



Digital Bridge Workgroup

Charge

Legal and Regulatory Workgroup

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Statement of Workgroup Purpose

The Digital Bridge legal and regulatory workgroup is charged with identifying and defining the best available legal approaches to eCR, recommending alternative technical approaches to make eCR more feasible from legal and regulatory perspectives, and providing feedback to the law firm retained by the Digital Bridge project management office (PMO) for project phase 3.

Objectives

The legal and regulatory workgroup shall...

1. Advise the development of model or template legal instruments (e.g., business associate agreement, etc.) for Digital Bridge project phase 3 eCR implementations
2. Advise the PMO in surveys of legal and regulatory issues relevant to eCR implementation and health information exchange between health care and public health
3. Advise the development of a long-term legal and regulatory strategy that the Digital Bridge may use to advance bi-directional public health data exchange for various use cases
4. Advise the Digital Bridge governance body in using the findings to set strategic goals and objectives

Scope

The scope of the legal and regulatory workgroup shall be

1. Local, state and federal legal and regulatory issues pertinent to the electronic exchange of public health data between health care providers and public health agencies
2. Activities that will provide the Digital Bridge governance body with information regarding the legal and regulatory aspects of eCR implementation and future Digital Bridge use cases
3. Identifying information technology solutions that may reduce the legal and regulatory risks and barriers to establishing bi-directional public health data exchange

Out of scope for the legal and regulatory workgroup shall be:

1. Issues and tasks delegated by the governance body to other workgroups; i.e., eCR implementation task force, evaluation committee and strategy workgroup.

Assumptions

The work of the legal and regulatory workgroup assumes the following:

1. The Digital Bridge PMO will retain a law firm to support this work.
2. All communication between the law firm and the legal and regulatory workgroup shall be directed through PHII.

Deliverables

The deliverables of the Legal and Regulatory Workgroup shall include...

ID	Name	Description
1	Legal Risk Assessment	Legal and regulatory workgroup will prepare an outline of known and presumed liability risks associated with eCR approach. This outline will serve as an input to legal counsel. Legal counsel will review applicable laws and regulations governing patient privacy, electronic health data exchange and public health surveillance of reportable conditions to assess liability risks for eCR implementation site partners.
2	Template Agreements	Based on legal risk assessment, develop template bilateral agreements that can be referenced by entities implementing eCR approach.
3	Long Term Strategy	Develop a long-term strategy for 1) leveraging existing health information exchanges (HIEs) and emergent trust frameworks to support widespread adoption of the eCR approach, and 2) recommend alternative technical approaches to make eCR more feasible from legal and regulatory perspectives.

Process and Procedures

Meeting processes and procedures are designed to promote balanced representation, and constructive conversations and deliberations for timely completion of the above stated objectives and deliverables. To that end, the following meeting process and procedures will be instituted:

1. PMO will be responsible for coordinating meetings, creating meeting agendas and notes, gathering input from workgroup members, and tracking issues, risks and action items. Meeting agendas will be developed in consultation with the legal SME/team.
2. Only the primary or alternate members for an organization can attend the workgroup meetings as members with speaking, and—if necessary—voting privileges. Therefore,
 - a. Each organization has only one primary and one alternate member for participation purposes.
 - b. Organizations may appoint two to four additional professionals as workgroup observers.
 - i. Observers **may not** speak during legal and regulatory workgroup meetings or make decisions. The last five to ten minutes of every workgroup call will be reserved for observers to verbally ask questions or comment.
 - ii. Observers **may** send questions and suggested agenda items to the workgroup via the Digital Bridge PMO.
3. Decisions (e.g., approving a deliverable or communication to the Digital Bridge governance body) will be driven by consensus. If consensus is not clear or a decision must be made due to time constraints, the Digital Bridge governance body decision making procedures will be used.

Stakeholder Engagement

The Digital Bridge PMO will communicate Digital Bridge legal and regulatory activities to stakeholders and implementation sites. The legal and regulatory workgroup chairpersons or PMO will communicate with the governance body for all related issues.

Workgroup Meeting Schedule

The legal and regulatory workgroup shall meet by web meeting or conference call at a schedule that will be determined after a 60-90-minute workgroup kick-off meeting in May 2017. Meetings will be scheduled to accommodate attendance by the majority of workgroup members.

Members

Workgroup membership will include a broad range of stakeholders and vendors while limiting to a primary and secondary representative for each. The workgroup will be chaired by Walter Suarez of Kaiser Permanente, a health care representative.