It's Federal Law!

You must give your patients current Vaccine Information Statements (VISs)

To obtain current VISs in more than 30 languages, visit the Immunization Action Coalition's website at www.immunize.org/vis

As healthcare professionals understand, the risks of serious consequences following vaccination are many hundreds or thousands of times less likely than the risks associated with the diseases that the vaccines protect against. Most adverse reactions from vaccines are mild and self-limited. Serious complications are rare, but they can have a devastating effect on the recipient, family members, and the providers involved with the care of the patient. We must continue the efforts to make vaccines as safe as possible.

Equally important is the need to furnish vaccine recipients (or the parents/legal representatives of minors) with objective information on vaccine safety and the diseases that the vaccines protect against, so that they are actively involved in making decisions affecting their health or the health of their children. When people are not informed about vaccine adverse events, even common, mild events, they can lose their trust in healthcare providers and vaccines. Vaccine Information Statements (VISs) provide a standardized way to present objective information about vaccine benefits and adverse events.

What are VISs?

VISs are developed by the staff of the Centers for Disease Control and Prevention (CDC) and undergo intense scrutiny by panels of experts for accuracy. Each VIS provides information to properly inform the adult vaccine recipient or the minor child's parent or legal representative about the risks and benefits of each vaccine. VISs are not meant to replace interactions with healthcare providers, who should answer questions and address concerns that the recipient or the parent/legal representative may have.

According to CDC, every time one of these vaccines is given — regardless of what combination vaccine it is given in — regardless of whether it is given by a public health clinic or a private provider — regardless of how the vaccine was purchased — and regardless of the age of the recipient — the appropriate VIS must be given out prior to the vaccination.

Source: www.cdc.gov/vaccines/hcp/vis/about/facts-vis.html

Use of the VIS is mandatory!

Before a healthcare provider vaccinates a child or an adult with a dose of any vaccine containing diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis A, hepatitis B, *Haemophilus influenzae* type b (Hib), influenza, pneumococcal conjugate, meningococcal, rotavirus, human papillomavirus (HPV), or varicella (chickenpox) vaccine, the provider is required by the National Childhood Vaccine Injury Act (NCVIA) to provide a copy of the VIS to either the adult recipient or to the child's parent/legal representative.

How to get VISs

All available VISs can be downloaded from the website of the Immunization Action Coalition at www.immunize.org/vis or from CDC's website at www.cdc.gov/vaccines/hcp/vis/index.html. Ready-to-copy versions may also be available from your state or local health department.

You can find VISs in more than 30 languages on the Immunization Action Coalition website at www.immunize.org/vis. To find VISs in alternative formats (e.g., audio, web-video), go to: www.immunize.org/vis/vis_sources.asp

Most current versions of VISs

As of April 24, 2015, the most recent versions of the VISs are as follows:

Adenovirus	6/11/14
Anthrax	3/10/10
Chickenpox	3/13/08
DTaP	5/17/07
Hib	4/2/15
Hepatitis A	10/25/11
Hepatitis B	2/2/12
HPV-Cervarix	5/3/11
HPV-Gardasil	5/17/13
HPV-Gardasil 9	4/15/15
Influenza	8/19/14
Japanese enceph.	1/24/14
MMR	4/20/12
MMRV	5/21/10
Meningococcal	10/14/11
Multi-vaccine	10/22/14
PCV13	2/27/13
PPSV	4/24/15
Polio	11/8/11
Rabies	10/6/09
Rotavirus	4/15/15
Shingles	10/6/09
Td	2/24/15
Tdap	2/24/15
Typhoid	5/29/12
Yellow fever	3/30/11

immunization action coalition
IAC
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Saint Paul, Minnesota ▪ 651-647-9009 ▪ www.immunize.org ▪ www.vaccineinformation.org

www.immunize.org/catg.d/p2027.pdf ▪ Item #P2027 (4/15)

Top 10 Facts about VISs

Fact 1 It's federal law!

Federal law requires that VISs must be used for the following vaccines when vaccinating patients of ALL ages:

- DTaP (includes DT)
- Td and Tdap
- Hib
- hepatitis A
- hepatitis B
- HPV
- influenza (inactivated and live vaccines)
- MMR and MMRV
- meningococcal
- pneumococcal conjugate
- polio
- rotavirus
- varicella

According to CDC, every time one of these vaccines is given — regardless of what combination vaccine it is given in — regardless of whether it is given by a public health clinic or a private provider — regardless of how the vaccine was purchased — and regardless of the age of the recipient — the appropriate VIS must be given out prior to the vaccination. There are also VISs for vaccines not covered by NCVIA: anthrax, Japanese encephalitis, pneumococcal polysaccharide, rabies, shingles, smallpox, typhoid, and yellow fever. CDC recommends the use of VISs whenever these vaccines are given. The VIS must always be used if vaccine was purchased under CDC contract.

By using the VISs with your patients, you are helping to develop a better educated patient population and you are doing the right thing.

Fact 2 VISs are required for both public and private sectors

Federal law requires use of VISs in both the public and private sector settings and regardless of the source of payment for the vaccine.

Fact 3 VIS must be provided *before* vaccine is administered to the patient

The VIS provides information about the disease and the vaccine and should be given to the patient before vaccine is administered. It is also acceptable to hand out the VIS well before administering vaccines (e.g., at a prenatal visit or at birth for vaccines an infant will receive during infancy), as long as you still provide the VIS right before administering vaccines.

Fact 4 You must provide a current VIS for each dose of vaccine

The most current VIS must be provided before each dose of vaccine is given, including vaccines given as a series of doses. If five doses of a single vaccine are required, the patient (parent/legal representative) must have the opportunity to read the information on the VIS before each dose is given.

Fact 5 You must provide VISs for combination vaccines too

There is a VIS available for MMRV (ProQuad). An alternative VIS — the multi-vaccine VIS — is an option to providing single-vaccine VISs when administering one or more of these routine birth-through-6-month vaccines: DTaP, hepatitis B, Hib, pneumococcal (PCV), or polio (IPV). The multi-vaccine VIS can also be used when giving combination vaccines (e.g., Pediarix, Pentacel, Kinrix) or when giving two or more routine vaccines at other pediatric visits (e.g., 12–15 months, 4–6 years). However, when giving combination vaccines for which no VIS exist (e.g., Twinrix), give out all relevant single VISs. For example, before administering Twinrix give your patient the VISs for both hepatitis A and hepatitis B vaccines.

Fact 6 VISs are available in other formats, including more than 30 languages

You may use laminated copies of VISs for patients and parents to read and return before leaving the clinic, but you must **also** offer the patient (parent/legal representative) a printed copy of the VIS to take home.

If they prefer to download the VIS onto a mobile device, direct them to CDC's VIS Mobile Downloads web page: http://m.cdc.gov/VIS

To download VISs in other languages, visit www.immunize.org/vis

Fact 7 Federal law does not require signed consent in order for a person to be vaccinated

Signed consent is not required by federal law (although some states may require them).

Fact 8 To verify that a VIS was given, providers must record in the patient's chart (or permanent office log or file) the following information:

- The published date of the VIS
- The date the VIS is given to the patient
- Name, address (office address), and title of the person who administers the vaccine
- The date the vaccine is administered
- The vaccine manufacturer and lot number of each dose administered

Fact 9 VISs should not be altered before giving them to patients

Providers should not change a VIS or write their own VISs. It is permissible to add a practice's name, address, or phone number to an existing VIS. Providers are encouraged to supplement the VIS with additional patient-education materials.

Fact 10 Provide VISs to all patients

For patients who don't read or speak English, the law requires that providers ensure all patients (parent/legal representatives) receive a VIS, regardless of their ability to read English. If available, provide a translation of the VIS in the patient's language.

Translations of VISs in more than 30 languages are available from IAC. Go to www.immunize.org/vis for VISs in multiple languages as well as in other formats.