**Introduction**

The following comments by ICSA Labs will focus on issues that may be able to be addressed through future rulemaking within the ONC certification program that govern the behavior of EHRs and other Health IT. We do not presume to be experts on clinical workflow or other areas of healthcare. However our experience in conducting thousands of hours of testing, certification, in-the-field surveillance, and complaints investigations of CEHRT does provide us some insight into many of the challenges faced by EHR developers and their users.

**“Out of scope” Issues**

This proposed rule describes issues that fall into those that may be able to be addressed via regulation and those that cannot be addressed directly via regulation. An example of the latter would include the section where it mentions the “interruption of eye contact”. While this may be disruptive to clinician and patient alike, ICSA Labs believes this is something that cannot be corrected via regulation.

ICSA Labs recommends that regulators attempt to identify which areas of concern are best addressed at the organizational or end-user level. Given the unique circumstances of individual practices and clinicians, attempts to regulate this level of interaction is likely to introduce more challenges for clinicians than it resolves.

**Stakeholders**

The ONC also identifies a variety of stakeholders who will need to participate in coordinated action in order to reduce the burden on clinical users of Health IT. Noticeably absent from this list is the accredited ONC-ATLs and ONC-ACBs. ICSA Labs believes that since these institutions are directly responsible for enforcing the testing and certification program requirements of Certified EHR Technology it is necessary to also consider the impact of regulatory burden on these organizations.

Though the focus on this proposed rule is designed to reduce the burden on clinicians as consumers of Health IT and EHRs, it is important to view any proposed changes through the lens of how changes might impact other stakeholders within the Health IT community. Though patient health and safety must always take precedent, an undue burden placed on other stakeholders could compromise the integrity of the entire Health IT ecosystem. An example of this may be proposing changes to the certification program that may prove too costly or ambitious for many EHR developers to implement.

Therefore, ICSA Labs recommends that the ONC evaluate the impact of all changes on all stakeholders, including ONC-ATLs and ONC-ACBs.

**Roadmap**

ICSA Labs believes that the ONC should clearly publish roadmaps for future rulemaking. All future goals, even if not currently required by existing regulations, should be clearly defined along with expected implementation dates. The roadmap should then be revisited at a minimum annually and updated to reflect changing dynamics.

Software development oftentimes requires several months of development and quality assurance before changes can be fully implemented. The need for careful planning and implementation is even more urgent with Health IT since poorly written software could result in significant harm to patients. Providing clear, attainable goals established years in advance will greatly improve the ability of Health IT companies to develop safe and secure software that coincides with the ever-changing regulatory environment.

Further to this point, ICSA Labs recommends that the ONC avoid implementing interim solutions to the certification criteria which only “muddy the water”. For example, the 2014 Edition criteria mandated that EHR developers seeking certification had to only declare if they used a QMS in the development of their CEHRT. Many developers simply attested they did not use a QMS.

Then when the 2015 Edition criteria mandated that a QMS be used in the development of CEHRT, many of those same developers had not yet fully implemented a QMS. This left them at a disadvantage. ICSA Labs believes it would have been more useful to have explicitly stated that a QMS would be required in the development of CEHRT for all certifications beginning in calendar year 20XX.

ICSA Labs sees a similar pattern forming with the introduction of the API criteria in the 2015 Edition final rule. It seems apparent that the ONC intends to introduce more explicit API requirements in the next set of certification criteria, but developers are left to guess what those requirements may be.

**Clinical Documentation**

ICSA Labs believes the ONC should move away from a document-centric view of healthcare data. Currently, the certification requirements are centered on encounter-driven documentation via the Consolidated CDA requirements. While it is important to maintain many of the interoperability aspects of these criteria, such as specifying which fields should be supported and which standards must be used for coding, the resulting records are often limited to a single encounter and do not represent a patient’s complete record which is necessary for longitudinal care.

Furthermore, this puts the burden on the sender to correctly identify which data or records the recipient may need to receive. This leads to an approach that frequently results in excess data being shared, which in turns forces the recipient to have to parse through pages of potentially unimportant data to locate the data they require.

ICSA Labs believes that the ONC should be considering more robust data sharing methods such as those offered by API driven requirements. Using API models to share data provides a number of advantages, including potentially allowing the recipient to request the data they require instead of being dependent on the sender to define which data is relevant to be sent.

This would also require eliminating all requirements surrounding Direct Messaging as a means of information sharing as it is explicitly document-centric. It is also worth noting that Direct Messaging requires a large amount of technical and administrative overhead to build and maintain, making it difficult for smaller providers to participate. ICSA Labs recommends phasing out all requirements for the use of Direct Messaging for CEHRT and its use by eligible providers and hospitals in lieu of better alternatives such as APIs.

**Data Provenance**

One of the biggest challenges facing clinicians is the overwhelming amount of data being stored and shared via Health IT. Further complicating matters is an inability to sort which data came from which source. This introduces a number of different challenges.

First, it can be difficult to determine what records are current. Allergies for example may change over time. Being able to determine when an allergy was first diagnosed and when it was last verified is of extreme value.

Second, it can be difficult to determine if separate diagnoses were given by a single provider based on separate symptoms or if they are the result of different diagnoses from different providers based on the same symptoms.

Third, it is virtually impossible to correct an error in a patient’s record if it is not known who introduced the error and when, and what the scope of that error may be. For example, without the use of a universally accepted unique patient identifier, it is not unusual to see records of one patient contaminated with those of another patient with a similar name. Correcting both records is virtually impossible without knowing who to contact, and the scope of the impact may never be fully realized without confirming when the errors were introduced.

ICSA Labs recommends moving towards a system of blockchain ledgering to provide data provenance of healthcare records. This should allow providers the means to better evaluate patient histories and ensure their records are up-to-date and without error.

ICSA Labs also believes it is imperative that providers have the ability to correct a patient’s record in the case of obvious errors, but it is also important to provide a means of allowing some sort of appeals process to adjudicate certain disputes or discrepancies.

**Conclusion**

ICSA Labs believes the recommendations above will contribute to reducing the burden on users of healthcare IT systems through improved usability and better sharing of patient records. ICSA Labs also believes that careful planning and coordination with all stakeholders to build a long-term roadmap with clearly defined goals will help contribute to an easier transition for all stakeholders.