Interoperability MATTERS
an initiative of The Sequoia Project

Operational Considerations Raised by Moving to the Full Definition of EHI

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This document provides guidance to Actors that must comply with the Information Blocking rules on operational steps needed to accommodate the full definition of EHI that will be in effect in October 2022. It was created by the Information Blocking Compliance Workgroup of The Sequoia Project's Interoperability Matters Initiative, with the assistance of several additional subject matter experts. This work reflects the operational experience of the individuals who volunteered their time and expertise to share operational experiences and approaches. We especially thank the following individuals who led the development of this resource: Josh Mast*, Alex Desilets, Peggy Frizzell, Hilary Greer, Morgan Landerman, Bridget Leon, Virginia Lorenzi, Sid Thornton, and Chantal Worzala* (*Workstream co-chairs).

Actors subject to the Information Blocking rules issued by the Office of the National Coordinator for Health Information Technology (ONC) first developed processes to comply with sharing the constrained and standardized set of clinical data contained in the U.S. Core Dataset for Interoperability version 1 (USCDI v1). This initial, limited definition of Electronic Health Information (EHI) subject to the information blocking prohibitions generally maps to standards and functionality contained in the Health Information Technology (Health IT) certification criteria established by ONC for the 2015 Edition and the 2015 Cures Update.

With the expanded definition of EHI that takes effect on October 6, 2022, Actors will need to modify their operations to enable responding to requests for a much broader scope of EHI, much of which will not be in standardized forms and formats, or supported by ONC certified technology, especially for 2022 and for some time to come. This expanded definition is:

> **Electronic Health Information (EHI)** means electronic protected health information as defined in 45 CFR 160.103 [HIPAA], to the extent that it would be included in a designated record set as defined in 45 CFR 164.501 [HIPAA], regardless of whether the group of records are used or maintained by or for a covered entity as defined in 45 CFR 160.103 [HIPAA], but EHI shall not include: (1) Psychotherapy notes as defined in 45 CFR 164.501 [HIPAA]; or (2) information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding.

In addition, with this expanded definition of EHI, Actors are likely to encounter more requests that require them to use one of the exceptions to information blocking that were enumerated by ONC in its rulemaking (such as Privacy, Harm, Content and Manner, or Infeasibility). Actors identified by ONC include Health Care Providers, Developers of Certified Health IT, and Health Information Exchanges/Networks (HIE/HIN).

This document presents seven operational steps relevant for many Actors as they prepare to comply with the expanded definition of EHI. It identifies some of the implications of the expanded definition for operations, and it highlights associated challenges and opportunities.

The seven steps are:

1. Identify where EHI resides.
2. Assess available tools for fulfilling requests, with gap analysis and identification of alternative approaches.
3. Review and modify internal governance of information blocking compliance, as appropriate.
4. Modify processes and policies for receiving and assessing requests against the definition of EHI.
5. Establish processes and staffing needed to understand requests and engage in discussion with requesters.
6. Conduct internal communications and training.
7. Engage clinicians (particularly for provider Actors).

Although the operational steps outlined below provide certain considerations and implications, Actor organizations will likely need to follow their own internal change management processes to ensure that their operations are updated to accommodate the expanded definition of EHI. The challenge of implementing operational processes to share the broad scope and varied types of information contained in the full definition of EHI should not be underestimated. It will therefore be very important for Actors to continue to share their experiences, successes and challenges as they expand capabilities for information sharing.

This tool should be used in tandem with the other deliverables from the Information Blocking Workgroup released during September 2022 to develop a comprehensive understanding of and response to the complexity of EHI.

Note: The materials developed by the IBWG are intended to be educational and informational resources. These materials will be most helpful to those who have a strong understanding of the regulatory requirements but seek to understand real-world implications and approaches to implementation. They are not, and are not intended to, constitute legal advice or a treatise on the Information Blocking Rule. Regulated Actors are encouraged to seek appropriate counsel to advise on the Actor's legal compliance. No Actor should act or refrain from acting on the basis of the IBWG materials without first seeking legal advice from counsel. All liability with respect to actions taken or not taken based on the IBWG materials are hereby expressly disclaimed. The IBWG materials are provided "as is;" no representations are made that the content is error-free.

Implications of Expanded Definition of EHI for Operations	Challenges/Opportunities
1. Identify where EHI resides	

• Review designated record set (DRS) policy (of a Provider) and consider whether changes are needed
 	
• Map electronic systems that contain electronic PHI in the designated record set to identify where it resides and which departments use it as part of data governance.
  ○ Look across health IT ecosystems:
  ■ Administrative and clinical systems
  ■ Specialty systems
  ■ Archives
 	
• Identify ability to share information from all of the identified source systems.
 	
• Consider the need to deploy a patient data aggregation solution to consolidate across source systems and provide a single source to fulfill requests (may depend on scale of activity and resource constraints).
 	
• Consider defining several default templates for sharing information for different purposes (portal, various information exchange use cases) in addition to "all EHI" that can be made available upon request.
 	
• Considerations for Developers: Developers generally are not HIPAA covered entities but still need to have a concept of what is in their versions of a DRS, especially given their clients' implementations of the DRS.
  ○ Develop organizational list of data classes and elements that represent organizational understanding of EHI
  ○ Determine ability and manner(s) in which EHI can be shared.
	The extent and nature of the ePHI in the DRS will vary by organization and is likely to involve many different systems with varied levels of connection to tools that will allow for sharing.

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Considerations for HIE/HIN: Data that is available to be shared is generally constrained by Data Use Agreements (DUAs) and Business Associate Agreements (BAAs) signed with participants.	
2. Assess available tools for fulfilling requests, with gap analysis and identification of alternative approaches	

• Identify approaches currently used (portal, API, HL7 interface, etc.)
 	
• Evaluate existing processes to assess whether they are sufficient to handle requests beyond the contents of the USCDI v1. For example, requests for electronic financial and billing records or actual images (as opposed to imaging reports).
 	
• Evaluate process changes to accommodate the expanded definition of EHI, such as coordination across IT source system managers (for example, medical devices, billing and finance, inpatient and ambulatory).
 	
  • Review roles (if any) of business associates in supporting response to requests for EHI and ensure that business associate agreements appropriately reflect those roles.
 	
• Evaluate and monitor the need for additional features available that could be turned on or purchased.
  ○ Example: Withhold a note and document the reason, which may be needed for an exception
  ○ Example: Portal upgrade to allow additional information to be shared
  ○ Example: Custom integration needed to share additional information on the portal, which is infeasible under the circumstances, and documented as such.
	Opportunity for providers and HIEs to work with vendors to automate as much as possible.
	
	Opportunity to develop new tools. Priority tools for providers:
	
	○ Ability to segment data based on privacy or other considerations (example, block a portion of a note or a specific diagnosis on a claim, etc.)
	○ Sharing on the portal
	○ Patient-facing tools to sort and search on the portal
	○ Ability to customize the “proxy view” of a record via the portal in ways that comply with privacy rules (such as parental access to adolescent records).
	○ Move toward certified EHI Export as a function of the portal to allow individuals to automatically access all available information in portable format.
	○ Support in EHR system for clinicians to document use of the harm and privacy exceptions
	
	Challenge for developers: Tools for data segmentation and withholding of sensitive data that enable effective and efficient use of exceptions (Harm, Privacy) while also supporting the ability to share confidentiality restrictions with other health IT tools and actors.
	
	○ Example: if withholding lab results based on discussion with a patient, need to communicate the need for such a

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● Evaluate other staffing or technical resources that may be needed (release of information, health information exchange). ● Develop (or plan to purchase) needed new functionality, as able. ● Identify and implement workflow changes to expose data in new ways such as through API (which could implicate other systems/uses of data). ● Consideration: Speed of access may depend on approach used to share data - API vs HL7 interface vs. document-based exchange, etc. ● Consideration: With expanded definition of EHI, will have more information that is not in structured format. Creates need to determine both how shared by the actor and how consumed by the requester. ● Consideration: Meeting a request might require multiple modalities of exchange. ● Consideration: Licensing issues may arise with respect to certain code sets and other copyrighted data elements and organizations should consult with legal counsel with respect to this issue.	withhold to the clinical lab. ○ Example: If segmenting information so that it is unavailable on the portal, then the same data should be able to be segmented and withheld for API access. ○ Example: If withholding/ segmenting information for portal/API, also need to communicate restriction on access to the HIE. Concern: Lack of ability to tailor or limit API requests by data type could lead to too much information being shared. This result could be a challenge created by the standard and/or the certification requirements. Concern: Sharing of information in non-standard formats may limit usability. For example, if sharing information in "machine readable format," it will be up to the recipient to decide how best to use non-standardized data. However, it is not clear that the Actor holding the data will have the capability to fully understand the contents included in the machine-readable format file and also to properly screen for compliance with privacy rules and other obligations. Do they have sufficient analytic tools available? At this point in time, there is likely still a need for manual review to ensure compliance with privacy rules and other obligations - full automation not yet possible.
3. Review and modify internal governance of Information Blocking compliance, as appropriate	
● May need to add additional departments/ individuals representing new data sources to the governance process to facilitate: ○ Intake of requests across departments/ organization. ○ Internal communication on processes and expected response times. ○ Review of requests and documentation for use of exceptions.	Opportunity for greater collaboration across the enterprise. Creates increased need for training/operating procedures and maintenance of training (See training section below).

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• Expanded definition of EHI could lead to increased need to consider whether requester has legal right to the record, and whether the exceptions are needed, which could impact governance process (expertise represented, frequency of oversight, etc.). • Consider periodic review of processes and policies for responding to requests given changes in data included in health information systems and increased capability to share and/or segment EHI.	
4. Modify process and policies for receiving and assessing requests against the expanded definition of EHI	
• Evaluate existing processes to ensure requests for divergent types of EHI are all identified (includes, for example, financial and billing records, clinical records across departments, etc.). • Amend existing policies to accommodate expanded definition of EHI • Evaluate each request to understand scope and appropriateness of request, as well as the appropriate EHI to share in response. ○ Is the request about EHI? ○ Evaluate request for specific information against HIPAA constraints on access (is authorization required? What is the minimum necessary?) ○ Evaluate against state rules and regulations ○ Evaluate harm/privacy considerations ○ All EHI may not be the appropriate response ○ Who can request all EHI? ■ Patient (existing processes) ■ Third-party acting on behalf of patient (app developers, others, analytics) ■ Third-party engaged in payment	Information blocking compliance will require deployment of relatively sophisticated staff to evaluate requests and may require additional human resources in addition to new technical resources. Actors need to balance responding to requests and avoiding overwhelming the recipient of the EHI. All EHI is not necessarily always the right response. Challenge for Providers: Evaluating all of the relevant privacy and harm prevention requirements across jurisdictions and programs is time consuming and takes significant legal and financial resources. Challenge for Developers: Providers can establish policy consistent with “most restrictive” state privacy requirements, but Developers work across providers (examples: CA/KY require delay before release of certain labs). HIE/HINs likely have similar challenges: Opt-in/opt-out considerations and cross-border exchange present complex and potentially

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and health care operations (payer, value-based care) ■ Third-party with patient authorization ● Expanded definition of EHI will increase the number of situations where these analyses must be done. Example: Sexual orientation and gender identity (SOGI) data, patient questionnaires (particularly for adolescents and access by proxy), flow sheets, etc. ○ May increase clinician work to consider need to "hold back" sensitive information. ■ Do you have the ability to segment data fields that are sensitive? ■ Are there tools available to document the "why" data will not be shared? ■ May need an alternative to indicate that a patient's record is sensitive. ■ Clear education challenge to ensure clinicians understand the boundaries/nuances of the exceptions (Harm, in particular, is challenging) ● Expanded definition of EHI may require more interaction with the requestor to evaluate what is being asked for and whether the requestor has the authority to receive requested information. ○ Consider establishing a patient request workflow (including patient representatives): Begin with a portal that has available information and instructions to ask for additional data (begins HIM/ROI process); Interaction to determine what is being asked for and what is available. Or, begin with medical records and start the ROI process. ○ Consider establishing a workflow to	contradictory rules on what can be shared. Implementation challenge: State law may impact Actors differently even within a category (clinician versus a lab within a health system, for example). Implementation challenge: Differing requirements create implementation workflows so that individual pieces of information can be tagged by the customer for release/withholding in different contexts. Today, tagging is generally used at the document level as an optional certification criterion, rather than at the data element level. It is unclear how exchange will handle (or persist) the tagging given optional implementation. Implementation challenge: Withholding for state requirements may be handled via a time delay or a manual release – it is hard to know when a given approach is correct, which limits the ability to automate. Information management challenge: Information does not stay in a single place, which means that transmitting labels re: sensitivity becomes a challenge. Opportunity to develop standard approaches to document and share computable consent and "proxy" access to information beyond the patient portal. Need for tools to limit access in compliance with state and other laws. This is particularly relevant to comply with rules around parental access to certain health records of adolescents as well as other scenarios. In addition, need to address EHI that originated from non-HIPAA covered entities and/or non-Actors, where the originating organization may have its own consent models, such as where an opt-in is required for each referral for a social service organization.

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respond to requests from third parties not under any existing arrangement (TPO requests, HIEs, research, etc.) Begin with medical records and start the HIM/ ROI process within the context of HIPAA and state/local privacy rules. ○ Consider developing various standard scopes of EHI to be shared for common requests as a starting point for response. ● Expanded definition of EHI includes information that cannot be shared in electronic format due to system limitations and lack of standardization. This means that Actors will need to identify the information that is currently infeasible to provide and create a process to document in order to use Content and Manner and Infeasibility exceptions. ● Must have good documentation and audit tools to defend against possible complaints. ● Considerations for Developers: ○ If request is for patient-level EHI, direct requester to the relevant providers. ○ If request is from app developer, establish process to accommodate. ○ If request is from client, establish process to accommodate. ● Considerations for HIE/HINs: ○ If request is for patient-level EHI, consider provisions of BAA/DUA, and/or direct requester to the relevant providers. ○ If request is from an HIE member, consider provisions of BAA/DUA. ○ If request is from a non-member, evaluate ability to respond based on applicable law. ○ If request is for EHI you do not hold, establish standard response.	.

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5. Establish processes and staffing needed to understand request and engage in discussion with Requester	

• Expanded definition of EHI will likely lead to more requests that will need to be clarified to determine the Content to be shared and requested Manner for sharing it.
• Evaluate how requests are currently received and documented (e.g., use of EHR features, patient portal with identified link to request additional information not available in portal).
• Amend existing policies to identify Content and Manner that is being requested if not already part of process.
• Consider forming a core group in the Actor organization that can evaluate and respond to requests that require escalation beyond standing policy quickly. Consider engaging representatives from HIM, IT, privacy, information security, and legal/compliance.
• Evaluate ability to share the requested EHI in Content and Manner being requested against the tools that are available to the actor
  ○ Identify Alternative Manner, as needed
• Establish process to document each step
  ○ Work through traditional ROI
  ○ Different process outside of traditional HIM/ROI
• For Developers: Requests come into the organization in many different ways, such as account managers, internal accounts, outside organizations.
  ○ What is a request for EHI versus an enhancement to the system?	

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• For patients: What role do they have? What knowledge do they have today regarding their access rights?
• For Providers: Likely still need broad education of staff and clinicians outside of HIM/ROI on right of access and HIPAA authorization.
 	
• Content and Manner:
  ○ Full definition of EHI broadens scope of what can be asked for which vastly increases possibilities for specific content and specific manner
  ○ Limitations of specific standards and mapping requirements may limit the Content and Manner of response
  ○ For Actor: Establish your own understanding of the Manner in which certain content can be provided.
  ○ For Actor: Establish specific policy regarding approach to fulfilling requests and documenting supporting evidence around each exception to meet the requirements and conditions of each exception (ensuring that it is non-discriminatory, etc.).
  ○ Documentation will be needed for each request that involves Content and Manner discussions.	

6. Conduct internal communications and training	

• Tailored communications and training will be needed to share the expanded definition of EHI and revised procedures for fulfilling requests
 	
• Level of training may depend on staff roles ("tiered")
  ○ Variation by Actor type
  ○ For Developers: general training for all staff; extended training for core team with greater information blocking compliance responsibility; targeted training for specialized functions (such as creating interfaces). Build	

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knowledge and tools to provide expected responses so that data flows and then create processes for exceptions/questions. ○ For Providers: ■ Designate what is EHI and will be shared at a conceptual level. Core responsibilities for IT and HIM staff will require changes to workflow to accommodate expanded definition of EHI; this includes clear understanding of how to find and share a wide range of data types ■ Training/communications for front-line staff to create culture of information sharing; ■ Training/communications for clinicians to improve documentation and to ensure data are in expected locations, which includes workflow changes. ■ Create awareness of how to address technology issues. Requires involvement of privacy officer, security, IT, HIM, clinical informaticists ○ Consideration: put policies in place for when exceptions are going to be used. Limit staff that can decide to use an exception to those who understand the policies. ○ Culture change: Assume sharing is the default approach with specific guardrails laid out in policies. Encourage staff that have questions to send them to the central team that is responsible for IB decisions.	
7. Engage clinicians (particularly for Provider Actors)	
● Involve clinicians early and upfront to evaluate workflow implications of querying, retrieving, and reconciling data contained in the expanded definition of EHI.	Challenge: The expanded definition of EHI tied to the Designated Record Set definition (clinical and billing; information used to make a decision about patient care) may be different at a conceptual level versus the individual

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• Establish clinician champions to be a part of governance processes. They can assist with:
  ○ Periodic feedback and review of lessons learned
  ○ Education planning and development
  ○ Sharing of knowledge
 	
• Develop and communicate clear workflows to clinicians
 	
• Provide additional, targeted training to clinicians on the scope of the expanded definition, focused on the implications for them, and the potential for increased need to consider when it might be necessary to use the preventing harm and privacy exceptions.
  ○ Example: Move to all EHI opens up all notes, which clinicians should be aware of.
  ○ Example: Clinician-to-clinician communications may be EHI but be hard to capture across an organization (consider policy to not use this mechanism for patient information).
  ○ Example: Move to all EHI includes billing information that may also include sensitive information, such as diagnoses
 	
• Establish and communicate standard and simple processes for clinicians to get answers to their questions, such providing a single point of contact.
 	
• Consider auditing use of exceptions across clinicians
	patient level.
	
	• It is not feasible to tag all data as used/not used to make a decision.
	• Can tag data types to automate.
	
	Implementation challenge: Clinicians will need to be involved in decision to use some of the exceptions. How can Actors best document the use of an exception?
	
	• Clinician decision to use the Harm exception could potentially be documented in EHR (labs, notes, medications, diagnoses are all data points that might be the subject of the Harm exception).
	
	• Need tools for clinicians to document privacy concerns.
	
	• Other exceptions would probably need to be documented elsewhere by non-clinical staff (Infeasibility, Health IT Performance, etc.)

