2023-2024 Interoperability Matters Privacy & Consent Workgroup Charter

Purpose

While information sharing has become the standard in U.S. health care, the inherently sensitive nature of health information creates significant operational challenges for health information exchange. The Interoperability Matters Privacy & Consent (P&C) Workgroup is charged with cataloguing key impediments and discussing whether and how standards-based, automated solutions can support proper information exchange that appropriately protects privacy.

The Workgroup shall remain cognizant of the implementation-level implications of proposed and final rules issued by the appropriate government authorities (e.g., HHS, CMS) as they relate to consent management and data segmentation for privacy. The Workgroup shall consider the broader needs of public and private sector stakeholders and simultaneously stay focused on implementation-level and operational aspects of privacy and consent related activities. The Workgroup efforts will consider existing and future policy developments.

Background

The HIPAA regulations provide a federal framework in the U.S. for health information privacy and security. However, the rules do not preempt state or local laws that provide greater privacy protections. This includes laws that may:

- specify that individuals must opt-in to health information exchange;
- vary based on an attribute of an individual (such as protections specific to adolescents);
- apply to the specific data contained in a record (such as data related to substance use disorders, HIV data, or other information deemed sensitive under a state or local law); or
- require universal checks for consent before information is exchanged.

Furthermore, in the aftermath of the [Dobbs v. Jackson Women's Health decision by the Supreme Court](#), the Biden-Harris Administration, some state governments, and many individuals have expressed increased concern that inappropriate disclosure of sensitive information, such as reproductive health information, could harm individuals. For example, the Office for Civil Rights within the Department of Health and Human Services have proposed rules to prohibit the sharing of reproductive health information for certain purposes and in certain circumstances. Additionally, the Office of the National Coordinator (ONC) for Health Information Technology has proposed that certified health IT developers embed the ability to "flag" data deemed sensitive in their products.

Initial Areas of Focus

Given both the increase in health information exchange and the growing attention to the sensitivity of health information, the issues of consent management and data segmentation for privacy come to the fore. Practical and universal solutions are needed to maintain and build on the growing momentum toward interoperability.

The Workgroup will conduct a landscape review of key privacy and consent challenges impacting interoperability and data exchange in healthcare. Given the current environment, the Workgroup will focus initially on the following topics:

> **Consent Management.** Those receiving requests for information must determine what level of exchange is permitted and when consent may be required. If an individual's consent (or authorization) is required for sharing information in each circumstance, the process to obtain and electronically share consent in a computable format is not yet standardized. While some exchanges do have the ability to identify when a request needs consent to be fulfilled and share related consent materials, this process is not standardized. Computable consent that is standardized could facilitate information sharing and reduce the burden of consent management.

> **Data Segmentation for Privacy.** There is limited capability to segment data today and no widespread agreement on a standardized approach to doing so. Although HL7 has developed Data Segmentation for Privacy Implementation Guides for FHIR® and Clinical Document Architecture (CDA), they have undergone limited testing and are not yet widely used. The Shift Task Force (formerly Protecting Privacy to Promote Interoperability [PP2PI]) is currently focused on maturing granular data segmentation standards and implementation guidance. ONC recently published a request for information on data segmentation for privacy. In response, several stakeholders noted the need for industry convening, identification of uses case, and pilot testing of approaches to build from the existing HL7 DS4P IGs and suggested that federal funding is needed.

As appropriate the Workgroup will expand to other areas of focus as the work effort evolves.

Key Deliverables

The Workgroup will focus on the following key areas:

#	Deliverable	Additional Commentary
1	Conduct a landscape analysis of key privacy and consent challenges impacting interoperability and data exchange in healthcare.	Identify and review the existing workstreams within the healthcare community focused on the initial issues
2	Catalogue and identify key paint points around consent management and data segmentation for privacy, and other topics that the Workgroup deems appropriate.	Leveraging the findings from the landscape analysis, the Workgroup will identify and define additional needs that will move it towards its stated goal of cataloguing key impediments and determining whether standards-based, automated solutions can support proper information exchange that appropriately protects privacy. Prioritization will be given to the needs that Interoperability Matters convenings can address through deliverables such as best practices and practical real-world oriented implementation guidance in the field.
3	Cultivate a robust Community of Practice (CoP), by convening Sequoia members and subject matter experts.	The CoP will share lessons learned, innovations and practices across the community, while identifying opportunities to remove key impediments to implementation focused on the initial areas of focus (e.g., consent management, data segmentation for privacy, etc.).

Other deliverables may be defined by the P&C Workgroup Co-Chairs and/or the Interoperability Matters Leadership Council in coordination with The Sequoia Project's leadership.

Proposed Roadmap

Timeframe	Action	Description
November 2023	Kickoff Workgroup & Begin Landscape Analysis	- Present high-level strategy and roadmap for the year - Share opportunity and relevant information at the Sequoia Project Annual Meeting

Winter 2023 and Spring 2024	Finalize Landscape analysis & Cataloguing of key impediments around initial issues (e.g., consent management, data segmentation for privacy, etc.)	- The use of Task Groups will be leveraged to work on deliverables simultaneously as appropriate
Summer and Fall 2024	Ongoing deliverable refinement & publication	- Work with Co-Chairs and Sequoia Project staff to finalize work products and communicate via appropriate channels
Fall 2024 and 2025	Ongoing Workgroup considerations and work efforts defined	- Workgroup deliverables and timelines determined

The Workgroup will meet virtually, on a monthly basis, with the potential for Task Groups to convene in-between the full Workgroup meetings. Task Groups will focus on targeted tasks and disband once the task has been completed. The monthly Workgroup meetings will serve as a forum to cultivate a community of practice for privacy and consent.

Workgroup Composition

Full P&C Workgroup: The full P&C Workgroup is composed of a diverse group of stakeholders selected based on identified needs by Sequoia Project Staff and Workgroup Co-Chairs. The workgroup will be comprised of The Sequoia Project members, with the exception of enlisting the help of subject matter experts and topical presenters for educational purposes and deliverable validation. These members represent healthcare provider organizations, health IT developers and vendors, health information networks and health information exchanges, regulatory/legal, consumers, payers, public health, associations, and organizations representing the health IT community, federal government representatives, and other subject matter experts.

Task Groups: Members of the full P&C Workgroup will volunteer to participate in one or more Task Groups. Task Group sizes will, ideally, be limited to 10-15 members that actively participate and contribute to deliverable production. Members who are not actively contributing to their assigned Task Group tasks may be asked to resign from the Task Group and possibly the full Workgroup.

In addition, to ensure that the Workgroup and Task Groups are of a manageable size but can draw on the broadest and deepest perspectives, the Co-Chairs and Sequoia staff may hold one or more webinars/telephone conference calls, establish a project Wiki, and use online survey tools to gather input beyond Workgroup members.

Workgroup Responsibilities & Operating Principles

In its role as a Workgroup for The Sequoia Project's Interoperability Matters Cooperative, the Workgroup members will fulfill the following responsibilities:

- Maintain personal involvement in Workgroup and Task Group meetings and related activities;

- Respect any confidential discussion held in the Workgroup and Task Groups;

- Contribute to the development of Task Group deliverables by providing substantive feedback, subject matter expertise, and drafting assistance;

- Share progress with Leadership Council and through public forums;

- Accept assignments and tasks between meetings;

- Respect diversity, as there are many different perspectives;

- Listen and speak respectfully and share their points of view.

The P&C Workgroup will operate under the authority and guidance of The Sequoia Project Board and Interoperability Matters Leadership Council. It will also actively seek input from a wide range of stakeholders and subject matter experts, when appropriate. The Workgroup will be organized and operate in a manner that is compliant with applicable antitrust laws and its deliberations will be confined to topics that are consistent with these legal requirements.

Decision-Making and Relationship to Interoperability Matters and The Sequoia Project

The Workgroup will aim to reach consensus, where possible, and will capture differing views. Regardless of whether there is consensus, the Workgroup will assure that diverse stakeholder views are heard. Areas of agreement will be identified, and divergent views captured. Where there is not consensus, the group will move issues forward by such approaches as identifying a range of issues raised within the Workgroup and considering recommendations for further study to move towards consensus.

Workgroup Leadership and Staffing

The Sequoia Project Staff (contract and employees) assist in facilitating the full P&C Workgroup and the smaller Task Groups. The Sequoia Project Leadership will appoint Co-Chairs for the full Workgroup and the Task Groups.

Co-Chair duties include:

- Leading and facilitating Workgroup efforts, including the development, review, and maintenance of Task Group deliverables;

- Facilitating Workgroup and Task Group meetings in a manner that assures that all members are actively contributing to the Workgroup's efforts;

- Enabling balanced opportunities for all members to contribute to the discussions and minimizing a few individuals from dominating the discussion;

- Conducting the work in a manner that is efficient, in accordance with the work plan; and

- Meeting with Sequoia staff prior to each Workgroup and Task Group meeting to prepare the

agenda and discussion topics.