American Hospital Association

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Karen DeSalvo, M.D., M.P.H., M.Sc.
Acting Assistant Secretary for Health
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

Re: Request for Comment: ONC Interoperability Roadmap

Dear Dr. DeSalvo:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, the American Hospital Association (AHA) 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.

The ONC roadmap contains a list of principles, goals and critical actions that focus on a 10-year vision to achieve a future state of data exchange in support of a learning health system. **While the AHA agrees with ONC's aspirations for the future, we are concerned that the roadmap is not sufficiently grounded in an assessment of present realities or focused enough on the steps that will enable public and private stakeholders to travel from the present regulatory, clinical and technology environment to the future state envisioned**.

The AHA supports the use of a roadmap to establish a shared understanding among stakeholders of the standards, policies and actions needed to reach the goal of nationwide interoperability. However, we believe that to be successful the roadmap will need to be more specific about the immediate steps and resources that are needed to move everyone toward the interoperability goal. Additionally, we believe the ONC roadmap should indicate what metrics will be applied to measure the success of the activities undertaken within the stated short-term, intermediate-term and long-term timeframes.

America's hospitals strongly support the creation of an efficient and effective infrastructure for health information exchange that supports the delivery of high-quality, patient-centered care across health care settings. Our members are actively engaged in building their information infrastructures and view information exchange as vital to care improvement, as well as to successful implementation of new models of care. As primary end-users of electronic health

records (EHRs), they have a vested interest in purchasing systems that support their growing information-sharing needs. Yet, hospitals and health systems report that the EHRs purchased during the past five years do not easily share information and that the cost and complexity of the many interfaces needed to connect systems today are simply not sustainable. **Given the significant investments already made, the AHA urges ONC to adopt the current requirements of the meaningful use program and the capabilities of the 2014 Edition certified EHRs as the starting point for the nationwide interoperability roadmap.**

Within that context, we recommend that ONC focus its efforts on:

- Ensuring a common clinical data set based on the data currently captured by 2014 Edition certified EHRs can be shared among providers to support care delivery and new delivery models;
- Improving the performance of the Consolidated Clinical Document Architecture (C-CDA) and meaningful use regulatory requirements linked to its use;
- Further developing standards, constrained implementation specifications and education on the use of standards;
- Identifying and prioritizing use cases as a method to drive improvements in interoperability;
- Implementing more robust testing and certification in support of interoperability;
- Creating more and better transparency about how EHR vendors support interoperability;
- Developing efficient and affordable exchange networks;
- Addressing the patient identification and matching problem;
- Improving the interoperability of medical devices and EHRs; and
- Aligning the business cases for interoperability across stakeholders.

In addition to setting forth steps to improve interoperability, the roadmap contains lengthy discussions of regulatory drivers for providers to share information, as well as consideration of changes to privacy and security policies. **The AHA disagrees with the roadmap presumption that current government and private sector programs provide insufficient incentives for interoperability across the care continuum.** Providers face numerous requirements to share health information in support of care coordination, including meaningful use requirements, new models of care and growing consumer demand, among others. **Additional levers imposed on providers, such as the Medicare Conditions of Participation (CoP), are not necessary. With regard to privacy and security issues, the AHA strongly believes that improving the infrastructure to support secure data sharing in support of clinical care can be accomplished within the existing Health Insurance Portability and Accountability Act (HIPAA) requirements. Similarly, we urge ONC to work within the existing framework of cybersecurity policy.**

The nation must make rapid progress to develop secure systems for interoperability, not only to improve care, but to support new models of care that can move the country forward to achieve the Triple Aim of better health care, better health and lower costs. To do so, we must have a clearly defined scope of activity and clarity on the path forward. Certain activities will require federal government actions, but the private sector also should play a driving role. Through

coordination and collaboration of targeted activities, we can reach our shared goal of functional and efficient information exchange.

Our detailed comments are attached. They elaborate on the recommendations above to advance interoperability in the near term, and address issues raised in the roadmap according to the interoperability "building blocks" identified by ONC. We hope our comments are helpful as you consider revisions to the roadmap.

Thank you for opportunity to provide our thoughts on this very important issue. If you have any questions, please feel free to contact me or Diane Jones, senior associate director of policy, at djones@aha.org.

Sincerely,

/s/

Linda E. Fishman
Senior Vice President
Public Policy Analysis and Development

Attachment

RECOMMENDATIONS TO ADVANCE INTEROPERABILITY IN THE NEAR TERM

Common Clinical Data Set. **ONC should make the exchange of the common clinical data set established in meaningful use Stage 2 final rule and supported by the 2014 Edition of EHR certification criteria a short-term goal for the interoperability roadmap.** The roadmap identifies a common clinical data set that includes the current stage 2 data elements and additional data elements not currently included in meaningful use. As a result, the roadmap would begin at a place that is a step ahead of current regulatory requirements for interoperability. Hospitals have made significant strides to attest to the current meaningful use data set, but fewer than 40 percent have attested to Stage 2 of meaningful use using the 2014 edition of certified EHRs. The physicians and other providers with whom they would exchange information have significantly lower rates of attestation.

C-CDA. **ONC should work to improve and constrain its implementation of the C-CDA used to support interoperability of health information content. We also recommend the development and publication of case studies and operations research to better understand the strengths and limits of the C-CDA.** The EHR certification requirements mandate the use of the C-CDA standard, which is intended to organize information for exchange. The lack of constraint in its implementation results in a standard that does not meet the needs of clinicians for relevant clinical data. Additionally, the set of data that providers are required, by regulation, to share under the transitions of care requirement in meaningful use is too big and risks doing harm by overloading clinicians with too much information, rather than providing the most relevant information. Clinicians need greater flexibility in the set of data to share to make the information usable and actionable.

Standards and Implementation Specifications. **ONC should mature standards through pilots and demonstrations to determine their readiness for use before inclusion in federal regulation that mandates their use. We also recommend the development of a single, federally-supported and nationally-recognized crosswalk between SNOMED CT and ICD-10.** While multiple standards have been included in the meaningful use program, many of them are immature. As a result, vendors have the flexibility to interpret and implement them differently. Hospitals and health systems find it challenging to share information to support clinical care because of unique system configurations and unique implementation of standards by vendors. The result is that sharing and integrating data across EHRs is complex and costly due to unique interfaces supporting data exchange. Sometimes, it is simply not possible. Draft standards that are being matured in pilots or demonstration projects signal federal support for innovation without imposing an immature standard on the entire provider community. Relying on evidence from real-world pilots that a draft standard can be scaled for ubiquitous use and become a mature standard, the federal government can then use the regulatory process to advance use of the standard, if needed.

Use Cases. **The AHA recommends that ONC support the work of the Centers for Medicare & Medicaid Services (CMS) to identify a set of specific use case scenarios that make the existing meaningful use Stage 2 requirements for sharing information achievable**. The roadmap includes a list of 56 separate use cases. To make progress, the federal government

should focus its efforts on a set of use cases that will accelerate the exchange of data that is currently taking place. Additionally, specific use cases would signal to vendors that they should work on priorities that support health information exchange in support of care coordination, collaboration and new models of care.

Testing and Certification Infrastructure. **The AHA strongly recommends a more active federal role in conformance testing of systems to support interoperability. Specifically, ONC should modify the certification program for EHRs to require that certified EHRs undergo rigorous conformance testing that reflects real-world stress rather than ideal conditions. In addition, ONC should make the testing infrastructure available by 2017.** 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. After making sizeable investments over the past five years, AHA members report that the EHRs they purchased do not easily exchange information. They continue to be unable to pull patient data from disparate sources to facilitate patient-centered care without impeding workflow. Given the significant investments already made, the 2014 Edition certified EHRs and the testing and certification infrastructure must be a starting point for efforts to improve interoperability.

Test beds should be widely available to developers and end-users of EHRs on an ongoing basis to support development, certification and assessment of standards that support interoperability. We recommend the inclusion of the National Institute of Standards and Technology (NIST) in a plan to advance the development of test beds. NIST has significant expertise in helping craft industry consensus on standards and developing methods to test standards conformance. It is only by thorough and widely available testing that true interoperability can be achieved. Rigorous conformance testing of EHRs and of interfaces to ancillary systems (such as lab information systems) that connect to EHRs is 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 have "built in" interoperability, rather than the current scenario in which information sharing is "added on" via multiple point-to-point interfaces post-certification**.**

Transparency Concerning How Products Support Interoperability. **The AHA urges ONC to work with vendors to support disclosure of the documentation that confirms conformity to standards for interoperability.** Greater transparency of the information conveyed during the testing and certification process is a good starting point. Specifically, as part of the conformance testing infrastructure, the federal government should support processes that permit the end user to view the testing infrastructure. This would allow providers to determine product performance and give purchasers of EHRs the knowledge needed to make more informed choices. **We also recommend that ONC develop additional transparency metrics about how well EHR products and their vendors support interoperability.** This concept is comparable to the many reporting requirements that Medicare places on providers and health plans, such as *Hospital Compare* or the Medicare Advantage Star ratings.

Exchange Networks. **ONC should support development of efficient and affordable exchange networks that providers can use to share information through either point-to-point or**

query exchange. We also urge ONC to make accessible provider and patient directories, and mandate that all health information exchanges (HIEs) offer provider and patient directories at little or no cost for authorized users. Delivery system reform is building the business case for appropriate sharing of patient information. Available and affordable exchange networks will support the ability of all providers to meet the growing demand for information exchange. The current patchwork of vendor-provided solutions and regional or state-based HIEs does not meet providers' needs, and leads to redundant costs when providers must connect to multiple exchanges in order to share information for different uses. For example, many providers are engaged in multiple HIEs and also have multiple point-to-point connections for public health reporting, sharing lab data or other information-sharing objectives.

Unique Patient Identifier. **The AHA regrets that the Department of Health and Human Services (HHS) is prohibited by Congress from advancing a unique patient identifier to support the safe exchange of health information. A national patient identifier solution is urgent. At a minimum, we believe the federal government should fund a study of consumer attitudes about a patient identifier in the digital age.** The absence of a national mechanism for identifying individuals, such as a unique patient identifier, creates additional challenges, both within a single health care organization and nationally. We lack an eMaster Patient Index that will match across multiple EHR platforms and also lack mechanisms that record and manage patient consent and preferences for data-sharing. Patient safety concerns arise when data are incorrectly matched, so that, for example, a patient's current medication is not listed, or the wrong medications are included in the record. Probabilistic matching is not a solution. From a cost perspective, hospitals and health systems devote significant technical and human resources to avoid both the creation of duplicate records and the incorrect merging of records.

Medical Device Interoperability. **The interoperability of medical devices and EHRs within the hospital also requires urgent attention.** Intra-hospital barriers to interoperability arise from the number and variety of data collected by medical devices that should be integrated into the record. 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. This creates a safety risk if, for example, a drug pump sends incorrect medication information that is then used in clinical decision-making. Providers need confidence that the data presented are correct as they move from their source to the EHR.

Alignment of the Business Cases for Interoperability. **ONC should leverage the testing and certification recommendations stated above to accelerate a more standardized approach to information exchange that does not include exacting tolls on providers through the creation of interfaces between data sources.** The meaningful use program has been an accelerant of the adoption of EHRs, yet the priorities of meaningful use have not necessarily advanced the availability of technology that supports interoperability. There is currently a distinction between the business case for a provider (interoperability in support of clinical transformation) and the business case for a vendor (interoperability that is sufficient to meet a certification requirement). The current structure of repeated tolls 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 that we can move from potential data access to data exchange and use.

COMMENTS ON SPECIFIC INTEROPERABILITY BUILDING BLOCKS

Interoperability Roadmap Building Block 1- Rules of Engagement and Governance. The roadmap envisions a public-private governance body that would set the "rules of the road" for health information exchange. Governance mechanisms should focus on the technical standards that support the sending, receipt and use of accurate health information in support of clinical care by organizations that do not share IT systems. We further recommend that any nationwide governance framework for interoperability align, and not conflict with, the flow of information within existing delivery systems or between health care organizations.

The roadmap proposes to identify common policies, as well as operational and business practices, to establish trust across electronic health information trading partners. The AHA appreciates the inclusion of a governance structure that is sufficiently inclusive and flexible to take into account the wide variety of entities and transaction types that exist in the marketplace. Currently, there are many different exchange activities at the local, regional and state level that are not necessarily compatible with each other, and these activities are subject to multiple regulations, including federal and sometimes state regulations. This variability impedes uniform, trusted and secure information exchange nationwide at a time when hospitals increasingly need and are required to exchange information in support of the coordination of care with each other, with post-acute care providers and with providers in community settings. Thus, governance is needed to ensure all of these parties are moving toward a common approach that is less cumbersome and facilitates sharing across entities. The governance framework also must actively engage all parties that will use any business practices and technical standards that emerge, particularly those on the front lines of care. To that end, we recommend that providers and consumers make up a majority of representatives on any governance body.

Interoperability Roadmap Building Block 2 - Supportive Business, Cultural, Clinical and Regulatory Environments. **The AHA opposes proposals in the roadmap to increase the number of policy levers linking payment to achieving interoperability.** There are already many levers on providers to exchange health information, such as the meaningful use requirements, ongoing public health reporting requirements and growing consumer demand that their information follow them as they move through the health system. New payment models, such as accountable care organizations (ACOs), bundling initiatives and capitation arrangements, also require health information exchange. HHS Secretary Sylvia Burwell announced Medicare specific goals to move fee-for-service payments from volume to value by 2018, including tying 50 percent of payments to alternative payment models and 90 percent of payments to some type of quality or value metrics. The existing market pressures and regulatory requirements are motivating information sharing and will continue to do.

The AHA strongly opposes the use of Medicare CoPs to advance interoperability. The CoPs are requirements that the HHS Secretary finds necessary in the interest of protecting the health and safety of patients receiving services in hospitals. The use of CoPs and/or guidance to require interoperability is an inappropriate and heavy-handed regulatory lever. The AHA applauds the ongoing work by CMS to update the CoPs continually to ensure that regulations are current, and reflect the best and most recent knowledge about the safe operation of hospitals. As the standards

that support interoperability are used and mature, we recommend that ONC and CMS conduct a study about the experience with the use of interoperability standards to support the health and safety of patients in hospitals.

The AHA recommends that the roadmap not link the alignment of electronic clinical quality measures (eCQMs) reported by EHRs to the advancement of interoperability. Additionally, we do not support a date certain for eCQM reporting from certified EHRs for Medicare quality or value-based payment programs. CMS and ONC have identified and are working to address challenges to the ability of EHRs to generate valid, feasible and reliable eCQMs. Despite the availability of an option to report eCQMs for both the EHR Incentive Program and the Hospital Inpatient Quality Reporting Program in the same payment year, there is little evidence that this option is being used. Moreover, in the 2015 payment rules, CMS specifically stated that a date certain for required use of eCQMs could not be determined.

Interoperability Roadmap Building Block 3 - Privacy and Security Protections for Health Information. The roadmap states that participation in a learning health system will be highly dependent upon reliable mechanisms to ensure privacy and security protections for health information. In order to provide consistent representation of permission to collect, share and use identifiable health information, the roadmap lists several goals and actions that would address access within the HIPAA privacy requirements. **The AHA strongly believes that improving the infrastructure to support secure data sharing in support of clinical care can be accomplished within the existing HIPAA requirements. The proper focus should be on making these requirements the prevailing standard nationwide if it is essential to address access to health information within the interoperability context.** The roadmap proposals could exacerbate the existing conflict among federal, state and local laws, rather than working to limit them. 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.

In addition, ONC should work with the HHS Office for Civil Rights to determine where additional guidance may be needed to help stakeholders understand how HIPAA privacy and security rules apply in ACOs and other multi-stakeholder alternative delivery system entities. Under the current HIPAA privacy rule, the use and/or disclosure of protected health information between covered entities for health care operations that expressly qualify as quality assessment and improvement activities is permissible only when both the disclosing and receiving covered entity have or had a relationship with the patient about whom the information pertains. Achieving the meaningful quality and efficiency improvements that a clinically integrated setting promises requires that all participating providers be able to share and conduct population-based data analyses.

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. **The AHA recommends that ONC work within the broader framework of existing cybersecurity policy.** The roadmap includes proposed activities for ONC or HHS, but activities in this area must align with 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.