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April 3, 2015

Karen B. DeSalvo, MD, MPH, MSc
National Coordinator for Health Information Technology
Office of the National Coordinator for Health
Information Technology (ONC)
Hubert H. Humphrey Building
Suite 729D
200 Independence Ave, SW
Washington, DC 20201

RE: *Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap Draft Version 1.0*

Dear Dr. DeSalvo:

The Academy of Nutrition and Dietetics (the "Academy") appreciates the opportunity to submit comments on *Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap Draft Version 1.0.* With over 75,000 members comprised of registered dietitian nutritionists (RDNs)[1] dietetic technicians, registered (DTRs), and advanced-degree nutritionists, the Academy is the largest association of food and nutrition professionals in the United States committed to improving the nation's health through food and nutrition across the lifecycle. While not considered as an Eligible Professional (EP) in the EHR Meaningful Use program, the Academy has been an active participant in the policy, standards and vocabulary proceedings, as evidenced by the following:

- Academy representation and comment at both the Health Information Technology (HIT) Policy and HIT Standards Committee Meetings since they began in Summer 2009
- Participation in the ONC Standards and Interoperability Framework's Initiatives since its inception in 2011
- Development of nutrition-related content in relevant health information technology standards within Health Level Seven (HL7)
- Contribution of resources to integrate nutrition care into ONC identified clinical terminologies and HIT standards on an accelerated timeline to promote industry adoption and use

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[1] The Academy recently approved the optional use of the credential "registered dietitian nutritionist (RDN)" by "registered dietitians (RDs)" to more accurately convey who they are and what they do as the nation's food and nutrition experts. The RD and RDN credentials have identical meanings and legal trademark definitions.

- Organizational level Commitment for the ONC Blue Button Pledge

The Academy's members are highly committed to improving care through direct nutrition evaluation and care using the Academy's Nutrition Care Process[2] across the care continuum, through education, interventions at the local, state, and national levels; as researchers and educators; as corporate dietitians supplying products or services to foodservice operations; as consultants in nutrition and wellness; and as systems analysts for EHR vendors and health care facilities.

We appreciate this opportunity to comment on the first draft of the Interoperability Roadmap and look forward to the shared goals which support the nations learning health system. We also appreciate the ONC leadership as the United States health care system implements policies using a common set of health information technology standards, tools and terminologies. We have provided the following comments according the questions posed by ONC. Please contact either Jeanne Blankenship, MS, RDN or Lindsey Hoggle, MS, RDN, PMP at (202) 775-8277 for questions and/or comments.

Sincerely,

Jeanne Blankenship, MS, RDN
Vice President, Policy Initiatives and Advocacy
Academy of Nutrition and Dietetics

Lindsey Hoggle, MS, RDN, PMP
Director, Nutrition Informatics
Academy of Nutrition and Dietetics

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[2] Nutrition Care Process (NCP) is a systematic process for identifying, planning for, and meeting nutritional needs to provide high quality care. It includes four interrelated steps: Nutrition Assessment, Nutrition Diagnosis, Nutrition Intervention, and Nutrition Monitoring and Evaluation. [Nutrition Care Process, http://www.eatrightpro.org/resources/practice/nutrition-care-process, accessed April 3, 2015.

General

I. 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?

This *Interoperability Roadmap* provides many necessary actions for nationwide sharing of appropriate health information being available for patient centric decisions and goals. While a learning health system focus has been in existence for several years, more focus on how the learning health system depends upon consistent interoperability across health settings is needed. Patients and treatment team members need additional guidance on expectations and diverse tools which allow for affordable business cases.

In developing the Interoperability Roadmap, the ONC quite appropriately recognizes how financial incentives can be leveraged to drive health information technology (HIT) adoption by health care providers to help achieve the Triple Aim. As short-term and long-term actions are defined, several key points should be considered. While the ONC to some extent recognizes these issues as evidenced by content in the Roadmap (specifically guiding principle #7), we think they are worthy of emphasis:

- Current federal efforts to incentive adoption of HIT are physician- and hospital-centric. While this focus is understandable considering the proportion of health care delivery and spending provided by these entities--as ONC acknowledges--there is a much broader health care eco-system. Interoperability is necessary among all parties within this broad eco-system in order to achieve the vision set forth by the ONC. Therefore, incentive programs aimed at driving adoption of HIT (whether public or private) must be made available to all providers, ranging from individual providers to large health systems, in a fair and equitable manner. It is reasonable to make addressing the needs of the broader eco-system a long-term versus a short term focus, but these needs must be addressed.

- If government payers are going to require health IT adoption and interoperability, funding options to support such efforts must be made to all health care providers. Allied health professionals such as registered dietitian nutritionists play an equally important role in a person's health and meeting the Triple Aim.

- As noted by the ONC, interoperability must increase/strengthen before payment based on shared accountability is implemented. Advances/changes in payment and technology must move in unison.

- Providers who desire to provider services in a "connected" world but don't have the resources to achieve interoperability should not be penalized. If payment models are not carefully designed and their roll-out carefully considered the unintended consequence will be driving providers who deliver quality services out of the health care market.

- Caution should be exercised when considering tying provider credentialing with health IT adoption and interoperability. For the reasons noted above, such practices, if not carefully designed and timed, could put providers out of business and/or limit consumer access to providers who deliver high quality care but have resource limitations. In the same vein, private payers should not drive consumers to providers who have adopted IT and achieved interoperability without first ensuring that all providers (large and small) had fair opportunity (time, resources) to do so. As already noted, providers should not be penalized for a lack of resources when it is beyond their reasonable control.

- IT adoption and interoperability do not, in and of themselves, result in better care that is worthy of payment. As payment systems evolve to incorporate elements based on interoperability, the concept of "meaningful use" is critical. Access to information in and of itself does not directly equate to better quality care. It is wise and appropriate use of the information to develop and effectively implement a plan of care that has the potential to lead to better outcomes and wise use of resources.

- Looking at the needs of small providers and organizations, a potential action step on the part of private payers would be to help support such "small businesses" with IT resources, similar to how many now provide embedded case managers in primary care practices.

- Payments that recognize coordination of care should not be limited to certain provider types. For example, the CCM services notes in the Roadmap currently are limited to payment to primary care providers (PCPs). While PCPs certainly play a major role in coordinating care, other members of the care team often take the lead in coordinating care for specific patients and/or situations. A registered dietitian nutritionist, for example, may coordinate many aspects of care for an adult or pediatric patient receiving a home tube feeding. If we are to truly embrace the concept of extended care-teams and a "community of care," all providers within that "community" should have equal opportunity for financial rewards/penalties.

- Actions need to be included in the Roadmap that speak to coordination of payment policies between public and private payers. Just as CMS has made strides in coordinating its incentive programs, similar coordination needs to happen across payers. It is challenging, to say the least, for providers of any size to effectively operate within multiple payment systems with differing requirements.

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

We believe the following are gaps need stronger incentives, best practices, and/or guidance in order to realize their potential for interoperability.

Patient Generated Data

The use of patient-generated data needs guidance and boundaries. If more care is to be delivered as patients "age in place", usable summaries of specific data should be included in the electronic health systems. As with other areas of data entry, there should be a reasonable standard for data provenance. Actionable data provided by patients and/or caregivers should be aligned with patient care plans, goals, concerns and interventions developed in collaboration of the patient. Until there is an array of specific data submitted by the patient –and agreed to acceptance by patient providers, health care professionals will continue to be overwhelmed with the possibility of receiving "too much data". At present providers and health care facilities have understandable liability concerns associated with the inability to review endless patient generated data streams. Until there is further guidance and standardization on what is accepted, use of patient-generated data will not be part of a learning health system.

Potential third party management of patient-generated Data Delivery

Patient monitoring tools and applications have an established market as patients/consumers utilize devices to track their sleep, caloric intake and expenditure and physical activity. In addition, third parties such as Validic[3] and Continua Alliance[4] are serving as third parties to assist with management and sharing data usefully so that health and health care quality can be optimized. Innovative models for patient-provider goal setting and monitoring are evolving. Such models allow for and support the concept of promoting health care between care episodes. Patients in a learning health system need to understand the expectations associated with their interventions and goals, utilize the health behaviors necessary to manage their goals and "own" their decisions which best address their conditions. At present, patients typically have options presented to them in brief snapshots in time and rarely have an evidence-based overview of actionable choices for disease management. Encouraging full analysis of both treatment options and side effects of treatment over time is necessary for longitudinal management of chronic conditions. An example of this model is that a newly diagnosed hypertensive, overweight male should understand the treatment choices – medication (including the full likelihood of side effects) and the well-established impact of moderate weight loss via behavioral changes on hypertension.

Common Clinical Data Set

We support the use of a Common Clinical Data Set where the data represents a collective snapshot of critical key areas of health. We have requested use of "allergies and intolerances" rather than

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[3] https://validic.com/
[4] http://www.continuaalliance.org/

"medication allergies". Consistent, patient-friendly terminology should be used such that patients report a "list" of allergies –with relevant metadata and also substances that identify personal intolerances and preferences. The Academy of Nutrition and Dietetics has supported the development of the Health Level Seven (HL7) Allergies and Intolerances draft standard for trial use (DSTU) such that there is a standardized method of reporting food, medication and environmental allergens and intolerances.

We request that the following data be included in the Common Clinical Data Set:

- **Nutrition/Diet Orders** have developed by the Academy to provide foundational guidance for a consistent documentation of nutrition orders within HL7 Version 3 Domain Analysis Model: Diet and Nutrition Orders, Release 2[5], Version 3 Nutrition Orders Clinical Messages, Version 3 Food and Medication Preferences and Fast Healthcare Interoperability Resources Nutrition Orders (proposal)[6].

- **Social Determinants of Health** should include functional, social, economic elements which should be factored into goals and overall patient decisions.

- **Patient Goals** should be generated by team insight and recommendation and patient response to clinical decision support options.

- **Instructions related to goals** Recent publication of the HL7 Consolidated Clinical Document Architecture Release 2.0 provides related functional, social, and between-care aspects that should be documented.

- **Notes/Narrative** Further clarification is needed to limit the extensive possibilities of notes and narrative content to include. Guidance as to "most recent visit" narrative, summary narrative and/or goal related narrative should be provided. In many cases, the decision on what data to be sent via summary documents is made by technical personnel rather than clinical personnel. This often results in an overwhelmingly lengthy narrative discourse that is not read during the complex, brief episode of care.

3. Is the timing of specific actions appropriate?

The timeline of the Meaningful Use Program has been overly ambitious, however an important factor in holding to the goals of an improved health care system, has been the timeline modifications made to the timeline. Such adjustments should be considered based upon the progress of implementation and are necessary to assure that speed of implementation not hamper the usefulness or safety involved with use of health information systems.

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[5] http://www.hl7.org/implement/standards/product_brief.cfm?product_id=289
[6] http://wiki.hl7.org/index.php?title=Nutrition_Management

4. Are the right actors/stakeholders associated with critical actions?

In reality, every individual in the United States is impacted by the work described in the Interoperability Roadmap, be they consumers or providers of health care. An important component of interoperability success is based upon the realization by all Americans that they have a role in their own care (as consumers) and the care of others (any health care provider). The message that health care can improve with a gentle balance of empowerment and shared decision making needs to be communicated consistently across care settings. The Academy of Nutrition and Dietetics has supported the development of nutrition related health IT standards and terminologies within the guidelines of certification criteria and regulations. All professional organizations of health care providers must be aware of and respond to the call for interoperability.

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

We recommend grouping like use cases based upon the scope of each use case, rather than focus on single specific use cases.   We grouped use cases into three categories indicated below. We also recommend considering use cases related to complex management of multiple chronic diseases.
In particular, the following use cases represent the best overall application of a learning health systems and interoperability:

- **Patient Generated Data**

(7) Individuals integrate data from their health records into mobile apps and tools that enable them to better set and meet their own health goals.

(14) Patients routinely engage in healthcare encounters using electronic communications such as eVisits and telemedicine.

(20) Patients, families and caregivers are able to use their personal devices such as smartphones, home BP cuffs, glucometers and scales to routinely contribute data to their longitudinal health records and use it or make it available to providers to support decision-making.

(26) Individuals integrate data from their health records into apps and tools that enable them to better set and meet their own health goals

(36) Individuals integrate data from their health records into apps and tools that enable them to better set and meet their own health goals

- **Transitions of Care**

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

(6) Providers and their support staff should be able to track all orders, including those leaving their own organization and EHR, to completion.

(33) Providers have the ability to query data from other sources in support of care coordination (patient generated, other providers, etc.) regardless of geography or what network it resides in

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

(40) Hospitals automatically send an electronic notification and care summary to primary care providers when their patients are discharged

(42) Providers can query or access case management information about patients' care in outside organizations

(43) System users have access to provider directory information that is developed to support healthcare communications as well as other use cases

- **Consistent Implementation of Health IT Standards and Terminologies (Administrative and Clinical)**

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

(24) Benefits communication needs to be standardized and made available on all plans through HIT to providers and patients as they make health and healthcare decisions, in a workflow convenient to the decision-making process.

(35) Individuals have electronic access to an aggregated view of their health information including their immunization history

(15) Researchers are able to use de-identified clinical and claims data from multiple sources with robust identity integrity.

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

Please continue to include those with health care responsibilities outside the typical physician and nurse-related care, including but not limited to nutrition, physical therapy, occupational therapy, and speech and language therapy. It would be helpful to provide examples of consumer centric, team-based models for recognition and duplication.

IV. Supportive Business, Cultural, Clinical and Regulatory 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?

We concur that inclusion of data exchange and use should be aligned with federal policies that require use of standards. Certification of EHRs should be completed in such a way that systems must demonstration functional and regression testing, rather than the present unit based approached to EHR testing. Health plans and purchasers must embrace sustainable models that discourage duplication of tests and other procedures when previous results and data should be utilized.

V. Privacy and Security Protections for Health Information What security aspects of RESTful services need to be addressed in a standardized manner?

The privacy and security components and practices that are necessary to protect health data must be standardized and communicated in such a fashion that providers understand key critical requirements. Lay terms with simple definitions need to be used where non-technical users are involved in order to prevent a "weakest link" component to privacy and security. It would be helpful for ONC, the Office of Civil Rights or other appropriate parties to clarify HIPAA as it relates to Accountable Care Organizations and other multi-stakeholder entities, as well as mobile technologies/applications. Individual providers need to understand and apply privacy and security in a manner that is not cost prohibitive.

VI. Core Technical Standards and Functions

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

- Rather than separate medication allergies from food and allergies, we recommend consumer friendly terms which bring all allergies and intolerances into one list. We have participated in the development of the HL7 Allergy and Intolerance model.[7] Several government agencies are involved in this development but terminology bindings have not yet been harmonized. Reconciliation and standardization across all settings is necessary for the safe and effective documentation of all allergies and intolerances.
- A Nutrition/Diet Order baseline should be listed for all individuals in summary and transition of care documents. Please see HL7 work referenced in this document.

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[7]http://wiki.hl7.org/index.php?title=Allergy_%26_Intolerance

- Class of Information: functional status – being able to walk, swallow, ability to deal with environment – has an impact on nutritional status downstream.
- Provider visit: Can you ambulate? Can you swallow? Hearing? Feed self? Look in NCP – many terms. FUNCTIONAL Status should be part of Clinical Data set? Focus on team work. SAFETY – Should be part of clinical data set -
- As we age in place (more important than smoking status)?

VII. Certification and Testing

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

As stated previously, we believe that functional and regression-type testing must occur to demonstrate the functionality of systems. Due to the recent release of the C-CDA R2, we recommend testing of all document types and usefulness to the receiver, as well as downstream consumption of coded, structured data is necessary. In addition further clarification is necessary on both the "optional" aspect of implementation of the standard and the amount of data to be generated and sent between providers and facilities. Clarification and extension of the common data set inclusion is necessary in all document types.

VIII. Measurement

Our comments on measurement are general in nature, as we believe that there needs to be consistency in data integrity and quality prior to making assumptions of care. We believe one of the first quality metrics to address should be the "closed loop referral". If patients do not complete the treatment plan and goals associated with referrals, a significant reconsideration of the care plan should occur. In short, providers need to know when the best system of referrals works. The second metric addressed should be the value of the receiving data as used for the health care treatment plan. Is the data consumed by the receiver in such a way that the exchange of data was meaningful? We also recommend the extension and refinement of Value Set Creation in such a way that allows for consistent measurement of care across care settings. The Academy is committed to improving access to and use of nutrition related quality data that will embrace interoperability and allow for improved health in a valued learning health system.