

Vaccine Accountability, Management Policies and Business Rules

2012-2013

**Vaccine Management Team/Vaccines for Children
Program
Colorado Immunization Section
Colorado Department of Public Health and
Environment**



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Terms and Abbreviations

- CDC** **The Centers for Disease Control and Prevention:** The federal public health agency that oversees the VFC program.
- CDPHE** **The Colorado Department of Public Health and Environment:** The Colorado State public health agency.
- CIP** **Colorado Immunization Program:** The program within CDPHE that manages the Vaccines for Children Program. A separate division within the Colorado Immunization Section.
- CIIS** **Colorado Immunization Information System:** A web-based statewide immunization registry of patient’s demographic and immunization data. A division of the Colorado Immunization Section.
- FQHC** **Federally Qualified Health Center:**
- LPHA** **Local Public Health Agency:** The local public health organization, either a county or district department.
- McKesson** **McKesson Distribution:** The vaccine distributor contracted by the CDC. Colorado’s distribution center is located in Memphis, TN.
- RHC** **Rural Health Clinic:**
- VFC** **Vaccines for Children Program:** The federal vaccine program for Medicaid eligible, American Indian/Alaskan Native, or Uninsured children ages 0-18 years of age.
- VIS** **Vaccine Information Statements**
- VMT** **Vaccine Management Team:** The managing body for the VFC program at the state level.
- VTrckS** **Vaccine Tracking System:** The vaccine ordering, tracking, and management system from the CDC that is used to place orders for the VFC vaccines.

Vaccine Management Team Roles and Responsibilities

Vaccine Management Team Roles and Responsibilities

The Vaccine Management Team (VMT) is responsible for the accountability and management of all vaccines that are supplied to the citizens of Colorado from the Colorado Immunization Program (CIP) and the VFC program. Vaccines managed by the team include all vaccines from the VFC program and assorted vaccines available with Section 317 federal funds, as well as vaccines for Emergency Preparedness and outbreak control.

The VMT is comprised of 4 members and a Manager. The members of the team are the VFC Operations Coordinator, the VFC Clinical Coordinator (a Public Health Nurse Consultant), the International Travel Vaccine Coordinator (and regional Public Health Nurse Consultant), a data specialist, and the team manager.

VFC Operations Coordinator:

Responsibilities include:

- Oversees operations of the Colorado VFC Program
- Management of the Vaccine Spend Plan for the VFC Program
- Management of all Master Provider data files in VTrckS
- Fraud and Abuse Coordinator
- Management of provider storage and handling issues
- Analyze and approve all vaccines orders placed with the CIP
- Management of all Provider Enrollment/Re-enrollment Data
- Responds to questions from providers related to VFC business rules
- Responds to provider and public questions related to the VFC program
- Responsible for tracking compliance and retention of VFC providers guaranteeing VFC Program standards and federal rules are met
- Colorado VFC Policies and Procedures

Reports to the VMT Manager and is supervised by the CIP Section Director.

VFC Clinical Coordinator:

Responsibilities include:

- Oversight of all VFC Site Visit Personnel
- Review and Revise VFC Site Visit Policies and Procedures
- Colorado VFC Policies and Procedures
- Review orders for appropriateness and contact providers if orders are questionable
- Coordinates with Colorado Department of Health Care Policy and Finance (Medicaid) regarding VFC vaccines and any changes to VFC supplied vaccines.
- Coordinates VFC site visit CoCASA data for completion of the VFC Management Survey
- Coordinates VFC provider enrollment visits and provider education re: the VFC program
- Coordinates with the VFC Operations Coordinator related to Enrollments/suspensions/terminations from the VFC program
- Performance of VFC compliance site visits as necessary
- Performance of VFC Enrollment Site Visits as necessary
- Performance of Joint Supervisory Site Visits with contractors as required by CDC policy
- Responds to provider and public questions related to the VFC program
- Responds to provider and general public questions related to vaccines/schedules/etc.

Reports to the VMT Manager and is supervised by the CIP Section Director.

Data Specialist:

Responsibilities include:

- Direct data entry of paper orders/inventory into the VTrckS system
- Tracking and data entry of vaccine returns/wastages into VTrckS
- Responding to provider inquiries regarding order tracking
- Reporting any problems or issues with providers or vaccine ordering to the VFC Operations Coordinator

- Handles all incoming calls regarding VFC related questions that pertain to vaccine orders/returns
Reports to the VFC Operations Coordinator and is supervised by the CIP Section Director

Public Health Nurse Consultant for International Travel Vaccines: This individual is located on the western slope (west of the Continental Divide) in Colorado

Responsibilities include:

- Assisting the VFC Clinical Coordinator with training and oversight of VFC Site Visit personnel
- Review orders for appropriateness and contact providers if orders are questionable
- Performance of VFC compliance site visits, as necessary
- Performance of VFC Enrollment Site Visits, as necessary, on the west slope
- Performance of Joint Supervisory Site Visits with contractors, as needed
- Responds to provider and public questions related to the VFC program
- Responds to provider and general public questions related to vaccines/schedules/etc.
- Responds to providers and public related to questions about international travel vaccines
- Coordinates with providers of Yellow Fever Vaccine and oversees the certification process for Yellow Fever Stamp

Reports to the VMT Manager and is supervised by the CIP Section Director.

VMT Manager:

Responsibilities include:

- Oversees the day-to-day operations of the VMT staff
- Responds to questions from providers related to VFC business rules
- Participates in CIP Leadership Team Meetings
- Communicates with CDC
- Guarantees that VMT activities are addressed in CDC grant activities
- Acts as CIP representative with vaccine manufacturer representatives

Reports to/and is supervised by the CIP Section Director.

**Enrollment
And
Program Participation**

Enrollment and Program Participation

Provider Enrollment

Any health care provider providing routine childhood/adolescent vaccines may enroll in the Vaccines for Children by contacting the CIP. Providers wishing to enroll must complete the following:

1. Complete a Provider Pre-enrollment Request which is available at www.coloradovfc.com.
2. Complete and return a VFC Provider Enrollment Agreement:
 - a. New Provider Enrollment Form (Form1)
 - b. Provider Enrollment Agreement (Form 2)
 - c. Prescriber List (Form 3)
 - i. All potential providers must supply current Colorado Medical License number and provider Medicaid number.
 - ii. The enrollment process will be placed on hold until all information is collected and is validated.
 - d. Provider Profile Form (form 4)
3. Satisfactorily complete a Provider Enrollment Site Visit which includes new provider training.
 - a. Provider must:
 - i. Have acceptable vaccine storage unit or be able to purchase appropriate storage.
 - ii. Have calibrated thermometers with current certificates.
 1. CIP will provide these if unavailable
 - iii. Have an understanding of vaccine accountability procedures.
 - iv. Have a completed Vaccine Management Plan with all components required by the CDC.
 1. CIP has a template for providers to use that has all required points which is available at www.coloradovfc.com.
 - v. Be willing to offer all ACIP recommended vaccines and follow ACIP schedules
 - vi. Understand VFC program requirements for Eligibility Screening, record retention, vaccine ordering and return procedures.
 - b. Providers unwilling or unable to meet the above criteria will be allowed to make corrections and the Enrollment site visit will be redone.
 - i. If 4 months or more has passed since first Enrollment visit was completed and the provider has no corrected the issues or contacted the VFC program, they will need to complete the entire enrollment process again.
4. Upon satisfactory completion of the Enrollment site visit and training, the provider will be issued their Personal Identification Number (PIN) and assisted by the Public Health Nurse Consultant to place their first VFC vaccine order.
5. Providers must have a current, signed VFC Provider Agreement in place to participate in the VFC program and order vaccine.
6. Providers must ensure accurate shipping and contact information is available to the VMT at all times.
 - a. Providers are required to submit a Provider Change of Information to the VFC Program at least 30 days prior to any change. This allows for adequate time to make changes to master data in the VTrckS system.
 - b. The form is available on the CIP-VFC web site at www.coloradovfc.com.
7. Vaccines available for provider orders will be identified on the standardized order form, available at www.coloradovfc.com or on the VTrckS system for those providers ordering via internet.

Types of Provider Enrollment

Providers are divided into two categories:

1. Public Providers: those entities that receive public (city/county/state/federal funding to operate)
 - a. LPHA's
 - b. FQHC's
 - c. RHC's
 - d. Public Hospitals and associated clinics

- e. Youth Corrections
 - f. Community Health Clinics
 - g. School Based Health Centers operated by FQHC's Public Hospitals,
 - h. Public University Clinics
2. Private Providers: any provider that does not fit the above categories
 - a. Private Physicians (individual, group, and HMO's)
 - b. Private University Clinics
 - c. Private not-for profit hospitals/clinics
 - d. RHC's
 3. Pharmacies are not allowed to enroll in the Colorado VFC program per the Medicaid/Immunization Program Collaborative agreement.

Patient Eligibility

All active enrolled providers must screen every child, at every immunization visit, for VFC eligibility. VFC eligibility is not verified, but must be documented on the first visit to the clinic/practice, and every time eligibility status changes. All children 0-18 years of age who meet one or more of the following criteria are considered eligible to receive VFC vaccines.

1. Is enrolled, or is eligible to be enrolled in Medicaid;
2. Has no health insurance;
3. Is American Indian/Alaskan Native, or;
4. Is underinsured
 - a. Underinsured children are covered by private insurance, but that insurance may not have vaccine coverage, insurance only covers selected vaccines (the child is VFC eligible for non-covered vaccines), or coverage may cap at a certain amount (once the coverage amount is reached, these children are categorized as underinsured). Underinsured children are eligible to receive VFC vaccines only through a FQHC, RHC, or LPHA that has signed a deputization agreement with a FQHC.

Deputization of LPHA's

The CIP has secured agreements with the number of FQHC's and LPHA's thorough out Colorado. The following list is those agencies have been in cooperation since 2009. There are a large number of LPHA's that do not have deputization authority granted to them due to lack of FQHC's in their communities.

LPHA	FQHC
Alamosa County Public Health	Valley-Wide Health Systems, Inc.
Boulder County Health Department	Clinica Campesina
Costilla County Public Health	Valley-Wide Health Systems, Inc.
Denver County Public Health	Denver County Community Health Services
Dolores County Public Health	Community Health Clinic
Tri-County Health Department	Metro Community Provider Network
El Paso County Health Department	Peak Vista Community Health Centers
Garfield County Public Health	Mountain Family Health Center
Jefferson County Health Department	Metro Community Provider Network
Kit Carson County Public Health	Plains Medical Center
Larimer County Health Department	Salud Family Health Centers and Sunrise
	Community Health Center
Northeast Colorado Health Department	Salud Family Health Center
Northwest Colorado VNA	Northwest Colorado Community Health
	Center
Park County Public Health	Metro Community Provider Network
Prowers County Public Health	High Plains Community Health Center
Pueblo City-County Health Department	Pueblo Community Health Center
San Miguel County Public Health	Uncompahgre Medical Center
Teller County Public Health	Peak Vista Community Health Centers
Weld County Health Department	Sunrise Community Health Center

Those providers, public and private who do not have signed deputization agreements must notify parents of underinsured children, that free vaccines may be available at a FQHC or RHC. At this time, Colorado does not have any deputization agreements with private providers.

Program Participation Requirements

1. Providers enrolling in the VFC Program are required to successfully complete an enrollment site visit (as stated on page 6) which the VFC Clinical Coordinator or designee will complete with the provider and staff who will be involved in the day-to-day management of the program.
 - a. Providers must understand the enrollment agreement, the requirements of the program, and what is expected of them prior to their PIN being issued.
 - b. For provider enrollment process to be complete, the provider must supply at least two weeks worth of temperature logs, taken with a calibrated thermometer, demonstrating that all temperatures for ALL storage units that will store VFC vaccines can maintain temperatures in the proper storage ranges (either refrigerated or frozen).
 - c. Provider/VFC responsible staff is required to have a valid email address, which is supplied to the VMT to use for all VFC communications.
2. Providers are not required by the state of Colorado to participate in the CIIS registry; however the VFC program strongly encourages participation to assist providers with determining their provider profile during the re-enrollment process.
 - a. Other means to determine provider profile is Medicaid billing data, or doses administered data can be used in lieu of registry data.
3. Active enrolled providers are required to have a VFC Compliance Site Visit, done by a CDPHE Public Health Nurse Consultant, (or an LPHA Public Health Nurse that has contracted with CDPHE) every other year, starting a minimum of 6-12 months after the initial enrollment process is complete.
4. Providers whose vaccine shipments have been suspended for accountability issues, and have not taken steps to correct the issues, may be inactivated and will be required to re-enroll and complete the re-enrollment site visit prior to having vaccine ordering privileges reinstated.
 - a. Successful completion of either secondary or tertiary educational activities will supersede the re-enrollment site visit process.
5. Prior to the enrollment of a provider in the VFC program, the VMT will review the information on the Prescriber list and check the information against the *"List of Excluded Individuals/Entities"* at: <http://oig.hhs.gov/fraud/exclusions.asp> . If any person is found to be on the list, that provider's office/clinic will not be allowed to be enrolled in the VFC program.
6. Providers are required to have a VFC Compliance Site Visit, done by a CDPHE Public Health Nurse Consultant, (or an LPHA Public Health Nurse that has contracted with CDPHE) every other year, starting a minimum of 6-12 months after the initial enrollment process is complete.
7. Providers are required to complete a Re-enrollment process that takes place every April. Failure to complete the re-enrollment process will cause providers to be inactivated and must complete a new enrollment and enrollment site visit.
8. Providers failing to meet all program deadlines for program participation may cause providers to have orders placed on hold until all deadlines have been met.



Vaccine Ordering

Vaccine Ordering

Vaccine Funding

The CIP supplies all ACIP recommended vaccines for VFC eligible children ages 0 through 18 years of age. These vaccines are purchased with federal dollars, and are available to active enrolled VFC providers. At this time there is no purchase of vaccines with state dollars.

Vaccines Supplied for Colorado VFC Providers

The following vaccines are available through the VFC program at no cost for eligible children/adolescents:

- ✓ **DTaP** (Diphtheria, Tetanus, Acellular Pertussis)
- ✓ **DT** (Diphtheria, Tetanus-pediatric)
- ✓ **Td** (Tetanus, Diphtheria-ages 7 through 18)
- ✓ **Tdap** (Tetanus, Diphtheria, Acellular Pertussis-ages 7-18)
- ✓ **Hib** (Haemophilus Influenza type b)
- ✓ **MMR** (Measles, Mumps, Rubella) combination vaccine
- ✓ **EIPV** (Polio)
- ✓ **Hep A** (Hepatitis A)
- ✓ **Hep B** (Hepatitis B)
- ✓ **Varicella** (Varicella)
- ✓ **PCV 13** (Pneumococcal Conjugate-routine ages 2 months through 59 months of age)
- ✓ **PPSV 23** (Pneumococcal Polysaccharide-high risk children ages 2 -18 years of age)
- ✓ **Rotavirus** (Rotavirus vaccine)
- ✓ **Influenza vaccines**
- ✓ **HPV** (Human Papillomavirus Vaccine-for both males and females through age 18)
- ✓ **MCV4** (Quadrivalent conjugate meningococcal vaccine)
- ✓ **Pediarix®** (DtaP, IPV, Hepatitis B) combination vaccine)
- ✓ **Pentacel®** (DTaP, IPV, Hib) combination vaccine
- ✓ **Kinrix®** (DTaP, IPV) combination vaccine for ages 4-6 years.

Because Colorado is a provider-choice state, all vaccines available through the VFC program, are available to order in all available presentations.

Vaccine Ordering and Approval

All VFC orders, submitted either electronically or on paper, are reviewed by the VMT for the following information prior to the approval of the order:

1. Provider contact, shipping address, shipping instructions, and provider status are verified.
2. The order is reviewed for appropriateness (timing of the order, size of the order, antigens being ordered, etc.)
3. Provider has submitted a valid order form.
4. Provider has submitted accountability reports
 - a. At this time, acceptable accountability reporting is inventory on hand for ALL VFC doses in the storage unit.
5. Orders may be held for review for a number of reasons:
 - a. Vaccine management plan is incomplete;
 - b. Provider has not submitted required paperwork after an incident;
 - c. Provider has failed to complete the re-enrollment process as required;
 - d. Provider has not supplied change of information as requested if staff, clinic address, or hours of operation have changed since last order;
 - e. Order is received during the last calendar week of the month.
 - i. Provider will be notified that order received after the ordering deadline will be voided. Provider will need to re-submit the order the following month.

Ordering Process

1. Providers are allowed to order no more frequently than once per calendar month. At this time, providers are placing orders by one of the following methods:

- a. Electronically directly via VTrckS, or
 - b. On paper, via fax, which is then transcribed and ordered via VTrckS by VMT staff.
2. Orders received more frequently than once/month will be either cancelled or voided and a message sent back to the provider reminding them that they can only order once/month.
3. All orders will be monitored by VMT staff.
 - a. This provides for quality assurance related to vaccine order management
 - b. See Vaccine Ordering and Approval for steps related to reviewing the order:
 - i. Appropriateness:
 1. Is order consistent with previous orders,
 2. Has there been another order placed in the last 30 days,
 3. Antigens being ordered are consistent with provider type
 - a. Eg., Family Practice Physician ordering large quantities of PPSV23 instead of PCV13, or DT instead of DtaP, or Tdap.
 - ii. Is provider on hold or has had ordering privileges suspended
 - iii. If order placed by fax instead of electronically, why.
 - iv. Orders received that are not consistent with previous orders will be sent to the VFC Clinical Coordinator for review and investigation.
 1. After discussion with the provider, the order may be modified or submitted as received.
4. Providers submitting orders, regardless of method, will receive a confirmation memo verifying that the order was received by the VMT.
 - a. The memo may have a reason that the order has been cancelled or voided.
 - i. Reasons for cancellation or voided order a may be:
 1. Old order form-only current order forms will be accepted.
 - a. Order forms are available at: www.coloradovfc.com .
 2. Inventory being reported is not complete and accurate.
 - a. All VFC vaccine in inventory must be reported.
 - i. Lot numbers may NOT be lumped together.
 - ii. Every lot number must be accounted for.
 - iii. Each lot number on hand should have total doses reported.
 3. Provider re-enrollment paperwork has not been received, or is incomplete.
 - a. Only current year re-enrollment is acceptable.
 4. Order is received after the monthly deadline to order.
 5. Provider is on ordering suspension as the result of a failed VFC Compliance Site Visit.
 6. VFC PIN is missing from order form, or the number is incorrect.
 7. Provider has been placed on hold until vaccine loss has been accounted for and restitution has been made.
 8. Electronic orders through VTrckS may be cancelled or voided because:
 - a. Vaccine intent is not correct.
 - i. All vaccines ordered through VTrckS must have intention listed, and they all must be pediatric.
 - b. Inventory is not complete.
 - c. Order has not passed other business rules listed above.
5. Once the order has been approved, and the inventory updated in the VTrckS system, the order will be manually entered into VTrckS by either the VMT data specialist or the VFC Operations Coordinator.
 - a. At this point, once all business rules have been reviewed, and the inventory and order have been transcribed into VTrckS, the provider will receive a confirmation email that the order has been processed.

Influenza Ordering

The VFC program ordering process for influenza vaccine begins in February, when providers are asked to determine the amount of influenza vaccine (in what presentation(s)) they would like to receive for the up-

coming influenza season. They CDC required that state VFC programs pre-book influenza in late February or early March of the current year, thus Colorado VFC providers must use previous year doses administered data to determine the amount of influenza vaccine to request from the Colorado VFC program. Providers are notified by memo in early February to begin determining the number of doses they will need. They are asked to submit those doses to the VFC program via an internet to an online order form. Once all pre-book orders are received, they are placed in a spreadsheet by presentation and brand, and totaled. These numbers are then sent to the CDC upon request. Colorado builds in an additional 10-15% to account for provider increases (or providers who failed to pre-book) that occur during the year.

The pre-book spreadsheet is then used to upload the provider orders once the vaccine is available for distribution by the warehouse.

If a provider fails to pre-book vaccines, they will place an influenza vaccine order in September or October and will be able to receive vaccines after all pre-booked orders have been fulfilled.

Provider Order Forms

Those providers placing orders by fax are required to use the most current version of the Colorado VFC Program order form. The form is available at: www.coloradovfc.com and are updated as required to maintain the current manufacturer NDC codes. Order forms will have the updated date on the form. Orders received on older forms will be voided and returned to the provider with the voided reason; providers must resubmit the order on the current form for the order to be processed. VTrckS will only accept current NDC codes.

Influenza vaccines are NOT available for order on the standard VFC Order Form, as stated in the previous section.

Frozen Vaccine Eligibility

Only providers who have acceptable freezer storage are allowed to order frozen vaccines from the VFC program. Acceptable Varicella vaccine storage units include chest or upright freezers, refrigerator/freezer combinations with separate external doors (and preferably separate refrigerator and freezer controls), either household or laboratory grade. Providers wishing to receive Varicella vaccines must have their storage unit(s) approved (during either an enrollment visit or site visit by VMT staff) prior to placing the first order.

Providers wishing to order Varicella vaccine for the first time must also supply the VMT with a minimum of two weeks of temperature logs for the freezer unit. All temperatures taken must be within the appropriate storage temperature range and be recorded twice daily.

Provider Inventory Maintenance

The CIP supplies over \$40 million dollars worth of federally purchased vaccine to active enrolled VFC providers annually. Providers must conduct monthly inventory of their VFC supplied vaccines and report it to the VFC program each time an order is placed.

1. Providers ordering directly in VTrckS, can enter inventory up to two weeks (14 days) prior to entering an order.
 - a. It is preferable to enter the current inventory on the date the order will be placed, rather than what was available 2 weeks earlier.
2. Providers placing faxed orders must include ALL VFC supplied vaccines in inventory on their order submission.
 - a. Orders will be voided if ALL VFC inventory is not reported.
 - b. Incomplete order forms may be given to VFC Clinical Coordinator, or designee for follow-up and educational component, if necessary.
 - c. Providers with voided or cancelled orders must resubmit a correctly completed order form before an order can be placed.
3. Providers are expected to only store a 30-45 day inventory of vaccines.

Exceptions to Established Provider Ordering Practices

In general, unless a provider is on hold for storage and handling issues, Colorado enrolled VFC providers are

allowed to order once/calendar month, regardless of the size of the practice. There should be no reason for a provider to need to order more frequently. Emergency/Priority orders will be addressed later in this document.

Assessing Order Appropriateness

Part of the duties of the VMT is to assess all provider orders for appropriateness. Much of this can be accomplished by reviewing order history, vaccine wastage and returns, and inventory logs that are available for each active enrolled VFC provider in VTrckS. These numbers are compared to the previous year's benchmarking (provider profile) that is supplied by providers during the re-enrollment process. Unusually large or small orders will be addressed by either the VFC Operations Coordinator, or the VFC Clinical Coordinator, on a clinic by clinic basis.

Colorado does not utilize Economic Ordering Quantity (EOQ). Data analysis of ordering patterns and doses of vaccines distributed to providers over the last several years has revealed that providers actually have divided themselves into categories and order accordingly. The largest providers with the largest vaccine distribution order monthly while the small private providers in the rural areas may only order once or twice a year minimal amounts of vaccine.

Seventy-five percent of all Colorado VFC supplied vaccines goes to one-quarter of the active enrolled providers. Eight-five percent of all the vaccine distributed goes to fifty percent of the enrolled providers. These providers generally order monthly. The remaining fifteen percent of vaccines distributed by the Colorado VFC program goes to the remaining fifty percent of active enrolled VFC providers, and these providers order bimonthly, quarterly or semi-annually.

Emergency/Priority Orders

Emergency/Priority orders are reserved for outbreak control or natural disaster response, since priority shipping is charged by dose of vaccine and not by bulk package. This vaccine is Section 317 funded vaccines or paid for by purchase order from funds available through Emergency Preparedness and Response (EPR) budgets.

Since all orders placed in VTrckS by providers with access must be reviewed by the VMT prior to submission, any order with priority status instead of routine status, will be cancelled and the provider notified. No provider with ordering privileges in VTrckS may submit a priority order. VMT may place a priority order for a provider who lost vaccines due to a power-outage or mechanical failure but each incident will be reviewed prior to placing such an order.

Provider Order Placement Methods

Currently there are only two approved methods for submitting vaccine orders in Colorado:

1. VTrckS:
 - a. Public and large private provider offices that are used to online vaccine ordering systems
2. Paper faxed orders:
 - a. All other provider not included in the above two categories.

Granting Providers Access to VTrckS

Providers allowed access to VTrckS ordering is based on provider size, distribution and type of facility. Providers initially brought on to the system were active participants in the online vaccine ordering pilot. Providers wishing to use the system must be cleared by the CDC, and complete the training process. Providers must understand that each individual allowed to order vaccines in their clinic must NOT share passwords and follow all guidelines set forth in the Colorado VFC Provider Enrollment Agreement. Failure to follow the guidelines will lead to suspension of ordering privileges, until successful completion of a Secondary education process.

Processing and Submission of Provider Orders

The VMT will review and process orders for submission to McKesson daily during the first three weeks of each

month, except on recognized holidays or other days that either CDPHE or McKesson are closed. McKesson is traditionally closed during the final two weeks of December, so no orders will be either processed or shipped during this time.

Vaccine shipments should arrive within 3 weeks of the time that the order was placed. This is particularly true for frozen vaccines shipped directly from Merck.

Vaccine Management Practices

Vaccine Management Practices

Principles of Provider Receiving

Prior to the first vaccine shipment to a newly enrolled VFC provider, the clinic/practice must demonstrate a clear understanding of vaccine management and storage and handling protocols. The CIP has developed and made available via the internet, a fill-able .pdf Vaccine Management Plan that addresses all items required by CDC.

- ✓ Designation of primary and back-up Vaccine Coordinator
- ✓ Proper Storage and Handling of vaccines
- ✓ Vaccine shipping (receiving and transport)
- ✓ Procedures for relocation of vaccine in the event of power or mechanical failure
- ✓ Vaccine ordering
- ✓ Stock rotation
- ✓ Vaccine wastage
- ✓ Yearly review and update

This document is reviewed by VMT staff, and updated as protocols are refined or changed by the CDC. Providers are made aware of changes, and should revise their protocol as needed. Per the Vaccine Management Plan, providers are required to have at least two trained staff persons available to receive and store vaccines then they are received. Vaccine losses resulting from failure to store vaccines properly upon arrival will result in corrective actions that could include reimbursement to CIP for vaccines lost. More specifics regarding the Vaccine Management Plan will be addressed later in this document.

Providers are instructed how to properly receive and store vaccines during the initial enrollment visit.

1. Comparison of the invoice with the order form (providers ordering from VTrckS are asked to print a copy of their order when prompted by the system).
2. Review of the shipping invoice to guarantee vaccines received are what are listed on the invoice.
 - a. Lot numbers should match
 - b. Number of doses and antigen types should match
 - c. Expiration dates should match.
 - i. Expiration dates should be at least 12 months.
3. Package and/or contents should be intact and not damaged
4. Cold chain monitors¹ have not been activated.
 - a. Take proper action if monitor(s) have been activated.

Providers discovering problems with vaccine shipments should notify McKesson and CIP immediately. Vaccines should be stored correctly and labeled "DO NOT USE" until the issue is resolved, or vaccines are returned.

Monitoring Order Status

VMT does not routinely monitor vaccine shipments to providers. VMT does have that capability, however, if a provider calls and wants to know order status. VTrckS will show a Fedex tracking number in the most current provider order, once the order has left the warehouse. By accessing the Fedex site and copying and pasting the tracking number, all shipment information is available.

- ✓ Date vaccine was shipped
- ✓ To whom vaccine was shipped (clinic name, address, contact, etc.)

Delivering and Receiving Frozen Vaccines

Providers cleared to order and receive frozen vaccines will be instructed on the following information:

1. Frozen vaccines are ordered at the same time as all other non-frozen vaccines.
2. Frozen vaccines may arrive after the refrigerated vaccines have been received in the clinic.

¹ Cold Chain Monitors (CCMs) - These single-use devices come in three basic types: those that indicate whether packages have reached temperatures that are too warm, those that indicate whether packages have reached temperatures that are too cold, and those that continuously record the temperature. These types of monitors are designed to be irreversible indicators of inappropriate temperatures.

- a. Frozen vaccines are shipped directly from the manufacturer.
- b. They are no longer shipped on dry ice, but are shipped frozen with bio-degradable freezer blocks.
 - i. These blocks must be discarded and not refrozen.
- 3. Receiving procedures for frozen vaccines are the same as refrigerated vaccines.
 - a. Comparison of the invoice with the order form (providers ordering from VTrckS are asked to print a copy of their order when prompted by the system).
 - b. Review of the shipping invoice to guarantee vaccines received are what are listed on the invoice.
 - i. Lot numbers should match
 - ii. Number of doses and antigen types should match
 - iii. Expiration dates should match.
 - 1. Expiration dates should be at least 12 months.
 - c. Package and/or contents should be intact and not damaged
 - d. Cold chain monitors¹ have not been activated.
 - i. Take proper action if monitor(s) have been activated.

Providers discovering problems with vaccine shipments should notify McKesson and CIP immediately. Vaccines should be stored correctly and labeled “DO NOT USE” until the issue is resolved, or vaccines are returned.

Decision Making Regarding Central Pharmacy Practices

Decisions related to participation in the VFC program by organizations using a central pharmacy for vaccine management will be considered on a case by case basis.

CIP and the VMT will work with the organization to establish best practices for vaccine ordering, delivery, quality assurance, and accountability.

Organizations with central pharmacies may continue to order vaccines for satellite clinics; however they must guarantee that the satellite clinic site(s) contact and ship to information is up to date.

All sites with central pharmacy distribution will be subject to VFC Compliance Site Visits, as are any standard provider sites.

Emergency Deliveries

Emergency distribution of vaccines through the VFC program should be the exception and only occur in the event of an unexpected vaccine loss due to a power-outage, or vaccine preventable disease outbreak management.

Emergency distribution can be accomplished within 24 hours of submission of and emergency order from CIP to the distributor. Providers are not allowed to place priority orders. Those orders are stopped by the CIP-VMT and reviewed and investigated prior to their being sent to McKesson.

Use of Alternate Deliver Sites

CIP will not allow providers to have alternate delivery sites for vaccines, with the exception of those sites with central pharmacy distribution practices.

Quality Assurance and Accountability

Quality Assurance and Accountability

Promoting “Best Practices”

The CIP has numerous forms and educational resources available at no cost to providers. They can be ordered online at www.coloradovfc.com 24 hours a day, seven days a week. Resources available include:

- ✓ Calibrated Digital thermometers, with certificates
- ✓ Temperature log sheets in Fahrenheit and Celsius
- ✓ Vaccine Information Statements
- ✓ Epidemiology and Prevention of Vaccine Preventable Diseases, current edition;
- ✓ VFC stickers for vaccine boxes,
- ✓ Breaker tags,
- ✓ Refrigerator outlet tags,
- ✓ Colorado Immunization Program Manual (CIM)
- ✓ Clinic Vaccine Administration Records (includes VFC Patient Eligibility Screening Form)
- ✓ Guidelines for purchasing Vaccine Storage equipment
- ✓ All VFC order and return forms
- ✓ Vaccine Management Plan-a fill-able .pdf document

CIP and the VMT are the point of contact for provider reports of loss.

1. VMT will provide consultation and follow-up to providers to ensure that remedial action occurs and further incidents are avoided.
 - a. Providers are required to have a written plan or procedure to reduce and document vaccine wastage.
 - b. Providers are asked for this document, an incident report, and an action plan when a vaccine loss occurs.
2. VMT may hold provider orders until accountability issues are resolved or until completion of other follow-up deemed necessary to ensure correct vaccine storage and use.

Vaccine Administration

Per federal statute 42 US Code 300aa-25 and 26, providers must provide a copy of the appropriate VIS prior to each vaccination. Electronic links to the current VIS are available on the VFC Program web page at: www.coloradovfc.com . Providers are encouraged to sign up for the e-Updates from the CDC, also. The National Childhood Vaccine Injury Act (NCVIA) *requires* the following information be documented and maintained in the child’s record. This record can be either a paper record, an electronic health record, or entered into CIIS.

- ✓ Type of vaccine, (DTaP, IPV, MMR, etc.)
- ✓ Name of the vaccine manufacturer,
- ✓ Lot number,
- ✓ Date the vaccine was given, (month, day, year),
- ✓ Specific site where the vaccine was administered (right deltoid, left antero-lateral thigh, etc.),
- ✓ Date VIS given to patient/parent,
- ✓ Publication date of the VIS,
- ✓ Name, title, and business address of the health care provider administering the vaccine.

Route of vaccine administration is not required documentation by NCVIA, but is highly recommended, as is documentation of the expiration date.

Vaccines provided by the VFC program must be administered in accordance with the Recommended Childhood and Adolescent Immunization Schedules, approved by the ACIP and other Colorado vaccine guidelines and recommendations.

Pre-filling of vaccine into syringes is **not** an acceptable practice. Providers should draw vaccines only at the time of administration to ensure that the cold chain is maintained and the vaccines are not inappropriately exposed to light.

Vaccine Borrowing/Replenishment

VFC-enrolled providers are expected to maintain an adequate vaccine supply for both VFC and non-VFC eligible patients.

1. The provider must assure that borrowing of VFC vaccine will not prevent a VFC eligible child from receiving a needed vaccination because VFC vaccine was administered to a non-VFC eligible child.
2. Borrowing may only occur when there is lack of appropriate stock due to unexpected circumstances such as a delayed vaccine shipment, vaccine spoiled in-transit to provider, or new staff that calculated ordering time incorrectly.
 - a. VFC vaccine cannot be used as a replacement system for a provider's privately purchased vaccine inventory.
 - b. The reason cannot be provider planned borrowing from either the private stock or the VFC stock. This information must be documented on the CIP Borrowing Form located on www.coloradovfc.com and maintained for a minimum of three years.
 - c. Examples for when borrowing may occur:
 - i. Private stock vaccine is used for a VFC eligible patient,
 - ii. Private stock is administered to a patient who is later determined to have been VFC-eligible (not because of unmet deductibles or co-payment).
 - iii. VFC order was delayed.
 - iv. VFC order was received non-viable.
 - v. VFC-only vaccine used for a non-VFC patient (e.g. HPV vaccine)
 - vi. Private stock order was delayed.
 - vii. Private stock was received non-viable.

This is a dose-for-dose replacement of vaccine stock and must be documented on the CIP Borrowing Form for all vaccines. Borrowing and replenishment should be infrequent. Providers suspected of abusing the borrowing policy will be investigated.

Ensuring Provider Information is Correct

Providers must review shipping information prior to placing their order in VTrckS. **ALL** providers must notify the VMT via fax of any changes in shipping information before an order can be processed. For changes to the Master Data records to take effect in VTrckS, the system must have overnight to replicate the changes. Changes to master data that are not allowed to replicate will automatically cancel any order that is placed.

At the time of enrollment and re-enrollment, all contact information should be verified. All providers listed on the Prescribers List in the enrollment/re-enrollment packet; need to be checked against the "List of Excluded Individuals/Entities" at: <http://oig.hhs.gov/fraud/exclusions.asp>. This verification will be documented in the notes section of the current version of COCASA. If any person is found to be on the list, that provider's office/clinic will not be allowed to be enrolled in the VFC program. Please refer to page 8, number 5 for more information. Provider information is also reviewed and updated as part of the VFC Compliance Site Visit.

Vaccine Transfers

Providers may have a need to transfer vaccines, or CIP may transfer vaccines between providers to prevent excess wastage of vaccines. Providers wishing to transfer vaccines must notify the VMT of the transfer, and receive instructions for the completion of the process. A Vaccine Transfer Form must be obtained from the VMT and utilized for the transport. A copy of the transfer form, or the original, must be returned to the VMT. A vaccine transfer is not completed until the VMT makes the necessary vaccine transfers in the VTrckS system. This must be done to allow providers to identify the vaccines in stock, by NDC and lot number, when they are doing inventory reconciliation. It also allows the VMT to track lot numbers and NDC, in the event of a vaccine recall.

Prior to the actual transfer of the vaccine, the vaccine transport protocol must be reviewed by the provider, or CIP staff. Providers must have a current transport protocol and transport equipment available to complete the transfer.

1. A cooler large enough to hold the volume of vaccine to be transferred, adequate ice packs and padding material for the inside of the cooler, and thermometers to monitor temperature during the actual transport process.

2. CIP-VMT has several coolers, ice packs, and calibrated thermometers available, in addition to two portable vaccine refrigerators/freezers at their disposal to use for transporting vaccines over long distances.
 - a. The portable vaccine cooler units are located in the “vaccine” storage room, and are plugged in and cool at all times.
3. For transfers that may take several hours to complete, CIP has access to a medical courier service that can also transport the vaccines, if necessary.

Before the transfer takes place there must be a visual inspection of the temperature logs for at least the last three months. Prior to the physical moving of the vaccine from the cooler to the refrigerator at the destination, the current temperature of the accepting refrigerator/freezer must also be assessed and documented. If the temperatures are not acceptable the transfer must not take place. Vaccines that have been exposed to out of range temperatures that have not been reported to the VMT, will not be accepted for transfer and the vaccine management plan for out of range temperatures may be activated to determine the viability of the vaccines.

Ideally, providers should request a vaccine transfer at least 90 days prior to the expiration of the vaccine. VMT will make every effort to move vaccines prior to expiration, so there is less wastage, however, depending on the circumstances, the amount of vaccine, and the type of vaccine, it may not be possible to find a location to accept it. In such instances, the provider will be asked to use as much of the vaccine as possible, before the expiration date.

Processing Vaccine Returns

Providers are asked to complete the following steps when reporting expired/spoiled vaccines:

1. Remove the wasted/expired vaccines from the storage units to prevent inadvertent administration.
2. Implement their written procedure for reporting and responding to vaccine losses.
3. All vaccine returns will be returned to McKesson for excise tax processing.

The steps providers take to return vaccines are outlined on the Vaccine Return Form available from CIP-VFC program.

The VFC program must be notified of all vaccine returns and the reason for the return. Vaccine returns will be only accepted with the most current Vaccine Return Form that is available at: www.coloradovfc.com . Most current forms must be used, as all returns must be processed through VTckS and must have current NDC numbers. Each dose that is wasted/expired must be entered onto the form, in addition to lot numbers, NDC, and total cost of doses wasted must be calculated by the provider. Reason for the expiration/wastage must also be entered on the form. Corrective action is also required, if wastage due to provider negligence.

VMT will provide follow-up consultation on all returns to ensure any necessary remedial action is completed in a timely fashion.

Vaccine Loss and Replacement

VFC providers are entrusted with federally purchased vaccine to immunize children at *no cost*; however, **providers will be required to replace vaccines lost due to provider negligence.**

Situations Requiring Vaccine Reimbursement or Replacement

Below is a list of situations that are considered “provider negligence” and may require financial restitution. This list is not exhaustive. Failure of a provider or staff to adhere to the current “CIP Policies and Guidelines” will result in a restitution situation. Restitution will be in the form of a dose-for-dose replacement or financial restitution at the provider’s discretion. Situations that occur which are not listed here will be considered on an individual basis by the CIP.

1. Failure to log temperatures twice daily during normal operating hours and temperatures are found to be out-of-range, resulting in vaccine loss. Failure to rotate or request to transfer vaccine that results in expired vaccine (notify CIP 90 days before the vaccine is to expire).
2. Preparing vaccines prior to patient screening.
3. Handling and storage mistakes.

4. Vaccine left out of the refrigeration unit that becomes non-viable. Call CIP first to help determine the stability/viability of vaccine left out of the refrigerator/freezer.
5. Freezing vaccine meant to be refrigerated.
6. Refrigerating vaccine meant to be frozen.
7. Refrigerator left unplugged or electrical breaker switched off.
8. Refrigerator door left open or ajar.
9. Refrigerator/freezer equipment problems where proof of repair or equipment replacement is not provided to the CIP within 30 days from the date of discovery.
10. Any power outages in which the provider fails to act according to the posted plan.

Providers are responsible for the cost of re-vaccination due to negligence.

Situations Not Requiring Financial Restitution

Below is a list of situations that are not considered “provider negligence”. This list is not exhaustive. In these situations, the provider is deemed not to be at fault. Providers may be required to produce a letter from the alarm/alert company or the power company.

1. Vaccine shipment is not delivered to the provider in a timely manner or is otherwise damaged or stored improperly during transit. Before making the determination that the vaccine is non-viable, call the CIP and the distributor.
2. A provider who has a current contract with an alert/alarm company has a refrigerator that malfunctions and the alarm/alert company does not notify the provider.
3. A provider moves vaccine to a location with a secure power source due to anticipated inclement weather, the location experiences a power failure, and the vaccine is later deemed not viable.
4. Power was interrupted or discontinued due to acts of nature, and after consultation with the CIP and the vaccine manufacturers, it is determined that vaccine is not viable.
5. A vaccine vial that is accidentally dropped or broken by a provider.
6. Vaccine that is drawn up after screening for contraindications and parental education, but not administered, due to parental refusal or a change in physician orders.
7. Expired vaccine that is not due to provider negligence (including seasonal influenza vaccine).
8. Refrigerator/freezer equipment problems where proof of repair or equipment replacement is provided to the CIP within 30 days from the date of discovery.
9. Extraordinary situations not listed above which are deemed by the CIP to be beyond the provider’s control.

Procedures for Vaccine Replacement/Restitution

The following guidelines are followed in determining if a provider will be asked to reimburse the VFC program for wasted/expired doses of vaccine.

1. CIP-VFC Program will require providers to make restitution for any doses of federal purchased vaccines that have been lost due to the provider’s failure to properly receive, store, or use vaccines (as outlined in Vaccine Storage Basics-below) if:
 - a. It is the 1st incident and the total loss is over 5% of total distribution for the previous calendar year, or
 - b. It is the 2nd incident (or greater) regardless of total value, or
 - c. It is due to a failure to immediately open a vaccine shipment from McKesson or Merck resulting in damaged vaccine regardless of total value.
2. Depending on the severity of the issue, the provider’s ordering privileges may be suspended until there is an investigation/education by the VMT, and the provider is cleared to again receive VFC vaccine.

Vaccine Management

Vaccine Personnel

1. Providers must designate one staff member to be the primary vaccine coordinator and at least one back-up vaccine coordinator, who is able to perform the same responsibilities as the primary vaccine coordinator in the event that the primary person is unavailable.
 - a. These positions will be responsible for key requirements and will provide oversight for all vaccine management within the office.

- b. The designated vaccine coordinator and backup are responsible for the following vaccine management activities:
 - i. Documenting the temperature, twice a day, on the temperature logs for each storage unit;
 - ii. Adjusting the temperature of a vaccine storage unit, if needed;
 - iii. The primary vaccine coordinator reviews temperature logs weekly when daily monitoring is being conducted by a backup person to ensure proper temperature recording.
 1. The backup staff will monitor the temperature logs if the primary coordinator is unavailable;
 - iv. Training staff that are administering vaccines; and
 - v. Following the office's vaccine storage and handling plan.
 1. A simple log sheet with the staff member's name and date of training should be kept as documentation.
- c. Unless otherwise noted, the vaccine coordinator and/or backup will be the immunization contact(s) for the office.

Vaccine Storage Practices

The vaccine storage practices listed below are the responsibility of the vaccine coordinator or can be delegated to another staff member. If the practices are delegated, the vaccine coordinator must monitor the activity.

- ✓ Mark and/or separate state supplied vaccine from private purchase vaccine. Suggestions to differentiate between vaccines:
 - ✓ Utilize the VFC stickers provided by the CIP;
 - ✓ Place vaccine on separate, marked shelves;
 - ✓ Place vaccine in separate storage units;
- ✓ Rotate vaccine stock by placing vaccines with shorter expiration dates in front of those with longer expiration dates;
- ✓ Check for short-dated vaccine.
- ✓ Notify the VMT within 3 months of any vaccine doses that will expire before they can be administered.
 - ✓ Only with the approval and direct guidance of the CIP and only if the cold chain can be ensured, redistribute short-dated vaccines to providers who are able to administer it before the vaccine expires.
- ✓ Store vaccines requiring refrigeration in the middle of the refrigerator compartment away from the coils, walls, floor, and cold air vent.
- ✓ Store vaccines that require freezer storage in the middle of the freezer compartment, away from the walls, coils, and peripheral areas.
- ✓ Space stored vaccine to allow for cold air circulation around the vaccine.
- ✓ Do not store vaccines in the door of the storage unit.
- ✓ Remove vegetable bins from the refrigerator; replace with cold water bottles.
- ✓ Stabilize refrigerator and freezer temperatures with proper placement and use of water bottles and frozen packs.
- ✓ Store all opened and unopened vials of vaccine in their boxes inside the appropriate storage unit so that their contents and expiration dates are easily visible. Prevent vaccines from inadvertently being exposed to light. Many vaccines will be inactivated by exposure to light.
- ✓ Store vaccine products that have similar packaging in different locations to avoid confusion and medication errors.

Storage and Handling Plans

Providers may develop their own written routine and emergency storage and handling plans or use the CIP supplied storage and handling template and customize the template to reflect office practices. Both the routine and the emergency plans should be simple and the processes outlined in the plan should be presented in a clear and concise manner.

1. Routine vaccine storage and handling plans should include guidance on the following aspects of routine vaccine management:
 - a. Ordering vaccines;
 - b. Controlling inventory;
 - c. Storing vaccines and monitoring storage conditions;
 - d. Minimizing vaccine wastage;
 - e. Vaccine shipping, including receiving, packing and transporting.
2. Emergency vaccine storage and handling plans should include guidance on what to do in the event of refrigerator or freezer malfunctions, power failures, natural disasters, or other emergencies that might compromise appropriate vaccine storage conditions. The emergency plan should include the following:
 - a. Person(s) responsible for preparing and transporting vaccine, including contact information;
 - b. How this person will be notified that vaccine needs to be moved;
 - c. Location that will receive vaccine;
 - d. How receiving location will be notified of transport;
 - e. How to pack vaccine for transport;
 - f. Worksheet to document vaccine involved in power or equipment failure.

At a minimum, both plans must be reviewed and updated annually or as necessary. For example, when there is a change in staff responsibilities specified in the emergency plan.

Vaccine Storage Equipment

Storage Units

Providers must have appropriate equipment that can store vaccine and maintain proper conditions. All VFC providers must have an acceptable storage unit (listed below) prior to receiving vaccine. Providers that do not have an acceptable storage unit will not be shipped vaccine.

Two types of storage units are acceptable:

1. A refrigerator that has a separate freezer compartment with a separate exterior door and dual temperature controls, or
2. Stand-alone refrigerators and freezers.

Dormitory style refrigerators are not acceptable storage units.

Refrigerators or freezers used for vaccine storage must comply with the following requirements:

1. Be able to maintain required vaccine storage temperatures year-round;
2. Be large enough to hold the year's largest inventory.

As funding is available, the CIP will assist providers with the purchase of laboratory grade vaccine storage on an as needed basis.

Thermometers

Vaccine storage units must be equipped with calibrated temperature monitoring devices. Temperature monitoring devices must be covered by a Certificate of Traceability and Calibration. The traceability declaration is to confirm that the measurement standards and instructions used during calibration of the product are traceable to an ISO/IEC 17025 accreditation testing laboratory, or to the National Institute of Standards and Technology. The current certification and calibration information is kept on file with the CIP, as the thermometers are provided to active enrolled VFC providers free of charge. For optimal use, place thermometers in the center of the refrigerator and freezer to ensure it is not positioned directly under the cold air vent.

The batteries must be changed at least once a year. Most of the units that are available have a minimum 3 year calibration certificate. Providers needing to replace thermometers prior to their scheduled site visit can order them from CIP at www.coloradvfc.com.

Vaccine Security and Equipment Maintenance

Providers must post warning notices at both the electrical outlet and the circuit breaker of every storage unit to prevent power from being interrupted to the vaccine storage unit(s). Safeguard vaccines by providing facility security, such as temperature alarms and restricted access to vaccine storage and handling areas. The CIP-VFC program does not require alarm/security systems for vaccine storage; however providers are encouraged to have a security system if they store large quantities of vaccine.

Temperature Ranges for Storing Vaccine

Providers must store vaccines at the appropriate temperatures. The temperature range for refrigerated vaccines is **35-46°F (2-8°C)**. Freezer vaccine must be kept at **5°F or below (-15°C or lower)**. ***Failure to store vaccine at the proper temperature can seriously compromise or destroy vaccine efficacy.***

Temperature Monitoring

Temperature monitoring should be the primary responsibility of the vaccine coordinator and backup. If other staff must monitor temperatures, they must be trained on how to respond to and document actions taken then temperatures are outside the appropriate range.

- ✓ Post a temperature log on the vaccine storage unit door or nearby in a readily accessible place.
- ✓ Record refrigerator and freezer temperatures twice each day (beginning and end):
 - ✓ Ensuring that refrigerator temperatures are between 35°F and 46°F (2°C and 8°C).
 - ✓ The freezer temperature should be 5°F or lower (-15°C or lower).
- ✓ Twice-daily temperature monitoring and recording is required even if a continuous graphing/recording thermometer or a digital data logger is used.
- ✓ The actual temperature is preferred on the temperature log; however, an “x” or “✓” is acceptable.
- ✓ Take immediate action to correct improper vaccine storage conditions, including inappropriate exposure to light and inappropriate exposure to storage temperatures outside the recommended ranges.
 - ✓ Document actions taken on the temperature log or a separate sheet of paper attached to the log.
- ✓ Maintain an ongoing file of temperature logs and store completed logs for three years.
- ✓ The preferred logs for documentation are provided by the CIP at www.coloradovfc.com .

Temperature Incidents (Out of range temperatures)

Immediate corrective action must be taken when vaccine storage temperatures are found to be outside of the acceptable temperature ranges. Providers **must notify CIP** if their facility has had a temperature incident. After determining the scope of the temperature incident, the program will work with the provider and vaccine manufacturers to assist in determining if the vaccines are still viable. Contact the CIP by calling 303-692-2650.

In addition to potentially being required to make financial restitution to CIP-VFC program for vaccines that have been determined to be non-viable, providers may be targeted for a compliance and/or educational site visit by site visit staff to look for other issues related to vaccine storage, handling, or potential abuse of the VFC program.

Records Retention

All VFC providers are required to keep all VFC related documents for a minimum of three years. The following documents must be made available for review during the VFC Compliance Site Visit.

- ✓ Temperature logs and associated documentation for out of range temperatures
- ✓ Thermometer calibration certificates
- ✓ Vaccine Borrowing forms and associated shipping invoices for replenishment
- ✓ Completed Vaccine Order Forms and shipping invoices
- ✓ Completed Vaccine Return Forms
- ✓ Vaccine Transfer forms
- ✓ VFC Eligibility Screening Documentation
- ✓ Incident Reports

Fraud and Abuse

The CIP is required to report suspected VFC fraud and abuse to state and federal authorities.

The following are general examples of fraud and abuse that require corrective actions to take place:

1. Providing VFC-only vaccine to non-VFC children.
2. Selling or otherwise misdirecting VFC vaccine.
3. Billing a patient or third party for VFC vaccine.
4. Charging more than the established CMS maximum regional charge for administration of a VFC vaccine to a VFC eligible non-Medicaid child.
5. Not providing eligible children VFC vaccine because of parents' inability to pay for the administration fee.
6. Not implementing provider enrollment requirements of the VFC program.
7. Failing to screen patients for VFC eligibility.
8. Failing to maintain VFC records and comply with other requirements of the VFC program.
9. Failing to fully account for VFC supplied vaccine.
10. Failing to properly store and handle VFC vaccine.
11. Ordering VFC vaccine in quantities or patterns that do not match provider profile or otherwise involve over-ordering of VFC vaccine.
12. Excessive wastage of VFC vaccine, (over 5% of the provider's total yearly distribution).

All cases of fraud and/or abuse will be investigated to determine the intent of the provider. If it is found that the intent was to commit fraud and/or abuse, a formal investigation referral will be made. In the event that the fraud and/or abuse was/is due to oversight in training, provider will be placed in the Secondary or Tertiary education protocol developed by the CDC.

Definitions:

Rumors:	Any report of erroneous practice concerning an enrolled provider
Technical Error:	Any contact that initiates follow-up and further investigation
Wasted:	Any vaccine that cannot be used. This includes expired, spoiled and lost vaccines.
Expired:	Any vaccine with an expiration date that has passed.
Spoiled:	Any vaccine that exceeds the limits of the approved cold chain procedures or is pre-drawn and not used within acceptable time frames. Always consult with the CIP before determining that the vaccine is non-viable.
Lost:	Vaccine that is unaccounted for.

Protocol for Colorado Vaccines for Children (VFC) Program staff to respond to any suspected fraud, abuse and/or waste:

- ✓ The Colorado VFC Program staff will respond to any suspected fraud, abuse and/or waste reported to the VFC Program.
- ✓ Each incident will be recorded on the Fraud and Abuse tracking spreadsheet. This spreadsheet is managed by the VFC Operations Coordinator.
- ✓ The VFC Program will request an incident report, vaccine management plan, temperature logs, and the Vaccine Return form. The provider will be temporarily suspended from ordering vaccine pending review of the case.
- ✓ A site visit will be conducted if applicable.
- ✓ The Colorado VFC Program will initiate appropriate action which may include; reimbursement of vaccine costs, provider education including secondary or tertiary visits, and/or termination if issue(s) cannot be satisfactorily resolved.

Formal Investigation Referral:

A formal investigation referral will be made on all suspected cases of fraud and/or abuse where there appears intent to commit fraud and/or abuse as determined by the CIP. The agency that will be responsible for conducting the investigation will be the Colorado Medicaid Fraud & Abuse Program Integrity Unit.

The determination of which type of referral is made will be at the discretion of the CIP. All instances of fraud

and/or abuse will result in either an education resolution referral or for investigation by the Colorado Medicaid Fraud & Abuse Program Integrity Unit.

The Centers for Disease Control and Prevention (CDC) and Centers for Medicare and Medicaid Services (CMS) will be notified within 5 working days in the event that a provider commits fraudulent abuse of the VFC program. The entire Fraud and Abuse policy is available from the CIP upon request.

Quality Assurance

The CIP-VFC program will conduct annual quality assurance site reviews at provider offices. These site visits will review compliance with the VFC program requirements including:

- ✓ VFC screening and eligibility
- ✓ Patient chart review
- ✓ Vaccine storage and handling
- ✓ Vaccine administration
- ✓ Vaccine accountability
- ✓ General immunization knowledge

Since the CDC requires that 50% of providers be visited on a yearly basis, the VMT has devised a strategy guarantee this. All LPHA's, FQHC's, RHC's and 1/3 of all private providers will be visited in one year and the remaining 2/3rds of private providers will be visited in the next year.

Site visits should take no more than 2-4 hours. A final report, including immunization rates, will be given to all offices following the visit.