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February 06, 2015

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

Dear Dr. DeSalvo,

On behalf of the Electronic Health Record Association (EHRA), we are pleased to comment to the Office of the National Coordinator (ONC) regarding the Federal Health IT Strategic Plan 2015-2020. As always, our comments reflect the collaborative review and input from members representing EHR companies, large and small, serving the vast majority of hospitals and ambulatory practices using EHRs to deliver safe, efficient care to their patients.

#### **General Comments**

A critical role for ONC is to ensure that the Strategic Plan is synchronized with the recently released Interoperability Roadmap as we work together to achieve greater interoperability and health information exchange across the entire healthcare system. As the Interoperability Roadmap is refined and implemented over time, harmonizing these two plans will become increasingly important.

EHRA encourages ONC and the other government agencies involved in health IT to identify existing metrics that can measure the progress of the Plan. This step will also serve to clarify the specific role each agency plays in supporting the Plan. Each agency should develop a metric or metrics that supports the objective for which they are responsible, or identify those that may already be in use in existing programs, to measure their progress toward attaining their objective(s). This approach would aim to provide valid data to be reviewed at the proposed annual meeting to assess our collective progress toward achieving Plan objectives.

## **Goal 1: Expand Adoption of Health IT**

- **Objective 1A: Increase the adoption and effective use of health IT products, systems, and services**
  - **3-year Outcome: Increase the percentage of hospitals and professionals who successfully demonstrate meaningful use**

Although EHRA supports Strategy 1, we have consistently noted opportunities for improvement of the current certification program. EHRA has worked closely with ONC and others to plan for and will participate in the February 11 ONC-led Kaizen on the certification process, where we expect to discuss this and other proposals for its expansion. We will continue to emphasize that increased certification requirements across government programs will require more resources from both health IT developers and providers, which can detract from the important focus on usability and patient safety.

EHRA supports Strategy 2, to expand the capacity of the workforce to support use of health IT. We have seen progress in this regard as part of various ONC-funded programs, and recommend reviewing those programs to support expansion of educational and professional opportunities in health IT.

Relative to Strategy 3 for this objective, which focuses on establishing technical guidance and standards, EHRA continues to recommend that ONC and its federal partners allow standards to develop and be tested in the private sector, encouraging stakeholders to collaborate on shared solutions for health information exchange (HIE) challenges. Regardless of how standards evolve, however, it is important that common interoperability certification criteria are applied to all health IT subject to the ONC certification program.

EHRA supports adoption of telehealth and mobile technologies among providers and individuals, as described in Strategy 4.

Noting that Strategy 5 focuses on expansion of the ONC Certification Program to certify products useful to providers across the care continuum, EHRA requests more specifics as to the intent of this objective and how it would be administered. We have expressed concerns regarding the efficacy and efficiency of the current certification program and would like to see improvements in processes and testing tools before expanding the program.

- **Objective 1B: Increase user and market confidence in the safety and safe use of health IT products, systems, and services**
  - **3-year Outcome: Refine and implement frameworks for health IT safety and innovation**

In general, EHRA reinforces our persistent position that providers must be included in the dialog about health IT and patient safety. Although we are uncertain about the ways in which Strategy 2 to integrate evidence on safe use of health IT into health IT certification, would be implemented in a way that does not add to certification complexity and burden, EHRA does support Strategies 3 through 5 to encourage the application of human factors, health literacy, and user-centered design in the development and use of health IT products, systems, and services; to implement a balanced, transparent, and risk-based approach to health IT oversight; and to develop, select, promote, and implement health IT standards in transparent ways that promote competition, foster innovation, and minimize barriers to market entry for developers and users.

And although we support the general intent of Strategy 6, to promote data portability and interoperability, EHRA questions whether the federal government is the most appropriate mechanism to effectively monitor or regulate the technologies and policies required to achieve broad HIE. We caution

that data portability has many dimensions and that this must be approached in a practical and non-disruptive fashion.

Reflecting EHRA's ongoing support for refining and implementing frameworks for health IT safety and innovation, we encourage ONC to incorporate the final FDASIA report ([FDASIA Health IT Report: Proposed Risk Based Regulatory Framework](#)) into this Plan to ensure that there is alignment between the Plan and the final FDASIA Report so there can be no questions as to the intent of HHS in this area.

- **Objective 1B: Increase user and market confidence in the safety and safe use of health IT products, systems, and services**
  - **6-year Outcome: Increase the ability of health IT to manage information flow and adjust for context, environment, and user preferences**

Recognizing the range of health IT solutions that need to be included in this objective, EHRA believes that the discussion must include payers and other health IT developers, as well as providers, given the large stake these stakeholders have in moving data across the entire healthcare continuum. It is important to acknowledge that EHRs are not the only systems responsible for patient safety in the health IT paradigm.

## **Goal 2: Advance Secure and Interoperable Health Information**

The EHRA supports the overall objective to enable individuals, providers, and public health entities to security, send, receive, find, and use electronic health information. We agree that it is important to enable all stakeholders to have access to the right data at the right time for the intended purpose with the least amount of effort.

To that end, it is important to understand use case priorities first and then determine what standards are needed and/or missing to effectively support those use cases. We are concerned that the current plan aims to prioritize standards before understanding and prioritizing use cases based on clear support of quality and cost improvements.

We seek clarification on the meaning of:

*"In order to promote consistent standards implementation and reduce implementation variability, the federal government will continue to work with standards development organizations (SDOs) and industry stakeholders to assure that newer versions of standards and implementation specifications more clearly and more often describe discrete requirements."*

If the focus is on the need to reduce ambiguity in implementation guidance that promotes more efficient deployment processes, EHRA is supportive. If, however, the statement intends to focus on the need of shifting from document-level interoperability to discrete data-based interoperability, it must be clarified that before document-level interoperability was conceived, discrete data-level exchange was the norm and still is the predominant form of interoperability (see X12, NCPDP, and HL7 based transaction capabilities). Neither document-only, nor discrete data-only interoperability will allow us to support the wide range of interoperability required by the myriad of use cases that must be supported; as discussed in detail in the recently released Interoperability Roadmap, both approaches to data exchange and interoperability are important and the increasing use of discrete data exchange will take some time.

- **Objective 2A: Enable individuals, providers, and public health entities to securely send, receive, find and use electronic health information**
  - **3-year Outcome: Increase the percentage of individuals, providers, and public health entities that electronically and securely send, receive, find and use a basic set of essential health information across the health care continuum**

EHRA requests more specificity about the current status of federal agencies in terms of enabling individuals to engage in exchange (e.g., what percentage of patients are electronically and securely sending, receiving, finding, and using essential health information). This kind of information would be helpful in establishing a baseline to measure future progress.

We suggest that Strategies 1 and 2 must be closely executed together for each use case to avoid gaps in implementations – e.g., the Direct implementation had substantial focus on the standards, but less on the directories, policies, and other deployment steps, which caused substantial deployment challenges.

Use of incentive programs will help focus and prioritize interoperability efforts that provide clear value and are sustainable.

However, EHRA seeks to clarify the scope of interoperability for this objective. Is the primary focus on inter- or intra-organization/stakeholder interoperability? Considering the focus is on sharing of health information across the care continuum, we suggest focusing on the primary outcome measures on inter-organization/stakeholder interoperability.

- **Objective 2B: Identify, prioritize, and advance technical standards to support secure and interoperable health information**
  - **3-year Outcome: Increase use of common standards among federal agencies, private industry, and the biomedical research community**

EHRA is strongly supportive of federal initiatives to “advance” appropriate standards, rather than developing them outside of the public/private sector. It is also important to consider standards maturity in order to avoid unnecessary rework or introducing new standards (or versions of standards) that have not been well tested and proven.

We agree that prioritization of use cases is important to provide focus and clear maturation opportunities in support of high-value use cases. Those, in turn, will identify the relevant standards, implementation guides, infrastructure, trust and legal frameworks, deployment components, and gaps that may exist. Therefore, the driver should not be prioritizing standards first as suggested in the statement, “*Focusing on the highest priority standards can help accelerate their widespread adoption more quickly*”; but rather the driver should be high priority use cases and their value propositions to then identify gaps as interoperability is a means to an end, not an end in itself.

EHRA notes that, regarding Strategy 2, not only technology, but also processes and skills are required to achieve compliance. To the extent compliance can rely on technology, compliance will have to rely substantially on robust testing tools to ensure verifiable compliance.

We note that Strategy 4 creates an impression that the focus is the immediate and direct exchange of data between medical devices to certified health IT. In reality, however, various architectures can be deployed involving various forms of intermediary systems to enhance data management and capabilities. Therefore, we suggest that the focus should be on the general capability of enabling data

from medical devices to be incorporated into health IT software, such as EHRs, decision support tools, business intelligence, etc.

EHRA suggests that, for Strategy 5, having robust, public, and open source testing tools will provide opportunities to further streamline certification processes and focus on interoperability capabilities (e.g., edge behaviors, certain privacy/security capabilities) that can only be validated by a human.

- **Objective 2C: Protect the privacy and security of health information**
  - **3-year Outcome: Increase the reach of education and training information and tools for health IT privacy, security and cybersecurity**

EHRA notes this objective could be more specifically described by the inclusion of security risk assessment and risk mitigation. In our experience, providers generally are not adequately educated and trained on how to effectively assess and mitigate risks for health IT privacy, security and cybersecurity.

In general, EHRA supports Strategies 1 and 3, but suggests that, for Strategy 2, there needs to be clarification about what is possible under HIPAA and where it may fall short in a fully automated healthcare system.

Regarding Strategy 4, it is important to note that many privacy and security safeguards relevant to EHRs actually operate at the enterprise level – i.e., the operating system, not within EHRs. As an industry, we should focus on mature standards in this area and apply them appropriately to relevant technologies.

### **Goal 3: Strengthen Healthcare Delivery**

EHRA believes strongly that we cannot move away from the payment-for-volume model to payment-for-value (outcomes) without health IT, including but not limited to EHRs, to provide data to assess outcomes and quality. We appreciate that the Plan acknowledges the time required to make this transition (e.g., development and testing of eQMs, etc.).

- **Objective 3C: Improve clinical and community services and population health**
  - **3-year Outcome: Increase use of health IT systems to provide evidence-based guidance on appropriate use of screening and prevention services**

EHRA suggests that using data collected from health IT tools other than EHRs should also be highlighted in this objective — i.e., patient generated health data should be included — to exploit mobile applications and technologies. In addition, the concept of promoting wellness and quality leading to value also should be included.

- **Objective 3C: Improve clinical and community services and population health**
  - **6-year Outcome: Identify innovative uses of health IT to connect individuals and providers to community resources, social services, and health education programs**

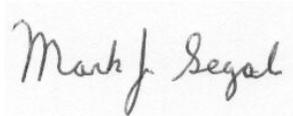
Connecting to community services will require tools beyond EHRs, as the data required to provide useful information comes from multiple sources.

### **Goal 4: Advance the Health and Well-Being of Individuals and Communities**

EHRA recognizes that all stakeholders have a responsibility for individuals who are not part of the healthcare system at all, and that health IT can support efforts to identify and reach out to those people.

As always, EHRA recognizes the thoughtful and extensive effort that has gone into developing this Plan and congratulates ONC for engaging a variety of stakeholders in refining it. We look forward to our ongoing collaboration in this important work.

Sincerely,



Mark Segal, PhD  
Chair, EHR Association  
GE Healthcare IT



Sarah Corley, MD  
Vice Chair, EHR Association  
NextGen Healthcare

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#### About the EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of nearly 40 companies that supply the vast majority of operational EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

The EHR Association is a partner of HIMSS. For more information, visit [www.ehrassociation.org](http://www.ehrassociation.org).