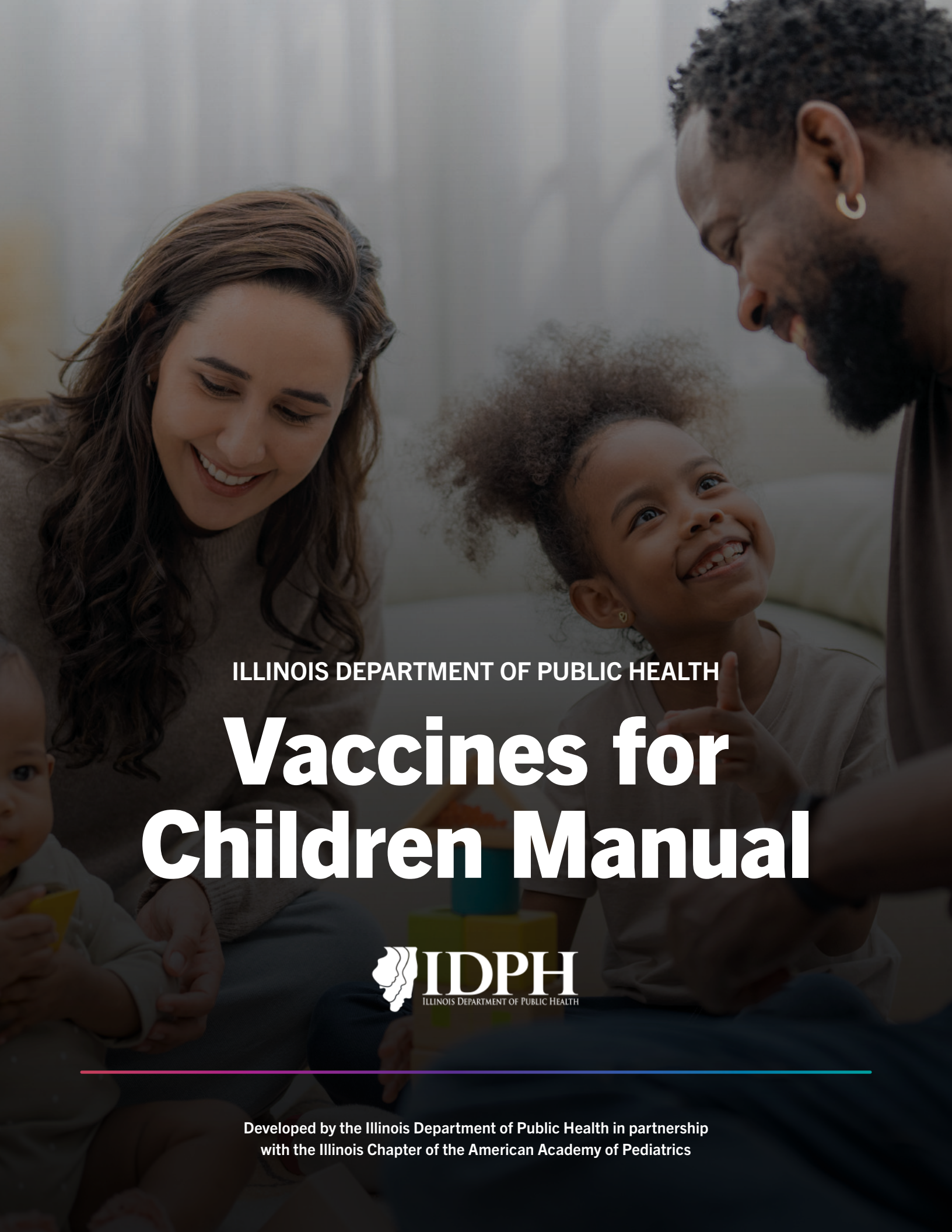

ILLINOIS DEPARTMENT OF PUBLIC HEALTH

Vaccines for Children Manual

IDPH
Illinois Department of Public Health

Developed by the Illinois Department of Public Health in partnership with the Illinois Chapter of the American Academy of Pediatrics

Quick Assist

These are important links that can also be found in the Quick Assist tab in I-CARE.

HL7/EMR/Data Quality Updates – Use this form when a site or organization is changing its EMR, implementing HL7, experiencing HL7 connection issues, or addressing vaccine-related data quality concerns.

I-CARE Enrollment – Register for I-CARE using this form.

I-CARE User Updates – Use this form to request updates to a user's I-CARE account.

Password Reset/Log-In Issues – Use this form if a password cannot be reset using the password reset information and to report log-in issues.

Report Organization Acquisition/ Merger – Use this form to report an organizational acquisition or merger.

Site/Organization Updates – This form is used to request updates to site information.

Submit/Contact Us – Use this form for questions about I-CARE.

Vaccine Locator Dashboard Update – Use this form to update a site name, website, and phone number on the publicly facing Vaccine Locator Dashboard. This form is **not** used to request updates in I-CARE.

Appeal Restitution – Use this form to appeal a restitution determination.

Ask a Question – Use this form to submit general questions.

Data Logger File Review – This form allows sites to upload data logger files for review and provide documentation that units are stable after relocations.

Different Brand Vaccine Restitution – This form allows providers to submit restitution for wasted vaccine doses when identical replacements are unavailable.

Emergency Vaccine Request for Outbreak Response – Use this form to request emergency vaccine supply in response to an outbreak.

Inventory Discrepancy – Use this form to request assistance with an inventory discrepancy.

Off-Site Clinic Dashboard – Information on planning for and conducting off-site vaccination clinics.

Replacement Return Label – Use this form to request a return label if one was not received or if a duplicate shipping label is needed.

Request Memorandum of Understanding (MOU) – LHDs can use this form to request authority to vaccinate underinsured children via deputization by a Federally Qualified Health Center or Rural Health Center.

Request VFC Tab Access – Use this form to request VFC tab access for new Vaccine Coordinators who already have access to I-CARE.

Request to Release New Order Hold – Use this form to request to release an ordering hold.

Unenrollment Request – Use this form to unenroll from the VFC program. Request must be submitted at least 30 days in advance.

Update Patient Population – Use this form to update patient population, throughout the enrollment period, whenever populations change, or when populations automatically tracked in I-CARE do not reflect the population.

Vaccine Transfer Request – Use this form to request a vaccine transfer.

Vaccine Contact Log – Use this form to transfer vaccines before they expire AND locate a facility to receive them. Use the I-CARE Provider List Report on the REPORTS tab to identify locations for vaccine transfers. Document all contacted locations on this form.

Vaccine Cost and Distribution Report – Use this form to request a report that provides details on the cost and amount of vaccines received by providers for federal auditing purposes.

Vaccine Program Medical Director Updates – Use this form to notify IDPH of a Medical Director update.

Vaccine Shipping Incident Report – Use this form to notify IDPH about shipping issues (missing vaccines, lot number discrepancies, etc.) within two hours of receiving the shipment.

Vaccine Storage Incident Report – Use this form to report a vaccine incident (e.g. a temperature excursion with vaccines that are in stock).

Feedback Form – Use this form to provide feedback on how to improve the VFC program.

Important Program Links/Information

From IDPH

- Vaccine Access Program
  - Email: dph.vaccines@illinois.gov
  - Phone: 217-785-1455, select option 2
- Immunization Program Webpage
- Immunization Program Regional Staff – Use this regional map of VFC program contacts to identify and connect with the appropriate IDPH staff.

CDC VFC Operations Guide – From the Centers for Disease Control and Prevention (CDC).

ICAAP VFC Webpage – Use this webpage from the Illinois Chapter, American Academy of Pediatrics (ICAAP) for additional VFC resources for Chicago and Illinois providers.

CDPH VFC Webpage – From the Chicago Department of Public Health (CDPH) for VFC providers located within the City of Chicago. Some clinics may have sites in both jurisdictions.

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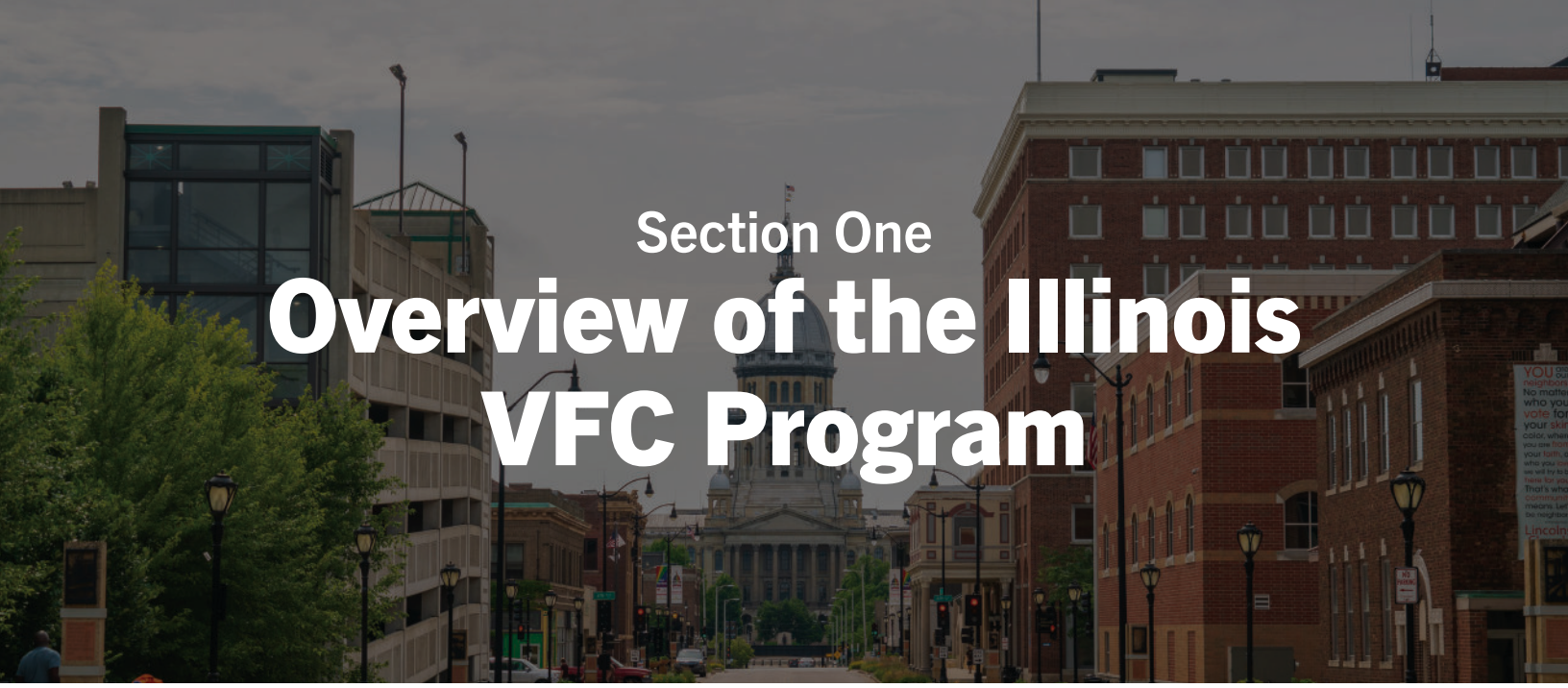


Section One

Overview of the Illinois VFC Program

About the Illinois VFC Program

The Vaccines for Children (VFC) program is a federally funded program from the Centers for Disease Control and Prevention (CDC) that provides vaccines at no cost to children who might not otherwise be vaccinated. The benefits of the VFC program include:

- Reducing referrals of children from private providers to state health departments for vaccination.
- Saving Illinois VFC-enrolled providers out-of-pocket expenses for vaccine.
- Eliminating or reducing vaccine cost as a barrier to immunizing eligible children.

Illinois VFC providers contribute to increased immunization coverage level rates and reduced delays in immunizations and, subsequently, the risk of serious illness or death from vaccine-preventable diseases.

The Illinois Department of Public Health (IDPH) and the Chicago Department of Public Health (CDPH) run Illinois' and Chicago's VFC programs. VFC programs provide immunizations for children through the age of 18 (under 19) who are uninsured (patients may be referred to as "self-pay"), Medicaid-enrolled or Medicaid-eligible, American Indian or Alaskan Native and those who are underinsured. Note that those who are underinsured can only access VFC vaccines at participating federally qualified health centers (FQHC), rural health clinics (RHC), or local health departments (LHD) under an approved deputization agreement.

General questions about Illinois/downstate publicly funded vaccine programs can be submitted here.

State-Level Immunization Guidance

Illinois House Bill 767 empowers the IDPH to issue state-level immunization guidance through adopting recommendations from the Immunization Advisory Committee (IAC). State-level guidance can be found on IDPH's Immunizations webpage.

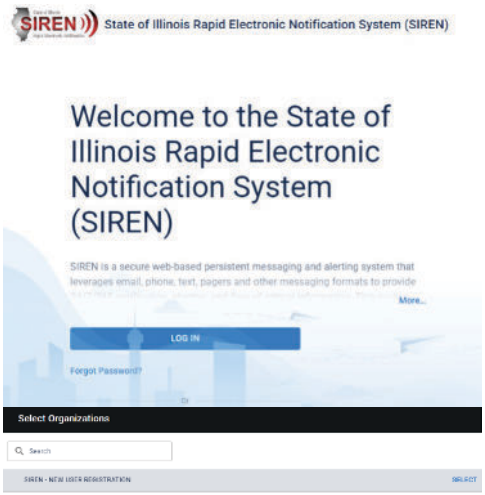
History of the VFC Program

The VFC program was established by Congress in 1994 to increase access to vaccination for children who might not get vaccinated because of financial barriers. The VFC program was created as part of the Omnibus Budget Reconciliation Act of 1993 and was officially implemented in October 1994 as part of the President's Childhood Immunization Initiative. It was established as a new entitlement program required to be a part of each state's Medicaid plan. The VFC program is a Title XIX Medicaid program. Section 1928 of the Social Security Act (42 U.S.C.§1396S) provides the legal authority for the VFC program by requiring each state to establish a program for pediatric vaccine distribution to registered provider locations.

To reach VFC-eligible children, the CDC uses federal funds to purchase vaccines and distribute them at no cost to public health clinics and provider locations enrolled in the program. CDC provides funding to 63 state, local, and territorial immunization program award recipients to implement and oversee the VFC program. These award recipients provide vaccines to participating provider locations to meet the specific needs of eligible children in their jurisdictions.

VFC providers are required to offer ACIP recommended vaccines consistent with their VFC enrollment type. Specialty VFC providers are only required to provide the ACIP recommended vaccines that fall within their designated specialty.

Sign Up to Receive Important Information



State of Illinois Rapid Electronic Notification (SIREN) is a secure web-based persistent messaging and alerting system that leverages email, phone, text, pagers, and other messaging formats to provide 24/7/365 notification, alerting, and flow of critical information. A variety of updates are shared through SIREN, including vaccine recommendations and outbreak detection. Signing up for SIRENs is quick, easy, and free. Go to siren.illinois.gov, and scroll down to **"Register"**. Fill out the requested information, clicking **"Next"** to progress through the form. Required information is indicated by an asterisk (*). On page 5, **"Membership"**, click **"+ Add Organizations"** and select **"SIREN – NEW USER REGISTRATION"**.

Depending on the level of detail provided in user's profile, the SIREN team will automatically assign users to receive topic-specific notifications.

VFC Provider Requirements

Here is an overview of Illinois VFC provider requirements. All these requirements are covered in detail throughout this manual.

REQUIREMENT	COMPONENT
Clinical Requirements	• Be licensed in Illinois to administer vaccines to children aged 18 and younger. • Be willing and able to follow all VFC program requirements, policies, and procedures, including participation in site visits and educational opportunities. • Have the capacity to order, receive, manage, store, and monitor the temperature of vaccines. • Be open at least four consecutive hours for at least three days a week to receive vaccines. • VFC responsible staff should be signed up for SIREN notifications.
Provider Agreement	• Complete and sign CDC's Provider Agreement. • The Medical Director in a group practice must be authorized to administer pediatric vaccines under state law. • The person signing the Provider Agreement on behalf of a multi-provider practice must have authority to sign on behalf of the entity. • All licensed health care providers in an enrolled practice and corresponding professional license numbers must be listed in the VFC Enrollment Form. • Submit a Provider Population Profile at initial program enrollment and update at least annually or when order patterns indicate a change.
Patient Eligibility Screening	• Screen for and document VFC eligibility in the patient's permanent medical record (paper-based using the VFC Patient Eligibility Screening Record OR by documenting the required elements in the electronic medical record) with every immunization visit. • Check the eligibility status in the MEDI system or an equivalent system receiving HFS 270/271 electronic transaction data.
Vaccine Management	**Comply with vaccine management guidelines in the CDC's Vaccine Storage and Handling Toolkit, including:** • Use of correct storage units and digital data loggers (DDLs) with continuous monitoring capabilities and a current Certificate of Calibration. • Receiving and documenting vaccine shipments. • Daily monitoring and recording of unit temperatures, including responding to any temperature excursions. • Managing expired, spoiled, or wasted vaccines. • Proper vaccine handling and preparation. • Adhering to procedures for emergency situations. • Sufficient storage space to accommodate vaccine stock at the busiest time of year (including anticipated new vaccines) without overcrowding.

VFC Provider Requirements Continued

REQUIREMENT	COMPONENT

Vaccine Management Plan(s)	**VFC sites must have Vaccine Management Plan(s). They must be updated annually or more frequently as needed. A review date and signature are required on all plans to validate they are current.**
	
	Vaccine Management Plan should include:
	
	• Contact information for current Primary and Backup Vaccine Coordinators.
	• Staff roles and responsibilities.
	• Documented training related to vaccine management.
	• Proper storage and handling practices, including how to handle temperature excursions.
	• Procedures for vaccine ordering, receiving, inventory control, stock rotation, and handling vaccine loss and waste.
	
	Emergency Vaccine Management Plan should include:
	
	• Procedures for emergency situations, including transport, equipment malfunction, power failure, and natural disasters.
	• Ready access to the supplies needed for emergency transport. Appropriate materials include:
	  ◦ Portable vaccine refrigerator/freezer units or qualified containers and packouts.
	  ◦ Hard-sided insulated containers or Styrofoam™. Use in conjunction with the Packing Vaccines for Transport During Emergencies tool. This system is only to be used in an emergency.
	  ◦ Coolant materials such as phase change materials (PCMs) or frozen water bottles that have been conditioned to 4°C to 5°C.
	  ◦ Insulating materials such as bubble wrap and corrugated cardboard - enough to form two layers per container.
	  ◦ Temperature-monitoring devices for each container.

Immunization Schedule	• Offer vaccines outlined by ACIP recommendations and VFC program resolutions. • Make available the vaccines identified in the Provider Profile based on the provider type and population served, including non-routine vaccines, if applicable. • Understand state laws related to vaccination requirements and acceptable vaccine exemptions. • Use ACIP recommendations and vaccine package inserts to understand contraindications for each vaccine type available through the VFC program.

VFC Provider Requirements Continued

REQUIREMENT	COMPONENT
National Childhood Vaccine Injury Act (NCVIA)	• Obtain and distribute the most current Vaccine Information Statements (VIS) for all vaccines included in the National Vaccine Injury Compensation Program. • Follow the record-keeping requirements for the NCVIA. • Report adverse reactions to Vaccine Adverse Event Reporting System (VAERS). • For RSV monoclonal antibody products (e.g., nirsevimab [Beyfortus]), when not co-administered with other vaccines, report all suspected adverse reactions to MedWatch.
Fraud and Abuse	• Operate in a manner intended to avoid fraud and abuse.
Vaccine Restitution	**Agree to replace vaccines purchased with state and federal funds on a dose-for-dose basis with privately purchased vaccines in the following situations and as described in the VFC Loss and Replacement Policy for Providers Participating in Publicly Funded Vaccine Programs:** • Doses deemed non-viable due to provider negligence. • Doses accidentally borrowed. • Doses administered to ineligible patients.
VFC Visits	• Agree to VFC program site visits, which may include compliance visits, unannounced storage and handling visits, educational site visits, and others as needed.
Training	• All key staff (includes at least VFC Primary and Backup Coordinators listed in I-CARE) must be fully trained on VFC program requirements at all times. ◦ CDC's You Call the Shots Module 10 (Storage and Handling) and Module 16 (Vaccines for Children Program) OR ◦ Attendance at an Illinois Chapter – VFC Summit (not held in Chicago City limits) • All training must be documented and uploaded into I-CARE; it should never expire and is good for 365 days.

How to Enroll as a VFC Provider

All eligible clinics are encouraged to become VFC providers. The VFC program helps to ensure all children in Illinois have access to vaccines at little to no cost. Enrollment is completed through the Illinois Comprehensive Automated Immunization Registry Exchange (I-CARE).

New Enrollment Checklist

Follow the order of the steps below to complete enrollment in the Illinois VFC program.

1. **Apply for I-CARE access for the location enrolling and all individuals that may need access.**
2. **Fill out the Provider Profile and Provider Agreement form (in I-CARE).**
3. **Complete additional steps to enroll in I-CARE as prompted.**
4. **Identify Primary and Backup Vaccine Coordinators.**
5. **The Primary and Backup Vaccine Coordinators must complete the CDC's You Call the Shots Module 10 (Storage and Handling) and Module 16 (Vaccines for Children Program).**

   NOTE: "Audit Only" versions of these modules do not count for VFC training purposes.
6. **Complete Vaccine Management and Emergency Vaccine Management Plans.**
7. **Prepare storage units for vaccines, including the proper equipment and DDLs, "do not unplug" signage and temperature logs.**
8. **Schedule an enrollment site visit.**
   For scheduling or help email dph.vaccines@illinois.gov or a regional contact.

Vaccine Staff

Each facility must identify a Primary and Backup Vaccine Coordinator. The Coordinators are responsible for ensuring all vaccines are stored and handled correctly from the moment they arrive at the facility through the entire period of use. Coordinators should be experts in the clinic's Vaccine Management and Emergency Vaccine Management Plans and the CDC's Vaccine Storage and Handling Toolkit.

The Coordinators are responsible for overseeing all vaccine management within the facility, including:

- Developing and maintaining the Vaccine Management Plans.
- Monitoring storage and handling and vaccine administration practices in the facility.
- Ensuring and documenting annual vaccine management training for designated staff, as well as training new staff upon hire.
  - Participating in and documenting completion of annual training on VFC requirements.
  - **Storing all required documentation for a minimum of three years,** or longer if required by state statutes or rules.

The Coordinators' responsibilities include:

- Ordering vaccines.
- Overseeing proper receipt and storage of vaccine deliveries.
- Documenting vaccine inventory information.
- Organizing vaccines within storage units.
- Setting up temperature monitoring devices.
- Checking and recording the current temperatures at the start and end of each workday.
- Checking and recording minimum/maximum temperatures at the start of each workday.
- Reviewing and analyzing DDL temperature data at least weekly for any shifts in temperature trends.
- Saving DDL temperature data to the "cloud", or a regularly backed-up network drive, for access and archive.
- Rotating stock at least weekly so vaccines with the earliest expiration dates are used first.
- Removing expired vaccine from storage units.
- Review mismatch report (monthly at least) and have a goal of 0 patients listed.
- Responding to temperature excursions (out-of-range temperatures).
- Maintaining all documentation, such as inventory and temperature logs.
- Organizing vaccine-related training and ensuring staff completion of training.
- Ensuring all VFC Coordinators remain up-to-date on VFC program changes and I-CARE updates to remain knowledgeable on program requirements and recommendations.
- Monitoring operation of vaccine storage equipment and systems.
- Overseeing proper vaccine transport per Vaccine Management Plan(s).
- Overseeing emergency preparations per Vaccine Management Plan(s):
  - Tracking inclement weather conditions.
  - Ensuring appropriate handling of vaccines during a disaster or power outage.

All changes in key staff must be communicated to IDPH in the manner and the time frame defined by the Immunization Program. Key staff include: the Medical Director or equivalent who signed the Provider Agreement and the Vaccine Coordinator(s).

VFC Recertification

VFC sites are required to complete recertification in I-CARE every two years. When recertification is taking place, instructions will be sent through a SIREN notification.

Re-enrollment may include updating necessary forms in I-CARE, such as the Provider Agreement, Policy Acknowledgement, training module certificates of completion, and certificates of calibration for DDLs.

Routine and Emergency Vaccine Management Plans

A Vaccine Management Plan which includes procedures for routine temperature monitoring, inventory management, etc., and an Emergency Vaccine Management Plan with detailed emergency protocols for equipment failure, power outages, or natural disasters, etc. ensuring all vaccines are protected and the cold chain is maintained. To create these plans, follow the requirements outlined in the **CDC's Vaccine Storage and Handling Toolkit**. Management plans must be updated annually or more frequently as needed. Plans should include:

- Contact information for current Primary and Backup Vaccine Coordinators.
- Staff roles and responsibilities.
- Documented training related to vaccine management.
- Storage and handling practices, including how to handle temperature excursions.
- Procedures for vaccine ordering, receiving, inventory control, stock rotation, and handling vaccine loss and waste.
- Procedures for emergency situations, including transport, equipment malfunction, power failure, and natural disaster.

Site Visits

VFC site visits are designed to evaluate different aspects of provider compliance with and understanding of requirements. There are different types of site visits, which are outlined below.

Enrollment Site Visit

The enrollment site visit is completed before a clinic can receive VFC vaccines. The goals of the enrollment site visit are to:

- Educate providers about VFC program requirements and proper vaccine storage and handling.
- Certify locations have the appropriate resources to implement program requirements.
- Confirm staff know who to contact at IDPH if problems arise, especially with storage and handling issues.
- Review Vaccine Management Plans.

Compliance Site Visit

Sites must be enrolled and active in the VFC program for 3-6 months before receiving a compliance site visit. The compliance site visit is repeated every 12-24 months. The goals of a compliance site visit are to:

- Verify provider details, eligibility, and documentation.
- Review storage and handling best practices (per unit and sitewide).
- Ensure inventory management follows the requirements outlined in the Provider Agreement.

Storage & Handling Site Visit

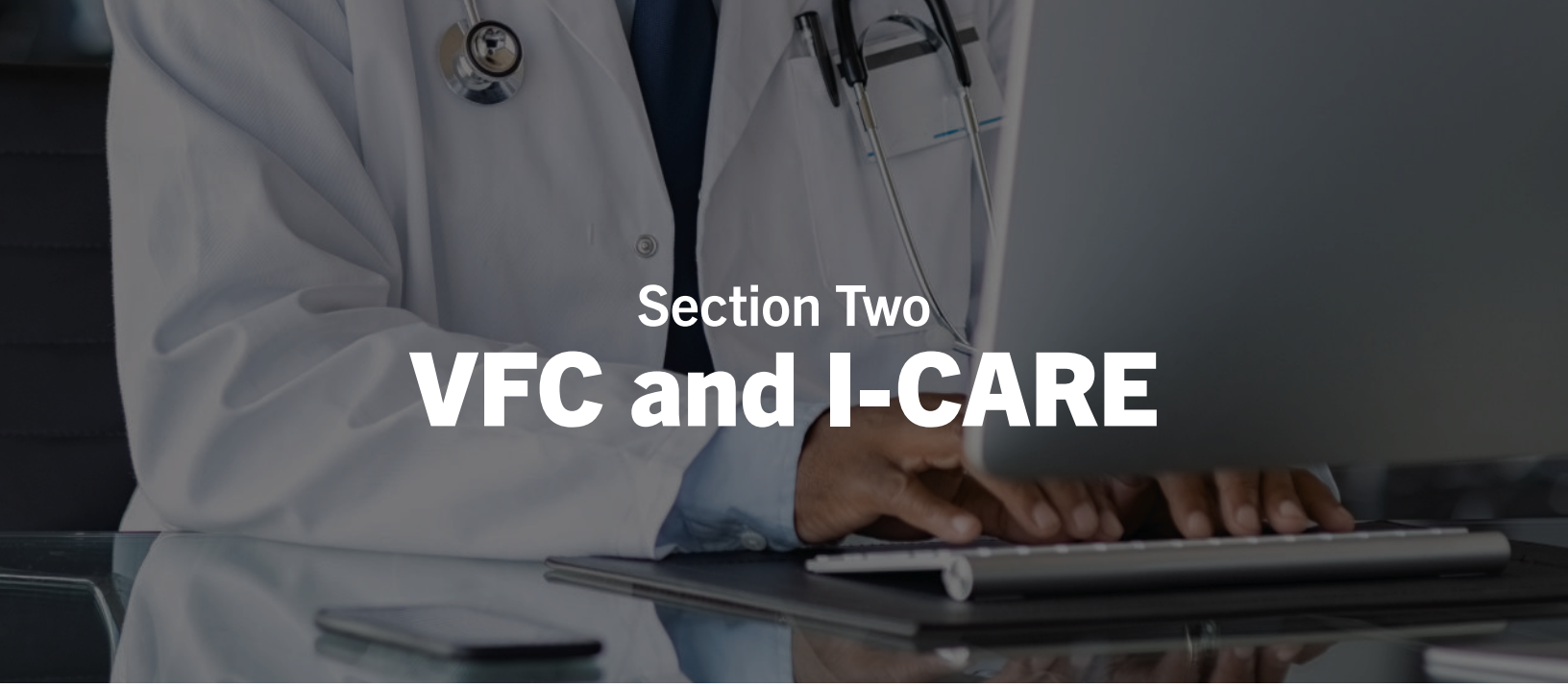
These visits may be scheduled or unannounced. The goals of storage and handling site visits are to:

- Assess storage units and DDLs.
- Assess overall storage and handling operations based on program requirements and CDC's Vaccine Storage and Handling Toolkit.

Educational Site Visit

These visits are scheduled in advance. The goals of educational site visits are to:

- Introduce new clinical staff and IDPH staff.
- Review and understand vaccine storage and temperature activity.
- Discuss steps to complete the onboarding processes, and more!



Section Two

VFC and I-CARE

I-CARE Requirements

I-CARE is a requirement for VFC providers. Having multiple people within a VFC site with the ability to manage and maintain I-CARE can help streamline daily administrative processes.

All VFC providers must provide individual patient immunization records for each publicly funded vaccine dose administered. The individual patient immunization records can either be manually entered directly into I-CARE or can be electronically transmitted to I-CARE from the clinic's electronic medical record (EMR) system. VFC providers not in compliance with this requirement will not be able to continue participating in the VFC program.

Electronic transmission is done via HL7 connection. HL7 is a set of international standards used to provide guidance with transferring and sharing data between various healthcare providers. This is the preferred method for reporting doses administered.

EMR/HL7 Transmissions

An EMR or Electronic Health Record (EHR) is a digital version of a patient's paper-based medical history, which contains all the relevant medical and treatment information in electronic format. EMRs/EHRs allow clinicians to securely access and share patient information with other providers involved in the patient's care.

EMRs/EHRs typically include patient demographics, medical history, and laboratory test results, among other things. EMRs/EHRs also track a patient's vaccination records. These records are sent to I-CARE.

To ensure clear communication between systems, it is crucial for both the sender and recipient to adopt a standard messaging format. Complying with CDC recommendations, data from providers' EMRs/EHRs is sent encoded via the HL7 standard. The HL7 standard defines a common language and syntax for the exchange of medical information. For specific use in immunization messaging, the CDC and American Immunization Registry Association (AIRA) have developed the **HL7 Version 2.5.1 Implementation Guide (IG)**, which further refines the HL7 standard. I-CARE supports both a one directional connection as well as a bidirectional connection. A bidirectional connection is preferred because the EMR will not only send the data to the registry but will also ingest doses back into their EMR if there is a vaccine record in the registry.

The HL7 IG outlines the required formatting for electronic immunization messages to ensure readability by information systems such as I-CARE. It specifies the appropriate message types for each situation, the order in which data should appear, and the specific data elements that each message type should include.

Compliance with the HL7 IG can be compared to using proper formatting and grammar in written communication, as it establishes a clear set of rules to accurately convey messages. Additionally, the HL7 IG recommends specific code and value sets for common data elements such as the use of National Drug Codes (NDCs) to identify a specific product.

Sites should fill out the **HL7/Data Quality Updates Form**, which can also be found under the Quick Assist tab in I-CARE, when changing its EMR, implementing HL7, experiencing HL7 connection issues, or addressing vaccine-related data quality concerns.

Obtaining I-CARE Access

Enrolling a Clinic and Requesting Individual User Access

I-CARE access can be requested after a clinic/site has been enrolled in I-CARE. To enroll a clinic, complete the Organization – Site and PRA Enrollment Form and the I-CARE enrollment team will set up a site agreement through DocuSign and send via email to the Portal Registration Authority (PRA) and authorized representative of the organization for signature/approval. Once approved, the IDPH enrollment team will create the site in I-CARE and send a welcome email.

Individual user requests are completed through the I-CARE Individual User Agreement Form. The I-CARE enrollment team will set up an individual user agreement through DocuSign and send via email to the user. Once signed, it will be routed to the user's supervisor for signature, and the final routing will go to the organization's PRA for approval. Once approved, a user account will be created in I-CARE, and the user will be sent a welcome letter with instructions on how to log in.

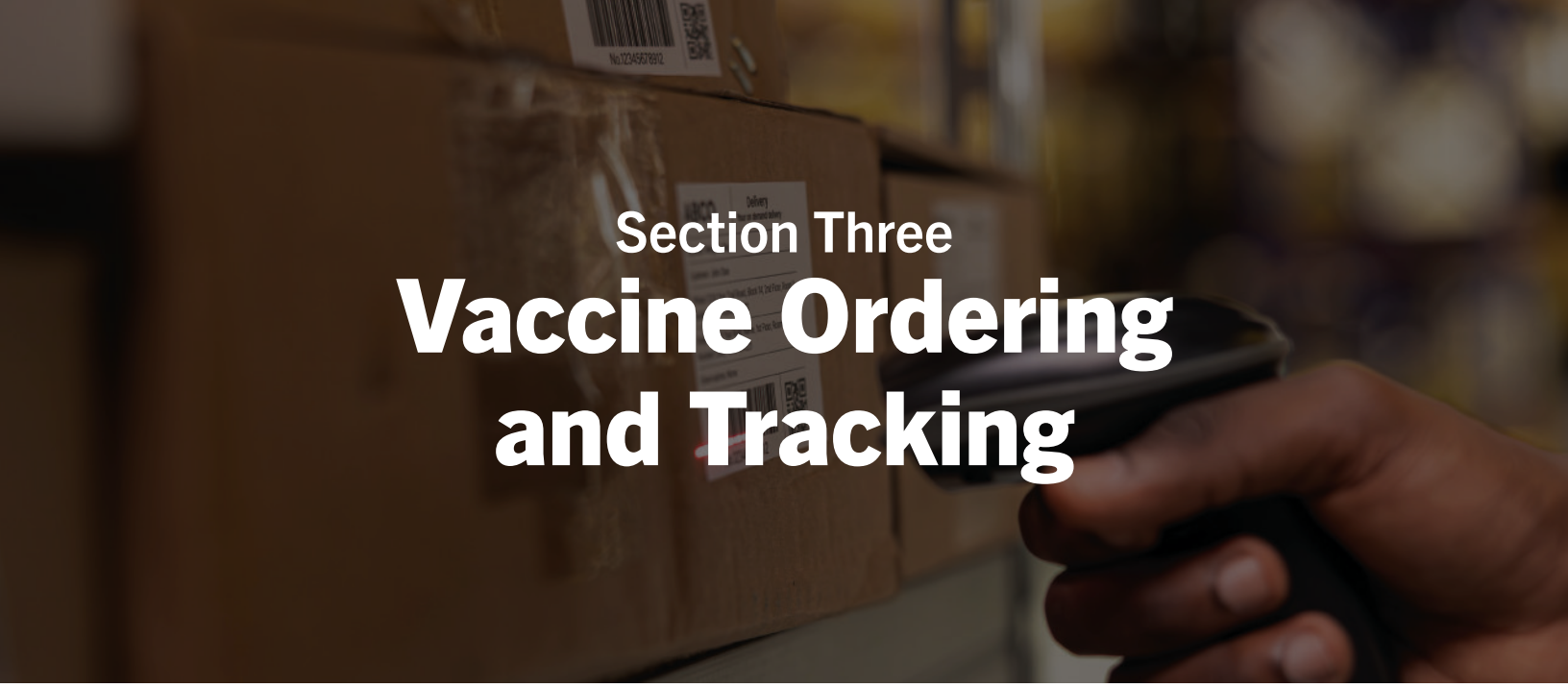
If this email is not received, steps are missing. Please check spam for the email. If a site has questions about the enrollment process, please contact the I-CARE team, using this form: Submit/Contact Us.

Other I-CARE resources, which can also be found under the Quick Assist tab in I-CARE:

- I-CARE User Updates – To request updates to user accounts. This includes a user's name change, email, site placement, access level, and deleting a user.
- Password Reset/Log-In Issues – To be used if a password cannot be reset using the password reset help information or for other log-in issues.
- Report Organization Acquisition/ Merger – To report an organizational acquisition or merger (change of ownership).
- Site/Organization Updates – To request updates to site information (name, address).
- Submit/Contact Us – To submit questions about I-CARE or contact the I-CARE team.

Administering Respiratory Virus Vaccines as a VFC Provider

Flu, COVID-19, and RSV immunizations are available through the VFC program. They should be ordered by participating sites and recommended to all eligible patients. Before the start of respiratory virus season, current information about product formulations and presentation, storage and handling, reimbursements, ordering, clinical guidance, etc. will be shared.



Section Three

Vaccine Ordering and Tracking

Vaccine Ordering and Tracking

VFC providers are expected to maintain an adequate inventory of vaccine for all VFC-eligible patients served and non-VFC-eligible patients that may be vaccinated. The CDC recommends that providers maintain a minimum four-week supply of inventory. IDPH suggests ordering smaller, more frequent orders to reduce waste; order as often as needed.

It is the responsibility of the provider to appropriately schedule and place vaccine orders and to rotate vaccine stock properly to ensure timely use of short-dated vaccine. Borrowing of vaccine between private and public inventories must be a rare, unplanned occurrence and CANNOT serve as a replacement system for a provider's privately purchased vaccine inventory. All instances of borrowing must be properly documented and reported, and borrowed doses must be replaced.

How to Place an Order for Vaccines

The following should be up-to-date before submitting a vaccine order:

- Vaccine inventory
- Patient immunization records
- Temperature logs for all appliances
- All data logger certificates of calibration are valid and not expired
- All temperature excursions must have a vaccine incident report on file
- Delivery hours, including specifying lunch hours or other closures

Training certificates for all Primary and Backup Vaccine Coordinators completing these steps means sites are now ready to order vaccines. Vaccine ordering can be completed in I-CARE by VFC Coordinators. Navigate to the Programs tab > Vaccine Requests to add a new vaccine order.

After an order is placed, please allow at least three business days for order approval. This may take longer in times of high demand. Orders may be delayed if inventory is not accurately tracked in I-CARE.

For up-to-date information on product ordering requirements, sites can refer to the CDC's VFC Program Operations Guide linked on the CDC's webpage.

Track When Vaccine Shipments Will Arrive

Track when shipments will arrive in I-CARE by following these steps:

- Log-in to I-CARE and navigate to the Vaccine Program tab.
- Navigate to the programs tab and select the program associated with the shipment and select **"Vaccine Requests"**. Click on the corresponding Order ID and scroll down to the list of vaccines.
- Click the drop-down arrow under the **"Detail"** column to reveal the tracking number. If no tracking number is listed the order has yet to be shipped.
- After an order is approved, please continue to check the shipping status to ensure it is ready to be received.

What to Do if a Vaccine Shipment Is Missing or Incorrect

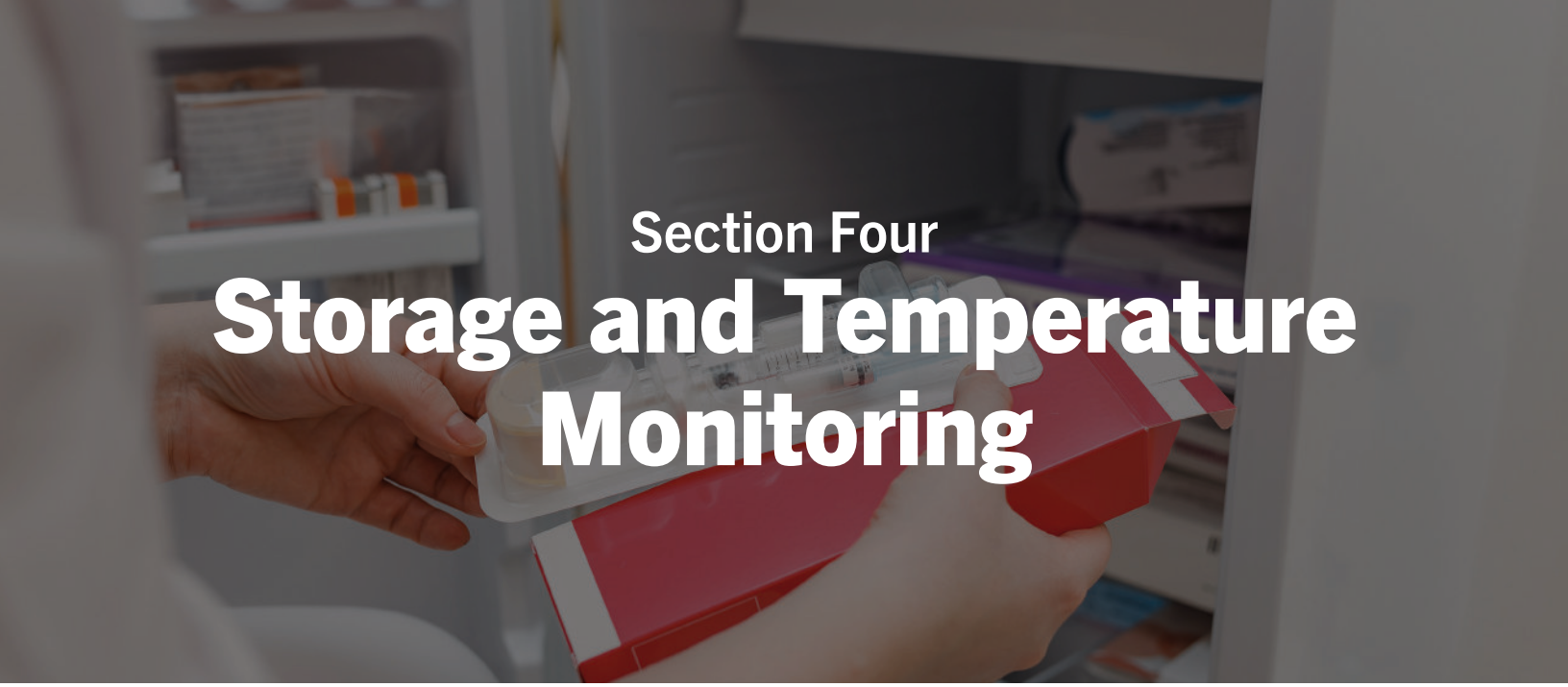
When a vaccine shipment is received, check to ensure the shipment is correct. The packing slip should match the vaccines received. Cross-check lot numbers that are listed as inventory in I-CARE. Lot numbers will be automatically added to I-CARE once the order status is "complete" in I-CARE.

Vaccine Shipping Incident Report – Use this form to notify IDPH of shipping issues. This could include out of range temperatures, missing vaccines, lot number discrepancies, damaged vaccine, or shipments that never arrived.

Shipping labels are emailed to the VFC Primary Coordinator. If the Primary Coordinator is gone/out of office and someone else needs to receive it in their absence, that can be requested here: Replacement Return Label. This form can also be used if a shipping label needs to be replaced.

Things to note:

- Frozen vaccines ship separately from other refrigerated vaccines.
  - Varivax and ProQuad will arrive with a different tracking number and box and will be shipped directly from the manufacturer.
- Any issues should be reported within two hours to the Illinois VFC Program Services Staff at 217-785-1455. If you do not immediately reach anyone, please call again and follow up with an email to dph.vaccines@illinois.gov.
  - When emailing about an order, clinics must include these details:
    - VFC site PIN
    - I-CARE order number ID
    - What vaccines are incorrect or missing from the order



Section Four

Storage and Temperature Monitoring

Storage Requirements

To ensure the viability of VFC products, provider locations must have:

1. Storage units that maintain correct temperatures at all times.
2. Refrigerator temperature between 2°C and 8°C (36°F and 46°F).
3. Freezer temperature between -50°C and -15°C (-58°F and +5°F).
4. DDLs with continuous monitoring capabilities and a current and valid Certificate of Calibration Testing for each unit, as well as at least one backup DDL.

Storage units must have enough room to store the largest inventory a provider location might have at the busiest point in the year without crowding. Providers should follow the manufacturer's storage specifications for each immunization, found in the product's package insert. Providers must also protect the power source for all storage equipment. This can be done by using a "Do Not Disconnect" warning label at the electrical outlet and circuit breaker.

CDC recommends the following units, starting with the most preferable, for storing VFC vaccines:

- Purpose-built or pharmaceutical/medical-grade units, including doorless and vending-style units.
- Vaccine storage units that conform to NSF/ANSI Standard 456 (which have been tested rigorously to be used for the storage of vaccines).
- Stand-alone refrigerator and freezer units.
- Combination household refrigerator/freezer unit, using only the refrigerator compartment to store vaccines. Use a separate stand-alone freezer to store frozen vaccines.

Storage Requirements Continued

Storage Unit Best Practices

- Never store food or beverages in a unit with immunizations.
- Do not store products in the removable or non-removable deli, fruit, or vegetable bins, the doors, on the floor of the unit, or under or near cooling vents.
- Dorm- and bar-style units are prohibited for vaccine storage. These units have a single exterior door and an evaporator plate or cooling coil, which is usually located in an icemaker or freezer compartment. Vaccines stored in dorm-style units are considered non-viable.
- Vaccines should be stored in their original manufacturer (or CDC centralized distributor) packaging. They should be placed in the middle of the unit with space between the vaccines and the side/back of the unit to allow cold air to circulate.
- Water bottles are recommended for household-grade units and are not recommended for use with the majority of pharmaceutical-grade and purpose-built units. For pharmaceutical-grade and purpose-built units, follow the manufacturer's guidance.

Temperatures and Digital Data Loggers Introduction

Each provider uses a DDL to monitor and record continuous temperatures on each unit. The temperature-monitoring device (or probe) must be placed in a central area of the storage unit directly with the vaccines to properly measure vaccine temperature. Devices should not be placed near the door, near or against the walls, close to vents, or on the floor of the unit.

The data logger unit data must be downloaded at least weekly and stored digitally on the provider's designated computer. Some DDLs continuously record their data in the cloud; this is permitted as long as the data is stored for at least **3 years** per federal VFC requirements. It is important to note that some DDLs have storage limits and will stop recording once they reach that limit. DDL data should be thoroughly reviewed by the Vaccine Coordinator every time data is downloaded.

The IDPH VFC Program requires temperatures on units that store VFC vaccines to be reviewed twice daily and the minimum, maximum, and current temperatures to be recorded. Temperature logs must be entered into I-CARE at the end of each clinic week and be kept for at least three (3) years.

Data Logger File Review – This form will allow sites to upload data logger files for review and to evidence stable units after relocations. Please deliver files exclusively on MS Excel format.

VFC Temperature Log – Consolidated version of the IDPH VFC Temperature Log form for either appliance type and either temperature scale.

Immunize.org offers temperature log templates on their website under: Clinical Resources: Storage & Handling.

Data Logger Requirements

Pre-calibrated probes will need to be replaced every two years, unless specifically stated otherwise.

DDLs Must Be Equipped With:

- A buffered temperature probe or sensor.
- An active temperature display outside the unit that can be easily read without opening the unit's door.
- Continuous temperature monitoring and recording capabilities and capacity to routinely download data.
  - Data should be downloaded in Excel format to be able to review min/max temperatures.

Backup DDLs:

- VFC providers must have a readily available continuous temperature-monitoring backup device with a current and valid certificate of calibration testing.
- To prevent the certificate of calibration testing of the primary and backup devices from expiring at the same time, the date of calibration testing of the backup device should be staggered, or different from, the date of calibration testing of the primary device.
- IDPH recommends that clinics have at least two backup DDLs for emergency transport, or as many DDLs needed to properly transfer all vaccines in stock, if needed.

Additional Recommended DDL Features:

- Alarm for out-of-range temperatures (an alarm set before an excursion occurs would be good practice).
- Temperature display showing current, minimum, and maximum temperatures.
- Low battery indicator.
- User-programmable logging interval (or reading rate) is recommended every 5-15 minutes, but at a maximum time interval of no less frequently than every 30 minutes.

Certificates of Calibration Testing Must Include:

- Model/device number.
- Serial number.
- Date of calibration (report or issue date).
- Confirmation that the instrument passed testing (or instrument in tolerance).

Certificates of Calibration Must Indicate at least One of the Following:

- Conforms to ISO 17025.
- Testing was performed by an ILAC/MRS Signatory body accredited laboratory.
- Traceable to the standards maintained by NIST.
- Meets specifications and testing requirements for the American Society for Testing and Materials (ASTM) Standard E2877 tolerance Class F (0.5 °C) or better.

Temperature Excursions

Refrigerators where products are stored should remain between 2-8 degrees Celsius or 36-46 degrees Fahrenheit. Freezers should remain between -50°C and -15°C (-58°F and +5°F).

Vaccines must be stored at appropriate temperatures as described in the manufacturer package inserts at all times. Any temperature outside of the recommended range found on the package insert is considered an excursion. Documented temperatures should never be rounded.

Example: a temperature of 46.1°F is out of range, and the provider should follow the Vaccine Storage Incident Report process.

Vaccine Storage Incident Report – Complete this form to report a vaccine incident. This is typically completed when a temperature excursion occurs with vaccines that are in stock.

If a unit goes out of range, HOLD on administering any of the impacted vaccines and mark vaccines "Do Not Use" until the Vaccine Storage Incident Report is completed and the vaccine manufacturer has been contacted. Someone may follow up with additional questions: please respond to any emails in a timely manner as this information will help determine next steps. Please be patient during this process as sometimes manufacturers do not respond immediately.

Refer to the **CDC's Vaccine Storage and Handling Toolkit** for additional storage and handling information.

Section Five

Inventory Management

Inventory Management

Vaccine accountability is a cornerstone of the VFC program and one of the program's highest priorities. Vaccine losses are absorbed directly by the VFC program's budget. Since the Illinois VFC program is so important to the health and well-being of the children in Illinois, it is essential that every dose of vaccine is used to provide protection against preventable diseases. All VFC providers should continually monitor vaccine storage and handling practices. Providers may contact the Illinois VFC program to request an educational visit regarding vaccine storage and handling.

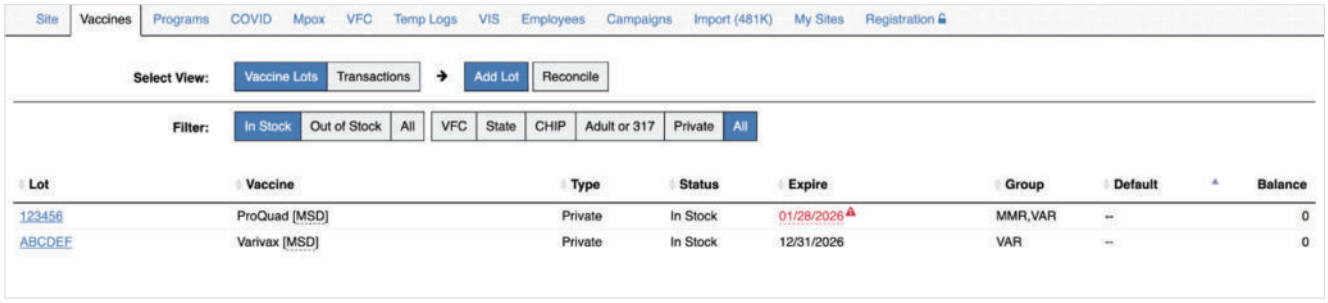
The Vaccine Loss and Replacement Policy serves as the IDPH Immunization Program's policy for management of incidents that result in loss of all publicly funded vaccines provided through the IDPH Immunization Program. VFC providers are required to report all wasted, expired, spoiled or lost vaccine to the Illinois VFC program.

Medicaid Expansion

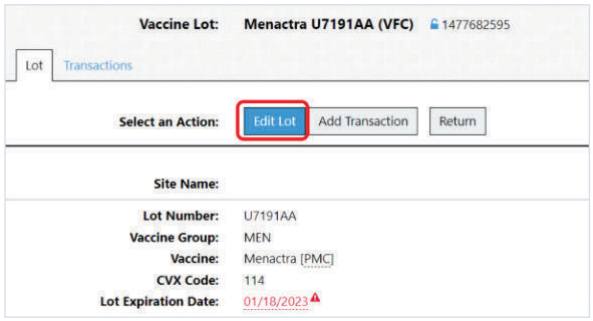
Medicaid expansion in Illinois increased eligibility for children covered under Medicaid-funded programs. As part of this change, children who were previously eligible under the Children's Health Insurance Program (CHIP) are now fully eligible for the Vaccines for Children (VFC) program. With this shift, VFC providers screen all previously CHIP-eligible children using standard VFC eligibility categories, and publicly supplied pediatric vaccines are managed within a single VFC inventory.

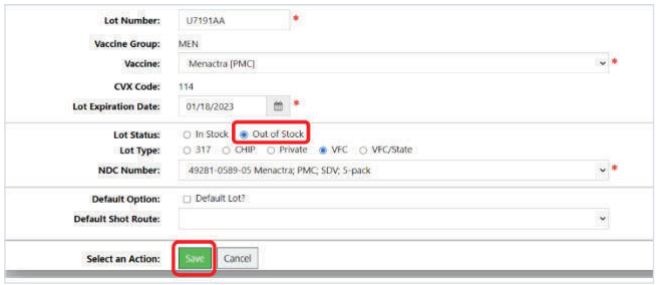
How to Remove Zero Quantity Vaccines

Removing zero quantity vaccines in I-CARE is easy and providers should keep up with doing so regularly. Moving zero quantity vaccines out of stock will prevent sites from reaching a negative balance accidentally. To remove zero quantity vaccines, navigate to the I-CARE inventory by clicking on the **"Site"** tab in the top left-hand corner of I-CARE, clicking the **"Vaccines"** tab, and selecting the lot.



Hit **"Edit Lot"** and select the **"Out of Stock"** bubble and hit the green **SAVE** button.



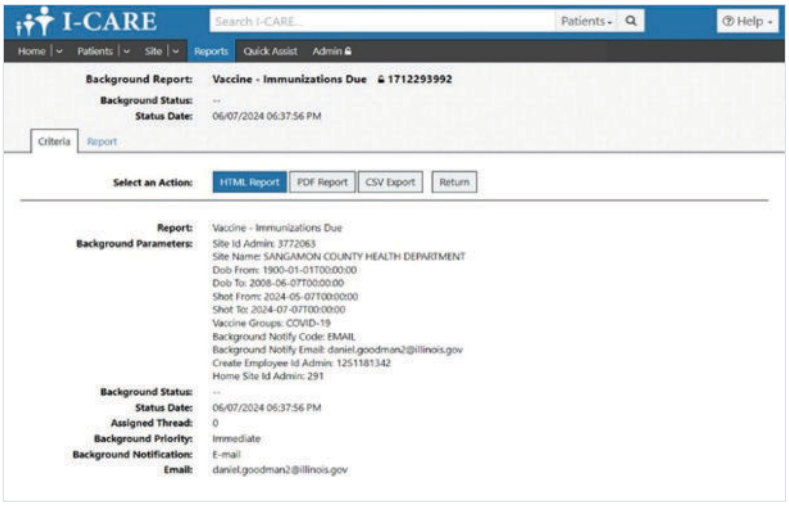


That lot should no longer show up in a site's **"In Stock"** inventory. All vaccines marked out of stock can be found by clicking the **"Out of Stock"** button above the I-CARE inventory.

Do not move any vaccines with any other balance or quantity to out of stock. Doing so will incorrectly adjust the inventory and will continue to be reflected in reports.

Soon-to-Expire Vaccines

Use vaccines prior to expiration. Sites must attempt to transfer all vaccines with an expiration date within the next three months. Before doing this, run an Immunizations Due Report in I-CARE. There may be patients who are overdue for doses set to expire and clinics should reach out to ensure patients know.



How to Transfer Vaccines to Another Site

Products may be transferred to another provider or clinic if: vaccines are needed urgently, there is an outbreak, or vaccine doses will not be used at a current site before expiration. The transfer must occur with another Illinois (outside of Chicago) VFC site and should be approved in advance.

Vaccine Transfer Request – Use this form to request a vaccine transfer to a different site.

If sites do not have a place to transfer vaccines to, use the Provider List on the REPORTS tab (I-CARE Provider List Report) to get a list of locations to call to accept a vaccine transfer. If a site cannot find another location, staff should use this Vaccine Contact Log to ask for assistance from IDPH to transfer vaccines before they expire AND locate a facility to receive them. Sites will need to report which locations were contacted by the clinic.

Once the form is received, IDPH staff will review, approve, and transfer the doses in I-CARE. The doses will automatically be deducted from the sender's inventory and appear in the receiving site's inventory.

To complete the physical vaccine transfer, please ensure a portable vaccine storage unit or qualified container and pack out is used with a DDL. Coolers and conditioned water bottles are not allowed for vaccine transfers. It must be a portable vaccine unit or qualified container/pack out.

Qualified Container and Packout: A type of container and supplies specifically designed for use when packing vaccines for transport. They are containers that are "qualified" through laboratory testing under controlled conditions to ensure they achieve and maintain desired temperatures for a set amount of time.

How to Add Private Stock Doses to Inventory

While it is not a requirement of the Illinois VFC program, some providers add private vaccine inventory to I-CARE also. Sites that input a full inventory in I-CARE have a clearer picture of exactly which vaccines are available. To do this, follow the step-by-step instructions from this guide.

Section Six

Off-Site Clinics

What is an Off-Site Clinic?

Temporary Off-Site Clinics include community vaccinators, mobile*, and off-site clinics. Examples: workplaces, community centers, schools, churches, makeshift clinics in remote areas, mass vaccination events, walk-through, curbside and drive-through clinics.

*This is different from a mobile provider, which is a provider type that ***exclusively*** stores and administers vaccines out of a mobile facility.

Benefits of Off-Site Clinics

Off-site vaccine clinics offer several advantages, including:

- Increased accessibility.
- Reaching communities with limited healthcare access.
- Facilitating large-scale immunizations during emergencies, and promotion of public health and equity.

Steps to Hold Off-Site Clinics

As of August 1, 2024, there is a new process for notifying IDPH of temporary off site vaccination clinics. The annual Off Site Vaccination Clinic Plan must be submitted and approved by the IDPH Immunization Section before any off site clinics are held. Once the annual plan is approved, providers must notify IDPH within 48 hours prior to each individual clinic; however, they do not need to wait for pre approval of each event, as long as the clinic follows the approved plan.

Resources for Off-Site Clinics

- A webinar on the IDPH Off-Site Clinic Procedures and Best Practices was held on July 26, 2024: **Slides** and **recording**
- An overview of the process: **Off-Site Clinic Dashboard**
- **How to Complete the Form Guide**
- **Best Practices for Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations**
- **How to Transport Vaccines for an Off-Site Clinic**
- **What is a Qualified Container for Vaccine Transport?**
- **How to Monitor Vaccine Temperatures**

Questions? Contact **dph.vaccines@illinois.gov** or call 217-785-1455, opt 2.

Section Seven

Achieving Inventory Accuracy

Achieving Inventory Accuracy

Maintaining an accurate inventory is a core responsibility of the VFC and other publicly funded vaccine programs. Doing so allows clinics to receive vaccines faster, and when requested, provides accurate records for patients and clinic operations. Regularly monitoring inventory in I-CARE will help avoid errors.

Complete vaccine inventory weekly to ensure physical stock matches I-CARE's inventory. When counting inventory, be sure to monitor temperatures as to not cause an excursion. Doors should remain closed as much as possible to maintain temperatures.

The main components to ensure a clean inventory are outlined below:

1. Review the clinic's I-CARE vaccine inventory listed within the Vaccines Tab. Alternatively, view and print the Vaccine Inventory Report found in the I-CARE Reports section.
2. Compare I-CARE inventory to your physical vaccine inventory. Note any discrepancies.
3. Mark any expired/spoiled vaccines appropriately and return those doses, if appropriate. If discrepancies exist, run the site's Immunization Activity Report and compare your site's EHR records to ensure all doses are accounted for.
4. If discrepancies still exist, run the site's Mismatch Report and Inventory Analysis Helper Report. Keeping these two reports as clean as possible will help reduce inventory issues and speed up vaccine orders.
5. If discrepancies still exist, use the Inventory Discrepancy form to request assistance.

Inventory Analysis Helper Report

The Inventory Analysis Helper Report (IAHR) is a tool in I-CARE that shows administered shot errors that may not be deducted properly from a site's vaccine inventory. If this report is reviewed often, errors can be caught early, saving time and manual corrections. It will also help if an order needs approval quickly.

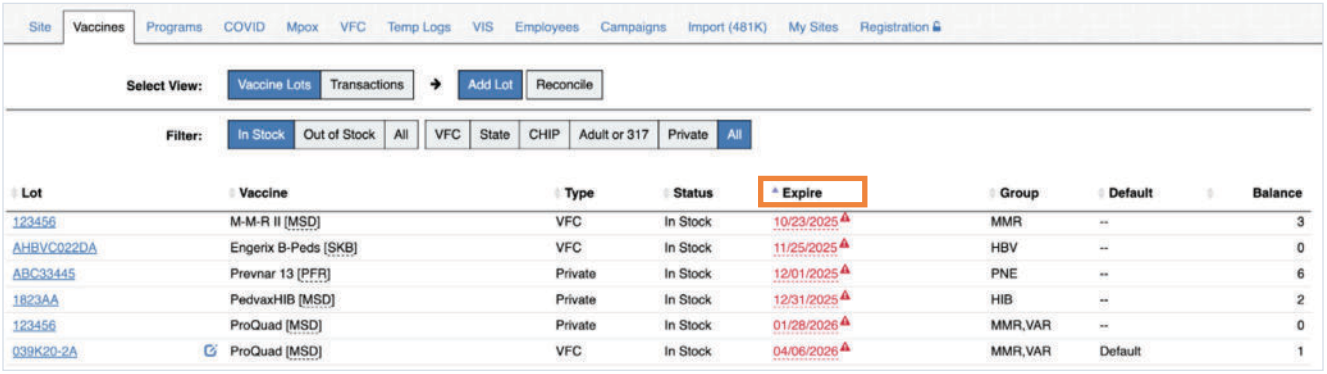
To run this report, navigate to the **"Reports"** tab in I-CARE and then scroll down to click on **"Inventory Analysis Helper Report."** Run that report from the date of the last vaccine order (or three months ago) until today. An **"HTML Report"** will open the report as a web page, **"PDF Report"** will open the report as a PDF, and **"CSV Export"** will create a CSV file that can be opened with Excel.

> Please keep in mind that this report contains Patient Health Information covered under HIPAA, so it **should not be sent by email** unless the email is encrypted.

Removing Expired Vaccines

Use the I-CARE Vaccine Tab to view all vaccines in a site's inventory. The column titles at the top, **"Lot," "Vaccine," "Type," "Status," "Expire," "Group,"** and **"Balance"** can be clicked on individually to order vaccines according to a given category.

"Expire" will list vaccines in order of expiration date either newest to oldest or oldest to newest. Click on **"Expire"** again to order vaccines from oldest to newest. This will bring all expired vaccines to the top of the list to easily manage. Vaccines listed in red are expired.



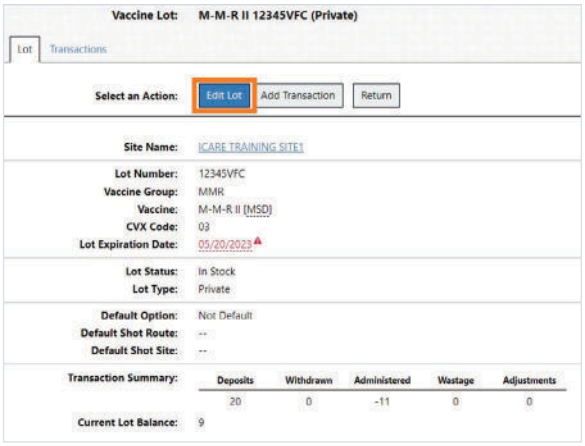
Lot	Vaccine	Type	Status	Expire	Group	Default	Balance
123456	M-M-R II [MSD]	VFC	In Stock	10/23/2025	MMR	--	3
AHBVC022DA	Engerix B-Peds [SKB]	VFC	In Stock	11/25/2025	HBV	--	0
ABC33445	Prevnar 13 [PFR]	Private	In Stock	12/01/2025	PNE	--	6
1823AA	PedvaxHIB [MSD]	Private	In Stock	12/31/2025	HIB	--	2
123456	ProQuad [MSD]	Private	In Stock	01/28/2026	MMR,VAR	--	0
039K20-2A	ProQuad [MSD]	VFC	In Stock	04/06/2026	MMR,VAR	Default	1

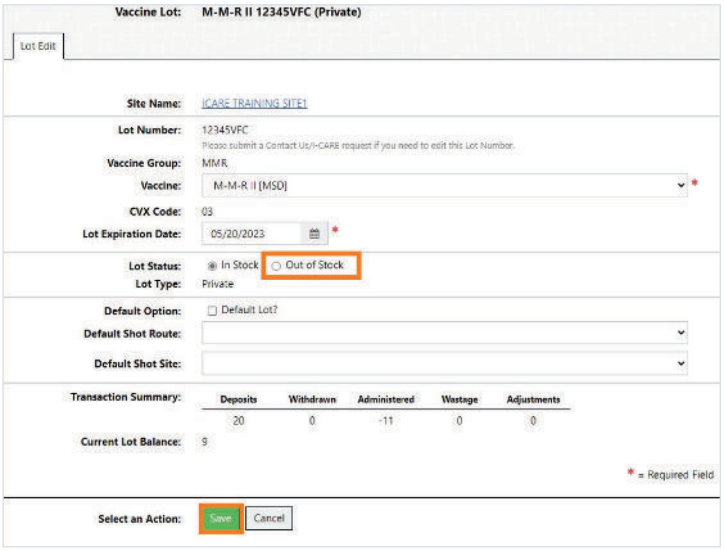
Removing Expired Vaccines Continued

Sites must keep I-CARE inventories free from expired vaccines. To remove expired vaccines from an inventory, follow these steps:

- Click on the lot and select **"Add Transaction."**
- Select the **"Transaction Type"** as **"Expired/Spoiled (Return)"**
- Enter the appropriate **"Wastage Code"** and fill in the quantity. Make sure that the number entered matches the vaccine physically sent back, and it should match the return form.
    - Do not worry if this creates a negative balance as this will be corrected in the Vaccine Accountability Report.
- Enter the date and leave a note, if applicable.
- Hit the green SAVE button. The lot balance should be adjusted to reflect the new deduction.

If a site's inventory has remained accurate, after marking the expired vaccine, the new balance for the lot should be at 0. If so, a site can move the lot out of stock. To do so, select the lot, hit **"Edit Lot"** and select the **"Out of Stock"** bubble and hit the green SAVE button. The lot should now be removed from inventory. ***Please do not use this function to zero out or correct an inventory.*** If there is still an incorrect balance in I-CARE once this transaction is completed, please contact IDPH with an edited Vaccine Accountability Report. This will allow IDPH staff to adjust the inventory without misreporting vaccine waste.





Before removing expired vaccines from a site's inventory, complete all the steps to correct errors on the IAHR and record waste.

Different Brand Vaccine Restitution – This form will allow providers to submit restitution for wasted vaccine doses when identical replacements are unavailable. Providers may substitute any vaccine of equal or greater value if approved by IDPH, ensuring that program requirements are met efficiently and without delays in inventory reconciliation.

Returning Vaccines

All VFC vaccines received from IDPH, including seasonal vaccines such as flu and COVID, should be returned upon expiration. If vaccines expire, they can no longer be stored in the same storage unit with viable vaccines. They must be placed in a container or bag clearly labeled **"Do Not Use"** and separated from viable vaccines to prevent inadvertent use. Expired vaccines must be returned to the centralized distributor within 6 months of expiration.

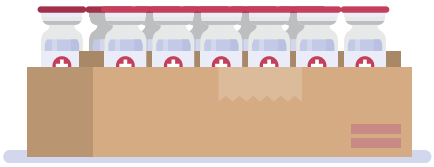
Vaccines should also be returned after a temperature excursion if deemed no longer viable. Do not return punctured or broken vials, instead please dispose of them in hazards and record as **"Wasted (No Return)"** in I-CARE. Note there are some vaccines that should or should not be returned to McKesson (refer to this one-pager What NOT to Return to McKesson). To receive a mailing label to return the vaccines to McKesson, remove any expired vaccines from the storage unit and enter the expired vaccine transaction into I-CARE. Once the waste/return transaction is complete, the Primary Coordinator will receive an email with the Return Label and packing slip.

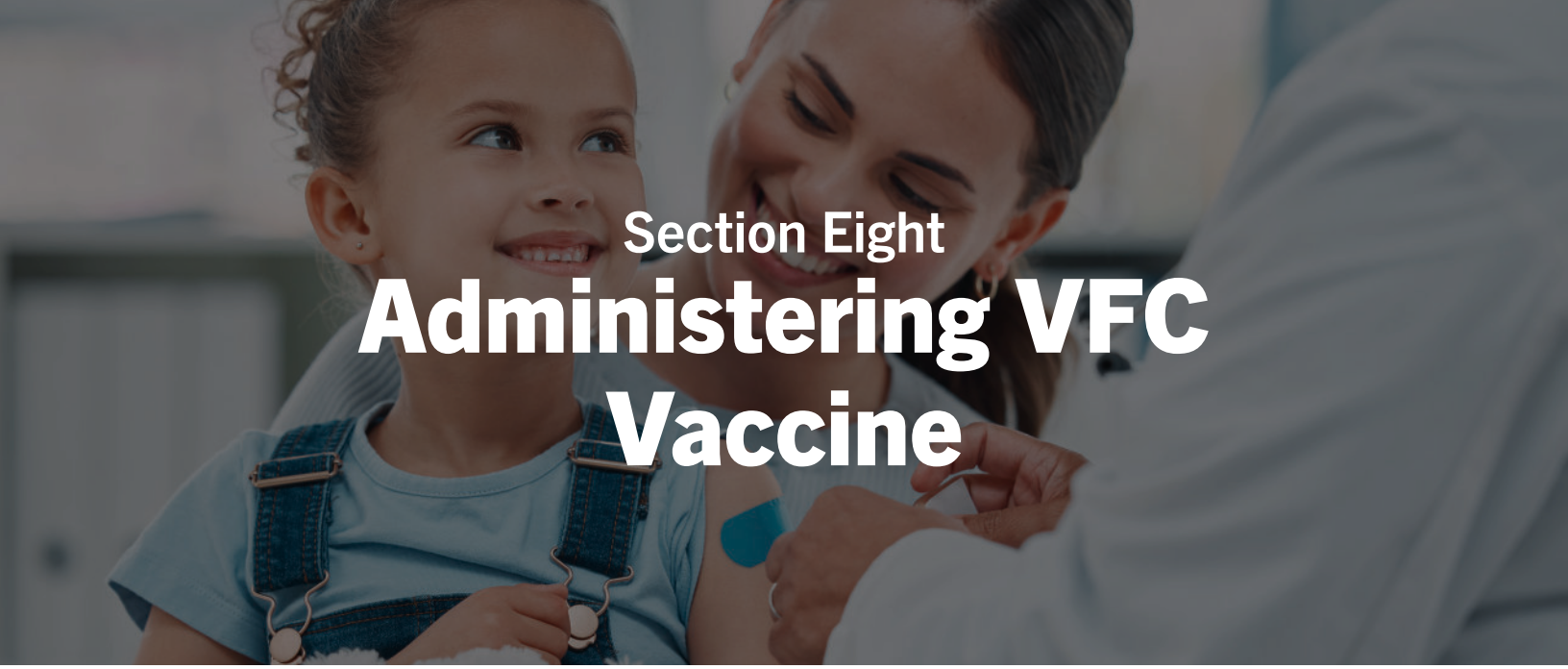
Vaccines that have not yet expired cannot be returned.

Please use as many vaccines as possible prior to expiration.

Tips for returning vaccine:

- Pack vaccines in any box and print out the shipping label to send it out.
- Once a return has been processed, additions and changes are not permitted.
- If multiple returns need to be made, they can be consolidated into a single box. Packing slips should be attached to the correct vaccine and a single shipping label can be used for the entire return. If returning a large number of vaccines, more than one shipping label may be sent in case multiple boxes are needed. If one box is used, disregard the extra labels.
- Return mailing labels are only valid for 30 days.
- If a return label was not received and is needed, or a return label has not been used within 30 days, one can be requested here: Replacement Return Label. The return label will be sent by email.





Section Eight

Administering VFC Vaccine

How to Determine a Patient's VFC Eligibility

Providers must screen, document, and verify VFC eligibility with every immunization visit, on the day of the visit, following the **Illinois VFC Eligibility Policy** before administering vaccines. Providers must check the eligibility status in the **MEDI system** or an equivalent system receiving the HFS 270/271 electronic transaction data. Children (regardless of their state of residency) through the age of 18 (the day someone turns 19 they are no longer eligible) must meet at least one of the following criteria to be eligible to receive VFC vaccine:

1. Medicaid-eligible: A child who is enrolled in Medicaid.

2. Uninsured: A child who is not covered by any health insurance plan

3. American Indian or Alaskan Native (AI/AN): A child who is part of this population as defined by the **Indian Health Care Improvement Act (25 U.S.C. 1603)**

4. Underinsured:*
   - A child who has health insurance, but coverage does not include any vaccines.
   - A child who has health insurance, but coverage does not include all vaccines recommended by ACIP.
   - A child who has health insurance, but coverage has a fixed dollar limit (or cap) for vaccines.
   - A child who has health insurance, but insurance does not provide first dollar coverage for vaccines.

*Underinsured children are eligible to receive VFC vaccine only through a FQHC, RHC, or LHD under an approved deputized agreement.

How to Determine a Patient's VFC Eligibility Continued

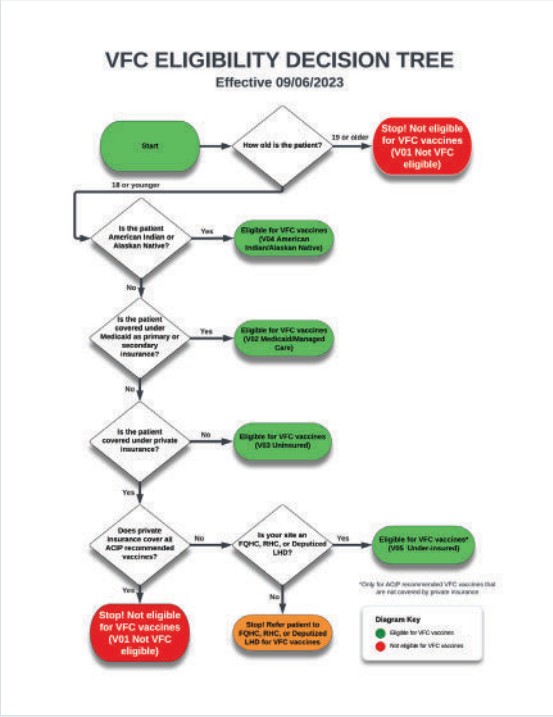
Deputized Agreements

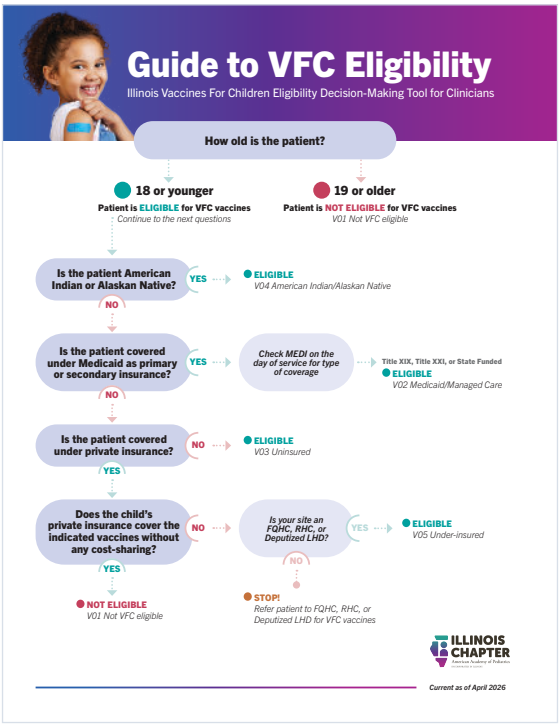
LHDs can use this form to request delegated authority from an FQHC or an RHC to vaccinate underinsured children. The FQHC or RHC must be a VFC provider. Request Memorandum of Understanding (MOU).

LHDs should retain a copy of their MOU and submit it every 24 months during VFC recertification to continue to be able to administer VFC vaccine to underinsured patients. This should be done more frequently if the signers change.

Occasionally, children may be VFC-eligible for more than one eligibility category. A provider must select and document the VFC eligibility category that will require the least amount of out-of-pocket expenses to the parent/guardian for the child to receive necessary immunizations. VFC is an entitlement program, and eligible children are not required to participate.

For further guidance on a patient's VFC eligibility status, please refer to this decision tree from IDPH or this decision tree from ICAAP.





Please use this form (also available in Spanish) or a similar paper-based or electronic form that captures all reporting elements for VFC patient eligibility.

How to Determine a Patient's VFC Eligibility Continued

CHILD'S INSURANCE STATUS	VFC-ELIGIBLE?	VFC ELIGIBILITY CATEGORY
Enrolled in Medicaid	Yes	Medicaid (V02)
Has private health insurance plan with Medicaid as secondary Insurance.	Yes	Medicaid (V02)
Has health insurance covering all vaccines but either: • Does not include first dollar coverage • Has not yet met plan's deductible or • Has not paid for other services received at visit	Yes	Underinsured (V05). This applies even when primary insurer would deny reimbursement for the cost of the vaccine and its administration because the family has not met the plan's deductible.
Has health insurance covering all vaccines and has Medicaid as secondary insurance, but: • Has not yet met plan's deductible or • Paid for other services received at visit	Yes	Medicaid (V02)
Has health insurance covering all vaccines, but the plan has a fixed dollar limit (or cap) on amount that it will cover.	Yes	• Insured (V01) until the family meets the plan's fixed dollar limit. • Underinsured (V05) after the family reaches the plan's fixed dollar limit.
Has an insurance plan that does not cover all ACIP-recommended vaccines.	Yes	Underinsured (V05). Child can only receive vaccines not covered by the plan.
Has health insurance, but plan does not cover any vaccines.	Yes	Underinsured (V05). With implementation of ACA, this situation should be rare.

How to Determine a Patient's VFC Eligibility Continued

CHILD'S INSURANCE STATUS	VFC-ELIGIBLE?	VFC ELIGIBILITY CATEGORY
Enrolled in a Health Care Sharing Ministry.	Yes	Uninsured (V03) – Illinois Department of Insurance does not recognize health care sharing ministries as insurance.
Enrolled in a Medicaid-expansion Children's Health Insurance Program (CHIP)	Yes	Medicaid (V02)
Has no health insurance coverage.	Yes	Uninsured (V03)
Is AI/AN and has private health insurance that covers all vaccinations.	Yes	AI/AN (V04). The provider should choose the eligibility category that is most cost effective for the child's family.
Is AI/AN and has Medicaid.	Yes	Medicaid (V02) or AI/AN (V04). Providers should use Medicaid for the administration fee. This poses the lowest out-of-pocket expense for the child's family.

Administering VFC Vaccines

The CDC recommends preparing vaccines immediately prior to administration to ensure viability of vaccine and prevent vaccine wastage. Vaccines that are not administered immediately are at risk of exposure to temperatures outside of the required range, which can affect vaccine viability and, ultimately, leave children unprotected against vaccine-preventable diseases.

Before administering vaccine to a VFC patient, providers must give each patient or patient's guardian a current version of the VIS for any vaccine being administered that is covered under the National Vaccine Injury Compensation Program (NVICP). Immunize.org has vaccine information statements available in 47 languages, including statements for vaccines not covered by the NVICP. Vaccine manufacturer fact sheets can be provided for other vaccines.

Providers must present current VISs before they administer every vaccine. Before administering VFC monoclonal antibody immunizing products (e.g. nirsevimab, clesrovimab), provide an Immunization Information Statement.

Do not delay use of an ACIP-recommended vaccine because a VIS is unavailable. For any ACIP-recommended vaccine or immunization product that does not yet have a VIS or Immunization Information Statement, clinics can use the manufacturer's package insert, written FAQs, or any other document to inform patients about the benefits and risks of that vaccine. Providers may also produce their own information materials for patients. Once a VIS is available, it should be used. If the vaccine is under an Emergency Use Authorization (EUA), use the EUA Fact Sheet for Recipients in place of a VIS.

In accordance with federal law, VFC providers must maintain immunization records that include ALL of the following elements: 1) name of vaccine administered; 2) date vaccine was administered; 3) date VIS was given; 4) publication date of VIS; 5) name of vaccine manufacturer; 6) vaccine lot number; 7) name and title of person who administered the vaccine; 8) address of clinic where vaccine was administered.

Vaccine Stock

If a VFC provider serves and plans to vaccinate privately insured, non-VFC-eligible patients, the vaccine supply for this population should be stored clearly. To ensure VFC vaccines are administered only to VFC-eligible children, VFC providers serving both VFC and non-VFC-eligible children must maintain vaccine inventories in such a way that they can clearly differentiate public stock from private stock.

CDC does not require VFC providers to maintain a full stock of all ACIP-recommended vaccines for non-VFC-eligible patients if they do not plan to offer all ACIP-recommended vaccines to this population. This guidance includes, but is not limited to, COVID vaccines and RSV monoclonal antibody products.

If a VFC provider chooses to vaccinate privately insured (non-VFC-eligible) patients, the provider should maintain a separate supply of the vaccines they plan to offer to this population.

Using VFC stock to immunize non-VFC-eligible patients is not allowed. VFC vaccine must be stored separately from privately purchased, state-funded, and Section 317-funded (including AIP) vaccine inventories.

Billing — Medicaid Secondary Insurance*

If a child has Medicaid as secondary insurance, there are two options for billing:

1 Administer the VFC vaccine and bill Medicaid for the administration fee. Considerations:

- Easiest way for a provider to use VFC vaccines and bill Medicaid for the administration fee.
- No out-of-pocket costs to the parent for the vaccine or the administration fee.

2 Administer the private stock vaccine and bill the primary insurance. Considerations:

- Provider must bill the patient in a way that is most cost-effective for the family.
- Provider may be reimbursed a higher dollar amount if privately purchased vaccine is administered and both the vaccine and the administration fee are billed to the primary insurer.
- When administering VFC vaccine, providers should NEVER bill two different "payers" (i.e. patient, Medicaid, insurance) for the same vaccine administration fee amount.

Either way, providers must bill the patient in a way that is most cost-effective for the family. The family of a child with Medicaid as secondary insurance should never be billed for a vaccine or an administration fee.

* Consider these options for AI/AN populations that qualify for VFC under a second category as the family may be responsible for administration fees.

Vaccine Administration Fees

VFC vaccines must be provided to an eligible child at no cost for the vaccine. Patients, Medicaid agencies, and third-party payers can never be billed for the cost of the VFC vaccine or other vaccines purchased through CDC federal contracts.

Administration fees can be charged to non-Medicaid VFC-eligible children only and cannot exceed **$23.87** per vaccine dose. VFC providers may issue a single bill for the administration fee for non-Medicaid VFC-eligible children within 90 days of vaccine administration.

Unpaid VFC vaccine administration fees may not be sent to collections. Providers cannot refuse to vaccinate an eligible child whose parents cannot pay or have unpaid vaccine administration fee(s).

Only bill Medicaid for the administration fee for VFC-eligible children enrolled in Medicaid (billed per vaccine and not per antigen).

Reporting Adverse Reactions

VAERS is a national vaccine safety surveillance program that collects reports of adverse events after a vaccine is administered. Clinicians, providers, vaccine manufacturers, and the public can submit reports to VAERS.

Healthcare providers are required by law to report to VAERS:

- Any adverse event listed in the **VAERS Table of Reportable Events Following Vaccination** that occurs within the specified time period after vaccinations.
- An adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine.

Healthcare providers are strongly encouraged to report to VAERS:

- Any adverse event that occurs after the administration of a vaccine licensed in the United States, whether it is or is not clear that a vaccine caused the adverse event.
- Vaccine administration errors.

Adverse events can be reported on the VAERS website via this **online form**. A link to the form can be found in I-CARE under **Home** > **Immunization Links** > **VAERS.**

Also, clinicians must report any additional selected AEs and/or any revised safety reporting requirements per FDA's conditions of authorized use of vaccine(s) throughout the duration of any COVID-19 vaccine's Emergency Use Authorization (EUA) as outlined in the **Fact Sheet for Healthcare Providers**.

Adverse events that occur after administration of RSV monoclonal antibodies (nirsevimab or clesrovimab) alone should be reported to **MedWatch online**. Adverse events that occur after the coadministration of an RSV monoclonal antibody and vaccine should be reported to VAERS. In this case, reporting the same adverse events to MedWatch is not necessary.

Record Keeping

The National Childhood Vaccine Injury Act requires providers to document the date and name of the vaccine, manufacturer, lot number, name and business address of the person who administered the vaccine, VIS version date, and the date the VIS was provided to the parent/guardian. Records should be maintained for a minimum of three years or longer, if required by state law (even in the case of provider retirement or provider location closure). Digital or electronic storage of records is allowable. As requested, site must make these records available for review. VFC records include, but are not limited to:

- VFC screening and eligibility documentation
- Medical records that verify receipt of vaccine, vaccine ordering records, and vaccine purchase and accountability records
- Billing records

Section Nine

Compliance Site Visits & Immunization Quality Improvement for Providers

Site Support

Each VFC site is assigned a Regional Coordinator from IDPH. The Regional Coordinator will review and provide technical assistance to meet the VFC compliance requirements. The Regional Coordinator will support the implementation of provider-level quality improvement strategies designed to increase vaccine uptake among child and adolescent patients in adherence to the ACIP recommended routine immunization schedule.

According to law, providers may disclose patient health records to health officials within the VFC Program without patient permission. Information obtained from patient records will be kept confidential.

Compliance Site Visit

Compliance site visits (CSV) involve a review and evaluation of VFC provider practices. These types of visits are a legal requirement of the VFC program. A Regional Coordinator will conduct the compliance site visit. The visit will allow IDPH to determine if VFC vaccines are being distributed, handled, and given to patients according to program policies.

Each VFC provider is required to have a CSV every 12–24 months. This visit includes reviewing and ensuring compliance with:

- The Provider Profile.
- Vaccine ordering and inventory management.
- Policies, procedures, and Vaccine Management Plan.

Compliance Site Visit (CSV) Continued

- Vaccine storage and handling equipment, procedures, and documentation
- VFC screening requirements and billing practices
- Availability of all ACIP vaccines to VFC-eligible patients
- VFC-related document retention

If problems are identified during the visit, the Regional Coordinator will work with provider staff to create a corrective action plan. A provider is required to take action to correct any VFC deficiencies within the specified time given. Failure to do so may result in vaccine delivery suspension or termination from the VFC program.

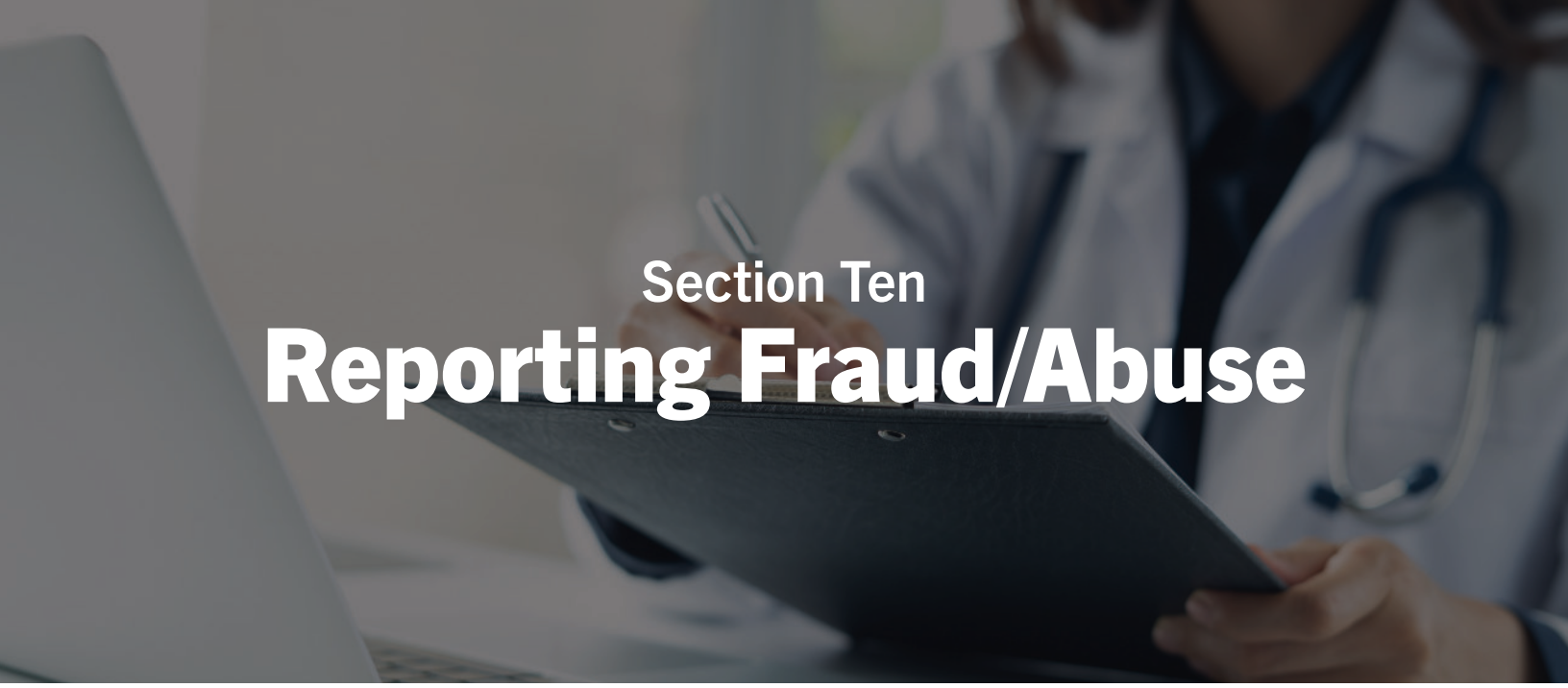
Immunization Quality Improvement for Providers (IQIP)

The purpose of IQIP is to support providers in implementing quality improvement strategies that increase childhood and adolescent coverage levels in line with the ACIP schedule. “Coverage” refers to the proportion of a target population that has received a specific number of vaccine doses within a given timeframe. It is measured as a percentage and is an important indicator of how well communities are protected against vaccine-preventable diseases.

IQIP helps providers understand their current coverage levels and missed opportunities, adopt new immunization delivery strategies, refresh patient data, and use I-CARE’s data and reports to strengthen services.

IQIP is a 12-month process that includes **four visits over the course of one year.** The initial site visit reviews clinic workflow, baseline child and adolescent coverage levels, and a review of the national IQIP Strategies and best practices. IDPH IQIP Consultants will help your clinic identify action items for increasing coverage levels among child and adolescent patients. Following the initial visit, there are three check-ins completed at two, six, and 12 months. Technical assistance is provided at each visit, and coverage levels are compared to baseline at six and 12 months.

IQIP is a collaborative process focused on partnership and quality improvement and is not an audit. VFC providers should expect to participate in IQIP every three to four years and visits typically take place virtually but can be scheduled in person if a site prefers. IDPH staff will reach out to VFC Coordinators to schedule IQIP visits. If your clinic is interested in scheduling an IQIP visit, please email your regional staff representative.

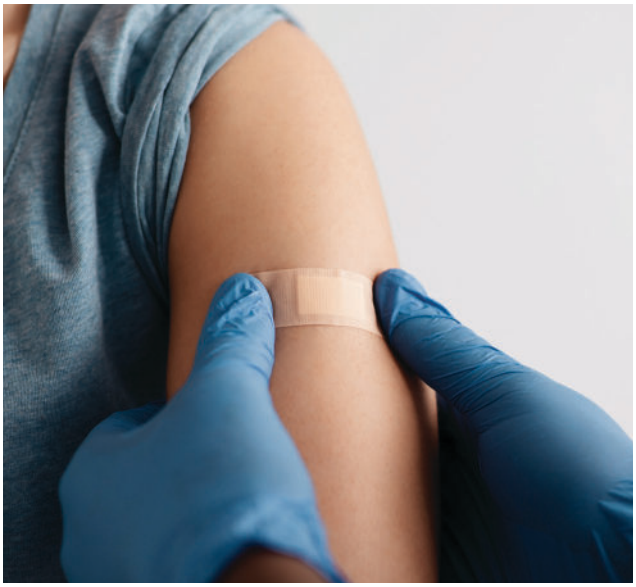


Section Ten

Reporting Fraud/Abuse

Reporting Fraud/Abuse

Misuse of publicly funded VFC or other publicly funded vaccines is prohibited, and all enrolled sites are expected to follow program requirements. Everyone involved in a site's VFC operations is responsible for reading and understanding the Fraud and Abuse Policy. The policy outlines examples of actions that constitute fraud or abuse—such as providing VFC vaccine to ineligible patients, misdirecting vaccine, improper billing, failing to follow VFC enrollment or eligibility screening requirements, or improper vaccine storage—and explains the steps IDPH may take if concerns arise. Providers should review the full Fraud and Abuse Policy for detailed guidance and expectations.



Fraud and Abuse Protocol for Illinois Providers

Section Eleven

I-CARE Reports

I-CARE Reports

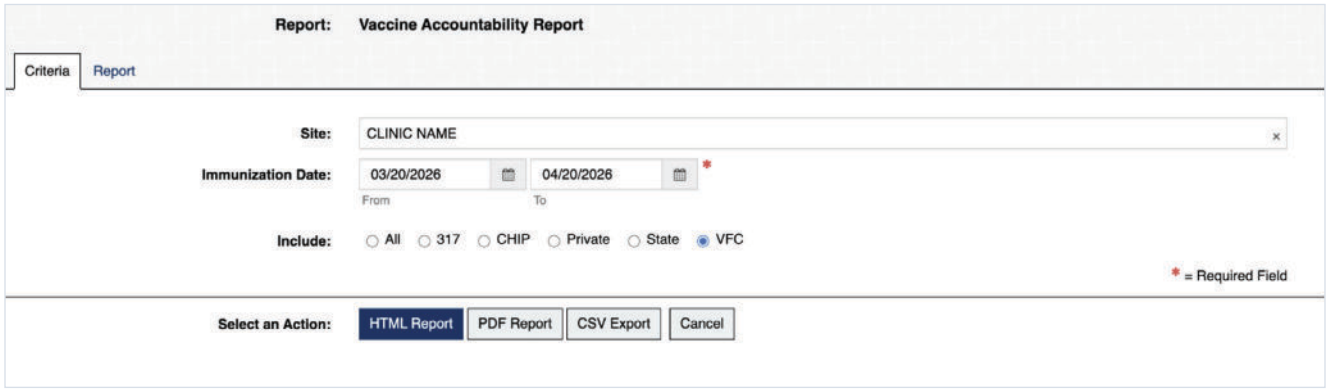
I-CARE is where clinics can log immunization records, pull reports, enroll in programs, manage vaccine inventory, and more. It is an extremely helpful tool. Here are some of the most common types of reports that can and should be used to improve inventory practices and vaccine uptake.

- **Coverage Level Reports:** Track coverage rates; generate patient lists; review childhood and adolescent coverage.
- **Ad Hoc Reports:** Build customizable patient or immunization lists.
- **Reminder/Recall:** Customize letters/postcards; generate notices for patients due or overdue for vaccines.
- **Site Reports:** Identify invalid addresses/doses; review missed opportunities; monitor missing lots; view monthly stats; export patient lists; track shot refusals; review HL7 upload errors.
- **Vaccine Management Reports:** View appliances and temperature logs; see immunizations due/given; monitor activity; track accountability, VIS dates, inventory, and transactions; view NDC-to-I-CARE mapping.
- **VFC Reports:** Identify VFC inventory issues; review mismatches; view active provider lists; export shipping data.

Vaccine Accountability Report

Generate a report summarizing doses administered, wasted, and expired during a selected time period. Users can choose both the date range and the correct funding source (VFC, 317 for AIP, or State for IVAP) to ensure the report reflects only the doses from that program's inventory. A 12-Month Inventory Summary, including the provider's wastage level, is also included in this report and can help identify trends and support compliance with vaccine accountability requirements.

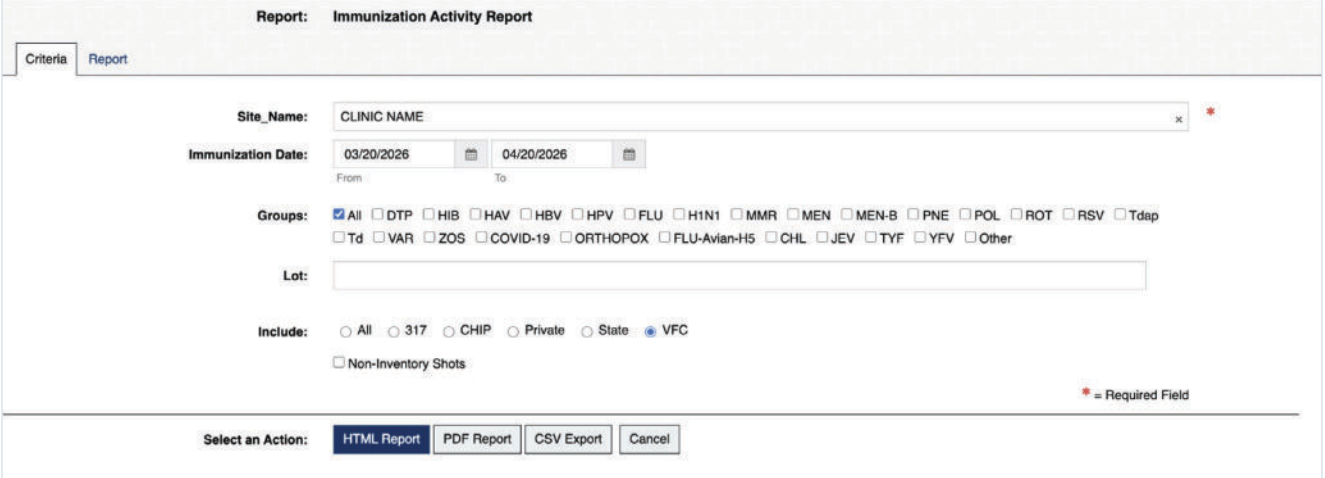
Note: Excessive waste is defined as three (3) percent of the total amount of vaccines received in the previous 12 months. Wastage percent can be found on the site's 12-Month Inventory Summary (the last page of the Accountability Report).



Vaccine	Brand	NDC	Doses on Hand	Lot Num/ Exp Date	Wst/Exp Doses	Age: <1	1	2	3-5	6	7-10	11-12	13-18	>18	Total
COVID-19	Spikevax COVID-19 (2025-2026 12+ years)	80777-0112-96	10	3052741 (VFC) 05/15/2026	--	--	--	--	--	--	--	--	--	--	--
COVID-19	Spikevax COVID-19 (2025-2026 12+ years)	80777-0112-96	10	3052668 (VFC) 05/14/2026	--	--	--	--	--	--	--	3	5	--	8
COVID-19	Spikevax COVID-19 (2025-2026 6m-11y)	80777-0113-80	17	3053481 (VFC) 06/11/2026	--	--	--	1	3	1	3	1	--	--	9
DTP	INFANRIX	58160-0810-52	34	M4ZE7 (VFC) 11/13/2027	--	--	5	--	2	1	--	--	--	--	8
DTP,HIB,POL,HBV	VAXELIS	63361-0243-15	38	U8372AA (VFC) 01/31/2028	--	34	2	--	--	--	--	--	--	--	36
DTP,HIB,POL,HBV	VAXELIS	63361-0243-15	20	U8512AA (VFC) 04/30/2028	--	--	--	--	--	--	--	--	--	--	--

Immunization Activity Report

Generate a summary list of all immunizations administered during a selected time period. Users can specify the date range and select the appropriate funding source (such as VFC, 317 for AIP, or State for IVAP) to view only the doses associated with that program. This report is useful for reviewing administered doses, reconciling inventory, and confirming that documentation aligns with vaccine usage.

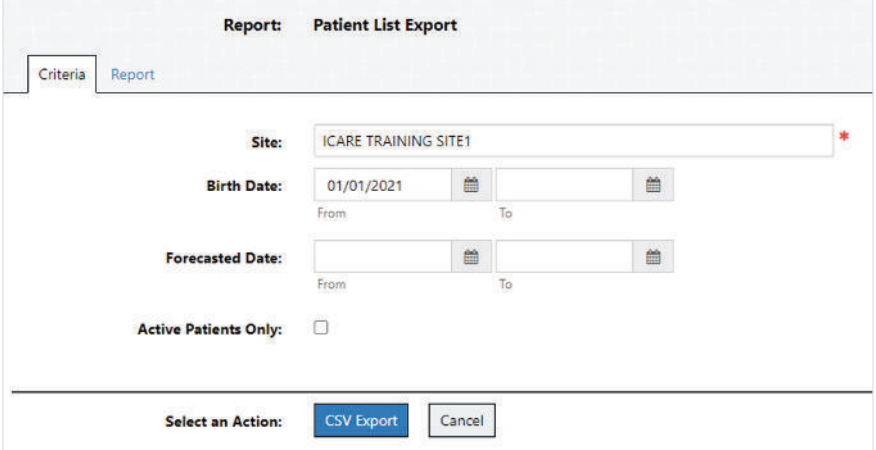


Name	Birth Date	Shot Date	Tran Date	From Stock	Vaccine Groups	Vaccine Name	Lot Number	VFC Status	Lot Type
[redacted]		03/31/2026	03/31/2026	Y	FLU	Fluzone Trivalent, Pfree	U8889BA	V02	VFC
		04/14/2026	04/14/2026	Y	DTP,HIB,POL,HBV	VAXELIS	U8372AA	V02	VFC
		04/14/2026	04/14/2026	Y	PNE	PREVNAR 20	MH1445	V02	VFC
		04/14/2026	04/14/2026	Y	ROT	Rotarix	94A7Z	V02	VFC
		04/10/2026	04/10/2026	Y	DTP,HIB,POL,HBV	VAXELIS	U8372AA	V02	VFC
		04/10/2026	04/10/2026	Y	PNE	PREVNAR 20	MH1445	V02	VFC
		04/10/2026	04/10/2026	Y	ROT	Rotarix	94A7Z	V02	VFC

Patient List Export & Managing Active Patients

Before running any reports, consider completing a **Patient Refresh**. This will ensure patient data is the most up-to-date and reports do not include patients who have not been seen in a long time.

I-CARE can generate a comma-delimited text file, i.e. an Excel spreadsheet, of patients that match a given criterion. Under the reports tab, scroll down to **"Site Reports,"** and then click on the **"Patient List Export"** link.



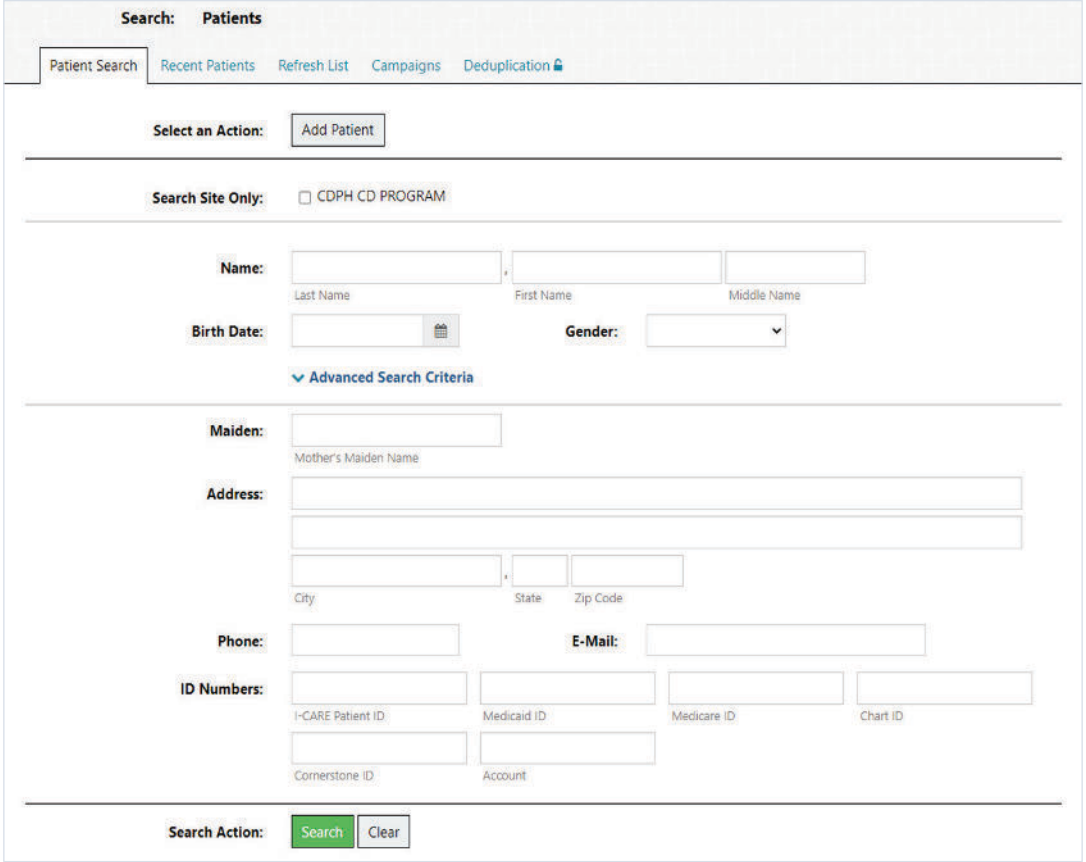
Select the site for the requested report by typing the name or entering the associated VFC pin. Then select a range of patient DOBs for **"Birth Date."** Next to **"Forecasted Date,"** select the range for the desired vaccination dates. Next, select the **"Active Patients Only"** checkbox unless searching for historical data. Click the **"CSV Export"** button and I-CARE will generate a report based on the criteria entered.

Active patients can be monitored in I-CARE in two ways, either by searching in the top search bar with **"Patients"** selected in the dropdown menu:

Or under the **"Patients"** tab located just below that:

Patient List Export & Managing Active Patients Continued

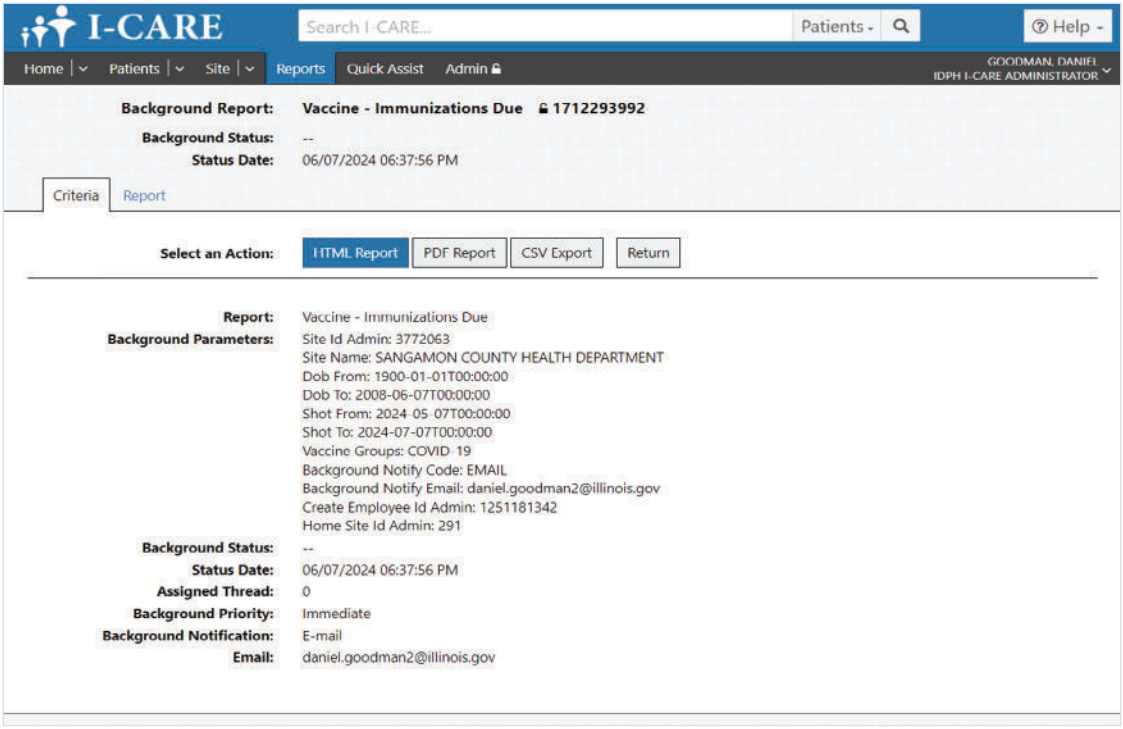
While the main search bar is useful for finding the records for individual patients, the **"Patients"** tab provides a more robust search, the option of an advanced search function, as well as a button to manually add a new patient.



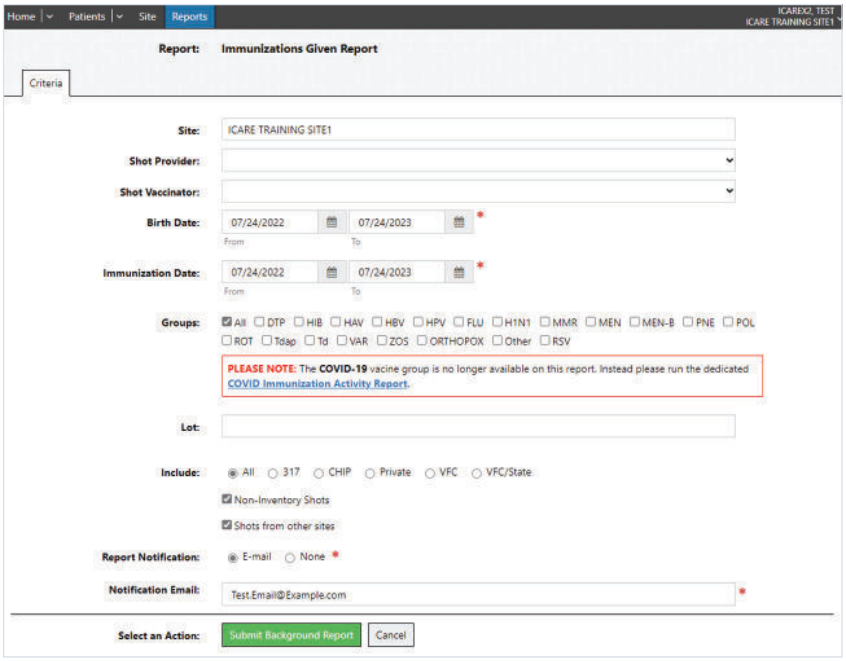
Clicking on the downward facing arrow next to the word **"Patients"** will show a list of recently viewed patients, as well as an option to clear that list.

Immunizations Due & Immunizations Given

The Immunizations Due Report will generate a list of active patients who are overdue for a particular vaccination. Use this report to determine which patients need to come in and to help use vaccines that are expiring soon.

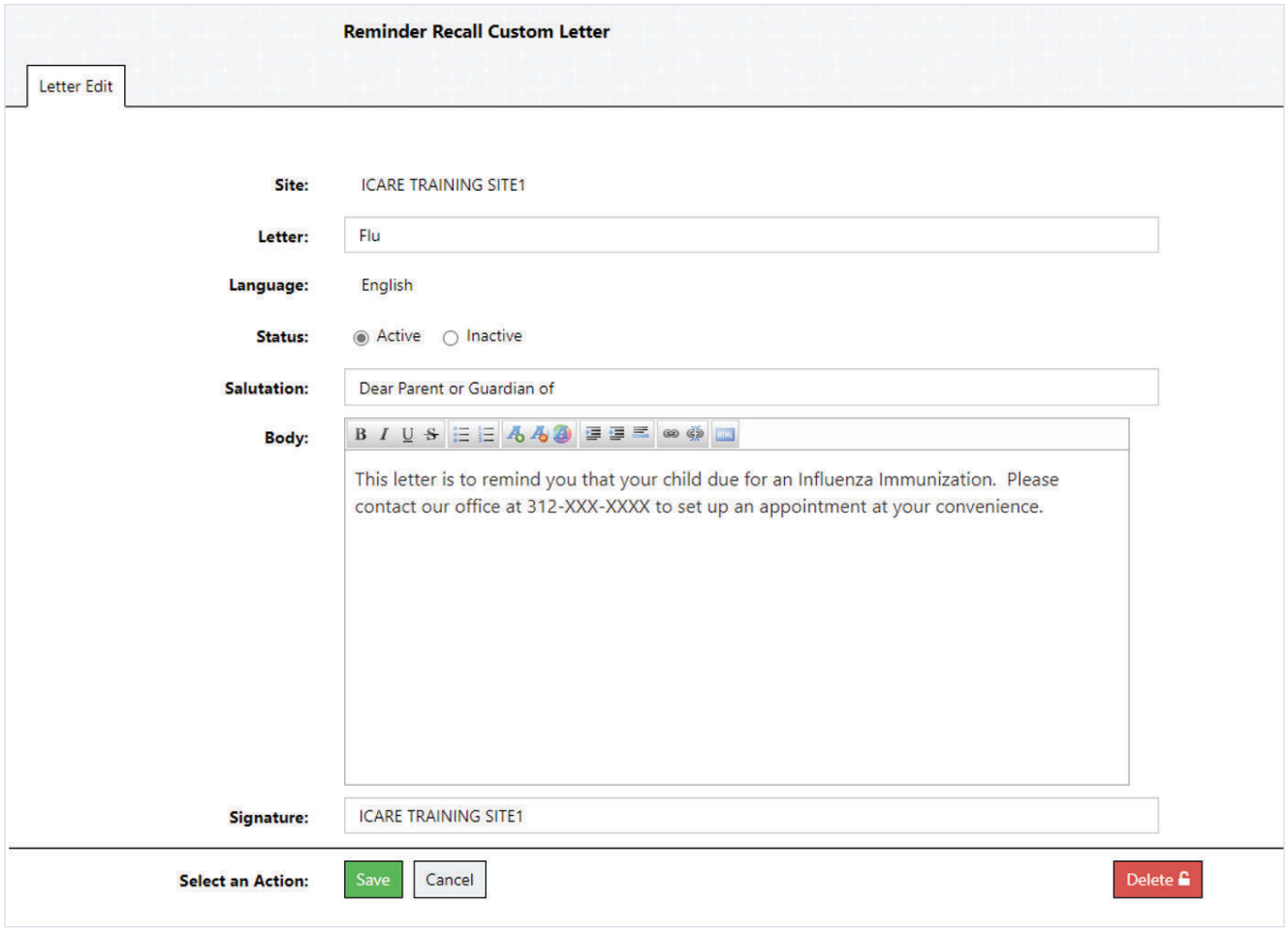


The Immunizations Given Report will generate a list of active patients who received a dose during the specified time frame. Use this report to review immunizations given over specific time frames, to target missing doses, or to review possible data entry issues.



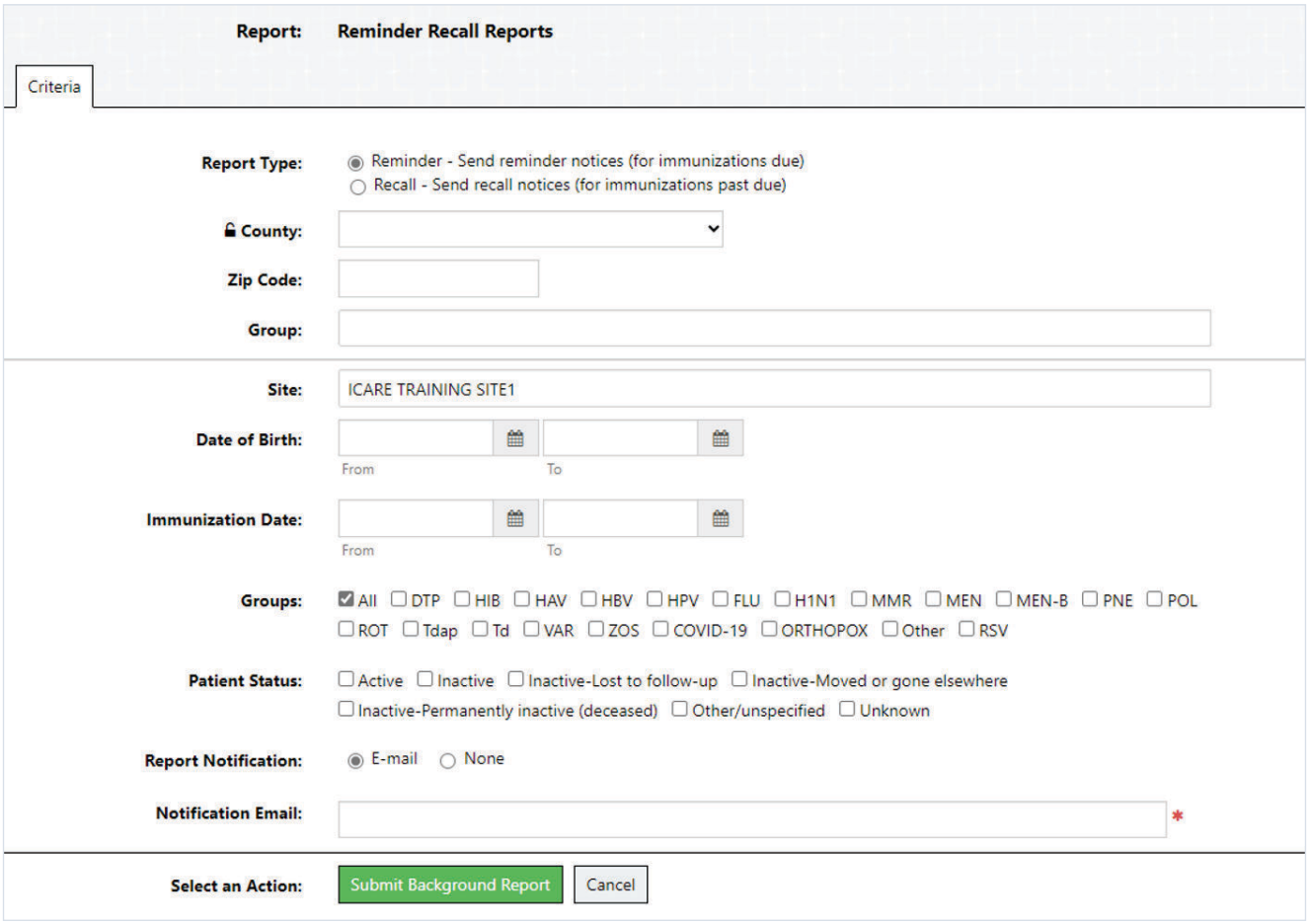
Customize Letters & Reminder Recall

Customize Letters can be used to create customized messages to send to patients about returning for forecasted or overdue vaccinations. Custom Letter options include: **“Site Name,” “Letter Subject,” “Language/ Translation,” “Status (Active or Inactive Patients),” “Salutation, Body, and Signature.”** These messages are most used during a reminder recall campaign to send mass mailings to a large patient population.

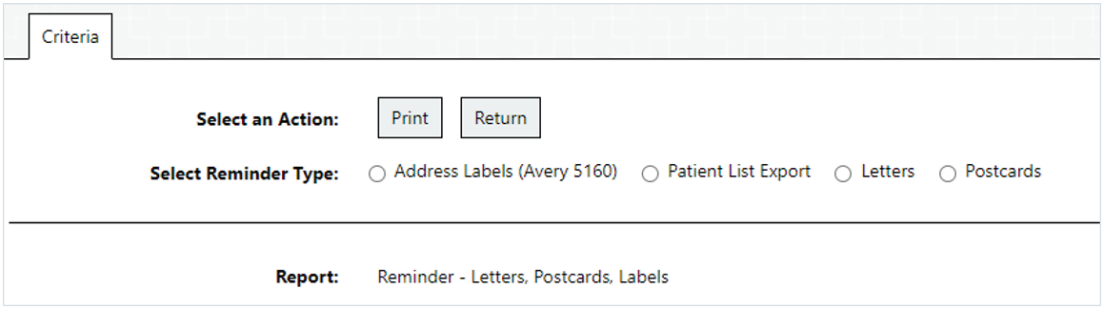


Customize Letters & Reminder Recall Continued

Reminder Recall Reports are used to remind patients of a future vaccination or to target patients who are past due for a vaccination. Providers can generate a patient list or use customized letters to send out notifications.



Once the background report is completed, sites can print address labels, download the list, or send customized letters/postcards to patients.



Coverage Level Childhood & Coverage Level Adolescent

These reports are used to generate immunization coverage levels on active patients which match the search criteria.

Vaccinations received by their 2nd birthday for all active patients that are 2 years old as of the report date

TOTAL SELECTED PATIENTS: 365

VACCINE SPECIFIC COVERAGE LEVELS	Number of Patients	Percent	Healthy People 2020/2030 Target
DTaP 4+:	290	79.5%	90%(1)
Polio 3+:	339	92.9%	90%
MMR UTD:	330	90.4%	90%(1)
Hib UTD:	316	86.6%	90%
Birth Dose Hep. B (HBV):	330	90.4%	85%
Hep. B (HBV) UTD:	340	93.2%	90%
Varicella (VAR) 1+:	328	89.9%	90%
PCV UTD:	323	88.5%	90%
Rotavirus (ROT) UTD:	315	86.3%	80%
Hep. A (HAV) 1+:	322	88.2%	85%
Hep. A (HAV) 2+:	197	54.0%	85%
Flu/Influenza (Flu) 2+:	187	51.2%	80%

Childhood Coverage Level

Childhood Coverage Level counts how many active patients are at a clinic and provides a percentage of how many patients are fully vaccinated for each vaccine group before their 2nd birthday. This report measures 2-year-olds and shots received before age 2.

Vaccinations received by their 13th birthday for all active patients that are 13 years old as of the report date.

TOTAL SELECTED PATIENTS: 506

VACCINE SPECIFIC COVERAGE LEVELS	Number of Patients	Percent	Healthy People 2020/2030 Targets
Tdap 1+:	461	91.1%	80%
Polio UTD:	490	96.8%	95%
MMR UTD:	502	99.2%	95%(1)
Hep. B (HBV) UTD:	497	98.2%	95%
Varicella (VAR) 2+:	494	97.6%	90%
MenACWY UTD:	455	89.9%	80%
MenACWY 1+:	455	89.9%	80%
HPV 1+:	398	78.7%	
HPV UTD:	305	60.3%	80%
Hep. A (HAV) 2+:	480	94.9%	
VACCINE SERIES COMPLETE COVERAGE LEVELS Tdap 1+, MenACWY 1+, HPV UTD:	303	59.9%	

Vaccinations received by their 17th birthday for all active patients that are 17 years old as of the report date.

TOTAL SELECTED PATIENTS: 545

VACCINE SPECIFIC COVERAGE LEVELS	Number of Patients	Percent	Healthy People 2020/2030 Targets
Tdap 1+:	535	98.2%	80%
Polio UTD:	513	94.1%	95%
MMR UTD:	533	97.8%	95%(1)
Hep. B (HBV) UTD:	515	94.5%	95%
Varicella (VAR) 2+:	521	95.6%	90%
MenACWY UTD:	366	67.2%	80%
MenACWY 1+:	536	98.3%	80%
MenACWY 2+:	422	77.4%	
MenB 1+:	364	66.8%	
HPV 1+:	512	93.9%	
HPV UTD:	449	82.4%	80%
Hep. A (HAV) 2+:	512	93.9%	
VACCINE SERIES COMPLETE COVERAGE LEVELS Tdap 1+, MenACWY 1+, HPV UTD:	447	82.0%	

Adolescent Coverage Level

Adolescent Coverage Level reports: A 13-year-old report and a 17-year-old report. The 13-year-old report measures whether a 13-year-old child is up to date before their 13th birthday. The 17-year-old report does the same for 17-year-olds before their 17th birthday.

Invalid Doses

This report is used in quality assurance review and flags any problems. It looks at each vaccine and vaccine group and matches against the vaccine administration schedule to make sure vaccines are being administered correctly.

Patient Name	Birth Date	Shot Date	Vaccine	Vaccine Group	Reason
NAME, EXAMPLE	03/07/2023	04/13/2023	DTaP, unspecified formulation	DTP	Minimum age for 1st shot is 6 weeks old

Missed Opportunities Detail

This report shows a summary of patients who have missed opportunities; it is also used in quality assurance visits. Generate a Missed Opportunity Summary report that will show all missed opportunities for an entire site. When a patient presents for vaccination, make sure to give all vaccines that are due and overdue at the same time if possible.

Childhood Birth Range: From 06/25/2020 To 07/24/2021

Patient Name	Birth Date	Vaccine Missed	Dose # Missed	Last Visit Date	Forecasted Date
NAME, EXAMPLE	12/13/2020	DTP	1	04/13/2021	02/13/2021
NAME, EXAMPLE	12/13/2020	HBV	1	04/13/2021	12/13/2020
NAME, EXAMPLE	12/13/2020	PNE	1	04/13/2021	02/13/2021
NAME, EXAMPLE	12/13/2020	POL	1	04/13/2021	02/13/2021

Section Twelve

Site Updates

Moving to a New Location

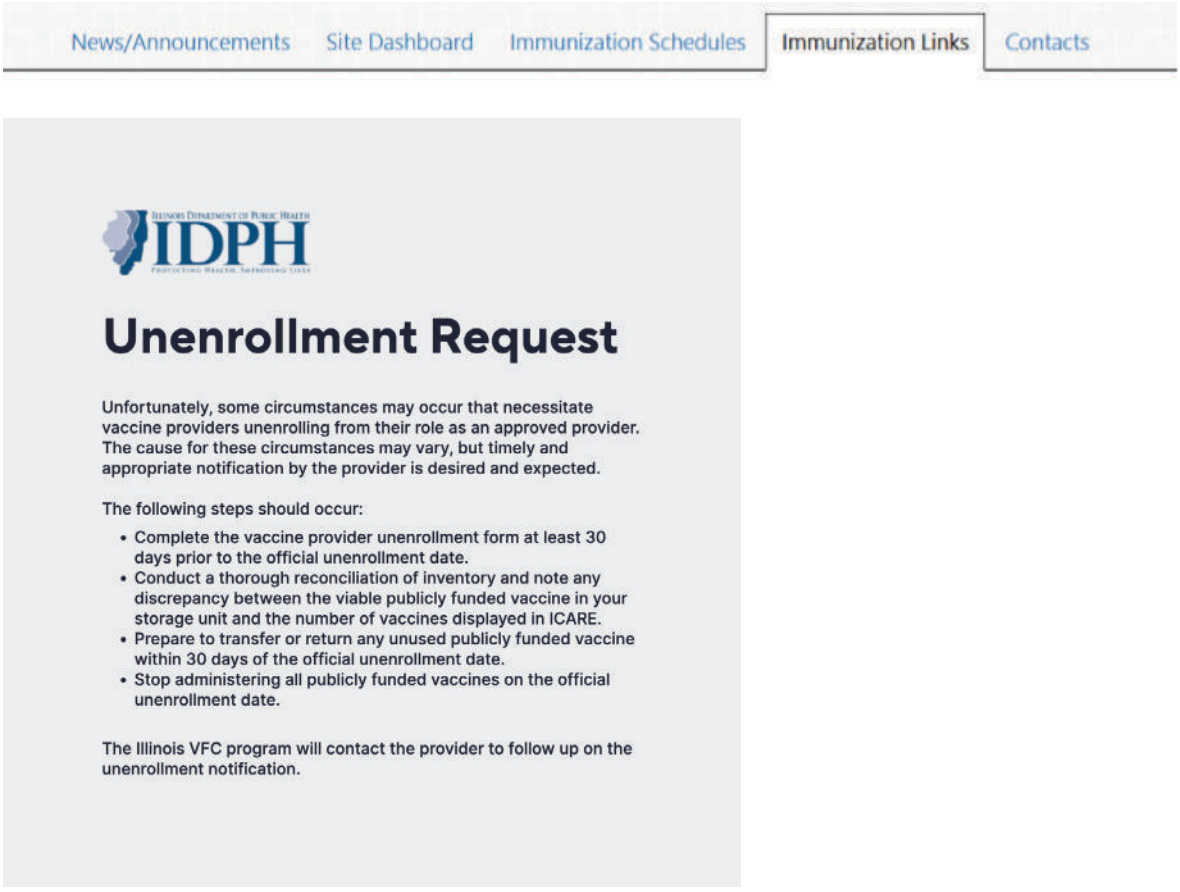
Sites must notify the IDPH Immunization Program before a clinic moves so the equipment and plan to transport the VFC vaccines can be reviewed/approved. Use the **"Vaccine Program Site Updates"** in I-CARE's Quick Assist, under Illinois/Downstate Publicly Funded Vaccine Programs. Do this ***at LEAST 30 DAYS ahead of time.*** Sites must report any new equipment that may be used. A newly-installed or -repaired refrigerator can take 2-7 days for temperature stabilization, and a freezer can take 2-3 days to stabilize temperature. There must be a minimum of two consecutive days of stabilized temperatures in newly installed, newly repaired, or moved refrigerators and freezers for **existing providers.**

Unenrolling From VFC

If a site is planning to unenroll, it is important to notify IDPH as soon as possible by completing this unenrollment form. Please keep documenting temperatures of vaccines until the established unenrollment date.

Helpful Tips:

- Provide at least a 30-day notice of unenrollment.
- Be ready to provide at least 3 months of DDL temperature data to IDPH.
- Reconcile inventory.
- Try to transfer remaining viable vaccines. LHDs are a great place to start!



Thank You for Being a VFC Provider

Your commitment to offering the Vaccines for Children program at your clinic makes a real difference in the lives of the families you serve. The work you do every day, screening patients, managing vaccine inventory, staying up to date on requirements, and ensuring no child misses a recommended immunization due to cost, is what makes vaccines truly accessible for all children in Illinois. We are grateful for your partnership and dedication, and we look forward to continuing to support you in this important work.