



AMERICAN OSTEOPATHIC ASSOCIATION

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April 2, 2015

Karen B. DeSalvo, MD, MPH, MSc
National Coordinator for Health Information Technology
Acting Assistant Secretary for Health
Department of Health and Human Services
200 Independence Avenue, SW
Washington DC, 20201

Re: Connecting Health and Care for the Nation; A Shared Nationwide Interoperability Roadmap Draft Version 1.0

Dear Dr. DeSalvo:

Thank you for the opportunity to provide comments on the draft Nationwide Interoperability Roadmap. The American Osteopathic Association, which represents 110,000 osteopathic physicians (DOs) and osteopathic medical students nationwide, commends the Office of the National Coordinator for Health IT (ONC) for its collaborative efforts to address the important issue of interoperability.

The AOA shares the premise and principles of ONC's vision for a person-centered health IT ecosystem. The osteopathic approach to medicine is to work in partnership with patients and empower them to be active managers of their health by developing lifestyles and behaviors that help prevent disease and promote wellness. To help patients succeed in managing their health requires the support of local, state, and federal resources, given that many factors including socioeconomic challenges contribute to the overall health and well-being of the individual.

The AOA believes creating a nationwide environment that links the health care delivery system with communities and societal supports to enable continuous learning and improved health, begins with the patient-centered medical home (PCMH).

The PCMH provides the foundation for an integrated health care delivery system. Expanding the PCMH's foundation into networks establishes the medical neighborhood (ie accountable care organizations). From that neighborhood, a nationwide learning health system can begin to take shape. Health IT, when used appropriately, provides the necessary infrastructure for the integrated health care delivery system and, by way of enhancements, the nationwide learning health system.

The AOA appreciates that the proposed Roadmap as a living document which will evolve over time. We agree that developing a nationwide learning health system will take a phased in approach expanding over several years. Our comments and recommendations, which focus on the tools needed to build a strong foundation and secure infrastructure over the next three years, are as follows:

- The infrastructure must be clinically-driven and without provider-to-provider communication challenges.
- Physicians should have a prominent voice in the governance process.
- The initial set of high-value use cases should focus on routinely practiced clinical or health care activity that support the greatest number of physicians, medical staff, or patients.
- Given the financial hurdles that impede the widespread adoption of interoperable HIT, public and private payers must design their incentives in a scalable way to help small practices take advantage of HIT and to assure them that their HIT investments are worthwhile.
- Vendors must be held accountable to ensure that their products are not designed for planned obsolescence forcing practices and providers to make significant investments in upgrades as they do currently under the Meaningful Use/EHR Incentive Program.
- EHR vendors must work alongside practicing primary care teams to create optimal clinically useful EHR.
- ONC should adopt the recommendations offered in the American Medical Association's (AMA) recent coalition [EHR Certification Letter](#).
- Measures to bridge the digital divide should be specified in the Roadmap.

Governance

The Roadmap's vision expands the types of information, information sources, and information users well beyond clinical information derived from electronic health records. As indicated in the Roadmap, to establish a sound HIT infrastructure for a fully integrated health care system and ultimately a nationwide learning health system, the initial focus must be on progressing further with EHR interoperability and usability. In addition to being patient-centered, the infrastructure must be clinically-driven and provider-to-provider communication challenges must be resolved.

The AOA agrees that a critical component of interoperability is a common set of standards, services, policies, and practices that facilitate appropriate electronic health information exchange nationwide. We support the proposed shared governance process, composed of public and private stakeholders, who will work together to identify and address issues that currently inhibit interoperability. As the Roadmap considers the current environment to support multiple levels of advancement, it should address the different stages of interoperability that providers will have to move through.

Physicians must have a prominent voice in the governance process which should be clinically-driven. ONC must consider and incorporate clinician feedback in every step of implementation of the Roadmap. Physicians balance personalized care with population-based trends to ensure optimal care for their patients. The most integral part of our health care system – our physicians and their expertise - should be considered and leveraged in the development of an effective governance mechanism, particularly as it relates to alleviating the administrative and costs burdens for small practices, especially in rural and underserved areas.

The Roadmap rightfully refers to a number of organizations that already have been created or enhanced to define policies, practices and standards to enable interoperability. The Roadmap further recognizes that these organizations play an important part in the governance landscape. Their work should be considered a resource to be leveraged so that stakeholders are not required to “reinvent the wheel.”

According to the Roadmap, the coordinated governance process should support functions related to technical standards including the prioritization of use cases for which standards are needed. Focusing initially on a set of high-value use cases could vastly reduce the policy and administrative burden in programs like the EHR Incentive Program and enhance provider-to-provider communication, particularly in a PCMH setting. The initial set of high-value use cases should focus on routinely practiced clinical or health care activity that supports the greatest number of physicians, medical staff, or patients such as:

- **#3: The status of transitions of care:** Enables effective transitions and closing referral loops will decrease incidents of patients being lost in referral process. It also will increase communication between the primary care physician and specialist physicians.
- **#6: Track all orders:** Enables physicians to track services provided to their patients particularly when received outside the PCMH.
- **#9 Access to notifications** regarding Emergency Room visits, admission to or discharge from a hospital.
- **#12 Access to x-rays and images:** Enables the treating physician to receive a complete record. If a complete radiologic record including the report and accompanying images can be accessed by all clinicians from any facility it would be helpful to making a diagnosis in a more timely manner.
- **#33: Providers have ability to query data:** Allows the physicians to retrieve information regardless of where the physician is located geographically to use in care coordination.

Supportive business, clinical, cultural, and regulatory environments

ONC acknowledges in the Roadmap that costs can impede the widespread adoption of interoperable HIT systems. According to the Roadmap, all stakeholders who pay for health care must explore opportunities to accelerate interoperability as a key component of broader efforts to move toward a value-based health care system. HHS plans to pursue the natural lifecycle of policies to drive interoperability beginning with incentives, followed by payment adjustments, and then conditions of participation in the Medicare and Medicaid programs.

The AOA agrees that a key barrier to interoperability arises from the way in which health care has been traditionally reimbursed through fee-for-service models. Medicare's fee-for-service system has hampered innovation and care coordination. Unless Medicare moves to a new payment system that fosters innovation and higher quality outcomes, widespread adoption of an interoperable HIT system will continue to be impeded. The AOA remains hopeful Congress will approve the "Medicare Access and CHIP Reauthorization Act of 2015" (H.R. 2) to that end.

Adopting and maintaining an interoperable HIT system to establish a PCMH requires a significant amount of upfront and ongoing capital, which many physician practices lack. Current incentives are not sufficient to cover the investments made by physician practices, particularly solo and small group practices. In addition, as HHS pursues ways to promote interoperability as a core element of delivery system reform, such as requiring the use of certified HIT to furnish chronic care management services to beneficiaries, payment rates for those services are also called into question.

We agree that payment policy should encourage incremental steps toward interoperability and address those disincentives that make the transition too costly. The AOA supports the transition to alternative payment models which are value-based. The payment rates must foster investments needed to provide efficient high quality care which is based on value and not volume. Those shared savings must be enough to recoup the money practices spend to make the transformation and maintain the level of resources and services needed for an integrated health care delivery system.

The Roadmap also noted that commercial payers can make adoption of certified health IT systems or demonstration of interoperability a condition of participation for providers. For many underserved communities osteopathic physicians are the sole physicians providing complete health care within multiple county areas. If they are unable to meet the conditions of participation, patients will be denied access to care. Support mechanisms must be available from these payers for small practices to ensure they are not excluded from provider networks because they could not afford or meet certain requirements relating to an interoperable HIT system.

Health IT infrastructure of the future, like payment systems, will need to emphasize value, quality and transparency. Reforms in incentives (and reduction in costs) will help build a stronger and more flexible national health IT infrastructure, including re-engaging physicians through financial incentives beyond meaningful use, and redesigning health IT systems with more user-friendly interfaces and data structure that are flexible across clinical areas. The AOA believes vendors must be held accountable to ensure that their products are not designed for planned obsolescence forcing practices and providers to make significant investments in upgrades as they currently do under the Meaningful Use/EHR Incentive Program.

To achieve the goal of a nationwide learning system, significant financial investments by all stakeholders are necessary. Subsidies, grants, small business loans must be more readily available for practices that could conceivably be winnowed out if they are unable to meet the financial demands of HIT. In addition, public and private payers must design their incentives in a scalable way to help small practices take advantage of HIT and to assure them that their HIT investments are worthwhile.

Physician-Patient Partnerships: Osteopathic physicians encourage active participation of their patients in their health care. PCMHs and medical neighborhoods facilitate those partnerships between individual patients and their personal physicians, and when appropriate, the patient's family. All aspects of care are integrated across the complex health care system (e.g., subspecialty care, hospitals, home health agencies, nursing homes) and the patient's community (e.g., family, public and private community-based services). Care is facilitated by registries, information technology, health information exchange, and other means to assure patients get the indicated care when and where they need and want it in a culturally and linguistically appropriate manner.

A recent Mathematica study of PCMHs entitled Electronic Health Records and Support for Primary Care Teamwork published in the Journal of the American Medical Informatics Association found benefits that EHR systems showed include improved communication and task delegation with the help of instant messaging and task management software. Included in the areas where EHR functionalities were weakest and posed challenges to teamwork is unstructured data that are not easily incorporated into another system's record. We agree with the Roadmap's call for a standardized common clinical data set that is consistently and reliably shared during transitions of

care to achieve the near-term goal of establishing a foundation of interoperability that can be expanded over time.

To date, EHR systems have been vendor-driven and business-centered. To ensure effective interoperability, vendors must change their focus to provide more clinically-driven, patient-centered products and programs. The AOA agrees with Mathematica's conclusion that EHR vendors need to work alongside practicing primary care teams to create more clinically useful EHR systems.

Clinically-driven, patient-centered products and programs that enhance provider-to-provider exchange of health information will improve the overall quality of data to be made available to patients for the management of their health. The greater availability and accessibility of health care information through HIT will provide a greater opportunity and platform for patients to engage with their health care providers in shared decision-making.

Health care information includes access to timely, accurate, and actionable data on cost and health plan coverage of tests and treatments. We support the Roadmap's call to action that providers and purchasers of care should work together to have access to patient out-of-pocket costs as well as costs to payers and purchasers. This is important information for clinicians to have for decisions regarding patient care.

Digital Divide: ONC acknowledges that not every individual or clinical practice will incorporate health IT into their work in the next three to 10 years, and not every practice will adopt health IT at the same level of sophistication. We agree that the Roadmap must take into account for a range of capabilities among information services and information users, including EHR and non-EHR users as interoperability is advanced.

The Federal Communications Commission (FCC) noted in its 2015 Broadband Progress Report that deployment of broadband – particularly in rural areas – is not keeping pace with current capabilities. For example, physician practices and patients located in rural, frontier, or mountainous areas do not always have reliable access to health information technologies.

While the Roadmap makes references to persistent challenges to accessing health information, particularly for individuals in underserved communities, due to disparities in technology access and digital literacy, ways to bridge the digital divide are not clear. A nationwide learning health system must be all inclusive in order to ensure the most vulnerable populations receive the benefit of better care and better health.

In addition, as the Roadmap moves forward in this process to expand interoperable health IT to enhance patient engagement, the following use cases should be considered:

- **#14:** Patients routinely engage in health care encounters using electronic communications such as eVisits and telemedicine.
- **#20:** Patients, families and caregivers are able to use their personal devices such as smartphones, home BP cuffs, glucometers and scales to routinely contribute data to their longitudinal health records and use it or make it available to providers to support decision-making.

- **#52:** At-risk patients engage in healthcare monitoring programs which can detect life threatening situations (such as patient down and unresponsive) using at-home monitoring devices and electronic communications such as eVisits and telemedicine.

Patient Education: We agree with ONC that changing to a more person-centered vision is vital to improving health and health care outcomes, particularly since the individuals' actions have a great impact on their health outcomes.

Improving health outcomes requires patient education which is a key element in the osteopathic approach to medicine. With osteopathic medicine's emphasis on prevention and wellness, shared decision-making in a patient's care plan requires patients to be well-educated about their conditions and health care options. Patients often have incorrect information regarding health conditions, medical and surgical procedures, medications, and vaccinations. Physician practices must be well-prepared to counter these challenges with patient-level, evidence-based information.

According to the Roadmap, the person-centered care vision is that "the power of each individual is developed and unleashed to be active in managing their health and partnering in their health care, enabled by information and technology." As indicated in the Roadmap, achieving this vision will require a continuing educational effort that extends well beyond the physician's office to increase health literacy for the general public in the digital age. This educational effort must come before additional demands are made on physician practices.

While we believe HIT can support interaction and augment available information upon which to base medical decisions, caution should be taken so that HIT does not create a wedge between the physician and patient. We agree that patients should have access to their medical records and have the ability to contribute information to their records; however, measures need to be in place that patient-provided corrections are medically accurate and providers do not make treatment decisions based on false information for which they can be held liable.

The Roadmap also should specify how the needs of special populations will be met in this educational effort. Economic circumstances, educational disparities, as well as physical and/or emotional challenges facing certain patient populations may inhibit their ability to increase their digital health literacy.

According to the Roadmap, consumer advocacy groups in collaboration with government agencies, associations, and payers should develop and disseminate resources based on consumer needs to assist individuals with increasing their digital health literacy. As part of that effort, HHS should consider pulling together the most effective patient educational material and outreach messages from physician associations and disseminate that information nationally.

Privacy/Security

According to a Federal Bureau of Investigation's April 8, 2014 notification, "the health care industry is not as resilient to cyber intrusions compared to the financial and retail sectors, therefore the possibility of increased cyber intrusions is likely." The Roadmap recognizes that large organizations have the resources and expertise to have a dedicated information security team to address cybersecurity; however, small and mid-sized health care organizations may not have the resources and may not be able to afford them.

In addition to ONC's plans to work with payers to explore the availability of private sector financial incentives to increase the rate of encrypting, starting with casualty insurance carriers who offer cyber security insurance, we believe additional specified efforts are necessary to help small to mid-sized practices particularly in underserved areas adopt security measures.

The Roadmap also recommends establishing common identity proofing practices at the point of care and require multi-factor authentication for all patient and provider access to health IT systems. In moving forward with these efforts, we urge that security recommendations from the January 21, 2015 AMA coalition letter on certification be included, such as examining piloted identification solutions associated with the National Strategy for Trusted Identities in Cyberspace.

The Roadmap calls for stakeholder input regarding best practices for identity proofing methods. Alleviating administrative burdens associated with security measures also must be factored in. Security measures without legal guidance and without stakeholder input can turn into a technical constraint on access to data.

Given that physicians and other providers must comply with a multitude of federal and state laws regarding patient privacy and security of health care information, we agree that greater harmonization is needed between state and federal laws and regulations with the understanding that individual privacy rights must not be eroded.

We appreciate that the Roadmap recognizes the need for outreach and education. As laws and regulations are harmonized, additional educational efforts will be necessary particularly for physician practices to raise the level of understanding of the HIPAA privacy provisions as the nation progresses towards a nationwide health learning system.

Certification

According to the Roadmap, testing and certification are methods that can be used to assure technology users that HIT meets specific technical requirements. Currently there is no assurance that when a physician makes a significant investment in a certified HIT product that the product will be useful and beneficial to their practice.

Physicians have expressed dissatisfaction with current certified HIT products and their usability. In January, the AOA signed onto a coalition letter submitted to ONC by the American Medical Association, expressing concern over EHRs and the certification process.

We understand the Roadmap's intention is to improve interoperability by modifying the certification program to include network technologies and resources, payer systems, and population health resources and systems. Moving forward, we urge ONC to adopt the recommendations offered in the coalition letter to address the more immediate concerns related to certification.

ONC should use lessons learned from the current certification process and as stated in the letter, ONC should consider convening "a software certification learning session with participants from organizations that have experience producing, testing, and certifying software used in other high-risk or consumer-facing industries such as financial, automotive, aviation or e-commerce" in the effort to advance the certification program.

Data and Usability

We agree with the Roadmap that it will be necessary for the industry to converge and agree on the same content and vocabulary standards to satisfy interoperability because using multiple data formats is not sustainable and retains systemic costs and burdens.

According to the Roadmap, over the next six to 10 years, the industry will need to develop standards for granular data elements that can be used in documents and move toward ways of exchanging information that do not require information to be in document form. We agree that accommodating new methods of exchanging information will require the industry as a whole to invest time in planning the migration and transition from one standard to another as well as from one version of a standard to a newer version.

The governance process must address the unique needs of small to mid-sized practices particularly in underserved areas throughout the progression to a nationwide learning health system. Moving toward common data standards will necessitate system upgrades which could prove to be costly. Given the limited resources of physician practices, major upgrades should be kept to a minimum in order to prevent potentially diverting time and resources away from patient care.

Although data quality is outside the scope of this Roadmap, the Roadmap acknowledges that accurate data collection is of the utmost importance to matching data later. We agree that public and private stakeholders should establish and document best practices for patient registration, patient verification of information and patient updates, and corrections to information to ensure data quality and accuracy.

The Roadmap also describes resource location, which acts as a shared directory or collection of directories, as a core functional requirement to support nationwide interoperability. Given our experience with current provider directories which are often inaccurate and out of date, the most important focus in defining the architecture for resource location is how information will be managed, updated, and kept accurate.

While usability is outside the scope of this roadmap, we believe future interoperable HIT systems must align with the needs of the physician, in order for them to invest in those systems which will to progress to a fully integrated health care delivery system and the establishment of a nationwide learning health system. We appreciate that the Roadmap acknowledges usability along with data quality and workflow deserve separate dedicated attention.

Conclusion

We agree that as the nation progresses toward a nationwide learning health system, efforts must be made to track and measure success. We believe the Roadmap's plan to monitor progress is a step in the right direction; however, in the effort to track progress, the issue of sustainability should be addressed.

Adopting and implementing EHR systems, including maintenance and upgrades, have been costly endeavors for physician practices. While ONC acknowledges in the Roadmap that costs impede the widespread adoption of interoperable HIT systems, it does not go into detail about how costs will be determined or controlled as the nation progresses toward a nationwide learning health system. The cost of complying with and sustaining an interoperable HIT ecosystem needs to be addressed.

The AOA commends the agency for its collaborative work to date, and appreciates the opportunity to comments on ways to achieve the goals outlined in the Roadmap. We look forward to working collaboratively with ONC and other stakeholders on this national endeavor and other issues of importance to the osteopathic profession and our patients.

Sincerely,

A handwritten signature in black ink, reading "Robert S. Juhasz, DO". The signature is written in a cursive style with a large initial 'R' and a long, sweeping underline.

Robert S. Juhasz, DO
President