

6. NATIONAL CHILDHOOD VACCINE INJURY ACT REQUIREMENTS



The National Childhood Vaccine Injury Act (NCVIA) of 1986 was enacted to provide a cost-effective arbitration and compensation system for vaccine injury claims and reduce the potential liability of vaccine manufacturers. It also created a system for reporting and tracking adverse events related to vaccinations. Health care professionals who administer vaccines must adhere to the following NCVIA requirements when administering vaccinations. Please note that these requirements apply to ALL vaccinations administered at your facility, not just those given through the VFC Program.

Vaccine Information Statements (VIS)

VISs are published by the CDC and provide information to vaccine recipients about the risks and benefits of each vaccine. You must provide a current vaccine-specific VIS to your patient or your patient’s legal guardian at each vaccination visit.



VISs are updated periodically, and the CDC maintains current print, audio, and foreign language versions on their website at <http://www.cdc.gov/vaccines/pubs/vis/default.htm> .

Whether managed as electronic or paper documents, in a paper folder or through your EHR—you must provide *current* VISs to your patients. We recommend storing all VISs in one location and designating one person responsible for updating them. The CDC VIS webpage (link provided above) offers a “Get email updates” function that notifies you by email when VISs are changed. Another option is to download VISs directly from the CDC website as needed. That way, they are always up to date.

Vaccine Adverse Event Reporting System (VAERS)

VAERS is a national vaccine safety surveillance program created through the NCVIA and co-sponsored by the CDC and the Food and Drug Administration (FDA). VAERS provides a nationwide system for reporting, analyzing, and publishing information on adverse events related to vaccines. The VAERS website is:

<http://vaers.hhs.gov/professionals/index>.

Reportable Events – Required

The NCVIA requires health care providers to report to VAERS:

- Any adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine



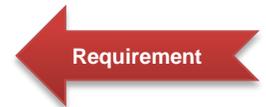
- Any adverse event listed in the [VAERS Table of Reportable Events Following Vaccination](#) that occurs within the specified time period after vaccination.

Reportable Events – Voluntary

You may report any adverse event that occurs after the administration of a vaccine licensed in the US, even if you are unsure whether a vaccine was the cause.

Vaccine Charting Requirements

The NCVIA requires that vaccination records be included in a patient's permanent medical record and that they include the following information:



- Name of the vaccine
- Date of vaccine administration
- Vaccine manufacturer and lot number
- Name and title of the person giving the vaccine
- Address of the clinic where vaccine was given
- Publication date of the VISs and date it was provided to the patient.

A number of resources are available for charting records. The Immunization Action Coalition website (<http://www.immunize.org/handouts/document-vaccines.asp>) provides free immunization charts (downloadable as PDFs) that capture all the information required by the NCVIA.