Agenda

Objective: Enrich your ability to form data exchange relationships with multi-state immunization providers by learning from the HHS Immunization (IZ) Gateway portfolio

Topic	Presenter	Organization	Time
IZ Gateway Introduction	**Lori Moore**	Centers for Disease Control and Prevention	*10 mins*
IZ Gateway Overview	**Dan Chaput**	Office of the Chief Technology Officer	*15 mins*
Policy & Technology Requirements	**Kelly Carulli**	Audacious Inquiry	*10 mins*
Onboarding Status Overview & Next Steps	**Erin O'Shea**	American Immunization Registry Association	*10 mins*
Q&A	All	All	*15 mins*

COVID-19 Mass Vaccination Campaign

- **Multiple Focuses on Monitoring End-to-End Vaccination Efforts**
  - Supply Chain Management
  - Vaccine Administration

- **Current Challenges in Existing Infrastructure**
  - Lack of comprehensive vaccine coverage reporting
  - Lack in electronic connectivity and submission
  - Gaps between non-IIS connected provider organizations (BOP, State/Local correctional facilities, IHS, DoD, VA, & Long-Term Care Facilities) and immunization information systems (IIS)
  - Lack in consumer record access for those on the move

- **Steps to Readiness**
  - Ensuring high quality data entry on both supply chain management and in vaccine administration activities
  - Implement the IZ Gateway to remove electronic connectivity challenges
  - Optimize reporting capabilities across jurisdictions, government and state and local partners

COVID-19 Mass Vaccination Campaign

The IZ Gateway Three Guiding Principles:

1. **Optimize Existing Connections Already in Use**
   - Leverage existing pathways and infrastructure and fill in gaps for new partners

2. **Leverage Existing Strategic Partners while Building NEW Connections with Non-IIS Provider Organizations**
   - Expand existing connections by using lessons learned from current IIS strategic partners

3. **Reduce – NOT add – Burden**
   - Focus on making it less burdensome for all stakeholders involved (Federal government, states, providers, consumers)

COVID-19 Mass Vaccination Campaign

Continue Preparedness Activities

- Discovery efforts with partners to ensure CDC has a complete picture of existing capabilities

- Additional guidance & assistance to help ready systems for expanded data sharing capabilities

- Frequent updates in routine calls along with special sessions

- Continued efforts focused on high quality data transmissions

Striving Towards

- Having timely and accurate vaccine coverage reporting

- Accurately tracking and linking doses distributed to those administered

- Tracking vaccination of priority/tiered groups and high-risk populations

- Enabling providers to prompt interjurisdictional exchange

- Supporting ways to ensure patients have easy, electronic access to their vaccination record

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
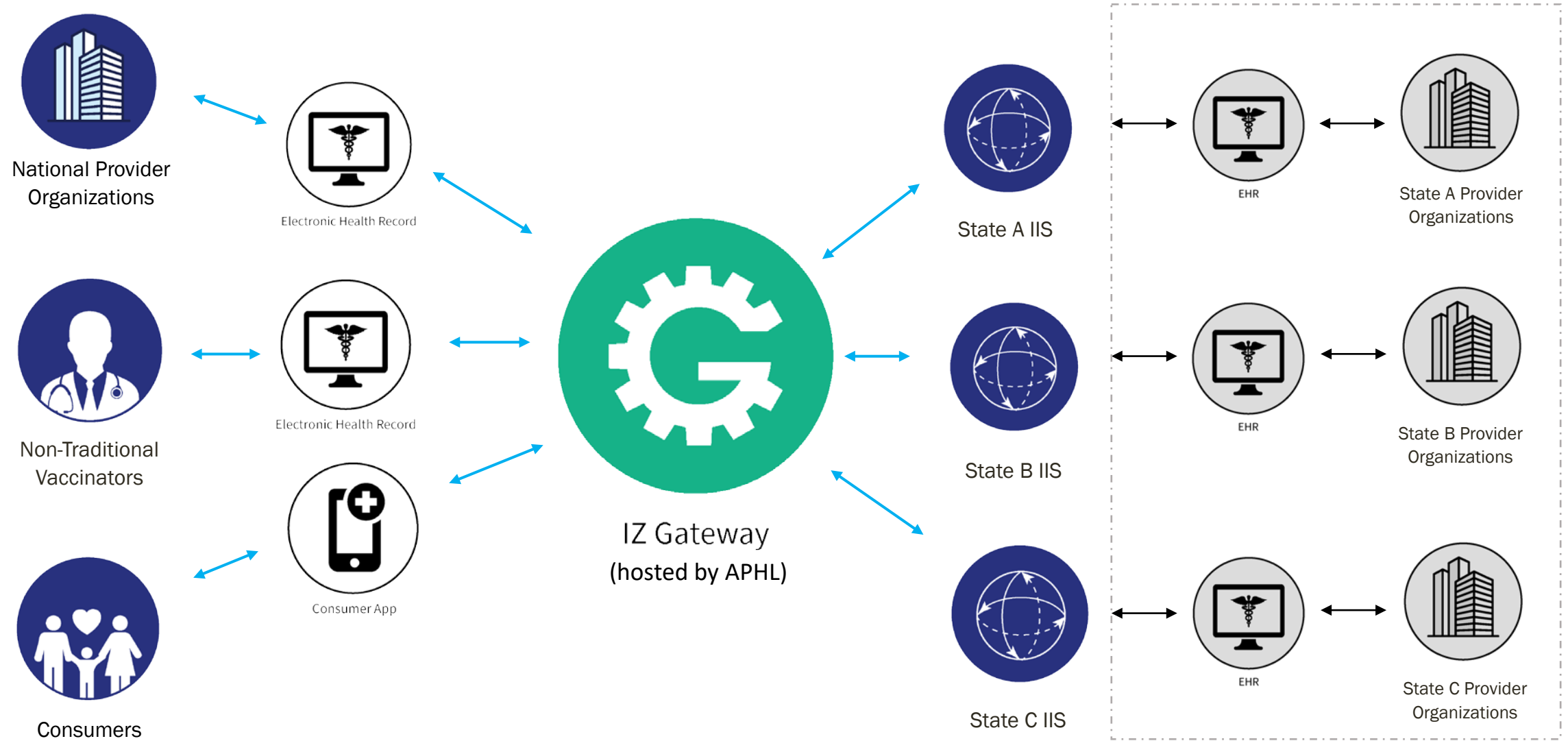Cross-jurisdictional IIS to IIS

Access
Consumer Access to IIS through Digital Tools

Provider-initiated Multi-Jurisdictional Data Exchange
Query multiple jurisdictions to receive consolidated immunization data

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

National Provider Organizations

Electronic Health Record

Non-Traditional Vaccinators

Electronic Health Record

Consumers

Consumer App

IZ Gateway
(hosted by APHL)

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

Value to COVID-19 Response Effort

IZ Gateway Portfolio Component	Type of Data Exchange	Benefit
Connect	Provider Organization and IIS	VAMS (Vaccine Administration Management System) will route vaccination administration information to the IZ Gateway. IZ Gateway will route the information to participating IIS'. Will onboard non-traditional vaccinators (Bureau of Prisons, Skilled Nursing Facilities, etc.) to route vaccinations through the Gateway to jurisdictions.
Share	IIS and IIS	Will support clinical workflows to deal with the details of multiple vaccines, with multi-dose series. Critical for clinical workflows and clinical decision support. Vaccinators can query for vaccine history and recommendations.
Access	Consumer Access tools and IIS	Enable consumer access to online immunization records and sets groundwork for consumer access models for immunity certifications
Provider-Initiated Multijurisdictional Query Exchange	Provider Organization and IIS	Receive consolidated vaccine record from multiple states where needed

Call to Action for COVID-19 Response

IIS are encouraged to take the following steps in preparing for COVID-19 mass vaccination:

1. Complete preliminary steps to onboard IIS to IZ Gateway Connect
   - Onboard the IZ Gateway to TEST & PROD environments by setting up IIS credentials for the Gateway and completing initial integration testing with AIRA test tools.
   - This component is the lowest lift as IIS will onboard the IZ Gateway as they would other provider organizations.
   - Review and sign the APHL Data Use Agreement
2. Begin preparing for IZ Gateway Share
   - Review and sign the Interjurisdictional MOU and the APHL Data Use Agreement
   - Upgrade to the latest version of your IIS platform. The team intends to prepare all states for IZ Gateway Share readiness before onboarding and turning on connections between jurisdictions

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Legal Agreements

Policy Requirement Key

MOU

- **Interjurisdictional MOU – Jurisdiction IIS and Jurisdiction IIS:**
  - Public Health Interjurisdictional Memorandum of Understanding (MOU) (Updated August 2019)
  - Signed among public health jurisdictions
  - Share/Multi-Jurisdictional Exchange

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
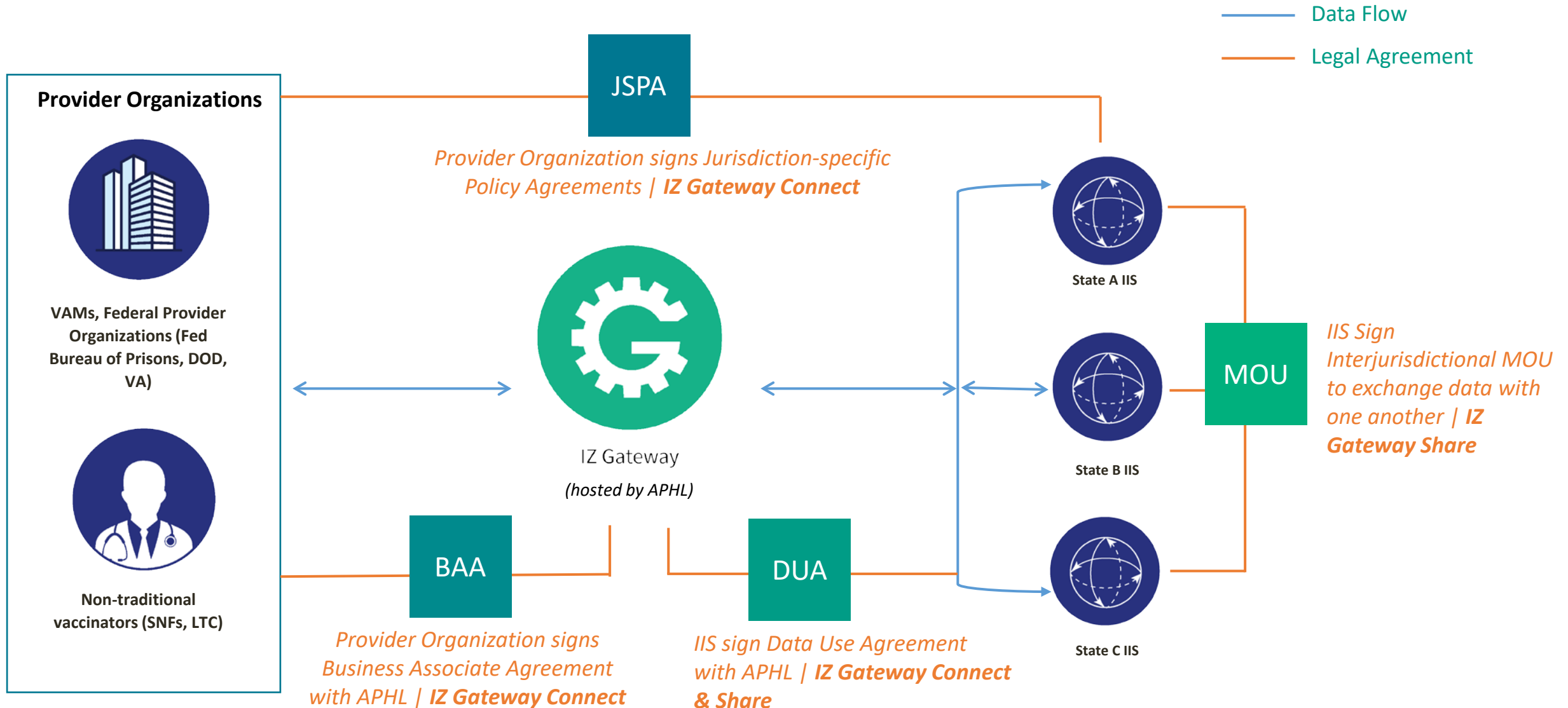 - Connect/Share/Multi-Jurisdictional Exchange/Access

BAA

- **Business Associate Agreement – Provider Organization and APHL**
  - Recognizes that the IZ Gateway sends and receives data on behalf of the provider organization
  - Addresses use and disclosure of protected health information, security, privacy, incident response and other clauses
  - Connect

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

IZ Gateway Connect & Share Legal Agreements

Data Flow

Legal Agreement

Provider Organizations

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

Non-traditional vaccinators (SNFs, LTC)

JSPA

*Provider Organization signs Jurisdiction-specific Policy Agreements | **IZ Gateway Connect***

IZ Gateway

(hosted by APHL)

State A IIS

State B IIS

State C IIS

MOU

*IIS Sign Interjurisdictional MOU to exchange data with one another | **IZ Gateway Share***

BAA

*Provider Organization signs Business Associate Agreement with APHL | **IZ Gateway Connect***

DUA

*IIS sign Data Use Agreement with APHL | **IZ Gateway Connect & Share***

IZ Gateway Legal Agreements: Facilitating Secure Data Sharing for IIS

Initiatives to expedite IIS signature of APHL DUA (updated Aug 3) and Interjurisdictional MOU hosted by the Network for Public Health Law (NPHL)

Webinars

- Public Health Programs are invited to learn about the legal and policy constructs supporting immunization information exchange across the IZ Gateway
- States Attorneys will have opportunity to ask questions and learn from the experts that crafted the agreements.
- Earn 60 minutes of *free* CLE
    - August 20 | 2:00 – 3:00 p.m. ET
    - September 9 | 12:00 – 1:00 p.m. ET

Q & A Sessions

- Thursday, August 13 | 3:00 – 4:00 pm ET
- 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

Webinar Link: https://www.networkforphl.org/resources/iz-gateway-project-portfolio-legal-relationships-and-required-agreements/

Q & A Sessions Link: https://www.networkforphl.org/wp-content/uploads/2020/08/IZ-Gateway-Data-Use-Agreement-QA-Sessions.pdf

Technology Considerations

- Participation in all IZ Gateway components require:
  - Provide Immunization Gateway credentials to IIS test system
  - CDC WSDL and HL7 2.5.1 Release 1.5

- **IZ Gateway Share** requires additional functionality which may require IIS upgrades for some jurisdictions including:
  - Capability to recognize out of state address in incoming HL7 message and in data at rest
  - Trigger creation of a new historical VXU to send to another IIS based on out of state address
  - Capability to install client-side certificate
  - Modified CDC WSDL and HL7 2.5.1 Release 1.5

IIS-IZ Gateway Connect | Onboarding Goal

Goal: Onboard 38 jurisdictional IIS to connect to IZ Gateway Connect as receivers of data and query by September 30, 2020.

Approach:

- Group IIS into 4 Onboarding groups
- Complete onboarding in 4 waves targeting 2-4 weeks per group of IIS.
- First onboarding group will serve as a learning experience in navigating rapid onboarding and overcoming challenges.
- Following onboarding of IIS, onboard provider organizations/VAMS to IIS through the IZ Gateway
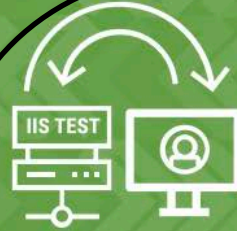
PROCESS – IMPROVEMENTS AND BEST PRACTICES

STEP 1:
DISCOVERY & PLANNING

- **Registration**
- **IIS Site Enrollment**
- **Kick Off Call**
- **Forms Completion**
- **Other Pre-Prep Activities** (Checklists, Self-service testing, Code comparisons, Etc.)

STEP 2:
DEVELOPMENT AND TESTING

- **Connectivity and transport**
- **Testing environments/ platforms**
- **Use of test data or production data**
- **Volume of records needed for testing/validation**
- **Technical vs. programmatic testing**
- **Importance of ACKs**
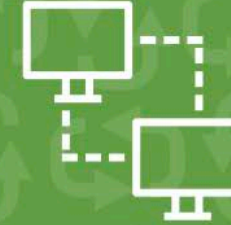- **Self-service opportunities**

STEP 3:
PRODUCTION APPROVAL

- **Production approval**
- **Pre-production forms completion**
- **Training (optional)**
- **Move provider credentials to Prod**

STEP 4:
ONGOING MONITORING

- **Short-term production monitoring**
- **Long-term production monitoring**
- **Re-onboarding triggers**

SPECIAL:
QUERY/ RESPONSE

- **Differences in processes and procedures compared to standard interfaces (VXU only)**
- **Discovery and Planning**
- **Development and Testing**
- **Production Approval and Monitoring**
- **Additional steps**

IIS-IZ Gateway Connect | Onboarding Packet

1. IZ Gateway Connect 1-Pager: Project overview document

2. Onboarding Checklist: Overview of each step for rapid onboarding

3. Technical Specifications: Includes all technical details for onboarding

4. DUA: Signed between IIS and APHL

5. Interjurisdictional MOU: Out of scope for Connect, however, states that are interested in participating in Share (IIS to IIS exchange) are encouraged to start reviewing

IZ Gateway Specific HL7 IG: Currently in development, will be shared in August

IZ Gateway Connect Onboarding Checklist

IIS Activity	Purpose	Complete	Date	IZ Gateway Team Response	Via
Participate in onboarding kick-off call with identified priority group.	*Ask questions and get started.*	☐		Provide onboarding checklist and support IIS through next steps. Send requests for signed DUA and Test Credentials.	Email
Submit signed Data Use Agreement (DUA) securely with the provided electronic REDCap form.	*DUA between IIS and APHL for exchanging production data through IZ Gateway Connect.*	☐		Send confirmation of receipt for signed DUA. *We recommend continuing with testing, even while the DUA is in the process of being signed.*	REDCap Email
Submit IZ Gateway Test Credential Request securely with provided REDCap electronic form.	*Test connection will be used for onboarding IIS now, and onboarding providers through the IZ Gateway in the future.*	☐		Send confirmation of receipt for test credentials. Additional emails may be exchanged to establish test connection.	REDCap Email
Monitor for test HL7 messages submitted from the AART Tool through the IZ Gateway to your IIS test environment. Note date of successful message receipt.	*Test messages will confirm the test connection between IIS and IZ Gateway is successful.*	☐		If issues arise, team member will contact IIS with next steps. AIRA will confirm when messages process successfully, then will send Production Credential Request.	Email
Submit IZ Gateway Production Credential Request securely with provided REDCap electronic form.	*Production connection will be set up now to prepare for COVID-19 response, but not yet connected to providers.*	☐		Send confirmation of receipt for production credentials. Additional emails may be exchanged to establish connection.	REDCap Email
Wait for communication from AIRA team indicating successful connection status. Note date of successful connection.	*A test QBP message intended to fail (invalid Org/Facility fields) will confirm the production connection between IIS and IZ Gateway.*	☐		*AIRA team and IIS will collaborate to prevent compromising production environment with test data.* Send confirmation that production connection is successfully established.	Email

Tracking Tools

- REDCap Central Tracking

- Tableau for Sharing + Data Visualization

Onboarding Timeline Estimate by Wave

These dates are adjusting as onboarding continues.
Start Date = Kickoff Email Sent
End Date = Connected to IZ Gateway Production (goal date)

- Wave 1
  - Start: July 15
  - End: August 14

- Wave 2
  - Start: July 30
  - End: August 28

- Wave 3
  - Start: August 12
  - End: September 10

- Wave 4
  - Start: August 28
  - End: September 28

Current Onboarding Status

- 2 Test Connections In Progress
- 6 Test Connections Complete
- 8 DUAs sent out for signatures
- Average # Days to Establish
  Test Connection: 7
  - Shortest Duration to Date: 4 days
  - Longest Duration to Date: 12 days

Future Status Tracking:
- Average # Days for IIS to Sign DUA
- Average # of Days for APHL
  to Sign DUA
- Average # Days to Fully
  Signed DUA
- # of Production Connections
  In Progress
- # of Production
  Connections Complete
- Average # Days
  to Establish Production Connection

Lessons Learned

- Send onboarding packet at the same time as requesting the kick-off call to share all information up front.

- Connection issues may be due to IIS URL side, IZ Gateway, or HL7 message content. Troubleshooting the connection requires expertise and real-time collaboration.

- Monitoring and evaluation steps and expectations are important once in production.

- The DUA was sent out on August 8 and takes time to sign. This will likely delay request for production credentials and final onboarding step timeline for Wave 1.

- Test messages are mostly erroring due to missing or incorrect information that is IIS specific (as expected). This information will be used to continue to shape the IZ HL7 Implementation Guide to provide guidance and support successful data exchange.

IZ Gateway | Future State

- By September 30, 2020:
  - 45 IIS will be onboarded to IZ Gateway Connect
  - 16 IIS will be onboarded to IZ Gateway Share
  - At least one consumer facing portal to more than one jurisdiction to the IZ Gateway to access consolidated records.
  - Provider-initiated multi-jurisdictional query functionality enabling providers to query multiple IIS and return a consolidated record will be available.

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Acronym List

- AIRA – American Immunization Registry Association

- ASTHO – Association of State and Territorial Health Officials

- APHL – Association of Public Health Laboratories

- BAA – Business Associate Agreement

- CDC – Centers for Disease Control and Prevention

- DUA – Data Use Agreement

- HIPAA: Health Insurance Portability and Accountability Act

- HL7 – Health Level Seven International

- IIS – Immunization Information System

- MOU – Memorandum of Understanding

- WSDL – Web Services Description Language

IZ Gateway Portfolio Component	IZ Gateway System Security Considerations
Connect	- The technical standard for data messaging is CDC WSDL and HL7 version 2.5.1 release 1.5. - While messages transfer across the central hub, the data are not held or stored in the IZ Gateway. The Gateway routes data from the sender to the receiver and does not read data. - Refer to the Business Associate Agreement between the provider organization and APHL for more details on system security
Share	- The technical standard for data messaging is the modified CDC WSDL and HL7 version 2.5.1 release 1.5. - While messages transfer across the central hub, the data are not held or stored in the IZ Gateway. The Gateway routes data from the sender to the receiver and does not read data. - When the Public Health Interjurisdictional Memorandum of Understanding (MOU) to exchange data with other jurisdictions is signed, the agreement is that data the IIS sends will be incorporated and then governed by the receiving state's laws and policies. - Refer to the Data Use Agreement between the jurisdiction and APHL for a more details on system security.
Access	- The technical standard for data messaging is CDC WSDL and HL7 version 2.5.1 release 1.5. - While messages transfer across the central hub, the data are not held or stored in the IZ Gateway. The Gateway routes data from the sender to the receiver and does not read data. - Refer to the Data Use Agreement between the jurisdiction and APHL for a more details on system security.
Provider-initiated Multi-jurisdictional Data Exchange	- The technical standard for data messaging is CDC WSDL and HL7 version 2.5.1 release 1.5. - While messages transfer across the central hub, the data are not held or stored in the IZ Gateway. The Gateway routes data from the sender to the receiver and does not read data. - When the Public Health Interjurisdictional Memorandum of Understanding (MOU) to exchange data with other jurisdictions is signed, the agreement is that data the IIS sends will be incorporated and then governed by the receiving state's laws and policies. - Refer to the Data Use Agreement between the jurisdiction and APHL for a more details on system security.

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IZ Gateway project team

Project Sponsor: Centers for Disease Control and Prevention

- Audacious Inquiry, LLC

- JBS International

- ESAC Inc.

- Association of Public Health Laboratories

- American Immunization Registry Association

- Network for Public Health Law

- HLN Consulting, LLC

- Kahuina Consulting

- Office of the Chief Technology Officer

IZ Gateway Connect: Priority #1

Purpose: Enables **large national and non-traditional vaccinators** to report and query immunization data with multiple IISs using the centralized data exchange, avoiding multiple, individual, point-to-point connections

Benefits: Onboarding concierge services to help provider organizations navigate local policy and technology variations per IIS jurisdiction through centralized onboarding services including quality assurance and testing

Participation is essential for receiving data from national providers and mass vaccination applications.

Initial Participation Steps:

1. IIS provide IZ Gateway Credentials for test/prod
2. Test connectivity through AIRA test tools
3. IIS will be contacted when providers and mass vaccine reporting apps are identified and ready to be onboarded to each IIS

Policy Requirements: | BAA | JSPA | DUA

IZ Gateway Share: Priority #2

Purpose: Allows exchange of immunization information **across IIS jurisdictions** by automating messages to an IIS for patients immunized outside of their jurisdiction

Benefits: Gain a more complete and accurate assessment of vaccine coverage per jurisdiction through data sharing of appropriate vaccination records

Participation is important for receiving vaccine coverage information for those that are vaccinated across jurisdictional borders.

Initial Participation Steps:

1. Start reviewing/signing participation agreements
2. Work with vendor to upgrade (if necessary) to be prepared for project participation
3. Move all STC and Envision IIS to the upgraded product for Share
4. DXC work on the module to simplify implementation with each State
5. Prioritized second as participation requires significantly more effort on IIS and vendors to upgrade, test, and onboard

Policy Requirements:

MOU	DUA

IZ Gateway Access

Purpose: Enables consumer access to online immunization records and forecasts through easy-to-use digital tools

Benefits: Consumers can monitor and ensure vaccinations are up to date through convenient, secure online tools offering official state immunization records. Decreases record request burden on IIS programs and providers

Initial Participation Steps:

1. Review and select consumer access options
2. Participate in planning meetings with team and vendors
3. Sign DUA with APHL
4. Depending on product, complete testing and QA
5. Onboard product through IZ Gateway
6. Participate in and inform marketing and evaluation efforts

Policy Requirements: DUA

IZ Gateway Provider-initiated Multi-jurisdictional Data Exchange

Purpose: Allows providers to initiate a query for vaccine information from multiple jurisdictions and receive a consolidated record

Benefits: Enables provider organizations to query multiple IISs that have signed the Interjurisdictional MOU for IZ Gateway Share and provides a consolidated vaccine record from multiple states, where needed

Initial Participation Steps:

1. Ensure Provider Organization signs all Jurisdiction-specific Policy Agreements
2. Sign Interjurisdictional MOU
3. Sign DUA with APHL
4. Respond to provider/IZ Gateway query

Policy Requirements:

MOU	DUA	JSPA

IZ Gateway Technology Requirements by Component

IZ Gateway Portfolio Component	Technology Requirements
Connect	❑ Provide Immunization Gateway credentials ❑ CDC WSDL and HL7 2.5.1 Release 1.5
Share	❑ Provide Immunization Gateway credentials ❑ Capability to recognize out of state address in incoming HL7 message and in data at rest ❑ Trigger creation of a new historical VXU to send to another IIS based on out of state address ❑ Capability to install client-side certificate ❑ Modified CDC WSDL and HL7 2.5.1 Release 1.5
Access	❑ Provide Immunization Gateway credentials (depending on consumer access product) ❑ CDC WSDL and HL7 2.5.1 Release 1.5
Provider-initiated Multi-jurisdictional Data Exchange	❑ Provide Immunization Gateway credentials ❑ CDC WSDL and HL7 2.5.1 Release 1.5

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Current IIS Connected to the IZ Gateway

IIS	Project	Status
Delaware	Share	Production
Louisiana	Share, Access	Production
Maryland	Share, Access	Production
Mississippi	Share	Production
Philadelphia	Share	Production
West Virginia	Share, Access	Production
Arkansas	Share	Testing/Review
Kansas	Share	Testing/Review
Missouri	Share	Testing/Review
Oregon	Share	Testing/Review
Minnesota	Connect	Production
North Dakota	Connect	Production
Utah	Access	Consumer app pilot