

COVID-19 Vaccine Data Reporting Requirements

Overview

This document provides an overview of vaccine reporting requirements for jurisdictions, federal agencies, and pharmacies, which should be reporting the following types of COVID-19 vaccination data to CDC:

- Provider enrollment
- Ordering/shipment
- Vaccine inventory
- Vaccine administration

Options for reporting vaccine administration data will evolve over the course of the response as systems mature and expand (see Figure 1).

Figure 1: Evolution of COVID-19 Vaccine Administration Data Reporting

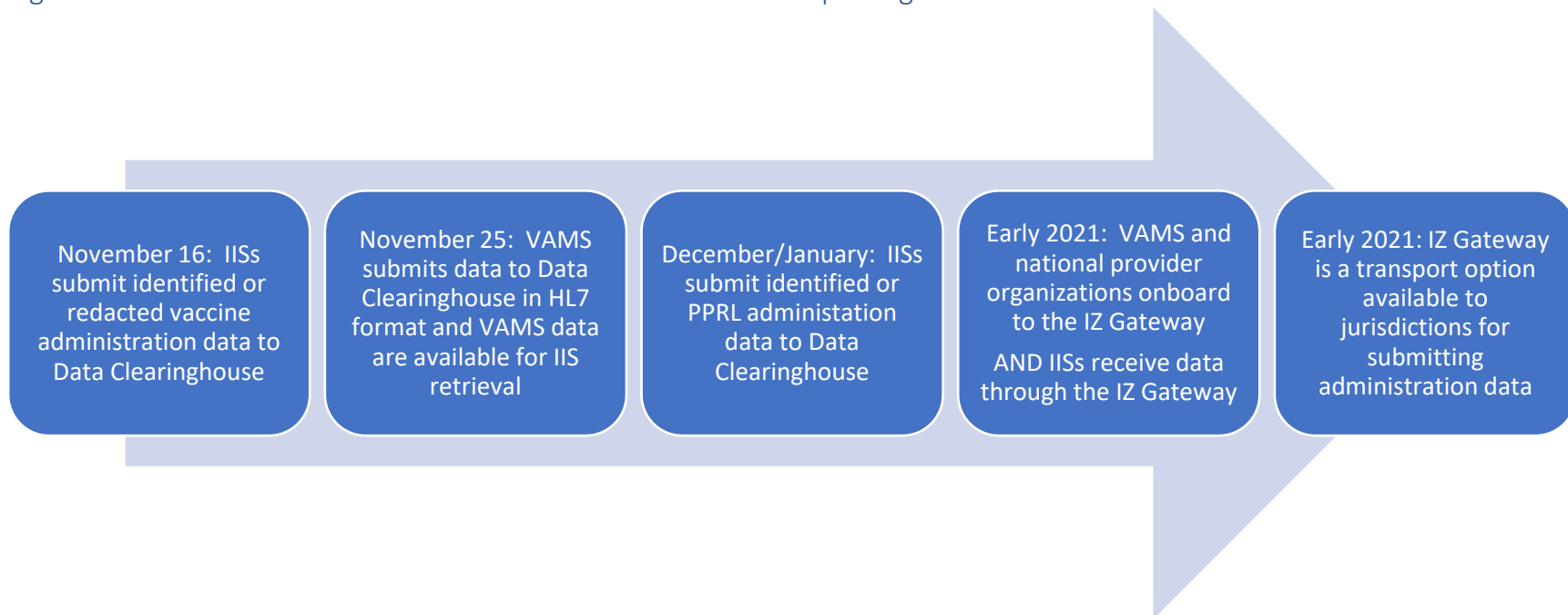


Table 1 provides an overview of reporting options that will be available in November 2020. Additional options may become available as the response and systems evolve.

Table 1: Overview of Reporting COVID-19 Vaccine Information to CDC

Data Type	Jurisdictions /Immunization Information Systems (IISs)	Federal Agencies					Pharmacies
		Indian Health Service (IHS)	Veterans' Health Affairs (VHA) ¹	Department of Defense (DOD)	Department of State (DOS)	Bureau of Prisons (BOP)	
Provider Enrollment/ Pharmacy Agreement <u>IZ Data Lake Partner Portal is live</u>	Submit CSV files using CDC file specification directly to the Data Lake at least twice per week (Monday & Thursday) via the IZ Data Lake Partner Portal	N/A	N/A	N/A	N/A	N/A	Pharmacies complete data file based on Pharmacy Agreement Template specifications and send to CDC POC for upload into the IZ Data Lake
Master Provider Data (for VTrckS) <u>VTrckS is live</u>	Submit ExIS Master Data File to VTrckS with COVID-19 provider designation	Submits CSV Provider Master Data File consistent with ExIS Specifications to CDC POC CDC POC shares with VTrckS ExIS team to build VTrckS profiles	Submits CSV Provider Master Data File consistent with ExIS Specifications to CDC POC CDC POC shares with VTrckS ExIS team to build VTrckS profiles	Submits CSV Provider Master Data File consistent with ExIS Specifications to CDC POC CDC POC shares with VTrckS ExIS team to build VTrckS profiles	Submits CSV Provider Master Data File consistent with ExIS Specifications to CDC POC CDC POC shares with VTrckS ExIS team to build VTrckS profiles	Submits CSV Provider Master Data File consistent with ExIS Specifications to CDC POC (initial submission for chain partners due 11/6; for non-chain partners 11/20) CDC POC shares with VTrckS ExIS	

¹ DHS employees will be vaccinated through VHA or community sites.

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		Indian Health Service (IHS)	Veterans' Health Affairs (VHA) ¹	Department of Defense (DOD)	Department of State (DOS)	Bureau of Prisons (BOP)	
		Provider enrollment data uploaded to VTrckS Partner Ordering Portal	Provider enrollment data uploaded to VTrckS Partner Ordering Portal	Provider enrollment data uploaded to VTrckS Partner Ordering Portal	Provider enrollment data uploaded to VTrckS Partner Ordering Portal	Provider enrollment data uploaded to VTrckS Partner Ordering Portal	team to build VTrckS profiles Provider enrollment data uploaded to VTrckS Partner Ordering Portal
Ordering/shipment Tracking VTrckS is live for jurisdictions/IISs <u>Key Dates:</u> <u>VTrckS Partner Ordering Portal</u> Testing Available: TBD Production Available: 11/20	IIS uploads provider and order information via ExIS or enters directly into VTrckS IIS downloads daily shipping file from VTrckS and populates provider inventory, including ground carrier tracking information	Providers submit orders into VTrckS Partner Ordering Portal Federal HQ POC reviews/approves and pulls consolidated CSV file out of Oracle in the ExIS format for submission to VTrckS HQ POC downloads daily shipping file and notifies sites of shipping information	Providers submit orders into VTrckS Partner Ordering Portal Federal HQ POC reviews/approves and pulls consolidated CSV file out of Oracle in the ExIS format for submission to VTrckS HQ POC downloads daily shipping file and notifies sites of shipping information	Providers submit orders into VTrckS Partner Ordering Portal Federal HQ POC reviews/approves and pulls consolidated CSV file out of Oracle in the ExIS format for submission to VTrckS HQ POC downloads daily shipping file and notifies sites of shipping information	Providers submit orders into VTrckS Partner Ordering Portal Federal HQ POC reviews/approves and pulls consolidated CSV file out of Oracle in the ExIS format for submission to VTrckS HQ POC downloads daily shipping file and notifies sites of shipping information	Providers submit orders into VTrckS Partner Ordering Portal Federal HQ POC reviews/approves and pulls consolidated CSV file out of Oracle in the ExIS format for submission to VTrckS HQ POC downloads daily shipping file and notifies sites of shipping information	Providers submit orders into VTrckS Partner Ordering Portal Pharmacy HQ POC reviews/approves and pulls consolidated CSV file out of the Ordering Portal in the ExIS format for submission to VTrckS

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		Indian Health Service (IHS)	Veterans' Health Affairs (VHA) ¹	Department of Defense (DOD)	Department of State (DOS)	Bureau of Prisons (BOP)	
Inventory <u>Key Dates:</u> Testing Available: TBD Production Available: 12/1	N/A Option 1: Providers report directly via VaccineFinder Option 2: IIS reports on behalf of all providers in the jurisdiction ²	TBD	TBD	TBD	TBD	TBD	Providers will report directly via VaccineFinder
Administration <u>Key Dates:</u> Testing Available: 11/6 Onboarding: 11/16 (CSV extracts) Production Available: 11/25 (CSV and HL7 for VAMS)	IIS extract file (CSV) using the CDC COVID-19 Vaccination Response Specification (CVRS) to the Data Clearinghouse via manual upload or RESTful API Alternative for later phases (Date: TBD): Option to submit CDC COVID-19 Response Vaccine Specification to the Data Clearinghouse	Option 1: Individual sites submit via connection to jurisdiction IIS Option 2: CSV extract file using the CDC COVID-19 Vaccination Response Specification to the Data Clearinghouse via manual upload or RESTful API	Option 1: Individual sites submit via connection to jurisdiction IIS Option 2: CSV extract file using the CDC COVID-19 Vaccination Response Specification to the Data Clearinghouse via manual upload or RESTful API	Option 1: Individual sites submit via connection to jurisdiction IIS Option 2: CSV extract file using the CDC COVID-19 Vaccination Response Specification to the Data Clearinghouse via manual upload or RESTful API	Option 1: CSV extract file using the CDC COVID-19 Vaccination Response Specification to the Data Clearinghouse via manual upload or RESTful API Option 2: HL7 Z22 or Z22.1 messages to the Data Clearinghouse via manual	Option 1: Individual site submit via connection to jurisdiction IIS Option 2: CSV extract file using the CDC COVID-19 Vaccination Response Specification to the Data Clearinghouse via manual upload or RESTful API	Option 1: Submit via connection to jurisdiction IIS/STC pharmacy network Option 2: CSV extract file using the CDC COVID-19 Vaccination Response Specification to the Data Clearinghouse via manual upload or RESTful API (CDC

² Jurisdictions that prefer this option must communicate it in advance to their IIS subject matter expert and must continue using this option for the duration of the response.

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	<p>using the IZ Gateway as the transport mechanism</p> <p>Note for Jurisdictions using VAMS: VAMS data will be submitted to the Data Clearinghouse directly and/or to the IIS</p>	<p>Option 3: HL7 Z22 or Z22.1 messages to the Data Clearinghouse via manual upload or RESTful API</p> <p>Alternative for later phases (Date: TBD): HL7 message from the central agency to the Clearinghouse via the IZ Gateway</p> <p>Note for agencies using VAMS: VAMS data will be submitted to the Data Clearinghouse directly and/or to the IIS</p>	<p>Option 3: HL7 Z22 or Z22.1 messages to the Data Clearinghouse via manual upload or RESTful API</p> <p>Alternative for later phases (Date: TBD): HL7 message from the central agency to the Clearinghouse via the IZ Gateway</p>	<p>Option 3: HL7 Z22 or Z22.1 messages to the Data Clearinghouse via manual upload or RESTful API</p> <p>Alternative for later phases (Date: TBD): HL7 message from the central agency to the Clearinghouse via the IZ Gateway</p>	<p>upload or RESTful API</p> <p>Note for agencies using VAMS: VAMS data will be submitted to the Data Clearinghouse directly and/or to the IIS</p>	<p>Option 3: HL7 Z22 or Z22.1 messages to the Data Clearinghouse via manual upload or RESTful API</p> <p>Alternative for later phases (Date: TBD): HL7 message from the central agency to the Clearinghouse via the IZ Gateway</p> <p>Note for agencies using VAMS: VAMS data will be submitted to the Data Clearinghouse directly and/or to the IIS</p>	<p>approval required)</p> <p>Option 3: HL7 Z22 or Z22.1 messages to the Data Clearinghouse via manual upload or RESTful API</p>

Technical assistance is available to all jurisdictions.

I need help with....	I am a....	Contact....
Data Use Agreement for Reporting COVID-19 Vaccine Data to CDC	Jurisdiction	IIInfo@cdc.gov
Provider Enrollment Data	Jurisdiction Pharmacy Federal Agency	IZDLhelpdesk@cdc.gov IZDLhelpdesk@cdc.gov Federal Agency Liaison
Master Provider Data	Jurisdiction, Pharmacy, or Federal Agency	VTrckSExIS@cdc.gov
Ordering/Shipment Data	Jurisdiction Pharmacy Federal Agency	vaccineordermgmt@cdc.gov TBD TBD
Inventory Data	Jurisdiction Pharmacy Federal Agency	VaccineFinder help desk (coming soon) Oracle help desk (coming soon)
Administration Data		
CVRS Data Extracts	Jurisdiction—NYC, RI, ND, MA, All STC, WIR, and Envision States	Audacious Inquiry and System Vendor, IZGateway@hhs.gov
	Jurisdiction—UT, AL, FL, IL, VT, NJ, Chicago, USVI, HI	AIRA, IZGateway@hhs.gov
	Jurisdiction—SD, MI, PA, San Diego	IZGateway@hhs.gov
	Federal Agency	Federal Agency Liaison
	Pharmacy	Pharmacy Liaison
IZ Gateway	Jurisdiction, Pharmacy, or Federal Agency	IZGateway@hhs.gov
VAMS	Jurisdiction, Pharmacy, or Federal Agency	VAMS Onboarding Liaison
VaccineFinder	Provider, Jurisdiction, Pharmacy, or Federal Agency	VaccineFinder help desk (coming soon)

Appendix 1: Supporting Jurisdictions in Enrolling Healthcare Providers for the COVID-19 Vaccination Program

As part of the COVID-19 vaccination planning process, jurisdictions are responsible for conducting outreach to providers to enroll them in the COVID-19 Vaccination Program. **Enrolling providers includes three main tasks:**

- Eligible providers signing the jurisdiction's Provider Agreement Memorandum of Understanding (MOU)
- The jurisdiction ensuring providers are enrolled in the immunization information system (IIS)
- The jurisdiction ensuring each provider is a registered COVID-19 vaccination provider in CDC's Vaccine Tracking System (VTrckS)

Guidance to support jurisdictions in enrolling COVID-19 vaccination providers and reporting provider enrollment information to CDC is provided below. This guidance does not apply to federal agencies or pharmacies. CDC will establish a separate process and agreement for federal agencies and pharmacies.

General Outreach Process Considerations

Jurisdictions will work with providers to enroll them in the COVID-19 Vaccination Program.

Starting now, jurisdictions should plan to:

- Develop an approach for recruiting eligible providers.
- Conduct outreach to eligible providers, including communicating the:
 - Vaccination program requirements (outlined below)
 - Jurisdiction's enrollment process.
- Establish a process to obtain completed provider agreements from providers.

Once provider agreements begin to be signed, the jurisdiction should:

- Per [CDC's COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations](#), report MOU enrollment data to CDC electronically every Monday and Thursday by 9 pm EST.
- Enroll providers in the [IIS](#).
- Enroll providers in [VTrckS](#).
- Ensure the COVID-19 vaccine label (Special Project Provider) in the ExIS interface is added to the provider's master record in VTrckS using one of these methods:
 - **ExIS Interface.** CDC is updating the ExIS Provider Master Data file to support the pandemic response using the existing field known as "Special Project Provider." In addition, CDC will be adding a specific value for COVID-19 to the Special Project Provider option. Information about the value will be published in the VTrckS ExIS Specification document and available for use by all ExIS awardees.
 - **VTrckS.** Update individual provider records directly in CRM or use the marketing mass attribute update or the upload tool to update multiple records.
- Ensure the provider's master record in VTrckS includes an email address for the main contact or provider facility to facilitate enrollment in VaccineFinder.

Once COVID-19 vaccine is being administered, the jurisdiction should:

- Monitor [VaccineFinder](#) daily for COVID-19 vaccine inventory reports from enrolled providers.
- Continue outreach to encourage more providers to complete and sign the MOU. As more COVID-19 vaccine supply becomes available, jurisdictions will need more providers to administer vaccine.

Requirements to Consider when Planning Eligible Provider Enrollment

When recruiting providers for enrollment, jurisdictions must ensure each provider can meet the MOU requirements to participate in the COVID-19 Vaccination Program:

- Administer COVID-19 vaccine in compliance with CDC and Advisory Committee on Immunization Practices ([ACIP](#)) recommendations.
- Report vaccine administration data to CDC within 24 hours (via the IIS or CDC's Vaccine Administration Management System [VAMS]).
- Report daily supply/inventory via VaccineFinder including the number of vaccine doses on hand
- Report the number of vaccine and diluent doses that are unused, spoiled, expired, or wasted.
- Avoid selling or seeking reimbursement for supplies provided to administer vaccine.
- Administer the vaccine, regardless of recipient's ability to pay the administration fee.
- Provide an Emergency Use Authorization (EUA) patient fact sheet or vaccine information statement to each vaccine recipient, caregiver, or legal representative.
- Provide vaccines safely by following [CDC's guidance for immunization services during the COVID-19 pandemic](#).
- Comply with vaccine management requirements:
 - Store and handle vaccine under proper conditions.
 - Monitor vaccine storage unit temperatures.
 - Comply with the jurisdiction immunization program's guidance for handling temperature excursions.
 - Monitor and comply with COVID-19 vaccine expiration dates.
 - Preserve COVID-19 vaccine management records for a minimum of three years.
- Comply with federal instructions and timelines for disposing of vaccine and diluent, including unused doses.
- Report vaccine administration errors (whether or not associated with an adverse event [AE]), serious AEs (irrespective of attribution to vaccination)³ multisystem inflammatory syndrome (MIS) in children or adults, and cases of COVID-19 that result in hospitalization or death following vaccination to the Vaccine Adverse Event Reporting System ([VAERS](#)). Any additional clinically significant AEs may also be reported to VAERS even if it is not certain whether vaccination caused the event. Report any additional select AEs and/or any revised safety reporting requirements per the Food and Drug Administration's (FDA) conditions of authorized use of vaccine(s) throughout the duration of the EUA if applicable. Check FDA's [EUA website](#) for letter(s) of authorization including any updates that may occur.
- Provide a vaccination record card to each vaccine recipient, caregiver, or legal representative.

³ Serious AEs are defined as: death, a life-threatening AE, inpatient hospitalization or prolongation of existing hospitalization, persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, a congenital anomaly/birth defect, or an important medical event that may not result in death, be life-threatening, or require hospitalization when, based upon appropriate medical judgment, it may jeopardize the patient and may require medical or surgical intervention to prevent one of the outcomes listed above. Serious AEs should be reported regardless of causality.

- Comply with applicable FDA requirements, including but not limited to requirements in any EUA that covers COVID-19 vaccine, and state and territorial vaccination laws.

Continue to check the CDC IIS Awardee SharePoint portal for updates or contact your project officer.

Appendix 2: COVID-19 Vaccination Reporting Specifications (CVRS)

This document provides steps jurisdictions, pharmacies, and federal agencies reporting vaccine administration data to CDC should take to prepare to generate and submit to CDC an extract file that complies with the COVID-19 Vaccination Reporting Specifications. In addition, this document includes answers to frequently asked questions.

Preparation Activity	Jurisdictions will.....	CDC will....
Validate message content complies with CVRS	<ul style="list-style-type: none"> • Generate CSV test extract file according to CVRS • Verify that your test extract does NOT contain PII • Zip file, if required • Submit to IZ Gateway Operations Team member by email 	<ul style="list-style-type: none"> • Use a validation tool to review and validate the file to ensure compliance with requirements • Iterate as needed with IIS if message content does not align with CVRS
Establish secure method for IIS to submit extracts and for IZ Clearinghouse to recognize sender	<ul style="list-style-type: none"> • IIS completes credentialing process with the IZ Clearinghouse 	<ul style="list-style-type: none"> • Ensure completion of credentialing with IIS/IZ Clearinghouse Team and note completion date in RedCap
Validate integration with IZ Clearinghouse test environment	<ul style="list-style-type: none"> • IIS submits test extract to test IZ Clearinghouse endpoint 	<ul style="list-style-type: none"> • Validate whether IZ Clearinghouse test environment received message • Review any records that were rejected • Iterate as needed until all records are accepted
Sign Data Use and Sharing Agreement for secure data exchange.	<ul style="list-style-type: none"> • Sign and execute the Data Use and Sharing Agreement to Support the U.S. Government’s COVID-19 Emergency Response – Jurisdiction Immunization and Vaccination Administration Data Agreement 	<ul style="list-style-type: none"> • Track execution of Data Agreement
Validate integration with IZ Clearinghouse production environment	<ul style="list-style-type: none"> • Submit test extract to production endpoint 	<ul style="list-style-type: none"> • Validate whether IZ Clearinghouse production environment received message • Review any records that were rejected • Iterate as needed until all records are accepted

Submit data to CDC for national COVID-19 vaccination tracking	<ul style="list-style-type: none"> • Submit daily COVID-19 data extracts to the IZ Clearinghouse 	<ul style="list-style-type: none"> • Provide ongoing maintenance and operations
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Questions and Answers

General Questions

Does the data extract include cumulative data or a single day's data?

Each extract should include one specific day of all newly created COVID-19 vaccination data.

What is the reporting time period and the reporting deadline?

The reporting time period is 12:00 am to 11:59 pm, and the deadline for submitting extract files is 12:00 pm local time the following day.

In our IIS, when a duplicate record is found, we merge one patient into the other patient, meaning one patient ID would remain. If that person gets another dose, should we report using the new ID in the extract or try to determine the original ID?

If the IIS can track it back to the original patient ID, that would allow the Data Clearinghouse to complete a match based on that ID. If you have the capability to report using the original ID, this is preferable.

There are many data elements in the CVRS that are not currently collected by the IIS. Will sending a high rate of "unknowns" have a negative impact?

The more data elements that can be submitted, the more information there will be to make decisions, but limited data are better than no data.

Generally, are historical COVID-19 vaccinations supposed to be sent to the Clearinghouse?

Yes, both administered and historical doses should be sent unless the dose is a confirmed duplicate.

Not all vaccinations from providers reach the IIS within 24 hours, so they can't necessarily be reported to the Clearinghouse within 24 hours of administration. Is that a problem? It would be an immense amount of work and introduce risk to try to accelerate the pace for submitted doses from providers.

If providers can report within 24 hours, that is the expectation and the ideal, but the Clearinghouse will allow 72 hours for reporting. IISs should not sacrifice data quality for reporting speed. IISs do not need to make significant changes to their internal processes or extend an unreasonable amount of resources to ensure their providers meet the 24-hour expectation.

Formatting Questions

Are data case-sensitive?

No, data are not case-sensitive.

Should extract files be new-line terminated or carriage-return new-line terminated?

Data extract files can be either new-line terminated or carriage-return new-line terminated.

In regard to the extract type, de-identified data vs. fully identified data, what is the difference and what do we send?

A: The extract type will be “D” for deidentified or “I” for identified.

What is a PPRL-generated ID?

Until privacy preserving record linkage (PPRL) tools are available, the PPRL generated ID will not be used. An empty placeholder or blank value should be used. CDC will provide free PPRL software to jurisdictions that will preserve and protect PII and PHI by:

- Linking to an individual’s COVID-19 vaccination records to inform booster dose decisions without sharing PII across jurisdictional boundaries
- Enabling CDC to associate a specific individual’s vaccine administration data from multiple sources without receiving any PII that might compromise that person’s privacy

Field-Specific Questions

What is the event’s unique ID?

The vaccination event ID serves as the event’s unique identifier.

Is the vaccination event ID provided by the IIS or by the Data Clearinghouse?

Vaccination event ID is a unique identifier as assigned by the IIS or submitting system, such as VAMS.

Should we send missed appointments?

No, missed appointments should not be included in the extract.

If a refusal is recorded for a patient, but then they decide to receive the vaccine, how should that be reported?

If someone refused a vaccine initially, then changed their mind and received it later, the IIS should report two rows of data for that patient: one for the refusal and one for the vaccination event.

Field Number 33 in the CVRS references the responsible organization as a parent organization. This assumes a parent and child organizational relationship, but our IIS does not collect parent organizations, so how should we report this field?

IIS should duplicate the child organization in both fields 33 and 34 if there is no parent organization.

Field number 34 in the CVRS defines the physical vaccination site. Does this equate to RXA-11 in an HL7 message?

Yes.

In regard to the VTrckS provider PIN, many providers report historical vaccinations rather than administered, and, under those circumstances, there may not be a Vaccines for Children PIN and the IIS may not be able to discern whether the provider gave the vaccine or is simply reporting that the vaccine was administered at a previous point in time. Should these still be sent?

It is common that the VTrckS provider PIN is not sent in the HL7 message but is later associated in the IIS. If known, the submitting source should send the reporting entity's VTrckS provider PIN.

Administered at location type: Admin site type is collected for providers that receive publicly funded vaccine. However, for providers administering private stock vaccine, the admin site type would always be unknown to our IIS. Would it still be appropriate to send those data?

If there is no other option, it is better to report the data.

Are the specifications saying the IIS or submitting system is expected to report all COVID-19 vaccines given in the previous 24 hours, or expected to report all new data reported to the IIS within a 24-hour period?

The IIS extract should include new data that have been reported for that day, regardless of when vaccine was administered.

When have providers met their obligation for the 24-hour reporting of immunization records? Is it when they send a message to the IIS (or to the HIE if this is part of the flow)? Or is it when their data are included in the IIS report?

Providers have met their obligation when they have sent their data to the IIS or HIE.