CHAPTER 7: DOCUMENTATION REQUIREMENTS

I. Vaccine Record Keeping Requirements

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

- Name of vaccine administered;
- Date vaccine was administered (month, day, year);
- Date vaccine information statement (VIS) was given;
- Publication date on VIS;
- Name of vaccine manufacturer;
- Vaccine lot number;
- Name and title of the health care provider administering the vaccine; and
- Address of the clinic where the vaccine was administered.

Immunization cards are designed to capture all information required when vaccines are administered. Immunization cards for providers (C-100) and clients (C-102 and C-104) can be ordered free of charge from the DSHS Immunization Unit (See Chapter 10: Ordering Forms and Literature).
The TVFC Program suggests the following recommendations regarding record keeping:

- Designate an immunization staff member to answer immunization questions for staff and parents;
- File patient records, keeping the immunization record and TVFC Patient Eligibility forms together;
- Place immunization records at the front of each patient’s chart and make immunizations a priority;
- Encourage parents to bring their children’s immunization records with them to facilitate complete documentation in the child’s record of previous immunization history;
- If a child presents with no immunization record, obtain the history through the Texas Immunization Registry (ImmTrac2), or call previous providers to obtain the history;
- Empower all staff to become “Immunization Advocates” and have them assess each child’s immunization status at every encounter; and
- Give a personal immunization record to each vaccine recipient showing the date (month, day, and year) of when each vaccine was administered.

Copies of all TVFC documents must be maintained for five years and made available on request by the TVFC Program, the Responsible Entity (DSHS HSR or LHD), or DSHS QA contractor.
II. The Texas Immunization Registry (ImmTrac2)

The TVFC Program strongly encourages the use of ImmTrac2, the Texas Immunization Registry, to maintain patient immunization records. ImmTrac2 is operated by the DSHS Immunization Unit and is an important component of Texas’ strategy to improve immunization coverage rates. Texas Law requires medical providers to report all immunizations administered to children 17 years of age and younger to ImmTrac2 within 30 days of administering the vaccine.

ImmTrac2 is designed to consolidate immunization records from multiple sources throughout the state, including clinics, pharmacies, and health care providers. The registry allows authorized organizations easy access to immunization histories of participating clients, as well as “Reminder” and “Recall” capabilities.

Adults can consent to ImmTrac2, which stores their immunization information for a lifetime. Individuals who turn 18 years old and were participating in ImmTrac2 as a minor, must sign an adult consent form by their 26th birthday to keep their immunization information in ImmTrac2.

With access as a registered user of ImmTrac2, providers can confirm whether a patient is in ImmTrac2 and can consent individuals in ImmTrac2 who desire to participate.

TVFC providers must register as an authorized organization with ImmTrac2 by completing an online form. For information about ImmTrac2 or to register, call the ImmTrac2 Customer Support Line at (800) 348-9158 or visit the ImmTrac2 webpage at: http://www.dshs.texas.gov/immunize/immtrac/default.shtm.
III. Addressing Vaccine Hesitancy

Maintaining public confidence in immunizations is critical for preventing a decline in vaccination rates that can result in disease outbreaks. While the majority of parents believe in the benefits of immunizations and have their children vaccinated, some have concerns about the safety of vaccines. The concerns about vaccine safety are preventing some parents from having their children immunized.

Overcoming barriers requires both knowledge and interpersonal skills on the part of the provider. Immunization providers should have an understanding of vaccines, up-to-date recommendations, and reliable resources to direct parents and patients to in order to find accurate information. Also, the providers will need to have the skills necessary to deal with fears and misconceptions about vaccines, and the ability to provide a supportive and encouraging environment for patients.

When a parent or patient initiates the discussion regarding a vaccine concern, the provider should discuss the specific concern and provide factual information. The Vaccine Information Statement (VIS) provides an outline for discussing vaccine benefits and risks. Providers can reinforce key points regarding each vaccine, including safety, and emphasize risks encountered by unimmunized children. Parents should be informed about state laws pertaining to school or child care entry, which might require unimmunized children to stay home from school during outbreaks. Documentation of these discussions in the patient’s record might reduce any potential liability if a vaccine-preventable disease occurs in the unimmunized patient.
IV. Vaccine Adverse Events

The Vaccine Adverse Event Reporting System (VAERS) is a national vaccine safety surveillance program co-sponsored by the Food and Drug Administration (FDA) and the CDC. The purpose of VAERS is to detect possible signals of adverse events associated with vaccines. VAERS collects and analyzes information from reports of adverse events that occur after the administration of U.S. licensed vaccines.

Reports of adverse events are welcome from all concerned individuals, including, but not limited to:

- Patients;
- Parents;
- Health care providers;
- Pharmacists; and
- Vaccine manufacturers.

Use the VAERS Reporting Website to report adverse events. All information requested on VAERS should be completed. It is very important to record the vaccine manufacturer, lot number, and injection site on VAERS. VAERS also requests the types of vaccine received, the timing of vaccination and onset of the adverse event, a description of the event, current illness and medication, past history of adverse events following vaccination, and demographic information about the recipient (e.g., age, gender, etc.).