

CHAPTER 7

DOCUMENTATION REQUIREMENTS

Last Updated: 10/2014

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 healthcare provider administering the vaccine
- Address of the clinic where the vaccine was administered

Immunization cards for providers (C-100) and clients (C-102 and C-104) can be ordered free of charge from the DSHS Immunization Branch (See Chapter 10 Ordering Forms and Literature). These cards are designed to capture all information required when vaccines are administered.

II. Decision to Not Vaccinate

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

When a parent or patient initiates discussion regarding a vaccine concern, the provider should discuss the specific concern and provide factual information. The VIS provides an outline for discussing vaccine benefits and risk. Providers can reinforce key points regarding each vaccine, including safety, and emphasize risks encountered by unimmunized children. Parents should be informed about state laws pertaining to school or child care entry, which might require unimmunized children stay home from school during outbreaks. Documentation of

these discussions in the patient's record might reduce any potential liability if a vaccine-preventable disease occurs in the unimmunized patient.

III. 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 (possible side effects) that occur after the administration of U.S. licensed vaccines.

Reports are welcome from all concerned individuals: patients, parents, health-care providers, pharmacists, and vaccine manufacturers.

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

Reports of events following vaccination at clinics using TVFC vaccine should be reported directly to DSHS.

Please mail to:

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

The VAERS Reporting Form (C-76) is on the TVFC web page:

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

Reports of events following vaccination at clinics using privately purchased vaccine should be reported directly to VAERS. Adverse events may be reported online, by mail, or fax. Contact (800) VAC-RXNS or (800) 822-7967 for information or to request pre-addressed VAERS forms. More information can be obtained from the FDA web site:

www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/VaccineAdverseEvents.

IV. ImmTrac, the Texas Immunization Registry

ImmTrac, the Texas Immunization Registry, is operated by DSHS. Texas Law requires medical providers to report all immunizations administered to children 17 years of age and younger to ImmTrac within 30 days of administering the vaccine. Before a provider can report the immunization information to ImmTrac, providers will need to register for registry participation and access.

For information about ImmTrac or to register to be an ImmTrac user, please call the ImmTrac Customer Support Line at (800) 348-9158 or visit the ImmTrac webpage at:

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