date, if no “normative” alternative exists. EHRA suggests the following edits in red bold/underline/strike out text to the Standards Advisory text that should be maintained as edits in the final version to clarify these points:

**EHRA Comment:** The value of a snapshot is closely linked to its predictability. In healthcare, 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.

• **EHRA Comment:** We support the concept of an ONC statement expressing its perception of the current state of the “industry” or “market” for the best available standards/implementation specifications evaluated during the year prior to publication of the Standards Advisory. An annual update is appropriate, but many elements should remain unchanged if we collectively expect to improve interoperability and avoid constant change and churn.

• **EHRA Comment:** A clear set of criteria associated with any recommendation for a standard/implementation specification is lacking in this document but required for its recommendations to be as credible as possible: o Standards and implementation specifications need to be stable and DSTUs should be avoided.

o An active maintenance process must be in place.

o Robust testing tools need to be available.

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*“Standards and implementation specifications in the* ***initial*** *list were included as the “best available” based on the following characteristics and in consideration of past analyses and factors for assessing standards and implementation specifications*1*:*

− *The standard or implementation specification is adopted for a given purpose by HHS in 45 CFR Part 170 Subpart B (entitled “Standards and Implementation Specifications for Health Information Technology”) or required for compliance by another federal agency for that purpose;*

− *The standard or implementation specification is used by federal agencies to electronically exchange health information with organizations participating in the eHealth Exchange (and which generally serve as the basis for electronically exchanging with such agencies);*

− *A “normative”* ***~~or “draft standard for trial use (DSTU)”~~*** *(or equivalently labeled) standard or implementation specification is published and in use by a significant number of stakeholders for a given purpose;*

− *A “normative” or “draft standard for trial use (DSTU)” (or equivalently labeled) standard or implementation specification is published and there is no known alternative or available equivalent to that standard or implementation specification for a given purpose; or*

~~−~~ ***~~The next version of a “normative” or “draft standard for trial use (DSTU)” (or equivalently labeled) standard or implementation specification is published and its prior version is included as a best available standard for a given purpose.”~~***

− ***When for a use case, multiple standards qualify per the above criteria, all such standards shall be listed.”***

• **EHRA Comment:** We suggest adding an explicit list of criteria used to determine “best available” going forward with future versions of the Standards Advisory:

o *Standards and Implementation Specifications in the lists were included as the “best available” based on the following characteristics:*

*Standards along with the needed Implementation Specifications have reached a “normative state (or equivalent labelled).* *They have an active maintenance process in place.*

*They have testing tools covering the standards along with the needed implementation specifications that have been used by at least six software developers.*

*They have undergone at least two distinct pilot deployments with actual clinical usage for six months.*

*And they are explicitly labelled as “ready for national use” in the Standards Advisory.*

o *Standards, along with the needed implementation specifications with an explicit version, have reached a “draft standard for trial use (or equivalent label) and there is no known alternative or available equivalent to that standard or implementation specification for a given purpose. They:* *Have an active maintenance process in place;*

*Have testing tools covering the Standards along with the needed implementation specifications that have been used by at least six software developers;*

*Include an explicit label as “good enough for initial pilot only” in the Standards Advisory. Users are cautioned that non-backward updates may be required following pilot and progression as “normative or equivalent.”*

*A draft for trial use implementation specification is more acceptable when the underlying standards are normative/final.*

*o When the Standards Advisory is updated and a standard and/or implementation specification that has reached a “normative state (or equivalent label)” is updated, backward and forward compatibility should be considered:*

*The two are incompatible and will coexist in the Advisory for an explicit period of time (at least a year) to ensure migration. A bridging solution between the two versions will be identified and piloted. In some cases (e.g., documents), there are situations where sunsetting an older version may not be possible.*

*There is backward and forward compatibility between the two versions and will coexist in the Advisory for an explicit period of time (at least a year) to ensure migration.*

*Testing tools for compatibility should be available.*

*In either case, the benefits that make the update desirable will be explicitly documented.*

**SA39** • We believe that broad industry adoption of a particular technology standard should be considered to be equivalent to Health Level Seven Draft Standards for Trial Use (HL7 DSTU).

**SA43** We applaud the designation of “best available” and encourage the continuation and inclusion of emerging standards where relevant. While the Academy continues to advocate and contribute to nutrition-related health IT standards and terminologies, there is additional work and pilots that need to occur. In some cases, there are standards under development that fulfill the purpose of an existing “gap.” These standards may not yet be in use by a significant number of stakeholders, but represent the collective input of experts and those who are struggling to merge best practices with existing processes that exist in electronic health record (EHR) technology. An example is the standard for parenteral and enteral nutrition orders within current EHR systems. The American Society for Enteral and Parenteral Nutrition (A.S.P.E.N.) has created the A.S.P.E.N. Parenteral Nutrition Safety Consensus Recommendations,2 which identify best practices for minimizing errors in parenteral nutrition therapy, including prescribing, order review and verification, compounding and administration. While there have been discussions between stakeholders – including physicians, pharmacists and dietitian/nutritionists – these critical guidelines have not yet been incorporated into standards. Inclusion of emerging standards allows for greater awareness and potential piloting of often critical gaps in standards.

We also request that you provide clarification on the appropriate use and listing of the ONC Common Data set as mentioned in the Interoperability Roadmap.

SA47 **IHE Comments:**

* 1. To assist in forward planning for developers and SDOs alike, ONC should collect information from various initiatives, SDOs, and professional organizations about emerging standards and implementation guides in conformance with the Roadmap. This information should be made publicly available but through a different vehicle than the Standards Advisory to indicate its tentative nature. This information could also help ONC identify duplications and gaps that ONC could use to harmonize standards and development efforts, as well as identify innovative work that ONC can encourage and support. This information could also include projected timeframes for when these standards may be ready for wider adoption, and any standards that it might be wise to deprecate. Examples of efforts that would be included in such information are the development and testing of implementation guides which are strong candidates for 2016 Standards Advisory implementation specifications such as the:
     1. Joint S&I Framework and IHE Data Access Framework Implementation Guide soon to be released for public comment
     2. EHR | HIE I Interoperability Workgroup implementation specifications covering Direct and Community Query functionality now being used in the pilot ConCert by HIMSSTM Testing and Certification program

* 1. We suggest that versioning, where applicable, be added to the Standards Advisory to help avoid mismatches and drive harmonization industry wide. An example of where this could be helpful is in selecting specific HL7 v2.x and HL7 v3 versions. This would save time in connecting two vendor systems by providing clear direction when the vendors bring different versions to an implementation. However, this is not necessary for IHE profiles in Final Text which are not versioned.
  2. As stated in the body of the document, the present intent is that the judgment for “best” be ultimately that of (1) ONC with input from and (2) a review by the HIT Standards Committee, and (3) public consultations.  IHE proposes the establishment of a dedicated non-regulatory committee to drive the work. This committee would include appropriate representation and would add value to ONC’s decision making by providing more expertise and rigor. Members of the committee and its workgroups would be selected to be:
     + - * Technically expert, drawing from industry
         * Experienced in the use of the standards, drawing from provider and other organizations using the standards
         * Expert in developing standards and implementation specifications, drawing on standards development organizations (SDOs) and professional societies.
  3. IHE recommends establishment of a process to measure actual adoption/use of standards and implementation specifications with links to case studies, evaluations, etc. That information should be shared publicly.
  4. 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.  In healthcare, 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.  Thus IHE recommends that the annual process encourage continuity while not stifling innovation. When implementing best available standards, stability is essential to ensure that adherence to the Standards Advisory is a worthy investment.

* 1. A clear set of criteria associated with any recommendation for a standard/implementation specification is required for the recommendations to be credible. IHE recommends adherence to the following:
     + - * Standards and implementation specifications need to be stable.  DSTUs should be avoided for inclusion in the Standards Advisory.
         * An active maintenance process must be in place.
         * Robust testing tools need to be available for software developers and provider organizations to test against the standards.
         * Some production piloting / early deployments need to have been performed for inclusion.
  2. IHE recommends mapping use cases to standards and implementation specifications. Interoperability specifications 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) 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. For example, a Personal Health Record Use Case.

**SA48** We recommend that pilot or emerging standards should be named and agree that all should include an Implementation Specification, or other supporting documents, such as Implementation Recommendations documents from NCPDP.

**SA51**

Response:

As currently presented, a “standard” may involve one or more of the categories or purposes. Interoperability depends upon a mutual understanding of this information and the way it is specified. A significant reorganization may facilitate getting at the root cause of our interoperability problem. To implement an operation that might be present in one of these standards, the following are needed:

* Inputs to an operation – what input schema do operations expect?
* Operations – what are the operations this standard purports?
* Outputs of an operation – what is the output schema?

For many of the standards contemplated in this document, the Operations are called “Implementation Guides,” and are devoted to generating a structured output from inputs that are underspecified and operational logic that is not computable.

Inputs and outputs should conform to one or more semantic standards with an information model that adheres to specific constraints communicating how they should be parsed.

Knowledge artifacts are often, but not always, bundled with terminology standards – ontologies. Occasionally, these are coupled with generalized relational assertions based on definitional aspects (“is a”; “is an order for”), or knowledge (drug-drug interaction).

The value of terminology standards is directly related to the amount of knowledge that can be accurately linked to them, and the scope under which that knowledge is valid (that is, the “Purpose”). Page 4 of 10

In addition to *Timeliness & Availability* and *Stability & Adoptability:*

* Completeness of the standard
* Extensibility of the standard to meet future needs
* Interoperability with evidence base, knowledge base and other standards.

The **criteria** for demonstrating evidence of “Stability & Adoptability” should be very clear:

* Incentives for adoption and maintenance.
* History of successful implementation in generalizable contexts.

o If new, reference implementation that allows comparison to alternatives.

* Availability and quality of implementation guide, including the specificity of inputs, operations, and outputs that are assumed in any given implementation.
* Has a reference implementation been demonstrated for a significant number of use-cases?

**SA55** The Purpose of the Advisory is not entirely clear. The Executive Summary states two purposes:

*“…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.”*

* **NextGen Healthcare Comment:** The judgment for “best” is ultimately that of ONC at a point in time (with input from a public consultation and review by the HIT Standards Committee). Nowhere is there a consideration for the expected stability/sustainability of the selection made over time. This consideration is critical as interoperability progresses only if stability and backward compatibility are ensured. We suggest that such a “policy commitment” should be added.

*“…prompts dialogue, debate, and consensus among industry stakeholders when more than one standard or implementation specification could be listed as the best available.”*

* **NextGen Healthcare Comment:** The dialogue is needed not only to arbitrate cases where alternative standards or implementation specifications exist, but equally about the criteria for introduction/removal from the Advisory (maturity, availability of test tools, piloting use, etc.). This second statement needs to be broadened with this point.
* **NextGen Healthcare Comment:** Although not in the executive summary, as stated in the body of the document, the present ONC intent is that the judgment for “best” be ultimately that of (1) ONC with input from and (2) a review by the HIT Standards Committee, and two (3) public consultations. (1) and (3) are appropriate, but NextGen Healthcare believes that the “HIT Standards Committee or one of its sub-groups” is not the right body to conduct the comment resolution. We believe that a dedicated committee for this task would be more effective and provide more technical rigor.

o A broader and more expert representation is needed, as it is not a regulatory action.

o Avoid confusion with the regulatory process

o It is important to get input from the standards development organizations (SDOs) as sources of standards and implementation specifications.

o Establish an explicit process to measure actual use.

o Include other key stakeholders, including NCVHS for administrative standards and associations representing developers and providers.

The relationship with the regulatory process is not entirely clear. It is stated on page 4:

*“While the standards and implementation specifications included in an advisory may also be adopted in regulation (already or in the future), required as part of a testing or certification program, or included as procurement conditions, an advisory is non-regulatory and non-binding in nature. Overall, an advisory is intended 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.”*

* **NextGen Healthcare Comment:** Non-regulatory and Non-Binding -- We understand that the Advisory is not intended to be an early heads-up about what standards and implementation specifications are intended to be included in certification in the future (although this action may happen, but is in no way assured or required). We suggest clarifications on the potential inferences that could be made or not made about the presence of a standard or implementation specification in relation to the regulatory process would be very helpful to set appropriate expectations.
* **NextGen Healthcare Comment:** The linking of the Interoperability Roadmap evolution process and the Standards Advisory evolution process is not described. It is quite important to decide if the Roadmap drives only the regulatory process and/or also the Standards Advisory. If it is the latter, the annual revision of the Standards Advisory may be out of synch with the Interoperability Roadmap for a given time period.

The Standards Advisory is proposed as a “point-in-time” assessment that is updated yearly.

* **NextGen Healthcare Comment:** The value of a snapshot is closely linked to its predictability. In healthcare, 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.
* **NextGen Healthcare Comment:** We support the concept of an ONC statement expressing its perception of the current state of the “industry” or “market” for the best available standards/implementation specifications evaluated during the year prior to publication of the Standards Advisory. An annual update is appropriate, but many elements should remain unchanged if we collectively expect to improve interoperability and avoid constant change and churn.
* **NextGen Healthcare Comment:** A clear set of criteria associated with any recommendation for a standard/implementation specification is lacking in this document but required for its recommendations to be as credible as possible:

o Standards and implementation specifications need to be stable and DSTUs should be avoided.

o An active maintenance process must be in place.

o Robust testing tools need to be available.

o Some production piloting / early deployments need to have been performed.

* **NextGen Healthcare Comment:** In the tradeoff between the widest adopted standard and the better standard, one should generally prefer the widest adopted. This consideration should be part of the criteria.
* **NextGen Healthcare Comment:** Statements in the Standards Advisory about intent to consider adoption of a standard/implementation specification in a future Standards Advisory release may not be of significant value for the implementers. We recommend that the Standards Advisory use such

statements mainly when the standard or implementation guide cannot demonstrate sufficient piloting. Such statements, if made, should have an automatic expiration date of one or two years.

* **NextGen Healthcare Comment:** A standard or implementation specification should have a version number unless the standard or profiling body policy is explicit on ensuring backward compatibility during maintenance (e.g., IHE Profiles in final text status).
* **NextGen Healthcare Comment:** Delayed or non-adoption of a new version of a standard or implementation specification may often be appropriate, for example, to ensure longer term stability of the Standards Advisory. The rationale to adopt new versions of standards should be weighed against the usage impact in terms of upgrade and non-backward/forward compatibility
* **NextGen Healthcare Comment:** NextGen Healthcare suggests that the role of federal agencies and their choice of standards and implementation guides should not be given priority over other uses. Furthermore, DSTU or similar specifications should only be allowed and versioned for a temporary period with a one year expiration date, if no “normative” alternative exists.
* **NextGen Healthcare Comment:** We suggest adding an explicit list of criteria used to determine “best available” going forward with future versions of the Standards Advisory:

o *Standards and Implementation Specifications in the lists were included as the “best available” based on the following characteristics:*

*Standards along with the needed Implementation Specifications have reached a “normative state (or equivalent labelled).*

*They have an active maintenance process in place.*

*They have testing tools covering the standards along with the needed implementation specifications that have been used by at least six software developers.*

*They have undergone at least two distinct pilot deployments with actual clinical usage for six months.*

*And they are explicitly labelled as “ready for national use” in the Standards Advisory.*

o *Standards, along with the needed implementation specifications with an explicit version, have reached a “draft standard for trial use (or equivalent label) and there is no known alternative or available equivalent to that standard or implementation specification for a given purpose. They:*

*Have an active maintenance process in place;*

*Have testing tools covering the Standards along with the needed implementation specifications that have been used by at least six software developers;*

*Include an explicit label as “good enough for initial pilot only” in the Standards Advisory. Users are cautioned that non-backward updates may be required following pilot and progression as “normative or equivalent.”*

*A draft for trial use implementation specification is more acceptable when the underlying standards are normative/final.*

o *When the Standards Advisory is updated and a standard and/or implementation specification that has reached a “normative state (or equivalent label)” is updated, backward and forward compatibility should be considered:*

*The two are incompatible and will coexist in the Advisory for an explicit period of time (at least a year) to ensure migration. A bridging solution between the two versions will be*

*identified and piloted. In some cases (e.g., documents), there are situations where sunsetting an older version may not be possible.*

*There is backward and forward compatibility between the two versions and will coexist in the Advisory for an explicit period of time (at least a year) to ensure migration.*

*Testing tools for compatibility should be available.*

*In either case, the benefits that make the update desirable will be explicitly documented.*

**SA56 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 deployments and implementation within HIT systems is maintained as systems are upgraded and new innovations are added.

o 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?*

**Identity Related Comments**

SA 05 Introduction

SAFE--‐BioPharma Association is grateful for the opportunity to review and comment on ONC’s draft, “A Shared Nationwide Interoperability Roadmap.” SAFE--‐BioPharma was created by the biopharmaceutical industry and its regulators to provide global high--‐assurance identity trust for cyber--‐transactions across the biopharmaceutical and healthcare sectors. SAFE--‐BioPharma is the only industry collaborative that operates two trust federations approved by the U.S. Federal Identity, Credential and Access Management (FICAM) subcommittee of the US CIO Council and that includes high assurance authentication and digital signing services recognized by the European Union and the European Telecommunications Standards Institute Qualified Certificate Program.

**SAFE--‐BioPharma believes that one of the fundamental requirements for national healthcare interoperability is standardized identity trust. It provides a tool for firms, vendors, regulators and others to standardize trust for authentication and signing. It allows industry, government, vendors and individuals to know that their products or the products/applications they are using are acceptable across the healthcare landscape and can be confidently used by all stakeholders. Further, standardized identity trust allows users to have only one on--‐line identity for use with all partners, should they so choose.**

General Comments   
The SAFE--‐BioPharma Association believes that one of the most powerful steps that ONC can take to protect the privacy, security and confidentiality of medical data is to recognize the critical need for high assurance of identity for all entities that touch the Health IT architecture. This includes identity for devices, for government, for business entities and for individual practitioners and providers. Devices communicating with the Health IT architecture must assert identities as reliably as persons. The FDA is currently developing a program to confidently identify Internet--‐connected medical devices and we recommend that this initiative be folded into Roadmap design and planning.

We also believe that all assertions of identity within the Health IT architecture should conform to NIST standards and guidelines for cybersecurity and online identity assertion and the US FICAM policies regarding trustworthiness of identity assertions based on those guidelines. While we also believe that “one size does not fit all,” ***we believe that there must be a minimum baseline “size,” which replaces all single factor userID/password authentication implementations with two--‐factor authentication implementations.***

As technology advances more rapidly than government policymaking, it is important to understand that standards, guidelines and policies are based upon the principle of identifying risks and developing adequate mitigation strategies to counteract them. There are many ways to implement use case appropriate two--‐factor authentication implementations that satisfy NIST standards and guidelines.

One example might be for the identity assurance of a low--‐assurance, single factor identity credential such as userID/password to be improved when the relying party employs a second factor test at time of login, as 2 is currently done at many online banking sites. This aligns well with industry, technology and societal migration to universal connectivity and mobile device proliferation. A stronger, two--‐factor credential would be more appropriately required for a systems administrator to log in to a critical, PHI--‐filled data repository.

Requirement of such a credential likely would have saved Anthem from the hacking disaster it recently experienced. For privacy, security and regulatory compliance reasons, we reiterate that all sensitive data be encrypted at rest and in motion with asymmetric key cryptography conformant with NIST standards and guidelines and with the guidelines of the CA Browser Forum. In order to ensure broad interoperability and trust, all device, individual and organizational digital certificates for high assurance of identity should be issued and managed by services cross--‐certified with the US Federal PKI Architecture directly or indirectly.

Assured identity management is one of the three foundations of cybersecurity identified in the President’s Report on cybersecurity issued in 2009. The Interoperability Roadmap rests upon the assumption of broad sharing and collaboration and it must therefore include a substantive, yet flexible, identity management component. We support the Roadmap’s position in its section on “Verifiable Identity and Authentication of All Participants” while recommending a more nuanced requirement for minimum two--‐factor authentication based on risk and risk mitigation as a design principle.

Specific Actions

SAFE--‐BioPharma Association would welcome the opportunity to share its expertise in support of ONC efforts to focus on implementation of identity assurance and the important part that interoperability contributes as part of any overall cybersecurity initiative. Mollie Shields--‐Uehling President and CEO The SAFE--‐BioPharma Association Mollie@SAFE--‐BioPharma.org 201 925--‐2173 [www.SAFE--‐BioPharma.org](http://www.SAFE--‐BioPharma.org)

SA 27 Yes – in addition to the four standards categories included in this advisory, we identified the following standards categories to consider as well:

* **Data capture**. Interoperability specifications should consider a standard for data capture. One cannot construct longitudinal data records for analysis without understanding the terminology and its membership in value set’s and relationships to specific data elements in the user interface. We need to emphasize that the semantics need to convey the context in which this information is communicated and interpreted.

o **Example**: If a person’s status is currently that of a non-smoker, does the information shared convey the understanding that they have been a smoker for the last 20 years? What are the socio-determinants of today vs. 5 years vs. 20 years?

* **Security standards.** There should be more in depth and attention to security standards. There are more considerations than the transport security standards referenced in the Interoperability Standards Advisory.

o **Example:** Digital certifications and encryption.

**SA32** Yes, we believe the following should be added:

Administrative

Privacy and Security

Patient identification and matching

Consumer/patient engagement

Consumer generated data

**Section V 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.

SA27: In addition to the “purposes” already listed in Sections I through IV, we identified the following additional purpose to consider adding as well:

|  |  |  |
| --- | --- | --- |
| **Purpose** | **Standard(s)** | **Implementation Specification(s)** |
| Cancer Staging | TBD | TBD |

**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?*

*SA 27:* Yes - We recommend including SNOMED-CT to the 2015 version of Standards Advisory. The “standard” is a foundation that a skilled developer needs to turn into a “tight” implementation guide. There will need to be an unambiguous implementation guide for every use case that needs to be supported. Further work may be required that is unique to the vendor systems in place and the internal IT architecture of each provider organizations IT infrastructure. Furthermore, IT documentation, testing beds and procedures and nation-wide standard revision levels for terminologies will also have to be carefully managed to current levels.

In addition to the standards and implementation specifications associated with the purposes that are already listed in Sections I through IV, we identified the following standards to consider including as well:

Section I: Best Available Vocabulary / Code Set / Terminology Standards and Implementation Specifications

|  |  |  |
| --- | --- | --- |
| **Purpose** | **Standard(s)** | **Implementation Specification(s)** |
| Food allergies | SNOMED-CT | TBD |
| Functioning and disability | SNOMED-CT | TBD |

SA28 The CDISC comments are presented to you in the form of a table that contains standards we feel should be included in the ONC Standards Advisory. These standards are mature and in use for research purposes and to link with healthcare. The categories in our table comply with the categories of the table in the Standards Advisory document (although the CDISC transport standards may not be defined in exactly the same manner as those listed in the Transport Standards section of the table provided). We feel that including these CDISC and IHE standards, which have been developed through a robust and globally accepted standards development process, will provide a glide-path for ONC to enable a true learning health system. These standards, used in a complementary way, have been demonstrated to save significant time and resources in conducting research studies and in the use of EHRs for research, safety surveillance, and registry reporting, while ensuring traceability (provenance) and increasing data quality by eliminating transcription. They are also endorsed and soon to be required by FDA and by Japan’s analogous regulatory authority, PMDA. Europe’s EMA has already adopted the CDISC requirements for the use of eSource (i.e. EHRs, eDiaries, ePatient Reported Outcomes) from the CDISC eSource Data Interchange Initiative. CDISC standards were developed to support provenance as a core requirement to ensure that research results are trustworthy, retain appropriate patient privacy and maintain data integrity and traceability from the point of collection through analysis and reporting.

Published CDISC Standards & IHE Profiles

|  |  |  |
| --- | --- | --- |
| **CDISC Standard** | **Description** | **Implementation Version Release Date** |
| ***Vocabulary/Code Set/Terminology Standards & Implementation Specifications*** | | |
| **Controlled Terminology** | >20,000 Controlled terms and definitions coded in NCI Thesaurus, supporting regulatory CDISC standards such as SDTM, SEND, ADaM, CDASH. CDISC Terminology developed and published in partnership with NCI Enterprise Vocabulary Services (EVS). | Posted Quarterly;  Pkg 21 released March 2015 |
| **Questionnaires** | SDTM Implementation Guide Supplements with annotated CRFs and Controlled Terminology for representing data from Questionnaires commonly used in clinical studies. | 2013-2015 |
| **BRIDG Model** | Biomedical Research Integrated Domain Group (BRIDG) UML model of the semantics of the protocol-driven clinical research domain, collaboratively developed by CDISC, FDA, NCI, HL7 and ISO.  Version 4.0 includes clinical genomics domain from NCI and CDISC Pharmacogenomics standard; undergoing ballot currently within HL7 and CDISC. | V3.2 (CDISC & HL7 Standard 2012; Final ISO Standard 2015) |
| **Protocol Representation Model (PRM)** | BRIDG-based model representing standard protocol elements and relationships | V1 2010 |
| **CDISC Shared Health And Research Electronic Library (SHARE)** | CDISC Metadata Repository; electronic source for all CDISC standard content, metadata and terminology | R2 2015 |
| **Glossary** | Glossary with definitions of acronyms and terms commonly used in clinical research. | 2011 |
| ***Content/Structure Standards & Implementation Specifications*** | | |
| **Study Data Tabulation Model (SDTM)** | Ready for regulatory submission of tables of data compiled from clinical research studies  \* Required by FDA for clinical trial submissions in 2016 | V1.4 2013  V1.3 2012 |
| **SDTM Implementation Guide (SDTMIG)** | SDTM IG for Human Clinical Trials (Drug Products and Biologics)  \* Required by FDA for clinical trial submissions in 2016 | V3.2 2013  V3.1.3 2012 |
| **Standard for the Exchange of Non-clinical Data (SEND)** | Standard for Exchange of Nonclinical Data: SDTM IG to represent data from nonclinical studies.  \* Required by FDA for clinical trial submission in 2016 | V3.0 2011 |
| **SDTMIG-MD** | SDTM Implementation Guide for Medical Devices – to represent data from clinical trials using medical devices | V1.0 2012 |
| **SDTMIG-AP** | SDTM Implementation Guide for Associated Persons Devices – to represent data about persons who are not study subjects (family, caregivers) | V1.0 2013 |
| **Analysis Dataset Model (ADaM)** | Analysis Data Model describing fundamental principles and standards for creating analysis datasets and metadata.  ADaM Time to Event Model  ADaM Adverse Event Model  \* Required by FDA in 2016 | V2.1 2009  V1 2013  V1 2013 |
| **ADaM IG** | IG describing standard data structures, conventions and variables used with the ADaM model.  \* Required by FDA in 2016 | V1 2009 |
| **Clinical Data Acquisition Standards Harmonization (CDASH)** | Minimum Core Research Dataset; Clinical Data Acquisition Standards Harmonization – describes basic data collection fields for Case Report Form (CRF) data necessary (across all research studies globally), published with implementation guidelines, best practices and examples provided | V1 2010 |
| **CDASH SAE Supplement** | CDASH standard describing basic data collection fields for ICH E2B Serious Adverse Events (SAE) data (safety surveillance) | V1 2013 |
| **LAB** | Standard model for the acquisition and interchange of clinical lab data for research | V1.0.1 2003 |
| ***Transport Standards & Implementation Specifications*** | | |
| **Operational Data Model (ODM)** | CDISC Standard for the regulatory compliant acquisition, exchange and archive of clinical trials data and metadata; forms-based and readily transports CDASH standard CRF data retaining provenance and traceability | V1.3.2 2013 |
| **Study Design Model**  **(SDM-XML)** | XML schema specification based on ODM for representing clinical study design, including structure, workflow and timing. | V1 2011 |
| **Define-XML** | XML Schema Specification to describe metadata for SDTM, SEND and ADaM submission datasets | V2.0 2013\* |
| **Dataset-XML** | Dataset-XML – schema specification for representing study datasets associated with Define-XML metadata. | V1 Draft 2013 |
| ***Standards & Implementation Specifications for Services*** | | |
| **Therapeutic Area Standards (to complement the prior CDISC foundational standards that apply across all TAs)** | Therapeutic Area (TA) Standards to date, realized through contributions from Patient Foundations, National Cancer Institute and FDA-NIH grants: Alzheimer’s, Asthma, Cardiovascular Disease, Diabetes, Hepatitis C, Influenza, Multiple Sclerosis, Parkinson’s, Polycystic Kidney Disease, Schizophrenia, Tuberculosis, Virology  New TA’s in development: Traumatic Brain Injury, Breast & Prostate Cancer, COPD, Diabetic Kidney Disease, Rheumatoid Arthritis | Ongoing Since 2011; posted at [www.cdisc.org](http://www.cdisc.org) – Standards |
| ***Healthcare Link Standards***  *IHE Profiles (developed with CDISC)* | | |
| **Retrieve Form for Data Capture (RFD)** | RFD provides for gathering data within a user’s current application to meet the requirements of an external system. RFD supports the retrieval of forms from a form source, display and completion of a form, and return of instance data from the display application to the source application. | 2008 |
| **Clinical Research Document (CRD)** | CRD describes the pre-population content pertinent to the clinical research use case within the Retrieve Form for Data-Capture (RFD) profile. | 2012 |
| **Drug Safety Content (DSC)** | DSC describes the content and format to be used to pre-populate data for safety reporting purposes. | 2012 |
| **Redaction Services** | Provides a means to extract pertinent data from an EHR export document, and eliminates the risk of providing more data to a research system than what the protocol authorizes. | 2010 |
| **Retrieve Process for Execution (RPE)** | RPE enables a healthcare provider to access a process definition, such as a research protocol, and to execute automated activities, without leaving an EHR session. | 2011 |
| **Clinical Research Process Content (CRPC)** | CRPC specifies content to automate the sharing of information among systems during the clinical research process using the transactions from the Retrieve Process for Execution (RPE) profile. | 2012 |
| **Research Matching** | Specifies a method for publishing research process definitions to interested EHR systems to enable matching patients and investigators with appropriate clinical research studies. | 2013 |
| **Data Element Exchange (DEX)** | DEX leverages the concept of a metadata registry to add mapping metadata to an annotated data capture form at the point of form design. DEX has recently demonstrated through a new project called keyCRF and keyHCSF. | 2013 |
| **Structured Data Capture (SDC)** | SDC utilizes the IHE Retrieve Form for Data Capture (RFD) profile for retrieving and submitting forms in a standardized and structured format. This supplement is based on the work of the US Office of the National Coordinator for Health Information Technology, Standards & Interoperability (S&I) Framework SDC Initiative. | 2014 |

SA29: touted the FHIM for its contributions in 5 areas:

1. The model catalogs a large number of key shared information exchange needs
2. Actual use case scenarios were provided by 20 federal partners
3. It is a structured model populated with consensus-based industry standards
4. It documents the model-building processes, which are key to building understanding, confidence and support
5. It enhances automation of healthcare data exchange, thus promoting higher quality and efficiency

Our review of the 2015 Interoperability Standards Advisory leads us to offer one observation and to ask two questions.

**Observation 1:**

In our review of the Open Draft Report of the Advisory, we did not see evidence that the Federal Health Architecture’s FHIM (Federal Health Information Model) or the best practices used in the modeling of the FHIM were considered and incorporated in the Report. Although we would not expect the Advisory to note every source of best available standards it considered, we note that the Clinger-Cohen Act of 1996 provides general authority for a Federal Enterprise Architecture (FEA) and that in 1999 the US Office of Management and Budget’s (OMB) Federal CIO Council created the FEA to direct each federal agency to manage its work according to best business practices to foster interoperability, consistency, efficiency, data utility, and transparency.

In 2004, the OMB established the Federal Health Architecture (FHA) program to produce a common way to represent exchanged healthcare information. More specifically, the FHA was initiated to bring together the decision-makers in federal health IT for inter-agency collaboration – resulting in effective healthcare information exchange, enhanced interoperability among federal health IT systems, and efficient coordination of shared services. The FHA is a program managed by the ONC. The FHA supports federal agency (and their private sector collaborators’) development of internationally-recognized interoperability standards and policies for efficient, secure healthcare information exchange.

Therefore, it would seem that ONC would direct the 2015 Interoperability Standards Advisory to thoroughly review and adopt best available practices developed and used by the FHA. Yet, as noted, we do not see evidence that this has been done and wonder whether this is an unintended (but very important) omission?

**Question 1:**

To what extent, if at all, did the Advisory examine the FHIM as the Advisory developed the best available standards and implementation specifications in Sections I-IV? If the FHIM was considered and not used, could you provide a rationale?

**Question 2:**

Has the Advisory made the ONC fully aware of the quality and nature of work undertaken by the FHIM modelers with its federal partners and standards development organizations and the S&I initiative?

SA32 We do not recommend any other standards to be considered alongside the ones already identified. However, for each of the standards and implementation specifications identified in this 2015 Advisory, information and documentation should be provided in the tables regarding the clearly defined metrics assessed and documented that define their level of maturity

**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? If so, why?*

SA27 Yes - All are credible and need to be put through a set of structured trials to make sure that the different selected messaging and terminology standards and revision level will produce the needed accurate interoperation of process and data.

For Sections I through IV, we identified the following standards to consider removing from the list:

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| --- | --- | --- |
| **Purpose** | **Standard(s)** | **Implementation Specification(s)** |
| Care team member (health care provider, non-physician ancillary providers) | National Provider Identifier (NPI) | TBD |
| Encounter diagnosis | ICD-10-CM | TBD |
| Immunizations – administered | National Drug Codes (NDC) | TBD |

* For the purpose of “Care team member (health care provider)”, Care team members should include non-physician ancillary providers – these members of the care team don’t necessarily have a NPI. Therefore, NPI may not be the appropriate standard to identify care team members.
* For the purpose of “Encounter diagnoses”, we recommend that ICD-10-CM be removed. We recommend this because having more than one standard creates the need to do mapping which opens up interpretation of matching concepts to one another to an individual’s preference. This defeats interoperability.
* For the purpose of “Immunizations – administered”, we recommend that National Drug Codes (NDC) be replaced with RxNorm as the standard. NDC code should never be used in data capture for a number of reasons including ambiguity in representation as well as the reuse of codes by manufacturers.
* General note: While use of HL7 V3 messaging may have narrow niche roles, their inclusion is probably not on a roadmap for extension and one might consider flagging interest in alternatives, such as FHIR messages.

SA32 Generally, IHE products should be listed in the specification column. IHE constrains existing standards, it does not create new standards.

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

SA27 No. The value sets need to be clearly defined, and updated regularly. Given that this is a very sensitive area, we found that at the moment the best option is to go with the value sets for race and ethnicity that are in prevalent use. There is not a great alternative, just an alternative with different issues. This should be left to an implementation guide given that as genomic data becomes more readily available, our concept of ethnicity will fall away as antiquated. Detailed value sets should be identified as an implementation specification, to allow the same standard to be used for multiple use cases.

**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?*

SA27 No – we do not recommend removing more traditionally considered “administrative” standards. ICD-10 serves a broad use and purpose especially in the Healthcare Payer and Provider/Payer IT market segments. Clinical context is often reliant on an administrative under-layer.

SA32 We recommend maintaining ICD-10 and other “administrative” standards, given the considerable overlap between “clinical” and “administrative” standards and vocabularies. In the case of ICD-10 (or ICD-9), sending both clinical and administrative concepts in a new e-prescription will help tie the clinical rationale to the billable concept.

**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?*

SA27 Yes – we recommend including “Food allergies” as a purpose in the document. SNOMED-CT should be listed as the “best available” standard for this purpose. In addition, we recommend separating food intolerance from actual food allergy.

SA32 Food allergies are one of the many different types of allergies that should be assessed and recorded about a patient, but singling out Food Allergies as a purpose in the table is not necessary. Rather, documentation should be done using SNOMED-CT for types of allergies along with other standards such as RxNorm, National Drug File - Reference Terminology (“NDF-RT”), and UNique Ingredient Identifier (“UNII”) to support capturing such information.

**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?*

SA27 Yes – the “Functional and disability” purpose category should be included in the document and the ICF should be included as a standard for this category. A similar standard that could be considered for inclusion is SNOMED-CT as it would simplify implementation and give a more robust classification and maintenance process.

**5-10 [Section I]** *Should the MVX code set be included and listed in tandem with CVX codes?*

SA27 No – we do not recommend including the MVX code set and listing it in tandem with CVX codes. The MVX code system is not updated frequently enough to reflect the constant merger and acquisition of Pharma companies where the manufacturer may change. Furthermore, MVX should not be used given that the data that will be available indirectly through RxNorm. RxNorm has a much better refresh rate and carries with it the necessary data for someone to look up a manufacturer at a point in time.

**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?*

SA27 Yes - Vaccines administered could be listed as a separate purpose, however, if listed as a separate purpose, NDC would not be the correct code set to use. We recommend using RxNorm or sticking to CVX or CVX /MVX.

**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?*

SA27 Yes – we recommend that the Standard Occupational Classification (SOC) codes be used as a “best available” standard to represent industry and occupation in the 2016 Advisory.

**5-13 [Section I]** If 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?

**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?*

SA27 No – we do not recommend adding a new column for value sets. If a preferred or specific value set exists for a specific purpose and the standard adopted for that purpose, it can be listed in the “implementation specification” column. If a preferred or specific value set exists for a specific purpose and the standard adopted for that purpose, we recommend that it be listed in the “implementation specification” column. Since the value sets will need to be changed over time in referencing the value set, it would only be useful where it is intentionally defined. If a corresponding value set applies then a reference to the value set, a URL link if appropriate and available as well publication and revision level identification should be included.

**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?*

SA27 Yes – HL7 v2 messaging is what is currently in broad, national use and it is unrealistic to go away from it right now. The reference lab industry settled on the HL7 2.5.1 standards with implementation guides several years ago. The current activities in HL7 are to update these standards, implementation guides, and any changes necessary to value sets associated with these implementations. However, for the future, a switch to CDA or FHIR should be considered and they should be listed as alternative mechanisms of transport to allow gradual deprecation of HL7 v2 messaging.

Electronic directory of services (eDOS) should be considered best available for 2016 once finalized. This will save significant time and effort for providers to manage the master data and lab services offered by labs.

**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?*

SA27: Yes – we suggest considering the outcomes of the HL7 Patient Friendly Consent project for the purpose of “Patient preference/consent”. IHE BPPC should be considered as the support for varying levels of confidentiality is needed.

**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?*

SA27 No – we are not aware of an alternative standard that exists to the DS4P standard. However, we do recommend extensive piloting to determine how it works with secondary disclosures, information incorporated into new documents and disruption of workflow be investigated.

**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?*

SA27: Yes – we recommend in terms of the 2015 Interoperability Standards Advisory including both Consolidated CDA Release 1.1 and 2.0 for the “summary Care Record” purpose. We recommend this since C-CDA R1.1 adoption has grown exponentially and since systems using C-CDA R1.1 will not quickly move to version 2.0. However, in terms of future Interoperability Standards Advisories, we would recommend listing C-CDA Release 2.0 solely as the “summary Care Record” purpose standard.

**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?

**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?*

SA27: Yes – HL7 message types should be listed. There are HL7 v2 message equivalents for many of the IHE profiles defined in this section. Given the wide adoption of HL7 v2 messaging, we should allow for them. There should also be an option for FHIR to allow vendors to slowly deprecate HL7 v2 messaging.

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