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Key Topics in a Model Contract for Health Information Exchange

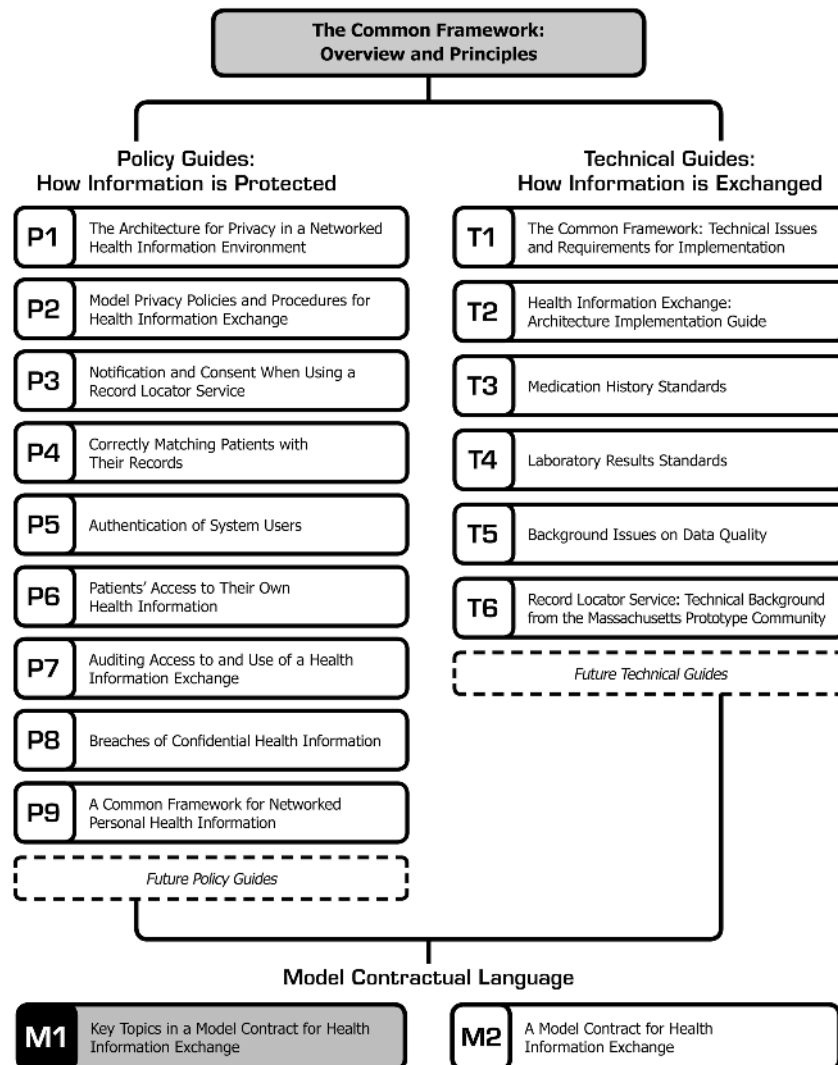
Key Topics in a Model Contract for Health Information Exchange

Version 1.1

Revision History

Version	Date	Description
1.0	December 2005	
1.1	April 2006	Revisions to Introduction, Secs. 8, 13 and formatting.

The document you are reading is part of *The **Connecting for Health** Common Framework*, which is available in full and in its most current version at: <http://www.connectingforhealth.org/>. The Common Framework will be revised and expanded over time. As of October 2006, the Common Framework included the following published components:



Key Topics in a Model Contract for Health Information Exchange, *Version 1.1*

Topic List

Introduction. This document (Topic List) describes the issues addressed by the **Connecting for Health** Model Contract for Health Information Exchange (Model).

Background. A SNO is to operate as a health information data exchange organization (both regional and affinity) that operates as a part of the National Health Information Network ("NHIN"), a nationwide environment for the electronic exchange of health information.

Use of Model. The Model is based on a number of assumptions, which are described in the following discussion. The Model is not the "answer" for all SNOs. Instead, it is intended to assist in the organization of a SNO by providing a basis upon which to begin drafting that SNO's Terms and Conditions. All language provided in the Model is intended for informational and educational purposes only. It is not intended, nor should it be used, as a substitute for legal advice. In preparing its own terms and conditions, or other legal documents used in connection with its participation in the NHIN, an organization should consult with legal counsel. Each SNO will have to draft its Terms and Conditions based upon its own organization, operations, system and services, regulatory environment, and so on. Some of the Model's terms will be inapplicable to some SNOs. The Model shows where some of the variations might be expected to occur.

Overview of Structure

Common Framework Policies and Procedures. The Model assumes that the NHIN will be implemented in accordance with a compilation of documents to be known as the "Common Framework Policies and Procedures." The Common Framework Policies and Procedures will describe how the NHIN works and will include certain terms that should apply to all SNOs. The Model makes a number of assumptions about the future structure and content of the Common Framework Policies and Procedures, which are identified throughout the document. The Model should be revisited and revised as necessary to work with the Common Framework Policies and Procedures as they develop.

SNO Terms and Conditions. The Model assumes that each SNO will adopt its own "Terms and Conditions" which will be comprised of terms that apply to that SNO only, and will also incorporate the provisions of the Common Framework Policies and Procedures that apply to all SNOs.

Registration and Registration Agreements. The Model assumes that Participants will receive access to the SNO's Services and/or access to the SNO's System by registering with a SNO and entering into a "Registration Agreement." The Registration Agreement will incorporate the SNO Terms and Conditions by reference and will require the Participant to comply with those parts of the Terms and Conditions that apply to the Participant, based on how the Participant uses the SNO's Services and/or System.

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SNO Organization and Operations. The Model assumes that the SNO is a non-profit or for-profit legal entity that is organized and operated for a single purpose, i.e., to operate as a SNO. The SNO is assumed to operate with a record locator service-based, peer to peer network, and to provide, or provide access to, the software Participants require to use the SNO's Services. SNOs may provide a different system or services, such as by acting as an application service provider ("ASP"), and the Model identifies some of the variations that are likely if the SNO is organized differently from what the Model assumes.

Defined Terms. The Model assumes that a variety of different types of entities will participate in the SNO, and that these Participants will have a variety of roles. Section 2 (Definitions) of the Model provides a framework for naming these different Participants and their respective roles.

For each section of the Model, this document provides a brief description of the contents of the section and the critical legal and policy issues raised by each. For some sections, alternative provisions are offered.

Model Terms and Conditions

Topic List

1. **Introduction.** A description of the Sub-Network Organization or "SNO" and how it is organized and operated, in order to provide information that may be helpful for putting the remainder of the Terms and Conditions into context.

1.1 **Nature of Organization.** The legal structure within which the SNO is organized, and the SNO's essential relationships to sponsors, founders and others.

1.2 **Purposes.** The purposes for which the SNO is organized.

1.3 **Description of Services.** The facilities and services of the SNO that are subject to the SNO Terms and Conditions, and that are available to Participants.

1.4 **Change or Termination of Services.** The SNO's right to change its services or to cease providing services.

2. **Definitions.** The definitions of certain important terms used in the Terms and Conditions. Some of these definitions may not correspond to their use in certain other contexts, and are likely to vary if the SNO's organization, operations, system, services and/or relationships with others are different than those assumed by the Model.

"Authorized User" means an individual Participant or an individual designated to use the SNO's Services on behalf of the Participant, including without limitation, an employee of the Participant and/or a credentialed member of the Participant's medical staff.

"Data Provider" means a Participant that is registered to provide information to the SNO for use through the SNO's Services.

"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 SNO to act as a Data Provider and/or as a Data Recipient.

“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).

“Registration Agreement” means a legally-binding agreement between the SNO and a Participant pursuant to which the SNO registers the Participant in accordance with, and the Participant agrees to comply with, the SNO Terms and Conditions.

“SNO’s Services” means the 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).

“SNO Terms and Conditions” means the terms and conditions set forth in this document, as amended, repealed and/or replaced from time to time as described herein.

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

3. Terms and Conditions. The role of the SNO Terms and Conditions, and how they are developed and administered. These terms are intended to be helpful in putting the other provisions of the SNO Terms and Conditions into context.

- 3.1 Generally. An overview of how the SNO Terms and Conditions are developed and administered.

- 3.2 Development and Dissemination; Amendments. How the SNO adopts the SNO Terms and Conditions, makes changes, and informs Participants of those changes.

- 3.3 Relationship to Common Framework Policies and Procedures. The relationship of the SNO Terms and Conditions to the Common Framework Policies and Procedures.

4. Registration Agreements. Who may be a Participant, and how the SNO will register each Participant. The Model uses the concept of “registering” Participants as the device by which the SNO will monitor and control who uses the SNO’s System and Services, and assumes that the SNO will require Participants to enter into “Registration Agreements” in order to assure that all parties with access to the SNO’s System and Services will be covered by an agreement to comply with the SNO Terms and Conditions.

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

- 4.2 Registration by Agreement. How Participants may enter into a written Registration Agreement with the SNO.

- 4.3 Online Registration. How Participants may register online.

- 4.3.1 Registration Form. How the SNO administers online registration.

- 4.3.2 Participant Type. How the SNO 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.
- 4.3.3 Review of Registration Forms. The SNO's rights to review registration forms and decide whether or not to accept any given party's registration.
- 4.3.4 Acceptance of Registration. How registration agreements will be created for online registrants.
- 4.4 Effect of Terms and Conditions Upon Registration Agreements. How Participants will agree to comply with the Terms and Conditions.
- 4.5 Changes to Terms and Conditions. How Participants will be made aware of the SNO Terms and Conditions, and will be legally obligated to comply therewith.
- 4.6 Termination Based on Objection to Change. How a Participant may avoid being bound to a Registration Agreement if the Participant objects to a change to the SNO Terms and Conditions.
- 4.7 Participant's Other Rights to Terminate Registration Agreement. 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 a Registration Agreement if the SNO 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 SNO may terminate a Participant's Registration Agreement.
- 4.10 Effect of Termination. The consequences of terminating a Registration Agreement.
- 4.11 Survival of Provisions. The provisions of the Registration Agreement that shall continue to bind the Participant following termination.
- 5. Authorized Users. Terms that govern use of the SNO Services by the Participant's Authorized Users. The Model assumes that "user agreements" will not be required of every individual who uses the SNO's System or Services. Instead, Participants will be responsible for designating the individuals within their organizations who would be authorized to use the SNO's System and Services ("Authorized User").
 - 5.1 Identification of Authorized Users. How the Participant will designate individuals who will use the SNO's Services.
 - 5.2 Passwords and Other Security Mechanisms. How security mechanisms will be administered, including without limitation how log-on passwords will be provided to Authorized Users.
 - 5.3 No Use by Other than Authorized Users. A requirement that the SNO's System and 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 Recipient's Right to Use Services. Provisions that apply specifically to "Data Recipients" (i.e., Participants registered to use the SNO's Services). Provisions that apply specifically to "Data Providers" (i.e., Participants registered to provide data to the SNO) appear at Section 7 (Data Provider's Obligations).
 - 6.1 Grant of Rights. The nature of the Participant's right to use the System and Services.
 - 6.1.1. Grant by SNO. The rights granted by the SNO.
 - 6.1.2. NHIN. The rights granted by the NHIN.
 - 6.2 Permitted Uses. The permitted uses of the SNO's System and Services.
 - 6.3 Prohibited Uses. The prohibited uses of the SNO System and the SNO Services applicable under the Common Framework Policies and Procedures, and additional prohibitions imposed by the SNO, if any.
7. Data Provider's Obligations. Provisions that apply specifically to "Data Providers" (i.e., Participants registered to provide data). Provisions that apply specifically to "Data Recipients" (i.e., Participants registered to use the SNO's Services) appear at Section 6 (Data Recipient's Right to Use Services).
 - 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 Network, e.g., format, standards, etc.
 - 7.3 Measures to Assure Accuracy of Data. The Data Provider's obligations to provide accurate, complete, and timely information.
 - 7.4 License. The Data Provider's agreement that the data it provides will be available for use through the Network.
 - 7.5 Limitations on Use of Patient Data. Limitations the SNO will impose upon the uses of information provided by Data Providers, including uses prohibited by the Common Framework Policies and Procedures, state or local laws and regulations specific to the SNO, and other prohibitions the SNO determines are appropriate (but not in conflict with the Common Framework Policies and Procedures).
8. Software and/or Hardware Provided by SNO. The Model assumes that the SNO will provide certain software and/or hardware Participants would use to access the System ("Associated Software and/or Hardware"). If the SNO does not provide software and/or hardware to Participants, this section would be omitted.
 - 8.1 Description. A description of any software and/or hardware that the SNO will provide to Participants.
 - 8.2 Grant of License. A description of the Participant's right to use the Associated Software and/or Hardware.
 - 8.3 Copying. Restrictions upon the Participant's right to copy software provided by the SNO.

- 8.4 Third-Party Software, Hardware and/or Services. How the SNO 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.
 - 9.1 Compliance with Policies and Procedures. Provisions requiring compliance with the Common Framework Policies and Procedures.
 - 9.2 Additional Requirements. Provisions requiring compliance with patient information privacy, security and use laws imposed at the state and/or local level and/or other requirements that the SNO otherwise determines are appropriate (but not inconsistent with the Common Framework Policies and Procedures).
 - 9.3 Business Associate Agreement. Provisions addressing the SNO's potential role as a business associate of the Participant.
- 10. Other Obligations of Participants. Additional terms governing the conduct of Participants.
 - 10.1 Compliance with Laws and Regulations. The Participant's obligations to comply with applicable laws and regulations, generally.
 - 10.2 System Security. The Participant's obligations to implement reasonable and appropriate measures to maintain the security of the SNO System and to notify the SNO of breaches in security.
 - 10.3 Software and/or Hardware Provided by Participant. Provision requiring the Participant to 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.
 - 10.4 Viruses and Other Threats. Requirements that Participants take appropriate measures to prevent damage to the SNO's System.
 - 10.5 Training. A description of the training, if any, that the SNO will require the Participant to provide to its personnel.
- 11. SNO Operations and Responsibilities. Provisions describing the role and responsibilities of the SNO.
 - 11.1 Compliance. The SNO's obligations to require that all Participants agree to be bound by the SNO Terms and Conditions.
 - 11.2 Training. The SNO's obligations to provide training for Participants and/or their Authorized Users.
 - 11.3 Telephone and/or E-Mail Support. The SNO's obligations to provide support for the Participant's use of the SNO's System and/or Services.
 - 11.4 Audits and Reports. Audits the SNO is to perform, and reports it is to provide, to Participants.
 - 11.5 Management Committee. Any role Participants would have in governance or decision-making by the SNO.

- 11.5.1 Composition. The composition of a body in which Participants would be involved.
- 11.5.2 Meetings and Responsibilities of Management Committee. The responsibilities of such a body and how often it would meet.
- 11.5.3 Management Committee Bylaws. How this body would be organized and governed.
- 12. Fees and Charges. Terms regarding amounts, if any, that the Participant will be required to pay to the SNO in order to use the Services.
 - 12.1 Agreed-Upon Fees. Provision for a Participant's written agreement to take precedence over the SNO Terms and Conditions.
 - 12.2 Service Fees. The SNO's fees for Participants.
 - 12.3 Changes to Fee Schedule. Provisions allowing the SNO to change its Fee Schedule.
 - 12.4 Miscellaneous Charges. Provisions addressing the SNO's ability to charge for additional services.
 - 12.5 Payment. How and when payment is due and payable.
 - 12.6 Late Charges. Whether the SNO would impose late charges on delinquent Service Fees and Miscellaneous Charges.
 - 12.7 Suspension of Service. Whether the SNO would be permitted to suspend services until the Participant pays amounts that are due.
 - 12.8 Taxes. The party responsible for payment of taxes arising out of the use of the SNO's System and/or Services.
 - 12.9 Other Charges and Expenses. The extent to which Participants and/or the SNO are responsible to pay for other expenses relating to their respective roles.
- 13. Proprietary Information. Provisions concerning the parties' respective obligations to preserve the confidentiality of others' proprietary information (i.e., other than health information).
- 14. Disclaimers, Exclusions of Warranties, Limitations of Liability and Indemnifications. Standard terms directed to avoiding inappropriate legal claims between the parties.
 - 14.1 Carrier lines. The parties' respective responsibilities with respect to the use of carrier, e.g., telephone lines.
 - 14.2 No Warranties. The extent to which the SNO disclaims warranties it might otherwise be assumed to be making to Participants.
 - 14.3 Other Participants. The extent to which the SNO is responsible for uses of information and/or the Network by others.
 - 14.4 Participant's Actions. The extent to which the Participant assumes responsibility for its own actions or those of its Authorized Users.

- 14.5 Unauthorized Access; Lost or Corrupt Data. The extent to which the parties are responsible for others' access to information through the Network, or for misconduct related to the use and/or disclosure of that data, or for the accuracy or completeness of that data.
- 14.6 Inaccurate Data. The extent to which the parties are responsible for inaccurate data obtained through the Network.
- 14.7 Patient Care. The parties' responsibilities with respect to patient outcomes affected by use of the Network.
- 14.8 Limitation of Liability. The extent to which the parties' potential legal liabilities to each other are limited.
- 15. Insurance and Indemnification.
 - 15.1 Insurance. Whether and to what extent the parties are to be required to carry insurance.
 - 15.2 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.
 - 15.3 General Provisions. General provisions appropriate to a contract including the foregoing terms.

Acknowledgements

The members of the **Connecting for Health** Policy Subcommittee have accomplished an extraordinary task in less than a year's time—the development of an evolving piece of work that can serve as the core of nationwide health information exchange—the policy components of **The Common Framework**.

During this time, we have been fortunate to work with respected experts in the fields of health, information technology, and privacy law, all of whom have contributed their time, energy, and expertise to a daunting enterprise. Our consultants and volunteers have worked long hours in meetings and conference calls to negotiate the intricacies of such issues as privacy, security, authentication, notification, and consent in health information exchange. We offer them our heartfelt thanks for taking on this journey with us, and look forward to the remaining work ahead.

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