

Texas Vaccines
for Children



OPERATIONS MANUAL
JANUARY 2009

Texas Vaccines
for Children



OPERATIONS MANUAL
JANUARY 2009

Table of Contents

**Texas Vaccines for Children Program
Operations Manual
January 2009**

SECTION ONE: GENERAL INFORMATION

I.	Introduction	1
II.	Public Health Law Establishing the VFC Program	1
III.	Vision and Mission of the Immunization Branch	2
IV.	Goals of the TVFC	2
V.	TVFC Regional Contacts	3
VI.	HIPAA Privacy Rule	4

SECTION TWO: STANDARDS AND POLICIES

I.	Provider Eligibility	
	A. Organization Participation	5
	B. Provider Participation	6
	C. Provider Enrollment	6
	D. Provider Exclusion	8
	E. Provider Withdrawal	8
	F. Provider Fraud & Abuse Reporting	9
II.	Patient Eligibility	
	A. Requirements for Patient Eligibility Screening	11
	B. Two-Tiered Vaccines	11
III.	Vaccine Management	
	A. Vaccine Distribution	13
	B. Vaccine Ordering	13
	C. Maximum Stock Levels and Tier Ordering Frequency: Calculating and Updating	15
	D. Receiving Vaccine	17
	E. Vaccine Received Warm or Questionable	18
	F. Vaccines Received in Error	21
	G. Expired Vaccine	21
	H. Procedures for Vaccine Loss and Returning Vaccine	22
	I. Approved Vaccines	24

J. Adult Safety Net Program and Adult Hepatitis B Initiative	25
K. Storage and Handling	31
L. Emergency Vaccine Storage Contingency Plan	36
M. Box Recycling	37
IV. Administrative Fees	38
V. Immunization Documentation	40
VI. Consent	
A. Consent	42
B. Vaccine Information Statements (VIS)	42
VII. Public Education	44
VIII. Provider Recruitment	45

SECTION THREE: PROGRAM EVALUATION

I. TVFC Visits	
A. Site Monitoring Activities	46
B. AFIX	48
C. Reminder/Recall Training	48
II. Provider Compliance	50

SECTION FOUR: DATA REPORTING

I. Program Reports	
A. TVFC Monthly Reports	51
B. Order Processing Timeline	53
C. VAERS	54

SECTION FIVE: MISCELLANEOUS REFERENCES

I. Appendices	56
A. Vaccine Ordering Instructions	
B. TVFC Provider Enrollment Form (E6-102)	
C. Patient Eligibility Screening Form (C-10)	
D. Adult Eligibility Screening Record (F11-12842)	
E. Monthly Biological Report (EC-33)	
F. Temperature Recording Form (C-105)	

- G. VAERS Reporting Form (C-76)
 - H. Daily Tally Sheet for Immunizations (C-88)
 - I. Biological Order Form (EC-68)
 - J. Vaccine Loss Report (EC-69)
 - K. Abbreviations
 - L. Vaccine Storage Contingency Plan
 - M. Quality Assurance Checklist (EC-68 & EC-33)
 - N. VFC Vaccine Borrowing Report
 - O. Provider Withdrawal Form (F11-11443)
 - P. Provider Compliance
-
- II. Recommended Childhood Immunization Schedule
 - III. Recommended Adolescent Immunization Schedule
 - IV. Catch-up Immunization Schedule
 - V. Recommended Adult Immunization Schedule
 - VI. Operations Manual Survey

Section One: General Information

SECTION ONE: GENERAL INFORMATION

I.	Introduction	1
II.	Public Health Law Establishing the VFC Program	1
III.	Vision and Mission of the Immunization Branch	2
IV.	Goals of the TVFC	2
V.	TVFC Regional Contacts	3
VI.	HIPAA Privacy Rule	4

Section One: General Information

I. Introduction

The Texas Department of State Health Services (DSHS), Immunization Branch, has prepared the Texas Vaccines for Children Program (TVFC) Operations Manual. Consultation on the policies in this manual are conducted routinely with the Centers for Disease Control and Prevention (CDC), the Center for Medicare and Medicaid Services (CMS), DSHS, and many other organizations.

The purpose of the Operations Manual is to consolidate TVFC policies and information into one source document for health service regions (HSR) and local health departments (LHD). The contents are intended only for those entities and not for other providers enrolled in the TVFC. The Operations Manual will be updated and distributed on an annual basis. Throughout the year, the Immunization Branch and the TVFC will continue to educate providers on new policies via official memorandums. Each memorandum should be placed in the back of the Operations Manual. At the time of the annual update, all policy memorandums for the previous year will be incorporated as policy within the manual.

After reviewing this manual, partners are asked to complete the survey in the back. Your input is important so that future versions of the TVFC Operations Manual can be improved.

II. Public Health Law Establishing the VFC Program

The federal Vaccines for Children (VFC) Program is authorized by the Omnibus Budget Reconciliation Act (OBRA), section 1928 of the Social Security Act.

Funding from the federal VFC is supplemented with 317 and state General Revenue funds to support TVFC and all immunization activities across Texas.

The TVFC enables thousands of children to have access to affordable immunizations. This is accomplished through a network of support within DSHS and with support from private and public entities, such as the LHDs and private physicians.

III. Vision and Mission of the Immunization Branch

Vision

A Texas free of vaccine-preventable diseases.

Mission

To provide leadership to increase vaccine coverage levels and reduce the burden of vaccine preventable diseases (VPDs).

IV. Goals of the TVFC

To ensure that policy makers understand the effectiveness of preventive measures against vaccine-preventable diseases and continue to value and support disease prevention through vaccination.

To mobilize local, state, and national resources required to achieve and to sustain immunization levels sufficient to stop the threat of vaccine-preventable diseases.

To foster the development of appropriate knowledge, skills, and attitudes among both immunization providers and consumers to achieve and sustain a disease-free environment.

V. TVFC 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 REGIONS 2 & 3

Sonna Sanders
Immunization Program Manager
1301 South Bowen Road, Suite 200
Arlington, Texas 76013-2262
(817) 264-4791
(817) 264-4800 - Fax

Sonna.Sanders@dshs.state.tx.us

HEALTH SERVICE REGIONS 4&5 NORTH

Toni Wright
Immunization Program Manager
1517 West Front Street
Tyler, Texas 75702
(903) 533-5266
(903) 533-9502 - Fax

Toni.Wright@dshs.state.tx.us

HEALTH SERVICE REGIONS 6&5 SOUTH

Angel Angco
Immunization Program Manager
5425 Polk, Suite J
Houston, Texas 77023
(713) 767-3410
(713) 767-3889 – Fax

Angel.Angco@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 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 9 & 10

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

Jose.Padilla@dshs.state.tx.us

HEALTH SERVICE REGION 11

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

Ivette.Nunez@dshs.state.tx.us

VI. Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule

OVERVIEW:

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191, was enacted on August 21, 1996. Sections 261 – 264 of HIPAA require the Secretary of Health and Human Services (HHS) to publicize standards for the electronic exchange, privacy and security of health information. The resulting legislation, the Privacy Rule, was finalized and published in August 2002.

One major purpose of the Privacy Rule is to define and limit the circumstance in which an individual's Protected Health Information (PHI) can be used or disclosed to covered entities. A covered entity may not use or disclose PHI, except either: (1) as the Privacy Rule permits or requires; or (2) as the individual who is the subject of the information (or the individual's personal representative) authorizes in writing.

IMPACT ON PUBLIC HEALTH:

45 CFR § 164.512 (b) of the Privacy Rule advises that a covered entity may disclose, without individual authorization, PHI to a public health authority* that is legally authorized to collect or receive the information, a covered entity for the purposes of preventing or controlling disease, injury, or disability including but not limited to

- Reporting of disease, injury, and vital events (e.g., birth or death); and
- Conducting public health surveillance, investigations, and interventions

*Or to an entity working under a grant of authority from a public health authority, or when directed by a public health authority.

Section Two: Standards and Policies

SECTION TWO: STANDARDS AND POLICIES

I.	Provider Eligibility	
	A. Organization Participation	5
	B. Provider Participation	6
	C. Provider Enrollment	6
	D. Provider Exclusion	8
	E. Provider Withdrawal	8
	F. Provider Fraud & Abuse Reporting	9
II.	Patient Eligibility	
	A. Requirements For Patient Eligibility Screening	11
	B. Two-Tiered Vaccines	11
III.	Vaccine Management	
	A. Vaccine Distribution	13
	B. Vaccine Ordering	13
	C. Maximum Stock Levels and Tier Ordering Frequency: Calculating and Updating	15
	D. Receiving Vaccine	17
	E. Vaccine Received Warm or Questionable	18
	F. Vaccines Received in Error	21
	G. Expired Vaccine	21
	H. Procedures for Vaccine Loss and Returning Vaccine	22
	I. Approved Vaccines	24
	J. Adult Safety Net Program and Adult Hepatitis B Initiative	25
	K. Storage and Handling	31
	L. Emergency Vaccine Storage Contingency Plan	36
	M. Box Recycling	37
IV.	Administrative Fees	38
V.	Immunization Documentation	40
VI.	Consent	
	A. Consent	42
	B. Vaccine Information Statements (VIS)	42
VII.	Public Education	44
VIII.	Provider Recruitment	45

Section Two: Standards and Policies

Policy: All agencies offering and utilizing TVFC vaccine must abide by the guidelines outlined in this Section.

Purpose: To provide instruction and to ensure consistency and adherence regarding TVFC activities and standards.

I. Provider Eligibility

A. Organization Participation

These organizations are eligible for state and federally funded vaccines:

1. Public hospitals, medical school clinics, and hospitals that will vaccinate children according to Chapter 43, Health and Safety Code (Senate Bill 266, 73rd Texas Legislature).
2. Texas state agencies.
3. Public and private schools, colleges, universities, and private hospitals.
4. Federally funded community health centers, migrant health centers, rural health initiatives clinics, urban Indian health programs, housing programs, homeless programs, and other federally qualified health centers.
5. Health Service Regions (HSRs) and Local Health Departments (LHDs).

These organizations **ARE NOT** routinely eligible for state and federally funded vaccines:

1. No federal organization that receives funds for their own immunization programs, such as the Immigration and Naturalization Service, Veterans Administration, and military organizations.
2. Health maintenance organizations and preferred provider organizations. (Individual providers who participate in these organizations may enroll in the TVFC.)

B. Provider Participation

To be eligible to enroll in the TVFC, providers must be one of the following:

1. Physician (Medical Doctor (MD) or Doctor of Osteopathy (DO))
2. Nurse Practitioner (NP)
3. Certified Nurse Midwife (CNM)
4. Physician Assistant (PA)

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

1. Pharmacists (RPH)
2. Nurses (Registered Nurses (RN) or Licensed Vocational Nurses (LVN))
3. Medical Assistants (MA)
4. Nurse Assistants (NA)
5. Emergency Medical Technicians (EMT)

Medicaid and Children's Health Insurance Plan (CHIP) providers must enroll in the TVFC or use their private stock vaccines. They may not refer children to LHDs or other entities for routinely recommended vaccinations. A TVFC Provider Enrollment Form is included in the Medicaid provider enrollment packet.

NOTE: Medicaid and CHIP programs do not reimburse providers for the cost of routinely recommended childhood vaccines but do reimburse an administration fee.

C. Provider Enrollment

1. The TVFC Provider Enrollment Form must be completed at initial enrollment and updated annually. A signed enrollment by the Medical Director of the HSRs or LHDs/districts, private physicians (MD or DO), NP, PA, or CNM must be in DSHS- Austin Office (AO) prior to receiving state and federally funded vaccines. Generally, the individual who signs the TVFC Provider Enrollment Form will be the physician who signs the standing delegation orders for the clinic or the physician-in-chief.

- a) The Provider Enrollment Form must be updated when the provider who signed the original form is no longer associated with the clinic.
 - b) Each clinic site that maintains a TVFC vaccine inventory must be enrolled as a separate TVFC clinic site. Group practices may elect to enroll as one entity, or each physician may enroll separately.
 - c) The LHD will forward initial enrollments to the HSR. The HSR must fax or mail all initial enrollments to AO to obtain a Provider Identification Number (PIN). AO staff will notify regional staff of the new PIN via email or phone. The PIN will be the clinic's identification number for the duration that the clinic is enrolled in the TVFC. All subsequent enrollment forms and vaccine orders must have the PIN written on all forms. Any form without this PIN will not be processed and will be returned to the sender.
2. The Provider Enrollment, Provider Profile, and Provider List Addendum Forms must be completed at initial enrollment and updated annually.
- a) HSRs have two options when obtaining public annual re-enrollments:
 - i. The Provider Enrollment, Provider Profile, and Provider List Addendum Forms may be completed during the annual TVFC On-site Quality Assurance Visit or Contract Monitoring Visit and submitted to AO.
 - ii. The Provider Enrollment, Provider Profile, and Provider List Addendum Forms may be completed for all public providers at one time and then submitted to AO.
 - b) The quality assurance contractor will obtain the Provider Enrollment, Provider Profile, and Provider List Addendum Forms for private providers during the annual TVFC On-site Quality Assurance Visit and will post the enrollment forms on the TVFC website; hard copies will also be submitted to the AO. If the quality assurance contractor cannot obtain all required information for the re-enrollment, the incomplete paperwork will then be sent to the AO. The AO will forward to the HSR to obtain all required information.
 - c) The patient numbers requested on the Provider Profile form 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, e.g. registry data, billing data.
 - d) The Provider List section of the Provider Profile Form and the Provider List Addendum must list the provider who signs the Provider Enrollment Form. All licensed and/or certified individuals within the practice who will be administering TVFC supplied vaccines must be listed on this form. This includes MD, DO, NP, CNM, RPH, PA, RN, LVN, EMT, MA, and NA.

3. Vaccine may not be supplied to TVFC providers who do not have current enrollment information on file. Providers will be granted a 90-day grace period from the date the enrollment expires to allow a site visit to be conducted and the enrollment paperwork completed. Failure to obtain the required paperwork will result in vaccine shipment delays or removal of provider from program.

See Appendix B for the Provider Enrollment, Provider Profile and List, Provider List Addendum.

D. Provider Exclusion

AO staff will verify all doctors listed on the provider list section of the enrollment/re-enrollment forms against the Medicaid Provider Exclusion List before assigning a PIN. The Medicaid Exclusion List is a database used to verify if a MD or DO is eligible to participate in the Medicaid program. Any provider who has been excluded from participation in Medicaid will be denied enrollment into the TVFC. The form can be signed and resubmitted by another MD, DO, NP, PA, or CNM in the clinic. However, the excluded physician will not be eligible to receive or administer TVFC vaccine and cannot be listed on the provider list. Once a provider has been reinstated, they may enroll in the TVFC.

E. Provider Withdrawal

If a provider withdraws from the TVFC, a Provider Withdrawal Form must be completed and submitted to AO within one business day after the date of withdrawal. Provider Withdrawal Forms completed by the LHD shall be forwarded to the HSR. The HSR will forward the form to the AO. When providers withdraw from the TVFC, viable and non-viable vaccines must be removed from the provider's clinic site within five business days by the HSR or LHD. Viable vaccine should be redistributed to other enrolled clinics. Non-viable vaccine should be returned to the third party distributor along with the HSRs non-viable stock. If a vaccine loss occurred, a Vaccine Loss Report Form (EC-69) should be generated by the LHD or HSR and forwarded to the AO.

See Appendix O for the Provider Withdrawal Form

Note: Picking up viable and non-viable vaccine from a withdrawn provider is the responsibility of the facility directly overseeing the site (either the LHD or HSR).

F. Provider Fraud & Abuse Reporting

HSRs and LHDs and other contractors must report all cases of alleged or suspected fraud according to the procedures outlined in the DSHS Policy AA-5042. DSHS employees and contractors shall immediately report all allegations of fraud and other unlawful activities to the Office of Inspector General (OIG) as directed by OIG procedures. These procedures are located at https://oig.hhsc.state.tx.us/Fraud_Report_Home.aspx. This site contains forms and instructions for either on-line or paper reporting. Vaccine Services is currently working with the CDC and OIG to improve the process for prevention, identification, investigation and resolution of suspected cases of fraud and abuse.

It is important that TVFC providers understand that the TVFC is subject to all federal fraud and abuse laws, and that unintentional abuse or error is nevertheless unacceptable. The following definitions and examples are provided so that DSHS staff can better identify and intervene in activities that could be defined as fraud or abuse.

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.

Abuse

Abuse is defined as provider practices that are inconsistent with sound fiscal, business, or medical practices, and that 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.

Examples of Fraud and Abuse

Fraud and abuse can occur in many ways, and some types of fraud and abuse are easier to prevent or detect than others. TVFC staff and contractors should familiarize themselves with the examples below that illustrate common practice errors that could result in fraud or abuse allegations. Prevention education is critical. In order to prevent unintentional fraud or abuse situations, providers should be educated at every opportunity (including site visits, trainings, and phone calls)

regarding appropriate use of TVFC vaccines, and warned that federal fraud and abuse laws apply to the TVFC.

Some examples of potential fraud and abuse that TVFC staff might encounter include:

Fraud

- Selling or otherwise misdirecting TVFC vaccine;
- Billing a patient or third party for TVFC vaccine;
- 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 a vaccine-eligible child;
- Failing to screen patients for TVFC eligibility;
- Failing to fully account for TVFC vaccine;
- Failing to properly store and handle TVFC vaccine;
- Wastage of TVFC vaccine.

Abuse

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

II. Patient Eligibility

A. Requirements for Patient Eligibility Screening

1. The Patient Eligibility Screening Form may be used to document the category of eligibility. Although this form is not required, providers must document the eligibility category of each client receiving TVFC vaccine. Providers may document eligibility in the patient's chart or in an electronic data file; however, the information should be easily retrievable. Federal law requires that the provider maintain the screening record for three years.
2. The Patient Eligibility Screening Form is a one-time form until the child's category of eligibility changes. When eligibility changes happen, a new form must be completed.
3. No clinic or provider is waived from conducting patient eligibility screening - it is a federal requirement. The screening is a self-declaration by the parent or guardian. Providers are not required to verify that the self-declaration is accurate.
4. Any child who meets any 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) Does not have health insurance, or
 - c) Is an American Indian, or
 - d) Is an Alaskan Native, or
 - e) Underinsured (has health insurance that does not pay for vaccines, has a co-pay or deductible the family cannot meet, or has insurance that provides limited wellness or prevention coverage), or
 - f) Enrolled in CHIP
 - g) Is a patient who is served by any type of public health clinic and does not meet any of the above criteria
5. Immigration status does not affect a client's eligibility for the TVFC. Immigrants should be offered the same immunization services that other customers receive in public health clinics.

B. Two-Tiered Vaccines

Due to certain funding limitations, some vaccines may not be available to underinsured children except when they present at a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC). These vaccines may be referred to as two-tiered. AO will notify all TVFC providers via official memorandum when funding limitations exist and vaccines are two-tiered.

All two-tiered vaccines designated by AO may be administered in all TVFC-enrolled clinic sites to children in Categories a, b, c, d, f, and g only (see above). This vaccine can only be administered to children in Category e (underinsured) when they present for services in a FQHC or RHC. Provider offices that do not have one of these designations should assist qualified patients with the appropriate referral. As a public service, HSRs, LHDs, and enrolled clinics should provide this referral to the nearest FQHC/RHC that is providing immunization services to underinsured children, regardless of the distance. All public and private TVFC-enrolled provider sites must follow this guideline.

See Appendix C for the Patient Eligibility Screening Form

III. Vaccine Management

Throughout 2009, public sites may be implementing the Pharmacy Inventory Control System (PICS) to electronically receive, track, transfer, and maintain vaccine inventory that is purchased through the TVFC. Sections B and C below will separate PICS and non-PICS responsibilities.

A. Vaccine Distribution

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

B. Vaccine Ordering

1. Non-PICS Users

All TVFC provider sites submit vaccine orders to their LHD or HSR. The LHD or HSR reviews the order to ensure that all information is included on the form, and that providers are ordering within the established MSL agreed upon with the LHD or HSR. The LHD or HSR submits the order to AO.

All clinics must provide the following information each month in order to receive vaccine:

- a) The Monthly Biological Report Form (EC-33),
- b) The Temperature Recording Form (EC-105),
- c) Complete the Biological Order Form (EC-68) when appropriate

Providers must order using their established MSL. For vaccine orders outside a provider's MSL, an explanation should be added to the comment section on the EC-68. Incomplete or inaccurate forms should be returned to the provider.

HSR/LHD Procedures

When a vaccine order and/or report is received from a provider, the LHD or HSR will perform a quality assurance check to include the following:

- a) Verify the address, shipping hours, and shipping days on the EC-68 are correct.
- b) Verify that the amount ordered equals the MSL or has a valid reason for being above or below the MSL.

- c) Verify the PIN is correct.
- d) Verify that an authorized person listed on the TVFC Provider Enrollment Form signed the EC-68.
- e) Review the EC-33 to ensure that the beginning inventory matches last month's ending inventory and that calculations are correct. Check column I, net lost or gained, to ensure that it does not exceed 5 doses of any one vaccine. Report any corrections to the originating clinic so they can adjust their records.
- f) Resolve discrepancies with clinic involved.
- g) Review the EC-105 to determine if refrigeration problems exist in the clinic.
- h) Submit EC-33 and EC-68 forms to AO as they are received and processed (do not hold forms for large batches).

NOTE: To assist LHD/HSR with QA on EC-68s and EC-33s, a checklist has been developed and is located in Appendix M.

In extenuating circumstances an urgently needed order (UNO) may be submitted. A valid reason must be noted in the comment section of the EC-68 for the UNO to be processed. HSRs/LHDs should verify that providers are ordering up to the max stock levels on all vaccines. HSRs/LHDs should also verify that a current Temperature Recording Log is on file and temperatures are within range.

2. PICS Users

Replenishment of vaccines will occur on a monthly basis. All recording of usage and reconciliation activities must be completed to initiate the replenishment order. The initiation of automatic replenishment involves five steps:

- a) Complete usage recording on a daily, weekly or monthly basis. It is recommended that a site record usage on a daily basis; however, it must be completed by the week of replenishment. Each site will have vaccine replenishment amounts determined by min/max stock levels. Each vaccine will have a min/max stock level determined by historical usage patterns. Recording of usage deducts product from site's inventory and ensures successful automatic replenishment. Usage recording also provides the information necessary to generate reports such as the Monthly Biological Report (EC-33).
- b) Verify that the physical inventory is in line with the electronic inventory. If adjustments are required: PICS allows the site to record doses that have been expended for reasons other than patient usage, including expired, spoiled, wasted, or gained

vaccines. If you record a loss in PICS, follow the TVFC guidelines for the submission of the Vaccine Loss Report (EC-69).

- c) PICS enables the Site Administrator to modify specific demographic information to minimize risk of vaccine loss due to incorrect information. Important information includes the site's **Contact Person, Days/Hours of Operation, Phone Number, Fax Number, Mailing Address, and Shipping Address**. A site may be billed for any vaccine loss due to incorrect site demographic information.
- d) Each site must conduct an electronic reconciliation process in PICS. This must be completed no more than 4 days prior to the replenishment deadline. If missed, the site must contact the appropriate Approval Authority immediately.
- e) Site **MUST** click the 'Submit' button for the replenishment process to be complete.

C. MSL and Tiered Ordering Frequency (TOF): Calculating and Updating

MSL: 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.

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

MSL

LHDs and HSRs are expected to develop MSL for every new TVFC provider. MSL and/or TOF should be re-calculated every six months, or more often if necessary to ensure that vaccine orders are consistent with current usage. Providers should always be consulted when adjusting tiers or significantly increasing vaccine order amounts to ensure that adequate storage is available and that the provider is willing to take on any added liability of maintaining a larger inventory.

MSL revisions typically begin by updating the doses administered data to the most current 12 months in the calculation spreadsheet. However in some cases the most current 12 months may not reflect current or usual usage patterns, and fewer months may need to be used to calculate the MSL. Examples of this include:

- o new vaccines -- uptake and usage changes very quickly and may need to be re-evaluated every 2 to 3 months;
- o clinic loses or gains providers -- uptake could be significantly increased or decreased, and doses administered information from months prior to the change should not be considered in the MSL calculation.

- provider has a special clinic for one vaccine such as Hepatitis A during an outbreak -- usage for that month is much higher than a normal month's usage, and should not be used in calculating the MSL;
- provider was not practicing for a period of time and usage declines significantly -- do not include that month's usage data in the MSL calculation; and
- provider was unable to give a vaccine due to a shortage or some other factor -- that month's data should not be used in the MSL calculation.

MSLs are calculated using the following process:

1. Obtain an average of the doses administered data 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).
2. 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.
3. The number obtained in step 2 is the MSL for the provider.

Recommendations on MSL and TOF should be submitted to the appropriate health service region for approval and submission to the AO.

MSL is 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 (3.5 months)
Quarterly	45 (1.5 months)	+	90 (3 months)	=	135 (4.5 months)

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 orders:

- Once a month (monthly)
- Once every other month (Bi-Monthly)
- Every three months (Quarterly)

Large providers will order more frequently, while smaller providers will order less often. The chart below is a gauge of how to categorize a provider's TOF based on vaccine usage.

Order less than 500 doses/year	Order vaccines every 3 months (Quarterly)
Order 500-1999 doses/year	Order vaccines every 2 months (Bi-monthly)
Order more than 2000 doses/year	Order vaccines every month (Monthly)

In addition to usage, a provider must have enough refrigeration/freezer space to accommodate a maximum order based on TOF and MSL. A guide to help determine TOF based on storage space is below.

Storage Capacity	Frequency
2-4 Cubic feet of storage in refrigerator	MONTHLY OR BI-MONTHLY (<250)
6-14 Cubic feet of storage in refrigerator	MONTHLY OR BI-MONTHLY (depends on annual orders)
15+ Cubic feet of storage in refrigerator	MONTHLY, BI-MONTHLY OR QUARTERLY (depends on annual orders)

D. Receiving Vaccine

1. Non-PICS Users

Provider Procedures:

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:

- a) Check actual vaccine received against packing list to verify all vaccines have been received.
- b) Put vaccine into appropriate storage immediately. Make sure to check expiration dates and rotate stock so short-dated vaccine can be used first.
- c) Make sure diluent that accompanies MMR and varicella matches amount of vaccine received.
- d) Each order generates a faxed confirmation that shows the vaccines that have been ordered. Checking the packing list against the faxed confirmation will verify that all vaccines ordered by DSHS were received.
- e) If a provider does not receive the appropriate vaccine, he/she will contact the LHD or HSR immediately.

- f) Providers should expect their orders approximately three weeks from the time of submission of paperwork.
- g) Vaccine is packed to maintain the cold chain for 72 hours (3 days).
- h) Vaccine will be shipped using high quality cardboard boxes with Styrofoam inserts.
- i) 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.
- j) Each package comes with a temperature monitor(s). If monitors indicate, or if staff suspects that the cold chain has not been maintained, staff must place vaccines in the refrigerator and immediately contact their appropriate approval authority—LHD or HSR.

LHD/HSR Procedures:

In the event a provider receives vaccines they did not order the LHD or HSR will:

- a) Check with assigned TVFC Consultant for the reason behind the error
- b) Request that the provider absorb the received vaccine into their stock
- c) If the provider does not want to keep the vaccine, LHD/HSR will arrange for the redistribution within the HSR
- d) If the vaccine cannot be placed within the HSR, the HSR will contact their TVFC Consultant for assistance with placement.

Note: Picking up and redistributing vaccine from a provider is the responsibility of the facility directly overseeing the site (either the LHD or HSR).

2. PICS Users

Vaccines must be received into PICS before usage can be recorded. The initiation of receiving vaccine involves:

- a) Upon receipt, the site must compare the information in PICS with the actual vaccine information to include: vaccine type, lot number, expiration date, and amount received.
- b) When the site accepts the receipt of the vaccine, the products are added to the doses on hand.

E. Vaccine Received Warm or Questionable

NOTE: Providers should always accept vaccine shipments. Never refuse or return vaccine shipments without instructions from AO. If

there are questions about improperly handled vaccine while in transit, providers will call the LHD or HSR immediately.

Examples of potentially non-viable vaccines are:

1. Vaccine shipment is received with the temperature indicator strip showing out of range.
2. No ice packs or dry ice (Varicella) are present.
3. The vaccine is **warm** to touch.
4. Vaccines are received damaged.

Provider Procedures:

If vaccine is suspected of being non-viable at receipt, providers should:

1. Place a thermometer in the shipping container with the vaccines before removing them from the container. Document the temperature.
2. **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 LHD/HSR. Instruct staff not to write on the vaccine itself. Large lettering on paper attached to the container is recommended.
3. After steps above are complete place the vaccine in appropriate storage.
4. Contact appropriate approval authority (LHD or HSR) immediately. Providers should never contact the distributor or manufacturer directly unless directed to do so by AO.
5. Await information from their LHD or HSR on a procedure for replacement, reporting loss, etc. The LHD or HSR may recommend contacting the DSHS Pharmacist at (512) 458-7500, or Merck for varicella and/or zoster for determination of vaccine viability.

LHD/HSR Procedures:

If vaccine is non-viable at receipt, LHDs and HSRs should:

1. Instruct the provider to place a thermometer in the shipping container if the vaccines haven't already been removed from the shipping container. Document the temperature.
2. Isolate the questionable vaccine in a bag, box, or shipping container.

3. **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 LHD/HSR. Instruct staff not to write on the vaccine itself. Large lettering on paper attached to the container is recommended.
4. Obtain the pertinent information from the clinical staff to contact pharmacy or Merck. If vaccine is MERCK vaccine, instruct the staff to immediately contact MERCK for further instructions and provide a call back number for staff to report vaccine determination. If no call is received within 2 hours, contact staff for follow up.
5. Contact the DSHS pharmacy with information received from provider, or have provider call the pharmacy directly at (512) 458-7500.
6. After receiving directions from the pharmacist, contact the provider to discuss vaccine viability.
7. If the vaccines are deemed viable, return them to the inventory with other vaccines and discard the **Do Not Use** sign. Remind staff to correctly rotate this inventory into existing stock.
8. If vaccine is not viable, it should be immediately removed from the refrigerator or freezer and labeled **Do Not Use**.
9. Assist the provider with completion of vaccine loss report (C-69). Notify AO of loss immediately.
10. Assist the provider with obtaining replacement stock, if appropriate, and the method to return ruined vaccines (See H. Procedures for Vaccine Loss and Returning Vaccine below).
11. Document the name and titles of all personnel, including DSHS Pharmacist, and any unusual circumstance, and submit to TVFC consultant along with C-69.

AO Procedures:

1. If necessary, log the problem on the issue log and notify the PPOC via email identifying the number on the issue log.
2. Assist HSR with any needs

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

F. Vaccines Received in Error

If vaccine is received and was not ordered, the TVFC provider should call the LHD or HSR immediately. The HSR should contact the AO once notified by the LHD or provider that vaccine was received in error. The AO will research the problem and then notify the HSR with further information.

1. If vaccine was shipped in error to a provider, the LHD/HSR should contact the AO. McKesson will be notified by AO staff and may arrange to have the vaccine picked-up. The vaccine may also be redistributed to other providers (see 2.b. below).
2. If the provider ordered the vaccine in error, the provider has two options:
 - a) Vaccine can be shipped back to the third party distributor at a cost to the provider.
 - b) Vaccine can be redistributed to other providers in the region who can use the vaccine. TVFC providers should contact the LHD or HSR for assistance.

Note: Picking up and redistributing vaccine from a provider is the responsibility of the facility directly overseeing the site (either the LHD or HSR).

G. Expired Vaccine

The Immunization Branch requires that all unopened or unused vials of expired vaccines/toxoids/biologicals be returned to the third-party distributor. Vaccine manufacturers reimburse Texas for the federal excise tax portion of the cost of the vaccine, and in some cases, for the total cost of the vaccine. Therefore, providers should not discard vaccines unless specifically directed by HSR/LHD or AO. Expired vaccines should be kept together and labeled for return to distributor. Any exception to this rule will be announced by the AO on a case-by-case basis. For return process, see H below.

NOTE: Providers should notify the LHD or HSR 90 days prior to vaccine expiration if the vaccine cannot be used before expiration. The LHD or HSR is responsible for assisting with redistribution of the vaccine.

H. Procedures for Vaccine Loss and Returning Vaccine

1. Provider Procedures:

If a provider has a vaccine loss of 5 doses or more (expired or ruined) the following procedures should be followed:

- a) Separate expired or ruined vaccine from other viable vaccines.
- b) Contact your appropriate approval authority (LHD or HSR) immediately with the following information:
 - Antigen, lot number, expiration date
 - Reason for expiration/loss –

Note: If storage was compromised, provide LHD or HSR with amount of time product was out-of-range and highest temperature recorded.

- c) Submit the Vaccine Loss Report Form (EC-69) explaining the cause(s) of the vaccine loss and outlining the steps taken to ensure vaccines will be protected in the future. This report is due to the HSR within 4 business days of the loss. The report may be faxed or mailed, and includes the following sections:
 - Clinic demographics
 - Date loss was discovered
 - Type of loss
 - Reason for loss
 - Explanation of loss
 - Corrective action taken to avoid re-occurrence
 - List of vaccines by antigen, manufacturer, lot number, expiration date, and doses lost

Note: Form must be signed by a provider enrolled in TVFC.

- d) HSR or LHD may inform the provider to contact the DSHS Pharmacy to determine if the vaccines in question can still be used. The DSHS Pharmacy may instruct the provider to contact the vaccine manufacturer to request an opinion on whether the vaccine can be used.
- e) The TVFC provider that has lost vaccine must assess how long the vaccines have been stored improperly and how many children have received the vaccines. After discussing this with the DSHS Pharmacy and manufacturers, the clinic site must determine whether or not children will need to be recalled. The TVFC 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.

- f) TVFC providers should report vaccine losses on column F of the EC-33 at the end of the month. This will ensure that the vaccine inventory balances. Losses totaling less than 5 doses should be listed on column F of the EC-33 with an explanation in the comments section for the loss.

TVFC providers may be billed for vaccine losses due to negligence. (See K. Storage and Handling #5 for definition of negligence.)

2. HSR and LHD Procedures:

- a) HSR/LHD will assist provider in contacting DSHS Pharmacy Branch or Merck (varicella, zoster) and in completing EC-69. EC-69 should be requested when the EC-33 indicates a loss of 5 doses or more of any one vaccine.
- b) HSR will review EC-69 for completeness and forward to AO for processing.
- c) The HSR/LHD that serves the provider must notify DSHS, Immunization Branch, VSG within 8 working hours of notification from the provider. The QA contractor may also contact the LHD or HSR. The HSR will confer with the AO consultant about the TVFC provider's loss and the details of that loss, including the number of doses of vaccine lost and the vaccine loss history of the TVFC provider.
- d) HSR/LHD must re-contact TVFC providers within 5 business days for follow-up, to retrieve vaccines, and ensure the problem that created the loss has been corrected.
- e) HSR should approve additional orders only after safe storage for vaccines has been confirmed.
- f) HSR/LHD will advise the provider on how to return vaccines using the McKesson packing boxes, and ensuring that a copy of the C-69 paperwork is correct and included with the physical vaccines.

Instruct providers to:

- Enclose non-viable vaccine in the empty storage container;
- Enclose a copy of the fully completed EC-69 inside the container;
- If more than one box is used, mark the boxes with box 1 of 2, etc.;
- Reverse the box flaps exposing the postage paid return label and tape with clear shipping tape;
- The provider can either wait until they receive a vaccine shipment to give the container to the courier for return to McKesson, or if UPS is not the provider's regular shipper, UPS can be called to provide a pick-up free of charge;
- Providers should not be charged a pick-up fee for this service;
- Contact your consultant if UPS requests payment for box pick-up.

3. AO Procedures:

AO will review all EC-69s for completeness and consideration for billing provider for loss.

- Based on the information supplied by the TVFC provider and LHD/HSR, the Immunization Branch will determine whether the vaccine was lost due to negligence or an unpreventable occurrence (natural disaster, area power outages, etc.). A review of the provider's loss for the past 24 months may also be reviewed at this time to determine if the provider will be notified in writing or billed for the loss. (TVFC providers may be financially responsible for the cost of TVFC vaccine lost due to negligence.)
- A vaccine loss that was due to negligence may be billed regardless of prior history of preventable vaccine loss. (See K. Storage and Handling #5 for definition of negligence.) TVFC providers having three or more preventable vaccine losses within the prior 24-month period of time may be billed for the vaccine loss, regardless of the loss amount. TVFC providers who are newly enrolled (less than 24 months) with two or more preventable vaccine losses may be billed for the vaccine.
- A vaccine loss that was due to negligence may result in a warning letter that outlines the type of loss and the amount of the loss, but does not include a bill for the loss.
- Once it is determined that the TVFC provider will be responsible for reimbursing DSHS for the vaccine loss, DSHS Immunization Branch will bill the TVFC provider in writing. Copies of the billing letter will be provided to the appropriate HSR.

Note: The Immunizations Branch Manager will review losses that are \$2,000 or more to determine if the provider will be billed for the lost vaccines.

4. Third Party Distributor Procedures:

Third party distributor will document Texas losses and return vaccines to the manufacturer for excise tax credit.

I. **Approved Vaccines**

The vaccines/toxoids covered under this policy are:

1. Diphtheria and Tetanus toxoids, adsorbed (DT)
2. Diphtheria-Tetanus toxoids and acellular Pertussis vaccine (DTaP)
3. Diphtheria-Tetanus toxoids and acellular Pertussis vaccine, Hepatitis B, and Inactivated Polio vaccine (DTaP-HepB-IPV)

4. Diphtheria-Tetanus toxoids and acellular Pertussis vaccine, Inactivated Polio vaccine, and *Haemophilus influenzae* type b vaccine (DTaP-IPV/Hib)
5. Diphtheria-Tetanus toxoids and acellular Pertussis vaccine and Inactivated Polio vaccine (DTaP-IPV)
6. Flumist (LAIV)
7. Hepatitis A vaccine (HepA)
8. Hepatitis B vaccine (HepB)
9. *Haemophilus influenzae* type b (Hib)
10. Hepatitis B and *Haemophilus influenzae* type b (HepB-Hib)
11. Human Papillomavirus (HPV) vaccine
12. Influenza vaccine
13. Inactivated Polio vaccine (IPV)
14. Measles, Mumps, and Rubella (MMR)
15. Measles, Mumps, Rubella and Varicella virus vaccine (MMRV) – when available
16. Meningococcal Conjugate (MCV4)
17. Meningococcal Polysaccharide vaccine*
18. Pneumococcal Conjugate (PCV7)
19. Pneumococcal Polysaccharide 23-valent vaccine (for high-risk patients)*
20. Rabies*
21. Rotavirus vaccine
22. Tetanus and Diphtheria toxoids, adsorbed (Td for adult use)
23. Tetanus and Diphtheria toxoids and acellular Pertussis vaccine (Tdap)
24. Varicella
25. Zoster
26. Immune Globulin (IG)*

*Some of the vaccines listed above are not for routine use. Due to funding limitations, all vaccines may not be available to vaccinate children.

*See Appendix A, *Additional Vaccine Ordering Instructions*.

J. Adult Safety Net Program and Adult Hepatitis B Initiative

Adult Safety-net Program:

The adult Vaccine Safety-net 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 is not mandated by the Texas legislature and funding comes out 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 to cover 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, and not state purchased safety-net vaccine. Additionally, special immunization clinics should not be held for adults using safety-net vaccines (with the exception of HSR flu clinics), and advertising should not be used to promote the adult safety-net program.

The adult safety-net vaccines are available only through LHD and HSR clinics, as well as agencies contracted by a LHD to provide vaccines. Safety-net vaccines may be provided to uninsured and under-insured patients only, and eligibility must be documented and stored for three years. Eligibility is a self declaration by the patient and need not be verified by health department staff. Private providers are not authorized to provide vaccine to adults 19 years of age or older, with one exception: any person who was TVFC-eligible and started a series before his/her 19th birthday may finish the series with TVFC vaccine.

All adult vaccine doses administered should be reported on the Monthly Biological Report (C-33) under the "19+" Doses Administered column. It is important 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.

Vaccine	DSHS Health Service Regions	Local Health Departments*	TYC State Schools	Other Providers
Hepatitis A	A	A	A	L
Hepatitis B	B	B	A	L
Human Papillomavirus (HPV)	C	C	C	L
Influenza	D	E	D	X
MMR	F	F	A	L
MCV4 19-55 years only	G	G	A	X
Pneumococcal Polysaccharide (PPV23)	H	H	A	X
Td/Tdap	I	I	A	L
Varicella (chickenpox)	J	J	A	L
Zoster 60 years and older	K	K	X	X

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

- a. All uninsured and underinsured adults.
- b. All uninsured and underinsured adults.

Exception: Refugee Health Programs (RHP) receive separate funding for hepatitis B vaccine, and therefore clients of RHPs who live in an area covered by a RHP are excluded.

- c. All uninsured and underinsured women between the ages of 19-26.

Note: Ideally, vaccine should be administered before potential exposure to HPV through sexual activity; however, women who are sexually active should still be vaccinated. Sexually active women who have not been infected with any of the HPV vaccine types

receive the full benefit of the vaccination. Vaccination is less beneficial for women who have already been infected with one or more of the four HPV vaccine types. Vaccination is not recommended during pregnancy. If a woman is found to be pregnant after initiating the vaccination series, the remainder of the 3-dose regimen should be delayed until after completion of the pregnancy.

- d. Persons at highest risk of complications from influenza disease as defined by the ACIP. Excluding those at residential or occupational risk of exposure where the organization, proprietor, or employer is required to offer the vaccine by law.
- e. Vaccine purchased with LHD funds can be used at the discretion of the LHD.
- f. All uninsured and underinsured adults who met the following criteria:
 - Persons born during or after 1957 should receive at least one dose of MMR unless they have documentation of at least one dose, a history of measles based on health-care provider diagnosis, or laboratory evidence of immunity. Women whose rubella vaccination history is unreliable or who lack laboratory evidence of immunity should also receive one dose of MMR.
 - A second dose of MMR is recommended for adults who 1) have been recently exposed to measles or in an outbreak setting; 2) have been previously vaccinated with killed measles vaccine; 3) have been vaccinated with an unknown type of measles vaccine during 1963-1967; 4) are students in postsecondary educational institutions; 5) work in a health-care facility; or 6) plan to travel internationally.
- g. Uninsured and underinsured adults 19-55 yrs who are risk. The following groups are considered at risk:
 - Medical indications: adults with anatomic or functional asplenia or terminal complement component deficiencies. Revaccination after 5 years might be indicated for adults previously vaccinated with MPSV4 who remain at high risk for infection.
 - Other: first-year college students living in dormitories
 - Uninsured and underinsured persons who travel to or live in countries in which meningococcal disease is hyperendemic or epidemic.
- h. Uninsured and underinsured adults who are at risk. The following groups are considered at risk:
 - All adults 65 years of age or older, including one-time revaccination of those who have not received vaccine within 5 years and were less than 65 years of age at the time of primary

vaccination. All persons over 65 who have unknown vaccination status should receive one dose of vaccine.

- Adults 19-64 who are at risk per ACIP recommendations, which includes the following:
 - Chronic disorders of the pulmonary system (excluding asthma)
 - Cardiovascular diseases
 - Diabetes mellitus
 - Chronic liver diseases, including liver disease as a result of alcohol abuse (e.g., cirrhosis)
 - Chronic renal failure or nephritic syndrome
 - Functional or anatomic asplenia (e.g., sickle cell disease or splenectomy) [if elective splenectomy is planned, vaccinate at least 2 weeks before surgery]
 - Immunosuppressive conditions (e.g., congenital immunodeficiency, HIV infection [vaccinate as close to diagnosis as possible when CD4 cell counts are highest], leukemia, lymphoma, multiple myeloma, Hodgkin disease, generalized malignancy, or organ or bone marrow transplantation)
 - Chemotherapy with alkylating agents, antimetabolites, or high-dose, long-term corticosteroids
 - Cochlear implants
- *Others included:* Alaskan Natives and certain American Indian populations.

- i. All uninsured or underinsured adults.
Please note that Tdap is only licensed for adults 19-64, and Td is indicated for adults 65 and older. Adacel® is the only Tdap vaccine licensed for adults. Another Tdap vaccine, Boostrix®, is not approved for adult use.
- j. Uninsured or underinsured adults born after 1980* who are without evidence of immunity to Varicella should have received two doses of Varicella vaccine. Those who have received only one dose should receive the second dose.

*For health-care workers, pregnant women, and those born outside the U.S. before 1980 should not be considered evidence of immunity.

Do not vaccinate women who are pregnant or might become pregnant within 4 weeks of receiving the vaccine. Varicella vaccine is to be administered post-partum only.

Exception: Refugee Health Programs (RHP) receive separate funding for Varicella vaccine, and therefore clients of RHPs who live in an area covered by a RHP are excluded.

- k. Uninsured or underinsured adults 60 years of age and older whether or not they report a prior episode of herpes zoster. Persons with chronic medical conditions may be vaccinated unless a contraindication or precaution exists for their condition. Contraindications and precautions for use of zoster vaccine are available at: <http://www.fda.gov/cber/label/zostavaxLB.pdf>
- l. Any person who was TVFC-eligible **AND** started the series **BEFORE** their 19th birthday.
- X. Not eligible for state-supplied vaccine for adults at this site. Other providers may purchase their own vaccine inventory to vaccinate adults at the client's expense.

Adult Hepatitis B Initiative

In fiscal year 2008, the CDC provided DSHS with limited grant funds to implement a hepatitis B vaccine program for at-risk, uninsured, and underinsured adults. Funding is available again this year. Agencies eligible to participate in this initiative include: FQHCs, Family Planning Clinics (FPC), STD and HIV clinics, LHDs, and HSRs.

Two vaccines/toxoids are available under this initiative (1) Recombivax®, an Adult Hepatitis B vaccine manufactured by Merck and (2) Twinrix®, an adult hepatitis A/hepatitis B combination vaccine manufactured by GlaxoSmithKline.

To be eligible for the adult hepatitis B initiative, providers must be enrolled in the TVFC. Additionally, providers must complete and submit a Vendor Profile Form (see Appendix) to their LHD or HSR prior to receiving the adult hepatitis B vaccines. Providers may also use the Vendor Daily Tally sheet, which is an optional form that can assist with tracking doses administered.

All adult hepatitis B vaccine doses administered using state-provided vaccine should be reported on the Monthly Biological Report (EC-33) under the "19+" Doses Administered column. It is **important** 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.

Adults eligible for hepatitis B vaccine include those who are uninsured or underinsured, and have some risk factor for contracting hepatitis B. Underinsured is defined as any adult who: (1) has insurance that does not cover the cost of vaccines, (2) has a co-pay or deductible the person

cannot meet, or (3) has insurance that provides limited or capped vaccine coverage.

Adults at-risk for Hepatitis B Virus (HBV) include those who meet one of the following conditions:

Persons at risk for infection by sexual exposure

- Sex partners of hepatitis B surface antigen (HBsAg)-positive persons
- 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
- Men who have sex with men

Persons at risk for infection by percutaneous or mucosal exposure to blood

- Current or recent injection-drug users
- Household contacts of HBsAg-positive persons
- Residents and staff of facilities for developmentally disabled persons
- Health-care and public safety workers with reasonably anticipated risk for exposure to blood or blood contaminated body fluids
- Persons with end-stage renal disease, including predialysis, hemodialysis, peritoneal dialysis, and home dialysis patients

Others

- International travelers to regions with high or intermediate levels (HBsAg prevalence of >2%) of endemic HBV infection (see Recommendations of the Advisory Committee on Immunization Practices Part II: Immunization of Adults for complete details: <http://www.cdc.gov/mmwr/PDF/rr/rr5516.pdf>)
- Persons with chronic liver disease
- Persons with HIV infection

K. Storage and Handling

1. TVFC requires that all HSR, LHD, and private providers have written procedures for vaccine storage and handling. A vaccine management protocol should be easily accessible to all clinic staff in the event of a power outage. Clearly written procedures help prevent vaccine losses (see Section L. Emergency Vaccine Storage Contingency Plan).

2. Proper Equipment for Storage:

- a) Providers are required to have certified, calibrated thermometers in all refrigerators and freezers used for vaccine storage. Providers should retain their accompanying certificate as proof of certification. The certification must not be more than one year past the due date. Additionally, an alarm system and back-up generator are appropriate for larger clinics.

Note: Use of continuous recording devices, temperature alarm systems, and other equipment will not replace the need to have a certified thermometer in each refrigeration/freezer unit.

Thermometers that have a re-certification date that is more than one year past due must either be replaced with a new certified thermometer, or recertified at the provider's expense.

Certified calibrated thermometers undergo a second individual calibration against a reference standard from an appropriate agency, such as the National Institute of Standards and Technology (NIST) or a laboratory recognized by NIST. Calibration can be traceable to NIST using American Society for Testing and Materials (ASTM) methods for the calibration process. They are then given a certificate indicating successful completion of this process, which is provided with the instrument when purchased or re-certified. Thermometers must be certified by NIST or ASTM. No refrigerator or freezer unit should ever be without a certified thermometer, even during the re-certification period.

- b) The refrigerator compartment must maintain temperatures between 36°F and 46°F (2°C and 8°C) for vaccine viability. Temperature should be set at midrange, about 40° F (5°C).
- c) The freezer compartment should maintain temperatures at or below 5°F (-15°C).
- d) High volume clinics may find separate refrigerators and freezers useful. A standard "kitchen" side-by-side or top-freezer unit is sufficient. Frost-free freezers are preferred.
- e) Refrigerators with a freezer unit inside (that does not have a separate outside door) are not allowed for the storage of TVFC vaccine, whether or not varicella is stored. However, these units may be used to store a clinic's single-day supply of refrigerated-only vaccines; these refrigerated vaccines should be returned to the main refrigerator at the end of the day, and must be monitored during the day. 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 sized freezers that are

manufactured specifically to maintain very cold temperatures. These freezer units are acceptable for the storage of varicella or MMRV.

- f) Refrigerator/freezer units must be large enough to hold the year's largest inventory.
- g) MMR vaccine may be stored either frozen or refrigerated. MMR is sensitive to light and vaccine efficacy could be compromised if left out in the light.
- h) All vaccines except Varicella and MMRV are to be stored in the refrigerator and should never be frozen.
- i) Diluent may be stored in the door of the refrigerator and can provide extra insulation much like bottles of water.
- j) 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 about this on the refrigerator door.
- k) Plug guards should be used on all refrigerators that are used for storing TVFC vaccines. (The only exceptions would be if the refrigerator is equipped with a temperature sensitive alarm, or the plug guard does not accommodate the plug.) Plug guards are effective tools in preventing the accidental unplugging of equipment. HSRs, LHDs, and the quality assurance contractor are responsible for providing plug guards to providers.
- l) A written Vaccine Storage Contingency Plan that includes at least: name and phone number of emergency contact, plan of how to move vaccine to ensure cold chain, and address of location where vaccines will be temporarily stored should also be posted on or near the refrigerator.
- m) 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.
- n) It is important that vaccines be kept 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.
- o) Storing food or drinks in the same refrigerator as vaccine is not acceptable.
- p) "Do Not Unplug" sign must be posted on all outlets or all refrigerator units used to store vaccine.
- q) "Do Not Unplug" sign must be posted by each circuit breaker.

The following guidelines are required of TVFC providers:

- a) Check and record internal refrigerator and freezer temperatures on the Temperature Recording Form (EC-105) twice daily. If

temperatures fall outside the acceptable range, take immediate action to ensure vaccine viability.

- b) Store extra ice packs and/or gel packs along the walls, back, and door of the freezer compartment. This helps keep a steady temperature during the automatic defrosting cycles and provides additional reserves of cold in the event of a power failure. Air must circulate around the vaccines freely.
- c) Store large water bottles and/or diluent (as many as the refrigerator will accommodate) against the inside walls and door of the refrigerator. This helps maintain a stable temperature, and provide extra reserves of cold in the event of a power failure. Air must circulate around the vaccines freely.

Note: It is suggested to write “not for consumption” on the water bottles.

- d) 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. Temperatures are more stable in the body of the refrigerator/freezer.
- e) Stack vaccines with enough room for cold air to circulate freely around vaccine.
- f) Notify the LHD or HSR 90 days prior to vaccine expiration, if the vaccine cannot be used before expiration. The LHD or HSR will assist with redistribution of the vaccine.

See Appendix F for the Temperature Recording Form (EC-105).

3. Personnel

- a) Vaccine viability depends on the knowledge and habits of the clinic staff. One person should be trained and designated “in-charge” to ensure that temperatures are checked and vaccines are handled and stored properly. Each clinic must have a designated back-up person(s). However, all staff must be trained regarding proper storage and handling of vaccines.
- b) There must be written procedures for emergency situations to assure continued viability of the vaccines.
- c) All individuals responsible for vaccines should be knowledgeable about the required storage temperatures and handling conditions for the various vaccines. It does no good to record the temperature of the refrigerator daily if the person recording the temperature is not aware that a temperature above 48°F is too high. New employees must be trained properly and immediately.

4. End-of-Month Inventory

At the end of each month, physically count the inventory on hand. Pay close attention to the expiration dates of the vaccines. Use shortest-dated vaccine first. Clinics should contact their HSR or LHD if vaccine cannot be used 90 days before expiration. It is the responsibility of the LHD or HSR to pick-up and transfer short-dated vaccines to another clinic where the vaccines may be used. Too much vaccine kept in inventory increases the risk of vaccines reaching expiration dates, and increases the amount of loss in the event of refrigerator failure. When ordering vaccines, providers should keep no more than the designated maximum on hand. (See B. Vaccine Ordering)

Note: Picking up and redistributing vaccine from a provider is the responsibility of the facility directly overseeing the site (either the LHD or HSR).

5. Vaccine Loss Due to Negligence

Vaccine negligence may include but is not limited to the following:

- a) Vaccine stored improperly (i.e. refrigerating a vaccine that should be stored in the freezer, or freezing a vaccine that should be refrigerated).
- b) Vaccine left un-refrigerated or out of the freezer.
- c) Refrigerator or freezer unplugged (no plug guard used).
- d) Transporting vaccine inappropriately (appropriate cold chain not maintained).
- e) Improper maintenance of recommended refrigerator and freezer temperatures resulting in vaccine spoilage.
- f) Improper monitoring of temperatures in freezer or refrigerator.
- g) Allowing vaccine to expire without notifying the HSR or LHD in advance (90 days) that the vaccine could not be used.
- h) Refrigerator/Freezer door left open.
- i) Refusal of vaccine shipment

TVFC providers may be required to reimburse the state for vaccine losses occurring from any of the above conditions. DSHS will require payment by check or money order for the cost of the vaccine minus the federal excise tax (if the vaccine was returned to the DSHS Pharmacy Branch or third party contractor). The check or money order must be payable to the DSHS and must list the Immunization Branch's budget number, H3000, on the payment to ensure proper credit to the provider's account. (See G. Procedures for Vaccine Loss and Returning Vaccine)

6. Vaccine Borrowing

TVFC providers should not borrow TVFC vaccine to give to non-TVFC eligible children. In the event a provider inadvertently makes this mistake, the CDC requires that a *VFC Vaccine Borrowing Report* be completed and submitted. This report tracks the name of the child, the vaccines borrowed, the reason, and the replacement date.

See Appendix N for VFC Vaccine Borrowing Report

L. Emergency Vaccine Storage Contingency Plan

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

1. Identify a person to be responsible to enact the contingency plan and a knowledgeable alternate should the primary person not be available. Be sure to include contact information such as phone numbers (home and office).
2. Identify a location to take the state-provided vaccine for storage, preferably a location with a power generator or other alternate source of power such as a hospital or grocery store. 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.
3. Specify the steps to be taken to transport the vaccine to the alternate location being sure to include:
 - a) Note the time of the emergency situation/power outage.
 - b) Note the temperature of the refrigerator and freezer before removing any vaccine for transportation.
 - c) Indicate 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 to the vaccine packaging).
 - d) Inventory the vaccine as you remove it to the transport container being careful to indicate the number of doses of each antigen and the expiration dates.
 - e) Keep a thermometer in the transport container and note the temperature when you place the vaccine in the alternate storage

and the time. This tells us how long the vaccine was at a less-than-ideal temperature.

- f) Varicella (chickenpox) vaccine *MUST* be stored on dry ice for transportation! It takes 10 pounds of dry ice to transport 100 doses of varicella. If dry ice is not available and cannot be obtained, transport the varicella as quickly as possible with ice packs.
4. Contact HSR or LHD to inform them of the emergency or call the DSHS Pharmacy at (512) 458-7500. Be prepared to give them the information concerning the temperature of the vaccine, the amount of vaccine, expiration dates, and how long the vaccine was exposed to inappropriate temperatures. For varicella or MMRV, contact Merck at (800) 672-6372 for instructions on the viability of the vaccine.

Keep in mind that you will be asked to provide a copy of this document at site reviews, so be sure to keep the plan 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 in Appendix M of this manual. This template is not a required form, but is a tool that is available to providers should they need assistance in developing an emergency plan.

M. Box Recycling

Empty shipment containers will be returned free of charge to McKesson. Postage paid labeling for UPS is included to facilitate container return. Each time a provider receives a vaccine shipment, the empty containers from the previous shipment can be given to the courier for return to McKesson. Providers simply reverse the box flaps exposing the postage paid return label and tape with clear shipping tape. Gel packs and temperature monitors do not need to be returned. If UPS is not the provider's regular shipper, UPS can be called to provide a pick-up free of charge. Providers should not be charged a pick-up fee for this service. Providers should contact the LHD or HSR if UPS requests payment for box pick-up.

Note: Each site should maintain enough packing containers and supplies to transport entire inventory in the event of an emergency.

IV. Administration Fees

Requirements for Charging Fees

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 TVFC constitutes fraudulent behavior. Fraud in the TVFC will be handled the same as Medicaid fraud.
2. Medicaid and CHIP patients may not be charged any out-of-pocket fees either for vaccines or for administration of the vaccines. Both Medicaid and CHIP reimburse 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.
3. Providers may charge a reasonable administration fee (not to exceed \$14.85 for immunization-only services) to TVFC-eligible children excluding Medicaid and CHIP, but vaccines should be administered even if the patient/parent/guardian is unable to pay the administration fee. Providers may not deny services due to a client's inability to pay the administration fee.

Providers may not refer a TVFC-eligible child to another health care provider for immunizations if the provider has accepted that child into the practice as their patient.

4. When providers sign the Provider Enrollment Form, they agree to follow the DSHS guidelines for fees when administering vaccines. The Provider Enrollment Form contains the following statements regarding fees:
 - a) This office/facility will not charge for vaccines supplied by DSHS and administered to a child who is eligible for the TVFC.
 - b) This office/facility may charge a vaccine administration fee. This office/facility will not impose a charge for the administration of the vaccine in any amount higher than the maximum fee established by DSHS. Medicaid patients cannot be charged for the vaccine, administration of vaccine, or an office visit associated with Medicaid services.
 - c) 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.

DSHS Clinic Administration Fee Guidelines

DSHS has established these guidelines for administering a vaccine (injection, intranasal, or oral) to non-CHIP and non-Medicaid patients.

- a) The fees will be charged according to the Federal Poverty Income Guidelines scale.
 - i. Immunization only visit for a child is \$14.85 per vaccine.
 - ii. Immunization only fees for a child may not exceed \$14.85 per vaccine even if the Poverty Income Scale is higher.
- b) A person's ability to pay the entire amount of a fee will be considered and public health services will not be denied because of a person's inability to pay.
- c) The current Federal Poverty Income Guidelines scale is available upon request from the DSHS, Disease Prevention and Intervention Section, Immunization Branch, MC-1946, P.O. BOX 149347, Austin, Texas 78714-9347, (512) 458-7284 or (800) 252-9152. It is also available online at the Immunization Branch web site:
<http://online.dshs.state.tx.us/policy/program/povertyguidelines.pdf>

See Appendix B for Provider Enrollment Form

V. Immunization Documentation

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:

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

Immunization Cards for providers (C-100), and clients (C-102) are located in the *TVFC Tool Kit in Section 4*, and can be ordered from the DSHS Immunization Branch. These cards are designed to capture the required information listed above.

The TVFC also makes the following recommendations regarding record keeping:

- a) *Designate an immunization nurse to answer immunization questions for staff/parents.*
- b) *File immunization records in an accessible location within the chart, keeping the immunization record and TVFC Patient Eligibility forms together.*
- c) *Place records at the front of each child's chart and make immunizations a priority.*
- d) *Encourage parents to bring their children's immunization records with them, allowing complete documentation of immunization histories given elsewhere in patient records.*
- e) *If a child presents with no immunization record, obtain the history through the statewide tracking registry ImmTrac, or call previous providers to obtain the history.*
- f) *If a child presents with no immunization record and the history cannot be obtained, age-appropriately vaccinate during that visit to avoid a missed opportunity.*
- g) *Empower all staff to become "Immunization Advocates," and assess every child's immunization status at every encounter.*

- h) Simultaneously administer all needed vaccines, unless there is a true contraindication.*
- i) Implement a reminder/recall system to remind parents when immunizations are due and to recall patients whose immunizations are past due.*
- j) Identify clients that have not been seen within a twelve month time period and record the acronym MOGE (moved or gone elsewhere) in the chart. Proper documentation of MOGE is defined as one of the following:
 - i. Parent/Guardian/provider letter stating that they are going to a new practice.*
 - ii. Mailed reminder/recall card/letter returned without a local forwarding address.*
 - iii. Provider statement advising that they will no longer see the patient.*
 - iv. Request for medical record transfer.*
 - v. No visit to the clinic within the last twelve months.*
 - vi. Verbal notification from parent/guardian stating child is being seen by another provider.**

The provider should give a personal immunization record to each vaccine recipient showing the date (month, day, year) when each vaccine/toxoid was administered.

VI. Consent

TVFC requires providers to (1) obtain written consent for administration of a vaccine, and (2) provide information on the risks and benefits associated with each vaccine. These requirements are based on Texas and Federal laws listed below.

A. Consent

Definitions

Consent to Vaccinate- Approval or acceptance of a vaccine being administered to a minor or to self.

Delegation of Consent- Written authorization given by a parent, legal guardian or managing conservator of a child authorizing another adult to consent to vaccinate.

Texas Laws

1. Texas Family Code, Chapter 151 and 153 identifies who can consent for medical treatment.
2. Texas Family Code, Chapter 32 § 32.002 defines what information must be included in a Consent Form and that consent must be in writing.
3. Texas Family Code, Chapter 32 § 32.102 states a person authorized to consent to immunization of a child has the responsibility to ensure that the consent, if given, is an informed consent.
4. Delegation of Consent is defined in the Texas Administrative Code, Title 25 § 97.91 and may be required in addition to a consent form.

B. Vaccine Information Statements (VIS)

In addition to State Laws that address vaccinations there are also federal requirements that apply.

1. The 1986 National Childhood Vaccine Injury Act (NCVIA) 42 U.S.C. § 300aa-25 requires that all immunization providers (regardless of whether they are enrolled in the TVFC) give each parent/guardian or other responsible adult presenting with a child needing vaccinations a current VIS to keep for each vaccine the child is to receive, every time a vaccine is administered.

2. Providers must take reasonable steps to provide information in the appropriate languages in order to ensure that a client with limited English proficiency is effectively informed. The VIS can be downloaded in more than 20 additional languages from the Immunization Action Coalition website: www.immunize.org/vis/

VII. Public Education

Recommendations for Public Education

1. Mass communication is generally divided into print, radio, and television. Each offers different opportunities to present the TVFC to the public and health care providers.
2. Determine the mass media outlets that are available to you locally. Know the submission requirements and deadlines of each outlet.
 - a) Print – Consider weekly, biweekly, or monthly community papers, advertising papers that include some editorial space, and local magazines. Look for specialized publications for American Indians, Alaskan Natives, and other groups, that may be TVFC-eligible. Include pictures whenever possible.
 - b) Radio can be used to reach those who may be eligible for TVFC benefits. Spanish and other foreign language radio stations are effective communication channels for the non-English speaking public.
 - c) Television – Cable TV gives you access to a much larger audience when combined with viewers reached via the four primary broadcast networks; ABC, CBS, FOX, and NBC. Local community channels and bulletin boards on cable channels usually broadcast public service messages at no charge.
3. Specialized communications are strategically placed articles and spot messages, which may be included in non-traditional settings. For example:
 - a) Publications – Review all publications from your immunization program and incorporate TVFC messages whenever possible.
 - b) If your agency publishes a newsletter, include articles on the TVFC.
 - c) Include TVFC pictures, pamphlets, text, and graphic panels in your health exhibits.
 - d) Submit a TVFC notice to community church bulletins, mailings in utility bills, and club or subdivision newsletters.
 - e) Distribute TVFC posters and flyers to child-care centers, health clinics, churches, community groups, prenatal or childbirth classes, or in a gift bag distributed by Welcome Wagon, conventions, or hospitals (ob-gyn/peds).

VIII: Provider Recruitment

Requirements for Provider Recruitment

DSHS, HSRs, and LHDs will conduct recruitment activities to enroll new providers into the TVFC. Because the TVFC is routinely improving business processes and service to providers and because reasons for not enrolling can change over time, HSRs and LHDs should recruit eligible providers annually. At a minimum recruitment should include:

1. HSR/LHD will utilize the Texas Medical Board (TMB) physician listing, and other provider lists as provided by AO.
 - a) The TVFC spiral brochure, stock number 11-11118, promoting the TVFC will be mailed to each physician. The sender should include a business card. The return address should be the senders address to help keep track of recruitment efforts.
 - b) Provider enrollment forms will also be included in the mailing.
 - c) Include a local contact name as an immunization resource for the physician/provider.
2. The TMB, and other provided lists contain non-enrolled providers by county. The HSR/LHD should prioritize the geographic areas and populations that may be under-represented and take steps to reach providers most likely to serve TVFC-eligible children within pockets of need.
3. Contact providers annually who have previously declined to enroll.
4. If providers decline enrollment into the TVFC, document the reason(s) for the refusal and determine whether a follow-up recruitment effort with new information might favorably change the outcome.
5. HSRs and LHDs should follow the format provided by TVFC in reporting recruitment activity.
6. LHDs who are contractors of the Immunization Branch must document recruitment activity on the tri-annual report submitted to the AO.

If resources permit, additional recruitment activities may provide a better chance of enrolling new providers; these include provider phone calls and/or recruitment visits.

Section Three: Program Evaluation

SECTION THREE: PROGRAM EVALUATION

I.	TVFC Visits	
	A. Site Monitoring Activities	46
	B. AFIX	48
	C. Reminder/Recall Training	48
II.	Provider Compliance	50

Section Three: Program Evaluation

Policy: HSR and LHD must monitor TVFC-enrolled providers and clinic sites.

Purpose: To assure that enrolled providers comply with all TVFC requirements.

I. TVFC Visits

A. Site Monitoring Activities

For the purposes of this policy, public clinics are defined as HSR clinics, LHD clinics, and WIC clinics. Private clinics are defined as all other clinic sites.

1. HSRs/LHDs must:

Conduct TVFC On-site Quality Assurance **follow-up** visits in private clinics they directly serve, to assure that areas for improvement identified by the QA contractor are emphasized and that clinics are making progress in improving service delivery. Follow-up is conducted according to the following criteria when a “NO” response is recorded on the initial On-site Evaluation Report:

- a) Five working days from the receipt of the On-site Evaluation Report or notification from the QA contract staff, via telephone or visit for questions 48a, 50a, 50c, 50d, 50e, 51b, 51c, and 51d
- b) Ten working days from the receipt of the On-site Evaluation Report via telephone or visit for questions 4, 5, 6, 12, 14, 16a, 16b, 20, 21, 27, 28, 29, 32, 33, 35a, 35b, 47, 48b, 48c, 49a, 49c, 50b, 50f, 50g, 51a, 51e, 51f, 52, 53, 54a, 54b, 55, 56, 57, 59, 61a, 61b, 62, 63, and 64.
- c) **OPTIONAL: Follow-up** six months from the receipt of the On-site Evaluation Report for question 40. (AO recommends that the Comprehensive Clinic Assessment Software Application (CoCASA) be repeated whenever question 40 is a “NO”. HSRs and LHDs determine whether or not to repeat the CoCASA based on budgetary constraints.)
- d) Questions 15a, 15b, 36, 37a and 37b are informational in nature and a “NO” response on these does not indicate follow-up is needed in private clinics.

2. HSRs must:

- a) Conduct initial and follow-up on TVFC On-site Quality Assurance visits and Contract Monitoring Visits, including the Assessment Feedback Incentive and Exchange (AFIX) component utilizing

CoCASA, in all HSR, LHD, and WIC clinic sites that administer vaccines in the areas they cover. The follow-up criteria are the same as listed under A.1. Contract Monitoring Visits are conducted on entities that have a contract with the Immunization Branch, and every question on the On-site Evaluation Report must be answered. The TVFC On-site Quality Assurance visits are conducted on entities that do not have a contract with the Immunization Branch, and only the VFC questions on the On-site Evaluation Report must be answered.

- b) Prior to submitting to AO, HSRs must review all HSR and LHD-conducted site visits to ensure:
 - i) all questions have been answered,
 - ii) all “NO” responses have corrective actions documented that are in accordance with the instructions for each question, and
 - iii) all reports have been signed and dated by the reviewer.
- c) HSR must then submit via email the On-site Evaluation Report, Record Review Tool, Loss/Gain Calculation Chart, CoCASA data files and the CoCASA Summary Report to the AO within two weeks after the site visit is conducted.
- d) When the site visits are placed on the TVFC website and accepted by the AO, the visit will show up as “Pending” on the website. HSRs must document all follow-up activities conducted for each question that received a “NO” response on the website. HSRs must review all follow-up activities conducted by their LHDs to ensure appropriate follow-up has been done.
- e) Once the HSR is satisfied that the information on the follow-up is acceptable, a comment should be added to the website indicating that the follow-up is approved. The website will automatically record the name and date of the HSR staff approving the LHD follow-up.

3. LHDs must:

- a) Conduct the initial TVFC On-site Quality Assurance visit for subcontractors and WICs not directly operated by the LHD. Submit a completed report to the HSR within two weeks after the site visit is conducted.
- b) Conduct follow-up site visits in private clinics based on the criteria mentioned in the above section A.1. Document completed follow-up on the website within the assigned follow-up time frame.
- c) Review all reports to ensure that:
 - i. all questions have been answered,
 - ii. all “NO” responses have corrective actions documented that are in accordance with the instructions for each question, and
 - iii. all reports have been signed and dated by the reviewer.

NOTE: The HSR is responsible for ensuring that the provider receives a complete copy of the on-site evaluation report. HSRs may require LHDs to provide copies to the providers the LHD serves. LHDs should consult with their HSR.

B. AFIX

1. An AFIX visit consists of an immunization record review of patient records. Those records are entered into the Comprehensive Clinic Assessment Software Application, (CoCASA). CoCASA provides a report on the clinic's immunization coverage rates based on the records entered.
2. AFIX should be conducted in conjunction with TVFC On-site Quality Assurance Visits and Contract Monitoring Visits.
3. AFIX must be conducted in 100% of all public clinics (HSR, LHD, and WIC).
4. The quality assurance contractor will conduct an AFIX visit in conjunction with the TVFC site monitoring visit annually, thereby ensuring that all eligible private clinics are offered AFIX.
5. A CoCASA (50 records) is required for all public and private clinics. The TVFC Resource Manual: On-Site Evaluation Reports should be reviewed for other information regarding the use of the CoCASA software and AFIX visit information.
6. Reminder, recall, simultaneous administration, and proper record keeping techniques are the minimum required feedback to be given to each clinic during an AFIX visit.
7. HSRs and LHDs are encouraged to conduct AFIX (CoCASA) in non-enrolled clinic sites in the communities they serve.

Private providers (all clinics other than HSR, LHD, and WIC) may refuse the Co-CASA portion of the TVFC On-site Quality Assurance visit, but must allow all other components of the visit to be conducted. Providers who refuse should be educated on the importance of AFIX. HSRs and LHDs should consult the TVFC as necessary to obtain information to educate providers and remove barriers and increase participation in AFIX.

C. Reminder/Recall Training

1. Reminder/Recall Training should be conducted in conjunction with TVFC On-site Quality Assurance Visits and Contract Monitoring Visits, as needed.

2. The quality assurance contractor will conduct Reminder/Recall Training in conjunction with the TVFC On-site monitoring visit annually on providers that meet the criteria, thereby ensuring that all private clinics that qualify are offered Reminder/Recall Training.
3. HSRs and LHDs are to conduct Reminder/Recall Trainings in any clinic that shows interest but did not have the training conducted by the quality assurance contractor.
4. HSRs and LHDs are to conduct follow-up on any provider that received the Reminder/Recall Training from the quality assurance contractor.

Any provider can refuse the Reminder/Recall Training portion of the TVFC On-site Quality Assurance visit, but must allow all other components of the visit to be conducted. Providers who refuse should be educated on the importance of Reminder/Recall.

II. Provider Compliance Policy

The 2009 Draft Provider Compliance Policy is located in Appendix P.

Section Four: Data Reporting

SECTION FOUR: DATA REPORTING

I.	Program Reports	
	A. TVFC Monthly Reports	51
	B. Order Processing Timeline	53
	C. VAERS	54

Section Four: Data Reporting

Policy: Providers are required to submit TVFC monthly reports.

Purpose: To account for vaccine usage, wastage and inventory, and to document clients served.

I. Program Reports

A. TVFC Monthly Reports

The vaccine reports and forms are:

1. Monthly Biological Report (EC-33)

The Monthly Biological Report documents the actual (physical) count of the vaccine inventory. Instructions for completing the EC-33 are located on the back of the form. Any vaccine loss or gain should be addressed under the “Explanation of All Doses Returned and Doses Gained and Lost” on the EC-33.

The person completing the 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.

- a) HSR must collect and review reports from all enrolled clinics in their region monthly. A copy of the reports should be retained for one year.
- b) HSR must verify the PIN
- c) HSR must review EC-33 to ensure that the beginning inventory matched last month’s ending inventory, and that all calculations are correct. HSR should request a C-69 from providers when losses exceed 5 doses of any one vaccine. Report corrections to the originating clinic so they can adjust their records.
- d) HSR must submit all reports to AO after they have been reviewed.
- e) AO will retain the original reports for three years.

See Appendix E for Monthly Biological Report (EC-33).

2. Biological Order Form (EC-68)

The Biological Order Form 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.

- a) HSR/LHD must collect and review reports from all enrolled clinics in under their oversight when the clinic orders vaccine. A copy of the EC-68 should be retained for one year.
- b) The provider PIN must be on the form.
- c) HSR/LHD must review all vaccine orders for accuracy and completeness.
- d) Orders should reflect the max stock levels.
- e) HSR/LHD must verify that the address, shipping hours and days are correct on the EC-68.
- f) All C-68's must be submitted to AO after they have been reviewed.
- g) AO will return incomplete or erroneous reports to HSR for corrections.
- h) AO will retain the original reports for three years.

See Appendix H for Biological Order Form EC-68 and Appendix L For Quality Assurance Checklists for EC-68s and EC-33s.

3. Daily Tally Sheet for Immunizations (C-88) - Optional

- a) For local use only to assist with tracking doses administered throughout the month. Do not submit to AO.
- b) Information must be transferred to the C-33 form.

See Appendix G for Daily Tally Sheet for Immunizations (C-88).

4. Temperature Recording Form (EC-105)

- a) HSR/LHDs must collect and review reports from all enrolled clinic sites under their oversight monthly.
- b) HSR/LHDs must review all EC-105 forms to verify temperatures are within range, that temperatures are recorded twice daily, and take appropriate action when temperatures are out of range (e.g., contact the clinic site to investigate and address refrigeration problems. The Pharmacy Branch can provide technical assistance for refrigeration and vaccine efficacy issues related to breaks in the cold chain).
- c) HSRs must retain the EC-105 for a period of two years. Do not submit to AO.

See Appendix E for Temperature Recording Form (EC-105).

The EC-33, EC-68, and EC-105 must be submitted to the HSR/LHD for a vaccine order to be placed.

B. Order Processing Timeline

The following protocols and timelines for Monthly Biological Order Form (EC-68) and Monthly Biological Report (EC-33) reporting were implemented in 2007 as part of the change to a new nationwide distributor. There are five parties that must work together to make the ordering process successful. They include TVFC provider staff, Health Service Region (HSR) or Local Health Department (LHD) staff, Austin Office (AO) staff, the Centers for Disease Control and Prevention (CDC) staff, and the distributor/manufacturer.

TVFC providers

Providers perform a monthly physical inventory count and complete the EC-33. Information obtained from the EC-33 is used to complete the EC-68. Completed EC-33s, EC-68s, and other documents such as packing slips, transfer forms, and Temperature Recording Forms (C-105) are sent to the HSR and/or LHD offices. These documents are sent on a monthly basis with the possible exception of orders (EC-68). Some providers may order only every other month or quarterly.

HSR/LHD

HSR/LHD staff reviews the submitted EC-33s and EC-68s for accuracy and appropriate ordering. The HSR/LHD has a maximum of five business days to approve and mail EC-33s and EC-68s to the AO. HSR/LHD should not send packing slips, C-105s, or other documents to the AO unless specifically requested. Only the EC-33 and EC-68 are sent to the AO.

AO

Received EC-68s / EC-33s are date stamped and distributed to Vaccine Service Representatives (VSRs). VSRs have three business days from the date received (date stamp) to place orders. The orders are sent to the CDC daily. A confirmation of the order is faxed to the provider on the same afternoon the order is placed by the VSR.

CDC

CDC receives orders daily via the Vacman database and forwards to the distributor the following day.

Distributor

The distributor ships vaccine orders on Mondays, Tuesdays, and Wednesdays only. They have five shipping days (which can mean over two weeks) to ship the vaccine to providers.

Varicella is shipped directly from the manufacturer to the provider. The manufacturer has 15 business days to ship these vaccines.

In most cases providers will receive vaccine sooner, but vaccines are not considered delinquent until 12 working days after the provider has received their faxed confirmation. Holidays, and providers with limited shipping hours, can extend the shipping time. If 12 business days have elapsed since the faxed confirmation was received, contact your TVFC consultant.

Example timeline

In the example timeline, a provider whose order is received at the HSR/LHD on September 6th does not arrive until October 3rd. The faxed confirmation was received by the provider on the 18th. The distributor has five shipping days (Mondays, Tuesdays, and Wednesdays only) to ship the order, which would be October 1st. A two-day delivery gets the order to the provider on October 3rd.

Timeline for Order Processing																														
Sept/Oct	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	1	2	3	4
Provider sends order	X																													
HSR/LHD receives order		X																												
HSR/LHD receives and forwards									X																					
AO Receives										X																				
AO Places order														X																
Provider receives confirmation														X*																
CDC forwards to Distributor															X															
Distributor receives order																X														
Distributor ships order																											X			
Order arrives											X																		X	

* After 5 PM

C. Vaccine Adverse Event Reporting System (VAERS)

1. HSRs and LHDs are required to report possible adverse events following vaccine administration to DSHS.

The VAERS form can be completed by:

- a) Child’s parent/guardian
- b) Vaccine manufacturers/distributors

- c) Vaccine administrators
- d) An individual completing the form on behalf of the patient
- e) Healthcare professionals who administer vaccines

2. Publicly-Funded Vaccine

Reports of events following vaccination at clinics utilizing TVFC vaccine should be reported through the DSHS, Immunization Branch, MC 1946, P.O. Box 149347, Austin, TX 78714-9347. The VAERS form can be obtained from the DSHS, Immunization Branch by calling (800) 252-9152 and ordering form C-76. 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. This information should be available from the vaccine administrator since they are required to record it in the patient's chart. 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).

3. Privately-Funded Vaccine

Reports of events following vaccination at clinics using privately purchased vaccine should be reported directly to VAERS. Contact (800) VAC-RXNS for information and forms addressed to VAERS or print a VAERS form from the VAERS web site at <http://www.vaers.org>. Instructions are listed on the back of the form.

See Appendix F for VAERS (C-76).

Section Five: Miscellaneous References

SECTION FIVE: MISCELLANEOUS REFERENCES

- I. Appendices 56
 - A. Vaccine Ordering Instructions
 - B. TVFC Provider Enrollment Form (E6-102)
 - C. Patient Eligibility Screening Form (C-10)
 - D. Adult Eligibility Screening Record (F11-12842)
 - E. Monthly Biological Report (EC-33)
 - F. Temperature Recording Form (C-105)
 - G. VAERS Reporting Form (C-76)
 - H. Daily Tally Sheet for Immunizations (C-88)
 - I. Biological Order Form (EC-68)
 - J. Vaccine Loss Report (EC-69)
 - K. Abbreviations
 - L. Vaccine Storage Contingency Plan
 - M. Quality Assurance Checklist (EC-68 & EC-33)
 - N. VFC Vaccine Borrowing Report
 - O. Provider Withdrawal Form (F11-11443)
 - P. Provider Compliance
- II. Recommended Childhood Immunization Schedule
- III. Recommended Adolescent Immunization Schedule
- IV. Catch-up Immunization Schedule
- V. Recommended Adult Immunization Schedule
- VI. Manual of Operations Survey

Ordering Instructions for Vaccine (Non-Routine)

1. Influenza/Pneumococcal Polysaccharide Vaccines

The TVFC provides influenza for children 18 years of age and younger and pneumococcal polysaccharide vaccines for children 18 years of age and younger who are at high-risk for complications of pneumonia disease. High-risk is determined by the Advisory Committee on Immunization Practices (ACIP). Influenza vaccine is available seasonally and pneumococcal polysaccharide vaccine is available as needed year-round.

In addition to the vaccine provided by the TVFC for high-risk children, LHDs may purchase influenza and pneumococcal polysaccharide vaccines at the state contract purchase price. When a LHD purchases vaccine with their own local funds, they determine the eligibility locally as well.

Eligible Groups for Inactivated Influenza Vaccine

1. All children aged 6 months through 18 years of age.

Eligible Groups for Pneumococcal Polysaccharide Vaccines

Children and adolescents aged 2-18 years of age and have one of the following:

- a) Functional or anatomical asplenia,
- b) Chronic illness (cardiopulmonary disease excluding asthma, diabetes mellitus, of CSF leak),
- c) Immunocompromising conditions (HIV infection, AIDS, malignancies, chronic renal failure, nephritic syndrome, organ transplant including bone marrow, or receiving immunocompromising medications),
- d) Alaskan Native
- e) American Indian

2. Rabies: Post Exposure Prophylaxis

As mandated by the Texas Health and Safety Code (826.025), the DSHS supplies post-exposure rabies biologicals (vaccines and rabies immune globulin) for persons who may be or have been exposed to rabid or potentially rabid animals. This mandate has resulted in a unique partnership between the DSHS Immunization Branch and the Zoonosis Control Branch.

At the state level, the Immunization Branch purchases and provides rabies biologicals to the HSR, LHD or hospitals. All rabies biological reimbursements are handled through the DSHS Central Office Revenue Management Unit, Billing Branch. Although DSHS requires reimbursement for these biologicals (rabies biologicals are not covered with state or federal funding), no one who has a valid exposure to rabies will be denied access to post-exposure treatment because of their inability to pay. DSHS does not dispense vaccine for pre-exposure prophylaxis.

Depending upon the HSR, Zoonosis or Immunization Branch Staff manage rabies biologicals in their offices and in established depot sites. These staff collect surveillance information (mandated by 97.123 of the Rules of the Board of Health "Provision of Anti-Rabies Biologicals"); provide the technical assistance for post-exposure prophylaxis; follow-up on bite reports from the local animal control agencies; dispense rabies biologicals as needed; and obtain reimbursement information and agreements.

For more information on the availability of rabies biologicals or guidelines for rabies post-exposure prophylaxis, please contact the appropriate regional office.

3. Immune Globulin (IG)

IG is used for controlling the spread of infectious diseases. It is the responsibility of the LHD to obtain IG if warranted. DSHS will provide IG to areas without a LHD present. To determine whether IG is needed, please consult with IDCU staff at (512) 458-7676. Approval from IDCU will be needed prior to release of IG.

Procedure for the HSR to order IG:

1. Contact IDCU at (512) 458-7676 with information justifying need:
 - a) Date of exposure
 - b) Number of individuals exposed
 - c) Setting in which exposure occurred
 - i. Home
 - ii. Day-care*
 - iii. Restaurant/Food-handler*
 - iv. School*
 - v. Other

*All multi-person exposures are discussed with LHD, HSR, and epidemiology staff to determine how DSHS will respond.

2. IDCU will communicate the approved IG request and will provide the following information to the Immunization Branch:
 - a) Ship to Point of Contact and Phone Number
 - b) Ship to Address and Hours of Operation
 - c) Quantity of IG determined to be needed
 - d) Once the request is received by the Immunization Branch, an electronic Biological Order is completed and sent to the Pharmacy Branch
 - e) The Pharmacy Branch determines the proper method of shipping and ships the IG as soon as possible

Procedure for LHD to order IG from the distributor using the state contract:

1. Contact the Texas Building and Procurement Commission at (512) 463-6988 or e-mail purchaser.c@cpa.state.tx.us
2. Please refer to the Vaccines and Biological Contract (contract number 270-A2)
http://www2.cpa.state.tx.us/cat_page/cat_269_a2_0701.html

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

Name of Facility, Practice, or Clinic: _____

Provider Name (M.D., D.O., N.P., 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: (_____) _____ - _____

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 VFC eligibility at all immunization encounters, and administer VFC-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 (VFC- 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), or has insurance with a co-pay or deductible the family cannot meet, (5) is a patient who receives benefits from the Children's Health Insurance Plan (CHIP); (6) is a patient who is served by any type of public health clinic and does not meet any of the above criteria.
- 2) This office/facility will maintain all records related to the VFC program, including parent/guardian/authorized representative's responses on the Patient Eligibility Screening Form for at least three 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 VFC-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 VFC 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, or a Certified Nurse Midwife must sign the TVFC Enrollment form.

TEXAS VACCINES FOR CHILDREN PROGRAM

PROVIDER PROFILE FOR PIN _____

Is your facility a Federally Qualified Health Center, Migrant Health Clinic, or Rural Health Clinic?
 (Circle one) YES NO

Type of Clinic: (check one)

- | | |
|--|---|
| <input type="checkbox"/> Public Health Department/District | <input type="checkbox"/> Private Hospital |
| <input type="checkbox"/> Public Hospital | <input type="checkbox"/> Private Practice (Individual or Group) |
| <input type="checkbox"/> Other Public Clinic | <input type="checkbox"/> Other Private Clinic |

PATIENT PROFILE:

Please enter the number of children for each of the following categories and by age group who will be vaccinated at your clinic in the next 12-month period.

NUMBER OF CHILDREN IN EACH CATEGORY	< 1 year old	1 - 6 years	7 - 18 years	Total
Enrolled in Medicaid.				
Uninsured. <i>(Note: Children enrolled in Health Maintenance Organizations are considered insured)</i>				
American Indians.				
Alaskan Natives.				
Underinsured. (Has health insurance that Does Not pay for vaccines, has a co-pay or deductible the family cannot meet, or has insurance that provides limited wellness or prevention coverage.)				
(For Public Health Clinic Use ONLY) Children who do not meet any of the above criteria, but still receive vaccinations at public health clinics .				
Children who receive benefits from the Children's Health Insurance Plan (CHIP).				
Children who are vaccinated in your practice, but are NOT TVFC-eligible.				
TOTAL PATIENTS: (Add columns)				

TEXAS VACCINES FOR CHILDREN PROGRAM PROVIDER LIST

Please list all individuals within the practice who will be administering TVFC supplied vaccine.

Last Name (List provider who signed Provider Enrollment Formfirst)	First Name	Middle Initial	Title (M.D., D.O., N.P., P.A., R.N., L.V.N., M.A.)	National Provider Identification	Medical License Number	Specialty (Family Medicine, Pediatrics, etc.)



TEXAS VACCINES FOR CHILDREN PROGRAM (TVFC)
[EL PROGRAMA DE VACUNAS PARA LOS NIÑOS DE TEXAS,
TVFC, por sus siglas en inglés]
ARCHIVO QUE DETERMINA LA ELEGIBILIDAD DEL PACIENTE

uso de la clínica solamente: (CLINIC USE ONLY): TVFC Eligible: <input type="checkbox"/> Yes <input type="checkbox"/> No

Propósito: El determinar la elegibilidad y la fuente de los fondos para el reembolso al *Texas Department of State Health Services* [Departamento Estatal de Servicios de Salud de Texas] para las vacunas. Un archivo debe guardarse en la oficina del proveedor de atención médica, el cual refleja el estatus de todos los niños de 18 años de edad o menores quienes reciben inmunizaciones a través del Programa de Vacunas Para los Niños de Texas. El formulario podría ser llenado por el padre, la madre, el tutor legal o el individuo del registro. Este mismo formulario puede utilizarse para todas las visitas subsiguientes con tal de que el estatus de elegibilidad del niño no haya cambiado. Aunque la verificación de las respuestas no es requerida, es necesario retener éste, o un archivo similar, para cada niño que reciba vacunas.

Fecha de determinación: _____

Nombre del niño:

Apellido	Primer nombre	Inicial del segundo nombre
----------	---------------	----------------------------

Fecha de nacimiento del niño: _____
 (mes/día/año)

Padre / Madre / Tutor legal / Individuo del registro:

Apellido	Primer nombre	Inicial del segundo nombre
----------	---------------	----------------------------

Nombre del proveedor / nombre de la clínica:

El niño nombrado arriba cumple con los requisitos para recibir vacunas a través del Programa de Vacunas para los Niños de Texas porque él (marque la primera categoría que se aplica; marque solamente una):

- (a) está inscrito en Medicaid, o
- (b) no tiene seguro médico, o
- (c) es indio-americano, o
- (d) es nativo de Alaska, o
- (e) es un paciente que recibe beneficios del *Children's Health Insurance Plan* [Plan de seguro médico para niños, *CHIP*, por sus siglas en inglés], o
- (f) no tiene seguro médico suficiente (tiene seguro médico que **NO** paga por las vacunas; tiene un co-pago o un deducible que la familia no puede pagar; o tiene un seguro que proporciona una cobertura limitada para el bienestar o la prevención), o
- (g) tiene seguro privado, o esta pagando por servicios, o
- (f) es un paciente que recibe servicios de cualquier clínica pública y no reúne ninguno de los criterios indicados anteriormente.

Firma: _____ Fecha: _____

Con pocas excepciones, usted tiene el derecho a pedir y ser informado(a) sobre la información que el Estado de Texas reúne sobre usted. Usted tiene el derecho a recibir y examinar la información al pedirla. Usted también tiene el derecho a pedirle a la agencia estatal que corrija cualquier información que se determina ser incorrecta. Vaya a <http://www.dshs.state.tx.us> para más información acerca de la Notificación sobre la Privacidad. (Referencia: *Government Code, Section 552.021, 552.023, 559.003 y 559.004*)



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

ADULT ELIGIBILITY SCREENING RECORD

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 three years. The record may be used for all subsequent visits as long as the patient's eligibility status has not changed. Verification of responses is not required; it is a self-declaration of eligibility by the adult presenting for services.

Date of Screening: ____/____/____

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

Date of Birth: ____/____/____

Eligibility Criteria

I declare that I qualify for vaccines through the Texas Vaccines for Children-Adult Program because (check the first category that applies, check only one):

- (a) I do not have health insurance, or
- (b) I am underinsured (have health insurance that **Does Not** pay for vaccines, have a co-pay or deductible the I cannot meet, or have insurance that provides limited wellness or prevention coverage).

Patient Signature: _____ Date: ____/____/____

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 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)



**División de Vacunación del Departamento Estatal de Servicios de Salud (DSHS)
Programa de Vacunación de Protección Para Adultos**

REGISTRO DE EVALUACIÓN SOBRE LA ELEGIBILIDAD DE ADULTOS

PROPÓSITO: Determinar y registrar la elegibilidad para participación en el Programa de Vacunación de Protección Para Adultos de DSHS. Se debe guardar un registro del estado de la elegibilidad de los adultos que reciban vacunas suministradas por 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 visitas siguientes en tanto el estado de elegibilidad del paciente no haya cambiado. No se requiere la verificación de las respuestas; es una autodeclaración de elegibilidad por parte del adulto que se presenta para recibir servicios.

Fecha de Evaluación: ____/____/____

Nombre: _____
(Apellido) (Primer Nombre) (Inicial)

Fecha de nacimiento: ____/____/____

Criterios de Elegibilidad

Declaro que reúno los requisitos de vacunación del Programa de Vacunas para Niños y Adultos de Texas porque (marque la primera categoría que corresponda; marque sólo una):

- (a) No tengo seguro de salud o
- (b) Cuento con un seguro de salud limitado (mi seguro de salud **No** paga por las vacunas, no puedo pagar el copago o el deducible o tengo seguro que provee cobertura limitada de bienestar y prevención).

Firma del Paciente: _____ Fecha: ____/____/____

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

Usted tiene derecho a solicitar y a ser informado sobre los datos que el estado de Texas colecciona sobre usted, con ciertas excepciones. Usted tiene derecho a recibir y examinar la información al solicitarla. También tiene derecho a pedir a la agencia que corrija cualquier información que se determine ser incorrecta. Consulte <http://www.dshs.state.tx.us> para informarse sobre la notificación de privacidad. (Fuente: Código Gubernamental, sección 552.021, 552.023 y 559.004).



Instructions

This report should be completed monthly by all entities that receive state-supplied vaccines. Retain a copy for one year. Please do not report doses purchased with private funds.

- Column A:** Doses on Hand at Beginning of Month – must be the same as Column H from the previous month’s C-33 report. This is the beginning inventory.
- Column B:** Doses Received During Month – enter total doses of each biological received as shown on Biological Order Form C-68 or other documentation. These doses are added to the inventory.
- Column C:** Usable Doses Returned to Your Inventory – state-purchased vaccines received from other providers. These doses are added to the inventory. Do not include wasted or expired vaccines in this column.
- Column D:** Subtotal: Add sections A, B and C.
- Column E:** Doses Administered During Month – enter the number of doses administered to ages birth through 18 years of age in the <1-18 column. Enter the number of doses administered to ages 19 and older in the 19+ column. Add the <1-18 and 19+ doses administered and enter that number to the Total column. Total doses administered for the month are subtracted from inventory.
- Column F:** Doses Sent Back to Vaccine Distributor – this includes wasted and expired/expiring vaccines. Please give an explanation of all returned vaccines at the bottom of the form. These doses are subtracted from the inventory.
- Column G:** Doses Issued Out of Your Inventory to Other Providers – state-purchased vaccines issued out of your inventory to other providers. These doses are subtracted from the inventory. Do not include wasted or expired vaccines in this column.
- Column H:** Doses on Hand at End of Month (Actual Physical Count) – this is the physical count of each dose of each biological. This is the ending inventory for the month, and will also be the beginning inventory for next month’s report.
- Column I:** Net Doses Lost or Gained – enter net doses lost or gained computed as follows:
E+F+G+H should equal D. If E+F+G+H is larger than D, you have a gain. If E+F+G+H is smaller than D, you have a loss. Please explain all losses and gains.

Mailing Address:
Texas Department of State Health Services
MC-1946
P.O. Box 149347
Austin TX 78714-9347



Texas Department of State Health Services
Immunization Branch
www.immunizeTexas.com

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

TEMPERATURE RECORDING FORM
 Refrigerator/Freezer Fahrenheit

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

Date of Month	The internal temperature of the refrigerator should range between +36° to +46°F and the internal temperature of the freezer should not exceed +5°F.											Staff Initials						
	Too Cold (Record Actual Temperature)	+36°	+37°	+38°	+39°	+40° (Target Temp.)	+41°	+42°	+43°	+44°	+45°	+46°	Too Warm (Record Actual Temperature)	Fahrenheit Freezer Temperature	+5° or colder (Record Actual Temperature)	Warmer than +5° (Record Actual Temperature)	A.M.	P.M.
1	WARNING - TAKE IMMEDIATE ACTION!																	
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:

- 1 Complete the form heading, please print and do not abbreviate. Be sure to include the PIN.
- 1 Post on refrigerator/freezer door.
- 1 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.

1 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)**
- 1 Record initials of the person checking the temperature.
- 1 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.

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

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

Date of Month	Centigrade Refrigerator Temperature - Check twice daily in the A.M. and P.M.						Centigrade Freezer Temperature		Staff Initials					
	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)	A.M.	P.M.	
1	WARNING - TAKE IMMEDIATE ACTION!									WARNING - TAKE IMMEDIATE ACTION!				
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														

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.

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:

- 1 Complete the form heading, please print and do not abbreviate. Be sure to include the PIN.
- 1 Post on refrigerator/freezer door.
- 1 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.

1 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)**
- 1 Record initials of the person checking the temperature.
- 1 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.



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	<input type="checkbox"/> 11. Adverse event onset
	_____ / _____ / _____ mm dd yy Time _____ AM PM	_____ / _____ / _____ mm dd yy Time _____ AM PM

	Vaccine (type)	Manufacturer	Lot number	Route/Site	No. Previous doses
a.	_____	_____	_____	_____	_____
b.	_____	_____	_____	_____	_____
c.	_____	_____	_____	_____	_____
d.	_____	_____	_____	_____	_____

	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) <input type="checkbox"/> In patient Adverse Event Onset Age Type Vaccine Dose no. in series _____ <input type="checkbox"/> In brother or sister _____ _____	Only for reports submitted by manufacturer/immunization project	
	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.





Daily Tally Sheet For Immunizations

Date

Health Department / Public Health Region

Number of
Persons Screened

Clinic Site

VACCINE	Number of Doses of Vaccines Administered By Age Group											Total			
	<1	1	2	3-4	5	6-9	10-14	15-19	20-24	25-44	45-64		65+		
DTaP															
DT															
Td															
HIB															



Daily Tally Sheet For Immunizations

Number of Doses of Vaccine Administered By Age Group													
	<1	1	2	3-4	5	6-9	10-14	15-19	20-24	25-44	45-64	65+	Total
IPV													
MMR													
Measles													
VAR*													
PCV 7**													

* Varicella Vaccine (Chickenpox)

** Pneumococcal Conjugate Vaccine 7 Valent (pediatric use)



Daily Tally Sheet For Immunizations

Number of Doses of Vaccine Administered By Age Group													
	<1	1	2	3-4	5	6-9	10-14	15-19	20-24	25-44	45-64	65+	Total
Hepatitis A													
Hepatitis B													
Flu													
PNEUMO Adult***													

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



Abbreviations

AFIX	<u>A</u> ssessment <u>F</u> eedback <u>I</u> ncentive and <u>e</u> Xchange
AO	Austin Office
CASA	Clinic Assessment Software Application
CDC	Centers for Disease Control and Prevention
CHIP	Children's Health Insurance Program
DSHS	Department of State Health Services
DTaP	Diphtheria-tetanus toxoids and acellular pertussis vaccine
DT	Diphtheria and tetanus toxoids, absorbed (pediatric)
FQHC	Federally Qualified Health Center
HCFA	Health Care Financing Administration
Hep A	Hepatitis A vaccine
Hep B	Hepatitis B vaccine
Hib	<i>Haemophilus influenzae</i> type b
HIPAA	Health Insurance Portability and Accountability Act
HPV	Human Papillomavirus
HSR	Health Service Regions
IG	Immune Globulin
ImmTrac	Statewide Immunization Tracking Software
IPV	Inactivated polio vaccine
LHD	Local Health Department
MHC	Migrant Health Clinic
MMR	Measles, mumps, and rubella vaccine, live

MMRV	Measles, mumps, rubella and varicella vaccine, live
OBRA	Omnibus Budget Reconciliation Act
PICS	Pharmacy Inventory Control System
PCV-7	Pneumococcal Conjugate vaccine 7 valent
RHC	Rural Health Clinic
Td	Tetanus and diphtheria toxoids, absorbed (for adult use)
TVFC	Texas Vaccines for Children
VACMAN	Vaccine Management Software
VAERS	Vaccine Adverse Event Reporting System
Var	Varicella vaccine
VFC	Vaccines for Children
VIS	Vaccine Information Statement
WIC	Women, Infants, and Children

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:	()
dry ice:	()
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:
	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:
	Ice packs are in container separated from vaccine by crumpled paper
	Thermometer in container
	Time and temperature in container prior to transport:
	Person transporting vaccine:
Transport of frozen vaccine checklist	
	Temperature of freezer prior to transport:
	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 vaccine:
	Varicella packed in dry ice
	Thermometer in container
	Time and temperature in container prior to transport:
In the event of a city-wide evacuation, contact your health service region for evacuation plan.	
HSR Contact Name: _____ Phone number: (_____) _____	

Quality Assurance Checklist for EC-68

PIN: _____

Reviewer: _____

Date of Review: _____

TVFC Enrollment form current

- No – contact provider to obtain current enrollment - once received submit update to appropriate approval authority
- Yes – continue

C-33 – Current on submission and correct

- No – stop review and contact provider to obtain current/correct report – once received continue process
- Yes – continue

C-105 – Current on submission and all temperatures within range

- No – stop review and contact provide to see if issues with temperatures have been corrected and obtain a current temperature chart showing all within range – once received continue process
- Yes – continue

C-68 – Biological Order Form

1.0 Tiered frequency:

1.1 Appropriate order month

- A. Yes – continue
- B. No – 50% or less on hand based on maximum stock level
 - 1) Yes – process anyway
 - 2) No- stop review, educate provider on appropriate time frame for ordering and do not process order

2.0 Demographics:

2.1 Complete and correct PIN

- A. No – stop review and complete (Enrollment or C-33)
- B. Yes – continue

2.2 Correct Name/address

- A. No – stop review and complete (Enrollment or C-33)
- B. Yes – continue

2.3 Days/Hours of operation complete

- A. No – stop review and contact provider to determine days/hours to receive vaccine
- B. Yes – continue

2.4 Signature

- A. Yes – continue
- B. No – stop review and return order to provider to obtain signature

3.0 Form contents

3.1 Amount on hand –

A. Matches Column H on C-33

1) No – stop review and discuss different totals with provider

2) Yes – continue

3.2 Amount on hand 50% more than maximum stock levels

A. No – continue

B. Yes – contact provider and discuss re-distribution

3.3 Amount on hand is zero –

A. Yes –

1) Evaluate last three months of usage to see if maximum stock levels need to be adjusted

2) If order amount needs to be adjusted

a) Note on C-68 and initial as approved

3) If maximum stock level needs to be adjusted

a) Change amount (bolded text) on maximum spreadsheet

b) Frequency of ordering changed

(1) No – continue

(2) Yes –change (bolded text) on maximum spreadsheet

4) Submit updated spreadsheet to appropriate approval authority

5) Submit updated info or master C-68 to provider showing new maximum stock levels

B. No – continue

3.4 Amount ordered:

A. Amount on hand minus maximum stock level = amount to be ordered

1) Yes – continue

2) No – stop and evaluate based on steps outlined below

B. Amount ordered does exceed maximum stock level

1) Yes – justification included:

a) If special clinic – clinic dates noted

b) If additional vaccine needed because of increase of patient load or other reason

i. Yes –

a) Is request temporary?

(1) Yes - Note on order ‘temporary increase’ and initial beside each vaccine changed – continue

(2) No - evaluate last three months of usage to see if agree with amount requested

(a) No – contact provider for additional justification

(b) Yes

(1) Note approval by initialing amount on C-68;

(2) Change amount (bolded text) on maximum spreadsheet

(3) Change amount on master copy of C-68

(4) Is frequency of ordering changed?

(a) No – continue

(b) Yes – change (bolded) on maximum spreadsheet

(5) Submit updated spreadsheet to appropriate approval authority

(6) Submit updated info or master C-68 to provider

- 2) No, amount does not exceed maximum stock level proceed with evaluation of amount to be ordered:
 - a) Amounts for Pneumococcal Polyssacharide 23 – increments of 5 – Rounding examples: maximum stock level is 5 – amount on hand is 2 = 3 doses ordered rounded to 5 or example: maximum stock level is 5 – amount on hand is 3 = 2 doses ordered rounded to zero – amount cancelled.
 - b) Amount for DT – Pediatric and Zoster – increments of 1
 - c) Amounts for other vaccines – increments of 10
Rounding examples:
 - i. Less than or equal to 4 – amount rounded to next lowest 10 – example: maximum stock level is 50 – amount on hand is 37 = 13 doses ordered would be rounded down to 10 doses
 - ii. More than or equal to 5 – amount rounded to next highest 10 – example: maximum stock level 50 – amount on hand 23 = 27 doses ordered rounded to 30 doses

4.0 Corrections/additions made to form or spreadsheet:

- A. Yes
 - 1. Note 'Revised' at top of form and fax to appropriate approval authority and/or private provider –
 - 2. Copy and send hard copy onto appropriate approval authority
- B. No - copy and send hard copy onto appropriate approval authority

Sampling QA Internal Review Process

Summary evaluation done each month to review:

Data reported by”

HSR

Individual LHD

Number of C-68 submitted

Number with errors

Listed by types of errors – to allow training conducted on errors occurring with greatest frequency.

Legend for Chart:

Appropriate Tiered Frequency – ordering in the appropriate assigned tier

Demo/PIN – incorrect or incomplete

Days/Hours of Operation – incorrect or incomplete

Excessive Vaccine – 50% or more than maximum stock level on one or more vaccines

Order - based on amount on hand minus maximum stock level does equal to or greater than 5 doses
- order should have been placed

Amt not rounded – amount ordered was not rounded properly

Justification for exceeding maximum – insufficient or no justification for amount ordered exceeding maximum stock level

Amount on hand less than or equal to 5 doses* – amount on hand of one vaccine being at or below 5 doses – under stocking - *exception DT-Pedi, Pneumococcal and Zoster

No amount on hand – No current amount on hand noted

Change maximum stock level – Request to change or increase maximum stock level and not changed on maximum stock level column

No signature on form – self explanatory

Sampling of data –

Summary Report	Week of	Week of	Week of	Week of
# C-68 submitted				
# C-68 with errors				
Appropriate Tiered Frequency				
Demo/PIN				
Days/Hours of Operation				
Excessive Vaccine				
Order				
Amount not rounded				
Justification for exceeding maximum level				
Amount on hand <5 doses				
No amount on hand				
Chg of max stock levels				
No signature on order				

Corrective action:

Quality Assurance Checklist for EC-33

PIN: _____

Reviewer: _____

Date of Review: _____

TVFC Enrollment Form current

- No – contact provider to obtain current enrollment – once received submit update to appropriate approval authority
- Yes – continue

C-105 – Current on submission and all temperatures within range

- No – stop review and contact provide to see if issues with temperatures have been corrected and obtain a current temperature chart showing all within range – once received continue process
- Yes – continue

C 68– Biological Order Form

Appropriate month to order:

- Yes – stop review and contact provider to obtain vaccine order – once received continue process
- No – continue

C-33 Monthly Biological Order Form

1.0 Demographics:

1.1 Complete and correct PIN

- A. No – stop review and complete (Enrollment)
- B. Yes – continue

1.2 Correct Name/address

- A. No – stop review and complete (Enrollment)
- B. Yes – continue

1.3 Days/Hours of operation complete

- A. No – stop review and contact provider to determine days/hours to receive vaccine
- B. Yes – continue

1.4 Signature

- A. Yes – continue
- B. No – stop review and return form to provider to obtain signature

2.0 Form contents

2.1 Column A: Doses at Beginning of Month –

A. Matches Column H on previous month's C-33

- 1) No – stop review and discuss different totals with provider
- 2) Yes – continue

2.2 Column B: Doses Received During Month - Packing Slip Received

- A. Yes – continue
- B. No – contact provider and request copy to be faxed

2.3 Column D: $A+B+C=D$: Math is correct for each antigen

- A. Yes – continue
- B. No – correct and continue

2.4 Column E: 19+ doses administered

A. Provider is a public site

- 1) Yes – continue
- 2) No – stop and contact provider to see if doses administered was to complete a series for HPV, Hepatitis A or B?
 - a) Yes – continue
 - b) No
 - (1) Discuss policy with provider
 - (2) In comment section: note and initial that matter was discussed with provider and what arrangements have been made for re-payment

B. Column E: <1-18 and 19+ totals are correct

- 1) Yes – continue
- 2) No, correct and continue

2.5 Column C, F or G: Amounts transferred

A. Amounts noted in either column C, F or G

- 1) Yes – transfer slips received to document transfer of vaccine
 - a) Yes – continue
 - b) No – contact provider for copies of paperwork showing transfer or return of vaccine
- 2) No – continue to process

2.6 Column H: Doses on Hand

A. Amounts noted for each antigen noted in column A

- 1) Yes – continue
- 2) No – did the amount administered deplete the stock
 - a) Yes – continue
 - b) No – contact provider to determine amount on hand

2.7 Column I: Net Doses Lost or Gained:

A. Math requires column to be completed

- 1) Yes – amount correct:
 - a) Yes
 - (1) Comment section completed noting justification for loss/gain
 - (a) Yes – continue
 - (b) No – contact provider for explanation
 - b) No –
 - (1) Contact provider with corrections and request justification
- 2) No – continue to process

3.0 Corrections/additions made to form

- A. Yes
 - 1. Note 'Revised' and initials at top of form and fax to appropriate approval authority and/or private provider –
 - 2. Copy and send hard copy onto appropriate approval authority
- B. No
 - 1. Note initials at top of form
 - 2. Copy and send hard copy onto appropriate approval authority

Sampling QA Internal Review Process

Summary evaluation done each month to review:

Data reported by:

HSR

Individual LHD

Number of C-33 submitted

Number with errors

Listed by types of errors – to allow training conducted on errors occurring with greatest frequency.

Legend for Chart:

Demo/PIN – incorrect or incomplete

Days/Hours of Operation – incorrect or incomplete

Column A: Amount on Hand – does not match Column H amount from previous month's report

Column B: Amount Received – noted, but no packing slip to support receipt

Column D: Subtotal - incorrect or incomplete

Doses Administered to 19+ population – not a public site and not to complete series

Column E: Total - amount incorrect

Columns C, F or G: Amounts Noted: - no transfer documentation to support

Column I: Net Doses Lost or Gained – amount not noted and/or no comment

No signature on form – self explanatory

Sampling of data –

Summary Report	Week of	Week of	Week of	Week of
# C-33 submitted				
# C-33 with errors				
Demo/PIN				
Days/Hours of Operation				
Column A: Amount on Hand				
Column B: Amount Received				
Column D: Subtotal				
Doses Admin 19+				
Column E Total				
Columns C, F, or G: Amount Noted				
Column I Net Doses Lost/Gained				
No signature on form				

Corrective action:

SAMPLE COMPLETED VFC Vaccine Borrowing Report

Guidance:

VFC-enrolled providers are expected to maintain an adequate inventory of vaccine for their non-VFC-eligible patients. VFC vaccine cannot be used as a replacement system for a provider's privately purchased vaccine inventory. The provider must assure that VFC vaccine supply is adequate to meet the needs of the provider's VFC-eligible patients and that borrowing VFC vaccine will not prevent a VFC-eligible child from receiving a needed vaccination because VFC vaccine was administered to a non-VFC eligible child. Borrowing would occur only when there is lack of private-stock vaccine due to unexpected circumstances such as a delayed vaccine shipment, vaccine spoiled in-transit to provider, or new staff that calculated ordering time incorrectly. The reason cannot be provider planned borrowing from VFC stock.

Directions for use of this form:

When a provider has borrowed VFC vaccine for administration to a non-VFC-eligible child, this form must be **COMPLETELY FILLED OUT** for each non-VFC-eligible child receiving a VFC vaccine. **Each VFC vaccine a child receives must be listed on a separate row.** As soon as the borrowed doses of VFC vaccine are replaced by private stock vaccine, the form must be faxed to the immunization program:

Attention: Florence Nightingale
Fax Number: 555-444-3333
Time period of 10/19/2007 to 10/21/2007
Clinic/Provider Name: ABC Clinic
Office Contact Name: Suzie Que
Telephone Number/ fax: 555-444-2211/555-444-9889
E-mail address: Que@abc.com
VFC Number: 21122

For each VFC vaccine borrowed all information in that row of the table must be completely filled out.

It is acceptable to use " " to indicate the above child received another VFC vaccine as long as the additional vaccines are identified.

It is also acceptable for each VFC vaccine borrowed and administered to an individual to complete all information in each row of the table.

Circle or write in reason for no private stock was available.

Vaccine Borrowed	Patient Name/Patient Identifier	DOB	Date Borrowed	Reason no private stock vaccine was available	Date vaccine returned to VFC stock
DTaP	Shirley Temple	08/04/2007	10/19/2007	1. Private stock order shipment delayed 2. Private stock order non-viable on arrival 3. Other (specify)	10/21/2007
IPV	" "	" "	" "	1. Private stock order shipment delayed 2. Private stock order non-viable on arrival 3. Other (specify)	10/21/2007
DTaP	Mickey Rooney	08/15/2007	10/19/2007	1. Private stock order shipment delayed 2. Private stock order non-viable on arrival 3. Other (specify)	10/21/2007
IPV	Mickey Rooney	08/15/2007	10/19/2007	1. Private stock order shipment delayed 2. Private stock order non-viable on arrival 3. Other (specify)	10/21/2007
				1. Private stock order shipment delayed 2. Private stock order non-viable on arrival 3. Other (specify)	

"I hereby certify, subject to penalty under the False Claims Act (31 U.S.C. § 3730) and other applicable Federal and state law, that VFC vaccine dose borrowing and replacement reported on this form has been accurately reported and conducted in conformance with VFC provisions for such borrowing [(add cite to Ops Guide provisions or other guidance provided to VFC providers)] and further certify that all VFC doses borrowed during the noted time period have been fully reported on this form."

Provider Name: Dr. Sam Who Provider Signature: Dr. Sam Who Date: 10/21/2007

VFC Vaccine Borrowing Report

Guidance:

VFC-enrolled providers are expected to maintain an adequate inventory of vaccine for their non-VFC-eligible patients. VFC vaccine cannot be used as a replacement system for a provider's privately purchased vaccine inventory. The provider must assure that VFC vaccine supply is adequate to meet the needs of the provider's VFC-eligible patients and that borrowing VFC vaccine will not prevent a VFC-eligible child from receiving a needed vaccination because VFC vaccine was administered to a non-VFC eligible child. Borrowing would occur only when there is lack of private-stock vaccine due to unexpected circumstances such as a delayed vaccine shipment, vaccine spoiled in-transit to provider, or new staff that calculated ordering time incorrectly. The reason cannot be provider planned borrowing from VFC stock.

Directions for use of this form:

When a provider has borrowed VFC vaccine for administration to a non-VFC-eligible child, this form must be **COMPLETELY FILLED OUT** for each non-VFC-eligible child receiving a VFC vaccine. **Each VFC vaccine a child receives must be listed on a separate row.** As soon as the borrowed doses of VFC vaccine are replaced by private stock vaccine, the form must be faxed to the immunization program, and the provider should keep a copy of the completed form in the office records.

Attention:

Fax Number: _____

Time period of ___/___/___ to ___/___/___

Clinic/Provider Name: _____

Office Contact Name: _____

Telephone Number/ fax: _____

E-mail address: _____

VFC Number: _____

Vaccine Borrowed	Patient Name/Patient Identifier	DOB	Date Borrowed	Reason no private stock vaccine was available (circle one)	Date vaccine returned to VFC stock
				1. Private stock order shipment delayed 2. Private stock order non-viable on arrival 3. Other (specify)	
				1. Private stock order shipment delayed 2. Private stock order non-viable on arrival 3. Other (specify)	
				1. Private stock order shipment delayed 2. Private stock order non-viable on arrival 3. Other (specify)	
				1. Private stock order shipment delayed 2. Private stock order non-viable on arrival 3. Other (specify)	
				1. Private stock order shipment delayed 2. Private stock order non-viable on arrival 3. Other (specify)	

"I hereby certify, subject to penalty under the False Claims Act (31 U.S.C. § 3730) and other applicable Federal and state law, that VFC vaccine dose borrowing and replacement reported on this form has been accurately reported and conducted in conformance with VFC provisions for such borrowing [(add cite to Ops Guide provisions or other guidance provided to VFC providers)] and further certify that all VFC doses borrowed during the noted time period have been fully reported on this form."

Provider Name: _____ Provider Signature: _____ Date: _____

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: ___/___/___

Texas Vaccines for Children Provider Compliance Policy

POLICY:

As the cost of childhood vaccines increases and the complexity of immunization programs grow, the federal and state Vaccines for Children (VFC) programs become more vulnerable to fraud and abuse. The information within this policy will guide Health Service Regions, Local Health Departments and Austin Office staff to: (1) identify high risk non-compliance issues, (2) prevent re-occurrence through education and training, and determine when referral to Texas State Office of Inspector General (OIG) is appropriate.

DEFINITIONS:

Primary Education – Occurs during the initial VFC enrollment or new staff training. This education includes orientation/updates to the VFC Operations.

Secondary Education – Occurs when addressing moderate compliance issues. Moderate could include initial serious non-compliance activities, or repeat minor non-compliance. Secondary education is performed when a “No” is recorded on a QA On-Site Evaluation Report. Education is done on site at the time of the visit and follow-up occurs at five or 10 days, and at six months depending on the question. Follow-up can be performed by site visit, phone call, or letter. Secondary education may also include routine individual training, and TVFC provider educational meetings.

Formal Intervention Education – Targets education or training on how to correct the situation in areas of identified need.

Tertiary Education – Occurs when serious compliance issues, immediate and significant actions must occur to correct situation. 1) Is the non-compliant behavior causing or has it caused loss of TVFC vaccine? 2) Is the behavior placing the TVFC Program in *danger* if the behavior is not stopped immediately? 3) Has the provider received unintentional financial gain because of the behavior?

Danger – An action that places the program at risk for unintentional fraud or abuse; or provider actions placing TVFC children at risk.

Referral to External Agency – Provider actions that represent intentional fraud and/or abuse of the TVFC Program.

Primary Contacts – All cases of suspected fraud or abuse should be reported to the following individuals in the Austin Office (AO), who will; 1) confer with HSR managers regarding if and where identified potential fraud/abuse situations are to be referred; 2) identify the appropriate source to make the referral; and 3) notify appropriate governmental agencies (CDC, state Medicaid and others as appropriate).

Vaccine Services Group (VSG) Manager, Primary
VSG Operations Coordinator, back-up
VSG Projects Coordinator, back-up

Enforcement Agencies – The Texas State Office of Inspector General (OIG) receives reports of suspected fraud and abuse as directed by OIG procedures. Reporting may come from the Immunization Branch, any other private or public entity, or individual. After receiving a report, OIG will:

- Conduct a preliminary screening to determine if the report warrants a full scale investigation;
- Perform a field investigation; and if necessary;
- Conduct a full scale investigation;
- Develop a final report, and if necessary;
- Submit findings to Office of Attorney General (OAG) for further action.

The OIG and OAG have an Interagency Contract to define the duties and obligations of each agency.

Note: Once a case is referred to the OIG, the OIG office will only confirm a case is pending. It will not be possible to get details of the case until the investigation is complete and the final report is drafted. OIG is working with the Texas Immunization Branch to develop a system to forward those reports once finalized. The investigation process varies in time with the complexity of cases, and some cases can take years to complete.

PROCEDURES:

I. Non-Compliance Identified During On-Site Visit

Secondary Education

Secondary Education is performed any time a provider site receives a “NO” response on the On-Site Evaluation Report. The prescribed timeframe for this follow-up is identified in the *TVFC Operations Manual (Section Three: Program Evaluation, I. TVFC Visits, A. Site Monitoring Activities)*. Secondary education includes contacting the provider and addressing each problem with the appropriate education and resources identified in the TVFC Quality Assurance Tool Resource Manual (by question). Secondary Education may be performed via phone call, letter, or site visit, whichever method is deemed appropriate by the overseeing agency.

A. High-risk questions that require Formal Intervention, Tertiary education, and follow-up.

- 12. Vaccines provided regardless of inability to pay.**
- 14. Administration fee is less than or equal to the maximum fee.**
- 48a. Appropriate refrigerators/freezers are used to store vaccine.**
- 50a. Refrigerator/freezer temperature log is available for the last three months.**
- 50d. From the logs provided, all recorded refrigerator temperatures are within the recommended range.**
- 51c. From the logs provided, all recorded freezer temperatures are within the recommended range.**
- 55. A physical inventory of vaccine is done monthly.**
- 57. The loss/gain is less than 5%.**
- 59. TVFC vaccines can be distinguished from private stock.**
- 61a. All clients are screened for eligibility.**

B. Correction process

1. Previous Compliance Issues

If staff identifies a provider for which secondary education has proven unsuccessful, they should begin the next phase of Formal Intervention.

Formal Intervention Education

12. Vaccines provided regardless of inability to pay.

14. Administration fee is less than or equal to the maximum fee.

50a. Refrigerator/freezer temperature log is available for the last three months.

55. A physical inventory of vaccine is done monthly.

57. The loss/gain is less than 5% (Accounting Column).

59. TVFC vaccines can be distinguished from private stock (no private vaccine, but profile indicates insured children in practice).

61a. All clients are screened for eligibility.

Education for these questions (12, 14, 50a, 55, 57, 59, 61a):

- Provide appropriate education associated with high-risk non-compliance issue using memos, TVFC guidelines.
- If issue is resolved, correct and close.
- If issue is not resolved, begin Tertiary education.

48a. Appropriate refrigerators/freezers are used to store vaccine.

- On-site visit recommended at 3 months following Secondary Education to check for proper refrigeration/freezer equipment.
- If issue is resolved, correct and close.
- If issue is not resolved, begin Tertiary education.

50d. From the logs provided, all recorded refrigerator temperatures are within the recommended range.

- Provide appropriate education associated with high-risk non-compliance issue using memos, TVFC guidelines.
- If vaccine loss occurs due to inappropriate temperatures, an on-site education visit is recommended to ensure that the equipment is approved for vaccine storage and to authorize a new order.
- New/replacement or repaired Refrigeration/freezer units require five working days of temperature monitoring prior to receiving TVFC vaccine.
- If issue is resolved, correct and close.
- If issue is not resolved, begin Tertiary education.

51c. From the logs provided, all recorded freezer temperatures are within the recommended range.

- Same as '50d' above.

If staff identifies chronic offenders for which secondary education and Formal Intervention has proven unsuccessful, they should begin Tertiary Education and continue Follow-up. A chronic offender is defined as a provider that has received a 'No' for three years on one of the identified questions, or has received three separate trainings on the issue with no improvement.

Tertiary Education and Follow-up

- 12. Vaccines provided regardless of inability to pay.**
- 14. Administration fee is less than or equal to the maximum fee.**
- 50a. Refrigerator/freezer temperature log is available for the last three months.**
- 55. A physical inventory of vaccine is done monthly.**
- 57. The loss/gain is less than 5% (Accounting).**
- 59. TVFC vaccines can be distinguished from private stock (no private vaccine, but profile indicates insured children in practice).**
- 61a. All clients are screened for eligibility.**

Education for these questions (12, 14, 50a, 55, 57, 59, 61a):

- When a provider requires tertiary education, the LHD/HSR must perform on-site initial provider education. This education must include the development of a written corrective action plan.
- If corrective action plan is adhered to and effective, return to routine follow-up.
- If corrective action plan is not effective, notify HSR Manager for recommendation for termination from program and/or referral to Texas State Office of Inspector General (OIG).

48a. Appropriate refrigerators/freezers are used to store vaccine

- Conduct additional follow-up visit after 3 additional months (6-months since Secondary Education).
- If proper units are in place prior to or at six months, consider issue corrected and return to routine follow-up.
- If proper units are not in place after six months, termination from TVFC is recommended.
- Re-enrollment can occur when proper equipment is purchased, and tested.

50d. From the logs provided, all recorded refrigerator temperatures are within the recommended range.

- If the unit continues to not maintain appropriate temperatures.
- Remove vaccine immediately and suspend future orders.
- Require new, replacement, or repaired refrigerator/freezer units to be monitored for appropriate temperatures for five working days prior to receiving replacement TVFC vaccine.
- Other improper temperature issues, such as documentation errors, or thermometer reading errors, should be addressed with Secondary Education.
- If temperature issues are resolved, consider issue corrected and return to routine follow-up.
- If issues have not been corrected or additional losses occur, refer to HSR Manager for recommendation for termination from TVFC.
- Re-enrollment can occur when equipment is purchased or repaired and determined safe for vaccine storage.

51c. From the logs provided, all recorded freezer temperatures are within the recommended range.

- Same as 50d above.

2. Extenuating Circumstances Existed

- Each occurrence will be evaluated on a case-by-case basis.
- Secondary, Tertiary education, or referral to external agency will occur as appropriate.
- For these factors to influence how situation is handled it must be an unusual occurrence

3. No Previous Compliance Issues

- Follow Secondary Education steps above.

II. Non-Compliance Identified By Other Means

Secondary Education

Secondary education should include re-education, and individual training, when necessary. Re-education may be performed via phone call, letter, or site visit, whichever method is most appropriate and practical. The re-education/training should be performed by the overseeing agency.

A. High-risk non-compliance issues that require Formal Intervention, Tertiary Education, and follow-up.

1. Failure to comply with reporting requirements (Operations Manual, Section Four)

- Monthly Biological Report (C-33)
- Temperature Recording Form (C-105)
- Biological Order Form (C-68)

2. Billing for TVFC vaccine (Operations Manual, Section Two, Fraud & Abuse)

3. Selling TVFC vaccine (Operations Manual, Section Two, Fraud & Abuse)

4. Using TVFC vaccine on non-TVFC eligible children (Operations Manual, Section Two, Fraud & Abuse)

5. Failure to comply with site visit requirements (Provider Enrollment Form)

6. Failure to complete a Provider Enrollment or Re-enrollment Agreement (Provider Enrollment Form)

7. Routine borrowing of TVFC vaccine for use on non-eligible TVFC patients (Operations Manual, Appendix)

8. Vaccine Loss (Vaccine Loss Reports)

- Three or more vaccine losses in a year due to negligence or expiration (excluding influenza vaccines), or
- Two or more negligence or expiration vaccine losses of greater than \$2,000 within one year based on current CDC VFC vaccine price list.

B. Correction process

1. Previous Compliance Issues

If staff identifies a provider for which secondary education has proven unsuccessful, they should begin the next phase of Formal Intervention.

Formal Intervention Education

1. Failure to comply with reporting requirements

- Monthly Biological Report (C-33)
- Temperature Recording Form (C-105)
- Biological Order Form (C-68)
- Re-train on reporting requirements, and provide appropriate follow-up.
- Document re-training.

2. Billing for TVFC vaccine

3. Selling TVFC vaccine

4. Using TVFC vaccine on non-TVFC eligible children

5. Failure to comply with site visit requirements

6. Failure to complete a Provider Enrollment or Re-enrollment Agreement

Education for numbers (2, 3, 4, 5, 6):

- Provide appropriate education associated with high-risk non-compliance issue using memos, and other TVFC guidelines.
- Document re-education.

7. Routine borrowing of TVFC vaccine for use on non TVFC patients

- Ensure that provider completes the VFC Vaccine Borrowing Report
- Provide appropriate education associated with high-risk non-compliance issue using memos, and other TVFC guidelines.
- Document re-education.

8. Vaccine Loss (Vaccine Loss Reports)

- Three or more vaccine losses in a year due to negligence or expiration (excluding influenza vaccines), or
- Two or more negligence or expiration vaccine losses of greater than \$2,000 within one year based on current CDC VFC vaccine price list.
- Provide appropriate education associated with high-risk non-compliance issue using memos, and other TVFC guidelines.
- Ensure that provider has received letter regarding large Losses.
- Issue second level warning letter.
- Approve additional orders only after safe storage for vaccines has been confirmed.

If staff identifies chronic offenders for which Secondary Education and Formal Intervention has proven unsuccessful, they should begin Tertiary Education and Follow-up. A chronic offender is defined as a provider that has received a 'No' for three years on one of the identified questions, or has received three separate trainings on the issue with no improvement.

Tertiary Education and follow-up

1. Failure to comply with reporting requirements

- Monthly Biological Report (C-33)
- Temperature Recording Form (C-105)
- Biological Order Form (C-68)
- Perform on-site provider education. This education must include the development of a written corrective action plan signed by the provider.
- Continued failure to submit an accurate and complete Monthly Biological Report (C-33), Temperature Recording Form (C-105), and Biological Order Form (C-68) within required timeframes will require LHD/HSR to:
 - First month after written corrective action plan, a letter will be sent to notify the signing physician of the consequences of not submitting the accurate and complete reports on time (copy in HSR/LHD file).
 - At the end of the second month, LHD/HSR will contact provider and make arrangements to retrieve all TVFC vaccine.
 - At the end of the third month, if reports are not received, the recommend provider be withdrawn from the TVFC program.
- If accurate and complete reports are received, consider issue corrected and return vaccines to the provider. Provider will remain on probation for six months following the return of the vaccine.
- If reporting issues resume, the provider will be notified that:
 - Reports are not timely, accurate and complete
 - Reports must be received by the end of the month.
 - If reports are not received by deadline, vaccines will be retrieved and provider will be withdrawn from the TVFC program.
- After six-month probationary period is complete, resume routine follow-up.
- HSR and Austin Office must approve provider withdrawal upon receipt and review of Secondary, Formal Intervention, and Tertiary documentation.
- Re-enrollment can occur after provider has been withdrawn from the TVFC for at least 12 months.

2. Billing for TVFC vaccine

3. Selling TVFC vaccine

4. Using TVFC vaccine on non-TVFC eligible children

5. Failure to comply with site visit requirements

6. Failure to complete a Provider Enrollment or Re-enrollment Agreement

7. Routine borrowing of TVFC vaccine for use on non TVFC patients

Education for numbers (2, 3, 4, 5, 6, 7):

- When a provider requires tertiary education, the LHD/HSR must perform on-site initial provider education. This education must include the development of a written corrective action plan signed by the provider.
- If corrective action plan is adhered to and effective, return to routine follow-up.
- If corrective action plan is not effective, notify HSR Manager for recommendation for termination from program and/or referral to Texas State Office of Inspector General (OIG).

8. Vaccine Loss (Vaccine Loss Reports)

- Three or more vaccine losses in a year due to negligence or expiration (excluding influenza vaccines), or
- Two or more negligence or expiration vaccine losses of greater than \$2,000 within one year based on current CDC VFC vaccine price list.
- When a provider requires Tertiary Education, the LHD/HSR must perform on-site initial provider education. This education must include the development of a written corrective action plan signed by the provider.
- At the time of the visit bring a third level warning letter.
- If another loss occurs within 6 months of the third level warning letter, refer to HSR Manager for recommendation for termination from TVFC.
- If no loss occurs within the next 6 months, continue at second level warning for the next 6 months. If another loss occurs during the second 6 months, repeat level three letter.
- After one year of no losses return, to normal follow-up.
- Re-enrollment can occur after provider has been withdrawn from the TVFC for at least 12 months.

2. Extenuating Circumstances Existed

- Each occurrence will be evaluated on a case-by-case basis.
- Secondary, Tertiary Education, or referral to external agency will occur as appropriate.
- For these factors to influence how situation is handled it must be an unusual occurrence.

3. No Previous Compliance Issues

- Follow Secondary Education steps above.

Recommended Immunization Schedule for Persons Aged 0 Through 6 Years—United States • 2009

For those who fall behind or start late, see the catch-up schedule

Vaccine ▼	Age ►	Birth	1 month	2 months	4 months	6 months	12 months	15 months	18 months	19–23 months	2–3 years	4–6 years
Hepatitis B ¹	HepB	HepB	HepB		<i>see footnote 1</i>	HepB						
Rotavirus ²				RV	RV	RV ²						
Diphtheria, Tetanus, Pertussis ³				DTaP	DTaP	DTaP	<i>see footnote 3</i>	DTaP				DTaP
<i>Haemophilus influenzae</i> type b ⁴				Hib	Hib	Hib ⁴		Hib				
Pneumococcal ⁵				PCV	PCV	PCV		PCV			PPSV	
Inactivated Poliovirus				IPV	IPV			IPV				IPV
Influenza ⁶								Influenza (Yearly)				
Measles, Mumps, Rubella ⁷								MMR		<i>see footnote 7</i>		MMR
Varicella ⁸								Varicella		<i>see footnote 8</i>		Varicella
Hepatitis A ⁹								HepA (2 doses)			HepA Series	
Meningococcal ¹⁰											MCV	

Range of recommended ages

Certain high-risk groups

This schedule indicates the recommended ages for routine administration of currently licensed vaccines, as of December 1, 2008, for children aged 0 through 6 years. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. Licensed combination vaccines may be used whenever any component of the combination is indicated and other components are not contraindicated and if approved by the Food and Drug Administration for that dose of

the series. Providers should consult the relevant Advisory Committee on Immunization Practices statement for detailed recommendations, including high-risk conditions: <http://www.cdc.gov/vaccines/pubs/acip-list.htm>. Clinically significant adverse events that follow immunization should be reported to the Vaccine Adverse Event Reporting System (VAERS). Guidance about how to obtain and complete a VAERS form is available at <http://www.vaers.hhs.gov> or by telephone, 800-822-7967.

1. Hepatitis B vaccine (HepB). (Minimum age: birth)

At birth:

- Administer monovalent HepB to all newborns before hospital discharge.
- If mother is hepatitis B surface antigen (HBsAg)-positive, administer HepB and 0.5 mL of hepatitis B immune globulin (HBIG) within 12 hours of birth.
- If mother's HBsAg status is unknown, administer HepB within 12 hours of birth. Determine mother's HBsAg status as soon as possible and, if HBsAg-positive, administer HBIG (no later than age 1 week).

After the birth dose:

- The HepB series should be completed with either monovalent HepB or a combination vaccine containing HepB. The second dose should be administered at age 1 or 2 months. The final dose should be administered no earlier than age 24 weeks.
- Infants born to HBsAg-positive mothers should be tested for HBsAg and antibody to HBsAg (anti-HBs) after completion of at least 3 doses of the HepB series, at age 9 through 18 months (generally at the next well-child visit).

4-month dose:

- Administration of 4 doses of HepB to infants is permissible when combination vaccines containing HepB are administered after the birth dose.

2. Rotavirus vaccine (RV). (Minimum age: 6 weeks)

- Administer the first dose at age 6 through 14 weeks (maximum age: 14 weeks 6 days). Vaccination should not be initiated for infants aged 15 weeks or older (i.e., 15 weeks 0 days or older).
- Administer the final dose in the series by age 8 months 0 days.
- If Rotarix[®] is administered at ages 2 and 4 months, a dose at 6 months is not indicated.

3. Diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP). (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.
- Administer the final dose in the series at age 4 through 6 years.

4. Haemophilus influenzae type b conjugate vaccine (Hib). (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.
- TriHiBit[®] (DTaP/Hib) should not be used for doses at ages 2, 4, or 6 months but can be used as the final dose in children aged 12 months or older.

5. Pneumococcal vaccine. (Minimum age: 6 weeks for pneumococcal conjugate vaccine [PCV]; 2 years for pneumococcal polysaccharide vaccine [PPSV])

- PCV is recommended for all children aged younger than 5 years. Administer 1 dose of PCV to all healthy children aged 24 through 59 months who are not completely vaccinated for their age.

- Administer PPSV to children aged 2 years or older with certain underlying medical conditions (see *MMWR* 2000;49[No. RR-9]), including a cochlear implant.

6. Influenza vaccine. (Minimum age: 6 months for trivalent inactivated influenza vaccine [TIV]; 2 years for live, attenuated influenza vaccine [LAIV])

- Administer annually to children aged 6 months through 18 years.
- For healthy nonpregnant persons (i.e., those who do not have underlying medical conditions that predispose them to influenza complications) aged 2 through 49 years, either LAIV or TIV may be used.
- Children receiving TIV should receive 0.25 mL if aged 6 through 35 months or 0.5 mL if aged 3 years or older.
- Administer 2 doses (separated by at least 4 weeks) to children aged younger than 9 years who are receiving influenza vaccine for the first time or who were vaccinated for the first time during the previous influenza season but only received 1 dose.

7. Measles, mumps, and rubella vaccine (MMR). (Minimum age: 12 months)

- Administer the second dose at age 4 through 6 years. However, the second dose may be administered before age 4, provided at least 28 days have elapsed since the first dose.

8. Varicella vaccine. (Minimum age: 12 months)

- Administer the second dose at age 4 through 6 years. However, the second dose may be administered before age 4, provided at least 3 months have elapsed since the first dose.
- For children aged 12 months through 12 years the minimum interval between doses is 3 months. However, if the second dose was administered at least 28 days after the first dose, it can be accepted as valid.

9. Hepatitis A vaccine (HepA). (Minimum age: 12 months)

- Administer to all children aged 1 year (i.e., aged 12 through 23 months). Administer 2 doses at least 6 months apart.
- Children not fully vaccinated by age 2 years can be vaccinated at subsequent visits.
- HepA also is recommended for children older than 1 year who live in areas where vaccination programs target older children or who are at increased risk of infection. See *MMWR* 2006;55[No. RR-7].

10. Meningococcal vaccine. (Minimum age: 2 years for meningococcal conjugate vaccine [MCV] and for meningococcal polysaccharide vaccine [MPSV])

- Administer MCV to children aged 2 through 10 years with terminal complement component deficiency, anatomic or functional asplenia, and certain other high-risk groups. See *MMWR* 2005;54[No. RR-7].
- Persons who received MPSV 3 or more years previously and who remain at increased risk for meningococcal disease should be revaccinated with MCV.

Recommended Immunization Schedule for Persons Aged 7 Through 18 Years—United States • 2009

For those who fall behind or start late, see the schedule below and the catch-up schedule

Vaccine ▼	Age ►	7–10 years	11–12 years	13–18 years
Tetanus, Diphtheria, Pertussis ¹		see footnote 1	Tdap	Tdap
Human Papillomavirus ²		see footnote 2	HPV (3 doses)	HPV Series
Meningococcal ³		MCV	MCV	MCV
Influenza ⁴		Influenza (Yearly)		
Pneumococcal ⁵		PPSV		
Hepatitis A ⁶		HepA Series		
Hepatitis B ⁷		HepB Series		
Inactivated Poliovirus ⁸		IPV Series		
Measles, Mumps, Rubella ⁹		MMR Series		
Varicella ¹⁰		Varicella Series		

Range of recommended ages

Catch-up immunization

Certain high-risk groups

This schedule indicates the recommended ages for routine administration of currently licensed vaccines, as of December 1, 2008, for children aged 7 through 18 years. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. Licensed combination vaccines may be used whenever any component of the combination is indicated and other components are not contraindicated and if approved by the Food and Drug Administration for that dose of

the series. Providers should consult the relevant Advisory Committee on Immunization Practices statement for detailed recommendations, including high-risk conditions: <http://www.cdc.gov/vaccines/pubs/acip-list.htm>. Clinically significant adverse events that follow immunization should be reported to the Vaccine Adverse Event Reporting System (VAERS). Guidance about how to obtain and complete a VAERS form is available at <http://www.vaers.hhs.gov> or by telephone, 800-822-7967.

1. Tetanus and diphtheria toxoids and acellular pertussis vaccine (Tdap). (Minimum age: 10 years for BOOSTRIX® and 11 years for ADACEL®)

- Administer at age 11 or 12 years for those who have completed the recommended childhood DTP/DTaP vaccination series and have not received a tetanus and diphtheria toxoid (Td) booster dose.
- Persons aged 13 through 18 years who have not received Tdap should receive a dose.
- A 5-year interval from the last Td dose is encouraged when Tdap is used as a booster dose; however, a shorter interval may be used if pertussis immunity is needed.

2. Human papillomavirus vaccine (HPV). (Minimum age: 9 years)

- Administer the first dose to females at age 11 or 12 years.
- Administer the second dose 2 months after the first dose and the third dose 6 months after the first dose (at least 24 weeks after the first dose).
- Administer the series to females at age 13 through 18 years if not previously vaccinated.

3. Meningococcal conjugate vaccine (MCV).

- Administer at age 11 or 12 years, or at age 13 through 18 years if not previously vaccinated.
- Administer to previously unvaccinated college freshmen living in a dormitory.
- MCV is recommended for children aged 2 through 10 years with terminal complement component deficiency, anatomic or functional asplenia, and certain other groups at high risk. See *MMWR* 2005;54(No. RR-7).
- Persons who received MPSV 5 or more years previously and remain at increased risk for meningococcal disease should be revaccinated with MCV.

4. Influenza vaccine.

- Administer annually to children aged 6 months through 18 years.
- For healthy nonpregnant persons (i.e., those who do not have underlying medical conditions that predispose them to influenza complications) aged 2 through 49 years, either LAIV or TIV may be used.
- Administer 2 doses (separated by at least 4 weeks) to children aged younger than 9 years who are receiving influenza vaccine for the first time or who were vaccinated for the first time during the previous influenza season but only received 1 dose.

5. Pneumococcal polysaccharide vaccine (PPSV).

- Administer to children with certain underlying medical conditions (see *MMWR* 1997;46[No. RR-8]), including a cochlear implant. A single revaccination should be administered to children with functional or anatomic asplenia or other immunocompromising condition after 5 years.

6. Hepatitis A vaccine (HepA).

- Administer 2 doses at least 6 months apart.
- HepA is recommended for children older than 1 year who live in areas where vaccination programs target older children or who are at increased risk of infection. See *MMWR* 2006;55(No. RR-7).

7. Hepatitis B vaccine (HepB).

- Administer the 3-dose series to those not previously vaccinated.
- A 2-dose series (separated by at least 4 months) of adult formulation Recombivax HB® is licensed for children aged 11 through 15 years.

8. Inactivated poliovirus vaccine (IPV).

- For children who received an all-IPV or all-oral poliovirus (OPV) series, a fourth dose is not necessary if the third dose was administered at age 4 years or older.
- 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.

9. Measles, mumps, and rubella vaccine (MMR).

- If not previously vaccinated, administer 2 doses or the second dose for those who have received only 1 dose, with at least 28 days between doses.

10. Varicella vaccine.

- For persons aged 7 through 18 years without evidence of immunity (see *MMWR* 2007;56[No. RR-4]), administer 2 doses if not previously vaccinated or the second dose if they have received only 1 dose.
- For persons aged 7 through 12 years, the minimum interval between doses is 3 months. However, if the second dose was administered at least 28 days after the first dose, it can be accepted as valid.
- For persons aged 13 years and older, the minimum interval between doses is 28 days.

The Recommended Immunization Schedules for Persons Aged 0 Through 18 Years are approved by the Advisory Committee on Immunization Practices (www.cdc.gov/vaccines/recs/acip), the American Academy of Pediatrics (<http://www.aap.org>), and the American Academy of Family Physicians (<http://www.aafp.org>).

DEPARTMENT OF HEALTH AND HUMAN SERVICES • CENTERS FOR DISEASE CONTROL AND PREVENTION

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 • 2009

The table 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.

CATCH-UP SCHEDULE FOR 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 ¹	Birth	4 weeks	8 weeks (and at least 16 weeks after first dose)		
Rotavirus ²	6 wks	4 weeks	4 weeks ²		
Diphtheria, Tetanus, Pertussis ³	6 wks	4 weeks	4 weeks	6 months	6 months ³
<i>Haemophilus influenzae</i> type b ⁴	6 wks	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 ⁴ if current age is younger than 12 months 8 weeks (as final dose) ⁴ if current age is 12 months or older and second dose administered at younger than age 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 ⁵	6 wks	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 high-risk children who received 3 doses at any age	
Inactivated Poliovirus ⁶	6 wks	4 weeks	4 weeks	4 weeks ⁶	
Measles, Mumps, Rubella ⁷	12 mos	4 weeks			
Varicella ⁸	12 mos	3 months			
Hepatitis A ⁹	12 mos	6 months			
CATCH-UP SCHEDULE FOR PERSONS AGED 7 THROUGH 18 YEARS					
Tetanus, Diphtheria/ Tetanus, Diphtheria, Pertussis ¹⁰	7 yrs ¹⁰	4 weeks	4 weeks if first dose administered at younger than age 12 months 6 months if first dose administered at age 12 months or older	6 months if first dose administered at younger than age 12 months	
Human Papillomavirus ¹¹	9 yrs	Routine dosing intervals are recommended ¹¹			
Hepatitis A ⁹	12 mos	6 months			
Hepatitis B ¹	Birth	4 weeks	8 weeks (and at least 16 weeks after first dose)		
Inactivated Poliovirus ⁶	6 wks	4 weeks	4 weeks	4 weeks ⁶	
Measles, Mumps, Rubella ⁷	12 mos	4 weeks			
Varicella ⁸	12 mos	3 months if the person is younger than age 13 years 4 weeks if the person is aged 13 years or older			

1. Hepatitis B vaccine (HepB).

- Administer the 3-dose series to those not previously vaccinated.
- A 2-dose series (separated by at least 4 months) of adult formulation Recombivax HB[®] is licensed for children aged 11 through 15 years.

2. Rotavirus vaccine (RV).

- The maximum age for the first dose is 14 weeks 6 days. Vaccination should not be initiated for infants aged 15 weeks or older (i.e., 15 weeks 0 days or older).
- Administer the final dose in the series by age 8 months 0 days.
- If Rotarix[®] was administered for the first and second doses, a third dose is not indicated.

3. Diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP).

- The fifth dose is not necessary if the fourth dose was administered at age 4 years or older.

4. *Haemophilus influenzae* type b conjugate vaccine (Hib).

- Hib vaccine is not generally recommended for persons aged 5 years or older. No efficacy data are available on which to base a recommendation concerning use of Hib vaccine for older children and adults. However, studies suggest good immunogenicity in persons who have sickle cell disease, leukemia, or HIV infection, or who have had a splenectomy; administering 1 dose of Hib vaccine to these persons is not contraindicated.
- If the first 2 doses were PRP-OMP (PedvaxHib[®] or Comvax[®]), and 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 2 doses separated by 4 weeks and a final dose at age 12 through 15 months.

5. Pneumococcal vaccine.

- Administer 1 dose of pneumococcal conjugate vaccine (PCV) to all healthy children aged 24 through 59 months who have not received at least 1 dose of PCV on or after age 12 months.
- For children aged 24 through 59 months with underlying medical conditions, administer 1 dose of PCV if 3 doses were received previously or administer 2 doses of PCV at least 8 weeks apart if fewer than 3 doses were received previously.
- Administer pneumococcal polysaccharide vaccine (PPSV) to children aged 2 years or older with certain underlying medical conditions (see *MMWR* 2000;49[No. RR-9]), including a cochlear implant, at least 8 weeks after the last dose of PCV.

6. Inactivated poliovirus vaccine (IPV).

- For children who received an all-IPV or all-oral poliovirus (OPV) series, a fourth dose is not necessary if the third dose was administered at age 4 years or older.
- 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.

7. Measles, mumps, and rubella vaccine (MMR).

- Administer the second dose at age 4 through 6 years. However, the second dose may be administered before age 4, provided at least 28 days have elapsed since the first dose.
- If not previously vaccinated, administer 2 doses with at least 28 days between doses.

8. Varicella vaccine.

- Administer the second dose at age 4 through 6 years. However, the second dose may be administered before age 4, provided at least 3 months have elapsed since the first dose.
- For persons aged 12 months through 12 years, the minimum interval between doses is 3 months. However, if the second dose was administered at least 28 days after the first dose, it can be accepted as valid.
- For persons aged 13 years and older, the minimum interval between doses is 28 days.

9. Hepatitis A vaccine (HepA).

- HepA is recommended for children older than 1 year who live in areas where vaccination programs target older children or who are at increased risk of infection. See *MMWR* 2006;55(No. RR-7).

10. Tetanus and diphtheria toxoids vaccine (Td) and tetanus and diphtheria toxoids and acellular pertussis vaccine (Tdap).

- Doses of DTaP are counted as part of the Td/Tdap series
- Tdap should be substituted for a single dose of Td in the catch-up series or as a booster for children aged 10 through 18 years; use Td for other doses.

11. Human papillomavirus vaccine (HPV).

- Administer the series to females at age 13 through 18 years if not previously vaccinated.
- Use recommended routine dosing intervals for series catch-up (i.e., the second and third doses should be administered at 2 and 6 months after the first dose). However, the minimum interval between the first and second doses is 4 weeks. The minimum interval between the second and third doses is 12 weeks, and the third dose should be given at least 24 weeks after the first dose.

Recommended Adult Immunization Schedule – United States, 2009

MMWRTM
QuickGuide

Weekly

January 9, 2009 / Vol. 57 / No. 53

The Advisory Committee on Immunization Practices (ACIP) annually reviews the recommended Adult Immunization Schedule to ensure that the schedule reflects current recommendations for the licensed vaccines. In October 2008, ACIP approved the Adult Immunization Schedule for 2009. No new vaccines were added to the schedule; however, several indications were added to the pneumococcal polysaccharide vaccine footnote, clarifications were made to the footnotes for human papillomavirus, varicella, and meningococcal vaccines, and schedule information was added to the hepatitis A and hepatitis B vaccine footnotes.

Additional information is available as follows: schedule (in English and Spanish) at <http://www.cdc.gov/vaccines/recs/schedules/adult-schedule.htm>; adult vaccination at <http://www.cdc.gov/vaccines/default.htm>; ACIP statements for specific vaccines at <http://www.cdc.gov/vaccine/pubs/acip-list.htm>; and reporting adverse events at <http://www.vaers.hhs.gov> or by telephone, 800-822-7967.

Changes for 2009

Format Changes (Figures 1 and 2)

To make the figures easier to understand, several formatting changes were implemented to both the age group–based schedule and the medical and other indications schedule. The changes include 1) increasing the number of age groups; 2) deleting the hatched yellow bar for tetanus, diphtheria, pertussis (Td/Tdap) vaccine while adding explanatory text to the Td/Tdap bar; 3) simplifying the figures by removing schedule text from the vaccine bars; 4) revising the order of the vaccines to more appropriately group the vaccines, and 5) adding a legend box to clarify the meaning of blank spaces in the table.

Footnote (Figures 1 and 2)

- The human papillomavirus (HPV) footnote (#2) has language added to indicate that health-care personnel are not at increased risk because of occupational exposure, but they should be vaccinated consistent with age-based recommendations. Also, text has been added to indicate that vaccination with HPV may begin at age 9 years.
- The varicella footnote (#3) has language added to clarify that adults who previously received only 1 dose of vaccine should receive a second dose.
- Asthma and cigarette smoking have been added as indications for pneumococcal polysaccharide vaccination (#7). Also, text has been added to clarify vaccine use in Alaska Natives and American Indians.
- The Hepatitis A footnote (#9) has additional schedule information for the 4-dose combined hepatitis A/hepatitis B vaccine.
- The Hepatitis B footnote (#10) has additional schedule information for the 4-dose combined hepatitis A/hepatitis B vaccine, and a clarification of schedule information for special formulation indications has been added.
- The meningococcal vaccine footnote (#11) clarifies that the revaccination interval is 5 years.

The Recommended Adult Immunization Schedule has been approved by the Advisory Committee on Immunization Practices, the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, and the American College of Physicians.

Suggested citation: Centers for Disease Control and Prevention. Recommended adult immunization schedule—United States, 2009. *MMWR* 2008;57(53).

FIGURE 1. Recommended adult immunization schedule by vaccine and age group — United States, 2009

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

*Covered by the Vaccine Injury Compensation Program.

 For all persons in this category who meet the age requirements and who lack evidence of immunity (e.g., lack documentation of vaccination or have no evidence of prior infection)

 Recommended if some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indications)

 No recommendation

NOTE: The above recommendations must be read along with the footnotes on pages Q2–Q4 of this schedule.

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

Tdap should replace a single dose of Td for adults aged 19 through 64 years who have not received a dose of Tdap previously

Adults with uncertain or incomplete history of primary vaccination series with tetanus and diphtheria toxoid-containing vaccines should begin or complete a primary vaccination series. A primary series for adults is 3 doses of tetanus and diphtheria toxoid-containing vaccines; administer the first 2 doses at least 4 weeks apart and the third dose 6–12 months after the second. However, Tdap can substitute for any one of the doses of Td in the 3-dose primary series. The booster dose of tetanus and diphtheria toxoid-containing vaccine should be administered to adults who have completed a primary series and if the last vaccination was received 10 or more years previously. Tdap or Td vaccine may be used, as indicated.

If a woman is pregnant and received the last Td vaccination 10 or more years previously, administer Td during the second or third trimester. If the woman received the last Td vaccination less than 10 years previously, administer Tdap during the immediate postpartum period. A dose of Tdap is recommended for postpartum women, close contacts of infants aged less than 12 months, and all health-care personnel with direct patient contact if they have not previously received Tdap. An interval as short as 2 years from the last Td is suggested; shorter intervals can be used. Td may be deferred during pregnancy and Tdap substituted in the immediate postpartum period, or Tdap may be administered instead of Td to a pregnant woman after an informed discussion with the woman.

Consult the ACIP statement for recommendations for administering Td as prophylaxis in wound management.

2. Human papillomavirus (HPV) vaccination

HPV vaccination is recommended for all females aged 11 through 26 years (and may begin at age 9 years) who have not completed the vaccine series. History of genital warts, abnormal Papanicolaou test, or positive HPV DNA test is not evidence of prior infection with all vaccine HPV types; HPV vaccination is recommended for persons with such histories.

Ideally, vaccine should be administered before potential exposure to HPV through sexual activity; however, females who are sexually active should still be vaccinated consistent with age-based recommendations. Sexually active females who have not been infected with any of the four HPV vaccine types receive the full benefit of the vaccination. Vaccination is less beneficial for females who have already been infected with one or more of the HPV vaccine types.

A complete series consists of 3 doses. The second dose should be administered 2 months after the first dose; the third dose should be administered 6 months after the first dose.

HPV vaccination is not specifically recommended for females with the medical indications described in Figure 2, “Vaccines that might be indicated for adults based on medical and other indications.” Because HPV vaccine is not a live-virus vaccine, it may be administered to persons with the medical indications described in Figure 2. However, the immune response and vaccine efficacy might be less for persons with the medical indications described in Figure 2 than in persons who do not have the medical indications described or who are immunocompetent. Health-care personnel are not at increased risk because of occupational exposure, and should be vaccinated consistent with age-based recommendations.

3. Varicella vaccination

All adults without evidence of immunity to varicella should receive 2 doses of single-antigen varicella vaccine if not previously vaccinated or the second dose if they have received only one dose, unless they have a medical contraindication. Special consideration should be given to those who 1) 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 2) 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).

Evidence of immunity to varicella in adults includes any of the following: 1) documentation of 2 doses of varicella vaccine at least 4 weeks apart; 2) U.S.-born before 1980 (although for health-care personnel and pregnant women, birth before 1980 should not be considered evidence of immunity); 3) history of varicella based on diagnosis or verification of varicella by a health-care provider (for a patient reporting a history of or presenting with 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 laboratory-confirmed case or evidence of laboratory confirmation, if it was performed at the time of acute disease); 4) history of herpes zoster based on health-care provider diagnosis or verification of herpes zoster by a health-care provider; or 5) laboratory evidence of immunity or laboratory confirmation of disease.

Pregnant women should be assessed for evidence of varicella immunity. Women who do not have evidence of immunity should receive the first dose

FIGURE 2. Vaccines that might be indicated for adults based on medical and other indications — United States, 2009

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

* Covered by the Vaccine Injury Compensation Program.

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

NOTE: The above recommendations must be read along with the footnotes on pages Q2–Q4 of this schedule.

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.

4. Herpes zoster vaccination

A single dose of zoster vaccine is recommended for adults aged 60 years and older regardless of whether they report a prior episode of herpes zoster. Persons with chronic medical conditions may be vaccinated unless their condition constitutes a contraindication.

5. Measles, mumps, rubella (MMR) vaccination

Measles component: Adults born before 1957 generally are considered immune to measles. Adults born during or after 1957 should receive 1 or more doses of MMR unless they have a medical contraindication, documentation of 1 or more doses, history of measles based on health-care provider diagnosis, or laboratory evidence of immunity.

A second dose of MMR is recommended for adults who 1) have been recently exposed to measles or are in an outbreak setting; 2) have been vaccinated previously with killed measles vaccine; 3) have been vaccinated with an unknown type of measles vaccine during 1963–1967; 4) are students in postsecondary educational institutions; 5) work in a health-care facility; or 6) plan to travel internationally.

Mumps component: Adults born before 1957 generally are considered immune to mumps. Adults born during or after 1957 should receive 1 dose of MMR unless they have a medical contraindication, history of mumps based on health-care provider diagnosis, or laboratory evidence of immunity.

A second dose of MMR is recommended for adults who 1) live in a community experiencing a mumps outbreak and are in an affected age group; 2) are students in postsecondary educational institutions; 3) work in a health-care facility; or 4) plan to travel internationally. For unvaccinated health-care personnel born before 1957 who do not have other evidence of mumps immunity, administering 1 dose on a routine basis should be considered and administering a second dose during an outbreak should be strongly considered.

Rubella component: 1 dose of MMR vaccine is recommended for women whose rubella vaccination history is unreliable or who lack laboratory evidence of immunity. For women of childbearing age, regardless of birth year, rubella

immunity should be determined and women should be counseled regarding congenital rubella syndrome. 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.

6. Influenza vaccination

Medical indications: Chronic disorders of the cardiovascular or pulmonary systems, including asthma; chronic metabolic diseases, including diabetes mellitus, renal or hepatic dysfunction, hemoglobinopathies, or immunocompromising conditions (including immunocompromising conditions caused by medications or human immunodeficiency virus [HIV]); any condition that compromises respiratory function or the handling of respiratory secretions or that can increase the risk of aspiration (e.g., cognitive dysfunction, spinal cord injury, or seizure disorder or other neuromuscular disorder); and pregnancy during the influenza season. No data exist on the risk for severe or complicated influenza disease among persons with asplenia; however, influenza is a risk factor for secondary bacterial infections that can cause severe disease among persons with asplenia.

Occupational indications: All health-care personnel, including those employed by long-term care and assisted-living facilities, and caregivers of children less than 5 years old.

Other indications: Residents of nursing homes and other long-term care and assisted-living facilities; persons likely to transmit influenza to persons at high risk (e.g., in-home household contacts and caregivers of children aged less than 5 years old, persons 65 years old and older and persons of all ages with high-risk condition[s]); and anyone who would like to decrease their risk of getting influenza. Healthy, nonpregnant adults aged less than 50 years without high-risk medical conditions who are not contacts of severely immunocompromised persons in special care units can receive either intranasally administered live, attenuated influenza vaccine (FluMist®) or inactivated vaccine. Other persons should receive the inactivated vaccine.

7. Pneumococcal polysaccharide (PPSV) vaccination

Medical indications: Chronic lung disease (including asthma); chronic cardiovascular diseases; diabetes mellitus; chronic liver diseases, cirrhosis; chronic alcoholism, chronic renal failure or nephrotic syndrome; functional or anatomic asplenia (e.g., sickle cell disease or splenectomy [if elective splenectomy

is planned, vaccinate at least 2 weeks before surgery]); immunocompromising conditions; and cochlear implants and cerebrospinal fluid leaks. Vaccinate as close to HIV diagnosis as possible.

Other indications: Residents of nursing homes or other long-term care facilities and persons who smoke cigarettes. Routine use of PPSV is not recommended for Alaska Native or American Indian persons younger than 65 years unless they have underlying medical conditions that are PPSV indications. However, public health authorities may consider recommending PPSV for Alaska Natives and American Indians aged 50 through 64 years who are living in areas in which the risk of invasive pneumococcal disease is increased.

8. Revaccination with PPSV

One-time revaccination after 5 years is recommended for persons with chronic renal failure or nephrotic syndrome; functional or anatomic asplenia (e.g., sickle cell disease or splenectomy); and for persons with immunocompromising conditions. For persons aged 65 years and older, one-time revaccination if they were vaccinated 5 or more years previously and were aged less than 65 years at the time of primary vaccination.

9. Hepatitis A vaccination

Medical indications: Persons with chronic liver disease and persons who receive clotting factor concentrates.

Behavioral indications: Men who have sex with men and persons who use illegal drugs.

Occupational indications: Persons working with hepatitis A virus (HAV)–infected primates or with HAV in a research laboratory setting.

Other indications: Persons traveling to or working in countries that have high or intermediate endemicity of hepatitis A (a list of countries is available at <http://www.cdc.gov/travel/content/diseases.aspx>) and any person seeking protection from HAV infection.

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, administered on days 0, 7, and 21 to 30 followed by a booster dose at month 12 may be used.

10. Hepatitis B vaccination

Medical indications: Persons with end-stage renal disease, including patients receiving hemodialysis; persons with HIV infection; and persons with chronic liver disease.

Occupational indications: Health-care personnel and public-safety workers who are exposed to blood or other potentially infectious body fluids.

Behavioral indications: Sexually active persons who are not in a long-term, mutually monogamous relationship (e.g., persons with more than 1 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.

Other indications: Household contacts and sex partners of persons with chronic hepatitis B virus (HBV) infection; clients and staff members of institutions for persons with developmental disabilities; international travelers to countries with high or intermediate prevalence of chronic HBV infection (a list of countries

is available at <http://wwwn.cdc.gov/travel/content/diseases.aspx>); and any adult seeking protection from HBV infection.

Hepatitis B vaccination is recommended for 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.

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, administered on days 0, 7, and 21 to 30 followed by a booster dose at month 12 may be used.

Special formulation indications: For adult patients receiving hemodialysis or with other immunocompromising conditions, 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.

11. Meningococcal vaccination

Medical indications: Adults with anatomic or functional asplenia, or terminal complement component deficiencies.

Other indications: First-year college students living in dormitories; 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 (e.g., the “meningitis belt” of sub-Saharan Africa during the dry season [December–June]), particularly if their contact with local populations will be prolonged. Vaccination is required by the government of Saudi Arabia for all travelers to Mecca during the annual Hajj.

Meningococcal conjugate vaccine (MCV) is preferred for adults with any of the preceding indications who are aged 55 years or younger, although meningococcal polysaccharide vaccine (MPSV) is an acceptable alternative. Revaccination with MCV after 5 years might be indicated for adults previously vaccinated with MPSV who remain at increased risk for infection (e.g., persons residing in areas in which disease is epidemic).

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

Hib vaccine generally is not recommended for persons aged 5 years and older. No efficacy data are available on which to base a recommendation concerning use of Hib vaccine for older children and adults. However, studies suggest good immunogenicity in patients who have sickle cell disease, leukemia, or HIV infection or who have had a splenectomy; administering 1 dose of vaccine to these patients is not contraindicated.

13. Immunocompromising conditions

Inactivated vaccines generally are acceptable (e.g., pneumococcal, meningococcal, and influenza [trivalent 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>.

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, 2009. 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 (<http://www.cdc.gov/vaccines/pubs/acip-list.htm>).

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 <http://www.vaers.hhs.gov> or by telephone, 800-822-7967.

Information on how to file a Vaccine Injury Compensation Program claim is available at <http://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 <http://www.cdc.gov/vaccines> or from the CDC-INFO Contact Center at 800-CDC-INFO (800-232-4636) in English and Spanish, 24 hours a day, 7 days a week.

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.

TVFC Operations Manual Survey

1. Please rate the overall manual. (Content)

Poor 1 2 3 4 5 *Very Good*

2. The policies and purposes were clearly outlined.
(Communication)

Not at All 1 2 3 4 5 *Well Outlined*

Comments:

1. What did you like best about this manual?

2. What did you like least about this manual?

3. What topics would you like to see expanded in future editions?

Please fax (512) 458-7743 or mail response to:

Texas Department of State Health Services
Immunization Branch – Mail Code: 1946
TVFC Program – G301A
P.O. BOX 149347
Austin, TX 78714-9347



Texas Department of State Health Services
Immunization Branch

Stock No. 11-11215
Revised 01/09