

**APPENDIX C.
MODEL IOA PUBLIC ENTITY DATA SHARING AGREEMENT**

HEALTH INFORMATION EXCHANGE AGREEMENT

between

Insert party and
Insert party

for

Pilot Test of the Insert Parties Public Health Data Exchange Project

Template prepared by:

The Health Information Security and Privacy Collaboration (HISPC)
Interorganizational Agreements (IOA) Collaborative – Public Health Workgroup
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Introduction

Background

This agreement is designed to facilitate secure, electronic exchange of immunization records between insert state A¹ and insert state B, using each state's computerized registry.

States and territories across the U.S. have developed electronic immunization registries to capture immunization records for their residents. The registries are a vital public health tool for monitoring immunization rates and status, and enable health care providers to access a database of immunization histories for their respective patients.

Immunization registries have been partially funded through the Centers for Disease Control and Prevention (CDC), yet states were given autonomy in choosing the design and technical specifications for their respective systems. Such is the case for insert state A and insert state B; each maintains a distinct immunization registry system.

The Pilot Test of the insert state A Immunization Data Sharing Project is designed to demonstrate:

- a. that parties will sign a cross-state data sharing agreement developed by a national Privacy and Security project workgroup² and**
- b. the feasibility of cross-state data exchange, in light of the distinctiveness of the registry systems. Evaluation of several components (e.g., technology, privacy/security, legal processes, resources) will occur throughout the Pilot Test process in order to determine feasibility as well as expansion potential for this type of multi-state, data exchange effort.**

¹ State(s)=state(s) or territories

² The Health Information Security and Privacy Collaboration (HISPC) Interorganizational Agreements (IOA) Collaborative (comprised of 7 states and territories: AK, Guam, IA, NC, NJ, PR, SD) funded by the Office of the National Coordinator for Health Information Technology during HISPC Phase III April 2008-March 2009.

Rationale

Insert state A and insert state B residents often travel back and forth between the states for health care services, including the administration of immunizations for vaccine preventable diseases. Both states have electronic registry systems that track immunizations given to residents. Insert state A's system is called insert system A name. Insert state B's system is called insert system B name.

Both insert system A name and insert system B name follow the functional standards established by the National Immunization Program, which include protecting the confidentiality of health care information and ensuring the security of health care information. Both systems are HIPAA compliant and conform to Public Health Information Network standards, and both use several layers of security and data encryption to protect data in the systems.

Currently, insert state A public health officials cannot monitor the immunization status of their residents who receive health care in insert state B. Any immunizations are tracked in insert system A name and are not shared with Insert state B public health officials for entry into insert system B name. The reverse is true for insert state B. As a result, public health officials in both states cannot effectively monitor immunization status or the spread of vaccine preventable disease outbreaks among residents in their respective states. Other states experience similar disease monitoring problems; therefore, the Pilot Test of the insert states A and B Immunization Data Sharing Project has the potential to lay the foundation for more widespread immunization data exchange efforts.

Project Benefits

While neither insert state A nor insert state B currently shares immunization data on its residents who receive care in the other's state, both seek to enable secure, electronic exchange of immunization data to update and provide for more complete records. Such an exchange will assist each state in realizing a number of benefits:

- **Measure statewide immunizations more accurately**
- **Reduce inefficiencies and costs associated with duplicate vaccines**
- **Provide valuable information during a public health alert (e.g., bad lot of vaccines; vaccine preventable disease outbreak)**
- **Limit resource expenditure with automated electronic processes for exchange**
- **Test and validate privacy and security standards in a pilot atmosphere**
- **Build provider and public trust for electronic, multi-state exchange of patient data**
- **Enhance immunization registry systems by learning the unique features of counterparts in other states**

- **Quantify the technological resources and legal effort required for executing agreements and processes for data exchange**
- **Demonstrate willingness of states to collaborate to promote and protect the health of citizens**
- **Establish a replicable model for similar public health data exchange projects**
- **Substantially benefit consumers/patients by making patient immunization/vaccination records electronically accessible**

AGREEMENT

This Health Information Exchange Agreement (“Agreement”) is made effective this ____ day of _____, 20__ (the “Effective Date”), by and between the Public Health Agency of _____, (“A”); and the Public Health Agency of _____, (“B”) (each, a “Participant” and together, “Participants”).

WITNESSETH:

WHEREAS, Participants have established secure, electronic public health data exchange systems to allow Authorized Users (as defined below) to electronically exchange Public Health Information (as defined below); and

WHEREAS, each Participant seeks to have the ability to exchange Public Health Information (as defined below) with the other for the purposes set forth below; and

WHEREAS, the Participants agree that the exchange of data will comply with federal and state laws pertaining to Protected Health Information necessary for medical treatment, medical claims payment and public health care operations pursuant to the Health Information Portability and Accountability Act [HIPAA, as defined below]; and

WHEREAS, each Participant desires to enhance the privacy and security of Public Health Information and its System;

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants and agreements set forth below, and other good and valuable consideration, the receipt and legal sufficiency of which are hereby acknowledged, and wishing to be legally bound hereby, the Participants hereto agree as follows:

1.0 Definitions

- a. “Agreement” has the meaning set forth in the in the recitals above.
- b. “Authorized User” shall mean a Participant’s employees, agents, assigns, representatives, independent contractors, or other persons or entities authorized by such Participant to access, use or disclose information from another Participant’s System.
- c. “Authorized User Agreement” shall mean the confidentiality agreement each Participant requires each of its Authorized Users to sign prior to gaining access to Public Health Information.
- d. “Data” is a collection of numbers, characters, images or other outputs from devices to convert physical quantities into symbols or images. Data includes numbers, words, images, etc. typically accepted as they stand. Data is typically further processed by a human or entered into a computer (input), stored and processed there, or transmitted (output) to another human, computer or other system to create information.

- e. **“HIPAA” has the meaning set forth in Section 2 below.**
- f. **“Participant” or “Participants” has the meaning set forth in the recitals above.**
- g. **“Protected Health Information” shall mean PHI shared under this Agreement as that phrase is defined in 45 CFR § 160.103 of the HIPAA regulations.**
- h. **“Public health” shall mean program(s) that promote, maintain, and conserve the public's health by providing health services to individuals and/or by conducting research, investigations, examinations, training, and demonstrations. Public health services may include but are not limited to the control of communicable diseases, immunization, maternal and child health programs, sanitary engineering, sewage treatment and disposal, sanitation inspection and supervision, water purification and distribution, air pollution control, garbage and trash disposal, and the control and elimination of disease-carrying animals and insects.**
- i. **“Public Health Information” shall mean information collected and used by states, territories and federal agencies to support Public Health activities as described above. The information is typically stored in electronic databases, such as immunization registries, cancer registries, vital statistics and newborn testing databases, to facilitate disease reporting and epidemiological and population research.**
- j. **“Significant Breach” shall mean a successful unauthorized access, use, disclosure, modification, or destruction of Public Health Information, or interference with a Participant’s System, of which such Participant has knowledge or should have knowledge.**
- k. **“State” shall mean any state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, and any territory or possession subject to the legislative authority of the United States.**
- l. **“System” shall mean software, portal, platform, or other electronic medium controlled or utilized by a Participant through which or by which the Participant exchanges information under this Agreement. For purposes of this definition, it shall not matter whether the Participant controls or utilizes the software, portal, platform or other medium through ownership, lease, license, or otherwise.**

2.0 Purpose and Scope

The Participants agree to permit access to the Public Health Information to share immunization data between participants.

This Agreement governs how Public Health Information will be used and disclosed by and between the Participants.

It is the intent of all Participants to protect the confidentiality and security of Public Health Information subject to this Agreement, in accordance with applicable state and federal law, including, without limitation, the federal Health Insurance Portability and Accountability Act of 1996 and its implementing regulations on privacy and security found at 45 C.F.R. Parts 160 and 164, as the same may be amended from time to time (“HIPAA”).

This Agreement does not apply to the exchange of Protected Health Information that is contained in or is a part of any other electronic health care exchange or network, unless that exchange or network is a party to this Agreement.

3.0 Use of & Access to Public Health Information

- a. Permitted Uses and Disclosures. The Participants may use and disclose Public Health Information in furtherance of the purposes and goals of this Agreement when necessary for their proper management, administration or execution of their legal responsibilities and privileges established herein.³ The Participants agree not to use or further disclose Public Health Information other than as authorized by this Agreement or permitted by law. Under this Agreement, Participants will provide Public Health Information dating as far back as the information is maintained on each Participant’s System.**
- b. Authorized Users. Each Participant shall identify, and upon reasonable request provide the names of, persons designated as its Authorized Users for purposes of this Agreement. Participants shall use reasonable care in selecting such individuals and shall place appropriate privacy and security restrictions on their Authorized Users. Participants shall apply appropriate sanctions against any Authorized User who fails to comply with the requirements of this Agreement. Each Participant shall immediately remove an Authorized User’s access to Public Health Information if the Authorized User no longer qualifies as an Authorized User. Before allowing use or disclosure of Public Health Information, Participants shall require their Authorized Users to agree to an Authorized User Agreement.⁴ Each Participant’s Authorized Users’ consents to the Authorized User Agreement must be logged in an audit trail or otherwise documented.**

³ The participants should agree upon the technical scope of the Agreement. The technical scope may be included as an exhibit, with language to be added stating, “as set forth in Attachment X”. Paragraph 17 removes the need for “incorporation” language.

⁴ Form of Authorized User Agreement should be attached and insert “as set forth in Attachment ___”.

c. Access to Public Health Information

- i. **Under this Agreement, the Participants will provide Public Health Information dating as far back as the information is generally accessible in electronic format and is maintained on each Participant's System. The Participants are not responsible for the absence of medical information in a public health record and are only obligated to provide such information as they currently possess. The Participants acknowledge that the Public Health Information provided is drawn from numerous sources and the Public Health Information provided may not include an entire record.**
 - ii. **Each Participant shall maintain Public Health Information on its System for the greater of six years or as required by the Participant's local law.**
 - iii. **The Participants shall provide Public Health Information to other Participants in a timely manner.⁵**
 - iv. **The Participants understand that this Agreement primarily depends on the Participants to reasonably determine that information disclosed is accurate and complete. Each Participant shall notify the other(s) in advance of any planned changes to its System that may impact the availability of Public Health Information accessed by another Participant. If a Participant becomes aware of any material inaccuracies in its own Public Health Information or System, it agrees to communicate such inaccuracy to all Participants as soon as reasonably possible.**
- d. **Ownership. Disclosure of the information under this Agreement does not change the ownership of such information under state and federal law. If Public Health Information has been added to a Public Health Registry, it may be thereafter integrated into the recipient's database. This Agreement does not grant to a Participant any rights in the System or any of the technology used to create, operate, enhance or maintain the System of another Participant.**

4.0 Participant Requirements

Each Participant, whether providing, receiving or using information hereunder, shall:

- a. **establish and implement appropriate policies and procedures to prevent unauthorized access, use and disclosure of Public Health Information and ensure that such policies and procedures do not conflict with and are not less restrictive than this Agreement;⁶**
- b. **monitor and audit access to the Public Health Information no less than annually, and take reasonable steps to pursue, address and mitigate any breach(es) or other privacy and security issues detected by such monitoring and auditing;⁷**

⁵ The Participants should agree upon standards for the timely delivery of information. These standards may be included as an exhibit with language added stating "as set forth in Attachment X".

⁶ It is anticipated that the Participants will agree upon standards that will be included in an attachment. This attachment would then be referenced here by stating, "Such policies and procedures shall comply with the standards set forth in Attachment __".

- c. notify the affected Participants as soon as reasonably possible of any Significant Breach, and take all reasonable steps to mitigate the breach(es);**
- d. provide all Authorized Users with appropriate education and training on the requirements of this Agreement; and**
- e. provide copies of its privacy and security policies and procedures to the other Participants and, upon reasonable request by another Participant, demonstrate compliance with its policies and procedures.**

5.0 Privacy and Security Safeguards

- a. Each Participant will use administrative, technical and physical safeguards to protect the confidentiality, integrity and availability of Public Health Information and to prevent the use or disclosure of any Public Health Information received from or on behalf of another Participant other than as permitted or required by federal or state law and by this Agreement. To that end, each Participant shall: (i) provide for identification and authentication of Authorized Users; (ii) provide access authorization; (iii) guard against unauthorized access to Public Health Information; and (iv) provide security audit controls and documentation.**
- b. A Participant shall apply sanctions against any person, subject to the Participant's policies and procedures, who fails to comply with such policies and procedures. The type and severity of sanctions applied shall be in accordance with the Participant's policies and procedures. Participants shall make employees, agents, and contractors aware that certain violations may result in notification by a Participant to law enforcement officials as well as regulatory, accreditation, and/or licensure organizations.**
- c. A Participant may, at its discretion, deny access to any person it has reason to believe accessed, used or disclosed Public Health Information, other than as permitted under this Agreement.**
- d. This Agreement is subject to the provisions of HIPAA.**
- e. Participants are also required to comply with the privacy and security provisions established within their own jurisdiction and are not required to adhere to the law or regulations of any other Participant.**

⁷ Under CDC regulations auditing occurs annually for Immunization Registries.

- a. **Term.** The term of this Agreement shall commence as of the Effective Date, and shall continue in full force and effect for as long as the Participants elect. Any Participant may terminate its own participation in this Agreement without cause by providing thirty (30) days' prior written notice to the other Participants. The withdrawal of less than all of the Participants shall not be considered a termination of the Agreement, and the remaining Participants shall continue to participate under the terms of the Agreement.
- b. **Immediate Termination.** Each Participant shall have the right to immediately terminate this Agreement to comply with any legal order, ruling, opinion, procedure, policy, or other guidance issued, or proposed to be issued, by any federal or state agency, or to comply with any provision of law, regulation, or any requirement of accreditation, tax-exemption, federally funded health care program participation or licensure which: (i) invalidates or is inconsistent with the provisions of this Agreement; (ii) would cause a Participant to be in violation of the law; or (iii) jeopardizes the good standing status of licensure, accreditation or participation in any federally funded healthcare program, including without limitation the Medicare and Medicaid programs. Notwithstanding the foregoing, the withdrawal of less than all of the Participants shall not be considered a termination of the Agreement, and the remaining Participants shall continue to participate under the terms of the Agreement, as amended.
- c. **Termination With Cause.** Notwithstanding any other provision of this Agreement, any Participant may terminate its participation in this Agreement if another Participant has materially violated its responsibilities under this Agreement, unless the breaching Participant provides satisfactory assurances to the non-breaching Participant within ten (10) days of receiving notice of such material violation that reasonable steps are being taken to effect a cure, and in any event: (i) such cure will be completed no later than thirty (30) days from notice of such material violation; and (ii) the breaching Participant has taken reasonable steps to prevent the recurrence of such material violation.
- d. **Termination of Access to Public Health Information.** Notwithstanding subsection (c) above, each Participant reserves the right to terminate immediately another Participant's access to Public Health Information at any time if the Participant has suffered a significant breach of the security of its System, has violated any of the terms of this Agreement, including without limitation accessing any information that a Participant would not otherwise be authorized to receive pursuant to this Agreement, improperly disclosing Public Health Information or failing to abide by appropriate policies and procedures.
- e. **Effect of Termination.** Upon a Participant's withdrawal, the Public Health Information stored by such Participant shall no longer be accessible by the other Participants. Following the termination of this Agreement, any and all Public Health Information shall continue to be subject to the provisions of this Agreement with regard to the handling of Public Health Information, including, without limitation, provisions regarding privacy and security.

7.0 Warranties and Limitation of Liability

- a. Participants hereby disclaim all implied and express warranties, conditions, and other terms, whether statutory, arising from course of dealing, or otherwise as it pertains to Public Health Information. No Participant warrants that the performance or delivery of the Public Health Information will be uninterrupted or error-free. No Participant shall be liable for any consequential, incidental, indirect, punitive, or special damages suffered by another Participant or any other third party. No Participant shall be liable for any damages arising out of or related to the acts or omissions of another Participant in accessing, disclosing or using Public Health Information.**
- b. Without limiting any other provision of the Agreement, each Participant and such 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 resulting from or in any way related to the use of the Public Health Information. No Participant or Authorized User shall have any recourse against, and each shall waive any claims against, other Participants for any loss, damage, claim, or cost relating to or resulting from its own use or misuse of Public Health Information.**

8.0 Agreement's Compliance with Laws and Regulations

The Participants intend and in good faith assert and believe that this Agreement complies with all federal, state, and local laws. If any provision of this Agreement is declared void by a court, or rendered invalid by any law or regulation, and if such provision is necessary to effectuate the purposes of this Agreement, the Agreement shall terminate.

9.0 Insurance

Each Participant agrees to obtain and maintain in force and effect reasonable policies of liability insurance or self-insurance to insure itself and its employees, agents and contractors for liability arising out of activities to be performed under, or in any manner related to, this Agreement.

10.0 Notices

Any notice or other communication required under this Agreement shall be in writing and sent to the address set forth below, or to such other address as the Participants shall designate in writing from time to time. Notices or communications to or between the Participants shall be deemed to have been delivered: (a) by email notification; (b) by deposit in the U.S. mail when mailed by first class mail; (c) if sent by established courier service; or (d) when received by a Participant, if personally delivered.

Placeholder for names and addresses

11.0 Subrogation

Participants waive claims against each other for any loss, damage, claim, or cost relating to or resulting from their own misuse, or misuse by their Authorized Users, of the Public Health Information.

12.0 Choice of Law

In the event of a dispute between or among the Participants arising out of this Agreement: (a) the Participant requesting the Public Health Information will abide by its own state law and federal law; (b) the Participant providing the Public Health Information will abide by its own state law and federal law; and (c) if the dispute cannot be resolved, the Participants agree to look to federal common law.

Any reference in this Agreement to a section of a federal, state, or local statute, law, or regulation means the section as then in effect or as amended.

13.0 Amendment

This agreement may be modified, altered, or amended only by express written consent of all Participants.

14.0 Assignment

This Agreement shall be binding on the Participants, their successors and permitted assigns. The Participants shall not assign or transfer this Agreement or any part thereof, without the prior review and written consent of all other Participants.

15.0 Waiver

No failure or delay by any Participant in exercising its rights under this Agreement shall operate as a waiver of such rights, and no waiver of any breach shall constitute a waiver of any prior, concurrent, or subsequent breach.

16.0 Integration

This Agreement sets forth the entire and only Agreement between the Participants relative to the subject matter hereof. Any representation, promise, or condition, whether oral or written, not incorporated herein shall not be binding upon any Participant.

17.0 Incorporation by Reference

All exhibits attached to this Agreement are incorporated by reference and made a part of this Agreement as if those exhibits were set forth in the text of this Agreement.

18.0 Relationship of Participants

Nothing contained in this Agreement shall constitute or be construed to create a partnership, joint venture, agency or any other relationship other than that of independent contractors to this Agreement.

19.0 Third Party Beneficiaries

This Agreement does not and will not create in any natural person, corporation, partnership, or other organization any benefits or rights, and this Agreement will be effective only as to the Participants and their successors and assigns.

20.0 Force Majeure

Notwithstanding any provision hereof to the contrary, in the event of a disruption, delay or inability to complete the requirements of this Agreement due to natural disasters, acts of terror or other similar events out of the control of a Participant, such Participant shall not be considered in breach of this Agreement.

21.0 Counterparts

This Agreement may be executed in any number of counterparts, each of which will be deemed an original as against the Participant whose signature appears thereon, but all of which taken together will constitute one and the same instrument.

22.0 Authority to Sign

The Participants warrant that they have the capacity to enter into and perform the obligations under this Agreement and all activities contemplated herein.

23.0 Survival

The respective rights and obligations of the Participants under Sections 3, 4, 5, 6, 7, 11 and 12 of this Agreement shall survive the termination of this Agreement to the extent that such provision contemplates continued application after termination of this Agreement.

IN WITNESS WHEREOF, the Participants have caused this Agreement to be signed by their duly authorized representatives as of the Effective Date.

Signatures:

Placeholder for Name & Title

Date

Placeholder for Name & Title

Date