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

Subject: AHIMA Comments on Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap DRAFT Version 1.0

On behalf of the American Health Information Management Association (AHIMA), I am pleased to submit comments related to the Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap DRAFT Version 1.0 (Roadmap).

AHIMA is the not-for-profit membership-based healthcare association representing more than 100,000 health information management (HIM) and informatics professionals who work in more than 40 different types of entities related to our nation's public health and healthcare industry.

The Roadmap is aimed at building "*an interoperable health IT ecosystem*" and calls for "*work in 3 critical pathways: (1) Requiring standards; (2) Motivating the use of those standards through appropriate incentives; and (3) Creating a trusted environment for the collecting, sharing, and using of electronic health information.*" (p. 4)¹ These efforts align very closely with AHIMA's Strategy, "Drive the Power of Knowledge — Health Information Where and When It's Needed," aimed to:

1. Ensure information governance and standards for electronic health information;
2. Contribute to sound healthcare decision-making through analytics, informatics and decision support; and
3. Empower consumers to optimize their health through management of their personal health information.²

AHIMA applauds the ONC commitment "*to leading and collaborating with the health IT and health sector to define a shared Roadmap for achieving interoperable health IT that supports a broad scale learning health system*" (p.4) and we look forward to working with ONC on the following endeavors:

1. Help "*catalyze collaboration and action across government, communities and the private sector*" (p.8-9) and

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

² American Health Information Management Association (AHIMA). [Drive the Power of Knowledge- Health Information Where and When It's Needed. Strategy 2014--2017.](#)

2. Through this public-private collaboration, help with the adoption of standards-based interoperable health information technology (HIT) across various healthcare settings can enable:
 - a. Healthcare transformation towards person-centric care, and
 - b. Integration of “*traditional institutional healthcare delivery settings*” with societal domains “*such as employment, retail, education and other*” (p.8) that impact the health status of individuals, communities and population at large.

AHIMA agrees with ONC's assessment of the “current context” regarding “*health information-sharing arrangements that currently exist in communities across the nation... which have often formed around specific geographies, networks and/or technology developers*” and “*several barriers <that> continue to inhibit nationwide interoperability despite these arrangements... These barriers include:*

1. *Electronic health information is not sufficiently structured or standardized and as a result is not fully computable when it is accessed or received. ... It is also difficult for users to know the origin (provenance) of electronic health information received from external sources. Workflow difficulties also exist in automating the presentation of externally derived electronic health information in meaningful and appropriately non-disruptive ways.*
2. *Even when technology allows electronic health information to be shared across geographic, organizational and health IT developer boundaries, a lack of financial motives, misinterpretation of existing laws governing health information sharing and differences in relevant statutes, regulations and organizational policies often inhibit electronic health information sharing.*
3. *While existing electronic health information sharing arrangements and networks often enable interoperability across a select set of participants, there is no reliable and systematic method to establish and scale trust across disparate networks nationwide according to individual preferences. (p.10-11)*

AHIMA’s major comments show that AHIMA is ready to work with ONC and the nation on the public-private approach to address the “*barriers*” and build “*an interoperable health IT ecosystem.*”

Comment 1:

Nationwide consensus-based definitions for the fundamental terms used in the Roadmap need to be developed. These terms include:

- * **Interoperability**
- * **Levels of Interoperability**
- * **Learning Health Systems (LHS)**
- * **Interoperability Standards** and
- * **Use Case and National Priority Use Cases**

AHIMA is ready to work with ONC and a public-private collaborative to facilitate the national, consensus-based process for defining the fundamental terms used in the Roadmap.

Comment 2:

The Roadmap document must be shortened 30 pages, and written in actionable terms. The graphics should be used more effectively to demonstrate the relationship between the Roadmap's components and outcomes.

AHIMA is ready to work with ONC and a public-private collaborative to assist in developing an actionable document.

Comment 3:

The 10 Interoperability Principles must be aligned with the definition of interoperability. The three pillars of interoperability (**Semantic, Technical, and Functional**) could serve as a basis for stakeholders to clearly define interoperability principles and approach for Roadmap development and execution.

AHIMA seeks to work with ONC and a public-private collaborative to improve definitions of Interoperability Principles.

Comment 4:

The Roadmap lacks a clear approach and methodology for enabling interoperability. Specifically, the Roadmap does not define business and functional requirements for interoperability. Instead, it defines the requirements for LHS, which are not the same as interoperability requirements.

AHIMA is ready to help develop and execute a clear approach and methodology for enabling interoperability. Specific details on the proposed approach for interoperability—Interoperability Constituents (leadership, accountability and methodology); Interoperability Framework (semantic, technical and functional) and Infrastructure; and Building Blocks (policy, technology and people) as well as overall methodology for the execution of this approach—are available upon request.

Comment 5:

The Roadmap lists out-of-scope topics that are fundamental to achieving interoperability. The rationale for putting these topics out of scope was not provided.

AHIMA strongly believes current out-of-scope issues should be included in the Roadmap.

Comment 6:

An identifier standards category must be included in the list of technical standards for interoperability.

AHIMA is ready to work with the ONC and a public-private collaborative to include an Identifier standards category in the list of technical standards.

Comment 7:

The timeline is unclear and must be adjusted due to the challenges inherent in the absence of a Nationwide Interoperability Framework and infrastructure.

AHIMA is ready to work with the ONC and a public-private collaborative to better align the Roadmap timeline and capabilities of stakeholders to support this timeline.

Comment 8:

The list of business and technical actors for health information systems interoperability has to be presented in a separate chapter in a concise table with clear definitions.

AHIMA is ready to work with ONC and a public-private collaborative to better align the Roadmap's business and technical actors.

Comment 9:

A list of national Use Cases should be developed based on clearly defined Use Case definitions and methodology used for the Use Case development.

AHIMA is ready to work with the ONC and a public-private collaborative to define Use Case development methodology, Use Case description format, process for the prioritization and selection of the national Use Cases.

Comment 10:

The Roadmap is lacking a clear approach for governance: governance of stakeholders (organizations) and information produced via interoperable solutions.

AHIMA is ready to work with ONC and a public-private collaborative to build and execute a clear approach/framework for governing interoperable information exchanges as well as the information itself.

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

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

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

Sincerely,



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

Attachments: supporting comment materials; responses to ONC questions

Detailed Responses to ONC Questions

1. General

1. Are the actions proposed in the draft interoperability Roadmap the right actions to improve interoperability nationwide in the near term while working toward a learning health system in the long term?

2. What, if any, gaps need to be addressed?

We will respond to questions 1 and 2 in reverse order in this section.

1.2. What, if any, gaps need to be addressed?

We found the following gaps in the Roadmap:

- Definitions
- Overall document
- Overall approach
 - Interoperability Principles
 - Actions and Building Blocks
 - Out-of scope issues
 - Standards
 - Timelines
 - Actors

DEFINITIONS—Understanding Each Other

Definitions are critical to the full understanding among all participants involved in a complex multi-dimensional, multi-domain, multi-stakeholder, technologically challenging activity. The Roadmap uses many concepts (terms) brought together, each of these terms are complex and not very well defined on its own.

Sections below describe the terms to be well defined through a nationwide consensus-based process (e.g., the process used by the standards-development organizations (SDOs), to enable the definition and the execution of the “*shared*” Roadmap called in the following statement:)

“...Define a shared Roadmap for achieving interoperable health IT that supports a broad scale learning health system.” (p.4)

Interoperability

The Roadmap uses Institute of Electrical and Electronic Engineers (IEEE) definition of interoperability as follows: *“In the context of this Roadmap, interoperability is defined as the ability of a system to **exchange** electronic health information with and **use** electronic health*

*information from their systems without special effort on the part of the user. Interoperability is made possible by the implementation of standards”*³ (p.149)

AHIMA believes the IEEE definition of “interoperability” does not define all necessary aspects of information and knowledge sharing needed under the learning health system (LHS) because the IEEE definition focuses only on electronic information exchange and use.

This definition does not adequately take into consideration the **central role of human intervention** with the electronic information generation and exchanges that LHS is fundamentally based on. These human interventions include defining:

- (a) information needs and priorities for a medical problem and its solution ("Why" question)
- (b) information gathering and accessing (business rules and information governance rules related to information generation, sharing, and use in an electronic environment) (technical solutions),
- (c) information processing (information analysis about problem-solution using electronic tools) and, lastly,
- (d) information utilization, that is, meaning (was the "Why" question answered appropriately?)

AHIMA strongly believes a national consensus-based adequate definition of the interoperability for the LHS must be established to address the full array of data, information, and knowledge management needs under the LHS.

In the meantime, we propose to replace the current IEEE definition in the Roadmap with the definition of interoperability provided in 2007 by Health Level Seven (HL7) as follows:

"Interoperability" means the ability to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks in various settings, and exchange data such that clinical or operational purpose and meaning of the data are preserved and unaltered."⁴

HL7's approach to interoperability is based on the following three interoperability components (pillars)⁵ that specifically focus on the ONC identified barriers 1--3 under “current context” above:

1. **Semantic** interoperability—shared content
2. **Technical** interoperability—shared information exchange infrastructure
3. **Functional** interoperability—shared rules of information exchanges, i.e., business rules and information governance (“*the rules of the road*”).⁶

These interoperability pillars could serve as a basis for the Nationwide Interoperability Framework and supporting infrastructure needed to enable data, information, and knowledge generation, sharing, and utilization under LHS.

³ The Institute of Electrical and Electronic Engineers (IEEE). [Standards Glossary](#).

⁴Health Level Seven (HL7). [Coming to Terms: Scoping Interoperability for Healthcare](#). White Paper. 2007.

⁵Ibid.

⁶ Dimick C. [Governance apples and oranges. Differences exist between information governance, data governance, and IT governance](#). *JAHIMA*. 2013; 84(11): 60-2.

Levels of Interoperability

The concept “*best minimum level of interoperability*” appears on page 18. This concept was not defined in the glossary or anywhere in the document. If levels of interoperability are introduced, these definitions have to be provided.

Learning Health System

The Roadmap defines **Learning Health System** as:

“The concept of a continuously Learning Health System (LHS), first expressed by the Institute of Medicine in 2007, is now being rapidly adopted across the country and around the world. The LHS is based on cycles that include data and analytics to generate knowledge, leading feedback of that knowledge to stakeholders, with the goal to change behavior to improve health and to transform organizational practice.

<http://healthinformatics.umich.edu/lhs>” (p.150)

AHIMA believes the current definition of LHS in the context of the Roadmap needs more specificity to define the “LHS concept” itself. The provided definition also needs to be balanced as it uses the terms *data* (noun, that is, WHAT) and *analytics* (verb, that is, HOW to transform data into information) both with the term *cycles* (process of the translating data and information into knowledge) but is missing key concepts of *information* and *meaning* (ability to utilize and improve knowledge). It is not clear what “*leading feedback of that knowledge*” means and why/where/when/how/by whom this “*feedback*” is led to stakeholders.

AHIMA is very supportive of ONC applying the knowledge management approach—understanding the knowledge creation cycle, learning organization and performance, and overall system thinking—in healthcare and the ONC Interoperability Roadmap, specifically. This approach was successfully used in the past 30 years by various industries that successfully used interoperability of information and communication technology (ICT) such as banking, retail, transportation, and others.⁷

In healthcare, however, as the Roadmap described, the term LHS was introduced by IOM in 2007. Additional efforts are needed to align the understanding of all healthcare stakeholders on (1) how this knowledge management concept – LHS – was used/is used/will be used in healthcare and population health, (2) how it should be supported by ICT and HIT in healthcare, and (3) more importantly, how it can be integrated into the learning systems of other societal domains “*such as employment, retail, education and other*”.

Interoperability Standards

The Roadmap does not define the term “interoperability standards.” Only the term “standard” is listed in the glossary (p. 160).

AHIMA believes that interoperability standards are special products of standards harmonization activities –a meta-standard (standard about standards), an assembly of standards, interoperability specification, interoperability guidelines, reference standards portfolio, etc.—that define how

⁷ Allee V. The Knowledge Evolution. Expanding Organizational Intelligence. Routledge Taylor and Francis Group. London and New York. 1997. 274pp.

individual standards have to work together to enable interoperability for a specific healthcare domain (Use Case) (care coordination, radiology, laboratory, pharmacy, data reporting, population health, etc.).

The term “recognized interoperability standards” was introduced in 2006 in President Bush’s Executive Order⁸ as:

"Recognized interoperability standards" means interoperability standards recognized by the Secretary of Health and Human Services (the "Secretary"), in accordance with guidance developed by the Secretary, as existing on the date of the implementation, acquisition, or upgrade of health information technology systems under subsections (1) or (2) of section 3(a) of this order.

Defining the term “interoperability standards” is specifically important because ONC also published the 2015 ONC Interoperability Standards Advisory.⁹ However, the Advisory does not provide the definition of “interoperability standards.” There is also a need to differentiate the “advisory” or “recognized” role that interoperability standards will play in enabling interoperability.

The experience of the Health Information Technology Standards Panel (HITSP)¹⁰ showed that individual standards by themselves will not enable interoperability. There is a need for additional constraints defined by the meta-standard (interoperability specification) for individual standards to work together.

The International Organization of Standardization (ISO) Technical Committee (TC) 215 Health Informatics,¹¹ with leadership from the US Technical Advisory Group (TAG) for ISO/TC 215 and the active engagement and support of many TC215 member nations, is defining an interoperability standards portfolio for a specific domain as a grouping of individual standards. This work should be taken into account to align national and international definitions for interoperability standards.

Use Cases and National Priority Use Cases

Appendix H of the Roadmap presented *Priority Interoperability Use Cases* (p.163--166). The following definition of the Use Case is provided (p.163):

“A use case is a descriptive statement that defines a scope (or boundary), interactions (or relationships) and specific roles played by actors (or stakeholders) to achieve a goal. The methodology is commonly used to support the identification of requirements and is a simple way to describe the functionalities or needs of an organization.”

⁸Health Level Seven (HL7). [Coming to Terms: Scoping Interoperability for Healthcare](#). White Paper. 2007.

⁹ U.S. Department of Health and Human Services (HHS). Office of the National Coordinator for Health Information Technology (ONC). [2015 ONC Interoperability Standards Advisory](#).

¹⁰ [Health Information Technology Standards Panel \(HITSP\)](#).

¹¹ International Organization of Standardization (ISO) [Technical Committee \(TC\) 215 Health Informatics](#).

There is no reference provided for the source of this definition. It is also not clear whether the “Use Case” is a statement, methodology, or if the connection between the first and second sentences is missing in the provided definition.

The list of fifty-six (56) two-line sentences (statements) (p.163--166) presented as priority use cases are not balanced. Some statements encompass the full universe of healthcare, others just represent a specific document to be exchanged. Some statements represent capabilities that are needed across all document-specific statements. It is not clear if the ONC provided any guidance to submitters on the use case definition and format.

The European Union (EU) Antilope project (2013--2015) “was focused on the dissemination and adoption of the eHealth European Interoperability Framework (eEIF) as defined by the eEIF study (also known as the “Deloitte study”) published in July 2013.¹² Antilope project developed a consistent framework that will help projects or implementers to deploy their own interoperable solutions.”¹³

Antilope's project clearly defined a list of use cases¹⁴:

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

This Use Case list clearly reflects the healthcare priority areas selected by EU. Healthcare in the EU is provided as nationalized care, and the public and population health data exchanges are included in the context of these Use Cases.

AHIMA proposes that the ONC consider EU experience in (a) defining Use Cases from nationwide perspectives and (b) selecting the priority Use Cases.

The US-based experience in defining priority Use Cases by the American Health Information Community (AHIC) in 2005--2009 (which defined 152 US national priority Use Cases) and the AHIC methodology for defining/documenting these Use Cases, should be re-visited to eliminate duplication of activity already conducted in the US. It will also be important to align US Use Cases with the EU to support the ongoing collaboration between the ONC and the EU.

¹² [eHealth Interoperability Framework Study](#). 2013.

¹³ [European Union Antilope Project](#).

¹⁴ Vincent Van Pelt, [Refinement of the eHealth European Interoperability Framework](#).

Additional comments on the Roadmap's Use Cases are provided under ONC question 2 on Use Cases below.

Comment 1:

Nationwide consensus-based definitions for the fundamental terms used in the Roadmap need to be developed. These terms include:

- * **Interoperability**
- * **Levels of Interoperability**
- * **Learning Health Systems (LHS)**
- * **Interoperability Standards**
- * **Use Case and National Priority Use Cases**

AHIMA is ready to work with ONC and a public-private collaborative to facilitate the national, consensus-based process for defining the fundamental terms used in the Roadmap.

OVERALL ROADMAP DOCUMENT

AHIMA believes the document must be shortened to a maximum of 30 pages. The current 166 page document is difficult to read and follow. It resembles a white paper or essay rather than an actionable document. The document contains supporting information in each section that could be presented in separate documents as references or addenda.

Graphics and diagrams must be used to demonstrate the relationship between Roadmap components and outcomes.

Comment 2:

The Roadmap document must be shortened to a maximum of 30 pages and written in actionable terms. The graphics should be used more effectively to demonstrate the relationship between the Roadmap's components and outcomes.

AHIMA is ready to work with ONC and a public-private collaborative to assist in developing an actionable document.

OVERALL APPROACH

The Roadmap is lacking a clear approach for enabling interoperability.

Interoperability Principles

The Roadmap describes 10 Interoperability Principles (Figure 1, p. 9).

While we recognize that most of these Interoperability Principles came from the earlier Vision Paper ("Connecting Health and Care for the Nation: A 10-Year Vision to Achieve an Interoperable Health IT Infrastructure,") they are not related, integrated, and could be complimentary to or dependent on each other. It is also not clear what logic or sources (references) were used in selecting these principles and what the color-coding scheme represent (if any) in depicting these principles in (Figure 1, p.9). It is not clear why these Principles have been introduced.

Specific descriptions of each of these principles in the body of the document (p.20--21) do not relate to the overall description of the Roadmap, which is organized by building blocks unconnected to the Principles.

It is critical to build the national interoperability Roadmap grounded on the consensus-based principles. The work on the definitions of interoperability, LHS, and interoperability standards proposed under Comment 1 will help build nationwide consensus on these principles—the foundation for the Interoperability Roadmap.

The three pillars of interoperability (**Semantic, Technical, and Functional**) could serve as a basis for stakeholders to clearly define Interoperability Principles and overall approach for the Roadmap development and execution.

Comment 3:

The 10 Interoperability Principles need to be aligned with the definition of interoperability. The three pillars of interoperability (**Semantic, Technical, and Functional**) – could serve as a basis for stakeholders to clearly define Interoperability Principles and approach for the Roadmap development and execution.

AHIMA is ready to work with ONC and a public-private collaborative to improve definitions of Interoperability Principles.

Approach—Actions and Building Blocks

1.1 Are the actions proposed in the draft interoperability Roadmap the right actions to improve interoperability nationwide, in the near term, while working toward a learning health system in the long term?

The approach for achieving interoperability is unclear. The Roadmap refers to various components that are not consistent or logical, and do not align with each other. The outcomes of interoperability are not clearly defined. ONC must be more specific in defining the outcomes of interoperability rather than declaring it will be LHS. Below are several specific examples of “non-interoperability” of the Roadmap components.

The Roadmap specifies that the “*four most important actions for public and private sector stakeholders to take to enable nationwide interoperability of electronic health information through health IT in the near term are:*

Action 1—establish a coordinated governance framework and process for nationwide health IT interoperability;

Action 2—improve technical standards and implementation guidance for sharing and using a common clinical data set;

Action 3—enhance incentives for sharing electronic health information according to common technical standards, starting with a common clinical data set; and

Action 4—clarify privacy and security requirements that enable interoperability.

The Roadmap further specifies that “*additional actions are needed in several other areas such as clinical culture, state and organization-level policies; these actions are described in greater detail throughout the Roadmap. However, these four foundational actions are linchpins to achieving the near-term and long-term goals described in Connecting Health and Care for the Nation (Figure 2).*” (p.12)

Figure 2 (p. 15) presents a timeline (2015—2020) for some activities that may or may not be relevant to Actions 1--4 because the Figure does not specifically call for the actions above. In fact, the Figure introduces four new categories of undefined concepts as follows:

1. Coordinated governance, exchange, and trust communities
2. Standards and interoperability
3. Drivers and regulatory
4. Care providers and consumer use of technology

Furthermore, it is also stated that the Roadmap is organized “*according to the following five fundamental building blocks.*

1. *Core technical standards and functions*
2. *Certification and testing to support adoption and optimization of health IT products and services*
3. *Privacy and security protections for health information*
4. *Supportive business, clinical, cultural and regulatory environments*
5. *Rules of engagement and governance”* (p.14)

These blocks are further described in reverse order in the Table in the section *How the Roadmap is Organized: Business and Technical Requirements for a Learning Health System* (p.23-24).

While we recognize that these building blocks originated in the earlier Vision Paper, no description is provided within the Roadmap on how they are aligned with the Interoperability Principles (Figure 1, p.9), Actions 1--4 (p.11--14) and Categories 1--4 in Figure 2 mentioned above.

More importantly, the building blocks 1--5 are presented as business and technical requirements for LHS, not interoperability. In the Roadmap it appears that the terms of “business and technical requirements for LHS” and “business and technical requirements for interoperability” are synonyms. This approach in itself will lead to confusion among stakeholders, with non-interoperability as the result.

In addition, statements made under each of the Interoperability Principles, Actions 1--4, Categories 1--4 in Figure 2, and building blocks present separate, not-connected, general declarations of certain issues related to the information and communication technology (ICT) and, specifically, health IT adoption. The description of activities under the building blocks (p.27-112) is lengthy and diluted by the supplemental information. Redundant descriptions of activities across building blocks result in confusion and lack of clarity on what will be accomplished. It is not clear what these blocks represent, how these blocks fit together, and what will be built from/with these blocks.

These inconsistencies and the lack of cohesiveness between various Roadmap components contribute to the overall impression that the Roadmap is lacking an overall approach as well as a methodology for achieving interoperability. This may have happened because the Roadmap document mixed two very different concepts: interoperability and LHS. While the document contains business and technical requirements for LHS (p.23--25), interoperability requirements (both business and technical) were not formulated. In fact, interoperability is presented as a vision (p.17) not as a technological challenge that has very clear semantic, technical, and functional solutions. These solutions have been successfully implemented by other industries (transportation, banking, retail, etc.) and should be modeled by the healthcare industry.

AHIMA Proposed Approach

A sound approach for health information systems interoperability for safer, effective and efficient care—the true outcome of interoperability—is expected from the ONC and the nation. This approach has to be based on the following three overarching constituents:

- 1. Leadership**
- 2. Accountability**
- 3. Methodology**

ONC Leadership to establish public-private partnerships to define, develop and execute the Interoperability agenda on the policy and technical levels should be based on Federal regulation on the role of the Federal Government in standardization.^{15,16,17,18}

Accountability in ensuring fiscal responsibilities of participating stakeholders in delivering standards-based interoperable solutions in healthcare for data, information and knowledge generation, sharing and use should be based on the federal regulation with check and balance policies.

Methodology for enabling the development, implementation, and operation of standard-based interoperable ICT solutions in healthcare, performed in other industries, should be based on merging two domains of knowledge: medicine and computer science. This enables overall computer science and ICT methodologies to work in the healthcare environment. In merging these two domains, there is a need for an overarching Interoperability Framework under which an interoperability methodology will be employed.

The three pillars of interoperability (**Semantic, Technical, and Functional**) serve as pillars of the Interoperability Framework. Under each pillar and across pillars, computer science interoperability methodologies will focus on the following activities:

¹⁵ [National Technology Transfer and Advancement Act \(NTTAA\)](#).

¹⁶ Office of Management and Budget (OMB). [Circular A-119, Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities](#).

¹⁷ Executive Office of the President. National Science and Technology Council. Federal Engagement in Standards Activities to Address National Priorities. [Background and Proposed Policy Recommendations Subcommittee on Standards](#). Washington, DC. October 10, 2011.

¹⁸ [Principles for Federal Engagement in Standards Activities to Address National Priorities](#). Executive Office of the President, Office of Management and Budget, United States Trade Representative, Office of Science and Technology Policy. Memorandum for Heads of Executive Departments and Agencies, 2012.

1. Define needs and priorities for interoperability
2. Define and develop interoperability components for semantic, technical and functional interoperability
3. Test interoperability components
4. Certify interoperability components
5. Deploy interoperability components
6. Evaluate deployment outcomes

The building blocks of interoperability components include:

1. **Policy** (regulatory framework and governance)
2. **Technology** (Standards-based technology (both HIT/ICT and Healthcare))
3. **People** (Healthcare and HIT workforce and consumers)

Interoperability Infrastructure (electronic communication channels, tools and resources for functional, semantic and technical interoperability products development and maintenance, educational resources and other) should be developed to enable effective and efficient capabilities for the interoperability overarching constituents, methodology components and building blocks to work together. Figure 1 presents a proposed approach for interoperability for ONC's consideration. [Figure 1. Proposed Approach for Interoperability](#)

Comment 4:

The Roadmap is lacking a clear approach and methodology for enabling interoperability. Specifically, the Roadmap does not define business and functional requirements for interoperability. Instead, it defines the requirements for LHS, which are not the same as interoperability requirements.

AHIMA is ready to work with the ONC in a public-private collaborative to develop and execute a clear approach and methodology for enabling interoperability. Specific details on the proposed

approach for interoperability—Interoperability Constituents (leadership, accountability and methodology); Interoperability Framework (semantic, technical and functional) and Infrastructure; and Building Blocks (policy, technology and people) as well as overall methodology for the execution of this approach—are available upon request.

Out of Scope Issues

The Roadmap contains statements regarding out-of-scope issues that are contradictory to the overall effort of interoperability and LHS.

The statement at the end of the paragraph in question (p.18) says that the Roadmap “*focuses on decisions, actions and actors required to establish the best minimum level of interoperability across the health IT ecosystem, starting with clinical health information, in support of a learning health system.*” (See our comment under the Definitions section above on the need to define the levels of interoperability).

The statement in the same paragraph above, however, says: “*The intersection of clinical and administrative electronic health information is a critical consideration, but is out of scope for this version of the Roadmap. Use cases, standards, technologies and tools that leverage both administrative and clinical electronic health information will be an important topic to address in future iterations.*” (p.18)

This statement contradicts the List of Use Cases supplied in Appendix H (p.164--166), which contains 10 use cases related to data exchanges with payer systems (administrative information) (that is, 18 percent of all Use Cases.) This clearly indicates the priority of this data exchange type for the industry. Administrative electronic health information must be included in the Roadmap. By delaying this integration, ONC is potentially creating future duplicate efforts when administrative data is included “*in future iterations.*”

The following sentences in the same paragraph add: “*There are also many aspects of health IT beyond interoperability that are important and will be critical to a learning health system, including technology adoption, data quality, documentation and data entry, usability and workflow. However, these topics are out of scope for this Roadmap and deserving of separate, dedicated attention.*” (p.18)

These statements conflict with the overall effort of interoperability that is based on technology adoption (*out of scope*). How will data for the LHS be collected without data entry and documentation (*out of scope?*) What kind of data will be collected for LHS without data quality checks (*out of scope?*) Why mention standardized common data set (Actions 2 and 3) when data quality, usability and workflow are *out of scope?*

This Roadmap covers the next 10 year period (2015--2024). When will the out-of scope issues be addressed? What does “*deserving of separate, dedicated attention*” mean?

How can a LHS and interoperability be achieved without addressing these fundamental issues?

Comment 5:

The Roadmap lists out-of-scope topics fundamental to achieving interoperability. The rationale for putting these topics out of scope was not provided.

AHIMA strongly believes that current out-of-scope issues have to be included in the Roadmap.

Standards

AHIMA agrees with the categories of standards that are included in the Roadmap (p.77--78) as follows:

1. **Vocabulary/terminology standards** that are unique to healthcare and often purpose-specific (e.g., codes to represent medications cannot be also used for lab tests);
2. **Content/structure standards** that are also usually unique to healthcare, are often purpose-specific and often designed to represent data captured from a specific clinical workflow (e.g., the content standard used for electronic prescribing would not be used for a referral to a specialist.)
3. **Transport standards** that are typically non-unique to healthcare because they are used to connect two or more parties together without a focus on the data that would be transported from one party to another.
4. **Security standards** that are non-unique to healthcare and often applied in different ways to meet the data protection requirements specified by a use case (although in healthcare there are legal minimums for functional security outcomes stated in the HIPAA Security Rule.) In any event a security standard supports achieving the security outcomes prescribed by the Security Rule. These standards are discussed in the privacy and security protections building block.
5. **Standards for Services** that typically represent technical infrastructure used to simply connect different systems together to perform actions in order to support the accomplishment of a use case. These are discussed further in the Secure Standards Services section and include, but are not limited to, APIs that enable systems to talk to each other.”

While we recognize there are sections in the Roadmap dedicated to patient matching and resource location, and the “*unique device identifier(s) for a patient’s implantable device(s)*” are included in the common clinical dataset (p. 12), **Identifier standards category** is missing from this list above.

Identifier standards provide a universal method to identify and match entities and objects participating in the information exchange. Identifiers are the lexical tokens that name entities in all information systems which are essential for any kind of symbolic processing.¹⁹ A 2008 RAND study concluded that identifiers are “clearly desirable for reducing errors, amplifying interoperability, increasing efficiency, improving patient confidence, promoting architectural flexibility and protecting patient privacy.”²⁰ ONC Standards & Interoperability (S&I) Framework Data Provenance initiative²¹ is aimed to identify the owner of information.

¹⁹ Orlova, Anna. "[An Overview of Health IT Standards.](#)" *Journal of AHIMA* 86, no.3 (March 2015): 38--40.

²⁰ [Rekindling the patient ID debate](#), January 29, 2013

²¹ ONC Standards & Interoperability (S&I) Framework. [Data Provenance Initiative.](#)

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

Identifier standards category must be included in the list of technical standards for interoperability.

Comment 6:

An identifiers standards category must be included in the list of technical standards for interoperability.

AHIMA is ready to work with the ONC and a public-private collaborative to include an Identifier standards category in the list of technical standards.

1.3 Is the timing of specific actions appropriate?

The length of the document and redundancies make it difficult to understand the proposed timeline. From the table headings we derive the following timeline:

2015--2017 Send, receive, find and use a common clinical data set to improve health and healthcare quality

2018--2020 Expand interoperable health IT and users to improve health and lower cost

2021--2024 Achieve a nationwide learning health system

On p. 12 of the Roadmap the example of the common clinical data set is provided. This data set is essentially the Meaningful Use (MU) Stage 2 Transitions of Care (ToC) data set. The Stage 3 MU Notice of Proposed Rules Making (NPRM) proposed a more precise data set. Which one should serve as a common data set for the Interoperability Roadmap? When will this be decided?

In the absence of a Nationwide Interoperability Framework (an approach for stakeholders to work together) and the absence of agreement on a common clinical data set (standardized content) in the first quarter of 2015, the ability to “*Send, receive, find and use a common clinical data set*” in 2015--2017 appears to be problematic.

If agreed upon by all stakeholders, the Interoperability Framework and Interoperability Infrastructure (Figure 1) as well as a common data set (or an approach for managing a standards-based data set) will be available by 2017, then the completion of the first milestone may be feasible by 2018--2019.

The second and third milestones should be replaced with achievable expectations.

Comment 7:

The timeline is unclear and must be adjusted due to the challenges inherent in the absence of a Nationwide Interoperability Framework and infrastructure.

AHIMA is ready to work with the ONC and a public-private collaborative to better align the Roadmap timeline and capabilities of stakeholders to support this timeline.

1.4 Are the right actors/stakeholders associated with critical actions?

The Roadmap does not clearly identify the actors/stakeholders. Instead, various listings, groups, entities, and undefined bodies such as “*data holders and entities*” are scattered across various sections, tables and figures.

Please see comment below under the Governance section regarding undefined “*data holders and entities*” that appeared on p. 30 of the Roadmap.

We believe that the list of stakeholders is presented in *Figure 5: Stakeholder Perspectives* (p.22). According to Figure 5, we believe that ONC identified the following stakeholders:

- Consumers—“*People who receive care or support the care of others*”
- Providers— “*People and organizations that deliver care and services*”
- Payers— “*Organizations that pay for care*”
- Government— “*People and organizations that support the public good*”
- Academia— “*People and organizations that generate new knowledge, whether research or quality improvement*”
- HIT Vendors— “*People and organizations that provide health IT capabilities*”
- Oversight Agencies— “*People and organizations that govern, certify and/or have oversight*”
- SDOs— “*People and organizations that develop and maintain standards*”

These are examples of business actors (stakeholders). It will be important to normalize naming for these stakeholders with the naming conventions used for business actors in various HIT policy and standards documents.

The list of technical actors—health information systems (clinical and ancillary systems) and ICT applications including mobile applications—is missing and has to be added to represent the technology component (building block) of Interoperability Framework (see figure 1 of AHIMA Comments above).

Overall, a list of business and technical actors for health information systems interoperability has to be presented in a separate chapter in a concise table with clear definitions.

Comment 8:

List of business and technical actors for health information systems interoperability has to be presented in a separate chapter in a concise table with clear definitions.

AHIMA is ready to work with ONC and a public-private collaborative to better align the Roadmap’s business and technical actors.

3. Priority Use Cases

Appendix H lists the priority use cases submitted to ONC through public comment, listening sessions, and federal agency discussions. The list is too lengthy and needs further prioritization. ***Please submit 3 priority use cases from this list that should inform priorities for the development of technical standards, policies and implementation specifications.***

The list of Use Cases in Appendix H is difficult to follow. It is not clear why some of these statements are called Use Cases. Did the ONC provide any guidance to submitters for a Use Case definition and format?

For prioritization, it would be more productive to conduct a triage of submitted statements and/or group them under some categories. We conducted this triage and grouping, which in itself provides prioritization by the number of submitted use cases as follows:

Use Case Category by Actor/Domain	Number of Use Cases, N (%)
1. Public health and population health	8 (15%)
2. Direct care	31 (55%)
a. Provider	18
b. Patient	13
3. Payer	10 (18%)
4. Research	3 (5%)
5. Technology	3 (5%)
6. Quality measure	1(2%)
Total	56(100%)

The three priority Use Cases AHIMA identified are all from Direct Care/Provider category:

4. Federal, state, provider and consumer use of standardized and interoperable patient assessment data to facilitate coordinated care and improved outcomes.

12. Providers are able to access x-rays and other images in addition to the reports on patients they are treating, regardless of where the films were taken or housed.

39. Primary care providers share a basic set of patient information with specialists during referrals; specialists “close the information loop” by sending updated basic information back to the primary care provider

AHIMA feels that Use Cases 3, 8, 21, 22 describe capabilities needed across various Use Cases to move interoperability forward:

(3) The status of transitions of care should be available to sending and receiving providers to enable effective transitions and closure of all referral loops.

(8) CEHRT should be required to provide standardized data export and import capabilities to enable providers to change software vendors.

(21) *Patients have access to and can conveniently manage all relevant consents to access or use their data.*

(22) *Those who pay for care use standardized transactions and interoperability to acquire data needed to justify payment (We are assuming this refers to the HIPAA standard transactions, but clarification is needed).*

Additional comments on the Use Case list and ONC approach for prioritization are provided in the Definition section above.

Comment 9:

A list of national Use Cases has to be developed based on the clearly defined Use Case definitions and methodology used for the Use Case development.

AHIMA is ready to work with the ONC and a public-private collaborative to define Use Case development methodology, Use Case description format, process for the prioritization and selection of the national Use Cases.

4. Governance

The draft interoperability Roadmap includes a call to action for health IT stakeholders to come together to establish a coordinated governance process for nationwide interoperability. ONC would like to recognize and support this process once it is established. How can ONC best recognize and support the industry-led governance effort?

The Roadmap described “*shared governance of policy and standards that enable interoperability*” rules of the road. Because the overall description of this topic is so lengthy (p.27--36) – it is not possible to follow what exactly is proposed. Though the title states that this is governance of policy and standards, the text is confusing by adding operations. There is a long list of “principles;” however, it is not clear what these principles are aimed to do or how they relate to the 10 Interoperability Principles. Statements are vague and generic. For example, under the section **Standards** we read:

“Data holders and entities facilitating exchange of electronic health information should ensure standards are prioritized, developed and implemented to support the public interest, national priorities and the rights of individuals (healthcare delivery, privacy).” (p. 33)

Who are “*data holders and entities*”? (Please note that these actors appear for the first time on p. 30 without any definitions. These terms are used throughout the Roadmap.) Why do data holders and health information exchange entities have to ensure standards are prioritized, developed, and implemented? Is this the role of standards development organizations?

“Where available and appropriate for the desired exchange of health information federal vocabulary, content, transport and security standards and associated implementation specifications are used.” (p. 34)

What are “*federal*” vocabulary, content, transport, and security standards? What does “*available and appropriate*” mean? What is “*the desired exchange*”?

“Standards development and adoption should not unfairly provide an advantage to one sector or one organization over others.” (p. 34)

Which “*sector*” is referred to here?

In Table 1 under the 2015--2017 column, it is stated that “*ONC will define a nationwide governance framework with common rules of the road for trust and interoperability and a mechanism for identifying compliance with common criteria. These rules will first focus on interoperability of a common clinical data set for purposes of treatment.*” (p. 34)

This statement raises several concerns. It is not clear what the nationwide governance framework will govern: Organizations, people, technology, standards, information, LHS? a common clinical data set, or all of the above?

The Roadmap does not specify a business model or incentive for stakeholders to come together in a coordinated governance process. All business actors of the Roadmap have to be clearly defined, invited, and properly incentivized to fully participate in establishing the governance process of organizations for interoperability. ONC and stakeholders should consider existing governance models and principles (rules of engagement, process measures, desired outcomes) such as those developed by AHIMA²² in establishing a governance process of organizations for interoperability.

Specific attention has to be devoted to information governance. This is the governance of information under the functional interoperability (business rules or rules of the roads) that define/govern how information is generated, managed, shared, used, and disposed of within and across organizations. AHIMA has been leading information governance initiatives^{23,24} and will be happy to work with ONC to define the need for/role of information governance in the Interoperability Framework.

Comment 10:

The Roadmap is lacking a clear approach for governance: governance of stakeholders (organizations) and as governance of information produced through interoperable solutions.

AHIMA is ready to work with ONC and a public-private collaborative to build and execute a clear governance approach/framework for governing interoperable information exchanges as well as information in itself.

5. Supportive Business, Cultural, Clinical, and Regulatory

²² Kloss, Linda. [Implementing Health Information Governance: Lessons from the Field](#). Chicago, IL: American Health Information Management Association, 2015. *AHIMA Store*. AHIMA, 2015. Web.

²³ AHIMA [Information Governance Benchmarking White Paper](#).

²⁴ AHIMA [Information Governance Principles for Healthcare \(IGPHC\)](#)TM.

How can private health plans and purchasers support providers to send, find or receive common clinical data across the care continuum through financial incentives? Should they align with federal policies that reinforce adoption of standards and certification?

Private health plans, purchasers, and providers should consider the inclusion of patient-mediated exchange to send, find, or receive clinical data across the healthcare continuum. This means facilitating patient access to all their clinical data and supporting them with the technology, processes, education, and other resources to enable exchange. Patients are the biggest stakeholders here and are essential in any exchange activity. Patients can be provided with a financial incentive to facilitate exchange.

It is essential for incentives to align with the adoption of standards and certification. Not doing so would defeat the purpose of stakeholders and information governance, as there would not be a standardized goal to work towards (A1.3, page 34). All stakeholders should be working towards the common goal of interoperability—not yet defined in the Roadmap. There should be a clear path towards achieving that goal (objectives, milestones, outcomes). The goal should be defined through consensus of all the stakeholders. In addition, a mandate for specific interoperable technical standards, policies and implementation specifications that allow interoperability between systems must be implemented.

6. Privacy and Security Protections for Health Information

What security aspects of RESTful services need to be addressed in a standardized manner?

Access control, authorization, consent preferences, audit trail, and secure transfer protocols must be agreed upon through consensus of the stakeholders; they must be standardized and these standards-based solutions implemented in health information systems. Security controls must be in place to monitor, track, trend, and ensure the security and an individual's privacy rights are not misused or breached. Data provenance attributes must be included in the standardized data content in the exchange.²⁵

Considerations for how to handle health records with additional constraints such as a legal hold must be addressed. Electronic discovery (e-discovery) of electronically stored information (ESI) (the medical information in EHR systems falls into the ESI category) must be addressed according to the Federal Rules of Civil Procedures (FRCP).²⁶

7. Core Technical Standards and Functions

7.1 Which data elements in the proposed common clinical data set list need to be further standardized? And in what way?

As we stated above under the Timeline section, on p.12 of the Roadmap the example of the common clinical data set is provided. This data set is essentially the Meaningful Use (MU) Stage 2 Transitions of Care (ToC) data set. The Stage 3 MU Notice of Proposed Rules Making

²⁵ ONC Standards & Interoperability (S&I) Framework. [Data Provenance Initiative](#).

²⁶ [Federal Rules of Civil Procedures \(FRCP\)](#).

(NPRM) proposed a more precise data set. It is not clear why the dataset from MU Stage 2, and not MU Stage 3, was selected.

For the common data set, all data elements must be clearly defined and agreed upon by stakeholders and then mandated. Here are some examples of data elements to clearly define:

- **Race and Ethnicity:** More detailed standards than the OMB standard for clinical data are needed, specifically for understanding genetic issues, cultural differences, and so on. The National Center for Health Statistics (NCHS), Centers for Control and Prevention (CDC) maintains the broader list of race and ethnicity codes for vital records that must be used;
- **Sex:** With the recent expansion of what can be considered “sex” this needs to be re-addressed to determine which new designations must be included (the top five or the full range;)
- **Preferred language:** With the influx of new cultures entering the United States and non-adaptation to the common language (English), this category may need to be expanded to include the broader base of languages spoken;
- **Patient name** (more specifically, needs to be a standardized name field, so it is stored the same way across disparate systems (for example how to treat patients with only a one name such the Native Americans;) and
- **Date of birth** (standardized DOB field.)

In addition to data elements, a standardized method for defining the record content (standardized templates) must be defined. This includes records amendments, notifications and/or alerts to providers that the new record is available on their patients, and/or an amendment has been made, so this information may be reviewed to ensure treatment for the patient is still appropriate and the amended record must not overwrite or delete the original record. This must be maintained to show what was available at the time of the treatment.

7.2 Administrative data must also be included and clearly defined and agreed upon by stakeholders. This will aid in accurate patient matching and help to ensure patient safety.

Since the original HIPAA language prohibits HHS from moving forward to find an acceptable solution to the need of a unique patient health information identifier, AHIMA requests the support of nationally recognized standard data elements to be used for patient identification management.²⁷

Data elements such as, but not limited to the following should be included in the administrative dataset:

- Address (USPS standardized field)
- Telephone (Have a standardized field to include the country code)
- Insurance information/status

²⁷ American Health Information Management Association (AHIMA.) Patient Identification and Data Quality. AHIMA’s Request of Congress. 2015 Hill Day.

- Driver's license
 - Number
 - Expiration date
 - Issuing Agency
 - Country/Nation
- Last four digits of social security number
- Alias
- Next of kin, guarantor

These elements and other administrative data must be included in the core technical functions and standards to ensure accurate data matching²⁸.

8. Certification and Testing

In what ways can semantic interoperability be best tested? (for example, C-CDA content and semantics)

Semantic interoperability for content using the HL7 Clinical Document Architecture (CDA) standards can be tested via Schematron testing. ONC should work with NIST and the IHE Connection (for a major industry testing event) to clearly define the conformance criteria for the Schematron testing to ensure semantic interoperability of health information systems using CDA standard for data exchanges. Additional testing tools must be developed to test content expressed using the HL7 version 2 messages. The development of the conformance criteria must involve appropriate subject matter experts (clinicians, HIM professionals involved in clinical documentation improvement (CDI) activities and developers of the Content Profiles at IHE and CDA Implementation Guides at HL7), that is, developers and end users of standardized content. Financial resources for representatives from professional associations, and healthcare organizations participating in the development and testing of standardized content, must be provided.

Additional tools for the development of the standardized content (content profiles and implementation guides) must be developed as an integral part of the nationwide Interoperability Infrastructure (Figure 1). Various existing tools such as Model Driven Health Tools (MDHT)²⁹, ART-DECOR³⁰, Trifolia³¹, and The College of American Pathologists electronic Cancer Checklists (CAP eCC)³² should be evaluated and offered to both standards developers and end users to build standardized content. These tools contain built-in validation of the content and therefore could be used in the Schematron testing.

Schematron testing must be required for the certification of the EHR technology in addition to the integration testing that validates the standardized data exchange (send, receive, upload, retrieve) capabilities. This will enable providers to exchange data with the systems supported by different HIT vendors or to change vendors as needed.

²⁸ Lusk, Katherine, et al. "[Patient Matching in Health Information Exchanges](#)." Perspectives in Health Information Management. Winter 2014.

²⁹ [Model Driven Health Tools \(MDHT\)](#).

³⁰ [ART-DECOR](#).

³¹ [Trifolia](#).

³² The College of American Pathologists electronic [Cancer Checklists](#) (CPA beck).

9. Measurement

9.1. Does the measurement and evaluation framework cover key areas? What concepts are missing?

9.2. Should measurement focus on certain use cases, priority populations or at certain levels of the ecosystem (for example, encounter, patient, provider, organization?)

We agree that measures should focus on a specific Use Case and be developed through the consensus process of stakeholders (actors) participating in the Use Case.

9.3. What other types of metrics have been successfully used at the local or regional level that might be considered for nationwide use? Would stakeholders be willing to propose novel metrics and provide "test beds" to assess the potential for nationwide use?

Metrics and "test beds" should be specific to the Use Case and developed by the stakeholders (actors) participating in the Use Case. ONC should coordinate the harmonization of the metrics across various Use Cases to assess the potential of these metrics for nationwide use.

Measurements from patient safety organizations such as American Nursing Credentialing Center (ANCC) Magnet Recognition Program,³³ The Leapfrog Group,³⁴ or The Malcolm Baldrige National Quality Award³⁵ may be considered for nationwide use.

9.4. What measurement gaps should be prioritized and addressed quickly?

The adoption and implementation of standards must be measured. This can be the way to define ONC's "*best minimum level of interoperability*" (p.18). Please note that interoperability methodology in the AHIMA Proposed Interoperability Approach (Section 1.1, p.13--15 of the AHIMA Comments) includes Phase 6: Evaluate Standards-based Technology Deployment Outcomes. The outcomes to achieve the Interoperability needs and priority (Phase 1) should be formulated.

9.5. What other available data sources at the national level could be leveraged to monitor progress?

Centers for Medicaid and Medicare (CMS) data sources, (for example, Medicare Provider Analysis and Review (MEDPAR),³⁶) could be leveraged to monitor progress. Another data source to leverage is the networks of doctors and hospitals participating in accountable care organizations (ACOs.)³⁷

9.6. Are the potential mechanisms for addressing gaps adequate? What are other suggestions?

This question was answered under Question 9.4.

³³ American Nursing Credentialing Center (ANCC) [Magnet Recognition Program](#).

³⁴ [The Leapfrog Group](#).

³⁵ [The Malcolm Baldrige National Quality Award](#).

³⁶ CMS Medicare Provider Analysis and Review ([MEDPAR](#)).

³⁷ Accountable Care Organizations (ACO). URL: <http://www.hhs.gov/healthcare/rights/law/>

9.7. How should data holders share information to support reporting on nationwide progress?

The term “data holders” needs to be defined. The term “nationwide progress” must be defined. What progress does ONC seek to measure? What information should be shared? Question 9.7 needs to be clarified.

9.8. What are appropriate, even if imperfect, sources of data for measuring impact in the short term? In the long term? Is there adequate data presently to start some measurement of impact?

The term “impact” needs to be defined. The terms “short-term and long-term” need to be defined. The question needs to be clarified.

What other questions should we ask?

We do not offer additional questions.