

February 6, 2015

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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 IT's Federal Health IT Strategic Plan. The Academy believes that health information technology holds great potential to enable physicians to provide better care to and improve outcomes for the patients and communities they serve. We strongly support the goals outlined in the plan: 1) Expand Adoption of Health IT, 2) Advance Secure and Interoperable Health Information, 3) Strengthen Health Care Delivery, 4) Advance the Health and Well-Being of Individuals and Communities, and 5) Advance Research, Scientific Knowledge and Innovation. The Academy's comments addressing each of these goals are below.

Goal 1: Expand Adoption of Health IT

The Academy supports this important goal. Currently, the Electronic Health Records Incentive Program, "Meaningful Use," is the primary driver encouraging health IT adoption and use in the U.S. The Academy recognizes the importance of the program, but has concerns that the program and its requirements are not supporting the achievement of this goal "Expand Adoption of Health IT." In fact, the Academy is worried that the program's overly rigid and complex requirements, which increase in difficulty as physicians progress through the stages of the program, may discourage physicians from continuing their participation in the program, and from adopting new or upgrading their use of health IT.

The Academy encourages ONC to include in this strategic plan, steps aimed at reducing the burden on physicians associated with participating in the Meaningful Use program. Specifically, the Academy asks for:

- **increased flexibility and the elimination of the "all or nothing" structure of the program**
- **reduced penalties**
- **shorter reporting periods**
- **modification of certain Meaningful Use measures to make them more reasonable and meaningful for specialists to achieve**

Goal 2: Advance Secure and Interoperable Health Information

The Academy supports the second goal, to advance secure and interoperable health information. The Academy agrees that there is much work to be done to improve interoperability in order to securely exchange information electronically and use it to improve health and healthcare. Promoting standards-based transmission of patient images is one area in particular where more robust certification criteria would have tremendous value for patients and physicians, particularly for specialties such as ours that utilize a broad array of imaging for both diagnostic and therapeutic purposes. 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 diagnostic and management decisions for virtually every ophthalmology patient. However, an insufficient number of vendors currently comply with standards such as DICOM standards for the exchange of images and data among these imaging devices, picture archiving and communication systems, and EHRs. This creates the need for manual re-entry of data, purchasing costly proprietary interfaces, or creating awkward “work-arounds” to view results of ophthalmic imaging studies.

For over a decade, the Academy has worked with formal organizations such as DICOM and Integrating the Healthcare Enterprise (IHE) to develop standards relevant to ophthalmic imaging and workflow. However, adoption of these standards by vendors has been very slow, and the Academy strongly feels that this lack of interoperability is inconsistent with the goal of improving quality and safety of patient care and could hinder care in some cases.

The ability to view and exchange images through HIT has great potential to reduce healthcare costs by reducing repeat-testing, and is a critical element of meaningful use of HIT by image-based specialties like ophthalmology. **The Academy recommends that ONC undertake efforts to encourage the accessibility and transmission of images to further advance interoperability in this area. We recommend that DICOM be required as a standard for imaging results.**

- Clinical Data Registries:

The Academy strongly believes that physician-led clinical data registries hold great potential to improve patient care. However, clinical data registries that are EHR-based are dependent upon the interoperability of health IT. Clinical data registries, such as the Academy’s IRIS™ Registry, are capable of integrating health information from a variety of data sources to be used by providers, researchers and other stakeholders in a meaningful way to improve the efficiency and quality of care provided by clinicians, and to improve outcomes for patients. For example, IRIS Registry’s system-integration software program is designed to work with any EHR system, and to date, IRIS Registry has successfully integrated with 26 different EHR systems.

When interoperability is achieved, EHR-based registries are capable of integrating health information from a variety of data sources to be used by providers, researchers and other stakeholders to improve the efficiency and quality of care provided by clinicians, and to improve outcomes for patients. In order to effectively measure quality and performance, registries need access to data collected by electronic health records (EHRs). However, physicians often have difficulty in getting data out of their EHRs to participate in registries. Interoperability with registries is generally a low priority of EHR systems, and it often takes several months for EHRs to respond to their customer requests. While physicians and registries can make suggestions to EHR vendors to improve registries’ access to data for use in registries, they may not be adopted

unless required by the Office of the National Coordinator (ONC). In some cases, EHR vendors charge physicians significant “add on” fees to access their own patient data. Such charges and delays are preventing physicians from using valuable data to improve care for patients and to decrease health costs. The lack of interoperability between registries and EHR vendors does not stem from a technology challenge, but instead exists because EHR vendors have no business case to open their data to registries. ONC should leverage its certification program to create such an incentive.

As a first step, certified EHRs should be able to provide interoperability to external clinical data registries as part of their core functions. **Therefore, we recommend that ONC require EHRs certified for Meaningful Use to be capable of integrating with clinical data registries for quality improvement purposes.** This should not be an added cost but integral to the system core. Additionally, physicians should have the rights to data that regard their practice and performance.

If registries are successful in integrating with an EHR, additional challenges stem from the wide variation across EHR system architectures. This variation creates complications when the registry seeks to collect, aggregate, and compare data across many different EHR systems. Further, data exchange standards required by Meaningful Use for certified EHR technology are not always sufficient to meet the needs of clinical data registries. The current meaningful use standard for the electronic transfer of patient health information is the Consolidated-Clinical Data Architecture (C-CDA). This standard defines how critical data elements should be structured and encoded to support interoperability and information exchange. The C-CDA provides basic information for transfer of care, but it does not provide detailed specialty-specific data needed for the calculation of clinically significant outcomes measures.

We recommend that ONC facilitate the sharing of data elements specifically defined by the medical specialties that use them to help inform EHRs regarding what data elements to collect. Clinicians must define these standards, and ONC could make a common library available for all registries, EHRs, and primary data sources to use. This would serve as a set of structured data elements to be incorporated into clinical guidelines and specified for integration into the EHRs for quality measurement, clinical decision support and post market surveillance. National specialties would do the work of determining what data elements and analyses are most relevant to quality improvement and patient care within a particular specialty. This would help ensure that critical data elements are included in different EHR systems for users, and enhance aggregation of data across EHRs.

Addressing interoperability challenges faced by clinical data registries will result in better care and outcomes for patients through improved provider performance, faster development and implementation of meaningful quality measures, more efficient clinical trials, comparative effectiveness research and the development and adoption of best practices, and improved FDA post-market surveillance and Medicare coverage decisions. **Without ONC facilitated EHR interoperability and uniform data fields, EHRs will fail to provide their original intended benefit of improving care for patients at the local, state, and national level.**

Goal 3: Strengthen Health Care Delivery, Goal 4: Advance the Health and Well-Being of Individuals and Communities and Goal 5: Advance Research, Scientific Knowledge and Innovation

Alone, EHRs are not capable of achieving the important goals outlined in this plan; they cannot strengthen health care delivery, advance the health and well-being of individuals and communities, or advance research, scientific knowledge, and innovation. EHR systems are not structured in a way that facilitates and drives quality improvement efforts. EHR companies lack the expertise and capacity needed to interpret and evaluate performance across clinical quality measures. Given the limitations of EHR systems which preclude them from addressing quality of care and population health goals, clinical data registries are critical for realizing these specific items. Clinical data registries are the key to driving true quality improvements in healthcare, as well as patient outcomes, and better research, scientific knowledge and innovation. Registries are much better equipped than EHRs to engage physicians in quality improvement activities and improve outcomes.

The longitudinal data provided by such registries provide the opportunity to track and evaluate patients and patient populations over time. Using a clinical data registry, physicians can monitor patient interactions, track interventions, identify and address gaps in quality of care, and measure quality outcomes, to improve patient care. Patients will benefit greatly from the real-time physician access to point-of-care quality data and national benchmarks facilitated by national specialty registries. Additionally, the robust datasets provided by registries will support new discoveries and speed learning about the effects, benefits and harms of different treatments.

The Academy thanks you for the opportunity to provide input on this strategic plan. We would welcome the opportunity to work with you on the concerns and suggestions laid out in these comments. For questions or more information, please contact Rebecca Hancock, the Academy's Manager of Quality & HIT Policy, at rhancock@aaodc.org or 202-737-6662.

Sincerely,



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