

## Requirements for Vaccine Administrators

Vaccine administrators are afforded the liability protections of the National Childhood Vaccine Injury Act (NCVIA) of 1986, as amended, (the Act), if the vaccine is covered under the Vaccine Injury Compensation Program (VICP). Vaccines effective against more than twelve diseases are covered by the program. Hepatitis B vaccine is covered by the program (VICP), added effective August 6, 1997. There are no age restrictions on who may file a claim with VICP; claims may be filed on behalf of children, adolescents or by adults receiving VICP-covered vaccines.

The NCVIA includes certain requirements of vaccine administrators.

- **Provision of VIS:** As a requirement of the NCVIA, vaccine administrators must provide a copy of the relevant Vaccine Information Statement (VIS) prior to administration of each vaccine and every time the vaccine is given, including each dose of a multi-dose series. Anyone receiving a VICP-covered vaccine should be given the VIS. The purpose of the VIS is to inform the vaccine recipient of the benefits and risks of the vaccine.

The most up-to-date VIS should be provided to the patient or the parent/guardian of the vaccine recipient. VISs should be provided in the language that the patient or parent/guardian can understand. VISs are available in several languages.

- **Record-keeping requirements:** The NCVIA also mandates that vaccine administrators document the date of vaccine administration; the vaccine manufacturer; vaccine lot number; name, title, signature and business address of the professional administering the vaccine; VIS version date; and date the VIS was provided to the recipient or parent/guardian. (Templates are available for the vaccine administration record requirements).
- **Adverse event reporting:** The NCVIA requires that health care providers report adverse events following vaccination to the Vaccine Adverse Events Reporting System (VAERS). Health care providers should report any adverse event set forth in the *Vaccine Injury Table* that occurs within the time period specified or within 7 days, if that is longer, following vaccination. Providers should also report any event listed in a manufacturer's packing insert related to a contraindication or potential adverse event.