April 1, 2015

Dr. Karen B. DeSalvo, MD, MPH, MSc
National Coordinator for Health Information Technology
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Connecting Health and Care for the National, A Shared Nationwide Interoperability Roadmap

Dear Dr. DeSalvo,

On behalf of the American Academy of Family Physicians (AAFP), which represents 115,900 family physicians and medical students across the country, we appreciate the focus that the Department of Health and Human Services is putting on interoperability through the creation of an interoperability roadmap by the Office of the National Coordinator for Health Information Technology (ONC). Lack of interoperability is a key issue for family physicians and the lack of it creates a barrier to improving health outcomes, improving health care quality, and lowering health care costs.

The AAFP has dedicated significant resources over the last decade to support the achievement of health care interoperability. We work on key clinical and transport standards and participated in the national policy dialogues. Our position from the onset has been that true interoperability will not be achieved without fundamental changes in health care payment reform. We are excited to see the acknowledgment of this position by both the private sector and CMS. A good example of the latter is the recent announcement by Secretary Burwell on the desired deployment of value based payment by CMS. We believe that payment reform is the keystone to a nationwide interoperable health care delivery system.

The AAFP understands that this roadmap is intended to be a living document and to set high-level direction. Nonetheless, we are concerned about the lack of specificity of the roadmap, especially within the next few years. We urge HHS to provide more details around a path forward to continue the adoption of Direct Exchange and the need to refine and further define the clinical content standards. We stand ready to assist.

We would like to see greater acknowledgment of the current policies and regulations that are hindering the progress toward interoperability. The roadmap must address current documentation policies and regulations. The current polices were crafted in and for an era dominated by paper records and fee-for-service. The roadmap, in the 2015-2017 timeframe, should establish a process to identify such policies and regulations and implement plans to reform or replace them.

From the perspective of family physicians, we need interoperable health IT systems and workflows to support the achievement of the Triple Aim. We need interoperable systems to support:

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- Continuity of Care – the sharing of patient information between care settings;
- Care Coordination – beyond the exchange of patient information is the ability to interact in an orchestrated manner to support collaboration (computable transactions) among providers, including patients; and
- Changing Systems – providers are beholden to their current health IT vendors due to the enormous resources required to switch systems; substitutability is a key characteristic of an optimally functioning market.

In addition to interoperable systems, we must identify improved and optimal workflows for the implementation and utilization of these new systems. Interoperability requires more than interoperable systems, it requires a sociotechnical system designed to support interoperability. The focus on sociotechnical systems and complete, real-word solutions to achieve desired outcomes is a critical point and needs to be an overarching component in this roadmap.

Comments on Specific Aspects of the Roadmap

Principle-Based Interoperability

The AAFP agrees with the principles presented for an interoperable health ecosystem. We are concerned though that the principle of *Build upon Existing Health IT Infrastructure* not be used to justify limiting or restricting solutions to existing infrastructure. Part of the reason for the lack of interoperability is the absence of support by existing infrastructure. Ensuring the ability of new entrants will foster competition and innovation in the health IT market. Further, in the discussion of these principles, it was stated that "workflow" (along with technology adoption, data quality, and usability) was out of scope. We believe that workflow is an integral and critical component for the success of interoperability – where success is more than just moving data. We believe ONC must include workflow in this roadmap's work.

We appreciate including the principle *Consider the Current Environment and Support Multiple Levels of Advancement*. It is an important principle both for those providers on the leading edge of adoption as well as for those on the trailing end of the adoption curve. We have heard from members at both ends of the spectrum on the challenges of current policy.

Common Clinical Data Set

We are very supportive of defining common clinical data sets. This is evident in our leadership in the creation of the ASTM Continuity of Care Record (CCR) data set. In that work, we realized that such data sets must be clinically relevant and that a one-size-fits-all approach would not achieve the continuity of care and care coordination needed. We have seen evidence of this in the challenges with the Meaningful Use transition of care criterion for the consolidated Clinical Document Architecture (C-CDA). These "summaries" are not based on clinically relevant data, but rather a predefined one-size-fits-all common data set. Given then the principles of "simplify" and "one size does not fit all," we would recommend that a small set of congruent common clinical data sets be defined for specified clinical uses.

We need work on the semantics of the common clinical data set(s) apart from the technical standards for representation. Decoupling the definition of the data set from the representation on the wire would support (1) that the common clinical data set elements can be represented in multiple standards and (2) remove the limitations of specific technical representations from the definition of the data elements. It is important that we define the data needed and then conform the standard representation around that data rather than conforming the data set to what a current standard can represent.

Critical Actions for Near-Term Wins (page 11)
We agree with the four near-term wins outlined. In regard to governance of interoperability and improved guidance of standards, we would encourage continued collaboration with DirectTrust, which is a large community working on these issues and which has been supported in this work by a Cooperative Agreement under the ONC Exemplar Health Information Governance Program for the past two years. We feel that DirectTrust is a model of private sector and federal collaboration, and demonstrates how best to establish governance for a security and trust framework useful to the advancement of interoperability of health information exchange across the boundaries of disparate organizations and health IT systems. We believe it is important for ONC and HHS to continue to promote this kind of governance of interoperability, and in so doing to take a light handed approach that avoids interference with private sector efforts that are showing progress in terms of widespread adoption, standardization, and innovation.

How the Roadmap Is Organized (page 23)
In the table of requirements for the Learning Health System, Item A states, "make collective decisions between competing policies, strategies, standards in a manner that does not limit competition." We agree that competition that drives interoperability should not be limited, but we also believe that basic interoperability should not be used as a competitive advantage.

In the table of requirements for the Learning Health System, Item B promotes "a supportive business and regulatory environment that encourages interoperability." We would add that such a business and regulatory environment should foster competition that drives interoperability. We also recommend that ONC add the review of existing policies and regulations to identify those that hinder interoperability (e.g., current documentation requirements for billing) and create a plan for removal or replacement.

Table 1: Critical Actions for a Coordinated Governance Framework and Process for Nationwide Health Information Interoperability (pages 34-36)
The Roadmap outlines a coordinated governance process under category A3 Standards, for 2015-2017. This outline does not seem to differ from prior efforts, which have not delivered the desired results. We recommend that ONC consider the establishment of a new governance process, which does not replicate past efforts. We believe strong participation by the provider community is needed to succeed in this governance. We also believe single large organizations or single stakeholders should not be allowed to dominate the process.

In regard to health IT standards and the role of the federal government, we would ask where is the market failure to rectify? It is not in the development of standards. It is not in the market's ability to implement standards, if we look at billing transactions. It is in the creation of business incentives to drive interoperability. We would encourage the federal government to prioritize the focus on that market failure.

Moving Forward and Critical Actions (page 50)
This section starts off with two statements that are critically important: *This Roadmap shifts the nation's focus from meaningfully using specific technologies with specific features to working together as a nation to achieve the outcomes desired from interoperability and a learning health system. Providers should have the tools they need to support a cultural shift in the way they practice medicine and use technology that supports the critical role of information sharing.* The AAFP agrees completely with these two statements and appreciates including them in this document.

Table 4: Critical Actions for Care -- Providers Partner with Individuals to Delivery High Value Care (pages 52-54)

We would make the following comments regarding "D2 Providers embrace a culture of interoperability and work with vendors and other supporting entities to improve interoperability"

- Item 2 (i.e., providers recognize value of patient-generated data) expresses something family physicians experience constantly. They struggle to integrate seamlessly the needed data with their health information technology.
- Item 3 (i.e., embrace pub/sub and query based exchange), we believe clinicians already embrace these IT functionalities. The issue is that they are not made available to them and in the rare case in which they are, the functionalities are not integrated into the workflow. Clinicians' acceptance of interoperability is not a barrier. There is a concern though on the issue of achieving just data portability (i.e., data transmitted but not computable by the receiving system) and the potential for a deluge of data with a low signal-to-noise ratio. We are already seeing this issue with the Meaningful Use requirement of C-CDA for transitions of care.
- Item 6 (i.e., populate key data), misses the reality that health care is a team sport. We should make sure that providers capture such data but should not mandate solely what team member can or cannot enter that data.

For all of these items in D2, it is critical to understand that without interoperability to support changing of systems, providers will be dependent on their current health IT vendor to enable these capabilities. Small practices do not have the resources to negotiate new friendlier contracts.

Nationwide Privacy & Security Framework (page 65)

We are supportive of the eight items articulated in figure 7. We would recommend that item 1, Individual Access, be amended to include the ability of the individual to proxy his or her access to another individual or organization.

Table 9: Critical Actions for Stakeholder Assurance That Health IT Is Interoperable (page 76)

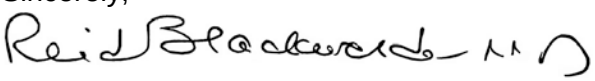
One area that we think should be added to the Roadmap here is a process to collect real-world feedback of certified electronic health record technology in use. ONC should create a resource to accept complaints from users when real-world use of certified technology does not allow for the interoperability required by certification criteria. This feedback would be used to inform the certification testing tools and to inform ONC of bad actors in interoperability.

Comments Spanning Multiple Document Sections

Throughout the document the term "data holder" is used. We believe a more formalized definition should be provided for this concept. We also believe that health IT vendors, federal government, and payers should be included as data holders in addition to providers.

We appreciate the opportunity to provide these comments. Please contact Steven E. Waldren, MD, MS, Director, Alliance for eHealth Innovation at 800-274-2237, extension 4100 or swaldren@aafp.org.

Sincerely,



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