April 2, 2015

Karen DeSalvo, M.D.
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Ave., SW, Suite 729-D
Washington, DC 20201

Re: Request for Comment: ONC Interoperability Roadmap

Dear Dr. DeSalvo:

On behalf of our 39 hospitals in Arizona, California and Nevada, Dignity Health appreciates the opportunity to comment on "Connecting Health and Care for the Nation, A Shared Nationwide Interoperability Roadmap," published by the Office of the National Coordinator (ONC) for Health Information Technology on Jan. 31, 2015.

As the nation's fifth-largest non-profit hospital system, Dignity Health is committed to our mission of providing compassionate, high-quality care to all and strongly supports the use of Health Information Technology (HIT) as the central tool used to transform health care delivery and change the tide from volume to value. Dignity Health's perspective is shared by our faith-based and community hospitals balancing our capital commitments, implementing cutting-edge technology, while providing the highest quality, most cost-effective care to the communities we serve.

Health Information Exchange (HIE) in particular is the key to breaking down the siloes of care and enhancing providers' ability to coordinate care across the spectrum while empowering patients to participate in their health care. Through MobileMD, Dignity Health connects nearly 8,500 physicians and 36 hospitals in three states to our private HIE, treating over 5 million patients across the inpatient and ambulatory care settings, while promoting efficiency and quality. The technology itself is a foundational element of Dignity Health's Clinical Integration Initiatives and is a tool to better incorporate physicians in the community into our care community by facilitating access to and retrieval of clinical data to provide safer, more timely, efficient, effective, and equitable patient-centered care. Dignity Health also participates in Healtheway and the eHealth Exchange as an anchor Participant, and looks to expand our current level

of interoperability with other healthcare organizations throughout the communities we serve. Through our deployment of MobileMD, Dignity Health has experience with the struggles and barriers associated with the safe and secure exchange of clinical data. It is through this lens that Dignity Health provides the comments below:

PRIORITIZED ACTIVITIES

To address the immediate need of patients and providers to exchange health information and to support the existing market and regulatory requirements accelerating demand for health information exchange, Dignity Health urges the ONC to prioritize short-term activities that address:

- ***Common Clinical Data Set and C-CDA.*** The roadmap appropriately identifies that a Common Clinical Data Set is needed; however the roadmap includes non-discrete data types that are not clearly specified. To make sure the data is useable and computable across systems of care, data elements of the Common Clinical Data Set should be further specified with appropriate constraints. For example, discrete data elements such as sex, race or ethnicity are already well specified and understood by both sender and receiver. However, clinical documentation such as care plans, goals, instructions, notes and narratives may include different data based on the type of provider and/or clinical setting. While the C-CDA content standard is becoming broadly adopted, the amount of optionality in the standard may lead to the exchange of clinical data not necessarily relevant to the provider at the bed side and runs the risk – as is occurring now under the transitions of care requirement in meaningful use – of potentially overloading clinicians with too much information, rather than providing the most relevant information. In order to be useful, greater implementation constraints are needed to make the information consumable and actionable in support of clinical care.

  While the elements contained in the common clinical data set are appropriate, Dignity Health urges the ONC to further specify the elements within the "care plan field(s), including goals and instructions" and "notes/narrative" sets to establish common definitions. In addition, the ONC should also consider including end of life care preferences, such as Physician Orders for Life Sustaining Treatment (POLST).

- ***Standards and Implementation Specifications.*** The meaningful use program includes multiple standards that were not appropriately tested or defined. As a result, vendors have had the flexibility to implement those standards based on their interpretation, creating inconsistency in data exchange protocols, thereby setting market dynamics that put providers at a significant disadvantage. Multiple vendors with unique implementations of standards and system configurations, all requiring specific interfaces to support data exchange

across disparate information systems, has created an uneven playing field for hospitals and health systems. Changes to any one information system could affect many interfaces, making sharing and integrating data across EHRs a complex, time consuming, costly and sometimes impossible enterprise.

Dignity Health urges the ONC to prioritize standards refinement, constrain implementation specifications and provide additional education on the use of standards in order to advance interoperability. To do this, the ONC should create a process for voluntary certification of draft standards to be matured in pilots or demonstration projects, signaling federal support for innovation without imposing an immature standard on the entire provider community. The ONC can then use regulations to advance use of the standard based on evidence from real-world pilots.

- ***Use Cases.*** Rather than identifying discrete use cases to support interoperability, the ONC should identify a set of use cases to illustrate where data moves across many systems to an endpoint that supports the delivery of care. The ONC Interoperability Roadmap lists a set of 56 separate use cases, showing there are many examples of successful interoperability. To make progress, the ONC should focus its efforts on a small prioritized set of use cases that accelerate the exchange of data that is currently taking place. Additionally, specific use cases signal an expectation that vendors would work on priorities that support the demand for health information exchange that supports coordination and collaboration and new models of care. **Dignity Health urges the ONC to collaborate with the Centers for Medicare & Medicaid Services (CMS) to identify priority use case scenarios, to support one or more Medicare innovation models.**

- ***Testing and Certification Infrastructure.*** A more robust testing and certification process is urgently needed. While the current certification process involves some testing, it is not sufficient to meet the needs of end-users. Despite significant investments in EHRs, Dignity Health has found it difficult and expensive to exchange information outside of our private HIE. The ability to exchange clinical information should ultimately result in sharing and incorporating data, and should not simply be a "data dump." Rather, shared data should be consumable for incorporation into the requesting/receiving system. In our experience, Dignity Health has found that system-to-system communication is not the problem. The challenge is whether the content is (or is not) appropriately incorporated from one system into another. For example, currently, there is little assurance that a C-CDA that passes conformance testing is truly interoperable, largely due to the optionality in the data specifications. **Dignity Health urges the ONC to create more specific content standards to ensure shared data elements are consumable to end-users and can be incorporated into the requesting/receiving system.**

Rigorous conformance testing of EHRs and interfaces to ancillary systems (such as lab information systems) that connect to EHRs is also urgently needed and will support greater confidence that certified products may be reliably used to meet regulatory and market requirements. Conformance testing for interoperability also will communicate to vendors that the products required for use in federal programs must be interoperable, rather than an optional upgrade to a certified system. **Dignity Health urges the ONC to work with National Institute of Standards and Technology (NIST) to establish test beds make available to developers and end-users of EHRs to support development, certification and assessment of standards that support interoperability.**

- ***Transparency Concerning How Products Support Interoperability.*** Greater transparency of conformance testing is needed for the end user to better understand product performance based on how venders have designed products around their interpretation of standards, giving providers the ability to make more informed choices. This concept is comparable to the many reporting requirements CMS places on providers and health plans, such as Hospital Compare or the Medicare Advantage Star ratings, and would provide insight on the interoperability capability of products beyond the current Summary Record Exchange (SRE) designation in the Certified Health IT Product List (CHPL). **Dignity Health urges ONC to work with vendors to improve transparency around conformance testing and support the consistent use of standards and implementation specifications.**

- ***Patient Identification.*** The absence of a national mechanism for identifying individuals creates additional challenges, both within a single health care organization and nationally. While providers employ technological mechanisms and employ human intervention tactics to accurately identify and match patients and providers, the system is imperfect, unstandardized and expensive. **Dignity Health urges the ONC to prioritize the development of a unique patient identifier. Consistently and accurately resolving patient identity across systems is a critical step to enable broad, nationwide interoperability.**

- ***Medical Device Interoperability.*** The growing number and variety of medical devices collecting data that should be integrated into a patient's record has presented intra-hospital barriers to interoperability. The current approach of one-to-one interfaces between devices and the EHR introduces risk into the environment, where data collected from a device may not appear in the EHR or may be incorrect, and has stymied the efficacy of devices. At times, this barrier could also present a safety risk, if, for example, a drug pump sends incorrect medication information that is then used in clinical decision-making. This will be exacerbated by the proliferation of personal and/or home medical devices and the growing use of patient-generated data. Providers need

confidence that the data presented is trustworthy as it moves from its source to the EHR. **Dignity Health urges the ONC to prioritize medical device interoperability.**

- ***Alignment of the Business Case for Interoperability.*** The meaningful use program has been an accelerant of the adoption of EHRs, creating a fruitful market for EHR vendors. However, the meaningful use program has not necessarily advanced interoperability as a priority in the marketplace and in some cases, has created a perverse incentive for vendors to hold data hostage for their own monetary benefit. There is currently a distinction between the business case for a provider (interoperability in support of clinical transformation), the case for a payor (interoperability in support of patient care management) and the business case for a vendor (interoperability that is sufficient to meet a certification requirement, with the option to make data available to providers and payors for a fee). The current business structure for data exchange undermines the ability of providers to support patient care in a timely and efficient manner. Achieving interoperability will require partnership and accountability among stakeholders so we can move from potential data access to data exchange and use. **Dignity Health believes HIE should be considered a public utility and urges the ONC to leverage testing and certification requirements to standardize interoperability and preclude vendors from exacting tolls on providers through the creation of interfaces between data sources.**

GOVERNANCE STRUCTURE

There are a variety of exchange activities at the local, regional and state level that are not necessarily compatible with each other, and are subject to multiple state and federal regulations that do not align with one other. This variability impedes uniform, trusted and secure information exchange on a larger scale at a time when the health care ecosystem is transforming from volume to value and providers are challenged to exchange information in support of coordinating care with each other, including post-acute care providers and providers in community settings.

Thus, any nationwide governance framework for interoperability must strike a balance between providing the necessary technical standards to support sending, receipt and use of accurate health information and enough flexibility to support innovations in the flow of information within existing health care organizations or delivery systems or between health care organizations. It should also be sufficiently inclusive and flexible to take into account the wide variety of entities and transaction types. **Dignity Health urges the ONC to actively engage providers, payors, vendors and patients to consider standards and business practices for interoperability and create a coordinated governance structure. The ONC should look to existing examples in the market of effective**

governance, like Healtheway, promising new models like the Commonwell Health Alliance, and innovative cross-network initiatives like Carequality.

POLICY LEVERS

Health care is transforming to be more focused on coordination, collaboration and integrated delivery. Spurned by updated payment models that challenge providers to better understand the care patients are receiving and have a more complete view of their information, combined with a growing demand for patient and payor access to health data, providers already have sufficient market pressures and regulatory requirements motivating them to find better ways to share information. Payment levers are more effective than regulatory requirements to move innovation and accelerate interoperability. **Thus, Dignity Health urges the ONC to remove policy proposals that increase regulatory requirements, including:**

- **Conditions of Participation (CoPs).** To qualify for Medicare certification and reimbursement, providers must comply with minimum health and safety standards, called CoPs. In the roadmap, the ONC suggests CMS should add a new CoP to require interoperability. While Dignity Health appreciates CMS continually updating CoPs to ensure that regulations are current and reflect the best and most recent knowledge about the safe operation of hospitals, the use of CoPs and/or guidance to require interoperability is inappropriate given the lack existing and consistent implementation of standards for interoperability. It is premature to presume the best practices in interoperability could be supported under current structure. As standards mature to support interoperability and their use in CEHRT, the ONC and CMS should study and publically report on the experience with the use of EHRs to exchange and use care summaries in support of safe transitions of care. **Dignity Health strongly opposes the creation of new CoPs to require interoperability.**

- **eCQMs.** Despite the availability of an option to report eCQMs for both EHR Incentive Program and hospital inpatient quality measure reporting in the same payment year, there is little evidence that this option is being utilized. Moreover, in the 2015 payment rules, CMS specifically stated that a date certain for required use of eCQMs could not be determined. CMS and ONC have identified and are working to address challenges to the ability of EHRs to generate valid, feasible and reliable eCQMs. **Dignity Health believes there needs to be standardization of metric definitions across measure developers, testing and certification of clinical content capture in EHRs (that drive numerator/denominator of eCQMs) and urges the ONC to work with CMS to further align and constrain clinical content standards like C-CDA as a method of obtaining and extracting the clinical information needed to compute eCQMs.**

PRIVACY AND SECURITY

The roadmap proposals related to privacy and security in the interoperability framework could exacerbate the conflict among federal and varying state and local laws. State laws often treat certain classes of information differently and require special protections beyond those in federal law. Moreover, the current patchwork of state and local laws creates significant barriers to robust information sharing for clinical treatment and quality improvement, and poses significant challenges for health care organizations that operate in multiple jurisdictions. For example, some state laws protect specific types of information (mental health, HIV, etc). **The proper focus should be on making the existing HIPAA requirements the prevailing standard nation-wide if it is essential to address access to health information within the interoperability context. In addition, a common floor should be established for those types of information that may need heightened protections beyond HIPAA so interoperability across state lines can be assured.**

As the need for information sharing accelerates, careful attention must be paid to keeping information secure. Maintaining the balance between sharing information and keeping it secure will be an ongoing tension. However, policy frameworks already exist that address this aspect, including the HIPAA Privacy and Security Rules and the NIST Cybersecurity Framework for Critical Infrastructure Programs. Improving the infrastructure to support secure data sharing in support of clinical care can be accomplished within the existing HIPAA Privacy Rule.

For example, under the Privacy Rule, the use and/or disclosure of protected health information (PHI) between covered entities for health care operations that expressly qualify as quality assessment and improvement activities are permissible only when both the disclosing and receiving covered entity have or have had a relationship with the patient about whom the information pertains. Guidance from OCR should look at the organizational structures available within the HIPAA Privacy Rule and expand them as necessary to allow for appropriate interoperable sharing of information for the kinds of new clinically integrated structures that are forming without requiring that individual patients have a direct relationship with all of the organizations and providers that use and have access to data that meets the definition of PHI. The appropriate level of protection for the security, integrity and accessibility of the patient information exchanged across the participating providers in the clinically integrated setting will continue to be ensured by the standards and obligations imposed by the HIPAA Security Rule.

Dignity Health urges the ONC to work with the HHS Office for Civil Rights (OCR) to develop additional guidance necessary to help stakeholders understand how HIPAA Privacy and Security rules apply in an environment where ACOs and other multi-stakeholder entities work to manage the health care of populations.

With respect to cyber security, any activities in this area must support the ongoing collaboration of the Departments of Homeland Security and HHS with public-private collaborations, including the Healthcare and Public Health Sector Coordinating Council, to work through health sector specific issues. Further, any detailed standards should be aligned with the NIST Cybersecurity Framework, which is the overarching federal approach to cybersecurity, and the existing HIPAA Security rules and should be applied across entities, including providers, vendors and HIEs. **Dignity Health urges the ONC to work within the broader existing framework to address cyber security policies.**

CONCLUSION

Dignity Health appreciates the opportunity to submit comments on the roadmap and hopes our comments are helpful. If you have any questions, please feel free to contact Clara Evans, Director of Public Policy & Fiscal Advocacy at 916.851.2007 or Clara.Evans@DignityHealth.org.

Sincerely,

Deanna Wise
Executive Vice President and
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