Louisiana
Vaccines for Children (VFC) Program
Provider Manual

Office of Public Health
Immunization Program

Revised January 2025

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SECTION I: VFC Program Overview

Introduction

The Federal Vaccines for Children (VFC) Program was created by the Omnibus Budget Reconciliation Act of 1993 and implemented as a new entitlement program to be a required part of each state's Medicaid program. The Centers for Disease Control and Prevention (CDC) purchases vaccines at a discounted rate from manufacturers and distributes them to its grantees, which include state health departments and certain local and territorial public health agencies, including the Louisiana Department of Health, Office of Public Health, Immunization Program. The grantees are then able to offer the vaccines at no charge to private physicians' offices and public health clinics registered as VFC providers.

Benefits to Providers and Patients

The VFC Program reduces barriers to immunization opportunities for Louisiana's children, helping to protect them from vaccine-preventable diseases and also helping them to maintain a consistent source of medical care. Children who might otherwise not have access to vaccines can receive them free of charge from VFC providers. In turn, VFC providers enjoy cost savings on vaccines, as well as access to a variety of resources that the Louisiana VFC Program offers.

Benefits to Providers

- VFC vaccine provided at no cost
- Free program participation
- Immunization coverage assessments
- Reduces families' out-of-pocket expenses
- Ensures timely vaccinations
- Keeps patients in medical home for comprehensive health care
- Easier to provide high-quality care to patients
- Updates and training for staff members

Benefits to Patients

- Ensures timely immunizations
- Reduces missed opportunities for immunizations
- No out-of-pocket costs to families for vaccines
- Easier to stay within the medical home for comprehensive health care

Provider Responsibilities Overview

Providers who are enrolled in the Louisiana VFC Program must comply with program requirements in order to receive VFC vaccines. Requirements include:

- Consistent screening of patients for VFC eligibility
- Administering VFC vaccines to VFC-eligible patients only
- Never denying vaccinations to VFC-eligible patients
- Never charging patients for the cost of VFC vaccine
- Ordering vaccines appropriately

- Complying with the current Advisory Committee on Immunization Practices (ACIP)-recommended Immunization Schedule
- Providing patients and/or parents with Vaccine Information Statements (VISs) for each vaccine administered
- Reporting clinically-significant adverse events to the Vaccine Adverse Event Reporting System (VAERS)
- Properly documenting all immunizations administered to patients in the Louisiana Immunization Registry (LINKS)
- Ensuring office staff are trained in vaccine storage and handling and vaccine administration
- Carefully managing vaccine stock through inventory reconciliation, maintaining proper storage temperatures, and the use of approved storage and temperature-monitoring equipment
- Communicate any vaccine storage issues to the VFC Program immediately

SECTION II: VFC Enrollment

The VFC Program benefits patients and practices by providing routine vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) at no cost. Providers interested in enrolling in the Louisiana VFC Program can request information and/or an application by contacting the Immunization Program at 504-568-2600 or La.Immunization@La.Gov.

Immunization Program staff will follow-up with the requesting provider or facility to review the application and discuss VFC Program requirements. VFC Program requirements include:

- Appropriate refrigerator and freezer storage equipment and circuit breakers.
- Appropriate temperature monitoring devices with certificates of calibration.
- Completion of Immunization Program and CDC modules and trainings.
- Letter documenting the facility's vaccination administration fee showing a cap of $21.30.
- Confirmation of the facility/practice's Vaccine Management Plan that identifies an emergency back-up facility and contact person.
- Confirmation of the facility/practice's floor plan showcasing the location of the vaccine storage equipment.

Immunization Program staff will work closely with providers during the enrollment process to ensure that providers are aware of VFC rules and regulations, have completed all required trainings, and storage equipment functionality has been tested and documented. Providers may begin ordering vaccine once they have been notified that all requirements have been met.

SECTION III: Provider Responsibilities for VFC

Patient Eligibility and Screening

Providers are responsible for ensuring that VFC vaccine is administered to VFC-eligible children only and are required to maintain a Patient Eligibility Screening Record on all VFC-eligible children.

Patient Eligibility

Children through 18 years of age who meet at least one of the following criteria are eligible for VFC vaccine under federal and/or Louisiana guidelines:

- **Louisiana Medicaid-enrolled** – a child who is eligible for, or enrolled in, the Louisiana Medicaid program
- **Uninsured** – a child who has no health insurance coverage
- **American Indian or Alaska Native** – as defined by the Indian Health Service Act (25 U.S.C. 1603)
- **Underinsured*** – a child who has commercial (private) health insurance, but the coverage does not include vaccines, a child whose insurance covers only selected vaccines (VFC-eligible for non-covered vaccines only), or a child whose insurance caps vaccine coverage at a certain amount. Once that coverage amount is reached, the child is categorized as underinsured.
  **Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC), a Rural Health Clinic (RHC), or a Parish Health Unit.*

Not Eligible for VFC

- LaCHIP (Louisiana's Children's Health Insurance Plan)
- Privately insured patients with full vaccine coverage
- Anyone 19 years of age and older

Screening for VFC Eligibility

VFC recommends the use of the Patient Eligibility Screening Record, which can be found in the LINKS document center. Providers may use this form to incorporate into their own practice forms, EHR, or EMR. All fields on the Patient Eligibility Form must be incorporated into their system.

- Screening of the child must occur at every immunization visit.
- Providers must maintain a record (paper or electronic) of the screening for at least three years after the last administered VFC vaccine. After three years have passed, these records may be archived.
- The record must be readily available, whether electronic or paper, in the provider's office.

Table 1: VFC Eligibility Scenario

Source: Centers for Disease Control and Prevention's VFC Operations Guide

VFC eligibility scenario: Child insured and…	***Insurance Status***	***Is child VFC eligible?***
Has not yet met plan's deductible.	*Insured*	***No, not VFC eligible***

Has health insurance plan that does not cover all ACIP-recommended vaccines.	*Under-Insured*	***Yes, VFC eligible***
Has health insurance, but plan does not cover any vaccines.	*Under-Insured*	***Yes, VFC Eligible***
*Plan covers only a portion of the vaccine cost and **does not** have Medicaid as secondary insurance.*	*Insured*	***No, not VFC eligible***
Seeking contraceptive or STD services at school-based clinic or facility whose main services are primary or acute care and wants to be immunized, but does not want to access insurance.	*Insured*	***No, not VFC eligible***
Seeking contraceptive or STD services at family planning clinic or STD clinic and wants to be immunized, but does not want to access insurance or doesn't know status.	*Uninsured*	***Yes, VFC eligible***
Has Private Insurance and Medicaid as secondary insurance.	*Medicaid eligible*	***Yes, VFC eligible***
*Plan covers only a portion of the vaccine cost **and** has Medicaid as secondary insurance.*	*Medicaid eligible*	***Yes, VFC eligible***
*Has not yet met plan's deductible **and** has Medicaid as secondary insurance.*	*Medicaid eligible*	***Yes, VFC eligible***
Has health insurance covering all vaccines, but the plan has a fixed dollar limit or cap on amount that it will cover.	• *Insured until the fixed dollar limit is met* • *Underinsured after the fixed dollar limit is reached*	***Yes, VFC eligible***
Has no health insurance coverage	*Uninsured*	***Yes, VFC eligible***

VFC Fees and Finance

Providers participating in the VFC Program must **not** charge patients for the cost of VFC vaccine. While providers may charge patients an administration fee for each vaccine, such a fee must not

exceed the fee cap established by the Center for Medicaid and Medicare Services (CMS) and the State of Louisiana, which is currently **$21.30** per vaccine dose. If providers choose to bill for the vaccine administration fee of a non-Medicaid, VFC-eligible child after the date of service, providers may issue only a single bill to the patient within 90 days of vaccine administration. Lastly, immunization services shall not be denied to any VFC-eligible child, even if the parent or guardian is unable to pay the administration fee (applies to non-Medicaid eligible children); in this case, the fee is waived.

ACIP-Recommended Schedule

VFC providers must comply with current immunization schedules, dosage, and contraindications as established by the ACIP.

- The VFC Program makes every effort to inform providers of changes to the schedule and vaccine recommendations, but it is ultimately the providers' responsibility to ensure their practice is following current guidance. The latest immunization schedule from birth to aged 18 can be found here.
- All recommended vaccines for a provider's patient population must be kept in supply and made available to eligible patients.
- Doses not given at the recommended age should be given at any future visit when indicated and feasible.
- Licensed combination vaccines such as Pediarix®, Pentacel®, and Vaxelis® may be used whenever any components of the combination are indicated and other components of the vaccine are not contraindicated.
- Providers should consult the manufacturers' package inserts for detailed recommendations.

Record Keeping

The National Childhood Vaccine Injury Act (NCVIA) of 1986 established a "no-fault" system to compensate children and their families following adverse events associated with childhood immunization. NCVIA also established documentation standards for immunization providers, mandated the use of Vaccine Information Statements (VISs), and mandated the reporting of certain adverse events following vaccination to Vaccine Adverse Event Reporting System (VAERS).

Documentation of Immunizations

Federal law requires that, for all vaccines covered by the NCVIA, regardless of the funding source (public or private), providers must record the following information for each dose of vaccine administered:

- The type of vaccine
- The manufacturer and lot number
- The date administered
- The signature of the person administering the vaccine
- Administration site
- The publication date of the Vaccine Information Statement (VIS)

This information may be maintained in the patient's electronic or paper chart, or in a central immunization log but must be available for review by Immunization Program staff. The Louisiana VFC Program requires the use of a Vaccine Administration Record in the patient's chart. This form consolidates all the required information on a single sheet, and allows rapid assessment of a child's immunization status.

Vaccine Information Statements (VISs)

As required under the National Childhood Vaccine Injury Act (42 U.S.C. §300aa-26), all health care providers in the United States who administer vaccines to any child or adult shall, prior to administration of each dose of the vaccine, provide a copy of the relevant current edition of the Vaccine Information Statement (VIS) to that individual or the parent/legal guardian.
Some of the legal requirements for providers regarding the use of VISs are as follows:

- Before vaccinating a child with a dose of any routine childhood immunization, a healthcare provider is required by federal law to provide a copy of the most current VIS available for that vaccine to the child's parent/legal guardian or the patient.
- The parent/guardian must be given time to read the VIS prior to administration of the vaccine.
- The parent/guardian must be offered a copy of the VIS to take home after the immunization is given.
- Providers must record in the patient's paper or electronic record the date the VIS was given (that is, the date the vaccine was administered).
- Providers must also record the publication date of the VIS (which appears at the bottom of the document).
- Providers must offer the parent/guardian a copy of the VIS every time a dose in a vaccine series is given, even if the child has received previous doses of the same vaccine.
- The law applies to all doses of vaccine covered by the National Childhood Vaccine Injury Compensation Program and administered by a provider, whether VFC vaccine or privately purchased.

If there is not a VIS for a non-routine combination vaccine (e.g., Pediarix® or Pentacel®), provide the VISs for all combination-vaccine components. CDC'S "multi-vaccine" VIS may be used as a substitute for any or all the VISs for routine vaccines given from birth through six months: DTaP IPV, Hib, PCV, Hepatitis B, and Rotavirus.

VISs may be downloaded and printed from the LINKS website.

VISs are also available in a variety of foreign-language translations; these may be downloaded from the Immunize.org website at www.immunize.org.

Adverse Event Reporting

The Vaccine Adverse Event Reporting System (VAERS), jointly managed by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA), provides monitoring of vaccine safety after a vaccine has been licensed for use. Reviews of adverse event reports submitted to VAERS can identify potential problems not observed during pre-licensure

trials, because certain rare adverse events become apparent only when a vaccine is used in a larger population.

Under federal law, any event listed in the manufacturer's package insert as a contraindication to subsequent doses of the vaccine must be reported. Providers may submit completed VAERS forms by mail or fax at (877) 721-0366. Providers may also enter reports online at: https://vaers.hhs.gov/reportevent.html.

In addition to the reports required by law, VAERS accepts reports from any interested party of real or suspected adverse events occurring after the administration of any vaccine. For further information, or additional VAERS reporting forms, please contact the VAERS Program at 1-800-822-7967.

SECTION IV: LINKS

Louisiana Immunization Network (LINKS)

Louisiana Sanitary Code Title 51, Part II, Chapter 1, Section 703, states that all immunization providers in Louisiana must be licensed or credentialed by their respective boards to administer vaccines and must register in LINKS, the state's immunization registry. The state Sanitary Code mandates that all providers update all vaccines administered and patient demographics in LINKS within one week of vaccine administration to the patient.

LINKS is a statewide computer-based system designed to keep track of all immunization records in Louisiana. The LINKS web application allows doctors, nurses, and other health professionals to enter and search patients' vaccination records in a central location. All VFC vaccines (including seasonal flu vaccine) given to all patients must be reported to LINKS.

Benefits of LINKS include:

- Immediate immunization records for new patients.
- Decreased staff time spent retrieving immunization records.
- Fewer missed opportunities to provide needed vaccinations.
- Fewer missed appointments with reminder cards and letters.
- Ability to identify coverage gaps.
- Availability of streamlined data reports.

Providers can also use LINKS to:

- Order vaccine through the Vaccine Ordering and Management System (VOMS).
- Manage vaccine inventory.
- Complete provider re-certification and training.

VOMS Ordering

Providers are to log in to the LINKS/IWeb system

- Under Menu click Inventory **Management → VOMS 2.0 → Orders/Transfers**

- Click **Create/View Orders**
- When the next screen appears click **Create Order**

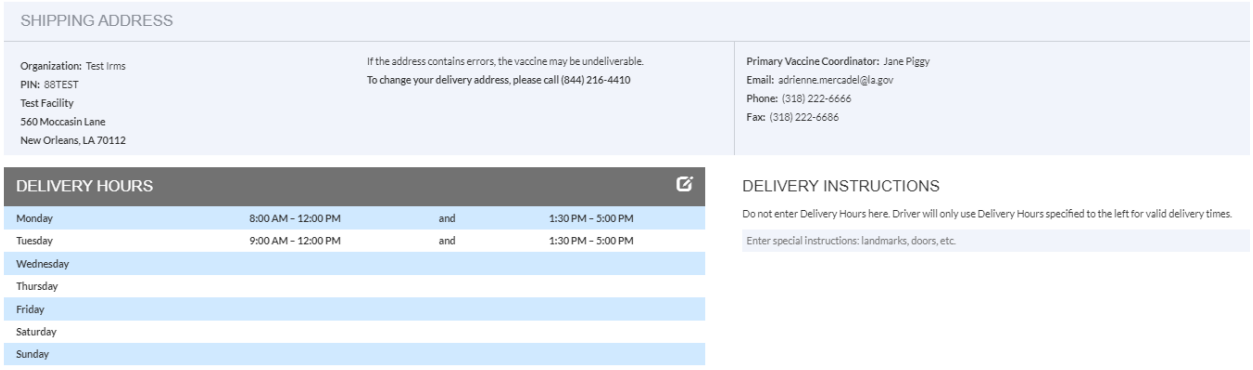
This will bring up the Inventory Reconciliation Page. Any current inventory must be reconciled before an order can be placed. Once inventory is reconciled and saved, the order form will appear.

- The next screen is **Order Details**. Providers shall utilize the drop-down box and select the vaccine types to order.

VERY IMPORTANT: All vaccine selections must include a description. The order will be considered incomplete without description information.

- Providers shall then select the quantity of doses needed under **Order Quantity**.

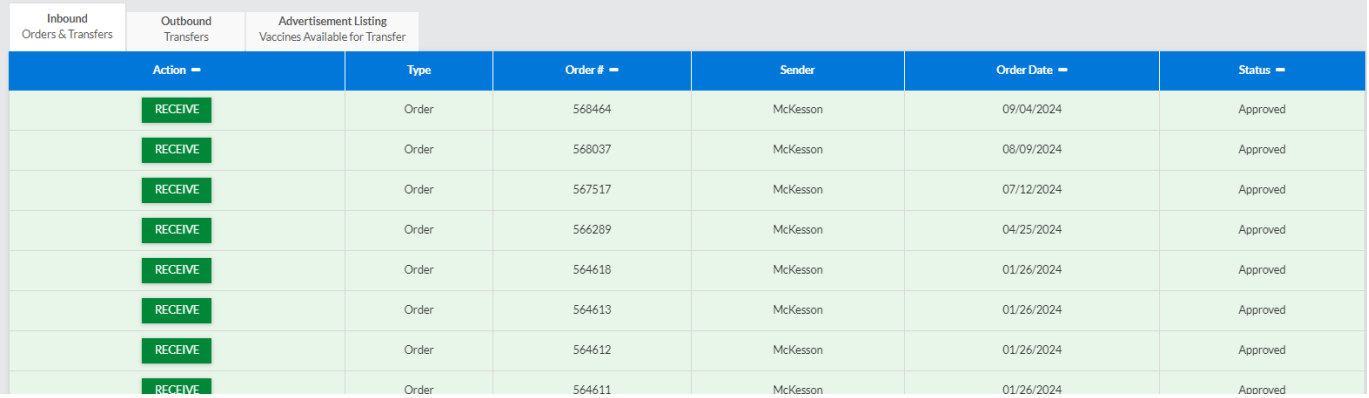
Providers can also add any additional information under the **Comments** field. Once all required information has been entered, the providers can **Save.**



Providers are to ensure that all contact information is correct. If any information is incorrect, please add revisions and then save.

The application will next route to the **Current Order/Transfer List** (shown below). Providers can then use the **Select** button to review the order entered into VOMS. The system will allow the provider/individual placing the order to review the order and ensure that vaccine type and quantity are entered correctly. Once the order is reviewed and determined to be correct, the provider/individual placing the order may select **Submit Order** at the bottom right of the screen.

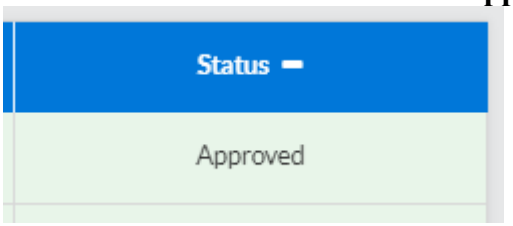
VOMS will then display the **Current Order/Transfer Page** and the order status will show "Pending State Approval". The order is complete and will be routed to the Immunization Program Office for processing and order fulfilment.



The provider can check the status of their order at any time by selecting **Orders/Transfers under the Menu option**

Create/View Orders

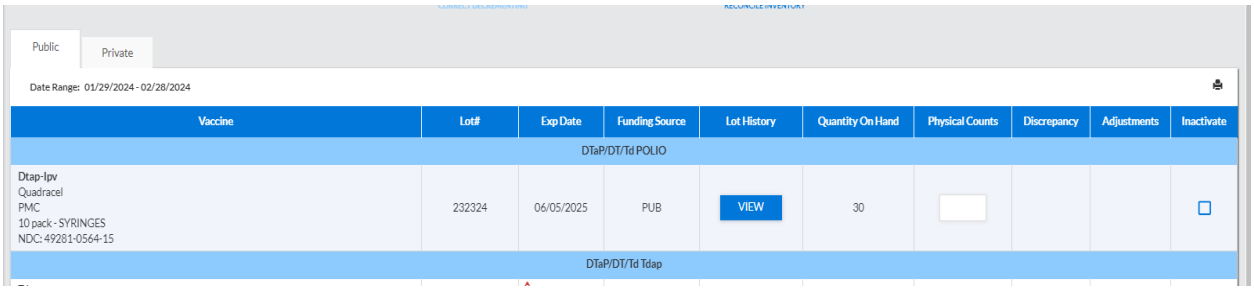
Once the order has been approved by the Immunization Program Office, it is sent to McKesson and the Status of the order will be **"Approved".**



Vaccine Inventory Management

LINKS must be updated every time a vaccine is administered, transferred, or marked as waste(d) to ensure proper tracking and monitoring.

Providers shall perform inventory checks at least monthly by counting all physical vaccine inventory and comparing what is present in LINKS. If the quantity of inventory on hand does not match the physical inventory, providers shall select the option to explain the discrepancy. Providers shall also notify their Regional Immunization Consultant to provide assistance with troubleshooting the issue.



Vaccine Waste

Expired or unusable vaccine must be reported to the Louisiana Office of Public Health Immunization Program, and LINKS inventory must be properly adjusted. Providers can report vaccine loss with the **Vaccine Transfer Loss Report**. The form must include the vaccine, lot number, total doses, and explanation of the vaccine loss.

Vaccines shall be returned to the Louisiana Immunization Program with a copy of the Vaccine Transfer Report. The mailing address for vaccines is **1450 Poydras St., Ste. 1938, New Orleans, LA 70112-1938**. The package shall be addressed to Adrienne Mercadel Whitney, Vaccine Distribution & Procurement Manager.

Vaccine Transfer

When any vaccine type (i.e. DTaP, HIB, DT (pediatric), Td (adult), Tdap, HBV, HAV, Polio, MMR, VAR, MMR-VAR, MCV4, MenB, Rotavirus, HPV, RSV, Influenza, Pneumococcal (PPSV or PCV15 or PCV20) is transferred from one Parish Health Unit to another, or to the Immunization Program in New Orleans, an **EPI-6** must be completed each time. The report is to be sent directly to the Immunization Program in New Orleans. All transfers of vaccine or shipping materials to the Immunization Program should be made through the courier service.

Rationale:
To support the integrity of the vaccine and assure accountability of vaccine products, it is necessary to maintain a formal protocol for the handling of vaccine that is being transferred between parish health units and/or branches of the Office of Public Health. This will enable the Immunization Program to maintain adequate supplies and to assure there is minimum loss.

Guidelines:

Unexpired vaccine must be transported under refrigerated conditions as specified by individual vaccine handling and storage procedures. Please see Policy on **Transporting Vaccine**.

Instructions for completing the EPI-6 are as follows (check the appropriate box):

- **Transferred to:** Name of the parish health unit or clinicthe vaccine is being transferred to, including the facility's PIN number, or;
- **Expired:** Vaccines that have expired and past expiration date, or;
- **Damaged:** This selection shall be used if the vaccine has been damaged or if vaccine has any other issues other than being expired. Providers shall also select:
  - Vaccine Type
  - Number of Doses (doses in each vial)
  - Lot Number (manufacturer's lot number that appears on the vaccine package)
  - Expiration Date (date that appears on the vaccine package)

- Remarks (can include any information relative to vaccine transfer or loss)
- Parish Health Unit or clinic transferring vaccine to another health clinic
- Facility PIN number
- Signature (name of person transferring the vaccine)
- Date of Transfer (date vaccine is released to another health unit/clinic)

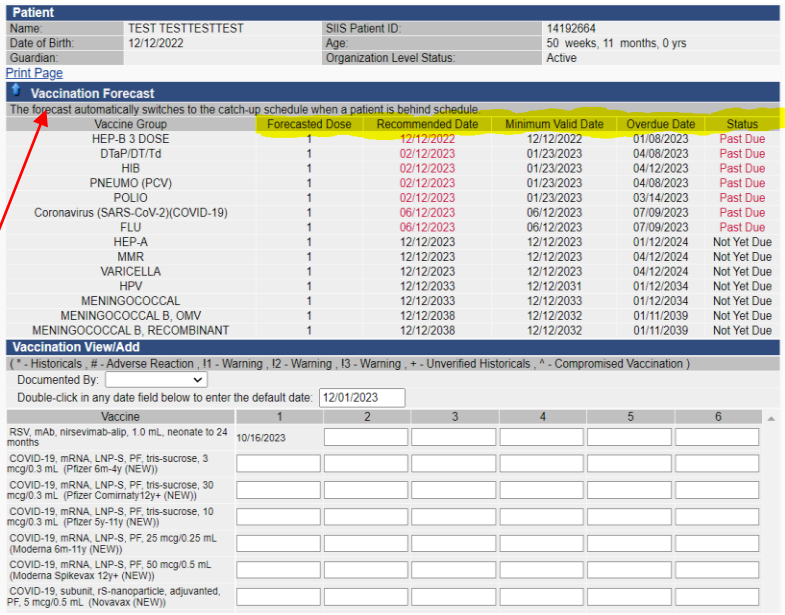
NOTE: One copy of the Vaccine Transfer Report should accompany the vaccine and a second copy should be forwarded to the Immunization Program.

Entering Vaccine Administration in LINKS

Administered vaccines must be properly documented in LINKS within one week, per the Louisiana Public Health Sanitary Code.

1. The first step is to go to the Vaccinations tab and select the View/Add option. The provider will then be taken to the next screen that has a list of vaccine types. The provider will select the vaccine that is being administered and select the option "Add Administered".
2. The next screen will take provider to the "Vaccination Detail Add Page". The provider is to select the option "Click to Select". This will create a pop-up tab which shows the vaccine administered, lot number, and amount of doses in the provider's inventory. The provider shall double check that the correct lot number is selected, as this option will subtract a dose from the provider's inventory.
3. The provider is to then choose the Vaccinator, Anatomical Site, and Route, and select the option "Save".

- The **View/Add** page allows you to:
    - Add administered vaccines
    - Add historical vaccines
    - Displays the vaccine forecast
- **Vaccination Forecast** shows which vaccines are due for the patient



Patient

Name:	TEST TESTTESTTEST	SIIS Patient ID:	14192664
Date of Birth:	12/12/2022	Age:	50 weeks, 11 months, 0 yrs
Guardian:		Organization Level Status:	Active

Print Page

Vaccination Forecast

The forecast automatically switches to the catch-up schedule when a patient is behind schedule.

Vaccine Group	Forecasted Dose	Recommended Date	Minimum Valid Date	Overdue Date	Status
HEP-B 3 DOSE	1	12/12/2022	12/12/2022	01/08/2023	Past Due
DTaP/DT/Td	1	02/12/2023	01/23/2023	04/08/2023	Past Due
HIB	1	02/12/2023	01/23/2023	04/12/2023	Past Due
PNEUMO (PCV)	1	02/12/2023	01/23/2023	04/08/2023	Past Due
POLIO	1	02/12/2023	01/23/2023	03/14/2023	Past Due
Coronavirus (SARS-CoV-2)(COVID-19)	1	06/12/2023	06/12/2023	07/09/2023	Past Due
FLU	1	06/12/2023	06/12/2023	07/09/2023	Past Due
HEP-A	1	12/12/2023	12/12/2023	01/12/2024	Not Yet Due
MMR	1	12/12/2023	12/12/2023	04/12/2024	Not Yet Due
VARICELLA	1	12/12/2023	12/12/2023	04/12/2024	Not Yet Due
HPV	1	12/12/2033	12/12/2031	01/12/2034	Not Yet Due
MENINGOCOCCAL	1	12/12/2033	12/12/2033	01/12/2034	Not Yet Due
MENINGOCOCCAL B, OMV	1	12/12/2038	12/12/2032	01/11/2039	Not Yet Due
MENINGOCOCCAL B, RECOMBINANT	1	12/12/2038	12/12/2032	01/11/2039	Not Yet Due

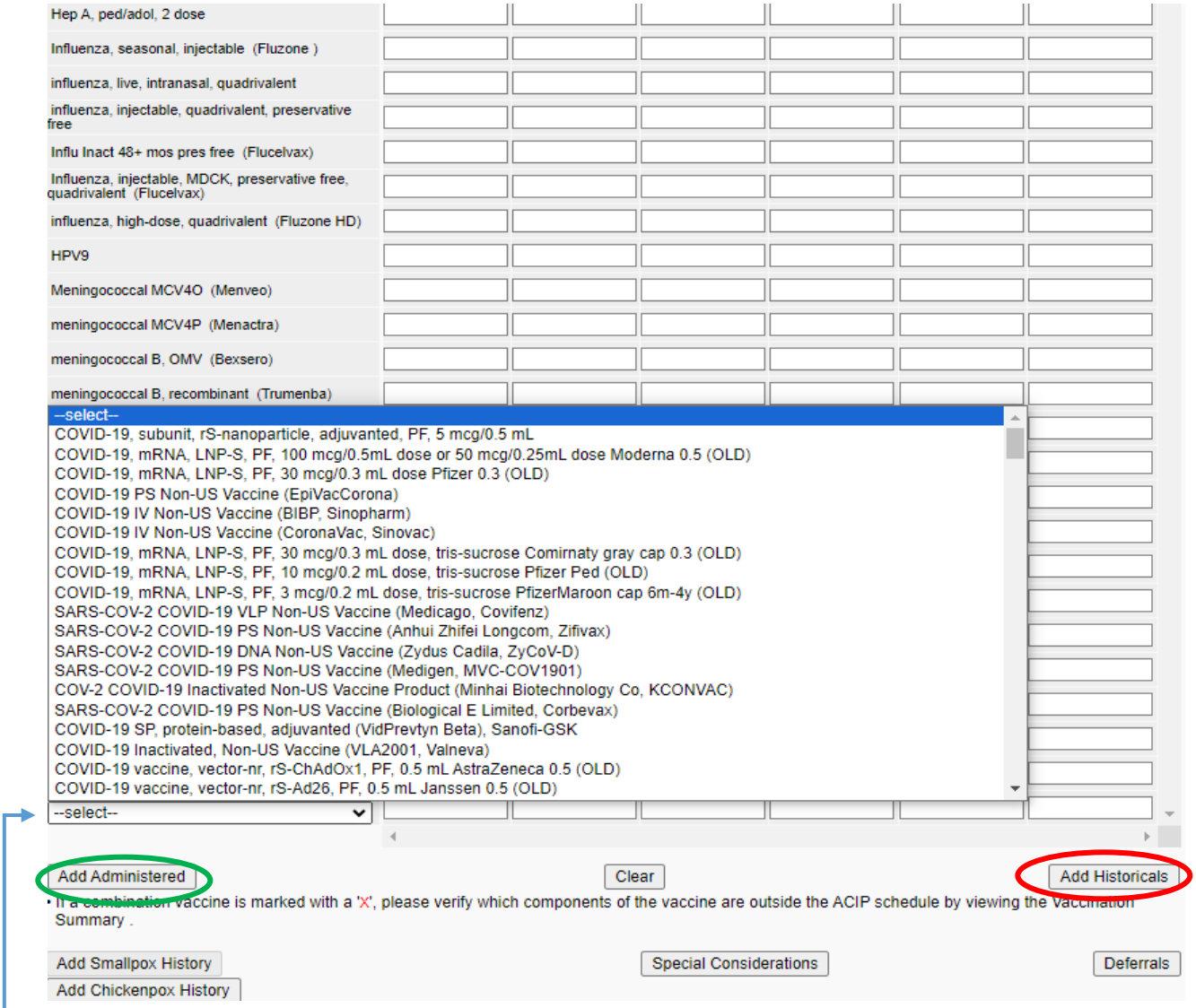
Vaccination View/Add

(* - Historicals , # - Adverse Reaction , I1 - Warning , I2 - Warning , I3 - Warning , + - Unverified Historicals , ^ - Compromised Vaccination)

Documented By:

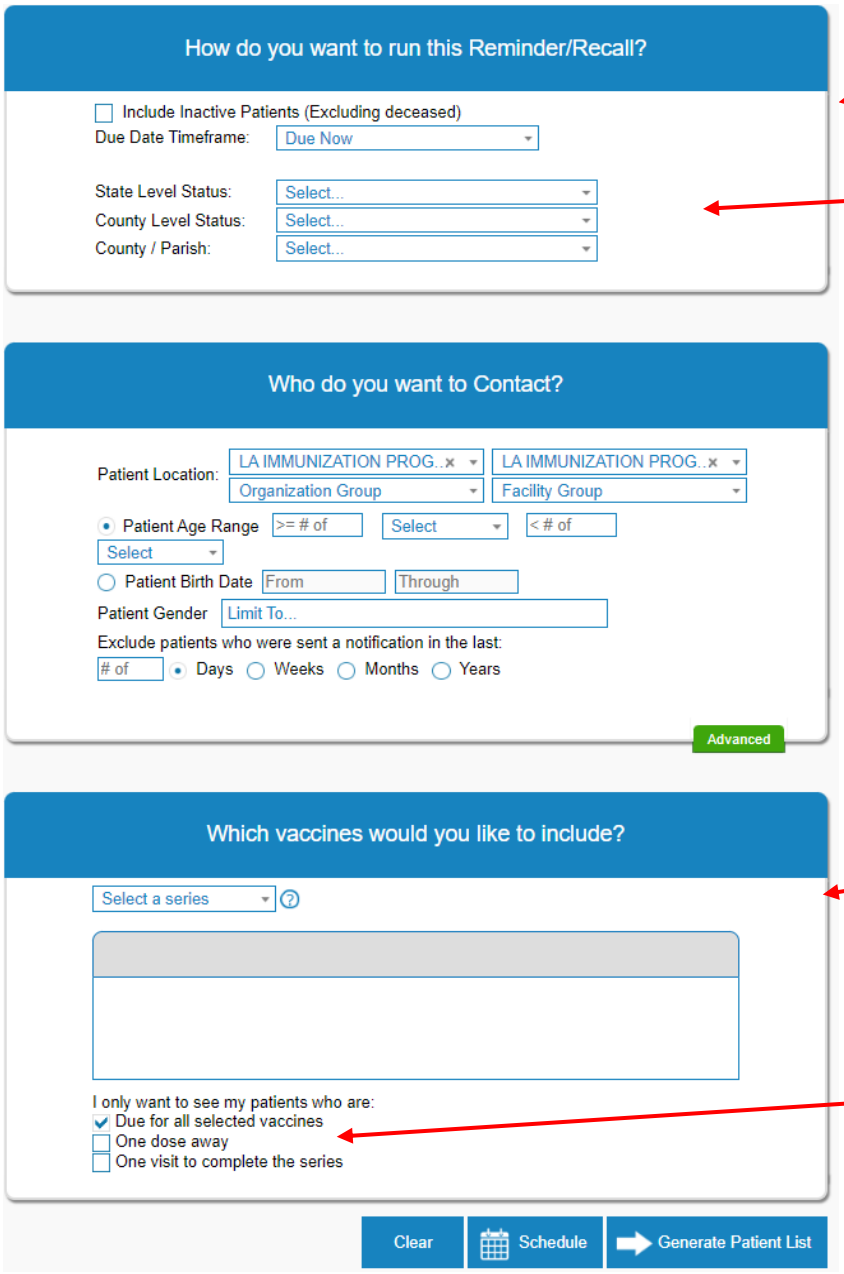
Double-click in any date field below to enter the default date: 12/01/2023

Vaccine	1	2	3	4	5	6
RSV, mAb, nirsevimab-alip, 1.0 mL, neonate to 24 months	10/16/2023					
COVID-19, mRNA, LNP-S, PF, tris-sucrose, 3 mcg/0.3 mL (Pfizer 6m-4y (NEW))						
COVID-19, mRNA, LNP-S, PF, tris-sucrose, 30 mcg/0.3 mL (Pfizer Comirnaty12y+ (NEW))						
COVID-19, mRNA, LNP-S, PF, tris-sucrose, 10 mcg/0.3 mL (Pfizer 5y-11y (NEW))						
COVID-19, mRNA, LNP-S, PF, 25 mcg/0.25 mL (Moderna 6m-11y (NEW))						
COVID-19, mRNA, LNP-S, PF, 50 mcg/0.5 mL (Moderna Spikevax 12y+ (NEW))						
COVID-19, subunit, rS-nanoparticle, adjuvanted, PF, 5 mcg/0.5 mL (Novavax (NEW))						



- **ADD ADMINISTERED:**
  - Used for facilities utilizing LINKS for inventory management such as VFC facilities
- **ADD HISTORICAL:**
  - To document previously administered vaccines
  - Used in non VFC clinics that do not use LINKS for inventory management
- The view add page displays the most common vaccines. All other vaccines are located on the **drop down menu**
  - Find your vaccine
  - Enter the date of vaccination
  - Click on “Add Administered” or “Add Historicals”

Using Reminder/Recall



Choose your due date time frame

- The timeframe will default to "Due Now" if not specified

- Make sure your org/facility are correct
- Select a patient age range
- Customize this by year, month, day
- Options available to narrow down by gender and birthdate

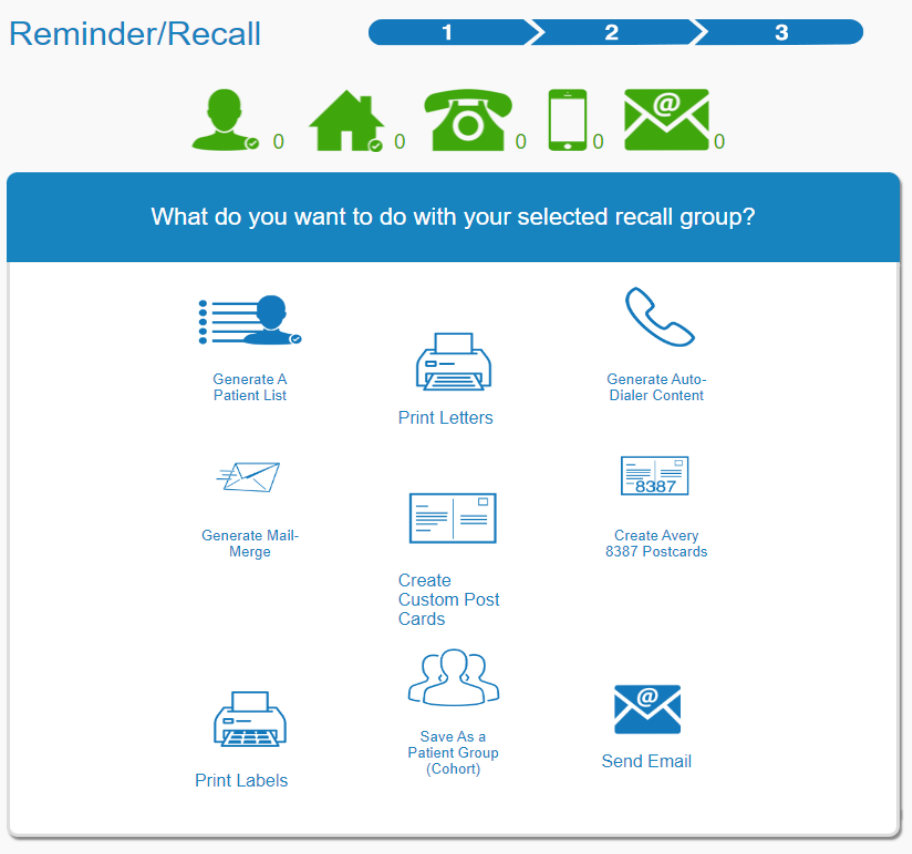
Once all of your specific selections have been made, click "Generate Patient List"

Select a vaccination series or select custom which allows you to pick and choose specific vaccines

Using Reminder/Recall Continued:

Once you have made your selections/have your recall group you can:

- Generate a list of patients who are past due with details
- Generate letters that can be printed for you to send out
- Generate custom postcards alerting patient on vaccines that are due
- Email notifications can be used if patient has updated information on demographic page

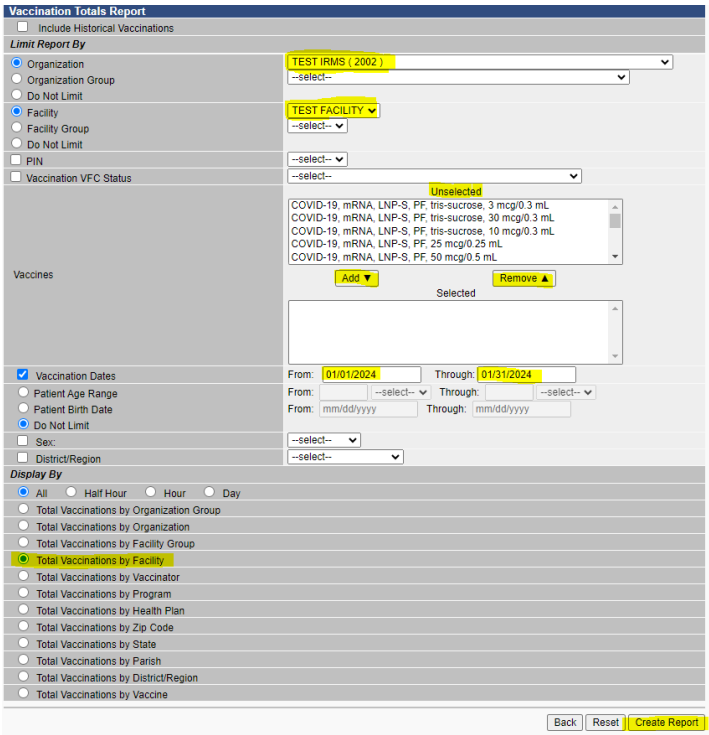


Reports in LINKS:
Once logged into LINKS, select “Report Module” on the menu on the left hand side of the page.

Vaccination Totals

This report allows you to see how many vaccines were administered at your facility

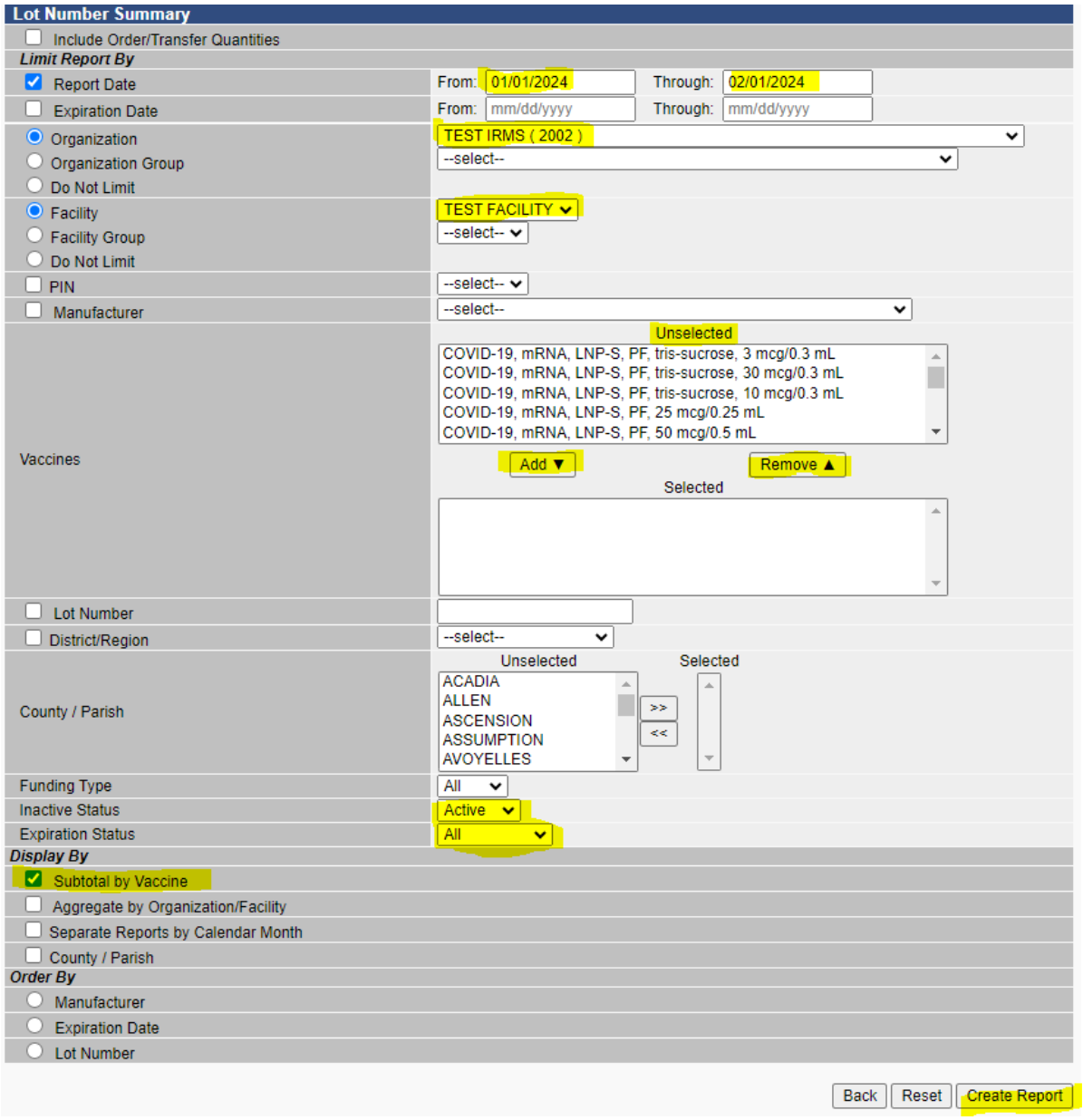
- Make sure org/facility are correct
- Select the vaccines you want to run totals on / or do not select any vaccines and get totals on all vaccines administered.
- Select a date range
- You can filter this by age range, birth date, by vaccinator, or by the total shots administered at your facility
- Select “Create Report”



Lot Number Summary Report

This report breaks down the vaccine inventory by lot number

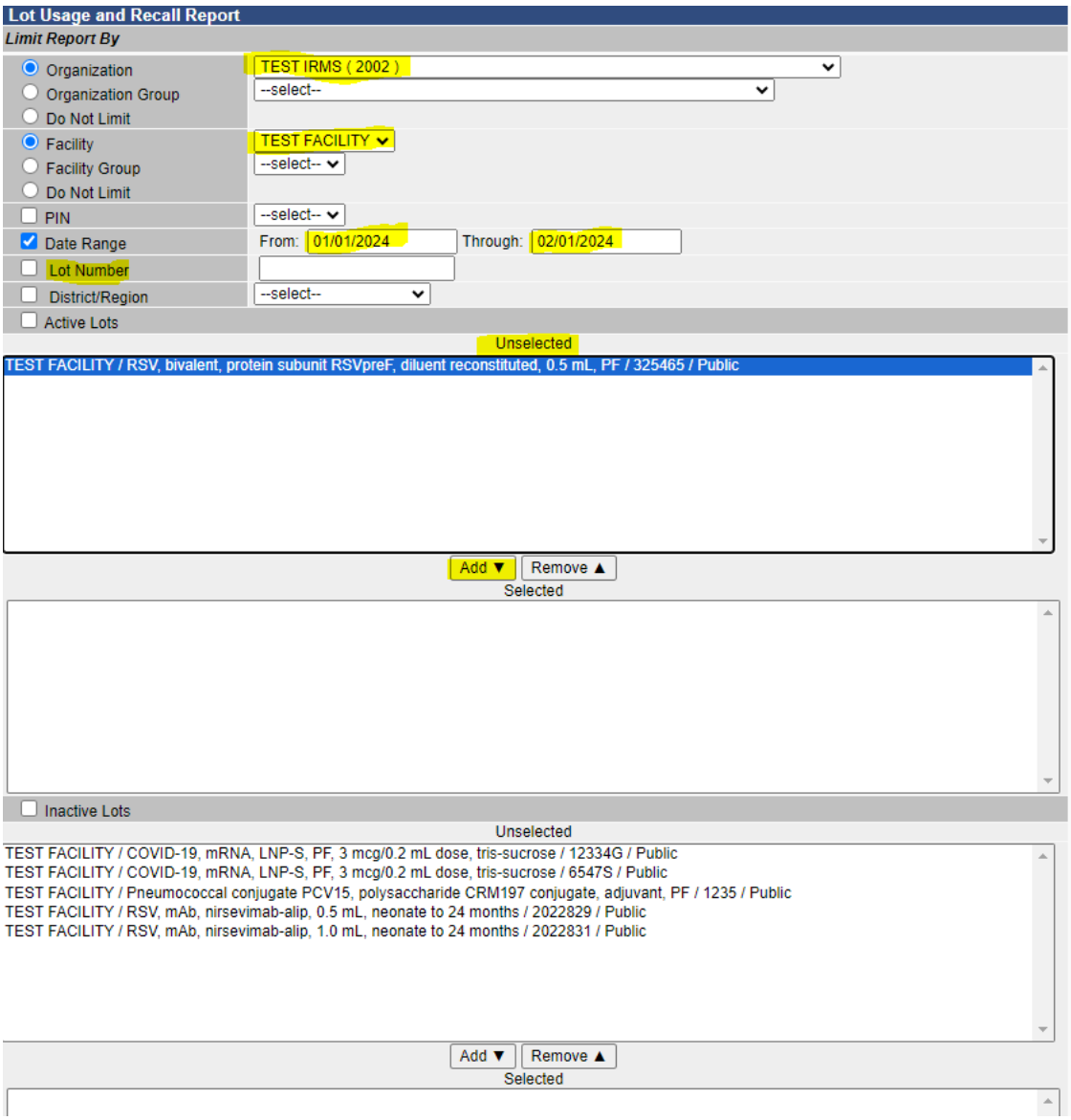
- Confirm Organization/Facility
- Select a date range
- You can select a specific vaccines or do not specify and see all lot numbers administered
- You can also enter a specific lot number and see totals administered vs. what is left in your inventory
- You can select active patients, inactive patients or all
- Once all of your selections have been made, click “Create Report”



Lot Usage & Recall Report

This report helps confirm the doses in inventory have successfully decremented and can also be used to identify lot numbers that have a recall.

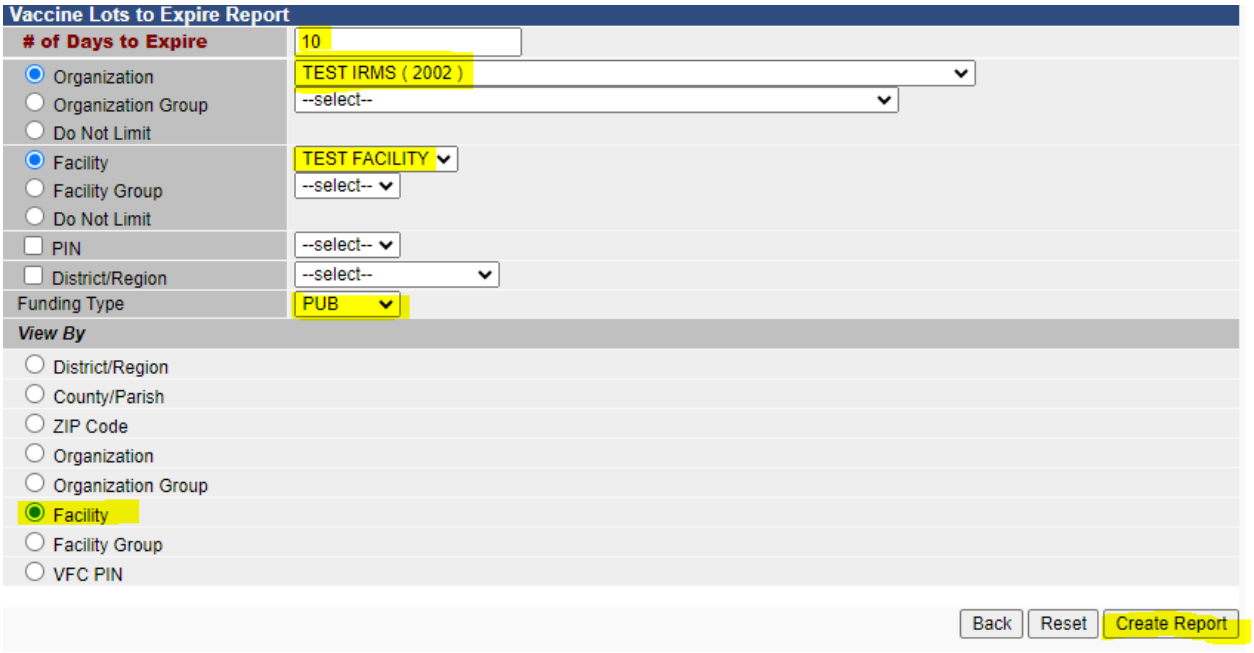
- Confirm Organization & Facility
- Select the appropriate lot number or lot numbers from the unselected box or type in a specific lot number in the “Lot Number” tab
- Use the down arrows to move it over to the selected box
- Filter by Date Range if applicable
- Click “Create Report”
    - If you are missing any doses from this report, please refer to the patient detail report to see why that record did not decrement correctly



Vaccine Lots to Expire Report

This report is used to see which lot numbers in your inventory are due to expire

- Confirm Organization and Facility
- Select # of days prior to expiration
  Select “Create Report” to see which vaccines are expiring within the days selected

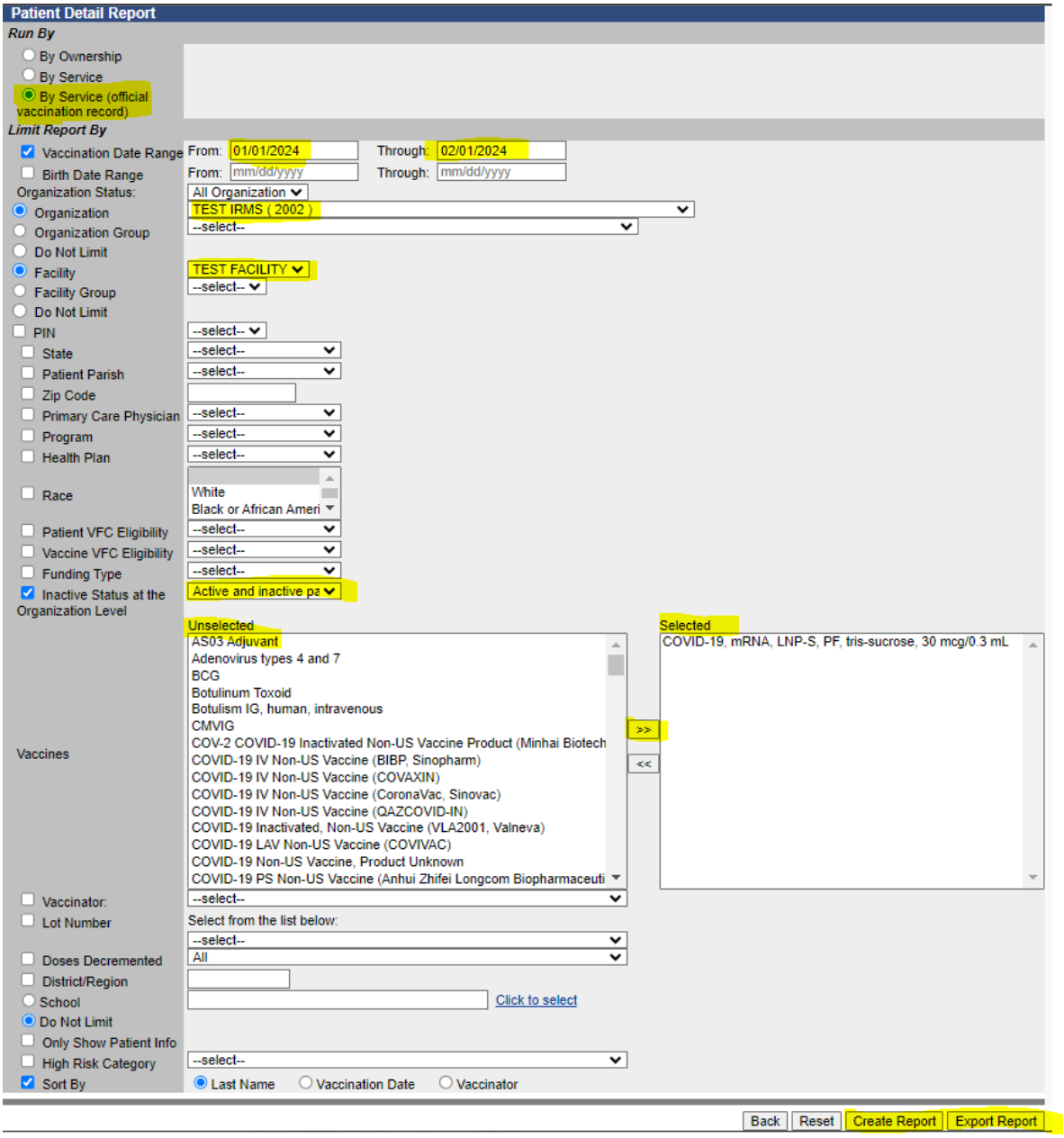


Patient Detail Report

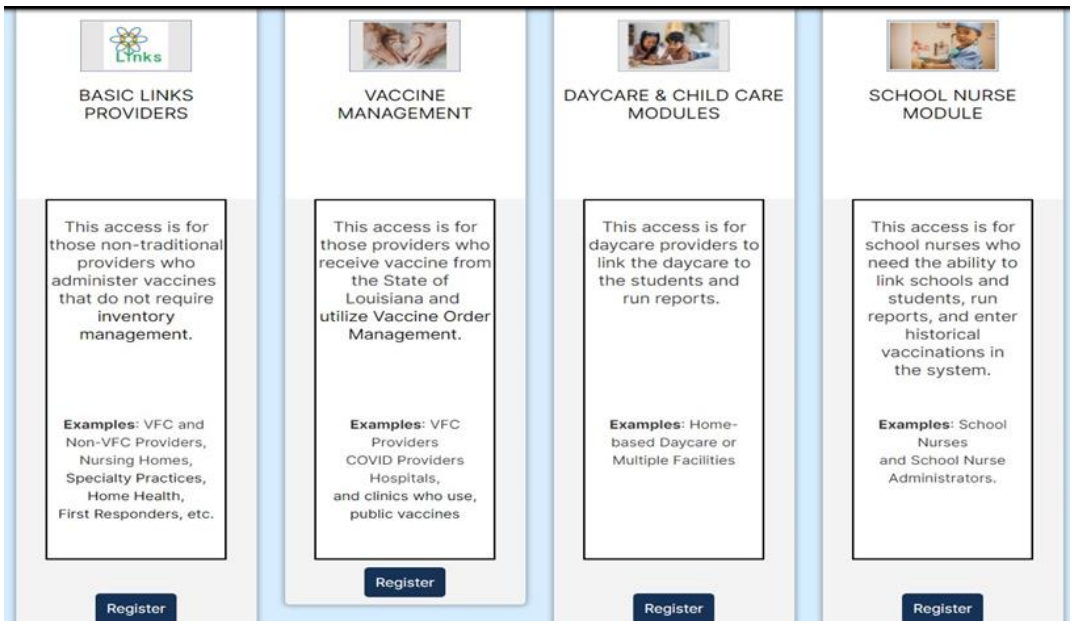
This report to find out details on the patients who received vaccines on a specific time frame.

- Always run this report by selecting “By Service (official vaccination record)”
- Filter by Vaccination Date Range (if applicable)
- Verify Org/Facility
- You can select active and inactive patients
- Select which vaccines you would like to see a patient list for or do not select any vaccines to see all vaccines administered by date range
- You can also filter by lot number if applicable

- Click “Create Report” to view online or “Export Report” for an excel spreadsheet



LINKS Learning Management System:
All LINKS users are required to complete the LMS LINKS Training prior to getting access to the LINKS system. The link to access the training is **https://louisianalms.stchealth.us/**
There are different types of training depending on the type of LINKS access you need such as Basic, VOMS, School Nurse Module & Child Care Module. Users will choose which courses they will enroll in according to their workflow. Users may also add courses by sending an email to the help desk located on the bottom of the homepage **STC_TrainingServices@stchome.com**



SECTION V: SITE VISITS

The Louisiana VFC Program conducts regular site visits of VFC-enrolled provider sites to ensure compliance with VFC Program requirements. Providers should expect a site visit every year. Depending on the type of visit, some preparation may be required of the provider/staff prior to the visit.

The Louisiana VFC Program conducts the following types of quality assurance visits:

1. Enrollment visits
2. Storage and handling visits
3. Compliance visits
4. Immunization Quality Improvement for Providers (IQIP) visits (select, eligible providers)

VFC Visits

Enrollment

Providers applying to participate in the VFC Program will receive a VFC Enrollment visit from their Regional Immunization Consultant. The purpose of the visit is to ensure providers have the appropriate equipment to assure compliance with storage and handling, that providers understand all VFC Program requirements, and that providers are proficient in the LINKS and VOMS systems.

The initial enrollment visit is a critical opportunity for providers to ask questions, provide feedback, and become familiar with VFC Program protocols and guidelines. Providers shall also be prepared to:

- Present the refrigerator, freezer, and temperature monitoring device that will be used along with the device's certificate of calibration
- Complete Site Enrollment and User Agreements
- Identify Primary and Backup VFC Coordinators for the facility
- Complete an Emergency Response plan

Compliance

Providers shall expect to receive annual compliance visits which are scheduled in advance. During the visit, an OPH Regional Immunization Consultant will inspect the storage units housing VFC vaccine to ensure that the vaccine is being properly stored in approved units and that storage temperature is being properly monitored using approved devices. The consultants will also review physical inventory to ensure inventory is accurately documented in LINKS. Lastly, consultants will ensure that VFC vaccines were administered to eligible patients and that required vaccination information has been entered in the patients' respective records.

Storage units will be reviewed to ensure vaccines are:

- placed appropriately within the units (i.e., not stored too closely to the walls of the unit),
- properly rotated,
- not expired or passed the "beyond use" date,
- not over-packed within the unit.

The Regional Immunization Consultant will also review temperature logs and Vaccine Information Statements (VISs) to ensure they are up-to-date. Lastly, the Regional Immunization Consultant will provide a visit summary to providers.

Storage and Handling

Providers may also be selected for an abbreviated Storage and Handling (S&H) visit which may be either scheduled in advance or unannounced at the Regional Immunization Consultant's

discretion. S&H visits focus solely on appropriate vaccine storage and temperature monitoring. Providers may be selected to participate in an S&H visit in situations where the provider:

- Has had storage and handling issues in the past.
- Is an existing VFC provider in a new location.
- Experiences frequent or significant vaccine loss.

Follow-Up Visits, As Needed

During or at the end of either a VFC compliance or S&H visit, the Regional Immunization Consultant shall offer education and technical assistance to the provider and/or staff when non-compliant behaviors or practices are observed or encountered in order to correct the situations. If the provider is found to be non-compliant, a provider follow-up plan will be completed and reviewed with the provider office. Follow-up visits may include components of storage and handling visits as well as components of the quality assurance program. Depending on the issues identified previously, charts may be reviewed and the practice will be alerted in advance if this is necessary. VFC provider sites may request follow-up visits for technical assistance and/or to educate staff on VFC policies, procedures, or visit findings.

Contact

Regional Immunization Consultants or Immunization Consultant Supervisors may, on occasion, reach out in person, on site, by telephone, or in writing to providers outside of enrollment, compliance, and S&H visits for a VFC matter not related to the most recent site visit or follow-up plan. This type of outreach, known as a contact, must be directly related to communicating VFC program requirements.

Examples of a VFC contact include:

- VFC education/training beyond that provided during an enrollment, compliance, or S&H visit.
- Assistance in handling a power outage.
- Requests for thermometer certificates of calibration, downloaded digital data-logger thermometer reports, training certificates, and/or temperature logs.

IQIP Visits

Immunization Quality Improvement for Providers (IQIP) is a quality assurance program developed by CDC as a component of the VFC Program. The goal of IQIP is to assess immunization practices, assist providers in the diagnosis and resolution of barriers to immunization, recognize providers with high immunization coverage levels, and facilitate the sharing of "Best Practices". VFC providers are considered eligible for an IQIP visit according to specific criteria established by the Louisiana VFC Program which, in turn, are based on CDC guidance.

IQIP deploys provider-level strategies aimed at improving vaccination rates through systematic approaches and evidence-based strategies. IQIP approaches problem-solving by:

1. Stating the problem and desired result.
2. Using data to understand the problem.
3. Identifying strategies for improvement.

4. Implementing strategies and refining as needed.
5. Evaluating outcomes.

With oversight from the Regional Immunization Consultant Supervisor and the Louisiana Immunization Program's IQIP Coordinator, the Immunization Consultant and the provider work collaboratively to analyze the provider's vaccine-coverage rates, implement new immunization delivery strategies, and evaluate outcomes. A complete IQIP visit consists of four phases (initial, baseline visit; two-month check-in; six-month check-in; and a final 12-month follow-up) which are conducted with providers with the aim of implementing new quality improvement (QI) strategies, evaluating successes and challenges during each phase of the visit, and modifying strategies as needed.

Implementation strategies can include, but are not limited to:

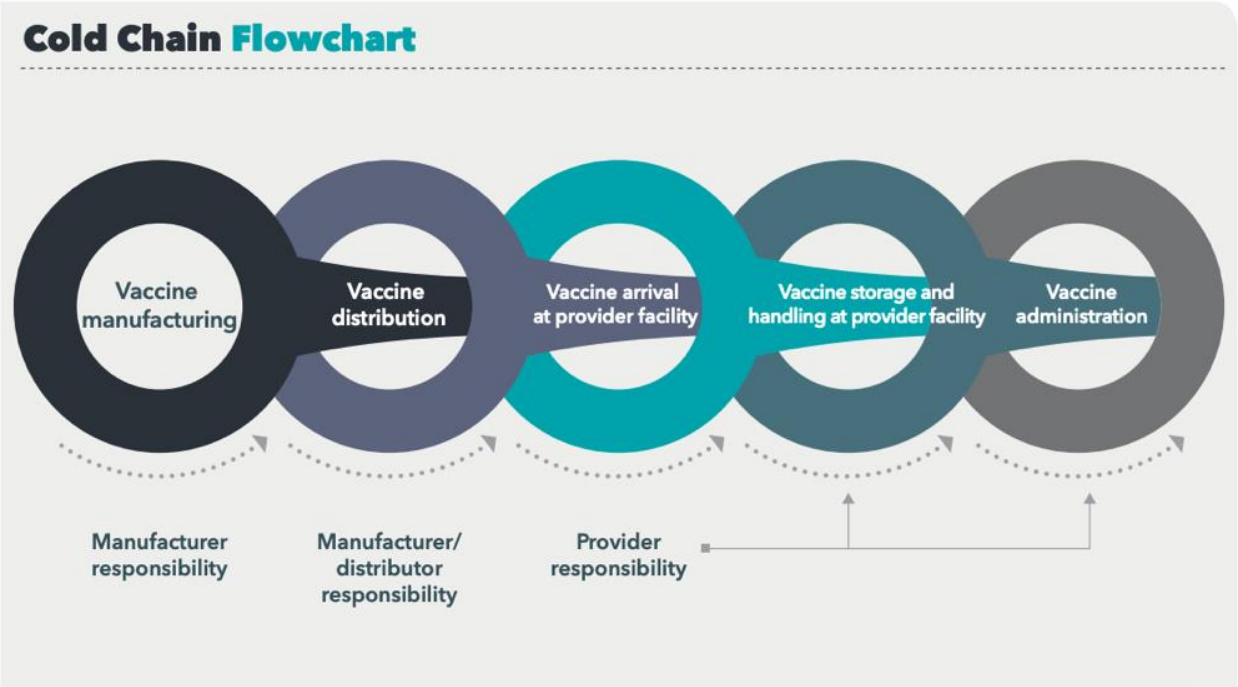
- Implementation of reminder/recall activities.
- Leveraging LINKS data to improve immunization practices.
- Methods to provide strong vaccine recommendations.
- Identifying vaccine education and communications resources.

SECTION VI: Vaccine Management

Storage and Handling Requirements

Vaccine management is of the highest importance for providers enrolled in the VFC Program. Vaccine management refers to proper storage and handling and management of vaccine inventory. Vaccines improperly stored can lead to reduced or lost vaccine effectiveness, thus leading to an inadequate immune response and poor protection against disease. Patients can lose confidence in vaccines and require revaccination. Improper storage and handling can also lead to significant financial loss due to wasted vaccines.

According to CDC, proper storage and handling begins with an effective vaccine *cold chain*. The cold chain shall be maintained from the vaccine manufacturer to vaccine administration. An appropriate cold chain shall be maintained from the manufacturer through vaccine transport and delivery and at the provider facility up until it is administered to the patient.



Vaccine potency is reduced (or even lost) each time a vaccine is overexposed to improper conditions, such as heat, cold, or light; an example would be a single occurrence where vaccine formulated for refrigeration is exposed to freezing temperatures (0° C (32° F) or colder). Therefore, providers must ensure each vaccine is stored according to the manufacturer's storage and handling guidelines. Vaccines must be stored in an appropriate storage unit in their original packaging with lids closed until ready for administration.

Storage Units

CDC and the Louisiana Immunization Program require healthcare providers who receive VFC vaccines to maintain required vaccine storage temperatures year-round. Temperature requirements are as follows:

- **Refrigerator:** 36º to 46º F (2º to 8º C)
- **Freezer:** -58º to 5º F (-50º to -15º C)

Refrigerators and freezers shall be dedicated to vaccine storage only, and any water bottles/frozen packs shall be included solely for the purpose of maintaining proper temperatures. Frozen vaccines must be stored in a "stand-alone" freezer unit and cannot be placed in a refrigerator/freezer combination unit. Dormitory style refrigerators are also not allowed.

Providers must also follow the refrigerator manufacturer's guidance on whether to place water bottles in the unit to help maintain stable temperatures. Some pharmaceutical-grade and purpose-built unit manufacturers do not recommend including water bottles within the unit. The facility VFC Coordinator shall also ensure that a visible sign is placed near the outlet alerting staff to not unplug the unit; likewise, a similar sign will be placed by the facility's circuit-breaker box.

More information on vaccine-storage units allowed by the VFC program may be found in the *Louisiana Vaccines for Children Program Refrigerator and Freezer Guide*.

Temperature Monitoring

CDC and the Louisiana Immunization Program require healthcare providers who receive VFC vaccines to use digital data-logger (DDL) thermometers with a current and valid certificate of calibration for monitoring vaccine-storage temperatures. All certificates must include:

- Model number
- Serial number
- Date of calibration testing
- Measurement results indicating that the unit passed testing

CDC also **requires** that DDL thermometers have the following features:

- Temperature probe
- Active temperature display that can be easily read from outside of the vaccine storage unit
- Capacity for continuous monitoring and recording capabilities where the data can be routinely downloaded

CDC also **recommends** the following additional features for DDL thermometers:

- Alarm for out-of-range temperatures
- Current, minimum, and maximum temperatures display
- Low-battery indicator
- Accuracy of +/-1° (0.5°C)
- Memory storage of at least 4,000 readings

CDC requires the use of DDLs that perform *continuous* temperature monitoring. Continuous monitoring devices are capable of recording and storing past temperatures with a previously set frequency (for example, every 30 minutes), unlike min/max devices that only record the minimum and maximum temperatures; the provider can then download a report of the recorded temperatures for review.

Temperature excursions (that is, instances in which vaccine was stored below or above the required temperature range) shall be reported to the provider's VFC Coordinator immediately, and exposed vaccines shall be marked as "DO NOT USE". The VFC Coordinator shall document:

- Date and time of the temperature excursion
- Storage unit temperature
- General description of what occurred
- An approximate length of time vaccine may have been affected
- Inventory of affected vaccines
- List of other items in the unit (e.g., water bottles)
- Any issues with the storage unit and/or affected vaccines before the event
- Other relevant information

Providers shall alert the Louisiana Immunization Program of the excursion and contact the vaccine manufacturer(s) for next steps which include a determination on whether or not the vaccine is viable, based on the information collected on the excursion. The vaccine shall not be marked as wasted until the Immunization Program and/or vaccine manufacturer confirms the vaccine cannot be administered.

More information on DDL thermometers allowed by the VFC program may be found in the *Louisiana Vaccines for Children Program Digital Data Logger Thermometer Guide*.

Emergency Preparedness and Response

Providers must submit to the Louisiana Immunization Program a *Vaccine Management Plan* which includes an emergency-response plan. The plan should be reviewed annually and must be updated as necessary, as a condition of participation in the VFC Program. Providers shall identify a backup storage location for situations of expected or unexpected power loss. Providers shall consider:

- Purchase of a backup generator
- Identification of a facility that has a backup generator and has capacity to store vaccines temporarily in the event of a power outage.
- Potential backup facilities include local hospitals, parish health units, retirement homes, fire stations, food banks, and police stations.

VFC and Private Vaccine "Borrowing"

The Louisiana VFC Program does **not** allow "borrowing" between private and VFC vaccine inventory. Therefore, providers are not allowed to administer VFC vaccine to privately insured patients or private vaccine to VFC-eligible patients. Providers shall maintain adequate inventories of vaccine for both privately insured and VFC-eligible children, which ensures that vaccine is not used as a continuous replacement system for a provider's privately purchased vaccine inventory.

Providers shall make every effort to screen patients for eligibility before administering VFC vaccine to prevent VFC vaccine administration to private-pay patients**.** However, the Louisiana VFC Program is aware there may be rare instances when providers inadvertently administer VFC vaccine to ineligible children. When inadvertent use of VFC vaccine occurs, providers must replenish the VFC vaccine on a dose-per-dose basis. Monetary reimbursement to the program is not allowed.

Vaccine Borrowing Documentation

A Vaccine Borrowing Report **must** be completed when:

- Privately purchased vaccine is administered to a VFC-eligible child, or
- VFC vaccine is administered to a privately insured child.

Invoices

Providers will maintain invoices to validate that privately purchased vaccine was used to replenish borrowed VFC vaccine. The invoices are to be submitted to the Regional Immunization Consultant.

Fraud and Abuse

The Louisiana Office of Public Health Immunization Program is committed to providing support to VFC providers to ensure appropriate inventory management, storage and handling, and vaccine accountability. However, significant and/or repeat instances of vaccine loss or misuse may warrant a fraud and abuse investigation. Providers are responsible for managing and monitoring inventory in accordance with Louisiana Immunization Program policies and procedures. Providers are also responsible for correcting inventory discrepancies and shall reach out to their Regional Immunization Consultant or the Louisiana Immunization Program when issues arise.

DEFINITIONS:

Discrepancy occurs when accountability data and other pieces of information indicate that vaccine may have been used for purposes other than the intended use (sold, traded, discarded, etc.).

Misuse occurs when vaccine is knowingly administered to patients for whom it is not intended or administered inappropriately. For example, administering DTaP vaccine to adults, using PCV-20 vaccine for fully insured children.

The severity or the degree of the discrepancy and/or misuse may lead to further investigation by other agencies for fraud and/or abuse.

Fraud, as defined in the Code of Federal Regulations (42 CFR 455.2), is "an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself/herself, or some other person".

Abuse is defined as provider practices that are inconsistent with sound fiscal, business, or medical practices. Consequently, these practices result in an unnecessary cost to the Medicaid program, or in reimbursement for services that are not medically necessary or that fail to meet the professionally recognized standard for health care.

CDC mandates that states prevent fraudulent use of vaccines purchased with public funds.

Therefore:

- The Louisiana Immunization Program has a responsibility to ensure appropriate use of public vaccine and to vigorously enforce measures to prevent fraud and abuse of public vaccine at the provider level, and
- Louisiana must immediately report to CDC instances of possible fraudulent use of vaccine purchased with federal funds. The state must work closely with Medicaid in VFC fraud investigations and complete a preliminary investigation report.

Unintentional Discrepancies and/or Misuse of Louisiana Immunization Program, Vaccines for Children Program Policy

If the Louisiana OPH Immunization Program determines the discrepancy or misuse to be **unintentional** and originating from a lack of program knowledge, Regional Immunization Consultants will assist providers in creating a performance improvement plan (PIP). The PIP is not a punitive measure, but a collaborative plan between the Immunization Program and the provider to correct discrepancies and ensure vaccine inventory is properly managed. PIP activities include, but are not limited to:

- Documentation of vaccines that were inadvertently administered
- VFC-enrolled Provider replacement of vaccine on a dose-by-dose basis
- Announced or unannounced compliance visits from Immunization Program staff
- Provider education of vaccine management and storage requirements
- Temporary suspension from the VFC Program pending completion of corrective actions

Failure to comply with conditions of the PIP can result in provider removal from the VFC Program.

Intentional Discrepancies and/or Misuse of Louisiana Immunization Program, Vaccines for Children Program Policy

If the Louisiana OPH Immunization Program suspects the discrepancy or misuse was **intentional**, the provider will be immediately removed from the VFC Program, pending further investigation. State programs are required to adhere to the following measures in cases of intentional vaccine misuse or abuse:

- Investigation by the Louisiana OPH Immunization Program to determine the origin of the suspected discrepancy and/or misuse.
- Consultation with the CDC (CDC Project Officer and/or federal VFC program staff).
- Submission of a formal report of the incident to the Louisiana Medicaid Program.

Cases of intentional misuse or abuse of VFC vaccine may also be reported to the Louisiana Commissioner of Insurance for further investigation and follow-up.

Providers and/or organizations determined to have intentionally misused VFC vaccine will be placed on a six-month probationary period and/or suspended from the VFC Program entirely. Providers may request to re-enroll after a 12-month period has passed and/or a PIP has been satisfactorily completed. Providers will be required to replace VFC vaccine on a dose-by-dose basis before being allowed to complete probationary status or re-enroll as a VFC provider.

Provider Probation

Providers who are noncompliant with VFC guidelines and regulations may be placed on probation for a six-month period. The probationary period will allow providers an opportunity to work closely with the OPH Immunization Program to receive additional guidance, make any required corrective actions, and showcase sustained VFC Program compliance. Providers will receive written notice when being placed on probation. The probation letter will explain probation terms and the probation period start and end date. During the probationary period, providers shall:

- Continue to adhere to all VFC guidelines and regulations.

- Send weekly VFC vaccine reconciliation reports to the Regional Immunization Consultant Supervisor for review.
- Expect up to six unannounced visits by Immunization Program staff to review provider site vaccine storage, handling, and inventory practices.
- Complete any required trainings identified by the Regional Immunization Consultant Supervisor.
- Proactively report any identified issues to the Regional Immunization Consultant Supervisor.

Providers will receive written notification upon successfully completing the probationary period. In the event the provider fails to meet all established probation terms, they will receive an official letter removing them from the VFC Program for a period of no less than 12 months. Providers may be removed before the end of the six-month if noncompliance is noted during the probation period.