

REDWOOD MEDNET
TOPIC OUTLINE FOR
MULTILATERAL DATA USE AGREEMENT

Redwood MedNet or another entity, to be formed now or in at a later time, intends to operate a health information data exchange (“Exchange”) that will conduct a clinical messaging program as its first activity. Through the Multilateral Data User Agreement (“Data Use Agreement”), the Exchange would obtain agreements with those who wish to participate in the Exchange’s programs as providers or users of data or both. The Exchange is to be structured to allow it to add additional programs and participants at later times.

The following outline of the Data Use Agreement describes the essential terms of the Agreement and identifies points for policy-related decision-making in the development of that Agreement.

1. Introduction. The Data Use Agreement should describe the Exchange and how it is organized and operated, in order to provide information that may be helpful for putting the remainder of the Agreement’s terms and conditions into context.

1.1 Nature of Organization. The legal structure within which the Exchange is organized, and the Exchange’s essential relationships to sponsors, founders and others, such as Redwood MedNet.

1.2 Purposes. The purposes for which the Exchange is organized.

1.3 Description of Services. The facilities and services of the Exchange that are available to Participants.

1.4 Change or Termination of Services. The Exchange’s right to change its services or to cease providing services.

2. Definitions. The Data Use Agreement will define certain important terms, including those described below.

Decision Point: Whether the Exchange will use the following definitions in its structure, or will adopt another definitional paradigm. The following definitions are based upon the Common Framework for Health Information Exchange.

“Authorized User” means a Participant that is an individual (*e.g.*, a physician in a solo office practice) or an individual designated by an institutional Participant (*e.g.*, an employee of a hospital or a physician who is a member of a large medical practice) to use the Exchange’s Services on behalf of the Participant.

“Data Provider” means a Participant that is registered to provide information to the Exchange for use through the Exchange’s Services.

“Data User” means a Participant that uses the Exchange’s Services to obtain health information.

“Exchange’s Services” means the specific information sharing and aggregation services and software described in Section 1.3 (Description of Services) for which the Participant registers as described in Section 4.1 (Registration Required).

“HIPAA” means the Health Insurance Portability and Accountability Act of 1996 and the regulations promulgated thereunder at 45 CFR Parts 160 and 164.

“Participant” means a party that registered with the Exchange to act as a Data Provider and/or as a Data User.

“Participation Agreement” means this legally-binding agreement between the Exchange and a Participant, pursuant to which the Exchange agrees to the Participant’s participation in the Exchange’s programs and the Participant agrees to comply with the Exchange’s rules.

“Participant Type” means the category of Participants to which a particular Participant is assigned based upon that Participant’s role in the health care system.

“Patient Data” means information provided by a Data Provider pursuant to Section 7.2 (Provision of Data).

3. Administration of Agreement. How the Data Use Agreement’s terms and conditions they are to be developed and administered.

3.1 Generally. An overview of how the Exchange’s rules, and the Agreement’s terms, are to be developed and administered.

Decision Point: How will the Exchange make policy decisions regarding the (i) development of necessary and appropriate amendments to the Data Use Agreement and (ii) administer the Exchange’s use of the Data Use Agreement’s terms? For example, will there be a steering or advisory committee that advises the Exchange in such matters, or will another mechanism be used? See Section 12.4 (Steering (or Advisory) Committee) for specific terms concerning the role of a steering or advisory committee.

3.2 Development and Dissemination; Amendments. How the Exchange makes changes to the Agreement from time to time and informs Participants of those changes.

4. Registration. Who may be a Participant, and how the Exchange will register each Participant. The Agreement will use the concept of “registering” Participants as the device by which the Exchange will monitor and control who uses the Exchange’s Services.

4.1 Registration Required. The requirement that Participants be registered with the Exchange.

4.2 Registration by Agreement. How Participants will be required to enter into a written Data Use Agreement with the Exchange.

4.3 Participant Type. How the Exchange will categorize Participants by their respective roles in the health care system, *i.e.*, for the purpose of determining the rights and obligations of those Participants.

Decision Point: Which initial categories of Participant Types will the Agreement address?

4.4 Review of Applications for Registration. The Exchange’s rights to review each prospective Participant’s application for registration and decide whether or not to accept any given party’s application.

4.5 Changes to Agreement. Because the Exchange will be permitted to amend the Agreement from time to time, how Participants will be made aware of amendments the Agreement, and will be legally obligated to comply with those amendments.

4.6 Termination Based on Objection to Change. How a Participant may avoid being bound to the Data Use Agreement if the Participant objects a proposed amendment, *i.e.*, unless the law requires otherwise, the Participant may terminate its participation and its Agreement prior to the effectiveness of the amendment.

4.7 Participant’s Other Rights to Terminate. How and under what circumstances a Participant may cease to be a Participant, generally.

4.8 Participant’s Right to Terminate for Breach of Business Associate Agreement. A Participant’s rights to terminate the Data Use Agreement if the Exchange fails to perform any obligations it may have as a business associate (as defined in HIPAA) of the Participant.

4.9 SNO’s Right to Terminate Registration Agreements. How and under what circumstances the Exchange may terminate a Participant’s Data Use Agreement and its participation in the Exchange’s programs.

4.10 Effect of Termination. The consequences of terminating the Data Use Agreement.

4.11 Survival of Provisions. The provisions of the Data Use Agreement that shall continue to bind the Participant following termination.

5. Authorized Users. Terms that govern use of the Exchange’s Services by the Participant’s Authorized Users. “User agreements” will not be required of every individual who uses the Exchange’s Services; instead, Participants will be responsible for designating the “Authorized Users” within their organizations who will be authorized to use the Exchange’s Services.

5.1 Identification of Authorized Users. How the Participant will designate individuals who will use the Exchange’s Services.

5.2 Security Measures. What security measures (*e.g.*, user names, passwords and other security measures) will be required for use of the Exchange’s Services and who will be responsible to administer those measures.

Decision Point: What security measures will the Exchange require and/or provide?

5.3 No Use by Other than Authorized Users. A requirement that the Exchange’s Services be accessed and used only by Authorized Users.

5.4 Responsibility for Conduct of Participant and Authorized Users. The Participant’s responsibility for the conduct of its Authorized Users.

6. Data User’s Right to Use Services. Provisions that apply specifically to “Data Users” (*i.e.*, Participants registered to use the Exchange’s Services).

6.1 Grant of Rights. The nature of the Participant’s right to use the Exchange’s Services.

6.2 Permitted Uses. The permitted uses of the Exchange’s System and Services.

6.3 Prohibited Uses. The prohibited uses of the Exchange’s Services.

7. Data Provider’s Obligations. Provisions that apply specifically to “Data Providers” (*i.e.*, Participants registered to provide data).

7.1 Grant of Rights. The nature of the Data Provider’s right to use the System.

7.2 Provision of Data. Terms that apply to the Data Provider’s delivery of data to the Exchange.

7.3 Measures to Assure Accuracy of Data. The Data Provider’s obligations to provide accurate, complete and timely information.

7.4 License. The terms upon which the Data Provider makes the data it provides available for use through the Exchange.

7.5 Limitations on Use of Patient Data. Limitations the Exchange will impose upon the uses of information provided by Data Providers, including uses prohibited by applicable laws and regulations.

Decision Point: What, if any, additional limitations are to be imposed upon the use of Patient Data?

8. Software and/or Hardware Provided by Exchange. Description. A description of any software and/or hardware that the Exchange will provide to Participants.

8.2 Grant of License. A description of the Participant’s right to use the software and/or hardware.

8.3 Copying. Restrictions upon the Participant’s right to copy software provided.

8.4 Third-Party Software, Hardware and/or Services. How the Exchange and Participants will address requirements imposed by third-party software, hardware and/or service vendors.

9. Protected Health Information. Provisions addressing compliance with applicable laws addressing the confidentiality, security and use of patient health information.

Decision Point: What confidentiality, security and use restrictions, other than those required by law, will be required? For example, what limitations, if any, are to be placed on the Data Provider’s sharing of information of patients who may not have consented to the sharing of their information?

10. Business Associate Agreement. Provisions addressing the Exchange’s (and/or a subcontractor of the Exchange’s) potential role as a business associate of the Participant.

11. Other Obligations of Participants. Additional terms governing the conduct of Participants.

11.1 Compliance with Laws and Regulations. The Participant’s obligations to comply with applicable laws and regulations, generally.

11.2 Security. The Participant’s obligations to implement reasonable and appropriate measures to maintain the security of the Exchange’s system and to notify the Exchange of breaches in security.

11.3 Software and/or Hardware Provided by Participant. The Participant’s obligations obtain and maintain all hardware and software required to use the SNO’s System and Services that are not to be provided by the SNO.

11.4 Viruses and Other Threats. Requirements that Participants take appropriate measures to prevent damage to the Exchange’s system.

11.5 Training. A description of the training, if any, that the Exchange will require the Participant to provide to its personnel.

12. Exchange Operations and Responsibilities.

Provisions describing the role and responsibilities of the Exchange.

12.1 Training. The Exchange’s obligations to provide training for Participants and/or their Authorized Users.

12.2 Telephone and/or E-Mail Support. The Exchange’s obligations to provide support for the Participant’s use of the Exchange’s Services.

12.3 Reports. Any reports the Exchange will provide to Participants.

12.4 Steering (or Advisory) Committee. Any role Participants and/or others would have in governance of or decision-making by the Exchange.

12.4.1 Composition. The composition of a body in which Participants and/or others would be involved.

12.4.2 Meetings and Responsibilities of Committee. The responsibilities of such a body and how often it would meet.

12.4.3 Committee Bylaws. How this body would be organized and governed.

13. Fees and Charges. Terms regarding amounts, if any, that the Participant will be required to pay to the Exchange in order to use the Services or that the Exchange will pay to the Participant in exchange for providing data.

Decision Point: Will the Exchange impose fees and/or charges?

13.1 Service Fees. The Exchange's schedule service fees for Participants.

13.2 Changes to Fee Schedule. Provisions allowing the Exchange to change its fee schedule.

13.3 Miscellaneous Charges. Provisions addressing the Exchange's ability to charge for additional services.

13.4 Payment. How and when payment is due and payable.

13.5 Late Charges. Whether the Exchange would impose late charges on delinquent fees and/or charges.

13.6 Suspension of Service. Whether the Exchange would be permitted to suspend services until the Participant pays amounts that are due.

13.7 Taxes. The party responsible for payment of taxes arising out of the use of the Exchange's Services.

13.8 Other Charges and Expenses. The extent to which Participants and/or the Exchange are responsible to pay for other expenses relating to their respective roles.

14. Proprietary Information. Provisions concerning the parties' respective obligations to preserve the confidentiality of others' proprietary information (*i.e.*, other than health information), such as standard non-disclosure terms and provisions for injunctive relief in case of violations or threatened violations.

15. Disclaimers, Exclusions of Warranties, Limitations of Liability and Indemnifications. Standard terms directed to avoiding inappropriate legal claims between the parties.

Decision Point: Each of the issues described below should be considered carefully and the Exchange's approach to each should be determined.

15.1 Carrier lines. The parties' respective responsibilities with respect to the use of carrier, *e.g.*, telephone, lines.

15.2 No Warranties. The extent to which the Exchange disclaims warranties it might otherwise be assumed to be making to Participants.

15.3 Other Participants. The extent to which the Exchange is responsible for uses of information and/or the Services by others.

15.4 Participant’s Actions. The extent to which the Participant assumes responsibility for its own actions or those of its Authorized Users.

15.5 Unauthorized Access; Lost or Corrupt Data. The extent to which the parties are responsible for others’ access to information through the Exchange, or for misconduct related to the use and/or disclosure of that data, or for the accuracy or completeness of that data.

15.6 Inaccurate Data. The extent to which the parties are responsible for inaccurate data obtained through the Exchange.

15.7 Patient Care. The parties’ responsibilities with respect to patient outcomes affected by use of the Exchange.

15.8 Limitation of Liability. The extent to which the parties’ potential legal liabilities to each other are limited.

16. Insurance and Indemnification.

Decision Point: Each of the issues described below should be considered carefully and the Exchange’s approach to each should be determined.

16.1 Insurance. Whether and to what extent the parties are to be required to carry insurance.

16.2 Indemnification. Whether and to what extent the parties would agree to indemnify each other for losses sustained as a result of their relationships or conduct.

17. Miscellaneous Provisions.