Blue Folder



Connecticut Vaccine Programs

Pediatric Connecticut Vaccine Program (CVP)



Connecticut Vaccines for Adult Program (CVFA)



Contact Information

Main Phone: 860-509-7929 (M-F 8:30AM-4:30 PM)

Secure Fax: 860-706-5429

Main Email: dph.immunizations@ct.gov

CVP Email: immi.dph@ct.gov

HelpDesk: Submit a Request

Webpage: Immunization Program

Mailing Address: Department of Public Health

Immunization Program

410 Capitol Avenue, MS# 11 MUN

P.O. Box 340308

Hartford, Connecticut 06134

Connecticut Vaccine Programs

Childhood Program

The <u>Vaccines for Children Program</u> (VFC) is a federal program that provides all Advisory Committee on Immunization Practices (ACIP) recommended vaccines at no cost to children who might not otherwise be vaccinated because of inability to pay. Not all children are eligible for the VFC Program.

The Connecticut Vaccine Program (CVP) is Connecticut's expanded pediatric vaccination program. The CVP is state and federally funded (through the VFC Program) and provides vaccines at no cost to all children under the age of 19 years, regardless of insurance status.

Adult Program

The Connecticut Vaccines for Adults Program (CVFA) provides certain adult vaccinations at no cost to healthcare providers for uninsured adults ages 19 years and older. Not all providers are eligible for this program. Those eligible include Public Health Departments or Federally Qualified Health Care Centers (FQHC's). Vaccines purchased and administered through this program are funded using limited federal 317 funds.

Updated 2024 BLUE FOLDER Click here to visit our webpage

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

CONNECTICUT VACCINE PROGRAM

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410 Capitol Avenue, MS #11MUN, P.O. Box 340308, Hartford, CT 06134 / Tel (860) 509-7929 / Fax (860) 706-5429



Connecticut Vaccine Program

VFC Provider Information

How Do I Enroll/Re-Enroll in CVP and/or CVFA?

Re-enrollment for existing providers occurs annually from October through December. New providers can enroll to join the CVP or CVFA program at any time. All enrollments/re-enrollments are done electronically in CT WiZ.

All public and private health care providers who receive vaccine from the Connecticut Vaccine Program (CVP) and/or the Connecticut Vaccine for Adult (CVFA) Program must re-enroll electronically in CT WiZ. This enrollment provides shipping information and helps to determine the amount of vaccine to be supplied. The enrollment is also used to compare estimated vaccine needs with actual vaccine supply. The CVP and CVFA will keep these enrollments in CT WiZ with the SIGNED "Provider Agreement". Any updates to clinic information such as: address, delivery hours, or staff can be made directly in CT WiZ. You must complete one enrollment for each office/site/satellite office.

New Provider Enrollment

If you are a new provider interesting in enrolling in either the CVP or CVFA Program, complete the appropriate enrollment steps here.

Existing Provider Re-enrollment

If you are a currently enrolled CVP or CVFA provider, please review the <u>re-enrollment steps</u> before you begin.

CONNECTICUT VACCINE PROGRAMS (CVP) VACCINE FRAUD & ABUSE STATEMENT





COOPERATION

Compliance with the Vaccines for Children (VFC), Connecticut Vaccine Program (CVP), and Connecticut Vaccines for Adults Program (CVFA) requirements are an important step in preventing fraud and abuse of state and federal resources. The VFC, CVP, and CVFA programs distribute approximately \$88 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.

The lack of adherence could lead to fraud and abuse charges for providers. This non-compliance may occur due to an unintentional lack of understanding of program requirements, or the behavior may be intentional. The terms "fraud" and "abuse" related to VFC are consistent with the definitions in Medicaid regulations (42 CFR § 445.2). 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:

Failing to comply with any part of the Provider Agreement	Failing to screen for and document eligibility status at
(+Failing to implement provider enrollment requirements of	each visit
VFC program)	
Providing VFC vaccine to non-VFC-eligible children	Failing to maintain VFC records for a minimum of three
	years
Selling or otherwise misdirecting VFC vaccine	Failing to fully account for VFC-funded vaccine
Billing a patient or third party for VFC vaccine	Failing to properly store and handle VFC vaccine
Charging more than the established maximum fee for	Over-ordering VFC vaccine (e.g., quantities or patterns
administration of VFC vaccine	do not match the provider's profile)
Denying VFC-eligible children VFC-funded vaccine because	Waste of VFC vaccine
of parents' inability to pay the administration fee	

^{*}This list provides examples only and should not be considered comprehensive.

FRAUD AND ABUSE HURTS EVERYONE!

CVP (Pediatric) ELIGIBILITY SCREENING & DOCUMENTATION REQUIREMENTS

Connecticut Department of Public Health

Vaccines are provided by both **federal and state funding**. Patient screening is necessary to ensure that children only receive the specific vaccine(s) for which they are eligible.

1. SCREEN FOR CVP ELIGIBILITY

Staff are required to screen ALL children (birth through 18 years) in the medical practice immunization encounter prior to administering CVP vaccines.

2. DOCUMENT THE PATIENT'S ELIGIBILITY

Three important elements are required for documenting patient eligibility include:

- 1. Date of screening;
- 2. Initials/name of person conducting the screening;
- 3. Patient's eligibility category. Use the table below to determine the appropriate category.

	Category Patient Description		Typical EMR/EHR Categories	
le	(A) Medicaid	Is enrolled in Medicaid – Husky A	Medicaid/Medicaid Managed Care VFC eligible – Husky A	
	(B) Uninsured	Has no health insurance coverage (self-pay)	UninsuredSelf-pay	
VFC-Eligible	(C) American Indian /Alaskan Native	Self-identifies as American Indian/Alaska Native. This requires no additional proof, and providers are not required to verify the patient's eligibility declaration.	American Indian/Alaskan Native	
VF((D) Under-insured (FQHC)	Has private 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)	
Eligible	(E) Under-insured (not FQHC)	Has private 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's office.	Under-insured, not FQHC Patient	
STATE E	(F) State-specific eligibility / S-CHIP	Is enrolled in the CHIP program – Husky B, a separate state health insurance that is NOT a Medicaid expansion program.	 State-specific eligibility (S-CHIP plan) State-specific eligibility – Husky B 	
ST	(G) Private*	Is privately insured.	Not VFC eligiblePrivate Insurance	

Please refer to CVP eligibility criteria for a complete list of offerings.

3. MAINTAIN PATIENT ELIGIBILITY RECORDS

Providers are required to document the results of the screening elements for every patient at every immunization encounter. Use either of these CVP-compliant record keeping systems:

- Electronic Medical Record (EMR)/Electronic Health Record (EHR)
 - **Note**: if the EMR/EHR does not capture all the necessary screening elements, the documentation can be recorded in the system's notes section or:
- CVP Patient Eligibility Screening Record Form

<u>Providers are required to maintain patient eligibility screening records for a minimum of 3 years and provide proof of documentation upon request to DPH.</u>

4. COMMUNICATE THE PATIENT'S ELIGIBILITY

The person who determines a patient's CVP eligibility should communicate it to the person who administers or bills for the immunization, if different. The office needs a system so the appropriate staff know the patient's eligibility category.

CVFA (Adult) ELIGIBILITY SCREENING & DOCUMENTATION REQUIREMENTS

Connecticut Department of Public Health

Vaccines are provided by limited 317 **federal funding**. Patient screening is necessary to ensure that adults receive the specific vaccine(s) for which they are eligible.

1. SCREEN FOR CVFA ELIGIBILITY

Staff are required to screen ALL adults ≥ 19 years of age and older in the medical practice immunization encounter prior to administering CVFA vaccines.

2. DOCUMENT THE PATIENT'S ELIGIBILITY

Three important elements are required for documenting patient eligibility include:

- 1. Date of screening;
- 2. Initials/name of person conducting the screening;
- 3. Patient's eligibility category. Use the table below to determine the appropriate category.

	Category	Patient Description	Typical EMR/EHR Categories
• Patient does not have health insurance • Patient has insurance but insurance does not cover vaccines, limits the vaccines covered or caps vaccine coverage at a certain amount • Patient is ≥19 years old		 Uninsured - Adult 317- Adult Underinsured - Adult 	
ult Patient Categories	(I) Is enrolled in Medicare	Is enrolled in Medication and only for patients ≥65 years old	MedicareInsured > 65
Other Adult Pa Eligibility Cate	(J) Is privately insured, (includes Medicaid insurance but not Medicare)	Is privately insured and patient is ≥19 years old	Not VFC eligiblePrivate InsuranceInsured 19-64
Oth	(K) Insurance status not checked	Patients ≥19 years old and eligibility is not determined in the EHR.	Unknown

Please refer to CVFA eligibility criteria for a complete list of offerings.

5. MAINTAIN PATIENT ELIGIBILITY RECORDS

Providers are required to document the results of the screening elements for every patient at every immunization encounter. Use either of these CVFA-compliant record keeping systems:

- Electronic Medical Record (EMR)/Electronic Health Record (EHR)
 Note: if the EMR/EHR does not capture all the necessary screening elements, the documentation can be recorded in the system's notes section or:
- CVFA Patient Eligibility Screening Record Form

<u>Providers are required to maintain patient eligibility screening records for a minimum of 3 years and provide proof of documentation upon request to DPH.</u>

6. COMMUNICATE THE PATIENT'S ELIGIBILITY

The person who determines a patient's CVFA eligibility should communicate it to the person who administers or bills for the immunization, if different. The office needs a system so the appropriate staff know the patient's eligibility category.

CONNECTICUT VACCINE PROGRAM: VFC & CVFA

RECOMMENDED BACK-UP PROTOCOL FOR VACCINE RECOVERY

	ame			
	nP			
Person Co	ompleting Form	Date		
	- UP PLAN MUST BE REVIEWED ANNUAL BLE FOR VACCINE CHANGES. PLEASE RE			
when you	iment offers guidance for developin ur refrigerator or freezer malfunction s about vaccine transportation or st	ns due to mechanical failure or natu		
VACCINE	RECOVERY PLAN			
	 i. 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 los and that they have access on weekends and off hours. 			
	es of designated employees:			
	NAME/TITLE	CELL PHONE	HOME PHONE	
If y pha	call for inclement cor	e, or an employee's home. with the site to store your vaccine the ditions (severe ice/snowstorms, homent cannot be fixed, or the power	nere when weather predictions urricanes etc.) and when your er cannot be restored within 6	
	LOCATION NAME/PHONE #	CONTACT PERSON	HOME PHONE	

- 2. 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 timeframe for the restoration of electrical power cannot be determined, contact your back-up location for temporary storage of vaccine.
- 3. 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.

iii. Transport of Vaccine

- 1. Conduct an inventory before you transport vaccine.
- 2. Package vaccine in a well-insulated container with ice packs.
- 3. 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.
- 4. 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.

iv. Staff Training/Posted Information

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

v. 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 TIPS

- 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.

CONNECTICUT VACCINE PROGRAM: VFC & CVFA VACCINE MANAGEMENT PLAN

Facility Name	PIN
Vaccine Coordinator	
Back-Up Coordinator	

PURPOSE

The purpose of this document is to ensure proper management of all 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/immunization/providers-landing-page/cvp

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.

Expired, wasted, spoiled, or lost vaccines are to be returned to McKesson. Please read and follow directions on how to <u>return vaccines</u> in CT WiZ.

PLEASE CONTACT THE CVP BY HELP DESK IF YOU REQUIRE FURTHER ASSISTANCE. SELECT: Immunizations (CT WiZ) – Clinic Administration – Report Vaccine Temperature Excursion – and select the sub-topic.



Connecticut Vaccine Program

Immunization Laws & Regulations

https://portal.ct.gov/immunization/laws-and-regulations

Laws & Regulations Medical Exemptions

Connecticut has laws requiring children to have specific vaccines before attending daycare or school. For Connecticut's immunization laws and regulations, visit our website. Connecticut requires medical providers to report administered vaccines to the state through CT WiZ. See below for information regarding immunization exemptions.

Non-Medical Exemptions

On April 28, 2021, Governor Lamont signed into law Public Act 21-6, "An Act Concerning Immunizations," which updates Connecticut's immunization requirements for students attending preK-12 schools, childcare programs, and institutions of higher education by *removing non-medical exemptions*.

To view the FAQs: Guidance Regarding Public Act 21-6

Medical Exemptions

Public Act 21-6 retains the prior law's medical exemption from immunization requirements for individuals who can document that the immunization is *medically contraindicated*.

In adherence to Section 7 of Public Act 21-6, healthcare providers are required by law to submit to the Connecticut Department of Public Health (CTDPH) all medical exemptions issued on or after July 1, 2021. Healthcare providers must submit the form issued by the department ("Student Medical Exemption Certificate for Required Immunizations") within the web-based portal established by the CTDPH.

To view the communication: Medical Exemption Reporting

Steps to report medical exemptions

- 1. Register as a submission user <u>here</u>
- 2. Login to the portal's submission page
- 3. Fill out the requested information
- 4. Submit

The portal can **generate and print a PDF copy** of the medical exemption. Providers can use this feature to share the entered information with the parent or guardian of the child and the school.

Out of state providers can submit the completed medical exemption form, but they need to register to use the portal.

PLEASE CONTACT THE CVP BY HELP DESK IF YOU REQUIRE FURTHER ASSISTANCE. SELECT: Immunizations (CT WiZ) – Medical Exemption Portal – I need assistance and share a brief description of the issue.

You Must Provide Patients with 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, NCIVA) requires a healthcare professional to provide 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 Immunize.org at www.immunize.org/vaccines/vis/about-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 40 languages on the Immunize.org website at www.immunize.org/vaccines/vis-translations/spanish/.

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

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 provide 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
- MMR and MMRV
- Td and Tdap
- meningococcal (MenACWY, MenB)
- hepatitis A
- pneumococcal conjugate
- hepatitis B
- poliorotavirus
- Hib
- varicella (chickenpox)
- HPV
- varicella (efficiel
- influenza (inactivated and live, intranasal)

For the vaccines not covered under NCVIA (i.e., adenovirus, anthrax, COVID-10, dengue, ebola, Japanese encephalitis, pneumococcal polysaccharide, rabies, RSV, smallpox/monkeypox, tick-borne encephaliatis, 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. When administering a vaccine under conditions of an emergency use authorization (EUA), an EUA fact sheet must be used.

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

FACT 2

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

CONTINUED ON THE NEXT PAGE

As of December 7, 2023, the most recent versions of the VISs are:

7 to 01 December 7	, 2020, the most
Adenovirus	1/8/20
Anthrax	1/8/20
COVID-19	10/19/23
Cholera	10/30/19
Dengue	12/17/21
DTaP	8/6/21
Ebola	6/30/22
Hepatitis A	10/15/21
Hepatitis B	5/12/23
Hib	8/6/21
HPV	8/6/21
Influenza	8/6/21
Japanese enceph	8/15/19
MenACWY	8/6/21
MenB	8/6/21
MMR	8/6/21

MMRV	8/6/21
Multi-vaccine	7/24/23
PCV	5/12/23
PPSV23	10/30/19
Polio	8/6/21
Rabies	6/2/22
RSV	10/19/23
Rotavirus	10/15/21
Smallpox/monkeypo	x 11/14/22
Td	8/6/21
Tdap	8/6/21
Tick-borne encephali	tis 12/7/23
Typhoid	10/30/19
Varicella	8/6/21
Yellow fever	4/1/20
Zoster	2/4/22





used, the goal is to provide a current VIS just prior to vaccination. (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 VIS 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, Vaxelis) you should provide the patient with individual VISs for the component vaccines, or use the Multi-Vaccine VIS.

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 40 languages, visit the Immunize.org 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)
- In addition, providers must record:
- The office address and name and title of the person who administers the vaccine
- The date the vaccine is

• The date the VIS is provided

(i.e., the date of the visit when

the vaccine is administered)

administeredThe 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:

Immunize.org

- VIS general information and translations in more than 40 languages: www.immunize.org/vaccines/vis/about-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



Vaccine Adverse Event Reporting System A National Program for Monitoring Vaccine Safety

Vaccine Adverse Event Reporting System

Vaccine Adverse Event Reporting System (VAERS)

The Vaccine Adverse Event Reporting System (VAERS) is a national program managed by the U.S. Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) to monitor the safety of all vaccines licensed in the United States. VAERS collects and analyzes information from reported adverse events that occur after vaccination. An "adverse event" is any health problem or "side effect" that happens after a vaccination. VAERS cannot determine if an adverse event was caused by a vaccine, but can help determine if further investigations are needed.



VAERS serves as an early-warning system to detect problems that may be related to vaccines. The system relies on reports from healthcare providers*, vaccine manufacturers, and the general public. Reporting gives CDC and FDA important and timely information to help identify health concerns and ensure vaccines are safe in order to protect the public's health.

VAERS staff evaluate adverse events of concern.

VAERS defines "serious adverse events" as those involving death, hospitalization, lifethreatening illness, persistent or significant disability/incapacity, or certain other medically important conditions. CDC and FDA evaluate individual reports and the reporting patterns to determine if in-depth reviews are needed before conducting additional studies. Once adverse events of concern are identified in VAERS they may be monitored in other immunization safety systems to evaluate if the event occurs more frequently after vaccination or to conduct more controlled scientific studies to confirm if a particular adverse event is related to a vaccination and identify any specific risk factors.

Anyone can report to VAERS.

Anyone can submit a report to VAERS, including patients, family members, healthcare providers, and vaccine manufacturers. CDC and FDA encourage anyone who experiences an adverse event after any vaccination to report to VAERS.

There are 3 ways to report.

- 1. Online at a secure Web site: https://secure.vaers.org/VaersDataEntryintro.htm.
- 2. Fax a completed VAERS form toll-free to 1-877-721-0366.
- 3. Mail the completed form to VAERS, P.O. Box 1100, Rockville, MD 20849-1100. You may download and print a VAERS form at http://vaers.hhs.gov/pdf/vaers_form.pdf, or you may get a form mailed to you by calling toll-free 1-800-822-7967, or by sending a faxed request to 1-877-721-0366.

VAERS data are available to the public.

VAERS data are made available on the VAERS Web site and can be searched for summaries on particular adverse events reported for specific vaccines. Personal identifying information (name, date of birth, address, etc.) is removed prior to posting the public data. The data is also screened to remove duplicate reports.

*Healthcare providers are required to report adverse events to VAERS including those found in the Reportable Events Table.







For more information about VAERS:

E-mail: info@vaers.org

Phone: 1-877-822-7967

Web site: www.vaers.hhs.gov



Connecticut Vaccine Program

Vaccine Administration Information

https://portal.ct.gov/immunization

PEDIATRIC 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).

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

Inactivated Polio Vaccine (IPV)

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

Tetanus, Diphtheria, and Pertussis 7 through 9 years of age

https://www.cdc.gov/vaccines/schedules/downloads/child/job-aids/tdap-1.pdf

Tetanus, Diphtheria, and Pertussis 10 through 18 years of age

https://www.cdc.gov/vaccines/schedules/downloads/child/job-aids/tdap-2.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/p406001.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

ADULT VACCINE ADMINISTRATION RESOURCES

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

RECOMMENDED IMMUNIZATION SCHEDULE FOR AGES 19 YEARS OR OLDER

https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf

ADDITIONAL GUIDANCE

Pneumococcal Vaccine Schedules for Adults

https://www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf

Check out <u>PneumoRecs VaxAdvisor</u>. This free app quickly and easily provides patient-specific pneumococcal vaccine guidance.

Shingles (Herpes Zoster)

https://www.cdc.gov/vaccines/vpd/shingles/hcp/index.html

RSV

For Older Adults https://www.cdc.gov/vaccines/vpd/rsv/public/older-adults.html
For Pregnant People https://www.cdc.gov/vaccines/vpd/rsv/public/pregnancy.html

HPV

https://www.cdc.gov/vaccines/vpd/hpv/hcp/index.html

Influenza

https://www.cdc.gov/vaccines/vpd/flu/hcp/index.html

DTaP, Tdap, and Td Catch-up Vaccination Recommendations by Prior Vaccine History and Age

https://www.immunize.org/wp-content/uploads/catg.d/p2055.pdf

SUMMARY OF RECOMMENDATIONS FOR ADULT IMMUNIZATION

https://www.immunize.org/wp-content/uploads/catg.d/p2011.pdf

SCREENING CHECKLIST FOR CONTRAINDICATIONS TO VACCINES FOR ADULTS

English - https://www.immunize.org/wp-content/uploads/catg.d/p4065.pdf

Spanish - https://www.immunize.org/wp-content/uploads/catg.d/p4065-01.pdf

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

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

CDC's Bridge Access Program – COVID-19

https://www.cdc.gov/vaccines/programs/bridge/index.html



Connecticut Vaccine Program

Information Resources

VACCINE COORDINATOR ROLE

Every clinic is required to have a designated primary vaccine and back-up vaccine coordinator who is responsible for overseeing the vaccine supplied by the CVP (Connecticut Vaccine Program) or the CVFA (Connecticut Vaccine for Adults Program). The primary coordinator is responsible for maintaining compliance with vaccine management. Vaccine management includes vaccine ordering, inventory and reconciliation, storage and handling, temperature monitoring, transfer of vaccines, administering and managing an emergency plan. The backup vaccine coordinator is accountable when the primary vaccine coordinator is not available.

Vaccine Coordinator "To Do" List

- Review information and bookmark these website pages in your internet browser:
 - CVP and CVFA Provider Page
 - Vaccine Providers Page
 - CT WiZ Training Page
 - <u>Inventory management-step by step instructions with slides</u>
 - Provider Enrollment Page
 - New coordinators, please ask an active CT WiZ user at your clinic to add you as a "new contact in CT WiZ. After you have been added to clinic staff in CT WiZ, request <u>User Access</u> to <u>CT WiZ</u>.
 - Complete these steps for CT WiZ inventory management training.
 - Review <u>CT WiZ Training Page.</u> These trainings are specific to your clinic and you must find out if your clinic is reporting through the User Interface (UI) or through your EHR (HL7). This will determine which training applies to you and your clinic.
 - Review the self-paced Patient Management (UI or HL7) video on the CT WiZ Training Page.
 - If you are unsure whether your facility is reporting doses administered in the UI/direct data entry or if your facility has an EHR connected to the CT WiZ HL7 interface, please contact CVP so we can direct you to the correct inventory management training.

Responsibilities:

Storage and Handling: Managing vaccine inventory involves identifying vaccines upon receipt, account for total inventory supply, rotate stock and records temperatures. In the event of an emergency, the vaccine coordinator is responsible for troubleshooting and instituting a backup protocol to safeguard the vaccine inventory.

- Label and store state supplied vaccines separately from privately purchased vaccines.
- Immediately contact CVP if there are any discrepancies with your shipment.
- 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. Logs can be downloaded from the 'CVP Information for Provider' web page or click on the links: Refrigerator Charts <u>Fahrenheit</u> / <u>Celsius</u> and Freezer Charts <u>Fahrenheit</u> / <u>Celsius</u>.
- Capture minimum and maximum temperatures once daily from data logger thermometers.
- Download data logger reports monthly.
- For sites with state supplied Berlinger data loggers, review the <u>Berlinger Fridge Tag</u>, Videos and Support Documents.

Temperature Excursions: Submit a <u>help desk ticket</u> to report the excursion and to get next steps and instructions. If deemed non-viable a return will need to be made in CT Wiz.

- Acceptable temperature ranges: Refrigerator Temp between 2–8°C (36–46°F), and we aim for 5°C (41°F). Freezer Temp between: -50°C and -15°C (-58°F and +5°F).
- Try to determine source of excursion and immediately secure the vaccine in another storage unit with a data logger. Or initiate your back up plan.
- Label vaccine "do not use" until viability is determined.
- For additional information please refer to the Temperature Excursion Troubleshooting Document in the <u>Blue Folder</u> or on the web page.
- Download the temperature data from your digital data logger and submit the PDF summary report to DPH.immunizations@ct.gov.
- Document the excursion on troubleshooting log supplied in the Blue Folder. Please mark boxes of vaccines exposed to an excursion so they can be easily identified in case of a future incident as excursions are cumulative.

Vaccine Ordering and Reconciliation: Vaccine orders should be based on population size and usage. It's a good idea to order vaccines more frequently than to have too much inventory on hand. Vaccine reconciliation must be done monthly even if you do not intend to order vaccine.

 Report all days that the practice will be closed during the coming month to prevent vaccines from getting delivered when the site is closed in CT WiZ. This can be done by updating your delivery hours in CT WiZ. • When submitting an order/managing vaccines through CT WiZ please refer to the following web page: Inventory management (ct.gov).

Transferring Vaccine: You should initiate transfer of vaccines to another CVP site willing to use the vaccines at least 4 months prior to the expiration date if you will not be administrating them to prevent wastage.

- Contact CVP providers in the area willing to accept vaccine transfer or view the list of <u>CVP providers</u> to find a provider in your area.
- Package vaccine appropriately to maintain the cold chain.
- Deliver vaccine to the accepting provider, have the receiving provider sign and date the vaccine.
- Submit the transfer in CT WiZ. Please refer to CT WiZ Inventory Management web page for additional information on how to complete the transfer in CT WiZ.

Returns and Wastage: Vaccines should be monitored closely to prevent wastage. If wastage occurs, those doses wasted will need to be recorded in CT WiZ. Expired vaccines and vaccines that have spoiled due to a breach in the cold chain should be returned to McKesson. Broken vials and partial vials should be adjusted out of your inventory on hand in CT WiZ since these cannot be physically returned to McKesson. Please make sure you include a comment as to why the doses are being wasted in your adjustment. If your vaccine has expired or is not viable due to a temperature excursion, please complete a return in CT WiZ. These doses will need to be returned to McKesson. Some wastage situations may require restitution as determined by the state in accordance with the Restitution Policy.

Reporting Wastage:

- Separate vaccine wasted from main supply and label "DO NOT USE"
- When submitting through CT WiZ determine if you document as a return to McKesson or an inventory adjustment. Refer to <u>CT WiZ Inventory Management</u> web page for guidance. Remember "Clinic Comments" on the return screen is how you document the spoilage letter for expired/non-viable vaccines.
- Use the return UPS label received via email after the return has been submitted and approved in CT WiZ from Quantum UPS to ship any unopened vials and pre-filled syringes back to McKesson.

Workflow:

Daily	Monthly	Yearly
 Check and record storage unit temperatures twice per day (first thing in the morning and before leaving for the day) on temperature logs. Record min/max at least once per day. Ensure temperatures are within acceptable range throughout the day. Refrigerator: between 36° and 46° Fahrenheit (2°-8°Celsius). Freezer temperatures are below 5°Fahrenheit (-15°Celsius). 	 Submit vaccine inventory reconciliation and order (if needed) directly in CT WiZ. Download and review data loggers reports. Inspect vaccine shipment and vaccine temperature upon arrival. Match packing slip with order for accuracy. Store vaccines immediately in the appropriate storage unit Contact CVP if any discrepancies. Rotate stock and inspect inventory; review dates of expiration to avoid wastage issues. Initiate transfer of vaccine when necessary and ensure proper vaccine transport. 	 Submit re-enrollment in CVP and/or CVFA via CT WiZ. Review any CDC modules assigned for that year. These can be found on the re enrollment webpage. Review/revise and date Vaccine Management and Back-up Plans. Review certificates of calibration on all data logger thermometers and ensure that the certificates are not due to expire. Ensure certificates do not expire on the same day. Purchase replacement data loggers if necessary.

As Needed

- Take action if the temperatures are outside the appropriate temperature ranges.
- Update "Clinic Tools" in CT WiZ with any staff or clinic changes.
- Update delivery hours in CT WiZ to reflect any days the clinic will be closed.
- Conduct routine maintenance on storage units; Keep coils dust free around units and defrost freezers, when needed.
- Review all communications received from CVP and review with staff.

Contact CVP staff with any questions on concerns regarding the CVP Program by calling 860-509-7929 Questions or concerns regarding CT WiZ please submit a <u>Help desk ticket</u>.

VACCINE EDUCATION MATERIALS

Education materials are free of cost through the Immunization Program. Items such as coloring books or booklets can be ordered using a <u>fillable ordering form</u> and used in your clinic. In stock items should be allowed 3-4 processing and delivery time.

CVP/CVFA FINANCIAL RESTITUTION POLICY



The Financial Restitution Policy was developed for the purpose of replacing state supplied vaccines 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 (CVP) and Connecticut Vaccines for Adults Program (CVFA). The policy also includes a provision that providers who notify the State of vaccines they will not be administering four months or more prior to expiration will not be financially liable for replacing any doses that ultimately expire. When reporting wastage of any kind, providers should document the staff's use of the practice's back-up protocol for vaccine recovery plan.

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 or Merck 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;
- Storage and handling negligence by provider or office staff;
- 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. Provider will be responsible for the cost of vaccine for re- vaccination;
- 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, the Immunization Program Vaccine Coordinator makes the final determination for all restitution situations. Providers should always contact the Connecticut Vaccine Program for a determination regarding the viability of suspect vaccine.

- Vaccine shipped from McKesson or Merck that is damaged, improperly stored during transit, or not delivered to the provider in a timely manner;
- 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, this does not apply to vials wasted due to a temperature excursion;
- 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 and COVID vaccine;
- Extraordinary situations not listed above which are deemed by the CVP to be beyond the provider's control.

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 CVP 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 CVO an invoice showing that they have replaced all wasted doses.

PROCEDURE FOR FINANCIAL RESTITUTION

- Each incident reported will be reviewed on a case-by-case basis by the CVP to determine whether restitution will be required or if extenuating circumstances prevail.
- The provider will be required to submit an invoice to the CVP 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.

PROCEDURE FOR RETURNING VACCINE

- Complete a Vaccine Return in CT WiZ for unopened, expired, or spoiled vaccines. 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 non-viable vaccine

YOU CAN CONTACT THE CVP AT lmmi.DPH@ct.gov or submit a help desk ticket

SCHOOL-BASED HEALTH CENTERS

The following are CVP rules for practitioners who administer pediatric vaccinations at school-based health centers (SBHC). This is a supplement to the vaccine coordinator role document found in the <u>Blue Folder</u>. Additional resources are available from the <u>CDC</u> or through the <u>Immunization Action Coalition (IAC)</u>. *Bookmark <u>CVP-Information for Providers webpage</u> for updates and resources.

Every CVP clinic is required to have a designated primary and backup vaccine coordinator. SBHCs may have more frequent staff turnover so be sure that the correct staff is associated to the appropriate clinic.

- 1. Make sure that the new staff have completed the CDC required online training.
 - a. Vaccines for Children & Vaccine Storage and Handling
- 2. Request CT WiZ user access if new to CVP (request access as primary or backup coordinator)
 - a. If you already have a CT WiZ login, request to be linked to the appropriate clinic via the Help Desk.
- 3. Log into CT WiZ and update the necessary clinic staff information.

STORAGE OF VACCINES AND MONITORING OF TEMPERATURES

All CVP clinics are required to monitor vaccine temperature via a digital downloadable data logger (DDL). SBHCs may not be open every day of the week therefore it is important to adhere to the following:

- 1. Monitor and document daily temperature via hand-written logs for each day the clinic is open.
 - a. Review DDL summary data for all the days you have been away from the clinic to ensure temperatures did not go out of the acceptable range.
- 2. Download and review DDL report monthly (or more frequently).

BACK-UP AND MANAGEMENT PLAN

Make sure that you have a designated location that you can bring your vaccines to during school and summer breaks as well as during an emergency.

School Breaks (longer than 4 day weekend)

- 1. Enact backup plan/location for any school breaks longer than 4 days.
 - a. Package and transport all vaccine to back-up location including open vials of IPV. IPV can be transferred for storage purpose only.
 - b. Keep an inventory list with the vaccines for the receiving provider and for yourself.

This is important in case there is an excursion during the break and that provider needs to assess vaccines.

- c. Upon return make sure that the inventory is correct (number of doses and lot numbers).

 Sometimes back up locations receive stock from many PIN#s and you may take home the wrong vaccines.
- d. CT WiZ users do not need to do an inventory transfer in CT WiZ for storage purposes since all vaccine will be returned into inventory.

Going on Summer Break

- Review expiration dates of vaccines and transfer out any stock that will expire over the summer/or that you may notuse.
- 2. Hold onto flu vaccine because it needs to be returned after it expires, which you will do in the fall when you return.
- 3. Enact backup plan/location (same as above).
- 4. Enter transfers in CT WiZ when moving vaccine for any school break

Returning from Summer Break

- 1. Make sure your storage units and Digital Data Loggers (DDL) are working appropriately.
 - a. Refrigerators should maintain temperatures between 2° C and 8° C (36° F and 46° F).
 - b. Freezers should maintain temperatures between -50° C and -15° C (-58° F and +5° F).
 - c. Prior to storing state vaccines at the SBHC's location(s), make sure to have up to 72 hours of stable temperatures. It is the facility's responsibility to ensure that the vaccine storage units and thermometers are working properly, and a current certificate of calibration is maintained.

All CVP clinics are required to have a valid backup data logger with certificate of calibration that can function in either the fridge or freezer. This does not need to be on site, you can share with other SBHC locations. However, you need to have a document with the exact location and process to obtain it with a copy of the certificate attached to your back up plan.

OTHER REMINDERS

- Submit a monthly reconciliation in CT WiZ, even if you did not administer or are ordering any vaccines.
- Report to CVP all temperature excursions above range for 2 hours or more or below range for 15 min or more.



Connecticut Vaccine Program

Vaccine Storage & Handling Information

VACCINE STORAGE AND HANDLING RESOURCES

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

CDC VACCINE STORAGE AND HANDLING

https://www.cdc.gov/vaccines/hcp/admin/storage/index.html

- CDC Vaccine Storage and Handling Toolkit:_ https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf
- CDC Vaccine Storage Labels: https://www.cdc.gov/vaccines/hcp/admin/storage/guide/vaccine-storage-labels.pdf

AMERICAN ACADEMY OF PEDIATRICS (AAP)

https://www.aap.org/Vaccine Storage and Handling (aap.org)

- Data Loggers and Vaccine Monitoring: <u>Frequently Asked Questions (ct.gov)</u>
- Refrigerators, Freezers, and Vaccine Storage: https://downloads.aap.org/DOPCSP/BuyingGuide%28RF%29AddAccuvax.pdf

IMMUNIZATION ACTION COALITION (IAC)

https://www.immunize.org/askexperts/storage-handling.asp

- Temperature Logs
 - Refrigerators
 - Celsius: https://www.immunize.org/catg.d/p3037c.pdf
 - Fahrenheit: https://www.immunize.org/catg.d/p3037f.pdf
 - o Freezer
 - Celsius: https://www.immunize.org/catg.d/p3038c.pdf
 - Fahrenheit: https://www.immunize.org/wp-content/uploads/catg.d/p3038f.pdf
- Checklist for safe vaccine storage and handling: https://www.immunize.org/catg.d/p3035.pdf
- Vaccines with Diluents: How to Use Them: https://www.immunize.org/catg.d/p3040.pdf
- Vaccine Storage Troubleshooting Record: https://www.immunize.org/catg.d/p3041.pdf
- Emergency Response Worksheet: https://www.immunize.org/catg.d/p3051.pdf
- Do not unplug refrigerator or freezer!: https://www.immunize.org/catg.d/p2090.pdf
- Do not turn off circuit breaker: https://www.immunize.org/catg.d/p2091.pdf

TRANSPORTING VACCINE

CDC Packing Vaccines for Transport: https://www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf

BERLINGER DATALOGGER RESOURCES

- Excursion FAQ/Troubleshooting: <a href="https://portal.ct.gov/-/media/Departments-and-departments-departments-departments-departments-departments-departments-departments-departm
- Fridge-tag® 2 & 2L Support: https://www.berlingerusa.com/support

TEMPERATURE EXCURSIONS

• CDC Handling a Temperature Excursion: https://www.cdc.gov/vaccines/hcp/admin/storage/downloads/temperature-excursion-508.pdf

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. **Return vaccines to appropriate storage conditions**. Until a final determination has been made, vaccines should be stored in appropriate temperatures and labeled "**Do Not Use**". 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. **Download the temperature data from your digital data logger**. As of January 1, 2018, all providers are required to have a certified, calibrated, downloadable data logger. This information should be included with the help desk ticket when the excursion is reported.

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 involv	ved exposed to out o	f 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. Determine which vaccines were involved in the excursion and, if necessary, complete an updated inventory report.
- 5. <u>Submit a help desk ticket</u>. All vaccine excursions should be reported through our help desk system. Select Immunizations (CT WiZ) Clinic Administration Report Vaccine Temperature Excursion and select the sub-topic.
- 6. Submit a return form and spoilage letter for any vaccines deemed non-viable.

Vaccine Storage 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.
- 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.
- 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.

- For more detailed guidance on emergency vaccine storage and handling, including COVID-19 vaccines, see CDC's Vaccine Storage and Handling Toolkit at www.cdc.gov/vaccines/hcp/admin/storage/ toolkit/storage-handling-toolkit.pdf.
- 4. Notify the state/local health department or call the manufacturer (see manufacturers' phone numbers below).
- 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)	Funding Source Public (e.g., VFC), Private, Other

Vaccines Stored in Freezer

Vaccine	Manufacturer	Lot#	Expiration Date	# of Doses Funding Source (i.e., not # of vials) Public (e.g., VFC), Private, Other	

Vaccine Manufacturers

AstraZeneca	(800) 236-9933	GSK	(877) 356-8368	Pfizer ³	(800) 438-1985
Bavarian Nordic ¹	(844) 422-8274	MassBiologics	(617) 474-3220	Pfizer-BioNTech (COVID-19)	(877) 829-2619
CSL Seqirus	(855) 358-8966	Merck	(800) 672-6372	Sanofi U.S.	(800) 822-2463
Dynavax	(844) 375-4728	Moderna	(866) 663-3762	Valneva ⁴	(301) 556-4500
Emergent BioSolutions ²	(866) 300-7602	Novavax	(844) 668-2829	VBI Vaccines	(888) 421-8808

Manufacturer for less commonly used vaccine:

- 1. Bavarian Nordic: Rabavert (rabies), Jynneos (smallpox and mpox)
- 2. Emergent BioSolutions: Biothrax (anthax), Cyfendus (anthrax), Vaxchora (cholera), Vivotif (typhoid)
- 3. Pfizer: Ticovac (tick-borne encephalitis)
- 4. Valneva: Ixiaro (Japanese encephalitis), Ixchiq (chikungunya virus)

Health Departments

Local Health Department phone	State Health Department phone	