Interoperability MATTERS
an initiative of The Sequoia Project

Draft Information Blocking Policy Considerations

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As the Information Blocking Workgroup developed materials on identifying Good Practices for compliance with the Information Blocking requirements and the operational implications of the expanded definition of Electronic Health Information (EHI), it identified several open and ongoing policy issues. This document outlines those policy issues and suggests areas where additional guidance from the Office of the National Coordinator for Health IT (ONC) and the Office of the Inspector General in the Department of Health and Human Services (OIG) would be helpful.

1. Overlapping Privacy and Security Rules

The need to balance information sharing requirements under the Information Blocking rules with the full range of privacy requirements under federal, state and local laws creates an enormous burden for Actors and could lead to significant challenges in operationalizing the regulatory provisions regarding information blocking. For example, the expenses (e.g., legal and regulatory) of cataloguing privacy requirements across levels of government and across specific government programs is a major challenge given the complexity and ongoing changes of privacy regulation. All Actors would have to conduct extensive legal analysis across all states and localities, which is both duplicative and burdensome. These requirements are particularly burdensome for multi-state Actors, who cannot readily identify which requirements are "most restrictive" (relevant to sub-exception #1 of the Privacy exception) due to the variability in laws and other requirements and hence, are unable to simplify as intended by this sub-exception via a focus on the "most restrictive" provision. There are also significant operational issues when individuals receive care across borders.

Implementation of privacy rules, including the Privacy exception, would be best served by a single set of rules. Given the lack of preemption of state laws by HIPAA and other sources of variability, however, we suggest that HHS create a consolidated public website that catalogues and enables targeted searches for the federal, state and local privacy and security rules. Alternatively, we suggest that HHS consider providing a template for the states to create a standard "profile" of their privacy and security rules that could be used by Actors and other stakeholders.

2. Interoperability Elements

It would be helpful for ONC to provide further clarification, in an FAQ or other guidance, on the regulatory definition of Interoperability Elements. In addition to being a very broad definition whose connection to information blocking practices and exceptions is somewhat unclear, there is concern that this definition is also ambiguous in its structure and could be interpreted as including for example, the entire electronic health record (EHR) and not just those elements of the EHR used for access, exchange, or use of EHI. Such an overly

broad application could lead to overuse of the Fees and Licensing exceptions for elements of the EHR or other health IT that are not, in fact, interoperability elements.

3. The U.S. Core Data for Interoperability (USCDI)

The initial rollout of information blocking limited the definition of EHI to the data elements contained in version 1 of the U.S. Core Data for Interoperability (USCDI). This alignment allowed Actors to leverage a set of data classes and standards that are supported by ONC certified health IT for information sharing. The expanded definition that will be effect starting October 6, 2022 departs from this approach and includes a wide array of information that is not standardized (See Draft Resource #1) often consistently and comprehensively supported for external access in Actors' health IT applications. This expanded definition therefore creates significant operational challenges (See Draft Resource #2).

While recognizing that ONC has stated that the full definition of EHI will become effective as planned, we recommend that the ONC collaborate with the Health IT Advisory Committee (HITAC) and stakeholders to develop a prioritized USCDI expansion roadmap to align, over time, more closely with the full definition of EHI, especially for those EHI elements that are likely to be the subject of a material number of requests for access, exchange, or use and for which standardization is both lacking and likely to be helpful to Actors and requesters. This approach would make it easier to share, access and use all of the information that is part of the full definition of EHI over time and reduce the need to use exceptions under the information blocking rules, to the benefit of all parties. This approach may require a more modular set of requirements for certified health IT that requires support of only those USCDI components relevant to the functionality of specific technology (e.g., relevant to certified EHR modules) rather than the full USCDI as it expands over time toward the full EHI definition.

4. Data Quality and Semantic Interoperability

For electronic protected health information (ePHI) that will meet the definition of the designated record set and that is outside of version 1 of the USCDI, information exchange is often limited by a lack of standards/ standardization, semantic interoperability, poor data quality, and technology capability. The Sequoia Project has a Data Usability Workgroup that is developing specific and pragmatic implementation guidance on clinical content for healthcare stakeholders in order to facilitate health information exchange. We recommend that ONC work with The Sequoia Project on a national roadmap so that common expectations of how data will be structured can be established across senders and recipients.

5. Technology Challenges

As the expanded definition of EHI takes effect, Actors will be required to comply with the information blocking prohibitions for data held in many different electronic systems for which they are responsible, whether ONC certified or not. If these many disparate systems do not enable mechanisms for standards-based sharing, it will limit the ability of Actors to fulfill the intent of the information blocking rules and result in extensive use of the exceptions. It would be helpful to have resources and incentives for technology developers of non-certified health IT to create mechanisms for standards-based information sharing to support Actors' compliance with information blocking regulations.

6. Privacy Exception

A SAMHSA-funded Center of Excellence on PHI is providing training resources on HIPAA and 42 CFR Part 2 applicability for clinicians. It would be useful if ONC could reference and use this material in support of Actor use of the Privacy exception, especially for smaller providers and community HIEs.

7. Harm Exception

A key part of compliance with the information blocking rules is documenting when an exception is applicable. Given that clinicians are integral to determining whether harm could result from sharing certain information, it would be useful for ONC and the OIG to work with Actors and their technology developers to interpret the Harm exception in a structured format that could be documented in the EHR. More generally, we suggest that ONC and OIG work with Actors and their technology developers to enhance the ability to document use of all applicable patient-centric exceptions (e.g., privacy, security, infeasibility) in a structured format that could be documented in the EHR.

We also suggest that ONC both provide additional guidance and consider policy revisions regarding the two specific criteria used under the harms exception: "substantial harm" and "endanger the life or physical safety". Clinicians and other Actors staff face challenges determining whether to release or withhold information that is likely to cause "substantial harm" when that criterion is insufficient to meet the conditions of the Harm exception. In addition, we ask ONC and OIG to address the interaction of the actual knowledge standard for providers (i.e., that a practice is "unreasonable") and the Harm exception in instances where a provide may feel professionally obligated to use "substantial harm" as a basis to deny individual access and the provider does not know "that such practice is unreasonable under the circumstances."

8. Fees Exception

Actors have observed that fees can meet the conditions of this exception but still be unaffordable to a particular requester. It would be helpful for ONC and OIG to provide guidance that addresses this perspective, both with respect to clarification to Actors and EHI requesters and also with respect to how exceptions like Content and Manner could be used to find EHI access options that might be more affordable to the requester.

9. Guidance

The following issues continue to need additional guidance from ONC and OIG to support effective compliance with the information blocking rules:

- What considerations are “reasonable” when assessing infeasibility?
- What will regulators be looking for when they assess whether an action or business process is “reasonable under the circumstances”?
- Actors find it particularly challenging to comply with information blocking rules when data pertains to adolescents, given the wide variation in privacy rules for these individuals and the possibility of unauthorized proxy access by parents and guardians. They would welcome additional guidance on how best to apply the Privacy and Harm exceptions for this group when they have legal obligations to protect adolescents’ health data that can appear to be in conflict with obligations to share these data with the adolescent or others. These challenges are likely to become especially acute as the scope of information to be shared increases under the expanded definition of EHI.
- What constitutes a “request” for EHI, notably for portal access (e.g., is a portal log-in a request for some EHI, specific EHI, all EHI)?
- Actors and data requesters seek written confirmation of the oral ONC staff statement at the April 13-14, 2022 ONC Annual Meeting that the 10-day period for Infeasibility starts after initial due diligence (e.g., is the requester entitled to the EHI and what is the specific request) has occurred.
- Would insufficient staff and resources to evaluate and respond to a large number of requests for EHI in a given period of time be an acceptable basis for using the third condition of the Infeasibility exception?
- Under the first condition of the Infeasibility exception, “events beyond the actor’s control,” we ask ONC to provide guidance on situations where it is not possible to provide the notice of infeasibility within 10 business days given the circumstances responsible for this condition being used such a natural disaster that disrupts hospital operations, including the teams responsible for handling requests for EHI.

- For the Preventing Harm exception, it would be very useful to have ONC guidance (or a regulatory clarification) on the definition of "clinician" as used in this exception or especially a definition that aligns with the definition of clinician used by the HHS Office of Civil Rights in the 2021 HIPAA Privacy Proposed Rule.
- For Provider Actors, who must know that a practice is "unreasonable" for it to constitute information blocking, to what extent can clinicians use their professional judgment when facing an ethical dilemma regarding access, exchange, or use of EHI in circumstances where they cannot fully meet the conditions associated with the Preventing Harm exception? In essence, if ethical considerations would argue against sharing EHI, how should that concern factor into considerations of whether withholding information is "unreasonable"?
- An Actor's organizational policy may instruct clinicians to not use certain data in decision making (e.g., Provider to provider messages, draft data, record retention cycles). Can such an organizational policy be relied upon when a provider fails to adhere to the policy and there is an allegation of information blocking when that information is not shared pursuant to a request?
- The definition of "care team" under USCDI V. 1 is broad and can vary across institutions. Additional clarity is needed for Actors using this standard to ensure they have sufficiently and consistently defined the scope of care team members.
- When considering whether chart corrections are included in the definition of EHI, additional guidance is needed on whether the data to be considered EHI includes the entire documented flow of the decision-making process, including the request from the patient, the amendment decision by the provider, a potential written disagreement by the patient, and the rebuttal from the provider if there is a disagreement regarding the chart correction between the patient and provider.
- With respect to data that is maintained by an actor in more than one HIT system or location, the HHS Office of Civil Rights has stated that "if the same PHI is maintained in more than one designated record set, a covered entity need only produce the information once in response to a request for access [by a patient]." Similarly, ONC, in the Information Blocking Final Rule, has stated that ". . . .. if the same PHI that is the subject of an access request is maintained in both the designated record set of the covered entity and the designated record set of the business associate, the PHI need only be produced once in response to the request for access."" The citation used by ONC to support this position is from the regulations governing the individual right of access cited above. It would be helpful for ONC to clarify whether the above policies re: provision of duplicate EHI extend beyond individual access.