1 May 2015

Karen DeSalvo, MD
National Coordinator for Health Information Technology
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. DeSalvo,

Thank you for the opportunity to comment on "2015 Interoperability Standards Advisory – Open Draft". We believe focus on key standards and implementation guidance is essential to realize a safe and effective nationwide strategy for health information technology and for proper capture, management, exchange and use of health data/information, including safeguards for patient care, privacy and security.

Key Point: Another day, another instance where ONC's proposed rules/guidance seem(s) to offer no consideration – much less concern – for truth (authenticity) and trust (assurance) as baselines/foundations for what is proposed. This is particularly evident when health data/records must maintain fidelity to source data/record content and thus qualify to support primary use (clinical care, interventions and decision making). We believe clinical integrity and most importantly, patient safety, are placed at risk by recommendations of this Advisory.

Please reference CentriHealth Comments on the ONC Interoperability Roadmap, submitted 3 April 2015. Noting that the 2015 Standards Advisory is specifically recommending "best available" standards that support interoperability, we've chosen to: a) use the same comment outline as before (following numeric section order); b) excerpt a subset of comments previously submitted (*in italics*); and c) add Advisory related comments where applicable (blue text).

Thank you for your consideration.

Regards,

Gary Dickinson
Director, Healthcare Standards, CentriHealth
Co-Chair, Health Level Seven (HL7) Electronic Health Record (EHR) Work Group

General Comments

Please reference CentriHealth Comments on the ONC Interoperability Roadmap, submitted 3 April 2015. (In the following, excerpts from previously submitted comments are in *italics*, new Advisory comments are in blue.)

1. Interoperability is Purpose-Based

Interoperability can only be described, measured and achieved if first understood as to its scope (what) and purpose (why).

What: are we striving to make interoperable?
A) Personal health and healthcare data/records?
B) Provider healthcare data/records?
C) Integration of data/records received from an external source?
D) Health data/record flows: point to point and/or end to end?
E) Data/record flows integral to process (work) flows?

Why: for what purpose?
F) To support primary use: clinical care, interventions and decision making?
G) To support secondary use: most everything else?
H) To ensure integrity of the clinical process, of the health system?
I) To ensure patient safety?
J) To render a facsimile representation of data/records (e.g., fax, photocopy, PDF) that is human readable?
K) To render a computable representation of data/records that is software process-able?
L) To render a precise copy of the original source provider health record: i.e., provider business, and evidentiary record for legal purposes?

Standards Advisory, Page 8: "When one standard or implementation specification is listed as the 'best available,' it reflects ONC's initial assessment and prioritization of that standard or implementation specification for a given interoperability purpose."

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*		
✔ *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*	➔➔➔	• *Belief (believability)* • *Certainty* • *Reliance* • *Traceable to a "source of truth"* • *Based on – and manifest in – evidence presented*
✔ *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

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6. Interoperability is Manifest by Integration

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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."

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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

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10. Interoperability Within and Without

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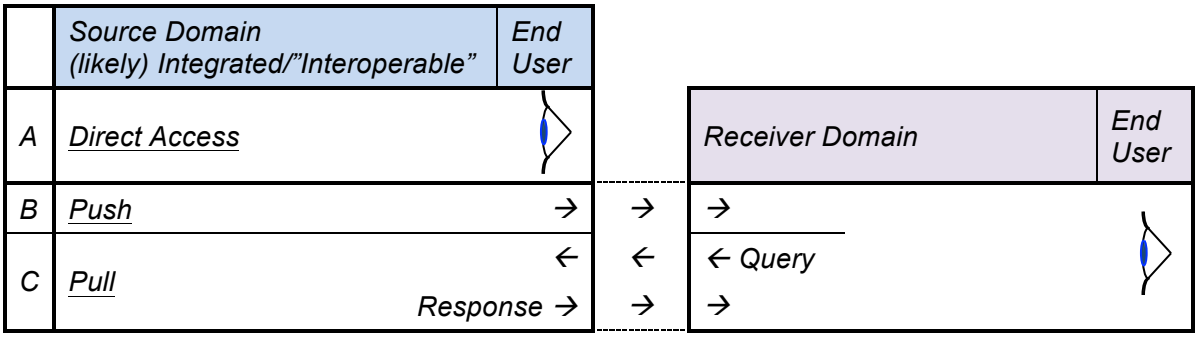
11. Interoperability Access/Exchange Methods, Initiators and Limitations

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.



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

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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* ✔ *From origination to use*	*Is Chain of Trust conveyed?*	*Is Chain of Trust manifest?*
✔ *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.

Health Data/Record Chain of Trust from Point of Origination to each Point of Access/Use					
Flow	*Point of Health Data/Record…*	*(For primary clinical use)*	*Audit Event*	*DPROV Event*	*Original Content (primary use)*
Source System					
↓	*Capture, Origination* *• Source of Truth* *• Anchor Point for Chain of Trust*	*• Clinical facts, findings and observations are captured* *• Clinical context is captured* *• Provenance is captured:* *• Who, what, when, where, why* *• Identities are established:* *• Patient: subject of care* *• Provider: organization, individual* *• Author of data/record content*	*X*	*X*	*Is captured*
↓	*Retention*	*Of Source Record Entry*	*X*		*Is retained*
↓	*Attestation*	*• Application of Signature* *• Bound to data/record content*	*X*	*X*	*Is attested/ signed*
↓	*Transformation*	*From Source Record Entry to Exchange Artifact: e.g., HL7 message or document*	*X*	*X*	*Is carried*
↓	*Transmission*	*Of Exchange Artifact*	*X*		*Is carried*
Receiving System					
↓	*Receipt*	*Of Exchange Artifact*	*X*		*Is carried*
↓	*Transformation*	*From Exchange Artifact to Receiver Record Entry*	*X*	*X*	*Is carried*
↓	*Retention*	*Of Receiver Record Entry*	*X*		*Is retained*
↓	*Access, view* *• Trust Decision*	*By End User* 	*X*		*Is accessed, viewed*

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

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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:

Provider A EHR		*Subject to*		*Provider B EHR*
Inner Sanctum Business/Legal Record	→ *Exchange Artifact(s)* →	*Algorithmic Verification*	→ *Accept* →	*Inner Sanctum Business/Legal Record*
			Reject ↓	
		Human Verification	→ *Accept* →	
			Reject ↓	

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

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26. Superstructure without First Infrastructure for Interoperability?

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27. Interoperability as a Destination

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[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.