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The Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
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Dear Dr. DeSalvo:

On behalf of Health IT Now's members, thank you for the opportunity to provide comments on the *Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap.*

Health IT Now (HITN, www.healthitnow.org) is a diverse coalition of health care providers, patient advocates, consumers, employers, and payers who support the adoption and use of health IT to improve health care and to lower costs.

General Comments

We are concerned HITECH is not achieving the goals set out by Congress, namely the goals of increased efficiency, improved health outcomes and better access to electronic information, largely because the program has failed to facilitate interoperation across systems and devices used by providers. We are likewise concerned that Meaningful Use is becoming more and more burdensome on health care providers with little resulting improvement in patient care. In fact, the program's costs may now outweigh the program's benefits. There are several reasons for this, including: program rules that focus on low priority measures; lack of adoption of standardized vocabulary and data elements; adoption of systems designed for fee-for-service rather than coordinated care; misaligned priorities across federal programs; and a lack of focus on achievable short-, mid- and long-term outcomes.

While we appreciate ONC's focus on some of these problems in the draft Roadmap, generally, we are concerned that the Roadmap is overly focused on ambiguous goals that lack specific strategies and tactics that will produce achievable outcomes. For example, the document outlines a series of steps private industry, providers, patients and others will or should take over the next three, six and ten years to achieve the goals of the Roadmap. While we applaud ambition, we question by what levers and through what means ONC proposes to change or align incentives to produce these actions considering the current statutory limits faced by the Agency. We further question whether many of the steps in the Roadmap are desirable, achievable or attainable. We are concerned the Roadmap may become another document in the pile of documents that outlines ambitious goals, but achieves little, due to a lack of focus on attainable outcomes.

We encourage ONC to focus on the achievable short-term and long-term goals that are within the Agency's ability to reform or change. We specifically encourage ONC to focus on improving the process for and adoption of interoperability standards and in its ability to certify (and decertify) products for use in federal programs. To avoid wasted effort, we encourage ONC to tailor their initiatives to complement the work Congress is currently undertaking, thus aligning the Agency's tools with the Nation's desire to leverage technology and data to improve health.

Our specific comments on the Roadmap are outlined below.

1. Timing.

We believe ONC can and should standardize vocabulary and data elements and foster open standards under a workable architecture more rapidly than the timeline outlined in the Roadmap. We are concerned the 10-year plan to a learning health system is too prolonged and would leave health care interoperability behind most other industries and countries.

2. Focus.

As indicated, the Roadmap contains multiple, ambiguous goals and strategies in the three, six and ten year timeframes. We encourage ONC to focus on the achievable goals by defining specific strategies and tactics that are within the Agency's purview. We also encourage ONC to clarify and/or add taxpayers as a stakeholder group when developing subsequent iterations of the Roadmap. Taxpayers have already invested $30 billion in ONC's programs and should expect a return on their investment.

3. Governance.

We appreciate ONC's recognition that the private market is moving ahead with governance mechanisms that support structures that advance interoperability. We believe ONC can best support these efforts by not impeding the work of CommonWell and other organizations that support their members in interoperating.

We once again call on ONC and CMS to use every lever available to end the practice of information blocking and artificial barriers to information exchange, including business practices. These include certification and decertification, application of the fraud laws, and conditions of participation in Medicare, among others. We believe it is unacceptable that these practices persist and are subsidized by taxpayers in programs designed to facilitate information exchange and interoperability.

We strongly support the Roadmap's call to develop a policy framework for patient-led APIs and sharing exchange of patient-generated health data. We believe patient directed information exchange and APIs are an elegant and significantly disruptive approach that will significantly advance interoperability.

Finally, we support creating clear feedback loops to Standards Development Organizations as these groups engage in critical, ongoing work to advance interoperability.

4. Supportive Business Case.

Many think the silver bullet to high health costs and poor healthcare quality lies in creating more incentive programs for health IT or in tweaking interoperability standards to get vocabulary or data content just right. In other industries, the key to improving quality, outcomes and costs rests in an organic (self-organizing) business case for use of technology to improve value (cost and quality) and to become more productive (output and cost). We believe that the U.S. health care system lacks a compelling business case to improve value or productivity. Many aspects of our current health care system encourage inefficiency, promote waste and facilitate concentrated and consolidated markets aided and abetted by data silos. In some instances, federal policy and taxpayer dollars subsidize this waste.

HITN believes that Meaningful Use (MU) program standards are insufficient to successfully support care coordination models, especially those being implemented as part of the Affordable Care Act. These include medical homes, Accountable Care Organizations, hospital readmission prevention programs and others that hold vast potential to lower costs and improve health outcomes.

We have also argued elsewhere that all Federal programs – including the various models in Medicare and Medicaid – should adhere to basic interoperability standards and that ONC has a key role to play in coordinating the efforts of various federal agencies. Specifically, we have suggested that ACOs, the Stark and Anti-Kickback laws, Medicare Conditions of Participation and other programs can be realigned to create powerful incentives to interoperate.

We suggest moving all the elements outlined in Table 2 related to critical actions to support the business case for interoperability into an end of 2018 timeframe as this more closely aligns to the expected changes in Medicare reimbursement policy and in the scheduled statutory movement to Value Based Payment models under current law.

Finally, we find it interesting the Roadmap makes little mention of the ONC HIE program that provided half a billion dollars to facilitate information exchange. To the extent there are lessons learned – both successes and failures – we encourage ONC to incorporate them into the Roadmap.

5. Privacy and Security.

The Roadmap does an excellent job of outlining the obvious need to update and modernize HIPAA and cyber security rules to match the great technological progress and cultural changes that have occurred since HIPAA, and even HITECH, were enacted. We believe that, with incentives, technology and data resources can be leveraged to speed treatments and cures to patients in a safe and secure manner. Therefore, HITN calls for a new nationwide framework and asks that ONC: (1) identify where HIPAA is and is not working; and (2) develop the context for a new law that will better protect privacy and the use of data in a more uniform, preemptive

fashion. We also ask HHS to provide further clarity around the privacy and security rules where there is identified and significant confusion. For example, HHS should clarify that individuals and their caregivers currently have access rights to their electronic health information and that they can direct Covered Entities to share information with Business Associates.

Regarding cyber security, we believe it is prudent to revise the Information Sharing and Access Centers (ISACs) process. We believe the ISACs, created a decade ago, require updating in order to improve their ability to identify and share best practices for emerging cyber threats. Much more can be done to make the ISAC's mission, goals, and operations more transparent, and we suggest that ISAC focus its efforts on emerging threat data rather than on all data.

6. Core Technical Standards.

We agree that electronic health information is not sufficiently structured or standardized and as a result is not fully computable when it is accessed or received. We believe ONC should identify and adopt the industry-developed standards related to semantic and syntactic interoperability retroactively for Stage 2 in order to facilitate the goal of enabling a majority of individuals and providers to send, receive, find, and use a common set of electronic clinical information nationwide by 2017.

As part of any interoperability and information exchange strategy, we suggest the Roadmap become much more aggressive in prioritizing and requesting industry development of standards for interoperability and exchange that support care coordination across CMS programs, including:

- Transport standards that account for diversity in delivering data;
- Vocabulary and data standards that uniformly promote standardization;
- Better alignment of standards and health information exchange policy to capitalize on the infrastructure supported by public and private HIEs; and
- An end to subsidies for business practices that block information.

As HITN has argued elsewhere, interoperability and information exchange are the cornerstones to achieving care coordination, quality improvement, and better patient engagement. Without the ability for patients and providers to easily locate and securely exchange health information, we believe the effectiveness of the Meaningful Use program will be limited.

7. Certification and Testing.

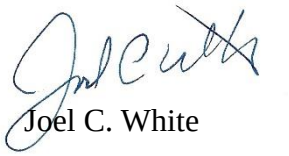
The CMS Stage 2 Final Rule requires EPs, EHs, and CAHs to conduct one or more successful exchanges of a summary of care document with a recipient who uses an EHR from a different vendor, or to conduct one or more tests with the CMS designated test EHR. ONC should adopt a performance standard that would require EHR technology to successfully electronically process validly formatted Consolidated CDAs no less than 99 percent of the time within the 2015 to 2017 time frame.

HITN believes this will facilitate both the exchange of the Consolidated CDA and its use across different EHR vendors and disparate providers. A 9 percent threshold recognizes that all CEHRT should be capable of at least receiving and consuming the Consolidated CDA, while allowing a one percent variation to account for limited failures in systems that cannot handle differently formatted CDAs. A 99 percent threshold applied to both the transport standard and the ability to process the Consolidated CDA would allow almost all Meaningful Users to trust that they will be able to both exchange and use summary of care records.

Conclusion

We believe the Administration stands at a crossroads in health information technology policy. We appreciate the work that is represented in the Roadmap and encourage you to leverage the programs under your control, direction, and stewardship, and help realize the Department's vision of an information-rich, person-centered, high performance health system where, "…every health care provider has access to longitudinal data on patients they treat to make evidence-based decisions, coordinate care and improve health outcomes."

Sincerely,



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