

Immunization (IZ) Gateway Project Legal Agreements: Facilitating Secure Data Sharing for IISs

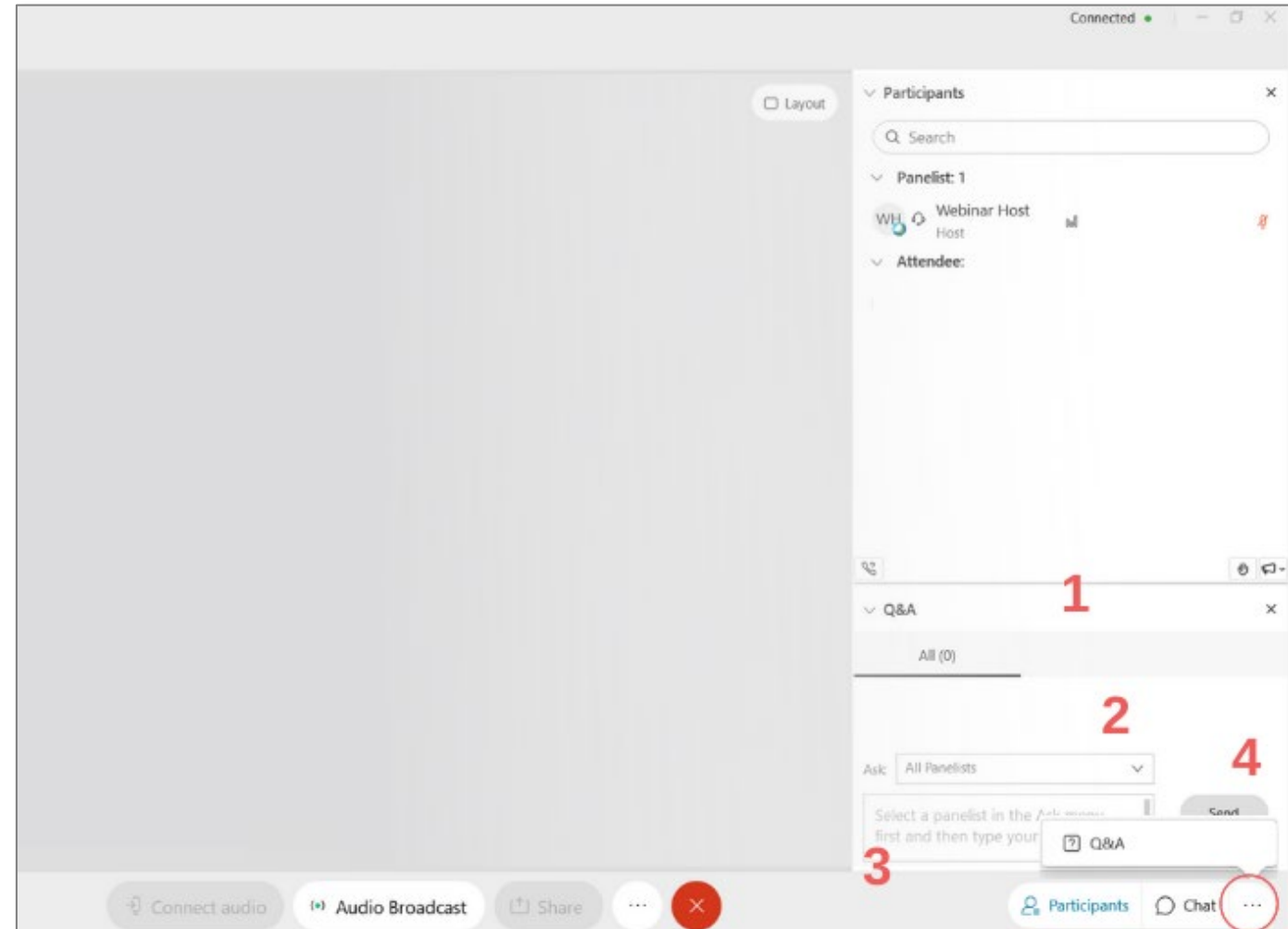
12:00 – 1:00 p.m. ET | July 12, 2021

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Agenda



Topic	Time	Presenter
IZ Gateway Background	5 Minutes	Jennifer Ratliff, CDC
Exploring the IZ Gateway's Use Cases	5 Minutes	Jennifer Ratliff, CDC
Security Overview	5 Minutes	Dan Chaput, HHS
Legal Relationships and Data Use Agreement	15 Minutes	Carrie Waggoner, NPHL
Public Health IIS Interjurisdictional Memorandum of Understanding	15 Minutes	Denise Chrysler, NPHL
Q & A	15 Minutes	Mary Beth Kurilo, AIRA

IZ Gateway Background

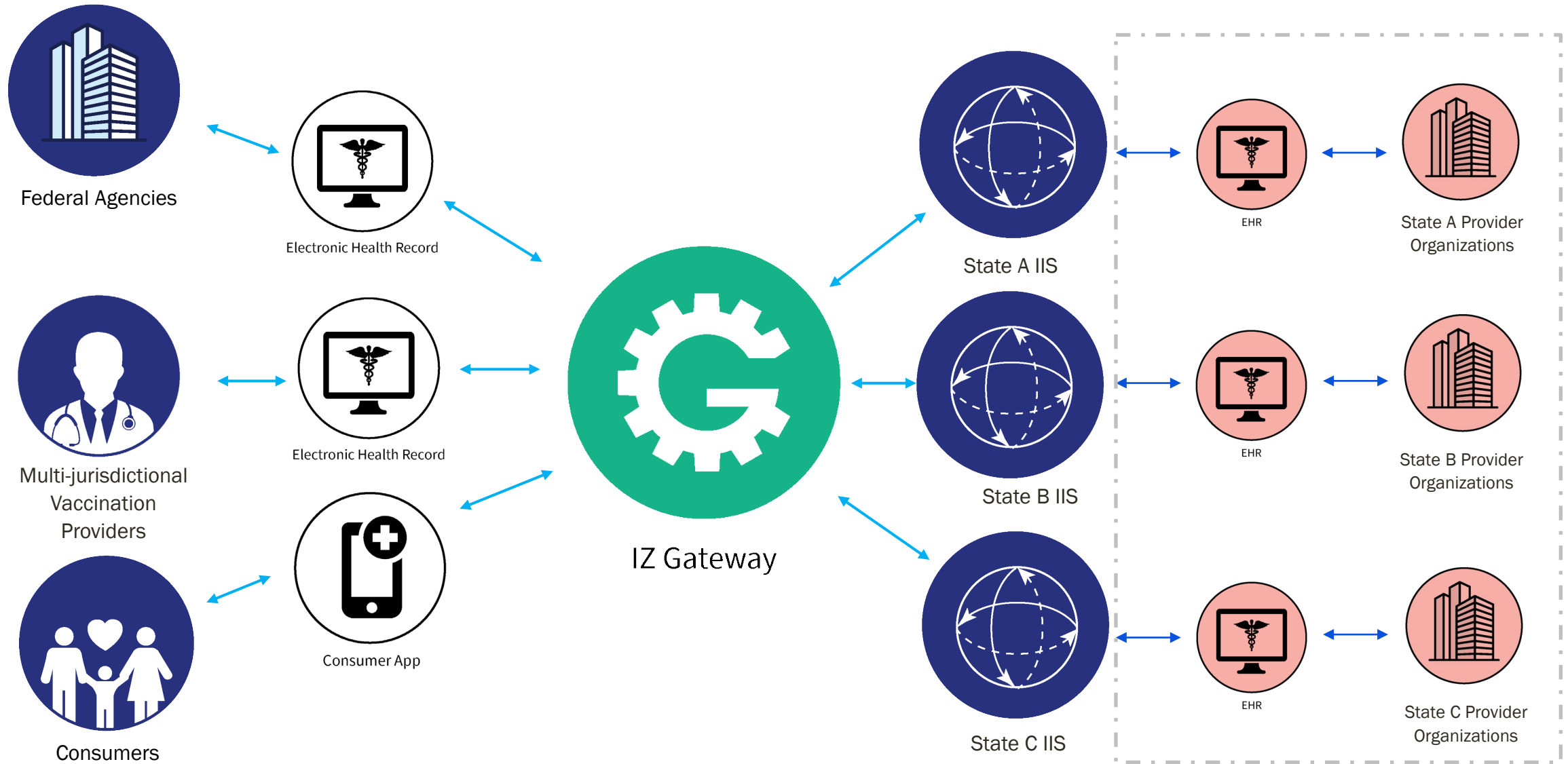
Jennifer Ratliff

IZ Gateway Background

WHAT IS THE GATEWAY?

-  A cloud-based **message routing service** intended to improve immunization data flow, integration, sharing, and access. The IZ Gateway allows for bidirectional exchange of immunization data.
-  Promotes **centralized data exchange** among jurisdictional IISs, other provider systems, and CDC

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



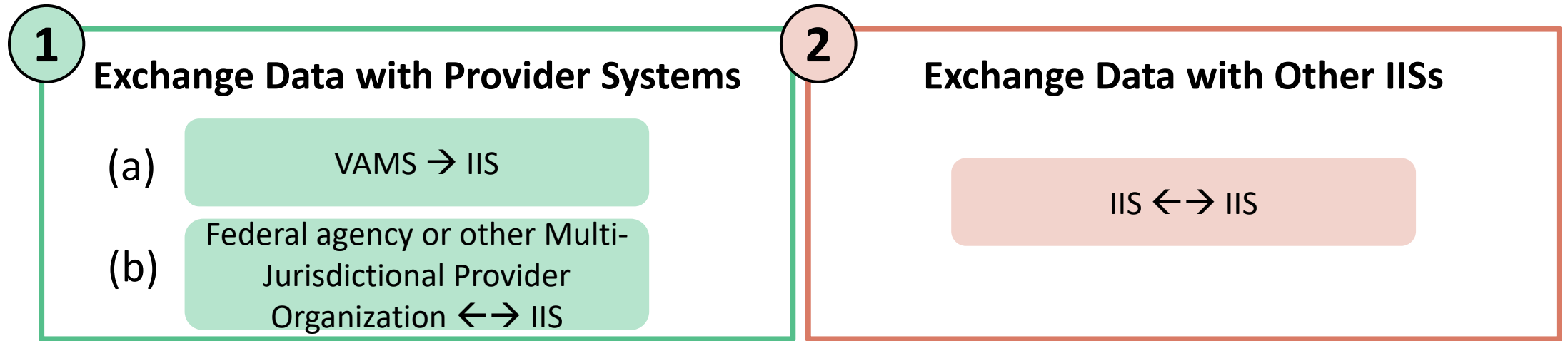
The IZ Gateway does not replace existing connections with state immunization information systems

Exploring the IZ Gateway's Use Cases

Jennifer Ratliff

Jurisdictional IZ Gateway Services Menu

The IZ Gateway offers the following services:





Exchange Data with Provider Systems

USE CASE *This service is referred to as Connect in the DUA.

1 Federal agency or SNF/LTCF organization ↔ IIS

Enhance completeness of IIS data
Federal agency or SNF/LTCF organization sends data to IIS through IZ Gateway
and
Improve provider access to IIS data
Agency/organization queries IIS and IIS responds through IZ Gateway

VALUE

-  Timely IIS data completeness
-  Provider access to complete and accurate immunization history at point of care

REQUIREMENTS

- APHL DUA, Jurisdiction-specific policy agreement(s) with each agency/organization

TIME TO IMPLEMENT

- Est. 3 to 6 weeks for each agency/organization

Exchange Data with Other IISs

USE CASE *This service is referred to as Share in the DUA.

2

IIS ↔ IIS

Enhance completeness of IIS data
IIS A queries IIS B for vaccination record and IIS B returns response to IIS A through IZ Gateway

and/or

Enhance completeness of IIS data
IIS A automatically sends vaccination record to patient’s home IIS (IIS B) through IZ Gateway

VALUE



IIS data completeness

REQUIREMENTS

- APHL DUA, “Share” Task Order, IIS Interjurisdictional MOU

TIME TO IMPLEMENT

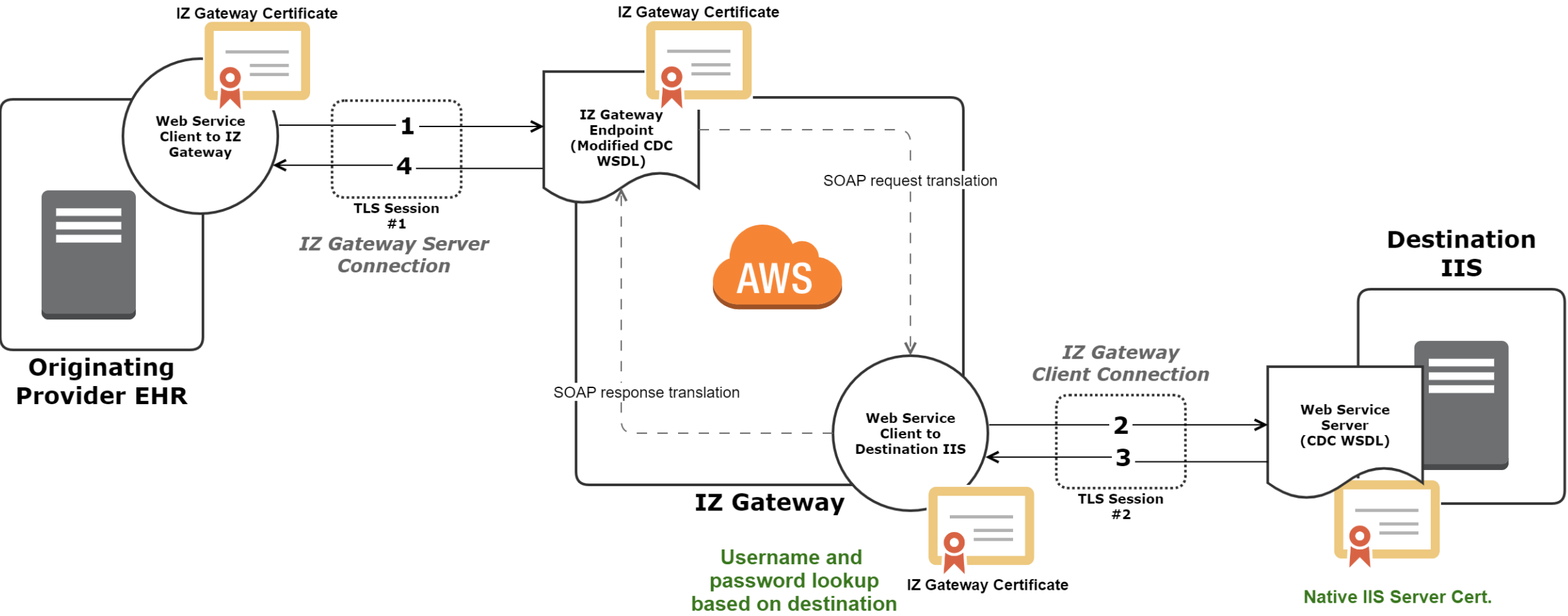
- Est. 3 weeks to 3 months

Security Overview

Dan Chaput

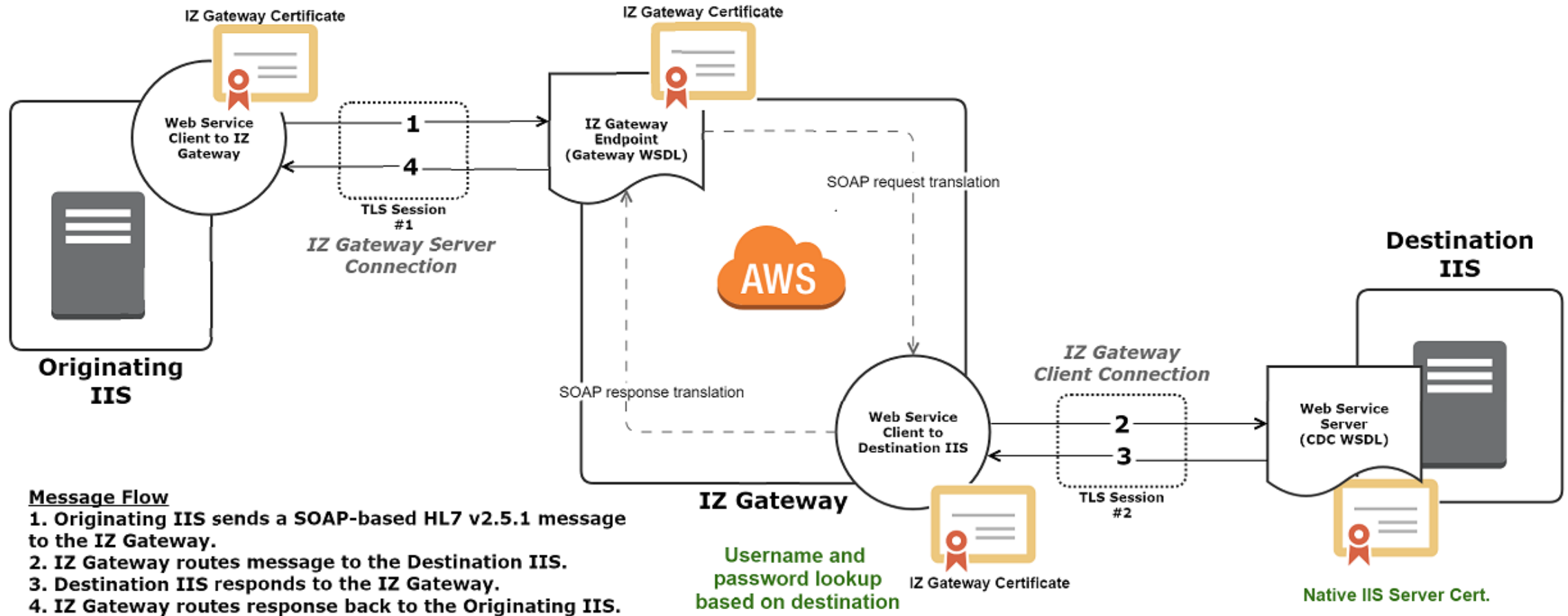
1

Provider to IIS Data Exchange Use Case



2

IIS to IIS Data Exchange Use Case



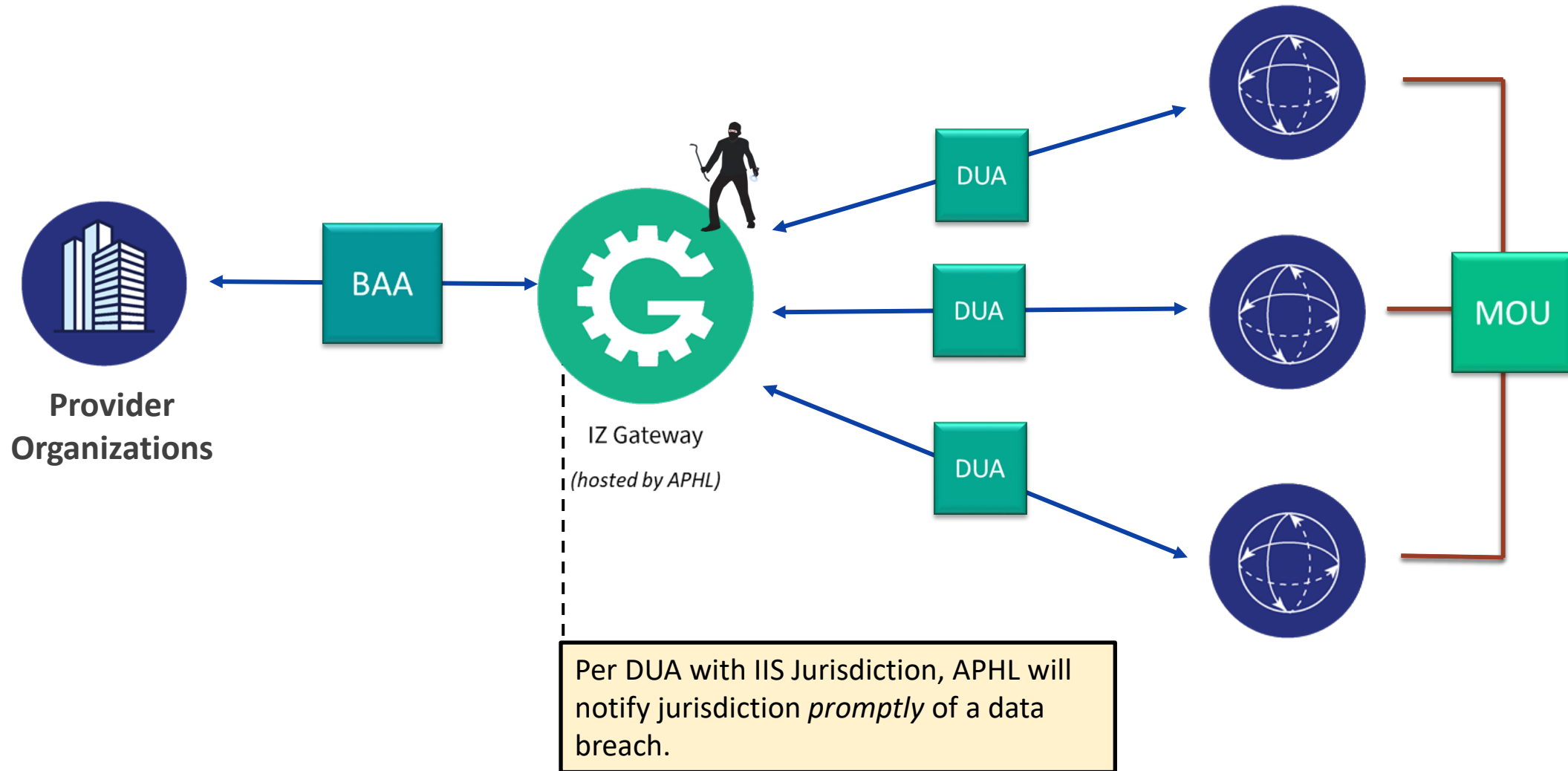
Security Overview

All IZ Gateway use cases/components are secured at the *HIPAA* level, leveraging The Association of Public Health Laboratories (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/IIS-IIS Exchange/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.

What Happens in the Event of a Breach?

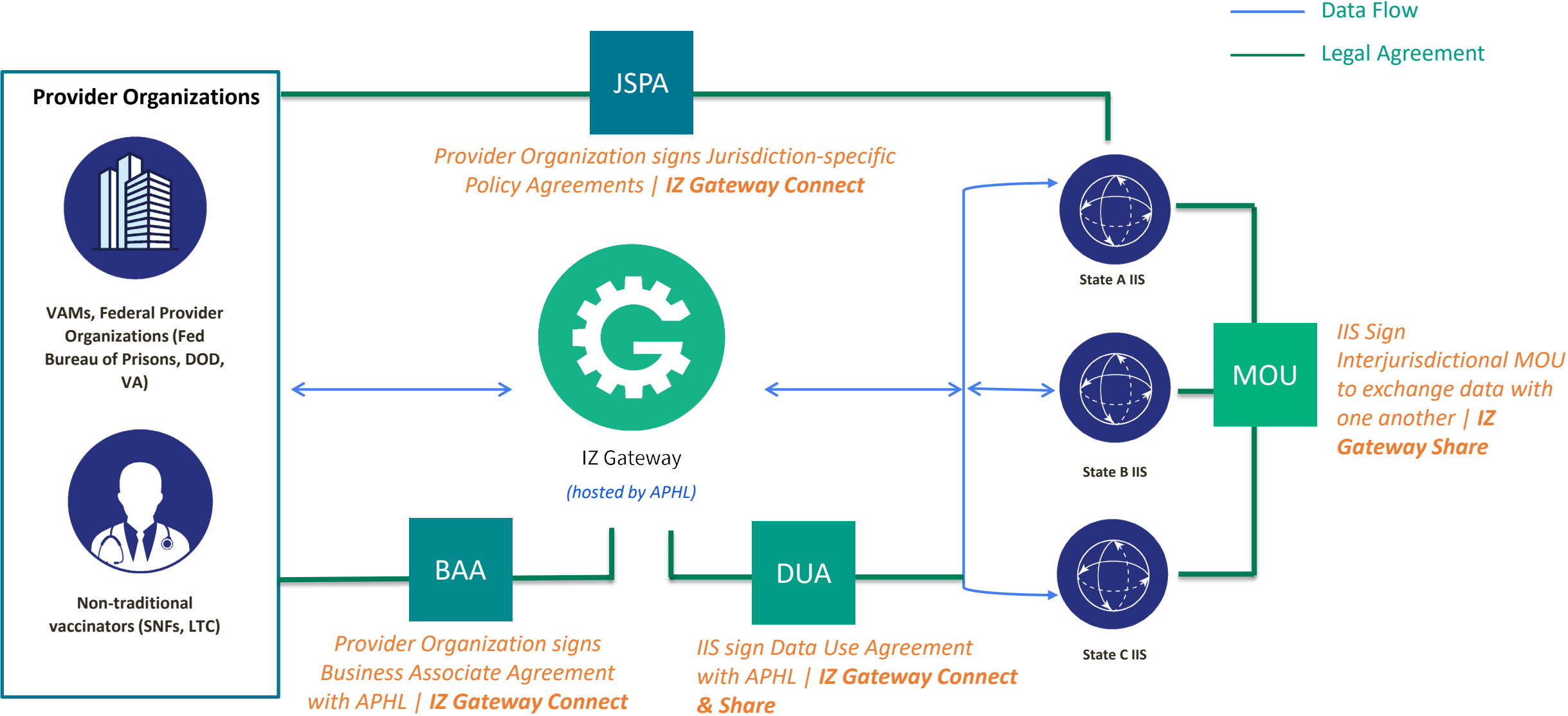


Legal Relationships and Data Use Agreement

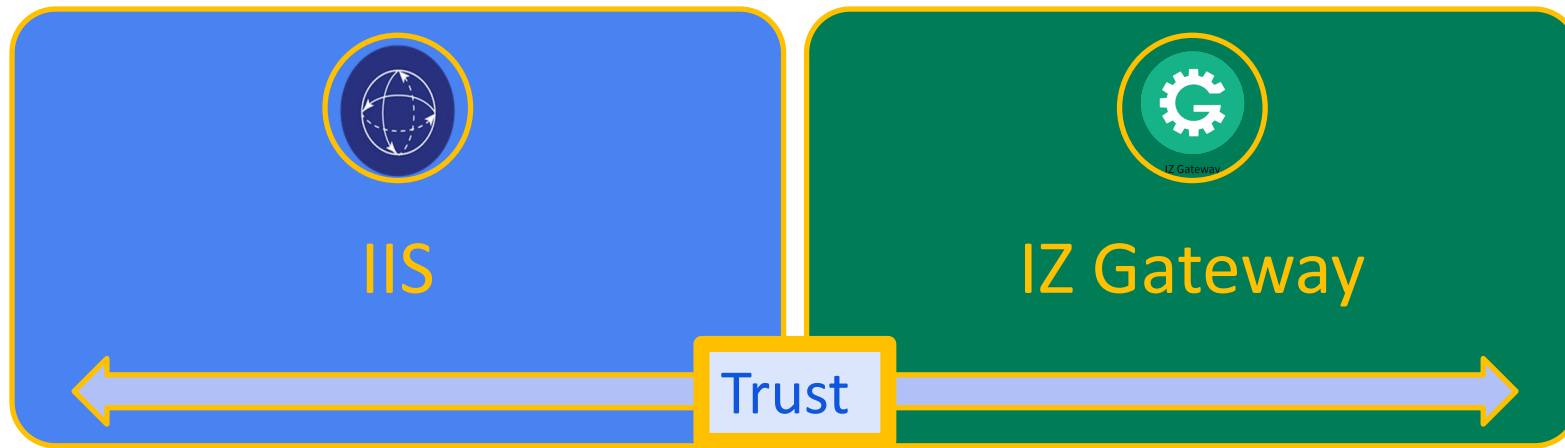
Carrie Waggoner, Senior Attorney, Network for Public Health Law – Mid-States Region

Baseline Legal Agreements

IZ Gateway Trust Framework



Trust Relationship Between IIS and 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
- IZ Gateway use cases
- Within the DUA, there is a Task Order that Jurisdictions should use to select use cases which they want to engage in

Data Use Agreement Overview

***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 project components they want to join

- **Ratification of the DUA** enables participation in Connect
- **Completion and execution of a Task Order** enables participation in additional project components

Data Use Agreement Overview- 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
- Ensure security of system
- Data access and use requirements
- Data breach notification
- Flow down requirements

Data Use Agreement Overview-Jurisdiction's Responsibilities

- Availability of staff upon request for creating and maintaining the environment on the AIMS platform
- Availability of staff upon request for 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>
- **IZ Gateway Project Legal Agreements Overview:** <https://www.networkforphl.org/resources/topics/health-information-and-data-sharing/iz-gateway-project/>

Data Use Agreement Task Order

- Task Order allows Jurisdictions to join components in addition to Connect
 - Share (IIS-to-IIS)
 - Provider-initiated multi-jurisdictional data exchange;
 - Consumer access; and
 - Consumer-initiated multi-jurisdictional data exchange
- APHL has additional responsibilities for provider-initiated multi-jurisdictional exchange and for consumer-initiated multi-jurisdictional exchange
 - New 4.A.iii
 - Access to data only for purposes of project (i.e. routing messages)
 - Encrypted messages to additional jurisdictions and sending consolidated information from multiple jurisdictions for query response

Business Associate Agreement



BAA

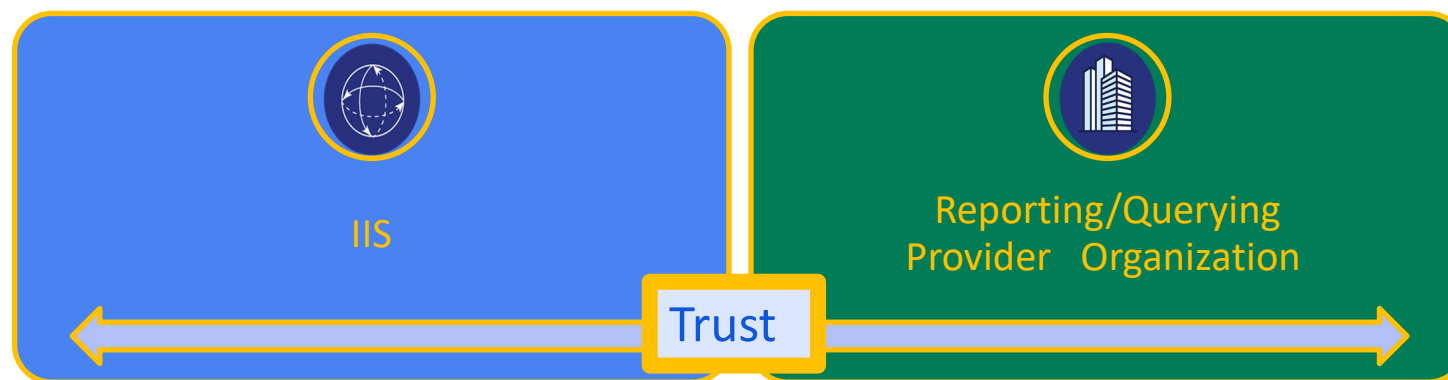
Business Associate Agreement – Provider Organization and HIPAA-covered IIS with APHL on behalf of IZ Gateway

- 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
- IZ Gateway use cases

IIS-Provider System Data Exchange Legal Agreements

*This service is referred to as Connect in the APHL DUA.

Trust Relationship Between the Jurisdiction and the Provider Organization

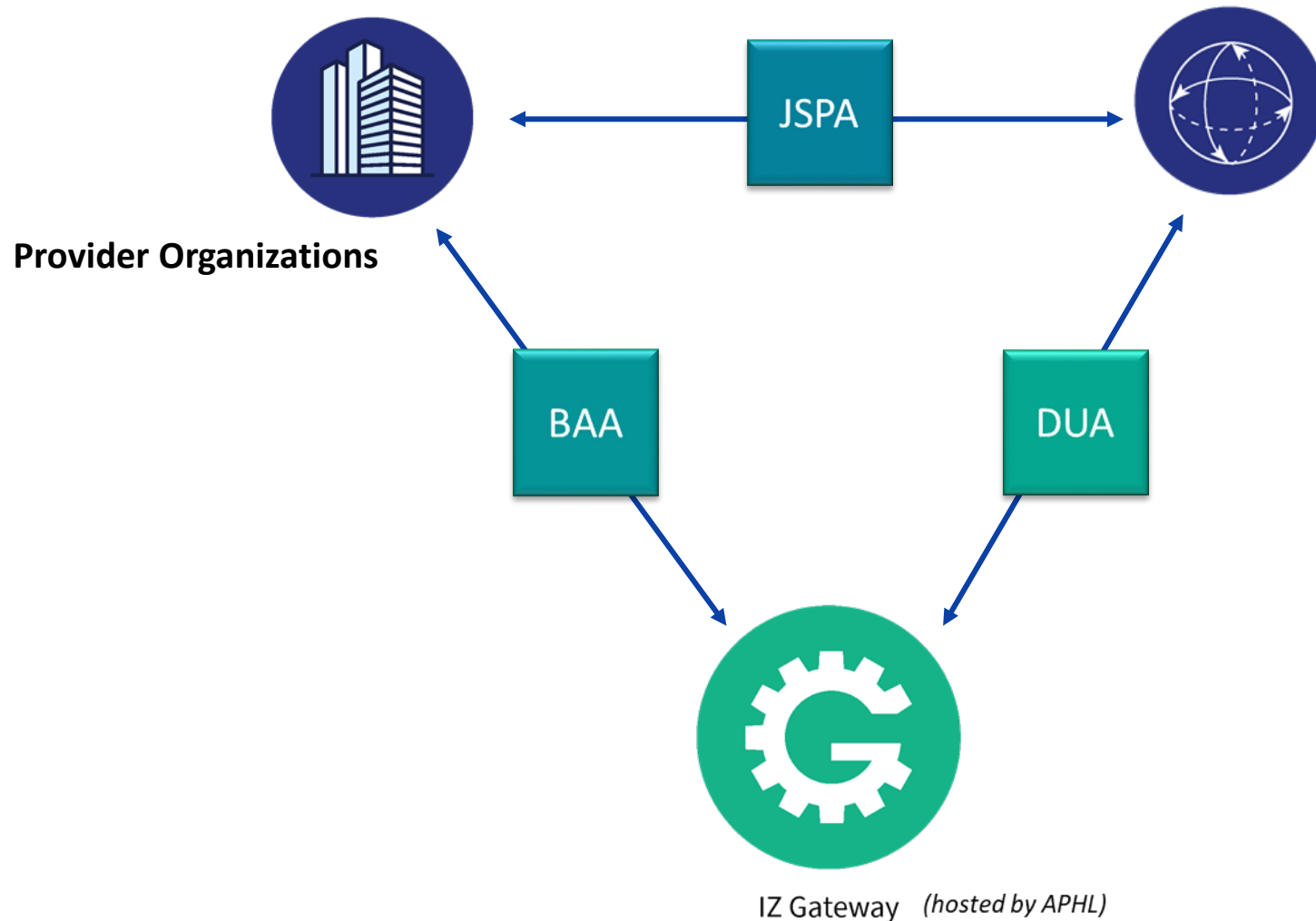


JSPA

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

- Specific to each jurisdiction
- Signed by provider organization
- Exchange with Provider Systems – Use Case 1b (Connect/Multi-jurisdictional Exchange)
- Team is working on streamlining individual JSPAs into a common agreement

Exchange with Provider Systems – Use Case 1b



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.

*Referred to as Connect/Multi-Jurisdictional Exchange in DUA Task Order

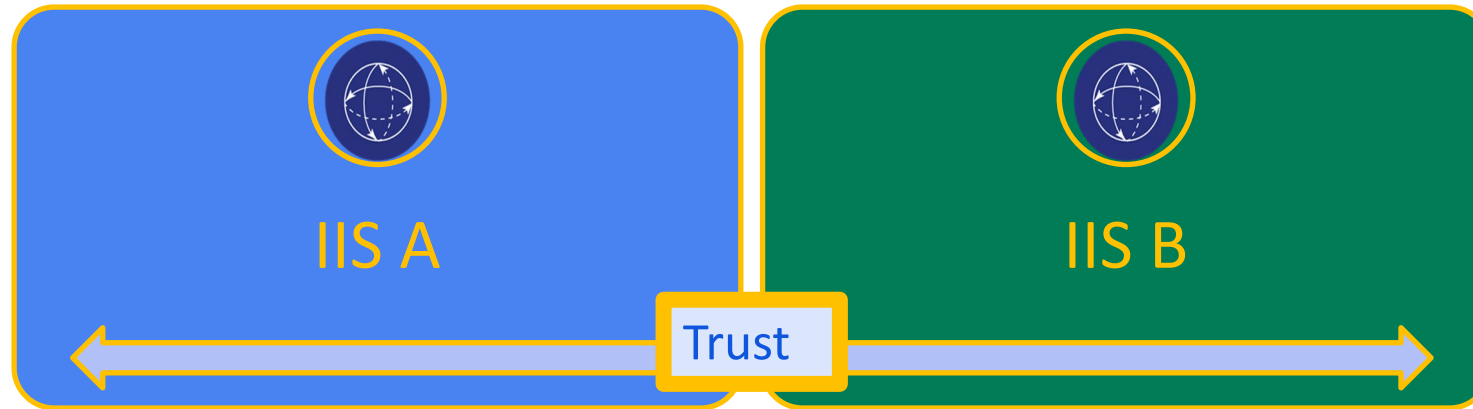
↔ Reflects Trust Relationships, Not Data Flow

IIS-IIS Data Exchange Legal Agreements

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

*This service is referred to as Share in the DUA.

Trust Relationship Among Jurisdictions



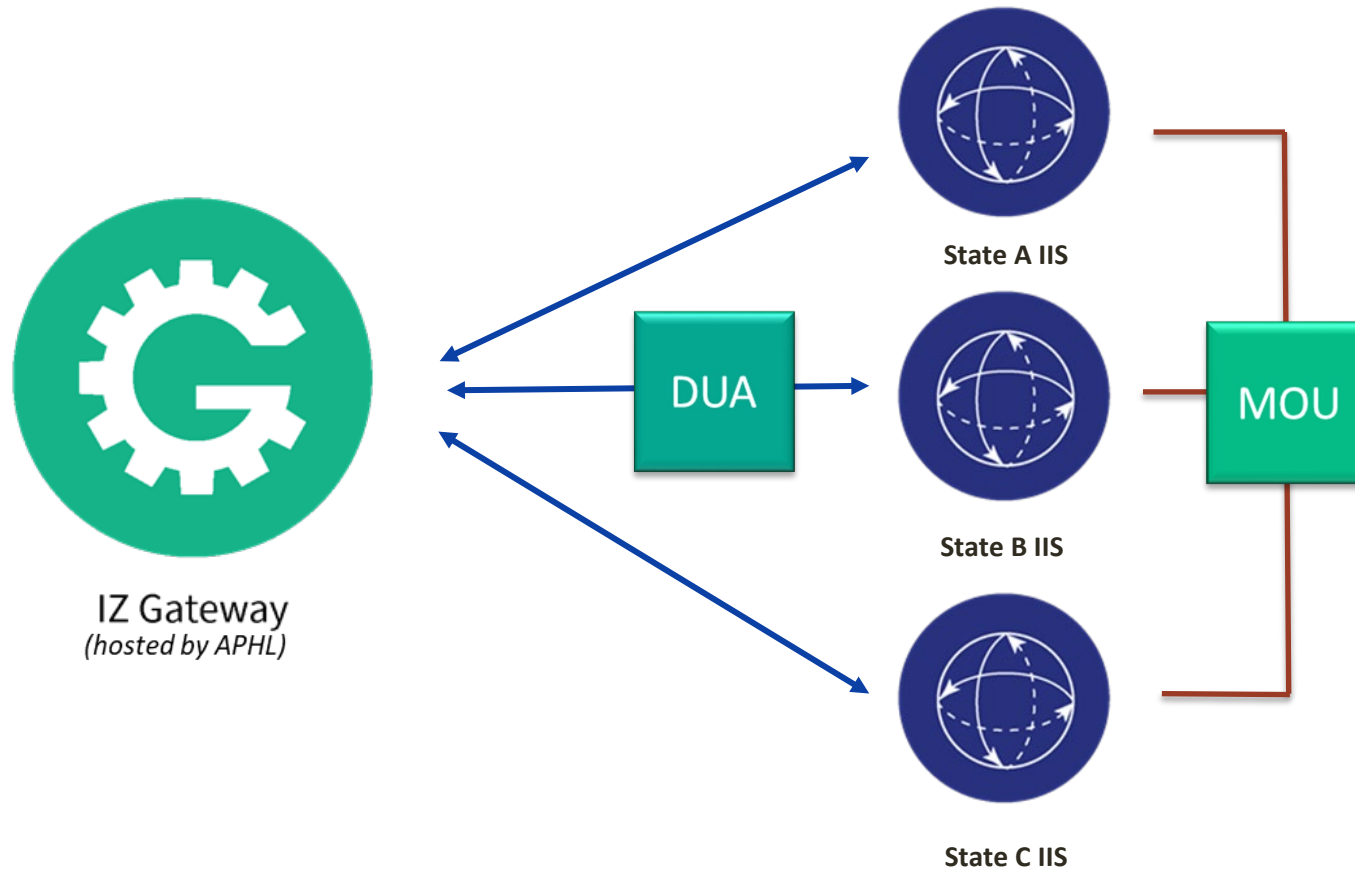
MOU

MOU – Jurisdiction IIS and Jurisdiction IIS:

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

*Multi-Jurisdictional Exchange under development.

Exchange with Other IIS – Use Case 2



IISs 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

*Referred to as Share in DUA Task Order

↔ Reflects Trust Relationships, Not Data Flow

Exchange with Other IIS – Use Case 2 (*Referred to as Share in DUA)

- **Public Health IIS Interjurisdictional 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>

Interjurisdictional 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 received 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

- MOU confirms IIS exchange authority, provides rules of the road
- 45 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 (preferable for all IIS to be on the July 2020 version)
 - <https://repository.immregistries.org/resource/public-health-iis-interjurisdictional-memorandum-of-understanding-mou/>
- Flexible – technology inclusive
 - Exchange immunization information via IZ Gateway, and/or
 - Establish independent means to exchange immunization information with another jurisdiction

45 Jurisdictions Have Already Signed the MOU

1. Alaska
2. PI – American Samoa
3. Arizona
4. Arkansas
5. California - San Diego
6. Colorado
7. Connecticut
8. Delaware
9. District of Columbia
10. Idaho
11. Indiana
12. Iowa
13. Kansas
14. Kentucky
15. Louisiana
16. Maine
17. PI - Republic of the Marshall Islands
18. Maryland
19. Michigan
20. Minnesota
21. Missouri
22. Mississippi
23. Montana
24. Nebraska
25. Nevada
26. New Jersey
27. New York City
28. New York State
29. North Dakota
30. Ohio
31. Oklahoma
32. PI - Palau
33. Pennsylvania
34. Philadelphia
35. Puerto Rico
36. Rhode Island
37. South Dakota
38. Tennessee
39. Utah
40. Vermont
41. Virginia
42. Washington
43. West Virginia
44. Wisconsin
45. Wyoming

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 IISs 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 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**
 - 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 a potential approaches to support immunization information exchange
- Reminder: For IIS-IIS Exchange, 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.

IZ Gateway Project Team

Project Sponsor: Centers for Disease Control and Prevention (CDC)



Audacious Inquiry, LLC



**Association of Public
Health Laboratories**



HLN Consulting, LLC

Deloitte. Deloitte



SRS



**American Immunization
Registry Association**



**Network for Public
Health Law**



ESAC Inc.

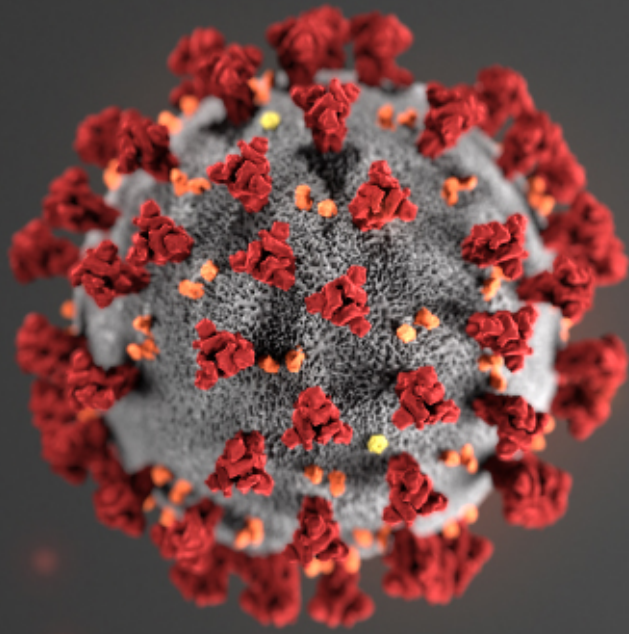


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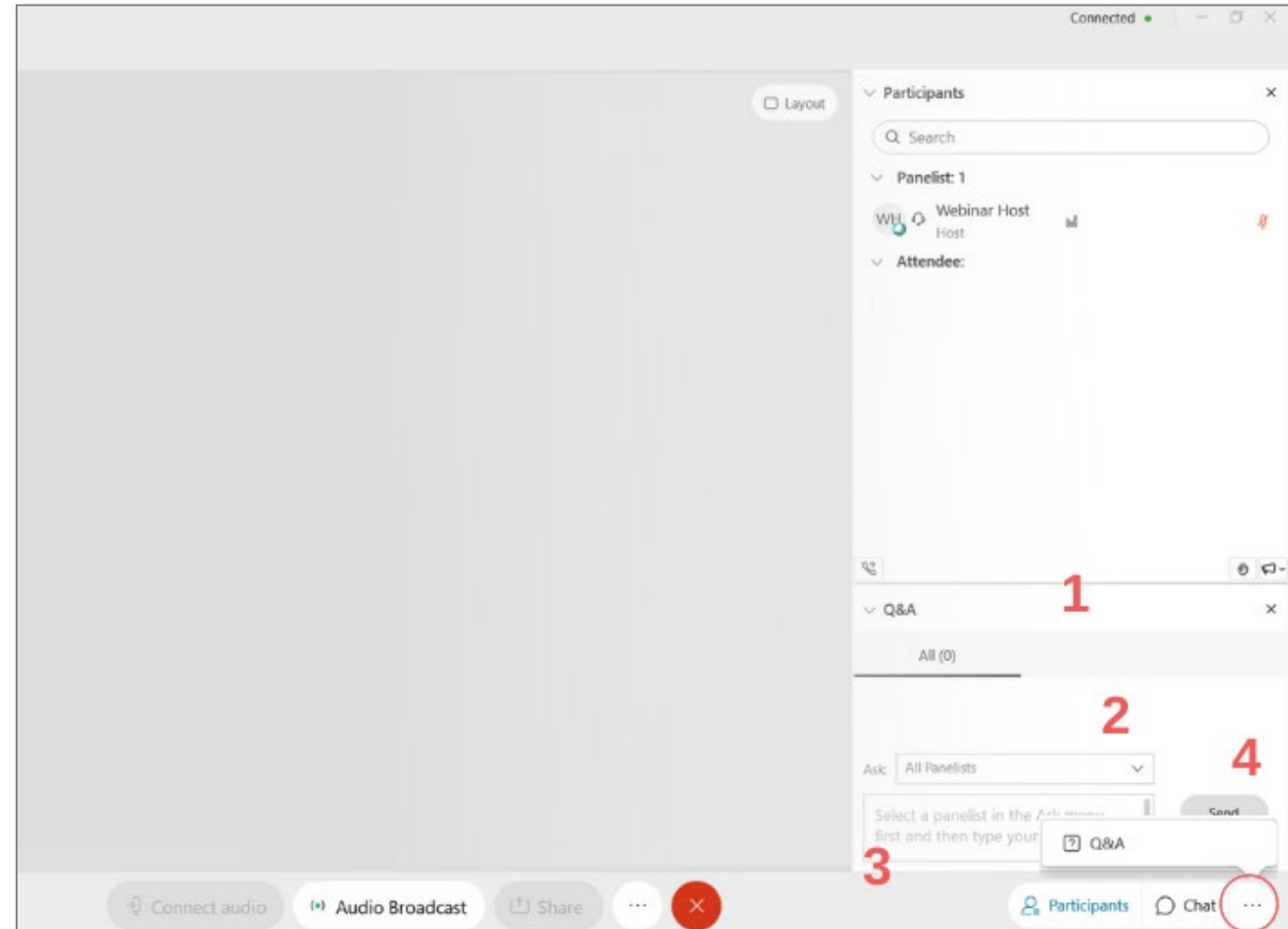
For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov
Email: IZGateway@cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.



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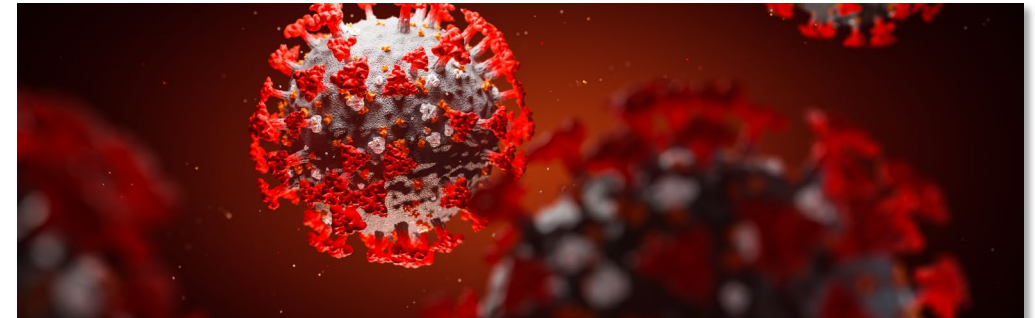
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