

Step 6: Documenting and Related Issues

Early in the previous chapter, “Step 5: Administering Vaccines,” you learned that you need to provide your patient with a Vaccine Information Statement (VIS) before you administer a vaccination. You also need to document in the patient’s medical record that you provided the VIS. There are a few other requirements too; read on. One of the most important documentation tasks that you will need to do is to make certain that every patient or client who you vaccinate goes home with a written record of that event. We have provided a sample supply of durable, wallet-sized “Adult Immunization Record” cards with this guide, and more can be ordered from the IAC catalog (print or on-line).

Record federally required information about your patient’s vaccinations in a permanent record or log

Much of the documentation involved in administering vaccines is required under federal law (Section 2125 of the Public Health Service Act [42 U.S.C. §300aa-26]). The National Childhood Vaccine Injury Act (NCVIA) was enacted to compensate those individuals, or families of individuals, who have been injured by

Step-by-Step Documentation Tasks	<ul style="list-style-type: none">• Record federally required information about your patient’s vaccinations in a permanent record or log<ul style="list-style-type: none">- Follow CDC guidelines for giving current VISs- Document five specific facts about each vaccination- Report adverse events that occur after vaccination• Update your patient’s personal vaccination record or provide a record card
---	---

certain vaccines. The vaccines that adults may need that are covered by this law include those that contain diphtheria, tetanus, measles, mumps, rubella, polio, hepatitis B, and varicella, either alone or in combination. While the term “childhood” is in the title of the Act, the law covers these vaccines when given to infants, children, and adults.

There are three main requirements of vaccination providers under the law. You must:

1. Give the patient a copy of the relevant federal “Vaccine Information Statement” (VIS) for the vaccine they are about to receive. If the patient is a minor, the VIS must be given to the parent or legal representative.
2. Record certain information about the vaccine(s) administered in the patient’s medical record or a permanent office log.
3. Document any adverse event following the vaccination that the patient experiences and that becomes known to the provider, whether you think the vaccine caused the event or not, and submit the report to the Vaccine Adverse Event Reporting System (VAERS).

**Materials
for you
to use**

- It’s Federal Law! You Must Give Your Patients Current Vaccine Information Statements (VISs) (93)
- Instructions for the Use of Vaccine Information Statements (94)
- Vaccine Administration Record for Adults (and example) (95–96)
- VAERS Table of Reportable Events Following Vaccination (97)
- Vaccine Adverse Event Reporting System reporting form (98–99)
- Adult Immunization Record cards (included with this guide)

Now we'll cover the details about complying with these three requirements.

Follow CDC guidelines for giving current VISs

The Centers for Disease Control and Prevention (CDC) is responsible for developing the one-page (two-sided) VISs and updating them when necessary. Each one contains specific information about the disease the vaccine prevents, the vaccine, when and how frequently it should be administered, possible side effects, what to do about serious reactions, and the phone numbers of the National Vaccine Injury Compensation Program and the Vaccine Adverse Event Reporting System. The VISs are available from the CDC website (www.cdc.gov/nip), CDC's Immunization Information Hotline at (800) 232-2522, or the Immunization Action Coalition (IAC) website (www.immunize.org/vis).

We have included a copy of the CDC publication "Instructions for the Use of Vaccine Information Statements" on page 94 in Appendix A. What is important for you to remember is that "providing" a VIS means giving the patient a physical copy to take home—letting them read an office copy does not suffice. And, it means giving it to the patient before you vaccinate, with enough time to read it, not after.

Document five specific facts about each vaccination

A second federal requirement is that the provider record certain information about the vaccines administered. The information can be recorded in the patient's permanent medical record or in a permanent clinic log. The information required includes:

- the date the vaccination was given
- the vaccine manufacturer and lot number of the

vaccine administered

- the name, address (location where the information will be stored), and the signature and title of the individual who administers the vaccine
- the edition (date of publication) of the VIS (found on the bottom of the back of the VIS)
- the date the VIS was given to the patient

See the sample office medical chart “Vaccine Administration Record for Adults” on pages 95–96 for an example of how you might record this information in an individual’s chart.

Report adverse events that occur after vaccination

The Vaccine Adverse Events Reporting System (VAERS) serves as a national database of reported adverse events that occur following immunizations and as a tool used by the Food and Drug Administration (FDA) and the CDC to look for patterns of events following vaccine administration. VAERS attempts to detect previously unrecognized vaccine-related events, unusual increases in previously reported events, pre-existing conditions that may cause certain reactions and contraindicate additional doses of the vaccine as well as to identify specific vaccine lots associated with reported events. Both the FDA and the CDC review data that are reported to VAERS.

All health care providers and vaccine manufacturers are required to report post-vaccination adverse events outlined in the “VAERS Table of Reportable Events Following Vaccination” on page 97, whether the provider thinks the vaccine caused the event or not. It’s important, too, to note that anyone, including vaccine recipients themselves, may submit a report.

A copy of the VAERS reporting form can be found on pages 98–99 and can also be obtained by calling VAERS at (800) 822-7967 or going to the VAERS website (www.vaers.org). Health care providers can also submit VAERS reports by following the “VAERS Web Submission” instructions on the VAERS website.

Update your patient’s personal vaccination record or provide a record card

In “Step 4: Deciding Whom to Vaccinate,” we covered how to find out your patient’s vaccination history. Once you have determined all previous vaccinations (or lack thereof), be sure to note them on the patient’s immunization record sheet you keep in your patient’s chart. We have included an example of such a record, the “Vaccine Administration Record for Adults,” on page 96. Include as much information as you’ve been able to uncover on the record sheet even if it’s not complete. The most important elements are the type of vaccine and the date it was given (month, day, and year). Don’t worry about not having all or any of the other information (such as the manufacturer and lot number) about the shots that were given elsewhere. That information will likely have been recorded in the original clinic’s records.

Don’t forget to give the patient a record of the vaccination(s) that she or he just received. If she or he has a personal record card, you can offer to update it. If not, give the patient an “Adult Immunization Record” card (see page 132) after you’ve filled in the information. You’ll note that this record also includes a column to indicate when the next dose is due, which you should complete for the patient. This is important for vaccines that are given more than once (e.g., Td, hepatitis B, hepatitis A, varicella).

It's important, too, that you provide information on the vaccinations just given to the patient's primary care provider if he or she has one. Remind the patient to have her or his primary care clinic update the clinic medical record from the information on the patient's personal immunization record card. Or, better yet, offer to provide the information for the patient if she or he can give you the primary care clinic's name and address.

That's it! Properly documenting vaccinations is not complex; it just needs to be done. Unfortunately, financing vaccination services, the topic of the next and last chapter, is a bit more complex.