HIMSS Electronic Health Record Association

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April 3, 2015

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

Dear Dr. DeSalvo:

We are pleased to submit the attached comments on ONC's Ten Year Interoperability Roadmap on behalf of our nearly 40 member companies which serve the majority of hospitals and ambulatory care settings using electronic health records (EHRs) to provide safer, more effective care to their patients. We applaud the general collaborative approach that the Office of the National Coordinator for Health IT (ONC) suggests to create and maintain this Roadmap.

The EHR Association (EHRA) has been a vocal proponent of advancing interoperability using standards-based technologies since its inception in 2004. Now in its third version, we published our Interoperability Roadmap in 2006 and recently posted proposals for the next iteration on our web site. We agree that interoperability is all about enabling individuals to access the right information at the right time when information has is shared across health IT systems. Overall, we are positive about the draft Roadmap, its identified principles, and the careful and pragmatic approach taken to well-established and emerging interoperability standards and technologies.

The execution of such a roadmap requires trust among stakeholder groups, and a collaborative spirit between the stakeholders and the federal government, without a federally-dominated process and also without prescriptive requirements. Instead, ONC and other federal agencies should be active partners with the private sector in governance across the various domains, such as standards development, testing, and other areas. Multiple organizations, and existing and potentially new governance processes, are essential to orchestrate all the components together to arrive at the necessary interoperability capabilities.

The attached detailed response goes into depth on a variety of interoperability-related topics covered in the Roadmap and responds to ONC's questions. Our key points are summarized here:

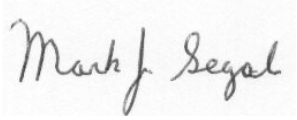
- We have concerns about ambitious timelines, as well as a new and not fully-defined "single governance process" that would, as proposed, have very broad scope and authority.
- Although the Roadmap framework being proposed is comprehensive in its analysis of the challenges the industry faces, there are opportunities for enhancement in several areas to shape a path forward. Ultimately, an interoperability roadmap should identify selected high-value use cases, as well as the major steps and timelines to get to wide, national deployment. In establishing a governance framework, it should be re-emphasized that identification of use cases with clear business cases and value propositions is essential, as only that will drive the adoption of interoperability capabilities in terms of standards, policies, and infrastructure.
- To create a robust roadmap that is practical and builds on the capabilities achieved to date, we must recognize that interoperability within and, to a lesser degree, across organizations has been operational for many years, mostly exchanging and querying discrete data, well before "documents" came about. However, replacing all document exchange with discrete data exchange is not appropriate, nor would replacing all discrete data exchange with document exchange be appropriate.
- Although we appreciate the comprehensive framework that ONC has put together to assist the industry in addressing relevant aspects of interoperability, and to ensure that interoperability supports attainment of the larger health outcome and cost objectives. We are concerned with the specified scope definition of this first Interoperability Roadmap iteration. Interoperability is very much about workflow support and requires core demographic data of the patient to ensure data is associated with the right patient. The Roadmap appears to exclude workflow support and administrative data in general, yet includes various actions specifically focused on workflow and administrative data.
- We appreciate the calls for action to emphasize a collaborative approach. We are unclear, however, why certain actions are called for and others are not, even though ONC or other federal agencies have control over the stakeholders necessary to successfully address those actions. We, therefore, suggest that those actions that ONC and federal agencies are ready to commit to should not be phrased as calls to action. For a number of the calls for action, we offer EHRA's active participation and leadership to help find practical solutions to the interoperability use cases we can best solve together.
- We urge ONC to recognize and leverage the successfully deployed health information exchange (HIE) projects such as the eHealth Exchange, CommonWell Health Alliance, the Care Connectivity Consortium, and others. Although there are different governance models in play, these all share the same technical approach based on the IHE XCA/XCPD for patient identification and document queries.
- EHRA also strongly urges ONC to make a realistic assessment of the readiness and maturity of the emerging and very promising HL7 FHIR standard. The roadmap needs to account for several critical facts, not the least of which is that the FHIR standard is not yet final or complete. Some components are more likely to become stable and robust first, and those need to be favored to support the use cases most essential to address high-priority gaps.
- EHRA proposes a roadmap in our detailed comments that can be shaped around four key principles:
  - Avoid regression from the levels of interoperability that have been achieved up to now, either by the meaningful use investment with C-CDA patient summaries and point-to-point push (Direct and XDR), or the operational nationwide eHealth Exchange using a query-based approach with XCA/XCPD/XDS.
  - Ensure inclusion, or allowance for, in the 2015 meaningful use Stage 3 regulation ONC certification final rule of the above robust standards/profiles to realize low-risk adoption and deployment.
  - Keep the current regulatory cycle with a three year cadence, targeting a 2018 Edition for clinical deployment starting in 2020.

    - Leverage the three year window (2015-2018) to assess our collective progress, and to specify and pilot a successful first level of FHIR deployment that can be bridged with C-CDA document push (Direct) and pull (XDS/XCA). To be accepted by providers, CMS and ONC regulations, as applicable, should enable pilots to be officially recognized as valid for meeting meaningful use measures (i.e., the same principles applied to eHealth Exchange in meaningful use Stage 2).
- We urge ONC to include promotion of unambiguous patient identification methods, whether private or public, to enhance our collective ability to associate the right information with the right person without manual intervention in over 99% of the transactions.
- Finally, we need clarity on the scope of the privacy and security protections intended. The reference to "learning health system" and introducing RESTful application programming interface (API) services imply a significant increase in the scope of the interoperability model to include a very broad spectrum of healthcare information systems, including consumer devices. We suggest that privacy and security protections should apply to all system components involved in the interoperability use case, not only to the EHRs, thus the Roadmap should clarify that the scope includes non-EHR system components.

The EHRA brings the collective experiences of its members who have been integrating health IT solutions, along with their EHRs, in healthcare organizations of varying sizes and specialties. We offer this experience to collaborative stakeholder efforts to develop a pragmatic technical infrastructure and plan to achieve broader interoperability over the next 3-10 years. Many of our individual member companies are also interested in participating in the development and pilot testing of test tools. We look forward to the opportunity to engage in these important initiatives. We strongly value the ability to share data across the care continuum. Working together with ONC and other federal partners, we can make great strides toward achieving interoperability.

We offer further detailed responses in the document attached.

Sincerely,



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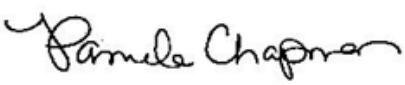

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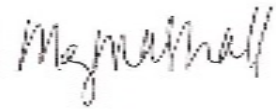

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About the EHR Association

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.

EHR Association Response to The Office of the National Coordinator for Health IT Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap

General Comments

Governance

We applaud the general collaborative approach that the Office of the National Coordinator for Health IT (ONC) suggests to create and maintain this Roadmap. We agree that interoperability is about enabling individuals to access the right information at the right time when information has to move across health IT systems. Overall, we are positive about the draft Roadmap, its identified principles, and the careful and pragmatic approach taken to well-established and emerging interoperability standards and technologies.

EHRA shares ONC's observations that healthcare transformation to a learning health system in the U.S. requires interoperable healthcare information exchange that supports a sophisticated level of care coordination. In order to achieve the learning health system in the future, organizations must develop a trust among stakeholder groups, and a collaborative spirit between the stakeholders and the federal government without a top-down process dominated by the federal government and also without prescriptive requirements. Instead, ONC and other federal agencies should be active partners with the private sector in governance across the various domains, such as standards development, testing, and other areas.

Multiple organizations, and existing and potentially new governance processes, are essential to orchestrate all the components to develop the necessary interoperability capabilities that must be available and consistent for all participants. No single network, organization, or process will be able to develop, provide, and manage the interoperability life cycle.

We, therefore, do not foresee a unitary and monolithic governance process, rather a set of processes that requires some coordination, and that can largely operate independently, as long as the overall scope, focus, and direction is well understood and shared. We urge ONC to work with stakeholders to establish such a lean coordination framework with a focused approach to support a small set of high-value, impactful use cases that can substantially benefit from improved interoperability. At the same time, prioritization should in no way hinder private sector and market efforts to develop and implement standards and technologies for other use cases or needs.

As we review the draft Interoperability Roadmap, we are struck by the tone that the document uses in the governance section, particularly the implication that the various initiatives underway are a problem to be solved. We see all of this great work already underway as a resource to be leveraged, and as a reflection of the different domains within governance, not a problem to be solved.

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

We do have a concern that the timetables reflected in the graphic on page 15, especially in the Standards and Interoperability section, are unrealistic -- particularly regarding readiness and uptake of new standards like Fast Healthcare Interoperability Resources (FHIR), and when providers would be implementing 2015 certified products. We are also concerned that too many of the tasks in this ambitious Roadmap are assigned to a new and not fully-defined single governance process that would, as proposed, have very broad scope and authority.

Many stakeholders must provide input and participate to ensure that we focus on those interoperability capabilities that support the most important, high-value use cases at a national level, and support end goals that are sustainable and useful – not merely interoperability for the sake of interoperability. A clear governance framework is important to manage the interoperability life cycle, from high-value use case identification to endorsement of the necessary standards and guidance to enable end-to-end, fully operational interoperability. In this context, we offer the following suggestions to evolve to such a framework:

- Interoperability provides a means to an end, so it is important that high-value use cases are clearly established from the standpoint of national policy to provide focus and purpose. To date, the challenge has been that too many use cases have been identified; fragmenting effort and focus, and thus not gaining wide support for these use cases. As high-value use cases are influenced by incentives and clinical needs, payers, and particularly the Centers for Medicare and Medicaid Services (CMS), play an important role, along with providers and developers, to help establish such focus.

- For each of the high-value use cases, it is important to understand the stages of an interoperability life cycle and how each stage is governed. For example, how do we arrive at establishing the use cases that require improvements on the state of interoperability? How do we arrive at necessary standards/guidance? How do we enable piloting and maturation of the standards/guidance before national endorsement/mandates? How is a testing infrastructure established? How does this fit with a trust framework that addresses the privacy, security, and legal requirements? How does the new notion of a Standards Advisory fit with a certification edition?

Multiple organizations, and existing and new governance processes, are essential to orchestrate all of the components together to arrive at the necessary capabilities that must be shared as part of a consistent set of basic interoperability capabilities. We suggest that this approach involves three governance perspectives to enable industry to collaborate in establishing a non-limiting basic interoperability toolkit:

- ***Principles*** – Identifying clear principles to which interoperability should adhere. Examples include absence of policy, business, operational, or technical barriers for data to flow; respect for patient choice on data access; health data not being subject to competition; transparency on exchange metrics.

- ***Processes*** – Because of the varied use cases, practice settings, and business needs, we do not foresee a single, monolithic governance process, but rather a set of processes that would be suitable to the situation that would require some coordination but could largely operate independently as long as the overall scope, focus, and direction is well understood and shared.

- ***Entities*** – We do not think that a single governance board/entity could manage the interoperability life cycle within and across use cases. However, some level of coordination will be required to provide insights into gaps and to help facilitate the various stakeholder organizations necessary to assume responsibilities, move forward, and contribute to a shared roadmap and timelines. Such a coordinating body or process(es) must have representation from the variety of data sharing networks, not only from a technical perspective, but also business, clinical, and administrative perspectives to help shepherd the interoperability initiatives through their life cycle. Data sharing networks were defined by the JASON Task Force as:

  > *Data Sharing Network (DSN**). An interoperable data sharing arrangement whose participants have established the legal and business frameworks necessary for data sharing. These DSNs need to conform to the Coordinated Architecture and use the public API. These could include, but are certainly not restricted to, existing networks such as those run by vendors or providers or health information exchange organizations.*

- Sample topics in scope for such governance would include addressing and ensuring the existence of minimum necessary rules for patient identity and authentication, as well as identification of the applicable standards for application programming interfaces (APIs), authentication, trust framework, content, vocabulary, and directories.

- Sample topics out of scope for such governance include functional, architectural, technical, and business approaches and capabilities within the data sharing networks as they provide opportunities for value add and innovative capabilities beyond the basic interoperability toolkit.

We urge ONC to work with the stakeholders to establish a lean coordination framework with a very focused approach to support a small set of high-value use cases that can substantially benefit from improved interoperability. Prioritization should not hinder industry and market efforts to develop and implement standards and technologies for other uses cases or needs.

As we establish the governance framework, we need to re-emphasize that identification of use cases with a clear business case and value proposition is essential, as only that will drive the adoption of the supporting interoperability capabilities in terms of standards, policies, and infrastructure.

Calls for Action

We appreciate the calls for action to emphasize a collaborative approach. However, we are unclear why certain actions are called for and others are not, even though ONC or other federal agencies have control over the stakeholders necessary to successfully address those actions. We, therefore, suggest that only those actions that ONC and federal agencies are ready to commit to should be phrased as calls to action.

For a number of the calls for action, we do offer EHRA's active participation and leadership to help find practical solutions to the interoperability use cases we can best solve together.

- The EHRA brings the collective experiences of its members who have been integrating health IT solutions, along with their EHRs, in healthcare organizations of varying sizes and specialties. We offer this experience to collaborative stakeholder efforts to develop a pragmatic technical infrastructure and plan to achieve broader interoperability over the next 3-10 years. Many of our individual member companies are also interested in participating in the development and pilot testing of test tools. We look forward to the opportunity to engage in these important initiatives**.**

Roadmap Scope

We appreciate the comprehensive framework that ONC has put together to assist the industry in addressing relevant aspects of interoperability, thus ensure that interoperability supports attainment of the larger health outcome and cost objectives. Having said that, we are concerned with the specified scope of this first Interoperability Roadmap iteration. Interoperability is very much about workflow support and requires core demographic data of the patient to ensure data is associated with the right patient. The Roadmap appears to exclude workflow support and administrative data in general, yet includes various actions specifically focused on workflow and administrative data. We suggest that the first Roadmap should include the notion of a common clinical data set, as well as clinical workflow capabilities, and the necessary administrative interoperability to support those, and casts these requirements in the context of themes (i.e., specific use cases) for the three phases identified:

- 2015-2017 focuses on establishing overall governance and exchange of a common clinical data set;
- 2018-2020 focuses on enhancing the clinical workflow; and
- 2021-2024 extends the reach to remaining administrative/financial interoperability beyond the first two phases.

Interoperability Approaches

Evolving interoperability must balance the need for both push and/or pull approaches, document and/or discrete data payloads, structured or unstructured data. For example, effective support of transitions of care (TOC) likely requires a push capability of a crisp summary document with the ability for the recipient to pull an exhaustive summary or further select information as needed to complement the summary. Such an approach would help mitigate some of the current challenges, where specifying a single document type (C-CDA) without a query capability yields 100+ page documents that are often deemed unusable by the recipient. We appreciate the

careful discussion of these various types of exchange, including the relative roles and timetables of document-level vs. data element exchange.

To create a robust roadmap that is practical and builds on the capabilities achieved to date, we must recognize that interoperability within and, to a lesser degree, across organizations has been operational for many years, mostly exchanging and querying discrete data, well before "documents" came about. Methods applied to discrete data are no longer necessarily the best tools to move forward for certain use cases. Replacing all discrete data exchange with document exchange is not appropriate; replacing all document exchange with discrete data exchange is not appropriate either. Queries for individual data elements based on HL7 V2 have been available for quite some time (e.g., PIX/PDQ), but FHIR offers newer and better opportunities to address such data-level queries more widely using different technologies (e.g., RESTful services). The Roadmap encompasses the variety of capabilities necessary to advance interoperability, as also is evidenced in the Standards Advisory, that is not limited to C-CDA R2.0 and FHIR. We suggest that the high-value, prioritized use cases drive the interoperability components most suited to achieve the objectives. As such, the timeline on page 15 should reflect those use cases and interoperability components.

Roadmap Proposals

Although the Roadmap framework being proposed is comprehensive in its analysis of the challenges the industry faces, there are opportunities for enhancement in several areas. An interoperability roadmap should identify selected high-value use cases and major steps and timelines to national deployment. EHRA would like to propose such a path forward. We believe that this approach is much more in line with what a roadmap should be. This proposal addresses a number of challenges (technical, clinical, testing, implementation, etc.), but needs to be enhanced in some areas such as establishing the adoption drivers for care providers. It also focuses on the next six years, laying out the critical actions for the first three years which are the most complex to balance:

- Constraints on organizing an Interoperability Roadmap for 2015-2020.
    - Recognize and leverage the most successfully deployed HIE projects of a national scale such as eHealth Exchange, CommonWell Health Alliance, Care Continuity Consortium, and others. They typically have rather different governances but share the same technical approach based on the IHE XCA/XCPD for patient identification and document queries.
    - Integrate a realistic assessment of the readiness and maturity of the emerging HL7 FHIR standard. The roadmap needs to account for several critical facts:
        - The FHIR standard is not yet final or complete. Some parts are more likely to become stable and robust first and those need to be favored to support the use cases most essential to address high-priority gaps.
        - A step-wise approach to advance FHIR should leverage the current Draft Standard for Trial Use (DSTU) V1 which is available, while planning the transition to the DSTU-V2 which can be realistically finalized by the end of 2015. Non-backward compatible changes have been introduced in moving from DSTU-1 to DSTU-2, and some other such changes are likely to happen when moving to the FHIR standard that can be expected sometime in late 2016. Such maturation is normal and positive, however it can result in non-backward compatibilities that could generate a major loss of investment if deployed on a large scale. The interoperability roadmap should be paced to balance progress and large scale deployment.
        - FHIR has much flexibility but effective interoperability using FHIR will require development of a set of profile specifications. Such FHIR-based profiles are not yet mature and their development needs to be planned and resourced to reach quality and stability. A first set of profiles was released in early 2015, based on DSTU-1 such as IHE Patient Demographic Query for mobile (PDQm), IHE Mobile health Document (MHD or XDS/XCA on FHIR), and IHE Internet User Authorization (IUA) based on OAuth. A first set of test tools is also now available. The plan is to evolve these profiles on the DSTU-2 and FHIR standards when approved. The development of a number of complementary profiles based on DSTU-2 is also being planned by HL7 for discrete data queries on a core data set for late 2015. Therefore,

the planning of FHIR pilots in 2016 based on this portfolio of DSTU-2 is realistic, while larger scale deployment can be targeted by 2017-2018. Indeed, large scale deployments require stability of implementation specifications and standards to deliver widely deployed interoperability.

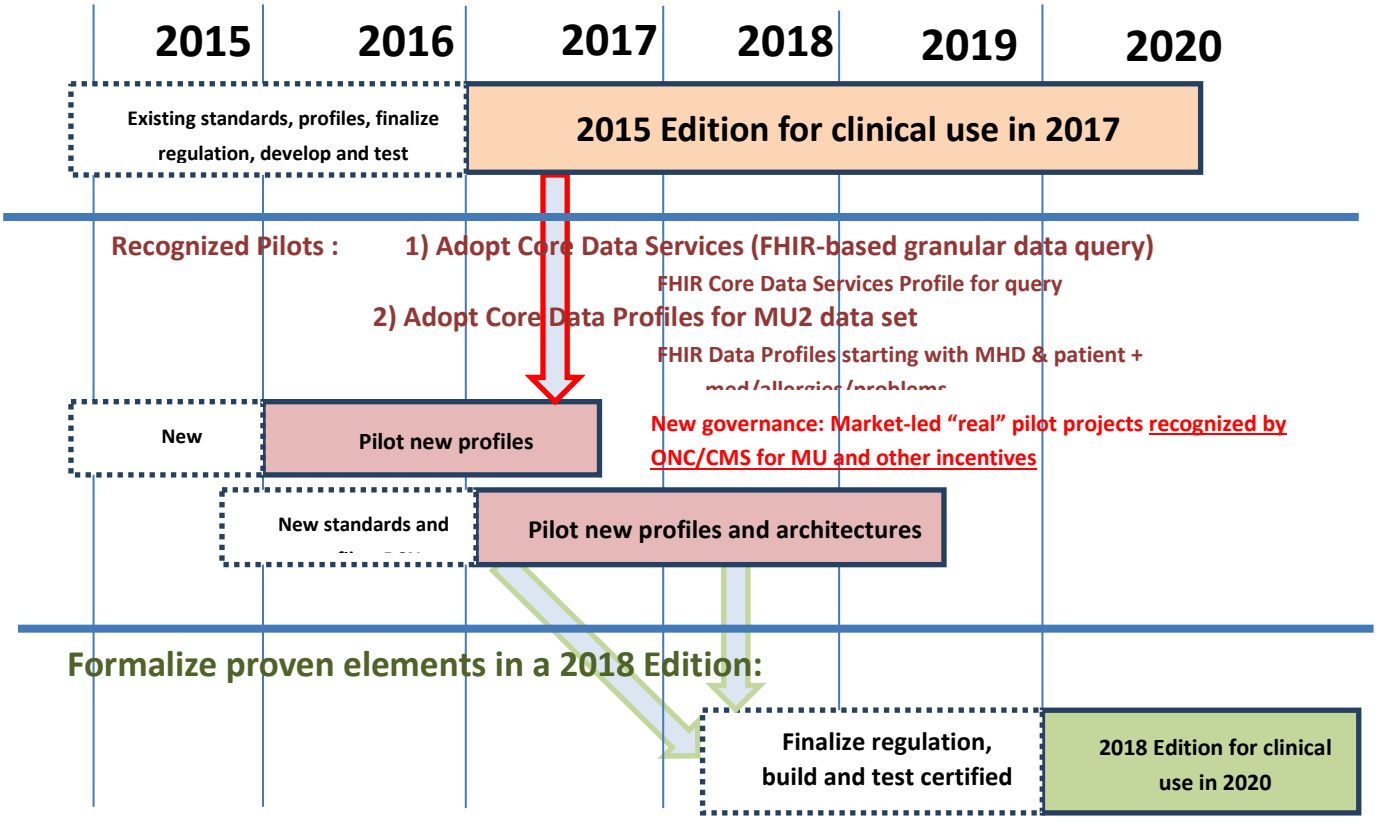
- Elements of a Realistic Interoperability Roadmap – Based on the above constraints and analysis, the EHRA proposes a roadmap shaped around four key principles:

  - Avoid regression from the levels of interoperability that have been achieved up until now either by the meaningful use investment with C-CDA patient summaries and point-to-point push (Direct and XDR), or the operational nation-wide eHealth Exchange using a query-based approach with XCA/XCPD/XDS.

  - Ensure inclusion, or allowance for, in the 2015 ONC certification final rule of the above robust standards/profiles to realize low-risk adoption and deployment.

  - Leverage the three year (2015-2018) window to consolidate progress to specify and pilot a successful first level of FHIR deployment that can either be bridged with C-CDA document push (Direct) and pull (XDS/XCA). To be accepted by providers, CMS and ONC regulations, as applicable, should enable pilots to be officially recognized as valid for meeting meaningful use measures (i.e., the same principles applied to eHealth Exchange in meaningful use Stage 2).

Given the above constraints and principles, consider a three-phased approach:



In summary, the 2015 Edition should include:

- Adopt Data Access Framework (DAF)-based transport (options):
  - MHD (document push/pull) based on DSTU 2 + PDQm + IUA (OAuth)
  - XCA/XDS (SOAP-based) – already adopted through eHealth Exchange in meaningful use Stage 2

- Move content to C-CDA R2.1 (with improved backward compatibility) for transitions of care.

Patient Identification and Matching

Matching records to the right person is critical to successful interoperability and to enable a complete health record across provider organizations where a patient may receive care. The Roadmap does not sufficiently address the need to arrive at common identification methods, nor acknowledge that existing matching methodologies, even when further enhanced with the proposals from the *Patient Identification and Matching Report* (February 7, 2014), will not sufficiently resolve patient mismatches in the absence of using unique nationwide patient identifiers. We urge ONC to include promotion of unambiguous identification methods, whether private or public, to enhance our collective ability to associate the right information with the right person without manual intervention in over 99% of the transactions.

Finally, we need clarity on the scope of the privacy and security protections intended. The reference to "learning health system" and introducing RESTful API services imply a significant increase in the scope of the interoperability model to include a very broad spectrum of healthcare information systems, including consumer devices. For example, many EHRs employ separate interoperability engines to communicate with other applications. In this example, where would the scope of the privacy and security rules apply? Would the certification process be limited to the interoperability engine, or the electronic health record (EHR) and other systems communicating via the interoperability engine? We suggest that privacy and security protections should apply to all system components involved in the interoperability use case, not only to the EHRs, thus the Roadmap should clarify that the scope includes non-EHR system components

Answers to ONC Questions

ONC Question: 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?

> ***EHRA Response:*** *Overall, we are positive about the strategy and approach in the Roadmap, including the principles established and the key tasks and timing. We are concerned with the volume of actions being called for and lack of focus. We suggest that targeting a few, high-value use cases would help address the need for focus in many of the action items.*

ONC Question: 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.

> ***EHRA Response:*** *Based on feedback from the EHRA membership, we suggest the following prioritization, recognizing that a number of the detailed use cases should be addressed together as identified below:*
> 1. *Exchange (query and send) of core content records across organizations (#11, #21, #29, #33, #46, #47, #49)*
> 2. *Patient access to an aggregate view of their records (#7, #18, #35)*
> 3. *Cross-organization results sharing (#12, #41)*
> 4. *Closed-loop referrals (#3, #39)*
> 5. *Alerts to ambulatory providers that a patient has been hospitalized (#9, #40)*
> 6. *EHR data submissions to Public Health (#1, #27)*
> 7. *Order submission (e.g., Lab, Imaging) and follow-up cross-organization (#6)*

ONC Question: What, if any, gaps need to be addressed?

> ***EHRA Response:*** *We will provide specific suggestions in the context of the respective tables through the Roadmap.*

ONC Question: Is the timing of specific actions appropriate?

EHRA Response: *We are generally concerned that the timing is not practical. For example:*

- *Figure 2 on page 15 suggests FHIR-based profiles and data provenance specifications be addressed by the end of 2015, when at best the FHIR DSTU 2 will be finalized Q4 2015.*
- *Figure 2 also unrealistically suggests that developers will be rolling out 2015 Edition certified products in 2017, when Stage 2 experience indicates that would leave insufficient time for provider implementation.*

- *Figure 2 introduces a use case that consumer applications aggregate health data across many providers' portals in one place via an application (app). The necessary infrastructure specifications and policies to make this work are not identified nor planned in the Roadmap. They have only been identified as requirements and standards to be developed.*

- *The Standards Advisory should call out the specific standards/implementation guides and be reflected only at a summary level in Figure 2 in the context of the agreed to high-value priority use cases. As the Standards Advisory is more fluid over time then the overall Roadmap, we need to make sure this fluidity can be managed without locking it prematurely in the Roadmap itself.*

ONC Question Are the right actors/stakeholders associated with critical actions?

EHRA Response: *Generally, we believe that appropriate stakeholders have been identified. However it is unclear how, without a governance framework, the stakeholders will be able to engage in a coordinated fashion. In particular, it seems as though too many critical tasks have been assigned to the yet-to-be-developed governance framework, and this dependency may undermine the feasibility of the plan.*

Principle-Based Interoperability: Working Toward a Long-Term Vision with Near-Term Wins

- **Page 10**
  - We suggest that exclusively focusing the first three years on send, receive, find, and use of a common clinical data set without addressing either a unique patient identifier or additional administrative data may add risks that data is not properly collected to enable accurate patient identification and matching. We strongly recommend that these two areas are addressed immediately.

Current Context

- **Page 10**
  - We agree with the identified barriers of insufficiently structured data, incomplete provenance, and challenges with workflow support. However, we are concerned that the scope and calls to action do not adequately address these barriers.

  - Achieving sufficiently structured data requires substantial efforts among and within the clinical community to determine the level of structured data and supporting vocabulary that effectively supports their documentation requirements, clinical decision support, and research/analysis. Typically, health IT and the interoperability standards are capable of supporting either structured or unstructured data, but cannot and should not completely force its use. We have already heard many complaints about the canned text that results from extensive use of structured data so a balance must be struck.

  - Data provenance must not only be addressed to support personal choice (as suggested in G5 (associate individual choice with data provenance), but to enable sufficient context for other uses as well. We

suggest addressing data provenance and the ability to communicate this consistently across all potential use cases to substantially address this barrier.

- Workflow was identified to be out of scope for this first iteration of the Roadmap, but this barrier further supports the need to include workflow considerations from the beginning when establishing an interoperability roadmap.

- **Page 11**

  - We support the goal of simplifying interoperability to a point that out-of-the-box basic interoperability is available. However, we have to be very careful setting an expectation that it is simply a matter of emulating the achievements of telephone or ATM technologies. These took decades to mature and generally involve a much smaller data set and interactions. Furthermore, the focus in these areas is on inter-network connectivity among relatively few service providers and banks, while health IT requires substantial harmonization across a vast number of stakeholders to have truly interchangeable data. We suggest that both cross-network and intra-network, such as HIEs, require harmonization, as well as intra-provider harmonization to enable consistent data sharing between health care stakeholders. Until all partners in data exchange agree to adhere to the same set of standards and implementation guides that vendors are certified to, there can be no out of the box interoperability.

  - It is not sufficient to focus on the nationwide level of interconnected service providers. This is ignoring that EHR systems need to be interfaced to each one of these service providers' data sharing arrangements. It is equally critical to standardize the baseline interface that has to be offered by these various private data sharing arrangements.

Critical Actions for Near Term Wins

- **Page 12 - Near Term Action 2**

  - We support the notion that both documents and discrete data are necessary to support the exchange of relevant elements of a common clinical data set for a given use case. The discussion in the Roadmap was excellent on recognizing the need for supporting both capabilities. This includes both static exchange of relevant data (e.g., TOC), or workflow management-focused exchange (e.g., ordering/resulting of diagnostic studies). One size will not fit all. We note that, with advances of technologies, one style of data exchange is not presumed to be suitable for only one technology.

- **Page 13 - Near Term Action 2**

  - We agree that data provenance should be incorporated into interoperability methods to enable consumers of the data to manage the data accordingly. Further efforts are required, particularly at the discrete data element level, to provide provenance at the relevant level of detail to make it manageable and useful. We propose that data provenance for documents is the best starting point where much experience exists. Then, in a second step, we should further deepen provenance for discrete data.

- **Page 15 – Figure 2**

  - Although the timeline indicates that all public and private payers are to evolve policy and funding levers, the design of such levers is not discussed. We point to our earlier comments that primary levers should be one of the end goals that interoperability supports, to avoid creating interoperability solutions for the sake of interoperability only.

  - We are concerned with the suggestion that consumers aggregate health information from many portals in one place via apps. This approach assumes a single prevailing technology to solve the multi-portal issue introduced with the CMS EHR Incentive Program which requires every participating provider to have a

patient portal. We suggest that the focus should instead be on enabling interoperability, such that providers and consumers can find the optimum use of portals that may or may not use so-called "apps", whether they access such data through portals and/or directly from the source. The better objective statement is that consumers have integrated access to their health information across their providers.

Scope

- **Page 18**

  - We are concerned that, by excluding discussions about the quality of the data being exchanged, quality is not being built into interoperability. As standards and guidance are established to exchange the common clinical data set, quality of such data should be considered from the start. This approach requires consideration of the feeders of all data, including administrative sources, to achieve high data quality (e.g., high patient matching rates). This observation does NOT necessarily require addressing all administrative documentation and data entry considerations, but would include clarity on a common vocabulary that is suited to clinical use, both operationally as well as for research and analysis purposes. Although addressing data quality may be one of the greatest challenges, without a complete, accurate vocabulary at the right level of granularity or accurate patient demographic data, interoperability will not be successful, and thus cannot support the intended outcome and cost improvements.

  - We are also concerned with the exclusion of workflow from the first iteration of the Roadmap. Successful interoperability demands support for optimal workflow and in many sections in the Roadmap, as well as the Standards Advisory, workflow-focused interoperability is suggested as required. We, therefore, strongly encourage ONC to also reflect in the Roadmap the variety of workflow-focused standards highlighted in the Standards Advisory. We suggest that, as high-value priority use cases are identified, the Roadmap considers as necessary workflow-focused interoperability requirements as well.

How the Roadmap is Organized: Business and Technical Requirements for a Learning Health System

- **Page 23 - Requirement G**

  - There is extensive variation across states with respect to the permission to collect, share, and use identifiable health information. Reducing such variations will reduce the costs of interoperability and simplify the management of trust frameworks to enable consistent, patient consent-based exchange of clinical data. We look forward to working with ONC and the states to address practical solutions to reduce the variations and enable deployment of consistent interoperability solutions across states.

- **Page 24 – Requirement I**

  - To prevent situations where certified health IT is conforming to endorsed standards and implementation guides but is not interoperable without significant implementation efforts, it is essential to have:

    - Unambiguously defined standards and implementation guides with full standard vocabularies accepted by providers;
    - Robust testing tools that can measure conformance with endorsed interoperability standards and implementation guides.

  - As demonstrated with the 2011 Edition and 2014 Edition, without these two components in place, testing (in support of certification) provides, at best, limited assurances and does not significantly reduce implementation efforts. We are committed to working with the standards development organizations (SDOs), whose members are actively improving the standards, implementation guides, and associated testing tools.

- **Page 24 – Requirement K**

    - This requirement is too limiting, focusing only on services as the suggested form of interoperability. Rather, we suggest stating the need for standard, secure APIs, recognizing that services, messages, etc., are types of APIs to which this requirement should apply.

Rules of Engagement and Governance

Shared Governance of Policy and Standards that Enable Interoperability

ONC Question: 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 an industry-led governance effort?

> ***EHRA Response:*** *While we support the intent expressed in the question that a governance process be an industry-led effort with public/private participation, we are concerned that Category A1, Action 1 implies an ONC-led governance or single, highly structured governance process. We suggest that ONC, in active collaboration with stakeholders, establishes a new governing framework that is empowered to orchestrate all aspects of interoperability governance (trust, testing, standards, etc.) in support of defined high-value use cases. The governance framework must be open, transparent, and sustainable with appropriate representation from all stakeholders where they are truly participating on behalf of their customers. We refer to our general commentary for further considerations.*

- **Page 27** – We agree that shared governance of policy, standards, and interoperability requires stakeholders to make collective decisions between competing strategies. We should recognize that multiple standards and strategies may be appropriate for a given use case, and it should be clearer that central to interoperability is a common language which requires unambiguous definition and interpretation of syntax and semantics. Dialects and extensions are acceptable as long as the core remains consistent as agreed. Having such a focus, driven by high-value use cases that interoperability is to support, we then can arrive at a suite of endorsed standards and guidance that can be used out-of-the-box when exchange has to occur, rather than driving the exchange statistics in isolation.

- **Page 28** – Standards alone are insufficient to achieve repeatable, consistent implementations of interoperability. Standards plus implementation guides robust testing tools, supporting processes, infrastructure, and trust frameworks, must all be addressed and "packaged" before a standard is widely mandated and rolled out. This approach has not been successfully applied to many use cases in the current state. Part of the challenge has been the volume of initiatives requiring access to the same resources to complete successfully.

- **Page 31** – We suggest that prioritization of use cases is a critical component of governance processes to ensure interoperability initiatives focus on capabilities that are recognized to have a clear and agreed upon value proposition. Depending on where the interoperability initiative is in its life cycle, the criteria for prioritization change. For example, initiating a pilot with associated development of standards and guidance may not have as high a bar on proven value, whereas roll-out at a national level must have not only a clear value proposition, but proven value that justifies the required investment all stakeholders, plus a fully tested set of tools and guidance that can be deployed.

- **Page 31-32** – We support the need for individual choice as appropriate and welcome ONC's action to clarify the interpretation of HIPAA in this context as well. We look forward to engaging in this discussion to help arrive at practical solutions that are manageable, without overburdening patients and providers alike.

- **Page 33** – We appreciate the practical focus on security and the notion that we seek to control risk, but are not necessarily able to eliminate all risks considering the complex network of people, software, and infrastructure.

Table 1: Critical Actions for a Coordinated Governance Framework and Process for Nationwide Health Information Interoperability

- **Page 34 - Category A1**

  - **General -** We support the need for a comprehensive governance framework that manages the full interoperability life cycle from use case definition through national roll-out of the necessary components to widely implement the targeted interoperability capabilities. It is essential that such a framework recognizes that the goal is not to set a "maximum bar", or the only way to achieve the interoperability capabilities, but that it enables a "minimum bar" of interoperability capabilities. Such an approach would also enable basic interoperability to be widely and consistently available with opportunities for innovation and growth.

  - **Action 3** – Although we support establishing a comprehensive governance framework, we suggest that focus should be on reinforcement of positive incentives and behaviors rather than the over-emphasis on calling out "bad actors". Reporting on outcome attainment and best practices would cultivate a more collaborative and positive ecosystem.

  - **Action 4** – We support the need for federal agencies to be involved in, perhaps through ONC, and adopt the outcomes within an enhanced governance framework to help ensure consistent interoperability across all of the healthcare industry.

- **Page 35 – Category A2**

  - **Action 2 –** This action is an example of the various levels of detail that the Roadmap attempts to address. At the governance level, patient-generated health data is a good example, but should not be called out explicitly as a policy and operations action. Rather, it should be considered part of the scope definition to clarify that the common clinical data set is made up of contributions by providers and individuals managing their health. Furthermore, prioritization of use cases should determine whether interoperability support for patient-generated health data is top of the list, or a future area of focus.

    As patient-generated health data is being considered, ONC should particularly consider device-generated data as such data relies most on interoperability.

  - **Action 4 –** This action is an example of the ambiguity in scope as the opening sections declare administrative/financial data out of scope, while this action considers it effectively in scope of this first Roadmap iteration. Administrative data is an essential element to be addressed in the first iteration of this Roadmap.

- **Page 36 – Category A3**

  - **General** – We suggest including an action to address testing tools to be made available with the standards and implementation guides as they are being developed to support the targeted use cases. This action should further clarify that availability of robust testing tools can address non-certification-related testing, and streamline, if not eliminate, the need for additional independent validation with a certification mark.

    We emphasize that the testing tools needed for certification and non-certification activities are the same and must be robust.

    - Test tools must be robust enough that developers, providers, and test labs can run them with consistent results.
    - An iterative test environment is essential.

- There needs to be clarity regarding how a standard evolves with associated test tools (iterative), moves into the Standards Advisory (i.e., what are the entry criteria?), and then on to a certification edition (again, what are the entry criteria?).

- **Action 2** – We support the concept underlying this action, but suggest that we should put this in the larger context of an interoperability life cycle of which the standards life cycle is an important part.

- **Action 5** – We support the need for ongoing review and evaluation of applicable standards. We suggest introducing a more formal approach to evaluate maturity of standards based on actual usage statistics and surveys and their efficacy (e.g., fit for purpose, variations in interpretations, etc.) to provide a better basis to assess when a standard can move from prototype to pilot to wider production to national adoption as a minimum bar.

  We also suggest that such evaluation must address backwards compatibility, particularly in the document exchange space.

  We would like to note that changing operational interoperability requirements that achieve the goal of exchanging the intended data set for the sake of a newer version/technology is unnecessarily disruptive. Therefore, we must distinguish between what software should be able to support at a minimum and what users of such software are required to implement to meet "use of CEHRT" or equivalent requirements. Forced upgrades to use newer standards without additional functionality only promotes interoperability for the sake of interoperability, rather than progressing toward the goals it seeks to achieve (i.e., relevant value-based use cases).

A Supportive Business and Regulatory Environment that Encourages Interoperability

ONC Question: 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?

- **Page 37 – 38**

  - The current state describes a demand among providers for further interoperability, and while there has been a desire expressed for such capabilities and how they could improve outcomes and reduce costs, this desire for cross-provider interoperability has not sufficiently translated into a real market demand for cross-provider interoperability without payer incentives. At the same time, intra-provider interoperability as seen substantial improvements as the benefits and incentives can be aligned within a provider organization. We suggest that this perspective be clarified as a real demand for cross-provider exchange that is based on clear value and willingness to invest in infrastructure in order to achieve similar progress as exists within provider organizations. So, on balance, we believe that private-sector payers can have the greatest impact on increased standards-based interoperability through adoption of value-based payment strategies and integrated care models that create real business cases for cross-organizational interoperability, rather than through replication of the highly detailed and prescriptive model used by Medicare and Medicaid.

- **Page 41-42**
  - Although we agree with the need for payers and states to be involved, we are concerned that asking them to act as a "powerful force" and "require adoption of certified health IT systems" has a risk of multiple, potentially conflicting initiatives. While there can be variations in state reporting and value-based payment programs, we suggest that ONC clearly reinforce that all stakeholders must come together to establish critical elements of a common interoperability framework. The overall healthcare system benefits more from consistent communication formats and vocabulary than having to support different formats and content as currently widely practiced, thus adding unnecessary cost to the system.

Table 2: Critical Actions for a Supportive Business and Regulatory Environment that Encourages Interoperability

- **Page 43 - Category B1**

  - **Actions 1, 3, 5, 6** – Although we clearly believe that alignment of incentives is essential to help focus, we re-emphasize that interoperability is a means to an end. As such, adjustments in incentives should not be primarily focused on increasing interoperability for its own sake, but rather on the targeted outcomes and cost parameters, which then will drive interoperability requirements and capabilities. As such requirements are clear, it must be the goal of the Roadmap and the governance processes to manage each of the relevant interoperability life cycles to arrive at a nationally-deployable interoperability toolkit that all stakeholders support. Consequently, we suggest de-emphasizing CMS actions that are not specific to interoperability. These should rather be documented as context and drivers that will yield use cases which rely on interoperability to be successful.

  - **Action 2** – We agree that federal agency grants and contracts towards health IT should include the requirement for such health IT to support the nationally agreed-to interoperability toolkit, as applicable.

  - **Actions 3, 4** – Reinforcement and encouragement should be achieved through committed participation in the proposed governance processes. States, providers, individuals, software developers, and other stakeholders must be committed participants to have a chance to achieve consistent, implementable interoperability based on a common set of core standards and guidance.

  - **Action 4** – In general, but specifically with respect to this action, we suggest emphasis on the need for structured/codified data to enable use of such data beyond human readability and use for clinical decision support, research, and reporting. It should, furthermore, be emphasized that stakeholders must to come together on how to balance the need for expressiveness in documentation versus the need for structured/codified data in interoperability through private endeavors.

  - **Action 7** – This action should be targeted for the 2015-2017 timeframe, as basic capabilities are already available through 2014 Edition compliant software. Enhancing the definition of relevant data for different settings that can be communicated with existing capabilities can lead to greater adoption and value without having to wait three years. For example, relaxing the need to include all laboratory results upon discharge in a document destined for a patient's primary care physician or follow-up specialist will help reduce the size of the document while making it more meaningful and manageable.

- **Page 44 – Category B2**

  - **Actions 2, 4** – We are very concerned that the call for states to enact state-autonomous policies in Action 4 is not in line with the need to have the cohesive interoperability framework at a national level effectively called for in Action 2. Neither providers nor patients are well served by having to develop and support 50+ different interoperability variants of essentially the same data sets. We do support, however, the need for states to improve their investments to enable participation in a national information infrastructure. This furthermore will help adjust situations where providers have deployed system capabilities that cannot communicate with state systems. We suggest that the federal government work with states to align investments that enable states to appropriately fund the necessary infrastructure and recognize the value of a common approach towards the interoperability aspects of their information requirements.

- **Page 44 – Category B3**

  - **General** – As indicated in our responses above, we suggest that, in general, payment and purchasing models should not be directly tied to the Interoperability Roadmap. Rather, such plans should focus on rewarding achievement of the intended outcome/cost targets. However, if while achieving such targets,

further benefits derive from the use of common interoperability solutions, it may facilitate funding to support the necessary interoperability infrastructure.

Individuals are Empowered, Active Partners in Their Health and Health Care

Table 3: Critical Actions for Individuals That Are Empowered, Active Partners in the Health and Health Care

- **Page 47 – Category C1**

  - **Action 1** – We agree that a demand from patients would increase the need for interoperability between provider and patient-focused health IT. We suggest that the first three years should be focused on working with providers and caregivers to understand the potential need, which then can translate in subsequent years to a majority demanding widespread availability of capabilities that then may or may not require interoperability capabilities beyond those that are available.

  - **Action 4** – We suggest that this action – to foster the development of a care planning process that is secure, controlled, and yet ubiquitously available – be preceded in the first three years by pilot programs to help clarify what interoperability needs will be essential to support longer term actions for 2018 and beyond.

    We also note that this is a clear example of workflow that supports inclusion of workflow in the initial iteration of the roadmap.

  - **Action 5** – It is unclear how this call to action would be accomplished. Rather, we suggest that first, outside of interoperability, capabilities are made available to patients that they use and would use more "if I just had access to more data". We are not yet at that point, and the activities to potentially get to that point are not applicable to an interoperability roadmap. The focus of the Interoperability Roadmap should be to recognize high-value use cases, which patient apps certainly have the potential to become, and then facilitate establishing components to enhance their value. Only if the patient apps provide value to the user will they regularly access and use the data.

- **Page 48 – Category C2**

  - **General** – We suggest that many of these actions are the precursors to Category C1 actions. However, as indicated above, an interoperability roadmap should be established based on a set of prioritized, high-value use cases. The current perspective creates an impression of promoting functional capabilities for the sake of enhancing interoperability, rather than prioritizing use cases, thus requiring interoperability to deliver those functions based on a roadmap on how to achieve functionality. We, therefore, suggest that the Roadmap begins with a set of prioritized use cases and then describes how over the next several years we go about establishing the necessary roadmap to support those use cases. As use cases emerge over time, and interoperability realities become clearer, the Roadmap can be enhanced accordingly.

  - **Action 4** – There continues to be confusion between the promotion of Blue Button separate from the view-download-transmit (VDT) capabilities in the 2014 Edition. We suggest that these should be addressed as part of one use case that focuses on the ability of patients to access their data using various push and pull interoperability techniques to connect the patient and their caregivers with the providers' health IT capabilities.

Care Providers Partner with Individuals to Deliver High Value Care

- **Page 50**

  - We strongly support and applaud the shift from "meaningfully using" specific technologies, which has led to unnecessarily prescriptive functional certification and meaningful use requirements, to a more outcomes-focused approach that addresses how interoperability can contribute to improving those functions. Interoperability is a key area where it is critical to have a strong common set of standards and capabilities to achieve reliable exchange of data. We must recognize though, as highlighted in prior comments, that interoperability measures in and of themselves and interoperability for the sake of interoperability will not yield success. We must reiterate that this Roadmap must provide the progression necessary to achieve interoperability in context and support of high-value use cases. We suggest that the final version of the first iteration of this Roadmap be organized based on the priority use cases identified, rather than the current mix of functional and interoperability action steps.

Table 4: Critical Actions for Care Providers Partner with Individuals to Deliver High Value Care

- **Page 52 – Category D1**

  - **Action 1** – We support the call for providers to be more actively engaged, particularly to help identify high-value use cases that require interoperability to enable them, establish common terminology that is accepted by the provider community, and help drive the pace of rolling out the necessary infrastructure. It is of particular importance to gain consensus on the right amount of data to exchange to support a particular use case, and how it best can be integrated with the data already in their own systems. Without such involvement, we run the risk of building interoperability capabilities without a demand to actually use them.

- **Page 52 – Category D2**

  - **General** – We are concerned that the actions focus too much on prescriptive interoperability utilization before clearly understanding the use cases and workflows that need to be supported. The focus of the Roadmap should be on addressing the high-value use cases and, in that context, establish a Roadmap on how we can enable those use cases with the right mix of interoperability capabilities.

  - **Action 3** – The focus of this action should not be on the adoption of specific technology, but rather focus on identifying the optimum workflow to exchange data (e.g., how much data should be pushed and when, and what data should can be pulled and where it should be inserted into workflows). Based on that understanding, we can then determine what interoperability capabilities are best applied to enable such exchange. Such exchange may use publish/subscribe technologies, query-based technologies, messaging technologies, and document as well discrete data exchanges.

    We do support the notion that regardless of techniques deployed, single sign-on is a reasonable requirement to minimize navigation required to get to the right data. We should note that this represents another element of workflow support that was initially ruled out of scope for the first iteration of the Roadmap. However, we believe this is an excellent example of why workflow should clearly be part of the first iteration.

  - **Action 4** – The EHRA introduced the EHR Developer Code of Conduct in 2013, with a specific tenet in support of interoperability and data portability. The Code calls for adopting organizations to enable their customers to exchange clinical information with other parties, including those using other EHR systems, through standards-based technology, to the greatest extent possible. EHR developers that commit to the Code agree to use available, recognized, and nationally uniform standards to the greatest extent possible in developing interfaces. They also agree that, as customers implement interfaces and work to achieve interoperability, they will share best practices with them about the safe deployment, implementation, and use of the supporting tools and technologies.

- **Page 53 – Category D3**

  - **Action 1** – We suggest that this call for action should be preceded, outside of this Roadmap, by improved and consistent definition of targeted quality measures tied to high-value use cases that can be used to measure the efficacy of introducing interoperability to improve on those use cases. We also suggest that perhaps this call to action should be directed towards software developers to create value-add applications that utilize the variety of data sources to enable providers to facilitate their decision making. Once we understand what data those applications need and how to further integrate them with provider's health IT, we then can determine how best to enable the data exchange necessary.

- **Page 53 – Category D4**

  - **General** – These are great examples of workflow enabling interoperability, and should be further prioritized in context of the high-value uses cases that should drive the Interoperability Roadmap. Generally, these actions are very actionable (once prioritized) and should serve as an example of how other actions should be described.

  - **Action 1** – Although as noted above, we agree that this is the right way to define these actions, we must recognize that for a number of the individual goals the necessary standards are not fully defined and a wide deployment would be a challenge in this timeframe. However, this Roadmap would gain in value if we further identify the necessary steps for each of these components to determine what it will take to move from prototypes, to pilots, to initial deployments, to wider deployments, and ultimately to national adoption, recognizing that each of these may require more or less work to complete its interoperability life cycle. Based on that, we can rally stakeholders to join and participate in these initiatives to help drive them forward.

- **Page 53 – Category D5**

  - **General** – We support the notion of engaging providers in improving the focus and appreciating the value of interoperability, and suggest that the Roadmap focus on establishing prioritized, high-value use cases that can benefit from interoperability.

  - **Action 2** – We suggest clarification of the definition of "registries", as interoperability with certain registries does not fit within training.

  - **Action 3** – Measurements and benchmark reporting are essential to measure progress and understand the contribution of interoperability to the use case outcomes it supports. To that end, we suggest that Action 3 should be moved into the first phase to establish a baseline against which progress can be measured. This action should be applied to all use cases and associated actions.

- **Page 54 – Category D6**

  - **General** – We fully support the need to strengthen the ties between providers and patient research communities. However, it is not clear from these actions what specific interoperability capabilities need to be addressed. We, therefore, suggest clarifying the specific use case in support of these overall goals that could benefit from interoperability. Such an approach will help focus on specific data requirements that could be addressed by health IT and communicated across the communities.

- **Page 54 – Category D7**

  - **General** – We support these calls for action and suggest identifying clear use cases for initial focus to ensure the necessary data can be exchange to support the implied improvements.

- **Action 3** – We note that the current VDT criteria in the 2014 Edition already support this action. However, as with many actions and capabilities, essential infrastructure components (e.g., directories, trust frameworks, policy alignment) have not received the necessary attention to achieve successful and wide deployment. This is a good example on how a robust governance process addressing the interoperability life cycle holistically in support of high-value use cases will help focus and drive the necessary actions to achieve the targeted outcomes and cost improvements.

Privacy and Security Protections for Health Information

Ubiquitous, Secure Network Infrastructure

Table 5: Critical Actions for Ubiquitous, Secure Network Infrastructure

- **Page 55**

  - With regard to the statement, "Finally, there is a significant behavioral and cultural change necessary", while not isolated to the healthcare industry, training and education need to be included to change behavioral and cultural understanding of the relevance of cybersecurity risks.

- **Page 57 – Category E1**

  - **General** – We support the need for federal agencies to take a number of actions to establish and implement a practical security framework that can protect patient privacy as data is exchanged across systems. However, this needs to be a collective action in which all stakeholders participate.

  - **Action 1** – There is a strong need for training and education to be included in the Roadmap to change behavioral and cultural understanding of the relevance of cybersecurity risks see last paragraph on page 55). While industry can help promote some education, most of the burden is going to fall on the government.

    - Patient involvement only increases this need. Without the proper training, there will be a lack of trust in patients sharing personal information.
    - Small and large organizations do not have equal access to training, skills, and tools, and this should be taken into account.
    - Educational information is needed on the basic practices for secure software development, perhaps with references to what is being done in the industry today (e.g., EHRA Developer Code of Conduct). The rapid growth of new healthcare applications being developed by small organizations with little or no healthcare experience call for this kind of basic information.

  - **Action 2** – We need a better understanding of the objectives of this coordinated effort and what types of issues might arise.

  - **Action 3** – We would like to have a better understanding of ONC's vision on this. How does ONC see the information exchange occurring? What specific information is to be shared (e.g., known threats, attacks, vulnerabilities)?

    - How would this be impacted by existing HIPAA business associate agreements?
    - Would this include application and/or system vulnerabilities?
    - Would there be a process and time period to allow a vendor or system owner to address discovered vulnerabilities without public disclosure?

- **Action 5** – There needs to be a uniform approach to enforcing cybersecurity; however, we need a clearer scope:

  - Does this include unifying state-level regulations?
  - Patient/consumer devices commonly do not provide any level of security, including encryption of data at rest.
  - Mobile devices (smart phone/tablets) and applications used by patients usually provide very little or weak security features.

- **Page 57 – Category E2**

  - **Action 1** – We are confused by the statement that "at rest" standards for data encryption need to be developed. We suggest that the 2014 Edition criteria for encryption are already very clear and sufficient to ensure data is appropriately encrypted within a security framework. Furthermore, data at rest is outside the scope of interoperability, thus should not be addressed in this Roadmap.

    The decision to encrypt data at rest should be based on threat analysis. It is important to differentiate between data at rest on mobile and removable devices (i.e., high risk) and data at rest in fixed secured facilities (i.e., lower risk). In each case, the value of encryption as a security control is limited to providing protection from direct media access but provides little or no protection from improperly accessed applications or hacked user accounts.

  - **Action 2** – We are confused by the statement that "in transit" standards for data encryption need to be developed. The 2014 Edition criteria for encryption are already very clear and sufficient to ensure data is appropriately encrypted within a security framework. If, however, there are perceived gaps, those should be addressed explicitly to understand next steps towards a practical, robust security framework around interoperability.

  - **Action 3** – The industry would benefit from any guidance ONC has to offer. However, encryption is one of many security controls available and any additional guidance would need to be holistic in its approach to addressing the larger issue of cybersecurity.

Verifiable Identity and Authentication of All Participants

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

EHRA Response: *Privacy and security is a holistic process that has a broader scope than just interoperability, and ONC needs to clarify its intent. In addition, there are existing standards in the industry today, and any additional guidance or rulemaking should recognize the existing guidance, regulations, and standards in place to focus on what is missing.*

- **Page 59**

  - We are concerned with the approach taken to an identity proofing process that requires that at least one of the two forms of identification must be a government-issued form of identification. The examples used may not be available to all, or be in a category that has limited support (e.g., social security number). However, utilizing a national unique identifier or other privately- managed unique identifier should be considered part of the authentication process, as well as other methods consistently used in other industries.

  - We suggest that, in this context, exploring application of OMB's M-04-04 levels of assurance (LOA) is a worthwhile action to take and should be included in Table 6, along with exploration of alternatives that are more practical in a non-government environment.

- The phrase "all participants" would include systems and services, and would require verifiable identity and authentication. But, there are only detailed references to providers and patient authentication. We suggest that more details are needed.

Table 6: Critical Actions for Verifiable Identity and Authentication of All Participants

- **Page 61 – General**

  - This table should include an action to explore the use of unique identifiers and improved guidance around such – specifically, appropriate use of social security number (or at least last 4 digits) in context of HIPAA and other considerations, a path towards a national unique identifier specifically for healthcare, and promotion of alternate industry initiatives that enable unique identification and matching. While standardization and enhancements of various demographic fields enhance matching, on their own they will not yield substantial improvements.

- **Page 61 – Category F1**

  - **Action 1** – We agree that multi-factor authentication is a direction many industries are moving toward and provides increased security for authentication. However, there is concern that providers and patients would be resistant to using it (and systems requiring it) due to the increased burden and cost required to implement it. In general, we question whether the healthcare market is ready to broadly accept this technology.

  - **Action 2** – Harmonization of standards is needed; however, lacking is any reference to SSO standards so that providers and patients can use one set of credentials and provide seamless integration of services. More research and discussion is needed. In a learning health system, providing seamless integration implies that the role of user authentication is not an application-specific requirement (such an EHR), but a system-level requirement that relies on external authentication systems/standards such as an enterprise LDAP systems, SAML, OAuth 2, OpenID HEART, and others.

  - **Action 3** – For users to trust the provenance of data and to support seamless access, there is a need for national identifiers for all actors in the system. This includes patients and health IT systems. However, we recognize the concern that there will be public resistance to any new national identification system.

    - There is a need for a trusted e-authentication standard for all participants, but it would be unduly burdensome for any non-government system to provide level 2 or level 3 e-authentication as described in NIST SP 800-63-2. We recommend that ONC research other alternatives.

- **Page 61 – Category F2**

  - **Action 1** – A percentage of patients will be denied access to online health services due to the inability to afford a cell phone to use even simple SMS codes or smart phone applications that would be required.

  - **Action 2** – We suggest that minimally acceptable authentication methods must be agreed to for all types of data exchange, not just RESTful services, as the landscape of exchange methods will not be limited to RESTful, but rather will remain very diverse for the foreseeable future.

Consistent Representation of Permission to Collect, Share and Use Identifiable Health Information

- Accountability is noticeably absent from the Roadmap and we ask ONC to provide more detail on how accountability will work and be enforced.

- With the increased scope of access, ONC needs to clarify how audit controls and audit data will interoperate. For example, an entity allows patient data exchange using restful services across different external business entities as discrete data elements. How does ONC envision any one entity (or patient) to track access to patient data across external business entities and the level of detail?

- We recommend that privacy-handling policies focus first on organizational boundary transitions and recipient obligations for handling disclosure restrictions and accountability. Considering the granularity of internal organizational, departmental, or individual authorization to access privacy restricted information, this could come as a later phase while recognizing that individual health information management systems will continue to address these topics as applicable federal, state, or local policies or individual customer needs and expectations warrant.

Table 7: Critical Actions for Consistent Representation of Permission to Disclose Identifiable Health Information

- **Page 69 – Category G2**

  We are concerned that "basic choice" does not address the consent challenges for sharing sensitive data, including behavioral health data, substance abuse information, and HIV status, which creates a significant gap in a learning health system. (See Appendix, use case #56.) We recommend development of policy standards that recognize the distinct component processes of:

  - Capturing patient consent as an agreement between the patient and current/originating custodian that is easily understandable;
  - Conveying handling obligations derived from the consent in cross-organizational disclosures that does not put an undue burden on health IT developers;
  - Enforcing and respecting the obligations within receiving processes and systems; and
  - Addressing accountability practices for reporting the history of access to information subject to varying privacy restrictions

- **Page 69 – Category G5**

  - **Action 1** – We do agree that "basic choice" is a realistic starting point for the harmonization of technical standards since privacy obligations are linked closely to the concept of provenance and may be considered in a broader discussion of provenance metadata tracking.

Consistent Representation of Authorization to Access Health Information

- **Page 71**

  - Many important issues are discussed in this section, including what an entity is legally authorized to disclose and the role of existing technical standards. We agree that ONC and the Office of Civil Rights (OCR) should have discussions with all stakeholders to ensure that practical solutions are implemented to address authorization, consent, and disclosure rules.

Certification and Testing to Support Adoption and Optimization of Health IT Products and Services

ONC Question: In what ways can semantic interoperability be best tested? (e.g., C-CDA content and semantics)

EHRA Response: *Semantic interoperability is difficult to insure with current testing tools and the manual verification/certification processes using existing standards and guidance. Standards, implementation specifications and implementation guides must be refined for essential use cases using a set of defined*

minimal clinical data sets to reduce the implementation variability and provide consistent representations of data. Robust testing tools must be capable of adequately ensuring that minimal datasets can be both exchanged and incorporated into patient records to test semantic interoperability. Collaboration with SDOs and NIST must drive development of the testing tools which can be used to continuously monitor, test and validate conformance of the minimal data sets between systems. Testing can be accomplished using established endpoints capable of monitoring compliance with requirements for the exchange and the consumption of data. Semantic interoperability testing should occur throughout the development process, including implementation and beyond with the use of such robust tools; therefore, lessening the dependence on third party intervention or additional testing requirements during the testing process for certification.

Stakeholder Assurance that Health IT Is Interoperable

- **Page 75**

  - We strongly support the position that testing throughout the interoperability life cycle is an essential component. We would not consider IHE Connectathons a proxy for conformance or certification testing. Rather, they are an essential development step to arrive at an implementation guide that then requires existence of robust testing tools to continuously enable evaluation of conformance without another system present. This goal may be addressed by the IHE Conformity Assessment program.

  - As software developers, we are intimately familiar with the concepts and practices of continuous testing during health IT development, implementation, and post-implementation/use, as well as regression testing, negative testing, and other concepts. However, it is unclear what value independent verification/certification adds with strong third party-developed testing tools and plans and attestation requirements in place.

Table 9 – Critical Actions for Stakeholder Assurance that Health IT is Interoperable

- **Page 76 – Category I1 and I2**

  - **General** – The proposed testing and certification actions should not be considered substitutes for Connectathons, targeted pilots, and limited roll-out to prove the value of the interoperability in support of the targeted use case and enable comprehensive guidance and infrastructure that wide deployment requires. For example, the experience with the Direct project clearly identified that standards alone are not enough.

- **Page 76 – Category I1**

  - **Action 3** – Beyond calling on SDOs to develop and maintain these testing tools, we suggest to call on all health IT stakeholders seeking to develop testing tools, and SDOs seeking to develop standards and implementation guides, to forge strong relationships to enable test-drive development of implementation guides. We note that efforts where test developers are engaged from the start in the development of the implementation guides yield substantially better guides, testable guides, and better test tools. We encourage all standards developers to embrace this approach through each interoperability life cycle.

- **Page 76 – Category I2**

  - **General** - We strongly support the need for robust testing tools that can validate that interoperability occurs as expected. Unlike other functional capabilities, interoperability lends itself to automated testing tools to ensure the right data is communicated and the respective systems respond appropriately to various error conditions. In the absence of such tools, it is a very labor intensive effort to validate interoperability and testers are likely to make errors. To date, the testing tools used in ONC's certification processes are not yet robust enough to sufficiently test the necessary interoperability

scenarios. Connectathons are not a substitute for such testing, although they have become essential activities to improve on the standards and implementation guidance definitions before wide deployment.

As a result a lack of robust testing tools, unfortunately, certification by an independent third party today is not improving on the state of interoperability. Once the testing tools are more robust, such independent validation still would not add further to the quality of interoperability capabilities.

Consequently, we suggest that primarily focus be on the build out of robust testing tools to validate operational software on its adherence to the endorsed standards and implementation guides, while promoting Connectathons and other methods to validate the standards and implementation guides in their various development stages. With such tools available, and essential to enabling interoperability out of the box, certification should focus on a transparent attestation process where we can publish successful test execution and claim conformance, as well as monitoring actual implementations to assess areas of improvements through feedback loops.

We note that in all such actions, the scope needs to include both the sender/receiver, requesting/responding parties in the interoperability use case. Addressing only the EHR side of the equation will limit the ability to achieve successful interoperability.

- We suggest including an action to explore how to enable provider organizations to test interoperability, as many provider organizations have the ability to configure, adjust, enhance, and replace interoperability capabilities. We do not suggest that providers should only be able to utilize the basic, out-of-the-box interoperability capabilities to meet their objectives. Rather, they should have the ability to maintain consistency with the semantics and syntax used in these capabilities to enable transparent exchange regardless of the technique and method chosen.

Core Technical Standards and Functions

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

EHRA Response: *While recognizing that the proposed common clinical data set represents a mix of simple and complex data types, the scope implied provides a reasonable start to address standardization of vocabulary and structure, while defining the use cases that require the exchange of all or some of this data using a variety of techniques most suited for those use cases. As indicated earlier, we need to look both at the static exchange as well as the workflow management for certain data. Depending on the use case, a push, pull, or combination is most appropriate to yield the most value. Transport methods and APIs may range from Direct to messaging to service-based APIs.*

Considering that neither vocabulary nor structure are fully defined or harmonized, we believe that further standardization is necessary in all areas. For example, there are varying perspectives on what the appropriate data set is to capture smoking status. There is a lively debate on how to express allergies or the absence thereof. The capture and communication of unique device identifiers (UDIs) is starting to be understood, but clear guidance on how and when to communicate UDI is not fully defined yet. Immunizations can be communicated using a variety of standards and interpretations thereof. In short, all data in the common clinical data set requires substantial efforts to further harmonize and deploy.

- **Page 77**
  - **General –** This section closely relates to the Standards Advisory and could act as an introduction to that document. However, this link is not firmly established in the draft Roadmap, thus creating ambiguity as to how the two are to be tied together.
  - **General** – The definition for "Standards for Services" creates confusion as it appears to be mixing concepts. We suggest considering that services are not always the more generic mechanism to

exchange data. A message or service-based architecture could be deployed, and both will be present in the foreseeable future. To some, APIs encompass both approaches, while for others APIs are limited to service-based exchanges. The Roadmap must be inclusive of these variations. Perhaps the term "implementation technology standard" (ITS) reflects a more appropriate context, within which we can recognize the necessary ITS for messages vs. services.

We also suggest listing Transport Standards last as it better reflects the transition from vocabulary and content to the wire.

- **Page 80-81**

  - **General** – We are concerned that the header "Consistent Format: Consolidated Clinical Document Architecture (C-CDA)" implies that the only acceptable format to exchange any of the common clinical data set is the C-CDA. This approach appears to be further reinforced in the last paragraph of that section. We must recognize that, depending on the use case, different formats and content will be communicated. We do agree that at a minimum, regardless of the format, common vocabulary must be used to enable the same data to be communicated consistently, without variation in meaning, regardless of how it is communicated. Perhaps FHIR offers the opportunity to converge on a fully compatible data set. But until HL7 V2, HL7 V3 C-CDA, HL7 V3 SPL, X12, and NCPD SCRIPT, considered the primary transaction sets, converge on FHIR; that is not a realistic ten-year outlook. As we indicated in prior commentary, the focus cannot be on static data exchange only.

  - **General** – We recognize that variances in C-CDA interpretations and implementations have led to some situations where the receiving system did not display the human-readable section. We must consider both the implementation guide and testing tools to ensure that such situations cannot occur. While any lag in support for the most current version may yield challenges to fully consume the structured data set, it should never be acceptable that the human-readable section cannot be displayed. Such receiving systems should not be able to pass the test.

- **Page 81**

  - **General** – Regarding footnote 59, we suggest that it is not appropriate to suggest a new definition of vital signs as part of the Roadmap. Rather, we suggest this be considered in the context of the necessary standards and professional organizations where this vocabulary is used.

- **Page 82**

  - **General** – We are concerned with the statement that, over the long-term, document-centric ways of exchanging data will likely be overtaken by data-centric ways of exchanging data. Long before document-centric data exchange there was data-centric data exchange. The larger volume of data exchange today is not document-centric, but discrete data-centric using HL7 V2, NCPDP SCRIPT, and X12. With the advent of document-centric exchange, there was a belief among some that documents would overtake all. What has been demonstrated is that there is a need for both a document- and a data-centric capability to exchange data. Having a document-centric discharge summary that can persist as it was created is helpful for certain use cases, while being able to communicate the individual elements as-is or enriched with more data than the discharge summary otherwise provides is valuable as well. We have learned that both must be enabled, as neither can fully satisfy the variety of data exchanges we have experienced to date and likely will encounter in the future. Notwithstanding our concerns, the ONC discussion on this issue was thoughtful and recognizes the continuing need for use of document-based exchange.

Table 10: Critical Actions for Consistent Data Formats and Semantics

- **Page 84 – Category J1**

  - **General** – We appreciate the direction and role the Standards Advisory appears to take. We suggest that further clarity be provided about the anticipated relationship between the Standards Advisory and a certification edition. Is there a progression for standards to move from pilot, to limited roll-out, to Standards Advisory, to certification edition? If so, how are these transitions gated? Certainly, adoption rates of the standards/implementation guides in the Standards Advisory can serve to drive market adoption and readiness to endorse through a certification edition.

    We suggest that in that progression, there is value to also list emerging standards that are not yet mature enough to (pre-)adopt (Action 2), but that can mark progress and direction.

  - **Action 1** – We suggest that, wherever possible, the governance processes should reduce development efforts of overlapping/competing standards. While clearly there will be overlap as standards mature and new approaches emerge, concurrent development of standards that have to be harmonized is not productive use of our collective resources. We recognize that allowing for variant profiles to flourish has its advantages but, as HL7 V2 has demonstrated, attempting to converge on a common interpretation across very diverse implementations has been very challenging. The governance process must recognize when convergence has national value and start that process as early as possible, while leaving divergent capabilities for market-driven solutions above and beyond the basic, out-of-the-box interoperability capabilities

  - **Action 3** – It is unclear why C-CDA R2 is called out specifically here, while other standards are not, although those also address various data in the common clinical data set. We suggest that the focus of the action should be on the use cases to which the Standards Advisory standards/implementation guides apply; and that a software developer intends to support; and that are indicated to be sufficiently mature; and that software developers plan to adopt those standards and make their support available to enable basic, out-of-the-box interoperability for that use case. There is no reason to single out C-CDA.

- **Page 84 – Category J2**

  - **General** – We are challenged to respond to this category on Architecture in Support of Standards Activities as is it not clear what type of architecture is being referenced. Is it the technical architecture, such as what the implementation technology should look like? In that case, it seems more appropriate in categories K and/or L. Or is it more focused on the governance process and framework to manage use cases, supporting standards/implementation guides, pilots, etc. (i.e., the interoperability life cycle's architecture of which standards activities are but one component)? We suggest this category requires more discussion and refinement.

- **Page 85 – Category J3**

  - **Action 1-7** – These include specific capabilities that are workflow focused. We support those, but in context of our prior comments.

    We suggest that once the use cases have been prioritized, these actions be revisited and adjusted. We suggest this may then be structured along the following lines:

    - Health IT developers, SDOs, and ONC will focus on updated semantic standards and associated testing tools, focusing first on:
      - Standards for use case 1
      - Standards for use case 2
      - Standards for use case 3

- Pilot the interoperability of common clinical data set elements with:
  - Clinical content management systems (so, EHR, PHR, …)
  - Research systems
  - Clinical trial communities
  - Public health and other clinical content analytical systems

- **Action 4** – We suggest that this action is beyond the scope of interoperability and should be addressed in the context of general functional capabilities of health IT outside this Roadmap.

- **Page 85 – Category J4 – J5**

  - **General** – We would like to note the absence of the NLM Value Set Authority Center (VSAC) as a critical stakeholder to facilitate a single source of vocabulary definitions.

- **Page 86 – Category J6**

  - **General** – This category seems to be redundant with all the other categories and statements that already addressed this. We suggest removing this category.

Consistent, Secure Transport Techniques

- **Page 88**

  - We strongly support the proposal to modularize requirements for transport separate from content. This approach will help enable communicating the same content using different transport methods depending on the use case, without having to adjust the content, thus creating consistency of interpretation and reducing variability.

Table 12: Critical Actions for Consistent, Secure Transport Techniques

- **Page 90 – Category L1**

  - **Action 1** – We suggest that identification of transport mechanism should be a collaboration among stakeholders rather than one party, ONC, unilaterally identifying transport standards.

- **Page 90 – Category L2**

  - Action 2 – It seems that this action is a potential example of L1 Action 1 and perhaps should be listed as an example under that action.

- **Page 90 – Category L2/L3**

  - **General** – We suggest re-defining Category L2 as Send/Receive and L3 as Query/Response, and perhaps have new category of Publish/Subscribe. The suggested actions do not seem to fit very well the current category definitions. For example, the Publish/Subscribe related actions do not fit the description of "Receive and Find".

- **Page 90 – Category L3**

  - **Action 2** – It is unclear what use cases stand to benefit from a publish/subscribe capability. While there are clear situations where publish/subscribe is a suitable approach, it is not necessarily suitable across the board as this call for action may imply.

Accurate Individual Data Matching

ONC Question: Do you believe the approach proposed for Accurate Individual Data Matching will sufficiently address the industry needs and address current barriers?

> ***EHRA Response:*** *While the proposed attributes and associated standard formatting are expected to improve the ability to match patient data, the lack of use of a (partial) unique patient identifier to substantially improve matching probability and quality remains glaring. Technology can contribute somewhat to standardization, but not to the accuracy of what are essentially text fields. We point to the RAND report, "*Identity Crisis? Approaches to patient identification in a National Health information Network", *which clearly demonstrated that inclusion of the last four digits of the social security number yielded substantial improvements in matching. We suggest that ONC explore further clarification on the appropriate use of such unique identifiers.*
>
> *Pursuing such a path will also help reduce ambiguity that the proposed fields raise. For example, how many historical phone numbers and addresses should one be able to maintain and communicate? Should these be sent with every transaction as part of every discharge summary or other document type? Furthermore, inclusion of these elements increases the requirements on administrative processes and staff to improve their accuracy to collect and maintain more data used in matching, while collecting and maintaining the current set is already a challenge.*

Table 13: Critical Actions for Accurate Individual Data Matching

Reliable Resource Location

Table 14: Critical Actions for Reliable Resource Location

- **Page 100**
  - **General** – We are concerned that everything is front-loaded in 2015-2017. We suggest that the initial focus should be on establishing provider directories to enable interoperability such as Direct. While that is being completed, progress can be made in exploring how to enable patient addressing to ensure that communication with patients can occur in a secure environment. Subsequently, as service-based APIs emerge, we can explore opportunities for service registries.

Tracking Progress and Measuring Success

In response to the ONC questions below, we believe that measurements are essential to understand progress toward success. However, we suggest that interoperability measures must be developed in support of understanding progress of the use case measurements. For example, if the use case is "reduction in readmission rates" (as a proxy for improved outcomes), then re-admission rate is the primary measure, while interoperability measurements can help understand to which interoperability contributes to its improvement.

We support development of appropriate interoperability measures and are ready to work with ONC to define a practical core set on which providers and software developers can report.