

Documentation

It is important to know the federal requirements for documenting the vaccines administered to your patients. The requirements are defined in the National Childhood Vaccine Injury Act enacted in 1986. The law applies to all routinely recommended childhood vaccines, regardless of the age of the patient receiving the vaccines. The only vaccines not included in this law are pneumococcal polysaccharide, zoster, and certain infrequently used vaccines, such as rabies and Japanese encephalitis.

The following information must be documented on the patient's paper or electronic medical record or on a permanent office log:

1. The vaccine manufacturer.
2. The lot number of the vaccine.
3. The date the vaccine is administered.
4. The name, office address, and title of the healthcare provider administering the vaccine.
5. The Vaccine Information Statement (VIS) edition date located in the lower right corner on the back of the VIS. When administering combination vaccines, all applicable VISs should be given and the individual VIS edition dates recorded.
6. The date the VIS is given to the patient, parent, or guardian.

The federally required information should be both permanent and accessible.

Federal law does not require a parent, patient, or guardian to sign a consent form in order to receive a vaccination; providing them with the appropriate VIS(s) and answering their questions is sufficient under federal law.

The Ohio Department of Health recommends the documentation of the following:

1. Route of administration (IM, SC, Nasal)
2. Site
3. Any identifiable immediate reactions to vaccine

Electronic Medical Records

With the increased use of Electronic Medical Records (EMR), providers should assure the EMR has the federally required field, for proper documentation (Manufacturer, lot number, date of administration, site of administration, verification of receipt of VIS, date of VIS, and documentation of who administered the vaccine).

The Ohio Department of Health also recommends the use of the vaccine registry system, Impact SIIS. Many of the current EMR systems are linked to Impact and upload the required information, however if your EMR does not automatically upload to Impact you can do it manually.

Use of National Drug Codes (NDC)

The CDC expects to implement new requirements in the future years for the Vaccines for Children (VFC) program that will require the use of National Drug Codes (NDC) in addition to lot numbers, and dose-level reporting for

inventory management operations. The NDC for an administered dose of vaccine will be provided by the CDC when available.