May 3, 2019

Don Rucker, MD
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
Washington, DC 20201

RE: RIN 0955-AA01; 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program

Dear Dr. Rucker:

The American Society of Cataract and Refractive Surgery (ASCRS) is a medical specialty society representing nearly 9,000 ophthalmologists in the United States and abroad who share a particular interest in cataract and refractive surgical care. We appreciate this opportunity to provide feedback on this proposed rule.

As physicians who see a high volume of Medicare beneficiaries, most ophthalmologists have integrated EHRs into their practices and have successfully participated in incentive programs—first under Meaningful Use and now as part of the Merit-Based Incentive Payment System (MIPS). As widespread adopters of health IT, ophthalmologists have implemented resources, notably the IRIS Registry, that integrate with EHR to provide information on clinical outcomes.

Despite this willingness to use new technology, ophthalmologists and their practice administrators often express frustration at the lack of interoperability between EHR systems. In particular, ophthalmologists often struggle to share a patient's ophthalmic health information, such as post-operative visual acuity, when a patient's post-operative care is provided by another physician, even when using an ophthalmic-specific EHR system. **While we share ONC's goal of improving the interoperability—and support many of the proposals included in this proposed rule—we continue to believe that many IT providers, particularly EHR vendors, will continue their efforts to circumvent regulations and block the interoperability of health information.**

We will provide comments on the following provisions of the proposed rule:

- **Support for ONC's proposal to require that patients and EHR users, such as physicians, are able to download complete electronic records.** This proposal will provide administrative burden relief to practices that struggle to extract and transfer patient records from an existing EHR system to a new system.

- **ASCRS supports ONC's proposal to require EHR vendors to make health information broadly available through applications programming interfaces (APIs); however, we continue to doubt whether EHRs will comply with these proposals in the spirit in which they are intended and truly make electronic health information interoperable.** EHRs are currently required to use APIs for health information exchange but often do not employ them in a way that is useful to physicians or create barriers to use in the form of fees.

- **While we appreciate that ONC is proposing a "general" prohibition against fees associated with APIs, we believe that EHR vendors will use the allowable fees, such as for program upgrades, as a barrier to providing interoperability between systems or other applications.**

- **ASCRS supports the proposal to require real-world testing of APIs and IT products.**

- **Responding to ONC's request for information on how to include price information, including price information for "shoppable" services, in a patient's electronic health information (EHI) with concern that physician practices will not be able to provide accurate cost estimates for some patients based on their individual insurance policies and other pending claims.**

- **Continued support for efforts to improve the flow of clinical information from EHR systems to data registries.**

Comments on these issues are provided below.

Transfer of Complete Electronic Medical Records

- **ASCRS strongly supports ONC's proposal to require that EHRs make available for download the medical records of individual patients or entire groups of patients.** While ASCRS believes that patients are entitled to complete access to their medical records, ophthalmologists generally treat a relatively older patient population, and it is unlikely that many of our members' patients will opt to download their own medical records. However, we chiefly support this proposal because it will reduce administrative burden on practices that are migrating from one EHR system to another. In our comments submitted late last year on the proposed EHR Reporting Program, we noted that there is a considerable burden when switching EHR systems. Most ophthalmologists do use EHR and have done for some years. As new products have come on the market or existing systems are modified, some practices have determined that their needs may be better met by a different system other than the one they had been using. When practices go to make these transitions, however, they have encountered difficulty in transferring their existing patient records out of the old system because the vendor refuses to take action to assist a customer who is terminating their service. The potential disruption to the practice associated with transferring records may be preventing some practices from switching to a more appropriate product. **We recommend ONC finalize this proposal.**

Applications Programming Interfaces (APIs)

- **ASCRS supports requiring health IT vendors, such as EHRs, to make the exchange of EHI available through the use of APIs, but we continue to caution that EHR vendors will likely develop methods to avoid full interoperability and seek to protect their own market share.** EHRs are already required to use APIs to make health information available, but they do not always make them broadly useful. The Provide Patients Electronic Access to Their Health Information measure in the Promoting Interoperability category of MIPS requires that physicians give patients' access to their records through any method that is configured to read the EHR's API. While EHR systems are complying with the certification standards to meet that measure,

other uses may be more limited. For example, an ophthalmic practice noted that they have joined with their referral network of optometrist practices to use scheduling software that allows the optometrist's office to access data in the ophthalmologist's EHR system through an API when referring a patient. However, the ophthalmologist's system API does not allow for bidirectional flow of information and will not accept any data back from the referring optometrist, thereby forcing the ophthalmology practice staff to enter the information into its system manually. The ophthalmology practice's EHR would allow bidirectional information flow if the practice chose to pay more to participate with a "preferred" service, which the local referring optometrists do not use. **While we continue to support the exchange of EHI through APIs, we believe physicians will continue to face difficulty in achieving interoperability since EHR systems have a long-established habit of configuring their systems so that they meet the required standards but still prevent unencumbered exchange of data.**

- **As a chief means of preventing interoperability, ASCRS is concerned that EHR vendors will pass on the cost of complying with increased regulations to physicians in the form of excessive fees or will increase the price of the EHR systems themselves.** While we realize that ONC proposes to require that health IT vendors make information exchange through APIs available at no cost, it does allow vendors to charge their users, such as physicians, fees for upgrades related to APIs. The proposed rule does not set specific guidelines on what constitutes an upgrade or how much the fee could be. It has been our members' experience that EHR systems often charge fees for such services as integrating with a clinical data registry or, as noted above, using outside or non-preferred software. We are also concerned that EHR vendors will use requirements to make data available via API as an excuse to increase the base price of the system for all users, regardless of whether they are using the API features. Many ophthalmology practices are solo or small and operate on thin margins. Implementing EHR systems can already be cost prohibitive without additional costs. **By proposing to allow vendors to charge their users for system upgrades, we are concerned that ONC is providing an exception for vendors to continue to engage in practices that prevent interoperability.**

- **ASCRS supports ONC's proposal to require real-world testing of APIs and health IT products, particularly in different specialty types and practice settings.** Ophthalmologists tend to practice in solo or small group practices that are independent of larger hospital or health systems. Because an ophthalmic practice is so specialized in its data and imaging, and not integrated into the larger health systems, most practices use EHR systems that are specifically designed for ophthalmology. Since these systems are customized to meet ophthalmic needs, it is reasonable that the vendor should be able to demonstrate that they were tested and refined through real-world experience. As noted above, implementing an EHR system is a significant investment for a small ophthalmic practice. Therefore, physicians should have the assurance that the system they are purchasing will meet their needs. **We recommend ONC finalize this proposal.**

Request for Information: Including Price Estimates in EHI

- **ASCRS is concerned that physician practices will have difficulty including accurate out-of-pocket cost estimates for covered "shoppable" services, such as cataract surgery, as part of EHI because each estimate will depend on the patient's individual insurance and claims in process.** ONC asks in a request for information if, as part of the EHI that must be available for

exchange through API, physicians should make cost estimates for out-of-pocket expenses and binding cost estimates for so-called "shoppable" services. While ophthalmologists offer a range of non-covered services, such as LASIK or premium intraocular lenses (IOLs), for which they provide transparent and stable price quotes, requiring price estimates for covered services could be difficult for any patient not covered by Medicare Part B. For patients with Medicare Advantage or other private insurers, patient out-of-pocket expenses can differ from day-to-day. For example, a patient may visit the ophthalmologist for testing prior to cataract surgery and receive an estimate on their expected cost-sharing. However, the ophthalmology practice would be unaware of any other claims from other physicians that may be in process before the cataract surgery claim is filed, which may mean the patient would have met the deductible. If a patient took the original estimate to another cataract surgeon seeking a lower price, it would be based on inaccurate information.

- **Furthermore, it would be difficult for most ophthalmology practices to compete on price for covered services, since they generally are not able to negotiate rates with insurers.** While we recognize that ONC is seeking to provide patients with more transparent information on the cost of healthcare services to help them make cost-efficient choices, most ophthalmology practices are unable to influence what insurers pay for their services. As noted above, ophthalmologists in small practices do not have the market share nor do they typically employ the personnel that large hospital or health systems may have that are needed to negotiate rates with large national insurers. When an ophthalmologist participates with an insurer, he or she is generally locked into a set fee schedule and thus cannot compete on price with other ophthalmologists in the market. In addition, small ophthalmology practices, especially sub-specialists, may not even have a choice of plans in which they participate. Over the last several years, many Medicare Advantage plans have dropped ophthalmologists and other specialists from their networks without notice or ability to appeal. **While we appreciate that ONC is attempting to provide patients with predictability and transparency related to their out-of-pocket costs, we are concerned that not only would ophthalmology practices have difficulty providing accurate estimates for covered services, beneficiaries will have no opportunities to seek more cost-efficient care for ophthalmology services because prices and networks are set solely at the discretion of the insurers.**

Request for Information: Clinical Data Registries

- **ASCRS continues to support efforts by ONC to facilitate the seamless flow of EHI between EHRs and clinical data registries.** Ophthalmologists rely heavily on the IRIS Registry to track clinical outcomes and to aggregate and report data for the MIPS program. While most ophthalmologists have integrated EHR into their practices, the measures included in the Promoting Interoperability category of MIPS are largely focused on primary care and may not be clinically relevant to ophthalmologists. By ensuring integration with the IRIS Registry, ophthalmologists are able to use health IT in a manner that is relevant to their practice. As we noted above, some EHR vendors are less willing to work with practices to integrate with the registry or may charge additional fees for connecting the systems. **As the most clinically relevant way for ophthalmologists to use health IT, we encourage ONC to provide oversight and ensure that EHR vendors are not inappropriately blocking physician access to clinical data registries, such as IRIS.**

- **ASCRS also believes EHR vendors should be encouraged to exchange clinically relevant information through summaries of care.** As discussed above, caring for ophthalmic disease requires specific data about the eye. However, EHR certification does not require that clinical data summaries exchanged between physicians include any ocular data. It has been our members' experience that even systems designed solely for ophthalmic or optometric practices were not including this data. For example, ASCRS learned that many of our members who co-manage the post-operative care of a patient with another provider after cataract surgery were having difficultly reporting the MIPS Quality Measure 191, Visual Acuity of 20/40 or Better 90 Days Following Cataract Surgery, because either they could not receive the final visual acuity electronically, and/or when entering the data into the EHR, a new visit would be created that did not occur. Finally, if the information was able to be included in the EHR, some systems did not display it in a field that was readable by the IRIS Registry. ASCRS had to intervene on behalf of its members to bring all current ophthalmic EHR systems together and advocate that they address this issue. **While we continue to advocate on behalf of our members, we are concerned without a clear signal from ONC that EHRs should be working to make data available to clinical data registries, including what is necessary to participate in MIPS, they will continue to limit the data they will make interoperable.**

Conclusion

Thank you again for the opportunity to provide comments on this proposed rule. ASCRS continues to support improving the interoperability of EHI. **While we support making EHI available through APIs, we are concerned that EHR vendors will continue to develop methods to circumvent these proposals and continue to block data and pass the cost of system modifications on to physician users.** In regard to efforts to increase price transparency, we appreciate that the administration is attempting to provide patients with this information, but we caution ONC that practices may not have up-to-date information on individual patients' insurance claims to provide accurate price estimates, and small practices are limited in their ability to negotiate rates with insurers, thereby limiting patients' ability to seek care at a lower cost. Finally, given that ophthalmology patients are generally an older cohort of Medicare beneficiaries, it is questionable whether patients will have the ability or would even elect to access this information to impact their decision-making.

If you have questions, please contact Allison Madson, manager of regulatory affairs, at amadson@ascrs.org or 703-591-2220.

Sincerely,

Thomas W. Samuelson, MD
President, ASCRS