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STATE OF CONNECTICUT DEPARTMENT OF PUBLIC HEALTH

CT Vaccine Program

Visit our website: https://portal.ct.gov/DPH/Immunizations/CONNECTICUT-IMMUNIZATION-PROGRAM

2018-2019 BLUE FOLDER REVISED 11/15/2018

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410 Capitol Avenue, MS #11MUN, P.O. Box 340308, Hartford, CT 06134 / Tel (860) 509-7929 / Fax (860) 509-7945



VFC Provider Information

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2019 Provider Profile

If re-enrolling, please save and rename this document to include your pin #. Email completed forms to DPH.IMMUNIZATIONS@ct.gov Include your pin number in the subject line of your email.

All public and private health care providers who receive vaccine from the Connecticut Vaccine Program (CVP) must complete this form. This document provides shipping information and helps to determine the amount of vaccine to be supplied. The form is also used to compare estimated vaccine needs with actual vaccine supply. The Connecticut Vaccine Program will keep this record on file with the <u>SIGNED</u> "Provider Agreement". The Provider Profile form must be updated annually or if: (1) the number of children change, or (2) the address of the facility changes. <u>Complete one Provider Profile for each office/site/satellite</u>. Click here to

Federal Employer Tax ID			Please Check One			PIN (If re-errequired)	nrolling, your pin i
			Re-Enrolling in CVP New Provider				
Facility Name							
Office Days and Hours S	Staff Available to I	Receive Vac	cine Shinments				
Monday	Tuesday		Wednesday	Thurs	day		Friday
nclude any time during norm	nal business hours w	hen the office i	 is closed and will not a	ccept vaccine	deliveries		
Гуре of Facility (check o	one)						
□ Federally Qualified Health Cederally Funded Rural Health Center School Based Health Center STD/HIV Clinic □ Drug Treatment Facility	alth Clinic (RHC)	Private Pra Hospital Cl Other (plea Specialty (c) Pediatrics	ase specify) check one)	9)	☐ Aller	nal Medicine	
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Patient Enrollment and I status in order to receive vacand DO NOT use percentage 1. Number of Privately Insure 2. Number of Medicaid Enrol 3. Number of Patients Withou	ed Patients Illed Patients (HUSKY at Insurance re American Indian or ad Patients (HUSKY B	All practices m New providers o 1 through 6 m A) Alaskan Native	edicine nust provide total patier can give an estimate. I must equal the total p Birth to 1 yr.	Do not count a patient enrolli	numbers b a patient ir ment by a	y age group n more than ge group in	and insurance one category row 7.
Patient Enrollment and I status in order to receive vacuand DO NOT use percentage 1. Number of Privately Insure 2. Number of Medicaid Enrol 3. Number of Patients Withou 4. Number of Patients who ar 5. Number of S-CHIP Enrolle	ed Patients Illed Patients (HUSKY at Insurance re American Indian or ad Patients (HUSKY B Patients Patients in your prace	All practices m New providers of through 6 m A) Alaskan Native	Birth to 1 yr.	Do not count a patient enrolli	numbers b a patient ir ment by a	y age group n more than ge group in	and insurance one category row 7.

Please remember to sign the accompanying "Provider Agreement" and complete the "Insert for Storage Units"

State of Connecticut, Department of Public Health; 410 Capitol Avenue, M.S. # 11MUN Hartford, CT 06134-0308 Phone: 860-509-7929 Fax: 860-509-8371 Revised 9/18/2018



2019 Provider Profile

Insert For Storage Units

Please complete the following information for each storage unit at your facility in which you store CVP vaccine. <u>Please</u> see last page for an example of how to complete this form and definition of terms.

Facility Name		PIN:
Refrigerator:		
Manufacturer:	Make:	Model:
Serial Number/ID:		Storage Grade: ☐ Pharmaceutical ☐ Commercial ☐ Household
Thermometer In Refrigera	ator:	
Manufacturer:	Make:	Model:
Serial Number/ID:		Thermometer Type: ☐ Data Logger ☐ Built-in ☐ Manual
- Francis		
Freezer: Manufacturer:	Make:	Model:
ivianulacturer.	iviake.	iviouei.
Serial Number/ID:		Storage Grade: ☐ Pharmaceutical ☐ Commercial ☐ Household
Thermometer In Freezer:		
Manufacturer:	Make:	Model:
Serial Number/ID:		Thermometer Type: □ Data Logger □ Built-in □ Manual

Please use for any additional units if applicable

Facility Name		Pin Number:
Refrigerator:		
Manufacturer:	Make:	Model:
Serial Number/ID:		Storage Grade: ☐ Pharmaceutical ☐ Commercial ☐ Household
Thermometer In Refrigerator:		
Manufacturer:	Make:	Model:
Serial Number/ID:		Thermometer Type: ☐Data Logger ☐ Built-in ☐Manual
Freezer:		
Manufacturer:	Make:	Model:
Serial Number/ID:		Storage Grade: ☐ Pharmaceutical ☐ Commercial ☐ Household
Thermometer In Freezer:		
Manufacturer:	Make:	Model:
Serial Number/ID:		Thermometer Type: □ Data Logger □ Built-in □ Manual

Example Page

Insert For Storage Units,

Below is an example of how the insert for Storage Units forms is to be completed and definition of terms.

Facility Name 1234 Pediatrics	<u> </u>	PIN: 1234
Refrigerator:		
Manufacturer: American Biotech Supply	Make: UCFS Series	Model: PH-ABT-HC-UCFS-0204
Serial Number/ID: SN123456789		Storage Grade:
Thermometer In Refrigerator:		
Manufacturer: Berlinger Serial Number/ID:	Make: Fridge-Tag	Model: Fridge-Tag 2L Thermometer Type:
SN123456789		Data Logger
Freezer:		
Manufacturer: Summit	Make: SCFU Series	Model: SCFU386
Serial Number/ID: SN123456789		Storage Grade: Commercial
Thermometer In Freezer:		
Manufacturer: Fisher Scientific	Make: Traceable	Model: Traceable Excursion-Trac
Serial Number/ID: SN123456789		Thermometer Type: Data Logger

Manufacturer: Brand name

Make: The trade name or series of a particular product. Please refer to owner's manual **Model:** May refer to a range or make of products. Please refer to owner's manual

Serial Number: A number indicating place in a series and used as a means of identification. Usually located on product

Storage Grade:

- **Pharmaceutical:** Also called "purpose-built," these units are designed by the manufacturer specifically to store vaccines or other biological materials. **Examples of manufacturers: ABS, AEGIS, AccuCold**
- **Commercial:** Although usually intended to store food and beverages, commercial units are often larger and more powerful than the household units found in most homes. Though these units are intended to meet the higher demands of larger facilities, these units are not specifically built for the storage of biological materials. **Examples of manufacturers: Summit, TurboAir, Avanti**
- Standard: Household (non-commercial/domestic): These units are usually smaller than commercial units and are intended for use in small offices and in homes and typically for food storage. Just like commercial units, they are not designed specifically for the storage of biological materials. Such units are usually available in common home supply stores. Examples of manufacturer:

 Frigidaire, Kenmore, Whirlpool, GE, Hotpoint

Thermometer Type:

- Data Logger or Continuous Temperature Monitoring device is equipped with: A temperature probe; an active temperature display
 that can be easily read from the outside of the unit; the capacity for continuous monitoring and recording capabilities where the
 data can be routinely downloaded. Examples of manufacturers: Fisher Traceable, Log Tag, Berlinger, Temperature Guard
- · Built-in: Integrated within storage unit, not free standing, must meet data logger definition
- **Manual:** Digital thermometer without downloadable logging feature. Please note as of January 2018 CDC requires all storage units to have data logger thermometers.



Connecticut Vaccine Program (CVP)

2019 Provider Agreement
E-mail completed forms to: DPH.IMMUNIZATIONS@ct.gov

FACILITY INFORMATION						
Facility					PIN:	
Name:						
Facility						
Address:						
City:		Cou	nty:	State:	Zip:	
Telephone:			Fax:	l		
Shipping Address (if different than faci	lity addres	s):				
City:		Cou	nty:	State:	Zip:	
MEDICAL DIRECTOR OR EQUIVA	LENT					
Instructions: The official registered health administer pediatric vaccines under state law and its providers with the responsible conditional must sign the provider agreement.	who will a	lso be l	neld accounta	able for compliance irollment agreemen	e by the entire organization	
Last Name, First, MI:	Title:			Specialty:	Specialty:	
License #:	Medicai	dicaid #:		National Property (NPI):	National Provider Identifier # (NPI):	
Provide Information for second individual as	needed (for	pharm	ıacists only):			
Last Name, First, MI:	Title:			Specialty:		
License #:	Medicai			National Pr (NPI):	National Provider Identifier # (NPI):	
VACCINE COORDINATOR						
Primary Vaccine Coordinator* First a	and Last N	Vame	•			
Telephone:	Email: (1	: (NOTE: this email address will receive CVP communications)				
Completed annual training: Yes No Type of Site v		of training received visit CDC on-line modules Other/specify:				
Back-Up Vaccine Coordinator* First	1				, Sp, ·	
Telephone:	Email: (1	NOTE:	this email ac	ddress will receive	CVP communications)	
Completed annual training:	Type of	traini	ng receive	d:		
Yes No	Site visit CDC on-			-line modules	Other/specify:	

^{*}The primary vaccine coordinator is the person at the office who has primary responsibility for ordering, monitoring, and ensuring the quality of vaccines at the practice; the back-up vaccine coordinator has responsibility in the vaccine coordinator's absence.



Connecticut Vaccine Program (CVP) 2019 Provider Agreement E-mail completed forms to: DPH.IMMUNIZATIONS@ct.gov

uctions: List below all licen ribing or administering autho			. (/ /	- ·- // F ······		, y ,
Provider First and Last Name	Title	Prescribes	Administers	License #	Medicaid #	NPI#
Tovider First and East Name	Title	rescribes		License #	Wicalcala #	141 117
		<u> </u>				
		_	_			



2.

3.

6.

Connecticut Vaccine Program (CVP) 2019 Provider Agreement

E-mail completed forms to: <u>DPH.IMMUNIZATIONS@ct.gov</u>

PROVIDER AGREEMENT

To receive publicly funded vaccines at no cost, I agree to the following conditions, on behalf of myself and all the practitioners, nurses, and others associated with the health care facility of which I am the medical director or equivalent:

I will annually submit a provider profile representing populations served by my practice/facility. I will submit more frequently if 1) the number of children served changes or 2) the status of the facility changes during the calendar year.

I will screen patients and document eligibility status at each immunization encounter for VFC eligibility (i.e., federally or state vaccine-eligible) and administer VFC-purchased vaccine by such category only to children who are 18 years of age or younger who meet one or more of the following categories:

- A. Federal Vaccine-eligible Children (VFC eligible)
 - 1. Are an American Indian or Alaska Native;
 - 2. Are enrolled in Medicaid;
 - 3. Have no health insurance:
 - 4. Are underinsured: A child who has health insurance, but the coverage does not include vaccines; a child whose insurance covers only selected vaccines (VFC-eligible for non-covered vaccines only). Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC), or Rural Health Clinic (RHC) or under an approved deputization agreement.

B. State Vaccine-eligible Children

1. In addition, to the extent that my state designates additional categories of children as "state vaccine-eligible", I will screen for such eligibility as listed in the addendum to this agreement and will administer state-funded doses to such children.

Children aged 0 through 18 years that do not meet one or more of the eligibility federal vaccine categories (VFC eligible), are **not** eligible to receive VFC-purchased vaccine.

For the vaccines identified and agreed upon in the provider profile, I will comply with immunization schedules, dosages, and contraindications that are established by the Advisory Committee on Immunization Practices (ACIP) and included in the VFC program unless:

- a) In the provider's medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate for the child;
- b) The particular requirements contradict state law, including laws pertaining to religious and other exemptions.
- I will maintain all records related to the vaccine program for a minimum of three years and upon request make these records available for review. Vaccine records include, but are not limited to, vaccine screening and eligibility documentation, billing records, medical records that verify receipt of vaccine, vaccine ordering records, and vaccine purchase and accountability records.
- 5. I will immunize eligible children with publicly supplied vaccine at no charge to the patient for the vaccine.

VFC Vaccine Eligible Children

I will not charge a vaccine administration fee to non-Medicaid federal vaccine eligible (uninsured or underinsured) children that exceeds the administration fee cap of \$21.00 per vaccine dose. For Medicaid children, I will accept the reimbursement for immunization administration set by the state Medicaid agency or the contracted Medicaid health plans.

State Vaccine Eligible Children

For private insurance patients I will accept the reimbursement for immunization administration up to the maximum allowed per the insurance company's policy.



Connecticut Vaccine Program (CVP) 2019 Provider Agreement E-mail completed forms to: DPH.IMMUNIZATIONS@ct.gov

Health E-mail completed forms to: DPH.IMMUNIZATIONS@ct.gov
I will not deny administration of a publicly purchased vaccine to an established patient because the child's parent/guardian/individual of record is unable to pay the administration fee.
I will distribute the current Vaccine Information Statements (VIS) each time a vaccine is administered and maintain records in accordance with the National Childhood Vaccine Injury Act (NCVIA), which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).
 I will comply with the requirements for vaccine management including: a) Ordering vaccine and maintaining appropriate vaccine inventories; b) Not storing vaccine in dormitory-style units at any time; c) Storing vaccine under proper storage conditions at all times. Refrigerator and freezer vaccine storage units and temperature monitoring equipment and practices must meet CVP storage and handling requirements including use of a data logger style thermometer for all CVP supplied vaccine; d) Returning all spoiled/expired public vaccines to CDC's centralized vaccine distributor within two months of spoilage/expiration
I agree to operate within the VFC program in a manner intended to avoid fraud and abuse. Consistent with "fraud" and "abuse" as defined in the Medicaid regulations at 42 CFR § 455.2, and for the purposes of the VFC Program: Fraud: is an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state law.
Abuse: provider practices that are inconsistent with sound fiscal, business, or medical practices and result in an unnecessary cost to the Medicaid program, (and/or including actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient); or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary cost to the Medicaid program.
I will participate in VFC program compliance site visits including unannounced visits, and other educational opportunities associated with VFC program requirements.
Should my staff, representative, or I access VTrckS, I agree to: a) Be bound by CDC's terms of use for interacting with the online ordering system. I further agree to be bound by any applicable federal laws, regulations or guidelines related to accessing a CDC system and ordering publically funded vaccines, and b) In advance of any VTrckS access by my staff, representative or myself, I will identify each member of my staff or representative who is authorized to order vaccines on my behalf. In addition, I will maintain a record of each staff member who is authorized to order vaccines on my behalf. If changes occur, I will inform the Connecticut Vaccine Program within 24 hours of any change in status of current staff members or representatives who are no longer authorized to order vaccines, or the addition of any new staff authorized to order on my behalf. I certify that my identification is represented correctly on this provider enrollment form.
For pharmacies, urgent care, or school located vaccine clinics, I agree to: a) Vaccinate all "walk-in" VFC-eligible children and b) Not refuse to vaccinate VFC-eligible children based on a parent's inability to pay the administration fee. Note: "Walk-in" refers to any VFC eligible child who presents requesting a vaccine; not just established patients. "Walk-in" does not mean that a provider must serve VFC patients without an appointment. If a provider's office policy is for all patients to make an appointment to receive immunizations then the policy would apply to VFC patients as well.
I agree to replace vaccine purchased with state and federal funds that are deemed non-viable due to provider negligence on a <u>dose-for-dose</u> basis.
I understand this facility or the Connecticut Vaccine Program may terminate this agreement at any time. If I choose to terminate this agreement, I will properly return any unused state and federal vaccine as directed by the Connecticut Vaccine Program.



Connecticut Vaccine Program (CVP) 2019 Provider Agreement E-mail completed forms to: DPH.IMMUNIZATIONS@ct.gov

By signing this form, I certify on behalf of myself and all immunization providers in this facility, I have read and agree to the vaccine enrollment requirements listed above and understand I am accountable (and each listed provider is individually accountable) for compliance with these requirements.				
Medical Director or Equivalent Name (print):				
Signature:	Date:			
Name (print) Second individual as needed:				
Signature:	Date:			



Connecticut Vaccine Program (CVP) 2019 Provider Agreement E-mail completed forms to: DPH.IMMUNIZATIONS@ct.gov

Provider Name	Title	Prescribes	Administers	License #	Medicaid #	NPI#
	- Indic			zieciisc ii		



Connecticut Vaccine Program Vaccine Fraud & Abuse Statement

Cooperation

Compliance with the Vaccines For Children (VFC) and Connecticut Vaccine Program (CVP) requirements is an important step in preventing fraud and abuse of state and federal resources. The VFC and CVP programs distribute approximately \$62 million dollars' worth of vaccine per year. A variety of methods are used to control and monitor misuse of state supplied vaccine. Monthly doses administered data reports and vaccine ordering patterns are monitored to ensure that vaccine is given to appropriate age groups. All complaints regarding vaccine misuse will be promptly followed up by the Immunization Program.

Fraud

Fraud is defined as the intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to themselves or someone else. It includes any act that constitutes fraud under applicable federal or state laws.

Abuse

Abuse is defined as provider practices that are inconsistent with sound fiscal, business or medical practices, and result in an unnecessary cost to the Medicaid program, and/or including actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient; or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary cost to the Medicaid Program.

What Can Be Done to Prevent Fraud & Abuse?

If you become aware of a situation or practice that you consider to be potential fraud or abuse, please contact the CVP at (860) 509-7929. There is also a Fraud and Abuse Hotline telephone number 1-800-842-2155. All reports of Fraud and Abuse by individuals or providers are strictly confidential. The name and phone number of the individual or the provider reporting the event is optional however it would be extremely helpful in the event the program would need to conduct further follow-up with the individual/provider for additional or clarifying information.

Examples of fraud and abuse include:

- -A provider discontinues privately purchasing vaccine for patients whose insurance covers immunizations and gives every patient in the practice state supplied vaccine whether they are eligible or not
- -A provider bills Medicaid for administration reimbursement when no vaccines were given
- -A provider administers state supplied vaccine to a child, then bills the child's insurance company for the cost of the vaccine
- -A provider charges the patient for state supplied vaccine

FRAUD AND ABUSE HURTS EVERYONE!

Revised 2/4/2014



Connecticut Vaccine Program HOW TO ESTABLISH AND MAINTAIN RECORDS OF PATIENT ELIGIBILITY

The following information will help you establish that a patient is eligible to receive vaccines from the CT Vaccine Program (CVP).

Why is eligibility screening required?

Vaccines are provided through a combination of both federal and state funding. Patient screening helps to ensure that children only receive the specific vaccine(s) for which they are eligible.

Who should complete the form?

The parent, guardian, individual of record or the healthcare provider may complete this form. Verification of responses is not required.

What form should I use?

The Patient Eligibility Screening Record

What procedure do I follow?

Maintain the screening record form with the patient's chart. If patient eligibility is unchanged from the date of the previous screening, simply date and initial the screening immediately in the record or EMR. If the patient eligibility has changed since the previous screening, then begin a new form with the new patient eligibility category completed. The screening record should be maintained for a minimum of 3 years after service to the patient is complete.

When do I use the form?

A record must be kept for *each* child receiving CVP vaccines. Screening and documentation that screening was performed is required at every immunization visit.

Helpful Information:

- The *Patient Eligibility Screening Record*, with the seven eligibility options, may be incorporated into a form your practice or clinic is presently using. Document the information in the electronic medical record (EMR) or paper chart and update the patient's status when the insurance changes. Always include the date of the screening.
- If you choose to use the CVP-provided *Patient Eligibility Screening Record*, the form may be copied as needed.
- If you have any questions, please call (860) 509-7929 and a CVP representative can assist you.



CONNECTICUT VACCINE PROGRAM (CVP) Patient Eligibility Screening Record



Child's	s Name:				_	"I'M AC
Date o	of Birth:					
Paren	t/Guardian:					
Provid	er:				_	
	child qualifies for immun e is under 19 years of a			Connecticut Vaccine Pro one box):	gram sin	ce
VFC (A)	eligible: Is enrolled in Medicaid	I (HUSKY A))			
(B)	Has no health insuran	ce/self-pay				
(C)	Is American Indian or	Alaskan Nat	ive			
(D)	select vaccines) and is	s a patient of	f a Fed	nat does not cover vaccing lerally Qualified Health ive all vaccines at their Fo		y covers
State (E)	covers select vaccines	s) and is a pa	atient o	nat does not cover vaccino of a private health care pro at their private health care	ovider.	
(F)	Is enrolled in S-CHIP	(HUSKY B)				
(G)	*Is Privately Insured					
Papillo Hepat	mavirus Vaccine (HPV) fo	or 9-10 & 13 th olds and Me	nrough ningoco	nes from the CVP except fo 18 year olds , Influenza for to occal Group B vaccines; the	5 through	18 year olds,
				fice (paper copy or in an EH o receive vaccine from the 0		nat reflects the
that eligib	oility screening was verif	ied with the i	initials	for every immunization v of the person who perform omplete a new patient elig	ned the	screening. If
Date of	screening (mo/day/year)	Initials		Date of screening (mo/da	y/year)	Initials



CONNECTICUT VACCINE PROGRAM Formulario Para La Elegibilidad del Paciente

Nombre del Paciente:



Fecha de nacimiento:						
Nombre de Padres/tutores:						
Proveedor de Servicios:						
Este paciente califica para inmunizaciones p menos de 19 años y (marque solamente uno		lel P	rograma de Vac	unas de Con	necticut porqu	ue él / ella tiene
Elegible para CVP:						
(A) Está registrado en Medicaid (Husky A)						
(B) No tiene seguro médico / pago propio						
(C) Es Indio Americano o persona nacida en	Alaska					
(D) Seguro limitado (tiene seguro que no cub y es un paciente de un Centro de Salud que pacientes pueden recibir todas las vacunas e	sea califica	ado i	federalmente (F	QHC). Estos	•	
Estado elegible:						
(E) Seguro limitado (tiene seguro que no cub y es un paciente de una oficina de los provec recibir todas las vacunas en su oficina de pro	edores de	salu	id privado. Esto:			
(F) Está registrado en S-CHIP (Husky B)						
(G) *Seguro privado						
*Pacientes que tienen seguro privado pued Influenza de 5 a 18 años de edad, la Hepatit papiloma humano (VPH) de 9 a 10, y 13 a 18 en las categorías A, B, C, D, E, y F.	is A de 2 a	18 a	años de edad, la	a vacuna mei	ningococo el g	grupo b, y el virus del
Un historial debe de mantenerse guardado e que tengan 18 años o menos que reciben va tutores, o individual del historial, o por el pro niño o niña ha cambiado. Mientras que la ve uno similar para cada paciente que recibe ur	cunas del p veedor méd rificación de	prog dico de re	rama CVP. El h . El historial no t	istorial pued iene que est	e ser completa ar al día a me	ado por los padres, nos que el estado de
La Elegibilidad del Paciente debe ser verifica que el formulario de elegibilidad fue verificad las preguntas de arriba (A-G) han cambiado,	o con las ir	inicia	iles de la persor	na que realizo	o el cribado. S	
Fecha de examen (mes/dia/año)	Iniciales		F	echa de exar (mes/dia/año		Iniciales
Pavised 11/14/2017 https://portal.ct.com/DDH//mmuni						

Please fill in the EHR Categories with the drop down selections from your EHR to ensure accurate screening and documenting of CVP eligibility.

Please share this 'cheat sheet' with staff to ensure the correct vaccine is given to the correct child.

Connecticut Vaccine Program (CVP) Patient Eligibility Screening Record Cheat Sheet							
VFC-Eligible:	Typical EMR/EHR Categories	Your EHR Categories					
(A) Is Enrolled in Medicaid (HUSKY A)	 Medicaid/Medicaid Managed Care VFC eligible – Husky A 	•					
(B) Has no health insurance/self-pay	UninsuredSelf-pay	•					
(C) Is American Indian or Alaskan Native	American Indian/Alaskan Native	•					
(D) Is under-insured (has health insurance that does not cover vaccines or only covers select vaccines) and is a patient of a Federally Qualified Health Center (FQHC). These patients can receive all vaccines at their FQHC	 Under-insured (FQHC) FQHC patient (under-insured) 	•					
STATE Eligible (CVP):							
(E) Is under-insured (has health insurance that does not cover vaccines or only covers select vaccines) and is a patient of a private health care provider. These patients can receive all vaccines at their private health care provider.	Under-insured, not FQHC Patient	•					
(F) Is enrolled in S-CHIP (HUSKY B)	 State-specific eligibility (e.g. S-CHIP plan) State-specific eligibility – Husky B 	•					
(G) * Is Privately Insured	Not VFC eligiblePrivate Insurance	•					

^{*} Private insurance patients can receive all vaccines from the CVP except: Rotavirus, Human Papillomavirus Vaccine (HPV) for 9-10 and 13-18 years old, Influenza for 5 through 18 years old, Hepatitis A for 2 through 18 year old and Meningococcal Group B vaccines. These vaccines are only available for patients in categories A, B, C, D, E, F.

Any questions, please contact the State Immunization Program

Phone: (860) 509-7929 Website: https://portal.ct.gov/DPH/Immunizations/CONNECTICUT-IMMUNIZATION--PROGRAM

Connecticut Vaccine Program (CVP) Eligibility Criteria as of October 1, 2018

Vaccine	Age Group	Status of Children				CPT
	_	VFC and	VFC and State Supplied Vaccine			
		VFC Eligible ¹	Non-VFC Eligible Privately Insured ²	Non-VFC Eligible Under-Insured ²	S-CHIP ²	Code(s)
Hepatitis B	Newborns in hospital	YES	YES	YES	YES	90744
	Children 0-18 years	YES	YES	YES	YES	90744
Varicella (Doses 1 & 2)	12 months-18 years ³	YES	YES	YES	YES	90716
Td	7-18 years ⁴	YES	YES	YES	YES	90714
MMR	12 months-18 years	YES	YES	YES	YES	90707
(Doses 1 & 2)	College (any age)	YES	YES	YES	YES	90707
MMRV (Doses 1 & 2)	12 months-12 years	YES	YES	YES	YES	90710
DTaP	2 months – 6 years	YES	YES	YES	YES	90700
Hib	2-59 months	YES	YES	YES	YES	90647, 90648
IPV	2 months-18 years	YES	YES	YES	YES	90713
DTaP/IPV	4-6 years	YES	YES	YES	YES	90696
DTaP/IPV/Hep B	2-83 months	YES	YES	YES	YES	90723
DTaP/IPV/Hib	2-59 months	YES	YES	YES	YES	90698
Meningococcal Conjugate-High Risk	2 months-10 years	YES	YES	YES	YES	90734
Routine Doses 1 & 2	11-18 years	YES	YES	YES	YES	90734
Tdap	7-18 years ⁵	YES	YES	YES	YES	90715
Pneumococcal Conjugate (PCV13)	2 months-18 years	YES	YES	YES	YES	90670
Pneumococcal Polysaccharide (PPSV23)	2-18 years	YES	YES	YES	YES	90732
Influenza	6-59 months 5-18 years	YES YES	YES NO	YES YES	YES YES	90672, 90674 90685, 90686 90672, 90674, 90686
Hepatitis A	12-23 months	YES	YES	YES	YES	90633
	2-18 years	YES	YES	YES	YES	90633
Rotavirus	6 weeks-8 months	YES	NO	YES	YES	90680, 90681
HPV (males &	9-10 & 13-18 years	YES	NO	YES	YES	90651
females)	11-12 years	YES	YES	YES	YES	90651
Meningococcal	10-15 years (High Risk)	YES	NO	YES	YES	90620, 90621
Serogroup B	16-18 years	YES	NO	YES	YES	90620, 90621

¹ VFC eligibility is defined as follows: (a) Medicaid enrolled; (b) NO health insurance; (c) American Indian or Alaskan native; or (d) underinsured seen at an FQHC.

As of October 1, 2018 the only childhood vaccines not available from the CVP are: Influenza for privately insured patients 5-18 years of age; Rotavirus for privately insured patients 6 weeks-8 months of age; Meningococcal Serogroup B for privately insured patients 10-18 years of age; and HPV for privately insured patients 9-10 & 13-18 years of age. Providers can purchase these vaccines privately and submit billing requests to the appropriate insurer in accordance with normal billing procedures.

Revised 7/26/18

² Non-VFC children refers to patients who have private insurance that covers the cost of immunizations, patients that are under-insured for some or all vaccines seen by a private provider; and S-CHIP children- those children enrolled in HUSKY B.

³ Susceptible children who do not have a clinical history of chicken pox.

⁴ Td vaccine can be given to children 7-18 years of age to complete their primary series, or to those children 7-18 years of age who are in need of a Tetanus containing vaccine and cannot receive Tdap.

⁵ Tdap vaccine should be administered routinely to children at the 11-12 year old preventive health care visit, and to children 7-10 years old who have not been fully vaccinated against pertussis and for whom no contraindication to pertussis containing vaccine exists.

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 (70ther or 130ther) is entered in the Vaccine Borrowing Report Table.

Reason for Vaccine Borrowing and Replacement Coding Legend

December Demonstra VEC December 1	Cada	December 1 Demonstrate December 1	Cada
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:	130ther
Other – Describe:	70ther		·

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.

Date Range of Vaccine Reporting (date of first dose borrowed to date of last dose borrowed):/t	o/	′/	
			_

VACCINE BORROWING REPORT TABLE								
A Vaccine Type Borrowed	B Stock Used (VFC or Private)	C Patient Name		D Patient DOB (XX/XX/XXXX)	E Date Dose Administered (XX/XX/XXXX)	F Reason Appropriate V Stock was not Use (Use legend code on page one reason for each dose	sed 1 to mark	G Date Dose Returned to Appropriate Stock (XX/XX/XXXX)
I hereby certify, subject to per replacement reported on this doses borrowed during the no	form has been accu	rately reported and co	nducte	d in conformance wit				
Provider Name:								

CONNECTICUT VACCINE PROGRAM (CVP)





			Date Reviewed	Initials	
Facility Name		PIN			
City/Town	Phone				
Person Completing Form		Date			

THE BACK-UP PLAN MUST BE REVIEWED ANNUALLY AND UPDATED WHENEVER PERSONNEL RESPONSIBLE FOR VACCINE CHANGES. PLEASE RECORD THE DATE IN THE SPACE ABOVE EACH TIME THE FORM IS REVIEWED.

This document offers guidance for developing a vaccine disaster recovery plan. Included are steps to follow when your refrigerator or freezer malfunctions due to mechanical failure or natural disaster. *If you have any questions about vaccine transportation or stability call (860) 509-7929*.

VACCINE RECOVERY PLAN

A. Designate a Vaccine Coordinator and a Back-up person within your practice to:

- ♦ Monitor the operation of the vaccine storage equipment and systems daily;
- ♦ Track inclement weather conditions. Set up and maintain a monitoring/notification system during times of inclement weather or other conditions that would create a shut down in power. An alarm/notification system is recommended for practices with an inventory or \$5,000 or more;
- ♦ Assure the appropriate handling of the vaccine during the disaster or power outage.
- ♦ Ensure procedures are in place to notify the Vaccine Coordinator and/or Back-up person if power is lost and that they have access on weekends and off hours.

Names of designated employees:

NAME/TITLE	CELL PHONE	HOME PHONE

B. Back-Up Systems

If you do not have a back-up generator, identify a location with one. This may be the local hospital, pharmacy, fire station, another practice, or an employee's home.

♦ Make arrangements with the site to store your vaccine there when weather predictions call for inclement conditions (severe ice/snow storms, hurricanes etc.) and when your vaccine storage equipment cannot be fixed or the power cannot be restored within 6 hours.

Document the location(s), contact person and phone number of your back-up system/generator:

CONTACT PERSON	HOME PHONE
	CONTACT PERSON

Connecticut Department of Public Health 410 Capitol Avenue, MS#11MUN; Hartford, CT 06134 Revised 5/2016

Phone: 860-509-7929 Web: https://portal.ct.gov/DPH/Immunizations/CONNECTICUT-IMMUNIZATION--PROGRAM

- Determine if your refrigerator is having a mechanical failure (no lights in the refrigerator, no fan noise, etc.) or if the building has lost electrical power. Check with building maintenance to ensure that the generator is operational and has been activated. If a time-frame for the restoration of electrical power cannot be determined, contact your back-up location for temporary storage of vaccine.
- ♦ In situations where a location with a back-up generator cannot be identified within a reasonable distance, preparations should be made to have coolers, and frozen ice packs available to temporarily and safely store your vaccine.

C. Transport of Vaccine

- ♦ Conduct an inventory before you transport vaccine.
- **♦ Package vaccine in a well-insulated container with ice packs.**
- ♦ Insulate refrigerated vaccine from direct contact with the ice packs by wrapping vaccine packaging in newspaper, bubble wrap, or a similar material. Do not expose refrigerated vaccine to freezing temperatures.
- ♦ Remember that varicella and MMRV vaccine must be kept frozen between -58°F and +5°F (-50°C to -5°C) and should be packaged separately from other vaccines (with the exception of MMR vaccine, which can be either kept frozen or refrigerated). Use of dry ice to transport varicella and MMRV may subject the vaccine to temperatures colder than recommended and should not be used.

D. Staff Training/Posted Information

- ♦ Post your Vaccine Recovery Plan on or near the vaccine storage equipment.
- ♦ Ensure that all staff (current and new) read the plan and understand it as part of their orientation

E. Large Practices and Medical Centers

If you are a very large practice or a medical center, and have large quantity of vaccine, consider joining with other practices and rent a refrigerated truck to transport or store your vaccine. Have the name and telephone number of a local refrigeration company available. You will need to monitor the temperature of the refrigerated truck until you can get your vaccine safely returned to your office.

REFRIGERATION COMPANY(S)	PHONE NUMBER	CONTACT PERSON & HOME PHONE

THINGS TO DO NOW...BEFORE IT IS TOO LATE!

- A. Complete this plan and update as staff changes occur. It will only take a few minutes and may save you hours of work later, not to mention our federal and state tax dollars.
- B. Fill the empty spaces in your refrigerator with jugs of water and line the sides and bottom of your freezer with ice packs. In the event that your refrigerator/freezer is out of order, this exercise will help maintain the temperature for a longer period of time.

IT IS IMPORTANT TO CUSTOMIZE A BACK-UP PLAN RELEVANT TO YOUR PRACTICE!

HELPFUL HINTS

- ♦ Fill a cup with water and put it in the freezer containing vaccine; once the water has frozen put a penny or paper clip on top of the frozen water. If you find the object has been frozen over you'll know the temperature rose above freezing at some point in time. This is especially helpful over a holiday weekend or school break.
- ♦ Use the blinking light of a digital clock or microwave as an indicator that power was lost some time during closing hours

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CONNECTICUT VACCINE PROGRAM (CVP) VACCINE MANAGEMENT PLAN



		Date Reviewed	Initials
Facility Name	PIN		
Vaccine Coordinator			
Back-Up Coordinator			

PURPOSE

The purpose of this document is to ensure proper management of vaccines received under the Connecticut Vaccine Program (CVP), including vaccine ordering, receipt, cold storage, transfer, and inventory control. All documents referenced in this plan as well as additional vaccine information may be found in the Department of Public Health Immunization Program provided Blue Folder. In addition, many of these documents can be found on the Connecticut Vaccine Program website: https://portal.ct.gov/DPH/Immunizations/CVP---Information-for-Providers

Designate a primary vaccine coordinator and at least one back-up staff at each practice site enrolled in CVP.

It is preferable for the primary vaccine coordinator to be a full time employee of the site. The vaccine coordinator is responsible for ensuring that the details of this plan are followed.

♦ Complete and follow the Vaccine Back-Up Plan.

The Vaccine Back-Up Plan is a contingency plan for vaccines in the event of a power failure. This plan should be reviewed and updated annually, or when there is a change in staff responsible for the plan.

Receive and review CVP vaccine from the distributor (McKesson or Merck).

Ensure that the shipment matches the packing slip, the appropriate diluent is included, the vaccine is unpacked/properly stored, and report any discrepancies to the state Immunization Program immediately.

(It may be helpful to maintain a running log for each shipment of vaccines for inventory control purposes; the log could include the number of doses of vaccine received, the date the vaccine was received, the date of expiry, and the new running total.)

- Rotate vaccine stock as it is received to ensure that vaccine expiring first is used first.
- **♦ Store Vaccines at their proper temperatures.**

Refer to the "Vaccine Storage and Handling Toolkit" for further information on the proper storage and handling of each vaccine. https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf

- ♦ Refer to the Vaccine Ordering Form (VOF) instructions when ordering CVP vaccines.
- Report all expired, wasted, spoiled or lost vaccine to the CVP by submitting a vaccine return form and spoilage letter.

Expired, wasted, spoiled, or lost vaccines are to be returned to McKesson. Please read and follow directions on the return form.

Submit a completed Vaccine Transfer Form to the CVP if viable CVP vaccine is transferred between sites.

PLEASE CONTACT THE CVP AT 860-509-7929 IF YOU REQUIRE FURTHER ASSISTANCE.

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Revised 5/2016



Immunization Laws & Regulations

Link to: http://portal.ct.gov/DPH/Infectious-Diseases/Immunization/Immunization--Laws-and-Regulations

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You Must Give Your Patients Vaccine Information Statements (VISs) – It's Federal Law!

What are Vaccine Information Statements (VISs)?

Vaccine Information Statements (VISs) are documents produced by the Centers for Disease Control and Prevention (CDC), in consultation with panels of experts and parents, to properly inform vaccinees (or their parents/legal representatives) about the risks and benefits of each vaccine. VISs are not meant to replace interactions with healthcare providers, who should address any questions or concerns that the vaccinee (or parent/legal representative) may have.

Using VISs is legally required!

Federal law (under the National Childhood Vaccine Injury Act) requires a healthcare provider to give a copy of the current VIS to an adult patient or to a child's parent/legal representative before vaccinating an adult or child with a dose of the following vaccines: diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis A, hepatitis B, *Haemophilus influenzae* type b (Hib), influenza, pneumococcal conjugate, meningococcal, rotavirus, human papillomavirus (HPV), or varicella (chickenpox).

Where to get VISs

All available VISs can be downloaded from the websites of the Immunization Action Coalition at www.immunize.org/vis or CDC at www.cdc.gov/vaccines/hcp/vis/index.html. Ready-to-copy versions may also be available from your state or local health department.

Translations: You can find VISs in more than 30 languages on the Immunization Action Coalition website at www.immunize.org/vis.

To obtain translations of VIS in languages other than English, go to www.immunize.org/vis.

According to CDC, the appropriate VIS must be given:

- Prior to the vaccination (and prior to each dose of a multi-dose series);
- Regardless of the age of the vaccinee;
- Regardless of whether the vaccine is given in a public or private healthcare setting.

Top 10 Facts About VISs



It's federal law! You must give current* VISs to all your patients before vaccinating them.

Federal law requires that VISs must be used for patients of **ALL** ages when administering these vaccines:

- DTaP (includes DT)
- Td and Tdap
- Hib
- hepatitis A
- hepatitis B
- HPV
- ro
- influenza (inactivated and live, intranasal)
- MMR and MMRV
- meningococcal (MenACWY, MenB)
- pneumococcal conjugate
- polio
- rotavirus
- varicella (chickenpox)

For the vaccines not covered under the National Childhood Vaccine Injury Act (i.e., adenovirus, anthrax, Japanese encephalitis, pneumococcal polysaccharide, rabies, typhoid, yellow fever, and zoster), providers are not required by federal law to use VISs unless they have been purchased under CDC contract. However, CDC recommends that VISs be used whenever these vaccines are given.

*Federal law allows up to 6 months for a new VIS to be used.



VISs can be given to patients in a variety of ways.

In most medical settings, VISs are provided to patients (or their parents/legal representatives) in paper form. However, VISs also may be provided using electronic media. Regardless of the format used, the goal is to provide a current VIS just prior to vaccination.

CONTINUED ON NEXT PAGE

Most current versions of VISs (table)

As of October 12, 2018, the most recent versions of the VISs are as follows:

Adenovirus	6/11/14
Anthrax	3/21/18
Cholera	7/6/17
DTaP	8/24/18
Hib	4/2/15
Hepatitis A	7/20/16
Hepatitis B	10/12/18
HPV	12/2/16
Influenza	8/7/15
Japanese enceph	1/24/14
MenACWY	8/24/18
MenB	8/9/16
MMR	2/12/18

MMRV	2/12/18
Multi-vaccine	11/5/15
PCV13	11/5/15
PPSV	4/24/15
Polio	7/20/16
Rabies	10/6/09
Rotavirus	2/23/18
Td	4/11/17
Tdap	2/24/15
Typhoid	5/29/12
Varicella	2/12/18
Yellow fever	3/30/11
Zoster	2/12/18

A handy list of current VIS dates is also available at www.immunize.org/catg.d/p2029.pdf.



Technical content reviewed by the Centers for Disease Control and Prevention

(For information on special circumstances involving vaccination of a child when a parent/legal representative is not available at the time of vaccination, see CDC's *Frequently Asked Questions* at www.cdc.gov/vaccines/hcp/vis/about/vis-faqs.html.)

Prior to vaccination, VIS may be:

- Provided as a paper copy
- Offered on a permanent, laminated office copy
- Downloaded by the vaccinee (parent/legal representative) to a smartphone or other electronic device (VISs have been specially formatted for this purpose)
- Made available to be read before the office visit, e.g., by giving the patient or parent a copy to take home during a prior visit, or telling them how to download or view a copy from the Internet. These patients must still be offered a copy in one of the formats described previously to read during the immunization visit, as a reminder.

Regardless of the way the patient is given the VIS to read, providers must still offer a copy (which can be an electronic copy) of each appropriate VIS to take home following the vaccination. However, the vaccinee may decline.



VISs are required in both public and private sector healthcare settings.

Federal law requires the use of VISs in both public and private sector settings, regardless of the source of payment for the vaccine.



You must provide a current VIS *before* a vaccine is administered to the patient.

A VIS provides information about the disease and the vaccine and must be given to the patient **before** a vaccine is administered. It is also acceptable to hand out the VIS well before administering vaccines (e.g., at a prenatal visit or at birth for vaccines an infant will receive during infancy), as long as you still provide a current VIS right before administering vaccines.



You must provide a current VIS for *each* dose of vaccine you administer.

The most current VIS must be provided before **each dose** of vaccine is given, including vaccines given as a series of doses. For example, if 5 doses of a single vaccine are required (e.g., DTaP), the patient (parent/legal representative) must have the opportunity to read the information on the VIS before each dose is given.



You must provide VISs whenever you administer combination vaccines.

If you administer a combination vaccine that does not have a stand-alone VIS (e.g., Kinrix, Quadracel, Pediarix, Pentacel, Twinrix) you should provide the patient with individual VISs for the component vaccines, or use the Multi-Vaccine VIS (see below).

The Multi-Vaccine VIS may be used in place of the individual VISs for DTaP, Hib, hepatitis B, polio, and pneumococcal when two or more of these vaccines are administered during the same visit. It may be used for infants as well as children through 6 years of age. The Multi-Vaccine VIS should not be used for adolescents or adults.



VISs should be given in a language / format that the recipient can understand, whenever possible.

For patients who don't read or speak English, the law requires that providers ensure all patients (parent/legal representatives) receive a VIS, regardless of their ability to read English. To obtain VISs in more than 30 languages, visit the Immunization Action Coalition website at www.immunize.org/vis. Providers can supplement VISs with visual presentations or oral explanations as needed.



Federal law does not require signed consent in order for a person to be vaccinated.

Signed consent is not required by federal law for vaccination (although some states may require it).



To verify that a VIS was given, providers must record in the patient's medical record (or permanent office log or file) the following information:

- The edition date of the VIS (found on the back at the right bottom corner)
- The date the VIS is provided (i.e., the date of the visit when the vaccine is administered)

In addition, providers must record:

- The office address and name and title of the person who administers the vaccine
- The date the vaccine is administered
- The vaccine manufacturer and lot number



VISs should not be altered before giving them to patients, but you can add some information.

Providers should not change a VIS or write their own VISs. However, it is permissible to add a practice's name, address, and contact information to an existing VIS.

Additional resources on VISs and their use are available from the following organizations:

Immunization Action Coalition

- VIS general information and translations in more than 30 languages: www.immunize.org/vis
- Current Dates of Vaccine Information Statements: www.immunize.org/catg.d/p2029.pdf

Centers for Disease Control and Prevention

- VIS website: www.cdc.gov/vaccines/hcp/vis
- VIS Facts: www.cdc.gov/vaccines/hcp/vis/about/facts-vis.html
- VIS FAQs: www.cdc.gov/vaccines/hcp/vis/about/vis-faqs.html

Understanding the Vaccine Adverse Event Reporting System (VAERS)

For more information on vaccines, vaccine-preventable diseases, and vaccine safety:

http://www.cdc.gov/vaccines/conversations

Last updated February 201

- The Vaccine Adverse Event Reporting System (VAERS) is one component of the United States' comprehensive vaccine safety monitoring system.
- VAERS reports are monitored carefully by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA).
- Reports of adverse events (possible side effects)
 after vaccination do not mean that the reported
 problem was caused by a vaccine. Reports are
 signals that alert scientists of possible cause-andeffect relationships that need to be investigated.
- Anyone can submit a report to VAERS including health care professionals, vaccine manufacturers, vaccine recipients, and parents or family members of people who have received a vaccine.

questions and answers

What is VAERS?

VAERS is a national vaccine safety surveillance program overseen by CDC and FDA. VAERS collects and analyzes reports of adverse events that happen after vaccination. Each year, VAERS receives around 30,000 reports. Most of these reports describe known, mild side effects such as fever. Scientists at CDC and FDA monitor VAERS reports closely to identify reported adverse events that need to be studied further. Sometimes, it is only after a vaccine has been approved and used broadly that rare side effects can be detected by monitoring systems such as VAERS.

How are the VAERS data used?

VAERS scientists look for unusually high numbers of reports of an adverse event after a particular vaccine or a new pattern of adverse events. If scientists see either of these situations, focused studies in other systems are done to determine if the adverse event is or is not a side effect of the vaccine. Information from VAERS and vaccine safety studies is shared with the public. Throughout the process of

monitoring VAERS, conducting studies, and sharing findings, appropriate actions are taken to protect the public's health.

For example, if VAERS identifies a mild adverse event that is verified as a side effect in a focused study, this information is reviewed by CDC, FDA, and vaccine policy makers. In this situation, the vaccine may continue to be recommended if the disease-prevention benefits from vaccination outweigh the risks of a newly found side effect.

Information about newly found side effects is added to the vaccine's package insert that lists safety information. Newly found side effects also are added to the Vaccine Information Statement (VIS) for that vaccine. If serious side effects are found, and if the risks of the vaccine side effect outweigh the benefits, the recommendation to use the vaccine is withdrawn.

Vaccine Information Statements (VISs) are information sheets produced by the Centers for Disease Control and Prevention (CDC) that explain to vaccine recipients, their parents, or their legal representatives both the benefits and risks of a vaccine. Federal law requires that VISs be handed out whenever (before each dose) certain vaccinations are given.

Adverse events reported to VAERS are not necessarily side effects caused by vaccination. An *adverse event* is a health problem that happens after vaccination that may or may not be caused by a vaccine. These events may require further investigation. By definition, a *side effect* has been shown to be linked to a vaccine by scientific studies.

Before the FDA licenses (approves) a vaccine for use, the vaccine must be tested with volunteers during clinical trials to make sure it is safe and effective. Sometimes side effects show up in clinical trials. Most often side effects found in clinical trials are minor, such as possible pain at the injection site, and the vaccine is licensed because the disease-prevention benefits outweigh the risk of getting the side effect.

As part of the United States' comprehensive vaccine safety monitoring system, VAERS detects rare vaccine adverse events, signaling to scientists that focused studies are needed to determine whether the adverse event is a side effect or if there is no medical link.











questions and answers | continued >

Vaccines are tested before they are used, so why are there possible unknown side effects?

When vaccines are ready for tests in humans, they are tested on thousands to tens of thousands of volunteers. However, even this large number is not always enough to find rare side effects, such as a one-in-a-million side effect. So, VAERS is needed to constantly look for possible side effects that might not have been detected previously.

Are all events reported to VAERS caused by vaccinations?

VAERS data alone usually cannot be used to answer the question, "Does a certain vaccine cause a certain side effect?" This is mainly because adverse events reported to VAERS may or may not be caused by vaccines. There are reports in VAERS of common conditions that are found shortly after vaccination, often related by chance alone, and investigations find no medical link between vaccination and the condition.

To know if a vaccine causes a side effect, scientists must know whether the adverse event is occurring after vaccination with a particular vaccine more often than would be expected without vaccination. They also need to consider whether the association between the vaccine and the adverse event is consistent with existing medical knowledge about how vaccines work in the body.

Who can report to VAERS?

Anyone can submit a report to VAERS including parents, patients, and health care professionals. Vaccine manufacturers who receive reports of adverse events also report the information to VAERS. FDA and CDC encourage anybody who experiences any adverse event after vaccination to report to VAERS. Individuals completing a report can work with a health care professional to make sure they fill out the report form completely. By working together, health care professionals and patients/parents can provide FDA and CDC with data that will be most useful and accurate for examining possible trends.

Why should I report to VAERS?

Reporting to VAERS gives valuable information that helps CDC and FDA ensure that vaccines are very safe. If a previously unknown adverse event does come up, timely reports will help scientists find it and determine how to best address the issue.

How do I report to VAERS?

Reports can be submitted online, by fax, or by mail. To report to VAERS online, go to https://vaers.hhs.gov/esub/step1 and follow the 5 steps. Or, to print out the form to return it by fax or mail, go to https://vaers.hhs.gov/resources/vaers_form.pdf. To request a form by phone, call 1-800-822-7967. Forms may be returned by fax to 1-877-721-0366 or mailed to VAERS, P.O. Box 1100, Rockville, MD 20849-1100. VAERS staff may call for more information.

What events should I report to VAERS?

VAERS encourages the reporting of all adverse events that occur after administration of any vaccine licensed in the United States.

How do I find out if a vaccine adverse event has been reported to VAERS?

VAERS data is available to the public for download at http://vaers.hts.gov/data/index. You may also request information about adverse events reported to VAERS by sending a fax to 301-443-1726, by calling 301-827-6500, or by writing to: Food and Drug Administration, Freedom of Information Staff (HFI-35), 5600 Fishers Lane, Rockville, MD 20857.

Remember, just because an adverse event or condition has been reported does not prove that the adverse event is caused by vaccination. Parents who are concerned about vaccine side effects should talk to their child's health care professional.

the science

These articles tell more about VAERS and provide examples of the important role it serves as part of the U.S. vaccine safety monitoring system.

An Overview of the Vaccine Adverse Event Reporting System (VAERS) as a Surveillance System by J.A. Singleton et al. Vaccine. July 1999. Vol 17: pages 2908-2917. http://www.sciencedirect.com/science?_ob=Mlmg&_imagekey=B6TD4-3WRB2MG-R-9&_cdi=5188&_user=856389&_pii=S0264410X99001322&_origin=search&_coverDate=07%2F16%2F1999&_sk=999829977&view=c&wchp=dGLzVlz-zSkzV&md5=a46c65b0b0e73287cf51d7ed0ec2aa9&ie=/sdarticle.pdf

Intussusception among Recipients of Rotavirus Vaccine— United States, 1998–1999 in CDC's MMWR. July 1999. Vol 48: pages 577-581. http://www.cdc.gov/mmwr/preview/mmwrhtml/ mm4827a1.htm

Intussusception among Infants Given an Oral Rotavirus Vaccine by T.V. Murphy et al. New England Journal of Medicine. February 2001. Vol 344: pages 564-572. http://content.nejm.org/cgi/reprint/344/8/564.pdf

The Role of the Vaccine Adverse Event Reporting System (VAERS) in Monitoring Vaccine Safety by John Iskander et al. Pediatric Annals. September 2004. Vol 33: pages 599-606. http://www.ncbi.nlm.nih.gov/pubmed/15462575 (abstract only)

Postlicensure Safety Surveillance for Quadrivalent Human Papillomavirus Recombinant Vaccine by Barbara Slade et al. *Journal of the American Medical Association*. August 2009. Vol 302: pages 750-757. http://jama.ama-assn.org/cgi/content/full/302/7/750

For more information on vaccines call 800-CDC-INFO (800-232-4636) or visit http://www.cdc.gov/vaccines.

VAERS Table of Reportable Events Following Vaccination*				
Vaccine/Toxoid	Event and interval** from vaccination			
Tetanus in any combination; DTaP, DTP, DTP-Hib, DT, Td, TT, Tdap, DTaP-IPV, DTaP-IPV/Hib, DTaP-HepB-IPV	A. Anaphylaxis or anaphylactic shock (7 days) B. Brachial neuritis (28 days) C. Shoulder Injury Related to Vaccine Administration (7 days) D. Vasovagal syncope (7 days) E. Any acute complications or sequelae (including death) of above events (interval - not applicable) F. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)			
Pertussis in any combination; DTaP, DTP, DTP- Hib, Tdap, DTaP-IPV, DTaP-IPV/Hib, DTaP-HepB- IPV	A. Anaphylaxis or anaphylactic shock (7 days) B. Encephalopathy or encephalitis (7 days) C. Shoulder Injury Related to Vaccine Administration (7 days) D. Vasovagal syncope (7 days) E. Any acute complications or sequelae (including death) of above events (interval - not applicable) F. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)			
Measles, mumps and rubella in any combination; MMR, MMRV, MM	A. Anaphylaxis or anaphylactic shock (7 days) B. Encephalopathy or encephalitis (15 days) C. Shoulder Injury Related to Vaccine Administration (7 days) D. Vasovagal syncope (7 days) E. Any acute complications or sequelae (including death) of above events (interval - not applicable) F. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)			
Rubella in any combination; MMR, MMRV	A. Chronic arthritis (42 days) B. Any acute complications or sequelae (including death) of above event (interval - not applicable) C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)			
Measles in any combination; MMR, MMRV, MM	A. Thrombocytopenic purpura (7-30 days) B. Vaccine-strain measles viral infection in an immunodeficient recipient			

VAERS Table of Reportable Events Following Vaccination*		
Vaccine/Toxoid	Event and interval** from vaccination	
	death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)	
Oral Polio (OPV)	A. Paralytic polio in a non-immunodeficient recipient (30 days) in an immunodeficient recipient (6 months) in a vaccine-associated community case (interval - not applicable) B. Vaccine-strain polio viral infection in a non-immunodeficient recipient (30 days) in an immunodeficient recipient (6 months) in a vaccine-associated community case (interval - not applicable) C. Any acute complication or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)	
Inactivated Polio in any combination-IPV, DTaP-IPV, DTaP-IPV, DTaP-HepB-IPV	A. Anaphylaxis or anaphylactic shock (7 days) B. Shoulder Injury Related to Vaccine Administration (7 days) C. Vasovagal syncope (7 days) D. Any acute complication or sequelae (including death) of the above event (interval - not applicable) E. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)	
Hepatitis B in any combination- HepB, HepA-HepB, DTaP-HepB-IPV, Hib-HepB	A. Anaphylaxis or anaphylactic shock (7 days) B. Shoulder Injury Related to Vaccine Administration (7 days) C. Vasovagal syncope (7 days) D. Any acute complications or sequelae (including death) of the above event (interval - not applicable) E. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)	
Haemophilus influenzae type b in any combination (conjugate)- Hib, Hib-HepB, DTaP-IPV/Hib, Hib-MenCY	A. Shoulder Injury Related to Vaccine Administration (7 days) B. Vasovagal syncope (7 days) C. Any acute complication or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	

VAERS Table of Reportable Events Following Vaccination*		
Vaccine/Toxoid	Event and interval** from vaccination	
	(interval - see package insert)	
Varicella in any combination- VAR, MMRV	 A. Anaphylaxis or anaphylactic shock (7 days) B. Disseminated varicella vaccine-strain viral disease. Vaccine-strain virus identified (time interval unlimited) If strain determination is not done or if laboratory testing is inconclusive (42 days) C. Varicella vaccine-strain viral reactivation (time interval unlimited) D. Shoulder Injury Related to Vaccine Administration (7 days) E. Vasovagal syncope (7 days) F. Any acute complication or sequelae (including death) of above events (interval - not applicable) G. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert) 	
Rotavirus (monovalent or pentavalent) RV1, RV5	A. Intussusception (21 days) B. Any acute complication or sequelae (including death) of above events (interval - not applicable) C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)	
Pneumococcal conjugate(7-valent or 13-valent) PCV7, PCV13	A. Shoulder Injury Related to Vaccine Administration (7 days) B. Vasovagal syncope (7 days) C. Any acute complication or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)	
Hepatitis A in any combination- HepA, HepA-HepB	A. Shoulder Injury Related to Vaccine Administration (7 days) B. Vasovagal syncope (7 days) C. Any acute complication or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)	
Seasonal influenzatrivalent inactivated influenza, quadrivalent inactivated influenza, live attenuated	A. Anaphylaxis or anaphylactic shock (7 days) B. Shoulder Injury Related to Vaccine Administration (7 days) C. Vasovagal syncope (7 days)	

VAERS Table of Reportab	le Events Following Vaccination*
Vaccine/Toxoid	Event and interval** from vaccination
influenza-IIV, IIV3, IIV4, RIV3, ccIIV3, LAIV4	D. Guillain-Barré Syndrome (42 days) E. Any acute complication or sequelae (including death) of above events (interval - not applicable) F. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Meningococcal - MCV4, MPSV4, Hib-MenCY, MenACWY, MenB	A. Anaphylaxis or anaphylactic shock (7 days) B. Shoulder Injury Related to Vaccine Administration. (7 days) C. Vasovagal syncope (7 days) D. Any acute complication or sequelae (including death) of above events (interval - not applicable) E. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Human Papillomavirus (Quadrivalent, Bivalent, or 9 valent) - 9vHPV, 4vHPV, 2vHPV	A. Anaphylaxis or anaphylactic shock (7days) B. Shoulder Injury Related to Vaccine Administration (7 days) C. Vasovagal syncope (7 days) D. Any acute complication or sequelae (including death) of above events (interval - not applicable) E. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children	A. Shoulder Injury Related to Vaccine Administration (7 days) B. Vasovagal syncope (7 days) C. Any acute complication or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)

* Effective date: March 21, 2017. The Reportable Events Table (RET) reflects what is reportable by law (42 USC 300aa-25) to the Vaccine Adverse Event Reporting System (VAERS) including conditions found in the manufacturer package insert. In addition, healthcare professionals are encouraged to report any clinically significant or unexpected events (even if not certain the vaccine caused the event) for any vaccine, whether or not it is listed on the RET. Manufacturers are also required by regulation (21CFR 600.80) to report to the VAERS program all adverse events made known to them for any vaccine.

Note that the RET differs from the Vaccine Injury Table (VIT) regarding timeframes of adverse events.

Timeframes listed on the RET reflect what is required for reporting, but not what is required for compensation.

To view timeframes for compensation, please see the VIT at

VAERS Table of Reportable Events Following Vaccination*		
Vaccine/Toxoid	Event and interval** from vaccination	
https://www.hrsa.gov/vaccinecompensation/vaccineinjurytable.pdf		
**Represents the onset interval between vaccination and the adverse event.		
For a detailed explanation of terms, see the Vaccine Injury Table at		
https://www.hrsa.gov/vaccinecompensation/vaccineinjurytable.pdf		

A list of vaccine abbreviations is located at: https://www.cdc.gov/vaccines/terms/vacc-abbrev.html



Vaccine Administration Information

VACCINE ADMINISTRATION RESOURCES

The following are suggested resources for practitioners who administer pediatric vaccinations. Additional materials are available from the CDC or through the Immunization Action Coalition (IAC).

STANDARDS FOR CHILD AND ADOLESECENT IMMUNIZATION PRACTICES

http://pediatrics.aappublications.org/content/pediatrics/112/4/958.full.pdf

RECOMMENDED AND CATCH-UP IMMUNIZATION SCHEDULES 0-18 YEARS

https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf

ADDITIONAL CATCH-UP GUIDANCE

Pneumococcal Conjugate Vaccine (PCV) 4 months through 4 years of age

https://www.cdc.gov/vaccines/schedules/downloads/child/job-aids/pneumococcal.pdf

Haemophilus influenza type b 4 months through 4 years of age

ActHib, Pentacel, Hiberix, or unknown

https://www.cdc.gov/vaccines/schedules/downloads/child/job-aids/hib-actHib.pdf

PedvaxHIB

https://www.cdc.gov/vaccines/schedules/downloads/child/job-aids/hib-pedvax.pdf

Diphtheria, Tetanus, and Pertussis 4 months through 6 years of age

https://www.cdc.gov/vaccines/schedules/downloads/child/job-aids/dtap.pdf

Tetanus, Diphtheria, and Pertussis 7 through 18 years of age

https://www.cdc.gov/vaccines/schedules/downloads/child/job-aids/tdap.pdf

RECOMMENDED AND MINIMUM AGES AND INTERVALS BETWEEN VACCINE DOSES

https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/A/age-interval-table.pdf

SUMMARY OF RECOMMENDATIONS FOR CHILDHOOD/TEEN IMMUNIZATION

http://www.immunize.org/catg.d/p2010.pdf

SCREENING CHECKLIST FOR CONTRAINDICATIONS TO VACCINES FOR CHILDREN AND TEENS

English - http://www.immunize.org/catg.d/p4060.pdf

Spanish - http://www.immunize.org/catg.d/p4060-01.pdf

Also available in Arabic, Chinese (simplified), French, Korean, Russian, and Vietnamese

from http://www.immunize.org/handouts/screening-vaccines.asp

GUIDE TO CONTRAINDICATIONS AND PRECAUTIONS TO ROUTINE VACCINATIONS

http://www.immunize.org/catg.d/p3072a.pdf

ADMINISTERING VACCINES: DOSE, ROUTE, SITE, AND NEEDLE SIZE

http://www.immunize.org/catg.d/p3085.pdf



Connecticut Vaccine Program

Information Resources

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CONNECTICUT VACCINE PROGRAM VACCINE ORDER FORM (VOF)

Please read the instructions on page 3 before completing and submitting this form Completed forms can be FAXED to: **(860) 509-8371** or email to: dph.immunizations@ct.gov

Page 1 of 3

Facility Name and	Shipping Address			Date of	Report		Completed	d by			Dates Practice will be closed for the month. Do not include weekends.			<u>PIN</u>
				Month /	Year Repo	rting:	Phone Nu	<u>mber</u>						
Vaccine Brand	Vaccine	NDC Codes	Pack Size	Doses Ordered	Doses On Hand	Lot #	Expiration Date	Doses On Hand	Lot #	Expiration Date	Doses On Hand	Lot#	Expiration Date	Doses Administered
ActHib	Hib	49281-0545-03	5											
Adacel	Tdap	49281-0400-10	10											
Boostrix	Tdap	58160-0842-11	10											
Daptacel	DTaP	49281-0286-10	10											
Engerix-B	Hepatitis B	58160-0820-52	10											
Fluzone-Quad	Influenza . 25 mL Syr.	49281-0518-25	10											
Fluzone-Quad	Influenza .5mL Syr.	49281-0418-50	10											
Fluzone-Quad	Influenza .5mL Vial	49281-0418-10	10											
FluLaval-Quad	Influenza .5mL Syr.	19515-0909-52	10											
FluMist	Influenza .2mL Spray	66019-0305-10	10											
Flucelvax-Quad	Influenza .5mL Syr.	70461-0318-03	10											
Gardasil 9	HPV 9	00006-4121-02	10											
Havrix	Hepatitis A	58160-0825-11	10											
Hiberix	Hib	58160-0818-11	10											
Infanrix	DTaP	58160-0810-11	10											
IPOL	IPV	49281-0860-10	10											
Kinrix	DTaP/IPV	58160-0812-11	10				_							

Revised 9/10/18 updated Gardasil ndc code

Facility Name:	DATE	PIN	Page 2 of 3
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Vaccine Brand	Vaccine	NDC Codes	Pack Size	Doses Ordered	Doses On Hand	Lot #	Expiration Date	Doses On Hand	Lot#	Expiration Date	Doses On Hand	Lot #	Expiration Date	Doses Administered
MMR II	MMR	00006-4681-00	10											
Menactra	MCV4	49281-0589-05	5											
Menveo	MCV4	58160-0955-09	5											
Pediarix	DTaP/IPV/Hep B	58160-0811-52	10											
Pedvax	Hib	00006-4897-00	10											
Pentacel	DTaP/IPV/Hib	49281-0510-05	5											
Prevnar 13	PCV 13	00005-1971-02	10											
ProQuad	MMRV	00006-4171-00	10											
Quadracel	DTaP/IPV	49281-0562-10	10											
Recombivax	Hepatitis B	00006-4981-00	10											
Rotarix	Rotavirus	58160-0854-52	10											
Rotateq	Rotavirus	00006-4047-41	10											
Td Vaccine	Td	13533-0131-01	1											
Tenivac	Td	49281-0215-10	1											
Vaqta	Hepatitis A	00006-4831-41	10											
Varivax	Varicella	00006-4827-00	10											
Bexsero	Meningococcal B	58160-0976-06	1											
Trumenba	Meningococcal B	00005-0100-10	10											
Pneumovax23*	PPSV23	00006-4943-00	1											

^{*}FOR HIGH RISK PATIENTS ONLY

How To Submit Your Vaccine Order Form (VOF) To The CVP

- FAX or email your VOF to the Immunization Program each month even if you do not require additional vaccine.
- Additional forms are available on our website at https://portal.ct.gov/DPH/Immunizations/CVP---Information-for-Providers. FAX completed forms to 860-509-8371 or email dph.immunizations@ct.gov
- If emailing, please save and name the document with your PIN and name of form. For example: PIN 2000.VOF.pdf. Attach your completed form and email to dph.immunizations@ct.gov. Save and print a copy for your records. Please call (860) 509-7929 with any questions.

Identification & Shipping Information

- Complete all the information at the top of form including facility name, vaccine shipping address, date of order, completed by, PIN, phone and date range of doses administered totals.
- Complete the box with any dates your practice will be closed during the month outside of normal business hours as stated on your provider profile. Do not include weekends.
- IMPORTANT! Please notify the Immunization Program if changes have occurred to your practice name, shipping address, hours and days to receive vaccine.

Vaccine Order

• Indicate number of doses needed under the **DOSES ORDERED** column. Order by number of doses needed rounding to the number of doses per pack according to the VOF. **Do not order by number of boxes.** It is recommended that providers maintain at least a 4 week supply of vaccine in inventory to avoid running out of vaccine.

Vaccine Inventory

- The Centers for Disease Control and Prevention (CDC) requires inventory tracking by NDC, lot number, and expiration date of State supplied vaccine. Indicate number of doses on hand for each lot number and expiration date. THREE columns per vaccine product have been provided to record this data. Do not combine lot numbers or post the same lot number twice. If you have more than three different lot numbers per vaccine product, please indicate additional vaccine inventory on a separate vaccine form and note this as an addendum to vaccine inventory accounting.
- Balance inventory from last month's report to physical current inventory: (previous inventory + order DA) = actual inventory (+ or transfers & returns). Resolve all descrepancies before submitting this form to the CVP.

Expiration Dates

• Record complete expiration dates for all state supplied inventory. If vaccines are approaching their expiration dates and may expire before they can be used an attempt to transfer the vaccine to another practice should be made **4 months before expiration**. Please call the Immunization Program to help facilitate transfer of the vaccine.

Doses Administered

- ONLY DOSES ADMINISTERED WITH STATE SUPPLIED VACCINE should be included in this count.
- Indicate the Month and Year for which you are reporting doses administered totals.

Thank you for following the above instructions. VOFs that are complete and accurate enable us to process your order quickly!

If you are interested in registering for VTrckS; CDC's online vaccine ordering and inventory management program, please send a request to: dph.immunizations@ct.gov

Revised 8/16 Dept. of Public Health • Immunizations Program • 410 Capitol Avenue; Hartford, CT 06134 Phone (860) 509-7929 • Fax (860) 509-8371 https://portal.ct.gov/DPH/Immunizations/CONNECTICUT-IMMUNIZATION--PROGRAM



Connecticut Vaccine Program Vaccine Transfer Form

FAX TO: 860-509-8371 or email: DPH.IMMUNIZATIONS@ct.gov
Click Here To download additional forms

Transferring Provider Instructions:

- 1. Open multi-dose vials are not eligible for transfer. If you have questions about this please contact the CVP.
- 2. Identify a provider willing to receive, and able to use, all doses of vaccine being transferred. Please refer to the <u>Vaccine Restitution Policy</u> for information on transferring vaccine expiring in four months or less.
- 3. Complete the transfer form in its entirety including receiving provider PIN and signature of transferring provider.
- 4. Follow cold chain instructions below.

Cold Chain Instructions:

- 1. For refrigerated vaccines: keep cold at 36°F to 46°F, do not freeze. Use refrigerated or frozen cold packs (frozen ice packs for hot weather, refrigerated packs for cold weather).
- 2. Make sure vaccines are kept in their original boxes. Place insulation (crumpled paper or bubble wrap) between vaccine boxes and cold packs to prevent vaccine freezing. Put crushed paper in cooler to keep vaccines from shifting during transport.

Transferring

- 3. Do not leave vaccine container unattended or in the trunk of your car.
- 4. For transport of varicella vaccine please review "Transport of Frozen Vaccines" in the "CDC Vaccine Storage & Handling Toolkit".

Receiving Transferred Vaccine

- 1. Upon arrival of vaccine, check the quantities and lot numbers against what is listed below. Store vaccines immediately.
- 2. Sign and date the bottom of the form in the appropriate place (Signature of Receiving Provider).
- 3. Submit completed form to CVP via FAX: (860) 509-8371 or email: DPH.Immunizations@ct.gov.

	Provider PIN #					
Transferring Provider Facility Name	Date					
Address	Phone					
City	Person Completing Form					
			1			
Receiving Provider Facility Name	Receiving Provider PIN #					
Address	Phone					
Vaccine	NDC Number	Lot Number	Number of Doses Transferred	Expiration Date		
Before Transfer please check that you have included all corresponding diluent.						
Signature of Transferring Provider: Date:						
Signature of Possiving Provider:	Dato					



VACCINE RETURN FORM

Connecticut Vaccine Program

Fax or email completed form to: FAX: 860-509-8371 email: DPH.Immunizations@ct.gov

Please use this form to report all types of state vaccine wastage

- 1. For vaccines that have spoiled please complete this form and a spoilage letter explaining why the vaccine spoiled and steps you will take to prevent future incidents from occurring. Fax or email the form and letter to the CVP using the contact information above.
- 2. The form and letter will be reviewed by the VFC Coordinator and a determination will be made if vaccine replacement is required in accordance with the Financial Restitution Policy. Please visit the CVP web page or contact the program at 860-509-7929 for a copy of the policy.
- 3. After you have submitted this form and spoilage letter to the CVP you will receive a label via email from UPS on behalf of McKesson Specialty Care. If an email is not on file with the CVP you will receive a UPS return label by U.S. mail from McKesson.
- 4. When you receive the UPS return label, package the vaccine, affix the UPS return label to the package and give to your UPS driver.
- 5. Return only the vaccine and quantities reported on this return form. Never return open multi-dose vials, broken vials or syringes with needles.
- 6. If you do not receive a UPS label within 5 days of submitting your return form call the CVP at 860-509-7929.

Revised 4/3/18 Dept. of Public Health, Immunizations Program, 410 Capitol Avenue; Hartford, CT 06134 Phone (860) 509-7929 Fax (860) 509-8371 www.ct.gov/dph/immunizations

FACILITY NAME		COMPLETED BY	DATE OF REPOR	PIN			
		PHONE	SPOILAGE LETTI	D (Y/N)?			
Vaccine Brand	Vaccine	NDC #	Lot #	Expiration Date	No. of Doses	Cost Per Dose	Reason For Return
ActHib	Hib	49281-0545-03				\$9.23	
Adacel	Tdap	49281-0400-10				\$30.89	
Bexsero	Meningococcal Serogroup B	58160-0976-06				\$129.06	
Boostrix	Tdap	58160-0842-11				\$31.95	
Daptacel	DTaP	49281-0286-10				\$17.61	
Engerix-B	Hepatitis B	58160-0820-11				\$14.03	
FluLaval-Quad	Influenza .5mL Syringe	19515-0912-52				\$14.43	
Flucelvax-Quad	Influenza .5mL Syringe	70461-0201-01				\$14.34	
Fluzone-Quad	Influenza .25 mL Syringe	49281-0517-25				\$19.14	
Fluzone-Quad	Influenza .5mL Vial	49281-0417-10				\$15.82	
Fluzone-Quad	Influenza .5mL Syringe	49281-0417-50				\$14.93	
Gardasil 9	HPV 9	00006-4119-03				\$168.10	
Havrix	Hepatitis A	58160-0825-11				\$19.58	
Hiberix	Hib	58160-0818-11				\$9.65	
Infanrix	DTaP	58160-0810-11				\$18.19	
IPOL	IPV	49281-0860-10				\$13.30	
Kinrix	DTaP/IPV	58160-0812-11				\$40.64	
Menactra	MCV4	49281-0589-05				\$91.81	
Menveo	MCV4	58160-0955-09				\$92.10	
MMR II	MMR	00006-4681-00				\$21.05	
Pediarix	DTaP/IPV/Hep B	58160-0811-52				\$57.97	
Pedvax	Hib	00006-4897-00				\$13.09	
Pentacel	DTaP/IPV/Hib	49281-0510-05				\$58.33	
Pneumovax23	PPSV23	00006-4943-00				\$53.11	
Prevnar 13	PCV13	00005-1971-02				\$131.77	
ProQuad	MMRV	00006-4171-00				\$125.11	
Quadracel	DTaP/IPV	49281-0562-10				\$39.57	
Recombivax	Hepatitis B	00006-4981-00				\$12.30	
Rotarix	Rotavirus	58160-0854-52				\$92.85	
Rotateq	Rotavirus	00006-4047-41				\$70.49	
Shingrix	Shingles	58160-0819-12				102.19	
Td Vaccine	Td	13533-0131-01				\$12.53	
Tenivac	Td	49281-0215-10				\$20.05	
Trumenba	Meningococcal Serogroup B	00005-0100-10				\$104.79	
Twinrix	Adult Hep A/HepB	58160-0815-52				\$55.35	
Vaqta	Hepatitis A	00006-4831-41				\$19.29	
Varivax	Varicella	00006-4827-00				\$98.24	
Zostavax	Shingles	00006-4963-41				\$134.16	



Connecticut Vaccine Program

Financial Restitution Policy Effective November 1, 2012

The Financial Restitution Policy was developed in accordance with the Connecticut Vaccine Program (CVP) for the purpose of replacing vaccine wasted or spoiled due to negligence and/or failure to properly store, handle, or rotate vaccine inventory. The policy has been updated to address the increased costs of replacing wasted, expired or spoiled vaccines provided through the Connecticut Vaccine Program. The policy also includes a provision that providers who notify the CVP of vaccine they will not be administering four months or more prior to expiration will not be financially liable for replacing any doses that ultimately expire.

Definitions

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 /

reconstituted and not used within acceptable time frames. Always consult with the State

Immunization Program before determining if a vaccine is non-viable.

Lost: Any vaccine ordered but not delivered (or not delivered in a timely manner) by McKesson resulting in

lost and/or spoiled vaccine.

Situations Requiring Financial Restitution

The following situations are examples of negligence that may require financial restitution. This list is not exhaustive:

- Failure to rotate vaccine that results in expired doses
- Handling and storage mistakes by provider staff
- Vaccine left out of the refrigeration unit that becomes non-viable
- Freezing vaccine meant to be refrigerated
- Refrigerating vaccine meant to be frozen
- Refrigerator left unplugged or electrical breaker switched off
- Refrigerator door left open or ajar by provider staff, contractors, or guests
- Refrigerator/freezer equipment problems where proof of repair or equipment replacement is not provided to the Immunization Program within 30 days from the date the problem is identified
- Situations in which health care providers must re-vaccinate due to previous administration of non-viable vaccine (i.e. spoiled or expired) or improper administration. <u>Provider will be responsible for the cost of vaccine for re-vaccination</u>.
- Ordering habits resulting in overstock that lead to expiration of vaccines
- Delivery of vaccine during the provider's stated business hours but the office is closed resulting in the loss of vaccine product

Examples of Situations Not Requiring Financial Restitution

The following examples are situations considered to be out of the providers' control, and generally do not require financial restitution. This list is not exhaustive. Providers should always contact the Connecticut Vaccine Program for a determination regarding the viability of suspect vaccine.

- Vaccine that is damaged, improperly stored during transit, or not delivered to the provider in a timely manner
- A company contracted to alert a provider when a refrigerator malfunctions fails to notify the provider
- A provider moves vaccine to a location with a secure power source due to anticipated inclement weather, but power is lost at that location
- Partially used multi-dose vials
- Vaccine drawn up but not administered due to a parent changing their mind
- A vial that is accidentally dropped or broken by a provider
- Vaccine that a provider transfers to another provider four months or more prior to expiration
- Vaccine accepted by a provider that expires in four months or less
- Vaccine returned to the immunization program for redistribution to another provider four months or more prior to expiration
- Expired doses of influenza vaccine
- Refrigerator/freezer equipment problems where proof of repair or equipment replacement is provided to the Immunization Program within 30 days from the date you become aware of the situation
- Extraordinary situations not listed above which are deemed by the Connecticut Vaccine Program to be beyond the provider's control (e.g. acts of mother nature). When reporting wastage of any kind, providers should document the staff's use of the practice's Back-Up Protocol For Vaccine Recovery Plan.

Wastage Allowance

All practices will be allowed a "one strike" credit towards vaccine wastage up to a limit of \$1300. On the first instance of vaccine wastage the Connecticut Vaccine Program will absorb the cost of vaccine replacement up to \$1300; any vaccine wastage totaling over \$1300 will result in the provider being responsible for replacing the vaccine on a dose for dose basis at their own cost. Any subsequent occurrences will require that the provider replace all wasted doses again at their own cost. Providers will not be allowed to order additional doses of vaccine until they submit to the Connecticut Vaccine Program an invoice showing that they have replaced all wasted doses.

Procedure for Financial Restitution

This policy applies to any vaccine reported to the Connecticut Vaccine Program as wasted on or after May 1, 2011. Providers who already have reported vaccine wastage since January 1, 2010 and experience a subsequent loss of vaccine will need to replace vaccine on a dose for dose basis at their own cost since they have already used up their one strike credit.

- Each incident reported will be reviewed on a case-by-case basis by the Connecticut Vaccine Program to determine whether restitution will be required or if extenuating circumstances prevail.
- The provider will be required to submit an invoice to the Connecticut Vaccine Program showing they have privately purchased the vaccine reported as wasted.
- Failure to replace any wasted vaccine will result in a delay or forfeiture of future program enrollment for the practice.

Revised 10/12



Procedure for Returning Vaccine

- Call the Connecticut Vaccine Program as soon as you suspect vaccine may be spoiled to determine viability status.
- Complete and fax a copy of the **Vaccine Return Form** to the Connecticut Vaccine Program. The Connecticut Vaccine Program will request a postage paid mailing label be sent from McKesson to the provider for return of the wasted vaccine.
- Once the mailing label is received the provider will return all **unopened vials & pre-filled syringes** of wasted vaccine to McKesson along with a copy of the **Vaccine Return Form.**

Vaccine Coordinator Role

Connecticut Vaccine Program (CVP)

Every facility is required to have a designated vaccine coordinator who is responsible for overseeing the vaccine supplied by the CVP. Each facility is also required to have a backup vaccine coordinator who is responsible when the vaccine coordinator is not available. For all coordinator or provider changes please send in a revised <u>Provider Agreement</u> with the updated contact information.

Receiving Vaccines

- Be present when vaccine shipments are delivered
- Review packaging, ensure the cold chain has been maintained
- Sort vaccine into appropriate storage units

Storing Vaccines & Monitoring Temperatures

- Label and store state supplied vaccines separate from privately purchased vaccines
- Store vaccines with shorter expiration dates in the front of the unit for proper rotation of stock
- Do not store vaccine in the door or inside drawers in the refrigerator/freezer
- Record refrigerator and freezer temperatures on the temperature log provided by the CVP twice daily and capture minimum and maximum temperatures once daily; retain logs for three years <u>Refrigerator Log</u> / <u>Freezer Log</u>
- Perform routine maintenance on storage unit
- Contact the CVP if temperatures are outside acceptable ranges and document on the troubleshooting log supplied in the provider Blue Folder.
 - For more information reference the <u>CDC Vaccine Storage and Handling Toolkit</u> and the CDC <u>"You Call the Shots: Vaccine Storage and Handling Module"</u>

Ordering Vaccines

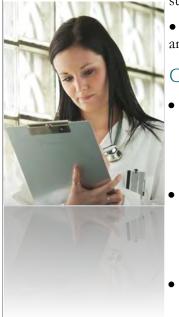
- Perform a physical inventory of vaccines on hand and doses administered since the date of the last report.
- Record inventory and doses administered on CVP supplied <u>Vaccine</u> <u>Order Form</u> and submit to CVP monthly.
- Check for any expired or soon to expire vaccine while performing the physical inventory (see <u>Managing</u>

Responsibilities

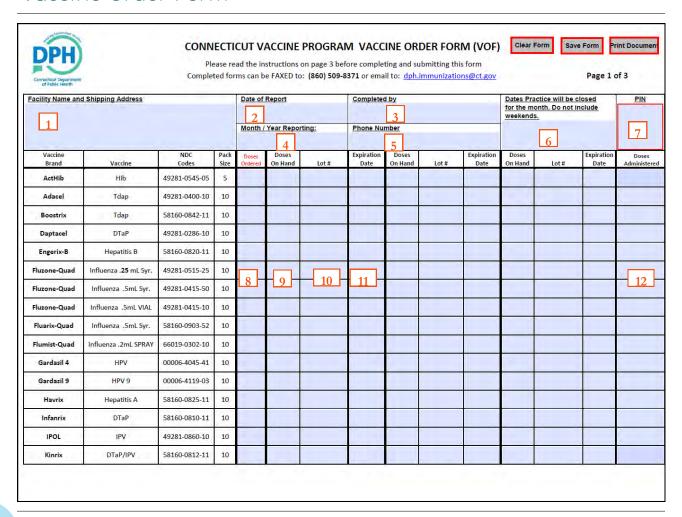
- Receive vaccines
- Store vaccines
- Monitor temperatures
- Order vaccine
- Manage vaccine inventory
- Complete required training modules (see "You Call the Shots" Required Training

Vaccine Inventory).

- Report all days that the practice will be closed during the coming month. It is important to report for the coming month and not the previous month as this impacts when the order can be delivered.
- Keep adequate vaccine on hand for the population of the practice.



Vaccine Order Form



- 1. Facility Name and Shipping Address
- 2. Date of Report—date the report is being completed
- 3. Completed by—name of the person completing the form
- 4. Month/Year Reporting—month and year the data was recorded for (ex: June 2015)
- 5. Phone Number—best contact number the form
- 6. Dates Practice will be Closed—any dates the practice will not be open to receive vaccine during normal business hours. (See Ordering Vaccines)

- 7. PIN—Provider Pin # for the practice
- Doses Ordered—number of doses requested for the specified vaccine rounded to the pack size
- 9. Doses on Hand—number of remaining doses for a specified lot number and brand
- 10. Lot # lot number for the specific box of vaccine being counted
- including extension for the person completing 11. Expiration Date—expiration date printed on the box of vaccine. (see Managing Vaccine Inventory)
 - 12. Doses Administered—total number of doses given during the month reported for that specific brand

Managing Vaccine Inventory

Practices should base the vaccine orders on the population size and should always use vaccine with the closest expiration date first. If the practice has vaccine that will not be used before the expiration date, transfer it to another CVP provider who can use it prior to the expiration date. Practices with single antigen vaccines close to expiring who typically use combination vaccines can give multiple shots to deplete expiring stock instead. For example, use MMR-II and Varicella instead of combination ProQuad.

Transferring Vaccine

- Locate providers in the area willing to accept vaccine (CVP can provide a list if necessary)
- Fill out the CVP provided <u>Vaccine Transfer Form</u> (please complete all fields including NDC and Receiving Provider PIN)
- Package vaccine appropriately to maintain the cold chain
- Deliver vaccine to the accepting provider, have the receiving provider sign and date the Vaccine Transfer Form
- Submit the completed form to the CVP

** If an attempt to transfer vaccine has been made and the CVP is contacted 4 or more months prior to the expiration date, someone from the CVP can pick-up the expiring vaccine. If the vaccine expires in less than 4 months, the practice is responsible for using or transferring the vaccine to another practice.

Wasted

 Any vaccine that cannot be used includes all below.

Expired

 Vaccine with an expiration date that has passed

Spoiled

 Vaccine that exceeds limits of approved cold chain or is predraw or reconstituted and not used w/in acceptable time frame.

Lost

 Ordered but not delivered (or not delivered in a timely manner)

Returns and Wastage

Vaccines should be monitored closely to prevent wastage. If wastage occurs, report it to the CVP.

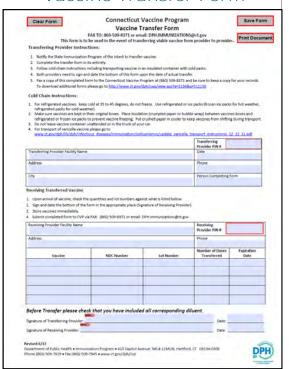
Expired vaccines and vaccines that have spoiled due to a breach in the cold chain should be returned to McKesson. Broken vials, expired open multi-dose vials and unused predrawn vaccine should be discarded appropriately.

Some wastage situations require restitution as determined by the CVP in accordance with the <u>Restitution Policy.</u>

Reporting Wastage

- Contact CVP as soon as you suspect vaccine may be spoiled to determine viability
- Separate vaccine wasted from main supply and label "DO NOT USE"
- Record vaccine lot number, expiration date, and number of doses on a CVP provided <u>Vaccine Return Form</u> and fax/email to the CVP. (Note: this form is used for all wastage.)
- Use the return mailing label received by the provider to ship any **unopened vials and pre-filled syringes**, along with a copy of the return form, to McKesson.

Vaccine Transfer Form



Additional Resources

Please contact CVP if you feel you require additional on site educational training from CVP staff.

* CDC "You Call the Shots" Required Training **Modules**

Vaccine Storage and Handling

http://www2a.cdc.gov/nip/isd/ycts/mod1/courses/ sh/ce.asp

Vaccines for Children

http://www2a.cdc.gov/nip/isd/ycts/mod1/courses/ vfc/ce.asp

Connecticut Vaccine Program—Provider Resources

All CVP supplied documents can be found on the CT DPH webpage. Follow the link below, click on Connecticut Vaccine Program (CVP) Providers under the Health Professionals heading.

https://portal.ct.gov/DPH/Immunizations/ CONNECTICUT-IMMUNIZATION--PROGRAM

CDC Storage and Handling Toolkit

http://www.cdc.gov/vaccines/recs/storage/toolkit/ default.htm

Advisory Committee on Immunization Practices (ACIP)

http://www.cdc.gov/vaccines/acip/index.html

Vaccine Information Statements (VIS)

http://www.cdc.gov/vaccines/hcp/vis/index.html

Contact Information

Main Phone 860-509-7929

Fax 860-509-8371

Email Dph.immunizations@ct.gov

Regional Program Contacts

Region 1

Maria Heinz | CVP 860-509-7931 Paul Sookram | Epidemiologist 860-509-7835

Region 2

Kimberly Gierla | CVP 860-509-7732

Heather Bohnwagner | Epidemiologist 860-509-7941

Region 3

Vacant | CVP

Deepa Mavani | Epidemiologist 860-509-7928

Region 4

Claudia Soprano | CVP 860-509-7712 Patricia Firmender | Epidemiologist 860-509-7776

Vaccine Coordinator

Mick Bolduc 860-509-7940

Department of Public Health Immunizations Program 410 Capitol Avenue Hartford, Connecticut 06134

Phone (860) 509-7929 | Fax (860) 509-8371

https://portal.ct.gov/DPH/Immunizations/CONNECTICUT-IMMUNIZATION--PROGRAM





DPH IMMUNIZATION PROGRAM

CT WIZ EDUCATIONAL MATERIALS ORDER FORM



All materials are free of cost, please allow 2-3 weeks for processing and delivery.

		Order Amount			Order Amount
The second secon	NEW!!! - CT WiZ Handout This NEW CT WiZ Handout comes bi-lingual in English and Spanish and is included in CT birth packets for parents to take home and can be posted in your office waiting room once you are online with CT WiZ. It replaces the CIRTS Enrollment Form and Brochure.		Prevaling Meninglis Warmen of them to the control of the control	NEW!!! Preventing Meningitis What Young People And Parents Should Know This booklet raises awareness of meningitis, how it is spread, symptoms to look for, and how to avoid infection. Urges readers to get vaccinated, avoid sharing personal items, wash hands often, and adopt other healthy habits. Includes a list of warning signs and recommends seeking medical care immediately if symptoms are observed. Comes bi-lingual in English and Spanish.	
POR TOURS	Shots For Tots-The Importance of Immunizations For Your Child Clearly explains why immunization is important for every child. Covers the leading childhood illnesses, and gives information on how to obtain a copy of your child's immunization history. Contains current childhood immunization schedule and references the Connecticut school and day care requirements. 16 pages, 5 ½" X 8". Classic illustrated booklet	English Spanish		My Child's Immunization Record A pocket-sized personal 6-page booklet for parents to keep track of their child's shots and other routine tests during a child's checkup. Contains important phone numbers for Connecticut resources. Comes bi-lingual in English and Spanish.	
The state of the s	The HPV Vaccine – Important Protection for your Son or Daughter This pamphlet educates parents about the important benefits of the HPV vaccine, describes how it protects people from cervical and other cancers, and refutes common misconceptions. With clear text in both English and Spanish, the pamphlet explains that both girls and boys should be vaccinated, describes the process, underscores the safety and effectiveness of the vaccine, and provides additional sources of information.		and the factor of the factor o	Immunize Your Child! Vaccine Info for Parents This easy-to-follow pamphlet, with text in both English and Spanish, emphasizes that all children need immunizations to protect them against serious illness. Pamphlet highlights the strong safety record of vaccines, the importance of keeping up with scheduled doses, and the low cost of immunization. It also urges parents to maintain careful records of their child's shots and lists additional sources of information.	
Protect Year Calif mit Vaccions	Protect Your Child with Vaccines Easy-reading resource stresses the vital role immunizations play in protecting children's health, lists the serious health problems associated with the illnesses that immunizations can prevent, and provides an immunization record.	English Spanish	Shots	Shots – For Your Child's Health Stresses the vital role immunizations play in protecting their child's health, lists the serious health problems associated with the illnesses that shots can prevent, and provides an immunization schedule. Also discusses possible side effects and gives information for those who need help paying for shots.	English Spanish

		Order Amount			Order Amount
immunize Your Child	9 Reasons to Immunize Your Child This booklet underscores that immunizations are both safe and effective. It also provides a list of tips that describe vaccine-preventable diseases, reminds readers that outbreaks can occur due to a lack of vaccination, and explains that immunizations are the safest way to build immunity against many diseases. It reminds parents that it's never too late to get an older child vaccinated.	English Spanish	The Part of the Pa	Flu Vaccines Why Everyone Needs Yearly Protection This pamphlet discusses in both English and Spanish the flu, its seriousness, and why a flu shot is the best way for everyone to protect themselves and their families. In clear terms, it discusses flu symptoms, possible complications, who should be vaccinated, and when to get a flu shot.	
The state of the s	Vaccines For A Healthy Pregnancy Helps dispel fears and confusion about immunizations during pregnancy, and clearly presents the basic information all pregnant women should know—including both the shots they need and the shots they should avoid during pregnancy.	English Spanish		Vaccine Safety-What Every Parent Should Know Emphasizes the benefits of vaccination and dispels common myths. Identifies the 11 diseases every child should be immunized against, citing their possible dangers. Reviews the standards that are in place to promote vaccine safety, tells parents the side effects to watch for and when to get help, and answers common questions.	English Spanish
Constant for Finder	Protect Your Preteen or Teen with Shots— They're Not Just for Babies! This informative, motivational booklet teaches parents that shots are just as important for preteens as they are for infants and toddlers. It provides a handy chart of "catch-up" and older child immunization. Also included: brief explanations of diseases of special concern that shots can protect against, special issues and those considered at high risk.	English Spanish	The state of the s	Reminder/Recall Postcards Recall your patients who have missed appointments or who are due for their well-child appointment. Colorful, 4X6" when folded, HIPAA-compliant. Comes bi- lingual in English and Spanish.	

Visit www.ct.gov/dph/immunizations for additional order forms.

Place your order by fax: **860-707-1925** or email form to rachel.reynolds@ct.gov

THE BOX BELOW IS USED AS THE <u>SHIPPING LABEL</u>. PLEASE PRINT CLEARLY AND PROVIDE MAIL STOPS OR FLOOR/AREAS.

In case we have questions about your order, please **print** your email and telephone number:

Email:						
Phone Number:						
	SHIPPING LABEL					
Date of Order: _						
Birthing Hospita	l Name:					
Address:						
Attn:						



Connecticut Vaccine Program

Vaccine Storage & Handling Information

52

Vaccine Storage & Handling Toolkit

January 2018





TO VIEW OR PRINT GO TO:

https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf

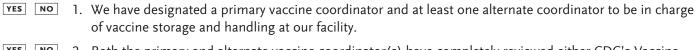
U.S. Department of Health and Human Services

Centers for Disease Control and Prevention

Checklist for Safe Vaccine Storage and Handling

Are you doing everything you should to safeguard your vaccine supply? Review this list to see where you might make improvements in your vaccine management practices. Check each listed item with either YES or NO.

Establish Storage and Handling Policies



- 2. Both the primary and alternate vaccine coordinator(s) have completely reviewed either CDC's Vaccine Storage & Handling Toolkit (www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit. pdf) or equivalent training materials offered by our state or local health department's immunization program.
- 3. We have detailed, up-to-date, written standard operating procedures for general vaccine management, including procedures for routine activities and an emergency vaccine retrieval and storage plan for power outages and other problems. Our procedures are based on CDC's Vaccine Storage & Handling Toolkit and/or on instruction from our state or local health department's immunization program.
- YES NO 4. We review these policies with all staff annually and with new staff, including temporary staff, when they are hired.

Log In New Vaccine Shipments

- 5. We maintain a vaccine inventory log that we use to document the following:
- a. Vaccine name and number of doses received
- b. Date we received the vaccine
- ves No c. Condition of vaccine when we received it
- d. Vaccine manufacturer and lot number
- e. Vaccine expiration date

Use Proper Storage Equipment

- We store vaccines in separate, self-contained units that refrigerate or freeze only. If we must use a house-hold-style combination unit, we use it only for storage of our refrigerated vaccines, maintaining frozen vaccines in a separate stand-alone freezer.
- **YES** NO 7. We store vaccines in units with enough room to maintain the year's largest inventory without crowding.
- 8. We never store any vaccines in a dormitory-style unit (a small combination freezer-refrigerator unit with the freezer compartment inside the refrigerator).
- 9. We use only calibrated thermometers that have a Certificate of Calibration Testing* ("Report of Calibration") and are calibrated every 1 to 2 years from the last calibration testing date or according to the manufacturer's suggested timeline.
- **YES** NO 10. We have planned back-up storage unit(s) in the event of a power failure or other unforeseen event.

CONTINUED ON THE NEXT PAGE

*Certificate of Calibration Testing ("Report of Calibration") with calibration measurements traceable to a laboratory with accreditation from the International Laboratory Accreditation Cooperations (ILAC) Mutual Recognition Arrangement (MRA) signatory body.



Technical content reviewed by the Centers for Disease Control and Prevention

Saint Paul, Minnesota • 651-647-9009 • www.immunize.org • www.vaccineinformation.org

Ensure Optimal Operation of Storage Units

YES NO 11.	We have a "Do Not Unplug" sign (e.g., www.immunize.org/catg.d/p2090.pdf) next to the electrical outlets
	for the refrigerator and freezer and a "Do Not Stop Power" warning label (e.g., www.immunize.org/catg.d/
	p2091.pdf) by the circuit breaker for the electrical outlets. Both signs include emergency contact information.

VES NO 12. We perform regular maintenance on our vaccine storage units to assure optimal functioning. For example, we keep the units clean, dusting the coils and cleaning beneath the units as recommended by the manufacturer.

Maintain Correct Temperatures

- 13. We always keep at least one accurate calibrated thermometer (+/-0.5°C [+/-1°F]) with the vaccines in the refrigerator and a separate calibrated thermometer with the vaccines in the freezer.
 - 14. We use a thermometer that
- a. uses an active display to provide continuous monitoring information.
- b. is digital and has a detachable probe that has been buffered against sudden temperature changes by being immersed in a vial filled with liquid (e.g., glycol, ethanol, glycerin), loose media (e.g., sand, glass beads), or a solid block of material (e.g., aluminum, Teflon®).
- ves NO c. includes an alarm for out-of-range temperatures.
- VES NO d. has a digital data logger that indicates current, minimum, and maximum tempreratures.
- e. can measure temperatures within +/-0.5°C (+/-1°F).
- f. has a low-battery indicator.
- **YES** NO 15. We maintain the refrigerator temperature at 2–8°C (36–46°F), and we aim for 5°C (40°F).
- **YES** NO 16. We maintain the freezer temperature between -50°C and -15°C (-58°F and +5°F).
- YES NO 17. We set the thermostat for the refrigerator and the freezer at the factory-set or midpoint temperatures.
- NO 18. We keep extra containers of water in the refrigerator (e.g., in the door and/or on the floor of the unit where the vegetable bins were located) to help maintain cool temperatures. We keep ice packs, ice-filled containers, or frozen water bottles in the freezer to help maintain cold temperatures and to have frozen water bottles available for conditioning in the event of an emergency.

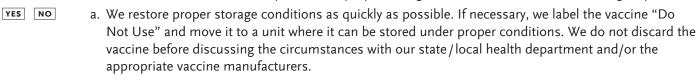
Maintain Daily Temperature Logs

- 19. On days when our practice is open, we visually inspect the vaccine storage unit twice a day (first thing in the morning and right before our facility closes) and document refrigerator and freezer temperatures on the appropriate log. (See selections at www.immunize.org/clinic/storage-handling.asp.)
- **YES** NO 20. We document the minimum and maximum temperature readings in the refrigerator and freezer once each day, preferably in the morning.
- **NO** 21. We consistently record temperatures on the log either in Fahrenheit or Celsius. We never mix temperature scales when we record our temperatures.
- VES NO 22. If the temperature log prompts us to insert an "x" by the temperature that's preprinted on the form, we do not attempt to write in the actual temperature.
- **YES** NO 23. We follow the directions on the temperature log to call appropriate personnel if the temperature in a storage unit goes out of range.
- 24. If out-of-range temperatures occur in the unit, we complete the Vaccine Storage Troubleshooting Record (www.immunize.org/catg.d/p3041.pdf) to document actions taken when the problem was discovered and what was done to prevent a recurrence of the problem.

CONTINUED ON THE NEXT PAGE

Checklist for Sa	afe Vaccine Storage and Handling (continued) page 3 of 3
YES NO 25.	Trained staff (other than staff designated to record the temperatures) review the temperature logs weekly.
YES NO 26.	We keep the temperature logs on file for at least 3 years.
	Store Vaccines Correctly
YES NO 27.	We post signs (e.g., www.immunize.org/catg.d/p3048.pdf) on the doors of the refrigerator and freezer that indicate which vaccines should be stored in the refrigerator and which in the freezer.
YES NO 28.	We do not store any food or drink in any vaccine storage unit.
YES NO 29.	We store vaccines in the middle of the refrigerator or freezer (away from walls and vents), leaving room for air to circulate around the vaccine. We never store vaccine in the doors.
YES NO 30.	We have removed all vegetable and deli bins from the storage unit, and we do not store vaccines in these empty areas.
YES NO 31.	If we must use a combination refrigerator-freezer unit, we store vaccines only in the refrigerator section of the unit. We do not place vaccines in front of the cold-air outlet that leads from the freezer to the refrigerator (often near the top shelf). In general, we try to avoid storing vaccines on the top shelf, and we place water bottles in this location.
YES NO 32.	We check vaccine expiration dates and rotate our supply of each type of vaccine so that vaccines with the earliest expiration dates are located close to the front of the storage unit, facilitating easy access.
YES NO 33.	We store vaccines in their original packaging in clearly labeled uncovered containers.

Take Emergency Action As Needed



34. In the event that vaccines are exposed to improper storage conditions, we take the following steps:

- YES NO b. We follow the Vaccine Storage Troubleshooting Record's (www.immunize.org/catg.d/p3041.pdf) instructions for taking appropriate action and documenting the event. This includes recording details such as the length of time the vaccine was out of appropriate storage temperatures and the current room temperature, as well as taking an inventory of affected vaccines.
- YES NO c. We contact our clinic supervisor or other appropriate clinic staff to report the incident. We contact our state / local health department and / or the appropriate vaccine manufacturers for consultation about whether the exposed vaccine can still be used.
- YES NO d. We address the storage unit's mechanical or electrical problems according to guidance from the unit's manufacturer or a qualified repair service.
- NO YES e. In responding to improper storage conditions, we do not make frequent or large changes in thermostat settings. After changing the setting, we give the unit at least a day to stabilize its temperature.
- YES NO f. We do not use exposed vaccines until our state/local health department's immunization program or the vaccine manufacturer has confirmed that the vaccine is acceptable for use. We review this information with our clinic medical director before returning the vaccine to our supply. If the vaccine is not acceptable for use, we follow our state/local health department instructions for vaccine disposition.

If we answer YES to all of the above, we give ourselves a pat on the back! If not, we assign someone to implement needed changes!



The Centers for Disease Control and Prevention (CDC) has developed guidance for storage and handling of vaccines. To see the current guidance issued by the CDC, view the <u>Vaccine Storage and Handling Toolkit</u>.

Key Points:

- CDC recommends that practices maintain a calibrated, temperature monitoring device (data logger) and manually record temperatures in each unit containing Vaccines For Children (VFC) vaccines. This should be done twice daily.
- Data loggers have many different features. CDC recommendations are below, but call your VFC coordinator to learn what is required in your state.
- Consider a phone-enabled or internet-aware alarm to alert you by phone/internet anytime temperature excursions occur. Multiple people should be on the notification list to ensure the best chance that appropriate action is taken to correct the problem.

It is recommended that your data logger have the following functionality:

- Hi/Lo auditory alarm for out-of-range temperatures;
- Displays current temperature, as well as the minimum and maximum temperatures recorded since last manual recording of temperature (values must be visible from outside of the vaccine storage unit);
- Low battery indicator;
- Accuracy of +/- 0.5 degrees C (+/-1 degrees F) as certified by a current Certificate of Traceability and Calibration.
 - o Certificates may last 1-2 years.
 - Speak to your VFC coordinator for your options. It may be cheaper to purchase a new device, or they can discuss acceptable testing laboratories.);
- Records continuously with memory storage of at least one month of data* (no less than 4,000 readings);
- Data recording loops when memory is full.* (Remember to download and transfer data to more permanent storage. Reset device after each data download.);
- Detachable, buffered temperature probe, that can remain in the unit while the temperature is displayed on the outside of the unit (near vaccines); and
- User programmable logging interval (or sampling rate) of 10 minutes or less.* While the CDC recommends 15 minutes or less, a more frequent sampling rate is allowed and may be preferable to capture more data points and to better estimate the duration of temperature excursions.

What do I do with the data stored on my data logger?

Even though the data logger is recording, the temperature will need to be checked and manually recorded by office staff twice daily, along with the maximum and minimum temperatures since the last data reset. This recommendation can prevent inadvertent loss of vaccine and the potential need for revaccination by allowing temperature excursions to be identified quickly so that immediate corrective action can be taken. This also provides an opportunity to visually inspect the storage unit, reorganize vaccines by date, and remove any expired vaccines.

^{*}Please note this adds to CDC guidance.



Data logger temperature data should be downloaded, reviewed weekly, and stored for at least 3 years. Documentation of known excursions or thermometer malfunctions should be recorded along with the temperature data and should include corrective actions taken to address the excursions. Software will likely be needed in order to view the stored data. Many data loggers are sold with software included, but some are sold separately. You must be able to review historical data.

What else do I need to consider?

- Contact your VFC Program to determine their requirements
 - The CDC has published recommendations for the local VFC Awardees who administer the VFC program to pediatricians. Being familiar with the CDC published recommendations will help pediatricians anticipate new requirements but it is the requirements of the pediatrician's individual VFC program that must be followed per VFC contracts.
- Alerts/Alarm phone-dialer (alerts through landline, text, e-mail and/or mobile phone)
 A phone-dialer is able to alert you to a temperature excursion during which no one is in the office to hear
 the local alarm. This allows someone to correct the problem in time to prevent the loss of vaccine. No
 single notification method works best in all situations sometimes you may need a combination of
 methods. Understand the likely outages (eg, local and regional power failure, local and regional internet
 service, local and regional phone/cellular/Voice over Internet Protocol) that you may experience and
 realize the notification system can fail under such adverse conditions. Your office should have a plan in
 place for vaccine storage and transport during emergencies. Please see the AAP Vaccine Storage and
 Handling Disaster Planning resource.
 - Equipment failure, door left open: This is by far the most common occurrence about which to be notified. As mentioned above, your data logger should have an alarm for temperatures exceeding either the high or low threshold. These alarms can notify staff who are physically near and able to respond. You may want to look for a unit that will allow you to program or specify a short/minimal delay before the alarm rings. This will allow you to avoid notification during routine inventory maintenance.
 - Off-site notification: This type of notification can be used after office hours to reach one or more staff responsible for immunizations. Each office should have at least one staff immunization champion a nurse or medical assistant who takes responsibility for and performs regular vaccine management tasks and one physician who oversees immunizations. These staff members can be alerted via phone call, e-mail, or text. The best devices require a response from the person notified a return text or acknowledgement code entered via the phone and will continue to dial staff members until the acknowledgement is received.
 - Power outages: Although the phone-dialer may have its own battery, the phone service going to the dialer may fail.
 - Local power failure (circuit breaker, single building outage) can disable most phone systems unless they have battery backup or a generator. A standard "land line," tied directly to the dialer (does not go through an office phone system) is the most reliable and does not require a power source. Cellular service is also quite reliable and has the advantage of texting and/or voice-calling. E-mail notification, cable phone service, and Voice over Internet Protocol phone systems require internet service which may also be dysfunctional in the building, as modems, routers, switches, and servers all need power to be working. Service



can also be lost in the immediate area, thus rendering these methods less dependable. Some internet devices constantly notify send notifications to an offsite device. If these notifications stop (for example in the case of a power outages), the offsite device will begin calling staff members. This method works even if total power failure occurs.

Regional power failure (natural disasters, foods, hurricane, snow storm, large-scale grid failure) can make notification more difficult since the infrastructure can be compromised. Usually a responsible staff can be aware of such events and should physically go to the site to inspect. Understand the likely outages (local and regional power failure, local and regional internet service, local and regional phone/cellular/VOIP) that you may experience and realize the notification system can fail under such adverse conditions.

A back-up thermometer

 Have a back-up thermometer to use if/when your primary unit is being tested for calibration. It may be more cost-effective to purchase a new thermometer than to maintain 2 with updated certifications of calibration.

A unit with a continuous-tracking feature

Older thermometers may directly record the unit's temperature onto a circular piece of graph paper. These have been totally replaced by electronic versions and should not be used. (Please note: use of continuous tracking with a data logger does not preclude you from manually recording the temperature twice daily!).

Vaccine Insurance

- When private-purchase vaccine expires or is destroyed by temperature excursions, the manufacturer may take back non-influenza vaccine and exchange all for new vaccine. Replacement is not an option if the vaccine is physically destroyed (fire) or in case of theft. Returning vaccine is not currently an option for doses purchased through the CDC VFC contract and given to practices. Practice owners may be financially responsible for all VFC vaccine spoilage. Follow state VFC program guidance on returning vaccine. The degree of VFC financial risk is determined by the local VFC program, not the CDC. Contact your local VFC program to determine your financial risk when storing VFC vaccine. Practices with excellent storage programs may be excused from financial responsibility for events beyond their reasonable control.
- o Insurance is an option for both private-purchase and VFC vaccine. As with any insurance policy, be very sure you understand exactly what is and is not covered write the insurance agent asking: "Please give me a list in writing as to what losses you **will not** cover."

• Spare refrigerator and transport containers

- Consider placing a spare thermometer (with a buffered probe) in your employee or break-room refrigerator and maintain/monitor that refrigerator between 2°C and 8°C
 (36° F and 46°F) just like you would a vaccine refrigerator. That way if you have an unexpected equipment failure, you can remove all food and have a readily available refrigerator that you know is capable of storing the vaccine at the appropriate temperature.
- Have coolers capable of safely transporting your vaccine to an alternate refrigerator in case of power failure stored in your building. Conditioned frozen water bottles make excellent coolant for transport of refrigerated vaccine and should be on hand at all times. (See <u>CDC Packing Vaccines</u> <u>for Transport during Emergencies</u>).



Electrical backup for refrigerators

- Although battery backups are appropriate for computers to help deal with minor power outages, battery backups are NEVER appropriate for refrigerators. Refrigerator compressors draw too much current for battery backup devices and will likely fail. If the power returns in a few moments, the device will remain "off" and so will the refrigerator.
- o In areas at risk for power outages, propane or natural gas emergency generators are appropriate. They must have automatic start and be professionally installed by an electrician.
- Gasoline and diesel fuel are not appropriate fuels for emergency refrigerators because they age quickly.
- o Be aware that refrigerators can exceed 8°C (46°F) in about 3 hours of no power at room temperature.

How do you determine if the refrigerator is failing or the data logger is wrong?

- o To check the accuracy of a data logger, you can do an Ice Melting Point Test. Watch this demonstration.
- O An easy method is to purchase a soup thermos, fill with more ice than water, and place the certified probe into the water + ice while in the refrigerator. If, after 10 minutes, the thermometer reads within +/- 0.5° of 0°C (+/-1° of 32°F) and holds that range for another 10 minutes, then the thermometer passed and demonstrated that it is accurate. If it fails, it should be replaced.
- Refrigerators can slowly decline in function. If you find that you are turning the thermostat colder and colder to maintain
 - 5°C (41°F)you should replace the refrigerator immediately.
- View the <u>Immunization Action Coalition Resources</u> for documenting and correcting any unacceptable vaccine storage event.
- o If testing shows the device is reporting inaccurate temperature do not try to adjust it, replace the temperature monitoring device.

How do you place a data logger in a refrigerator?

- The data loggers with a removable temperature probe usually have a wire leading to the probe. There are some that function wirelessly, but most use a wire. Purpose-built (vaccine/medical) refrigerators often have a plug that covers a hole through the side or rear wall of the unit designed to feed the probe wire into the unit without gapping the door.
- o If the storage unit has no port, the probe should enter through the door opening on the hinge side high in the top corner. The seals are sensitive to gaps caused by the monitor wire and frost will build up in freezers due to the gap allowing moist air to enter. This can be reduced by tightly taping the wire in the door frame with thin clear packing tape for a good seal.
- Place the probe in glycol in the center of the refrigerator with several loops of extra wire. That will
 allow you to move it throughout the vaccine storage area to verify that the entire refrigerator is kept
 at the temperature appropriate for vaccines.





Special thanks to the Oregon Immunization Program for sharing material from their 2012 Thermometer Guide!

Please note that the American Academy of Pediatrics cannot endorse or recommend specific products or brands. This guide is only meant to aid you in your selection of vaccine storage equipment. The terms and conditions related to your purchase are between you and the vendor.

While we attempt to keep this document updated, model numbers, styles, and features change often. Before making your final decision, contact the manufacturer/vendor for up-to-date pricing and specifications, and check with your VFC coordinator to verify a product meets their requirements.

Data logger manufacturers and distributors:

Accsense	http://www.accsense.com/p_p_a102.html
Berlinger	http://www.berlinger.com/en/temperature-monitoring/products-
	hardware/data-loggers/
Control Solutions Inc.	www.vfcdataloggers.com
Dickson	http://www.dicksondata.com/products/find/data-logger
DeltaTrak	http://www.deltatrak.com/product/381-flashlink-certified-vaccine-
	usb-pdf-data-logger-model-40527
Lascar Electronics	http://www.lascarelectronics.com/data-logger/
Onset (Hobo)	http://www.onsetcomp.com/
SensoScientific	http://www.sensoscientific.com/vaccine-vfc/
T&D Corporation	http://www.tandd.com/#fragment-1
Temperature Guard	http://temperatureguard.com/
Temperature@lert	http://www.temperaturealert.com/Temperature-Alarm.aspx
Tip Temperature Products	www.tiptemp.com

Alarm phone-dialer manufacturers:

Dickson	http://www.dicksondata.com/
DeltaTrak	http://www.deltatrak.com/flashtrak-wrm#specifications
Sensaphone	http://www.sensaphone.com
Temperature Guard	http://temperatureguard.com/
United Security Products	http://www.unitedsecurity.com/
Temperature@lert	http://www.temperaturealert.com/Temperature-Alarm.aspx



In order to be assured your data logger meets all desired specifications, you may want to discuss them with your vendor. Below is a list of questions to ask your vendor to help you understand all the functions of a data logger. You may use the chart on the next page to fill-in information and compare models.

Questions to ask about desired specifications:

- Does this data logger display the current, minimum, and maximum temperature? Is the display outside of the vaccine storage unit (refrigerator or freezer) where it can be easily accessed?
- Does the unit have an alarm that will alert the user if temperature exceeds the high/low thresholds?
- Does the unit have a reset button that clears the minimum and maximum temperatures since the last clearing?
- Does the unit have a low battery indicator?
- Does the unit have one or more detachable temperature probe(s) in glycol or suitable temperature buffer?
- Does the temperature probe and unit measure accurately, within +/- 0.5°C (+/-1°F) and come with a Certificate of Traceability and Calibration?
- Can it record at least a month worth of readings at a 10 minute sample rate?
- Does this unit loop data (record over the oldest data) when memory is full?
- Is the logging interval customizable? At what intervals can this device record?

Questions to ask about additional features:

- Can this unit connect more than one probe?
- Can this unit transmit data wirelessly?
- Is a power cord available?
 - o If not, does the battery last at least 1 year?
 - o How long does the battery last?
 - o Is the battery replaceable?
- Is software included or available for separate purchase? (If separate, considering purchasing to access your stored data).
- What are the system requirements for the software?
- Can this unit place phone calls (landline and mobile), send text messages, and/or send e-mail messages to several numbers and addresses if it detects a temperature excursion?
 - o If so, can a user query the monitor for additional readings while traveling to the office? (If it "recovers" as in a power outage, you want to be able to return home).



You may use this chart to fill-in information and compare models. Please note that the American Academy of Pediatrics cannot endorse specific products. This guide is only meant to aid you in your selection of vaccine temperature monitoring equipment. The terms and conditions related to your purchase are between you and the vendor.

Data logger make/model	Cost	Hi/Lo alarm	Current min & max temp display	Maximum and Minimum Temperature Reset button	Low battery indicator	Accuracy	Memory storage	Programmable logging interval of 10minutes or less? Y/N Rate?	Does data loop when memory is full?	Data displayed outside of unit and downloaded without disruption of probe?	Frequency & Cost of Re- Calibration Can an Ice Melting Point (IMP) Verification be done by user?	Other features
Monitor ABC	\$500	Yes	Yes	Yes, logger can be cleared	Yes (indicate s when A/C power is removed)	±0.45°C	60,000	Y Various intervals available	Yes	Yes, remote probe	Annually \$99-\$269 Check with VFC Coordinator	Relay (function for external alarm hook-up); UBS/flash card

Last Updated 2/2017



The Centers for Disease Control and Prevention (CDC) offers guidance on proper storage and handling of vaccines, including recommendations on storage units for vaccines, in the <u>Vaccine Storage and Handling Toolkit</u>.

The American Academy of Pediatrics (AAP) has assembled some tips to help you choose the best equipment to meet the needs of your practice and keep your vaccine stock safe.

NEVER FREEZE REFRIGERATED-VACCINE

Silently freezing vaccine is the biggest threat to the potency and efficacy of your refrigerated-vaccine. It is impossible to visually detect whether a vaccine has been frozen. If such a vaccine is given to children, it may not prevent disease. Take precautions against freezing your vaccine by using the recommended equipment and properly setting up your refrigerator. For visuals of how to do this see the CDC Vaccine Storage and Handling Toolkit and the EZIZ Preparing Refrigerators for Vaccine Storage.

Key Points:

- Stand-alone refrigerator and freezer units are safest for storing vaccines.
- Medical- or pharmacy- grade refrigerators have electronic thermostats, audible door-ajar alarms, wire shelves, interior fans and ports to pass through sensor wires.
- Freezers are much smaller and can be manual or auto-defrost. They can have simpler analog thermostats, but should have a port for sensor wires. If picking a manual defrost unit, there should be a spare or second unit in the same office capable of holding the frozen vaccine while the defrost is completed.

CDC recommendations for stand-alone refrigerators and freezers

CDC strongly recommends replacing old, combination (domestic) units with stand-alone refrigerator and freezer units. Dual pharmacy-grade units with independent refrigerator and freezer compressors (not combo domestic units sharing a single compressor) are also excellent in offices where space is limited. Refrigerator/Freezer units can vary in size, from a compact, under-the-counter style to large, double-door units. The use of standard domestic combination refrigerator/freezer units is no longer appropriate, and many VFC programs may require their immediate replacement. The use of dormitory or bar-style refrigerator/freezers (small refrigerator units with interior freezer sections) has been banned for several years due to freezing vaccine risks.

CDC recommendations for stand-alone refrigerators and freezers (continued)

The characteristics of an appropriate **refrigerator storage system** include:

- ability to maintain within +/- 2°C of 5°C despite fluctuating ambient temperatures
- vaccine storage areas do not exceed the +2°C to +8°C +36°F to 46°F temperature range
- electronic / digital thermostat preset to 5°C (or possibly 4°C)
- wire shelves with good interior circulation to minimize internal temperature variance to +/- 2°C
- door ajar audible alarm and temperature excursion alarm
- enough extra room to hold the practice's vaccine stock, including flu vaccine at least 4 inches from the unit's walls
- certified continuous data logger with max/min displaying thermometer accurate to +/-0.5°C +/-1°F



The characteristics of an appropriate **freezer storage system** includes:

- ability to store frozen vaccine not warmer than -15°C +5°F
- o nor colder than -50°C -58°F
- o room to store the year's largest inventory of Varivax, ProQuad and MMR II
- o certified data logging max/min displaying thermometer accurate to +/-0.5°C
- automatic defrost or ability to defrost manually (practices using a freezer that needs to be defrosted manually will need a second freezer in which to store vaccine during the defrost process)

Half-liter drinking water bottles can be added to vaccine refrigerators to increase cold mass and thus stabilize temperature swings. Always cool water bottles in an alternate refrigeration unit before placing in a vaccine refrigerator. Chilled water bottles may be placed in empty shelves or the floor, but do not allow them to obstruct the air flow by touching the rear wall, nor should vaccines block the cover of the unit motor compartment. Typically, the air flow is down the rear walls from the circulating fan in the top and then back up the front.

Frozen water bottles may be placed in freezers to add cold mass. To help freezers retain their temperature longer in power outages, a <u>phase change material -23°C -9°F</u> capable of passively maintaining temperatures below <u>-15°C +5°F</u> is needed.

Types of refrigerator & freezers

Biologic-grade Full-sized Refrigerators

Biologic-grade ("medical"; "purpose-built"; "vaccine"; "blood-bank"; "laboratory") refrigerators are considered the best, most secure option for vaccine storage. These are the "gold-standard" in vaccine units and have electronic thermostats, wire shelving to improve circulation, small ports for the entry of a temperature probe wire and interior fans to equalize the temperature throughout. Manufacturers in this category offer a range of sizes and options to fit any clinic's needs. Size options include one-door and two-door bulk storage units, under-counter units and small point of service units to replace the disallowed dorm units. Units with glass doors help with inventory management. Keep in mind, biologic-grade units often require over a month to deliver. Some manufacturers will sell refrigerators classified as "biologic grade" with a mechanical or analog thermostat – avoid these. If purchasing a vaccine grade refrigerator, it should always have a "microprocessor controlled" or "electronic / digital" thermostat. These units are designed to run at approximately 5° C 41° F and rarely need any adjustment by the end-user. They are much safer than refrigerator units with analog dials.

Biologic-grade Freezers and Domestic Freezers

Freezers are easier to construct since they do not need a precise range – they just need to be always colder than -15°C +5°F. Freezers can be much smaller than what is normally used in a home. Although frost-free freezers are recommended, that feature is often found only in freezers much larger than what is generally needed. (Large

practices with <5 providers might consider a large 5+ cu ft freezer.) If not specially designed, freezers advertised as "frost-free" may warm up considerably above -15°C $+5^{\circ}\text{F}$ during defrost when the evaporator coils are heated to melt any frost or ice. Often it is less expensive to purchase two small manual defrost units and keep one as a "cold spare", than to purchase an appropriate auto-defrost unit. (The cold spare unit could hold the vaccine while the primary unit is being manually defrosted.) Be careful not to purchase more freezer than you need – vaccines containing Varivax are the only pediatric vaccines that require frozen storage, although MMR can be optionally stored frozen. Adequate freezers for 3 or 4 pediatricians can be as small as 1.5 cubic feet and cost as little as

\$250. If ordering a unit for under the counter, check the height of your countertop before ordering. Standard countertops are 36" high and may not be able to accommodate all freezers.



Remember, small refrigerators and freezers can be sold as "counter top" or "built-in". That refers to the air circulation needed for cooling. "Built-ins" are able to exhaust waste heat out of the front of the unit.

Standard Refrigerators and Freezers and "Commercial Grade"

Standard domestic refrigerators and freezers are found in homes and appliance stores. Higher-end models are sometimes referred to as "commercial-grade," are most often used in the food service industry. They are not "biologic-grade". Currently, use of domestic refrigerator-only and freezer-only units is not prohibited, but future guidance may disallow them, as many VFC programs have done. Commercial food service refrigerators look very much like vaccine refrigerators, but there can be differences. Food service units are designed to rapidly cool large quantities of warm/hot food – and thus could get too cold (below $\boxed{0^{\circ}C}$ $\boxed{32^{\circ}F}$) when the compressor turns on. In an emergency, it is possible for a domestic refrigerator-only unit to be used safely for vaccine storage with proper precautions. If used for VFC vaccine, you should consult with your local VFC.

Other Features and Alarms

Glass doors may help the practice with inventory control, but they lose heat much faster in a power outage. While a solid door unit may maintain an acceptable temperature for 2 hours without power, glass door units rarely go longer than 30 minutes. Having generator power is prudent if looking for a glass door unit.

Certified, continuous data-logging thermometers with a maximum and minimum display are required. Read more about these. It is also important to purchase a temperature monitor that can call, text, or otherwise notify several people if the unit has a temperature excursion. Best are those that will keep calling/notifying a list of staff until one acknowledges the notification with a response. Active notification could prevent nearly 80% of vaccine wastage due to temperature excursions.

The refrigerator may come with an electronic digital display of temperature, but the VFC program will require a separate certified data logger in a glycol buffer.

Manufacturers and Distributers of Biologic-grade Units

The manufacturers and distributors below are a sample of some that you may wish to consider for safe vaccine storage in your practice. Please note that the American Academy of Pediatrics cannot endorse or recommend specific products or brands. If you are a manufacturer of equipment and wish to add or edit information below, please contact immunize@aap.org.

Aegis	http://www.aegisfridge.com
American Biotech Supply	http://americanbiotechsupply.com/find-a-dealer
Compact Appliance	http://www.compactappliance.com/on/demandware.store/Sites-Appliance-
	Site/default/Search-Show?q=american+biotech
Fisher Scientific	https://www.thermofisher.com/us/en/home/life-science/lab-
	equipment/cold-storage/vaccine-cold-storage-solutions.html
Follett	http://www.follettice.com
Helmer	http://www.helmerinc.com/
Lab Research Products	http://www.labresprod.com/
Migali Scientific Refrigeration	http://migaliscientific.com/
Panasonic Healthcare	http://www.panasonic-healthcare.com/us/biomedical
Powers Scientific	www.powersscientific.com
ThermoFisher Scientific	www.thermofisher.com/us/en/home.html



Use the following to determine the appropriate equipment size for your practice

Refrigerator:

Offices generally have either one large central storage unit, or a bulk storage unit with smaller refrigerators at a nursing desk that maintains a few days-worth of supply. The advantage of the central-storage style is that there is just one unit to be inventoried, set up, and monitored. Disadvantages include crowding by staff when multiple vaccine administrators need to retrieve vaccines, and inefficiency of the vaccine administrator needing to leave the area to retrieve the vaccine. In a bulk-storage style, a very large unit could be placed out of the high-flow area and infrequently accessed. The vaccine administrator would pull mainly from a smaller unit near their vaccine preparation area and not need to walk to the central unit. The disadvantage is that there are more units to monitor and larger initial cost.

Sizing a unit is difficult. Consider getting something larger than what exists currently. If just starting out, consider visiting a practice of the size you hope to be and look at their vaccine storage units. Vaccines come in many varied and oddly shaped boxes, so just counting expected dosages is rarely helpful. Remember to factor in the space needed for FluMist and injectable Flu vaccine.

Freezer:

Freezers can be much smaller. Since only Varivax containing vaccine must be stored in it, a 1.5 cu ft unit can hold enough vaccine for 3 or 4 pediatricians. Generally it works best to have a second cold spare unit so units can be manually defrosted. If you have a cold spare and you get tight for room, the second unit, if set up with its own certified thermometer, can serve as an overflow unit as well. MMR can be stored frozen and most pediatricians store it in the freezer. Since only two visits (12m and 4y) require Varivax and MMR, the freezer can be placed in a less busy area of the office. Again, in selecting a size, base your needs on your current storage ability or visit another practice to see what works for them.

Special thanks to the Oregon Immunization Program for sharing material from their 2012 Refrigerator Guide and to the California Department of Public Health for sharing material from their Refrigerator Buying Guide!

One final suggestion: When ordering large refrigerators, measure all doors and entry ways and check unit dimensions to verify that the unit(s) you ordered can fit into your building and into the appropriate room. Have two different people measure at least twice. These units are often used in university labs and hospitals and are quite large and tall. When ordering, ask for and pay extra for "inside delivery". Otherwise, the shipping company (which is not who sold you the unit) may leave your new 500 pound refrigerator crated in a box in the parking lot.



Temperature Log for Freezer – Fahrenheit DAYS 1-15

Monitor temperatures closely!

- 1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
- 2. If using temperature monitoring device (TMD; digital data logger recommended) that records min/max temps, document min/max once each workday, preferably in the morning. If using TMD that does not record min/max temps, document current temps twice, at beginning and end of each workday.
- 3. Put an "X" in the row that corresponds to the freezer's temperature.
- 4. If any out-of-range temp, see instructions to the right.
- 5. After each month has ended, save each month's log for 3 years, unless state/local jurisdictions require a longer period

Month/Year	VFC PIN or other ID#	 Page 1 of 3
Facility Name		

Take action if temp is out of range—too warm (above 5°F) or too cold (below -58°F).

- 1. Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
- 2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
- 3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
- 4. Document the action taken on the "Vaccine Storage Troubleshooting Record" on page 3.

Day of Month		1		2		3	_ '	4		5		6		7	8	3	9	9	10		11	1	2	1	3	1	4	1	5
Staff Initials																													
Exact Time	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM PI	A N	M PM	AM	PM	AM	PM	AM	PM	AM	PN
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Write any out-of-range temps (above 5°F or below -58°F) here.																													
Room Temperature				:		1		:				:		:											:				:

If you have a vaccine storage issue, also complete "Vaccine Storage Troubleshooting Record" found on page 3.



Temperature Log for Freezer – Fahrenheit

DAYS 16-31

Monitor temperatures closely!

- 1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
- If using temperature monitoring device (TMD; digital data logger recommended)
 that records min/max temps, document min/max once each workday, preferably in
 the morning. If using TMD that does not record min/max temps, document current
 temps twice, at beginning and end of each workday.
- 3. Put an "X" in the row that corresponds to the freezer's temperature.
- 4. If any out-of-range temp, see instructions to the right.
- 5. After each month has ended, save each month's log for 3 years, unless state/local jurisdictions require a longer period.

Month/Year	VFC PIN or other ID#	 Page 2 of 3
Facility Name		

Take action if temp is out of range – too warm (above 5°F) or too cold (below -58°F).

- Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible.
 Do not discard vaccines unless directed to by your state/local health department and/or the
 manufacturer(s).
- 2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
- 3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
- 4. Document the action taken on the "Vaccine Storage Troubleshooting Record" on page 3.

Day of	Month	1	6	1	7	1	8	1	9	20)	21	22	2	2	.3	24	25	2	16	2	27	28	29	3	30	3	31
Staff In	itials																											
Exact T	ïme	АМ	РМ	АМ	РМ	АМ	РМ	АМ	PM	АМ	РМ	AM PM	АМ	РМ	АМ	РМ	AM PM	AM PM	АМ	РМ	АМ	РМ	AM PM	AM PM	АМ	PM	АМ	PM
(since pr	ax Temp in Unit evious reading)																											
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ų –	-1°F																											
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- AC	58°F to -5°F																											
tem	ite any out-of-range nps (above 5°F or ow -58°F) here.																											
	om Temperature																											

If you have a vaccine storage issue, also complete "Vaccine Storage Troubleshooting Record" found on page 3.



Temperature Log for Refrigerator – Fahrenheit

DAYS 1-15

Monitor temperatures closely!

- 1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
- If using temperature monitoring device (TMD; digital data logger recommended)
 that records min/max temps, document min/max once each workday, preferably in
 the morning. If using TMD that does not record min/max temps, document current
 temps twice, at beginning and end of each workday.
- 3. Put an "X" in the row that corresponds to the refrigerator's temperature.
- 4. If any out-of-range temp, see instructions to the right.
- 5. After each month has ended, save each month's log for 3 years, unless state/local jurisdictions require a longer period.

Month/Year	VFC PIN or other ID #	Page 1 of 3
Facility Name		

Take action if temp is out of range – too warm (above 46°F) or too cold (below 36°F).

- Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible.
 Do not discard vaccines unless directed to by your state/local health department and/or the
 manufacturer(s).
- 2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
- 3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
- 4. Document the action taken on the "Vaccine Storage Troubleshooting Record" on page 3.

Day of Month		1		2		3	4	4	!	5		6		7	;	3	'	9	1	0	1	1	12		13	1	4	15
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Write any out-of-rang temps (above 46°F or below 36°F) here:																												
or below 36°F) here: Room Temperature																												

If you have a vaccine storage issue, also complete "Vaccine Storage Troubleshooting Record" found on page 3.

Adapted with appreciation from California Department of Public Health



Temperature Log for Refrigerator – Fahrenheit

DAYS 16-31

Monitor temperatures closely!

- 1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
- If using temperature monitoring device (TMD; digital data logger recommended)
 that records min/max temps, document min/max once each workday, preferably in
 the morning. If using TMD that does not record min/max temps, document current
 temps twice, at beginning and end of each workday.
- 3. Put an "X" in the row that corresponds to the refrigerator's temperature.
- 4. If any out-of-range temp, see instructions to the right.
- 5. After each month has ended, save each month's log for 3 years, unless state/local jurisdictions require a longer period.

Month/Year	VFC PIN or other ID #	Page 2 of 3
Facility Name		

Take action if temp is out of range – too warm (above 46°F) or too cold (below 36°F).

- Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible.
 Do not discard vaccines unless directed to by your state/local health department and/or the
 manufacturer(s).
- 2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
- 3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
- 4. Document the action taken on the "Vaccine Storage Troubleshooting Record" on page 3.

Day of Month	1	16		17	'	18	1	9	2	20	2	1	2	2	2	.3	24		25	2	26	2	7	2	8	2	9	30	<i>'</i>	31
Staff Initials																														
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Write any out-of-range temps (above 46°F or below 36°F) here:																														
or below 36°F) here: Room Temperature																		1												

If you have a vaccine storage issue, also complete "Vaccine Storage Troubleshooting Record" found on page 3.

Adapted with appreciation from California Department of Public Health

TEMPERATURE EXCURSION TROUBLESHOOTING

All providers are required to report temperature excursions above the acceptable range in for a period of 2 hours or more, or below the acceptable range for any period of time.

- 1. <u>Return vaccines to appropriate storage conditions</u>. Until a final determination has been made, vaccines should be stored in appropriate temperatures and labeled "<u>Do Not Use</u>". This may require vaccines to be relocated in accordance with the office back-up plan.
 - Refrigerated vaccines should be stored between 36°F and 46°F (2°C to 8°C).
 - Frozen vaccines should be stored between 5°F and -58°F (-15°C to -50°C).
- 2. <u>Download the temperature data from your digital data logger</u>. As of January 1, 2018, all providers are required to have a certified, calibrated, downloadable data logger. This information should be sent to the CVP when the excursion is reported.
 - For Berlinger data loggers, please submit the PDF summary report via fax (860-509-8371) or email (dph.immunizations@ct.gov).
 - For data logger models that provide an Excel or .csv read-out, please email the file and do not fax.
 - If no data logger is available, paper logs may be submitted by fax or email.

3. Compile the following information:

Excursion date:	Alarm time:	Person Reporting Excursion:							
Minimum temp:		Cumulative Duration out of range - current excursion (hours/mins):							
Maximum temp:		Were doses given since excursion:							
Were vaccines involved exposed to out of range temperatures previously: YES NO									

- Excursions are cumulative. If there has been more than one excursion, have data available on the total duration out of range over all excursions for proper viability assessment.
- Providers who use paper logs to estimate the excursion, you MUST assess the entire time period from when the previous in-range temperature was taken to when the next in-range temperature was taken. For help, please contact the CVP.
- 4. <u>Determine which vaccines were involved in the excursion and, if necessary, complete an updated inventory report.</u>
- 5. <u>Contact the CVP.</u> Call the main CVP line at 860-509-7929 so that staff can direct you to someone who can promptly address your excursion.
 - CVP staff will ask you to provide all of the information assessed above as well as the data from the logger. They will use this to provide viability data when possible.
 - If able, providers may also contact vaccine manufacturers for stability/viability information.
- 6. Submit a return form and spoilage letter for any vaccines deemed non-viable.

Emergency Response Worksheet

What to do in case of a power failure or other event that results in vaccine storage outside of the recommended temperature range

Follow these procedures:

- 1. Close the door tightly.
- 2. Ensure the vaccine is kept at appropriate temperatures. Make sure the refrigerator or freezer is plugged in and working properly, or move the vaccines into proper storage conditions as quickly as possible.
- 3. Do NOT discard the affected vaccines unless directed to by your state/ local health department and/or the manufacturer(s). Label the vaccines "Do Not Use" so that the potentially compromised vaccines can be easily identified.
- 4. Notify the state/local health department or call the manufacturer (see manufacturers' phone numbers below).
- 5. Document the inventory of affected vaccines below and document the circumstances of the event and the actions taken on the Vaccine Storage Troubleshooting Record (see www.immunize.org/catg.d/p3041.pdf).

Vaccines Stored in Refrigerator

Vaccine	Manufacturer	Lot #	Expiration Date	# of Doses (i.e., not # of vials)

Vaccines Stored in Freezer

Vaccine	Manufacturer	Lot #	Expiration Date	# of Doses (i.e., not # of vials)

Important Contact Information:

Vaccine Manufacturers

Dynavax Technologies (844) 889-8753 (877) 633-4411 Protein Sciences Corp. (800) 822-2463 MedImmune, Inc. Emergent BioSolutions ★1 (866) 300-7602 Merck & Co., Inc. Sanofi Pasteur (800) 822-2463 (800) 444-2080 GlaxoSmithKline PaxVax ★2,3 (888) 533-9053 (901) 432-3920 (877) 356-8368 Segirus MassBiologics (617) 474-3220 Pfizer Inc. (800) 438-1985 Valneva ★4 (301) 556-4500

- ★Manufacturer for less commonly used vaccine:
- 1. anthrax (Biothrax) 2. typhoid (Vivotif)
- 3. cholera (Vaxchora)
- 4. Japanesè encephalitis (Ixiaro)

Healt	h De	partn	nents

Local Health Department phone State Health Department phone

Adapted by the Immunization Action Coalition, courtesy of the Michigan Department of Community Health

Technical content reviewed by the Centers for Disease Control and Prevention

BERLINGER EXCURSION FAQ/TROUBLESHOOTING

1) How do I clear the X from My data logger?

a. To clear the X from the data logger the provider needs to use the "Read" button to review all data related to any excursions. If the excursion spanned multiple days or there is more than one non-related excursion they will need to review the data from each individual one before the X will leave the display.

2) HOW DO I DOWNLOAD MY REPORT?

- a. There is a USB plug built into the display portion of the data logger. Disconnect the probe from the display and bring the display to a computer. Plug the USB into one of the USB ports on the computer. The screen on the display will go blank and the data logger will install all of the software and drivers automatically, this process can take a few minutes. In most scenarios, a file folder will pop up automatically with a .txt file and a .PDF file. If this does not happen, instruct the provider to click on their "Start" button or "Windows" icon on the bottom left of their screen, go to Computer, and look for Fridge-tag or FT-2L in their list of drives on the left side of the "Computer" menu screen.
- b. If providers do the above and still can't pull up their reports, it is possible that their USB drives have been disabled by their IT people. Some of the larger networks do this to protect patient information from being downloaded. If you suspect this, have them contact whoever handles their IT.

3) WHEN I DOWNLOADED MY DATA/CHECKED MY MINIMUM AND MAXIMUM TEMPERATURES THERE WERE OUT OF RANGE TEMPERATURES, BUT I NEVER GOT AN ALARM.

a. The Berlinger is programmed to alarm once a unit has been above the acceptable range (46°F/8°C for the refrigerator, 5°F/-15°C for the freezer) for a period of 1 hour or more. It will alarm for a below range refrigerator excursion (below 36°F) after 15 minutes. If the unit goes out of range but does not meet one of these time requirements, it will not show an alarm. If the unit has multiple small excursions that are not consecutive and do not trigger an alarm, there is still the potential for the unit to be out of range for more than the total time required to report.

4) My temperatures have been in range since the data logger was installed and all of a sudden it's out of range. What happened?

- a. This really needs to be answered on a case by case basis, but a few possible avenues to explore are listed below.
 - i. Was the probe moved to a different location in the unit? Is it sitting directly on a glass shelf or under any cooling vents?
 - ii. Were the unit doors left ajar at any point?
 - iii. Does the functioning of the unit appear to be declining? Check if the minimum and maximum temperatures span/go beyond the distance of the acceptable range in a single day.
 - iv. Did the room temperature spike or drop dramatically? The ambient air temperature in the room can affect how hard a storage unit needs to function, and subsequently the internal temperatures.
 - v. Was there a decline in use? Opening and closing the storage unit door will have an effect on the unit temperature and if it is used to compensating for frequent use, a sudden decrease can result in an excursion.

PDF document of the Fridge-tag® 2

Identification number: Activation date Date and time of report creation: Upper alarm limit:

Lower alarm limit:

BDCV00969 11/18/2016 05/01/2017 08:52h Above +46 4°F for 1h Below +35.6°F for 15min

1

								Upper alarm limit					Ext. sensor connection error				
No.	Date (MM/dd/yyyy) 2	Events*	Average temp.	Status 5	Min. temp.	Duration out of range 7	Alarm trigger time 8	Alarm ambient temp.	Status 9	Max. temp	Duration out of range 11		Alarm ambient temp.	Status 13	Duration 14		Signature / notes Action taken
1	Today	am	+43.8°F	In progress	+42.6°F	0min			In progress	+46.0°F	0min			In progress	0min		
2	04/30/2017		+43.7°F	ok	+42.4°F	0min		16	ok	+45.8°F	0min	1	16	ok	0min	1	
3	04/29/2017			ok	+42.8°F	0min			ok		0min			ok	0min	-	
4	04/28/2017	am	+44.6°F	ok	+40.1°F	0min			ALARM	+52.7°F	4h 42min	15:09h	+73.9°F	ok	0min		
5	04/27/2017	am	+42.6°F	ok	+39.2°F	0min			ok	+47.1°F	12min			ok	0min		111
6	04/26/2017	am	+42.9°F	ok	+41.1°F	0min			ok	+44.7°F	0min			ok	0min		
7	04/25/2017	am	+42.9°F	ok	+41.5°F	0min			ok	+45.1°F	0min			ok	1min		
8	04/24/2017	am	+42.6°F	ok	+38.8°F	0min			ok	+45.6°F	0min			ok	0min		
9	04/23/2017		+42.6°F	ok	+41.3°F	0min		1	ok	+44.9°F	0min			ok	0min		
10	04/22/2017		+42.8°F	ok	+41.3°F	0min			ok	+44.9°F	0min			ok	0min	4	
11	04/21/2017	am	+42.8°F	ok	+41.0°F	0min			ok	+45.1°F	0min			ok	0min	-	
12	04/20/2017	am	+42.8°F	ok	+39.0°F	0min	1		ok	+45.1°F	0min		1	ok	0min		1
13		am	+42.8°F	ok	+41.0°F	0min			ok	+45.6°F	0min	1	P	ok	0min	1 1 1 1	
		am	+42.6°F	ok	+35.9°F	0min			ok	+46.2°F	0min	-		ok	1min		
		am	+42.8°F	ok	+41.1°F	0min			ok	+46.0°F	0min	1 1		ok	0min		
	04/16/2017			ok	+41.0°F	0min			ok	+45.1°F	0min			ok	0min		
17	04/15/2017		+42.8°F	ok	+38.8°F	0min			ok	+45.8°F	0min			ok	0min		
	04/14/2017		+42.2°F	ok	+38.8°F	0min			ok	+44.9°F	0min			ok	0min		
19	04/13/2017		+42.8°F	ok	+41.0°F	0min			ok	+45.1°F	0min	11	-	ok	0min		
	04/12/2017			ok	+41.1°F	0min		-	ok	+45.3°F	0min		1	ok	0min		
	04/11/2017			ok	+41.1°F	0min	je T		ok		0min			ok	0min	-	
22	04/10/2017			ok	+41.0°F	0min	11 71	2 - 9	ok		0min			ok	0min	-	
23	04/09/2017			ok	+39.2°F	0min	1		ok		0min			ok	0min		
24	04/08/2017			ok	+41.9°F	0min			ok	+44.6°F	0min	-	11	ok	0min		
25	04/07/2017	am		ok	+38.6°F	0min			ok	+47.3°F	10min			ok	0min		
26		am	+42.9°F	ok	+41.3°F	0min			ok	+44.9°F	0min			ok	0min		
27		am		ok	+41.0°F	0min			ok	+44.9°F	0min			ok	0min		
		am		ok	+38.3°F	0min			ok	+46.5°F	1min			ok	2min		
		am		ok	+38.3°F	0min			ok	+46.2°F	0min			ok	0min		
30	04/02/2017		+42.8°F	ok	+41.0°F	0min		-	ok	+44.7°F	0min			ok	0min		

* t = time / date changed, am/pm = Status checked

- 1. Logger specification including alarm parameters.
- 2. Date of reading
- 3. Will show when the status of the logger was checked (i.e. when they reviewed the data for the excursion) or if they changed the time/date in the logger menu.
- 4. The average temperature for the 24 hour period.
- 5. ALARM = Excursion parameters met for the lower limit.
- 6. Minimum temperature for 24 hour period. This is what should be reported when relaying excursion information.
- 7. Total time spent below the acceptable range. There may be a cumulative time out of range in this field, but no ALARM value in field 5. See point 3 on page 1.
- 8. Time of day the alarm was activated. 24 hour format.
- 9. ALARM = Excursion parameters met for the upper limit.

- 10. Maximum temperature for 24 hour period. This is what should be reported for excursions above the acceptable range.
- 11. Total time spent above the acceptable range. There may be a cumulative time out of range in this field, but no ALARM value in field 5. See point 3 on page 1.
- 12. Time of day the alarm was activated. 24 hour format.
- 13. ALARM = Excursion parameters met for length of time the probe has been disconnected.
- 14. Total time the probe has been disconnected from the display.
- 15. Time of day the alarm was activated. 24 hour format.
- 16. Ambient room temperature at the time of the excursion. Loggers purchased by providers may not have this data.

	ent any unacceptable vaccine	e storage event, such as expo	ng Record (check one) Reformer Reformer Reformer (check one) Reformer Refor	outside the manufacturers	Freezer s' recommended storage ranges.			
Date & Time of Event If multiple, related events occurred, see Description of Event below.	occurred, at the time the problem was discovered		Room Temperature at the time the problem was discovered	Person Completing Report				
Date:	Temp when discovered:		Temp when discovered:	Name:				
Time:	Minimum temp:	Maximum temp:	Comment (optional):	Title:	Date:			
· Inventory of affected vaccines, inc	event and last documented reluding (1) lot #s and (2) where was in the storage unit? For n any storage problems with	ther purchased with public (example, were there water b this unit and/or with the affe	ure in acceptable range (2° to 8°C [36° to 46°F] for refrige for example, VFC) or private funds (Use separate sheet ottles in the refrigerator and/or frozen coolant packs in ected vaccine?	f needed, but maintain th	o 5°F] for freezer) ne inventory with this troubleshooting record.			
	placed in proper storage conc le manufacturer[s].) incident? (For example, supe	ditions? (Note: Do not discar ervisor, state/local health dep	er the vaccine might still be viable!) rd the vaccine. Store exposed vaccine in proper conditio partment, manufacturer—list all.)	ns and label it "do not use	e" until after you can discuss with your state/			
Results • What happened to the vaccine? W	/as it able to be used? If not, v	was it returned to the distribu	utor? (Note: For public-purchase vaccine, follow your sta	nte/local health departmen	nt instructions for vaccine disposition.)			



WARNING! EXPENSIVE VACCINE IN STORAGE!

¡AVISO! Contiene vacunas caras.

DO NOT TURN OFF CIRCUIT BREAKER #___

No apague el interruptor de circuito #____

In the event of an electrical problem, immediately contact

Si hay un problema con la electircidad, comuniquese inmediatamente con

IMMUNIZATION ACTION COALITION Saint Paul, Minnesota • 651-647-9009 • www.vaccineinformation.org • www.immunize.org