



April 3, 2015

Karen DeSalvo, MD, MPH, MSc
National Coordinator
Office of the National Coordinator for Health IT
Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

Dear Dr. DeSalvo:

Carequality is a multi-stakeholder initiative formed in 2014 by industry and government stakeholders, as an initiative of Healthway, which operates as a non-profit in the public interest. Its mission is to build consensus on how to accelerate seamless health information exchange by enabling connectivity between and among different data sharing networks. As an action-oriented collaborative, Carequality is building upon existing exchange capabilities, leveraging existing standards, and agreeing upon innovative approaches to improve exchange workflows and adoption. Our objective is to accelerate the exchange of healthcare data through implementation of a common interoperability framework based on collaboratively developed governing principles and specifications.

Carequality collaborates across the entire healthcare ecosystem, and participation extends far beyond our formal membership. While our members span many areas within healthcare, it is essential for Carequality's success to have comprehensive stakeholder representation, including many who are not corporate members of the initiative, as we implement a common interoperability framework. We also are committed to including a consumer perspective, at the level of our Steering Committee. As a result, our overall community covers a broad group of healthcare perspectives:

- Physicians
- Consumers
- Government Agencies
- Data Sharing Networks
- Payers
- Behavioral Health
- Acute Care
- Long Term Care
- Hospice and Home Care
- Research
- Public Health
- Vendors
- Standards Development Organizations
- Pharmacies
- EMS Services
- Patient Safety Organizations



Based on this broad representation, Carequality is pleased to submit the following comments on the Office of the National Coordinator for Health IT (ONC) *Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap*. We commend ONC for its efforts in this complex area, where there is increasing demand for information to flow freely among clinicians across all care settings as organizations become more accountable for the care they provide to a mobile patient population.

Our comments will focus primarily on governance as proposed in the ONC *Roadmap*. Specifically, we address ONC's question 3:

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?

Overview

Over the past several weeks, Carequality has been working closely with healthcare community colleagues to respond to ONC's call to action for health IT stakeholders to come together to establish a coordinated governance process for nationwide interoperability. The group included more than a dozen organizations, including Carequality, CHIME, DirectTrust, Healtheway, HIMSS, and IHE USA, among others.

As a member of the group, Carequality 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. We do not believe that a top-down process, dominated by the federal government with very prescriptive requirements, is the answer. 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. No single network, organization or process will be able to 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, but largely can 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 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.

Additional Carequality Comments

In the remainder of our comments, Carequality expands on the points introduced in the Overview, to further address ONC's question of how it can best recognize and support an industry-led governance effort. Throughout our comments, we will expand on several recurring themes:

- Interoperability is a broad topic that involves a number of domains.
- In nearly all of these domains, great work is already underway that can be leveraged in a coordinated governance ecosystem.
- Carequality, specifically, is well down the path to implementing "rules of the road" for widespread connectivity among data sharing networks.



- The foundation for any successful governance structure is trust. Trust develops when stakeholders feel represented and empowered, and see that the governance structure addresses their concerns.

Governance for healthcare interoperability is a broad topic that encompasses a number of domains.

We believe that there are many domains within interoperability that have their own needs, characteristics, and stakeholders. Any governance structure for a domain must address the concerns of all types of stakeholders involved in or impacted by that domain.

Domains within interoperability include:

- Setting policy priorities
- Developing standards
- Testing conformance
- Implementing rules of the road
- Driving adoption
- Coordinating across federal agencies

A single governance mechanism to address this wide range of needs – particularly if it is dependent on the regulatory process – is not likely to succeed in the timeframes proposed by ONC and others. In addition, it is unlikely that regulation could keep pace with or completely reflect the needs of the implementation community and patients.

Each of the domains listed above has its own distinct governance needs. Each requires its own specific expertise, and in some cases involves its own set of stakeholders. Some, like developing standards, require highly abstract consideration of many technical options and possibilities. Others, like implementing rules of the road, require a very pragmatic focus on operational realities. All domains require direct input from across the entire health IT ecosystem. Each domain needs a mechanism to address the needs of its stakeholders, which may work with others in a coordinated fashion but will require freedom to appropriately address the considerations of that domain.



Many interoperability domains have existing efforts that can inform and lead governance for that domain.

An overall approach to interoperability should leverage these efforts within each domain. Carequality notes that in the description of the current state of non-governmental governance efforts, there appears to be an emphasis on the number and variety of different initiatives, rather than on the positive roles these organizations can play. The ONC Roadmap positions the variety of initiatives as a problem to be solved, when in fact the existing efforts are important resources to be leveraged. The many initiatives reflect the many domains within the broad scope of interoperability, and in the majority of cases their efforts are complementary.

Carequality, for example, is already well down the path described in the ONC Roadmap for implementing rules of the road in a public-private, collaborative process. We, in turn, are not attempting to start from scratch but are working with the many existing data sharing networks to connect their users to one another. These networks have already connected large groups of healthcare organizations, with their own governance structures that can be used to apply the Carequality rules to the data sharing network participants.

Recommendation

Carequality strongly recommends that ONC leverage the work of the initiatives already active in each domain. With a lightweight layer of overall coordination and unified direction on agreed-upon policy goals, stakeholders across industry and government can continue the work in which they are already engaged through existing initiatives. ONC's role would be as a coordinator, allowing the experts in each domain to define specific scope and responsibilities.

Setting Policy Priorities: This domain is one in which ONC is positioned to take the lead, although an inclusive process that empowers stakeholders should be applied in this domain just as in the others.

Developing Standards: As the Roadmap notes, SDOs have strong governance models and processes today. As all other domains encounter standards needs, SDOs should be encouraged to meet those needs. ONC should support the work of existing SDOs, and support the alignment of their work with the needs of all domains by convening standards coordination sessions among the groups involved.

Testing and Certification: Several initiatives are advancing in this area, such as IHE USA with its Connectathon, the eHealth Exchange with its network onboarding



program, and the joint efforts of HIMSS and the EHR/HIE Interoperability Workgroup to support a certification program. These efforts are largely complementary and would benefit from a collaborative, cross-domain forum to help them align their efforts with overall interoperability needs.

Implementing Rules of the Road: Enabling a trusted environment for operational exchange among a broad set of trading partners requires the right balance of stakeholder engagement, implementation experience, and flexibility. Carequality was formed for this express purpose, and possesses these attributes. Our governance model of a representative Steering Committee, use-case specific work groups, and a broadly inclusive Advisory Council is designed to obtain useful feedback from a diverse set of stakeholders while staying focused on practical implementation of a framework for secure, interoperable exchange across different technological platforms. It's important to emphasize again that we are not creating an infrastructure from scratch. We are providing a framework to allow widespread interoperability by leveraging the services, infrastructure, and local rules already in place through existing data sharing networks.

Driving Adoption: Interoperability will be adopted most effectively when there is a business case for it. Market-based strategies that center on purchasers of care and private payers, with the support and leadership of CMS, can incentivize adoption of the interoperability enabled by work in the other domains. CMS is already playing a leadership role through its efforts to shift incentives from volume to value. ONC should support CMS' efforts and encourage similar efforts in the private sector, and ensure that any direct policy actions to drive adoption are coordinated with and supportive of the industry's efforts in the other domains.

Coordinating Across Federal Agencies: For a collaborative and market-based interoperability ecosystem to function, it will need active participation and coordinated support from federal agencies. ONC can play a leadership role by engaging with other agencies to inform them about the activities across the domains and to encourage their participation.

Trust is essential.

Governance must be trusted to be effective. Trust develops when stakeholders feel represented and empowered, and see the governance structure address their concerns. A mandated approach does not engender trust. Even if it appears to address stakeholder concerns, it leaves them feeling disempowered, and with no



confidence in future mandates. A governance structure that is not trusted will not be embraced.

Carequality's operating principles include several that we believe are essential to establishing trust. Specifically, our principles of being inclusive and transparent, clear and equitable in our oversight, and vendor neutral are necessary for any organization or entity that strives to provide trusted governance in any interoperability domain.

Recommendation

Any entity that provides governance in one of the interoperability domains should demonstrate through its operational policies and practices that it engages with relevant stakeholder groups and distributes decision-making authority across multiple types of organizations.

Wherever possible, decision-making should be left in the hands of entities that are directly accountable to healthcare stakeholders. In most domains, ONC can best foster trust in governance efforts by convening and coordinating.

The ONC Roadmap principles reflect a policy goal focus, and will likely not engender the trust needed for widespread operational exchange. Policy goals are essential to set direction and establish broad objectives, but they represent only one of the interoperability domains, and the policy goals themselves should be distinguished from the principles underlying the governance process that produces the goals. Because we believe that governance principles must address the concerns and perspectives of all stakeholders, we believe that policy goals must be developed through a public-private collaborative process that is inclusive and provides for broad stakeholder representation.

While the policy goals outlined are generally admirable, a number of the details which accompany the policy goals are problematic. For example, a number of the items re-state existing requirements in HIPAA, while others are more prescriptive than existing law (e.g. consent requirements). One item would be challenging to implement while remaining in line with best practices for privacy and security – the recommendation that organizations share the results of their internal security audits with trading partners. In summary, while the policy topics and goals are beneficial, the policies do not address the needs of stakeholders seeking to trust other participants in widespread exchange. Principles that underlie rules of the road



will be different from those that underlie policy goals, and Carequality's principles demonstrate this fact. While there is alignment in spirit, there are key differences in details and focus between Carequality principles and the ONC Roadmap principles.

Carequality has published Universal Principles of Trust, which we encourage ONC to review as an example of public-private collaboration in the rules of the road domain. The principles are available on-line at http://healthwayinc.org/wp-content/uploads/2015/01/Carequality_Principles-of-Trust_Final_Carequality-template.pdf.

The principles focus on the pragmatic concerns of healthcare stakeholders who must balance the needs of interoperability with those of patient privacy and security. In some cases they touch directly on policy goals, but often the policy goal is distinct from the structure that enables it to be met.

Recommendation

A governance approach should not rely only on policy goals. Policy is essential but represents only one domain within interoperability governance. A policy goal that stands alone, without supporting structure from the other domains, is akin to an unfunded mandate.

Policy goals should be set according to a process that follows the same governance practices that apply to the other domains. Goals should be set and prioritized with the input of all stakeholders, with a view toward advancing overall value in healthcare.

Interoperability is not an end in itself. It is a means to advance other, higher-level goals for healthcare. Policy related to interoperability should never be divorced from the higher-level goals.

Sincerely,

Dave Cassel
Carequality Director

Michael Hodgkins, MD
Steering Committee Chair

Kathy Lewis
Steering Committee Vice-Chair