AMERICAN ACADEMY OF OPHTHALMOLOGY
The Eye M.D. Association

April 3, 2015

Suite 400
20 F Street, NW
Washington, DC 20001-6701

Tel: 202.737.6662
Fax: 202.737.7061
www.aao.org

Karen DeSalvo, MD, MPH, MSc
National Coordinator for Health Information Technology
Office of the 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

Dear Dr. DeSalvo:

On behalf of the American Academy of Ophthalmology, we appreciate the opportunity to provide comments on the Office of the National Coordinator for Health Information Technology's Interoperability 10-Year Roadmap. The Academy is the largest association of ophthalmologists, with over 90 percent of U.S. practicing ophthalmologists as members, and an additional 7,000 international members. The Academy supports the use of health IT, and recognizes the value that electronic health records can bring to patient care. Almost half of ophthalmologists in the U.S. have successfully demonstrated Meaningful Use of EHRs. In addition, the Academy has a sophisticated-EHR based qualified clinical data registry, IRIS Registry, which in its first year of operation, is integrated with over 26 different EHR systems, and collecting data from those systems for over 3,000 physicians for quality improvement and research purposes. Interoperability is key to the success of IRIS Registry. The Academy also strongly believes that standards-based interoperability is central to fulfilling the broader benefits associated with health IT. We support the implementation of standards that would help to move the health IT ecosystem toward open source solutions to interoperability to enhance the exchange of health information not only between providers, but also with clinical data registries.

The Academy applauds ONC for its attention to interoperability in developing this roadmap. We agree that interoperability is critical to improving healthcare quality and efficiency and to supporting delivery reform. However, we are concerned that this plan lacks the details necessary to achieve its desired goals, and that the roadmap fails to address the needs of a broad range of physicians, including ophthalmologists. We also are concerned with the pace of this roadmap, which outlines a ten year plan to achieve interoperability. We realize that the complexity of medical data makes interoperability of electronic systems a more complex problem than that faced by other industries. However, driven by the Meaningful Use Program, physicians have invested considerable resources in EHR systems, yet these systems are not interoperable and cannot easily share data. The full value of these systems, and the full value of the investments made by physicians, cannot be recognized until there is interoperability between EHR systems, and data can flow between providers to better inform and improve care.

Moreover, we believe this plan should better leverage technologies and standards already in place or in development to achieve the goals of the plan faster. For example, the Academy's IRIS Registry is integrated with over 26 different EHR systems, but full integration for everyone will only be possible once a standards-based approach is available. The data from systems that are integrated with the IRIS Registry is used to inform physicians about the quality of care they are providing to their patients, and allows physicians to make meaningful comparisons about their quality and to perform analytics on this data. This and other technologies that have already accomplished many of the goals outlined in this roadmap should be provided the tools to move on to a standards-based process that will be more uniformly acceptable in order to advance interoperability.

In the plan, ONC outlines five Interoperability Roadmap Building Blocks. The Academy's comments related to these building blocks are provided below:

A. Rules of engagement and governance:

The Academy is unclear around some of the suggested requirements outlined by ONC in this section. For example, ONC lists as "Shared governance of policy and standards that enable interoperability" as a requirement, but we are unclear around what roles that each stakeholder would play, and how actions should be prioritized. The Academy agrees that improving interoperability will require action by both the private and public sectors, but we ask for clarity regarding the requirements and how ONC will fulfill the requirements outlined for this building block.

The Academy agrees with the "Policy" governance principles outlined in this section. For example, the suggested principle "Access to personal health information" would ensure that no policy, business, operational or technical barriers to interoperability be built. ONC seeks to instruct that data holders, which often are EHR vendors, avoid, even if permitted by law, applying fees, policies, services or contracts that would prevent health information from being exchanged. Many EHR vendors charge exorbitant add-on fees to physicians in order to interface and exchange data with other systems. For instance, many physicians wishing to participate in the Academy's IRIS Registry for quality improvement purposes are charged significant fees by their EHR vendors in order to allow the registry to integrate with the EHR database. Such fees can preclude physicians from participating in the registry, and participating in the quality improvement efforts facilitated by the registry. We applaud ONC for discouraging the use of such fees.

Further, physicians that are interested in sharing their EHR data with outside systems are limited in doing so by their vendor agreements. Most ophthalmologists practice in settings with a small number of physicians. Practices of this size do not have sufficient resources and time to study and understand the complexities associated with vendor contracts as do larger institutions. As another example, the Academy recently worked with a member who switched EHR systems on January 1, and was charged close to $50,000 to transfer the data from one EHR system to the other. These business practices and expenses are prohibitive, and discourage physicians from switching to more interoperable systems. Clearly, these types of add on fees that inhibit interoperability and the flow of health information and should be avoided. **ONC should require EHR vendors to be transparent about their pricing strategies, and to disclose upfront the various add-ons that physicians may face, including if the vendor would charge to exchange data with outside systems**.

B. Supportive business, clinical, cultural and regulatory environments

Even if interoperability is achieved, its value will only be recognized if physicians are utilizing health IT. The Medicare EHR Incentive Program was intended to encourage and expand the adoption of EHRs. The Academy, however, is concerned that this program is overly rigid and the requirements are so complex that physicians that once were successful in the program are beginning to drop out rather than advance to even more difficult and complex stages of the program. We have heard from numerous members who were once some of the strongest advocates of EHRs, who now are abandoning their use of them because of the significant burden associated with the requirements of the Meaningful Use Program. Such overly stringent regulatory requirements, especially those that physicians do not agree advance quality patient care, are discouraging physicians from participating in Meaningful Use, and from using EHRs. **The Academy applauds CMS' recent announcement of its intent to reduce the reporting period for Meaningful Use from one year to 90 days, and to reduce the overall complexity of the program, and we believe these changes are necessary to support the goals of this roadmap.** We encourage CMS to release those revised provisions as soon as possible.

Ultimately, interoperability challenges do not exist because of a technological issue, but instead, these challenges exist because rather for a more dubious reason, that there is no business case or incentive for EHR vendors to integrate or share data outside of their own systems. The Academy does not believe that the similar cultural barriers preventing interoperability exist among providers. In this roadmap, ONC suggests that providers are concerned about the risk of competition that may come with interoperability, and therefore try to limit the exchange of data. However, the Academy strongly disagrees, and points out that physicians routinely share information with other providers using fax, or by printing and instructing the patients to bring his/her records to another provider because their EHR systems do not support such exchange.

In this section, ONC outlines new suggested policy levers including "1) new incentives to adopt and use interoperable health information systems to create additional demand for interoperability, and 2) requirements penalties that raise the costs of not moving to interoperable systems." While the Academy appreciates ONC's desire to move physicians to interoperable systems, we stress that whether or not an EHR system is interoperable is not under a physician's control. Coupled with the significant costs associated with switching EHR systems, **we ask ONC not to penalize physicians that responded to the Meaningful Use program early, and that have already invested significant resource in EHR systems that were certified by ONC, but that may not be interoperable.**

One of the critical actions outlined in this step calls for "providers to engage with an expanded set of interoperable workflows, including reporting to specialty society registries." Yet the Academy knows firsthand that there are some interoperability barriers that would prevent some physicians from reporting to a specialty society registry. Currently, our registry is capable of working with any EHR, and there is no technology challenge preventing us from working with any EHR system. However, because EHRs are not required to work with registries, some choose not to, or some charge their physicians high "add on fees", because it isn't a priority. The Academy believes that leveraging the Meaningful Use EHR Certification program would provide the incentive needed to encourage EHR vendors to work with and exchange data with clinical data registries. **Therefore, the Academy suggests that any EHR that is certified by ONC be required to comply with standards set by ONC that allow for the bidirectional,**

interoperable exchange of health information. This would incentivize EHRs to open up and share their data, because if they did not comply, they would lose their certification status.

C. Privacy and security protections for health information

We appreciate ONC's attention to the importance of privacy and security in achieving widespread interoperability. The Academy agrees that privacy and security protections for health information are critical. In order to support and encourage information exchange, providers and patients need to be able to trust that information will be shared using technology which is secure, and in a manner which protects the privacy of patients' health information. Inconsistent rules related to the privacy and security of health information as it relates to health IT and interoperability can serve as a barrier to advancing interoperability. Privacy and security requirements should be clarified so that providers feel confident exchanging health information, and patients can trust that their privacy will be protected.

D. Certification and testing to support adoption and optimization of health IT products and services

The Academy would support efforts to improve ONC's certification program to improve providers' confidence in the EHR products in which they have already invested significant financial resources. Physicians should be able to rely on their EHRs to perform the functions to which they are certified to perform, but unfortunately, this is not always the case. We would support better testing, and increased focus on EHR usability, interoperability and safety.

E. Core technical standards and functions

The Academy has a longstanding commitment to standards development, and we agree that core technical standards must be widely deployed and advanced to enable nationwide interoperability. Once standards are available, we believe it is then necessary for ONC to require EHR vendors to implement those standards. We appreciate that ONC has done some work to promote standards, but this has not yet reached a point where they are available in many EHR system, particularly those in specialty-specific systems like those used by many of our members. **Promoting standards-based transmission of patient images is one area in particular where more robust certification criteria would have tremendous value for physicians, particularly ophthalmologists.** Ophthalmologists use many in-office diagnostic tests and rarely send patients to laboratories for diagnostic studies or to radiologists for imaging studies. Results from these office-based ophthalmic measurement and imaging devices are used to make care management decisions for virtually every ophthalmology patient. **The Academy strongly encourages ONC to require the adoption of the Digital Imaging and Communication in Medicine (DICOM) standards.** It is important that images themselves and any accompanying explanation or information be accessible through electronic health records. DICOM standards can facilitate this, and the Academy recommends that DICOM be specified as the standard for this.

One suggestion would be for ONC to establish training regarding the development of standards needed for EHR interoperability. With a sufficient number of colleagues trained on standards development, specialty societies like ours would be able to support the development and shepherd standards that are clinically relevant to our members. For example, the C-CDA standard for clinical data exchange and DICOM for image and in-office test exchange would benefit from ongoing development efforts and input from a broad range of providers. However, without training on standards

development, providers can't provide sufficient input, and the standards may continue to inadequately address the broad needs of physicians and patients.

Moreover, the Academy is concerned that the data exchange standards required by Meaningful Use for certified EHR technology are not always sufficient to meet the needs of a broad range of physicians, or specialty-led EHR-based clinical data registries. The current meaningful use standard for the electronic transfer of patient health information is the C-CDA. The C-CDA provides basic information for transfer of care, but does not provide detailed specialty-specific data. Moreover, the C-CDA had very little real world testing, nor was it balloted or approved for standardization by HL7 prior to ONC's decision to require its use in Stage 2. A recent article in the Journal of the American Medical Informatics Association (JAMIA) found significant problems with C-CDA, including possible disruptions in critical care activities such as drug-allergy interaction alerting, medication prescribing, and medical terminology representation. Further, EHR vendors who utilize the consolidated clinical document architecture (C-CDA) have flexibility in how they create C-CDA documents. This creates variability in C-CDA construction, which causes a mismatch between the sending and receiving EHRs and limits the usefulness of information that is actually viewed by the physician and other medical professionals at the point of care.

In addition to facilitating the training of domain experts in the creation of standards, we also suggest that ONC include in the roadmap some way to facilitate decentralization in the standard development process. This is essential so that the many medical specialties and subspecialties can each work to develop the standards that are needed for their constituents while remaining harmonized with the overall needs of the interoperability effort. In our experience, DICOM has the best model in which specialized working groups (ophthalmology is represented by Working Group 9, for example) each can work on standards relevant to their area and then, once in draft form, send those proposals to a central Working Group responsible for ensuring harmonization across the specialized groups. A similar structure could be suggested or mandated by ONC in other standard development organizations. As the interoperability roadmap unfolds, similar arguments will apply to the development of standard APIs. Specialties like ours will need to be able to augment APIs that are otherwise primarily focused on general care.

Moreover, as a surgical specialty, the initial common data set proposed by ONC in this roadmap will not serve any needs that we have with regard to interoperability. We therefore encourage ONC to include ways for specialty societies like ours to efficiently augment and develop compatible standards to allow data relevant to us to be shared.

We appreciate ONC's consideration of these comments. We applaud ONC for their focus on interoperability, and would welcome the opportunity to work with ONC going forward on these efforts. For questions or more information related to these comments, please contact Rebecca Hancock, Manager of Quality & HIT Policy, at 202-737-6662 or rhancock@aaodc.org.

Sincerely,

William L. Rich III, M.D.
President Elect & Medical Director of Health Policy
American Academy of Ophthalmology