



digital bridge



Recommendations for Agreement Types

February 24, 2017

Recommendations and Agreements

Draft agreement content provided for discussion and Digital Bridge planning purposes. This includes references to regulatory issues specific to some state laws and regulations.

A. Provider to Intermediary

The Health Care Providers ["HCP"] must first enter into a **Business Associate Agreement ["BAA"] / Data Use Agreement ["DUA"]** with the Association of Public Health Laboratories ["APHL"]. The DUA can be incorporated into the BAA and should include the following provisions:

BUSINESS ASSOCIATE AND DATA USE AGREEMENT

NAME OF COVERED ENTITY: _____

COVERED ENTITY FEIN/TAX ID: _____

COVERED ENTITY ADDRESS: _____

This **Business Associate and Data Use Agreement** ("Agreement") is effective as of the date signed by both parties ("Effective Date") between _____ ("Covered Entity") and the Association of Public Health Laboratories ["APHL"] and shall continue until terminated in accordance with Section 10 below.

WHEREAS, Covered Entity desires to participate in the exchange of Protected Health Information ("PHI") with APHL, specifically infectious or communicable disease case or suspected case reports. This data platform administered by APHL requires Covered Entity to allow APHL to have access to Covered Entity's Protected Health Information ("PHI"); and

WHEREAS, Covered Entity and APHL may have entered into one or more certain written agreement(s) regarding Covered Entity's participation in the APHL program(s) ("Underlying Agreement(s)").

- a. General Business Associate and Data Use Provisions
- b. Definitions
- c. Specific Permitted Uses and Disclosures
- d. General Uses and Disclosures
- e. Obligations of APHL as Business Associate
- f. Data Use Agreement Obligations
- g. General Obligations of Covered Entity
- h. Insurance
- i. Indemnification
- j. Termination
- k. Effect of Termination on APHL Obligation to Destroy or Protect Data
- l. Effect of Termination on Provision of Data to APHL
- m. Regulatory References

- n. Amendment
- o. Interpretation
- p. Relationship to Underlying Agreement(s)
- q. Assignment
- r. Severability
- s. Entire Agreement
- t. Jurisdiction
- u. Third Party Beneficiaries
- v. Waiver
- w. Relationship of the Parties
- x. Authority
- y. Notices

DATA USE AGREEMENT

This Data Sharing [Use] Agreement is made and entered into by and between **MICHIGAN HEALTH INFORMATION NETWORK SHARED SERVICES**, a Michigan nonprofit corporation ("HIN"), and the undersigned Participating Organization APHL, on _____ 20__ ("Effective Day"). HIN and Participating Organization are referred to herein collectively as "**Parties**" and individually as a "**Party**."

RECITALS

- A. Participating Organizations have each individually entered into a Qualified Data Sharing Organization Agreement or similar agreement with HIN for participating in the HIE Platform, which is Michigan's initiative to improve health care quality, cost, efficiency and patient safety through electronic exchange of health information;
- B. Using the HIE Platform requires that the Parties electronically exchange data; and
- C. The purpose of this Agreement is to provide a legal framework within which the Participating Organizations will exchange cases and suspected cases of Infectious or Communicable Diseases through the HIE Platform.

NOW THEREFORE, the Parties agree as follows:

- A. APPLICATION; DEFINITIONS
- B. USE OF MESSAGE CONTENT
 - a. Permitted Purposes
 - b. Permitted Future Uses
 - c. Management Uses
 - d. Informed Opt Out
- C. SYSTEM ACCESS POLICIES
- D. USE CASES
 - a. Adoption of New Use Cases
 - b. General Compliance
 - c. Use Case Change Process
 - d. Determination of Materiality
 - e. Non-Material Changes to Use Cases
 - f. Material Changes to Use Cases
 - g. Withdrawing from a Use Case
- E. EXPECTATION OF PARTICIPANTS

- a. Exchanging Messages
 - b. Halt to Message Exchange
 - c. Participant Users and HSPs
 - d. Specific Duties of a Responding Participant
- F. REPRESENTATIONS AND WARRANTIES
 - a. Accurate Information
 - b. Execution of this Agreement and Use Cases
 - c. Compliance with this Agreement
 - d. Compliance with Use Cases
 - e. Accuracy of Message Content
 - f. Express Warranty of Authority to Transmit Message Content
 - g. Express Warranty of Authority to Request Message Content
 - h. Use of Message Content
 - i. Compliance with Laws
 - j. Agreements with Participant Users
 - k. Agreement with Technology Partners
- G. DISCLAIMERS
 - a. Reliance on a System
 - b. Performance of the HIE Platform
- H. TERM AND TERMINATION
 - a. Term
 - b. Disposition of Message Content Upon Termination
- I. MISCELLANEOUS PROVISIONS
 - a. Notices
 - b. Effect of Agreement
 - c. Assignment
 - d. Survival
 - e. Entire Agreement
 - f. Headings
 - g. Relation of the Participants

In the BAA and the DUA between the HCP and APHL, there will need to be references to the reportable, communicable or infectious diseases¹. The following statutes or regulations are included and made a part of this memorandum by attachment².

CALIFORNIA

CA HLTH & S §120130, California, list of reportable diseases

17 CA ADC §2500, California Reporting to the Local Health Authority

TEXAS

TX HEALTH & S §81.041, Texas Reportable Diseases

TX HEALTH & S §81.042, Texas Persons Required to Report

TX HEALTH & S §81.043 Texas Records and Reports of Health Authority

¹ For purposes of many State laws and Regulations, reportable, communicable, notifiable and infectious diseases are used synonymously.

² All referenced statutes and regulations will be attached to the memorandum in separate identifiable files.

TX HEALTH & S §81.044 Texas Reporting Procedures

TX HEALTH & S §81.046 Texas Confidentiality Statute

KANSAS

K.S.A §65-128, Kansas Reportable Diseases for Health Care Providers

K.S.A §§65-6001-65-6007

K.A.R. 28-1-2, 28-1-4, and 28-1-18

K.S.A §65-6828, Kansas controlling law on confidentiality of protected health information

K.S.A §65-6829, Kansas disclosure of protected health information, when required or permitted

K.S.A §65-6822, Kansas health information technology act

MASSACHUSETTS

105 MA ADC 300.020, Massachusetts Definitions

105 MA ADC 300.100, Massachusetts Diseases Reportable to Local Boards of Health

105 MA ADC 300.110³, Massachusetts Case Reports by Local Boards of Health to the Department of Health

105 MA ADC 300.120, Massachusetts Confidentiality

105 MA ADC 300.160, Diseases Reportable by Local Boards of Health to the Department

MICHIGAN

MCL 333.5111, Michigan Disease Reporting

R 325.173

MCL 333.2221, Michigan Department of Health general authority

MCL 333.2226, Michigan Department of Health powers

MCL 333.5111

MCL 333.5114

NEW YORK

NY PUB HEALTH §2139, New York Commissioner Duty to promulgate rules and regulations

NY PUB HEALTH §2101, New York Communicable Diseases physicians duty to report

NY PUB HEALTH §2102, New York Communicable Diseases laboratory duty to report

NY PUB HEALTH §2103, New York Communicable Diseases duty of Local Health Officers to report

NY PUB HEALTH §2104, New York Communicable Diseases duty of municipalities within a county or part-county health district to report

NY PUB HEALTH §2105, New York Communicable Diseases duty to report

CALIFORNIA

CA HLTH & S §120130, California reportable diseases

³ Pursuant to sections 300.100: Case Reports by Local Boards of Health and 300.160: Diseases Reportable by Local Boards of Health to the Department, local boards of health are required to utilize the Department's secure web-based disease surveillance and case management system, namely MAVEN (Massachusetts Virtual Epidemiologic Network), for notifiable diseases.

17 CA ADC §2500, California reporting to the Local Health Authority

B. State Agency to Intermediary

Memorandum of Understanding (“MOU”) with a Trading Partner Agreement (“TPA”)

The agreements between APHL and the State Agency should include terms from both a MOU and a TPA. The terms of the MOU include:

- A. Purpose
- B. Background
- C. Definitions
- D. Project/Opportunity
- E. Joint Responsibilities of the Parties
 - a. Data Sharing
 - b. Data Set Access and Use
 - c. Data Set Content Restriction and Requirements
 - d. Confidentiality and De-Identification/Encryption of Data
- F. APHL Role and Responsibilities
- G. Agency Role and Responsibilities
- H. Open Records Laws
- I. Data Retention/ Data Security
- J. Term and Termination
- K. Ownership of Data
- L. Warranties
- M. Indemnification
- N. Limitation of Liability
- O. Amendment; Waiver
- P. Severability
- Q. Entire Agreement; No Assignment
- R. Governing Law
- S. Notices

Trading Partner Agreement (“TPA”)

In some instances, specifically Massachusetts, a TPA may be used between APHL and Massachusetts Department of Health. An example of this agreement is attached to this document and included in the Massachusetts laws.

C. APHL and the Health Information Network

In most instances APHL will have to enter into Qualified Data Sharing Organization Agreements and a DUA with the State Health Information Network. The State of Michigan has the best illustration of the necessary agreements needed to work through the Health Information Network in a State.

Qualified Data Sharing Organization Agreement (“QDSOA”)

Generally, the terms in this agreement are as follows:

- A. Recitals
- B. Definitions

- C. HIE Platform
- D. Responsibilities of Participating Organization
- E. Responsibilities of HIN
- F. Warranty
- G. Payment
- H. Confidentiality
- I. Term and Termination
- J. Indemnification
- K. Limitation of Liability
- L. Services
- M. General Terms
- N. Debarment, Suspension and Investigation

Attachment A, Data Sharing Agreement

Attachment B, Minimum System Requirements

Attachment C, HIPAA Addendum

Attachment D, Service Levels of HIE Platform

Attachment E, Fees and Payment Schedule

Conclusion

This summation in no way covers all of the laws which might be encountered in negotiating electronic case reporting with the various HCPs, Public Health Agencies and Health Information Networks. The intent of this document is to identify the various agreements needed to implement electronic case reporting in an accurate and efficient way and increase surveillance and better the public's health.