

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																														
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).