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September 25, 2015

Karen DeSalvo, MD, MPH, MSc
National Coordinator for Health Information Technology
Acting Assistant Secretary for Health
U.S. Department of Health and Human Services

Dear Dr. DeSalvo,

In April, 2015, the Office of the National Coordinator for Health IT (ONC) issued the “Report on Health Information Blocking” in response to a request from Congress to report on the extent of health information blocking and a comprehensive strategy to address it.

The EHR Association (EHRA) carefully reviewed this report and appreciates the care with which ONC identified the potential and real challenges, as well as the proposed strategies to minimize information blocking. The EHRA is dedicated to establishing an environment where the right data can flow to the right party at the right time, using a set of agreed-upon standards. We look forward to addressing challenges to interoperability and advancing use of exchange. To that end, the EHRA will further review its EHR Developer Code of Conduct to determine how to strengthen it in support of this shared objective.

The following outlines the EHRA’s responses to specific topics in the report.

General

- The EHRA agrees with the definition and characteristics of information blocking, including the three-part test of interference, knowledge, and lack of reasonable justifications. However, we urge caution when labeling a fee as cost-prohibitive and, therefore, information blocking. Costs are not limited to fees that a developer might charge for interfaces and interoperability services, but also include the providers’ resources to deploy and maintain those interfaces. Costs must be evaluated in the context of the difficulty of developing and maintaining the interface, the number of potential users of that interface, the compliance with certification standards by the exchange partner, and the value gained from the data exchange. As providers’ processes further align to support consistent data exchange and as standards are harmonized around the content and methods of data exchange, it is reasonable to expect that overall interoperability-related costs may go down, but will not disappear entirely.

- Generally, as ONC asserts, measuring and assessing which of the specific identified “practices” (e.g., contract terms and policies, cost-prohibitive pricing, or implementing non-standard interoperability) cross the information-blocking threshold is challenging, requires careful consideration, and will be very situation-specific.
 - Although a number of scenarios in Appendix A represent obvious examples of information blocking, there are many more scenarios where information blocking may not be taking place. For example, a hospital receives two requests to connect: one is from a local provider from whom they receive frequent referrals; the other request is from a provider several states away with infrequent patient referrals. If the hospital prioritizes the local provider to connect now and indicates they will work with the remote provider at a future date, is the hospital engaging in “information blocking”? Or is this considered a reasonable justification? When a vendor makes the certified capability available to a provider, but offers more advanced/innovative interoperability features for a fee, is it information blocking? When providers and vendors actively engage with reasonable and non-discriminatory practices, it is clear that no information blocking has occurred. However, establishing the contrapositive is challenging in a world of limited resources.
 - One of the practices is described as, “developing or implementing health IT in non-standard ways that are likely to substantially increase the costs, complexity, or burden of sharing electronic health information, especially when relevant interoperability standards have been adopted by the Secretary.” We appreciate the reflection here of the fact that some industry stakeholders, such as public health entities and some health information exchange (HIE) organizations, do not use nationally-accepted, standards-based connectivity options, which is a challenge that results in unnecessarily adding costs to the larger healthcare system. However, standards adopted by the Secretary should only provide a minimum bar and not be an exclusive list; and use of other emerging technologies should not be prohibited or challenged as long as support for minimum standards remains a choice for the provider. Moreover, there is much about health IT development that is not or need not be standards-based, or even uniform from one vendor or product to another. Such variation is indeed a hallmark of a robust and innovative industry. It is essential that variations in such areas as database structures and information models not be considered prima facie information blocking, as they reflect very valid variations in use case requirements.
- As the report indicates, there are a limited number of anecdotes of information blocking, but determining which are truly information blocking per the definition is not easy. Any assessment of potential information blocking must be fact-based, given a specific situation, and include the perspectives of all stakeholders before declaring that information blocking has, in fact, occurred. The EHRA recognizes the perception that information blocking exists, but submits that, in many cases, there is no intent to interfere, but rather a series of events that result in less data exchange than desired by some parties (e.g., conflicting provider business models, misalignment of objectives/priorities, lack of funding, limited infrastructure, etc.).

This perspective was further emphasized during the recent HITPC Clinical, Technical, Organizational and Financial Barriers to Interoperability Task Force meeting that summarized that achieving interoperability is hard and that the barriers are not necessarily attributable to competition. Micky Tripathi, founder of the Massachusetts eHealth Collaborative, indicated that the task force did not hear a lot concerning blocking with malice. Paul Tang, chair of the task force, acknowledged that we are moving in the right direction, but not fast enough.

- The anecdotes and examples provided primarily focus on provider and vendor behaviors, but do not address regulatory drivers that can result in unintended or perceived data blocking. For example, the original certification criterion for secure transport was bundled with the HISP criterion, resulting in a certification requirement that was inflexible and inadvertently limited provider choice. Public health agencies do not always follow the same standards to which vendors must certify. Furthermore, certification criteria may not address all relevant aspects of the interoperability use case (e.g., provider directories), thus creating inadvertent gaps in the necessary toolset. These examples of unintended consequences of regulatory action indicate the need for great care in how we craft regulations, guidance, and best practices that allow for the necessary flexibility to avoid locking providers into specific solutions.
- Maturity of interoperability use cases is also an important aspect of the perception of information blocking. Less mature standards typically yield increased ambiguity, and thus are more challenging to successfully implement. The EHRA agrees that recognizing this aspect is important to better understand and distinguish real information blocking challenges from fundamental interoperability challenges. The proposed targeted actions represent a mix of actions that aim to improve interoperability in general, as well as focus on the essential issues of information blocking per the definition. While the detailed analysis recognizes the distinction between general interoperability issues and the subset of potential information blocking actions, the summary statements in the report do not. The report, therefore, can create a mistaken impression that areas where there are low levels of information sharing constitute information blocking. The EHRA urges ONC to be clear on the distinction between low rates of data sharing because of the lack of a return on investment (ROI) or immature infrastructure to enable clear focus and context. We suggest that only the following types of actions identified in the report in Table 1 should be considered potential areas to focus on enhancing the infrastructure or business cases to increase interoperability:
 - Establish governance rules that deter information blocking;
 - Potential public and/or private sector governance approaches that could deter information blocking or render it moot by virtue of clear and transparent voluntary agreements;
 - Work in concert with the Department of Health and Human Services (HHS) Office for Civil Rights to improve stakeholder understanding of the HIPAA requirements and permissions related to information sharing;
 - Coordinate with the HHS Office of Inspector General and the Centers for Medicare and Medicaid Services (CMS) concerning information blocking in the context of the federal Anti-Kickback Statute and Physician Self-Referral Law;
 - Refer illegal business practices to appropriate enforcement agencies.

The EHRA agrees that clarification in these areas (e.g., clarifying what data can and cannot be shared with whom according to HIPAA, and what agreements do or do not have to be in place with or without patient consent) would remove a number of unintentional information blocking practices and, therefore, also highlight any remaining intentional information blocking.

- We find, based on review of the report and subsequent policy discussions, that the concept of “information blocking” is still very heterogeneous, mixing perception, descriptive, and normative issues in ways that are not easily untangled. As a result, this concept and “label” does not provide a good basis yet for policy actions or enforcement, as it could encompass a broad range of actions, few of which are likely to warrant civil or other penalties.
- Provider and patient demand for data exchange is growing. The most powerful and promising driver of increased data exchange will be changing business models associated with new payment and

delivery models. New models have the opportunity to address current interoperability challenges related to lack of a business case for data exchange that are misperceived as information blocking, and will be a much more efficient and clear policy tool. These macro policy drivers, in combination with clarifying current laws and regulations as they pertain to data sharing, offer the most compelling and productive way to increase interoperability in support of critical advances of the desired healthcare outcomes.

Interoperability and data exchange require organizational, policy, legal, and technical infrastructure, with much of the infrastructure for information sharing existing outside of EHRs. This infrastructure will likely need to be supported by a mix of funding entities similar to other public infrastructure in this country, such as private sector and public/private data sharing and HIE initiatives. Consequently, the determinants of interoperability are not primarily found in the capabilities of EHRs or other health IT, adoption of which has already increased to very high levels based on standards and technology implemented prior to and through HITECH initiatives. Ultimately, the primary barrier to data exchange is the absence of strong market drivers and aligned incentives, as well as the fact that the burden to fund solutions is primarily placed on providers even where there is little ROI for their own organizations.

Focusing on general incentives that require data sharing for business success, while clarifying current regulations and their real allowances and restrictions on data sharing, can do much to reduce, if not eliminate, practices that are perceived as “information blocking”. Implementation of the MACRA interoperability provisions provides opportunities to focus on the key drivers and incentives to enhance coordination across providers. These in turn create the business cases and ROI opportunities for cross-provider interoperability to become firmly woven into the health IT fabric. The EHRA notes that different financial and business barriers need to be addressed, depending on the care environment. Small physician practices tell a different story on this topic than hospitals; critical access hospitals face different challenges than long-term care organizations or behavioral health practices. The stories vary by region, too. The mix of health systems and payers, in particular, can play a significant role in determining information exchange activity; and the adoption of advanced payment reform projects, such as the establishment of an accountable care organization (ACO) in a region, also has a large impact. Thus, it is critical to remember that no one set of incentives or policy fixes (legal or regulatory) will serve to address the obstacles facing all stakeholders; it will take a combined approach of many factors to see comprehensive success.

Until such time that these topics have been addressed, thus enabling identification of real information blocking practices and enabling the industry to identify appropriate actions and preventive measures, we run the risk of overreaction to what appear to be isolated incidents. In other words, by increasing the need and desire to share data, the desire not to share will diminish to isolated cases that do not require heavy regulatory oversight to prevent. The EHRA suggests that ONC continue to carefully monitor any reports of perceived information blocking.

- As ONC moves forward, clarity as to the focus of investigation and enforcement activities is necessary to help provide transparency in addressing the challenges with information blocking. This helps address providers’ and vendors’ concerns and challenges as a better definition develops and we better understand how to avoid information blocking practices.
- Overall, although the initial report was excellent given the time available to develop it, we do not believe that the concepts in the report, especially the enumerated “practices,” are ready for inclusion in legislation. A “light touch” national framework, emerging out of both public and private sector efforts, to provide guidance on common issues like governance and the use of standards,

would support more rapid progress toward our shared interoperability goals. We emphasize, however, that any government oversight in this area should focus on areas where the private sector cannot accomplish key national goals on its own (e.g., federal “recognition” of high priority, mature standards as guidance for the industry, and selection and focused adoption of nationwide standards for immunization reporting). Such oversight must be designed and implemented in ways that do not hinder innovation. To be clear, we are not referencing a technical framework or architecture, but rather policy and non-regulatory activities at the federal level that will support private sector response to market demand. Technical architectures will evolve to support the requirements and should not be hampered by prescriptive regulations that do not anticipate future capabilities.

More detailed feedback on the specific recommendations included in the report:

- Strengthen in-the-field surveillance of health IT-certified by ONC.
 - It is not clear how surveillance of certified health IT helps address any information blocking that is taking place. Information blocking as defined and the practices identified that are typically indicative of information blocking occur outside of health IT. Identifying those challenges involves a different skill set than that asserting whether installed health IT represents what was certified. The EHRA suggests that further review based on reported issues provides a more effective approach than to expand the in-the-field surveillance.
- Constrain standards and implementation specifications for certified health IT.
 - While variability in standards implementation can hinder interoperability in some instances, constraining standards and implementation specifications can also have an unintended consequence of not satisfying the variation in use cases. There are clear opportunities to harmonize vocabularies, formats, and transports (which we recommend and have supported for quite some time), while maintaining essential flexibility that enables additive capabilities rather than creation of incompatible alternatives. There is a clear need for a feedback process from users to understand where gaps are, and where constraints are needed to improve interoperability and minimize the perception of information blocking. Diverse perspectives between providers and developers must be considered to drive out ambiguity while remaining flexible enough to support necessary variability in practices and data needs.
- Promote greater transparency in certified health IT products and services.
 - The EHRA agrees that an improved understanding of all the components necessary to realize interoperability is essential to separate real information blocking from interoperability immaturity, cost, and value. But, clearly, no one in the industry would benefit from requirements that limit technologists’ or providers’ flexibility to develop and market new solutions.
- Establish governance rules that deter information blocking.
 - Effective governance for interoperability arrangements helps establish and increase trust and enables data to move. Such governance must be established jointly across public and private stakeholders, and cannot be mandated or regulated into a trusted framework. Examples range from the EHRA’s EHR Developer Code of Conduct to the Sequoia Project’s trust frameworks for eHealth exchange (Carequality), to Commonwell’s governance framework.

- Work in concert with the HHS Office for Civil Rights to improve stakeholder understanding of the HIPAA Standards related to information sharing.
 - The EHRA agrees that improved clarity can remove hesitation to share certain data.
- Coordinate with the HHS Office of Inspector General and CMS concerning information blocking in the context of the federal Anti-Kickback Statute and Physician Self-Referral Law.
 - The EHRA agrees that improved clarity can remove hesitations or perceived impediments to share certain data, thus removing situations that could be seen by some as “information blocking” practices. It would be helpful to understand who is permitted to make investments in interoperability (licenses, fees, infrastructure, management, etc.) on behalf of other parties, thus potentially removing obstacles to exchanging data more widely.
- Refer illegal business practices to appropriate law enforcement agencies.
 - It is unclear how to apply this action further, as the report indicates that there is insufficient clarity on when information blocking has truly occurred and what is considered legal or not. The legal framework when data is erroneously shared is clearer than when data is not shared and could have been.
 - The EHRA suggest that a focus on maturing interoperability in general is the more critical action at this point.
- Work with CMS to coordinate health care payment incentives and leverage other market drivers to reward interoperability and exchange, and discourage information blocking.
 - The EHRA suggests that this should be the primary action to establish the business case for interoperability, and that it will substantially reduce situations that lead to a perception of information blocking, at which time real cases of information blocking (interfering, with knowledge, without reasonable justification) will become more evident if and when they occur.
- Promote competition and innovation in health IT and healthcare.
 - The EHRA suggests that changing payment and delivery mechanisms, as well as associated competition and innovation aligned with these incentives, are most critical to advance interoperability and enhance data movement, while recognizing that interoperability is merely a means to an end. If there is no sustainable end, interoperability will not happen, and its absence can then not be considered information blocking.

In conclusion, EHRA looks forward to our continued dialog on this important issue. Our members are committed to working collaboratively with ONC and other stakeholders to ensure that data is moving securely to the right individuals at the right time to improve the quality and efficiency of healthcare delivery.

Sincerely,



Leigh Burchell
Chair, EHR Association
Allscripts



Sarah Corley, MD
Vice Chair, EHR Association
NextGen Healthcare

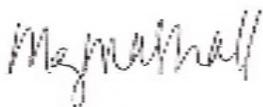
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About the EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of nearly 40 companies that supply the vast majority of operational EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

The EHR Association is a partner of HIMSS. For more information, visit www.ehrassociation.org.

CC:

Paul Tang, MD, MS, Chair, Health IT Policy Committee