



Interoperability Matters Information Blocking Workgroup: Charter

Purpose

The Sequoia Project Interoperability Matters Information Blocking Workgroup is charged with providing input to The Sequoia Project and the interoperability community on public and private sector implementation of U.S. federal government laws, regulations, guidance and enforcement for information blocking as defined in the 21st Century Cures legislation. The Workgroup will identify practical, implementation-level implications of proposed and final rules issued by the U.S. Department of Health and Human Services addressing information blocking. It shall focus on the broad needs of public and private sector stakeholders and will, at the same time, remain focused on implementation-level and operational aspects of information blocking rules and related activities.

The Information Blocking Workgroup will operate under the authority and guidance of The Sequoia Project Board and Interoperability Matters Leadership Council, considering input from the Interoperability Matters Advisory Forum. 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.

Charter

The Information Blocking Workgroup is chartered to:

1. Work on items as tasked by the Interoperability Matters Leadership Council.
2. Proceed in three anticipated work phases:
 - Phase I: Administrative matters, review of charter, review issue background, including relevant policies of existing networks and frameworks
 - Phase II: Review and provide perspectives on provisions of the forthcoming ONC 21st Century Cures proposed rule related to information blocking.
 - Phase III: After achieving its initial two charges, the Workgroup is expected to self-identify additional work items, potentially including

- (1) guidance and development of industry consensus points on practices relevant to information blocking laws and regulations as determined by the Workgroup, and the Interoperability Matters Leadership Council, with input from the Interoperability Advisory Forum; and (2) input to the federal government on implementation of information blocking laws and regulations.
3. Provide subject matter expertise, and work with other subject matter experts, to support development and maintenance of information blocking-related materials to support the community.
 4. Use webinars, wikis, online surveys and other mechanisms to gain feedback from the community on information blocking and its regulation.

The Workgroup will conclude at the discretion of the Interoperability Leadership Council, in consultation with The Sequoia Project Board.

Deliverables

The Workgroup's deliverables should be developed to meet the following objectives:

1. Workgroup deliverables should be generated through an open, inclusive, consensus-based approach process, including a published meeting agenda, meeting notes with roll, outcomes, roster of voting members, roster of all Workgroup members, documented decisions, etc.
2. Accommodate and reflect varying community perspectives and needs.
3. Focus on priority use cases consistent with the mission of The Sequoia Project and Interoperability Matters.
4. Remain vendor, provider, and technology neutral.

Three initial deliverables have been defined:

1. Perspectives on the forthcoming ONC 21st Century Cures proposed rule that can inform industry and Sequoia Project regulatory comments.
2. An assessment of the implications of the proposed rule for the community.
3. An assessment of the ONC proposed rule for the community, with identified follow-up actions needed by the federal government and the private sector.

Other deliverables can be defined by the Workgroup coauthors and/or the Leadership Council

Timeframe

| Activity | Targeted Completion Date |
|---|---|
| Launch Phase: Workgroup | |
| Call for participation | Oct/Nov/Dec 2018 |
| Complete charter | Jan 2019 |
| Determine Workgroup composition | Jan 2019 |
| Launch Workgroup | Feb/Mar 2019 |
| Workgroup Operations | |
| Weekly Meetings Begin following publication of NPRM | Mar – Apr 2019 |
| Input to the Interoperability Matters Leadership Council and input from the Interoperability Advisory Group regulatory comments for ONC | 40 days after proposed regulation published in the Federal Register |
| Continue industry discussions on implications of the proposed rule if finalized as proposed | 2019 – Monthly meetings |
| Review Final Rule and issue guidance to the community and ONC | Q3 2019 (estimated) |
| Ongoing monitoring of implementation and enforcement of information blocking legislation and regulation | Q3-4 2019 |

Workgroup Composition and Responsibilities

Workgroup Composition

There has been an initial public call for participation to serve on the Interoperability Matters forum, regardless of any affiliation with The Sequoia Project, to help ensure a diverse representation of stakeholders. The Workgroup will be open to all stakeholders, such as healthcare provider organizations, payers, public health, vendors and developers, and the general public). It is expected to be composed of subject matter experts (SMEs) with strong expertise in information exchange and information blocking-related issues, covering the range of technology approaches, including APIs and apps. At a minimum, the following stakeholder groups should be represented on the Workgroup:

- Healthcare provider organizations (e.g., medical groups (reflecting a range of group size and ownership models) physicians, hospital and health systems, other healthcare settings)
- Associations and organizations representing the health IT community and its key components
- Consumers
- Vendors (including EHR, other certified and non-certified health IT, and digital apps)
- Payers
- Public health
- Health information networks and service providers
- Federal government representatives
- Legal, technology, standards and policy subject matter experts

In addition, to ensure that the workgroup is 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.

Workgroup Leadership and Staffing

The Sequoia Project Staff (contract and employees) will assist in facilitating the Workgroup. Workgroup Co-Chairs will be appointed by the Interoperability Matters Leadership Council in consultation with The Sequoia Project Board. The Co-Chairs shall have the discretion to engage other stakeholders and subject matter experts as the Co-Chairs deem necessary. One Co-Chair should be from a healthcare provider organization and one Co-Chair should be an employee of, or a contractor for a health information network, vendor or payer. Workgroup Co-Chairs should have the requisite subject matter expertise, leadership and facilitation skills to assure the work is conducted in an effective, open and fair manner. The Co-Chairs may establish any necessary Workgroup subgroups. Such a subgroup will present its work to the full Workgroup for consideration as normal business as deemed necessary by the Workgroup Co-Chairs

Co-chair duties include:

- Leading and facilitating workgroup efforts, including the development and maintenance of workgroup deliverables and assigning subgroups, as necessary, to draft deliverables;
- Facilitating workgroup meetings in a manner that assures that all workgroup members are actively contributing to the workgroup's efforts;
- Enabling balanced opportunities for all workgroup 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 meeting to prepare the agenda and discussion topics.

Workgroup Responsibilities

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 meetings and related activities;
- Respect any confidential discussions held in the Workgroup;
- Represent the necessary expertise to contribute to the development of the Workgroup deliverables and enlist feedback from the constituents represented; and
- Accept occasional assignments tasks between Workgroup meetings.

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 diverse stakeholder views are heard. Areas of agreement will be identified and divergent views captured. Where there is not consensus, the group will consider recommendations for further study to move towards consensus.

Priority Use Cases

1. Hospital and provider organization willingness to share CCDS/USCDI-type document/data element data via C-CDA based on query
 - a. Vary by permitted purpose?
2. Hospital and provider organization willingness to share CCDS-type data via API with non-HIPAA covered entity
 - a. Patient directed per HIPAA
3. EHR developer willingness to support standard-based open API access for patient/consumer-focused Apps/Applications
 - a. Read
 - b. Write/integration
 - c. App Store/partner requirements
 - d. Authentication and security

4. EHR developer willingness to support standard-based open API access for provider-focused Apps/Applications, for example, via SMART on FHIR
 - a. Read
 - b. Write/integration
 - c. App Store/partner requirements
 - d. Authentication and security
5. Payer access to provider data
6. Public Health/Registries
 - a. Case reporting, etc.
 - b. NIH/precision medicine
7. Research: Basic and Applied
 - a. AI/Machine learning
 - b. Real-world evidence
 - c. Researchers/IRBs
8. Role of private sector trust agreements
 - a. CommonWell
 - b. eHealth Exchange
 - c. Carequality
 - d. Direct Trust
 - e. Carin Alliance
9. Role of TEFCA
10. HIEs
 - a. Subject to same penalties as developers
 - b. Practices
 - c. Sustainability issues

Use Cases Not In Scope

- EHR developer willingness to connect with ancillary systems (Intra-organizational)
- Patient safety data
- Interface development and pricing