Terms and Conditions for
Health Information Exchange Organization
Participant’s Agreement[[1]](#footnote-2)

Section 1
INTRODUCTORY AND GENERAL PROVISIONS

(Applicable to all Participants, All Models)

## Introduction.

These applicable provisions of these Terms and Conditions (the “Terms and Conditions”) are incorporated by reference into each Health Information Exchange Organization Participant’s Agreement (each, a “Participation Agreement”) entered into by and between [*Insert name of Health Information Sharing Organization, and its form of organization, e.g., a California nonprofit public benefit corporation*] (“HIO”), and a Participant.

## Effective Date.

The Effective Date of these Terms and Conditions is [*insert*].

## Nature of Organization.

HIO is [*insert type of organization and state in which organized, e.g., a California public benefit corporation*], organized by [*insert description of founders, sponsors, etc.]* to facilitate health information sharing and aggregation for treatment, payment, operations, public health and other lawful purposes in a manner that complies with all applicable laws and regulations, including without limitation those protecting the privacy and security of health information.

## Description of Services.[[2]](#footnote-3)

Model #1: HIO provides or arranges for the provision of data transmission and related services to Participants to enable a Participant to send Patient Data to another Participant. HIO’s services do not include establishing and applying standards for such exchange of Patient Data. HIO does not have access to and is not responsible to maintain any such Patient Data in the performance of HIO’s services.[[3]](#footnote-4)

Model #2: HIO provides or arranges for the provision of data transmission and related services to Participants to enable a Participant to send Patient Data to another Participant. HIO’s services include establishing and applying standards for such exchange of Patient Data. HIO does not have access to and is not responsible to maintain any such Patient Data in the performance of HIO’s services.[[4]](#footnote-5)

Model #3: HIO provides or arranges for the provision of data transmission and related services to Participants to enable a Participant to send Patient Data to another Participant. HIO’s services include establishing and applying standards for such exchange of Patient Data. HIO has access to and/or is responsible to maintain some or all of such Patient Data in the performance of HIO’s services.[[5]](#footnote-6)

Model #4: HIO provides or arranges for the provision of data transmission and related services to allow Participants to conduct searches for Patient Data, and to exchange Patient Data identified from those searches, from a federated computer system that facilitates the sharing of Patient Data among disparate Participants. HIO’s services include establishing and applying standards for such exchange of Patient Data. HIO has access to and/or is responsible to maintain some or all of such Patient Data in the performance of HIO’s services. HIO does not aggregate or maintain a repository of Patient Data.[[6]](#footnote-7)

Model #5: HIO provides or arranges for the provision of data transmission and related services to allow Participants to conduct searches for Patient Data, and to exchange Patient Data identified from those searches, from a federated computer system that facilitates the sharing of Patient Data among disparate Participants. HIO’s services include establishing and applying standards for such exchange of Patient Data. HIO has access to and/or is responsible to maintain some or all of such Patient Data in the performance of HIO’s services. HIO also aggregates and/or maintains a repository of Patient Data.[[7]](#footnote-8)

* 1. Definitions.

For the purposes of the Participation Agreement, the following terms shall have the meanings set forth below.

* + 1. “Additional Services” means products and/or services not expressly described in these Terms and Conditions that the HIO offers to certain Participants from time to time, as described in the Policies and Procedures and/or the applicable Participation Agreement.
		2. “Associated Hardware” and “Associated Software” shall have the meanings described in Section 8.1 (Description of Associated Hardware and/or Associated Software).
		3. “Authorized User” means an individual Participant or an individual designated to use the 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.[[8]](#footnote-9)
		4. “Breach of Privacy or Security” is a use or disclosure of Patient Data other than in compliance with these Terms and Conditions that either, (a) pursuant to applicable laws or regulations, must be reported to affected individuals and/or government officials, including without limitation federal or state data breach notification rules, or (b) adversely affects (i) the viability of HIO; (ii) the trust among Participants; or (iii) the legal liability of HIO or any Participant. “CMIA” means the California Confidentiality of Medical Information Act, California Civil Code Section 56 *et. seq.*
		5. “Data Provider” means a Participant that is registered to provide information to HIO for use through the Services.[[9]](#footnote-10),[[10]](#footnote-11)
		6. “Data Recipient” means a Participant that uses the Services to obtain health information.
		7. “Effective Date” means the Effective Date of these Terms and Conditions specified pursuant to Section 1.2 (Effective Date).
		8. “HIPAA” means the Health Insurance Portability and Accountability Act of 1996 and the regulations promulgated thereunder at 45 CFR Parts 160 and 164.
		9. “HITECH” means the Health Information Technology for Economic and Clinical Health Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (commonly known as “ARRA”), Pub. L. No. 111-5 (February 17, 2009).
		10. “Other HIO” means a person or entity similarly situated to the HIO[[11]](#footnote-12) with which HIO has entered into a legally binding agreement pursuant to which HIO and that person or entity have agreed to arrange for their respective participants to share data through HIO’s and the person’s or entity’s respective systems and services.
		11. “Participant” means a party that entered into a Participation Agreement with HIO to act as a Data Provider and/or as a Data Recipient.[[12]](#footnote-13)
		12. “Participant Type” means the category(ies) of Participant to which a particular Participant is assigned by HIO based upon that Participant’s role in the health care system, as more specifically described in Section 2.4.3 (Participant Type).
		13. “Patient Data” means information provided, or made available for exchange, by a Data Provider through HIO’s System and Services pursuant to Section 7.2 (Provision of Data).
		14. “Participation Agreement” means a legally binding agreement between HIO and a party pursuant to which that party acts as a Participant in accordance with, and agrees to comply with, these Terms and Conditions.
		15. “Services” means the health information exchange and related services described in Section 1.4 (Description of Services) for which the Participant registers as described in Section 2.4.1 (Participation Agreement Required).
		16. “Policies and Procedures” means, collectively, the policies and procedures adopted by HIO’s using approved processes (Note: HIO alone implies that it’s a community HIO with participants on the board; otherwise the HIO can essentially unilaterally amend the contract by amending its policies)for the operation and use of the System and the Services, including without limitation any operations manual, privacy and/or security policies, and technical specifications for the System and/or the Services.[[13]](#footnote-14)
		17. “System” means the technology provided by HIO incident to HIO’s performance of the Services, as described in the Policies and Procedures.
		18. “Terms and Conditions” means the terms and conditions set forth in this document that apply to a Participant and the HIO, respectively as amended, repealed, and/or replaced from time to time as described herein.
		19. “Unsecured Protected Health Information” means Protected Health Information that is not rendered unusable, unreadable, or indecipherable to unauthorized individuals through the use of a technology or methodology specified by the Secretary of the U.S. Department of Health & Human Services (“HHS”) through guidance issued pursuant to HITECH.
		20. “Unsuccessful Security Incident” means a security incident (as defined under HIPAA) that does not result in: (1) the unauthorized access, use, disclosure, modification or destruction of information; or (2) material interference with system operations in a party’s information system, including, without limitation, activity such as ping and other broadcast attacks on that party’s firewall, port scans, unsuccessful log-on attempts, denial of service and/or any combination of the foregoing, so long as no such incident results in unauthorized access, use or disclosure of electronic protected health information.

# Section 2 DEVELOPMENT AND ADMINISTRATION OF PARTICIPATION AGREEMENTS

(Applicable to All Participants, All Models)

* 1. Development and Dissemination of Terms and Conditions and Policies and Procedures; Amendments.

 HIO is solely responsible for the development of the Terms and Conditions and the Policies and Procedures, and may amend, or repeal and replace, the Terms and Conditions and/or the Policies and Procedures as described in 2.3 (Changes to Terms and Conditions and/or Policies and Procedures).

* 1. Relationships Between Terms and Conditions and Policies and Procedures.

 (a) The Policies and Procedures, in effect from time to time, are incorporated into these Terms and Conditions, and HIO and each Participant shall be required to comply with the applicable provisions of the Policies and Procedures as described in Section 2.4.5 (Effect of Terms and Conditions Upon Participation Agreements).

***Alternative A:***

 (b) HIO may exchange data with such Other HIOs that shall be identified in the Policies and Procedures, and to work with the Other HIOs to align their respective policies and procedures affecting the privacy and security of health information, as they are in effect on the Effective Date (“Other HIO Policies and Procedures”), which are incorporated by reference into these Terms and Conditions. HIO shall not agree to exchange data with Other HIO if and to the extent that the provisions of such Other HIO’s Policies and Procedures affecting the privacy and/or security of Patient Data do not meet or exceed the standards set forth in the Policies and Procedures. Subject to the foregoing, these Terms and Conditions are intended to, and shall be construed to, align with such Other HIOs’ policies and procedures. If and when such Other HIO’s policies and procedures change following the Effective Date and provided that they are in alignment with the Policies and Procedures, HIO shall determine whether it is appropriate to amend the latter to incorporate those changes pursuant to Section 2.3 (Changes to Terms and Conditions and Policies and Procedures).[[14]](#footnote-15)

***Alternative B:***

 (b) HIO may exchange data with such Other HIOs that shall be identified in the Policies and Procedures, provided that such Other HIOs have agreed in their legally binding agreements with the HIO[[15]](#footnote-16) to (i) comply with all laws applicable to the Other HIO[[16]](#footnote-17), including but not limited to HIPAA and HITECH, and to maintain and enforce appropriate policies and procedures in compliance therewith, (ii) appropriately and, in accordance with applicable industry standards, authenticate the identities and authorization of all the Other HIO’s participants[[17]](#footnote-18) capable of exchanging data with or through or otherwise electronically interacting with the Other HIO’s electronic systems, (iii) promptly revoke or reduce, as appropriate, the access privileges of the Other HIO’s participants[[18]](#footnote-19) who no longer have a need to electronically interact with the Other HIOs electronic systems in the manner or scope permitted by the privileges; and (iv) an appropriate indemnification provision[[19]](#footnote-20) regarding the Other HIOs act or omission related to the foregoing or receipt by an HIO of an inappropriate data request from or through Other HIOs’ systems.

* 1. Changes to Terms and Conditions and Policies and Procedures.

 ***Alternative A:*** Subject to Section 3.2 (Participant’s Termination of Participation Agreement Based on Objection to Change) [*optional:* and Section 12.2 (Meetings and Responsibilities of Management Committee),[[20]](#footnote-21) HIO may amend, repeal and replace these Terms and Conditions and/or the Policies and Procedures at any time, and shall give Participants notice of such changes not less than [thirty (30) days][[21]](#footnote-22) prior to the implementation of those changes. However, if the change is required in order for HIO and/or Participants to comply with applicable laws or regulations, HIO may implement the change within a shorter period of time as HIO determines is appropriate under the circumstances.[[22]](#footnote-23),[[23]](#footnote-24) Any such change to the Terms and Conditions and/or Policies and Procedures shall automatically be incorporated by reference into each Participation Agreement, and be legally binding upon HIO and the Participant, as of the effective date of the change.[[24]](#footnote-25)

 ***Alternative B:*** Subject to Section 3.2 (Participant’s Termination of Participation Agreement Based on Objection to Change) [*optional:* and Section 12.2 (Meetings and Responsibilities of Management Committee), HIO may amend, repeal and replace these Terms and Conditions and/or the Policies and Procedures at any time, as required in order for HIO and/or Participants to comply with applicable laws and regulations. HIO shall endeavor to give Participants notice of such changes not less than [thirty (30)] days prior to the implementation of those changes. However, HIO may implement the change within a shorter period of time as HIO determines is appropriate under the circumstances. Any such change to the Terms and Conditions and/or Policies and Procedures shall automatically be incorporated by reference into each Participation Agreement, and be legally binding upon HIO and the Participant, as of the effective date of the change.[[25]](#footnote-26)

 ***Alternative C:*** Subject to Section 3.2 (Participant’s Termination of Participation Agreement Based on Objection to Change) [*optional:* and Section 12.2 (Meetings and Responsibilities of Management Committee), HIO may amend, repeal and replace the Policies and Procedures at any time, and shall give Participants notice of such changes not less than [thirty (30)] days prior to the implementation of those changes. However, if the change is required in order for HIO and/or Participants to comply with applicable laws or regulations, HIO may implement the change within a shorter period of time as HIO determines is appropriate under the circumstances. Any such change to the Policies and Procedures shall automatically be incorporated by reference into each Participation Agreement, and be legally binding upon HIO and the Participant, as of the effective date of the change. The other provisions of these Terms and Conditions may be amended only upon the written agreement of HIO and the Participant.[[26]](#footnote-27)

* 1. Development and Administration of Participation Agreements.
		1. Participation Agreement Required.

 Only persons who enter into Participation Agreements with HIO shall be permitted to access the System and use the Services. A Participant may act as a Data Provider or as a Data Recipient, or as both, as described in this 1.5 (Development and Administration of Participation Agreements). A Participant may use some or all of the Services, as specified in Schedule 2 to that Participant’s Participation Agreement.

* + 1. Execution of Participation Agreements. A person may become a Participant by entering into a written Participation Agreement with HIO. Each such Participation Agreement shall describe:

(a) The Participant’s Participant Type, as described in Section 2.4.3 (Participant Type);

 (b) Whether the Participant is a Data Provider or a Data Recipient, or both;

 (c) Which of the Services the Participant may use; and

 (d) Such other terms and conditions as HIO and the Participant shall agree.

* + 1. Participant Type.

Each Participation shall specify the Participant Type of the

Participant, in accordance with the list of Participant Types set forth in the Policies and Procedures.[[27]](#footnote-28)

* + 1. Approval and Disapproval of Applications for Participation Agreements.

***Alternative A:*** Any party may apply to HIO to enter into a Participation Agreement, subject to the applicable terms of the Policies and Procedures. HIO shall review each application and shall approve or disapprove each in accordance with the Policies and Procedures and as HIO determines in its sole discretion is appropriate. HIO shall not be required to approve any application to be a Participant. [[28]](#footnote-29)

***Alternative B:*** Any party may apply to HIO to enter into a Participation Agreement, subject to the applicable terms of the Policies and Procedures. HIO shall review each application and shall approve or disapprove each in accordance with the Policies and Procedures [*optional:* and the applicable requirements of HIO’s Bylaws].[[29]](#footnote-30)

* + 1. Effect of Terms and Conditions and Policies and Procedures Upon Participation Agreements.

 Each Participation Agreement shall incorporate by reference, and require that the Participant agree to comply with, these Terms and Conditions and the Policies and Procedures. HIO may make exceptions to this Section 2.4.5 (Effect of Terms and Conditions Upon Participation Agreements), provided that such exceptions, either individually or in the aggregate, do not materially reduce the obligations of the Participant to HIO or other Participants, or provide that the Participant is not subject to those provisions of the Terms and Conditions and the Policies and Procedures regarding the privacy and security of Patient Data.[[30]](#footnote-31)

* 1. Change or Termination of Services.

 ***Alternative A:*** HIO may cease to participate in any Other HIO, or may reduce the functionality, or make any other change to, the System and/or the Services, or may cease providing the Services, at any time in its sole discretion upon not less than [ninety (90)] days prior notice to Participants.

 ***Alternative B:*** HIO may cease to participate in any Other HIO, or may or may reduce the functionality, or make any other change to, the System and/or the Services, or may cease providing the Services, at any time upon the approval of the Management Committee and upon not less than [ninety (90)] days prior notice to Participants.

 ***Alternative C:*** HIO may cease to participate in any Other HIO, or may or may reduce the functionality, or make any other change to, the System and/or the Services, or may cease providing the Services, at any time following the expiration of the Initial Term of the applicable Participation Agreement pursuant to Section 3.1 (Term of Participation Agreements), upon the approval of the Management Committee and upon not less than [ninety (90)] days prior notice to Participants.[[31]](#footnote-32)

1. TERM AND TERMINATION OF PARTICIPATION AGREEMENTS

(Applicable to All Participants, All Models)

* 1. Term of Participation Agreements.

***Alternative A:*** Each Participation Agreement shall take effect upon the date specified therein, and shall remain in force and effect until terminated by either the Participant or HIO, as provided in these Terms and Conditions.

***Alternative B:*** Each Participation Agreement shall take effect on the date specified therein, and shall remain in force and effect for a period of [one (1) year] (the “Initial Term”). The term of each Participation Agreement shall automatically be extended for an additional period of [one (1) year] (each, a “Renewal Term”) following the expiration of the Initial Term or any Renewal Term, unless either HIO or the Participant gives the other written notice of termination not less than [thirty (30) days] prior to the expiration of the then-current Initial Term or Renewal Term.[[32]](#footnote-33)

* 1. Participant’s Termination of Participation Agreement Based on Objection to Change.

 Notwithstanding Section 2.3 (Changes to Terms and Conditions and Policies and Procedures), the HIO shall not make any change to the Terms and Conditions and/or the Policies and Procedures that either (a) materially reduces the rights or increases the obligations of a Participant, (b) materially reduces the obligations of the HIO, or (c) substantially changes the provisions of the Terms and Conditions or Policies and Procedures regarding the privacy or security of Patient Data, without providing to the Participant the right to terminate its Participation Agreement by giving HIO written notice thereof not more than [thirty (30)] days following HIO’s notice of the change. Such termination of a Participation Agreement shall be effective as of the effective date of the change to which the Participant objects; provided, however, that any change to the Terms and Conditions or Policies and Procedures that HIO determines is required to comply with any federal, state, or local law or regulation shall take effect as of the effective date HIO determines is required, and the termination of any Participant’s Participation Agreement based on the Participant’s objection to the change shall be effective as of HIO’s receipt of the Participant’s notice of termination.[[33]](#footnote-34)

* 1. Participant’s Termination of Participation Agreement Without Cause.[[34]](#footnote-35)

 ***Alternative A:*** A Participant may terminate its Participation Agreement at any time without cause by giving notice of that termination to HIO.

 ***Alternative B:*** A Participant may terminate its Participation Agreement at any time without cause by giving not less than [ninety (90)] days prior notice to HIO.

 ***Alternative C:*** A Participant may terminate its Participation Agreement at any time without cause effective as of the next anniversary of the effective date of the Participant’s Participation Agreement, by giving not less than [ninety (90)] days prior notice to HIO.

* 1. Participant’s Termination of Participation Agreement Upon Uncured Breach.

 Without limiting the obligations of HIO pursuant to Section 11.1 (HIO’s Performance of Obligations, Generally), a Participant may terminate its Participation Agreement upon HIO’s failure to perform a material responsibility arising out of the Participant’s Participation Agreement, and that failure continues uncured for a period of [sixty (60)] days after the Participant has given HIO notice of that failure and requested that HIO cure that failure.[[35]](#footnote-36)

* 1. Participant’s Termination of Participation Agreement Upon Breach of Privacy or Security.

A Participant may terminate its Participation Agreement upon a Breach of Privacy or Security, as described in Section 9.2 (Reporting of Breaches and Security Incidents), when such Breach of Privacy or Security continues uncured for a period of [sixty (60)] days after the Participant has given HIO notice of that failure and requested that HIO cure that breach.[[36]](#footnote-37)

* 1. Participant’s Termination of Participation Agreement Upon Breach of Business Associate Agreement.

Notwithstanding any other provision of this 1.5 (Development and Administration of Participation Agreements) to the contrary, the Participant may terminate its Participation Agreement based upon HIO’s breach of its Business Associate Agreement with the Participant.

* 1. HIO’s Termination of Participation Agreement Without Cause.[[37]](#footnote-38)

 ***Alternative A:*** Except as provided otherwise in the applicable Participation Agreement, HIO may terminate any Participant’s Participation Agreement without cause by giving notice of that termination to the Participant.

 ***Alternative B:*** Except as provided otherwise in the applicable Participation Agreement, HIO may terminate any Participant’s Participation Agreement at any time without cause by giving not less than [ninety (90)] days prior notice to the Participant.

 ***Alternative C:*** Except as provided otherwise in the applicable Participation Agreement, HIO may terminate any Participant’s Participation Agreement at any time without cause effective as of the next anniversary of the effective date of the Participant’s Participation Agreement, by giving not less than [ninety (90)] days prior notice to the Participant.

[*Optional:* provided, however, that HIO shall not terminate the Participation Agreement of any Participant without cause except incident to HIO’s termination of the Participation Agreements of all Participants of the same Participant Type described in Section 2.4.3 (Participant Type).]

* 1. HIO’s Termination of Participation Agreement Upon Uncured Breach.

 Without limiting the obligations of the Participant pursuant to Section 5.1 (Participant’s Performance of Obligations, Generally), HIO may terminate any Participant’s Participation Agreement upon the Participant’s failure to perform a material responsibility arising out of the Participant’s Participation Agreement, and that failure continues uncured for a period of [sixty (60)] days after HIO has given the Participant notice of that failure and requested that the Participant cure that failure.[[38]](#footnote-39)

* 1. Effect of Termination of Participation Agreement.

 Upon any termination of a Participant’s Participation Agreement, that party shall cease to be a Participant and thereupon and thereafter neither that party nor its Authorized Users shall have any rights to use the System or the Services.

* 1. Survival of Provisions.

 The following provisions of the Terms and Conditions shall survive any termination of a Participant’s Participation Agreement: Section 4.5 (Responsibility for Conduct of Participant and Authorized Users), 9 (Privacy and Security of Patient Data), 10 (Business Associate Agreement), 14 (Proprietary and Confidential Information), Section 15.8 (Limitation on Liability) and Section 16.2 (Indemnification).

1. AUTHORIZED USERS[[39]](#footnote-40)

(Not Applicable to Model #1; Applicable to Models #2, #3, #4 & #5)[[40]](#footnote-41)

* 1. Identification of Authorized Users.

 ***Alternative A****:* Each Participant shall provide HIO with a list in a medium and format approved by HIO identifying all the Participant’s Authorized Users, together with the required information described in the Policies and Procedures concerning “Required Information for Authorized Users,” to enable HIO to establish a unique identifier for each Authorized User. The Participant shall update such list whenever an Authorized User is added or removed by reason of termination of employment or otherwise, in accordance with the processes described in the Policies and Procedures.[[41]](#footnote-42)

 ***Alternative B:*** Each Participant shall adopt and implement a protocol for the selection and identification of that Participant’s Authorized Users, and for those Authorized Users’ use of the System and the Services, a copy of which protocol shall be provided to HIO upon request. Such protocol shall comply with the requirements therefor set forth in the Policies and Procedures, and shall describe, without limitation, the process by which the Participant shall uniquely identify each individual as an Authorized User prior to allowing that individual to use the System and the Services and to verify the credentials of each Authorized User prior to enabling that Authorized User to use the System and the Services. Each Participant shall comply with such protocol in all material respects.[[42]](#footnote-43)

* 1. Certification of Authorized Users.

At the time that a Participant identifies an Authorized User to HIO pursuant to Section 4.1 (Identification of Authorized Users), the Participant shall certify to HIO that the Authorized User:

 (a) Has completed a training program conducted by Participant in accordance with Section 5.6 (Training);

 (b) Will be permitted by Participant to use the Services and the System only as reasonably necessary for the performance of Participant’s activities as the Participant Type under which Participant is registered with HIO pursuant to Section 2.4.3 (Participant Type);

 (c) Has agreed not to disclose to any other person any passwords [*and/or other security measures*] issued to the Authorized User pursuant to Section 4.3 (Passwords and Other Security Mechanisms);

 (d) Has acknowledged in writing that his or her failure to comply with the Terms and Conditions may result in the withdrawal of privileges to use the Services and the System and may constitute cause for disciplinary action by Participant; and

 (e) [*Insert others, if desired*].

* 1. Passwords and Other Security Mechanisms.

Based on the information provided by the Participant pursuant to Section 4.1 (Identification of Authorized Users), HIO shall issue a user name and password [*and/or other security measure*] to each Authorized User that shall permit the Authorized User to access the System and use the Services. HIO shall provide each such user name and password [*and/or other security measure*] to the Participant and the Participant shall be responsible to communicate that information to the appropriate Authorized User. When the Participant removes an individual from its list of Authorized Users, and informs HIO of the change, pursuant to Section 4.1 (Identification of Authorized Users), HIO shall cancel the user name and password [*and/or other security measure*] of such individual with respect to the Participant, and cancel and de-activate the user name and password [*and/or other security measure*] of such individual if that individual is as a result of the change no longer an Authorized User of any Participant.[[43]](#footnote-44)

* 1. No Use by Other than Authorized Users.

The Participant shall restrict access to the System and, if applicable, use of the Services, only to the Authorized Users the Participant has identified to HIO in accordance with Section 4.1 (Identification of Authorized Users).

* 1. Responsibility for Conduct of Participant and Authorized Users.

The Participant shall be solely responsible for all acts and omissions of the Participant and/or the Participant’s Authorized Users, and all other individuals who access the System and/or use the Services either through the Participant or by use of any password, identifier or log-on received or obtained, directly or indirectly, lawfully or unlawfully, from the Participant or any of the Participant’s Authorized Users, with respect to the System, the Services and/or any confidential and/or other information accessed in connection therewith, and all such acts and omissions shall be deemed to be the acts and omissions of the Participant.

* 1. Termination of Authorized Users.

The Participant shall require that all of its Authorized Users use the System and the Services only in accordance with these Terms and Conditions, including without limitation those governing the privacy and security of protected health information. The Participant shall discipline appropriately any of its Authorized Users who fail to act in accordance with the Terms and Conditions in accordance with the Participant’s disciplinary policies and procedures.

1. GENERAL OBLIGATIONS OF PARTICIPANTS

(Applicable to All Participants, All Models (subject to exceptions noted below)

* 1. Participant’s Performance of Obligations, Generally.

The Participant shall, in accordance with the terms of its Participation Agreement, diligently perform all of its obligations arising under the Terms and Conditions and the Policies and Procedures and shall, promptly following notice of any material breach thereof by HIO, cure such breach.

* 1. Compliance with Laws and Regulations.

Without limiting any other provision of these Terms and Conditions relating to the parties’ compliance with applicable laws and regulations, the Participant shall perform in all respects as contemplated by these Terms and Conditions in compliance with applicable federal, state, and local laws, ordinances and regulations.

* 1. System Security.

The Participant shall implement security measures with respect to the System and the Services in accordance with the Policies and Procedures, which is incorporated herein by reference. [*Optional*: Without limiting the generality of the foregoing, the Participant shall also adopt and implement the additional security measures described below:][[44]](#footnote-45)

* + 1. [*Additional Security Measures, if desired*].
	1. Software and Hardware Provided by Participant.

Except as provided in Section 8 (Associated Hardware and Software to be Provided by HIO), if applicable, each Participant shall be responsible for procuring all equipment and software necessary for it to access the System, use the Services, and provide to HIO all information required to be provided by the Participant (“Participant’s Required Hardware and Software”). Each Participant’s Required Hardware and Software shall conform to HIO’s then-current specifications, as set forth in the Policies and Procedures. As part of the Participant’s obligation to provide Participant’s Required Hardware and Software, the Participant shall be responsible for ensuring that all the Participant’s computers to be used to interface with the System are properly configured, including but not limited to the operating system, web browser, and Internet connectivity.

* 1. Malicious Software, Viruses, and Other Threats.

The Participant shall use reasonable efforts to ensure that its connection to and use of the System, including without limitation the medium containing any data or other information provided to the System, does not include, and that any method of transmitting such data will not introduce, any program, routine, subroutine, or data (including without limitation malicious software or “malware,” viruses, worms, and Trojan Horses) which will disrupt the proper operation of the System or any part thereof or any hardware or software used by HIO in connection therewith, or which, upon the occurrence of a certain event, the passage of time, or the taking of or failure to take any action will cause the System or any part thereof or any hardware, software or data used by HIO or any other Participant in connection therewith, to be destroyed, damaged, or rendered inoperable.

* 1. Training.

The Participant shall provide appropriate and adequate training to all of the Participant’s personnel, including without limitation Authorized Users, in the requirements of applicable laws and regulations governing the privacy and security of protected health information, including without limitation requirements imposed under HIPAA.[[45]](#footnote-46)

1. DATA RECIPIENT’S USE OF SYSTEM AND SERVICES

(Applicable to Data Recipients Only)

If, pursuant to the applicable Participation Agreement, the Participant is a Data Recipient, the terms of this Section 6 (Data Recipient’s Use of System and Services) shall apply to that Participant.

* 1. Grant of Rights to Use System and Services.
		1. Grant by HIO.

HIO grants to each Data Recipient, and each Data Recipient shall be deemed to have accepted, a non-exclusive, personal, nontransferable, limited right to have access to and to use the System and the Services to be provided to that Data Recipient pursuant to the applicable Participation Agreement, subject to the Data Recipient’s full compliance with the Terms and Conditions and the Data Recipient’s Participation Agreement. HIO retains all other rights to the System and all the components thereof. No Data Recipient shall obtain any rights to the System except for the limited rights to use the System expressly granted by the Terms and Conditions.

* + 1. Applicable Policies and Procedures. All issues concerning the ownership and rights in the System and the Services, and data and information obtained therefrom, shall be as set forth in the Policies and Procedures, which are incorporated herein by reference.

 Permitted Purposes for Use of System and Services.

 ***Alternative A:*** A Data Recipient may use the System and the Services only for the permitted purposes described in an Other HIO’s Policies and Procedures, which are incorporated herein by reference.[[46]](#footnote-47)

 ***Alternative B:*** A Data Recipient may use the System and the Services only to locate and retrieve the data sets described for each Service as described in the Policies and Procedures with respect to “Permitted Uses.”

 ***Alternative C:*** A Data Recipient may use the System and the Services only to locate and retrieve the data sets described in the Policies and Procedures that apply to the Participant Type under which the Data Recipient is assigned pursuant to Section 2.4.3 (Participant Type).[[47]](#footnote-48)

 ***Alternative D:***  A Data Recipient may use the System and the Services only to locate and retrieve Patient Data for purposes of treatment, payment or health care operations, as those terms are defined in HIPAA.

 ***Alternative E:*** A Data Recipient may use the System and the Services only to locate and retrieve Patient Data only for the purpose(s) specified in its Participation Agreement and in no event in any manner that is prohibited by applicable laws.

* 1. Permitted Degree of Access to Patient Data.

 ***Alternative A***: A Data Recipient shall use the System and the Services to request or seek access to only that amount of Patient Data that the Data Recipient is permitted to request pursuant to applicable laws and regulations.

 ***Alternative B***: Except for requests for Patient Data for treatment purposes, the Data Recipient shall use the System and the Services to request or seek access to only that amount of Patient Data that is the minimum necessary to accomplish the Data Recipient’s intended purpose in making the request or seeking access and, to the extent practicable, the Data Recipient shall limit its request for Patient Data to that Patient Data contained in a limited data set, as defined by HIPAA.

* 1. Compliance With Applicable Laws.

Without limiting the generality of Section 6.2 (Permitted Uses of System and Services), the Data Recipient shall in its use of the System and the Services comply with all applicable laws and regulations, including without limitation HIPAA and the CMIA.

* 1. Prohibited Uses of System and Services.

A Data Recipient shall not use or permit the use of the System or the Services for any prohibited use described in the Policies and Procedures, which are incorporated herein by reference. [*Optional*: Without limiting the generality of the foregoing, a Data Recipient shall not use or permit the use of the Services for any use or purpose described below:][[48]](#footnote-49)

* + 1. No Services to Third Parties.

Except as expressly permitted by the applicable Participation Agreement, the Data Recipient shall use the System or the Services for which the Participant is to receive pursuant to its Participation Agreement and only for the Data Recipient’s own account, and shall not use any part of the System or the Services to provide separate services or sublicenses to any third party, including without limitation providing any service bureau services or equivalent services to a third party.

* + 1. No Services Prohibited by Law.

The Data Recipient shall not use the System or the Services for which the Participant has registered for any purpose or in any manner that is prohibited by the laws of the State of California.

* + 1. No Use for Comparative Studies.

A Data Recipient shall not use the System or the Services to aggregate data to compare the performance of Participants and/or Authorized Users, without the express written consent of HIO and each of the Participants and Authorized Users being compared.

* 1. Permitted [and Prohibited] Uses and Disclosures of Patient Data.[[49]](#footnote-50)

 ***Alternative A:*** A Data Recipient may use and disclose Patient Data acquired through the use of the System and the Services as and to the extent permitted by applicable law.[[50]](#footnote-51)

 ***Alternative B:*** A Data Recipient may use and disclose Patient Data acquired through the use of the System and the Services as and to the extent permitted by law; provided, that the Participant shall not use or disclose Patient Data in any manner prohibited pursuant to Section 7.5 (Limitations on Use of Patient Data).[[51]](#footnote-52)

 ***Alternative C:*** A Data Recipient may use Patient Data exchanged through the use of the System and the Services only for the following purposes: [*specify, or describe in an exhibit or the Policies and Procedures*]. A Data Recipient may not use Patient Data for any use described in Section 7.5 (Limitations on Use of Patient Data).[[52]](#footnote-53)

* 1. Effect of Termination on Data Recipient.

Upon any termination of a Data Recipient’s Participation Agreement, the Data Recipient shall cease to be a Participant and thereupon and thereafter shall have no right to, and shall not be permitted to, acquire Patient Data through the use of the System and the Services.

1. DATA PROVIDERS’ USE OF SYSTEM AND SERVICES

(Applicable to Data Providers Only)

If, pursuant to the applicable Participation Agreement, the Participant is a Data Provider, the terms of this Section 7 (Data Providers’ Use of System and Services) shall apply to that Participant.

* 1. Grant of Rights by HIO.
		1. Grant by HIO.

HIO grants to each Data Provider, and each Data Provider shall be deemed to have accepted, a non-exclusive, personal, nontransferable, limited right to have access to and to use the System for the purposes of complying with the obligations described in this Section 7 (Data Provider’s Use of System and Services), subject to the Data Provider’s full compliance with the Terms and Conditions and the Data Provider’s Participation Agreement. HIO retains all other rights to the System and all the components thereof. No Data Provider shall obtain any rights to the System except for the limited rights to use the System expressly granted by the Terms and Conditions.

* + 1. Applicable Policies and Procedures.

All issues concerning the ownership and rights in HIO’s System shall be as set forth in the Policies and Procedures, which are incorporated herein by reference.

* 1. Provision of Data.[[53]](#footnote-54)

 ***Alternative A:*** The Data Provider shall participate in and maintain its connection to the System’s record locator service-based, federated network and provide through the System the Patient Data described in the Policies and Procedures as required for the Participant Type of the Participant pursuant to Section 2.4.3 (Participant Type).

 ***Alternative B:*** The Data Provider shall participate in and maintain its connection to the System’s record locator, service-based federated network and provide through the System the Patient Data the Data Provider has agreed to provide pursuant to the specific terms of its Participation Agreement.

* 1. Measures to Assure Accuracy of Data.[[54]](#footnote-55)
		1. Applicable Policies and Procedures.

 ***Alternative A:*** Each Data provider shall use reasonable care with respect to the accuracy and completeness of the Patient Data it provides through the System.

 ***Alternative B:*** Each Data Provider shall, in accordance with the Policies and Procedures, use reasonable and appropriate efforts to assure that all of the Patient Data it provides through the System is accurate, free from serious error, reasonably complete, and provided in a timely manner, as specified in the Policies and Procedures.[[55]](#footnote-56)

* + 1. Additional Requirements.

 Without limiting Section 7.3.1 (Applicable Policies and Procedures), each Data Provider shall comply with the following requirements respecting the accuracy, completeness and timeliness of the data it provides: [*insert specific description*].

* 1. Grant of License to Use Patient Data.

Subject to Section 7.5 (Limitations on Use of Patient Data), the Data Provider grants to HIO a perpetual, fully-paid, non-exclusive, royalty-free right and license (i) to license and/or otherwise permit others to access through the System and use all Patient Data provided by the Data Provider in accordance with the Policies and Procedures and these Terms and Conditions, (ii) to use such Patient Data to perform the Other Activities HIO performs pursuant to Section 11.9 (Other Activities), and (iii) to use such Patient Data to carry out HIO’s duties under the Policies and Procedures and these Terms and Conditions, including without limitation system administration, testing, problem identification and resolution, management of the System, data aggregation activities as permitted by applicable state and federal laws and regulations, and otherwise as HIO determines is necessary and appropriate.[[56]](#footnote-57),[[57]](#footnote-58)

* 1. Limitations on Use [and Disclosure] of Patient Data.

Notwithstanding Section 7.4 (Grant of License to Use Patient Data by Data Provider), Patient Data provided by a Data Provider shall not be used or disclosed for any of the following purposes:[[58]](#footnote-59)

* + 1. Uses and Disclosures Prohibited by Policies and Procedures. Any use or disclosure that is prohibited by the Policies and Procedures.
		2. Uses and Disclosure Prohibited by Law.

Any use or disclosure use that is prohibited by applicable laws.

* + 1. Other Uses and Disclosures.

[*Insert additional prohibited uses or disclosures, if desired, e.g.*, *data aggregation or other commercial activities of the HIO that are not directly related to the purpose of exchanging data among Participants* ].[[59]](#footnote-60)

* 1. Limitations on Data Provider’s Provision of Patient Data.[[60]](#footnote-61)

 ***Alternative A*:** The Data Provider shall provide Patient Data only to the extent permitted by applicable law.

 ***Alternative B*:** The Data Provider shall provide Patient Data only to the extent permitted by, and in accordance with the applicable requirements of, the Policies and Procedures.[[61]](#footnote-62)

 ***Alternative C:*** The Data Provider shall provide Patient Data only to the extent permitted by, and in accordance with the applicable requirements of, the Policies and Procedures. Without limiting the generality of the foregoing, except in connection with the provision of Patient Data for treatment purposes, as defined under HIPAA, the Data Provider shall, to the extent practicable, limit the Patient Data provided in response to a request received through the System for information or access to information to that information contained in a limited data set, as defined by HIPAA. The Data Provider shall in any event limit the Patient Data disclosed pursuant to a request received through the System for information or access to information to the Patient Data that is the minimum necessary to respond to the request.[[62]](#footnote-63)

* 1. Effect of Termination Upon Data Provider.

Upon any termination of a Data Provider’s Participation Agreement, that Data Provider shall cease to be a Participant and thereupon and thereafter shall have no obligation to provide Patient Data through the System and the Services. Without limiting Section 10 (Business Associate Agreement), if and to the extent that HIO maintains any Patient Data on the Data Provider’s behalf, the HIO shall not, from and after the effective date of the termination of the Data Provider’s Participation, provide or make that information available to Data Recipients. and thereupon and thereafter neither that party nor its Authorized Users shall have any rights to use the System or the Services.

1. ASSOCIATED HARDWARE AND SOFTWARE TO BE PROVIDED BY HIO

(Applicable Only to Participants as Expressly Provided by their Participation Agreements)

If, pursuant to the applicable Participation Agreement, the Participant has agreed to receive Associated Hardware and/or Associated Software from the HIO, the terms of this Section 8 (Associated Hardware and Software to be Provided by HIO) shall apply to that Participant.

* 1. Description of Associated Software and Associated Hardware.

 ***Alternative A:*** HIO shall provide to the Participant the software and/or hardware required to access the System and use the Services the Participant has expressly agreed to receive in its Participation Agreement, as more particularly described on Schedule 8 attached to the applicable Participation Agreement (the “Associated Software” and “Associated Hardware,” respectively). The Associated Software and Associated Hardware shall be provided in compliance with the specifications and/or service standards described on Schedule 8.[[63]](#footnote-64)

 ***Alternative B:***  HIO shall arrange for the provision of the software and/or hardware required to access the System and use the Services the Participant has agreed to receive pursuant to its Participation Agreement, as more particularly described on Schedule 8 attached to the applicable Participation Agreement (the “Associated Software” and “Associated Hardware,” respectively). The vendor or vendors of the Associated Software and/or Associated Hardware shall be responsible for the provision of, and the performance of, the Associated Software and Associated Hardware provided in accordance with the applicable license or subscription or other agreements described in Section 8.5 (Third Party Software, Hardware and/or Services).[[64]](#footnote-65)

* 1. Grant of License.

HIO grants to the Participant a non-exclusive, personal, nontransferable, limited license to use the Associated Software and the Associated Hardware for access to or use of the System and, if the Participant is a Data Recipient, for the purpose of obtaining the Services (the “Associated Software”).[[65]](#footnote-66)

* 1. Copying.

 ***Alternative A:*** The Participant shall not, without HIO’s prior written consent, copy any of the Associated Software.

 ***Alternative B:*** The Participant may make one (1) copy of the whole or any part of the Associated Software in executable form for back-up or archival purposes; provided, that such copy must reproduce and include the copyright notice of HIO.

* 1. Modifications; Derivative Works.

The Participant shall not modify, reverse engineer, decompile, disassemble, re-engineer or otherwise create or permit or assist others to create the Associated Software or the System otherwise, or to create any derivative works from the Associated Software or the System. The Participant shall not modify the Associated Software or combine the Associated Software with any other software or services not provided or approved by HIO.[[66]](#footnote-67)

* 1. Third-Party Software, Hardware, and/or Services.
		1. Licenses, Subscription, and/or Other Agreements.

The Associated Software includes certain third-party software, hardware, and services, which may be subject to separate licenses or subscription or other agreements or may require that a Participant enter into such agreements with third-party vendors. The Participant shall execute such agreements as may be required for the use of such software, hardware or services, and to comply with the terms of any applicable license or other agreement relating to third-party products included in Associated Software.

* + 1. Standards and Warranties.

The specifications, service standards and/or warranties to be provided by the vendor or vendors of the Associated Software and/or the Associated Hardware shall be described in the applicable agreements for those third-party products [*or* in the Policies and Procedures *or* Schedule 8].[[67]](#footnote-68)

1. PRIVACY AND SECURITY OF PATIENT DATA

(Applicable to all Participants, Except Model #1)[[68]](#footnote-69)

* 1. Compliance with Policies and Procedures.

 ***Alternative One:*** HIO and each Participant shall comply with the standards for the privacy and security of patient health information, including without limitation protected health information described in HIPAA and medical information described in the CMIA, as provided in the Policies and Procedures [*Optional*: and/or an Other HIO’s Policies and Procedures], which is incorporated herein by reference.

 ***Alternative Two:*** HIO and each Participant shall comply with the standards for privacy and security of patient health information, including without limitation, protected health information described by HIPAA and medical information described in the CMIA, as provided in the Policies and Procedures [*Optional*: and the [*identify policies and procedures adopted by an authoritative and/or other trusted outside agency and the name of that agency*]], which is [*are*] incorporated herein by reference.

* 1. Reporting of Breaches and Security Incidents.[[69]](#footnote-70)

***Alternative One:*** Without limiting any Business Associate Agreement entered into pursuant to Exhibit 1 (Business Associate Agreement), HIO and each Participant shall communicate with each other concerning Breaches and Security Incidents involving Patient Data in a manner that fosters trust among HIO and all Participants.

***Alternative Two:***

* + 1. Reporting Breaches and Security Incidents.

Without limiting any Business Associate Agreement entered into pursuant to Exhibit 1 (Business Associate Agreement), HIO and Participant shall report to the other any use or disclosure of Patient Data not provided for by these Terms and Conditions of which HIO or Participant becomes aware, any security incident (other than an Unsuccessful Security Incident) concerning electronic Patient Data and any Breach of Privacy or Security. This report shall be made without unreasonable delay and in no case later than [*insert number of days*].

* + 1. Reporting Unsuccessful Security Incidents.

The Participant shall annually provide a report to HIO describing in summary form the nature and extent of Unsuccessful Security Incidents concerning Patient Data or the Participant’s access or use of the System or the Services experienced by the Participant during the period covered by that report, as more specifically described in the Policies and Procedures.

* + 1. Reports to Participants. HIO shall on a monthly basis provide a report to all Participants describing all Breaches of Privacy or Security of which HIO becomes aware or that are reported by Participants to HIO during the prior month pursuant to Section 9.2.1 (Reporting Breaches and Security Incidents). HIO shall on an annual basis provide a report to all Participants describing in summary form Unsuccessful Security Incidents reported by Participants to HIO pursuant to Section 9.2.2 (Reporting Unsuccessful Security Incidents).[[70]](#footnote-71)
1. BUSINESS ASSOCIATE AGREEMENT

(Not Applicable for Model #1 or #2)[[71]](#footnote-72)

If, pursuant to the applicable Participation Agreement, the HIO is to act as the business associate (as defined by HIPAA) of the Participant, the HIO shall enter into a Business Associate Agreement with that Participant in the form attached hereto as Exhibit 1.

1. HIO’S OPERATIONS AND RESPONSIBILITIES[[72]](#footnote-73)

(Applicable to All Participants)

* 1. Performance of Obligations, Generally.

HIO shall, in accordance with the terms of the Participation Agreement, diligently perform all of its obligations arising under the Terms and Conditions and the Policies and Procedures and shall, promptly following notice from any Participant of a material breach thereof, cure that breach. Without limiting the generality of the foregoing, HIO shall perform all of its obligations arising under the Terms and Conditions and the Policies and Procedures in a manner that complies with all applicable laws and regulations.[[73]](#footnote-74)

* 1. Participation Agreements.

HIO shall require that all Participants enter into a Participation Agreement or another legally binding agreement to comply with the Terms and Conditions in accordance with Section 2.4.5 (Effect of Terms and Conditions and Policies and Procedures Upon Participation Agreements). Without limiting Section 2.4.4 (Approval or Disapproval of Applications for Participation Agreements), HIO shall enter into Participation Agreements only with those parties that satisfy the requirements for participation set forth in the Policies and Procedures.

* 1. Monitoring of Participants.

HIO shall regularly monitor Participant’s compliance with the requirements for participation set forth in the Policies and Procedures.[[74]](#footnote-75)

* 1. Maintenance of System.

HIO shall maintain the functionality of the System and the Services in accordance with the Policies and Procedures, and shall provide such service, security, and other updates as HIO determines are appropriate from time to time.

* 1. Training.

 HIO shall provide training to each Participant [and/or Authorized User] regarding the Participant’s [and/or the Authorized User’s] rights and obligations under its Participation Agreement and the Terms and Conditions, and the access and use of the System and Services, including such user manuals and other resources HIO determines appropriate to support the System and Services, including without limitation training for new or additional Authorized Users when added by the Participant.

* 1. Telephone and/or E-Mail Support.

 ***Alternative A:*** HIO shall provide, by telephone and/or e-mail, during normal business hours, support and assistance in resolving difficulties in accessing and using the System and the Services.

 ***Alternative B:*** HIO shall provide, by telephone and/or e-mail, during normal business hours, support and assistance to the Participant’s help desk or other facility that supports use of the System and Services by Authorized Users.

* 1. Audits and Reports.

HIO shall perform the following audits and provide the following reports to each Participant:

* + 1. Participation Reports. [*Specified reports concerning the names of and/or other information regarding other Participants*].
		2. Usage Reports. [*Specified statistical reports regarding the Participant’s usage of the Services*].
		3. Reports to Public Agencies. [*Specified reports that certain Participants may be required to make to public health agencies*].
		4. Audit Trail Reports. [*Specified reports that pertain to audit trail tracking*].
	1. Access to Patient Data.

HIO shall permit access to Patient Data maintained by HIO only by Participants and other parties authorized by the Data Provider that provided that Patient Data, and only in compliance with the Policies and Procedures.[[75]](#footnote-76)

* 1. Other Activities.

HIO shall perform the other activities, including without limitation any additional services or functions involving the System, the Services and/or Patient Data, whether performed for Participants and/or other parties, as and to the extent described in the Policies and Procedures.[[76]](#footnote-77)

1. GOVERNANCE[[77]](#footnote-78)

(Applies to all Participants)

* 1. Management Committee Composition.

HIO shall create and maintain a Management Committee (the “Management Committee”) composed of [*specified personnel/representatives of HIO and specified number of Participant representatives, who shall be selected in a specified manner*].

* 1. Meetings and Responsibilities of Management Committee.

The Management Committee shall meet [*describe intervals, e.g., monthly*] to consider and resolve various issues pertaining to the use of the System and the Services by Participants, including [*list, e.g.*, *approving material changes to Terms and Conditions and/or Policies and Procedures*].[[78]](#footnote-79)

* 1. Management Committee Bylaws.

The Management Committee shall adopt bylaws for the conduct of its meetings and other proceedings. Without limiting the generality of the foregoing, the Management Committee Bylaws shall provide procedures and rules concerning how the Management Committee shall call and conduct its meetings and take action.

1. FEES AND CHARGES

(Applicable to All Participants)

* 1. Agreed-Upon Fees.

If the Participant’s Participation Agreement describes the fees and charges to be paid by the Participant, the terms and conditions of that Participation Agreement with respect to the payment of fees and charges shall apply. If the Participant’s Participation Agreement does not describe such fees and charges, the other provisions of this Section 13 (Fees and Charges) shall apply.

* 1. Service Fees.[[79]](#footnote-80)

 ***Alternative A:*** Unless the Participant’s Participation Agreement provides otherwise, each Participant shall pay Service Fees to HIO, in accordance with HIO’s then-current Fee Schedule.

 ***Alternative B:*** Unless the Participant’s Participation Agreement provides otherwise, each Participant shall pay Service Fees to HIO, in accordance with the Fee Schedule set forth in the Policies and Procedures.

* 1. Changes to Fee Schedule.

 ***Alternative A:*** HIO may change its Fee Schedule at any time upon [thirty (30)] days prior written notice to Participants.

 ***Alternative B:*** HIO may change its Fee Schedule as of January 1 of any calendar year; provided, that HIO shall give Participants not less than [thirty (30)] days prior written notice of any such change.

* 1. Miscellaneous Charges.

Unless the Participant’s Participation Agreement provides otherwise, the Participant also shall pay HIO’s charges for all goods or services that HIO provides at the Participant’s request that are not specified in HIO’s then-current Fee Schedule (“Miscellaneous Charges”).

* 1. Payment.

The Participant shall pay all Service Fees and any Miscellaneous Charges within [thirty (30)] days following the date of invoice by HIO sent to the Participant’s address as shown in HIO’s records or e-mailed in accordance with the Participant’s Participation Agreement.

* 1. Late Charges.

Service Fees and Miscellaneous Charges not paid to HIO within [thirty (30)] business days following the due date therefor are subject to a late charge of five percent (5%) of the amount owing and interest thereafter at the rate of one and one-half percent (1 ½%) per month on the outstanding balance, or the highest amount permitted by law, whichever is lower.

* 1. Suspension of Service.

Failure to pay Service Fees and Miscellaneous Charges within [sixty (60)] days following the due date therefor may result in termination of the Participant’s access to the System and/or use of the Services on [ten (10)] days prior notice. A reconnection fee equal to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ shall be assessed to re-establish connection after termination due to non-payment.

* 1. Taxes.

All Service Fees and Miscellaneous Charges shall be exclusive of all federal, state, municipal, or other government excise, sales, use, occupational, or like taxes now in force or enacted in the future, and the Participant shall pay any tax (excluding taxes on HIO’s net income) that HIO may be required to collect or pay now or at any time in the future and that are imposed upon the sale or delivery of items and services provided pursuant to the Terms and Conditions.

* 1. Other Charges and Expenses.

 The Participant shall be solely responsible for any other charges or expenses the Participant may incur to access the System and use the Services, including without limitation, telephone and equipment charges, and fees charged by third-party vendors of products and services.

1. PROPRIETARY AND CONFIDENTIAL INFORMATION

(Applicable to all Participants, Except Under Model #1)

* 1. Scope of Proprietary and Confidential Information.

In the performance of their respective responsibilities pursuant to the Terms and Conditions, HIO and Participants may come into possession of certain Proprietary and Confidential Information of the other. For the purposes hereof, “Proprietary and Confidential Information” means all trade secrets, business plans, marketing plans, know-how, data, contracts, documents, scientific and medical concepts, member and customer lists, costs, financial information, profits and billings, and referral sources, existing or future services, products, operations, management, pricing, financial status, goals, strategies, objectives, and agreements of HIO or the Participant, as the case may be, whether written or verbal, that are confidential in nature; provided, however, that Proprietary and Confidential Information shall not include any information that:

 (a) Is in the public domain;

 (b) Is already known or obtained by any other party other than in the course of the other party’s performance pursuant to the Terms and Conditions, and without breach of any confidentiality, nondisclosure or other agreement by such other party;

 (c) Is independently developed by any other party;

 (d) Becomes known from an independent source having the right to disclose such information and without similar restrictions as to disclosure and use and without breach of the Terms and Conditions, or any other confidentiality or nondisclosure agreement by such other party; and/or

 (e) Is Patient Data.

* 1. Nondisclosure of Proprietary and Confidential Information.

HIO and the Participant each (i) shall keep and maintain in strict confidence all Proprietary and Confidential Information received from the other, or from any of the other’s employees, accountants, attorneys, consultants, or other agents and representatives, in connection with the performance of their respective obligations under the Terms and Conditions; (ii) shall not use, reproduce, distribute or disclose any such Proprietary and Confidential Information except as permitted by the Terms and Conditions; and (iii) shall prevent its employees, accountants, attorneys, consultants, and other agents and representatives from making any such use, reproduction, distribution, or disclosure.

* 1. Equitable Remedies.

All Proprietary and Confidential Information represents a unique intellectual product of the party disclosing such Proprietary and Confidential Information (the “Disclosing Party”). The unauthorized disclosure of said Proprietary and Confidential Information would have a detrimental impact on the Disclosing Party. The damages resulting from said detrimental impact would be difficult to ascertain but would result in irreparable loss. It would require a multiplicity of actions at law and in equity in order to seek redress against the receiving party in the event of such an unauthorized disclosure. The Disclosing Party shall be entitled to equitable relief in preventing a breach of this Section 14 (Proprietary and Confidential Information) and such equitable relief is in addition to any other rights or remedies available to the Disclosing Party.

* 1. Notice of Disclosure.

Notwithstanding any other provision hereof, nothing in this Section 14 (Proprietary and Confidential Information) shall prohibit or be deemed to prohibit a party hereto from disclosing any Proprietary and Confidential Information (or any other information the disclosure of which is otherwise prohibited hereunder) to the extent that such party becomes legally compelled to make such disclosure by reason of a subpoena or order of a court, administrative agency or other governmental body of competent jurisdiction, and such disclosures are expressly permitted hereunder; provided, however, that a party that has been requested or becomes legally compelled to make a disclosure otherwise prohibited hereunder by reason of a subpoena or order of a court, administrative agency or other governmental body of competent jurisdiction shall provide the other party with notice thereof within [five (5)] calendar days, or, if sooner, at least [three (3)] business days before such disclosure will be made so that the other party may seek a protective order or other appropriate remedy. In no event shall a party be deemed to be liable hereunder for compliance with any such subpoena or order of any court, administrative agency or other governmental body of competent jurisdiction.

1. DISCLAIMERS, EXCLUSIONS OF WARRANTIES, LIMITATIONS OF LIABILITY, AND INDEMNIFICATION

(Applicable to All Participants)

* 1. Carrier Lines.

By using the System and the Services, each Participant shall acknowledge that access to the System is to be provided over various facilities and communications lines, and information will be transmitted over local exchange and Internet backbone carrier lines and through routers, switches, and other devices (collectively, “carrier lines”) owned, maintained, and serviced by third-party carriers, utilities, and Internet service providers, all of which are beyond HIO’s control. HIO assumes no liability for or relating to the integrity, privacy, security, confidentiality, or use of any information while it is transmitted on the carrier lines, or any delay, failure, interruption, interception, loss, transmission, or corruption of any data or other information attributable to transmission on the carrier lines. Use of the carrier lines is solely at user’s risk and is subject to all applicable local, state, national, and international laws.

* 1. No Warranties.

Except as described on Schedule 8, or in the applicable third-party agreement described in Section 8.5.1 (Licenses, Subscriptions and/or Other Agreements), access to the System, use of the Services, and the information obtained by a Data Recipient pursuant to the use of those services are provided “as is” and “as available” without any warranty of any kind, expressed or implied, including but not limited to, the implied warranties of merchantability, fitness for a particular purpose, and non-infringement. The Participant is solely responsible for any and all acts or omissions taken or made in reliance on the System or the information in the System, including inaccurate or incomplete information. It is expressly agreed that in no event shall HIO be liable for any special, indirect, consequential, or exemplary damages, including but not limited to, loss of profits or revenues, loss of use, or loss of information or data, whether a claim for any such liability or damages is premised upon breach of contract, breach of warranty, negligence, strict liability, or any other theories of liability, even if HIO has been apprised of the possibility or likelihood of such damages occurring. HIO disclaims any and all liability for erroneous transmissions and loss of service resulting from communication failures by telecommunication service providers or the System.

* 1. Other Participants.

By using the System and the Services, each Participant shall acknowledge that other Participants have access to the System and Services, and that other parties have access to the information contained in the System through their participation in an Other HIO [*Optiona*l: and/or other applicable program]. Such other Participants have agreed to comply with the [*identify applicable policies and procedures, e.g.*, Policies and Procedures, or other applicable policies and procedures], concerning use of the information; however, the actions of such other parties are beyond the control of HIO. Accordingly, HIO does not assume any liability for or relating to any impairment of the privacy, security, confidentiality, integrity, availability, or restricted use of any information on the System resulting from any Participant’s actions or failures to act.

* 1. Participant’s Actions.

 The Participant shall be solely responsible for any damage to a computer system, loss of data, and any damage to the System caused by that Participant or any person using a user ID assigned to the Participant or a member of the Participant’s workforce.

* 1. Unauthorized Access; Lost or Corrupt Data.

HIO is not responsible for unauthorized access to the Participant’s transmission facilities or equipment by individuals or entities using the System or for unauthorized access to, or alteration, theft, or destruction of the participant’s data files, programs, procedures, or information through the System, whether by accident, fraudulent means or devices, or any other method. The Participant is solely responsible for validating the accuracy of all output and reports and protecting the Participant’s data and programs from loss by implementing appropriate security measures, including routine backup procedures. The Participant waives any damages occasioned by lost or corrupt data, incorrect reports, or incorrect data files resulting from programming error, operator error, equipment or software malfunction, security violations, or the use of third-party software. HIO is not responsible for the content of any information transmitted or received through HIO’s provision of the Services.

* 1. Inaccurate Data.

All data to which access is made through the System and/or the Services originates from Data Providers and other parties making data available through one (1) or more Other Health Information Sharing Programs, and not from HIO. All such data is subject to change arising from numerous factors, including without limitation, changes to patient health information made at the request of the patient, changes in the patient’s health condition, the passage of time and other factors. HIO neither initiates the transmission of any data nor monitors the specific content of data being transmitted. Without limiting any other provision of the Terms and Conditions, HIO shall have no responsibility for or liability related to the accuracy, content, currency, completeness, content, or delivery of any data either provided by a Data Provider, or used by a Data Recipient, pursuant to the Terms and Conditions.

* 1. Patient Care.

Without limiting any other provision of the Terms and Conditions, the Participant and the Participant’s Authorized Users shall be solely responsible for all decisions and actions taken or not taken involving patient care, utilization management, and quality management for their respective patients and clients resulting from or in any way related to the use of the System or the Services or the data made available thereby. No Participant or Authorized User shall have any recourse against, and through the Participation Agreements that apply thereto, each shall waive, any claims against HIO for any loss, damage, claim, or cost relating to or resulting from its own use or misuse of the System and/or the Services or the data made available thereby.

* 1. Limitation of Liability.

Notwithstanding anything in the Terms and Conditions to the contrary, to the maximum extent permitted by applicable laws, the aggregate liability of HIO, and HIO’s officers, directors, employees, and other agents, to any Participant with respect to the subject of these Terms and Conditions, regardless of theory of liability, shall be limited to the aggregate fees actually paid by the Participant in accordance with the Terms and Conditions for the six (6) month period preceding the event first giving rise to the claim; provided, however, that this Section 15.8 (Limitation of Liability) shall not apply with respect to [*insert description of type(s) of liability for which HIO’s exposure is to be subject to other limits or not to be limited*, *if any*].[[80]](#footnote-81)

1. INSURANCE AND INDEMNIFICATION

(Applicable to All Participants)

* 1. Insurance.

The Participant shall obtain and maintain insurance coverage in accordance with the Policies and Procedures, which is incorporated herein by reference. [*Optional*: Without limiting the generality of the foregoing, the Participant shall also comply with the insurance requirements described below:]

* + 1. [*Additional Insurance Requirements, if desired*].
	1. Indemnification.
		1. Indemnification, Generally.

 ***Alternative A:*** HIO and each Participant (each, an “Indemnifying Party”) each shall hold the other (the “Indemnified Party”) free of and harmless from all liability, judgments, costs, damages, claims, or demands, including reasonable attorneys' fees, net of the proceeds of insurance, arising out of the act or omission of the Indemnifying Party or any of the Indemnifying Party's Authorized Users, members, agents, staff, or employees, including the Indemnifying Party’s failure to comply with or perform its obligations under the applicable Participation Agreement.

 ***Alternative B:*** HIO and each Participant (each, an “Indemnifying Party”) each shall hold the other and, if the Participant is the Indemnifying Party, the other Participants (the “Indemnified Party”) free of and harmless from all liability, judgments, costs, damages, claims, or demands, including reasonable attorneys' fees, net of the proceeds of insurance, arising out of the act or omission of the Indemnifying Party or any of the Indemnifying Party's Authorized Users, members, agents, staff, or employees, including the Indemnifying Party’s failure to comply with or perform its obligations under the applicable Participation Agreement.

 ***Alternative C:*** Nothing in the Terms and Conditions or any Participation Agreement shall limit HIO’s or a Participant’s respective legal and equitable obligations to each other and to other Participants arising out of the doctrines of equitable indemnity, comparative negligence, contribution or other common law bases of liability.

* 1. Specific Indemnities.

 ***Alternative A:*** Notwithstanding Section 16.2.1 (Indemnification, Generally), HIO and each Participant (each, an “Indemnifying Party”) each shall hold the other (the “Indemnified Party”) free of and harmless from all liability, judgments, costs, damages, claims, or demands, including reasonable attorneys' fees, net of the proceeds of insurance, arising out of any Breach of Privacy or Security arising out of the act or omission of the Indemnifying Party or any of the Indemnifying Party's Authorized Users, members, agents, staff, or employees.

 ***Alternative B:*** Notwithstanding Section 16.2.1 (Indemnification, Generally), a Data Provider shall hold HIO free of and harmless from all liability, judgments, costs, damages, claims, or demands, including reasonable attorneys' fees, net of the proceeds of insurance, arising out of Data Provider’s provision of any Patient Data that is inaccurate, incomplete, or defamatory.

* 1. Rules for Indemnification.

Any indemnification made pursuant to the Terms and Conditions shall include payment of all costs associated with defending the claim or cause of action involved, whether or not such claims or causes of action are meritorious, including reasonable attorneys’ fees and any settlement by or judgment against the party to be indemnified. In the event that a lawsuit is brought against the party to be indemnified, the party responsible to indemnify that party shall, at its sole cost and expense, defend the party to be indemnified, if the party to be indemnified demands indemnification by written notice given to the indemnifying party within a period of time wherein the indemnifying party is not prejudiced by lack of notice. Upon receipt of such notice, the indemnifying party shall have control of such litigation but may not settle such litigation without the express consent of the party to be indemnified, which consent shall not be unreasonably withheld, conditioned or delayed. The indemnification obligations of the parties shall not, as to third parties, be a waiver of any defense or immunity otherwise available, and the indemnifying party, in indemnifying the indemnified party, shall be entitled to assert in any action every defense or immunity that the indemnified party could assert on its own behalf.

1. TRANSPARENCY, OVERSIGHT, ENFORCEMENT AND ACCOUNTABILITY

(Applicable to All Participants, except Model #1)

* 1. Transparency.

HIO shall develop, implement and conduct measures to provide Participants information concerning the ongoing operations of the System and the Services, including, without limitation, the efficiency, effectiveness, and security thereof, and the uses and disclosures of Patient Data made by and among Participants pursuant to their use thereof, as described in the Policies and Procedures. Such measures shall include HIO’s provision to Participants of the reports described in Section 9.2.2.1 (Reports to Participants).[[81]](#footnote-82)

* 1. Oversight.

 ***Alternative A:***  The Management Committee shall review and prepare periodic reports to HIO and Participants concerning the ongoing operations of and other information regarding the System and the Services. Such reports shall include without limitation information regarding the efficiency, effectiveness, and security of the System and the Services, and the accesses to and uses and disclosures of Patient Data made by and among Participants pursuant to their use thereof, including without limitation Participants’ adherence to the Terms and Conditions and /or Policies and Procedures regarding the privacy and security of Patient Data.

 ***Alternative B:*** HIO shall create and maintain an Oversight Committee (the “Oversight Committee”) composed of [*specified personnel and/or representatives of the HIO and Participants, who shall be selected in a specified manner*]. The Oversight Committee shall meet [*describe intervals, e.g., monthly*] to review and prepare periodic reports to HIO and Participants concerning the ongoing operations of the System and the Services, including without limitation information regarding the efficiency, effectiveness, and security thereof, and the accesses to and uses and disclosures of Patient Data made by and among Participants pursuant to their use thereof, including without limitation Participants’ adherence to the Terms and Conditions and/or Policies and Procedures regarding the privacy and security of Patient Data.

* 1. Enforcement and Accountability.

 ***Alternative A:*** The Management Committee [or the Oversight Committee] may, either independently or upon the request of a Participant, review the uses and disclosures of Patient Data by any Participant, including without limitation the Participant’s adherence to the Terms and Conditions and/or Policies and Procedures, and make recommendations to HIO regarding action to be taken by HIO with respect thereto. Such activities of the Management Committee [or the Oversight Committee] and HIO shall be conducted as described in the Policies and Procedures. Any action taken by HIO shall be taken only in accordance with the Terms and Conditions and the Policies and Procedures, and HIO shall provide the Participant an opportunity to provide information regarding the matter(s) involved in any such action to the HIO before any action is taken.

 ***Alternative B:*** HIO may take action with respect to any Participant, as permitted by the Terms and Conditions and the Policies and Procedures. HIO shall provide the Participant an opportunity to provide information to HIO regarding the matter(s) involved in any such action before any action is taken.

 ***Alternative C:*** Any Participant may, based upon a finding of HIO [or the Management Committee or Oversight Committee] with respect to another Participant’s failure to comply with the Terms and Conditions and / or the Policies and Procedures, temporarily or permanently suspend the sharing of Patient Data with that other Participant, upon giving notice to HIO and the other Participant, and an opportunity to the other Participant to cure the non-compliance or provide other information regarding same as described in the Policies and Procedures.

1. MISCELLANEOUS PROVISIONS

(Applicable to All Participants)

* 1. Applicable Law.

The interpretation of the Terms and Conditions and the resolution of any disputes arising under the Terms and Conditions and Participants’ Participation Agreements shall be governed by the laws of the State of California. If any action or other proceeding is brought on or in connection with the Terms and Conditions or a Participation Agreement, the venue of such action shall be exclusively in \_\_\_\_\_\_\_\_\_\_\_\_\_ County, in the State of California.[[82]](#footnote-83)

* 1. Non-Assignability.

No rights of the Participant under its Participation Agreement may be assigned or transferred by the Participant, either voluntarily or by operation of law, without the prior written consent of HIO, which it may withhold in its sole discretion.

* 1. Third-Party Beneficiaries.

There shall be no third-party beneficiaries of any Participation Agreement.

* 1. Supervening Circumstances.

Neither the Participant nor HIO shall be deemed in violation of any provision of a Participation Agreement if it is prevented from performing any of its obligations by reason of: (a) severe weather and storms; (b) earthquakes or other natural occurrences; (c) strikes or other labor unrest; (d) power failures; (e) nuclear or other civil or military emergencies; (f) acts of legislative, judicial, executive, or administrative authorities; or (g) any other circumstances that are not within its reasonable control. This Section 18.4 (Supervening Circumstances) shall not apply to obligations imposed under applicable laws and regulations or obligations to pay money.

* 1. Severability.

Any provision of the Terms and Conditions or any Participant Participation Agreement that shall prove to be invalid, void, or illegal, shall in no way affect, impair, or invalidate any other provision of the Terms and Conditions or such Participation Agreement, and such other provisions shall remain in full force and effect.

* 1. Notices.

Any and all notices required or permitted under the Terms and Conditions shall be sent by United States mail, overnight delivery service, or facsimile transmission to the address provided by the Participant to HIO or such different addresses as a party may designate in writing. If the Participant has supplied HIO with an electronic mail address, HIO may give notice by email message addressed to such address; provided that if HIO receives notice that the email message was not delivered, it shall give the notice by United States mail, overnight delivery service, or facsimile.

* 1. Waiver.

No provision of the Terms and Conditions or any Participant Participation Agreement shall be deemed waived and no breach excused, unless such waiver or consent shall be in writing and signed by the party claimed to have waived or consented. Any consent by any party to, or waiver of a breach by the other, whether expressed or implied, shall not constitute a consent to, waiver of, or excuse for any other different or subsequent breach.

* 1. Independent Contractors.

In the performance of their respective responsibilities under any Participation Agreement, HIO and the Participant are and shall be at all times acting as the independent contractor of the other, and not by virtue of that Participation Agreement or otherwise under these Terms and Conditions acting as an employee, agent, or partner of, or joint venture with, the other.[[83]](#footnote-84)

* 1. Complete Understanding.

With respect to any Participant Participation Agreement made pursuant to the Terms and Conditions, that Agreement and the Terms and Conditions together contain the entire understanding of the parties, and there are no other written or oral understandings or promises between the parties with respect to the subject matter of any Participation Agreement other than those contained or referenced in that Participation Agreement. All modifications or amendments to any Participation Agreement shall be in writing and signed by all parties.

# Exhibit 1

[*Insert Name of Health Information Sharing Organization*]

BUSINESS ASSOCIATE AGREEMENT

[*Insert Name of Health Information Sharing Organization*], a [*form of HIO’s organization, e.g., a California nonprofit public benefit corporation*] (“Business Associate”), and the Participant identified on the Signature Page hereof (“Covered Entity”), hereby agree to the following terms and conditions of this Business Associate Agreement (the “Business Associate Agreement”).

Recitals

 A. Covered Entity is a “covered entity” (as defined in HIPAA).

B. Covered Entity and Business Associate have entered into one (1) or more agreements (collectively, the “Participation Agreement”) pursuant to which Business Associate provides to Covered Entity certain services that now or in the future shall include, other than in the capacity of a member of the workforce of Covered Entity, the creation, receipt, maintenance and/or transmission of “protected health information” (as defined in HIPAA), on behalf of Covered Entity, for a function or activity regulated by HIPAA. Business Associate therefore shall act as a “business associate” (as defined in HIPAA) with respect to Covered Entity.

C. Covered Entity and Business Associate accordingly have agreed to enter into the following terms and conditions.

Agreement

In consideration of the foregoing recitals and the promises set forth herein, the parties agree as follows:

1. Definitions. For the purposes of this Business Associate Agreement, the term “HIPAA” means the Privacy and Security Rules promulgated under the Health Insurance Portability and Accountability Act of 1996 (45 C.F.R. Parts 160, 162 and 164), as in effect from time to time. All terms used in this Business Associate Agreement not specifically defined otherwise shall have the same definitions as given to them under HIPAA; provided, however, that the term “PHI” shall refer only to protected health information that Business Associate creates, receives, maintains or transmits on behalf of Covered Entity.

2. Obligations of Business Associate.

 (a) Compliance with Regulatory Obligations of Business Associate. Without limiting any other provision of this Business Associate Agreement, Business Associate shall perform and comply with all the applicable obligations and requirements imposed upon business associates pursuant to HIPAA [*Reference: 45 C.F.R. § 164.314(a)(2)(i)(A)*].

(b) Permitted Use and Disclosure of PHI. Business Associate shall use and disclose PHI only as necessary to perform Business Associate’s obligations, functions, activities and/or services under the Participation Agreement, or as otherwise permitted or required by this Business Associate Agreement, or as otherwise permitted by HIPAA, including without limitation 45 C.F.R. § 164.502(b) with respect to the minimum necessary use and disclosure of PHI, or required by law. Except as expressly permitted by this Business Associate Agreement, Business Associate shall not use or disclose PHI in any manner that would violate the requirements of HIPAA if done by Covered Entity. [*Reference:* *45 C.F.R. §§ 164.502(a)(3) & 164.504(e)(2)(i) & 45 C.F.R. § 164.504(e)(2)(ii)(A)*].

(c) Specified Permitted Uses of PHI. Without limiting the generality of Section 2(b) (Permitted Use and Disclosure of PHI), Business Associate may use PHI as follows, if necessary:

(i) For the proper management and administration of Business Associate [*Reference: 45 C.F.R. § 164.504(e)(2)(i)(A) & 45 C.F.R. § 164.504(e)(4)(i)(A)*].

(ii) To carry out the legal *responsibilities* of Business Associate [*Reference: 45 C.F.R. § 164.504(e)(4)(i)(B)*].

(iii) To provide data aggregation services relating to the health care operations of Covered Entity if and to the extent *provided* by the Participation Agreement [*Reference: 45 C.F.R. § 164.504(e)(2)(i)(B)*].

(d) Specified Permitted Disclosures of PHI. Without limiting the generality of Section 2(b) (Permitted Use and Disclosure of PHI), Business Associate may disclose PHI as follows:

(i) For the proper management and administration of Business Associate [*Reference: 45 C.F.R. § 164.504(e)(2)(i)(A)*] or to carry out the legal responsibilities of Business Associate [*Reference: 45 C.F.R. § 164.504(e)(4)(i)(B)*] if:

(A) If the disclosure is required by law [*Reference: 45 C.F.R. § 164.504(e)(4)(ii)(A)*]; or

(B) If Business Associate obtains reasonable assurances from the person to whom the information is disclosed that it will be held confidentially and used or further disclosed only as required by law or for the purposes for which it was disclosed to the person [*Reference: 45 C.F.R. § 164.504(e)(4)(ii)(B)(1)*], andif the person promptly notifies Business Associate of any instances in which it is aware in which the confidentiality of the information has been breached [*Reference: 45 C.F.R. § 164.504(e)(4)(ii)(B)(ii)*].

 (e) Safeguards. Business Associate shall use appropriate safeguards and comply, where applicable, with 45 C.F.R. §§ 164.302 through 164.316 with respect to electronic PHI, to prevent use or disclosure of the information other than as provided for by this Business Associate Agreement [*Reference: 45 C.F.R. §§45 C.F.R. § 164.314(a)(2)(i)(A)& 164.504(e)(2)(ii)(B)*]. Without limiting the generality of the foregoing Business Associate shall appropriately safeguard electronic PHI by implementing administrative safeguards in accordance with 45 C.F.R. § 164.308 [*Reference: 45 C.F.R. § 164.308(b)(1)*].

(f) Reporting Unauthorized Uses and Disclosures. Business Associate shall report to Covered Entity, without unreasonable delay, and in no cases later than [*insert number*] calendar days from discovery of the breach, any use or disclosure of PHI not permitted by this Business Associate Agreement of which Business Associate becomes aware, including without limitation any security incident involving electronic PHI and any breach of unsecured PHI as required by 45 C.F.R. § 164.410 [*Reference: 45 C.F.R. §§ 164.314(a)(2)(C) & 164.504(e)(2)(ii)(C)*].[[84]](#footnote-85) [[85]](#footnote-86)Without limiting the generality of the foregoing:

(i) Notwithstanding anything to the contrary in this Section 2(f) (Reporting Unauthorized Uses and Disclosures), Business Associate shall report to Covered Entity on a regular and periodic basis the ongoing existence and occurrence of Unsuccessful Security Incidents (as defined below). The parties agree that this section satisfies any notices necessary by Business Associate to Covered Entity of the ongoing existence and occurrence of unsuccessful Security Incidents, for which no additional notice shall be required. For purposes of this Business Associate Agreement, the term “Unsuccessful Security Incident” shall mean any security incident that does not result in any unauthorized access, use or disclosure of electronic PHI, including without limitation, activity such as pings and other broadcast attacks on a firewall, port scans, unsuccessful log-on attempts, denial of service and any combination of the above.

(ii) Except in the event of a law enforcement delay, Business Associate shall report the information described below to Covered Entity without unreasonable delay, and in no case more than [*insert number*] calendar days following discovery of a breach of unsecured PHI. Such notice shall include, to the extent possible:

(A) The identification of each individual whose unsecured PHI has been, or is reasonably believed by Business Associate to have been, accessed, acquired, or disclosed during the breach;

(B) The date of the breach;

(C) The date of the discovery of the breach;

(D) A description of the types of unsecured PHI that were involved; and

(E) Any other details necessary to complete an assessment of the risk that the PHI has been compromised.

[*Reference: 45 C.F.R. §§ 164.410 & 164.404(c).]*

(g) Arrangements with Subcontractors. Business Associate shall enter into a business associate agreement with any subcontractor of Business Associate that creates, receives, maintains, or transmits PHI on behalf of Business Associate, pursuant to which the subcontractor shall agree to comply with the applicable requirements of HIPAA and the same restrictions and conditions that apply to Business Associate with respect to that PHI pursuant to this Business Associate Agreement, and pursuant to which Business Associate shall obtain satisfactory assurances that the subcontractor shall appropriately safeguard that PHI [References: 45 C.F.R. § 164.308(b)(2), 45 C.F.R. § 164.314(a)(2)(i)(B) & 45 C.F.R. § 164.504(e)(2)(ii)(D)].

(h) Individuals’ Access to PHI. If and to the extent that Business Associate maintains PHI in a designated record set, Business Associate shall upon request by Covered Entity make that PHI available to Covered Entity within **[***insert number***]** business days as and to the extent required for Covered Entity’s compliance with its obligations to provide individuals with access to and copies of PHI pursuant to 45 C.F.R. § 164.524. If Business Associate receives an individual’s request for access to PHI, Business Associate shall forward that request to Covered Entity within **[***insert number***]** business days. Covered Entity shall be responsible for making all determinations regarding the granting or denial of an individual’s request, and for notifying individuals thereof, and Business Associate shall not make any such determinations or notifications [*Reference: 45 C.F.R. §§ 164.502(a)(4)(ii) & 164.504(e)(2)(ii)(E)*].

(i) Amendments to PHI. If and to the extent that Business Associate maintains PHI in a designated record set, Business Associate shall upon request by Covered Entity make that PHI available to Covered Entity within **[***insert number***]** business days for amendment, and shall promptly incorporate any amendments to PHI directed by Covered Entity, as and to the extent required for Covered Entity’s compliance with 45 C.F.R. § 164.526[[86]](#footnote-87). If Business Associate receives an individual’s request for an amendment to PHI, Business Associate shall forward that request to Covered Entity within **[***insert number***]** business days. Covered Entity shall be responsible for making all determinations regarding the granting or denial of an individual’s request, and for notifying individuals thereof, and Business Associate shall not make any such determinations or make any such amendments except as directed by Covered Entity [*Reference: 45 C.F.R. § 164.504(e)(2)(ii)(F)*].

(j) Accountings of Disclosures. Business Associate shall document disclosures of PHI as required to provide Covered Entity with information sufficient to respond to any request by an individual for an accounting of disclosures in compliance with 45 C.F.R. § 164.528, and shall provide such information to Covered Entity upon request within **[***insert number***]** business days.[[87]](#footnote-88) If Business Associate receives an individual’s request for an accounting of disclosures, Business Associate shall forward that request to Covered Entity within **[***insert number***]** business days. Covered Entity shall be responsible for providing all accountings of disclosures to individuals, and Business Associate shall not provide any such accountings to individuals directly [*Reference: 45 C.F.R. § 164.504(e)(2)(ii)(G)*].

(k) Other Obligations. To the extent that Business Associate is, pursuant to the Participation Agreement or this Business Associate Agreement, responsible to carry out an obligation of Covered Entity under HIPAA, Business Associate shall comply with the requirements of HIPAA that apply to Covered Entity in the performance of that obligation [*Reference: 45 C.F.R. § 164.504(e)(2)(ii)(H)*].

(l) Books and Records. Business Associate shall make its internal practices, books, and records relating to the use and disclosure of PHI received from, or created or received by Business Associate on behalf of Covered Entity, available to the U.S. Secretary of Health & Human Services for purposes of determining Covered Entity’s or Business Associate’s compliance under HIPAA [*Reference: 45 C.F.R. § 164.504(e)(2)(ii)(I)*]. Without limiting the generality of the foregoing, Business Associate shall disclose PHI when required by the U.S. Secretary of Health & Human Services under Subpart C of 45 C.F.R. Part 160 to investigate or determine Business Associate’s compliance with HIPAA [*Reference: 45 C.F.R. § 164.502(a)(4)(i)*].

3. Covered Entity’s Obligations.

(a) Notice of Change in Privacy Practices. Covered Entity shall notify Business Associate of any limitation(s) in Covered Entity’s notice of privacy practices in accordance with 45 C.F.R. §164.520, to the extent that such limitation may affect Business Associate’s use or disclosure of PHI.

(b) Notice of Change in Permissions. Covered Entity shall notify Business Associate of any changes in, or revocation of, permission by an individual to use or disclose PHI, to the extent that such changes may affect Business Associate’s use or disclosure of PHI.

(c) Notice of Change in Use. Covered Entity shall notify Business Associate of any restriction to the use or disclosure of PHI that Covered Entity has agreed to in accordance with 45 C.F.R. §164.522, to the extent that such restriction may affect Business Associate’s use or disclosure of PHI.

(d) Appropriate Requests. Covered Entity shall not request that Business Associate use or disclose PHI in any manner that would not be permissible under HIPAA if done by Covered Entity.

4. Term and Termination.

(a) Term. Subject to the other provisions of this Section 4 (Term and Termination), the term of this Business Associate Agreement shall be coextensive with that of the Participation Agreement.

(b) Termination. If Covered Entity knows of a pattern of activity or practice by Business Associate that constitutes a material breach or violation of Business Associate’s obligations under HIPAA or this Business Associate Agreement, and after taking reasonable steps to cure that breach have been unsuccessful, Covered Entity may terminate this Business Associate Agreement and the Participation Agreement, if feasible, subject to and in accordance with the terms and conditions of Section 3.4 of the Participation Agreement [*Reference: 45 C.F.R. §§ 164.504(e)(1)(ii) & 164.504(e)(2)(iii)*].

(c) Breach Pattern of Practice by Covered Entity. If Business Associate knows of a pattern of activity or practice by Covered Entity that constitutes a material breach or a violation of Covered Entity’s obligations under HIPAA or this Business Associate Agreement, and after taking reasonable steps to cure that breach have been unsuccessful, Business Associate may terminate this Business Associate and the Participation Agreement, if feasible, subject to and in accordance with the terms and conditions of Section 3.4 of the Participation Agreement.

(d) Conduct Upon Termination. Upon termination or expiration of this Business Associate Agreement, Business Associate shall, at Covered Entity’s written direction, either destroy or return to Covered Entity all PHI in Business Associate’s possession and/or in the possession of any subcontractor of Business Associate, and shall not retain any copies of such PHI; provided, however, that Business Associate and/or Business Associate’s subcontractor may retain PHI as and to the extent necessary, and only for so long as necessary, for Business Associate or that subcontractor to continue its proper management and administration or to carry out its legal responsibilities. In the event that return or destruction of PHI is not feasible, Business Associate shall provide to Covered Entity notification of the conditions that make return or destruction of the PHI not feasible, and Business Associate shall extend the protections of this Business Associate Agreement, including without limitation Section 2(e) (Safeguards), to such PHI that is not returned or destroyed, and limit further uses and disclosures of such PHI to those purposes that make the return or destruction not feasible, for as long as Business Associate or any subcontractor of Business Associate maintains such PHI. If PHI is to be destroyed pursuant to this Section 4(d), Business Associate shall certify in writing to Covered Entity that such PHI has been destroyed [*Reference: 45 C.F.R. § 164.504(e)(2)(ii)(J)*].

5. Relationship to Participation Agreement. In the event that a provision of this Business Associate Agreement is contrary to a provision of the Participation Agreement pertaining to Business Associate’s performance of its obligations as a business associate, the provisions of this Business Associate Agreement shall control.

6. Amendment. The parties agree to take such action from time to time as is necessary to amend this Agreement for Covered Entity and Business Associate to comply with HIPAA or other applicable law. The parties agree that this Agreement may only be modified by mutual written amendment, signed by both parties, effective on the date set forth in the amendment.

7. Interpretation. Any ambiguity in this Agreement shall be interpreted to permit compliance with HIPAA.

8. No Third Party Beneficiaries. Unless otherwise set forth herein, nothing contained herein is intended nor shall be construed to create rights running to the benefit of third parties.

9. Waiver. Any failure of a party to insist upon strict compliance with any term, undertaking or condition of this Agreement shall not be deemed to be a waiver of such term, undertaking or condition. To be effective, a waiver must be in writing, signed and dated by the parties to this Agreement.

10. Counterparts. This Agreement may be executed in multiple counterparts, each of which shall be deemed an original and all of which together shall be deemed one and the same instrument. Any photocopy of this executed Agreement may be used as if it were the original.

11. Governing Law. Notwithstanding any other provision to the contrary, this Agreement shall be governed and construed in accordance with the laws of the State of California.

Signature Page Follows

BUSINESS ASSOCIATE AGREEMENT

Signature Page

In witness whereof, Covered Entity and Business Associate have entered into this Agreement as of the Effective Date of the Participation Agreement.

|  |  |
| --- | --- |
| “Covered Entity”[*Name of Participant*], [*form of the Participant’s organization, e.g., a California corporation*]By: Name: Title:  | “Business Associate”[*Insert name of Health Information Sharing Organization*], [*insert form of Health Information Sharing Organization’s organization, e.g., a California nonprofit public benefit corporation*]By: Name: Title:  |

1. These materials are based in part on the Model Contract for Health Information Exchange published by the Markle Foundation (www.connectingforhealth.org). [↑](#footnote-ref-2)
2. Section 1.4 (Description of Services) should provide a brief description of the services the HIO provides, and should describe the basic relationships between the HIO and its Participants. [↑](#footnote-ref-3)
3. Under Model #1, the HIO serves as a conduit for the transfer of Patient Data from one Participant to another, such as in connection with the delivery of diagnostic testing results to the health care provider that ordered those tests. Under Model #1, the HIO’s services do not include establishing or applying standards for the Participants’ exchange of Patient Data; instead, Participants remain responsible to agree among themselves as to the privacy, security and other standards that are to apply to their exchange of Patient Data, *e.g.*, they may exchange data pursuant to the DURSA or another arrangement. Under Model #1, the HIO’s services do not cause it to have access to or to maintain Patient Data. [↑](#footnote-ref-4)
4. Under Model #2, the HIO serves as a conduit providing data transport services as under Model #1. However, under Model #2, the HIO establishes and applies privacy, security and/or other standards for the Participants’ exchange of Patient Data. [↑](#footnote-ref-5)
5. Under Model #3, the HIO serves as a conduit providing data transport services as under Models #1 and #2.  However, under Model #3, the HIO performs certain additional data transmission services that require it to have access to and/or to be responsible to maintain some Patient Data on behalf of its Participants. [↑](#footnote-ref-6)
6. Under Model #4, the HIO operates a federated health information exchange, pursuant to Participants make information available to other Participants who may gain access to that information upon request, and the HIO does not aggregate or maintain a repository of Patient Data. [↑](#footnote-ref-7)
7. Under Model #5, the HIO operates as a federated health information exchange as under Model #4, and the HIO aggregates and/or maintains a repository of Patient Data. [↑](#footnote-ref-8)
8. The term “Authorized User” is used to identify the individual users of the HIO’s Services. Authorized Users would receive their rights to use the HIO’s Services either by registering as Participants themselves or through their employment or other relationship with an organization that registers as a Participant and designates individuals who will be authorized to use the HIO’s Services on that Participant’s behalf. For example, an Authorized User may be an individual physician who registers as a Participant. In the alternative, an Authorized User may be a member of the physician-Participant’s office staff designated by the physician to act as an Authorized User, or an employee or medical staff member of a hospital-Participant authorized by the hospital to act as an Authorized User. [↑](#footnote-ref-9)
9. The Terms and Conditions distinguish between those Participants who provide data to the HIO (“Data Providers”) and those who use that data (“Data Recipients”). A Participant may be a Data Provider, a Data Recipient, or both. Participants are identified as Data Providers and/or Data Recipients during the application process (Section 2.4.1 (Participation Agreement Required)). [↑](#footnote-ref-10)
10. Under Model #4, the HIO operates as a record-locator service-based, federated network, and not as a party that maintains a repository of health information. Therefore, the Terms and Conditions do not contemplate that consumers will register as Data Providers to use the HIO’s System as a personal health record. However, the Terms and Conditions would permit an entity providing such a personal health record service to consumers could register as a Data Provider. [↑](#footnote-ref-11)
11. The phrase “similarly situated” is used here to convey that the term “Other HIO” need not be interpreted to refer only to entities that are currently described as “health information exchanges,” “RHIOs” and “health information organizations,” and so on. For example, it is possible that, in the future, electronic health records and other products and services will be deployed with some health information sharing capabilities, and the term “Other HIO is intended to apply to the operators of such other products and services. [↑](#footnote-ref-12)
12. Note that the term “Participant” is used to refer both to Data Providers and to Data Recipients. [↑](#footnote-ref-13)
13. The Terms and Conditions assume that the HIO will be operated in accordance with policies and procedures that the HIO develops, perhaps in consultation with Participants and other stakeholders. See Section 12 (Governance). [↑](#footnote-ref-14)
14. Alternative A for Section 2.2(b) assumes that the HIO has decided to participate in other health information sharing efforts, and therefore to comply with those other efforts’ applicable rules. If the HIO does not decide to do so, this provision should be omitted. [↑](#footnote-ref-15)
15. It is noted that the “legally binding agreements with the HIO” referred to here is commonly known as an “InterHIO Agreement.” [↑](#footnote-ref-16)
16. It is noted that the laws that apply to the Other HIO, and with which the Other HIO is to be obligated to comply by this provision, may be those of a State or jurisdiction other than California, *e.g.*, if that Other HIO operates in a State other than California. [↑](#footnote-ref-17)
17. The Terms and Conditions do not specify a method of authentication, because an industry consensus on this subject has not emerged as of the date of this document’s publication. [↑](#footnote-ref-18)
18. The Other HIO is called upon to disable access for users when they are no longer authorized in order to ensure that users that are no longer active could access the subject HIOs systems either. [↑](#footnote-ref-19)
19. The term “appropriate indemnification” in this context acknowledges that, in certain circumstances, indemnification may not be permitted by applicable law. The Terms and Conditions do not specify what, if any, indemnification obligations should be imposed upon the Other HIO, but the notion of cross-indemnification was recognized as a suitable approach, *i.e.,* in the case where the Other HIO is indemnified by its users then these indemnifications should flow to the HIO and its Participants as well. See Section 16.2 (Indemnification). [↑](#footnote-ref-20)
20. Some HIOs may find it appropriate to have changes to the Terms and Conditions and/or Policies and Procedures subject to prior review and/or approval by a body that represents the interests of Participants and/or other Stakeholders, *e.g.*, the Management Committee described in Section 12.2 (Meetings and Responsibilities of Management Committee). [↑](#footnote-ref-21)
21. Where the number of days is shown in brackets, *e.g.*, “[thirty (30)] days,” the user of this document is encouraged to determine the appropriate number of days to be used. [↑](#footnote-ref-22)
22. The Terms and Conditions assume that the HIO may make changes to the governing documents from time to time as it determines appropriate, but that Participants must either consent or acquiesce to changes that affect their rights or obligations (see Section 2.3 (Changes to Terms and Conditions and Policies and Procedures) and Section 3.2 (Participant’s Termination of Participation Agreement Based on Objection to Change). [↑](#footnote-ref-23)
23. The HIO may determine that it is appropriate for Participants and/or other stakeholders to be involved in the development of the Terms and Conditions and/or Policies and Procedures, as well as participate in decisions to make changes (see Section 12 (Governance)). [↑](#footnote-ref-24)
24. Under Alternative A, the HIO may make changes to the Terms and Conditions and/or the Policies and Procedures at any time, without the prior approval of the Participants. Participants who object to such changes may be given the right to terminate their Participation before those changes become effective, pursuant to Section 3.2 (Termination of Participation Agreement Based on Objection to Change). [↑](#footnote-ref-25)
25. Under Alternative B, the HIO may make changes to the Terms and Conditions and/or the Policies and Procedures at any time, without the prior approval of the Participants, but only as required to comply with applicable laws and regulations. Participants who object to such changes may be given the right to terminate their Participation before those changes become effective, pursuant to Section 3.2 (Termination of Participation Agreement Based on Objection to Change). [↑](#footnote-ref-26)
26. Under Alternative C, the HIO may make changes to the Policies and Procedures as needed, but may not amend the other terms of Terms and Conditions with respect to a Participant without the agreement of the Participant. [↑](#footnote-ref-27)
27. The Terms and Conditions assume that the HIO will wish to have each Participant assigned to a particular category or “Participant Type,” based on the role that Participant plays in the health care system. [↑](#footnote-ref-28)
28. The Terms and Conditions assume that HIO will describe procedures and other requirements for the process by which parties apply to become Participants. Alternative A is drafted to provide allow the HIO to approve or disapprove applications in its discretion. The HIO may wish to adopt specific credentialing criteria for Participants, which may, if desired by the HIO, be set forth in the Terms and Conditions. The HIO may wish to consider whether it wishes to disclose to an unsuccessful applicant the bases upon which its application for participation was not approved. [↑](#footnote-ref-29)
29. Alternative B recognizes that certain HIOs, *e.g.*, those organized to serve specific communities, may choose to limit their discretion to accept and/or reject potential participants. In addition, Alternative B contemplates that certain HIOs may have standards in their governing documents, *e.g.*, Bylaws that specify the criteria upon which Participants will be selected. [↑](#footnote-ref-30)
30. The Terms and Conditions give the HIO some discretion to create exceptions to the Terms and Conditions and Policies and Procedures, as the HIO determines necessary for particular Participants that enter into written Participation Agreements. For example, a Participant may wish to purchase additional services from the HIO for which it would not be appropriate to require all other Participants to pay, or a Participant may wish to enter into a Participation Agreement on behalf of a number of entities comprising an organized health care arrangement (“OCHA”), or a Participant that is a governmental entity might have unique contracting, procurement or other requirements. [↑](#footnote-ref-31)
31. Alternative C of Section 2.5 assumes that Alternative B of Section 3.1 (Term of Participation Agreements) is used. [↑](#footnote-ref-32)
32. Alternative B of Section 3.1 assumes that Alternative C of Section 2.5 (Change or Termination of Services) is used. [↑](#footnote-ref-33)
33. The Terms and Conditions allow the HIO to change the Terms and Conditions and/or the Policies and Procedures at will and allows Participants to opt out if they object to the change. [↑](#footnote-ref-34)
34. As the following alternatives show, the HIO may wish to allow Participants to terminate their participation freely at any time, or to require that termination be preceded by a substantial period of advance notice, or to require that Participants maintain their participation for a year (or longer) at a time. [↑](#footnote-ref-35)
35. Note that this basis for termination may be combined with Alternatives Two or Three and/or Five. [↑](#footnote-ref-36)
36. Note that this basis for termination may be combined with Alternatives Two or Three and/or Four. [↑](#footnote-ref-37)
37. The HIO may not wish to reserve the right to terminate Participation Agreements without cause. Section 3.7 (HIO’s Termination of Participation Agreement Without Cause) may be omitted. If, however, the HIO wishes to have the ability to terminate Participation Agreements without cause prior to the expiration of their terms (*see* Section 3.1 (Term of Participation Agreements, *Alternative B*), then it should consider one of the alternatives described in this Section 3.7 (HIO’s Termination of Participation Agreement Without Cause). [↑](#footnote-ref-38)
38. Note that this provision may be combined with Alternatives Two or Three. [↑](#footnote-ref-39)
39. The Terms and Conditions assume that user agreements will not be required of every individual who uses the HIO’s System or Services. Instead, Participants will be responsible for designating the individuals within their organizations who would be authorized to use the HIO’s System and Services (“Authorized Users”). [↑](#footnote-ref-40)
40. If the HIO is to act, as under Model #1, as a simple conduit for transmissions of Patient Data between Participants at their own control, and will not be establishing or applying or implementing privacy, security or other standards for those Participants, the provisions of Section 4 (Authorized Users) will not be necessary. [↑](#footnote-ref-41)
41. Alternative A provides that the HIO will administer the credentialing of Authorized Users and the management of their rights to use the System and Services. Alternative A assumes that the Participant will be permitted to select its Authorized Users without review or approval by the HIO. The HIO may, however, wish to adopt specific credentialing criteria for Authorized Users that would be administered by the HIO, and which may, if desired, be set forth in the Terms and Conditions. [↑](#footnote-ref-42)
42. Alternative B provides that the Participant will manage the rights of Authorized Users. The HIO may establish minimum standards that would be set forth in the Policies and Procedures. [↑](#footnote-ref-43)
43. The Terms and Conditions assume that the HIO will issue and manage passwords for Authorized Users. This provision may vary from HIO to HIO, depending upon how each HIO decides to allocate responsibilities between the HIO and Participants regarding the administration of Authorized Users and the security measures it chooses to adopt. It is also possible that the Policies and Procedures and/or Other Health Information Sharing Programs’ Policies and Procedures will impose minimum requirements for passwords and/or other security measures, with which the HIO and Participants would be required to comply. [↑](#footnote-ref-44)
44. Section 5.3 (System Security) may be omitted for Model #1, under which the HIO does not establish and apply privacy, security and other standards for health information exchange. [↑](#footnote-ref-45)
45. Section 5.6 (Training) may be omitted for Model #1, under which the HIO does not establish and apply privacy, security and other standards for health information exchange. [↑](#footnote-ref-46)
46. For Model #1, under which the HIO will not be establishing or applying privacy, security and/or other standards for health information exchange, Alternative A is appropriate. [↑](#footnote-ref-47)
47. Section 6.2 (Permitted Purposes for Use of System and Services) addresses the circumstances in which Data Recipients may use the HIO’s System and Services to obtain Patient Data. For example, a HIO may allow a Data Recipient to use the System and Services to obtain an individual’s Patient Data only in the context of providing treatment to that individual. The Terms and Conditions assumes that the HIO will also impose limits on the uses to which a Data Recipient may put that Patient Data, and those provisions are discussed in Section 7.5 (Limitations on Use [and Disclosure] of Patient Data). [↑](#footnote-ref-48)
48. For Model #1, under which the HIO will not establish or apply privacy, security or other standards for health information exchange, this optional language would be unnecessary. [↑](#footnote-ref-49)
49. For Model #1, under which the HIO will not establish or apply privacy, security or other standards for health information exchange, Section 6.6 (Permitted and Prohibited Uses of Patient Data) would be unnecessary. [↑](#footnote-ref-50)
50. It is anticipated that most HIOs will not impose restrictions upon Data Recipients’ uses and disclosures of Patient Data that they acquire through the use of the Services and the System, but for purposes of promoting trust among data-sharing Participants, the Terms and Conditions provide for their respective compliance with applicable laws. [↑](#footnote-ref-51)
51. Some HIOs may wish to impose specific limitations upon Data Recipients’ uses and disclosures of Patient Data they acquire through use of the System and the Services, by providing for specified prohibited uses and disclosures. [↑](#footnote-ref-52)
52. Some HIOs may wish to impose more general limitations upon Data Recipients’ uses and disclosures of Patient Data they acquire through use of the System and the Services, by providing only for limited permitted uses and disclosures. [↑](#footnote-ref-53)
53. Under Model #1, under which the HIO will not be establishing or applying privacy, security or other standards for health information exchange, Section 7.2 (Provision of Data) will be unnecessary. [↑](#footnote-ref-54)
54. Under Model #1, under which the HIO will not be establishing or applying privacy, security or other standards for health information exchange, Section 7.3 (Measures to Assure Accuracy of Data) will be unnecessary. [↑](#footnote-ref-55)
55. The HIO may wish to impose specified requirements upon Data Providers with respect to the measures they must take to assure the quality of the Patient Data they provide. These measures may include, for example, requiring Data Providers to adopt benchmark practices for increasing and maintaining data quality and/or requiring Participants to conduct a data quality assessment and improvement project either before or after becoming a Participant. [↑](#footnote-ref-56)
56. Under Model #1, under which the HIO will not be establishing or applying privacy, security or other standards for health information exchange, Section 7.4 (Grant of License to Use Patient Data) will be unnecessary. [↑](#footnote-ref-57)
57. For example, the Policies and Procedures may generally permit Data Recipients to use Patient Data obtained through the System and Services for any purpose that does not require patient authorization pursuant to HIPAA or applicable state law. In the interests of clarity, however, the Policies and Procedures can describe certain permitted uses including limitations, *e.g.*, for treatment, quality improvement activities, and/or evaluation by private accrediting organizations. [↑](#footnote-ref-58)
58. Under Model #1, under which the HIO will not be establishing or applying privacy, security or other standards for health information exchange, Section 7.5 (Limitations on Use of Patient Data) will be unnecessary. [↑](#footnote-ref-59)
59. Some HIOs may find it necessary to agree to Data Providers’ demands to impose specific limitations upon the use or disclosure of the Patient Data those Data Providers provide. See Section 6.6 (Permitted [and Prohibited] Uses and Disclosures of Patient Data). [↑](#footnote-ref-60)
60. Under Model #1, under which the HIO will not be establishing or applying privacy, security or other standards for health information exchange, Section 7.6 (Limitations on Disclosure of Patient Data) will be unnecessary. [↑](#footnote-ref-61)
61. Some HIOs may wish to impose specific limitations upon the extent to which Data Providers furnish Patient Data. Those specific limitations may be described in the Policies and Procedures. [↑](#footnote-ref-62)
62. Some HIOs may find it appropriate to articulate specific rules regarding the extent to which Data Providers are to furnish Patient Data, as a means of developing trust among Data Recipients that they will not be receiving information that the Data Provider was not permitted to share. Alternative C provides an example of how an HIO may address this issue. [↑](#footnote-ref-63)
63. The specifications and/or service standards that will apply to Associated Software and Associated Hardware provided by the HIO, and the warranties the HIO would make in connection therewith, will vary based upon the specific technology to be provided by the HIO. These technology-specific concerns are beyond the scope of this document. The document recognizes the importance of these matters and provides for them to be described on Schedule 8. [↑](#footnote-ref-64)
64. The Terms and Conditions assume that Stark, PORA, Business and Professions Code § 650 and Anti-Kickback law issues that, depending upon the relationship of the HIO to its Participant, may arise from the HIO’s provision of software, hardware and services, will have been resolved. [↑](#footnote-ref-65)
65. If the HIO uses open source software, the terms of Section 8.2 (Grant of License) and the following sections should be modified accordingly. [↑](#footnote-ref-66)
66. The HIO will be required to modify these provisions to reflect the limitations upon use of Associated Software appropriate to the HIO’s particular circumstances. For example, if the Associated Software were to be open source, this provision would not be appropriate. [↑](#footnote-ref-67)
67. If the HIO negotiates the terms of the applicable contracts with third-party vendors, it can assure Participants uniform terms and conditions that may be described either in the Policies and Procedures or in an attachment to this document. [↑](#footnote-ref-68)
68. Under Model #1, under which the HIO will not be establishing or applying privacy, security or other standards for health information exchange, 9 (Privacy and Security of Patient Data) will be unnecessary. [↑](#footnote-ref-69)
69. Health care providers and other entities covered by HIPAA (and their business associates) and/or CMIA are subject to multiple legal requirements regarding the reporting of data breaches and security incidents. The provisions of Section 9.2 (Reporting of Breaches and Security Incidents) are not required for compliance with those laws. However, HIOs may find that establishing the reporting mechanisms described in Section 9.2 (Reporting of Breaches and Security Incidents) will prove sufficiently valuable in promoting trust among Participants to justify their additional burdens. Further, to the extent an HIO is acting as a business associate to a HIPAA-covered entity, it will be under HIPAA required to make timely notification of a breach of unsecured PHI to that covered entity. See Exhibit 1. The obligations described in Section 9.2 (Reporting of Breaches and Security Incidents) to report breaches and security incidents apply only to events involving “Patient Data.” Section 1.5.13 defines “Patient Data” to include only Patient Data exchanged by the HIO’s System or Services. Thus, Section 9.2 (Reporting of Breaches and Security Incidents) requires that Participants only report breaches and security incidents that directly relate to the Patient Data exchanged through the HIO, and does not require Participants to report on other privacy breaches and security incidents that they are not otherwise required to disclose publicly. [↑](#footnote-ref-70)
70. While not required by HIPAA or HITECH, the HIO may find it helpful to establish mechanisms by which all Participants are kept informed of the breaches that are most likely to affect them and/or their participation in health information sharing. These mechanisms may support the HIO’s efforts to enhance accountability and transparency within the health information sharing effort (see Section 17 (Transparency, Oversight, Enforcement and Accountability)). [↑](#footnote-ref-71)
71. Under Model #1 and #2, pursuant to which the HIO does not access or maintain Patient Data, no business associate contract would be required. [↑](#footnote-ref-72)
72. The Terms and Conditions assume that the HIO will provide a variety of services to Participants. Responsibilities may include system support, installation support, initial and ongoing training, help desk, problem resolution, auditing and reporting access and use, and reporting unauthorized uses and security incidents. [↑](#footnote-ref-73)
73. A listing of all laws and regulations that may apply to an HIO’s responsibilities is beyond the scope of this document. It is noted, however, that Section 56.06 of the California Civil Code provides that “a business organized for the purpose of maintaining medical information in order to make the information available to . . . a provider of health care at the request of [an] individual or a provider of health care . . . for the diagnosis and treatment of [an] individual” shall be treated as a “provider of health care” under the California Confidentiality of Medical Information Act (California Civil Code § 56 – 56.37), and be subject to the applicable requirements of that Act. [↑](#footnote-ref-74)
74. The HIO’s monitoring of Participants might include such activities as periodic audits of Participant’s compliance with specifications listed in the Policies and Procedures. [↑](#footnote-ref-75)
75. This provision would apply only to Model #5, pursuant to which the HIO maintains a repository of Patient Data and would be permitting disclosures of that data. [↑](#footnote-ref-76)
76. The HIO may provide additional services to Participants and/or other parties that involve the use of the System, the Services and/or Patient Data, e.g., offering a patient portal and/or interfaces to such portals. [↑](#footnote-ref-77)
77. Certain HIOs may wish to include certain terms regarding internal governance and management as a part of the Terms and Conditions, to assure that Participants may be involved in their governance and/or management. The language provided here is for illustration only, and is not intended to limit how the HIO would structure its governance or Participants’ involvement in governance and management. HIOs that do not desire such provisions would omit this section entirely [↑](#footnote-ref-78)
78. Issues that a Management Committee could address include, without limitation, technical issues, privacy, the scope of information stored and accessed by Participants, the use of the information, changes to the Terms and Conditions and/or Policies and Procedures, and any other issues related to the network or the parties’ participation therein. [↑](#footnote-ref-79)
79. A Fee Schedule may include a variety of fee levels, permitting the HIO to charge greater and lesser amounts to Participants, depending upon the extent to which each elects to receive Services and/or hardware and software. [↑](#footnote-ref-80)
80. In certain circumstances, it may be necessary or appropriate for the HIO’s liability for certain matters not to be subject to a maximum aggregate limit, or to be subject to a different limit. For example, it may be decided that a limitation of liability will not apply if: (1) the liability arises from the HIO’s failure to comply with the Policies and Procedures; (2) from a specific type of event, such as a breach of unsecured protected health information that could have been prevented had the HIO taken steps to secure the information in question in accordance with applicable HHS guidance; or (3) other events for which the HIO determines that the risk of liability and associated expenses is outweighed by the benefit to be obtained by assuring Participants that the HIO will be responsible for specified risks of loss. [↑](#footnote-ref-81)
81. These provisions suggest mechanisms other than those available in law and equity to contractual parties by which HIOs and Participants may enforce adherence to the Policies and Procedures. These provisions suggest two basic additional mechanisms for enforcement: transparency, which will inform other Participants of each Participant’s conduct; and enforcement, whereby the HIO may expand its involvement in the enforcement of Participation Agreements by actively monitoring the conduct of Participants. [↑](#footnote-ref-82)
82. The Terms and Conditions do not propose a specific alternate dispute resolution mechanism, e.g. arbitration and/or mediation, but individual HIOs may wish to consider including such a mechanism. [↑](#footnote-ref-83)
83. The Terms and Conditions assume that the HIO will be acting as the independent contractor of each Participant, and not as an agent. If, pursuant to a Participation Agreement, the HIO assumes the obligations of an agent of a Participant, substantial revisions of the Terms and Conditions may be required. [↑](#footnote-ref-84)
84. Participants subject to reporting requirements such as those that apply pursuant to California Health & Safety Code Section 1280.15, will wish to require the reporting of breaches within a period of time that is sufficiently short to facilitate compliance with those reporting requirements. [↑](#footnote-ref-85)
85. Please see section 9.2.1 of the MMPA. Please also note that upon learning of a breach from a business associate, a covered entity must conduct a risk assessment to determine whether individual notification is necessary. If it is, a covered entity must notify individuals of the breach without unreasonable delay, but in no cases longer than 60 days from being informed of the breach. If a business associate is acting as an agent of a covered entity, which is determined using a “totality of the circumstances” test, the business associate’s discovery of a breach is imputed to the covered entity. This means the covered entity’s 60-day window to notify begins on the date of the business associate’s discovery. As a result of these requirements, a business associate and covered entity negotiating this contract may choose to substitute a timeframe that is shorter than 60 days. This is permissible under HIPAA, but any timeframe longer than 60 days would risk violating HIPAA. [↑](#footnote-ref-86)
86. Once a covered entity has received an individual’s request for an amendment of his or her designated record set, the covered entity must act on this request within 60 calendar days of receiving such a request and is allowed one 30-day extension under certain conditions. *45 C.F.R. § 164.526(b)(2).* Entrants into this contract should be aware of these HIPAA requirements when negotiating a timeframe for this provision. [↑](#footnote-ref-87)
87. With limited exceptions, covered entity must act on an individual’s request for an accounting of disclosures no later than 60 days after the receipt of such a request and is allowed one 30-day extension under certain conditions. *45 C.F.R. § 164.528(c).* Entrants into this contract should be aware of these HIPAA requirements when negotiating a timeframe for this provision. [↑](#footnote-ref-88)