

IZ Gateway Project Legal Agreements: Facilitating Secure Data Sharing for Jurisdictions' Immunization Information Systems

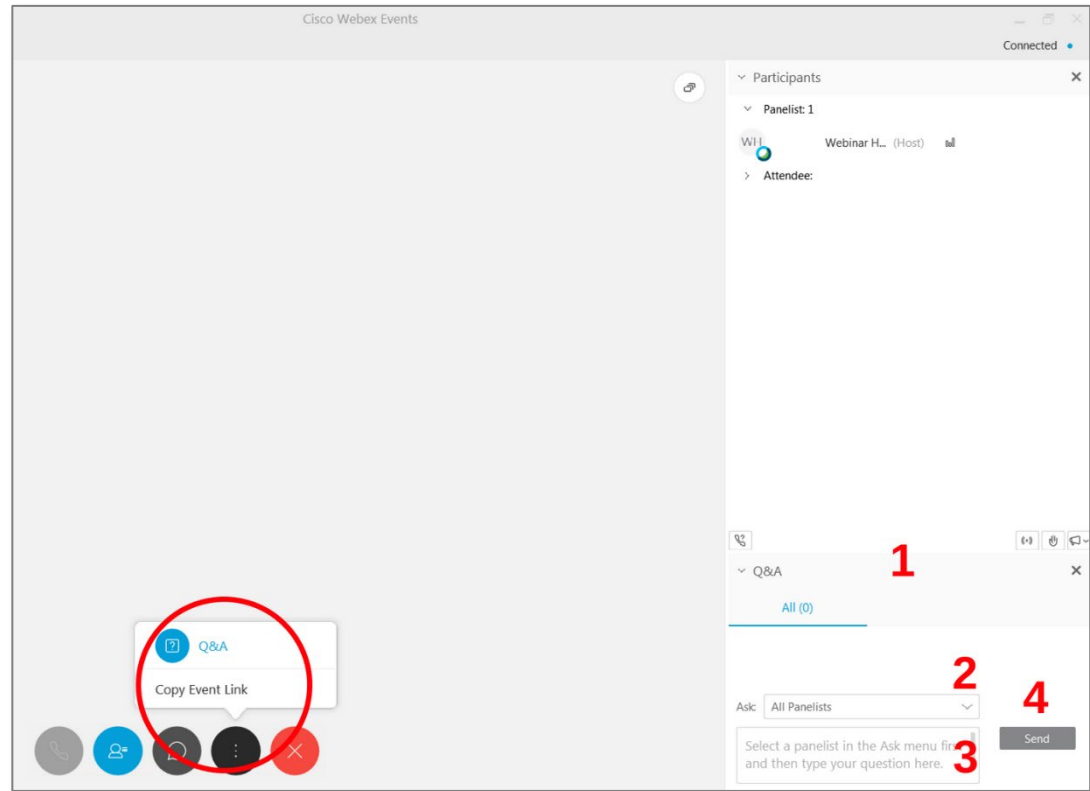
2:00 – 3:00 p.m. EST | August 20, 2020

12:00 – 1:00 p.m. EST | September 9, 2020

Co-sponsored by:

How to Use WebEx Q & A

1. Open the Q&A panel
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3. Type your question
4. Click “Send”



Moderator



Mary Beth Kurilo, MPH, MSW, Policy and Planning Director, American Immunization Registry Association

- M.P.H., M.S.W., University of Washington

Presenter



Daniel Chaput, MM, IT Specialist,
Office of the National Coordinator for
Health Information Technology, Health
and Human Services

Presenter



Matthew Tiller, MS, Project Manager
and Technical Lead, ESAC, Inc.

- M.S., Georgia Institute of Technology

Presenter



Sallie Milam, Deputy Director, the Network for Public Health Law – Mid-States Region Office

- J.D., University of Richmond School of Law
- C.I.P.P./U.S./G., International Association of Privacy Professionals

Presenter



Denise Chrysler, Director, Network for Public Health Law – Mid-States Region Office

- J.D., University of Michigan Law School

Agenda

Topic	Presenter	Organization	Time
IZ Gateway Project Portfolio and Mass Vaccination Overview	Dan Chaput	Office of the Chief Technology Officer	<i>5 mins</i>
Security Overview	Matt Tiller	ESAC, Inc.	<i>5 mins</i>
Legal Relationships and Data Use Agreement	Sallie Milam	Network for Public Health Law	<i>15 mins</i>
Public Health IIS Interjurisdictional Memorandum of Understanding (MOU)	Denise Chrysler	Network for Public Health Law	<i>15 mins</i>
Q&A	Mary Beth Kurilo	American Immunization Registry Association	<i>20 mins</i>

IZ Gateway Project Portfolio and Mass Vaccination Overview



Daniel Chaput, MM, IT Specialist,
Office of the National Coordinator for
Health Information Technology, Health
and Human Services

IZ Gateway Background

- **The Immunization (IZ) Gateway:**
 - Is a portfolio of components which share a common IT infrastructure that routes immunization data.
 - Aims to increase the availability and volume of complete and accurate immunization data stored within IIS.
 - Enables access to IIS data for providers and consumers regardless of jurisdictional boundaries.
 - Allows for rapid onboarding IIS to support state readiness for COVID-19 vaccine response through data exchange.
 - Enables exchange among IIS and between IIS; from federal providers and mass vaccination clinics; and access through consumer access tools.

Value to COVID-19 Response Effort

- IZ Gateway will support efforts to monitor COVID-19 vaccination administration and enable clinical workflows related to having multiple COVID-19 vaccines requiring more than a single dose.
- IZ Gateway enables the exchange and access of COVID-19 vaccines for providers and consumers across the country's 64 immunization registries run by state, territorial, and local health departments.
- IZ Gateway infrastructure:
 - Supports the onboarding of national provider organizations and mass vaccination efforts that span jurisdictional boundaries
 - Supports IIS and clinicians by enabling the tracking vaccine administration across jurisdictions and locations as people travel
 - Sets foundation for proof/confirmation of immunization

IZ Gateway Portfolio of Components



Connect

National Provider Organizations to Multiple IIS



Share

Cross-jurisdictional IIS to IIS



Access

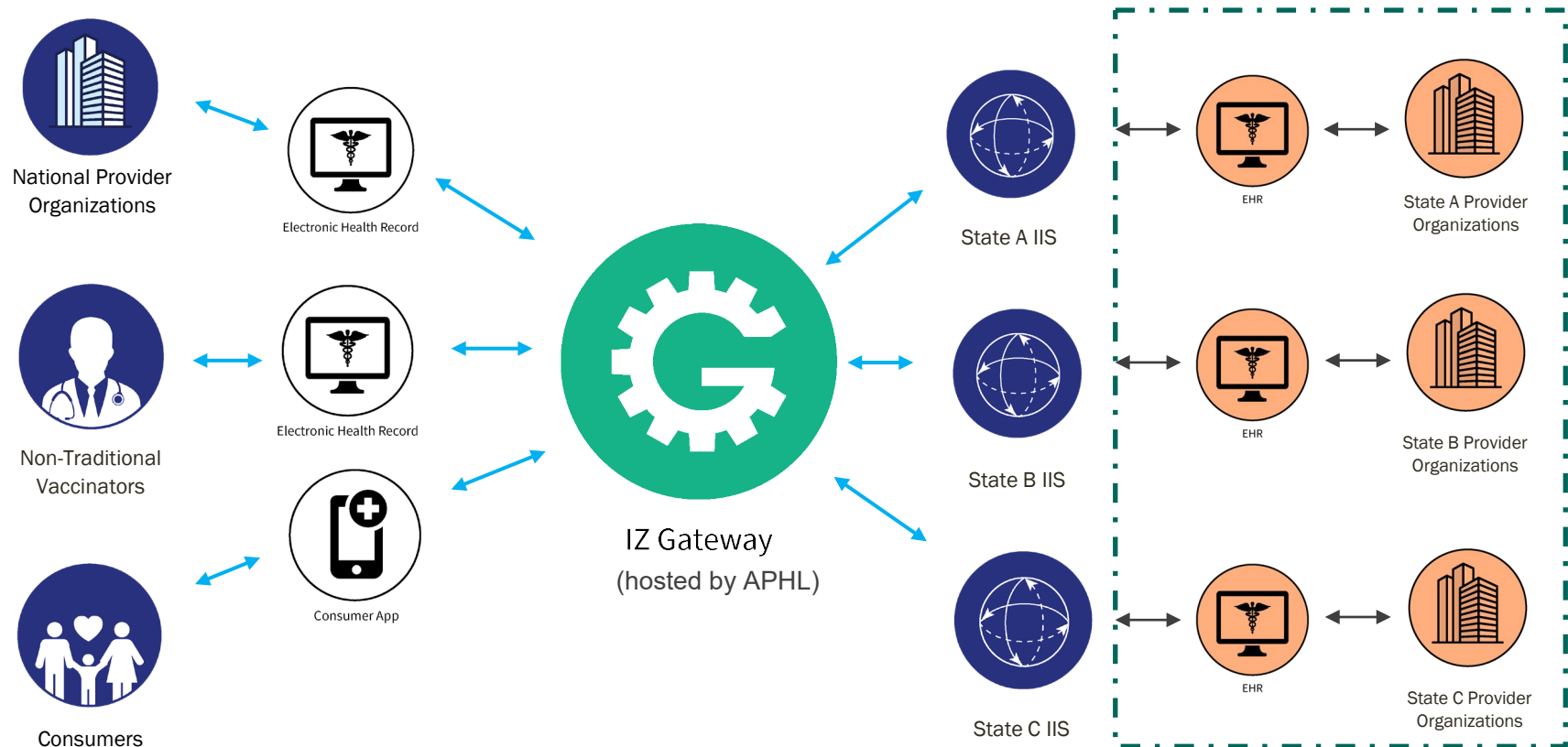
Consumer Access to IIS through Digital Tools



Provider-initiated Multi-Jurisdictional Data Exchange*

Query multiple jurisdictions to receive consolidated immunization data

The IZ Gateway is a centralized technical infrastructure that supports bidirectional exchange of immunization data.



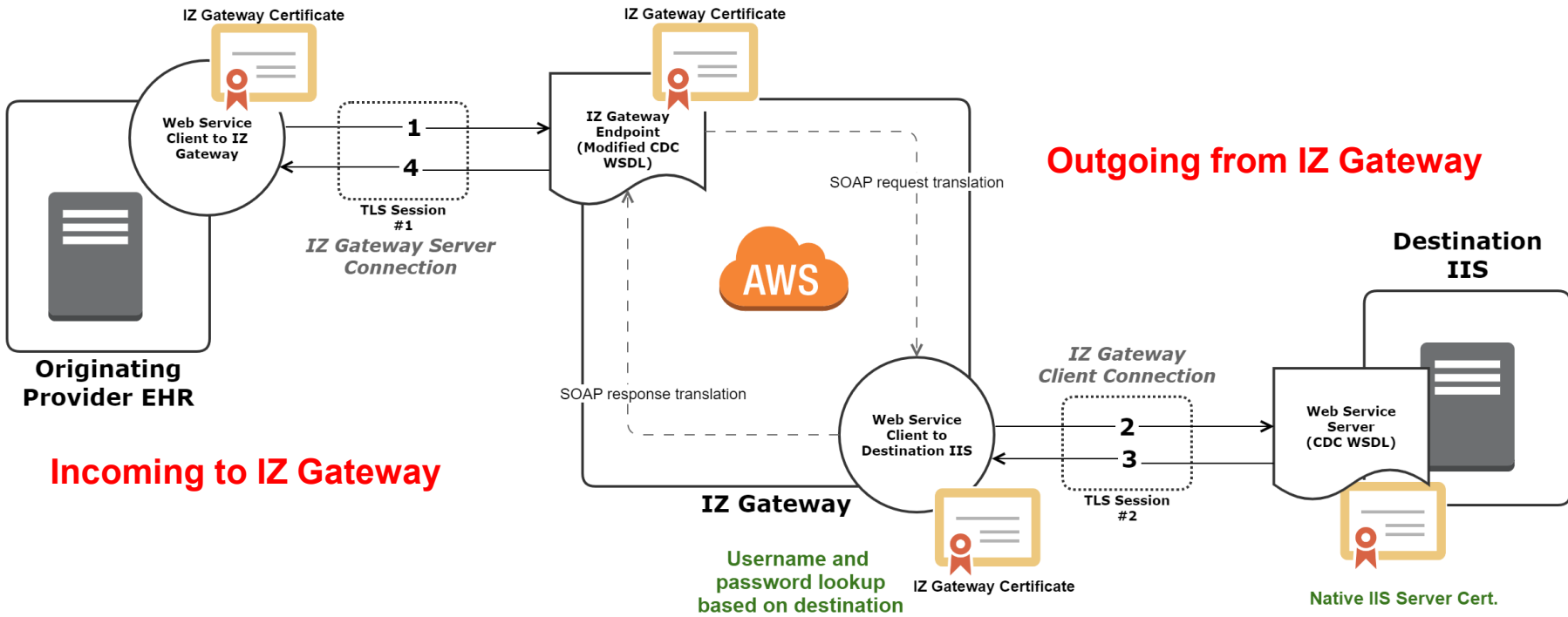
The IZ Gateway does not replace existing connections with state immunization information systems

Security Overview



Matthew Tiller, MS, Project Manager
and Technical Lead, ESAC, Inc.

- M.S., Georgia Institute of Technology



Security Overview

All IZ Gateway Portfolio Project components are secured at the *HIPAA* level, leveraging APHL's security and ensuring confidentiality, integrity and availability.

Examples of how IIS Jurisdictions' IZ information is safeguarded:

- All connections into the IZ Gateway use an IZ Gateway digital certificate, ensuring that only authenticated (authorized and verified) systems are allowed to connect.
- Outgoing connections only occur with known URLs to ensure data transmission to appropriate recipients.
- All IZ information is encrypted while in motion.
- IZ Gateway does not use, disclose or decrypt IZ information in Connect/Share/Access.
- *For Multi-Jurisdictional Data Exchange only*, which is still under development, the IZ Gateway will access and decrypt IZ information, such as when routing a query to additional Participating IIS Jurisdictions that are identified by the sender within the message and have executed the MOU.

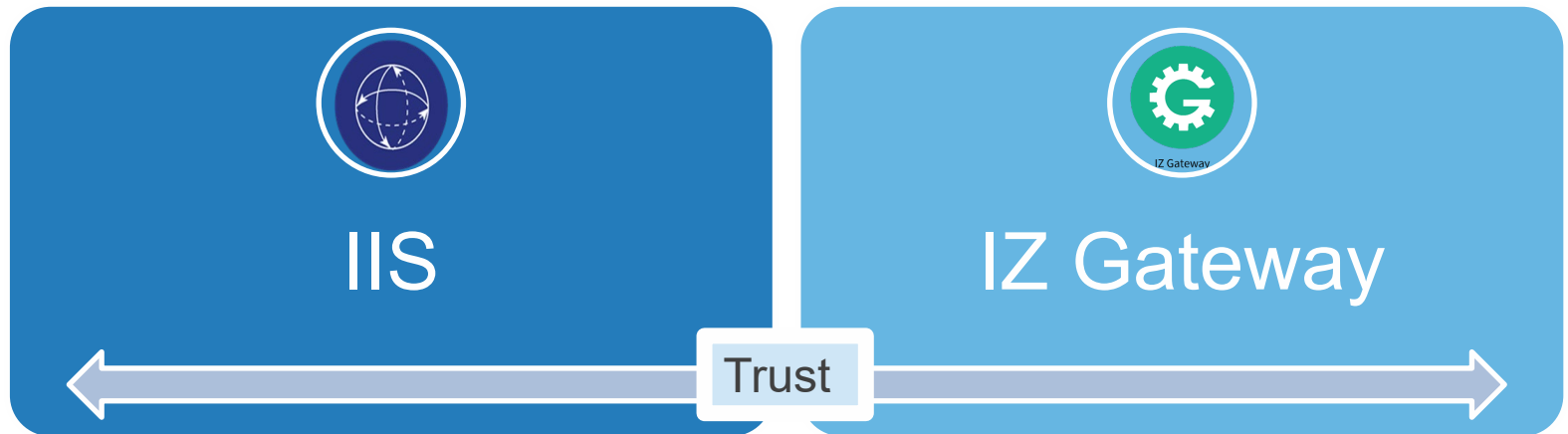
Legal Relationships and Data Use Agreement



Sallie Milam, Deputy Director, the
Network for Public Health Law – Mid-
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Trust Relationship Between the IIS Jurisdiction and the IZ Gateway



DUA

Data Use Agreement – Jurisdiction IIS and APHL

- Allows data to flow through the IZ Gateway which is hosted by APHL
- Addresses security, responsibilities, relationship of the parties, amendment, and incident response
- Connect/Share/Multi-Jurisdictional Exchange/Access



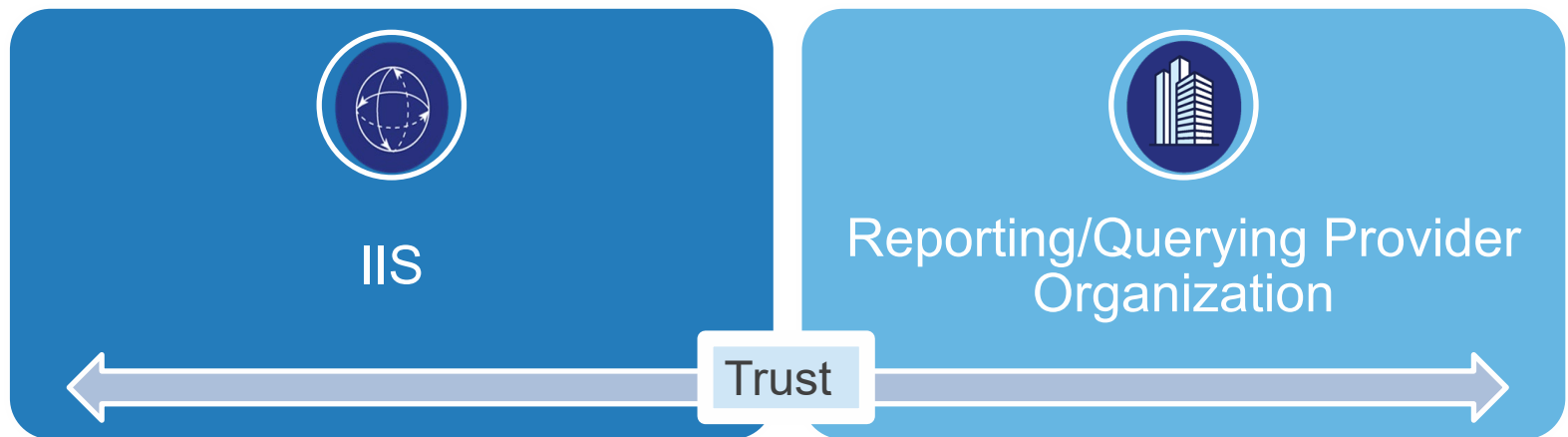
Business Associate Agreement

BAA

Business Associate Agreement – Provider Organization and HIPAA Covered IIS, with APHL on behalf of the IZ Gateway

- Recognizes that the IZ Gateway sends and receives data on behalf of HIPAA covered provider organizations
- Recognizes that some IIS jurisdictions may be covered by HIPAA
- Addresses use and disclosure of protected health information, security, privacy, incident response and other clauses
- Connect/Share/Multi-Jurisdictional Exchange/Access

Trust Relationship Between the Jurisdiction and the Provider Organization

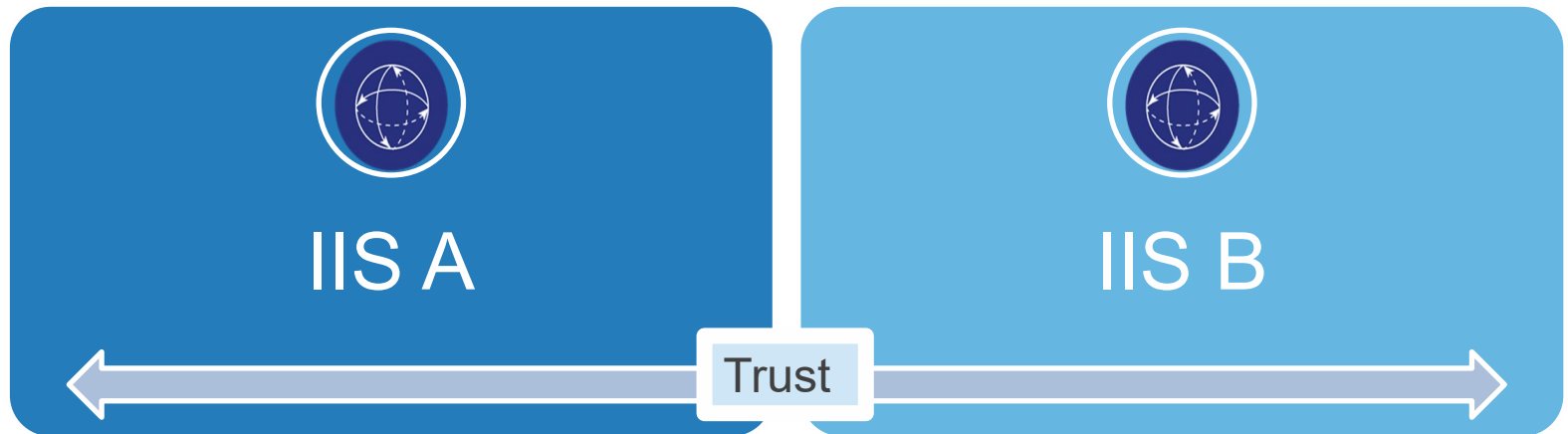


JSPA

Jurisdiction IIS-specific Policy Agreement(s) (e.g., provider site agreements, confidentiality agreements, etc.) - IIS and Provider Organization

- Specific to each jurisdiction
- Signed by provider organization
- Connect

Trust Relationship Among Public Health Jurisdictions

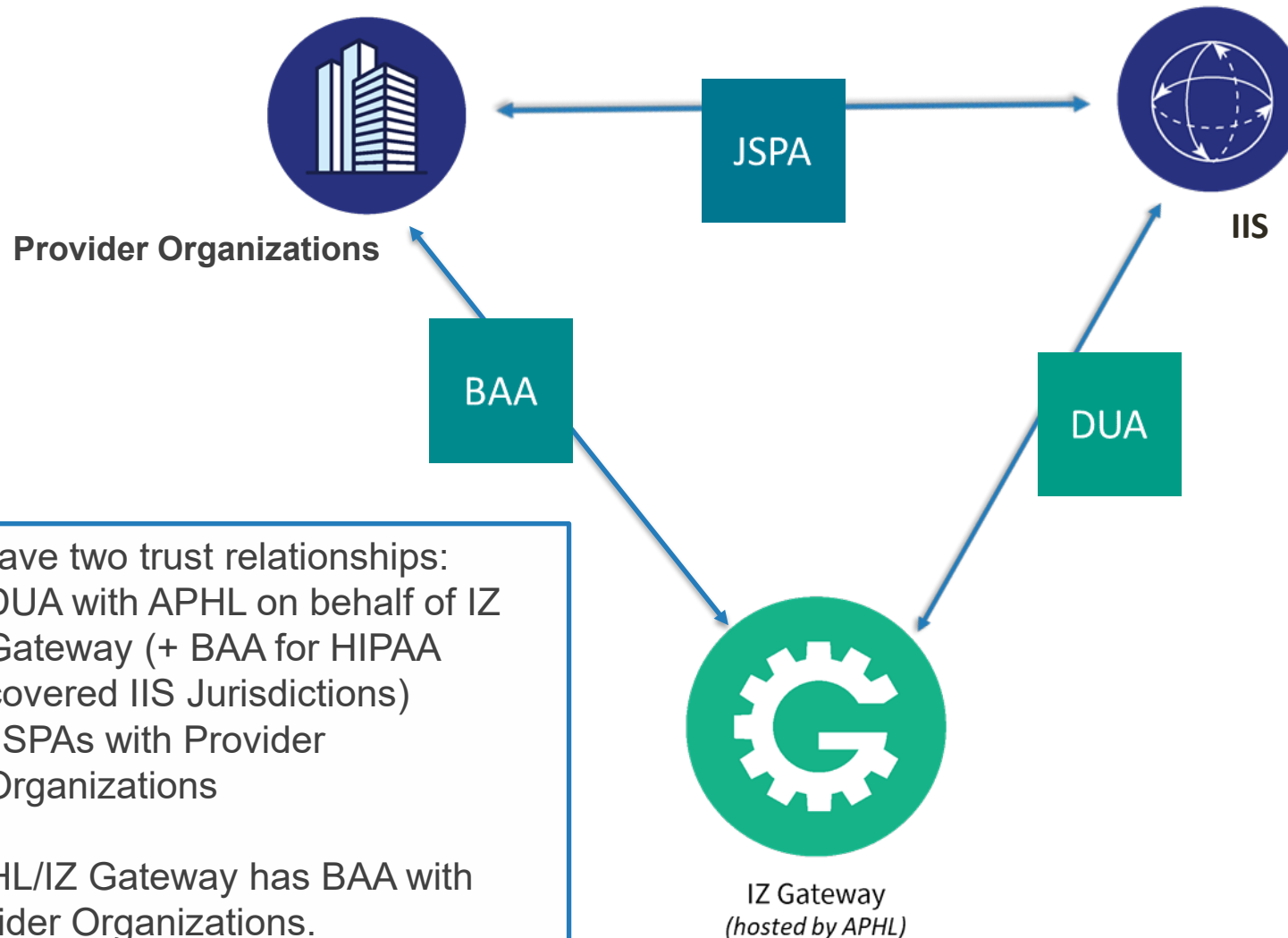


MOU

MOU – Jurisdiction IIS and Jurisdiction IIS:

- Public Health IIS Interjurisdictional Memorandum of Understanding (MOU) (Updated July 2020)
- Signed among public health jurisdictions
- Share/Multi-Jurisdictional Exchange

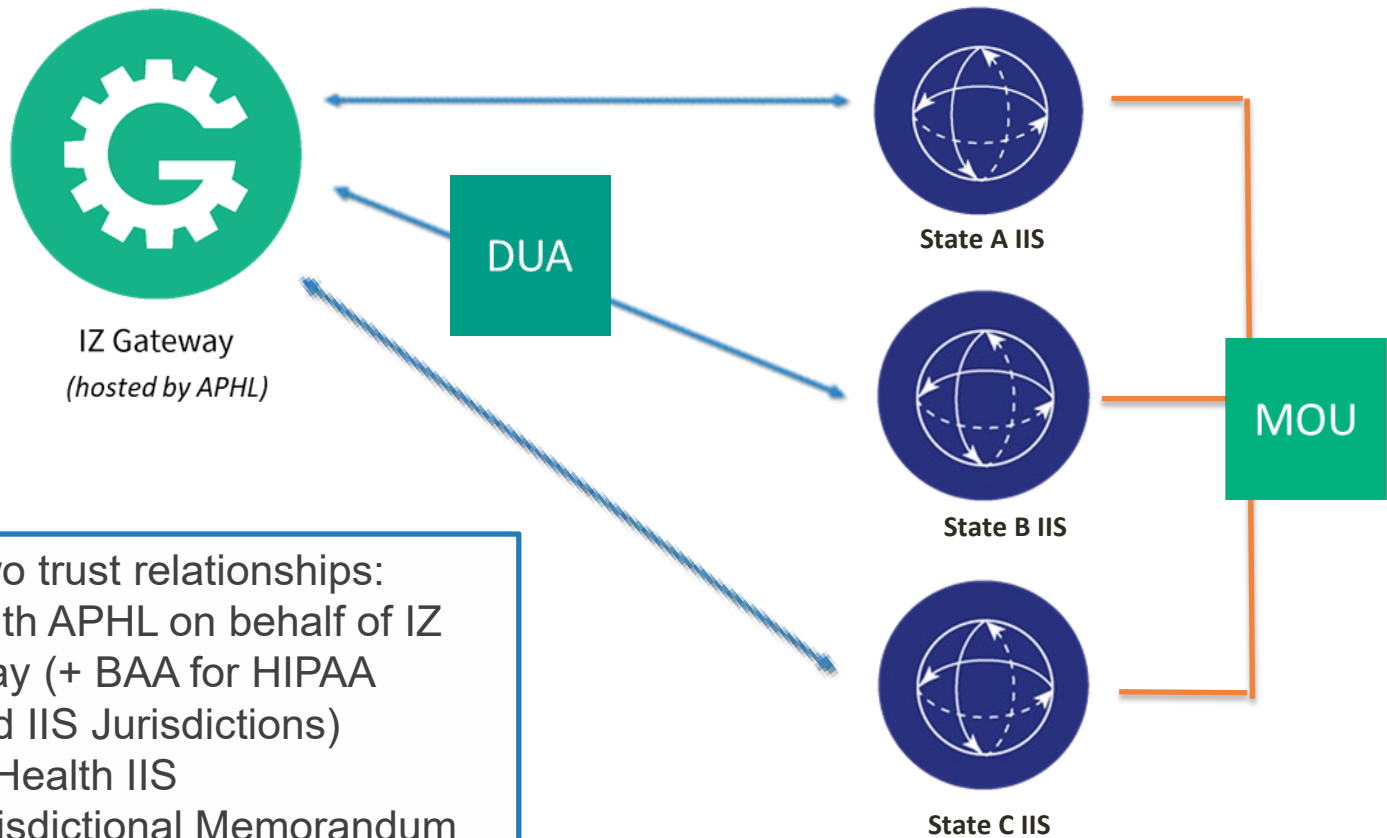
Connect: IIS Legal Relationships and Agreements



- IIS have two trust relationships:
1. DUA with APHL on behalf of IZ Gateway (+ BAA for HIPAA covered IIS Jurisdictions)
 2. JSPAs with Provider Organizations

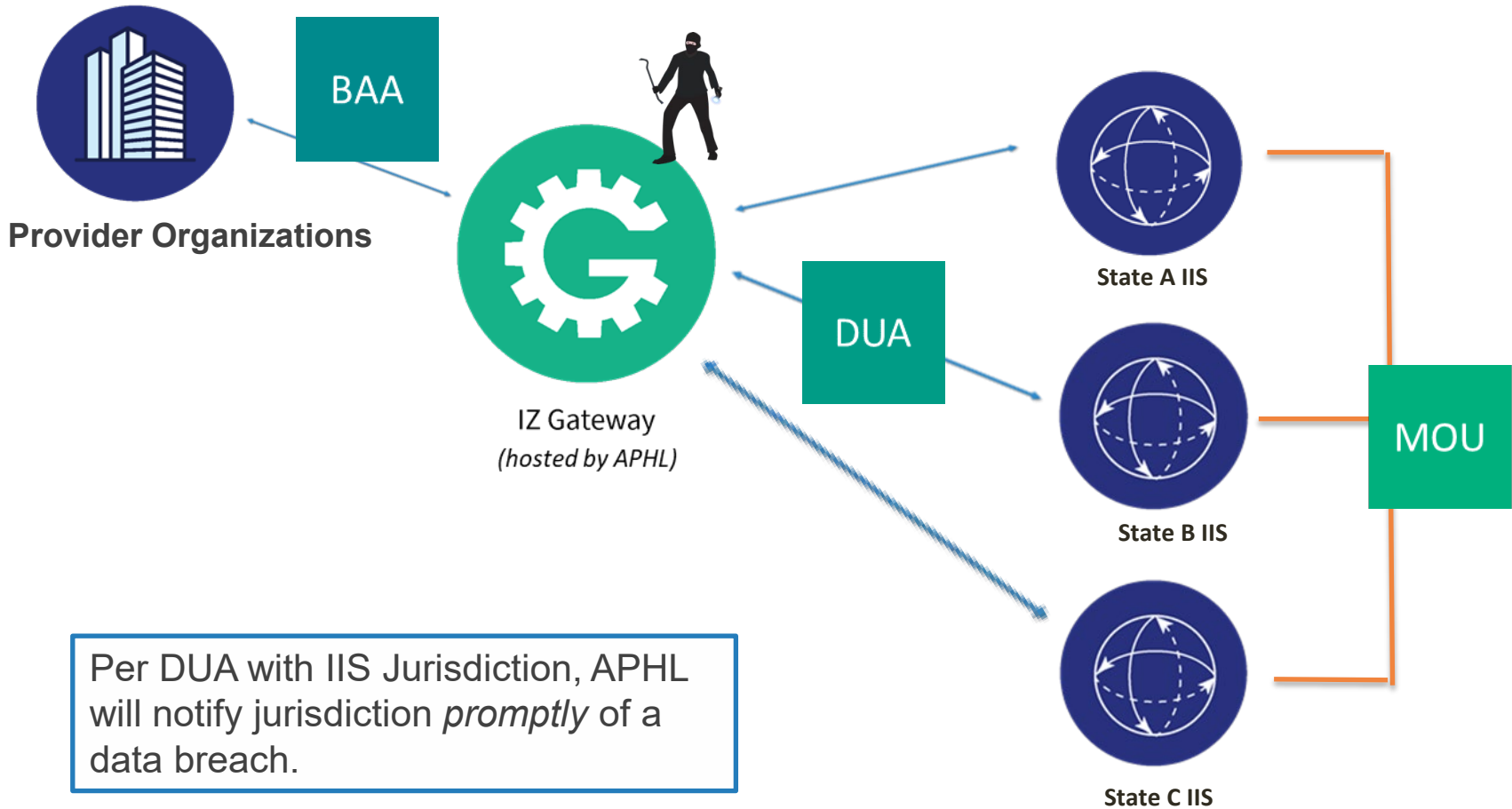
*APHL/IZ Gateway has BAA with Provider Organizations.

Share/Multi-Jurisdictional Exchange: IIS Legal Relationships and Agreements



- IIS have two trust relationships:
1. DUA with APHL on behalf of IZ Gateway (+ BAA for HIPAA covered IIS Jurisdictions)
 2. Public Health IIS Interjurisdictional Memorandum of Understanding (MOU) amongst IIS jurisdictions

What happens in the event of a breach?



***Required** for participation in *all* project components

Parties - Association of Public Health Laboratories, Inc. (APHL), on behalf of the IZ Gateway Project and the Jurisdiction

Term – project duration unless terminated by one of the parties

Security – industry recognized best practices and government requirements, including the Federal Information Security Management Act (FISMA), Title III of the E-Government Act of 2002, as amended (Pub. L. 107-347), the Federal Risk and Authorization Management Program (FedRAMP), and HIPAA

Modular – jurisdictions may select which projects they want to join

- **Ratification of the DUA** enables participation in Connect
- **Completion and execution of a Task Order** enables participation in Share, Multi-jurisdictional Exchange and Access

APHL Responsibilities

- Host the IZ Gateway Project
- Accept, route, generate and transform encrypted immunization information messages
- Create system users and provide appropriate user access
- Offer support via telephone or email
- Cyber security
- Data access and use requirements
- Data breach notification
- Flow down requirements

Jurisdiction's Responsibilities

- Availability of staff upon request regarding creating and maintaining the environment on the AIMS platform and
- Availability of staff upon request regarding verifying data flow, data, alert or other system message transmission
- Obtain all required consents

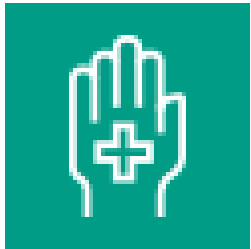
Access DUA here: <https://www.networkforphl.org/wp-content/uploads/2020/08/APHL-AIMS-DUA-IZ-Gateway-3August2020-revision.pdf>

Public Health IIS Interjurisdictional Memorandum of Understanding (MOU)



Denise Chrysler, Director, Network for Public Health Law – Mid-States Region Office

- J.D., University of Michigan Law School

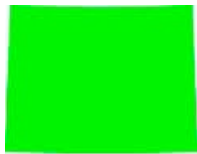


Share Cross-jurisdictional IIS to IIS

Public Health IIS Interjurisdictional Memorandum of Understanding (MOU), updated July 2020

- Provides for secure, electronic exchange of immunization information among governmental entities that operate a population-based immunization information system (IIS).
- Download fillable form from <https://www.immregistries.org/interjurisdictional-exchange>

MOU origin: First developed in 2015 for six state pilot in consultation with IIS managers and their attorneys



Colorado



Idaho



Michigan



Minnesota



North Dakota



Wisconsin

To ensure complete vaccination history for patient who:

- Moves between states
- Crosses border for care
- Is vaccinated while traveling
- Lives – and receives vaccinations – in multiple states (e.g., military, college students, migrant agricultural workers, snowbirds, prisoners)
- Is temporarily displaced because of a disaster or emergency

IIS – IIS exchange critical to COVID vaccination efforts, especially if immunity requires multiple shots

- MOU confirms IIS exchange authority, provides rules of the road
- Seventeen jurisdictions have signed
- Administered by the American Immunization Registry Association (AIRA)
- Uniformity of terms essential (agreement among up to 64 jurisdictions)
- July 2020 current version – parties that signed 2015/2016 and 2019 versions do not need to resign
- Flexible - technology inclusive
 - Exchange immunization information via IZ Gateway, and/or
 - Establish independent means to exchange immunization information with another jurisdiction



Provider-initiated Multi-Jurisdictional Data Exchange*

Query multiple jurisdictions to receive consolidated immunization data

- IZ information may be maintained by multiple IIS
- Optional: IIS may choose under DUA to participate in this IZ Gateway component
- Provider initiates a query [via IZ Gateway](#) for vaccine information from multiple IIS
- Triggers IZ information to be shared among IIS that have / or had relationship with patient
- MOU permits IZ information to be shared among IIS to create consolidated vaccine record

Key MOU provisions

- **Parties to MOU** – Original, additional, future; must provide signed copy to AIRA.
- **Purpose of MOU**
 4. Purpose. . . . The purpose of this MOU is to facilitate data exchange between IIS to help ensure complete and accurate immunization records for all individuals in signatory jurisdictions, including individuals who move or receive care across state or other jurisdictional borders.
 - 5.-7. Not intended to eliminate current or future point-to-point agreements.
- **Sending party is in driver's seat regarding immunization information it provides**
 10. IIS data exchange. Each party that signs this MOU agrees to provide immunization information to other parties that have signed this [or prior] MOU, concerning individuals who have a relationship with the receiving party's jurisdiction. Such relationships may include, but are not limited to individuals who reside in, work in, or obtain health care in the receiving jurisdiction. Each sending party determines what information it provides to each receiving party, based on the sending party's law and policies.

Key MOU provisions, continued

- **Receiving party incorporates data it receives into its IIS, which is then subject to the receiving party's control**

14. Control, use and disclosure of data. Upon receipt, immunization information is subject to the receiving state's control, use, and disclosure. As such, the receiving party is responsible for maintenance, use and disclosure of data that it has received under this MOU, consistent with the MOU's purpose and its laws and policies, as applicable.

- **Parties implement privacy and security safeguards**

15. Privacy and security. By signing this MOU, a party affirms that it implements written and approved confidentiality policies that protect the privacy of individuals whose data are contained in the system and appropriate administrative, technical, and physical safeguards to protect the privacy and security of data received under this MOU and to prevent unauthorized use of or access to it. Each sending party, with regard to the data that it provides, is subject to the privacy and security provisions established within its own jurisdiction and is not required to adhere to the law or policies of the receiving jurisdiction.

- **No warranties – Best efforts**

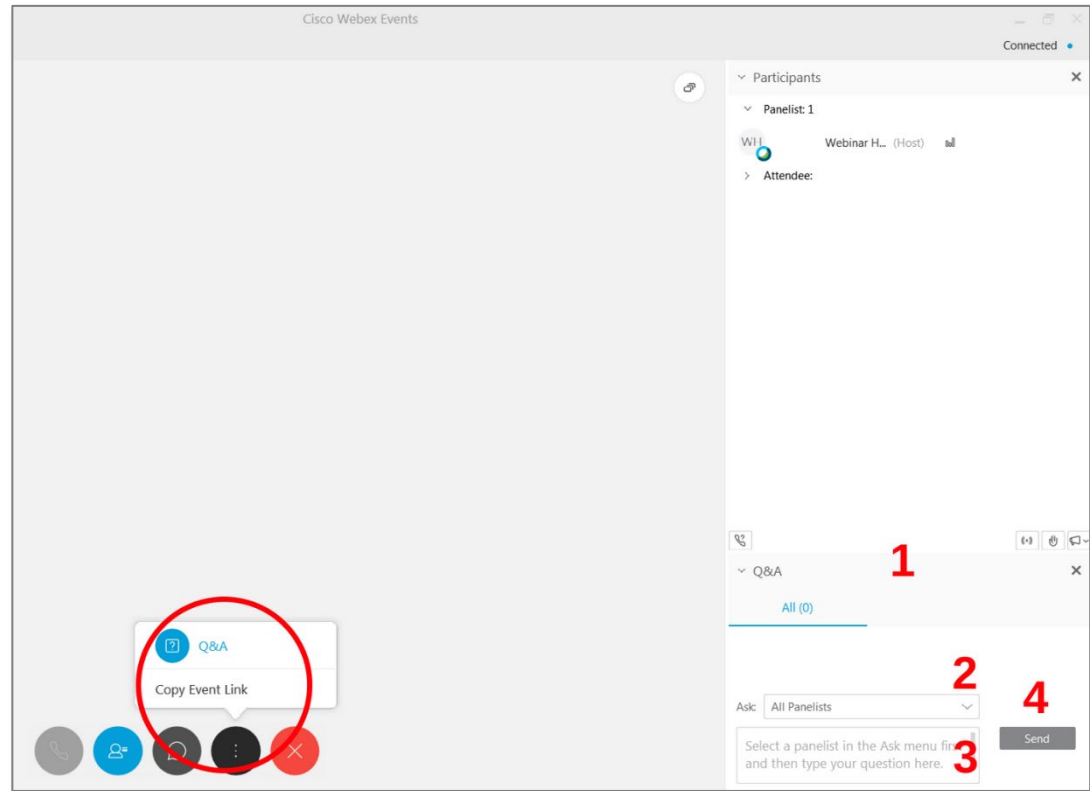
A starting point for attorneys...

Legal authority to exchange immunization information

- May have law specific to cross-jurisdictional exchange
- May be able to engage in cross-jurisdictional exchange under general powers and responsibilities, such as power and responsibility to prevent and control spread of disease
- Could implement emergency powers to exchange data during pandemic
- **Restrictive law?** We are available to answer questions, discuss your legal concerns, and assist you in identifying potential approaches to support immunization information exchange
- **Reminder:** For Share, each jurisdiction will sign a DUA with APHL, which provides the infrastructure for secure IIS - IIS exchange. DUA addresses security safeguards such as encryption and breach notification.

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Q&A Sessions for DUA

Come join your peers for an informal discussion around the DUA. Bring your questions to the session and have them answered by one of the DUA authors!

- Thursday, August 27 | 3:00 – 4:00 pm ET
- Thursday, September 3 | 1:00 – 2:00 pm ET
- Friday, September 18 | 11:00 – 12:00 ET
- Thursday, September 24 | 3:00 – 4:00 pm ET
- Q & A Sessions Link: <https://www.networkforphl.org/wp-content/uploads/2020/08/IZ-Gateway-Data-Use-Agreement-QA-Sessions.pdf>
- More info [here](#)

IZ Gateway project team

Project Sponsor: Centers for Disease Control and Prevention



Audacious Inquiry, LLC



American Immunization Registry Association



JBS International



Network for Public Health Law



ESAC Inc.



HLN Consulting, LLC



Association of Public Health Laboratories



Kahuina Consulting



Office of the Chief Technology Officer



Network for Public Health Law

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