

Supporting IZ Gateway HL7 Message Exchange in Accordance with the HL7 2.5.1 Implementation Guide and Addendum

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Contents

Funding acknowledgment3
Background and Context
Scope of Guidance
In scope
Out of scope 4
Limitations
National Immunization Data Exchange Additional Resources5
VXU Message Creation Requirements
VXU Message Known Jurisdiction Requirements7
MSH-11 Processing ID:7
PID-3 Patient Identifier List:7
PID-10 Race:
PID-11 Patient Address:
PID-22 Ethnic Group:
PD1-12 Protection Indicator:
PD1-13 Protection Indicator Effective Date:
Provider-IIS QBP (Z34 and Z44) Message Requirements: Differences from National IG
QBP Message Creation Requirements9
QBP Message Known Jurisdiction Requirements 10
QPD-3 Patient List:
IIS Message Processing
ACK messages
Vaccination Event Updates
Vaccination Event Deletion 11
IIS Identification Value Sets
Example Messages
VXU Message – Send Immunization History 12
QBP Message – Request Complete Immunization History (Z34)

Funding acknowledgment

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This document was created through a partnership with the American Immunization Registry Association (AIRA) and the Centers for Disease Control and Prevention (CDC)

Background and Context

The Immunization (IZ) Gateway is a centralized technical infrastructure that facilitates the flow of immunization data through an intelligent message router; the project is sponsored and led by the Centers for Disease Control and Prevention (CDC). The IZ Gateway is securely hosted on Amazon Web Services (AWS) through the Association of Public Health Laboratories (APHL) and does not save information; instead, it routes it securely among provider organizations' health information systems and Immunization Information Systems (IIS).

Utilizing the IZ Gateway to route vaccination information from one sending system to multiple IIS presents unique opportunities for data sharing as well as data exchange challenges. IIS are expected to align with the <u>HL7 Version 2.5.1 Implementation Guide for Immunization Messaging Release 1.5 and Addendum (National IG)</u>; however, it is important to document unique requirements specific to provider-IIS exchange through the IZ Gateway, as well as IIS jurisdiction-specific requirements for application identifiers and other key fields. In addition, some jurisdictions may have requirements that vary slightly for HL7 field content and mapping, while still meeting National IG standards requirements. CDC and AIRA partnered to develop this *Provider-IIS Companion Guide* to provide additional segment and field comments, constraints, and guidance to ensure consistent and successful message processing between providers and IIS through the IZ Gateway. This guide was developed with information from AIRA testing through the <u>Aggregate Analysis Reporting Tool</u> (AART), conversations with IIS teams, and IZ Gateway testing with jurisdictions. Additional partners such as AIRA's Standards and Interoperability Steering Committee (SISC) and IIS representatives provided valuable review and input to support the completion of this guide.

Together, the National IG and this *Provider-IIS Companion Guide* aim to support development and decision making for provider-IIS data exchange through the IZ Gateway. While every effort has been made to incorporate potential field requirement variations, the current specifications are not inclusive of every local variation across systems. IIS-specific requirements may need to be discussed and accommodated by the sending system at the time of exchange for messages to process successfully. The IZ Gateway Team will support the evaluation and communication of IIS-specific requirements as needed. Jurisdiction-specific testing between provider and IIS will still be needed and may necessitate further modifications.

This *Provider-IIS Companion Guide* is a living document and will be updated as needed as data exchange through the IZ Gateway expands and outcomes are evaluated. The core requirements and structure of the HL7 fields will not change; however, certain content expectations may be updated to support IZ Gateway exchange as needed. For guidance on items not in scope but related to HL7 message content, please refer to the National IG for guidance.

Scope of Guidance

In scope

- Unsolicited Vaccination Record Update (VXU) for administered and historical vaccinations and Query by Parameter (QBP) HL7 v2.5.1 content guidance for messages routed through the IZ Gateway for provider-IIS exchange.
- Guidance on potential content variations and solutions for specific HL7 message fields.
- Guidance for efficiently aligning HL7 message content with known business rules across IIS.
- VXU and QBP examples.

Out of scope

- IZG technical specifications/connectivity requirements and guidance.
- IZG HL7 message onboarding, testing, and evaluation steps and requirements prior to moving into production exchange.
- Detailed guidance on submitting non-administration events (e.g., serologic evidence of immunity, adverse events, refusals, and contraindications). For providers who decide to exchange non-administration events, please follow the National IG for non-administration events.
- Detailed guidance on processing patient-level data (e.g., patient address, next of kin). Discussions between provider and IIS may be needed to resolve issues discovered during testing.
- <u>Acknowledgment (ACK)</u> and <u>Response (RSP)</u> message guidance.
- Transport layer routing codes (e.g., destinationID). See the <u>Technical Specifications for IIS to</u> <u>Exchange Data via IZ Gateway</u> for more details.
- Guidance related to routing to the appropriate IIS within a single jurisdiction (e.g., New York state versus New York City).
- IIS-IIS data exchange through IZ Gateway (for more information see the *IIS-IIS Companion Guide*).

Limitations

- The returned acknowledgment messages (ACKs) that are triggered in response to submission messages (VXUs) provided much of the information about how a jurisdiction handles HL7 messages. ACKs that are off standard might not yield correct information.
- In addition to gathering information through testing by CDC's IZ Gateway team and conversations with jurisdictions, AIRA is leveraging testing through established connections between AIRA's Measurement and Improvement/AART tool and jurisdictional pre-production systems. Participation in AIRA's Measurement and Improvement (M&I) initiative is a required IPOM activity (D2a), but not all jurisdictions are connected yet. The information in this guide is based on results of these preproduction systems. Results may vary when testing with a jurisdiction's production system.
- This guidance should be considered a point-in-time analysis because of limited visibility into each IIS's profile configuration or planned enhancements to better accommodate incoming data.
- As with any testing process, it's difficult to anticipate every potential scenario to test; there may be missing, illogical, or conflicting data scenarios that have not been tested.

National Immunization Data Exchange Additional Resources

- IIS Technical Guidance: HL7 Implementation
 - CDC web page listing key resources for HL7 immunization messaging, including:
 - <u>HL7 Version 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5, 2018</u> <u>Update</u>
 - CDC and AIRA Standards and Interoperability Committee (SISC) guidance on HL7 immunization messages
 - National Institute of Standards and Technology (NIST) tools, including the <u>Immunization</u> <u>Test Suite</u>
- Immunization Data Code Sets

This CDC webpage with current immunization-related code sets from the CDC includes CVX codes, MVX codes, NDC crosswalk tables, and more. Subscribe to receive notices when codes are updated.

Provider-IIS VXU Message Requirements: Differences from National IG

VXU message requirements for provider-IIS exchange through the IZ Gateway are found in Table 1. These requirements are in addition to the National IG, and it's expected that all providers are able to generate a VXU message meeting these requirements. Following the table are further known local requirements IIS may have to receive a VXU message. IIS will need to discuss local requirements during onboarding to determine the best path forward where gaps exist.

VXU Message Creation Requirements

Table 1: VXU Message Creation Requirements¹

Segment	Seq	Element Name	National Usage	IZG Usage	IZG Constraints
MSH	3	Sending Application	RE	R	Value assigned by the IIS.
MSH	4	Sending Facility	RE	R	Value assigned by the IIS.
MSH	5	Receiving Application	RE	R	This is constrained to be an IZ Gateway assigned identifier of the IIS that will be receiving the transmission.
MSH	6	Receiving Facility	RE	R	This is constrained to be an IZ Gateway assigned identifier of the IIS that will be receiving the transmission.
MSH	22	Sending Responsible Organization	RE	RE	Value assigned by the IIS.
PID	3	Patient Identifier List	R	R	PID-3.1: Length- [136]. The max length of PID-3.1 (ID Number) is changed from 15 to 36 for provider-IIS data exchange through the IZ Gateway. IZ Gateway is aware of provider systems that have ID Number (e.g., MRN) with a length greater than 15 characters.
RXA	9	Administration Notes	C(R/O)	C(R/O)	Federal agencies not able to populate required fields for new vaccine administrations shall use '08^ Historical information - from public agency^NIP001' for new vaccine administrations.

¹ For more information on usage of HL7 elements refer to Table 3-2, Sending Application Conformance, in the <u>National IG</u>

VXU Message Known Jurisdiction Requirements

MSH-11 Processing ID:

This field is used to decide whether to process the message as defined in HL7 Application Processing rules. **The value "P" shall always be used for production** data exchange through the IZ Gateway.

Table 2 (below) identifies MSH-11 value constraints for each IIS in **their pre-production instance**. These are provided for onboarding purposes only. **IIS not listed in Table 2 accept all three values (Production (P), Training (T), and Debugging (D)) during onboarding.** Each IIS's rules for processing the value P, T, or D may vary in pre-production systems.

Jurisdictions Requiring "P"	Jurisdictions Accepting "P" or "T"	
CA CAIR2	АК	
HI	AZ	
ME	CA RIDE	
MN	GA	
NC	IA	
NE	ID	
NY NYSIIS	IN	
VA	LA	
	MS	
	MT	
	ND	
	NJ	
	ОН	
	OR	
	PA PHILAVAX	
	PR	
	TN	
	WA	
	WV	
	WY	

Table 2: MSH-11 pre-production value constraints

PID-3 Patient Identifier List:

• The following IIS may reject the message if the length of the ID Number exceeds the character limit of 15 as specified in the National IG (PID-3.1 is greater than 15): AL, WI.

PID-10 Race:

• The following IIS may reject the message if race is missing: LA.

PID-11 Patient Address:

• The following IIS will reject messages without address (including all components Street, City, State, and ZIP):

AK, AL, AZ, DC, FL, IA, IN, LA, NJ, OH, PR, TN, TX, WA, WV.

PID-22 Ethnic Group:

• The following IIS may reject the message if ethnic group is missing: LA.

PD1-12 Protection Indicator:

- The following IIS may reject the message if patient consent is missing: NJ, NY NYSIIS, TX.
- Provider-IIS planning should occur before the start of testing and onboarding to fully understand jurisdictional requirements and understand the potential for a high volume of rejections when PD1-12 is missing.

PD1-13 Protection Indicator Effective Date:

 The following IIS may reject the message if Protection Indicator (PD1-12) has a value and Protection Indicator Effective Date (PD1-13) is missing: NJ, NY NYSIIS, TX.

Table 3 summarizes the known variations in handling of Protection Indicator by the jurisdictions.

Jurisdiction	Protection Indicator Behavior
АК	State regulation requires all vaccines be sent to VacTrAK. It is important to note that all Alaskans are included in VacTrAK and state regulation 7AAC 27.650 requires all administered vaccines be added to VacTrAK. Therefore, patients cannot choose to opt out of VacTrAK or choose to otherwise prevent their data from being sent to VacTrAK.
CA CAIR2 and CA RIDE	An empty value will be interpreted by the IIS as "N" (No Protection), in accordance with California Health and Safety Code Section 120440.
HI	Controls visibility of records to other organizations. Default value is blank. "N" indicates that the patient's data will be stored in HIR. If a value of "Y" is sent, the record will be rejected.
ID	ID IRIS does not allow for Protection Indicator to be set via data exchange. Patients must have Protection Indicator of "N" indicating "No Protection" to be entered or updated in IRIS.
MT	Montana's law is about "consent to share," not "consent to store." The IIS will accept the VXU even if the sender does not provide the PD1-12. The state can use that record for public health purposes, but that record cannot be shared. This means when a subsequent query is made to the Montana IIS, that record will not be returned. The only way to retrieve the record is to set the PD1-12 value during the VXU process indicating consent to share. If a value of "Y" is sent in PD1-12, the record will be stored, but not returned in a subsequent query.
NJ	For patients born before 1998, this field must have a value to be reported. Additionally, the Protection Indicator Effective Date (PD1-13) must have a date.
NY NYSIIS	For patients aged 19 and above this field must be "N" to be reported. Additionally, the Protection Indicator Effective Date (PD1-13) must have a date.
ТХ	Texas's law pertains to "registry consent," not "consent to share or store." The IIS will accept the VXU even if the sender does not provide the PD1-12 and the state

Table 3: PD1-12 Protection Indicator Variations

Jurisdiction	Protection Indicator Behavior				
	will determine if the patient is an existing and consented IIS client or not, and				
	store data accordingly. If a patient signs the specific Texas Registry Consent				
	Forms, their patient consent can be reported electronically through the				
	affirmation process. Refer to the <u>Texas Immunization Registry: Consent Overview</u>				
	for an understanding of Texas Registry Consent. Refer to Affirmation of Registry				
	Consent via HL7 for an understanding of the specific HL7 requirements and forms				
	needed to report registry consent via HL7.				
	The IIS uses the local value set below for PD1-12:				
	 TXA – Consented Adult, >= 18 years old 				
	 TXY – Consented ImmTrac Child, < 18 years old 				
	 TXD – Disaster Consent 				
	Additionally, the Protection Indicator Effective Date (PD1-13) must have a date if				
	Protection Indicator (PD1-12) has a value.				

Provider-IIS QBP (Z34 and Z44) Message Requirements: Differences from National IG

QBP message requirements for provider-IIS exchange are found in Table 4. These requirements are in addition to the National IG, and it's expected that all providers are able to generate a QBP message meeting these requirements. Following the table are further known jurisdiction-specific requirements IIS may have in place in order to accept a QBP message and provide an RSP response. IIS will need to discuss jurisdiction-specific requirements during onboarding to determine the best path forward where gaps exist.

QBP Message Creation Requirements

All the MSH fields listed in Table 4 (e.g., MSH-3, 4, 5, 6, and 22) have the same requirements for VXUs and QBPs.

Segment	Seq	Element Name	National Usage	IZG Usage	IZG Constraints
MSH	3	Sending Application	RE	R	Value assigned by the IIS.
MSH	4	Sending Facility	RE	R	Value assigned by the IIS.
MSH	5	Receiving Application	RE	R	This is constrained to be an IZ Gateway assigned identifier of the IIS that will be receiving the transmission.
MSH	6	Receiving Facility	RE	R	This is constrained to be an IZ Gateway assigned identifier of the IIS that will be receiving the transmission.

Table 4: QBP Message Creation Requirements

Segment	Seq	Element Name	National Usage	IZG Usage	IZG Constraints
MSH	22	Sending Responsible Organization	RE	RE	Value assigned by the IIS.
QPD	3	PatientList	RE	RE	QPD-3.5: Recommend sending only the medical record number, documented as identifier type "MR." QPD-3.1: Length: [136]. The max length of ID Number is changed from 15 to 36 for provider-IIS data exchange through the IZ Gateway. IZ Gateway is aware of provider systems that have ID Number (e.g., MRN) with a length greater than 15 characters.
QPD	7	Patient Sex	RE	RE	Use the value "U" (for Unknown) if patient sex is not known.

QBP Message Known Jurisdiction Requirements

QPD-3 Patient List:

- The following IIS will reject any query that does not contain an MRN: FL, MA.
- The following IIS will reject any query that have Patient Identifier ID (QPD-3.1) with a length greater than 15 characters:

AL, WI.

• ID will reject any query if Assigning Authority (QPD-3.4) is not set to "IDA".

IIS Message Processing

ACK messages

To the extent possible, IIS jurisdictions should ensure their acknowledgment messages are fully compliant with National IG standards and meaningful, with appropriate usage of ERR-4 values of I, W, and E. Jurisdictions should be prepared to discuss acknowledgment messages with the multi-jurisdictional Vaccine Provider they are exchanging data with to communicate and plan for any issues/variances. Additional ACK guidance can be found in AIRA's <u>Guidance for HL7 Acknowledgement</u> <u>Messages to Support Interoperability</u>.

Vaccination Event Updates

In general, providers should send updates. However, further discussion during onboarding with IIS is recommended.

Table 5 lists the IIS that either do not support the processing of Update messages (RXA-21 = U) or support processing that is not in alignment with <u>Modeling of Immunization Registry Operations</u> <u>Workgroup</u> (MIROW) consolidation rules for consolidating vaccination records. IIS not listed in Table 5 process Update messages as expected.

AIRA executed one test case per IIS to exercise IIS vaccination event updates. First, a test message with a "HepB unspecified formulation" vaccination event was added to the IIS. Following the addition, AIRA submitted an Update message to change the record to a specific formulation of HepB. Finally, AIRA queried for the record and analyzed the record for consolidation per the MIROW guide. This test case can provide preliminary insights but does not address all the complexities of IIS vaccine record consolidation rule sets.

Table 5: Vaccination Event Update Processing Variation

IIS	Processes Updates
CA CAIR2	Yes, but not per MIROW rules
GA	Yes, but not per MIROW rules
HI	Yes, but not per MIROW rules
ID	Yes, but not per MIROW rules
MD	Yes, but not per MIROW rules
MN	Yes, but not per MIROW rules
NC	Yes, but not per MIROW rules
ND	Yes, but not per MIROW rules
NJ	Yes, but not per MIROW rules
NY CIR	No, created duplicate
RI	No, created duplicate
SD	Yes, but not per MIROW rules
ТХ	Yes, but not per MIROW rules
USVI	No, created duplicate
WI	Yes, but not per MIROW rules
WY	Not able to determine

Vaccination Event Deletion

In general, providers should send deletes. However, further discussion during onboarding with IIS is recommended.

Table 6 lists the IIS that do not support the processing of Delete messages via data exchange (RXA-21 = D). IIS not listed in Table 6 process the Delete message as expected.

AIRA executed one test to exercise IIS delete functionality. First, a test message with two vaccination events was submitted to the IIS. Second, a Query message was submitted to verify the two vaccination events were present. Third, a Delete message was submitted to delete one of the vaccination events. Finally, a second Query message was submitted to confirm the deleted vaccination event was removed from the patient record. This was one test case executed from the same organization that submitted the initial addition. IIS vaccination event deletion is a complex set of rules and not all of them could be

tested through this single test. In some cases, deletion of the vaccination event could not be confirmed; in these cases, the outcome was listed as "Not able to determine."

IIS	Processes Deletes
ID	No
IN	No
MS	No
PA	Not able to determine
RI	No
SD	Not able to determine
WV	No
WY	Not able to determine

Table 6: Vaccination Event Delete Processing Variations

IIS Identification Value Sets

The <u>IIS Identification Value Sets</u> tables are used for Provider-IIS exchanges through the IZ Gateway. Table 1, titled *IZ Gateway IIS Facility identifiers*, provides values used to populate MSH-6, while Table 2, titled *IZ Gateway application identifiers*, includes values used to populate MSH-5. Both tables are regularly updated when changes are made to identification values.

Example Messages

VXU Message – Send Immunization History

In the example that follows, the facility that administered the vaccine and is responsible for the content of the vaccine update message is the TestClinic, IIS-Assigned Identifier 1123. This is a clinic of the parent organization, TestHospital, IIS-Assigned Identifier 2234, and all patient identifiers are issued by this parent organization.

The patient is LaurenIZG ClaudiaIZG, a white, non-Hispanic female born 06/24/2021, whose permanent address is 15 Schenectady Road, Albany, NY 12084. Her mother's maiden name is MariaIZG NicholsIZG. Her Medical Record Number in the TestHospital is 223456.

She was vaccinated on 07/06/2022 for MMRV in the left thigh.

Table 7 describes the construction of the IIS-assigned identifier and supporting data for this example:

Table 7: VXU Construction

Message Location	HL7 Element Name	Example	Comments
MSH-4	Sending Facility	2234	Parent organization.
MSH-22	Sending Responsible Organization	1123	Clinic responsible for the vaccination and message content.

Message Location	HL7 Element Name	Example	Comments
PID-3	Patient Identifier List	223456^^^1000^MR	 PID 3.1 is the Patient Identifier. PID 3.4 is the assigning authority that issued the Medical Record Number. PID 3.5 indicates that the Identifier Type for the assigning authority is a Medical Record Number.
ORC-10	Entered By	^GrecoIZG^AlanaIZG^^^^ ^^ ^^^^RN	ORC-10.2 is the family name. ORC-10.3 is the given name. ORC-10.21 indicates the professional suffix of the individual who entered the data if applicable.
ORC-17	Entering Organization	1123^TestClinic^HL7036 2	ORC-17.1 is the IIS-Assigned Identifier of the facility that entered the vaccination data. ORC-17.2 is the name of the organization represented by the identifier.
RXA-10	Administering Provider	^GrecoIZG^AlanaIZG^^^^ ^^ ^^^^RN	RXA-10.2 is the family name. RXA-10.3 is the given name. RXA-10.21 indicates the professional suffix of the individual who administered the vaccine.
RXA-11	Administered at Location	^^^1123	RXA-11.4 is the IIS-assigned identifier for the clinic where the vaccination was administered.

Using these structures, the resulting VXU is:

MSH|^~\&|TestHospital|2234|NYCDOHMH|NYCDOHMH|20220706082240-0500||VXU^V04^VXU_V04|NIST-IZ-001.00|P|2.5.1|||ER|AL|||||Z22^CDCPHINVS|1123|

PID|1||223456^^^1000^MR||ClaudialZG^LaurenIZG^^^^L|NicholsIZG^MarialZG^^^^M|20210624|F||2106-3^White^CDCREC|15 Schenectady Road^^Albany^NY^12084^USA^P||^PRN^PH^^^989^6945384||||||||2186-5^not Hispanic or Latino^CDCREC

PD1|||||||||01^No reminder/recall^HL70215|N|20210909||||20210909

NK1|1|ClaudialZG^MarialZG^Marion^^^L|MTH^Mother^HL70063|15 Schenectady

Road^^Albany^NY^12084^USA^M|^PRN^PH^^^989^6945384

RXA|0|1|20220706||94^MMRV^CVX^00006-4171-00^ProQuad^NDC|0.5|mL^^UCUM||00^New immunization Record^NIP001|^GrecoIZG^AlanaIZG^^^^^^^^AA^^^^ARN|^^^1123|||233LB543|20221231|MSD^Merck and Co. Inc.^MVX|||CP|A

RXR|C38299^Subcutaneous^NCIT|LT^Left Thigh^HL70163

OBX11CE164994-7^{vaccine} fund pgm elig cat^LN11V01^vNot VFC elig ^{HL}700641111F1120220706

OBX|2|CE|30963-3^Vaccine funding source^LN|1|PHC70^Private funds^CDCPHINVS||||||F|||20220706

OBX|3|CE|69764-9^Document Type^LN|2|253088698300013411210806^MMRV VIS^cdcgs1vis|||||F

OBX |4 |TS | 29769-7^Date vaccine information statement presented^LN |2 | 20220706 || || || F

QBP Message – Request Complete Immunization History (Z34)

The following is an example query sent from TestClinic, IIS-Assigned Identifier 1123. This is a clinic of the parent organization, TestHospital, IIS-Assigned Identifier 2234.

The query is sent to NY CIR and it is requesting an immunization history for a person named LaurenIZG ClaudiaIZG, born on 06/24/2021, whose address is 15 Schenectady Road, Albany, NY 12084.

MSH|^~\&|TestHospital|2234|NYCDOHMH|NYCDOHMH|20220902091512.000-0100||QBP^Q11^QBP_Q11|3AZQ231|P|2.5.1|||ER|AL|||||Z34^CDCPHINVS|1123| QPD|Z34^Request Immunization History^CDCPHINVS|37374859|223456^^1000^MR|ClaudialZG^LaurenIZG^^^^L|NicholsIZG^MarialZG^^^^M| 20210624|F|15 Schenectady Road^^Albany^NY^12084^USA^M||| RCP|I|5^RD&records&HL70126