March 31, 2009

Health Information Security and Privacy Collaboration

Interorganizational Agreements Collaborative Final Report

Prepared for

RTI International
230 W Monroe, Suite 2100
Chicago, IL 60606

Jodi Daniel, JD, MPH, Director
Steven Posnack, MHS, MS, Policy Analyst
Office of Policy and Research
Office of the National Coordinator for Health IT
200 Independence Avenue, SW, Suite 729D
Washington, DC 20201

Prepared by

Interorganizational Agreements Collaborative
Alaska, Guam, Iowa, New Jersey, North Carolina, South Dakota

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EXECUTIVE SUMMARY

This document summarizes the work of the Interorganizational Agreements (IOA) Collaborative, a multistate project that is part of the Health Information Security and Privacy Collaboration (HISPC), to develop and pilot test legal agreements for electronic health information exchange across state lines.[1]

Overview

In 2006, HISPC was initiated to address privacy and security variations and challenges presented by electronic health information exchange at the state level. The project began with state-specific work in Phase I, followed by state implementation projects in Phase II, and resulted in a third phase focused on developing solutions to challenges presented during Phases I and II through multistate collaboration. Overall, 42 states[2] participated in HISPC Phase III from April 2008 to April 2009. States were split into seven privacy and security topics[3] for collaborative work, one of which was the HISPC Phase III IOA Collaborative (hereafter referred to as IOA Collaborative).

The IOA Collaborative included representatives from Alaska, Guam, Iowa, New Jersey, North Carolina, and South Dakota.[4] In earlier phases of the HISPC project, participants recognized that efforts to draft electronic health information exchange agreements, including legal language, could be time consuming and inefficient, and often presented barriers to electronic health information exchange. As a result, the IOA Collaborative proposed to develop and pilot test model data sharing agreements. The stated objectives were to:

- develop a standardized set of model data sharing agreements for electronic health information exchange, focused on privacy and security considerations; and
- test the use of the model data sharing agreements in actual data sharing pilot projects across state lines.

Given the project time frame, the IOA Collaborative agreed to limit the scope of the project to two types of data sharing agreements:

1. public entity data exchange (a public-to-public data sharing agreement); and
2. private entity data exchange (a private-to-private data sharing agreement).

A model agreement for exchanges between public and private entities was tabled for future project expansion activities.

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[1] The Health Information Security and Privacy Collaboration was funded in 2008–2009 by the U.S. Department of Health and Human Services Office of the National Coordinator for Health Information Technology (ONC).
[2] State = U.S. state or territory.
[3] Consumer Education, Patient Consent, Provider Education, Interorganizational Agreements, Harmonizing Privacy Laws, Standard Policies, Inter/intrastate Consent Options.
[4] Puerto Rico was an initial participant but was unable to continue participation due to local considerations.

Throughout the project, the IOA Collaborative coordinated with the Nationwide Health Information Network (NHIN) Data Use and Reciprocal Support Agreement (DURSA) Work Group. The scope of the IOA Collaborative project differs from that of DURSA, as explained later in this report; however, coordination between the two groups helped to ensure continuity and consistency among the agreements and avoid duplication of effort.

The IOA Collaborative provided the final agreements and other results to project sponsors for sharing and replication nationwide.

Relevance to Privacy and Security

Electronic health information exchange across state lines or between multiple entities begins with an agreement between the parties to the exchange. The agreement should address the purpose and scope of the exchange, as well as technical and legal considerations. The legal issues addressed by the agreement can be the most challenging, especially those surrounding privacy and security. To participate in a data sharing arrangement, the parties to the contract must be confident that privacy and security issues have been appropriately addressed.

Throughout the project, the IOA Collaborative maintained its focus on privacy and security as the priority concepts to address, in part because other project teams are addressing the technical and other aspects of such exchanges. The IOA Collaborative's work is founded on the premise that robust privacy and security provisions in a model data sharing agreement can provide a foundation on which any remaining customization can be easily included, thus streamlining the process toward actual data sharing.

Key Achievements

The key achievements of the IOA Collaborative included:

- two model data sharing agreements for electronic health information exchange, one for the public entity setting and one for the private entity setting;
- user guides to accompany the agreements and support implementation;
- a document containing the core privacy and security provisions from both agreements;
- review and compilation of 45 currently available electronic health information exchange agreements and policies gathered nationwide (i.e., the IOA Documents Library);
- close coordination with the NHIN DURSA Work Group's efforts including a crosswalk between the IOA data sharing agreements and the DURSA agreements;
- pilot testing of the model agreements in actual data exchange projects, building trust and further vetting the agreements;

- lessons learned from implementation of the pilot projects and all other project documentation; and
- formal review and endorsement of the model agreements by outside agencies and organizations.

The above work products are described in detail in this report. Many of the tools and deliverables are provided in the appendices and will be made available on ONC's website.

Benefits to Other States

The ultimate goal of the IOA Collaborative was to facilitate improved patient care and safety through increased electronic health information exchange across state lines. To support this goal, the IOA Collaborative created template data sharing agreements to increase the expediency of such exchanges.

From the start, the IOA Collaborative tried to avoid duplication of effort by developing products that other states could replicate and use. The IOA Collaborative took on this challenge so that an organization interested in electronic health information exchange would not have to go through a similar process and begin from scratch. Because of this effort, we expect other states will benefit from access to standardized, endorsed data sharing agreements that have been tested in real-world scenarios. Public entities and private entities in the health care industry can have confidence that the privacy and security aspects of the agreements have been thoroughly reviewed and vetted by experts in the field. Successes, best practices, and barriers were documented for use by other states and organizations. By providing template data sharing agreements, the IOA Collaborative has created momentum toward use of standardized agreements throughout the country.

The IOA Collaborative's efforts, combined with the work of all HISPC Collaboratives, have laid significant practical groundwork as the nation moves toward private and secure interoperable electronic health information exchange.

1. PROJECT BACKGROUND

This section provides background related to the IOA Collaborative project, including the project rationale, scope, issues, and challenges addressed. The mission of the IOA Collaborative was to develop model data sharing agreements, commonly called Memoranda of Understanding or Memoranda of Agreement (collectively referred to herein as DSAs), containing consistent privacy and security provisions to support electronic health information exchange.

The primary focus of the IOA Collaborative was to fine-tune the privacy and security components of these agreements. Throughout all phases of the work, the guiding principle was always the mutually acceptable resolution of barriers to health information exchange (HIE) consistent with applicable privacy and security laws and regulations.

The IOA Collaborative worked closely with the NHIN DURSA Work Group, and to ensure the timely and effective transfer of information between the two groups, the IOA Collaborative assigned a liaison to the DURSA Work Group.

As a starting point for development and to avoid duplicative groundwork, the Collaborative used the DURSA agreement and other agreements drafted and executed prior to HISPC Phase III (such as those provided by New Jersey, New York, New Mexico, and others), or already established by other groups involved in electronic health information exchange. Forty-eight documents were reviewed, parsed, compared, and discussed. From this starting point, the group expanded, analyzed, and field-tested the agreements from a privacy and security perspective. Two model DSAs were developed, one for public entity-to-public entity data sharing, and one for private entity-to-private entity health data sharing.

The IOA Collaborative conducted pilot electronic health information exchanges that utilized the model DSAs. These pilot projects included both public entity-to-public entity and private entity-to-private entity organization vetting and exchanges. The pilots resulted in a final set of model DSAs that can be shared nationwide and used to facilitate intra- and interstate electronic health information exchange.

1.1 Rationale for the Project

The United States is progressing toward increased sharing of health care data at the local, regional, and national level. These activities will require legal agreements that support private and secure data sharing.

The development and implementation of DSAs that can cross state lines requires multistate cooperation and collaboration. Various types of DSAs already exist, but they do not all use standardized, consistent formats or contain consistent privacy and security provisions. These inconsistencies can cause unnecessary costs for the renegotiation of such agreements each time parties enter into a new arrangement.

In many cases, the absence of properly executed agreements results in missed opportunities to share electronic health data across state lines. In addition, a single entity, such as a governmental agency or private health care organization, may execute a different agreement with each additional entity with which it exchanges data, causing increased confusion and expense for organizations that are party to more than one agreement. Tracking various contractual arrangements and agreements that vary depending on state law creates a significant administrative burden. All of these concerns are heightened in an interstate electronic exchange environment.

As a result, increased liability concerns and uncertainties can cause unnecessary delays in releasing critically necessary health information. The IOA Collaborative has demonstrated that these barriers to electronic health information exchange can be lessened and/or eliminated if the participating states or health care organizations enter mutually supporting, commonly agreed-upon, standard DSAs. Standard DSAs will help mitigate artificial and unnecessary boundaries that impede the flow of health information needed to deliver efficient, safe delivery of high-quality medical care.

1.2 IOA Scope

The IOA Collaborative was composed of six states focused on developing model DSAs for electronic health information exchange. The documents developed by the IOA Collaborative include a core set of standardized privacy and security components in template formats that can be replicated for use in health data sharing efforts.

Key aspects of the project included:

- Building on existing work in this area. As discussed above, the IOA Collaborative incorporated the work of HISPC Phase I and other related projects such as NHIN DURSA, New Jersey Immunization Sharing, Markle Foundation, and other HISPC Collaboratives to avoid duplication of effort and maximize progress.
- Pilot testing the model DSAs. Once the model agreements were established, they were tested for exchange of data across state lines. The pilot tests occurred in two settings: public entity-to-public entity data exchange and private entity-to-private entity exchange. Actual data were exchanged as part of the public entity-to-public entity exchange. Preliminary approval of the agreements for future exchanges was obtained through the private-to-private pilot project. Using both public and private entities helped validate and increase trust in the agreements for all types of entities that encounter and store health information.
- Publishing model agreements and lessons learned. As a result of this work, the Collaborative identified the privacy and security practices, procedures, and laws that pose challenges to interstate exchange of health information. The end products, including model DSAs and implementation findings, will be published nationally so that other organizations can learn from the challenges identified.

The IOA Collaborative expects these deliverables to help reduce or eliminate some of the barriers to electronic health information exchange across state lines identified during the

previous HISPC phases. During Phase I, it was determined that organizations sometimes did not exchange health information electronically, in part, because they did not have standardized DSAs with other entities. In addition, most states and other health care entities had their own privacy and security policies and procedures, but they exhibited limited confidence, trust, or knowledge of the safeguards employed by potential trading partners. Furthermore, it was determined that common, uniform, and mutually acceptable DSAs would lessen and/or eliminate many privacy and security concerns of the entities involved. Thus, the focus of the IOA Collaborative was to engage participating states in resolving variations and barriers to the smooth and efficient flow of electronic health information within and across state lines.

During the project period, the IOA Collaborative examined, recognized, and resolved, where possible, the privacy and security contract provisions, regulations, and statutes in its respective states that prevented health information contained in public health registries, provider systems, and other health record systems from being exchanged across state lines.

The work of the HISPC IOA Collaborative was completed in three stages:

1. Developing model DSAs, including a standardized core set of privacy and security components;
2. Testing the DSAs in pilot electronic health information exchange projects and developing the user guides; and
3. Evaluating the effectiveness and value of the model DSAs, including seeking endorsements and feedback from other organizations.

The final deliverables included a set of model DSAs that can be published, expanded, and used to facilitate electronic health information exchange both within and among states.

1.3 Issues and Challenges

1.3.1 Issues

In developing model DSAs and implementing pilot projects, the IOA Collaborative confronted the following privacy and security issues and challenges:

- differing state laws and regulations;
- differences in state and organizational requirements for patient consent/authorization, release and permission forms;
- other privacy concerns, including the protection of protected health information (PHI) held by each of the parties and assurances that it will not be used for any purpose that does not comply with applicable state and federal laws;
- liability of each entity involved and related indemnification issues;

- questions related to securing connections between the parties and the need for encryption and other security controls for the protection of data in transit and at rest;
- methodology to address potential breaches in security and privacy;
- statement of rights of parties involved should a breach occur; and
- methodology for alerting the other contracting party and patients, if necessary, to information regarding breaches of the system.

The issues outlined below were identified as secondary issues related to, but not part of, the Phase III work. Future IOA Collaborative work beyond HISPC Phase III could address the following items:

- governance and administration of the agreements, including auditing and monitoring methods;
- special treatment for more sensitive PHI, such as: genetic information, HIV-AIDS status, STDs, substance abuse, and mental health records;
- typical security issues implicated in any DSA, which include access, authorization, audit, and authentication;
- methodology to handle redisclosures;
- implications for business associates;
- differing technologies among organizations or within organizations, which may require agreed-upon security standards and privacy protections;
- location and availability of information; (for example, agreements may provide for locating data in a central repository or for accessing the other party's data where they reside. In so doing, certain data may need to be isolated from data accessed from other systems.);
- appeals processes for providers and patients with complaints;
- fraud prevention and detection plans;
- penalties for breach of the agreement;
- planning for emergency access; and
- disagreement on laws and practices associated with electronic health information exchange audit processes, authentication of providers, identification of patients, and role-based access.

1.3.2 Challenges

The IOA Collaborative sought to address two main challenges to interoperability identified in Phase I: (1) the significant number and variation of agreements used within and between states and organizations, and (2) the lack of standardized agreements to facilitate health information exchanges.

Other challenges identified in Phase I were also confirmed through the collaborative process, including misunderstanding of the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rule requirements, and variations in administrative, physical, and technical safeguards.

Lesser challenges were trust (or lack thereof) about security among organizations conducting health information exchanges, and variability in the way liability and risk management are addressed health information exchanges are conducted with different organizations.

These remaining challenges will provide future work for the IOA Collaborative or other Collaboratives.

2. TIMELINE AND PROCESS

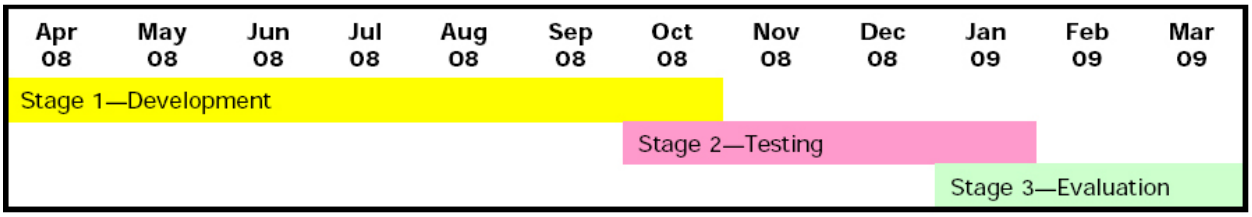
This section describes the 12-month timeline and processes the IOA Collaborative used to complete the project.

2.1 Timeline

The IOA Collaborative developed a 1-year, three-stage timeline to complete the work. The first and longest stage included the development and drafting of the model DSAs. The second stage focused on pilot testing and vetting of the agreements to assess their application in real data exchange projects. The final stage was dedicated to project evaluation, review, and/or endorsements from external organizations and agencies, and documentation of the results.

The project timeline is depicted in Figure 1.

Figure 1. IOA Collaborative Project Timeline



2.2 General Process

The general process the IOA Collaborative used to achieve project objectives is described below. Sections 2.3 and 2.4 describe each step in greater detail.

The IOA Collaborative process included examining, recognizing, and resolving where possible those privacy and security practices, procedures, and laws posing challenges to creating agreements for interstate electronic health information exchange. The desired outcome was to create replicable DSAs that other states and organizations could use to exchange health information. Through the use of Legal Work Groups (LWGs), many established in HISPC Phase I, the IOA Collaborative members reviewed a wide variety of DSAs and developed consensus on core content and language. The collaborative also coordinated with key groups such as the NHIN DURSA Work Group, as further described in Section 6.1 of this report.

2.3 IOA Collaborative Legal Review and Agreement Development

The work of the HISPC IOA Collaborative focused on three areas: (1) development of a standardized core set of privacy and security provisions for the DSAs and development of two model DSAs for public entity and private entity exchange; (2) testing of the DSAs in

pilot electronic health information exchange projects; and (3) evaluation of the effectiveness and value of the model DSAs, including external review and feedback.

The IOA Collaborative undertook significant tasks both at the Collaborative level and through state-specific LWGs to develop the agreements. These tasks, described in greater detail in Section 3 of this report, included:

- compilation of the starter IOA Documents Library of DSAs;
- development of a classification scheme to categorize the provisions;
- extraction of like provisions into a 350-page master document;
- review of the master document by state-specific LWGs to identify provisions that conflicted with state-specific laws and to rank preferred provision language;
- compilation of the state-specific results and language preferences into Excel tables;
- discussion at the Collaborative level to choose preferred language and vet complex issues;
- creation of a parking lot list of items for future resolution and ongoing documentation;
- comparison of the DSA with the NHIN DURSA and Markle Foundation provision categories;
- final selection of provisions and simple, understandable language through face-to-face discussions and multiple WebEx meetings;
- drafting of new provisions, where necessary, to address issues not sufficiently addressed in collected documents; and
- refining of the agreements.

The IOA Collaborative coordinated with and drew upon the work of other HISPC Collaboratives, other states and organizations, and the NHIN DURSA group. The IOA Collaborative worked most closely with the HISPC Adoption of Standard Policies (ASP) and Harmonizing State Privacy Law (HSPL) Collaboratives to ensure that work was not redundant or contradictory. For example, the ASP Collaborative developed detailed language and policies regarding authentication of users and auditing practices in a health information exchange setting. The IOA Collaborative will use these policies as optional addenda to the private-to-private agreement. Doing so will provide users of the DSAs with additional resource language for some of the more technical details that were outside the scope of the IOA Collaborative's work. As another example, the IOA Collaborative asked the HSPL Collaborative to review both model agreements and highlight any content that may conflict or raise red flags with state-specific laws and regulations discovered through their analysis. This coordination broadened the review and vetting of the agreement language outside the six IOA Collaborative member states.

To reduce duplication of effort, the IOA Collaborative attempted to use previously developed resources, such as:

- HISPC Phase I documents, including the privacy and security legal reviews accomplished by participating states and territories;
- Markle Foundation privacy and security framework and related documents; and
- 0ther documents and DSAs gathered by IOA Collaborative members for the starter IOA Documents Library. Altogether, this library contained 45 documents, of which 34 were used extensively in the process of developing the model DSAs.[5]

By developing mutually acceptable DSAs, participating states were required to discuss and resolve the internal issues that prohibit or restrain the electronic flow of health information between providers, public health databases, and across state lines. Phase III focused on the privacy and security issues associated with interstate interoperability and drafting of the other necessary provisions to make the document a fully executable contract. The IOA Collaborative expects that these model agreements will provide assurances to stakeholders and contracting parties that variations in state laws will not prohibit timely sharing of data.

2.4 Pilot Testing

Pilot testing the model DSAs developed by the IOA Collaborative was a key component of the process. The testing was intended to answer questions such as:

- What officials or personnel ultimately must sign the agreements?
- When do those officials or personnel need to get involved in the process?
- What other personnel need to be involved in the development process?
- Would personnel NOT associated with the development process actually sign the agreements?
- How long would it take to obtain approval of the agreements?
- Would electronic data exchange occur as a result of the signed agreements?

The pilot-testing stage began after the model agreements were finalized halfway through Phase III. Pilot electronic health information exchange project applications involved two or more states.

Numerous multistate electronic health information exchange pilot projects took place, including:

- Iowa and South Dakota conducted a public-health-to-public-health Immunization Registry Exchange Project. This pilot project exchanged the immunization registry data of those individuals 0–25 years of age who received treatment in bordering Iowa and South Dakota counties.

[5] The other documents were too specific to use in IOA work, for example, only related to the Centers for Medicare & Medicaid Services (CMS) data sharing; or data sharing in Canada.

- Iowa, South Dakota, New Jersey, and Guam conducted a four-way public-health-to-public-health Immunization Registry Exchange Project. This pilot project exchanged the immunization registry data of individuals born in 1990. This population represented a geographically mobile group of 18-year-olds that included both college and military-bound individuals.
- New Jersey undertook several initiatives to promote and advance the mission of the IOA Collaborative and to expand the acceptance and use of the IOA agreements. These activities included:
  - meetings with New York State and City health information technology officials to establish interstate exchanges of Immunization Registry data;
  - meetings with the City of Philadelphia Department of Health and Centers for Disease Control and Prevention (CDC) officials to promote interstate exchange of Public Health Registry data;
  - demonstrations of New Jersey's Immunization Registry for members of the IOA Collaborative and Puerto Rico to share opportunities related to electronic public health data exchange;
  - presentations to Healthcare Information and Management Systems Society (HIMSS), National Governors Association (NGA), Pennsylvania eHealth Initiative (PAeHI), and State level HIE Consensus Project (SLHIE Project) on DSAs and the ability to share public health information data;
  - engaging the American Immunization Registry Association (AIRA) to obtain endorsement of the public-to-public agreement; and
  - integration of DSAs into New Jersey's Electronic Medical Record exchange pilot project.
- North Carolina conducted a pilot of the private-to-private agreement with private health care entities from across North Carolina, including major health care providers such as Duke University Medical Center. Alaska participated in the pilot through observation and legal review. Seventeen organizations, representing various types of providers, legal counsel, and nonlegal personnel, reviewed and ultimately agreed upon a modified form private-to-private agreement.

Pilot electronic health information exchange project participants evaluated the effectiveness and overall value of the model DSAs in achieving the purpose, goals, and objectives of the pilots and fostering secure data exchange. The participating IOA Collaborative states documented the lessons, experiences, and implementation guidelines from the pilot projects for other states to consider.

Outside of the IOA Collaborative, Pennsylvania, Connecticut, Florida, Ohio, North Dakota, Nebraska, Minnesota, Virginia, and Wisconsin have expressed interest in working with the immunization data sharing project. This external interest, combined with the endorsements of the public entity DSA by AIRA and the Public Health Data Standards Consortium, well positions the IOA Collaborative to expand the immunization registry data sharing pilot projects pending future funding mechanisms.

The pilots resulted in two model DSAs that have been tested and will be published, expanded, and used to facilitate electronic health information exchange both within and across states.

2.5 Other IOA Collaborative Review Processes

A significant advantage of the IOA Collaborative methodology is that issues were identified and addressed using a bottom-up approach. For example, rather than having two entities draft and negotiate an agreement, each IOA Collaborative state used an LWG to identify state and national issues affecting the agreement. The IOA Collaborative then conducted a second round of negotiation and drafting. Only the best and most widely accepted types of provisions survived this process and were ultimately included in the final documents. The IOA Collaborative is confident that the model agreements have undergone a sufficiently rigorous review, vetting, and approval process.

The IOA Collaborative members reviewed the NHIN DURSA documents knowing that these documents were developed specifically for nationwide electronic health information exchange of test data across state borders. The documents were shared as appropriate within each state. This comparison added to the IOA Collaborative's knowledge base and broadened the applicability of the NHIN template at the same time. The IOA Collaborative issue discussion from these reviews was shared with the NHIN DURSA Work Group during 2008, and is included in this HISPC Phase III final report. Because the private-to-private pilot included participants in the NHIN, consistency between the agreements was promoted. A crosswalk was developed to compare and contrast the IOA agreements with the test data DURSA.

During Phase III, the IOA Collaborative could not vet every issue pertaining to DSAs, such as detailed technical specifications, sensitive data requirements, or alternative jurisdictional approaches. Also, during this scope of work, the group could not develop other necessary types of agreements, such as public entity to private entity DSAs. These issues were documented in a "parking lot" table for future review. Where applicable in the agreements, certain parking lot issues are noted as elements that may need to be addressed by users in an appendix to the document.

2.6 External Review

A final aspect of the project methodology included further review and vetting of the agreements by external parties and agencies beyond those involved in the pilot projects. This included review of the public entity agreement by AIRA for their consideration and endorsement as a standard agreement for immunization registry data exchange, and review by the Public Health Data Standards Consortium (PHDSC) for endorsement as a standard agreement for data exchange between public health agencies.

Additionally, the public-to-public DSA was utilized as a beginning point for a multistate CDC contract for sharing surveillance data among public health agencies. CDC awarded a contract to states in Region IV to explore the sharing of situational awareness and surveillance data among the public health agencies in states in the Southeast. The public-to-public DSA was viewed as a tool to significantly reduce the time and expense required to satisfy the needs of the CDC contract. The process provided another source of review and feedback on the IOA public health agreement and provided additional language to customize the agreement for biosurveillance purposes.

In addition to AIRA, PHDSC, and the CDC Region IV pilot, the public-to-public DSA was also reviewed or presented for review to other federal and state agencies to ensure that language in the agreement would not impede or interfere with the collection of data for state program purposes. Specifically, the agencies included:

- CDC—Centers for Disease Control and Prevention, Office of Health Policy;
- CMS—Centers for Medicare & Medicaid Services, Division of Privacy Compliance;
- NCHS—National Center for Health Statistics, Centers for Disease Control and Prevention;
- HRSA—Health Resources and Services Administration, Research and Policy Group, Department of Health and Human Services;
- KDPH—Kansas Department of Public Health;
- PDH—Pennsylvania Department of Health;
- MDH—Minnesota Department of Health; and
- SCDHEC—South Carolina Department of Health and Environmental Control.

Some of this review occurred during and after the DSA pilot projects; therefore, the Collaborative was not able to incorporate all comments on the model DSAs that resulted from the pilot process. These comments, while not substantial, may be considered for future enhancements to the model agreements.

The review by the above agencies and organizations helped to enhance the IOA Collaborative's final product and bolstered the validity and utility of the documents through additional endorsements. This coordination not only provided valuable feedback on the IOA DSAs, but also opened the door for broader use of the agreements and future opportunities to expand the Collaborative work.

3. DEVELOPMENT OF MODEL AGREEMENTS

As demonstrated in the timeline and process described earlier, the IOA Collaborative's final deliverables were successful pilots of model DSAs. One of the key requirements to achieve these deliverables was to draft model agreements for each of the pilot participants to review, approve, and use in the pilot exchanges. In determining the best method to draft one or more agreements, the IOA Collaborative members wanted to avoid recreating the past efforts of other organizations and agencies. In addition, the IOA Collaborative members wanted the resulting language to be appropriate for various applications and not directly conflict with any of their respective state laws.

After careful consideration, the Collaborative outlined four main steps to develop model agreements:

1. Collect and review a library of DSAs currently in existence.
2. Break down the library agreements into individual provisions to be labeled according to a detailed classification scheme.
3. Review and rank the categorized provisions within each state work group to determine the best language for the Collaborative agreements.
4. Organize, revise, and add to previously drafted provisions to create final agreements for public-to-public and private-to-private exchanges. These steps are described in further detail below.

3.1 Library of Examples

From the beginning of Phase III, the IOA Collaborative recognized the value of work completed in earlier HISPC phases, along with the value of work completed by other health information exchange entities. As a result, one of the first steps of the IOA Collaborative was to gather all of the agreements, policies, procedures, presentations, and other documents developed by DURSA, public health care entities, private health care entities, and by member and nonmember states during HISPC Phase I. Forty-five documents were collected and included in the Library of Data Sharing Agreements (the "Library"—a list is included as Appendix A of this report).

The Library documents ranged from general guidelines and model language, such as the Markle Foundation Model Contract for Health Information Exchange to very specific agreements directed at exchanges of limited categories of information, such as the Biosurveillance Data Use Agreement. These documents were obtained from several different states and organizations, and IOA Collaborative members worked with those entities to obtain approval to use and reference the documents in ongoing IOA Collaborative work.

In addition to obtaining approval for the IOA Collaborative's internal use of the documents, each of the states and organizations that provided documents for the Library were

contacted for permission to make some or all of the language publicly available[6] as part of the Classification Scheme described in Section 3.2. Because all of the IOA Collaborative deliverables will be publicly available, approval from the sources was necessary so that any of the language could be directly attributed to a particular organization and/or was proprietary or confidential. The IOA Collaborative found that most organizations were extremely cooperative and generous in sharing the language contained in their documents. Thus, the Library was useful as a drafting tool for the IOA Collaborative during development and will remain useful as reference material.

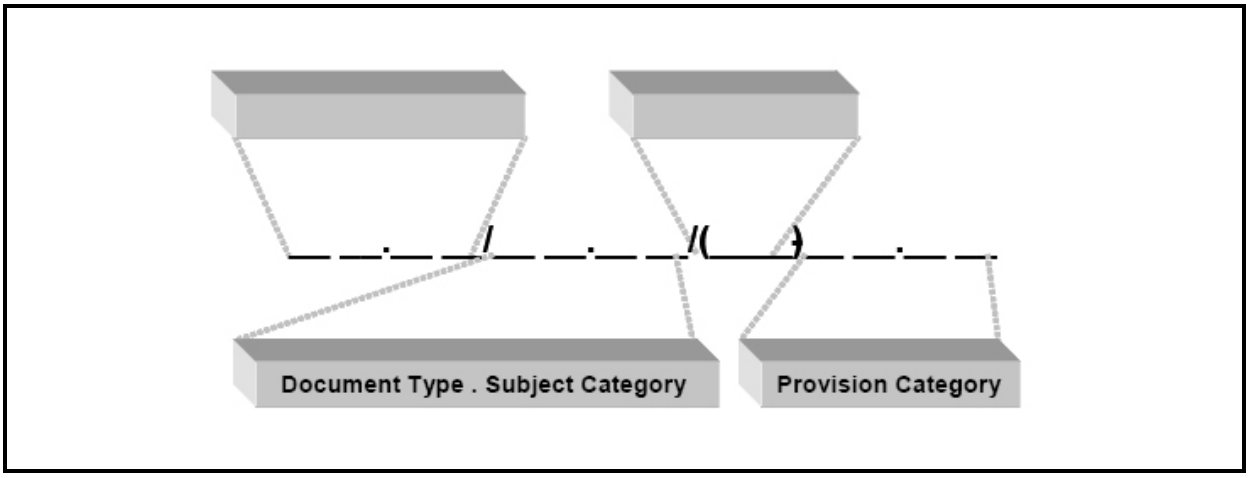
3.2 Classification Scheme

Once the Library was created, the IOA Collaborative's next task was to review, break down, and categorize the sections contained in each document for comparison to other, similar provisions. To accomplish this, the IOA Collaborative had to develop a relatively straightforward method for categorization that could be applied by all members. North Carolina devised a system called the Classification Scheme that allowed each document to be divided and labeled by document source, document identifier, document type, subject matter, page or section, and general category or subcategory of information.

Appendix B provides a detailed discussion of the Classification Scheme. The illustration of the Classification Scheme displayed in Figure 2 represents the IOA Collaborative's internal process for sorting through the many provisions in each of the agreements in the Library.

Figure 2. IOA Classification Scheme

_ _._ _/	_ _._ _/	(__)-	_ _._ _
Document Identifier	Document Type. Subject Category	Page or Section	Provision Category



[6] Not all documents were approved for public release; those not approved were removed from the Library after internal work group analysis.

The following is an example application of this Classification Scheme:

MF.01/hh.06/(s2)-DE.01

This translates under the Classification Scheme to: Markle Foundation, A Model Contract for Health Information Exchange, an electronic health information exchange to electronic health information exchange document covering general data sharing, Section Two—Definition of Authorized User.

This scheme was used to classify all provisions from the applicable documents in the IOA Library as follows: the 48 documents in the Library were divided among the IOA Collaborative member states for classification. The classifications were submitted to the IOA Collaborative and compiled into a 350-page document for use in ranking the provisions and creating model language. This document contained all of the substantive provisions from the 34 most applicable documents, carefully labeled using the Classification Scheme. The main categories applied to the provisions were:

- definitions,
- recitals,
- statement of relationship,
- data recipient requirements,
- data provider requirements,
- software/hardware,
- privacy,
- security,
- terms and termination,
- fees/consideration,
- confidentiality of proprietary information,
- disclaimers,
- insurance,
- indemnification, and
- boilerplate language.

The provisions were then organized into a table to be sorted by several different identifiers, as necessary, and ranked by state-specific LWGs, as described in the section below.

3.3 State-Specific Legal Work and Rankings

After an extensive assessment and aggregation of all similar provisions in accordance with the Classification Scheme, each state returned to its state LWGs to review and rank the provisions within each general category and subcategory of information. Language was ranked based upon several factors including:

- compliance with state law,
- clarity,
- functionality,
- style, and
- compatibility with Collaborative goals.

Some states met face-to-face to review the provisions, others met via teleconference or WebEx, and others sent the entire document out for written comment by LWG members. Table 1 provides an example of the ranking system applied to each set of contract provision topics.

Table 1. Ranking of Contract Provisions

Contract Provisions	Our State's Ranking
Patient privacy is a key issue in trans-border information exchange.	5
Define all conditions that can be used for defining a patient's privacy consent (type of data, type of access, etc.)	3
Parties agree to not use or further disclose PHI other than as authorized by this Agreement or as required by law.	1 (preferred)
Parties hereby authorize Provider to have access to the Network and the Databases accessible through the Network for the following uses and purposes: Treatment of a patient of or by Provider.	4
Each Network or Authorized User shall maintain patient information on its information system for the minimum amount of time required by law but in no event less than six (6) years following a patient's discharge or treatment.	2

Each state's results were provided to the IOA Collaborative for review at an in-person meeting in Chicago on July 14 and 15, 2008. During this meeting, the IOA Collaborative conducted a section-by-section review of the provisions to select those provisions that were necessary for a model agreement, with a focus on the following sections:

- privacy;
- security;
- recipient requirements;

- provider requirements;
- insurance; and
- indemnification.

Through this process, the group recognized that certain Library documents were too specialized or otherwise inappropriate for use by the IOA Collaborative and, accordingly, those documents were removed from consideration for final DSA language. Additionally, the IOA Collaborative realized that it would have to choose a few key areas to determine what would and would not be included in the body of the agreement. The Collaborative decided that the following items would be better addressed in an ancillary or secondary agreement (although they could be referenced in footnotes to the model agreements for future drafting):

- Notice of Privacy Practices,
- Business Associate Agreement (BAA), and
- Specific policies and procedures.

Additionally, the IOA Collaborative decided that the HIPAA requirements would serve as the floor for privacy and security standards under the model agreement. This allowed a single, invariable threshold that all states and entities would recognize.

In further discussions, the group agreed on a general scheme for additional categorization. Each of the provisions would be further divided into the following five categories:

1. Core—critical to the core document and should be included.
2. Special—specific to certain types of health care or certain organizations, such as research organizations: generally not included in the model agreements, except for some language regarding immunization registries.
3. Secondary—information that is better addressed in an ancillary document or attachment, such as highly technical specifications.
4. Delete—language that was duplicative, not useful or otherwise undesirable.
5. Compare—language that was not directly applicable to the current project but may have useful information or phrasing that should be reviewed during drafting.

Several issues were raised and placed into a “parking lot” for future discussion, including matters that may vary depending on state law, or that proved to be controversial or unaddressable within the project timeframe. By creating the parking lot, the IOA Collaborative was able to focus on drafting a baseline model DSA.

In Chicago the IOA Collaborative completed the ranking of provisions for privacy, security, insurance, and indemnification. Following the meeting, Collaborative members returned to their respective states to review and rank the remaining categories. Provisions related to definitions, recitals, software/hardware, and fees/consideration were placed on the back

burner, and states were tasked with reviewing recipient requirements, provider requirements, terms and termination, confidentiality of proprietary information, disclaimers, and boilerplate provisions. The states sent these rankings back to the IOA Collaborative, which held additional WebEx meetings to resolve discrepancies and finalize the selection of categories and provisions for the final model agreements. At that point, the IOA Collaborative began the DSA drafting process.

3.4 DSA Drafting Process

The IOA Collaborative met in person again on September 25 and 26, 2008, in Research Triangle Park, North Carolina (RTP) to finalize the base language for the IOA Collaborative model agreements. Prior to this meeting, the ranked provisions were narrowed down to those provisions labeled as "Core" by the IOA Collaborative members. For 2 days in RTP, the group worked through the core provisions to determine the best language and revise the language to best fit the goals of the Collaborative. This involved displaying the relevant language on a screen for the entire group (and via WebEx for those who could not attend in person) and redlining the language in accordance with the ongoing discussion. The core provisions also were organized into contract format with boilerplate language and formatting added to provide users with a complete document. The IOA Collaborative discussed the remaining parking lot issues and reached a consensus on those issues that had to be addressed in the model agreements. The group then broke into two subgroups: public-to-public and private-to-private. These subgroups began discussions on how to tailor the main model agreement to each of the subgroups; the result was that two different model agreements and one set of core provisions would apply to both.

After leaving RTP, each of the subgroups met via WebEx to continue tailoring the core provisions for each of their respective uses. Initial drafts were sent out within each subgroup for additional review and comment (including taking the documents back to the state work groups, if required by each state's respective process). After incorporating each state's comments, the drafts were sent out to the IOA Collaborative as a whole for yet another review. Those comments also were incorporated and, ultimately, each subgroup finalized a model agreement. The result was a public-to-public draft agreement and a private-to-private draft agreement, included in this report as Appendices C and E.

4. PILOT PROJECT: PUBLIC HEALTH / IMMUNIZATION REGISTRY EXCHANGE

This section provides details related to the public entity pilot project conducted by the IOA Collaborative members from Guam, Iowa, New Jersey, and South Dakota. The pilot focused on cross-state exchange of immunization registry data and was designed to determine whether the IOA model public entity DSA would be signed and executed in real-life settings. The process resulted in many lessons learned for application in future efforts. Note: although the IOA pilot tested immunization registry exchange, the public-to-public agreement is intended to facilitate all types of public entity data exchanges and is not limited to immunization registries.

4.1 Background

Consumer/patient health information is regularly, routinely, and automatically put into state-based electronic public health registries from birth to death. The health information in these systems includes:

- immunization records;
- communicable disease information;
- cancer/tumor information;
- lead exposure;
- birth deficiencies;
- hospital discharge summaries;
- STDs; and much more.

For the most part, these registries are supported by federal funds and are generally organized to aggregate specific kinds of information into common data sets. Because of privacy and security concerns implicit in the movement of health information from state to state, as well as local perceptions about the use of health information, these critical consumer/patient public health records are, at times, not available when needed. This lack of interoperable health information exchange capability results in redundant testing, unnecessary repeat vaccinations, and inefficient use of government and private funds.

States 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 they enable health care providers to access a database of immunization histories for their respective patients.

CDC has partially funded immunization registries yet states were given autonomy in choosing the design and technical specifications for their respective systems. Such is the

case for Guam, Iowa, New Jersey, and South Dakota; each maintains a distinct immunization registry system.

The pilot test of the Guam-Iowa-New Jersey-South Dakota Immunization Registry Exchange was designed to demonstrate:

a. that parties will sign a cross-state DSA developed by a national Privacy and Security project work group; and

b. that cross-state electronic data exchange is feasible, in light of the distinctiveness of the registry systems.

4.2 Rationale

Guam, Iowa, New Jersey, and South Dakota have electronic registry systems that track immunizations provided to residents. Guam's Immunization Information System is called GUWebIZ, Iowa's system is called Immunization Registry Information System (IRIS), New Jersey's system is called New Jersey Immunization Information System (NJIIS), and South Dakota's system is called South Dakota Immunization Information System (SDIIS).

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

Although Guam, Iowa, New Jersey, and South Dakota are geographically distant from one another, public health officials were interested in testing immunization registry exchange for future monitoring of immunization status. The pilot project for Guam-Iowa-New Jersey-South Dakota Immunization Registry Exchange has the potential to lay the foundation for more widespread regional and nationwide immunization data exchange efforts.

4.3 Project Benefits

While Guam, Iowa, New Jersey, and South Dakota currently do not share immunization data, all sought to enable secure, electronic exchange of immunization data to establish the ability to update and provide for more complete records. Such an exchange could ultimately 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);
- 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, multistate 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 states' willingness to collaborate to promote and protect the health of citizens;
- establish a replicable model for similar and related public entity data exchange projects;
- substantially benefit consumers/patients by making patient immunization/ vaccination records electronically accessible; and
- provide a foundation to expand into an electronic Childhood Medical Records System.

4.4 Technical Details—Guam-Iowa-New Jersey-South Dakota Exchange

Each state agreed to produce a batch data file containing immunization records as follows:

a. All patients 18 years of age (defined as date of birth January 1, 1990–December 31, 1990) contained in the system.

b. Create the file in pipe delimited text format.

c. Include data elements associated with these patient records as follows:

   – Patient data:

     - patient ID;
     - first name;
     - middle name;
     - last name;
     - suffix;
     - alias/nickname;
     - date of birth;
     - gender;
     - birth state/county;
     - race(s);
     - Hispanic origin(s);
     - health plan(s) w/ID(s);
     - SSN;
     - mother first name;

- mother middle name;
- mother last name;
- mother maiden name;
- street address line 1;
- street address line 2;
- street address – suite;
- city;
- county;
- state;
- zip code;
- primary phone;
- secondary phone;
- contraindications; and
- patient notes:
  - date;
  - note.

– Vaccination data:

- vaccine;
- vaccination date;
- clinic;
- lot number;
- manufacturer;
- injection site;
- provider name; and
- provider title.

Iowa provided the name of a secure file transfer protocol (FTP) site to utilize for this data sharing project. Each state agreed to provide an electronic copy of their immunization registry Data Dictionary, if requested.

Each state electronically transferred the batch file to the secure FTP site using standard and acceptable security measures for electronic exchange. Once placed on the site, the files were accessible to the parties to the agreement. It was agreed that the files would be sent to the FTP site within 3 weeks after the agreement was signed.

4.5 Technical Details—Iowa / South Dakota Exchange Only

I. Both states agreed to produce a batch data file containing immunization records as follows:

a. Patients ages 0 to 25 years (as of December 31, 2007) treated in counties contiguous between Iowa and South Dakota:

- Iowa counties include Lyon, Plymouth, Sioux, and Woodbury.
- South Dakota counties include Lincoln, Minnehaha, and Union.

b. Create the file in pipe delimited text format.

c. Include data elements associated with these patient records as follows:

- patient first name;
- patient last name;
- date of birth;
- vaccine name;
- vaccination date;
- source of the vaccination (clinic);
- unique patient identifier;
- optional data elements (if available):
  - patient middle name;
  - gender; and
  - mother's maiden name.

II. Iowa provided the name of a secure FTP site to utilize for this data sharing project.

III. Both states exchanged an electronic copy of their immunization registry Data Dictionary within 3 weeks of the signing of the agreement.

IV. Both states electronically transferred the batch file to the secure FTP site using standard and acceptable security measures for electronic exchange within 3 weeks of the signing of the agreement. The files were accessible to both states' project staff once placed on the site.

4.6 Signatures

The following individuals signed the IOA Collaborative public-to-public agreement:

From Iowa:

- Mary Jones, Deputy Director, Iowa Department of Public Health, October 31, 2008

From South Dakota:

- Doneen Hollingsworth, Secretary of Health, South Dakota Department of Health, November 7, 2008

From Guam:

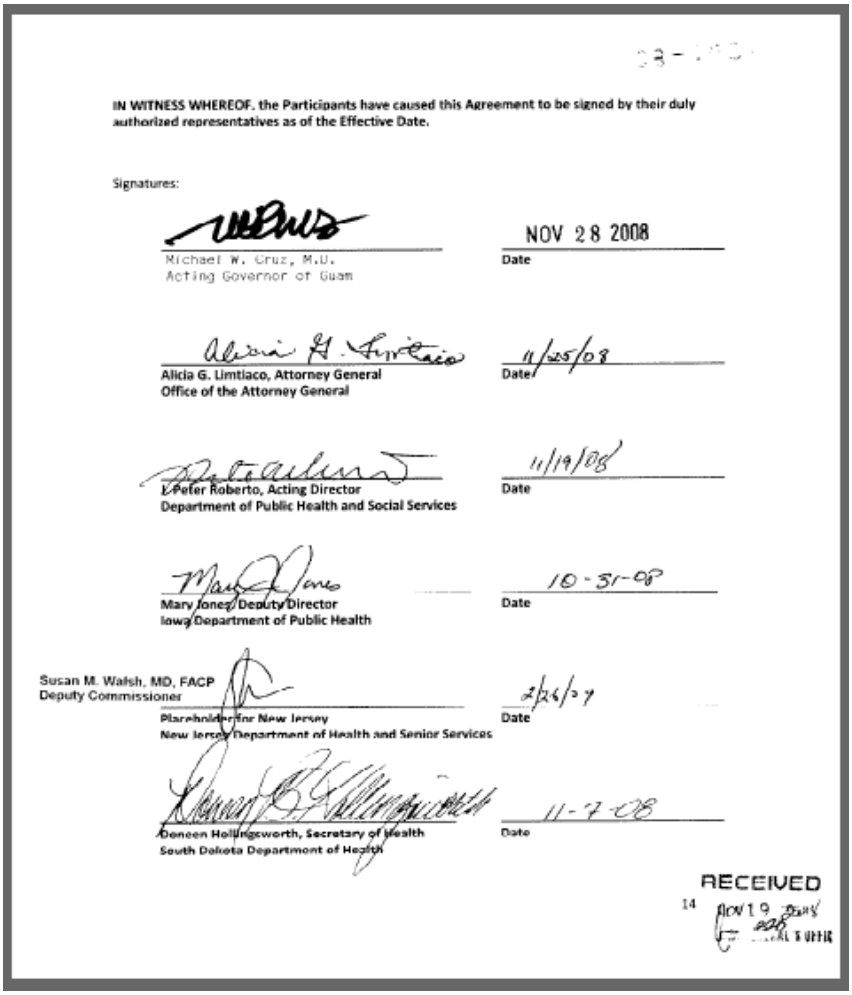
- J. Peter Roberto, Acting Director, Department of Public Health & Social Services, November 19, 2008
- Alicia G. Limtiaco, Attorney General, November 25, 2008
- Michael W. Cruz, MD, Acting Governor of Guam, November 28, 2008

From New Jersey:

- Susan M. Walsh, MD, FACP, Deputy Commissioner, New Jersey Department of Health and Senior Services, February 26, 2009

A screen shot of the signature page from the IOA Public Health Data Sharing Agreement is shown here:

Figure 3. Signature Page from IOA Public Health Data Sharing Agreement



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

Signatures:

Michael W. Cruz, M.D.
Acting Governor of Guam — Date: NOV 28 2008

Alicia G. Limtiaco, Attorney General
Office of the Attorney General — Date: 11/25/08

J. Peter Roberto, Acting Director
Department of Public Health and Social Services — Date: 11/19/08

Mary Jones, Deputy Director
Iowa Department of Public Health — Date: 10-31-08

Susan M. Walsh, MD, FACP
Deputy Commissioner
Placeholder for New Jersey
New Jersey Department of Health and Senior Services — Date: 2/26/09

Doneen Hollingsworth, Secretary of Health
South Dakota Department of Health — Date: 11-7-08

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4.7 Results and Lessons Learned

- **Iowa / South Dakota exchange:** Iowa and South Dakota exchanged 151,000 patient records and 1.16 million vaccine records in January 2009 using the public health agreement developed by the IOA Collaborative.
- **Guam / Iowa / New Jersey / South Dakota exchange:** Guam, Iowa, New Jersey, and South Dakota exchanged 50,000 patient records and 662,000 vaccine records in January 2009 using the Public Health DSA developed by the IOA Collaborative.
- The combined efforts resulted in the exchange of 201,000 patient records and 1.825 million vaccine records.

Lessons learned from the public-to-public pilot project are documented in Section 7 of this report (IOA Project Evaluation).

5. PILOT PROJECT: PRIVATE ENTITY HEALTH INFORMATION EXCHANGE

This section provides details related to the private-to-private pilot project that the IOA members from North Carolina and Alaska conducted. This process was designed to (a) further vet the IOA model private-to-private DSA by external parties including nonlegal representatives, and (b) obtain approval from pilot representatives that the IOA DSA is ready for signature at the relevant time for live data exchange.

The North Carolina and Alaska contingents completed a pilot test of the private-to-private agreement. In compliance and consistent with the IOA Collaborative's proposal, the IOA determined the most appropriate pilot location and participants, developed a plan for the pilot, implemented such plan, and then conducted an evaluation and analysis of the pilot. The following is a general description of the private-to-private pilot.

5.1 Choice of Pilot and Participants

The IOA Collaborative chose to use providers in North Carolina to test the private-to-private agreement. The advantage of using these particular providers was that they were already participating as one of the regional health informational exchange organizations (RHIOs) within the NHIN. As members of the NHIN, the overarching group, represented by the North Carolina Healthcare Information and Communications Alliance (NCHICA), had executed the initial test data agreement drafted by the NHIN DURSA. Therefore, the private data exchange agreement needed to be integrated with the DURSA, while allowing for the exchange of data among the individual participants in the health information exchange. As such, the choice of the particular group supported the collaboration between the IOA Collaborative and NHIN, tested its interaction with other documents, allowed a review of its potential for national use, and provided other related advantages. Because the providers within North Carolina are acting as a relatively new network, no longstanding agreements or fixed views had to be addressed. Nonetheless, the participants were familiar with similar language, insofar as the IOA Collaborative reviewed and utilized some of the language from North Carolina participants, including a form NCHICA developed and a form from an anonymous system in North Carolina. In addition, the network was familiar with the DURSA language. Finally, because North Carolina is a participant in the IOA Collaborative, the North Carolina LWG had previously participated as part of the IOA Collaborative, represented a variety of different entity types and viewpoints, and was interested in providing additional feedback as part of the pilot.

It is important to note that the private-to-private pilot was related solely to test data, although it is hoped that, going forward, actual PHI will be shared under this agreement.

5.2 Plan for Pilot

Based on the unique posture of the participants within North Carolina, the IOA Collaborative developed an eight-stage plan for implementation of the pilot.

- A first step was to obtain agreement to give NCHICA authority to sign the test DURSA with the understanding that the North Carolina providers ultimately would enter into an agreement among themselves based on the IOA Collaborative's DSA document when live PHI would be exchanged.
- The parties agreed that the participation of the LWG within North Carolina would be allowed and promoted.
- A delegation from Alaska would participate and assist in observing the negotiations.
- The DURSA and draft IOA DSA documents were distributed to each of the potential participants as well as the North Carolina LWG.
- During a scheduled phone call, novel provisions of the agreement were explained and discussed. Participants in the phone call included potential participants and other members of the LWG within North Carolina.
- Comments were collected following the phone call and any suggested revisions were also received. These comments and revisions were then included in a revised document that was distributed to members of the LWG and the participants.
- An in-person meeting was held with all participants and the LWG, as well as observers from Alaska.
- Approval from counsel was obtained for a majority of the participants that the agreement was ready to be signed at the relevant time.

Based on the above plan, NCHICA received authority from each of the North Carolina participants to execute the DURSA. Those participants, members of the North Carolina LWG, as well as the Alaska contingent then participated in creating an agreement for the exchange of data among the North Carolina participants in the NHIN. The participants reviewed and discussed the template DSA agreement during a conference call that generated comments and recommended revisions that were incorporated into a redlined document. Following two meetings, consensus was reached on the agreement and some relatively small changes other than Section 14 (regarding the ability to add new participants to the data exchange). A final document was distributed and the parties received approval of that form by counsel for the participants, with the understanding that it will be executed at such time as the final "live data" DURSA is accepted. Execution of the agreement and data exchange will be completed at that time, most likely later this year (2009).

5.3 Evaluation / Analysis

The broad spectrum of participants in the pilot project contributed to its overall success. This success can be measured in a number of relevant ways, including the breadth of input, the improvement of the document, and promotion of use of the document.

The pilot included active participation by a number of hospitals and academic medical centers, physician groups, the North Carolina Medical Society, other nonprofit entities, NCHICA, nonphysician and nonhospital participants, and others. Additional input came from a major clinical laboratory provider and others, including those with a legal background as well as some with a technical background in information technology (IT). These nonlegal backgrounds provided viewpoints that were not previously explicitly addressed. Interestingly, the discussion did not focus on major anticipated issues such as indemnification, because the participants appeared to agree upon many of the conclusions reached by the IOA Collaborative. Rather, much discussion focused on new issues such as the inclusion of independent contractors and whether large entities would want to include health care operations, as defined by HIPAA, as a permitted reason for access to the participants' PHI. Second, a number of the discussion points led to revisions to the DSA language that was shared with the leadership of the IOA Collaborative. We anticipate that the agreement ultimately will be revised to incorporate these changes. Finally, given the large number of participants in the pilot, we understand that some participants are likely to use this DSA for future exchanges. As stated by one participant who helped to create a large network of hospital providers, *"We wish that we had this document 3 years ago so that we could have saved a great deal of time and effort."* We believe that such providers are likely to use this agreement going forward.

5.4 Alaska Observations

From the beginning of HISPC Phase III, Alaska was interested in a private-to-private pilot based on the membership of the Alaska e-Health Network, which is composed mostly of private or nongovernmental health care entities. Because Alaska did not have the infrastructure to consider an actual pilot and did not have a pre-established pilot group such as North Carolina's electronic HIE group, the most practical and beneficial option was to assist and observe the North Carolina pilot. This allowed the Alaska representatives to see the effort and coordination necessary to launch an exchange and agree on terms for an exchange among numerous nongovernmental participants. Additionally, Alaska could provide a third-party viewpoint of the discussion and events that took place as part of the private-to-private pilot.

5.5 Lessons Learned from the Private-to-Private Pilot

The North Carolina pilot benefited from the previous formation of a pilot group for the NHIN project. However, even with this step accomplished, coordination of the parties involved several attempts at scheduling, numerous e-mails, and meeting accessibility by phone and WebEx. This highlighted the importance of scheduling meetings as soon as possible and factoring in scheduling as part of any timeline. This would be even more important in Alaska, where many providers would have to travel by plane to an in-person meeting and where fast Internet connections may not be available in all locations. It is also important to

make participants aware of deadlines, so that they can adjust their schedules accordingly and set aside time for any necessary review of exchange documents.

The actual discussions at the in-person and WebEx meetings were extremely insightful. Both Alaska and North Carolina had a primarily legal focus in all earlier discussions, and analysis in the pilot meetings brought others to the table. Business and technological issues were highlighted—an important consideration for private organizations. These topics rounded out the discussion, so that many potential areas of concern to a major health care entity were covered.

Through the private-to-private pilot project, this group learned a number of lessons for future implementation of a private-to-private exchange. One key lesson was to extend the discussion beyond the lawyers. Although lawyers may be the ones to ultimately provide the stamp of approval regarding the liabilities and protections necessary in a DSA, they are not the ones who deal with health information on a daily basis. The providers, privacy officers, and information technology personnel are able to relay insights on the actual implementation of the exchange that may never be considered by attorneys and executives. Without this input, the exchange agreement could be iron-clad with respect to liability, but still be significantly less useful in the real world.

Another key lesson was the importance of early coordination. When several private entities are involved in a project that may not initially provide a profit, or that may potentially open them up to liability, it is important to coordinate the schedules of all necessary personnel, whether it be the chief information officer, the general counsel, or the privacy officer. If a health information exchange does not have full participation by these individuals, a complete review and approval of exchange documents could drag on without end. This is particularly true when participants include entities of different sizes that may or may not be competitors in the health care market. This also ties in with the first lesson learned: when expanding the discussion beyond lawyers, be sure to involve all the participants as early as possible to avoid having to continually revise and redistribute the draft agreement.

Although many important insights were gained through the observation process, the final key lesson was to consider the language of the agreement from several different angles—an agreement that works perfectly for a small rural provider may not work at all for a large academic medical center. The parties may be able to compromise or draft alternative language for varying situations, but there also may be times where one party just cannot or will not agree. At that point, the group must return to the goals and priorities of the project and determine what is in the best interest of the exchange. If this means that one or more parties may be left out initially, that might be what it takes to get an exchange off the ground. The parties can then regroup and reconsider options after a working exchange is established.

In summary, observation of the North Carolina pilot was extremely beneficial for the Alaska HISPC team, and will assist future efforts of the Alaska e-Health Network. Additionally, the pilot helped both states realize some common areas where they could benefit from each other, such as providing services to rural communities or military populations. Alaska is grateful to have had this opportunity.

6. COORDINATION WITH EXTERNAL PARTIES

The IOA Collaborative intentionally coordinated with external parties, including the NHIN DURSA Work Group and the other HISPC Phase III Collaboratives, to ensure consistency and continuity with existing and ongoing work in this area. This process also included formal requests for review and feedback on IOA Collaborative work products by trade associations, such as AIRA, and other state and federal agencies, such as CDC.

6.1 NHIN DURSA

The IOA Collaborative's proposal stated that it would attempt to work closely with the NHIN DURSA Work Group, including assignment of an IOA liaison to DURSA and open invitations to the DURSA Work Group to attend IOA Collaborative meetings. The proposal noted that while use of the DURSA was not possible in the IOA DSA context, the IOA Collaborative would review the DURSA Work Group methodology and documents to avoid duplicative ground work. To meet the requirements of the proposal, Roy Wyman, Jr., from North Carolina was named as liaison to the DURSA group, and he participated in the majority of the DURSA meetings. At each IOA Collaborative meeting, he reported on the current status of the DURSA Work Group. Further, the IOA Collaborative used language from DURSA in its review of form documents. In addition, one of the DURSA co-chairs, Holt Anderson, actively participated in the IOA Collaborative as a part of the North Carolina contingent. Finally, as described in Section 5 above, the private-to-private entity exchange pilot used one of the exchange groups within the NHIN. As such, the IOA Collaborative has thoroughly engaged the DURSA group and the work product of the DURSA Work Group rather than duplicating efforts.

6.2 CDC Region 4

This section describes use of the IOA Collaborative's public-to-public DSA for the CDC-funded Contract for Exchange of Surveillance Data Among Public Health Agencies in Region IV.

CDC recently awarded a contract to explore the sharing of situational awareness and surveillance data among the public health agencies in states in Region IV (Southeast) beginning with an exchange between North Carolina and South Carolina. An important part of the contract activity will be the development and execution of a legal agreement among those states. The IOA Collaborative's public-to-public agreement was selected as the starting point to significantly reduce the time and expense required to satisfy the agreement needed for data sharing among the states. The context for the use of the public-to-public agreement was articulated in the proposal to CDC.

> "State public health agencies will engage their legal counsels to explore the legalities of the interstate health information exchange of near real-time data for the purposes of public health response and situational awareness to

> suspected or real population health threats. Local, state, and federal partners from the public and private sector will form a governance structure for the Charlotte metropolitan region public health information exchange."

NCHICA, North Carolina's representative to the IOA Collaborative, was named in the CDC proposal as the interface between the IOA Collaborative and the project for policy coordination. William O'Byrne, Holt Anderson, and Roy Wyman, Jr. participated in adapting the public-to-public agreement to the needs of North and South Carolina in sharing epidemiological data.

6.3 Other Agencies and Organizations

After the pilot process, the IOA Collaborative decided to seek feedback from additional agencies, organizations, and trade associations on the Public Health DSA to further vet the usefulness and applicability of the agreement.

6.3.1 Federal Agency Review

The IOA Collaborative sought permission from Office of the National Coordinator for Health IT in early February 2009 to seek additional federal agency review.

On February 12, 2009, the IOA Collaborative sent a cover letter and the public-to-public agreement to the following federal agencies for their review and comment:

- Centers for Disease Control and Prevention (CDC), Office of Health Policy
- Centers for Medicare & Medicaid Services (CMS), Division of Privacy Compliance
- CDC, National Center for Health Statistics (NCHS)
- Department of Health and Human Services, Health Resources and Services Administration (HRSA), Research and Policy Group

The IOA Collaborative will utilize any comments received from external agencies after release of this report in future work products insofar as the group remains intact.

6.3.2 American Immunization Registry Association (AIRA)

During HISPC Phase III, the IOA Collaborative approached the AIRA for their review and comment on the Public Health DSA since the document was being used in the Iowa-South Dakota-Guam-New Jersey pilot project for immunization registry exchange.

Over the last months of 2008 and January 2009, the IOA Collaborative and AIRA had a number of conversations to discuss changes that AIRA suggested. The changes converted the public-to-public agreement from a model agreement used in a pilot demonstration into a document that could be used for ongoing, continuing work among two or more public health registries. The suggested and accepted changes did not substantively change the public-to-public agreement.

The official endorsement from AIRA was obtained in January 2009 and stated that the IOA Public Health DSA was "…*formally endorsed by AIRA for use by all states and public health agencies for the interoperable exchange of public health immunization data.*"

AIRA has loaded the updated version of the public entity DSA to their website http://www.immregistries.org/ for download and use by their members. In addition, AIRA produced a press release, pictures, and promotional event about interoperable exchange of public health immunization data and use of the IOA DSA at the National Immunization Conference in Dallas March 29–April 2, 2009.

6.3.3 Public Health Data Standards Consortium (PHDSC)

The PHDSC, established in July 2003, is a nonprofit membership-based organization of federal, state, and local health agencies; professional associations; academia; public and private sector organizations; international members; and individuals.

The goal of the PHDSC is to empower the health care and public health communities with health IT standards to improve individual and community health.

On February 18, 2009, the PHDSC Board of Directors approved the endorsement of the IOA Collaborative's Public Health DSA developed and tested during the HISPC Phase III project.

The PHDSC stated that "…the availability of this model agreement will greatly simplify the establishment of much-needed health information exchanges between public agencies across state lines, such as the sharing of immunization information between states from immunization registries..." PHDSC looks forward to working with the IOA Collaborative to advance the adoption and use of this agreement.

6.3.4 Kansas Department of Public Health

In fall 2008, the Kansas Department of Public Health approached the IOA Collaborative with a request to review the public-to-public agreement. Kansas felt that the IOA DSA is too formal for sharing within Kansas "for the purposes of sharing data … among agencies … to support our Community Health Record pilot project to get immunization and lead screening data" as they have "good pre-existing relationships and DSAs in place for related projects."

Kansas stated that when they "embark on a statewide electronic record initiative in the future," they would use the provisions within the IOA public-to-public DSA as a foundational tool to help take this important statewide step.

7. IOA PROJECT EVALUATION

The IOA Collaborative efforts were evaluated from both a project management and technical perspective. The evaluation results are provided in this section so that lessons learned can be applied to future data sharing efforts.

7.1 Evaluation Summary

An important component of the IOA Collaborative's work was to evaluate within the collaborative how the managerial and technical aspects of the project were completed. Throughout the IOA Collaborative's work, project managers and technical directors captured feedback and other lessons learned so that both successes and pitfalls could be passed along.

7.2 Managerial Aspects

7.2.1 Process for Signing Data Sharing Agreements

The Public Health DSAs were signed by deputy commissioners, directors, or acting managers of departments of public health (in New Jersey, South Dakota, Iowa, and Guam) and the Deputy Commissioner, Department of Health and Senior Services (New Jersey). Signatures of the Lieutenant Governor and Attorney General from Guam were also obtained.

In some states, the signing process took place during a relatively short time frame. For example, in South Dakota, after health department staff and legal review, the Secretary of the Department of Health, Doneen Hollingsworth, reviewed the agreement overnight, asked several questions and signed it the next morning.

In Iowa, the Deputy Director of the Iowa Department of Public Health (IDPH) signed the IOA Agreement on October 31, 2008, within 2 weeks of receiving the final version. The process involved:

- meeting with the Director and Deputy Director of IDPH early in the project (May) to inform them of overall objectives, timeline, etc. and to determine who would ultimately sign the agreement;
- approval by the Iowa Attorney General's Office after multiple telephone conferences, face-to-face meetings, and communications to inform the Attorney General's representative throughout the IOA drafting process;
- review of technical aspects defined during many conference calls and e-mail exchanges with just the technical group; and
- forwarding of agreements to South Dakota upon signature.

For other states, this process took much longer. For example, the process in New Jersey involved four levels of review taking over 12 weeks.

7.2.2 Resources Required for the Approval Process

The number of hours required for the entire agreement approval process varied from state to state and is difficult to quantify. Alaska learned that states should anticipate and account for legal, clerical, and managerial time requirements. In South Dakota, 8–16 hours vendor hours were required to develop the technical attachment for each exchange, and to anticipate time and resource requirements for meetings with signatories and/or their staff well in advance of receiving the agreements. In Guam, participation of state-affiliated legal counsel (in this case, Governor's legal counsel) throughout the project expedited the signature process and ultimately reduced resource requirements associated with briefing government officials on the details.

7.2.3 Benefits of Participation in the Pilot Process

Reports confirm that the project helped state agencies further the exchange of records. All project directors concurred that the agreement was helpful and could be used by other states and organizations. By identifying key parties involved in cross-state data sharing efforts, the project created a path that will make future collaborations easier. The project was often described as initiating and promoting dialogue among health agencies (for the public-to-public version) and among private providers (for the private-to-private version). Guam anticipates that the project and the DSAs will assist in advancing electronic health information exchange on the island, between other jurisdictions in the region, and with other states. Alaska is planning to use the project documentation as a template to begin their statewide pilot project in 2009. A quote from South Dakota personnel summarizes an additional benefit of the project:

> *"We realized that this 'template' concept really could work, and began to think about the other registries we use for interstate exchange that could add valuable data. The value in State Officials signing these agreements is that it gives them a certain weight of importance so other states realize they can be used in real life."*

New Jersey also found participation to be useful, as demonstrated by their statement that:

> *"Both the IOA model DSAs will be of great use in New Jersey as we go forward joining our public health databases, bring up electronic health information exchanges around the state, and as we build a Route 95 immunization corridor of NJ, NY, PA, and DE that will eventually include FL and PR. New Jersey has a lot of hands-on experience in working through the many delays and challenges we have faced in working with [other agencies]."*

New Jersey also reported that linking the new Electronic Birth Registry with the Immunization Registry and New Jersey Medicaid demographic files will provide the foundation for a statewide record locator service upon which an electronic health record (EHR) network can be built.

Respondents expressed the wish for more time to document the value of the information that was exchanged relative to the agreements. Though the geographic differences of the states involved in the collaborative made that difficult, participants believe that documenting the clinical value of information exchange is an idea to explore.

7.2.4 Work Products Other States Can Use

The Collaborative strongly believes that the DSA and the technical attachment template will be of value to other states and territories, especially since the groups developing them were both geographically and demographically diverse (e.g., South Dakota, Iowa, Guam, New Jersey). Some of the products that have emerged from this work include an Implementation User Guide, a Library of Data Sharing Agreements, a DURSA/IOA Crosswalk, model DSAs for public entity and private entity exchange, frequently asked questions (FAQs) for using the agreements, and different versions of the model agreements for various purposes, such as an agreement tailored for use specifically by the AIRA and an agreement for biosurveillance purposes.

7.2.5 Feedback and/or Endorsements Provided by Organizations Outside the IOA

To date, numerous agencies have provided review and feedback on the public-to-public DSA, including:

- AIRA,
- Public Health Data Standards Consortium (PHDSC),
- Kansas Department of Public Health,
- Pennsylvania Department of Health,
- South Carolina Department of Health and Environmental Control, and
- CDC Region IV Pilot

These agencies have approved or endorsed the public-to-public DSA:

- Iowa Department of Public Health, October 2008
- South Dakota Department of Health, November 2008
- Office of the Governor, Guam, November 2008
- AIRA, January 2009
- PHDSC, February 2009
- New Jersey Department of Health and Senior Services, February 2009

Organizations involved in reviewing the private-to-private DSA include:

- Duke University,

- Western North Carolina Health Network,
- Blue Cross/Blue Shield of North Carolina,
- North Carolina Medical Society,
- North Carolina Department of Health and Human Services (DHHS),
- First Health Hospital,
- Alaska e-Health Network,
- Carolina Neurosurgery,
- Morehead Memorial,
- Pinehurst Surgical, and
- Southern Pines Women's Clinic.

The Alaska e-Health Network also played a role in reviewing and approving various parts of this project and it may endorse the model agreements for future use within the state.

7.2.6 State-Specific IOA Presentations during Phase III

Project managers presented the project to other groups both within and outside their state. These presentations included, but are not limited to:

South Dakota: South Dakota Health Information Technology Summit (October 2008); South Dakota Technology Summit (November 2008).

Alaska: Various Alaska health care organizations, professional associations and agencies; WEDI National Conference in California (November 2008); Alaska Bar Association health care section regarding the legal issues covered by this project (December 2008).

Iowa: Iowa Department of Public Health (May 2008); Iowa HISPC Steering Committee (May, August, and November 2008, March 2009); Iowa Hospital Association—Critical Access Hospitals HIT Committee (October 2008); Office of the Governor, Health Policy Staff (May 2008); Federation of Iowa Insurers (May 2008); Annual Iowa HIT Summit (August 2008); State e-Health Council (Jan-March 2009).

New Jersey: New York State and City health IT officials to establish interstate exchanges of Immunization Registry data; City of Philadelphia Department of Health and CDC officials to promote interstate exchange of Public Health Registry data; demonstrations of New Jersey's Immunization Registry for members of the IOA Collaborative and Puerto Rico to share opportunities presented in sharing public health data electronically; HIMSS, NGA, PAeHI, and SLHIE on DSAs and the ability to share public health information data; engaging the AIRA to obtain approval of the public-to-public agreement; and integration of IOA agreements into New Jersey's Electronic Medical Record exchange pilot project.

7.2.7 Additional Comments from the Evaluation

Participants in the public health pilot cited that preparatory work completed by state departments of health before the data exchange significantly affected the timeliness of getting the document signed. Otherwise, issues related to lean departmental staffing in public health agencies and other priorities within the Department of Health can delay the process significantly.

The tools resulting from this project should significantly speed up future pilots. Watching other states go through the process provided insight on how to approach signing the agreements, particularly regarding setting realistic timeframes for agreement involving several parties. Other practical tips for completing agreements include:

- Communicate the project context and the big picture from the start. To that end, the Collaborative drafted a list of FAQs that will help other states beginning the process.
- Identify and invite key stakeholders to the process as early as possible (vendors, agencies, providers, etc.).
- Allow sufficient time for planning and communication between the technical teams about the technical specifications; they are very important because they are used to pull the data files.
- Initially, keep the scope of cross state data exchange small. Test it, validate it, and then expand the scope after the system for exchange is vetted.
- For best results, select a point person to manage and walk others through the process (both the agreement signing and technical completion of data exchange).

One project manager put the information in context:

> *"Everything mentioned above lays the groundwork for future efforts that will have a greater impact on patient care and access to patient data. The impact of the current pilot exchanges was minimal in and of itself in terms of benefiting patient care and safety. The goal is to work toward improved quality and safety of care through data exchanges that are real time and hopefully automated to maximize access to data while still protecting privacy and security. We wanted to demonstrate that exchange can happen in a relatively short time, and the time frame should be lessened with our model data sharing agreements and implementation guides."*

7.3 Technical Aspects

Technical directors of participating states who had oversight of the programming processes required for the immunization registry exchanges provided the following information.

7.3.1 File Exchange Numeric Results and Technical Comments

Once agencies established connectivity, they uploaded and downloaded files with up to 37 data elements without incident. The initial exchanges between South Dakota and Iowa required some troubleshooting when the connections continually failed. However, when

server and client incompatibilities were resolved, the exchanges were successfully made (see Tables 2 and 3). Participants described security protocol as *"require[ing] tight coordination [making] troubleshooting the initial connectivity issues VERY difficult."* Results of the immunization exchange projects (Iowa–South Dakota two-way exchange and Guam-Iowa-South Dakota-New Jersey four-way exchange) are shown in Tables 2 and 3.

Table 2. Iowa–South Dakota Two-Way File Exchange Frequencies

Exchange	Iowa[1]	South Dakota[2]
Patient records	67,891	82,998
Vaccination records	896,624	266,801

[1]Iowa counties included Lyon, Plymouth, Sioux, and Woodbury.
[2]South Dakota counties included Lincoln, Minnehaha, and Union.

Table 3. Guam–Iowa–South Dakota–New Jersey Four-Way File Exchange Frequencies

Exchange	Guam	Iowa	South Dakota	New Jersey
Patient records	908	25,723	11,884	11,176
Alias	4	273	57	235
Race	639	15,567	1,167	11,176
Contraindications	0	2,937	380	0
Vaccination records	10,020	363,906	128,853	158,819

7.3.2 Record Duplication Analysis and Data Accuracy

Upon receiving the initial file from South Dakota, Iowa identified duplications in both patient and vaccination records (see Table 4). A complication in identifying vaccine duplications occurred when analysts discovered that Iowa and South Dakota use different coding schemes for vaccines (South Dakota uses "Vaccine Code" while Iowa uses the CVX code). Iowa then attempted to match vaccines according to the "Vaccine Abbreviation." Of the 3,691 patients that matched between Iowa and South Dakota, South Dakota's file contained 39,320 vaccinations. Iowa's file for the same patients contained 15,160 vaccinations. According to these calculations, approximately 24,160 vaccinations that Iowa did not have in their Registry could be downloaded to augment existing patient histories.

Table 4. Iowa-South Dakota Record Duplication Analysis

Records	Total	Duplications	Duplication Rate
Patient records	82,453	3,691[1]	4.48%
Patient records	82,453	2,798[2]	3.39%
Vaccination records	1,135,399	15,160	1.33%

[1]Records matched by first and last names and date of birth.
[2]Records matched by first, middle, and last names and date of birth.

Data accuracy was verified by importing the text file directly to a precreated database table. This table was then compared to Iowa's Registry database.

7.3.3 Required Technical Resources

Participants reported that time involved in the management and preparation of electronic data transfer including participating in conference calls, reading e-mail messages, troubleshooting connectivity issues, and conducting file comparisons ranged from 10 to 36 hours. Reports of time spent generating and transmitting the files ranged from 30 minutes to 2 hours. The longer response of 2 hours resulted from the manual translation of records, required to meet the file format.

7.3.4 Recommendations for Technical Enhancements to Improve Future Exchanges

Technical directors in the data transfer process identified some very specific issues to improve the exchange of data and adoption of the agreement.

- Identify technical and immunization program contacts for each collaborative partner at the start of the project.
- Ensure that all subcontractors are identified early in the process. The groups that make the decisions concerning the registry are not necessarily going to make the actual transfer or write the queries that will access the data from the registry.
- Recognize that error checking is a vital component from the onset; the parties should select the most appropriate method.
- Select values and guidelines that will create consistency in the file exchange (i.e., CDC HL7 specifications for data formats).
- Formalize requirements and technical definitions documents before beginning technical/programming aspects of projects.
- Establish a signoff procedure or similar method to ensure data transmissions to and from the secured FTP site are reconciled.

The primary goal of this project was to develop model DSAs and pilot test whether they would actually be signed as part of a real health information exchange project. The primary focus was not the data exchange itself, although it was important for the project to complete a data exchange to confirm the viability of the agreements.

8. FUTURE VISION AND NEXT STEPS

The groundwork of the HISPC Phase III IOA Collaborative has paved the way for continued and expanded efforts.

The IOA Collaborative's future vision is filled with challenges, hard work, and significant opportunities for the advancement of inter- and intrastate electronic health information exchange. When HISPC first began in early 2006, the health IT landscape was in the early stages of development. Technologically, there were IT systems and security and privacy practices that could securely exchange health IT but there was no standardized agreement between major trading partners and states to support the actual exchanges. Although independent networks were established and some health care providers had implemented EHRs and practice management systems, some RHIOs had failed, resulting in increasing concerns about sustainable business models to support electronic health information exchange. Amid this environment, HISPC was launched to gather state health IT leadership groups together to identify those business practices, policies, and state laws that presented challenges to interoperable electronic health information exchange.

Perhaps most importantly, HISPC showed the states how to collaboratively work together to solve common problems with rational and mutually agreeable solutions. Working with inter- and intrastate partners, participants quickly recognized that all states and private entities must address many of the same health IT and electronic health information exchange problems such as: identification and authentication, documents necessary to support data sharing, consent, public health records, architecture, format, local laws, education of providers and consumers, self-serving interests, use of existing technology and systems, open source and generic formats, fear of new ventures, lack of investment capital, and countless other obstacles. Having seen the similarity of shared problems, participants were able to direct their collective attention to consideration of mutually agreeable solutions that resolve barriers while respecting the individuality and sovereignty of each state. With this attitude as our foundation, the IOA Collaborative made considerable progress, which can be the foundation for a very bright health IT and electronic health information exchange future.

In looking toward the future, the IOA Collaborative sees the following opportunities for advancement of private and secure interoperable electronic health information exchange.

8.1 Developing a Standard NHIE Agreement

One of the fundamental, building-block components of the NHIN is the evolving NHIEs (defined local, state, and regional health information exchanges). These NHIEs are formed by individual organizations, such as health care providers, health plans, nonprofit organizations, local and state government entities, etc., coming together and agreeing to exchange health information via a secure, organized electronic health information exchange

structure. These NHIEs will need a standard DSA that all its "members" will have to abide by and comply with.

It is our understanding that there is no effort at this point to develop an agreement focused on the "N" in NHIE to meet the expectations and needs of the stakeholders that make up the NHIEs that join the NHIN.[7] One opportunity for the IOA could be to develop a harmonized model agreement at the NHIE level. Such development would include collecting examples of the types of agreements currently being used, including those listed above and others, performing the same type of analysis the IOA used in developing the two model agreements earlier in Phase III (gap analysis, harmonizing language, etc), using the model agreements for guidance, and then delivering a model NHIE agreement.

We hope to partner with ONC, AHIMA, or another sponsor to pursue this work. Table 5 depicts our proposal:

Table 5. Proposed Exchange and Data Sharing Agreement

Type of Exchange	Legal Agreement to Support	Responsible Group
National level: between electronic health information exchanges through the NHIN	DURSA	DURSA Work Group
Community-level electronic health information exchange: hospitals, labs, pharmacies, physician offices, public entities exchanging data with the electronic health information exchange	*No standard agreement available.* Existing electronic health information exchanges have independently developed their own agreements.	*Our proposed NHIN-NHIE Collaborative*
Point to point within a community or across state lines between public entities or private entities	IOA DSAs	HISPC IOA Collaborative

In essence, the current HISPC III IOA Collaborative would become the NHIN-NHIE Collaborative to develop a standard community electronic health information exchange DSA. This work would spring from existing IOA work and existing community electronic health information exchange agreements, and would be compatible and interoperable with the DURSA live data agreement. The scope would likely include development of a public entity-to-private entity DSA (not previously developed by the IOA Collaborative), since community electronic health information exchanges will need to exchange government data (including public health data) in addition to data held by private entities.

[7] A number of community-based data exchange agreements exist (for example, the Indiana Information Exchange, Utah's UHIN, Massachusetts NEHEN, etc.). There are also examples of model contracts for electronic HIE (Markle Foundation, eHealth Initiative).

8.2 Expanding Work with Immunization Registries

Another opportunity for the IOA is to continue work with AIRA to facilitate further immunization sharing projects. The AIRA has already endorsed the public-to-public agreement as the standard DSA for immunization registry exchange across state lines. This continued work would further advance and harmonize interstate immunization registries under the auspices of the HISPC IOA states, together with any other states and territories that may wish to join our efforts, including but not limited to Kansas, Nebraska, Pennsylvania, North Dakota, Minnesota, and Wisconsin (states that have already expressed interest in joining). We currently have the ability to expand to other states, regions, and the entire country and to include other public health registries. We expect that the immunization registry exchanges will not only involve public health immunization records, but will also be expanded to include additional modules such as lead testing, birth defects, certain demographic information, automatic mailings for repeat shots, and inventory information pertaining to inoculation supplies, communicable diseases, and other registries where permitted by local law.

8.3 Facilitating Further External Review of DSAs

The IOA Collaborative can further expand the use of the model DSAs by facilitating review and use of the model DSAs by outside agencies and organizations, such as CDC, to increase awareness that the DSAs were developed and to encourage adoption as standard agreements for cross-state data sharing efforts.

8.4 Exploring Parking Lot Issues

As discussed earlier, many IOA issues outside the scope of the Phase III project were placed into a “parking lot” for further discussion. Because a basis and context already exists for these issues, the IOA could further enhance the content of the agreements by addressing these issues.

8.5 Integration of Electronic Record Systems

The IOA expects that future enhancements to state Immunization Registries will result in linkages with state Vital Statistics and Electronic Birth Record Systems (EBRs) and Medicaid’s electronic medical records system under the Transformation Grants (MITA). Such integrated systems would create an electronic birth record and an electronic immunization registry within 24 hours of birth. Furthermore, demographic information would be captured to ensure timely and accurate payment of health care claims under insurance coverage or Medicaid. This kind of integration of electronic systems would never have been possible without the partnerships built during the HISPC years. Perhaps most importantly, assembly of health care data and demographic information at birth would resolve many perplexing privacy and security issues and help end some of the identification issues that health care systems deal with constantly.

These are just a few of the noteworthy projects and plans that have directly evolved from the HISPC efforts. If given the opportunity to continue, the IOA Collaborative is in an excellent position to hasten the advancement of private and secure electronic health information exchanges.

9. CONCLUSION

The IOA Collaborative and the HISPC project have provided a foundation that will positively benefit health IT/electronic health information exchange development at the state and national level for years to come.

The IOA Collaborative came together for a common purpose: to improve patient care and safety by developing model DSAs that support electronic health information exchange and encourage action to begin sharing data within and across state lines.

As this stage of the project concludes, we note a few key highlights.

- All participants will benefit from the established relationships and networking experienced through the collaborative approach of HISPC Phase III. This project helped to foster greater awareness, discussion, and interaction both within and outside the collaborative group related not only to HISPC goals but also other health IT/electronic health information exchange initiatives. The momentum created by this collaboration will carry forward and help facilitate continued sharing and more effective coordination of all of our efforts.
- Although the IOA Collaborative made great progress and successfully completed the stated goals and objectives, the momentum has just begun and much work remains. The group has demonstrated that results can be achieved in a relatively short period of time by working together. Given the cohesiveness, collective experience, and established relationships of the IOA Collaborative, it makes sense to continue to work together and move forward. The IOA Collaborative identified many options for expanding the project as described in Section 8.
- Finding resources to sustain the work after HISPC ends is critical for success. The group has created business cases to clearly state why continuation of this work is important and is pursuing additional funding to that effect.

The IOA Collaborative is pleased to share copies of all final reports, work products, and resources used upon approval from project sponsors.

The IOA Collaborative thanks ONC and RTI for the opportunity to participate and for the support provided by each organization. We look forward to using the final products of all HISPC Collaboratives as we progress toward private and secure interoperable health information exchange.

10. DESCRIPTION OF TOOLS AND DELIVERABLES APPENDICES

This section outlines and explains the IOA Collaborative Phase III tools and deliverables contained in the appendices of this report.

10.1 Overview of Documents Library of Data Sharing Agreements (Appendix A)

To begin the work of drafting DSA templates, the IOA Collaborative collected 45 agreements and related documents from across the country for its initial review. The documents were shared with the IOA Collaborative by public entities, private entities, individuals, trade associations, and others. This initial set of documents was put together as a library for future use and as documentation of where the IOA Collaborative gained its ideas and borrowed legal language.

This set of documents is not exhaustive, nor is it meant to be a legal formbook. It is a list of documents that were generously lent to and borrowed by the IOA Collaborative to use as our foundational work.

Appendix A is an overview of the IOA Documents Library of Data Sharing Agreements that the IOA Collaborative created in Phase III.

10.2 Document Classification Scheme (Appendix B)

To begin the review of the 45 documents collected as foundational material, the IOA Collaborative developed a classification scheme as a guide for reading, reviewing, and comparing the documents and the provisions within (see Section 3.2 of this report). This scheme provided a mechanism for reading and comparing documents that originated in many places and for many purposes; some were intended for a specific type of data sharing, while others were broader documents intended for a wide spectrum of exchange. The IOA Collaborative began this project with a pool of many resources from differing organizations and areas and needed a way to read, review, and compare one resource to another.

Eventually the material and provisions in the relevant documents were classified using this scheme. The major classification headings included:

- document source,
- document type,
- document subject matter,
- definitions,
- recitals,
- statement of relationship,

- data recipient requirements,
- data provider requirements,
- software/hardware,
- privacy,
- security,
- term and termination,
- fees or consideration,
- confidentiality of proprietary information,
- disclaimers,
- insurance,
- indemnification, and
- boilerplate, such as applicable law, notice and waiver.

The IOA Collaborative suggests that any project that begins with a pool of many resources from differing sources use a classification scheme if the resources are to be read, analyzed, and reviewed together.

10.3 Model IOA Data Sharing Agreements (Appendices C, D, and E)

The IOA Collaborative drafted two model DSAs, one for public entity data exchange and one for private entity data exchange. The public entity document was subsequently revised to accommodate cross-state immunization registry exchange, creating a third model agreement. The documents are legal contracts that cover topics such as the purpose and scope of the agreement, use of and access to information, participant requirements, privacy and security safeguards, termination of the agreement, warranties and limitations of liability, compliance with laws and regulations, insurance, notices, governing law, and other areas.

The initial agreements were developed simultaneously. Thus, the language in many of the provisions of the documents is the same or similar. Companion user guides to accompany the model DSAs are also available as described in Section 10.5.

10.3.1 Model IOA Public Entity Data Sharing Agreement (Appendix C)

The Public Entity DSA is intended for public entities to electronically exchange public health records, such as immunization data, lead paint data, and hearing data. As used in the IOA Collaborative public entity pilot, the document was the legal foundation for the sharing of immunization data electronically between Iowa, South Dakota, Guam, and New Jersey.

The Public Entity DSA is also being used by other public health data registries (other than HISPC) to share data as part of ongoing electronic health information exchange projects.

10.3.2 AIRA Version of Model IOA Public Entity Data Sharing Agreement (Appendix D)

The model Public Health DSA was revised slightly to accommodate the purposes of the AIRA in using the agreement specifically for cross-state immunization registry exchanges. This modified version is included as Appendix D.

10.3.3 Model IOA Private Entity Data Sharing Agreement (Appendix E)

The Private Entity DSA model template was designed to facilitate electronic health information exchange between private entities such as hospitals, clinics, and physician offices. An executable version of this agreement was approved by 17 organizations that participated in the private-to-private pilot. The participants in this pilot hope to implement the agreement as part of the NHIN DURSA live data exchange. The document will allow private entities to electronically share PHI without drafting and negotiating contract language from scratch. It is anticipated that in addition to NHIN entities, the document will also be used by other private and/or public entities that want to share PHI such as patient medical records.

10.4 Core Privacy and Security Provisions for an Electronic Health Information Exchange Agreement (Appendix F)

The IOA Collaborative extracted the core privacy and security provisions from the model DSAs to create a document entitled “Core Privacy and Security Provisions for an Electronic Health Information Exchange Agreement.” This document is a resource of provision language if, for example, the need should arise for entities to draft additional agreements or insert some of the language chosen by the IOA Collaborative into existing agreements. Privacy or security language is provided for the following categories:

- definitions,
- purpose and scope,
- use and access to protected health information,
- participant requirements,
- privacy and security,
- terms and termination,
- compliance with laws and regulations,
- insurance,
- subrogation, and

- governing law/choice of law.

10.5 Implementation User Guides (Appendices G and H)

The IOA Collaborative created two user guides to supplement the model DSAs. These documents detail how the DSAs were developed and provide additional considerations specific to the public and private DSAs. Appendix G is the user guide for the public-to-public DSA, and Appendix H is the user guide for the private-to-private DSA.

The user guides outline the development steps and policy decisions that were determined during the development of the template agreements. Understanding the policies, principles, and guidelines used to create the DSAs is essential for the agreements. The user guides outline what the DSAs include and do not include and the assumptions that were made in drafting the DSAs. For example, the security technical details specific to a given project are not part of the DSAs and should be included in an attachment to the IOA core agreement.

10.6 Coordination with the HISPC Phase III Steering Committee and Other HISPC Collaboratives (Appendix I)

The IOA Collaborative was represented on the HISPC Phase III Steering Committee, established to facilitate communication and coordination among the seven collaborative projects. Appendix I describes the results of the coordination activities among the IOA, the Steering Committee, and the other collaborative groups.

11. IOA COLLABORATIVE CONTACT LIST

Alaska
Rebecca Madison, Project Manager
Alaska e-Health Network
Phone: 907.729.3934
e-mail: ramadison@anthc.org

Guam
Doris Crisostomo, Project Manager
Office of the Governor of Guam
Phone: 671.475.9380
e-mail: healthyguam@gmail.com

Iowa
Susan Brown, Project Manager
Iowa Foundation for Medical Care
Phone: 515.440.8215
e-mail: sbrown@ifmc.org

New Jersey
William O'Byrne, JD, Project Manager
New Jersey Department of Banking and Insurance
Phone: 609.292.5316, ext. 50032
e-mail: wobyrne@dobi.state.nj.us

North Carolina
Roy Wyman, Jr., JD, Primary Contact
Williams Mullen
Phone: 919.981.4313
e-mail: rwyman@williamsmullen.com

South Dakota
Kevin DeWald, Project Manager
South Dakota Department of Health
Phone: 605.773.3361
e-mail: kevin.dewald@state.sd.us

12. IOA COLLABORATIVE FULL WORK GROUP MEMBERSHIP LIST

Alaska
Carolyn Heyman-Layne
Attorney
Dorsey & Whitney LLP

Rebecca Madison
Director
Alaska e-Health Network

Guam
Doris Crisostomo
Project Manager
Special Assistant, Health Policy & Initiatives
Office of the Governor of Guam

Shannon Taitano Lujan
Legal Counsel
Office of the Governor of Guam

Iowa
Susan Brown
Manager, Health Information Programs
Iowa Foundation for Medical Care

Jo Ellen Whitney
Attorney
Davis Brown Law Firm

New Jersey
Mark Gordon
Senior Fellow/Director of Healthcare Information Networks & Technologies (HINT)
Thomas Edison State College

Arnie Miller
Technical Consultant
Elite Business Services

Susan A. Miller
COO, CPO
HealthTransactions.com

William O'Byrne
Coordinator, Health Information Technology Development
New Jersey Department of Banking & Insurance

New Jersey (cont.)
Michele Romeo
Chief Information Officer
NJ Dept. of Human Services

Angela Sorrells
CDC/PHA Program Manager
NJ Dept. of Health and Senior Services

North Carolina
Holt Anderson
Executive Director
North Carolina Healthcare Information & Communications Alliance, Inc. (NCHICA)

Derek W.H. Kung, Esq.
Attorney
Williams Mullen

Roy H. Wyman, Jr.
Attorney
Williams Mullen

Andrew Weniger, CPA
Project Manager
North Carolina Healthcare Information & Communications Alliance, Inc. (NCHICA)

South Dakota
Kevin DeWald
SD HISPC Project Manager
Department of Health

Dorine Bennett
Director, Health Information Mgmt Programs
Dakota State University

Dan Friedrich
Director, Technology Support Services
Dakota State University

Richard D. Puetz, JD, CPA
Professor of Accounting and Business Law
College of Business & Information Systems
Dakota State University
NHIN 2 Project Manager

RTI
Ariana Napier
Collaborative Project Manager
RTI International

Technical Advisor
Walter Suarez
President & CEO
Institute for HIPAA/HIT Education & Research