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Karen DeSalvo, MD, MPH, M.Sc.
National Coordinator for Health Information Technology
Acting Assistant Secretary for Health
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. DeSalvo:

Health IT Now (HITN) is pleased to submit our comments on the *Request for Information Regarding Assessing Interoperability for MACRA.* HITN is a diverse coalition of health care providers, patient advocates, consumers, employers, and payers who support the adoption and use of health IT to improve health outcomes and lower costs.

General Comments

HITN believes the free flow of electronic health information is essential to improving health outcomes and lowering costs. We strongly support the widespread interoperability goal set in the *Medicare and CHIP Reauthorization Act of 2015* (MACRA). However, we believe that in order for any goal or measure to be successful, ONC must coordinate not only with other departments within the Department of Health and Human Services (HHS), such as the Centers for Medicare and Medicaid Services (CMS), but also with other agencies such as the Federal Trade Commission (FTC). Many of the barriers to widespread interoperability are not the result of technology, and in order to fully achieve the goal of widespread interoperability, HHS will have to coordinate outside of ONC's narrow jurisdiction over the voluntary Health IT Certification Program.

Healthcare organizations rely on information technology systems from a variety of vendors to support patient care, medical operations, administrative operations, and billing. Very few vendors have integrated enterprise-wide systems, resulting in limited data sharing within and across healthcare organizations. Vendors and healthcare organizations must be able and willing to share information. In order to deliver care in a mobile society and to those with chronic illnesses, information must flow freely between vendor products and across healthcare organizations.

We continue to have a disparate health IT architecture and restrictive regulations that fail the patient. Currently, there are a number of efforts to achieve interoperability that are experiencing varying degrees of success:

1. Provider-centric: The Direct provider directory allows data to be sent based on the patient's provider, assuming the providers are known.
2. Patient-centric: Functioning networks in the private sector, such as CommonWell Health Alliance, have emerged as network-based patient health information exchange edge services. They benefit members, their patients, and vendors through patient profiles, patient identification, record location pointers, and query and retrieval.

3. Vendor-centric: Software vendors, such as Orion Health, offer products that connect to core systems like EHRs and provide cross organization interoperability. This allows internal systems to focus on core functionality for operations and a separate engine to provide interoperability and information sharing with external systems.
4. Clinical data registries: Many specialty-led clinical data registries use software to extract and aggregate data from various EHR systems to enable quality improvement and enhance patient outcomes.

HITN recognizes the many private sector efforts to achieve the shared goal of widespread interoperability. Despite these efforts, business rules, outdated regulations, and agreements can still be restrictive and burdensome to implement and restrict exchange of information. Ultimately, we believe it is the government's role to ensure a fair marketplace where private sector solutions are allowed to flourish, while also monitoring for compliance.

Specific Comments

Despite the many barriers to achieving interoperability, we appreciate ONC's work in this area. We recognize that ONC's current jurisdiction complicates its ability to promote solutions. However, we do believe there are steps ONC can take through the Certification Program to measure widespread interoperability that are in line with the statutory requirements of MACRA.

To begin addressing these issues, interoperability and information blocking error reporting should be built into the certification requirements to automatically report if the system is unable to generate a request to another system or process a request from another system. The error report should include the following:

1. Technical issue or a business rule
2. Query Vendor system identification
3. Query Organization identification
4. Query Device type
5. Network speed or timeout
6. Response Vendor system identification
7. Response Organization identification
8. Response Device type
9. Error summary

In the case of technical error, the error report should be generated automatically and shared with the query organization, query vendor, response organization, response vendor, and Patient Safety Organizations. In the case of information blocking, providers should have better access to information blocking reporting.

Questions

Question: Should measurements be limited to "meaningful EHR users" as defined?
Response: Generally, HITN believes that ONC's should focus efforts more towards the vendors who participate in the Certification Program and less on the "meaningful EHR users." However, we do recognize that data from providers using the systems is important in measuring interoperability in practice. Along those lines, measurements should be limited to meaningful EHR users as it would be unfair and possibly inconsistent in implementations to comingle reporting for Meaningful Use users and non-users. However, we recognize that in order to truly achieve widespread interoperability and coordinated care, it is essential that electronic health information flow between eligible providers and non-eligible providers (such as behavioral health providers). We encourage ONC to work with CMS and

Congress on subsequent proposals to address barriers to sharing information between meaningful EHR users and non-users.

Question: How should eligible professionals under the Merit-Based Incentive Payment System (MIPS) and eligible professionals who participate in the alternative payment models (APMs) be addressed?
Response: In keeping with CMS' goal to streamline the Medicare and Medicaid EHR Incentives Programs under MACRA, HITN believes that in coordination with the error reporting system, CMS should allow this automatic reporting to satisfy health information exchange reporting.

Question: Should the focus be limited to certified EHR technology?
Response: As we stated before, ONC's authority under the HITECH Act only extends to certified EHR technology; therefore, we believe that in this case, the focus should be limited. However, we urge ONC to work across HHS and with other agencies to fully tackle the current barriers to interoperability.

Available Data Sources

HITN recommends that ONC use automatic electronic error reporting data (as outlined above) in lieu of the proposed national survey data. Given the inherent issues with survey data being objective and incomplete, we believe ONC should leverage the technology itself to collect data. Additionally, we believe that this automatic error reporting will address the issue of the data that are missing from CMS Meaningful Use data that is addressed in the RFI. The reporting would capture if the summary of care record was sent and received.

Additionally, we have some concerns with using performance data on Meaningful Use measures related to health information exchange as an indicator of widespread interoperability nationwide. 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 often needed by a broad range of physicians, especially specialists. Even if all providers in nation is consistently exchanged information using the C-CDA, the data needs for many specialty physicians would still not be met. Therefore, relying on Meaningful Use data may not be a sufficient indicator of widespread interoperability, and we encourage ONC to also consult with national medical specialty societies for input on the progress toward meeting the goal of widespread interoperability.

Overarching Questions

Question: Are there Medicare claims based measures that have the potential to add unique information that is not available from the combination of the CMS EHR Incentive Programs data and survey data?
Response: HITN believes claims data can be very useful and we believe that interoperability can be furthered by improving access to these data. While the CMS Qualified Entity (QE) program provides real time access to identifiable claims data, the application for QE status is burdensome and unnecessarily lengthy. With the transition to value-based reimbursement, providers are looking to health IT to aid in care coordination and provide analytic tools to help them and their patients make well-informed decisions. Vendor access to claims data through the QE program will trigger a proliferation of such tools that, while already common in nearly every other sector of our data-driven economy, are lacking and desperately needed in health care. As an example of some of the benefits of accessing claims data, some electronic clinical data registries not only use clinical data found in the EHR, but also have access a practice's administrative data base. These registries are able to collect data on and analyze practice expenses, visits, procedures, testing, pre-operative evaluations, lab results, and returns to the operating room. This makes it possible to appropriately measure resource use for diseases and conditions using registry collected data.

In order to empower physicians with data that exists today to make quality clinical care decisions, ONC should work with CMS to streamline the QE application process for entities that have already demonstrated compliance with its requirements through other certification/audit programs.

Question: How should ONC define "widespread" in quantifiable terms across these measures? Would this be a simple majority, over 50%, or should the threshold be set higher across these measures to be considered "widespread"?
Response: A provider should be able to inquire and get a response from another provider's certified product 100 percent of the time. If systems are certified to be interoperable, they must work each and every time. It is important to note that even though technology enables interoperability, the provider must be willing to use the capability and business practices must allow the technology to function.

Conclusion

We appreciate the opportunity to share our feedback on the *Request for Information Regarding Assessing Interoperability for MACRA*. We look forward to working with ONC to create a more competitive, transparent, and interoperable health IT marketplace.

Sincerely,

Robert James Horne
Executive Director