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**Re: Request for Public Comment on Connecting Health and Care for the Nation
A Shared Nationwide Interoperability Roadmap DRAFT Version 1.0 (released January 30, 2015)**

Dear Dr. DeSalvo:

Ascension appreciates the opportunity to comment on the Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap draft version 1.0, released by the Office of the National Coordinator (ONC) for Health Information Technology on January 30, 2015.

Ascension is transforming healthcare by providing the highest quality care to all, with special attention to the poor and vulnerable. Ascension, the largest Catholic and non-profit health system in the United States, provided \$1.8 billion in care of persons living in poverty and other community benefit programs last year. Our mission-focused Health Ministries employ more than 150,000 associates serving in more than 1,900 sites of care in 23 states and the District of Columbia. Our system represents a microcosm of the national healthcare delivery system with urban teaching hospitals, suburban community hospitals and rural critical access hospitals (CAHs) plus skilled nursing and long-term care facilities, behavioral health facilities and ambulatory clinics.

Our organization has made a commitment to a long-term vision of a sustainable, high-quality health system to serve individuals throughout their lifetime. We joined with key healthcare stakeholders from the insurance, hospital, physician, business and consumer sectors (America's Health Insurance Plans (AHIP), Families USA, the National Coalition on Health Care, and the Pacific Business Group on Health) to form the Partnership for Sustainable Health Care, working together to reach consensus about what is needed to control costs and improve quality. Our recommendations may be accessed at: <http://www.rwjf.org/content/dam/farm/reports/reports/2013/rwjf405432>.

General Comments

We support the ambition of the draft Interoperability Roadmap ("Roadmap") to advance a shared vision of a national interoperability framework as well as business and functional requirements, including adoption of specific vocabularies, document types and transport mechanisms to be used when sending or receiving data. We also appreciate ONC's approach to define long-term objectives with "near-term wins" centered on 10 Principles of Interoperability.

In order for these transformation goals to be realized, they must be backed by specific, concrete action steps and measurable milestones. The Roadmap is both very specific, such as its identification of discrete data elements or building blocks to interoperability, and noticeably vague, such as in process steps and timelines. We ask ONC to provide more detail around how its goals will be met and measured, specific activities (particularly related to "mid-term" milestones — the critical "white

space” between its long-term objectives and “near-term wins”), expected timelines for completing activities, and assessing whether there are sufficient federal resources to achieve all outlined goals.

Accountability and transparency should be evident for every milestone. Examples of mid-term milestones might include, for example, fully implemented data encryption for data both in transit and at rest; expanded adoption and use of audit logs beyond EHRs; and a shift from basic interfaces as the mode of data exchange to open and public access that allows systems to securely interoperate, such as utilizing standard Application Programming Interfaces (APIs).

In addition, we ask ONC to carefully consider the adoption timeline for its “near-term wins.” As the industry learned from Meaningful Use and ICD-10 implementation, particularly Meaningful Use Stage 2 and 2014 Edition EHR certification, implementation and adoption of new standards simply take time and maturity. We have collectively learned during the past four years that Certified EHR Technology (CEHRT) deployed in dynamic clinical settings do not always mirror the laboratory testing environment of the ONC Certification Program. The American Medical Association (AMA) in collaboration with 35 other professional physician organizations recently outlined in a joint letter to ONC the issues with the EHR certification program. They noted that the certification program’s disconnect from real-life implementation can result in “medical record errors, inaccurate documentation, lack of interoperability, slow performance, lost patient information, and safety concerns” in practice. We strongly encourage ONC to include milestones in the Roadmap that advance rigorous real-life, scenario-based testing of the standards against real-life certification scripts.

While we favor an aggressive move toward standardized data and implementation specifications, the industry will be challenged to meet some of the specified timeframes in the Roadmap, particularly where the common data set differs from the core Meaningful Use data set. A direct outcome of trying to do too much too soon will be the vendors producing marginally acceptable applications or products that will require providers to invest in costly re-work and potential patient safety implications.

Regulations will need to be developed. Software developers will need to understand the new requirements and build them into legacy and new product offerings. New testing must emphasize real-life scenarios and those identified issues need to have time allocated upfront for vendors to fix those as a priority before supporting secondary uses (such as research).

Additionally, the testing and certification processes will need to be developed and matured. Providers will need to procure, adopt, test and implement new technologies while competing for limited vendor resources to install, implement and train staff. The implementation requirements will be particularly challenging at a time when financial incentive dollars to support adoption have ended and providers along the continuum of care (such as skilled nursing facilities, community based organizations, laboratories, public health agencies) continue to have little incentive and few resources to adopt new technologies. The Roadmap should define requirements and incentives for all longitudinal care venues to ensure the success of interoperability.

On a separate but related note, we appreciate the inclusion of consumer access to their personal health data and empowerment of family / caregivers in the draft Roadmap. Ascension firmly believes that hospitals and other care providers are trusted stewards of a patient’s data and the patient’s access and use of their data is important for their engagement in care. We urge ONC to provide more specific information on consumer milestones (beyond protection of data) and how it sees both the federal government and the private sector advancing this goal. We encourage ONC to include milestones in the Roadmap that advance rigorous real-life patient engagement scenarios and ensure their use in testing of the standards against real-life certification scripts.

We also note that medical device interoperability is not addressed in the Roadmap. While there is much to be accomplished on that journey, the nation’s Roadmap to healthcare interoperability over a 10+ year time frame would be well served to contemplate a path forward.

Finally, we urge ONC and its colleagues across federal agencies to view all of the objectives outlined in the draft Roadmap with an eye toward clinical value and patient value. Health IT must be viewed as a tool to advance clinical care and patient wellness and engagement. Interoperability for the sake of exchanging data elements should not be our goal — interoperability for the sake of improving clinician and patient ability to make informed decisions at the point of care must be the end game and be measurable.

We have organized our comments around specific Roadmap sections or issue areas and questions raised therein, as requested:

Priority Use Cases

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.*

Response: We have identified the following three priority use cases (#5, #8, #18):

- # 5.** Population health measurement is supported at the community level and includes data from all relevant sources on each patient in the population and is accessible to providers and other stakeholders focused on improving health.
- # 8.** CEHRT should be required to provide standardized data export and import capabilities to enable providers to change software vendors.

In many ways, use cases #5 and #8, as currently outlined in Appendix H, are two sides of the same coin and both are critical to support population health and value-based healthcare efforts. Interoperability is more than just sharing information. To achieve the promise of interoperability, it is important to understand from where data is being drawn, to what systems it is being shared and how it will be used.

Population health management requires tools beyond EHRs, as the data needed to provide actionable information and to support care management comes from multiple sources, such as (but not limited to) community organizations, patient-generated health data, public health agencies, lab and imaging data, pharmacy data, ADT feeds, etc. In addition, new technology adoption including mobile applications and technologies aligned with personal health management applications need to be considered. Achieving interoperability across all these sources of data and information technology (IT) systems will be challenging — if not impossible — if everyone is speaking a different language. Universal data vocabulary and transport standards are essential as are implementation specifications.

While IT in and of itself will not drive the changes in practice and measurement of outcomes needed to support value-based care delivery, it provides the foundational support and data needed to enable workflow and culture changes. Without universally adopted standards, our system will continue to be hamstrung.

- #18.** Patients have the ability to access their holistic longitudinal health record when and where needed.

Too often today, a patient's medical record is episode-based, provider-centric and incomplete. Our clinical leadership has identified a patient-based, longitudinal record of wellness and care, with structured data as being a critical component of care transformation — both in terms of value-based care delivery and patient and care giver engagement. Most of the data elements to a patient's ongoing medical healthcare needs are universal (problem lists, medication history, lab and imaging test results, and care plans). As an industry, we waste billions of dollars in recreating this information

in episodic silos, and worse, despite best efforts, at times jeopardize patient safety because of incomplete medical information. Being able to analyze (with appropriate privacy and consent protections) longitudinal data also advances evidence-based protocols and research. Thus, ensuring seamless transfer of data between providers is crucial.

However, it is equally if not more important, that patients be able to access their personal health information when and where needed. Patients need to be empowered to make educated, informed decisions about their care and to be able to share their data with care givers and other providers, such as behavioral health or long term service and community based support organizations, at their own discretion. To have a complete picture of their health and wellness, patients also need longitudinal records, not isolated visit — or admission — only snapshots. Further, consumers are adopting and using innovative technologies at a far more rapid pace than their care providers are. The widespread adoption of mobile technologies and tablets combined with the growing availability of wearable sensors and biometric devices point to a need for the patient-facing components of our interoperability plan to evolve beyond a series of siloed, individual-provider operated patient portals.

Core Technical Standards and Functions

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

Response: With regard to specific data elements, we recommend further standardization for the medication allergies requirement of the common clinical data set. In current practice, a medication allergy often is indiscernible from a food or environmental allergy in many EHR configurations. In these cases, all allergy information is pulled into the same field in the C-CDA. While we support having fields available for other known allergies as this information can be valuable and extremely important for patients, in clinical practice it is not optimal to have medication allergies intermixed with other allergy comments.

We also note that in order for the common clinical data set to advance interoperability, the wide variability in interpretation and implementation of standards and implementation specifications by different vendors as well as amongst providers must be addressed and specific action steps be included in the next version of the Roadmap.

In most cases, the common clinical data set proposed will be used in a summary document. The data set outlined in the Roadmap includes 19 data fields; the C-CDA does not currently handle data versioning and data correction in the case of errors requiring manual intervention. As data from EHRs is used more widely for care coordination and population health efforts, the potential for patient harm is increasing significantly. We are concerned that the Roadmap does not go far enough in defining the action steps and near-term, intermediate and long-term milestones that will move the industry from an identified need for data standards to viable, trustworthy data exchange. In addition we must not forget that the data terminology standards that will enable successful patient engagement are not necessarily the same as those utilized by providers and the roadmap should recognize and enable the development of the tools for accurate translation to standards that will meet engagement goals.

Additionally, we recommend the Roadmap recognize the need for both public and private section initiatives to be more nimble in their responsiveness to standards updates as well as for the stewards of adopted standards to issue timely updates.

Perhaps most importantly, we strongly urge CMS and ONC to empower clinical discretion in sharing any information with referring providers or other institutions at a care transition. We support the advancement and adoption of universal data standards for the fields identified as part of the common data set, and agree that strict adherence to those standards and common implementation will foster a greater degree of interoperability. However, regulating use of each of those fields in every care transition we believe will be counter to the agencies' goals in the long run. In order for summary of care documentation to be relevant at a point in care, the receiving provider needs to quickly access

information that is of value to them and to the particular patient situation. A 25 page C-CDA, which is often the output among current Meaningful Use Stage 2 participants, is not clinically valuable. That said, we support the addition of a narrative field in the C-CDA (or other summary of care documents) that allow providers to emphasize significant events and/or provide a brief narrative summary or snapshot of a patient's health status and reason for transition.

To achieve this, EHR functionality is required that will allow providers to customize the summary of care transmission, even while allowing the option — because the data is standardized — to populate all fields.

Accurate Individual Data Matching

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

Response: Ascension strongly concurs with the American Hospital Association (AHA) and other industry experts who believe that progress in this area also relies on solving the problem of correctly matching patients to their records, as well as other methods to accurately authenticate information across data sources. We join AHA in urging ONC to build on the work it started in 2014 to make progress on patient matching. As the largest community hospital system in the country, we can provide specific examples at a local, regional and national level of how critical a patient matching solution is to advancing the goals outlined in both the draft ONC Strategic Plan and the draft Interoperability Roadmap.

We support the inclusion of identity matching in the Roadmap and believe that ONC has appropriately categorized key barriers, but note that this objective needs to be more specifically described with milestones, process steps and timeframes. The report addresses some policy challenges ahead while failing to outline a measurable action plan to address them. In particular, the Roadmap does not address how efforts under the Roadmap will interact with all of the existing state, regional and enterprise HIE efforts currently underway; each developing its own workaround in the absence of a unique or national patient identifier, nor does it take into account the variability in patient consent regulations.

We support the data elements listed in the Roadmap as the starting point for standardization as one prong of an identity matching approach but stress that data elements alone cannot solve the patient matching problem.

With regard to the specific data elements listed, we note that historical data (including addresses and phone) are not currently easy to capture and store. Most office management, patient registration and/or EHRs impose strict limits on the number of entries that can be stored and queried, some limiting the data entry to current information only. Further, patients often cannot recall multiple past addresses and many patients do not have a home phone number — often one of the key challenges for matching patient records is patients who are transient or move frequently. Consideration will need to be given to the limitations in current IT systems related to historical contact information and how a query would functionally work in operations to aid patient matching efforts.

Certification and Testing

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

Response: Semantic interoperability is critical in facilitating healthcare delivery transformation and we fully support inclusion of enhanced testing in the Roadmap. We recommend ONC evaluate facilitating semantic interoperability testing by building on the EHR Randomizer tool currently used in the CEHRT program. ONC should evaluate increasing both the number of vendors and the types of

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end-user systems that utilize the tool as well as the provider types asked to submit test data related to patient continuum of care scenarios.

Further, we recommend a “cycle” based approach to testing, similar to the approach employed by CMS for ICD-10 end-to-end testing initiatives, which involve multiple user groups such as intermediaries, clearing houses, payers, providers, DME, etc.

Measurement and Evaluation

The Roadmap references its vision as “By 2024, individuals, care providers, communities and researchers should have an array of interoperable health IT products and services that support continuous learning and improved health. This “learning health system” should also result in lower health care costs (by identifying and reducing waste), improved population health, truly empowered consumers and ongoing technological innovation.”

The Roadmap also refers to five goals outlined in the draft Federal Health It Strategic Plan 2015-2020 and objectives defined in “Connecting Health and Care for the Nation: A 10-Year Vision to Achieve an Interoperable Health IT Infrastructure (ONC’s 10-Year Interoperability Concept Paper).

The result is a broad set of ambitions that are difficult to express in terms of measureable goals and milestones. However, the visions commonly point to information exchange across a continuum of providers and settings. We are concerned that the near-term actions identified in the Roadmap largely center around data elements for capture in an EHR and the discussion of interoperability in the Roadmap stems from EHR-based data exchange.

The reality, post health reform and in a value-based delivery model driven healthcare system, is that providers, payers, researchers and patients use multiple technologies to support care delivery. Interoperability should be considered, measured and evaluated in terms of context and collaboration to support care across systems, not simply “interface-ability.” While the capacity to exchange summary of care documents at transitions in care is important and Meaningful Use provides a starting point for data collection, EHR-based data exchange is not sufficient to portray the state of interoperability in our healthcare system.

Measurement should reflect a broader picture of how data is being exchanged and used, including efforts in case management, public health, regional and state registry advancements, ADT and pharmacy data feeds being used by integrated delivery systems to identify gaps in care, remote patient monitoring and patient data sharing around chronic disease management.

Ascension appreciates the opportunity to share our comments. Ascension leadership offers its diverse health IT experience within multiple care settings as a resource and partner in your efforts to advance a federal health IT strategy. Please let us know if we can offer any additional assistance. We would welcome the opportunity to meet with you to further discuss our comments.



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