Introduction to the
IZ Gateway Multi-Jurisdictional Vaccine Provider – Jurisdiction Data Exchange Agreement (PJA)

IZ Gateway and Legal Agreement Overview

Co-Sponsored by:

IZ Gateway

The Network for Public Health Law
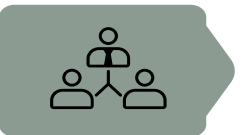
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Agenda

Purpose: Provide review of information needed by parties to support the execution of an agreement required to exchange data with the Department of Veterans Affairs and other Multi-Jurisdictional providers.
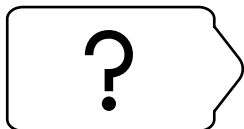
IZ Gateway Overview & Use Cases

Security Considerations and Jurisdiction Controls

IZ Gateway Legal Framework

IZ Gateway Multi-Jurisdictional Vaccine Provider – Jurisdiction Data Exchange Agreement ("PJA")

Q&A

Speaker Biographies

- **Lindsey Lowinski, Health IT Project Manager** at Audacious Inquiry, serves as a legal and policy liaison between the Center for Disease Control, The Network for Public Health Law, Immunization Information Systems, and Multi-Jurisdictional Vaccine Provider Organizations. Prior to joining Audacious, Lindsey served as an interagency coordinator for the Department of Defense facilitating the inclusion of U.S. and international non-profit/non-governmental organizations (NGO's), businesses, and academia in Department of Defense humanitarian assistance, community resilience, and security and stability activities in Latin America and the Caribbean. Lindsey earned a master's degree in International Disaster Management from Florida International University, Robert Stempel College of Public Health & Social Work with a focus on strategic engagement.

- **Carrie Waggoner is a Deputy Director** with The Network for Public Health Law's Mid-States Region Office. In her role, Carrie focuses on data, privacy, and general public health authority issues. Prior to joining the Network, Carrie worked in the legal administration at the Michigan Department of Health and Human Services (MDHHS). Carrie held a variety of roles at MDHHS, most recently as the Director of the Public Health Legal Division where she led teams providing legal support on public health, privacy, and FOIA-related matters. Carrie is a graduate of Michigan State University College of Law and has been licensed to practice law in Michigan since 2011.

Speaker Biographies, Cont.

- **Michelle Rubin, Senior Manager** at Audacious Inquiry, serves as an interim project director of the IZ Gateway team. Michelle's experience includes managing HIE data exchange efforts between public health entities and HIE participants and implementing care management software. Prior to joining Audacious, Michelle specialized in population health for a federally qualified health center, managing a transitions of care program and leading the implementation and use of an organization-wide population health management platform. Michelle earned her Master of Science in Public Health from Johns Hopkins Bloomberg School of Public Health with a focus on Health Policy and Management.

- **Kory Mertz, Senior Director** at Audacious Inquiry, is a subject matter expert in state and federal health policy and interoperability. He works with clients interpreting federal regulations and translating the requirements into actionable steps and strategies. He leads many Audacious Inquiry engagements with the Office of the National Coordinator for Health IT (ONC). Prior to joining Audacious Inquiry, he worked at ONC for six years in a variety of roles helping to launch and execute the HITECH Act. While at ONC, Kory was deeply involved in the State Health Information Exchange Program helping to lead its implementation. Kory also worked at the National Conference of State Legislatures and served as the lead staff for the Health Information Technology Champions Project, a public-private partnership that worked to increase state legislative leadership on health information technology.

Speaker Biographies, Cont.

- **Chris Alibrandi O'Connor,** a **Senior Attorney** at The Network for Public Health Law, provides legal technical assistance and training related to legal issues around the collection, maintenance, use, and storage of data for public health purposes, with expertise in health data privacy matters. Chris was a legal services attorney in Atlanta and Boston before transitioning to practicing health data privacy law and health policy work. She served as Privacy Legal Counsel and Director of Solutions Integration on a Medicaid waiver demonstration project, leading data reporting and health data sharing efforts across sectors. She also worked previously as the Director of Health Policy and HIPAA Privacy Officer for a dental benefits company. Chris has developed and delivered trainings for legal, workplace, boards of directors, professional organizations, and community audiences on a wide range of topics, including health data privacy laws, the Affordable Care Act, and non-health topics. She received her Juris Doctorate from Northeastern University School of Law. She is admitted to practice law in Massachusetts, Georgia, and New Hampshire.

IZ Gateway Overview

Introducing the IZ Gateway

Message Routing Service

A cloud-based message routing service for immunization data exchange
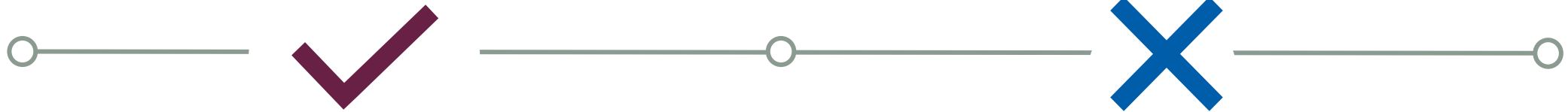
Centralized Data Exchange

Serves as one consolidated integration hub to facilitate data exchange through a standardized, repeatable onboarding/testing process

Policy Infrastructure

Offers standardized policy infrastructure for data exchange between IIS and with multi-jurisdictional vaccine providers

What the IZ Gateway Does and Does Not Do

THE IZ GATEWAY DOES

- ✓ Serve as a message router with standardized testing and onboarding procedures and a consolidated policy framework

- ✓ Exchange data among and between IISs and Multi-jurisdictional Vaccine Providers

- ✓ Enable more complete records of patient immunization history for IISs, providers, and consumers

THE IZ GATEWAY DOES NOT

- ✗ Act as a message repository, data lake or pool

- ✗ Send COVID-19 or routine vaccination data to CDC (It is not integrated with CDC Date Clearinghouse or IZ Data Lake)

- ✗ Access or store any messages

IZ Gateway Use Cases Explained

IZ Gateway Use Cases

Exchange Data with Vaccine Providers

1

VAMS → IIS
Federal Agency or Multi-jurisdictional Vaccine Provider ↔ IIS
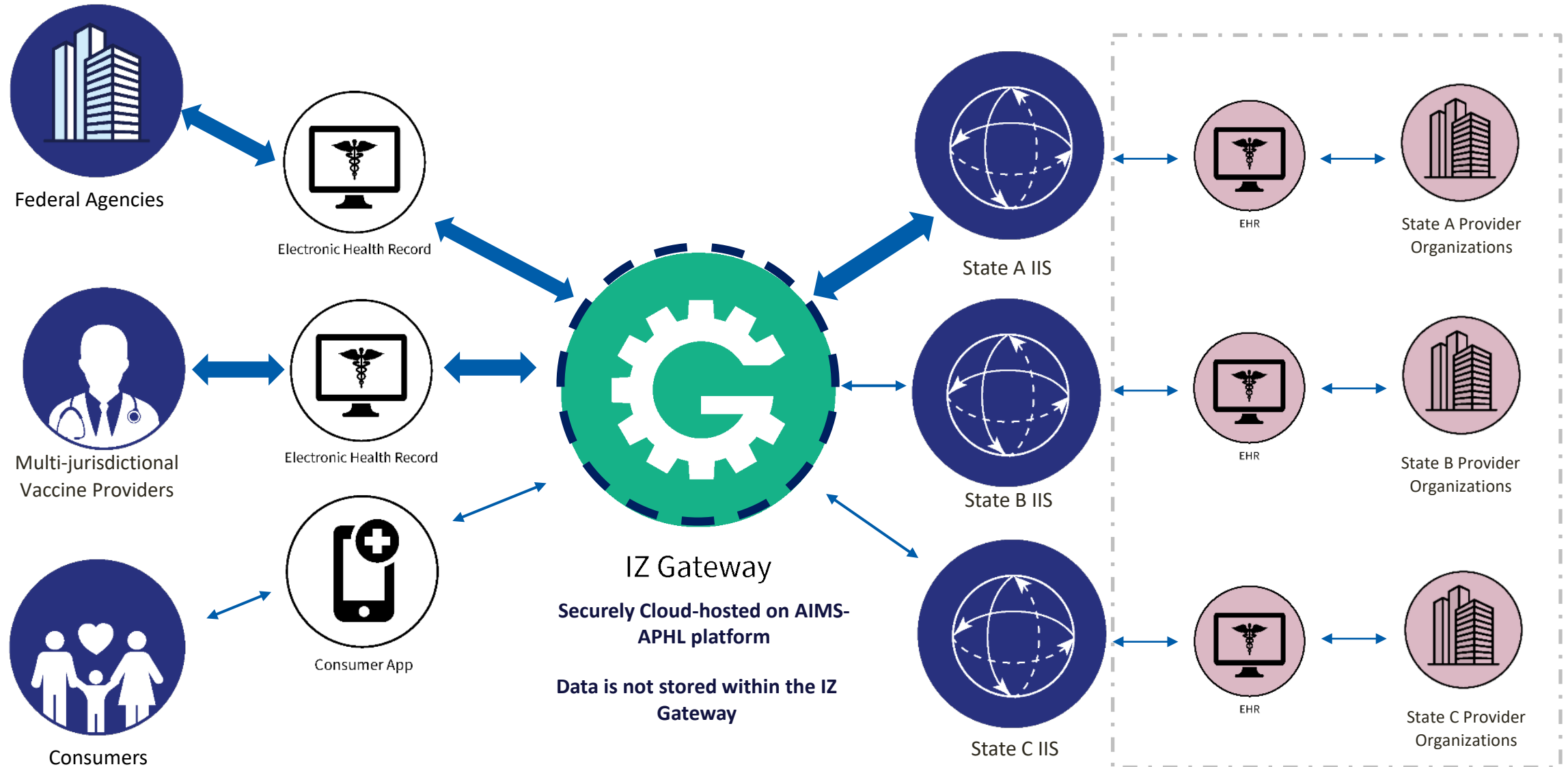
Exchange Data with other IISs

2

IIS ↔ IIS

Share Data with Patients

3

IIS → Patient App or Patient Portal

Use Case 1: Exchange Data with Vaccine Providers

Federal Agencies

Electronic Health Record

Multi-jurisdictional Vaccine Providers

Electronic Health Record

Consumers

Consumer App

IZ Gateway

Securely Cloud-hosted on AIMS-APHL platform

Data is not stored within the IZ Gateway

State A IIS

State B IIS

State C IIS

EHR

State A Provider Organizations

EHR

State B Provider Organizations

EHR

State C Provider Organizations

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

Use Case 1: Exchange Data with Vaccine Providers

Exchanging immunization data with vaccine providers improves access to and quality of IIS data

What are the sub-use cases?

- Send data **(VXU)** to their local IIS through the IZ Gateway
- Queries **(QBP)** their local IIS and the IIS responds through the IZ Gateway

What is Required of the IIS?

- Programs will need to **complete baseline onboarding connection testing**
- Programs need to have **signed the Association of Public Health Laboratories (APHL) DUA***
- Programs need to have **signed the PJA (Multi-Jurisdictional Vaccine Provider – IIS Data Exchange Agreement)***
- IIS must complete **end-to-end testing** with multi-jurisdictional vaccine provider

*Denotes a legal or policy requirement

Use Case 2: IIS-to-IIS Data Exchange

IIS-to-IIS data exchange allows IIS to share data with one another to improve IIS data completeness and access to accurate patient immunization history

What are the sub-use cases?

- **Automated VXU:** IIS automatically sends vaccine data to partner IIS through IZ Gateway

- **Manual QBP:** IIS uses queries for vaccine history based on patient's address information or conversation with the patient.

- **Automated QBP:** IIS automatically queries for vaccine history using the patient's current out-of-jurisdiction address (triggered by a new vaccine or updated demographics)

What is Required of the IIS?

- Each IIS will need to **complete baseline onboarding connection testing**

- Each IIS must have signed the **Interjurisdictional Memorandum of Understanding (MOU)***

- Each IIS must have signed the **Data Use Agreement (DUA) with Association of Public Health Laboratories (APHL),** including Appendix A (**"Share"** Task Order)*

- IIS have met **functional and technical readiness criteria**

- IIS have completed **end-to-end testing with data exchange partner**

*Denotes a legal or policy requirement

Use Case 3: Share Data with Patients

IIS-to-Consumer App or Patient Portal provides patients with direct access to their immunization records

How does it work?

- Patients use **an app or portal that is connected to IZ Gateway** to query the IIS for their immunization record

- Patients' access to the app or portal requires **two-factor authentication**

What is Required of the IIS?

- Programs will need to **complete baseline onboarding connection testing**

- Each IIS must have signed the **Data Use Agreement (DUA) with Association of Public Health Laboratories (APHL),** including Appendix A (**"Access"** Task Order)*

- IIS must complete **end-to-end testing** with app/portal vendor

*Denotes a legal or policy requirement

IIS Controls and Security

IIS have Control of their IZ Gateway Participation

- Each IIS determines in which data exchange use cases they want to participate, and with which partners they will exchange data.

- Each IIS controls which jurisdictions and vaccine providers they exchange data with via the IZ Gateway.

- IISs must set up/enroll data exchange partners in their system.

- IISs should standardize onboarding and testing for each data exchange partnership.

Security Controls Protect Data

- Data in transit are encrypted across the custody chain to ensure the security of patient data.

- APHL and the IZ Gateway do not collect, maintain, or store personally identifiable information (PII).

- The IZ Gateway conforms with policy framework security standards included in agreements signed by data exchange partners.
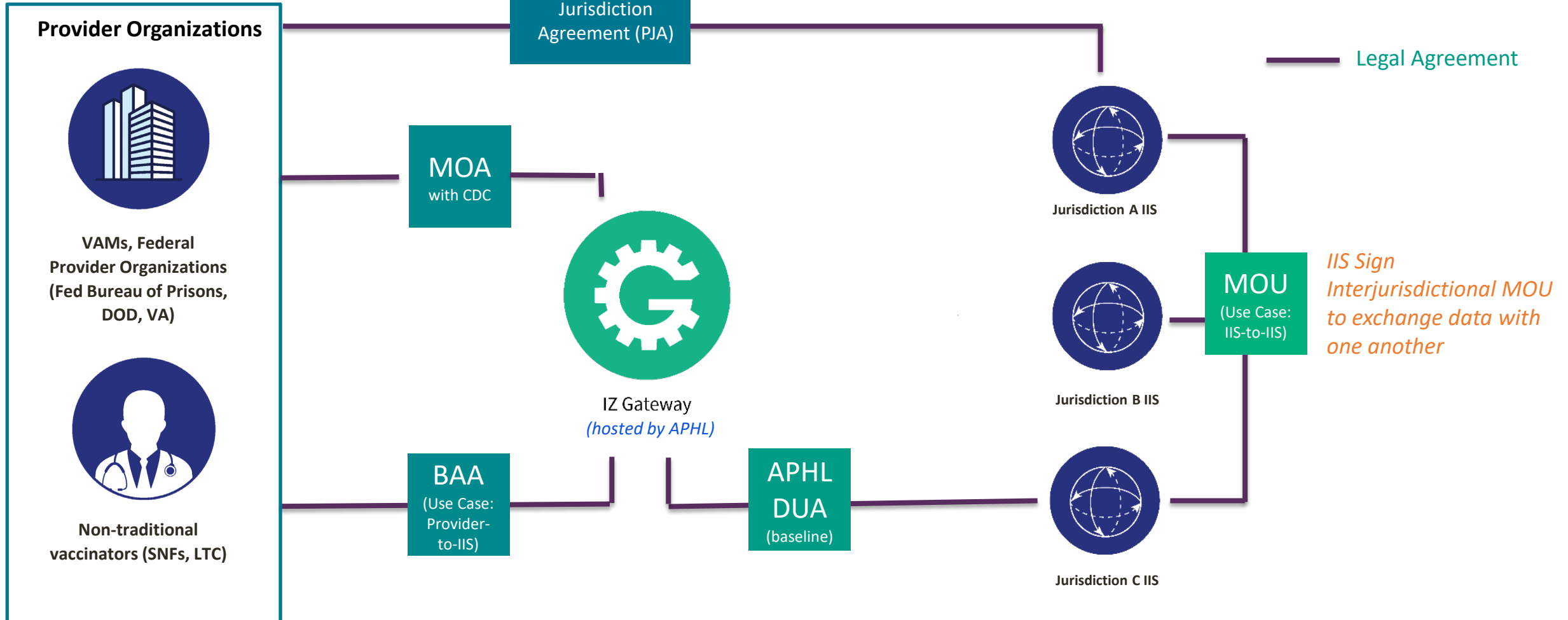
IZ Gateway Legal Framework

IZ Gateway Trust Framework

APHL DUA Overview

Data Use Agreement with APHL

Required for participation in all use cases

Purpose *(see Background)*

- To facilitate exchange of immunization information through the IZ Gateway

Security *(§ 2)*

- Compliance with FISMA, HIPAA, FedRAMP
- Uses a "Modular Certified Technology" to support meaningful use transaction.
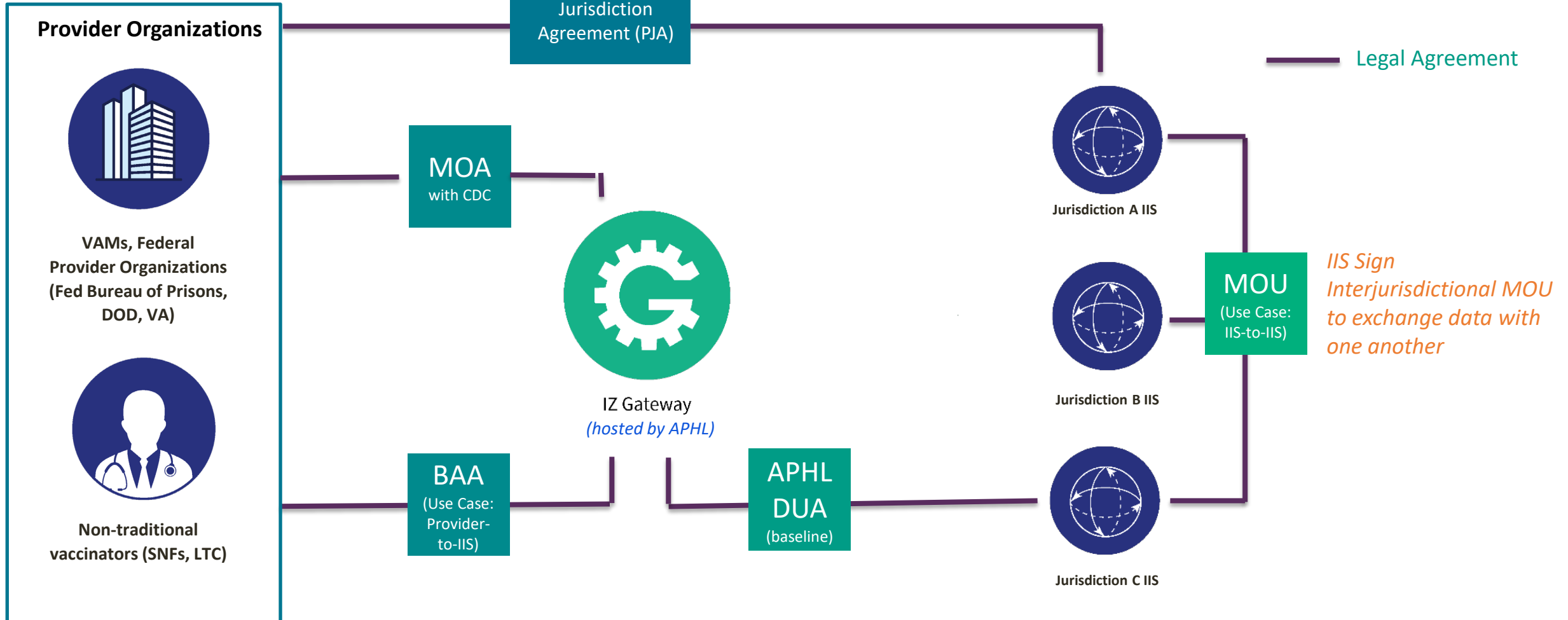
Task Order, Appendix A

- Allows jurisdiction to select the use cases/project components it wishes to participate in

IZ Gateway Trust Framework

Prior State: *Provider signs up to 64 individual IIS Agreements*
Current State: *Providers and Jurisdictions sign the PJA to participate in Provider-Jurisdiction data exchange*

Provider-Jurisdiction Agreement (PJA)

Legal Agreement

Provider Organizations

VAMs, Federal Provider Organizations (Fed Bureau of Prisons, DOD, VA)

Non-traditional vaccinators (SNFs, LTC)

MOA with CDC

BAA (Use Case: Provider-to-IIS)

IZ Gateway
(hosted by APHL)

APHL DUA (baseline)

Jurisdiction A IIS

Jurisdiction B IIS

Jurisdiction C IIS

MOU (Use Case: IIS-to-IIS)

IIS Sign Interjurisdictional MOU to exchange data with one another

PJA Deep Dive

Overview: Provider-Jurisdiction Agreement (PJA) for Multi-Jurisdictional Vaccine Providers and IIS

IZ Gateway Multi-jurisdictional Vaccine Provider and IIS Data Exchange Agreement ("PJA")

- Modeled after the Interjurisdictional MOU
- Reviewed 15 jurisdiction's IIS-related agreements
- Intended as a multi-party agreement to streamline the number of agreements provider organizations need to sign *(1 versus up to 64)*
- Solicited IIS Review/Feedback
- Veterans' Health Administration is now utilizing

PJA Key Terms

Parties *(§ 3)*

– Multi-jurisdictional vaccine providers *(§ 10)*

– Jurisdictions (i.e., IIS) *(§ 10)*

Purpose *(§ 2)*

– Terms and conditions re: data exchange of immunization information through the IZ Gateway, specifically immunization reporting and immunization query consistent with applicable law.

PJA Key Terms

Does not prevent other communications or agreements outside of IZ Gateway

- Granting direct access to IIS, or exercise of emergency authority. *(§§ 6, 7, 8, 9)*

Applicable Law *(§ 10)*

- All applicable statutes and regulations of the State(s) or jurisdiction(s), including federally recognized tribal governments and U.S. territories, in which a Party operates, as well as all applicable Federal statutes, regulations, standards, and policy requirements. Federal entities are subject to applicable federal laws only.

PJA Key Terms

Data Exchange *(§ 11)*

- Immunization Reporting (VXU) – consistent with applicable law, provider provides immunization information via IZ Gateway to a jurisdiction.

- Immunization Query (QBP) – consistent with applicable law, provider queries 1+ jurisdictions via IZ Gateway and 1+ jurisdictions provides immunization information to the querying provider.

Each Party determines the information it provides to another Party *(§ 12)*

PJA Key Terms

Immunization Information *(§ 10)* means:

- Information created by Provider or created within or received by IIS that relates to past, present, or future immunization status;

- Provision of vaccine(s) to an individual; and

- Medical or clinical information related to immunization.

Incorporation of Data *(§ 14)*

- Receiving Party, consistent with applicable law, may incorporate data into its data system (i.e., IIS or clinical records)

Control, Use, and Disclosure of Data *(§ 15)*

- Consistent with applicable law, data is subject to receiving party's control, use, and disclosure. Responsible for data protection.

PJA Key Terms

Privacy and Security *(§ 16)*

By signing, a Party affirms the following –

- Implementation of confidentiality policies consistent with applicable law that protect privacy of Immunization Information;

- Implementation of appropriate administrative, physical, and technical safeguards to protect privacy and security; and

- All reasonable efforts to implement industry standards for information security.

- HIPAA is the floor for providers

- Federal Agency Providers must comply with Applicable Law

Breach Notification *(§ 16)*

- Upon discovery, Receiving Party makes reasonable efforts to identify source of data received through IZ Gateway and to notify Sending Party and Administrator

PJA Key Terms

Governing Law *(§ 27)*:

- In event of a dispute, applicable federal and state conflicts of law provisions that govern the Parties will determine the governing law.

Withdrawal & Termination *(§ 25)*

No monetary exchange *(§ 19)*

No warranties (best efforts) *(§ 20)*

Limitation of Liability *(§ 22)* - parties responsible for own liability

Period of Agreement *(§ 23)* - no fixed term

PJA Key Terms

Agreement Administrator *(§ 5)*: The CDC

Notices (contact information) *(§ 26)*

Administrator's Responsibilities *(§ 32)*:

- Maintain signed copies from all signatories;
- Maintain contact information and make updates as needed;
- Receive and provide notice under PJA;
- Make accessible a list of all Parties to the PJA; and, among others,
- Facilitate addressing questions or concerns.

Q&A

Next Steps

- Review and garner signature on the PJA sent to IIS Managers and Immunization Program Managers on January 14, 2022.

- Ask questions or request an individual discussion by contacting [IZGateway@cdc.gov.](mailto:IZGateway@cdc.gov)

- To improve future PJA webinar content, complete the short 6 question survey that will pop up once the webinar ends.

For more information, contact CDC
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TTY: 1-888-232-6348   www.cdc.gov