August 19, 2022

Submitted electronically via: InteropMatters@sequoiaproject.org

Marianne Yeager
Chief Executive Officer
The Sequoia Project

RE: Information Blocking Compliance Workgroup Public Feedback on Draft Resources

Dear Ms. Yeager:

Thank you for the opportunity to comment on the draft resources developed by the Sequoia Project's Interoperability Matters Information Blocking Compliance Workgroup.

Ciox Health (Ciox), a Datavant Company, aims to connect the world's health data to improve patient outcomes. We work to reduce the friction of data sharing across the healthcare industry by building neutral, trusted, and ubiquitous technology that protects the privacy of patients while supporting the exchange of identified and de-identified health data across tens of thousands of healthcare institutions. In July 2021, Ciox merged with Datavant to create the nation's largest health data ecosystem, powering secure data connectivity on behalf of thousands of providers, payers, health data analytics companies, patient-facing applications, government agencies, research institutions and life science companies.

Ciox works closely with tens of thousands of hospital systems and medical practices across the country, supporting their efforts to provide patients with seamless access to their health information, digitizing electronic health records and ensuring interoperability of data, and unlocking the potential of data in medical records.

Ciox has closely followed the implementation to-date of the HHS Office of the National Coordinator's 21st Century Cures Act Final Rule, which updates EHR Certification Criteria and prohibits information blocking, and is supporting hospital systems and medical practices across the country in complying with the new rules. We appreciate the Sequoia Project's cross-cutting work to help health care entities in navigating compliance with the information blocking rules, including the considerations that arise from the move to the full definition of electronic health information (EHI) beginning on October 6 of this year.

Below, we provide feedback for your consideration on the draft "Good Practices for Information Sharing and Information Blocking Compliance Discussion Draft"; the draft "Operational Considerations of the Move to an Expanded Definition of EHI" document; and the draft "Understanding the Expanded Definition of Electronic Health Information in an Operational Context."

Good Practices for Information Sharing and Information Blocking Compliance Discussion Draft

The information blocking rules are multi-layered and complex, and will take time for actors across the country to adjust their business practices to ensure compliance with both information blocking and HIPAA. We appreciate the Information Blocking Workgroup's efforts to develop and publish this comprehensive resource for entities' use in planning and implementation for compliance with the information blocking regulations.

Our comments and feedback below are based on our experience in supporting hospitals and medical practices across the country in responding to requests for health information. We urge the Information Blocking Workgroup to make minor adjustments to its Best Practices to take into account some of the real-world operational complexities of this on-the-ground work. For instance, we recommend further

clarity to delineate between timelines required under HIPAA and under the information blocking rules, or to assist providers in determining whether a PDF is machine-readable.

Category	Recommended Best Practice	Ciox Feedback & Recommendations
Checklists, Sample Policies, Workflows	***(Page 11)*** **- Recommended Best Practice:** Create a centralized "funnel" process to capture potential EHI requests for further evaluation by the appropriate workflows and SMEs, without front-line staff needing to determine whether a valid request for EHI has been made. [All Actor-types] – Requests may come from many sources in addition to patient portals, including multiple internal staff and units (e.g., payer relations, public health, API requests to IT), reinforcing the need for broad staff training and a centralized intake and request evaluation function. These request handling processes can help demonstrate intent for information sharing and compliance. – If a data requester, team member or other person raises concerns about "information blocking," make sure that all relevant staff understand what that term means and how to get help from the right team members.	We have found that many third-party requestors, such as commercial requestors, often try to use information blocking to access large amounts of information, which may bog down the process for frontline and other staff. We would recommend including examples for frontline staff that would allow them to quickly distinguish between different types of requests for EHI.
	(*Page 13*) - Recommended Best Practice: Create training and compliance programs for staff who are not part of the regular Health Information Management (HIM)/Release of Information (ROI)/EHI access process but who might receive EHI requests or have responsibilities for activities that could implicate information blocking (e.g., pricing specialists, contract and procurement teams, legal teams, interface engineers, security teams, etc.). This training should address the role of these teams with respect to applicable exceptions, including Fees, Licensing, Security, Content and Manner and Infeasibility. [All Actor-types] – Include these teams in information blocking compliance workflows. – Update workflows and checklists used by these teams to ensure that information blocking compliance is addressed.	We recommend that ancillary staff also receive or are incorporated into the training described in this Best Practice.

	(*Page 17*) - Recommended Best Practice: Create a clear process and forms to manage and document use of exceptions. [All Actor-types]	We believe this Best Practice should also recommend that actors create a cross-walk for exceptions. For example, if an actor's health information management vendor finds that an authorization is not HIPAA-compliant, staff should easily be able to cross-walk that use case to the Privacy Exception for documentation purposes.
Responding to Complaints of Information Blocking:	***(Page 28)* - Recommended Best Practice:** Like with other compliance programs, conduct regular risk assessments and use external audits and/or event simulations to review compliance adequacy (e.g., as applicable, HIPAA and privacy vendors could incorporate information blocking assessment into periodic privacy and security program assessments.)	We recommend that this Best Practice also include a review of correspondence letters being sent by the provider's HIM/ROI vendors for continuous improvement opportunities.
Is it Information Blocking	**(*Page 33*) - Recommended Best Practice:** Be mindful of ONC regulations and guidance on the 10-day timing to use the Infeasibility exception (and to meet the Licensing exception). Establish clear workflows to meet these timing requirements and to document timely responses. Also establish workflows for instances when 10-day timing cannot be met (e.g., because of an unsuccessful effort to use the Content and Manner exception) to demonstrate good intent through documentation of good faith efforts to respond timely (and to use the Content and Manner exception if that was the initial goal).	We recommend clarifying here that this Best Practice is specific to the 10-day timing requirement in the Infeasibility exception, and should not be confused with the existing 30-day timeliness requirement under HIPAA.
Privacy Exception	**(*Page 62*) - Recommended Best Practice:** Except for an individual's access to their own EHI, Actors operating in multiple states should determine if they wish to use the regulatory ability to rely for this sub-exception on documented organizational policies and procedures that adopt the more restrictive state (and applicable Federal) law for the entire organization. Note that such a uniform approach is unavailable if a case-by-case approach to applying this sub-exception is used rather than a formal policy.	We note that while most providers have individual policies for each provider site/state, this Best Practice recommends that providers accept the more restrictive law. This is not always feasible from state to state.

Content and Manner Exception	**(*Page 87*) - Recommended Best Practice:** ONC has stated in an FAQ that a PDF document could meet this criterion if it meets the National Institute of Standards and Technology's definition of machine-readable – " Product output that is in a structured format, typically XML, which can be consumed by another program using consistent processing logic." If a data output format is structured so that the EHI it conveys is machine readable, then that output format is a machine-readable format, regardless of the file extension.	We recommend providing additional detail here to help providers to determine in practice whether a scanned document or pdf is machine-readable.

***Draft* Operational Considerations of Full Definition of EHI Comments**

This draft document outlines seven operational steps that Actors should consider when preparing to comply with the expanded definition of EHI.

Overall, we support and agree with the operational steps outlined in the document. However, we recommend that as a first step, providers should map their Designated Record Set (DRS) and then determine what EHI contains DRS data elements. In our experience, most clients are using an Excel spreadsheet to map out their DRS and are having difficulties in getting and maintaining this information.

Additionally, we believe it would be helpful for providers to put in place an overarching information governance system that maps the EHI/DRS that all departments must utilize. This will help providers to better understand and maintain documentation related to their DRS and EHI.

***Draft* Understanding the Expanded Definition of Electronic Health Information in an Operational Context**

This draft document provides guidance to Actors that must comply with the Information Blocking rules and the operational steps needed to comply with the full definition of EHI that will soon be in effect.

Overall, we appreciate the Workgroup's efforts to map out the types of data elements and data classes that may be included in EHI. However, on page 24, the draft document includes "Provider-provider messages with patient-identifiable information (e.g., chat/email inbox, sticky notes, secure messages)" as an additional data class discussed as a potential component of EHI. We have some concern that providers will not be able to adequately and comprehensively capture this information across the enterprise. For instance, if an individual clinician uses a personal device to text another clinician about a patient, it may be difficult for the Actor to identify and account for such communication in requests for all EHI.

* * * * *

Thank you again for the opportunity to comment on the draft documents. Please contact Aden Fine, Chief Privacy Officer (aden@datavant.com), with any questions regarding our feedback or if we can be a resource to you in the future.

Respectfully,

Bob Bailey, Chief Legal Officer