



# South Dakota Immunization Program – Policy Updates Highlights and Changes

10 May 2016

# Policy Updates

- Reduced policies from 11 to 10
- 1 VFC Program Overview for Enrolled Providers
- 2 VFC Program Fraud & Abuse
- 3 VFC Management Plan
- 4 VFC Vaccine Exposed to Abnormal Temperatures
- 5 VFC Vaccine Transfer and Transport

# Policy Updates

- 6 Vaccine Borrowing Between Public and Private Stock
- 7 VFC Vaccine Wastage and Return
- 8 Utilizing Publically Funded Vaccine in School Settings
- 9 Billing Rules for Publically Funded Vaccine
- 10 Record Retention

# Presenters

- Brett Oakland
- Jodi Smith
- Misty Pickner
- Summer Gillaspie
- Tammy LeBeau
- Tim Heath

# 1 VFC Program Overview for Enrolled Providers

- VFC Eligibility
  - Medicaid
  - Uninsured
  - American Indian/Alaskan Native
  - Underinsured at FQHC, RHC, CHS

# **SOUTH DAKOTA IMMUNIZATION PROGRAM POLICY #01**

## **VFC Program Overview for Enrolled Providers**

- Enrollment II F – Medical Director Signature when not on site (page 3)
- VFC Storage Units II B – Thermal Ballast – use of Frozen Water Bottles in Freezer (page 4)
- Temperature Monitoring II A 2 – recording the minimum and maximum temperature from previous day(s) (page 5)
- VFC Management S & H – no longer allowable to ship vaccines from provider to provider – Must be directly transported to receiving facility within 8 hours (page 7)

Temperature Log — Celsius

# REFRIGERATOR



Month/Year: \_\_\_\_\_

Facility Name: \_\_\_\_\_ VFC PIN: \_\_\_\_\_

- 1) Record the A.M. AND P.M. temperatures each workday. Note the exact time of each temperature reading and the initials of the reader.
- 2) In A.M., record MIN/MAX temperatures from the previous day, and for any days the facility was closed (e.g. weekends/holidays).
- 3) In the event of a temperature excursion, refer to SD Immunization Program Policy #04 — VFC Vaccines Exposed to Abnormal Temperatures.

Day of the Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15				
Staff Initials																			
Exact Time	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM			
MAX Temperature																			
MIN Temperature																			
<b>Danger!</b> Temperatures above 8.4° Celsius are too warm! Record any out-of-range temperatures and refer to Policy #04 — VFC Vaccines Exposed to Abnormal Temperatures!																			
8° C																			
7° C																			
6° C																			
Aim for 5° C 5° C																			
4° C																			
3° C																			
2° C																			
<b>Danger!</b> Temperatures below 1.5° Celsius are too cold! Record any out-of-range temperatures and refer to Policy #04 — VFC Vaccines Exposed to Abnormal Temperatures!																			
Record any out-of-range temperatures above 8.4° C or below 1.5° C here																			
Initial	Signature				Initial	Signature				Initial	Signature				Initial	Signature			

Temperature Log — Celsius

# REFRIGERATOR



Month/Year: May 2016

Facility Name: SD Dept. of Health VFC PIN: SDAXXXX

- Record the A.M. AND P.M. temperatures each workday. Note the exact time of each temperature reading and the initials of the reader.
- In A.M., record MIN/MAX temperatures from the previous day, and for any days the facility was closed (e.g. weekends/holidays).
- In the event of a temperature excursion, refer to SD Immunization Program Policy #04 — VFC Vaccines Exposed to Abnormal Temperatures.

Day of the Month	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15	
Staff Initials	SG	SG	BO	MP	SG	TH	BO	SG	SG	TH	SG		TH		BO	MP	TH	SG												
Exact Time	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
			0800	1630	0810	1615	0800	1630	0805	1423	0815	1430					0810	1416	0800											
MAX Temperature	5.2		5.5		5.1		9.2		5.1		5.4		5.0		5.2		5.2													
MIN Temperature	4.5		4.7		4.3		4.3		4.7		4.8		4.8		4.7		4.7													

Danger! Temperatures above 8.4° Celsius are too warm! Record any out-of-range temperatures and refer to Policy #04 — VFC Vaccines Exposed to Abnormal Temperatures!

↑	8° C																													
	7° C																													
	6° C																													
	5° C		5.1	5.0					5.0	5.1	5.0						5.0	5.0												
	4° C				4.7	4.9		4.5	4.8								4.8													
	3° C																													
↓	2° C																													

Danger! Temperatures below 1.5° Celsius are too cold! Record any out-of-range temperatures and refer to Policy #04 — VFC Vaccines Exposed to Abnormal Temperatures!

Record any out-of-range temperatures above 8.4° C or below 1.5° C here							9.2																							
--	--	--	--	--	--	--	-----	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

Initial	Signature						Initial	Signature						Initial	Signature												
SG	Summer Gillaspie, DIS						BO	Brett Oakland, DIS						TH	Tim Heath						MP	Misty Pickner					

# **SOUTH DAKOTA IMMUNIZATION PROGRAM POLICY #01**

## **VFC Program Overview for Enrolled Providers**

- Must screen for eligibility and document screening every single immunization visit even if the eligibility has not changed
  - EMR, SDIIS, Screening Record
- Monthly Reports due on 5<sup>th</sup> of month
  - Inventory – physical count
  - Temperature documents – temp chart, digital data logger report
  - Provider Certification and Doses Received Report
  - Doses Administered

# **SOUTH DAKOTA IMMUNIZATION PROGRAM POLICY #01**

## **VFC Program Overview for Enrolled Providers**

- **Training**
  - All primary and Back-up VFC coordinators must receive annual training on VFC and Storage and handling
  - Must maintain training file
  - All involved should be trained in the function they perform

# **SOUTH DAKOTA IMMUNIZATION PROGRAM POLICY #02**

## **VFC Program Fraud and Abuse**

- No changes to content

# **SOUTH DAKOTA IMMUNIZATION PROGRAM POLICY #03**

## **VFC Vaccine Management Plan**

- Replaces old **Immunization Policy #009EP – Vaccine Management/Emergency Relocation Template**
- Keep copies near Storage Units in each storage area
- Primary & Secondary Coordinators responsible
  - Routine Vaccine Management
  - Storage & Handling
  - Emergency Relocation
- ALL staff should be aware of the contents pertaining to Emergency action
  - Medical staff, clerical, custodial, security
  - Acute Care/Urgent Care staff

# **SOUTH DAKOTA IMMUNIZATION PROGRAM POLICY #03**

## **VFC Vaccine Management Plan**

- CLINIC and PIN
  
- Designate Primary & Secondary Coordinators
  - Name and contact numbers
  - Responsible for all tasks in this policy – whether done themselves or assigned to others

# **SOUTH DAKOTA IMMUNIZATION PROGRAM POLICY #03**

## **VFC Vaccine Management Plan**

- Vaccine Ordering
  - MONTHLY – BI-MONTHLY – QUARTERLY
  - Mark ordering months
- Receiving Vaccine Shipments
- Vaccine Storage & Handling
  - Vaccine Placement
  - (Frozen) Water Bottles in storage units
- Inventory Control

# **SOUTH DAKOTA IMMUNIZATION PROGRAM POLICY #03**

## **VFC Vaccine Management Plan**

- **Temperature Monitoring**
  - New Temp Logs – twice-daily, date & time, initials & signature, min/max
  - Temp Excursions – referral to appropriate policies
- **Vaccine Transfer/Transport – refer to Policy #05**
- **Emergency Vaccine Relocation**
  - Refer to Policy #05 – Transfer/Transport
  - Alternate Safe Location – address, phone
  - Obtain permission from Alternate Safe Location
  - Back-up generator does not protect against malfunction

# **SOUTH DAKOTA IMMUNIZATION PROGRAM POLICY #03**

## **VFC Vaccine Management Plan**

- Vaccine Wastage – refer to Policy #07
- Vaccine Borrowing – refer to Policy #06
- Monthly Reporting
- Staff Education
- Annual Review – complete annually
- Contact Information
  - Immunization Program
  - Additional numbers – (optional) fridge/freezer maintenance company, utility/power company, storage unit alarm company, DIS, etc.

# **SOUTH DAKOTA IMMUNIZATION PROGRAM POLICY #04**

## **VFC Vaccine Exposed To Abnormal Temperatures**

**Combines old Immunization Policies #006EP & #007EP**

- Routine Temp Recording – refer to Policy #01
- Allowable Limits

<b>Refrigerator</b>		<b>Freezer</b>
<b>8.4° C</b>	<b>Upper Limit</b>	<b>-14.5° C</b>
<b>2 to 8° C</b> <b>(35° F to 46° F)</b>	<b>Normal Range</b>	<b>-50° C to -15° C</b> <b>(-58° F to +5° F)</b>
<b>1.5° C</b>	<b>Lower Limit</b>	<b>-50.4° C</b>

# **SOUTH DAKOTA IMMUNIZATION PROGRAM POLICY #04**

## **VFC Vaccine Exposed To Abnormal Temperatures**

- **TEMPERATURE EXCURSION** – temp exceeds allowable limits
  - NOTE: Periodic defrost cycles that cause the temp to exceed allowable limits are NOT excusable
- **DO NOT USE!...DO NOT DISCARD!** (yet)
- Report to Immunization Program
- Contact manufacturers – numbers provided
- Document manufacturers' recommendations on the **Vaccine Exposed to Abnormal Temperatures Worksheet**.

# **SOUTH DAKOTA IMMUNIZATION PROGRAM POLICY #04**

## **VFC Vaccine Exposed To Abnormal Temperatures**

- If compromised, refer to Policy #07 – Wastage
  - Vaccine Wastage Report & Return Form
- Submit ALL documentation to Central Office
- Offer re-immunization to those who received any compromised vaccine
- **Vaccine Exposed to Abnormal Temperatures Worksheet** – no major changes



SOUTH DAKOTA IMMUNIZATION PROGRAM  
VACCINE EXPOSED TO ABNORMAL TEMPERATURES WORKSHEET

Date: \_\_\_\_\_

PROVIDER NAME: \_\_\_\_\_ PROVIDER NUMBER: \_\_\_\_\_ CONTACT PERSON: \_\_\_\_\_

1.) Please Explain the Incident: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

2.) The vaccine was exposed to temperatures that were too: High Low (circle one)

3.) What was the highest or lowest temperature that was recorded on the Digital Data Logger? \_\_\_\_\_

**Please send a copy of the report from the Digital Data Logger that recorded the incident along with this form to the SD Department of Health.**

4.) How long was the vaccine out of temperature range? \_\_\_\_\_ hours

Please fill out this form completely. If this temperature excursion results in any vaccine wastage, please fill out a **Vaccine Wastage Report & Return Form** and submit with this form to the SD Department of Health.

**A photocopy of this form must be included with any wasted vaccine sent back to McKesson for excise tax credit.**

MANUFACTURER NAME	VACCINE TYPE (Example: DTaP)	BRAND NAME (Example: Tripedia)	LOT NUMBER	EXPIRATION MM/DD/YY	NUMBER OF DOSES	RECOMMENDATION GIVEN BY MANUFACTURER	ACTION TAKEN BY YOUR CLINIC

## **South Dakota Immunization Program Policy #05 VFC Vaccine Transfer & Transport**

**Vaccine Transfer:** the change in possession of the VFC vaccine from the inventory of one enrolled provider to the inventory of another enrolled provider. The receiving provider adds the vaccine to their inventory and assumes all responsibility for its storage and administration.

**Vaccine Transport:** the act of moving vaccine from one location to another.

## **Vaccine Transfers**

VFC enrolled providers must request permission from the Immunization Program to transfer vaccine to another enrolled provider. All vaccine transfers must be documented on the **Vaccine Transfer and Transport Form**. Each provider must reconcile their own vaccine inventory in SDIIS to reflect the transfer.

1. Avoid Vaccine Expiration
2. Distribute and Share Vaccine Inventory

# Vaccine Transport

## Vaccine Management During Transport

1. If transporting to an off-site/satellite facility, the amount transported should be limited to only what is needed for that workday. Transport time and workday should total no more than a maximum of 8 hours.
2. Monitor vaccine with a digital data logger (LogTag)
3. Do not place vaccine in the vehicle trunk
4. Deliver vaccine directly to the facility
5. Promptly unpack vaccine and place into appropriate storage unit(s)
6. Commercial shippers such as UPS and FedEx cannot be used to transport VFC vaccines. Private couriers may be used. The vaccine must reach its destination within 8 hours.

## Transporting Refrigerated Vaccines

1. Pack refrigerated vaccines before packing frozen vaccines
2. CDC recommends transport with a portable refrigerator unit. If not available, use a hard-sided cooler with at least 2-inch walls.

Must be able to maintain recommended temperature range of 35 to 46 degrees F or (2 to 8 degrees C).

1. Refer to packing instructions found in **South Dakota Immunization Program Policy #05 – VFC Vaccine Transfer & Transport**
2. Immediately place the vaccine in an appropriate storage unit upon arrival to destination.

## Transporting Varicella-containing Vaccines

1. The vaccine manufacturer does not recommend transporting varicella-containing vaccines to off-site/satellite facilities.
2. Do not use dry ice
3. CDC recommends transport in a portable freezer unit, however if one is not available Varicella-containing vaccines may be transported at refrigerator temperature.
  1. This will result in a temperature excursion.
  2. Follow South Dakota Immunization Program Policy #04 – VFC Vaccine Exposed to Abnormal Temperatures and the corresponding worksheet

## **Diluents**

1. Diluents should be transported with their corresponding vaccines.
2. Diluents that contain antigen should be transported with their corresponding vaccines at refrigerator temperature.
3. In advance, refrigerate diluents stored at room temperature before transporting in the same container with refrigerated vaccines so they will not increase the temperature in the cooler.
4. Never freeze diluents, even in transport.

## VACCINE TRANSFER & TRANSPORT FORM

**TRANSFERRING/TRANSPORTING PROVIDER:** Refer to South Dakota Immunization Program Policy #05 — VFC Vaccine Transfer & Transport.

Notify the Immunization Program Vaccine Management Specialist of the intent to transfer vaccines at (605) 773-4963. Fill out the table below completely. Keep the PINK copy of this form and send the WHITE and YELLOW copies along with the vaccine to the receiving provider.

**Transferring or Transporting Clinic/Hospital Name:** \_\_\_\_\_ VFC PIN #: \_\_\_\_\_

Signature of Person Responsible for this Transfer/Transport: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Signature of Person Transporting Vaccine: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Name of Vaccine	Manufacturer	Lot Number	Expiration	# Doses	Reason for Transport/Transfer:	
					Record time vaccine was removed from original storage unit.	
					Temperature on digital data logger after vaccine is packed for transport.	
					Record time vaccine is unpacked and placed in destination storage unit.	
					Temperature on digital data logger at the end of transport (from the digital data logger that traveled with the vaccine)	
					Minimum and maximum temperature during transport (from the digital data logger that traveled with the vaccine)	Minimum Temp: _____
						Maximum Temp: _____

**RECEIVING PROVIDER:** Upon receipt of vaccine, confirm the quantities and lot numbers in the table above. Complete this form and keep the YELLOW Copy.

**Did this transfer/transport result in a temperature excursion?**  NO  YES ⇔ If the vaccine experienced a temperature excursion during transfer/transport refer to South Dakota Immunization Program Policy #04 — VFC Vaccine Exposed to Abnormal Temperatures and the corresponding worksheet.

**Receiving Clinic/Hospital Name (if applicable):** \_\_\_\_\_ VFC PIN #: \_\_\_\_\_

Signature of Receiving Provider: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

**Mail WHITE Copy to:** South Dakota Department of Health  
 Attn: Immunization Management Specialist  
 615 E. 4<sup>th</sup> St.  
 Pierre, SD 57501

**OR Fax to:** (605) 773-4113

**Immunization Program Phone Numbers**

Immunization Program Coordinator: (605) 773-5323  
 Vaccine Management Specialist: (605) 773-4963  
 Immunization Registry Coordinator: (605) 773-4783  
 Immunization Education Coordinator: (605) 773-2664

## VACCINE TRANSFER & TRANSPORT FORM

**TRANSFERRING/TRANSPORTING PROVIDER:** Refer to South Dakota Immunization Program Policy #05 — VFC Vaccine Transfer & Transport.

Notify the Immunization Program Vaccine Management Specialist of the intent to transfer vaccines at (605) 773-4963. Fill out the table below completely. Keep the PINK copy of this form and send the WHITE and YELLOW copies along with the vaccine to the receiving provider.

Transferring or Transporting Clinic/Hospital Name: \_\_\_\_\_ SD DOH \_\_\_\_\_ VFC PIN #: \_\_\_\_\_ SDAXXXX \_\_\_\_\_

Signature of Person Responsible for this Transfer/Transport: \_\_\_\_\_ Summer Gillaspie \_\_\_\_\_ Date: \_\_\_\_\_ 05 / 10 / 2016 \_\_\_\_\_

Signature of Person Transporting Vaccine: \_\_\_\_\_ Summer Gillaspie \_\_\_\_\_ Date: \_\_\_\_\_ 05 / 10 / 2016 \_\_\_\_\_

Name of Vaccine	Manufacturer	Lot Number	Expiration	# Doses	Reason for Transport/Transfer:	
<u>Boostrix</u>	GSK	43SP7	04/18/2017	10	Sharing vaccine order with a sister clinic.	
<u>PedvaxHIB</u>	Merck	L030870	06/10/2018	5	Record time vaccine was removed from original storage unit.	0935
<u>Menactra</u>	Sanofi Pasteur	U5180AA	01/22/2017	5	Temperature on digital data logger after vaccine is packed for transport.	4.7° C
					Record time vaccine is unpacked and placed in destination storage unit.	1115
					Temperature on digital data logger at the end of transport (from the digital data logger that traveled with the vaccine)	6.1° C
					Minimum and maximum temperature during transport (from the digital data logger that traveled with the vaccine)	Minimum Temp: <u>4.0° C</u> Maximum Temp: <u>6.1° C</u>

**RECEIVING PROVIDER:** Upon receipt of vaccine, confirm the quantities and lot numbers in the table above. Complete this form and keep the YELLOW Copy.

Did this transfer/transport result in a temperature excursion?  NO  YES ⇨ If the vaccine experienced a temperature excursion during transfer/transport, refer to South Dakota Immunization Program Policy #04 — VFC Vaccine Exposed to Abnormal Temperatures and the corresponding worksheet.

Receiving Clinic/Hospital Name (if applicable): \_\_\_\_\_ XYZ Clinic \_\_\_\_\_ VFC PIN #: \_\_\_\_\_ SDAXXXX \_\_\_\_\_

Signature of Receiving Provider: \_\_\_\_\_ Tim Heath \_\_\_\_\_ Date: \_\_\_\_\_ 05 / 10 / 2016 \_\_\_\_\_

Mail WHITE Copy to: South Dakota Department of Health  
Attn: Immunization Management Specialist  
615 E. 4<sup>th</sup> St.  
Pierre, SD 57501

**Immunization Program Contact Phone Numbers**  
Immunization Program Coordinator: (605) 773-5323  
Vaccine Management Specialist: (605) 773-4963  
Immunization Registry Coordinator: (605) 773-4783  
Immunization Community Educator: (605) 773-2664

OR Fax to: (605) 773-4113

## Temperature Monitoring at Off-site/Satellite Facility

1. A digital data logger (LogTag) must be used to monitor temperature of VFC vaccine storage units at off-site/satellite facilities.
2. Immediately upon arrival place vaccine in an on site refrigerator, in recommended temperature range and monitor with LogTag unit.
  1. If you must use the transport cooler, temperature should be read at least hourly.
  2. Preferable to use a portable refrigerator or freezer unit.
3. Download report from digital data logger and examine report for excursions during storage at off-site/satellite facility.
  1. Attach this report as well as the VFC Vaccine Transfer & Transport Form and submit to the Vaccine Management Specialist.
  2. If any temperature excursions are noted, refer to South Dakota Immunization Program Policy #04 – VFC Vaccine Exposed to Abnormal Temperatures and the corresponding worksheet.

## PACKING VACCINE FOR TRANSPORT

### Materials Needed For Transporting Vaccine



**Obtain a qualified container and pack-out or portable refrigerator.**

- Vaccine manufacturers do not recommend reuse of shipping containers or packing material.
- Do NOT use soft-sided collapsible coolers.



**Conditioned frozen water bottles**

- Use 16.9 oz. bottles for medium/large coolers or 8 oz. bottles for small coolers (enough for 2 layers inside cooler).
- Do NOT reuse coolant packs from original vaccine shipping container, as they increase risk of freezing vaccines.
- Freeze water bottles (can help regulate the temperature in your freezer).
- **Before use, you must condition the frozen water bottles.** Put them in a sink filled with several inches of cool or lukewarm water until you see a layer of water forming near the surface of bottle. The bottle is properly conditioned if the ice block inside spins freely when rotated in your hand.



**Insulating material — You will need two of each layer**

- Insulating cushioning material – Bubble wrap, packing foam, or Styrofoam™ for a layer above and below the vaccines, at least 1 in thick. Make sure it covers the cardboard completely. Do NOT use packing peanuts or other loose material that might shift during transport.
- Corrugated cardboard – Two pieces cut to fit interior dimensions of cooler(s) to be placed between insulating cushioning material and conditioned frozen water bottles.



**Temperature monitoring device – Digital Data Logger (DDL) with buffered probe**

- Accuracy of  $\pm 1^{\circ}\text{F}$  ( $\pm 0.5^{\circ}\text{C}$ ) with a current and valid certificate of calibration testing.
- Pre-chill buffered probe for at least 5 hours in refrigerator.



**Vaccine Transport and Transfer Form**

- This form is used to record what type of vaccine is being transported, who is transporting the vaccine, and the time and temperatures during transport.

**Why do you need cardboard, bubble wrap, and conditioned frozen water bottles?**

- Conditioned frozen water bottles and corrugated cardboard used along with one inch of insulating material such as bubble wrap keeps refrigerated vaccines at the right temperature and prevents them from freezing. Reusing vaccine coolant packs from original vaccine shipping containers can freeze and damage refrigerated vaccines.

## PACKING VACCINE FOR TRANSPORT

### Step-by-Step Instructions for Packing the Transport Cooler



**Conditioned Frozen Water Bottles**—Line bottom of the cooler with a single layer of conditioned water bottles.



**Insulating Material**—Place 1 sheet of corrugated cardboard over water bottles to cover them completely.



**Insulating Material**—Place a layer of bubble wrap, packing foam, or Styrofoam™ on top of the corrugated cardboard. (layer must be at least 1 inch thick and must cover the cardboard completely).



**Vaccines**—Stack boxes of vaccines and diluents on top of the insulating material.

**Temperature Monitoring Device**—When cooler is halfway full, place the digital data logger buffered probe in the center of the vaccines, but keep the digital data logger display outside the cooler until finished loading.



**Insulating Material**—Cover vaccines with another 1 inch layer of bubble wrap, packing foam or Styrofoam™.



**Insulating Material**—Another sheet of cardboard is placed on top to support top layer of water bottles.



**Conditioned Frozen Water Bottles**—Fill the remaining space in the cooler with an additional layer of conditioned frozen water bottles.



**Close Lid**—Close the lid and attach the digital data logger display and the Vaccine Transfer & Transport Form to the top of the lid. This form is used to record what type of vaccine is being transported, who is transporting the vaccine, and the time and temperatures during transport. Submit it to the Immunization Program after the transport has taken place.

# SOUTH DAKOTA IMMUNIZATION PROGRAM POLICY #06

## Vaccine Borrowing Between Public and Private Stock

- Expected to manage and maintain an adequate inventory of vaccine for both VFC and non-VFC patients.
- Planned or routine borrowing of VFC vaccine is not permissible.
- Ensure that borrowing VFC vaccine will not prevent or delay a VFC-eligible child from receiving vaccination.
- Infrequent exchange between VFC and private stock, while not recommended, is acceptable in certain immediate circumstances as described on the corresponding **Vaccine Borrowing Report**.
- Complete and submit a **Vaccine Borrowing Report** whenever a dose of VFC vaccine is administered to a non-VFC-eligible patient AND whenever a dose of private vaccine is administered to a VFC-eligible patient.
- All borrowed vaccine doses must be replaced as soon as possible and documented on the **Vaccine Borrowing Report**.
- The completed **Vaccine Borrowing Report** must be submitted to the Immunization Program Central Office.

Facility Name:

Pin #:

## VACCINE BORROWING REPORT

VFC-enrolled providers are expected to manage and maintain an adequate inventory of vaccine for both their VFC and non-VFC-eligible patients. **Planned borrowing of VFC vaccine including the use of VFC vaccine as a replacement system for a provider's privately purchased vaccine inventory is not permissible.**

VFC-enrolled providers must ensure borrowing VFC vaccine will not prevent a VFC-eligible child from receiving a needed vaccination. Infrequent exchanging between VFC and private stock of a short-dated vaccine dose may be performed if the provider serves a small number of private pay patients, the dose is one month from expiration, or the dose of vaccine cannot be used for the population it is intended for prior to the expiration date.

### COMPLETE THIS FORM WHEN:

- A dose of VFC vaccine is administered to a non VFC-eligible child
- A dose of privately-purchased vaccine is administered to a VFC-eligible child

### HOW TO COMPLETE THIS FORM:

- Enter information on each dose of vaccine borrowed in a separate row in the Vaccine Borrowing Report Table.
- All columns must be completed for each dose borrowed
- The provider must sign and date at the bottom of this report
- Enter the corresponding reason code in column F of the Borrowing Report Table on page 2.
- Enter details of reason in Column F if an Other code (7 or 13) is entered in the Vaccine Borrowing Report Table.

### Reason for Vaccine Borrowing and Replacement Coding Legend

Reason for Borrowing VFC Dose	Code	Reason for Borrowing Private Dose	Code
Private vaccine shipment delay (vaccine order placed on time/delay in shipping)	1	VFC vaccine shipment delay (order placed on time/delay in shipping)	8
Private vaccine not useable on arrival (vials broken, temperature monitor out of range)	2	VFC vaccine not useable on arrival (vials broken, temperature monitor out of range)	9
Ran out of private vaccine between orders (not due to shipping delays)	3	Ran out of VFC vaccine between orders (not due to shipping delays)	10
Short-dated private dose was exchanged with VFC dose	4	Short-dated VFC dose was exchanged with private dose	11
Accidental use of VFC dose for a private patient	5	Accidental use of a Private dose for a VFC eligible patient	12
Replacement of Private dose with VFC when insurance plan did not cover vaccine	6	Other – Describe:	13
Other – Describe:	7		

### WHAT TO DO WITH THIS FORM:

- Completed forms must be retained as a VFC program record and made available to the State/Local or Territorial Immunization Program upon request.

Fax completed form to (605) 773-4113. Retain the original form in your files and make available to the state upon request.



# **SOUTH DAKOTA IMMUNIZATION PROGRAM POLICY #07**

## **VFC Vaccine Wastage and Return**

- Strive to keep wastage at a minimum
- Paperwork

## VACCINE WASTAGE REPORT & RETURN FORM

**PROVIDERS - complete this form to report ALL wastage of publicly funded vaccine. Record wasted vaccine below and use the reason codes below the table to determine whether the vaccine can be returned to McKesson for excise tax credits. Submit this form only once, and by only one method (either fax or mail, not both).**

VFC Provider ID: \_\_\_\_\_ Facility Name: \_\_\_\_\_ Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

If returning vaccine to McKesson, how would you like to receive your shipping invoice?  E-mail  Fax How many boxes will need shipping labels? \_\_\_\_\_

Preferred E-mail or Fax #: \_\_\_\_\_ Contact Person: \_\_\_\_\_

- **Wastage not returning to McKesson** can be reported on this form monthly, or whenever it occurs.
- **Wastage returning to McKesson** may be submitted quarterly (or as necessary), but must be reported at minimum by the end of the calendar year. Once this form is received by the Immunization Program, your invoice will be mailed or e-mailed to you (whichever as indicated above). **A copy of the invoice must accompany the vaccine being returned to McKesson.**
- **McKesson** will mail or e-mail a return label within two weeks. If you do not receive the return label within two weeks, contact the Immunization Program. **DO NOT RESUBMIT THIS FORM!**
- Retain copies of this form and the return invoice for your records for a minimum of three (3) years, as per South Dakota Immunization Program Policy#10—Record Retention, for guidance.

Name of Vaccine	NDC Number	Manufacturer	Lot Number	Expiration Date	# Doses	Reason Code **	Return to McKesson *
							<input type="checkbox"/>
							<input type="checkbox"/>
							<input type="checkbox"/>
							<input type="checkbox"/>
							<input type="checkbox"/>
							<input type="checkbox"/>
							<input type="checkbox"/>

**VACCINE ELIGIBLE FOR RETURN TO MCKESSON \***  
Reason Code\*\*

1. Expired vaccine
2. Natural disaster / Power failure
3. Failure to store vaccine properly upon receipt
4. Refrigerator temperature too cold
5. Refrigerator / Freezer temperature too warm
6. Vaccine spoiled in transit (freeze / warm monitor activated)
7. Mechanical / Unit failure
8. Recall

**WASTAGE: (DO NOT RETURN TO MCKESSON)**  
Reason Code\*\*

9. Broken vial / Syringe
10. Lost or unaccounted for vaccine
11. Open multi-dose vial but not all doses are administered
12. Vial drawn into syringe but not administered
13. Other (specify) \_\_\_\_\_

South Dakota Department of Health  
Attn: Immunization Program  
615 E. 4th St.  
Pierre, SD 57501  
Fax: (605) 773-4113



SOUTH DAKOTA  
DEPARTMENT OF HEALTH

If you have questions regarding wastage returns, call the Immunization Management Specialist at (605) 773-4963.

## VACCINE WASTAGE REPORT & RETURN FORM

**PROVIDERS - complete this form to report ALL wastage of publicly funded vaccine. Record wasted vaccine below and use the reason codes below the table to determine whether the vaccine can be returned to McKesson for excise tax credits. Submit this form only once, and by only one method (either fax or mail, not both).**

VFC Provider ID: SDAXXXX Facility Name: SD DOH Date: 04 / 10 / 2016

If returning vaccine to McKesson, how would you like to receive your shipping invoice?  E-mail  Fax How many boxes will need shipping labels? 1

Preferred E-mail or Fax #: summer.gillaspie@state.sd.us Contact Person: Summer Gillaspie

- **Wastage not returning to McKesson** can be reported on this form monthly, or whenever it occurs.
- **Wastage returning to McKesson** may be submitted quarterly (or as necessary), but must be reported at minimum by the end of the calendar year. Once this form is received by the Immunization Program, your invoice will be mailed or e-mailed to you (whichever as indicated above). **A copy of the invoice must accompany the vaccine being returned to McKesson.**
- **McKesson** will mail or e-mail a return label within two weeks. If you do not receive the return label within two weeks, contact the Immunization Program. **DO NOT RESUBMIT THIS FORM!**
- Retain copies of this form and the return invoice for your records for a minimum of three (3) years, as per South Dakota Immunization Program Policy #10—Record Retention, for guidance.

Name of Vaccine	NDC Number	Manufacturer	Lot Number	Expiration Date	# Doses	Reason Code **	Return to McKesson *
<u>Pediarix</u>	<u>58160-0811-52</u>	<u>GSK</u>	<u>L49EE</u>	<u>09/04/2017</u>	<u>8</u>	<u>4</u>	<input checked="" type="checkbox"/>
<u>Menactra</u>	<u>49281-0589-05</u>	<u>Sanofi Pasteur</u>	<u>U5180AA</u>	<u>01/22/2017</u>	<u>5</u>	<u>4</u>	<input checked="" type="checkbox"/>
<u>IPOL</u>	<u>49281-0860-10</u>	<u>Sanofi Pasteur</u>	<u>U1234AA</u>	<u>03/06/2016</u>	<u>7</u>	<u>11</u>	<input type="checkbox"/>
<u>MMR</u>	<u>00006-4681-00</u>	<u>Merck</u>	<u>K012473</u>	<u>04/30/2016</u>	<u>2</u>	<u>1</u>	<input checked="" type="checkbox"/>
							<input type="checkbox"/>
							<input type="checkbox"/>
							<input type="checkbox"/>

**VACCINE ELIGIBLE FOR RETURN TO MCKESSON \***  
Reason Codes\*\*

- Expired vaccine
- Natural disaster / Power failure
- Failure to store vaccine properly upon receipt
- Refrigerator temperature too cold
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- Vaccine spoiled in transit (freeze / warm monitor activated)
- Mechanical / Unit failure
- Recall

**WASTAGE: (DO NOT RETURN TO MCKESSON)**  
Reason Codes\*\*

- Broken vial / Syringe
- Lost or unaccounted for vaccine
- Open multi-dose vial but not all doses are administered
- Vial drawn into syringe but not administered
- Other (specify) \_\_\_\_\_

South Dakota Department of Health  
Attn: Immunization Program  
615 E. 4th St.  
Pierre, SD 57501  
Fax: (605) 773-4113



If you have questions regarding wastage returns, call the Immunization Management Specialist at (605) 773-4963.

# **SOUTH DAKOTA IMMUNIZATION POLICY #08**

## **Utilizing Publicly Funded Vaccine in School Settings**

- Schools Must Follow all Policies
- Be enrolled
- Temp monitoring – Storage and Handling
- Monthly Reports
- Screening
- Documentation

**SOUTH DAKOTA IMMUNIZATION PROGRAM POLICY #09**

**Billing Rules for Publicly Funded Vaccine**

Revised: 04/01/2016 Issue Date: 01/01/2016

**Billing Rules for Publicly Funded Vaccine**

1. Providers shall not charge for any VFC or other publicly funded vaccines.
2. Providers may charge a vaccine administration fee up to, but not exceeding, the regional cap fee to VFC-eligible patients. The administration fee applies per vaccine dose, and not per antigen. The administration cap fee for enrolled providers in the South Dakota Immunization Program is **\$20.73**.
3. For Medicaid-enrolled patients providers must accept the reimbursement for immunization administration set by the state Medicaid agency or the contracted Medicaid health plans. Providers may not seek additional administration charges.
4. Providers must not deny immunization services to an established VFC-eligible patient due to inability to pay the administration fee.
5. Children who do not meet one or more categories for VFC-eligibility are “not eligible” for VFC vaccine. These children must receive privately purchased vaccine.

**Immunization Program Contact Information**

Immunization Program Coordinator	(605) 773-5323
Vaccine Management Specialist	(605) 773-4963
Immunization Registry Coordinator	(605) 773-4783
Immunization Education Coordinator	(605) 773-2664
Immunization Program Fax	(605) 773-4113
Phone Toll Free	(800) 592-1861

# VFC Billing/ Administration Fees

VFC Vaccine must be provided at no cost ; however providers may charge an administration fee.

For Non-Medicaid patients (American Indian/Alaska native, Uninsured, Underinsured), VFC providers **cannot collect an administration fee in excess of \$20.73 per vaccine (*not per antigen*)**

**For Medicaid VFC–eligible patients** providers must accept the reimbursement rate set by SD Medicaid (*not per antigen*) **\$9**



# **SOUTH DAKOTA IMMUNIZATION PROGRAM POLICY #10**

## **Record Retention**

- 3 years or longer

# Record Retention

- 1. **Vaccine Administration Record:** Retain the same as a medical record.
- 2. **Annual Provider Profile and Provider Agreement:** Retain for three (3) years; then destroy.
- 3. **VFC/AFIX Site Visit Documentation:** Retain for three (3) years; then destroy.
- 4. **Vaccine Written Temperature Logs:** Retain for three (3) years; then destroy.
- 5. **Vaccine Digital Data Logger Weekly Reports:** Retain for three (3) years; then destroy.
- 6. **Vaccine Wastage Form:** Retain for three (3) years; then destroy.
- 7. **Vaccine Transfer Form:** Retain for three (3) years; then destroy.
- 8. **Vaccine Borrowing Report:** Retain for three (3) years; then destroy.
- 9. **Monthly Provider Certification and Doses Received:** Retain for three (3) years; then destroy.
- 10. **Vaccine Packing Slip:** Retain for three (3) years; then destroy.
- **Facilities that do not utilize the South Dakota Immunization Information System (SDIIS) must also retain the following documents:**
- 11. **Monthly Vaccine Administration Report:** Retain for three (3) years; then destroy.
- 12. **Monthly Inventory Report:** Retain for three (3) years; then destroy.
- 13. **Vaccine Requisition/Order Form:** Retain for three (3) years; then destroy.

# Monthly Clinic Inventory (SDIIS)

## \*\*Required

South Dakota

### CLINIC INVENTORY

Clinic: [REDACTED]  
 Address: [REDACTED]  
 Phone: [REDACTED]  
 Fax: [REDACTED]

VACCINE	FUNDING SOURCE	LOT #	EXPIRATION DATE	VOLUME	REFRIGERATOR COUNT	MANUFACTURER	VENDOR
DTaP	VFC	F43Z7	10/31/2016	26	<input type="text"/>	GlaxoSmithKline	State
DTaP	Private	7BK43	03/05/2017	41	<input type="text"/>	GlaxoSmithKline	Private
DTaP-IPV	Private	MH9T7	09/29/2017	56	<input type="text"/>	GlaxoSmithKline	Private
Hep A-Adult	Private	L048460	01/14/2017	4	<input type="text"/>	Merck	Private
Hep A-Peds	VFC	K012457	06/04/2017	8	<input type="text"/>	Merck	State
Hep A-Peds	Private	L041676	03/15/2017	1	<input type="text"/>	Merck	Private
Hep B	Private	L044694	02/04/2018	15	<input type="text"/>	Merck	Private
HIB	VFC	UI346AAA	02/03/2017	66	<input type="text"/>	Sanofi Pasteur	State
HIB	Private	UI416AAA	04/15/2017	12	<input type="text"/>	Sanofi Pasteur	Private
HPV	VFC	L016428	07/30/2017	1	<input type="text"/>	Merck	State
HPV	Private	L026602	10/19/2017	49	<input type="text"/>	Merck	Private
Influenza	VFC	UI443AD	06/30/2016	11	<input type="text"/>	Sanofi Pasteur	State
Influenza	Private	UI516AB	06/30/2016	5	<input type="text"/>	Sanofi Pasteur	Private
IPV	Private	K1694-1-Private	11/26/2016	4	<input type="text"/>	Sanofi Pasteur	Private

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# Doses Administered Report (SDIIS)

## \*\*Required

**South Dakota**

### DOSES ADMINISTERED REPORT

April 01, 2016 - May 01, 2016

**REPORT CRITERIA**

CLINIC: [REDACTED] PROVIDER: ALL FUNDING: ALL VACCINE: ALL

**AGE GROUP**

	<1	1	2	3-5	6	7-10	11-12	13-18	19-24	25-44	45-64	>64	Total
Total	345	154	30	66	1	7	37	66	13	43	38	68	868

**VACCINE**

	<1	1	2	3-5	6	7-10	11-12	13-18	19-24	25-44	45-64	>64	Total
DTaP	3	13	6	12	0	0	0	0	0	0	0	0	34
DTaP-IPV	0	0	0	11	0	0	0	0	0	0	0	0	11
DTaP-IPV-Hib	24	0	0	0	0	0	0	0	0	0	0	0	24
Hep A-Adult	0	0	0	0	0	0	0	0	0	0	0	1	1
Hep A-Peds	1	31	11	8	1	1	4	14	0	0	0	0	71
Hep B	22	0	2	0	0	2	0	0	0	3	2	1	32
HIB	56	15	6	0	0	0	0	0	0	0	0	0	77
HPV	0	0	0	0	0	0	12	29	3	1	0	0	45
Influenza	36	9	0	1	0	0	0	0	0	0	1	2	49
IPV	1	0	1	12	0	1	0	0	0	0	0	0	15
Meningococcal	0	0	0	0	0	0	10	13	1	0	0	0	24
Meningococcal B	0	0	0	0	0	0	0	2	0	0	0	0	2
MMR	0	27	1	0	0	0	0	0	0	0	1	0	29
MMRV	0	0	0	22	0	0	0	0	0	0	0	0	22
Pediax	52	1	0	0	0	0	0	0	0	0	0	0	53
Pneumonia Conj	80	30	2	0	0	1	0	0	0	1	2	35	151
Pneumonia Poly	0	0	0	0	0	0	0	0	0	0	2	17	19
PPD	0	1	0	0	0	0	0	0	2	4	4	0	11

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# SDIIS Ordering Page New required check boxes

The screenshot shows a web browser window with the URL <https://apps.sd.gov/ph30sdiis/secure/addNewOrder.asp>. The main content area displays a list of vaccines with their respective product numbers and names in parentheses. Each vaccine entry has a corresponding input field for the quantity, all of which are currently set to '0'. The vaccines listed are:

HPV	00006-4119-03 (Gardasil)	0
Influenza	49281-0623-15 (Fluzone MDV)	0
Influenza	49281-0515-25 (Fluzone .25ml)	0
Influenza	58160-0903-52 (Fluarix .5ml)	0
Influenza	66019-0302-10 (Flumist)	0
IPV	49281-0860-10 (Polio)	0
Meningococcal	49281-0589-05 (Menactra)	0
Meningococcal	46028-0208-01 (Menveo)	0
Meningococcal B	00005-0100-10 (Trumenba)	0
Meningococcal B	46028-0114-01 (Bexsero)	0
MMR	00006-4681-00 (MMR II)	0
MMRV	00006-4171-00 (ProQuad)	0
Pediarix	58160-0811-52 (Pediarix)	0
Pneumonia Conj	00005-1971-02 (Prevnar 13)	0
Pneumonia Poly	00006-4943-00 (Pneumovax23)	0
Rotavirus	00006-4047-41 (Rotateq)	0
Rotavirus	58160-0854-52 (Rotarix)	0
Td	49281-0215-15 (Td)	0
Tdap	58160-0842-11 (Boostrix)	0
Tdap	49281-0400-10 (Adacel)	0
Varicella	00006-4827-00 (Varivax)	0

Below the vaccine list, there are two new required check boxes:

- By checking this box I take full responsibility for this information and attest that there is a current temperature log at this practice site with documentation in compliance with the Vaccines for Children vaccine temperature log documentation requirements.
- By checking this box I take full responsibility for this information and attest that the Department-supplied vaccine inventory listed is an accurate reflection of the inventory on hand at this practice site.

At the bottom of the form, there are two buttons: "UPDATE" and "CANCEL". Below these buttons, the text "\* Required" is displayed in red.

The Windows taskbar at the bottom shows several open applications: Immunization..., Public Health I..., Public Health I..., W..., Skype for Busi..., Policy #10 - R..., and Presentation1... The system clock indicates the time is 12:50 PM on 05/05/2016.