
STATE OF IOWA DEPARTMENT OF

Health AND **Human**

SERVICES

Iowa's Vaccines for Children Program

July 19, 2023

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Presentation Outline

- VFC Re-enrollment – due July 28, 2023
- COVID-19 Vaccine & VFC Program
- VFC Vaccine Return
- VFC Influenza vaccines – 2023-24 season
- Program updates – Site visits & new MCO
- Tips & Tricks to avoid common noncompliance issues
- Q&A - Ask your questions!

VFC Re-enrollment

All VFC Providers need to complete annual Re-enrollment by July 28, 2023

VFC Re-enrollment due by July 28, 2023

- Each VFC Provider is required to re-enroll in the VFC Program on an annual basis, which will occur July 17-28, 2023
- Part 1: Training:
 - Primary and back-up vaccine coordinators are required to complete two of CDC's "[You Call the Shots](#)" modules: [Vaccine Storage and Handling 2023](#) and [Vaccines for Children \(VFC\) 2023](#)
- Part 2: Update IRIS Contacts & Complete Re-enrollment page:
 - In IRIS under "Edit Organization," review the generated VFC Patient Activity chart
 - Review and update the organization's contacts, including address and email, and providers practicing at the facility
 - Last step is to complete the VFC Re-enrollment form

VFC Re-enrollment due by July 28, 2023

- Enrollment occurs in IRIS
 - Iowa VFC Program does not accept any paper forms
 - Do not fax or email forms to the Iowa VFC Program
- Only IRIS Admin users have access to complete the VFC re-enrollment:
 - To add additional Admin Users, complete the [IRIS Site Enrollment Form](#) and send to IRISenrollment@idph.iowa.gov
- Failure to complete the re-enrollment process by July 28 will result in suspension and the inability to place VFC vaccine orders in IRIS.
- **Action: Complete Re-enrollment by July 28, 2023**

VFC Re-enrollment due by July 28, 2023

- VFC providers must annually train ALL staff with vaccine management responsibilities on proper vaccine storage and handling procedures
- Staff training must be documented and included as part of the facility's Storage and Handling Plan
- **Action Item: Review the Vaccine Storage and Handling Plan template with ALL staff with vaccine management responsibilities, including after key staffing changes**

VFC Re-enrollment due by July 28, 2023

VFC re-enrollment demonstration

1) “You Call the Shots” modules: Vaccine Storage and Handling 2023 and Vaccines for Children (VFC) 2023

2) IRIS: <https://iris.iowa.gov/>

COVID-19 Vaccine & VFC Program

COVID-19 Vaccine & VFC Program

- Pediatric COVID-19 vaccine will be added to the VFC contract after commercialization
 - VFC providers will be able to order and administer COVID-19 vaccines for VFC eligible pediatric patients
 - Like other routine vaccines, providers expected to maintain inventory
 - An updated recommendation for all age groups is expected in the mid to late September timeframe after anticipated FDA regulatory authorizations or approvals of an updated COVID-19 vaccine composition (Monovalent XBB.1.5)
 - A child's eligibility criteria for VFC COVID-19 vaccines the same as for other VFC vaccines
 - VFC COVID-19 vaccines will be expected to be returned through same processes as other VFC vaccines
 - **More information to come regarding COVID-19 vaccines**

VFC Vaccine Return

Return spoiled and expired VFC vaccines to McKesson

VFC & Seasonal Influenza Vaccine Return

- Seasonal influenza VFC vaccines expired on June 30, 2023
- VFC Providers are **expected** to return **all spoiled and expired VFC vaccines** as soon as possible within the first 30 days but not to exceed six months after expiration date
 - Single dose syringes, unopened single dose vials, and only full, unopened multi-dose vials to McKesson
 - Products in open boxes can be returned, however opened multi-dose vials cannot be returned
- Nonviable Vaccine Return Instructions: IRIS contains functionality to manage nonviable vaccine returns, including notifications prompting providers to return nonviable VFC vaccines to McKesson.
- At this time, **do not return any expired COVID-19 vaccines**

Influenza Vaccine Return Process

- **Maintain current VFC Vaccine Delivery contact information in IRIS**
 - Update contact information in IRIS in Edit Organization prior to completing return
- **Return single dose syringes, unopened single dose vials, and only full, unopened multi-dose vials**
- **Print nonviable vaccine return list** from the Manage Returns page using the blue hyperlink
 - Include the return list in the box with the nonviable vaccines
- **Print the UPS postage paid return label emailed from McKesson**
 - Label is sent to the “Main Contact Information” e-mail address listed in IRIS.
 - Not Immediately Processed - May take up to a week to be sent to the email address
 - All McKesson return label communications will come UPS Quantum View pkginfo@ups.com
 - Providers should confirm that this e-mail address will not be blocked by their e-mail spam filters and check spam/junk folder for labels
- **Do NOT return vaccines not included on the return list**
- **Contact Iowa VFC Program with questions or concerns**

Influenza Vaccine – 2023-24 Distribution

2023-24 Influenza vaccine shipments to start after Labor Day

2023-24 VFC Influenza Vaccine Shipping

- Shipping to commence when vaccine is available in early September
- Providers may not receive entire pre-booked amount in first shipment
 - Vaccine manufacturers routinely distribute influenza vaccine as it is produced and released by the Food and Drug Administration (FDA)
 - Vaccine is distributed in partial shipments to allow all providers to receive a portion of their vaccine order
 - Remaining vaccine amounts distributed as additional vaccine is available
- Iowa is historically ranked #1 for proportion of influenza vaccine doses distributed as soon as product is available

2023-24 VFC Influenza Vaccine Pre-book

- **Viewing Flu Prebook in IRIS:** [Influenza Vaccine Pre-book and Order Receiving Instructions](#)
 - To review what products and quantities were prebooked by your organization, go to the 'flu prebook' menu in IRIS
 - Select the Flu Prebook Window, 2023-2024 VFC Flu Season
 - Prebooked products and quantities will display
- [2023-24 Available Pre-book Influenza Vaccine Products](#)
- Contact the VFC Program at IowaVFC@idph.iowa.gov with questions or changes to your pre-book quantities



Resuming in-person VFC visits

- All VFC site visits will be conducted in person unless local pandemic conditions indicate medium or high rates of COVID-19 hospitalizations
 - Compliance
 - Enrollment
 - Unannounced S&H
- The Iowa VFC Program will resume unannounced storage and handling visits

Molina Healthcare of Iowa – new MCO

- Newly VFC eligible – Medicaid
 - No changes to Iowa Total Care & Amerigroup

Molina Healthcare of Iowa

Medicaid

Name/Nombre: <Member First Name> <Last Name> **RXBIN:** 004336
Member ID#: <XXXXXXXXXXXX> **RXPCN:** MCA/DADV
DOB: <MM/DD/YYYY> **RXGRP:** RXS1BW
Effective/Fecha efectiva: <MM/DD/YYYY>

Bring your Molina ID card when you see your doctor or go to receive care.
 Lleve su tarjeta de identificación de Molina cuando vea a su médico o vaya a recibir atención.
 If you have an emergency, call 911 or visit the nearest emergency room (ER). For non-emergencies, call your primary care provider (PCP) or the 24/7 Nurse Advice Line.
 Si tiene una emergencia, llame al 911 o vaya a la sala de emergencia más cercana. Si no está seguro de si necesita ir a la sala de emergencia, llame a su proveedor de cuidados primarios (primary care provider, PCP) o la línea de consejo de enfermería de atención 24/7

HMO Molina Healthcare of Iowa, Inc.

Member Numbers

Member Services: (844) 236-0894
TTY: 711

24/7 Nurse Advice/24/7 Línea de Consejos de Enfermeras: (844) 236-2096
National Suicide & Crisis Lifeline/Línea Nacional de Suicidio y Crisis: 988

Cost Shares are a summary only. Visit MyMolina.com for plan details.

Transportation/Access2Care: (866)-849-2062

MyMolina.com This card is for identification purposes only and does not prove eligibility for service.

Provider Numbers

CVS Caremark Help desk: (800) 349-0679
Prior authorization/notification of hospital admission: (844) 236-1464
Inpatient admissions: Provider to notify plan within 24 hours of admission.

- Not VFC eligible – Hawki or private insurance



Tips & Tricks to Avoid Common Noncompliance Issues

How to ace your next site visit!

VFC Non-Compliance Issues

- S&H Per Unit: Temperature Documentation
- S&H Per Unit: Temperature Excursions
- S&H: Expired Vaccines
- Vaccine Preparation
- Maintain all VFC Documents for Minimum of 3 Years

I) S&H Per Unit: Temperature Documentation

Requirement:

- Storage unit(s) current temperatures are checked and recorded on a temperature log twice daily (at the start and end of the workday) along with staff initials and time of readings
- Storage unit(s) minimum and maximum temperatures are checked and recorded on a temperature log at the start of each work day along with staff initials and time of reading

Action Step:

- Designated staff must check and record temperatures **twice** daily (at the beginning and end of each day) and min/max at start of day
- Ensure recordings capture staff initials/name and time of reading

I) S&H Per Unit: Temperature Documentation

Requirement:

- Storage temperature logs are maintained for at least 3 years for each unit either in electronic or paper format
- The designated person reviews temperature logs at least weekly to ensure proper temperature recording and takes action if out of range temperatures are found on the logs during review
- The data logger is downloaded and reviewed at least every two weeks and whenever the data logger alarms

Ordering Replacement DDLs

- Immunization Program has Log Tag 400s available to VFC Providers at no cost
- Send email request to iowaVFC@idph.iowa.gov

2) S&H Per Unit: Temperature Excursions

- **Requirement:**

- Any temperature outside the ranges recommended in the manufacturer's package inserts is considered a temperature excursion
 - Refrigerator: 2 to 8° C or 36 to 46° F
 - Freezer: -15 to -50° C or 5 to -58° F
- Never assume vaccine is nonviable in the event of a storage or handling issue

Action Step:

- Clinic staff is trained to take immediate action if temperatures are out of range, as outlined in the 'Temperature Excursion' section of S&H Plan Template

2) S&H Per Unit: Temperature Excursions

Action Step: NOTIFY:

- Notify the primary or alternate vaccine coordinator immediately
- Label exposed vaccines “Do Not Use”
- Continue to store vaccines under correct temperature storage conditions
- DO NOT discard the vaccines
- Keep exposed vaccine separated from unaffected vaccine and any new vaccine received
- Notify the Iowa HHS Immunization Program to report the excursion event

2) S&H Per Unit: Temperature Excursions

Action Step: NOTIFY:

Vaccine Storage and Handling Incident Response Worksheet

Action Taken (<i>select all that apply</i>)	
<input type="checkbox"/>	Vaccine marked as "Do Not Use"
<input type="checkbox"/>	Shut unit door if left open
<input type="checkbox"/>	Resupplied power to unit
<input type="checkbox"/>	Adjusted thermostat
<input type="checkbox"/>	Monitored temperatures for 30 minutes for return to stable ranges
<input type="checkbox"/>	Vaccine stored in unit after temperature stabilized
<input type="checkbox"/>	Vaccine moved to back-up storage unit if necessary
<input type="checkbox"/>	Manufacturers called
<input type="checkbox"/>	VFC primary and back-up contacts notified
<input type="checkbox"/>	Medical director informed of incident
<input type="checkbox"/>	Immunization nurse consultant notified
<input type="checkbox"/>	Added dry ice
<input type="checkbox"/>	Moved to new storage unit

2) S&H Per Unit: Temperature Excursions

Action Step: DOCUMENT:

- Document details on Vaccine Storage and Handling Incident Response Worksheet
 - Date and time of the excursion
 - Overview of the incident
 - Type of storage unit(s)
 - Storage unit(s) temperature-current and minimum/maximum temperatures during the time of the event
 - Total length of time storage unit(s) was outside of normal range
 - Inventory of affected vaccines
 - Name of person completing the report

2) S&H Per Unit: Temperature Excursions

Action Step: CONTACT:

- Contact the manufacturer's of the affected vaccines.
 - [Vaccine Storage and Handling Incident Response Worksheet](#) and [Vaccine Storage and Handling Plan Template](#) contain vaccine manufacturer contact information
 - Provide DDL data for guidance on vaccine viability
 - If multiple excursions have occurred with any of the affected vaccines, provide this cumulative exposure time/temperatures to the manufacturers

Vaccine Manufacturer Contact Information for Excursions		
Manufacturer	Phone number	Online Stability Calculator or Website
AstraZeneca	1-800-236-9933	https://www.astrazeneca-us.com/az-in-us/Contact-us.html (general manufacturer website)
GlaxoSmithKline	1-888-825-5249	https://www.gskusmedicalaffairs.com/stability-calculator.html
Grifols	1-888-474-3657	https://www.grifols.com/en/home (general manufacturer website)
Johnson & Johnson - Janssen	1-800-565-4008	https://vaxcheck.jnj/
Merck	1-800-672-6372	https://www.merckmedicalportal.com/s/temperature-stability-calculator
Moderna	1-866-663-3742	https://tools.modernamedinfo.com/excursion
Novavax	1-844-668-2829	https://us.novavaxcovidvaccine.com/hcp (general manufacturer website)
Pfizer	1-800-438-1985	https://www.pfizermedicalinformation.com/en-us/stability-calculator
Sanofi Pasteur	1-800-822-2463	https://www.sanofimedicalinformation.com/s/stability-calculator
Seqirus	1-855-358-8966	https://www.csseqirus.com/products (general manufacturer website)

2) S&H Per Unit: Temperature Excursions

Action Step: CONTACT:

- Document manufacturer recommendations per vaccine

	Vaccine/Manufacturer	Lot Number	Expiration Date	Number of Doses	Opened Vials	Manufacturer Recommendations
Freezer						

- If determined to be nonviable, remove from storage units and initiate process to return spoiled vaccines in IRIS

2) S&H Per Unit: Temperature Excursions

Action Step: CORRECT:

- If the temperature alarm goes off repeatedly, do not disconnect the alarm until the cause has been determined
- Check the basics (power supply, unit door(s), DDL placement in unit, thermostat settings)
- Do not allow vaccines to remain in a nonfunctioning unit following a temperature excursion
 - If the storage unit has failed or is not stabilizing, implement the vaccine storage and handling protocol for transporting vaccine to a back-up unit
 - If alternative storage is available within the facility, transfer vaccine to that storage unit
 - If not, contact the backup facility to notify them of a refrigerator/freezer failure and the need to store vaccine at the backup location

2) S&H Per Unit: Temperature Excursions

Action Step: CORRECT:

Vaccine Storage and Handling Incident Response Worksheet

CORRECTIVE ACTION PLAN

Corrective Action Plan <i>(select all that apply)</i>	
<input type="checkbox"/>	No corrective action needed
<input type="checkbox"/>	Assure temperature probe is properly placed and secured
<input type="checkbox"/>	Purchase/Repair storage unit
<input type="checkbox"/>	Purchase notification system
<input type="checkbox"/>	Perform maintenance on unit
<input type="checkbox"/>	Pull unit out from wall
<input type="checkbox"/>	Clean coils
<input type="checkbox"/>	Check seals and door hinges
<input type="checkbox"/>	Defrost manual-defrost freezers
<input type="checkbox"/>	Update Storage and Handling Plan
<input type="checkbox"/>	Conduct staff education
<input type="checkbox"/>	Review Storage and Handling Plan with staff
<input type="checkbox"/>	Provide training for clinic staff on temperature monitoring
<input type="checkbox"/>	Other, describe below
<div style="background-color: #e6f2ff; height: 40px;"></div>	

2) S&H Per Unit: Temperature Excursions

- Submit completed Storage and Handling Incident Response Worksheet
 - Fax to 1-800-831-6292 or email to iowaVFC@idph.iowa.gov
 - Contact the Iowa VFC Program if you have questions or need to discuss recommendations

3) S&H: Expired Vaccines

Requirement:

- Expiration dates should be checked regularly (at least monthly) and stock should be rotated to ensure the soonest to expire is in front.
 - CDC best practice is to rotate weekly and whenever new vaccine is received.
- Expiration dates vary by type of vaccine or diluent and lot number.
 - Expiration dates that list only month and year are viable through the last day of the month.
 - Multi-dose vials of vaccine shall be administered until the expiration date printed on the vial or vaccine package unless otherwise noted in the vaccine package insert.

Action Steps:

- Rotate vaccine and check expiration dates
- Remove expired vaccines and diluents to avoid accidental administration
- Return all spoiled/expired public vaccines to CDC's centralized vaccine distributor within six months of spoilage/expiration
- Returns occur in IRIS - Providers must manage returns in IRIS and receive shipping label

4) Vaccine Preparation

Requirement:

- Prepared in a designated area away from any areas where potentially contaminated items are placed
- Only prepared when ready to administer them. Manufacturer-filled syringes (MFS) are only activated (removing syringe cap and attaching needle) when ready to use
- Vaccine and diluent expiration dates are checked prior to administration
- Only administered by the person that prepared them
- Single-dose vials (SDV) are only used one time for one patient
- Only the number of doses indicated in the package insert are withdrawn from multidose vials (MDV)
- Partial doses from two or more vials are never used to obtain a dose of vaccine
- Prefilled syringes, unused activated MFS, and unused SDV without a protective cap are stored according to manufacturer recommendations and are discarded at the end of the clinic day if not used. The manufacturer package insert is referenced for storage and handling recommendations of reconstituted vaccines

Action Step: Train staff on appropriate vaccine preparation

5) Maintaining VFC Documents:

- **Requirement:**

- Maintain all records related to the VFC Program for a minimum of three years
- VFC records includes, not limited to: VFC screening and eligibility documentation, billing records, medical records verifying receipt of vaccine, vaccine ordering records, vaccine purchase and accountability records (shipping invoices/packing slips), and paper temperature logs or electronic data
- Digital or electronic storage of records is allowable

Action Step:

- Maintain all VFC documents for minimum of 3 years

Clinic Status Changes Must Be Reported

- VFC providers must communicate changes to clinic status to the Iowa VFC Program, including, but not limited to:
 - Permanent closures
 - Temporary closures
 - Moving locations
 - Anything that would affect delivery, storage or monitoring VFC vaccine

- Send email to iowaVFC@idph.iowa.gov

VFC Program Resources

- [Iowa HHS VFC Program](#)
- [Immunization Materials Order Form](#): Includes Temp Logs
- [2023 VFC Provider List](#)
- [VFC Operations Guide](#)
 - [MCO/IA Health Link Member ID Cards](#)
 - [MCO/hawk-I Member ID Cards](#)
 - [VFC Eligibility and Insurance Situations - Quick View](#)
- [Vaccines for Children Program \(CDC\)](#)
- Register for 2023 VFC Webinar Series:
 - [November 29, 2023](#)

Questions?



- Email: iowaVFC@idph.iowa.gov
- Phone: 1-800-831-6293
- Fax: 1-800-831-6292

Website: <https://hhs.iowa.gov/immmtb/immunization/vfc>