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Karen DeSalvo, MP, MPH, MSc National Coordinator for Health Information Technology U.S. Department of Health and Human Services 200 Independence Avenue, S.W., Suite 729-D Washington, D.C. 20201

April 3, 2015

Re: Request for Comment on the ONC Interoperability Roadmap

Dear Dr. DeSalvo:

Trinity Health appreciates the opportunity to comment on "Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap" Version 1.0. Trinity Health shares your vision for a future health information technology ecosystem where electronic health information is appropriately and readily available to empower consumers, support clinical decision-making, inform population and public health and value-based payment and advance science. Trinity Health is pleased that the development of the nation's interoperability roadmap is an iterative process, and that ONC is working so assiduously to gain feedback and input from all stakeholders. Trinity Health Chief Information Officer Marcus Shipley and I enjoyed meeting with you and members of your team last month in Washington and we commit to you that Trinity Health stands ready to assist in fulfilling our shared vision.

Interoperability is a key strategic imperative for Trinity Health in our mission-driven move to a peoplecentered health system. We are pleased to see that the Roadmap acknowledges that health care is being transformed to deliver care and services in a person-centered manner. We believe that a person- or people-centered health system demands the widespread exchange through interoperable health information technology sharing information through structured data and standard codes. Clinicians, patients and all health care stakeholders, as well as the entire nation, will benefit when health information systems and their components are able to exchange clinical and other information and use that information using common standards that provide access to longitudinal information for health care providers across the continuum of care. This will facilitate engagement with the healthcare consumer, coordinated care and improved patient outcomes and enable real progress toward a peoplecentered health system.

Trinity Health is one of the largest multi-institutional Catholic health care delivery systems in the nation. We serve people and communities in 21 states with 86 hospitals, 128 continuing care facilities, and home health and hospice programs that provide nearly 2.8 million visits annually. Trinity Health returns almost \$900 million to its communities annually in the form of charity care and community benefit programs, and employs about 89,000 people including 3,300 employed physicians. We have 28

teaching hospitals with Graduate Medical Education programs providing training for 1,720 residents and fellows in almost 200 programs.

Trinity Health is known for its focus on the country's aging population. As a single, unified ministry, the organization is the innovator of Senior Emergency Departments, the largest not-for-profit provider of home health care services – ranked by number of visits – in the nation, as well as the nation's leading provider of PACE (Program of All Inclusive Care for the Elderly) based on the number of available programs.

We are committed to leveraging technology to provide higher quality and more proficient care to patients. Our Genesis initiative is an integrated platform, which includes a common EHR and clinical support tools. In our experience, appropriate use of health information technology can lead to smarter, safer, and less costly care. We are continually working to identify high-risk/high-cost individuals, enhance care coordination and communication, share best practices and improve population health.

Trinity Health is currently participating in 13 Shared Savings Plan (SSP) Accountable Care Organizations (ACOs) with an additional 8 ACO SSP programs under CMS review. Trinity Health is part of 5 commercial ACO programs. In addition, we have 65 patient-centered medical home programs across our ministry and are pursuing bundled payment programs in 6 communities. We have filed applications for another 38 hospitals to participate in the Bundled Payments for Care Improvement (BPCI) program. We are firmly committed to transforming our delivery system into a people-centered health system focused on delivering the triple aim in our communities.

Trinity Health President and CEO Rick Gilfillan participated in Secretary Burwell's recent announcement of milestones in the movement to value-based payment. Indeed, Dr. Gilfillan is chairing a Healthcare Transformation Task Force that is committed to rapid, measurable change. Plan and provider members of the Task Force, including Trinity Health, have committed to put 75% of their business into value-based payment arrangements by 2020. Trinity Health firmly believes that payment reform is essential to achievement of interoperability because value-based payment will incentivize the highly coordinated care that requires the availability of the right information at the right time in the right place.

In this letter, we offer focused recommendations on certain key topics discussed in the Roadmap. We also suggest that ONC work with stakeholders to quickly prioritize those areas that demand immediate attention. Interoperability will not be achieved overnight but tackling areas of immediate importance that will yield the most significant progress makes sense and will spur near-term advancement on the road to interoperability.

Patient Identification

The potential for mismatch between patients and their clinical information is a significant and increasing patient safety issue as well as a considerable cost driver. Ensuring the ability of providers to accurately match patients with their data is essential to interoperability, to a learning health system, and most importantly, to patient safety. Trinity Health spends enormous resources on both people and technical resources in order to maximize the likelihood that patients are matched to all of their available data.

While we recognize the congressional prohibition on the use of appropriated funds to promulgate or adopt any final standard for a unique individual identifier, it is time to acknowledge that this block – put in place in 1999 – is a major impediment to interoperability. In order to realize the benefits of a longitudinal patient health record that includes data from various settings of care across multiple geographies, a national solution to the conundrum of patient identification is vital. We hope to work with you to overcome the obstacle that patient matching poses to interoperability.

Standards Development and Implementation Specifications

Because standards provide the technical means to achieve interoperability, the need for mature standards that have been appropriately tested and evaluated is imperative. Standards provide the framework for the exchange, sharing, integration and retrieval of electronic health information. Standards should not be open to various interpretations and unrestrained variation. Problems have arisen in the Meaningful Use program, for example, because vendors have had the flexibility to interpret and implement standards in various ways. Unique system configurations and varying implementation of standards by vendors have complicated efforts to exchange data between systems - even between systems purchased from the same vendor. This means that expensive and often cumbersome interfaces must be created to exchange data. The cost of these interfaces could significantly be curtailed or eliminated with enforceable "rules of the road" for information exchange. Not only is a process needed to come to agreement on the array of standards that are necessary for interoperability and to facilitate the development of those standards that are not yet mature or available, but rigor needs to be imposed on vendors so that the multiplicity in standards implementation is minimized. Vendors should be responsible and accountable for ensuring their products will work smoothly with other vendors' products and with all of their own products regardless of location. Further, there must be some mechanism to ensure that standards are utilized. Interoperability will not be achieved unless agreed upon standards are enforced.

Trinity Health also supports the definition of common clinical data sets that will buttress new models of care delivery. We believe the common clinical data set described in the Interoperability Roadmap is the correct starting point. The challenges posed by the Meaningful Use transitions of care criterion for the consolidated Clinical Document Architecture (C-CDA) illustrate the importance of mature standards. The data that Stage 2 requires to be included in the summary of care document is, in our experience, often too voluminous to be clinically useful. Indeed, this is one reason why many providers are reluctant to accept these documents. Clinically relevant data should be prioritized. The need for clinically relevant data sets for specified clinical uses should drive the development of the standard. The data set should not be shoehorned into the available standard; this will only result, for example, in summaries of care that either obscure or lack clinically relevant data.

Privacy and Security of Patient Information

Trinity Health believes that establishing current HIPAA requirements relating to the privacy and security of individually identifiable health information as a common national standard would facilitate appropriate information sharing and interoperability. We also believe that patients have a vital role to play in a people-centered health system and we are pleased to see that inclusion of patient-generated information in the EHR is recognized as meritorious in the Meaningful Use Stage 3 proposed rule. We recommend

expanding the role of the National Institute of Standards and Technology (NIST) to support R&D regarding an efficient technical implementation of these standards as well as emerging standards supporting privacy and security.

Certification and Testing

Trinity Health is pleased that ONC envisions the development and implementation of certification standards that would extend beyond the hospitals and eligible professionals that participate in the Meaningful Use program to newly include post-acute care, long-term care, and behavioral health settings as well as home and community based services in in non-institutional settings and other facilities along the care continuum. Truly effective coordination of care necessitates interoperability among all care providers and settings. The current certification program should also be modified to include vigorous conformance testing of EHRs and of interfaces to other systems. Certification should also include scenario-based testing. Today, certified product does not always work as intended "out of the box," and often requires numerous patches and expensive workarounds. Vendors are understandably focused on meeting Meaningful Use certification requirements, which has resulted in a dearth of end-use testing by clinicians and product that lacks clinical usability and effective clinical workflow. Indeed, information received by providers is not always able to be incorporated into their EHR or presented to a clinician in a contextual and useful manner. This needs to change.

Further, transparency with respect to product performance so that specific information about how products support interoperability should be incorporated into the certification process and made publicly available. Certification should also confirm that certified technology is capable of producing the information that will allow the provider to satisfy audit requirements, including Meaningful Use audits. Additionally, certification should ensure that certified product actually works as intended; if this is not the case, there should be a post-certification review and surveillance process that includes mechanisms to address and remedy underperformance of certified technology. Providers should also have the programmatic flexibility to change vendors if they are dissatisfied with their current technology. Switching vendors, for example, is complicated when providers must attest year in and year out for 365 days, for example.

Electronic Clinical Quality Measurement

Trinity Health agrees with the shared recommendation from the College of Healthcare Information Management Executives (CHIME) and the Association of Medical Directors of Information Systems (AMDIS) in their joint comment letter that calls for CMS and ONC to "prioritize a unified strategy for capturing and communicating quality in healthcare" and makes three specific recommendations:

- 1. Implement aggressive and thorough comprehensive quality measures testing within the CMS and ONC to ensure measures are adequately defined and tested before requiring them for use in federal reporting programs.
- 2. Ensure that all quality reporting requirements are coordinated and consistent within federal reporting/incentive programs within 18 months.
- 3. Establish and adequately fund a National Measurement Enterprise consisting of open and transparent measure development, measure endorsement (e.g. National Quality Forum), and measure application (e.g., NQF's Measure Applications Partnership)."

Thank you for the opportunity to submit our views. Trinity Health believes that America's healthcare system should ensure access to high quality health care at affordable costs. Health information technology plays a major role as providers tackle spending and aim to improve care and patient safety. Without interoperability, the potential of health information technology will not be fully realized.

We look forward to working together to achieve our shared vision for the nation's health care delivery system. If you have any questions about our comments, please feel free to contact me at 734.343.0824 or wellstk@trinity-health.org.

Sincerely,

Tonya K. Wells Vice President, Public Policy & Federal Advocacy Trinity Health