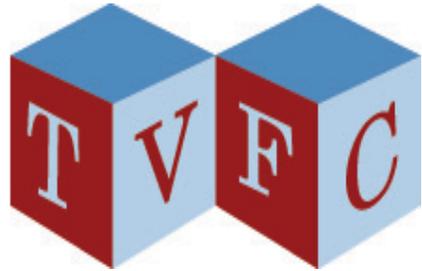


Texas Vaccines
for Children



PROVIDER MANUAL

2012



Texas Vaccines for Children Program PROVIDER MANUAL

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Texas Vaccines for Children



Since its inception in 1994, Texas has participated in the Federal Vaccines for Children Program (VFC). Our version is called the Texas Vaccines for Children Program (TVFC). The Program was initiated by the passage of the Omnibus Budget Reconciliation Act of 1993. This legislation guaranteed vaccines would be available at no cost to providers, in order to immunize children (birth through 18 years of age) who meet the eligibility requirements.

Today there are more than 3,500 Texas providers enrolled in TVFC. Texas leads the nation in the number of uninsured and underinsured children. We also have over 3 million Texas children on Medicaid (Federal Fiscal Year 2009 data). Many of these children are not receiving the complete series of immunizations required to protect them from vaccine-preventable diseases.

We need your help in order to ensure the health and future of Texas children.

If you are not enrolled in TVFC, please consider enrolling. The process is simple:

- fill out Provider Enrollment and Provider Profile forms,
- agree to screen for eligibility,
- agree to maintain screening records, and
- agree to maintain vaccine safety and inventory.

Under TVFC, the following groups of children (birth – 18 years of age) should receive free vaccines:

- uninsured or underinsured children,
- children who are covered by CHIP,
- children who are of Native American or Native Alaskan heritage, and
- children on Medicaid.

By enrolling in TVFC, you can provide numerous benefits to the families in your practice and to the people of Texas. One of the most important benefits is removing barriers to immunizations. For instance, you will no longer have to refer an uninsured child to a public health center for immunizations. TVFC removes the burden of the financial cost of vaccines, thereby eliminating the need to refer clients. Children are then kept in their “medical home,” which is beneficial to the provider and client. Families who are currently paying for vaccinations may be TVFC eligible.

There are cost savings of immunizing versus treatment for diseases to taxpayers. For example, for every dollar spent on DTaP vaccine, \$27.00 is saved in direct and indirect costs. Additionally, vaccine contracts are negotiated at a federal level, thus ensuring the lowest price and a standardized cost. Vaccine is ordered through regional state offices and is supplied to providers at no cost. A TVFC provider may not charge for the vaccine, but is permitted to charge a reasonable administration fee.

TVFC does not tell enrolled providers whom they must see or dictate that they accept Medicaid clients. Providers continue to serve the same populations they have always served. Except now, through enrollment in the TVFC, more children will be receiving their complete series of immunizations. This benefits everyone by maintaining a higher level of immunity in our community. TVFC automatically covers all vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) and approved by the Centers for Disease Control and Prevention (CDC).

A fully immunized society is necessary to reach optimum eradication of vaccine-preventable infectious diseases. With your help, we can reach these goals leading to a healthier Texas.

QUESTIONS?

Contact
the nearest Health
Services Regional Office
or a TVFC Consultant at
(512) 458-7284, or toll-
free at (800) 252-9152.



I. Vaccine Protection in the Event of an Emergency

Every facility maintaining an inventory of state-provided vaccine is required to develop and display a **contingency plan** in the event of emergencies that could result in the loss of vaccine. The following items must be addressed in this contingency plan:

- Identify a responsible person to enact the contingency plan and a knowledgeable alternate if the primary person is not available. Be sure to include contact information such as home, office, and cell phone numbers.
- Identify a location to take the state-provided vaccine for storage. A location with a power generator or other alternate source of power such as a hospital or grocery store is preferable. Ideally, this facility should be located within a reasonable distance from your clinic. Be sure to contact the alternate location for their approval before including them on your plan and list their contact person(s) and phone number(s) on your plan.
- Specify the steps to transport refrigerated vaccine to the alternate location. Steps should include:
 - Noting the time of the emergency situation/power outage.
 - Noting the temperature of the refrigerator and freezer before removing any vaccine for transportation.
 - Indicating what containers will be used and how the vaccine should be packed for transportation (i.e., ice packs separated from the vaccine by plastic bubble wrap or paper to prevent freezing and damage).
 - Inventorying the vaccine as you move it into the transport container being careful to indicate the number of doses of each vaccine and the expiration dates.
 - Keeping a thermometer in the transport container and noting the time and temperature when you place the vaccine in the alternate storage. This reveals how long the vaccine was at less-than-ideal temperature.
- Varicella-containing vaccines are fragile! The Centers for Disease Control and Prevention (CDC) and the vaccine manufacturer do not recommend transporting varicella-containing vaccines. If these vaccines must be relocated in an emergency situation, the CDC recommends transport with a portable freezer unit that maintains the temperature between -58°F and +5°F (-50°C and -15°C). Portable freezers may be available for rent in some places.
- If varicella-containing vaccines must be transported and a portable freezer unit is not available, complete the following actions. Specify the steps to be taken to transport frozen vaccines to the alternate location.

Steps should include:

- Placing a calibrated thermometer in the container used for transport as close as possible to the vaccine.
- Recording:
 - The time the vaccine was removed from the freezer and placed in the transport container
 - The temperature during transport
- Documenting the time and temperature at the beginning and end of transport.
- Placing the vaccine in the freezer immediately upon arrival at the alternate storage facility.
- Documenting the time the vaccine was removed from the transport container and placed in the alternate storage unit.
- Immediately contacting the manufacturer at (800) 637-2590 for stability data and guidance.

The CDC and the vaccine manufacturer DO NOT recommend transporting varicella-containing vaccines on dry ice, even for temporary storage or emergency transport. Dry ice may subject vaccine to temperatures colder than -58°F (-50°C).

- Do not discard the vaccine without contacting the manufacturer and/or your state or local immunization program for guidance.
- Contact your Health Service Region (HSR) or Local Health Department (LHD) to inform them of the emergency. Be prepared to provide the following information:
 - the temperature of the vaccine,
 - the amount of vaccine,
 - expiration dates, and
 - how long the vaccine was exposed to inappropriate temperatures.
- You will be asked to provide a copy of the contingency plan at site reviews. The plan should be posted on or near the refrigerator containing state-provided vaccine. Make sure all employees involved with vaccine handling or use are aware of this plan. A **Vaccine Contingency Plan** template is located on **page 11** of this manual. This template is not a required form, but is a valuable tool available to providers should they need assistance in developing an emergency plan.

Vaccine Management Plan

All providers enrolled in the TVFC program are responsible for the proper management of their vaccine inventory. This document, along with the TVFC Provider Manual and Emergency Contingency Plan, serves as your vaccine management plan. **A copy of this page along with the Vaccine Storage Contingency Plan should be posted on or near the refrigerator used to store vaccines.**

***This plan will be reviewed during your annual TVFC on-site visit. Make sure to →	<ul style="list-style-type: none"> • Provide the appropriate staff names in the spaces provided below, • Have your written emergency contingency plan available, and • Write in the date of the most recent review/update to your emergency plan in the space provided below. 		
Designate a primary vaccine coordinator and at least one back-up staff →	Primary:	Back-up #1:	Back-up #2:
Proper vaccine storage and handling →	<ul style="list-style-type: none"> • Refer to page 33 of the Provider Manual Section V., A.-D., Vaccine Storage and Handling. 		
Vaccine shipping (includes receiving and transport) →	<ul style="list-style-type: none"> • Shipment arrival – verify that your clinic shipping address and delivery hours are accurate on the Provider Information tab when completing your vaccine order in Electronic Vaccine Inventory (EVI) system. • Shipment receipt – Clinics may choose to have one designated receiver who checks-in and stores vaccines. However, all staff should be trained on vaccine receiving and storage and given back-up instructions in case the designated receiver is out. • Proper handling of shipments: <ul style="list-style-type: none"> ○ Refer to page 24 of the Provider Manual, Section IV., E. Receiving Vaccine and page 25, Section F., Vaccines Received Warm or Questionable. 		
Procedures for vaccine relocation in the event of a power failure, mechanical difficulty, or emergency situation (emergency plan) →	<ul style="list-style-type: none"> • Every facility maintaining an inventory of state-provided vaccine is required to develop and display an emergency contingency plan in the event of emergencies that could result in the loss of vaccine. • Refer to page 7 of the Provider Manual, Section I., Vaccine Protection in the Event of an Emergency. • Refer to the following section of the Provider Manual – Contingency Plan. 		
The emergency plan should be reviewed or updated annually, or after any change in responsible staff →	<ul style="list-style-type: none"> • Date of last review/update to Emergency and Contingency plans: _____ 		
Vaccine Ordering →	<ul style="list-style-type: none"> • Refer to page 22 of the Provider Manual, Section IV., C. Vaccine Ordering. 		
Inventory Control (e.g., stock rotation) →	<ul style="list-style-type: none"> • Refer to page 43 of the Provider Manual, Section VIII., A. Reports Summary. 		
Vaccine Wastage →	<ul style="list-style-type: none"> • Refer to page 27 of the Provider Manual, Section IV., I. Procedures for Vaccine Loss. 		

Vaccine Storage Contingency Plan

Facility Name: _____ TVFC PIN: _____
 Address: _____ Date: _____
 City, State, Zip Code: _____ Phone: _____

Clinic staff responsible for transfer of vaccine:		Phone number:
Name:	()	
Name (back-up):	()	
Transfer vaccine to:		Phone number:
Facility Name:	()	
Address:	Generator: <input type="checkbox"/> Yes <input type="checkbox"/> No	
Contact Name:	Date of agreement:	
Where to obtain:		Phone number:
Ice Packs:	()	
Cooler:	()	
Shipping Agent:		Phone number:
Tracking number:	()	
Contact with LHD/HSR made prior to transport by:		
Transport of refrigerated vaccine checklist:		
	Temperature of refrigerator prior to transport (record temperature here):	
	Inventory of vaccine (use C-33) and included in bag with vaccine. Keep a copy for your records.	
	Bag labeled with PIN, clinic name, clinic contact, phone number.	
	Container used to transport refrigerated vaccine (record type of container here):	
	Ice packs are in container separated from vaccine by bubble wrap or crumpled paper.	
	Thermometer in container.	
	Time and temperature in container prior to transport (record time and temperature here):	
	Person transporting vaccine (record name here):	
Transport of frozen vaccine checklist:		
	Temperature of freezer prior to transport (record temperature here):	
	Inventory of vaccine (use C-33) and included in bag with vaccine. Keep a copy for your records.	
	Bag labeled with PIN, clinic name, clinic contact, phone number.	
	Container used to transport frozen vaccine (record type of container here):	
	Ice packs are in container separated from vaccine by bubble wrap or crumpled paper.	
	Thermometer in container.	
	Time and temperature in container prior to transport (record time and temperature here):	
In the event of a city-wide evacuation, contact your health service region for evacuation plan.		
HSR Contact Name: _____ Phone number: () _____		

II. TVFC ELIGIBILITY

A. Provider Eligibility Requirements

Providers must be one of the following in order to enroll in the TVFC program:

1. Physician (Medical Doctor or Doctor of Osteopathy)
2. Nurse Practitioner
3. Certified Nurse Midwife
4. Physician Assistant
5. Registered Pharmacist

All other health care providers must enroll under the standing delegation orders of a physician including:

1. Nurses (Registered Nurses or Licensed Vocational Nurses)
2. Medical Assistants
3. Nurse Assistants
4. Emergency Medical Technicians

B. Patient Eligibility Requirements

1. Any child who meets one of the eligibility criteria listed below and who is 18 years of age or younger qualifies for TVFC vaccine.

- a. Enrolled in Medicaid, or
- b. Enrolled in CHIP, or
- c. Is an American Indian, or
- d. Is an Alaskan Native, or
- e. Does not have health insurance, or
- f. Is underinsured: has commercial (private) health insurance but coverage does not include vaccines; a child whose insurance covers only selected vaccines (TVFC eligible for non-covered vaccines only); or a child whose insurance caps vaccine coverage at a certain amount. Once that coverage amount is reached, the child is categorized as underinsured.

Note: Please be aware of the new definition of the Underinsured eligibility category.

2. Children who have private insurance that covers vaccines are no longer be eligible to receive TVFC vaccines in public health department clinics, but instead will be referred to their medical home for immunizations.

Exception: In some cases, local health departments may be the medical home that provides comprehensive healthcare services. In these cases, private insurance is accepted in those public health settings. Private stock vaccine must be purchased and/or acquired in order to continue vaccinating fully, privately insured children.

3. Insured children with vaccine coverage who have high copays or deductibles are no longer considered underinsured and are no longer eligible for TVFC vaccines.
4. TVFC eligible individuals who begin a vaccine series at age 18 or younger and turned 19 years of age may only finish that series at public health clinics that are Adult Safety Net (ASN) providers. The series must be completed prior to the individual's 20th birthday.
5. If a child under age 19 loses access to his or her health insurance because of incarceration, the child is considered uninsured and TVFC eligible.

C. New Standardized TVFC Forms

Three forms have been revised and/or created to support the revised TVFC eligibility policies.

- 1. TVFC Patient Eligibility Screening Record** (Stock No. C-10, Rev. 03/2012)
It is a federal requirement that providers document the eligibility of each client receiving TVFC vaccine. Providers may use the Patient Eligibility Screening Form (C-10) or electronically store this information. The new C-10 (revised 03/2012) is now consistent with the updated definitions and insurance status guidelines. A new C-10 must be completed once for all patients, including patients with an old form on file. Once the new form is completed it may be used until the child's category of eligibility changes. Patient eligibility must be verified each time prior to vaccine administration.
- 2. TVFC Patient Screening Decision Tree** (Stock No. 11-13789, Rev. 12/2011)
This diagram may be used by screeners in both public and private clinics to aid in determining patient eligibility for TVFC under the new guidelines. This diagram also indicates when providers should use private stock vaccine or refer patients to another provider that accepts the patient's private insurance.
- 3. Patient Referral Form for Vaccination from Local Health Department or Public Health Clinics** (Stock No. 11-13788, Rev. 12/2011)
This form may be used when a fully, privately insured child presents for services in a public health clinic and must be referred to their medical home. The second page of the form includes a recommended referral process (questions to help identify eligibility) that can be used by clinic staff when a patient calls or presents in-person. Also included on the form is space to include any identified referral sites. Public health agencies are encouraged to coordinate with local immunization providers to establish options for referring fully insured patients.

D. Patient Eligibility Screening

Screening for eligibility is the foundation of provider-level accountability. Screening children for eligibility at every visit is the only way to ensure that TVFC vaccine is used only for TVFC eligible patients. Consequently, provider sites must screen all children at every immunization visit.

1. Screening and documentation must be conducted on all patients from birth through 18 years of age.
2. During a child's initial visit to the provider site, documentation of the child's eligibility category must be collected and then maintained on future visits.
3. Verbal screening is sufficient for subsequent visits after initial documentation *as long as the child's eligibility status has not changed*; if the child's eligibility status changes, it must be documented.
4. Since the TVFC requirement is to screen children at all immunization encounters, anything less than full compliance will be discussed with the enrolled provider and may require additional follow up actions.
5. The Patient Eligibility Screening form (C-10, Rev. 3/2012) provides a means of recording responses to TVFC eligibility. The parent, guardian, or provider may complete this form. Verification of parent/guardian response is not required. The eligibility documentation must be easily retrievable.
6. Patient eligibility screening records must be maintained on file for a minimum of **five (5) years** after service to the patient has been completed.
7. Immigration status does not affect a client's eligibility for the TVFC program. Immigrants should be offered the same vaccination services other customers receive in public health clinics.

III. ENROLLMENT PROCESS

A. Vaccine Accountability

1. Vaccine accountability is a cornerstone of the TVFC program and one of the Department of State Health Services (DSHS) highest priorities. The TVFC Program will operate in such a way as to ensure:

- Vaccines purchased with TVFC funds are administered only to TVFC-eligible children.
- Vaccine loss and waste are minimized.
- The TVFC program is protected against fraud and abuse.
- TVFC and other federally- and state-purchased vaccines are ordered appropriately based on a provider's TVFC-eligible population.

2. Accountability Requirements

Every TVFC provider is required to submit a Provider Enrollment Form (Stock No. 6-102, Rev. 02/2012) at the time of initial enrollment and annually thereafter. By signing the Provider Enrollment Form, TVFC providers agree to certain accountability requirements as a condition of participation in the TVFC program. The requirements include:

- Screening patients at all immunization encounters for eligibility and administering TVFC-funded vaccine only to TVFC-eligible patients.
- Complying with the requirements for ordering, vaccine accountability, and vaccine management.
- Agreeing to operate within the TVFC program in a manner intended to avoid fraud and abuse.

B. Specific Terms of Agreement

In order to participate in the Texas Vaccines for Children Program and/or to receive federally- and state-supplied vaccines provided to enrolled clinics at no cost, each office must agree to follow program requirements. By signing the TVFC Enrollment Form the office and any/all practitioners associated with the medical office agree to the following:

1. Screen for TVFC eligibility at each immunization encounter and administer TVFC purchased vaccine only to children 18 years of age or younger who meet the established eligibility criteria.
2. Maintain all records related to the TVFC program for at least **five** years.
3. Comply with appropriate vaccination schedule, dosage, and contraindications as established by the Advisory Committee on Immunization Practices (ACIP).

4. Provide current Vaccine Information Statements (VIS) for each vaccine at the time of administration.
5. Not charge for vaccines supplied by DSHS and administered to an eligible child.
6. Not charge an administration fee in excess of \$14.85 per vaccine.
7. Not deny administration of a TVFC vaccine to an eligible child because of the inability of the child's parent/guardian to pay the administration fee.
8. Comply with DSHS requirements for vaccine ordering.
9. Operate within the TVFC program in a manner intended to avoid fraud and abuse.
10. Abide by proper storage and handling practices for state-supplied vaccine.
11. Allow DSHS or its contractors to conduct on-site visits as required.
12. Acknowledge that DSHS may terminate the agreement at any time for failure to comply with established requirements. If the agreement is terminated, the office/facility agrees to return any unused TVFC vaccines.

C. Initial Enrollment

1. The TVFC Provider Enrollment form, (Stock No. 6-102, Rev. 2/2012), includes three pages: (1) Provider Enrollment, (2) Provider Profile, and (3) Provider List Addendum. The Provider Enrollment Form includes basic information on the clinic and responsible provider. It also briefly outlines the provider responsibilities and must be renewed **annually** by the provider prior to receiving federally- and state- funded vaccines. Providers may include Medical Directors of a Health Service Region (HSR) or Local Health Department (LHD); private physicians (M.D. or D.O.); nurse practitioners; physician assistants; pharmacists; or certified nurse midwives. Generally, the individual who signs the TVFC Provider Enrollment Form will be the same one who signs the standing delegation orders for the clinic.
2. The Provider Profile Form requests information on the type and numbers of patients expected to receive TVFC vaccines. These numbers must be specific to the clinic site where the child will be vaccinated and not combined with other clinics' patient numbers. The numbers must be based on real data (i.e., registry data, billing data, etc.)
3. The Provider Profile Form must list the provider who signs the Provider Enrollment Form and all licensed and/or certified individuals within the practice who will be administering TVFC-supplied vaccines. The Provider List Addendum can be used if additional space for providers is required.

4. All providers enrolling in the TVFC program must receive an Enrollment Visit prior to receiving any vaccine through the TVFC program. The visit will include the following content:

- Reviewing and confirming that provider and staff understand and can implement the TVFC requirements.
- Confirming the provider has the proper equipment to maintain TVFC vaccine and staff understands how to properly store, handle, and monitor TVFC vaccine, and staff knows who to contact if problems arise.

D. Provider Choice

House Bill 448 from the 81st Legislature gives Texas Vaccine for Children and Adult Safety Net providers the opportunity to choose their preferred brands and presentations of vaccines. By signing the TVFC Enrollment form, the office/facility agrees to the following statements which are fundamentals of choice operating procedures.

1. This office/facility acknowledges that only vaccines supplied to the Texas Department of State Health Services (DSHS) through the contracts with the Centers for Disease Control and Prevention (CDC) will be available for choice.
2. This office/facility acknowledges that vaccines exceeding 115% of the lowest-priced equivalent vaccine may not be available for choice.
3. This office/facility understands that the vaccine choices do not apply in the event of a disaster or public health emergency, terrorist attack, hostile military or paramilitary actions, or an extraordinary law enforcement emergency.
4. This office/facility is enrolled in the Texas Vaccines for Children and/or Adult Safety Net programs.
5. This office/facility's vaccine choices will remain in effect until the vaccine choice optional update is opened on a quarterly basis.
6. This office/facility will make every effort to use all vaccines by the expiration date on the vaccine regardless of brand or presentation.
7. This office/facility acknowledges that in the event any vaccine chosen is not available, DSHS has the authority to replace the chosen vaccine with a comparable substitution until such time the chosen vaccine becomes available.

E. Choice Selections

The medical provider who signs the TVFC Enrollment Form must either choose vaccine brands and presentations, or be consulted with and agree to the choices made for the clinic. The provider will convey vaccine choices to their responsible entity (HSR/LHD). The responsible entity will establish Maximum Stock Levels (MSL) and Tiered Ordering Frequency (TOF).

F. Provider Identification Number (PIN)

A Provider Identification Number (PIN) will be assigned when a provider initially enrolls. The PIN will be the clinic's vaccine account number for the duration that the clinic is enrolled in the TVFC. All subsequent forms must have the PIN written or printed on the forms (all six digits).

G. Provider Change of Information

1. If a provider changes location or phone numbers, it is not necessary to change the PIN number unless moving to another Health Service Region.
2. It is the provider's responsibility to maintain correct demographics, days/hours of operation, and profile information in Electronic Vaccine Inventory (EVI). If a provider changes location the HSR/LHD must be contacted immediately to inform them of the change. In addition, the provider must correct the information in EVI.
3. Failure to properly update current information may result in vaccine delays and possible vaccine loss.

H. Annual Re-Enrollment

The (1) Provider Enrollment, (2) Provider Profile, and (3) Provider List Addendum Forms must be updated **annually** and/or when the provider who signed the form is no longer associated with the clinic. In most cases, this will be handled during the annual TVFC Site Visit (See Section XII., Program Evaluation, Site Visit). The reviewer may assist in this process. In rare cases, such as when a TVFC Site Visit is delayed, an HSR or LHD may request clinics complete the re-enrollment paperwork separately from a visit. Vaccine shipments may be interrupted if TVFC providers do not have current enrollment information on file.

I. Provider Withdrawal from TVFC

Providers wanting to withdraw from the TVFC program should contact the HSR or LHD to arrange for vaccine pick-up and assistance with final paperwork. Prior to withdrawal the provider should complete a Provider Withdrawal Form, (Stock no. F11-11443, Rev. 11/08) (See Appendix K) and submit the form to the HSR or LHD.

IV. VACCINES

A. Approved Vaccines

1. The TVFC program supplies the following ACIP routinely recommended vaccines/toxoids to enrolled providers. All providers participating in the TVFC program are expected to offer all relevant vaccines to the eligible population they serve, including influenza.

Diphtheria and Tetanus toxoids, adsorbed (DT)
Diphtheria-Tetanus toxoids and acellular Pertussis vaccine (DTaP)
Diphtheria-Tetanus toxoids and acellular Pertussis vaccine, Hepatitis B, and inactivated polio vaccine (DTaP-Hep B-IPV)
Diphtheria-Tetanus toxoids and acellular Pertussis vaccine, inactivated polio vaccine, and *Haemophilus influenzae* type b vaccine (DTaP-IPV/Hib)
Diphtheria-Tetanus toxoids and acellular Pertussis vaccine and inactivated polio vaccine (DTaP-IPV)
Hepatitis A vaccine (Hep A)
Hepatitis B vaccine (Hep B)
Haemophilus influenzae type b (Hib)
Haemophilus influenzae type b and Hep B (Hib-Hep B)
Human Papillomavirus vaccine (HPV)
Influenza vaccine
Inactivated polio vaccine (IPV)
Measles, Mumps, and Rubella (MMR)
Measles, Mumps, Rubella and Varicella virus vaccine (MMRV)
Meningococcal Conjugate (MCV4)
Pneumococcal Conjugate (PCV13)
Pneumococcal Polysaccharide 23-valent vaccine (PPSV23)
Rotavirus vaccine (RV)
Tetanus and diphtheria toxoids, adsorbed (Td)
Tetanus and diphtheria toxoids and acellular Pertussis vaccine (Tdap)
Varicella

2. Some of the vaccines listed above are not for routine use or may not be available to vaccinate children due to funding limitations.

B. Vaccine Distribution

Texas Department of State Health Services (DSHS) uses three vaccine distribution centers: McKesson Specialty, a third party distributor which ships the majority of TVFC vaccines; the DSHS Pharmacy Branch; and Merck, the manufacturer of varicella-containing vaccines, which ships directly to providers.

C. Vaccine Ordering

1. Electronic Vaccine Inventory (EVI)

Beginning September 1, 2010, TVFC transitioned to an Electronic Vaccine Inventory (EVI) accounting system to meet all program requirements.

EVI allows providers to manage their vaccine inventory online. Providers can now complete their Monthly Biological Report (EC-33) online, allowing an electronic capture of vaccine received, transferred, doses administered, doses on hand, and wasted or expired vaccine. Providers record current inventory and place vaccine orders online. Providers must continue to submit paper copies of the Temperature Recording Form (C-105) each month. TVFC continues to move forward with EVI functionalities and additional system enhancements will continue to roll out as they are developed.

All orders will be approved in EVI by the HSR or LHD pending completion and submission of the Temperature Recording Form (C-105) and resolution of any outstanding issues. Orders placed by providers without internet access will be entered and approved by the HSR or LHD pending completion and/or receipt of the Monthly Biological Report (EC-33), Temperature Recording Form (C-105), and resolution of any outstanding issues.

The HSR and/or LHD review the online orders to ensure all necessary information is included and providers are ordering within their maximum vaccine stock levels. The HSR/LHD approves the orders. DSHS Austin Office (AO) will then process vaccine orders for distribution. Once the vaccine order is processed in Austin, a fax confirmation will be sent to the provider. Each order generates a confirmation showing which vaccines have been ordered. Providers should verify the online order placed in EVI matches the faxed confirmation. Contact the HSR or LHD immediately if the vaccine order and faxed confirmation do not match.

Vaccine wastage is now captured electronically in EVI. When a provider documents, as required, any expired or wasted vaccine in EVI, the system will automatically place any subsequent orders on Hold until the nature of the loss is determined (expired, negligent, or non-negligent).

Providers must ensure accurate shipping address and delivery hours. Include the PIN on each form submitted. Submit the paperwork by email, fax, or mail to the HSR or LHD.

Providers may be held responsible for incomplete or erroneous information entered into EVI which results in a vaccine loss.

Providers must continue to submit vaccine orders within their established Maximum Stock Levels (MSLs) and Tiered Ordering Frequency (TOF). For vaccine orders outside a provider's maximum stock level, an explanation should be added to the Comment section on the Place Order Tab. Incomplete or inaccurate online orders will be placed on Hold pending corrections by the provider and orders may be delayed. (See Section IV., D. for MSL and TOF information.)

2. Providers without Internet Access

TVFC providers without access to the internet should contact their HSR or LHD. The following paper reports must be submitted to HSR or LHD to place a vaccine order:

- EC-33 Monthly Biological Report (use most current form posted on TVFC website)
- EC-68 Biological Order form (use most current form posted on TVFC website)
- EC-105 Temperature Recording Form (rev. 01/05)

The most current EC-33 and EC-68 are located at: www.dshs.state.tx.us/immunize/tvfc - TVFC Forms

3. Newly Enrolled Providers

Until a provider is established in the EVI system to order vaccines online, the provider's office must coordinate their initial order through their HSR or LHD. To receive their initial order, the following paper reports must be submitted to the HSR or LHD:

- EC-68 Biological Order form (use most current form posted on TVFC website)
- EC-105 Temperature Recording Form (rev. 01/05)

4. Adult Safety Net Providers (ASN)

Qualified providers participating in the ASN must order and maintain their ASN vaccine inventory separate from their TVFC vaccine.

D. Maximum Stock Levels (MSL) and Tiered Ordering Frequency (TOF)

Maximum Stock Level: A calculated peak dose inventory (per vaccine type). The standard number of doses a provider should order up to on each regularly scheduled vaccine order.

Tiered Ordering Frequency: The period of time between scheduled vaccine orders. There are three typical TOFs: monthly, bi-monthly, and quarterly.

1. Maximum Stock Levels (MSL)

HSRs and LHDs are expected to develop maximum stock levels (MSL) for every **new** TVFC provider. Once EVI is fully developed MSLs will be monitored, calculated, and revised online. Online MSL adjustment will include a variable MSL based on season and an adjustment for upward or downward administration trends.

MSLs are calculated manually using the following process:

- Obtain an average of the doses administered for each vaccine, excluding any month's data that could skew the result. The average can be based on any number of months as long as they are reflective of current or predicted future usage (typically 12 months).
- Multiply the average obtained in step one by 2.5 for a monthly provider, 3.5 for a bi-monthly provider or 4.5 for a quarterly provider.
- The number obtained in step 2 is the MSL for the provider.

Maximum stock levels are based upon a 45-day base of vaccine, plus vaccine for the number of days between orders. See table below:

Tier	Base Days		Days Between Orders		Total Days of Vaccine
Monthly	45 (1.5 months)	+	30 (1 month)	=	75 (2.5 months)
Bi-Monthly	45 (1.5 months)	+	60 (2 months)	=	105 (3.5months)
Quarterly	45 (1.5 months)	+	90 (3 months)	=	135 (4.5 months)

2. Tiered Ordering Frequency (TOF)

HSR/LHD should determine a provider’s TOF upon enrollment along with the MSL. The TOF is based upon actual or projected annual vaccines usage and provider storage capacity. Providers will be scheduled to place vaccine orders:

- Once a month (**Monthly**) if they order more than 6,000 doses/year
- Once every other month (**Bi-Monthly**) if they order between 800 – 6,000 doses/year
- Every three months (**Quarterly**) if they order between 200 - 799 doses/year

Large providers will order more frequently, while smaller providers will order less often.

3. Storage Capacity

In addition to usage, a provider must have enough refrigeration/freezer space to accommodate a maximum order based on TOF and MSL. A storage calculation tool and instructions are also available on the TVFC website under Provider Resources at <http://www.dshs.state.tx.us/immunize/tvfc/default.shtm>.

E. Receiving Vaccine

Providers should always accept vaccine shipments. Never refuse or return vaccine shipments without specific instructions from DSHS Austin Office, your Health Service Region, or Local Health Department.

1. Providers can expect their orders approximately one to three weeks after placing their online order in EVI. It is important to recognize and store vaccine shipments immediately to ensure vaccine viability. The following steps should be taken when a vaccine shipment arrives:

- Check actual vaccine received against packing list to verify all vaccines have been received.
- Verify the packing list against the previously received faxed confirmation to ensure all vaccines ordered by DSHS were received.
- Ensure adequate diluent is included for vaccines requiring reconstitution (i.e., MMR, Hib, varicella).
- IMMEDIATELY contact the HSR or LHD if the appropriate vaccine (or diluent) is not received.

- Place vaccine in appropriate storage immediately.
 - Make sure to check expiration dates and rotate stock to ensure short-dated vaccine is used first.
 - Each package shipped from McKesson comes with a temperature monitoring strip(s). If the monitor strip indicates or if staff suspects that the cold chain has been compromised, staff should immediately contact their appropriate responsible entity (HSR or LHD). Follow the procedures below in Section F., Vaccines Received Warm or Questionable.
2. Providers must record the receipt of vaccine in EVI at the time of the occurrence to maintain correct online vaccine inventory.
 3. Refrigerated vaccine is packed to maintain the cold chain for 72 hours (3 days). Vaccine will be shipped using high quality cardboard boxes with Styrofoam inserts. Packages are imprinted with 'Temperature Sensitive Product' and include red stickers reading 'Refrigerate upon Arrival' to alert clinic staff to refrigerate contents immediately upon arrival.

F. Vaccines Received Warm or Questionable

Vaccine should always be stored properly, even if viability is questionable.

If vaccine is received warm, damaged, or otherwise questionable, the provider must immediately contact the HSR or LHD. Questionable vaccine should be labeled "Do Not Use" and segregated *in proper storage* until viability can be determined.

1. Examples of potentially non-viable vaccines are:
 - Vaccine shipment received with temperature indicator strip showing out of range.
 - Vaccine is warm to touch.
 - Vaccines are received damaged.
2. Instructions to follow if vaccine viability is questionable upon receipt:
 - Place a thermometer in the shipping container and document the temperature. Do not remove vaccines from the shipping container until temperature is recorded.
 - Before storing the questionable vaccines in the refrigerator and/or freezer, label the outside of the container "**Do Not Use**" until further directions are received from the HSR/LHD. Do not to write on the vaccine itself. Place questionable vaccines in a bag labeled "Do Not Use" or attach a piece of paper with "Do Not Use" written in large letters. Then store labeled vaccine in appropriate storage.
 - Contact appropriate approval authority (HSR or LHD) immediately. Providers should never contact the distributor or manufacturer unless instructed to do so by the HSR or LHD.
 - Wait for the instructions for replacement, reporting loss, etc. from the HSR or LHD. The HSR or LHD will recommend whom to contact for determination of vaccine viability.

Note: Vaccine returns to McKesson must occur within 48 hours.

G. Short Dated Vaccine

1. Clinic staff should make note of vaccine expiration dates when physically counting on-hand inventory at the end of the month. Vaccine with the shortest date should be used first.
2. Providers are required to notify the HSR or LHD **90 days** prior to vaccine expiration. If the vaccine cannot be used before expiration, the HSR or LHD will assist with re-distribution of the vaccine.
3. Placing orders according to the established maximum stock levels and rotating vaccines so that shortest dated vaccines are used first will help to prevent losses due to expiration.
4. Too much vaccine kept in inventory increases the risk of vaccine expiration and increases the amount of loss in the event of refrigerator failure. When ordering vaccines, providers should keep no more than the designated maximum stock level.

H. Vaccine Wastage

1. The Immunization Branch requires all unopened or unused vials and syringes of expired TVFC vaccines/toxoids/biologicals be returned to the third-party distributor (McKesson). Vaccine manufacturers reimburse Texas for the federal excise tax portion of the cost of the vaccine; therefore providers should not discard any vaccine unless specifically directed by HSR/LHD or AO. Any exception to this rule will be communicated by the AO on a case-by-case basis. Providers must immediately notify the LHD/HSR of vaccine cold chain failure events or vaccine wastage incidents involving TVFC vaccines upon discovery of the incident.
2. **Wasted vaccine** is any non-viable vaccine that cannot be returned for excise tax credit. This includes dropped vaccines, broken vials or syringes, and drawn-up but not administered vaccine.
3. **Expired vaccine** is any nonviable vaccine in its original container (vial or syringe) that can be returned for excise tax credit. This includes expired vaccine that cannot be used because it is past the manufacturer expiration date on the vial/syringe (the last date on which the vaccine may be used), expiration after reconstitution (depending on the vaccine and in accordance with the manufacturer instructions), or vaccine that has spoiled as a result of less-than-ideal temperatures.
4. Wasted and expired/spoiled vaccines should be removed from storage with viable vaccine to prevent inadvertent administration. Wasted and expired/spoiled vaccine should be segregated, labeled "Do Not Use," and stored pending return to distributor. The third party distributor, McKesson, will document Texas losses and return vaccines to the manufacturer for excise tax credit.

(See below for wasted vaccine process, Section I., Procedures for Vaccine Loss.)

5. Diluents should be managed similar to vaccines; the expiration date of diluents should be checked prior to every reconstitution. Providers should also rotate diluent stock to use the shortest expiration date first. Expired diluents do not need to be returned.
6. Vaccine wastage will be documented electronically in EVI. As wastage occurs it must be documented in EVI *no later than four days past the date* of the occurrence(s).

I. Procedures for Vaccine Loss

1. Every dose of vaccine that is lost (wasted or expired) must be reported to the TVFC program on a Vaccine Loss Report (VLR) form electronically generated in EVI, and expired vaccine must be returned to the distributor. Providers should follow the procedures listed below when vaccine loss occurs:

- Separate expired/spoiled vaccine from other viable vaccines.
- Contact your responsible entity (HSR or LHD) immediately with the following information: antigen, lot number, expiration date, and reason for expiration/loss. If storage was compromised, provide HSR or LHD with amount of time product was out-of-range and the highest and lowest temperatures recorded.
- Document the vaccine loss online in EVI explaining the cause(s) of the loss and outlining the steps taken to ensure vaccines will be protected in the future.
- The EVI report should be printed and then faxed, emailed, or mailed to the responsible entity, and is due within *four days of the date* of the loss.
- The completed VLR form must be signed or acknowledged by the medical provider who signed the TVFC Provider Enrollment form. The Vaccine Loss Report form (EC-69) includes the following sections:
 - Clinic demographics
 - Date loss was discovered
 - Type of loss
 - Reason for loss
 - Corrective action taken to avoid re-occurrence
 - Explanation of loss
 - List of vaccines by antigen, manufacturer, lot number, expiration date, and number of doses lost
- The Vaccine Loss Report form should be included in the box when returning the non-viable vaccine. Any wasted vaccine listed on the VLR (dropped or broken vials/syringes) should be marked through with a single line as they are not included in the box for return.
- **Important Note:** Only unbroken, sealed vaccine vials/syringes may be included for return. Broken vials/syringes or exposed syringe needles should **NEVER** be included in the box.
- Providers should contact their HSR or LHD for return of nonviable vaccine. A postage paid return label must be requested from the HSR or LHD. Providers will have to wait until UPS returns to their office with the next delivery to return the cooler. If the provider calls to schedule a pickup, the provider will be charged a pick up fee. McKesson will not schedule pickups on behalf of TVFC providers unless special arrangements are made by the AO.

2. TVFC providers must report all vaccine losses online in EVI. This will ensure that the vaccine inventory balances.

3. TVFC providers who have lost vaccine as a result of improper temperature storage must assess how long the vaccines have been stored improperly and how many children may have received the affected vaccines. The medical doctor should discuss the situation with their responsible entity to determine whether or not children will need to be recalled. The TVFC program will not provide the vaccine for recalled children in these circumstances. The clinic will assume all financial responsibility for the cost of vaccines for recalls.

4. TVFC providers may be held responsible for vaccine losses due to **negligence** and may be required to reimburse the State. Vaccine negligence may include but is not limited to the following:

- Vaccine stored improperly (i.e., refrigerating a vaccine that should be stored in the freezer or freezing a vaccine that should be refrigerated).
- Vaccine left out of the refrigerator or left out of the freezer.
- Refrigerator or freezer unplugged (plug guard not used).
- Transporting vaccine inappropriately (appropriate cold chain not maintained).
- Improper maintenance of recommended refrigerator and freezer temperatures resulting in vaccine spoilage.
- Improper monitoring of temperatures in refrigerator or freezer.
- Allowing vaccine to expire without notifying the HSR/LHD 90 days in advance that the vaccine could not be used.
- Refrigerator/Freezer door left open.
- Refusal of a vaccine shipment.

5. Certain vaccine loss circumstances may qualify for insurance policy reimbursement. Loss of TVFC vaccine under the following circumstances may be covered by insurance.

Some examples include loss of vaccine as a result of:

- Power outages due to inclement weather (flood; hurricane; freezing temperatures; tornado)
- Fire
- Robbery

6. If reimbursement is required, payment can be made to DSHS by check or money order for the cost of the vaccine minus the federal excise tax. The vaccine must be returned to the DSHS Pharmacy Branch or third party contractor. To ensure your account is properly credited, write or print on the check **“BUDGET # ZZ304-008”**.

Send payment to:

Texas Department of State Health Services
Immunization Branch
MC-1946
P.O. Box 149347
Austin, TX 78714-9347

J. VACCINE BORROWING

Providers that serve TVFC-eligible and privately insured children must maintain two separate inventories of vaccine: one inventory of publicly provided vaccine for administration to TVFC eligible children and another inventory of privately purchased vaccine for those children who are not TVFC eligible.

TVFC providers should not borrow TVFC vaccine to give to non-TVFC eligible children.

K. ADULT SAFETY NET PROGRAM (ASN)

Important Note: Until notified otherwise all qualified providers participating in the Adult Safety Net Program must order their adult vaccine inventory separate from their TVFC vaccine.

The Adult Safety Net Program was developed to ensure that adults who ordinarily seek services through local health departments or Health Service Regions would have access to recommended adult vaccines. The Adult Safety Net Program is not mandated by the Texas legislature; funding comes out of the same budget as emergency vaccines and biologicals. In order not to strain this budget, the public agencies using state adult safety net vaccines are meant to be **‘providers of last resort’**. Patients with insurance that covers the cost of vaccines are not eligible for safety net vaccine. Insured patients should be referred to a physician or agency that purchases vaccine and bills the appropriate insurance.

LHDs may choose to immunize insured patients, but must use locally purchased vaccines. State purchased safety net vaccine may not be administered to insured adult patients. Additionally, special immunization clinics should not be held for adults using safety net vaccines (with the exception of HSR flu clinics). Advertising should not be used to promote the Adult Safety Net Program.

The Adult Eligibility Screening Record (Stock No. 11-12842, Rev. 2/2012) is required when administering any ASN vaccine. This form has been updated to screen for **uninsured patients only** and should be stored for five years. All patients receiving adult vaccines provided by DSHS must complete this form. The Adult Eligibility Screening Record is located in Appendix F and can also be found online at <http://www.dshs.state.tx.us/immunize/tvfc/default.shtm>

Only **Uninsured** adults (have no health insurance coverage) meet the criteria to receive Adult Safety Net vaccines.

Private providers are not authorized to provide TVFC vaccine to adults 19 years of age or older, including finishing a series for a TVFC-eligible person that started the series prior to their 19th birthday. It is now DSHS policy to have 19 year-olds who need to complete a vaccine series finish the series at a participating Adult Safety Net public health clinic. The series must be completed by the 20th birthday.

Providers participating in the Adult Safety Net Program may charge an administration fee not to exceed \$25 per shot.

Providers participating in the Adult Safety Net Program should not deny administration of an ASN vaccine to an eligible uninsured adult because of their inability to pay the administration fee.

All adult vaccine doses administered must be reported as “19 and over” in EVI under the Doses tab. It is required to accurately report all doses provided to adults. The Immunization Branch uses this information to account for adult usage and to project and maintain supply.

The following chart outlines each of the adult vaccines to be made available through public health clinics with its respective eligibility criteria.

ADULT VACCINE SAFETY NET ELIGIBILITY CHART				
	DSHS Health Service Regions	Local Health Departments (LHDs)	Providers Enrolled in Adult Safety Net Program	Special Comments
Hepatitis B	UNINSURED adults 19 years of age and older in accordance with CDC ACIP recommendations			Finish series started while TVFC eligible prior to 19 th birthday in ASN enrolled clinic. Must finish series by age 20.
Influenza	UNINSURED adults 19 years of age and older in accordance with CDC ACIP recommendations	None	None	None
MMR	UNINSURED adults 19 years of age and older in accordance with CDC ACIP recommendations			Finish series started while TVFC eligible prior to 19 th birthday in ASN enrolled clinic. Must finish series by age 20.
Pneumococcal polysaccharide (PPSV23)	UNINSURED adults 19 years of age and older in accordance with CDC ACIP recommendations	None	None	None
Td/Tdap	UNINSURED adults 19 years of age and older in accordance with CDC ACIP recommendations			Finish series started while TVFC eligible prior to 19 th birthday in public health clinic. Must finish series by age 20.

**Agencies contracted by Local Health Departments to provide vaccines may immunize adults under the same guidelines as the Local Health Department.*

Adult Safety Net sites that have other adult vaccines provided by DSHS in their inventory may continue to provide these vaccines to **uninsured adults** until the stock is depleted.

L. REFUGEE PROGRAM

The TVFC program is no longer able to provide adult vaccines to Refugee Programs. Adult vaccine choices have been removed from ordering options for each enrolled Refugee provider. The adult vaccines will no longer appear on their place order screens. TVFC-enrolled Refugee providers should continue to use current inventory until the stock is depleted. Refugee programs should contact Sam Householder at (512) 776-6976 with questions regarding future purchasing of adult vaccines.

TVFC will continue to provide pediatric vaccines to the Refugee Program.

V. VACCINE STORAGE AND HANDLING

Each clinic must post and adhere to the CDC's *Recommendations for Handling and Storage of Selected Biologicals*.

A. Refrigerator and Freezer Requirements

1. Providers must have appropriate equipment that can store vaccine and maintain proper conditions. Two types of storage units are acceptable for permanent storage: a refrigerator that has a separate freezer compartment with a separate exterior door or stand-alone, single-purpose refrigerators and freezers.
2. Small combination refrigerator-freezer units outfitted with a single external door are **never allowed for the permanent storage of TVFC vaccine**. However, these units may be used to store a clinic's single day supply of refrigerated-only vaccines. Vaccines that require freezing are not allowed to be stored in these units. Any refrigerated vaccines stored in day-use refrigerators must be returned to the main refrigerator for permanent storage at the end of the day.
3. High volume clinics may find separate refrigerators and freezers useful. A standard side-by-side or top-freezer unit is sufficient. Frost-free freezers are preferred.
4. Refrigerators with a freezer unit inside that does not have a separate outside door should NEVER be used to store Varicella or MMRV vaccine. There are small, stand-alone freezers specifically manufactured to maintain very cold temperatures. These freezer units are acceptable for the storage of Varicella or MMRV only.
5. The refrigerator compartment must maintain temperatures between 36°F and 46°F (2°C and 8°C) for vaccine viability. The refrigerator temperature should be set at midrange, 40°F (5°C). The freezer compartment should maintain temperatures at or below 5°F (-15°C). An alarm system and back-up generator are recommended to help reduce vaccine loss when unexpected temperature fluctuations occur.
6. Refrigerators and freezers must contain certified calibrated thermometers which are centrally located. Thermometers may be supplied by the TVFC program when funding allows; however, the provider is ultimately responsible for ensuring they have a calibrated thermometer with a valid certificate in each refrigerator and freezer that stores TVFC vaccine.

Each thermometer is to be covered by a Certificate of Traceability and Calibration. The traceability declaration is to confirm the measurement standards and instruments used during calibration of the product are traceable to an ISO/IEC 17025 accredited testing laboratory, to the National Institute of Standards and Technology (NIST), or to another internationally recognized standards agency. The accompanying certificate should be

retained as proof of certification. **The certificate is valid for two years from the Date of Calibration.** A continuous-read temperature-recording device does not replace the requirement for a certified thermometer.

Refrigerators and freezers that are manufactured with built-in temperature monitoring capability must be accompanied by a certificate of calibration for the thermometer. The temperature probe in the unit must be centrally located, and the temperature thermostat must be capable of adjustment.

7. It is important to store vaccines at the proper temperatures at all times. Opening the door frequently interrupts the cold chain and can result in cumulative loss of vaccine potency over time. The temperature inside the refrigerator (and freezer) may be stabilized by the addition of sufficient bottles of water (labeled “not for consumption”) or gel packs. Some diluents may be stored in the door of the refrigerator and can provide extra insulation much like bottles of water. Sufficient bottles of water and/or gel packs along the walls, back, and door of the refrigerator/freezer compartment helps keep a steady temperature during the automatic defrosting cycles and provides additional reserves of cold in the event of a power failure.

Depending on the size of the unit, the amount of vaccine stored, and the time of year, “sufficient” may differ from one clinic to the other. However, in each refrigerator or freezer there should be adequate water bottles or freezer packs to help maintain proper storage temperature during peak usage of the unit or until vaccine can be moved to another refrigerator/freezer.

8. If the refrigerator is new or newly repaired, allow at least 24 hours for temperature adjustment. Read the instructions carefully before adjusting the temperature control settings, and then make sure temperatures do not change overnight. Some manufacturers recommend resetting the controls in the summer and winter. If so, post instructions on the refrigerator door.

9. All TVFC providers should identify sufficient alternative space to store vaccines and maintain the cold chain during any period when the refrigerator is out of service.

10. Refrigerators and freezers that store TVFC vaccine must be dedicated to storing vaccine only. Food or drinks in the same refrigerator as vaccine is not acceptable.

B. Vaccine

1. Some vaccines are sensitive to light; vaccine efficacy could be compromised if exposed to the light. Providers should safeguard the following vaccines from light: MMR, MMRV, HPV, MCV4, rotavirus, varicella, and zoster.

2. All vaccines are to be stored in the refrigerator and should never be frozen. The exceptions are varicella, MMRV, and zoster.

3. All vaccine should be stored on the refrigerator/freezer shelves, not in the vegetable bins, meat drawer, or in the door. Storing vaccine in the central body of the refrigerator/freezer helps maintain vaccine at proper temperatures.
4. Vaccines should be stored and/or stacked to allow cold air to circulate freely.
5. Adult vaccine must be accounted for and inventoried separately from TVFC pediatric vaccine and providers must segregate and store adult vaccine separately.

C. Protective Equipment

1. Plug guards should be used on all refrigerators that store TVFC vaccines. Plug guards are effective tools in preventing the accidental unplugging of equipment. If a plug guard will not fit then tape the appliance cord to the wall and post on the wall nearby a sign stating “Do Not Unplug.” HSRs, LHDs, and the quality assurance contractor are responsible for providing plug guards to providers.
2. A “Do Not Unplug” sign must be posted on or near all outlets and refrigerators/freezers used for storing vaccine.
3. A “Do Not Disconnect” sign must be posted by each circuit breaker.

D. Personnel

1. Vaccine viability depends on the knowledge and habits of the clinic staff. All staff who handles TVFC vaccine should be trained on proper storage, handling, and administration of vaccine. One person should be designated “in-charge” to ensure that TVFC vaccines are handled and stored properly. Each clinic must have a designated back-up person(s).
2. All staff that handle TVFC vaccine must be aware of and familiar with the written procedures for emergency situations to assure continued viability of the vaccines.
3. New employees must be adequately trained regarding the proper vaccine storage and handling prior to administering TVFC vaccine.
4. The DSHS Immunization Branch has developed the Texas Vaccine Education Online to provide short online training courses on topics related to vaccines. After enrolling online, individuals may log in and take any course free of charge. Additional information and a course listing are available at www.vaccineeducationonline.org.

E. Box Recycling

Note: Each site should maintain enough packing containers and supplies to transport their entire inventory in the event of an emergency. Additionally, providers should keep one or two boxes on hand for use in returning nonviable vaccine.

1. McKesson

With the June 2009 implementation of the new shipping box, empty box returns to McKesson are no longer required or permitted. Providers are encouraged to recycle the boxes through their local recycling programs.

For return of nonviable vaccine, postage paid UPS return labels must be requested from the HSR or LHD. Providers will have to wait until UPS returns to their office with the next delivery to return the cooler. If the provider calls UPS to schedule a pick-up the **provider will be charged a pick-up fee**. McKesson will not schedule pick-ups on behalf of TVFC providers.

2. Merck

Merck has implemented a cooler recycling program for direct ship products.

- EMPTY the container. Remove vaccines and store as directed.
- SEAL the empty container using provided tape and prepaid UPS shipping label. Be sure to remove any old address labels or old tracking information.
- SHIP the sealed, labeled empty container.

Providers will have to wait until UPS returns to their office with the next delivery to return the cooler, or providers can take the box to any UPS authorized shipping outlet. If the provider calls UPS to schedule a pick-up, the **provider will be charged a pick-up fee**. Merck will not schedule pick-ups on behalf of TVFC providers.

F. Cold Chain

1. Vaccines must be stored properly from the time they are manufactured until the time they are administered. The system used to maintain and distribute vaccines in optimal condition is called the **cold chain**.

2. All TVFC providers should identify sufficient alternative space to store vaccines and maintain the cold chain during any period when the refrigerator or freezer is out of service. Supplies for packing and transporting vaccine should be sufficient to handle the entire provider vaccine supply/inventory.

3. Avoid prolonged temperature extremes by transporting containers containing vaccine inside vehicles and taking the quickest route possible. Do not leave vaccine unattended in vehicles.

4. Pack refrigerated vaccine first. Following the steps below will help maintain the cold chain during transport of refrigerated vaccines.

- **Assemble packing supplies**
 - **Cooler.** Use Styrofoam coolers. Attach a “*Vaccines: Do Not Freeze*” label to the cooler.
 - **Cold packs.** Do not use dry ice.
 - **Thermometer.** If possible prepare the thermometer by placing it in the refrigerator at least 2 hours before packing the vaccine.
 - **Packing material.** Use two 2-inch layers of bubble wrap or crumpled paper. Not using enough bubble wrap/crumpled paper can cause the vaccine to freeze.

- **Pack Refrigerated Vaccine**
 - Spread cold packs to cover the bottom of the cooler.
 - Completely cover the cold packs with a 2-inch layer of bubble wrap/crumpled paper. Place the thermometer/probe on top of the bubble wrap directly above a cold pack.
 - Stack layers of vaccine boxes on the bubble wrap. Do not let boxes of vaccine touch the cold packs.
 - Completely cover the vaccine with another 2-inch layer of bubble wrap/crumpled paper.
 - Spread cold packs to cover the bubble wrap/crumpled paper. Make sure the cold packs do not touch the boxes of vaccine.
 - Fill the cooler to the top with bubble wrap or crumpled paper. Place the thermometer’s digital display on top.

- **As soon as you reach the destination site, check the vaccine temperature.** If the vaccine is:
 - Between 36°F and 46°F, place it in the refrigerator.
 - Below 36°F or above 46°F, label the vaccine “Do Not Use,” place it in the refrigerator, and immediately contact your responsible entity.

Note: Always keep vaccine properly stored until otherwise instructed by a pharmacist or the manufacturer.

5. Pack frozen (varicella-containing) vaccine.

- CDC strongly discourages transport of varicella-containing vaccines to off-site clinics**. To maintain potency, the product must be stored frozen between -58°F and +5°F. However, if varicella-containing vaccines must be relocated in an emergency situation, a transport container that maintains a constant temperature of less than +5°F is the recommended method. The manufacturer recommends that the vaccine NOT be transported on dry ice. Use of dry ice may subject vaccine to temperatures cooler than -58°F.
- Pack frozen vaccine in a separate cooler from refrigerated vaccine. Maintain frozen vaccine at or below +5°F but no colder than -58°F.

- Label the container with facility name and “*Fragile Vaccines – Keep Frozen*” and the date and time the vaccine was removed from the permanent storage unit.
- Call the manufacturer for stability data any time frozen vaccine has been exposed to a temperature above +5°F. Viability determination can be made on case by case basis.

** <http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/vac-storage.pdf>

VI. FRAUD AND ABUSE

As the complexity of immunizations and immunization related programs grow, TVFC program participants may become more vulnerable to unintentionally committing acts that could be construed as fraud and/or abuse. A working understanding of what constitutes fraud and abuse is critical for all persons working in the TVFC program. Fraud and abuse, whether intentional or not, is subject to all Federal fraud and abuse laws.

The following definitions and examples are provided so TVFC providers can avoid mistakes that could be defined as fraud or abuse.

A. Definitions

1. Fraud: Fraud is defined as 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.

2. 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.

B. Examples

Fraud or abuse can occur in many ways and some types of fraud and abuse are easier to prevent or detect than others. TVFC program staff and contractors should familiarize themselves with the examples below illustrating common practice errors that could result in fraud or abuse allegations. Some examples of potential fraud and abuse TVFC staff might encounter include:

Fraud

- Selling or otherwise misdirecting TVFC vaccine;
- Billing a patient or third party for TVFC vaccine; or
- Failing to meet licensure requirements for enrolled providers.

Fraud or Abuse

- Providing TVFC vaccine to non-TVFC eligible children;
- Charging more than \$14.85 for administration of a TVFC vaccine to an eligible child;
- Failing to screen patients for TVFC eligibility at every visit;

- Failing to fully account for TVFC vaccine;
- Failing to properly store and handle TVFC vaccine; or
- Waste of TVFC vaccine.

Abuse

- Failing to annually complete and submit a Provider Enrollment or Re-enrollment Agreement;
- Denying TVFC-eligible children TVFC vaccine because of parents' inability to pay the administration fee;
- Not implementing provider enrollment requirements of the TVFC program;
- Failing to maintain TVFC records for five years and comply with other requirements of the TVFC program; or
- Ordering TVFC vaccine in quantities or patterns that do not match provider profile or otherwise involve over-ordering of TVFC doses.

C. Failure to Comply with TVFC Requirements

When providers enroll in the TVFC program, they agree to comply with all the requirements of the program. Lack of adherence to the TVFC program requirements by an enrolled provider could lead to fraud and abuse of the TVFC program by that provider. Non-compliance with program requirements may occur due to an unintentional lack of understanding of the TVFC program requirements or the behavior may be intentional. If the non-compliance appears intentional and the provider has received financial benefits from the behavior, the situation would require immediate referral to an outside agency for investigation of suspected TVFC fraud and abuse.

D. Fraud and Abuse Prevention

TVFC will actively work with enrolled providers to help prevent fraud and abuse in the TVFC program. The best methods to prevent fraud and abuse are strong educational components discussed during the provider enrollment process and during TVFC Compliance visits. Both occasions provide the opportunity to identify and prevent situations that may develop into fraud and abuse. Along with education, well-organized and correctly administered TVFC accountability programs are the cornerstones for preventing situations from developing into potential fraud and abuse incidents.

VII. BILLING/ADMINISTRATION

A. Administration Fees

Providers may charge a reasonable administration fee to TVFC-eligible children. Vaccines must be administered even if the patient/guardian/parent is unable to pay the administration fee. The maximum fee a provider may charge for administration is \$14.85 per vaccine.

B. Medicaid and CHIP Clients

Medicaid and CHIP patients may **not** be charged any out-of-pocket fees for vaccine or for vaccine administration. Medicaid reimburses providers for an administration fee. Medicaid and CHIP do not reimburse providers for the cost of routinely recommended childhood vaccines. Providers must enroll in the TVFC if they want to obtain free vaccine to use for these children.

C. Billing for Vaccine

1. Providers enrolled in the TVFC are prohibited from charging eligible patients, Medicaid, CHIP, or other entities for the **cost** of vaccine. The vaccine is provided at no cost to the provider to vaccinate eligible children. Charging for the cost of vaccine supplied by the State constitutes fraudulent behavior. Fraud in the TVFC will be handled the same as Medicaid fraud.
2. Private providers may not refer a TVFC-eligible child to another health-care provider for immunizations if the provider has already accepted that child into the practice as their patient, unless directed by DSHS.

VIII. REPORTING REQUIREMENTS

The reports and forms are outlined in this section.

TVFC requires providers to monitor the temperatures of all refrigerators and freezers containing state-purchased vaccine and to submit reports on DSHS forms documenting vaccine inventory and usage.

All records related to the TVFC program must be maintained for **five** years. These records include (but are not limited to): Patient Eligibility Screening Forms (C-10 and F11-12842), Temperature Recording Forms (C-105), Monthly Biological Report Form (EC-33), Biological Order Forms (EC-68), and any other reports or required documents.

A. Reports Summary

1. MONTHLY BIOLOGICAL REPORT (EC-33)

The Monthly Biological Report (EC-33) is now documented in EVI as vaccine received, doses administered, vaccine transferred, wasted vaccine, and physical count. The Tally and Physical Count report in EVI may be used to help document vaccine management.

Qualified providers who participate in the Adult Safety Net Program are required to distinguish between their adult and pediatric vaccines and order and report adult vaccines separately from TVFC pediatric vaccines. The Combined Tally and Inventory (EC-88) worksheet is an optional form that may assist in tracking pediatric doses versus adult doses administered.

If the provider does not have internet access, the person completing the paper EC-33 should always sign and date the report and provide a telephone number where they can be reached. This is required in case discrepancies are identified on the report and a follow-up phone call is needed.

2. BIOLOGICAL ORDER FORM (EC-68)

This form is only for initial orders or for those providers that do not have internet access. The Biological Order Form (EC-68) documents the amount of vaccine the clinic will need to order. All vaccines should be ordered to bring the clinic up to their pre-determined maximum stock level. For orders either above or below the maximum stock level, an explanation is required in the comment section.

3. TEMPERATURE RECORDING FORM (EC-105)

The completed Temperature Recording Form (EC-105) for the previous month must be submitted to the HSR or LHD. The refrigerator/freezer temperatures and the time of day must be recorded twice daily on the EC-105. An EC-105 must be maintained on all refrigerators and freezers that store TVFC vaccine (including temporary day storage units). Providers must continue to submit their Temperature Recording Form(s) to their responsible entity each month indefinitely.

B. Daily Requirements

TVFC vaccines must be maintained at proper storage temperatures at all times. To ensure proper temperatures are maintained, TVFC requires providers to check refrigerator and/or freezer temperatures twice daily for all units that store TVFC vaccine and document the results on the Temperature Recording Form (EC-105). Instructions for completing the EC-105 are listed on the back of the form. If an out-of-range temperature is observed and documented, immediately contact the LHD or HSR. Report the out-of-range temperature to the responsible entity and document the instructions and procedures given, including with whom you spoke. All documentation regarding temperature deviations should be retained for review during the annual site visit.

- 1. The Temperature Recording Form (EC-105)** is located under TVFC Forms at: <http://www.dshs.state.tx.us/immunize/tvfc/default.shtm>.
- If you need assistance completing the Temperature Recording Form, go to the Vaccine University link at: <http://www.vaccineeducationonline.org/>
Healthcare Providers, TVFC Vaccine Accounting

C. Monthly Requirements

On a monthly basis the following documents should be forwarded to the HSR or LHD:

- EC-33 Biological Report (only if internet access is unavailable)
- EC-105 Temperature Recording Form
- EC-68 Order Form (only if internet access is unavailable)
- Any additional/associated forms as required by HSR or LHD

Online vaccine management is required in EVI regardless of whether an order is submitted. Providers without internet access must continue to submit the Monthly Biological Report (EC-33) each month to their assigned HSR or LHD.

- 1. The Monthly Biological Report (EC-33)** is located under TVFC Forms: <http://www.dshs.state.tx.us/immunize/tvfc/default.shtm>
- If you need help completing the Monthly Biological Report, go to the Vaccine University link at <http://www.vaccineeducationonline.org/>
Healthcare Providers, TVFC Vaccine Accounting

IX. DOCUMENTATION REQUIREMENTS

A. Vaccine Record Keeping Requirements

The 1986 National Childhood Vaccine Injury and Compensation Act requires providers nationwide to record specific information in the medical record each time a vaccine is administered. The following information is required:

- Vaccine given
- Vaccination date (month, day, year)
- Vaccine lot number
- Name of vaccine manufacturer
- Signature and title of the health-care provider administering the vaccine
- Organization name and address of the clinic location (where the records are kept)
- Date on Vaccine Information Statement issued to patient, parent, or guardian.

Immunization cards for providers (C-100) and clients (C-102 and C-104) can be ordered free of charge from the DSHS Immunization Branch (See Section XI., Ordering Forms and Literature). These cards are designed to capture all information required when vaccines are administered.

B. Decision to Not Vaccinate

Maintaining public confidence in immunizations is critical for preventing a decline in vaccination rates that can result in outbreaks of disease. While the majority of parents believe in the benefits of immunization and have their children vaccinated, some have concerns about the safety of vaccines. These concerns about vaccine safety are preventing some parents from having their children immunized. Overcoming barriers calls for both knowledge and interpersonal skills on the part of the provider. Immunization providers should have an understanding of vaccines, updated recommendations, and of reliable sources to direct patients to find accurate information. Also necessary are the skills to deal with fears and misconceptions about vaccines, and the ability to provide a supportive and encouraging environment for patients.

When a parent or patient initiates discussion regarding a vaccine concern, the provider should discuss the specific concern and provide factual information. The Vaccine Information Statements (VISs) provide an outline for discussing vaccine benefits and risk. Providers can reinforce key points regarding each vaccine, including safety, and emphasize risks encountered by unimmunized children. Parents should be informed about state laws pertaining to school or child care entry, which might require unimmunized children stay home from school during outbreaks. Documentation of these discussions in the patient's record might reduce any potential liability if a vaccine-preventable disease occurs in the unimmunized patient. (See Appendix O., Decision to Not Vaccinate My Child.)

Please note the form in Appendix O is **not** an official Exemption from Immunizations for Reasons of Conscience Form issued by the Texas Department of State Health Services and **cannot be used** by the parent or patient for non-compliance with the Texas Minimum State Vaccine Requirements for **Public and Private Schools, Child-Care Facilities, and Institutions of Higher Education** incorporated in the Texas Administrative Code (TAC), Title 25 Health Services, Sections 97.61 to 97.72

C. Vaccine Adverse Events

1. The Vaccine Adverse Event Reporting System (VAERS) is a national vaccine safety surveillance program co-sponsored by the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC).
2. The purpose of VAERS is to detect possible signals of adverse events associated with vaccines. VAERS collects and analyzes information from reports of adverse events (possible side effects) that occur after the administration of U.S. licensed vaccines.
3. Reports are welcome from all concerned individuals: patients, parents, health-care providers, pharmacists, and vaccine manufacturers.
4. All information requested on the VAERS form should be recorded. It is very important to record the vaccine manufacturer, lot number, and injection site on the VAERS form. The VAERS form also requests the types of vaccine received, the timing of vaccination and onset of the adverse event, a description of the event, current illness or medication, past history of adverse events following vaccination, and demographic information about the recipient (age, gender, etc.).
5. Reports of events following vaccination at clinics using **TVFC vaccine** should be reported directly to DSHS.

Please mail to:
Department of State Health Services
Attn: **VAERS**/Immunization Branch
MC-1946
P.O. Box 149347
Austin, TX 78714-9347

6. The VAERS Reporting Form (C-76) is located in Appendix L, is on the TVFC web page and can also be obtained from the FDA web site:
www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/VaccineAdverseEvents
7. Adverse events may be reported online, by mail, or fax. Contact (800) VAC-RXNS or (800) 822-7967 for information or to request pre-addressed VAERS forms.
8. Reports of events following vaccination at clinics using privately purchased vaccine should be reported directly to VAERS.

D. ImmTrac

Texas Law requires all medical providers to report all immunizations administered to children under 18 years of age to ImmTrac, the Texas immunization registry operated by DSHS (Texas Health and Safety Code, §§161.007-161.009). Providers must report all immunization information within 30 days of administering the vaccine. Prior to reporting immunizations to ImmTrac, providers must register with ImmTrac for registry participation and access. For information on ImmTrac or to register to be an ImmTrac user, call the ImmTrac Customer Support Line at (800) 348-9158.

X. VACCINE INFORMATION STATEMENTS (VIS)

- 1.** Federal law requires all immunization providers (regardless of whether they are enrolled in the TVFC) to provide a parent, guardian, or other responsible adult a current VIS for *each* vaccine the child is to receive, *every time* a vaccine is administered. Copies of VISs can be found on the Immunization Branch main page, www.dshs.state.tx.us/immunize/literature/litlist.
- 2.** Providers should ensure they are using the most current version of each VIS. A list of current VIS dates for each vaccine can be found on the Immunization Action Coalition (IAC) website at www.immunize.org/vis.
- 3.** Providers must take reasonable steps to provide information in the appropriate languages in order to ensure clients with limited English proficiency are effectively informed. VISs in more than 20 additional languages can be downloaded from the Immunization Action Coalition (IAC) website at www.immunize.org/vis.

XI. ORDERING FORMS AND LITERATURE

1. DSHS offers providers various forms, literature, brochures, posters, and vaccine information statements that can be ordered free of charge directly from the DSHS Immunization Branch. Forms are available to view and download OR can be ordered and shipped directly to the provider. Forms may be ordered monthly and providers should allow 10 business days for delivery. A complete list of forms is available online at <https://secure.immunizetexasorderform.com/default.asp>
2. If internet access is unavailable, providers may send their literature request directly to DSHS. When placing orders in writing please include the following:
 - stock number and requested quantity,
 - physical address for delivery, and
 - telephone number, including area code.

The request may be sent in one of the following ways:

Mail to:

Department of State Health Services
Immunization Branch
MC-1946
P.O. Box 149347
Austin, Texas 78714-9347

Fax to: (512) 458-7288 Attn: Jack Shaw

If you have questions regarding forms or the ordering process, please call Jack Shaw at (512) 776-6516 or toll free at (800) 252-9152.

XII. PROGRAM EVALUATION

A. Site Visit

1. Providers participating in the TVFC program can expect to receive an annual visit from a HSR/LHD reviewer or DSHS quality assurance contractor. By signing the TVFC Provider Enrollment form, the signing physician agrees to allow a DSHS or DSHS-contracted entity to conduct an on-site visit.
2. The purpose of the visit is to assess, support, and educate the clinic regarding TVFC policies and procedures. If areas of need are identified, the HSR or LHD will provide a follow-up call or visit to assist the clinic with any changes or questions.
3. An updated TVFC Provider Enrollment Form (E6-102) will be collected at the time of the site visit. Providers should have the Enrollment Form complete, signed, and available for the reviewer during the site visit.
 - a. Providers are required to submit an updated provider profile with the enrollment agreement annually. The provider is required to estimate the number of children who will receive vaccinations at the provider site and the number of children expected to be TVFC eligible.
 - b. TVFC will assess if the patient population estimate reported in the provider profile is a reasonable estimate that coincides with the provider site's vaccine ordering patterns and reported doses administered.
4. The site visit reviewer will assess the provider site visit procedures for eligibility screening. The purpose is to monitor whether providers are appropriately identifying eligible populations to receive TVFC vaccine. At a minimum, at least 10 records/charts will be reviewed for documentation of screening for TVFC eligibility. Since the TVFC requirement is to screen children at all immunization encounters, anything less than full compliance (that is, identifying any chart that does not have documentation of screening) will be discussed with the provider and will require additional follow up.

B. Electronic Medical Records

In recent years, the use of Electronic Medical Records (EMR) has become routine and has changed the way record reviews are conducted. Providers with EMRs have the following two immunization record review options, one of which should be available at the time of the visit:

1. A dedicated staff member who can log-in to the EMR and sit with the field reviewer throughout the record review process to pull up EMR immunization and eligibility records.

Note: It is not acceptable to have a staff member log-in and then turn the EMR screens over to the reviewer; the staff person must be present. This is because every EMR system varies in complexity and the time it takes to master navigation and data extraction from an EMR can be time consuming. With provider staff assistance, the data extraction should be manageable within the limited visit timeframe.

2. Print outs from the EMR of the immunization records and documentation of the child's eligibility. The immunization records need to include all immunization history including records from other providers.

Note: TVFC or the quality assurance contractor will not pay for or reimburse providers for the copies when the provider chooses to print out immunization records from their EMR system.

C. Immunization Coverage Level Assessment

In conjunction with the annual site visit, an immunization coverage level assessment for children aged 19 to 35 months may be conducted using the Comprehensive Clinic Assessment Software Application (CoCASA). This assessment informs the provider of the percent of children aged 19 to 35 months who were age appropriately immunized by 24 months of age. Recommendations on improving immunization rates are also offered during this assessment.

If there are no children in the 19 to 35 month age range then an adolescent immunization coverage level assessment may be conducted if a sufficient number of patients are available in the 11 to 15 year age range.

XIII. IMMUNIZATION GUIDELINE RESOURCES

The following resources regarding immunization practices are available in the DSHS Online TVFC Provider Tool Kit at:

<http://www.dshs.state.tx.us/immunize/toolkit/kit1.shtm>

Contraindications Poster

(DSHS Online TVFC Provider Tool Kit, Section 10)

This poster outlines (1) true contraindications, (2) precautions to giving immunizations, and (3) not true contraindications to immunization. It should be posted in each VFC clinic for easy reference.

Giving All the Doses Chart

(DSHS Online TVFC Provider Tool Kit, Section 4)

This picture demonstrates how and where to give immunizations when up to seven shots are required.

General Recommendations on Immunization

(DSHS Online TVFC Provider Tool Kit, Section 4)

This CDC publication offers providers technical guidance on common immunization issues and concerns.

Recommended Childhood Immunization Schedule

(DSHS Online TVFC Provider Tool Kit, Section 4)

The schedule shows the ages when vaccines are routinely recommended for children ages 0-18 years. The CDC updates this schedule yearly. The latest version can be downloaded from the CDC website at <http://www.cdc.gov/vaccines/recs/schedules/child-schedule.htm>

Vaccine Storage and Handling modules

The new Vaccine Storage & Handling video series was created during the fall of 2011 as a resource to help TVFC enrolled providers stay up-to-date on the latest standards for protecting their vaccine supply.

<http://www.dshs.state.tx.us/immunize/tvfc/default.shtm>

APPENDIX

APPENDIX A
Texas Vaccines for Children Regional Contacts

HEALTH SERVICE REGION 1

Keila Johnson
Immunization Program Manager
300 Victory Drive
Box 60968 WATMU Station
Canyon, TX 79016
(806) 655-7151
(806) 655-7159 - Fax

Keila.Johnson@dshs.state.tx.us

HEALTH SERVICE REGION 7

Diane Romnes
Immunization Program Manager
2408 South 37th Street
Temple, Texas 76504-7168
(254) 778-6744
(254) 771-2612 - Fax

Diane.Romnes@dshs.state.tx.us

HEALTH SERVICE REGIONS 2 & 3

Sonna Sanders
Communicable Disease Manager
1301 South Bowen Road, Suite 200
Arlington, Texas 76013-2262
(817) 264-4771
(817) 264-4991 - Fax

Sonna.Sanders@dshs.state.tx.us

HEALTH SERVICE REGION 8

Laurie Henefey
Immunization Program Manager
2201 East Main, Suite A
Uvalde, Texas 78801
(830) 591-4386
(830) 278-1831 – Fax

Laurie.Henefey@dshs.state.tx.us

HEALTH SERVICE REGIONS 4&5NORTH

Toni Wright
Communicable Disease Manager
1517 W. Front Street
Tyler, Texas 75702
(903) 533-5266
(903) 533-9502 - Fax

Toni.Wright@dshs.state.tx.us

HEALTH SERVICE REGIONS 9 & 10

Racheal Porras
Immunization Program Manager
2301 N. Big Spring #300
Midland, Texas 79705-7649
(432) 571-4131
(432) 571-4190 - Fax

Racheal.Porras@dshs.state.tx.us

HEALTH SERVICE REGION 6&5SOUTH

Kathleen Ingrando, RN, MS
Immunization Program Manager
5425 Polk, Suite J
Houston, Texas 77023
(713) 767-3410
(713) 767-3889 – Fax

Kathleen.Ingrando@dshs.state.tx.us

HEALTH SERVICE REGION 11

Ana Ivette Nunez, BA
Immunization Program Manager
601 W. Sesame Drive
Harlingen, Texas 78550
(956) 423-0130
(956) 444-3216 - Fax

Ivette.Nunez@dshs.state.tx.us

TEXAS VACCINES FOR CHILDREN PROGRAM (TVFC): PROVIDER ENROLLMENT

Initial enrollment* Re-enrollment Provider PIN Number _____

(*Contact the Health Services Region [HSR] in your area to obtain PIN) Responsible Entity _____

Name of Facility, Practice, or Clinic: _____

Provider Name (M.D., D.O., N.P., R.Ph., P.A., or C.N.M.*): _____
(Last Name) (First Name) (MI) (Title)

Contact: _____
(Last Name) (First Name) (MI) (Title)

Mailing Address: _____
(P.O. Box or Street Address) (City) (Zip)

Address for Vaccine Delivery: _____
(Street Address and Suite Number) (City) (County) (Zip)

Telephone Number: (_____) _____ - _____ Fax Number: (_____) _____ - _____
(Area Code) (Area Code)

E-mail Address: _____

In order to participate in the Texas Vaccines for Children Program and/or to receive federally- and state-supplied vaccines provided to me at no cost, I, on behalf of myself and any and all practitioners associated with this medical office, group practice, health department, community/migrant/rural health clinic, or other organization, agree to the following:

- 1) This office/facility will screen patients for TVFC eligibility at all immunization encounters, and administer TVFC-purchased vaccine only to children 18 years of age or younger who meet one or more of the following criteria: (1) Is an American Indian or Alaska Native; (2) is enrolled in Medicaid; (3) has no health insurance; (4) is underinsured: children who have commercial (private) health insurance but the coverage does not include vaccines, children whose insurance covers only selected vaccines (TVFC- eligible for non-covered vaccines only), children whose insurance caps vaccine coverage at a certain amount (once that coverage amount is reached, these children are categorized as underinsured); 5) is a patient who receives benefits from the Children's Health Insurance Plan (CHIP).
- 2) This office/facility will maintain all records related to the TVFC program, including parent/guardian/authorized representative's responses on the Patient Eligibility Screening Form for at least **five** years. If requested, this office/facility will make such records available to the Texas Department of State Health Services (DSHS), the local health department/authority, or the U.S. Department of Health and Human Services.
- 3) This office/facility will comply with the appropriate vaccination schedule, dosage, and contraindications, as established by the Advisory Committee on Immunization Practices, unless (a) in making a medical judgment in accordance with accepted medical practice, this office/facility deems such compliance to be medically inappropriate, or (b) the particular requirement is not in compliance with Texas Law, including laws relating to religious and medical exemptions.
- 4) This office/facility will provide Vaccine Information Statements (VIS) to the responsible adult, parent, or guardian and maintain records in accordance with the National Childhood Vaccine Injury Act which include reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS). Signatures are required for informed consent. (The Texas Addendum portion of the VIS may be used to document informed consent.)
- 5) This office/facility will not charge for vaccines supplied by DSHS and administered to a child who is eligible for the TVFC.
- 6) This office/facility may charge a vaccine administration fee to non-Medicaid or non-CHIP TVFC eligible patients not to exceed \$14.85. Medicaid patients cannot be charged for the vaccine, administration of vaccine, or an office visit associated with Medicaid services. For Medicaid patients, this office/facility agrees to accept the reimbursement for immunization administration set by the state Medicaid agency or the contracted Medicaid health plans.
- 7) This office/facility will not deny administration of a TVFC vaccine to a child because of the inability of the child's parent or guardian/individual of record to pay an administrative fee.
- 8) This office/facility will comply with the State's requirements for ordering vaccine and other requirements as described by DSHS, and operate within the TVFC program in a manner intended to avoid fraud and abuse.
- 9) This office/facility or the State may terminate this agreement at any time for failure to comply with these requirements. If the agreement is terminated for any reason this office/facility agrees to properly return any unused vaccine.
- 10) This office/facility will allow DSHS (or its contractors) to conduct on-site visits as required by VFC regulations.

(Signature*)

(Date)

(Print Name and Title)

* A licensed Medical Doctor, Doctor of Osteopathy, Nurse Practitioner, Physician Assistant, Registered Pharmacist, or a Certified Nurse Midwife must sign the TVFC Enrollment form.



TEXAS VACCINES FOR CHILDREN (TVFC) PROGRAM PATIENT ELIGIBILITY SCREENING RECORD

CLINIC USE ONLY:	
TVFC Eligible:	
<input type="checkbox"/> Yes	<input type="checkbox"/> No
_____ Screener's Initials	

A record of all children 18 years of age or younger who receive immunizations through the Texas Vaccines for Children Program must be kept in the health care provider's office. The record may be completed by the parent, guardian, individual of record, or by the health care provider. TVFC eligibility screening must take place with each immunization visit to ensure the child's eligibility status has not changed. This same record will satisfy the requirements for all subsequent vaccinations, as long as the child's eligibility has not changed. If patient eligibility changes, a new form must be completed. While verification of responses is not required, it is necessary to retain this or a similar record for each child receiving vaccines under the TVFC Program.

Date of Screening: _____
mm/dd/yyyy

Child's Name: _____
Last Name First Name MI

Child's Date of Birth: _____ Age: _____
mm/dd/yyyy

Parent/Guardian/Individual of Record: _____
Last Name First Name MI

Provider's Name/Clinic's Name: _____ Phone Number: (_____) _____
Area Code + number

Please check the first category that applies; check only one.

(a) Is enrolled in Medicaid, or

Medicaid Number: _____ Date of Eligibility (mm/dd/yyyy) _____

(b) Is a patient who receives benefits from the Children's Health Insurance Plan (CHIP), or

CHIP Number: _____ Date of Eligibility (mm/dd/yyyy) _____

(c) Is an American Indian, or

(d) Is an Alaskan Native, or

(e) Does not have health insurance (uninsured), or

(f) Is underinsured:

- 1) has commercial (private) health insurance, but coverage does not include vaccines; or
- 2) insurance covers only selected vaccines (TVFC-eligible for non-covered vaccines only); or
- 3) insurance caps vaccine coverage at a certain amount. Once that coverage amount is reached, the child is categorized as underinsured.

(g) Has private insurance that covers vaccines:

Name of Insurer: _____ Insurer Contact Number: (_____) _____
Area Code + number

Policy/Subscriber Number: _____ Group Number (if applicable): _____

NOTE: Knowingly falsifying information on this document constitutes fraud. By signing this form, I hereby attest that the above information is true and correct. I declare that the person named above is an authorized person and is eligible to receive TVFC vaccines.

Signature: _____

Date: _____
(mm/dd/yyyy)

With few exceptions, you have the right to request and be informed about information that the State of Texas collects about you. You are entitled to receive and review the information upon request. You also have the right to ask the state agency to correct any information that is determined to be incorrect. See <http://www.dshs.state.tx.us> for more information on Privacy Notification. (Reference: Government Code, Section 552.021, 552.023, 559.003, and 559.004)





PROGRAMA DE VACUNAS PARA NIÑOS DE TEXAS (o TVFC)

REGISTRO DE DETERMINACIÓN DEL DERECHO A LA PARTICIPACIÓN DEL PACIENTE

PARA USO DE LA CLÍNICA
CLINIC USE ONLY:
TVFC Eligible:
[] Yes [] No
Screener's Initials

Debe mantenerse el registro de todos los niños de 18 años de edad o menos que reciban inmunizaciones mediante el Programa de Vacunas para Niños de Texas en el consultorio del proveedor de salud. El registro lo puede rellenar el padre o madre, el tutor, el individuo que consta en el registro, o el proveedor de salud. La determinación del derecho a la participación del TVFC debe realizarse en cada consulta de inmunización para asegurarse de que el derecho a la participación del niño no ha cambiado. El mismo registro cumplirá con los requisitos de todas las vacunas posteriores, en tanto el derecho a la participación del niño no haya cambiado. Si cambia el derecho a la participación del paciente, debe rellenarse un nuevo formulario. Aunque la verificación de las respuestas no se requiere, es necesario quedarse con este registro, o uno similar, para cada niño que reciba vacunas bajo el Programa de TVFC.

Fecha de la determinación: _____ (mm/dd/aaaa)

Nombre del niño: _____
Apellido Primer nombre Inicial del 2.o nombre

Fecha de nacimiento del niño: _____ Edad: _____
(mm/dd/aaaa)

Padre o madre, tutor o individuo que consta en el registro: _____
Apellido Primer nombre Inicial del 2.o nombre

Nombre del proveedor o de la clínica: _____ Número telefónico: (____) _____
Código de área + el número

Marque la primera categoría que corresponda; marque sólo una.

(a) [] Está inscrito en Medicaid, o

Número de Medicaid: _____ Fecha del derecho a la participación (mm/dd/aaaa)

(b) [] Es paciente que recibe prestaciones del Plan de Seguro Médico Infantil (o CHIP), o bien

Número de CHIP: _____ Fecha del derecho a la participación (mm/dd/aaaa)

(c) [] Es indio americano, o

(d) [] Es nativo de Alaska, o

(e) [] No tiene seguro médico (no asegurado), o

(f) [] Está subasegurado:

[] 1) tiene seguro médico comercial (privado), pero la cobertura no incluye las vacunas; o

[] 2) el seguro cubre sólo algunas vacunas (reúne los requisitos del TVFC sólo para las vacunas no cubiertas); o

[] 3) el seguro limita la cobertura de las vacunas a cierta cantidad. Una vez alcanzada esa cantidad de cobertura, se categorizará al niño como subasegurado.

(g) [] Tiene seguro privado que cubre las vacunas:

Nombre del asegurador: _____ Número de contacto del asegurador: (____) _____
Código de área + el número

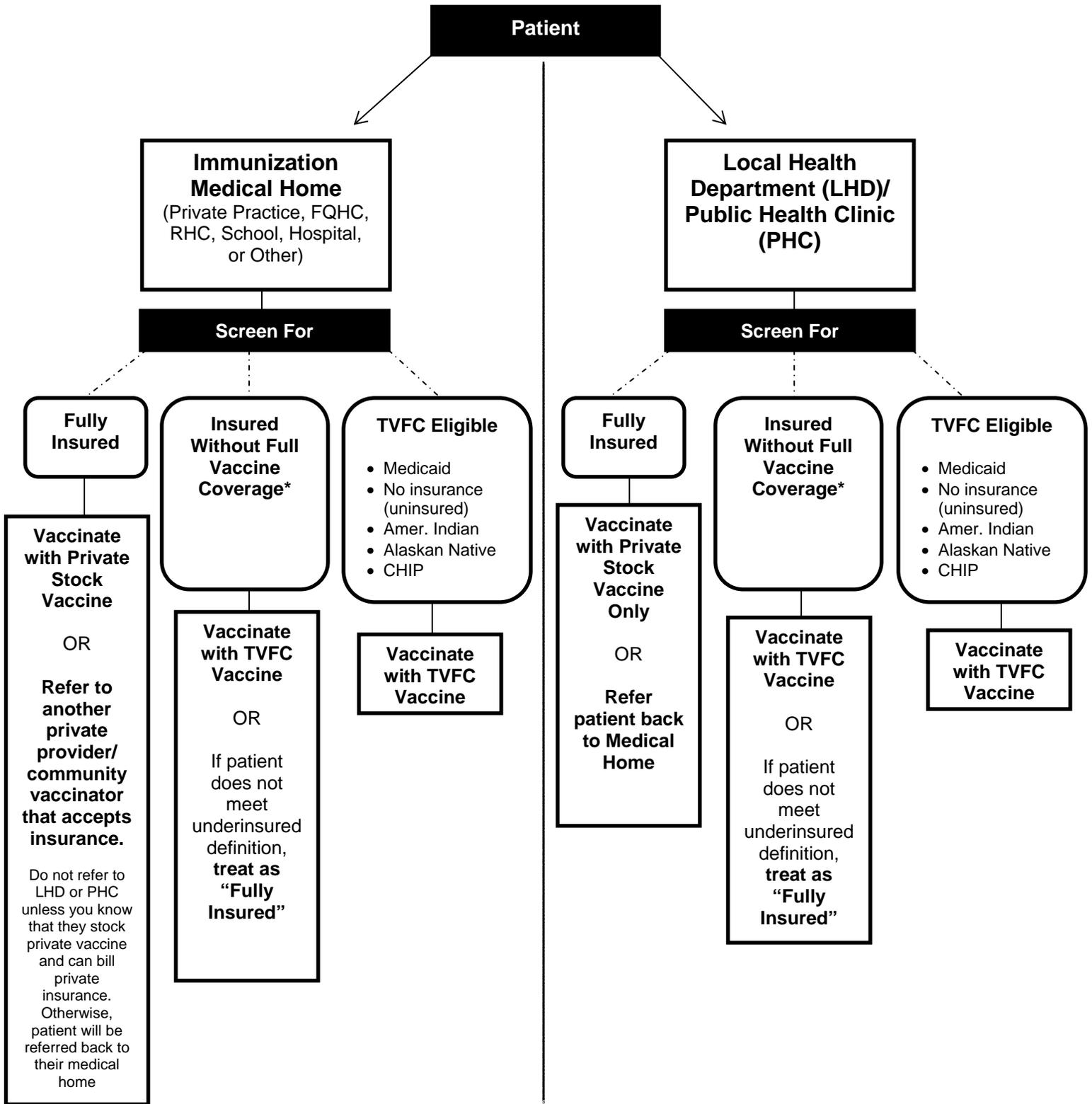
Número de póliza/suscriptor: _____ Número del grupo (de ser aplicable): _____

NOTA: Falsificar información en este documento a sabiendas constituye un fraude. Al firmar este formulario, por este medio doy fe que la información es verdadera y correcta. Yo declaro que la persona nombrada arriba es una persona autorizada y reúne los requisitos para recibir vacunas del TVFC.

Firma: _____ Fecha: _____ (mm/dd/aaaa)

Con ciertas excepciones, tiene derecho a pedir y a ser informado sobre la información que el estado de Texas reúne sobre usted. Tiene derecho a recibir y examinar la información al pedirla. También tiene derecho a pedir a la agencia estatal que corrija cualquier información que se determine es incorrecta. Consulte http://www.dshs.state.tx.us para obtener más información sobre la notificación de privacidad. (Referencia: Código gubernamental, sección 552.021, 552.023, 559.003 y 559.004)

Texas Vaccines for Children Patient Screening Decision Tree



* Effective January 1, 2012, the definition of “Underinsured” is: 1) commercial (private) health insurance, but coverage does not include vaccines; or 2) insurance covers only selected vaccines (TVFC-eligible for non-covered vaccines only); or 3) insurance caps vaccine coverage at a certain amount. Once that coverage amount is reached, the child is categorized as underinsured.

**Patient Referral Form for Vaccination
From Local Health Department or Public Health Clinic**

(Patient Name) _____

Date of Birth (_____/_____/_____) _____

This patient needs one or more vaccinations but has private health insurance and is not eligible for publically purchased vaccines available through the Texas Vaccines for Children (TVFC) Program.

Effective January 1, 2012, Public Health no longer vaccinates clients who are privately insured. *Therefore, we are referring this patient to his/her medical home for the needed vaccinations.*

If the medical home is not able to provide the immunization(s), the patient should be referred to another clinic that accepts the patient's medical insurance.

Referring Public Health Clinic:

NOTE: Issuance of this Patient Referral Form for Vaccination does not extend any state mandated vaccine requirements, or allow children to enter school without appropriate immunizations.

Referral Process

When a patient presents for services at a local health department or public health clinic, staff should first ask if the patient has health insurance.

If no: The patient is eligible for TVFC vaccine.

If yes: Is the insurance Medicaid, CHIP, or other private insurance?
If private insurance: Explain to the patient that the clinic no longer accepts their insurance due to billing issues, and they need to receive vaccines from their medical home. Provide *Patient Referral Form for Vaccination* if helpful or necessary.

If the patient has Medicaid or CHIP: The patient is eligible for TVFC vaccine.

Local Referral Sites (if available):

Name	Phone number	Address
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		



**Department of State Health Services (DSHS)
 Immunization Branch
 Adult Safety Net Program**

Clinic Use Only ASN Eligible	
<input type="checkbox"/> Yes	<input type="checkbox"/> No
_____ Screener's Initials	

ADULT ELIGIBILITY SCREENING RECORD (ASN)

PURPOSE: To determine and record eligibility for the DSHS Adult Safety Net Vaccination Program. A record of the eligibility status of adults receiving vaccine supplied by DSHS must be maintained either in hard copy by the clinic providing the service or in an electronic system such as TWICES. Hard copies should be maintained for **five** years. The record may be used for all subsequent visits as long as the patient's eligibility status has not changed.

Date of Screening: _____
(mm/dd/yy)

Name: _____
(Last) (First) (Middle initial)

Date of Birth: _____
(mm/dd/yy)

Eligibility Criteria:

- I declare that I qualify for vaccines through the Texas Vaccines for Children - Adult Safety Net Program because I do not have health insurance.
- I am 19 years of age and I have been referred to the public health department clinic to finish a vaccine series that I began when I was 18 years of age or younger and eligible under the Texas Vaccines for Children (TVFC) Program.

Referring Provider: _____

Patient Signature: _____ Date: _____
(mm/dd/yy)

NOTE: Knowingly falsifying information on this document constitutes fraud. By signing this form, I hereby attest that the above information is true and correct. I declare that the person named above is an authorized person and is eligible to receive ASN vaccines.

NOTE: HIV/STD clinics that are participating in the hepatitis B special initiative are not required to use this form; all clients in an HIV/STD clinic are eligible for Hepatitis B vaccine. The form is required if the HIV/STD clinic is providing vaccines other than hepatitis B.

With few exceptions, you have the right to request and to be informed about information that the State of Texas collects about you. You are entitled to receive and review the information upon request. You also have the right to ask the agency to correct any information that is determined to be incorrect. See <http://www.dshs.state.tx.us> for more information on Privacy Notification. (Reference: Government Code, Section 552.021, 552.023, and 559.004)





Departamento Estatal de Servicios de Salud de Texas (DSHS)

Rama de Inmunización del Programa de Protección Para Adultos (ASN)

REGISTRO DE DETERMINACIÓN DEL DERECHO A LA PARTICIPACIÓN DE LOS ADULTOS

SÓLO PARA USO CLÍNICO: Clinic Use Only ASN Eligible	
<input type="checkbox"/> Yes	<input type="checkbox"/> No
_____ Screener's Initials	

PROPÓSITO: determinar y registrar el derecho a la participación en el Programa de Vacunación de Protección Para Adultos del DSHS. Se debe guardar un registro del estado del derecho a la participación de los adultos que reciban vacunas suministradas por el DSHS ya sea en copia impresa o en un sistema electrónico como TWICES. Las copias impresas se deben guardar por tres años. Se puede utilizar el registro en todas las consultas posteriores en tanto el estado del derecho a la participación del paciente no haya cambiado.

Fecha de la determinación: _____
(mm/dd/aa)

Nombre: _____
(Apellido) (Primer nombre) (Inicial del 2.º nombre)

Fecha de nacimiento: _____
(mm/dd/aa)

Criterios de participación:

- Declaro que reúno los requisitos de vacunación del Programa de Vacunas Para Niños - Protección para Adultos de Texas porque no tengo seguro médico.
- Tengo 19 años de edad y me han referido a la clínica del departamento de salud pública para terminar una serie de vacunas que inicié cuando tenía 18 años de edad o menos y elegible bajo el programa Vacunas Para Niños de Texas (TVFC).

Proveedor que hizo la derivación: _____

Firma del paciente: _____ Fecha: _____
(mm/dd/aa)

NOTA: Falsificar información en este documento a sabiendas constituye un fraude. Al firmar este formulario, por este medio doy fe que la información es verdadera y correcta. Yo declaro que la persona nombrada arriba es una persona autorizada y reúne los requisitos para recibir vacunas del ASN.

NOTA: No se requiere que las clínicas de VIH/ETS que participan en la iniciativa especial de la hepatitis B usen este formulario; todos los clientes en clínicas de VIH/ETS tienen derecho a recibir la vacuna contra la hepatitis B. Se requiere el formulario si la clínica de VIH/ETS provee vacunas distintas a la de la hepatitis B.

Con ciertas excepciones, tiene derecho a pedir y a ser informado sobre la información que el estado de Texas reúne sobre usted. Tiene derecho a recibir y examinar la información al pedirla. También tiene derecho a pedir a la agencia que corrija cualquier información que se determine es incorrecta. Consulte <http://www.dshs.state.tx.us> para obtener más información sobre la Notificación de privacidad. (Referencia: Código gubernamental, sección 552.021, 552.023 y 559.004)





**Texas Vaccines for Children
Monthly Biological Report (Rev. 05/2012)**

TVFC PIN:*

Month* Year*

Contact Person*

() ()
Phone* Fax*

Clinic Name and Address:*

Use additional forms for additional lot #s		A	B	C	D	E	F	G	H	I	J	K	
Vaccine Type	Lot Number	Expiration Date	Doses on Hand BEGINNING OF MONTH	Doses Received DURING THE MONTH	SUBTOTAL A+B=C	Doses Administered AGE		TOTAL DOSES ADMINISTERED D+E=F	Doses Transferred EC-67	Doses Ruined or Expired EC-69 Required	Doses on Hand END OF MONTH C-F-G-H=I	Physical Count END OF MONTH	Doses Lost - or Gained + J - I = K +/-
						<=18	>=19						
DT													
DT, SDV (Ped)													
GRAND TOTAL Number of Doses													
DTaP													
DAPTACEL, SDV (Ped)													
INFANRIX, SDV (Ped)													
INFANRIX, PFS (Ped)													
TRIPEDIA, SDV (Ped)													
GRAND TOTAL Number of Doses													
DTaP/HepB/IPV													
PEDIARIX, PFS (Ped)													
GRAND TOTAL Number of Doses													
DTaP/IPV													
KINRIX, SDV (Ped)													
KINRIX, PFS (Ped)													
GRAND TOTAL Number of Doses													
DTaP/IPV/Hib													
PENTACEL, SDV (Ped)													
GRAND TOTAL Number of Doses													
Hep A													
HAVRIX, SDV (Ped)													
HAVRIX, PFS (Ped)													
VAQTA, SDV (Ped)													
GRAND TOTAL Number of Doses													



**Texas Vaccines for Children
Monthly Biological Report (Rev. 05/2012)**

TVFC PIN:*

Month* Year*

Use additional forms for additional lot #s			A	B	C	D	E	F	G	H	I	J	K
Vaccine Type	Lot Number	Expiration Date	Doses on Hand BEGINNING OF MONTH	Doses Received DURING THE MONTH	SUBTOTAL A+B=C	Doses Administered AGE		TOTAL DOSES ADMINISTERED D+E=F	Doses Transferred EC-67	Doses Ruined or Expired EC-69 Required	Doses on Hand END OF MONTH C-F-G-H=I	Physical Count END OF MONTH	Doses Lost - or Gained + J-I=K+/-
						<=18	>=19						
Hep B													
ENGERIX B, SDV (Ped)													
ENGERIX B, PF syringe (Ped)													
RECOMBIVAX HB, SDV (Ped)													
GRAND TOTAL Number of Doses													
Hep A / Hep B													
TWINRIX, SDV (Ped)													
TWINRIX, PFS (Ped)													
GRAND TOTAL Number of Doses													
Hep B-HIB													
COMVAX, SDV (Ped)													
GRAND TOTAL Number of Doses													
HIB													
ACTHIB, SDV (Ped)													
HIBERIX, SDV (Ped)													
PEDVAXHIB, SDV (Ped)													
GRAND TOTAL Number of Doses													
HPV													
CERVARIX, SDV (Ped)													
CERVARIX, PFS (Ped)													
GARDASIL, SDV (Ped)													
GRAND TOTAL Number of Doses													
IPV													
IPOL, MDV													
GRAND TOTAL Number of Doses													



**Texas Vaccines for Children
Monthly Biological Report (Rev. 05/2012)**

TVFC PIN:* _____

Month* Year*

Use additional forms for additional lot #s			A	B	C	D	E	F	G	H	I	J	K
Vaccine Type	Lot Number	Expiration Date	Doses on Hand BEGINNING OF MONTH	Doses Received DURING THE MONTH	SUBTOTAL A+B=C	Doses Administered AGE		TOTAL DOSES ADMINISTERED	Doses Transferred	Doses Ruined or Expired	Doses on Hand END OF MONTH	Physical Count END OF MONTH	Doses Lost - or Gained +
						<=18	>=19						
MCV4								D+E=F	EC-67	EC-69 Required	C-F-G-H=I		J-K=L+/-
MENACTRA, SDV (Ped)													
MENVEO, SDV (Ped)													
GRAND TOTAL Number of Doses													
MMR													
MMR II, SDV (Ped)													
GRAND TOTAL Number of Doses													
MMRV													
PROQUAD, SDV (Ped)													
GRAND TOTAL Number of Doses													
PCV13													
PREVNAR 13, PFS (Ped)													
GRAND TOTAL Number of Doses													
PPSV23													
PNEUMOVAX 23, SDV (Ped)													
GRAND TOTAL Number of Doses													
Rotavirus													
ROTARIX, oral (Ped)													
ROTATEQ, oral (Ped)													
GRAND TOTAL Number of Doses													
Td													
DECAVAC, SDV (Ped)													
DECAVAC, PFS (Ped)													
MassbioLogics, SDV (Ped)													
TENIVAC, SDV (Ped)													
TENIVAC, PFS (Ped)													
GRAND TOTAL Number of Doses													



**Texas Vaccines for Children
Monthly Biological Report (Rev. 05/2012)**

TVFC PIN:*

Month* Year*

Use additional forms for additional lot #s			A	B	C	D	E	F	G	H	I	J	K
Vaccine Type	Lot Number	Expiration Date	Doses on Hand BEGINNING OF MONTH	Doses Received DURING THE MONTH	SUBTOTAL A+B=C	Doses Administered AGE		TOTAL DOSES ADMINISTERED D+E=F	Doses Transferred EC-67	Doses Ruined or Expired EC-69 Required	Doses on Hand END OF MONTH C-F-G-H=I	Physical Count END OF MONTH	Doses Lost - or Gained + J-I=K+/-
						<=18	>=19						
TDAP													
ADACEL, SDV (Ped)													
ADACEL, PFS (Ped)													
BOOSTRIX, SDV (Ped)													
BOOSTRIX, PFS (Ped)													
GRAND TOTAL Number of Doses													
VARICELLA													
VARIVAX, SDV (Ped)													
GRAND TOTAL Number of Doses													

* Required Field

This certifies that this report is a true accounting of the above biologicals received from the Texas Department of State Health Services that were administered during the reported time period. No one was refused immunizations for failure to pay an administrative fee or make a donation to the provider.

Approved by: (Physician or other authorized signature)*

Date

Comment Section: Must explain lost or gained doses from column K

DSHS/LHD USE ONLY

Processed By:

Date:



**Texas Vaccines for Children
Adult Safety Net Monthly Biological Report (Rev. 05/2012)**

TVFC PIN:* _____

Month* Year*

Contact Person*

() ()
Phone* Fax*

Clinic Name and Address:*

Use additional forms for additional lot #s			A	B	C	D	E	F	G	H	I	J	K
Vaccine Type	Lot Number	Expiration Date	Doses on Hand BEGINNING OF MONTH	Doses Received DURING THE MONTH	SUBTOTAL A+B=C	Doses Administered AGE		TOTAL DOSES ADMINISTERED D+E=F	Doses Transferred EC-67	Doses Ruined or Expired EC-69 Required	Doses on Hand END OF MONTH C-F-G-H=I	Physical Count END OF MONTH	Doses Lost - or Gained + J - I = K +/-
						<=18	>=19						
HEP A													
HAVRIX, SDV (Adult)													
HAVRIX, PFS (Adult)													
GRAND TOTAL Number of Doses													
HEB B													
ENGERIX-B, SDV (Adult)													
ENGERIX-B, PFS (Adult)													
RECOMBIVAX HB, SDV (Adult)													
GRAND TOTAL Number of Doses													
HEP A/HEP B													
TWINRIX, SDV (Adult)													
TWINRIX, PFS (Adult)													
GRAND TOTAL Number of Doses													
HPV													
CERVARIX, SDV (Adult)													
CERVARIX, PFS (Adult)													
GARDASIL, SDV (Adult)													
GRAND TOTAL Number of Doses													
MCV4													
MENACTRA, SDV (Adult)													
MENVEO, SDV (Adult)													
GRAND TOTAL Number of Doses													
MMR													
MMR II, SDV (Adult)													
GRAND TOTAL Number of Doses													



**Texas Vaccines for Children
Adult Safety Net Monthly Biological Report (Rev. 05/2012)**

TVFC PIN:* _____

Use additional forms for additional lot #s			Month* Year*										
Vaccine Type	Lot Number	Expiration Date	A Doses on Hand BEGINNING OF MONTH	B Doses Received DURING THE MONTH	C SUBTOTAL A+B=C	Doses Administered AGE		F TOTAL DOSES ADMINISTERED D+E=F	G Doses Transferred EC-67	H Doses Ruined or Expired EC-69 Required	I Doses on Hand END OF MONTH C-F-G-H=I	J Physical Count END OF MONTH	K Doses Lost - or Gained + J - I = K +/-
						<=18	>=19						
PPSV23													
PNEUMOVAX 23, SDV													
PNEUMOVAX 23, SDV													
PNEUMOVAX 23, MDV													
GRAND TOTAL Number of Doses													
Td													
DECAVAC, PFS (Adult)													
TENIVAC, SDV (Adult)													
TENIVAC, PFS (Adult)													
Akorn, SDV (Adult)													
MassBioLogics, SDV (Ad)													
GRAND TOTAL Number of Doses													
TDAP													
ADACEL, SDV (Adult)													
ADACEL, PFF (Adult)													
BOOSTRIX, SDV (Adult)													
BOOSTRIX, PFS (Adult)													
GRAND TOTAL Number of Doses													
VARICELLA													
VARIVAX, SDV (Adult)													
GRAND TOTAL Number of Doses													
ZOSTER													
ZOSTAVAX, SDV (Adult)													
GRAND TOTAL Number of Doses													

* Required Field

This certifies that this report is a true accounting of the above biologicals received from the Texas Department of State Health Services that were administered during the reported time period. No one was refused immunizations for failure to pay an administrative fee or make a donation to the provider.

Comment Section: Must explain lost or gained doses from column K

Approved by: (Physician or other authorized signature)* _____ Date _____

DSHS/LHD USE ONLY
 Processed By: _____ Date: _____



**Texas Vaccines for Children
Influenza Monthly Biological Report (Rev. 05/2012)**

TVFC PIN:* _____

Contact Person*

() _____ () _____
Phone* Fax*

Month* Year*

Clinic Name and Address:*

Use additional forms for additional lot #s		A	B	C	D		E	F	G	H	I	J	K
Vaccine Type	Lot Number	Expiration Date	Doses on Hand BEGINNING OF MONTH	Doses Received DURING THE MONTH	SUBTOTAL A+B=C	Doses Administered AGE		TOTAL DOSES ADMINISTERED D+E=F	Doses Transferred EC-67	Doses Ruined or Expired EC-69 Required	Doses on Hand END OF MONTH C-F-G-H=I	Physical Count END OF MONTH	Doses Lost - or Gained + J - I = K +/-
						<=18	>=19						
Influenza													
Fluzone, 0.25 mL PF Syringe													
Fluzone, 0.5 mL single-dose vial													
Fluzone, 0.5 mL PF Syringe													
Fluzone, 10 Dose Vial													
Fluarix, 0.5mL PF Syringe													
Flumist, Intranasal													
Fluvirin, 0.5mL PF Syringe													
Fluvirin, 10 Dose Vial													
Afluria, 0.5mL PF Syringe													
GRAND TOTAL Number of Doses													

* Required Field

This certifies that this report is a true accounting of the above biologicals received from the Texas Department of State Health Services that were administered during the reported time period. No one was refused immunizations for failure to pay an administrative fee or make a donation to the provider.

Comment Section: Must explain lost or gained doses from column K

Approved by: (Physician or other authorized signature)* _____ Date _____

DSHS/LHD USE ONLY
Processed By: _____

Date: _____

Texas Department of State Health Services

INITIAL ORDER

PEDIATRIC Biological Order Form

PIN:

CLINIC DAYS/HOURS	AM		PM	Contact Person:
MONDAY	_____ to _____	_____	_____ to _____	Phone: _____
TUESDAY	_____ to _____	_____	_____ to _____	Fax: _____
WEDNESDAY	_____ to _____	_____	_____ to _____	Clinic Name: _____
THURSDAY	_____ to _____	_____	_____ to _____	Address: _____
FRIDAY	_____ to _____	_____	_____ to _____	_____
Holidays/closed:	_____			_____

PROVIDER TIER AND ORDERING SCHEDULE

PICK FROM LIST

VACCINE	MAXIMUM STOCK LEVEL	% SELECTED	ORDER AMOUNT
DT			
DT, single-dose vial (Ped)			
DTaP			
DAPTACEL, single-dose vial (Ped)			
INFANRIX, single-dose vial (Ped)			
INFANRIX, PF syringe (Ped)			
DTaP/Hep B/IPV			
PEDIARIX, PF syringe (Ped)			
DTaP-IPV			
KINRIX, single-dose vial (Ped)			
KINRIX, PF syringe (Ped)			
DTaP/IPV/Hib			
PENTACEL, single-dose vial (Ped)			
Hep A			
HAVRIX, single-dose vial (Ped)			
HAVRIX, PF syringe (Ped)			
VAQTA, single-dose vial (Ped)			
Hep B			
ENGERIX B, single-dose vial (Ped)			
ENGERIX B, PF syringe (Ped)			
RECOMBIVAX HB, single-dose vial (Ped)			
Hep A/Hep B			
TWINRIX, single-dose vial			
TWINRIX, PF syringe (Ped)			
Hep B/HIB			
COMVAX, single-dose vial			
HIB			
ACTHIB, single-dose vial (Ped)			
HIBERIX, single-dose vial (Ped)			
PEDVAXHIB, single-dose vial (Ped)			
HPV			
CERVARIX, PF syringe (Ped)			
GARDASIL, single-dose vial (Ped)			
IPV			
IPOL, multi-dose vial (Ped)			

**Texas Department of State Health Services
PEDIATRIC Biological Order Form Continued**

PIN:

VACCINE	MAXIMUM STOCK LEVEL	% SELECTED	ORDER AMOUNT
MCV4			
MENACTRA, single-dose vial (Ped)			
MENVEO, single-dose vial (Ped)			
MMR			
MMR II, single-dose vial (Ped)			
MMRV			
PROQUAD, single-dose vial (Ped)			
PCV13			
PREVNAR 13, PF syringe (Ped)			
PPSV23			
PNEUMOVAX 23, single-dose vial (Ped)			
ROTAVIRUS			
ROTARIX, oral applicator (Ped)			
ROTATEQ, oral applicator (Ped)			
Td			
DECAVAC, single-dose vial (Ped)			
DECAVAC, PF syringe, (Ped)			
Td-MassBiologics, single-dose vial (Ped)			
TDAP			
ADACEL, single-dose vial (Ped)			
ADACEL, PF syringe (Ped)			
BOOSTRIX, single-dose vial (Ped)			
BOOSTRIX, PF syringe (Ped)			
The following vaccine will ship separately. Allow additional time to receive:			
Varicella			
VARIVAX, single-dose vial (Ped)			

Date of Order

Approved (Authorized Signature)

Comments and/or justification for order amounts if outside MSL:



INSTRUCTIONS:

- ⌚ Complete the form heading, please print and do not abbreviate. Be sure to include the PIN.
- ⌚ Post on refrigerator/freezer door.
- ⌚ Record refrigerator and freezer temperatures twice daily throughout the workweek, once upon staff arrival and again before leaving for the day. Record the actual **time** for the refrigerators. Record the actual **time** and **temperature** for the freezers.
- ⌚ Record the temperature by writing in “A” for morning or “P” for afternoon, in the box, under the appropriate temperature and day of the month. It is appropriate to have written an “A” and “P” in the same box, if the temperature has the same reading in the morning and afternoon. See examples:

40°
11:20A
6:45 P

40°
11:20A
6:45 P

- Refrigerator: Use the shaded column to record any temperature that is outside the range of +36° to +46° Fahrenheit or +2° to +8° Centigrade. Record the actual time and temperature for refrigerators. **Take immediate action! (Example: call health service region or local health department)**
- Freezer: Use the shaded column to record any temperature warmer than +5° Fahrenheit or -15° Centigrade. Record the actual time and temperature for freezers. **Take immediate action! (Example: call health service region or local health department)**
- ⌚ Record initials of the person checking the temperature.
- ⌚ Attach a copy of completed forms to the Monthly Biological Report Form (stock no. C-33) and return to your Health Service Region.



DO NOT DISCARD ANY BIOLOGICAL WITHOUT FIRST CONTACTING THE TEXAS DEPARTMENT OF STATE HEALTH SERVICES (DSHS), PHARMACY BRANCH!

When the proper storage of a biological has been interrupted (refrigerator and/or freezer mechanical failure, loss of electricity, refrigerator and/or freezer door left open, biological left unrefrigerated, etc.), immediately place the biological into proper storage and contact the DSHS, Pharmacy Branch for instructions on the use of the biological.

DO NOT assume that the biological is damaged or spoiled without contacting the DSHS, Pharmacy Branch at 512-458-7500.

Separate thermometers should be placed in the refrigerator and freezer.

For additional forms, contact the DSHS, Immunization Branch at (800) 252-9152.

TEMPERATURE RECORDING FORM
Refrigerator/Freezer Centigrade

PIN: _____
 Month & Year of Report: _____ / _____
 Name of Person Completing Form: _____

Clinic Name: _____
 Address, City, Zip: _____
 Telephone Number: (____) _____

Date of Month	<i>The internal temperature of the refrigerator should range between +2° to +8° C and the internal temperature of the freezer should not exceed -15° C.</i>										Staff Initials		
	Centigrade Refrigerator Temperature - Check twice daily in the A.M. and P.M.									Centigrade Freezer Temperature		A.M.	P.M.
	Too Cold (Record Actual Temperature)	+2°	+3°	+4°	+5° (Target Temp)	+6°	+7°	+8°	Too Warm (Record Actual Temperature)	-15° or colder (Record Actual Temperature)	-14° or warmer (Record Actual Temperature)		
1													
2													
3													
4													
5													
6													
7													
8													
9													
10													
11													
12													
13													
14													
15													
16													
17													
18													
19													
20													
21													
22													
23													
24													
25													
26													
27													
28													
29													
30													
31													

Write date of month next to all actions taken while temp was out of range: _____ Regional or local health department notified. _____ Thermostat increased. _____ Thermostat decreased. _____ Vaccine moved to another refrigerator/freezer. _____ Maintenance notified. _____ Measured temperature with a different thermometer to check accuracy of reading. _____ Refrigerator replaced. _____ Freezer replaced. _____ Other

Instructions and vaccine warning on back of form! Destroy Prior Revisions.

INSTRUCTIONS:

- ⌚ Complete the form heading, please print and do not abbreviate. Be sure to include the PIN.
- ⌚ Post on refrigerator/freezer door.
- ⌚ Record refrigerator and freezer temperatures twice daily throughout the workweek, once upon staff arrival and again before leaving for the day. Record the actual **time** for the refrigerators. Record the actual **time** and **temperature** for the freezers.
- ⌚ Record the temperature by writing in “A” for morning or “P” for afternoon, in the box, under the appropriate temperature and day of the month. It is appropriate to have written an “A” and “P” in the same box, if the temperature has the same reading in the morning and afternoon. See examples:

40°
11:20A
6:45 P

40°
11:20A
6:45 P

- Refrigerator: Use the shaded column to record any temperature that is outside the range of +36° to +46° Fahrenheit or +2° to +8° Centigrade. Record the actual time and temperature for refrigerators. **Take immediate action! (Example: call health service region or local health department)**
 - Freezer: Use the shaded column to record any temperature warmer than +5° Fahrenheit or -15° Centigrade. Record the actual time and temperature for freezers. **Take immediate action! (Example: call health service region or local health department)**
- ⌚ Record initials of the person checking the temperature.
 - ⌚ Attach a copy of completed forms to the Monthly Biological Report Form (stock no. C-33) and return to your Health Service Region.



DO NOT DISCARD ANY BIOLOGICAL WITHOUT FIRST CONTACTING THE TEXAS DEPARTMENT OF STATE HEALTH SERVICES (DSHS), PHARMACY BRANCH!

When the proper storage of a biological has been interrupted (refrigerator and/or freezer mechanical failure, loss of electricity, refrigerator and/or freezer door left open, biological left unrefrigerated, etc.), immediately place the biological into proper storage and contact the DSHS, Pharmacy Branch for instructions on the use of the biological.

DO NOT assume that the biological is damaged or spoiled without contacting the DSHS, Pharmacy Branch at 512-458-7500.

Separate thermometers should be placed in the refrigerator and freezer.

For additional forms, contact the DSHS, Immunization Branch at (800) 252-9152.

TEXAS
Vaccine Loss Report

Please fill out form completely. You may be contacted if additional information is required.

Clinic Name: _____ PIN: _____

Address: _____
Street
City
Zip
County

Contact: _____ Phone: _____
Person Completing Form

Date loss was discovered: _____

Circle Reason(s) for Loss:

- | | |
|--------------------------------------|---|
| 1. Expired | 5. Failure to store properly upon receipt |
| 2. Natural Disaster/power outage | 6. Vaccine spoiled in transit |
| 3. Storage temperature too warm | 7. Mechanical Failure |
| 4. Refrigerator temperature too cold | 8. Spoiled |
| | 9. Other |

Explanation of Loss (required entry): _____

In order to ensure that this will not happen again, the following steps will/have been taken: _____

- Trained staff to notify LHD or HSR 90 days before vaccines expire (if loss due to expiration)
- Trained staff to rotate stock using the shortest dated product first (if loss due to expiration)
- Trained staff to take immediate action to correct out of range temperatures, and to contact LHD or HSR (if loss due to temperature maintenance)

Please note losses of state-supplied vaccine in doses (not vials). Do not include private stock.

Vaccine	Manufacturer	Lot No.	NDC Number	Expiration Date	# Doses Lost

 Provider Signature (person who signed TVFC enrollment: MD, DO, NP, PA, CNM)

 Date

 Print Name and Title



PROVIDER WITHDRAWAL FORM

*PIN: _____

*Withdrawal Date: _____

Please complete this form when you no longer wish to participate in the Texas Vaccine for Children (TVFC) Program. Fax the completed form to your Regional TVFC contact. Any remaining state vaccine will be picked up within 5 days of withdrawal from the TVFC Program. Please remember that Texas Health Steps providers may not refer Texas Health Steps patients elsewhere for immunizations.

Name of Facility: _____

Provider Name: _____
(Last Name) (First Name) (MI) (Title)

Contact Name: _____
(Last Name) (First Name) (MI) (Title)

Address: _____
(Street Address) (City) (Zip) (County)

Phone #: (____) _____ - _____ Fax #: (____) _____ - _____

*Reason for Withdrawal:

- | | |
|--|---|
| <input type="checkbox"/> 1. Facility is Closing | <input type="checkbox"/> 7. No Longer Enrolled in Medicaid |
| <input type="checkbox"/> 2. No Longer Seeing Children | <input type="checkbox"/> 8. Relocating Out of Area
*New County |
| <input type="checkbox"/> 3. Too Much Paperwork | _____ |
| <input type="checkbox"/> 4. Staffing Issues | New Address |
| <input type="checkbox"/> 5. Physician no longer practicing | _____ |
| <input type="checkbox"/> 6. Not Using TVFC Vaccine | <input type="checkbox"/> 9. Other: |
| | _____ |
| | _____ |
| | <input type="checkbox"/> 10. Provider Withdrawn by HSR/AO |

*Required Fields

For HSR/LHD Use Only:

Date faxed to HSR: ___/___/___

Date faxed to AO: ___/___/___

Date vaccines picked up: ___/___/___



VACCINE ADVERSE EVENT REPORTING SYSTEM
 24 Hour Toll-Free Information 1-800-822-7967
 PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only

VAERS Number _____

Date Received _____

Patient Name: _____ Last First M.I. Address _____ _____ _____ City State Zip Telephone no. (____) _____	Vaccine administered by (Name): _____ Responsible Physician _____ Facility Name/Address _____ _____ _____ City State Zip Telephone no. (____) _____	Form completed by (Name): _____ Relation <input type="checkbox"/> Vaccine Provider <input type="checkbox"/> Patient/Parent to Patient <input type="checkbox"/> Manufacturer <input type="checkbox"/> Other Address (if different from patient or provider) _____ _____ _____ City State Zip Telephone no. (____) _____
---	---	---

1. State	2. County where administered	<input type="checkbox"/> 3. Date of birth	<input type="checkbox"/> 4. Patient age	5. Sex	6. Date form completed
		_____ / _____ / _____ mm dd yy		<input type="checkbox"/> M <input type="checkbox"/> F	_____ / _____ / _____ mm dd yy

<input type="checkbox"/> 7. Describe adverse event(s) (symptoms, signs, time course) and treatment, if any.	<input type="checkbox"/> 8. Check all appropriate: <input type="checkbox"/> Patient died (date _____ / _____ / _____) <input type="checkbox"/> Life threatening illness <input type="checkbox"/> Required emergency room/doctor visit <input type="checkbox"/> Required hospitalization (_____ days) <input type="checkbox"/> Resulted in prolongation of hospitalization <input type="checkbox"/> Resulted in permanent disability <input type="checkbox"/> None of the above
---	--

9. Patient recovered <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> UNKNOWN	<input type="checkbox"/> 10. Date of vaccination _____ / _____ / _____ mm dd yy Time _____ AM PM	<input type="checkbox"/> 11. Adverse event onset _____ / _____ / _____ mm dd yy Time _____ AM PM
--	--	--

13. Enter all vaccines given on date listed in no. 10					
Vaccine (type)	Manufacturer	Lot number	Route/Site	No. Previous doses	
a. _____	_____	_____	_____	_____	
b. _____	_____	_____	_____	_____	
c. _____	_____	_____	_____	_____	
d. _____	_____	_____	_____	_____	

14. Any other vaccinations within 4 weeks prior to the date listed in no. 10						
Vaccine (type)	Manufacturer	Lot number	Route/Site	No. Previous doses	Date given	
a. _____	_____	_____	_____	_____	_____	
b. _____	_____	_____	_____	_____	_____	

15. Vaccinated at: <input type="checkbox"/> Private doctor's office/hospital <input type="checkbox"/> Military clinic/hospital <input type="checkbox"/> Public health clinic/hospital <input type="checkbox"/> Other/unknown	16. Vaccine purchased with: <input type="checkbox"/> Private funds <input type="checkbox"/> Military Funds <input type="checkbox"/> Public funds <input type="checkbox"/> Other/unknown	17. Other medications
--	---	-----------------------

18. Illness at time of vaccination (specify)	19. Pre-existing physician-diagnosed allergies, birth defects, medical conditions (specify)
--	---

20. Have you reported this adverse event previously? <input type="checkbox"/> No <input type="checkbox"/> To health department <input type="checkbox"/> To doctor <input type="checkbox"/> To manufacturer	Only for children 5 and under	
	22. Birth weight _____ lb. _____ oz.	23. No. of brothers and sisters

21. Adverse event following prior vaccination (check all applicable, specify)	Only for reports submitted by manufacturer/immunization project	
<input type="checkbox"/> In patient Adverse Event Onset Age Type Vaccine Dose no. in series _____ <input type="checkbox"/> In brother or sister _____ _____ _____	24. Mfr./imm. proj. report no.	25. Date received by mfr./imm.proj.
	26. 15 day report? <input type="checkbox"/> Yes <input type="checkbox"/> No	27. Report type <input type="checkbox"/> Initial <input type="checkbox"/> Follow-Up



POSTAGE WILL BE PAID BY ADDRESSEE



NO POSTAGE NECESSARY IF MAILED IN THE UNITED STATES



VAERS
C/O DEPARTMENT OF STATE HEALTH SERVICES
IMMUNIZATION BRANCH
MC1946
PO BOX 149347
AUSTIN TX 78714-9909



Fold in thirds, tape & mail --- DO NOT STAPLE FORM

DIRECTIONS FOR COMPLETING FORM

(Additional pages may be attached if more space is needed.)

GENERAL

- Use a separate form for each patient. Complete the form to the best of your abilities. Items 3, 4, 7, 8, 10, 11, and 13 are considered essential and should be completed whenever possible. Parents/Guardians may need to consult the facility where the vaccine was administered for some of the information (such as manufacturer, lot number or laboratory data.)
Refer to the Reportable Events Table (RET) for events mandated for reporting by law. Reporting for other serious events felt to be related but not on the RET is encouraged.
Health care providers other than the vaccine administrator (VA) treating a patient for a suspected adverse event should notify the VA and provide the information about the adverse event to allow the VA to complete the form to meet the VA's legal responsibility.
These data will be used to increase understanding of adverse events following vaccination and will become part of CDC Privacy Act System 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems". Information identifying the person who received the vaccine or that person's legal representative will not be made available to the public, but may be available to the vaccinee or legal representative.
Postage will be paid by addressee. Forms may be photocopied (must be front & back on same sheet).

SPECIFIC INSTRUCTIONS

Form Completed By: To be used by parents/guardians, vaccine manufacturers/distributors, vaccine administrators, and/or the person completing the form on behalf of the patient or the health professional who administered the vaccine.

- Item 7: Describe the suspected adverse event. Such things as temperature, local and general signs and symptoms, time course, duration of symptoms, diagnosis, treatment and recovery should be noted.
Item 9: Check YES if the patient's health condition is the same as it was prior to the vaccine, NO if the patient has not returned to the pre-vaccination state of health, or UNKNOWN if the patient's condition is not known.
Item 10: Give dates and times as specifically as you can remember. If you do not know the exact time, please
and 11: indicate AM or PM when possible if this information is known. If more than one adverse event, give the onset date and time for the most serious event.
Item 12: Include negative or normal results of any relevant tests performed as well as abnormal findings.
Item 13: List ONLY those vaccines given on the day listed in Item 10.
Item 14: List any other vaccines that the patient received within 4 weeks prior to the date listed in Item 10.
Item 16: This section refers to how the person who gave the vaccine purchased it, not to the patient's insurance.
Item 17: List any prescription or non-prescription medications the patient was taking when the vaccine(s) was given.
Item 18: List any short term illnesses the patient had on the date the vaccine(s) was given (i.e., cold, flu, ear infection).
Item 19: List any pre-existing physician-diagnosed allergies, birth defects, medical conditions (including developmental and/ or neurologic disorders) for the patient.
Item 21: List any suspected adverse events the patient, or the patient's brothers or sisters, may have had to previous vaccinations. If more than one brother or sister, or if the patient has reacted to more than one prior vaccine, use additional pages to explain completely. For the onset age of a patient, provide the age in months if less than two years old.
Item 26: This space is for manufacturers' use only.



FIGURE 1: Recommended immunization schedule for persons aged 0 through 6 years—United States, 2012 (for those who fall behind or start late, see the catch-up schedule [Figure 3])

Vaccine ▼	Age ►	Birth	1 month	2 months	4 months	6 months	9 months	12 months	15 months	18 months	19–23 months	2–3 years	4–6 years	
Hepatitis B ¹		Hep B	HepB			HepB								Range of recommended ages for all children
Rotavirus ²			RV	RV	RV ²									
Diphtheria, tetanus, pertussis ³			DTaP	DTaP	DTaP		see footnote ⁹	DTaP					DTaP	
<i>Haemophilus influenzae</i> type b ⁴			Hib	Hib	Hib ⁴			Hib						Range of recommended ages for certain high-risk groups
Pneumococcal ⁵			PCV	PCV	PCV			PCV				PPSV		
Inactivated poliovirus ⁶			IPV	IPV		IPV							IPV	
Influenza ⁷						Influenza (Yearly)								
Measles, mumps, rubella ⁸								MMR		see footnote ⁹			MMR	Range of recommended ages for all children and certain high-risk groups
Varicella ⁹								Varicella		see footnote ⁹			Varicella	
Hepatitis A ¹⁰								Dose 1 ¹⁰				HepA Series		
Meningococcal ¹¹						MCV4 — see footnote ¹¹								

This schedule includes recommendations in effect as of December 23, 2011. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. The use of a combination vaccine generally is preferred over separate injections of its equivalent component vaccines. Vaccination providers should consult the relevant Advisory Committee on Immunization Practices (ACIP) statement for detailed recommendations, available online at <http://www.cdc.gov/vaccines/pubs/acip-list.htm>. Clinically significant adverse events that follow vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS) online (<http://www.vaers.hhs.gov>) or by telephone (800-822-7967).

- Hepatitis B (HepB) vaccine.** (Minimum age: birth)

At birth:

 - Administer monovalent HepB vaccine to all newborns before hospital discharge.
 - For infants born to hepatitis B surface antigen (HBsAg)-positive mothers, administer HepB vaccine and 0.5 mL of hepatitis B immune globulin (HBIG) within 12 hours of birth. These infants should be tested for HBsAg and antibody to HBsAg (anti-HBs) 1 to 2 months after receiving the last dose of the series.
 - If mother's HBsAg status is unknown, within 12 hours of birth administer HepB vaccine for infants weighing $\geq 2,000$ grams, and HepB vaccine plus HBIG for infants weighing $< 2,000$ grams. Determine mother's HBsAg status as soon as possible and, if she is HBsAg-positive, administer HBIG for infants weighing $\geq 2,000$ grams (no later than age 1 week).

Doses after the birth dose:

 - The second dose should be administered at age 1 to 2 months. Monovalent HepB vaccine should be used for doses administered before age 6 weeks.
 - Administration of a total of 4 doses of HepB vaccine is permissible when a combination vaccine containing HepB is administered after the birth dose.
 - Infants who did not receive a birth dose should receive 3 doses of a HepB-containing vaccine starting as soon as feasible (Figure 3).
 - The minimum interval between dose 1 and dose 2 is 4 weeks, and between dose 2 and 3 is 8 weeks. The final (third or fourth) dose in the HepB vaccine series should be administered no earlier than age 24 weeks and at least 16 weeks after the first dose.
- Rotavirus (RV) vaccines.** (Minimum age: 6 weeks for both RV-1 [Rotarix] and RV-5 [Rota Teq])
 - The maximum age for the first dose in the series is 14 weeks, 6 days; and 8 months, 0 days for the final dose in the series. Vaccination should not be initiated for infants aged 15 weeks, 0 days or older.
 - If RV-1 (Rotarix) is administered at ages 2 and 4 months, a dose at 6 months is not indicated.
- Diphtheria and tetanus toxoids and acellular pertussis (DTaP) vaccine.** (Minimum age: 6 weeks)
 - The fourth dose may be administered as early as age 12 months, provided at least 6 months have elapsed since the third dose.
- Haemophilus influenzae* type b (Hib) conjugate vaccine.** (Minimum age: 6 weeks)
 - If PRP-OMP (PedvaxHIB or Comvax [HepB-Hib]) is administered at ages 2 and 4 months, a dose at age 6 months is not indicated.
 - Hiberix should only be used for the booster (final) dose in children aged 12 months through 4 years.
- Pneumococcal vaccines.** (Minimum age: 6 weeks for pneumococcal conjugate vaccine [PCV]; 2 years for pneumococcal polysaccharide vaccine [PPSV])
 - Administer 1 dose of PCV to all healthy children aged 24 through 59 months who are not completely vaccinated for their age.
 - For children who have received an age-appropriate series of 7-valent PCV (PCV7), a single supplemental dose of 13-valent PCV (PCV13) is recommended for:
 - All children aged 14 through 59 months
 - Children aged 60 through 71 months with underlying medical conditions.
 - Administer PPSV at least 8 weeks after last dose of PCV to children aged 2 years or older with certain underlying medical conditions, including a cochlear implant. See *MMWR* 2010;59(No. RR-11), available at <http://www.cdc.gov/mmwr/pdf/rr/rr5911.pdf>.
- Inactivated poliovirus vaccine (IPV).** (Minimum age: 6 weeks)
 - If 4 or more doses are administered before age 4 years, an additional dose should be administered at age 4 through 6 years.
 - The final dose in the series should be administered on or after the fourth birthday and at least 6 months after the previous dose.
- Influenza vaccines.** (Minimum age: 6 months for trivalent inactivated influenza vaccine [TIV]; 2 years for live, attenuated influenza vaccine [LAIV])
 - For most healthy children aged 2 years and older, either LAIV or TIV may be used. However, LAIV should not be administered to some children, including 1) children with asthma, 2) children 2 through 4 years who had wheezing in the past 12 months, or 3) children who have any other underlying medical conditions that predispose them to influenza complications. For all other contraindications to use of LAIV, see *MMWR* 2010;59(No. RR-8), available at <http://www.cdc.gov/mmwr/pdf/rr/rr5908.pdf>.
 - For children aged 6 months through 8 years:
 - For the 2011–12 season, administer 2 doses (separated by at least 4 weeks) to those who did not receive at least 1 dose of the 2010–11 vaccine. Those who received at least 1 dose of the 2010–11 vaccine require 1 dose for the 2011–12 season.
 - For the 2012–13 season, follow dosing guidelines in the 2012 ACIP influenza vaccine recommendations.
- Measles, mumps, and rubella (MMR) vaccine.** (Minimum age: 12 months)
 - The second dose may be administered before age 4 years, provided at least 4 weeks have elapsed since the first dose.
 - Administer MMR vaccine to infants aged 6 through 11 months who are traveling internationally. These children should be revaccinated with 2 doses of MMR vaccine, the first at ages 12 through 15 months and at least 4 weeks after the previous dose, and the second at ages 4 through 6 years.
- Varicella (VAR) vaccine.** (Minimum age: 12 months)
 - The second dose may be administered before age 4 years, provided at least 3 months have elapsed since the first dose.
 - For children aged 12 months through 12 years, the recommended minimum interval between doses is 3 months. However, if the second dose was administered at least 4 weeks after the first dose, it can be accepted as valid.
- Hepatitis A (HepA) vaccine.** (Minimum age: 12 months)
 - Administer the second (final) dose 6 to 18 months after the first.
 - Unvaccinated children 24 months and older at high risk should be vaccinated. See *MMWR* 2006;55(No. RR-7), available at <http://www.cdc.gov/mmwr/pdf/rr/rr5507.pdf>.
 - A 2-dose HepA vaccine series is recommended for anyone aged 24 months and older, previously unvaccinated, for whom immunity against hepatitis A virus infection is desired.
- Meningococcal conjugate vaccines, quadrivalent (MCV4).** (Minimum age: 9 months for Menactra [MCV4-D], 2 years for Menveo [MCV4-CRM])
 - For children aged 9 through 23 months 1) with persistent complement component deficiency; 2) who are residents of or travelers to countries with hyperendemic or epidemic disease; or 3) who are present during outbreaks caused by a vaccine serogroup, administer 2 primary doses of MCV4-D, ideally at ages 9 months and 12 months or at least 8 weeks apart.
 - For children aged 24 months and older with 1) persistent complement component deficiency who have not been previously vaccinated; or 2) anatomic/functional asplenia, administer 2 primary doses of either MCV4 at least 8 weeks apart.
 - For children with anatomic/functional asplenia, if MCV4-D (Menactra) is used, administer at a minimum age of 2 years and at least 4 weeks after completion of all PCV doses.
 - See *MMWR* 2011;60:72–6, available at <http://www.cdc.gov/mmwr/pdf/wk/mm6003.pdf>, and Vaccines for Children Program resolution No. 6/11-1, available at <http://www.cdc.gov/vaccines/programs/vfc/downloads/resolutions/06-11mening-mcv.pdf>, and *MMWR* 2011;60:1391–2, available at <http://www.cdc.gov/mmwr/pdf/wk/mm6040.pdf>, for further guidance, including revaccination guidelines.

FIGURE 2: Recommended immunization schedule for persons aged 7 through 18 years—United States, 2012 (for those who fall behind or start late, see the schedule below and the catch-up schedule [Figure 3])

Vaccine ▼	Age ►	7–10 years	11–12 years	13–18 years	
Tetanus, diphtheria, pertussis ¹		1 dose (if indicated)	1 dose	1 dose (if indicated)	Range of recommended ages for all children
Human papillomavirus ²		see footnote ²	3 doses	Complete 3-dose series	
Meningococcal ³		See footnote ³	Dose 1	Booster at 16 years old	Range of recommended ages for catch-up immunization
Influenza ⁴		Influenza (yearly)			
Pneumococcal ⁵		See footnote ⁵			Range of recommended ages for certain high-risk groups
Hepatitis A ⁶		Complete 2-dose series			
Hepatitis B ⁷		Complete 3-dose series			
Inactivated poliovirus ⁸		Complete 3-dose series			
Measles, mumps, rubella ⁹		Complete 2-dose series			
Varicella ¹⁰		Complete 2-dose series			

This schedule includes recommendations in effect as of December 23, 2011. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. The use of a combination vaccine generally is preferred over separate injections of its equivalent component vaccines. Vaccination providers should consult the relevant Advisory Committee on Immunization Practices (ACIP) statement for detailed recommendations, available online at <http://www.cdc.gov/vaccines/pubs/acip-list.htm>. Clinically significant adverse events that follow vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS) online (<http://www.vaers.hhs.gov>) or by telephone (800-822-7967).

- Tetanus and diphtheria toxoids and acellular pertussis (Tdap) vaccine.** (Minimum age: 10 years for Boostrix and 11 years for Adacel)
 - Persons aged 11 through 18 years who have not received Tdap vaccine should receive a dose followed by tetanus and diphtheria toxoids (Td) booster doses every 10 years thereafter.
 - Tdap vaccine should be substituted for a single dose of Td in the catch-up series for children aged 7 through 10 years. Refer to the catch-up schedule if additional doses of tetanus and diphtheria toxoid-containing vaccine are needed.
 - Tdap vaccine can be administered regardless of the interval since the last tetanus and diphtheria toxoid-containing vaccine.
- Human papillomavirus (HPV) vaccines (HPV4 [Gardasil] and HPV2 [Cervarix]).** (Minimum age: 9 years)
 - Either HPV4 or HPV2 is recommended in a 3-dose series for females aged 11 or 12 years. HPV4 is recommended in a 3-dose series for males aged 11 or 12 years.
 - The vaccine series can be started beginning at age 9 years.
 - Administer the second dose 1 to 2 months after the first dose and the third dose 6 months after the first dose (at least 24 weeks after the first dose).
 - See *MMWR* 2010;59:626–32, available at <http://www.cdc.gov/mmwr/pdf/wk/mm5920.pdf>.
- Meningococcal conjugate vaccines, quadrivalent (MCV4).**
 - Administer MCV4 at age 11 through 12 years with a booster dose at age 16 years.
 - Administer MCV4 at age 13 through 18 years if patient is not previously vaccinated.
 - If the first dose is administered at age 13 through 15 years, a booster dose should be administered at age 16 through 18 years with a minimum interval of at least 8 weeks after the preceding dose.
 - If the first dose is administered at age 16 years or older, a booster dose is not needed.
 - Administer 2 primary doses at least 8 weeks apart to previously unvaccinated persons with persistent complement component deficiency or anatomic/functional asplenia, and 1 dose every 5 years thereafter.
 - Adolescents aged 11 through 18 years with human immunodeficiency virus (HIV) infection should receive a 2-dose primary series of MCV4, at least 8 weeks apart.
 - See *MMWR* 2011;60:72–76, available at <http://www.cdc.gov/mmwr/pdf/wk/mm6003.pdf>, and Vaccines for Children Program resolution No. 6/11-1, available at <http://www.cdc.gov/vaccines/programs/vfc/downloads/resolutions/06-11mening-mcv.pdf>, for further guidelines.
- Influenza vaccines (trivalent inactivated influenza vaccine [TIV] and live, attenuated influenza vaccine [LAIV]).**
 - For most healthy, nonpregnant persons, either LAIV or TIV may be used, except LAIV should not be used for some persons, including those with asthma or any other underlying medical conditions that predispose them to influenza complications. For all other contraindications to use of LAIV, see *MMWR* 2010;59(No. RR-8), available at <http://www.cdc.gov/mmwr/pdf/rr/rr5908.pdf>.
 - Administer 1 dose to persons aged 9 years and older.
 - For children aged 6 months through 8 years:
 - For the 2011–12 season, administer 2 doses (separated by at least 4 weeks) to those who did not receive at least 1 dose of the 2010–11 vaccine. Those who received at least 1 dose of the 2010–11 vaccine require 1 dose for the 2011–12 season.
 - For the 2012–13 season, follow dosing guidelines in the 2012 ACIP influenza vaccine recommendations.
- Pneumococcal vaccines (pneumococcal conjugate vaccine [PCV] and pneumococcal polysaccharide vaccine [PPSV]).**
 - A single dose of PCV may be administered to children aged 6 through 18 years who have anatomic/functional asplenia, HIV infection or other immunocompromising condition, cochlear implant, or cerebral spinal fluid leak. See *MMWR* 2010;59(No. RR-11), available at <http://www.cdc.gov/mmwr/pdf/rr/rr5911.pdf>.
 - Administer PPSV at least 8 weeks after the last dose of PCV to children aged 2 years or older with certain underlying medical conditions, including a cochlear implant. A single revaccination should be administered after 5 years to children with anatomic/functional asplenia or an immunocompromising condition.
- Hepatitis A (HepA) vaccine.**
 - HepA vaccine is recommended for children older than 23 months who are at increased risk for infection, or for whom immunity against hepatitis A virus infection is desired. See *MMWR* 2006;55(No. RR-7), available at <http://www.cdc.gov/mmwr/pdf/rr/rr5507.pdf>.
 - Administer 2 doses at least 6 months apart to unvaccinated persons.
- Hepatitis B (HepB) vaccine.**
 - Administer the 3-dose series to those not previously vaccinated.
 - For those with incomplete vaccination, follow the catch-up recommendations (Figure 3).
 - A 2-dose series (doses separated by at least 4 months) of adult formulation Recombivax HB is licensed for use in children aged 11 through 15 years.
- Inactivated poliovirus vaccine (IPV).**
 - The final dose in the series should be administered at least 6 months after the previous dose.
 - If both OPV and IPV were administered as part of a series, a total of 4 doses should be administered, regardless of the child's current age.
 - IPV is not routinely recommended for U.S. residents aged 18 years or older.
- Measles, mumps, and rubella (MMR) vaccine.**
 - The minimum interval between the 2 doses of MMR vaccine is 4 weeks.
- Varicella (VAR) vaccine.**
 - For persons without evidence of immunity (see *MMWR* 2007;56[No. RR-4], available at <http://www.cdc.gov/mmwr/pdf/rr/rr5604.pdf>), administer 2 doses if not previously vaccinated or the second dose if only 1 dose has been administered.
 - For persons aged 7 through 12 years, the recommended minimum interval between doses is 3 months. However, if the second dose was administered at least 4 weeks after the first dose, it can be accepted as valid.
 - For persons aged 13 years and older, the minimum interval between doses is 4 weeks.

FIGURE 3. Catch-up immunization schedule for persons aged 4 months through 18 years who start late or who are more than 1 month behind —United States • 2012

The figure below provides catch-up schedules and minimum intervals between doses for children whose vaccinations have been delayed. A vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Use the section appropriate for the child's age. **Always use this table in conjunction with the accompanying childhood and adolescent immunization schedules (Figures 1 and 2) and their respective footnotes.**

Persons aged 4 months through 6 years					
Vaccine	Minimum Age for Dose 1	Minimum Interval Between Doses			
		Dose 1 to dose 2	Dose 2 to dose 3	Dose 3 to dose 4	Dose 4 to dose 5
Hepatitis B	Birth	4 weeks	8 weeks and at least 16 weeks after first dose; minimum age for the final dose is 24 weeks		
Rotavirus ¹	6 weeks	4 weeks	4 weeks ¹		
Diphtheria, tetanus, pertussis ²	6 weeks	4 weeks	4 weeks	6 months	6 months ²
<i>Haemophilus influenzae</i> type b ³	6 weeks	4 weeks if first dose administered at younger than age 12 months 8 weeks (as final dose) if first dose administered at age 12–14 months No further doses needed if first dose administered at age 15 months or older	4 weeks ³ if current age is younger than 12 months 8 weeks (as final dose) ³ if current age is 12 months or older and first dose administered at younger than age 12 months and second dose administered at younger than 15 months No further doses needed if previous dose administered at age 15 months or older	8 weeks (as final dose) This dose only necessary for children aged 12 months through 59 months who received 3 doses before age 12 months	
Pneumococcal ⁴	6 weeks	4 weeks if first dose administered at younger than age 12 months 8 weeks (as final dose for healthy children) if first dose administered at age 12 months or older or current age 24 through 59 months No further doses needed for healthy children if first dose administered at age 24 months or older	4 weeks if current age is younger than 12 months 8 weeks (as final dose for healthy children) if current age is 12 months or older No further doses needed for healthy children if previous dose administered at age 24 months or older	8 weeks (as final dose) This dose only necessary for children aged 12 months through 59 months who received 3 doses before age 12 months or for children at high risk who received 3 doses at any age	
Inactivated poliovirus ⁵	6 weeks	4 weeks	4 weeks	6 months ⁵ minimum age 4 years for final dose	
Meningococcal ⁶	9 months	8 weeks ⁶			
Measles, mumps, rubella ⁷	12 months	4 weeks			
Varicella ⁸	12 months	3 months			
Hepatitis A	12 months	6 months			
Persons aged 7 through 18 years					
Tetanus, diphtheria/ tetanus, diphtheria, pertussis ⁹	7 years ⁹	4 weeks	4 weeks if first dose administered at younger than age 12 months 6 months if first dose administered at 12 months or older	6 months if first dose administered at younger than age 12 months	
Human papillomavirus ¹⁰	9 years	Routine dosing intervals are recommended ¹⁰			
Hepatitis A	12 months	6 months			
Hepatitis B	Birth	4 weeks	8 weeks (and at least 16 weeks after first dose)		
Inactivated poliovirus ⁵	6 weeks	4 weeks	4 weeks ⁵	6 months ⁵	
Meningococcal ⁶	9 months	8 weeks ⁶			
Measles, mumps, rubella ⁷	12 months	4 weeks			
Varicella ⁸	12 months	3 months if person is younger than age 13 years 4 weeks if person is aged 13 years or older			

- Rotavirus (RV) vaccines (RV-1 [Rotarix] and RV-5 [Rota Teq]).**
 - The maximum age for the first dose in the series is 14 weeks, 6 days; and 8 months, 0 days for the final dose in the series. Vaccination should not be initiated for infants aged 15 weeks, 0 days or older.
 - If RV-1 was administered for the first and second doses, a third dose is not indicated.
- Diphtheria and tetanus toxoids and acellular pertussis (DTaP) vaccine.**
 - The fifth dose is not necessary if the fourth dose was administered at age 4 years or older.
- Haemophilus influenzae* type b (Hib) conjugate vaccine.**
 - Hib vaccine should be considered for unvaccinated persons aged 5 years or older who have sickle cell disease, leukemia, human immunodeficiency virus (HIV) infection, or anatomic/functional asplenia.
 - If the first 2 doses were PRP-OMP (PedvaxHIB or Comvax) and were administered at age 11 months or younger, the third (and final) dose should be administered at age 12 through 15 months and at least 8 weeks after the second dose.
 - If the first dose was administered at age 7 through 11 months, administer the second dose at least 4 weeks later and a final dose at age 12 through 15 months.
- Pneumococcal vaccines.** (Minimum age: 6 weeks for pneumococcal conjugate vaccine [PCV]; 2 years for pneumococcal polysaccharide vaccine [PPSV])
 - For children aged 24 through 71 months with underlying medical conditions, administer 1 dose of PCV if 3 doses of PCV were received previously, or administer 2 doses of PCV at least 8 weeks apart if fewer than 3 doses of PCV were received previously.
 - A single dose of PCV may be administered to certain children aged 6 through 18 years with underlying medical conditions. See age-specific schedules for details.
 - Administer PPSV to children aged 2 years or older with certain underlying medical conditions. See *MMWR* 2010;59(No. RR-11), available at <http://www.cdc.gov/mmwr/pdf/rr/rr5911.pdf>.
- Inactivated poliovirus vaccine (IPV).**
 - A fourth dose is not necessary if the third dose was administered at age 4 years or older and at least 6 months after the previous dose.
 - In the first 6 months of life, minimum age and minimum intervals are only recommended if the person is at risk for imminent exposure to circulating poliovirus (i.e., travel to a polio-endemic region or during an outbreak).
 - IPV is not routinely recommended for U.S. residents aged 18 years or older.
- Meningococcal conjugate vaccines, quadrivalent (MCV4).** (Minimum age: 9 months for Menactra [MCV4-D]; 2 years for Menveo [MCV4-CRM])
 - See Figure 1 (“Recommended immunization schedule for persons aged 0 through 6 years”) and Figure 2 (“Recommended immunization schedule for persons aged 7 through 18 years”) for further guidance.
- Measles, mumps, and rubella (MMR) vaccine.**
 - Administer the second dose routinely at age 4 through 6 years.
- Varicella (VAR) vaccine.**
 - Administer the second dose routinely at age 4 through 6 years. If the second dose was administered at least 4 weeks after the first dose, it can be accepted as valid.
- Tetanus and diphtheria toxoids (Td) and tetanus and diphtheria toxoids and acellular pertussis (Tdap) vaccines.**
 - For children aged 7 through 10 years who are not fully immunized with the childhood DTaP vaccine series, Tdap vaccine should be substituted for a single dose of Td vaccine in the catch-up series; if additional doses are needed, use Td vaccine. For these children, an adolescent Tdap vaccine dose should not be given.
 - An inadvertent dose of DTaP vaccine administered to children aged 7 through 10 years can count as part of the catch-up series. This dose can count as the adolescent Tdap dose, or the child can later receive a Tdap booster dose at age 11–12 years.
- Human papillomavirus (HPV) vaccines (HPV4 [Gardasil] and HPV2 [Cervarix]).**
 - Administer the vaccine series to females (either HPV2 or HPV4) and males (HPV4) at age 13 through 18 years if patient is not previously vaccinated.
 - Use recommended routine dosing intervals for vaccine series catch-up; see Figure 2 (“Recommended immunization schedule for persons aged 7 through 18 years”).

Clinically significant adverse events that follow vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS) online (<http://www.vaers.hhs.gov>) or by telephone (800-822-7967). Suspected cases of vaccine-preventable diseases should be reported to the state or local health department. Additional information, including precautions and contraindications for vaccination, is available from CDC online (<http://www.cdc.gov/vaccines>) or by telephone (800-CDC-INFO [800-232-4636]).

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Recommended Adult Immunization Schedule—United States - 2012

Note: These recommendations must be read with the footnotes that follow containing number of doses, intervals between doses, and other important information.

Figure 1. Recommended adult immunization schedule, by vaccine and age group¹

VACCINE ▼	AGE GROUP ►	19-21 years	22-26 years	27-49 years	50-59 years	60-64 years	≥ 65 years	
Influenza ²		1 dose annually						
Tetanus, diphtheria, pertussis (Td/Tdap) ^{3,*}		Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs						Td/Tdap ³
Varicella ^{4,*}		2 Doses						
Human papillomavirus (HPV) Female ^{5,*}		3 doses						
Human papillomavirus (HPV) Male ^{5,*}		3 doses						
Zoster ⁶						1 dose		
Measles, mumps, rubella (MMR) ^{7,*}		1 or 2 doses			1 dose			
Pneumococcal (polysaccharide) ^{8,9}		1 or 2 doses					1 dose	
Meningococcal ^{10,*}		1 or more doses						
Hepatitis A ^{11,*}		2 doses						
Hepatitis B ^{12,*}		3 doses						

*Covered by the Vaccine Injury Compensation Program

For all persons in this category who meet the age requirements and who lack documentation of vaccination or have no evidence of previous infection	Recommended if some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indications)	Tdap recommended for ≥65 if contact with <12 month old child. Either Td or Tdap can be used if no infant contact	No recommendation
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Report all clinically significant postvaccination reactions to the Vaccine Adverse Event Reporting System (VAERS). Reporting forms and instructions on filing a VAERS report are available at www.vaers.hhs.gov or by telephone, 800-822-7967.

Information on how to file a Vaccine Injury Compensation Program claim is available at www.hrsa.gov/vaccinecompensation or by telephone, 800-338-2382. To file a claim for vaccine injury, contact the U.S. Court of Federal Claims, 717 Madison Place, N.W., Washington, D.C. 20005; telephone, 202-357-6400.

Additional information about the vaccines in this schedule, extent of available data, and contraindications for vaccination is also available at www.cdc.gov/vaccines or from the CDC-INFO Contact Center at 800-CDC-INFO (800-232-4636) in English and Spanish, 8:00 a.m. - 8:00 p.m. Eastern Time, Monday - Friday, excluding holidays.

Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

Figure 2. Vaccines that might be indicated for adults based on medical and other indications¹

VACCINE ▼	INDICATION ►	Pregnancy	Immunocompromising conditions (excluding human immunodeficiency virus [HIV]) ^{4,6,7,14}	HIV infection ^{4,7,13,14} CD4+ T lymphocyte count		Men who have sex with men (MSM)	Heart disease, chronic lung disease, chronic alcoholism	Asplenia ¹³ (including elective splenectomy and persistent complement component deficiencies)	Chronic liver disease	Diabetes, kidney failure, end-stage renal disease, receipt of hemodialysis	Health-care personnel	
				<200 cells/ μ L	>200 cells/ μ L							
Influenza ²			1 dose TIV annually			1 dose TIV or LAIV annually	1 dose TIV annually			1 dose TIV or LAIV annually		
Tetanus, diphtheria, pertussis (Td/Tdap) ^{3,*}	Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs											
Varicella ^{4,*}		Contraindicated		2 doses								
Human papillomavirus (HPV) Female ^{5,*}		3 doses through age 26 yrs		3 doses through age 26 yrs								
Human papillomavirus (HPV) Male ^{5,*}		3 doses through age 26 yrs		3 doses through age 21 yrs								
Zoster ⁶		Contraindicated		1 dose								
Measles, mumps, rubella (MMR) ^{7,*}		Contraindicated		1 or 2 doses								
Pneumococcal (polysaccharide) ^{8,9}		1 or 2 doses										
Meningococcal ^{10,*}		1 or more doses										
Hepatitis A ^{11,*}				2 doses								
Hepatitis B ^{12,*}				3 doses								

*Covered by the Vaccine Injury Compensation Program

The recommendations in this schedule were approved by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP), the American Academy of Family Physicians (AAFP), the American College of Physicians (ACP), American College of Obstetricians and Gynecologists (ACOG) and American College of Nurse-Midwives (ACNM).

For all persons in this category who meet the age requirements and who lack documentation of vaccination or have no evidence of previous infection
 Recommended if some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indications)
 Contraindicated
 No recommendation

These schedules indicate the recommended age groups and medical indications for which administration of currently licensed vaccines is commonly indicated for adults ages 19 years and older, as of January 1, 2012. For all vaccines being recommended on the Adult Immunization Schedule: a vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Licensed combination vaccines may be used whenever any components of the combination are indicated and when the vaccine's other components are not contraindicated. For detailed recommendations on all vaccines, including those used primarily for travelers or that are issued during the year, consult the manufacturers' package inserts and the complete statements from the Advisory Committee on Immunization Practices (www.cdc.gov/vaccines/pubs/acip-list.htm). Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.



Footnotes — Recommended Adult Immunization Schedule—United States - 2012

1. Additional information

- Advisory Committee on Immunization Practices (ACIP) vaccine recommendations and additional information are available at: <http://www.cdc.gov/vaccines/pubs/acip-list.htm>.
- Information on travel vaccine requirements and recommendations (e.g., for hepatitis A and B, meningococcal, and other vaccines) available at <http://wwwnc.cdc.gov/travel/page/vaccinations.htm>.

2. Influenza vaccination

- Annual vaccination against influenza is recommended for all persons 6 months of age and older.
- Persons 6 months of age and older, including pregnant women, can receive the trivalent inactivated vaccine (TIV).
- Healthy, nonpregnant adults younger than age 50 years without high-risk medical conditions can receive either intranasally administered live, attenuated influenza vaccine (LAIV) (FluMist), or TIV. Health-care personnel who care for severely immunocompromised persons (i.e., those who require care in a protected environment) should receive TIV rather than LAIV. Other persons should receive TIV.
- The intramuscular or intradermal administered TIV are options for adults aged 18–64 years.
- Adults aged 65 years and older can receive the standard dose TIV or the high-dose TIV (Fluzone High-Dose).

3. Tetanus, diphtheria, and acellular pertussis (Td/Tdap) vaccination

- Administer a one-time dose of Tdap to adults younger than age 65 years who have not received Tdap previously or for whom vaccine status is unknown to replace one of the 10-year Td boosters.
- Tdap is specifically recommended for the following persons:
 - pregnant women more than 20 weeks' gestation,
 - adults, regardless of age, who are close contacts of infants younger than age 12 months (e.g., parents, grandparents, or child care providers), and
 - health-care personnel.
- Tdap can be administered regardless of interval since the most recent tetanus or diphtheria-containing vaccine.
- Pregnant women not vaccinated during pregnancy should receive Tdap immediately postpartum.
- Adults 65 years and older may receive Tdap.
- Adults with unknown or incomplete history of completing a 3-dose primary vaccination series with Td-containing vaccines should begin or complete a primary vaccination series. Tdap should be substituted for a single dose of Td in the vaccination series with Tdap preferred as the first dose.
- For unvaccinated adults, administer the first 2 doses at least 4 weeks apart and the third dose 6–12 months after the second.
- If incompletely vaccinated (i.e., less than 3 doses), administer remaining doses.

Refer to the ACIP statement for recommendations for administering Td/Tdap as prophylaxis in wound management (See footnote 1).

4. Varicella vaccination

- All adults without evidence of immunity to varicella (as defined below) should receive 2 doses of single-antigen varicella vaccine or a second dose if they have received only 1 dose.
- Special consideration for vaccination should be given to those who
 - have close contact with persons at high risk for severe disease (e.g., health-care personnel and family contacts of persons with immunocompromising conditions) or
 - are at high risk for exposure or transmission (e.g., teachers; child care employees; residents and staff members of institutional settings, including correctional institutions; college students; military personnel; adolescents and adults living in households with children; nonpregnant women of childbearing age; and international travelers).
- Pregnant women should be assessed for evidence of varicella immunity. Women who do not have evidence of immunity should receive the first dose of varicella vaccine upon completion or termination of pregnancy and before discharge from the health-care facility. The second dose should be administered 4–8 weeks after the first dose.
- Evidence of immunity to varicella in adults includes any of the following:
 - documentation of 2 doses of varicella vaccine at least 4 weeks apart;
 - U.S.-born before 1980 (although for health-care personnel and pregnant women, birth before 1980 should not be considered evidence of immunity);
 - history of varicella based on diagnosis or verification of varicella by a health-care provider (for a patient reporting a history of or having an atypical case, a mild case, or both, health-care providers should seek either an epidemiologic link to a typical varicella case or to a

7. Measles, mumps, rubella (MMR) vaccination (cont'd)

Rubella component:

- For women of childbearing age, regardless of birth year, rubella immunity should be determined. If there is no evidence of immunity, women who are not pregnant should be vaccinated. Pregnant women who do not have evidence of immunity should receive MMR vaccine upon completion or termination of pregnancy and before discharge from the health-care facility.

Health-care personnel born before 1957:

- For unvaccinated health-care personnel born before 1957 who lack laboratory evidence of measles, mumps, and/or rubella immunity or laboratory confirmation of disease, health-care facilities should consider routinely vaccinating personnel with 2 doses of MMR vaccine at the appropriate interval for measles and mumps or 1 dose of MMR vaccine for rubella.

8. Pneumococcal polysaccharide (PPSV) vaccination

- Vaccinate all persons with the following indications:
 - age 65 years and older without a history of PPSV vaccination;
 - adults younger than 65 years with chronic lung disease (including chronic obstructive pulmonary disease, emphysema, and asthma); chronic cardiovascular diseases; diabetes mellitus; chronic liver disease (including cirrhosis); alcoholism; cochlear implants; cerebrospinal fluid leaks; immunocompromising conditions; and functional or anatomic asplenia (e.g., sickle cell disease and other hemoglobinopathies, congenital or acquired asplenia, splenic dysfunction, or splenectomy [if elective splenectomy is planned, vaccinate at least 2 weeks before surgery]);
 - residents of nursing homes or long-term care facilities; and
 - adults who smoke cigarettes.
- Persons with asymptomatic or symptomatic HIV infection should be vaccinated as soon as possible after their diagnosis.
- When cancer chemotherapy or other immunosuppressive therapy is being considered, the interval between vaccination and initiation of immunosuppressive therapy should be at least 2 weeks. Vaccination during chemotherapy or radiation therapy should be avoided.
- Routine use of PPSV is not recommended for American Indians/Alaska Natives or other persons younger than 65 years of age unless they have underlying medical conditions that are PPSV indications. However, public health authorities may consider recommending PPSV for American Indians/Alaska Natives who are living in areas where the risk for invasive pneumococcal disease is increased.

9. Revaccination with PPSV

- One-time revaccination 5 years after the first dose is recommended for persons 19 through 64 years of age with chronic renal failure or nephrotic syndrome; functional or anatomic asplenia (e.g., sickle cell disease or splenectomy); and for persons with immunocompromising conditions.
- Persons who received PPSV before age 65 years for any indication should receive another dose of the vaccine at age 65 years or later if at least 5 years have passed since their previous dose.
- No further doses are needed for persons vaccinated with PPSV at or after age 65 years.

10. Meningococcal vaccination

- Administer 2 doses of meningococcal conjugate vaccine quadrivalent (MCV4) at least 2 months apart to adults with functional asplenia or persistent complement component deficiencies.
- HIV-infected persons who are vaccinated should also receive 2 doses.
- Administer a single dose of meningococcal vaccine to microbiologists routinely exposed to isolates of *Neisseria meningitidis*, military recruits, and persons who travel to or live in countries in which meningococcal disease is hyperendemic or epidemic.
- First-year college students up through age 21 years who are living in residence halls should be vaccinated if they have not received a dose on or after their 16th birthday.
- MCV4 is preferred for adults with any of the preceding indications who are 55 years old and younger; meningococcal polysaccharide vaccine (MPSV4) is preferred for adults 56 years and older.
- Revaccination with MCV4 every 5 years is recommended for adults previously vaccinated with MCV4 or MPSV4 who remain at increased risk for infection (e.g., adults with anatomic or functional asplenia or persistent complement component deficiencies).

11. Hepatitis A vaccination

- Vaccinate any person seeking protection from hepatitis A virus (HAV) infection and persons with any of the following indications:
 - men who have sex with men and persons who use injection drugs;

- laboratory-confirmed case or evidence of laboratory confirmation, if it was performed at the time of acute disease);
- history of herpes zoster based on diagnosis or verification of herpes zoster by a health-care provider; or
- laboratory evidence of immunity or laboratory confirmation of disease.

5. Human papillomavirus (HPV) vaccination

- Two vaccines are licensed for use in females, bivalent HPV vaccine (HPV2) and quadrivalent HPV vaccine (HPV4), and one HPV vaccine for use in males (HPV4).
- For females, either HPV4 or HPV2 is recommended in a 3-dose series for routine vaccination at 11 or 12 years of age, and for those 13 through 26 years of age, if not previously vaccinated.
- For males, HPV4 is recommended in a 3-dose series for routine vaccination at 11 or 12 years of age, and for those 13 through 21 years of age, if not previously vaccinated. Males 22 through 26 years of age may be vaccinated.
- HPV vaccines are not live vaccines and can be administered to persons who are immunocompromised as a result of infection (including HIV infection), disease, or medications. Vaccine is recommended for immunocompromised persons through age 26 years who did not get any or all doses when they were younger. The immune response and vaccine efficacy might be less than that in immunocompetent persons.
- Men who have sex with men (MSM) might especially benefit from vaccination to prevent condyloma and anal cancer. HPV4 is recommended for MSM through age 26 years who did not get any or all doses when they were younger.
- Ideally, vaccine should be administered before potential exposure to HPV through sexual activity; however, persons who are sexually active should still be vaccinated consistent with age-based recommendations. HPV vaccine can be administered to persons with a history of genital warts, abnormal Papanicolaou test, or positive HPV DNA test.
- A complete series for either HPV4 or HPV2 consists of 3 doses. The second dose should be administered 1–2 months after the first dose; the third dose should be administered 6 months after the first dose (at least 24 weeks after the first dose).
- Although HPV vaccination is not specifically recommended for health-care personnel (HCP) based on their occupation, HCP should receive the HPV vaccine if they are in the recommended age group.

6. Zoster vaccination

- A single dose of zoster vaccine is recommended for adults 60 years of age and older regardless of whether they report a prior episode of herpes zoster. Although the vaccine is licensed by the Food and Drug Administration (FDA) for use among and can be administered to persons 50 years and older, ACIP recommends that vaccination begins at 60 years of age.
- Persons with chronic medical conditions may be vaccinated unless their condition constitutes a contraindication, such as pregnancy or severe immunodeficiency.
- Although zoster vaccination is not specifically recommended for health-care personnel (HCP), HCP should receive the vaccine if they are in the recommended age group.

7. Measles, mumps, rubella (MMR) vaccination

- Adults born before 1957 generally are considered immune to measles and mumps. All adults born in 1957 or later should have documentation of 1 or more doses of MMR vaccine unless they have a medical contraindication to the vaccine, laboratory evidence of immunity to each of the three diseases, or documentation of provider-diagnosed measles or mumps disease. For rubella, documentation of provider-diagnosed disease is not considered acceptable evidence of immunity.

Measles component:

- A routine second dose of MMR vaccine, administered a minimum of 28 days after the first dose, is recommended for adults who
 - are students in postsecondary educational institutions;
 - work in a health-care facility; or
 - plan to travel internationally.
- Persons who received inactivated (killed) measles vaccine or measles vaccine of unknown type from 1963 to 1967 should be revaccinated with 2 doses of MMR vaccine.

Mumps component:

- A routine second dose of MMR vaccine, administered a minimum of 28 days after the first dose, is recommended for adults who
 - are students in postsecondary educational institutions;
 - work in a health-care facility; or
 - plan to travel internationally.
- Persons vaccinated before 1979 with either killed mumps vaccine or mumps vaccine of unknown type who are at high risk for mumps infection (e.g., persons who are working in a health-care facility) should be considered for revaccination with 2 doses of MMR vaccine.

- persons working with HAV-infected primates or with HAV in a research laboratory setting;
- persons with chronic liver disease and persons who receive clotting factor concentrates;
- persons traveling to or working in countries that have high or intermediate endemicity of hepatitis A; and
- unvaccinated persons who anticipate close personal contact (e.g., household or regular babysitting) with an international adoptee during the first 60 days after arrival in the United States from a country with high or intermediate endemicity. (See footnote 1 for more information on travel recommendations). The first dose of the 2-dose hepatitis A vaccine series should be administered as soon as adoption is planned, ideally 2 or more weeks before the arrival of the adoptee.

- Single-antigen vaccine formulations should be administered in a 2-dose schedule at either 0 and 6–12 months (Havrix), or 0 and 6–18 months (Vaqta). If the combined hepatitis A and hepatitis B vaccine (Twinrix) is used, administer 3 doses at 0, 1, and 6 months; alternatively, a 4-dose schedule may be used, administered on days 0, 7, and 21–30 followed by a booster dose at month 12.

12. Hepatitis B vaccination

- Vaccinate persons with any of the following indications and any person seeking protection from hepatitis B virus (HBV) infection:
 - sexually active persons who are not in a long-term, mutually monogamous relationship (e.g., persons with more than one sex partner during the previous 6 months); persons seeking evaluation or treatment for a sexually transmitted disease (STD); current or recent injection-drug users; and men who have sex with men;
 - health-care personnel and public-safety workers who are exposed to blood or other potentially infectious body fluids;
 - persons with diabetes younger than 60 years as soon as feasible after diagnosis; persons with diabetes who are 60 years or older at the discretion of the treating clinician based on increased need for assisted blood glucose monitoring in long-term care facilities, likelihood of acquiring hepatitis B infection, its complications or chronic sequelae, and likelihood of immune response to vaccination;
 - persons with end-stage renal disease, including patients receiving hemodialysis; persons with HIV infection; and persons with chronic liver disease;
 - household contacts and sex partners of persons with chronic HBV infection; clients and staff members of institutions for persons with developmental disabilities; and international travelers to countries with high or intermediate prevalence of chronic HBV infection; and
 - all adults in the following settings: STD treatment facilities; HIV testing and treatment facilities; facilities providing drug-abuse treatment and prevention services; health-care settings targeting services to injection-drug users or men who have sex with men; correctional facilities; end-stage renal disease programs and facilities for chronic hemodialysis patients; and institutions and nonresidential daycare facilities for persons with developmental disabilities.
- Administer missing doses to complete a 3-dose series of hepatitis B vaccine to those persons not vaccinated or not completely vaccinated. The second dose should be administered 1 month after the first dose; the third dose should be given at least 2 months after the second dose (and at least 4 months after the first dose). If the combined hepatitis A and hepatitis B vaccine (Twinrix) is used, give 3 doses at 0, 1, and 6 months; alternatively, a 4-dose Twinrix schedule, administered on days 0, 7, and 21–30 followed by a booster dose at month 12 may be used.
- Adult patients receiving hemodialysis or with other immunocompromising conditions should receive 1 dose of 40 µg/mL (Recombivax HB) administered on a 3-dose schedule or 2 doses of 20 µg/mL (Engerix-B) administered simultaneously on a 4-dose schedule at 0, 1, 2, and 6 months.

13. Selected conditions for which *Haemophilus influenzae* type b (Hib) vaccine may be used

- 1 dose of Hib vaccine should be considered for persons who have sickle cell disease, leukemia, or HIV infection, or who have anatomic or functional asplenia if they have not previously received Hib vaccine.

14. Immunocompromising conditions

- Inactivated vaccines generally are acceptable (e.g., pneumococcal, meningococcal, and influenza [inactivated influenza vaccine]), and live vaccines generally are avoided in persons with immune deficiencies or immunocompromising conditions. Information on specific conditions is available at <http://www.cdc.gov/vaccines/pubs/acip-list.htm>.

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Establish Storage and Handling Policies

Designate a primary vaccine coordinator and a back-up coordinator to be in charge of vaccine storage and handling at your facility. Ensure that both the primary and back-up coordinators have reviewed the vaccine storage and handling guidelines. Have detailed, up-to-date written policies for general vaccine management, including policies for routine activities and an emergency contingency plan for power outages and other problems. Base your policies on CDC's or DSHS's immunization program guidance. Review the policies with all staff annually and with new staff, including temporary staff, when they are hired.

Log In New Vaccine Shipments

Maintain a vaccine inventory log that documents the following:

- Date the vaccine is received
- Vaccine name and number of doses received
- Vaccine manufacturer and lot number
- Vaccine expiration date

Use Proper Storage Equipment

Store vaccines in refrigerator and freezer units designed for storing vaccines. Keep frozen vaccines separate from refrigerated vaccines in separate, free-standing freezer units or in a combination refrigerator/freezer with an external, sealed freezer door. **DO NOT USE** small, combination freezer-refrigerator units with an internal freezer compartment for permanent storage of vaccines. Use a thermometer that has a current certificate of calibration to monitor the refrigerator and freezer temperature. Make sure to have a designated back-up storage unit(s) in the event of a power failure or other unforeseen event. Perform regular maintenance to assure unit is functioning optimally.

Ensure Optimal Operation of Storage Units

Post a "Do Not Unplug" sign on or near the refrigerator/freezer and another next to the electrical outlets for the refrigerator and freezer. Post a "Do Not Break Circuit" warning sign by the circuit breaker. Make sure both warning signs include emergency contact information.

Maintain Correct Temperatures

Keep at least one calibrated thermometer in the refrigerator. Maintain the refrigerator temperature at 36° - 46°F (2° - 8°C). Aim for 40°F (5°C). Keep bottles of water in the door and along the walls of the refrigerator to help maintain cool temperatures. Keep at least one calibrated thermometer in the freezer. Maintain the freezer temperature below +5°F (-15°C) but no colder than -58°F (-50°C). Keep ice packs in the freezer to help maintain cold temperatures.

Store Vaccines Correctly

Do not store any food or beverages in the vaccine storage unit. Place vaccines in the middle of the refrigerator or freezer with room for air to circulate freely. Never store vaccines in the doors or bins of the storage unit. If using a combination refrigerator/freezer unit, do not store vaccines in front of the cold air outlet that leads from the freezer to the refrigerator. Check vaccine expiration dates, rotate stock of each vaccine, and use vaccines that will expire first. Store vaccines in their original packaging in clearly labeled, uncovered containers.

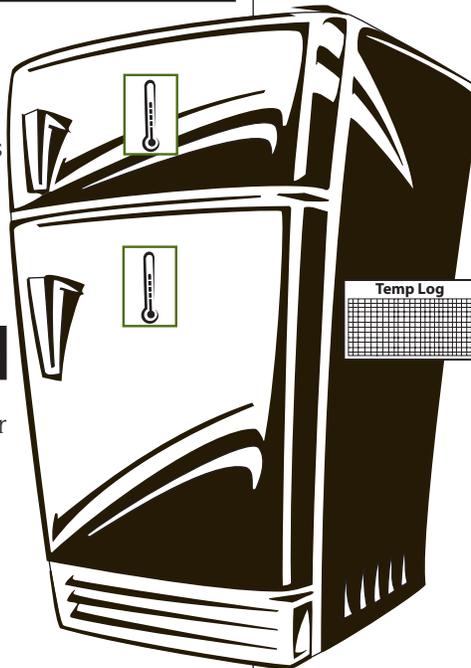
Maintain Daily Temperature Logs

Document refrigerator and freezer temperatures twice daily on the temperature log. Consistently record temperatures on the log either in Fahrenheit or Celsius. Always record the actual temperature. Make sure the temperature log shows whom to call if the temperature goes out of proper range. Always document on the temperature log if the thermostat setting is changed. Keep temperature logs on file for at least 5 years.

Take Emergency Action As Needed

Take the following actions if vaccines are exposed to improper storage conditions:

- Restore proper storage conditions as quickly as possible; if necessary, move the vaccine to your back-up storage unit.
- Address the unit's mechanical or electrical problems.
- Document the temperature in the storage unit and the amount of time the vaccines were outside of ideal temperature. Label exposed vaccines "Do Not Use" and immediately contact your local or state immunization program for guidance.



Decision to Not Vaccinate My Child

I am the parent/guardian of the child named at the bottom of this form. My healthcare provider has recommended that my child be vaccinated against the diseases indicated below. I have been given a copy of the Vaccine Information Statement (VIS) that explains the benefits and risks of receiving each of the vaccines recommended for my child. I have carefully reviewed and considered all of the information given to me. However, I have decided not to have my child vaccinated at this time. I have read and acknowledge the following:

- I understand that some vaccine-preventable diseases (e.g., measles, mumps, pertussis [whooping cough]) are infecting unvaccinated U.S. children, resulting in many hospitalizations and even deaths.
- I understand that though vaccination has led to a dramatic decline in the number of U.S. cases of the diseases listed below, some of these diseases are quite common in other countries and can be brought to the U.S. by international travelers. My child, if unvaccinated, could easily get one of these diseases while traveling or from a traveler.
- I understand that my unvaccinated child could spread disease to another child who is too young to be vaccinated or whose medical condition (e.g., leukemia, other forms of cancer, immune system problems) prevents them from being vaccinated. This could result in long-term complications and even death for the other child.
- I understand that if *every* parent exempted their child from vaccination, these diseases would return to our community in full force.
- I understand that my child may not be protected by “herd” or “community” immunity (i.e., the degree of protection that is the result of having most people in a population vaccinated against a disease).
- I understand that some vaccine-preventable diseases such as measles and pertussis are extremely infectious and have been known to infect even the very few unvaccinated people living in highly vaccinated populations.
- I understand that if my child is not vaccinated and consequently becomes infected, he or she could experience serious consequences, such as amputation, pneumonia, hospitalization, brain damage, paralysis, meningitis, seizures, deafness, and death. Many children left intentionally unvaccinated have suffered severe health consequences from their parents’ decision not to vaccinate them.
- I understand that my child may be excluded from his or her child care facility, school, sports events, or other organized activities during disease outbreaks. This means that I could miss many days of work to stay home with my child.
- I understand that the American Academy of Pediatrics, the American Academy of Family Physicians, and the Centers for Disease Control and Prevention all clearly support preventing diseases through vaccination.

Vaccine / Disease	VIS given (✓)	Vaccine recommended by doctor or nurse (Dr./Nurse initials)	I decline this vaccine (Initials of parent/guardian)
Diphtheria-tetanus-pertussis (DTaP)			
<i>Haemophilus influenzae</i> type b (Hib)			
Hepatitis A (HepA)			
Hepatitis B (HepB)			
Human papillomavirus (HPV)			
Influenza			
Measles-mumps-rubella (MMR)			

Vaccine / Disease	VIS given (✓)	Vaccine recommended by doctor or nurse (Dr./Nurse initials)	I decline this vaccine (Initials of parent/guardian)
Meningococcal (MCV)			
Varicella (Var)			
Pneumococcal conjugate (PCV)			
Polio, inactivated (IPV)			
Rotavirus (RV)			
Tetanus-diphtheria (Td)			
Tetanus-diphtheria-pertussis (Tdap)			

In signing this form, I acknowledge I am refusing to have my child vaccinated against one or more diseases listed above; I have placed my initials in the column titled “I decline this vaccine” to indicate the vaccine(s) I am declining. I understand that at any time in the future, I can change my mind and vaccinate my child.

Child’s name: _____

Date of birth: _____

Parent/guardian signature: _____

Date: _____

Doctor/nurse signature: _____

Date: _____

Additional information for healthcare professionals about IAC's "Decision to Not Vaccinate My Child" form

Unfortunately, some parents will decide not to give their child some or all vaccines. For healthcare providers who want to assure that these parents fully understand the consequences of their decision, the Immunization Action Coalition (IAC) has produced a new form titled "Decision to Not Vaccinate My Child." IAC's form, which accompanies this page of additional information, facilitates and documents the discussion that a healthcare professional can have with parents about the risks of not having their child immunized before the child leaves the medical setting. Your use of IAC's form demonstrates the importance you place on timely and complete vaccination, focuses the parents' attention on the unnecessary risk for which they are accepting responsibility, and may encourage a vaccine-hesitant parent to accept your recommendations. According to an American Academy of Pediatrics (AAP) survey on immunization practices, almost all pediatricians reported that when faced with parents who refuse vaccination they attempt to educate parents regarding the importance of immunization and document the refusal in the patient's medical record.¹

Recommendations from the child's healthcare provider about a vaccine can strongly influence parents' final vaccination decision.² Most parents trust their children's doctor for vaccine-safety information (76% endorsed "a lot of trust"), according to researchers from the University of Michigan.³ Simi-

larly, analyses of the 2009 HealthStyles Survey found that the vast majority of parents (81.7%) name their child's doctor or nurse as the most important source that helped them make decisions about vaccinating their child.⁴ Gust and colleagues found that the advice of their children's healthcare provider was the main factor in changing the minds of parents who had been reluctant to vaccinate their children or who had delayed their children's vaccinations.⁵ Vaccine-hesitant parents who felt satisfied with their pediatricians' discussion of vaccination most often chose vaccination for their child.⁶

All parents and patients should be informed about the risks and benefits of vaccination. This can be facilitated by providing the appropriate Vaccine Information Statement (VIS) for each vaccine to the parent or legal representative, which is a requirement under federal law when vaccines are to be given. When parents refuse one or more recommended immunizations, document that you provided the VIS(s), and have the parent initial and sign the vaccine refusal form. Keep the form in the patient's medical record. Revisit the immunization discussion at each subsequent appointment. Some healthcare providers may want to flag the charts of unimmunized or partially immunized children to be reminded to revisit the immunization discussion. Flagging also alerts the provider about missed immunizations when evaluating illness in children, especially in young children with fever of unknown origin.

What do others say about documentation of parental refusal to vaccinate?

American Academy of Pediatrics (AAP): "Pediatricians need to explain the risks of not vaccinating and should have (parents) sign an informed refusal document at each visit during which vaccination is declined. A sample AAP Refusal to Vaccinate form is available at www.aap.org/immunization."⁷

Association of State and Territorial Health Officials (ASTHO): "To address the risk of VPD, states should consider adopting more rigorous standards for non-medical vaccine exemptions that require parents to demonstrate that they have made a conscious, concerted, and informed decision in requesting these exemptions for their children. An example of such a standard might include a requirement for parents to complete a form that explicitly states the grounds for the exemption and requires them to acknowledge awareness of the disease-specific risks associated with not vaccinating their child(ren)."⁸

National Association of County & City Health Officials (NACCHO): "School systems and childcare facilities (where appropriate) should use an exemption application form that requires a parental signature acknowledging their understanding that their decision not to immunize places their child and other children at risk for diseases and ensuing complications. The form should also state that in the event of an exposure to a vaccine-preventable illness, their child would be removed from school and all school-related activities for the appropriate two incubation periods beyond the date of onset of the last case, which is standard public health practice."⁹

Pediatric Infectious Diseases Society (PIDS): PIDS "opposes any legislation or regulation that would allow children to be exempted from mandatory immunizations based simply on their parents', or, in the case of adolescents, their own, secular personal beliefs." PIDS further recognizes that many states have or are considering adopting legislation or regulation that would allow for personal belief exemptions and outlines specific provisions to minimize use of exemptions as the "path of least resistance." One of the provisions reads as follows: "Before a child is granted an exemption,

the parents or guardians must sign a statement that delineates the basis, strength, and duration of their belief; their understanding of the risks that refusal to immunize has on their child's health and the health of others (including the potential for serious illness or death); and their acknowledgment that they are making the decision not to vaccinate on behalf of their child."¹⁰

References

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