

# EHRA

**HIMSS Electronic Health Record Association**

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September 11, 2014

Karen DeSalvo, MD, MPH, MSc  
National Coordinator for Health Information Technology  
Office of the National Coordinator for Health Information Technology  
U.S. Department of Health and Human Services

Subject: EHR Association Response to *Connecting Health and Care for the Nation: A 10-Year Vision to Achieve an Interoperable Health IT Infrastructure*

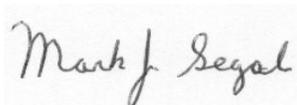
Dear Dr. DeSalvo:

The EHR Association (EHRA) appreciates the opportunity to collaborate with the Office of the National Coordinator for Health IT (ONC) in establishing a practical roadmap that substantially improves the level of end-to-end interoperability across providers and with patients and other stakeholders, e.g., payers, secondary data users, agencies, registries, and researchers.

We commend your office for its commitment and ongoing effort to move the industry forward in achieving broad-based interoperability for the benefit of all Americans. Clearly, the associated improvements in the efficiency and quality of healthcare delivery are well worth the needed investments by all stakeholders. EHRA members will continue to demonstrate our commitment through participation in standards development initiatives, pilot projects, and development and deployment of increasingly interoperable systems.

Our detailed responses to ONC's questions are included with this letter as an appendix and will be posted to the ONC Interoperability Roadmap Community Wiki for this project. We look forward to engaging in this important and ongoing discussion.

Sincerely,



Mark Segal, PhD  
Chair, EHR Association  
GE Healthcare IT

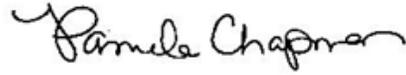


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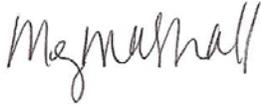
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### About HIMSS EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of nearly 40 companies that supply the vast majority of operational EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

The EHR Association is a partner of HIMSS. For more information, visit [www.ehrassociation.org](http://www.ehrassociation.org).

**Appendix**  
**EHR Association Response**  
**to the Office of the National Coordinator for Health IT's**  
***Connecting Health and Care for the Nation: A 10-Year Vision to Achieve an Interoperable Health IT Infrastructure***

1. **ONC Question:** *What are the three most important priority items that should be included in the national interoperability roadmap that will help advance interoperability nationwide?*

**EHRA Response:**

1. Progress the ability to identify and locate all stakeholders and their data engaged in data exchange (e.g., patients, providers, and others), while establishing a trusted network with appropriate directory support and authentication to build a trusted data exchange environment.
2. Improve on the process to arrive at consistent data exchange, grounded in well-defined implementation guides with matching and nationally-endorsed testing tools, while reducing the inefficiencies in the current certification process. We particularly want to emphasize the need for integrated implementation guides/testing tool kits where the testing tools are derived from the implementation guide specifications. NIST is already exploring these capabilities that can improve on the testing capabilities and drive improved implementation guidance as well.
3. Work with standards development organizations (SDOs) to improve on the currently available implementation guides and testing tools before embarking on adding new guides and tools – i.e., make the current scope of interoperability work well before introducing new capabilities.
  - Work with HL7 to improve C-CDA guides to address the findings of the recent article in JAMIA by the SMART CCD-A Collaborative and comments made at recent HIT Policy Committee hearings and elsewhere, and improve on associated testing tools such that we arrive at less ambiguous, better testable implementation guides with associated testing tools. Use C-CDA R2 as the basis to achieve this objective, allowing for a practical and non-disruptive roll-out.
  - Clarify the role of C-CDA vs. other exchange data packaging approaches.
  - Fill the gaps in directory and authentication infrastructure that enable Direct to be usable.

We also suggest that ONC does *not* focus as specifically on Cybersecurity. While clearly a concern for healthcare that ONC cannot ignore, other agencies may be better equipped to identify and drive solutions, as well as general industry establishing best practices. We do suggest that ONC can more specifically address the operational challenges and guidance for smaller provider organizations to maintain a secure environment that protects the privacy of their patients.

We are on a journey involving a learning process that requires many puzzle pieces to come together.

2. **ONC Question:** *What other topics should be included in the national interoperability roadmap that may not have been explicitly mentioned in the 10 year vision paper?*

**EHRA Response:**

We suggest a staged approach that builds on current capabilities and establishes appropriate levels of granularity based on specific use cases and practical experience. See also our response to Question 3. In that context, we suggest that the proposed timeline in the JASON report is not realistic, and that the proposed infrastructure is not practical as outlined in [our review of the JASON report](#), which was furnished to ONC.

We suggest that the development and harmonization of common terminology that can enable exchange of structured data is critical to drive increased value through decision support and secondary data analytics rather than the limited, although essential, value to view clinical documentation.

Collaboration with the provider community and relevant SDOs is paramount.

- The continued evolution of terminology should be focused and use case- driven, particularly the first 3-6 years of the roadmap to ensure that the current scope of interoperability (2014 Edition) is feasible.
- While establishing clear terminology is essential, ensuring wide adoption is equally important. The roadmap should identify specific steps to enable providers to migrate from their current vocabularies to a common vocabulary set that help us arrive at a common health language (clinical, medical, payer, and patient).
- Examples of current challenges around terminology include:
  - ICD-10 – ICD-9 – SNOMED variant terminology for diagnoses/problems – reduce variability;
  - LOINC incomplete (lab results less so, orderable tests more so) – continue to complete;
  - Radiology procedures – reduce variability and converge between SNOMED, LOINC, and RADLEX;
  - Inconsistent use of Unit of Measure encoding – establish a single vocabulary;
  - Immunizations – unification across CVX and VFC.

**3. *ONC Question:*** *What aspects of BUILDING BLOCK #1: CORE TECHNICAL STANDARDS AND FUNCTIONS are the most important to address?*

**EHRA Response:**

We suggest that of the items listed, 1 through 4, are most critical and support our response to Question 1. Items 5 through 7 can evolve over time, but as the roll-out of the Direct protocol has demonstrated, absence of either of the first 4 items yields incomplete interoperability rather than end-to-end interoperability in a trusted environment.

We note that items 1-4 should be addressed in the context of all relevant transport models, not just the push (e.g., Direct) method. Pull and query models at document and granular data element levels (as considered in the JASON report), including service-based publication/subscription, are more suitable for other use cases, as is also being demonstrated by the increased focus on query models.

Terminology refinement, development, harmonization, and adoption warrant specific focus. Although much progress has been made to establish common terminologies where local value sets were the norm, actual use of common terminologies will enable interoperability substantially. Without clearly agreed upon and complete terminology, interoperability at best can yield improved viewing of data, but not improved utilization of that data for many purposes. However, more work needs to be done to complete vocabularies to arrive at a common vocabulary nationally.

We also would like to raise a concern with item 6, “Methods for representing data at a granular level to enable reuse”. It is unclear what aspect of re-use is being considered. We propose that the definition is very broad and at least includes:

- Data element definition – re-use of the same, consistent definition of the data across standards, e.g., medication data across document types using sections, laboratory results in a message vs. document vs. service;
- Terminology and vocabulary - consistent nomenclature to enable consistency in interpretation;

- Operational vs. secondary data use – the ability of data collected in operational settings to be used for secondary purposes to avoid duplicate data collection, while not unduly impacting operational data use with over-collection of data.

We suggest that it is essential to drive the definition of the scope and content of that data set necessary for the data exchange, thus the level of granularity, based on specific use cases, with a cost-benefit perspective.

**4. *ONC Question:*** *And what are your recommended solutions or tactics for effectively addressing this building block?*

**EHRA Response:**

We suggest that government regulations/programs primarily focus on mature standards, while enabling emerging standards to evolve and mature before they are widely deployed. At the same time we recognize that if one waits for the standard to be fully mature before the regulations can pick it up, then it is perhaps too late to achieve the desired outcomes. To that end, we suggest enabling incentive programs to:

- Credit providers using emerging standards being piloted without requiring certification, as is now in place for NwHIN in CMS meaningful use regulations.
- Recognize alternative methods of exchange where those do not detract from common data definitions/content, e.g., variations in transport methods.

We must recognize that interoperability is a means to an end, not an end in itself. This point is further underscored by the PCAST report, *“Better Health Care and Lower Costs: Accelerating Improvement Through Systems Engineering”*, which recommends moving to “accelerate alignment of payment systems with desired outcomes”.

This approach will also encourage industry to move forward without regulations in place, as incentives are not dependent on use of very specific technologies, but rather are outcomes based.

At the same time, ONC should consider how to “promote” successful implementations to a national level through initiatives such as Healthway, EHR/HIE Interoperability Workgroup, and others. Fostering an incubation environment where practical interoperability use cases can be addressed, supporting standards can be developed, tested, and matured, and can ease the transition to national mandates to avoid many of the implementation challenges currently experienced with the roll-out of the 2014 Edition.

To improve on the chance of success, it is important to reconsider the current certification program and explore an attestation program approach that is specifically designed for interoperability to provide a leaner, yet equally effective, process to establish the use of common interoperability standards. We point to our responses to Building Blocks 2 and 4 for further considerations.

**5. *ONC Question:*** *What aspects of BUILDING BLOCK #2: CERTIFICATION TO SUPPORT ADOPTION AND OPTIMIZATION OF HEALTH IT PRODUCTS AND SERVICES are the most important to address?*

**EHRA Response:**

We suggest shifting from a focus on certification to a focus on attestation (well-defined implementation guides, testing tools, public attestation) tied to more aggressive pilot programs. This also must be tied to rewards for both providers and software developers to participate in pilot programs. This will allow for innovation to occur and participation to improve standards.

Certification adds substantial overhead to the development and deployment of software that can be more wisely spent on developing robust testing suites that are part of an integrated implementation guide/test environment. Robust testing tools provide for the opportunity of verifiable interoperability such that if two parties claim adherence (public attestation), the testing tool can act as an arbiter in case of a dispute. Certification to date has not been shown to prevent any such disputes, while robust testing tools would actually provide that.

We support the notion of separating content from the transport method. However, to avoid all stakeholders having to support multiple transport methods, we do suggest that at least one minimum transport method must be required for each data exchange type (e.g., one for pull, one for pull/query, etc.), and ensure that use of others does not disqualify a provider from an incentive program. As experience and adoption grows for other methods, a more appropriate method can be identified as the minimum after some period of time.

The development of the appropriate testing environment that enables validation of interoperability capabilities must address end-to-end interoperability. If there is a “middle” between to end points, e.g., a HISP or HIE, the testing must address the full flow of the data between the end points.

**6. *ONC Question:*** *And what are your recommended solutions or tactics for effectively addressing this building block?*

**EHRA Response:**

We suggest it is essential to develop a clear business model around establishing a suite of integrated implementation guide/test tools. We suggest the model should be based on three principles:

- Resulting tools are open source.
- A share of development is publicly funded.
- Governance is via a public/private entity.

Such suites are being developed in organizations such as IHE, Healthway, EHR/HIE Interoperability Workgroup, and others. Such efforts must be promoted and elevated to a national level.

Participation in these efforts and conformance to the resulting guides/test tools should be rewarded by foregoing the need to certify by a third party, rather than public attestation with proof of participation is adequate. This approach, furthermore, can direct investments towards the ongoing development of robust test tools.

Where the certification model is retained for select use case scenarios, it should focus on specific functional capabilities with a proven patient safety risk that cannot otherwise be verified to operate as required. Thus, certification can be targeted and selective rather than broad and overly prescriptive in space of functional capabilities.

Although there is much debate about the need to reduce optionality, we need to caution that reduction of optionality through standards/implementation guides that cover multiple use cases (e.g., specialties, settings, workflows) can easily result in effectively requiring providers to collect more information than is necessary for their operational and clinical needs. We suggest that ONC explore with providers and SDOs how to best model the various use cases such that data collection and transmission are optimally tailored to the providers operational needs and subsequent use, including secondary use for analytics.

It is worth repeating that robust testing tools are essential to any interoperability program. Equal care should be given to adequate testing of the testing tool as is to the interoperability they are targeted to test. We must learn from the lessons learned to date regarding the challenges of deploying testing tools. Certification is not a substitute for missing testing tools, but robust testing tools are sufficient to achieve the interoperability goals without the overhead of further certification by a third party.

**7. *ONC Question:*** *What aspects of BUILDING BLOCK #3: PRIVACY AND SECURITY PROTECTIONS FOR HEALTH INFORMATION are the most important to address?*

**EHRA Response**

ONC's proposed direction is appropriate: encouraging the advancement of the patient's right to access, amend, and make informed choices about the disclosure of their electronic health information – while finding balance for patients so they are not left of the wrong side of the digital divide – and enabling the electronic collection and management of consent, along with developing approaches that support distributed analytics and open evidence sharing without sharing PHI, are all critical components of Building Block 3 that need to be addressed. This approach can ensure that the national electronic health infrastructure is trusted by patients and has the ability to improve the overall population's health through data analytics.

The biggest challenge to enhance interoperability in the context of privacy and security is the requirement to have to conform to numerous variations of privacy policies. ONC and other elements of HHS must work closely with other agencies, states, and jurisdictions to harmonize these policies to enable consistent, secure exchange of data as patients move around and providers are involved in care teams across communities and remotely. We note that, while the PCAST report on "Big Data and Privacy" suggests deployment of privacy profiles, such a model in healthcare, considering the many state variations effectively in place, is not manageable. Until such a policy framework is established to address the level of data granularity that can be practically managed, any attempt to solve this problem through technical means only will not achieve the desired effect and will dilute the IT investments.

**8. *ONC Question:*** *And what are your recommended solutions or tactics for effectively addressing this building block?*

**EHRA Response:**

We suggest that this process begins with the adoption of basic, simple policies with associated standards that can be shared across jurisdictions to drive critical privacy and security issues, such as consent, right to access, encryption, notification, and audit records for EHRs. This approach will lay the groundwork for a harmonized, national framework that can be subsequently established. Collaboration across jurisdictions to roll out an initial set of basic and simple policies and standards will enable establishment of a trust environment that can then be further expanded.

**9. *ONC Question:*** *What aspects of BUILDING BLOCK #4: SUPPORTIVE BUSINESS, CLINICAL, CULTURAL, AND REGULATORY ENVIRONMENT are the most important to address?*

**EHRA Response:**

As also identified in the PCAST report on "Better Health Care and Lower Costs: Accelerating Improvement Through Systems Engineering", it is essential to have appropriate incentives in place for provider to exchange data. We need to get to a point where data is exchanged because providers and patients want to support their practices' information needs and business goals, not because they have to due to regulations. Data exchange is a means to end. Only then can interoperability be sustainable. Incentives should be:

- Simple

- Based on availability of data
- Driven by outcomes

As indicated in other responses, interoperability requirements must be consistent across national programs and states, e.g., CQM definitions and reporting, public health reporting.

**10. ONC Question:** *And what are your recommended solutions or tactics for effectively addressing this building block?*

**EHRA Response:**

We suggest it is important that we learn from the implementation efforts to date and establish success within the current scope before aggressively expanding the interoperability scope. That approach also means that, before we judge Stage 2/2014 Edition, we need to have more experience with the deployment to understand what worked, what didn't, and what is not relevant. Consequently, we suggest that the first phase of the roadmap focuses on deploying/fixing Stage 2/2014 Edition, then measure progress, identify gaps, and move forward based on that assessment.

In combination with the above, we suggest a survey to understand all barriers to interoperability and determine how to remove them. Without such knowledge, incentives may not work and we are concerned that we are pushing the wrong "buttons" or do not have the right size "carrot". Many debates to date occur in isolation, where each issue is the most important and critical to resolve. Yet, when reviewing the challenges with provider organizations, mostly the incompleteness of the basics are holding us back: incentives, infrastructure, trust framework, directories, etc.

Lastly, we suggest that as interoperability is a means to an end, it is the end through well-defined outcomes that matter, as those in turn will spur all stakeholders to improve interoperability to the extent needed to achieve those outcomes. Anything more has no perceived value, and thus becomes burdensome; anything less will generate pressure to improve. Such an approach will also help ensure that interoperability is considered and managed as a multi-stakeholder challenge as this cannot be achieved by software developers alone.

- Focus on creating payment models that will establish a business case for investment in and use of interoperable HIT and data exchange as best practices to meet financial, quality, and outcomes metrics.
- Use the macro-level incentives for HIT-enabled best practices vs. creating new prescriptive certification criteria for emerging functions like population health management

As indicated in other responses, we must look at this as a journey with continuous learning, not as a one-shot pass or fail.

**11. ONC Question:** *What aspects of BUILDING BLOCK #5: RULES OF ENGAGEMENT AND GOVERNANCE OF HEALTH INFORMATION EXCHANGE are the most important to address?*

**EHRA Response:**

The most important aspect is to address the governance through a multi-stakeholder, cross-jurisdiction, public/private framework. As indicated in our responses questions 1 and 2 above, many issues require the knowledge and buy-in from multiple stakeholders.

In that context, we believe that it is critical to build on existing public/private efforts to take advantage of their successes and elevate them to a national level in order to achieve a high degree of consistency across providers. Examples of such efforts are eHealth Exchange, EHR/HIE Interoperability Workgroup,

Direct Trust, and others. We should ask: Where has DirectTrust been successful in closing gaps? How can others model after that?

This process must result in a consistent, predictable governance framework that all parties conform to and can operate consistently (standards, privacy/security, etc.).

**12. ONC Question:** *And what are your recommended solutions or tactics for effectively addressing this building block?*

**EHRA Response:**

We suggest that initial efforts should focus on a few selected areas – e.g., trusted network – and expand the framework to cover other areas based on actual experience and success. Stage 2 /2014 Edition has not been sufficiently deployed to understand how much interoperability has actually been achieved, particularly as key fundamentals identified in Building Block 1 are not in place.

**13. ONC Question:** *What priority use cases should be considered for the 0-3 year agenda in the national interoperability roadmap?*

**EHRA Response:**

Finish what we have started with 2014 Edition and Stage 2:

Fix what we have with 2014 Edition and make it work before we move to new use cases.

Year 1: Fix guides and testing tools, and build trust among stakeholders.

Year 2: Testing – begin the transition to attestation based framework rather than a certification based framework.

Year 3: Deployment.

Establish pilots for new use cases, but do not roll them out widely until the current 2014 Edition is fully operational.

- Complement the transitions of care (TOC) push mode with a pull mode (not new data/content, rather additional transport) in pilot/emerging environment:
  - Review the use of current capabilities and any roadblocks to expansion;
  - Explore the use of new standards, e.g., FHIR;
- Use eHealth Exchange, and other public/private interoperability projects as the starting point;
- Introduce Appropriate Use Criteria (AUC) as the driver to establish consistent clinical decision support (CDS) standards for the knowledge artifact and decision support service.

**14. ONC Question:** *What priority use cases should be considered for the 3-6 year agenda in the national interoperability roadmap?*

**EHRA Response:**

Integrated push/pull framework definition (holistic vs. current “either/or” discussion) that has clarity on when to use messages/services to push (e.g., workflow initiation), document push/pull (e.g., C-CDA), or query (granular data and documents that include discrete/structured data).

Widely deploy TOC pull mode and other use cases that have sufficiently matured.

Establish and deploy discrete data APIs in addition to document exchange (deployment) of well defined, simple, focused use cases.

- Avoid “any data, all queries”, as practical value must be established first. Query models are already available, yet not widely used except PIX/PDQ. Immunization query definitions exist, but are not widely used.

**15. *ONC Question:*** *What priority use cases should be considered for the 6-10 year agenda in the national interoperability roadmap?*

**EHRA Response:**

Further deployment of specific use cases against the framework.

Deployment of further discrete data APIs in addition to document exchange (deployment) of simple/narrow use cases.

**16. *ONC Question:*** *Do you have any general suggestions or feedback?*

**EHRA Response:**

We suggest that, to make progress, the industry must learn from actual implementations, which is why we feel strongly that the success of the 2014 Edition interoperability capabilities must be confirmed. Any progress must then be built on a strong use case-driven approach, rather than broad-brush introduction of technology, within a holistic framework that recognizes the need for a mix of messages, services, documents, queries, etc. Focused, determined steps that attempt to solve a manageable scope of end-to-end interoperability use cases will enable the industry to move forward in concert rather than the current rush to “check a box”.

In this context, it is also worth noting that the Standards and Interoperability Framework process is well defined and has merit. However, the challenge is with the execution of the Framework process: the right stakeholders are frequently not engaged, too many parallel initiatives require the same stakeholders, and the pilot phase is frequently limited to small- scale testing rather than full-scale implementations. Additionally, the process of successful introduction of new interoperability requirements does not stop there before it can be widely rolled-out. The pilot phase to date has not been well executed and frequently limited to non-production environments. We suggest that further build out of the process that focuses on the pilot phase is critical to build a pipeline of new capabilities that can be managed in an orderly fashion and not be rolled out widely until adequate evidence is available that it works, is implementable, is sufficiently mature, and brings value to national adoption.

Throughout the evolution of standards and interoperability, we must maintain interoperability compatibility to ensure that persistent data expressed in one version can continue to be exchangeable, e.g., C-CDA documents. There are three levels that need to be addressed that are connected many to many:

- Use case (can use multiple data exchange formats);
- Data exchange format (can use different versions over time that must be compatible, e.g., a patient summary document, current medications list);
- Standards (can evolve over time, e.g. C-CDA R1.1, C-CDA R2.0, NCPDP V10, FHIR, etc.).