

## POLICY AND PROCEDURE Vaccine Information Statements (VISs)

Vaccine Information Statements (VISs) are information sheets produced by the Centers for Disease Control and Prevention (CDC). VISs explain both the benefits and risks of a vaccine to adult vaccine recipients and the parents or legal representatives of vaccines who are children and adolescents. Federal law requires that VISs be handed out whenever certain vaccinations are given (before each dose).

Copies are available in English and many other languages from CDC's website at [www.cdc.gov/vaccines/pubs/vis](http://www.cdc.gov/vaccines/pubs/vis).

**Purpose:** To educate adult patients or parents/guardians about the benefits and risks of any vaccinations(s) recommended for them.

**Procedure:** Provide a Vaccine Information Statement (VIS) when a vaccination is given. As required under the National Childhood Vaccine Injury Act (42 U.S.C. §300aa-26), all health care providers in the United States who administer, to any child or adult, any of the following vaccines – diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis A, hepatitis B, *Haemophilus influenzae* type b (Hib), trivalent influenza, pneumococcal conjugate, meningococcal, rotavirus, human papillomavirus (HPV), or varicella (chickenpox) – shall, prior to administration of each dose of the vaccine, provide a copy to keep of the relevant current edition vaccine information materials that have been produced by the Centers for Disease Control and Prevention (CDC):

- to the parent or legal representative\* of any child to whom the provider intends to administer such vaccine,

or

- to any adult<sup>†</sup> to whom the provider intends to administer such vaccine.

If there is not a single VIS for a combination vaccine, use the VISs for all component vaccines.

VISs should be supplemented with visual presentations or oral explanations as appropriate.

\*"Legal representative" is defined as a parent or other individual who is qualified under State law to consent to the immunization of a minor child or incompetent adult.

†In the case of an incompetent adult, relevant VISs shall be provided to the individual's legal representative. If the incompetent adult is living in a long-term care facility, all relevant VISs may be provided at the time of admission, or at the time of consent if later than admission, rather than prior to each vaccination.

### Record information for each VIS provided.

Health care providers shall make a notation in each patient's permanent medical record at the time vaccine information materials are provided, indicating:

- (1) the edition date of the Vaccine Information Statement distributed, and
- (2) the date the VIS was provided.

This recordkeeping requirement supplements the requirement of 42 U.S.C. §300aa-25 that all health care providers administering these vaccines must record in the patient's permanent medical record (or in a permanent office log):

- (3) the name, address and title of the individual who administers the vaccine,
- (4) the date of administration, and
- (5) the vaccine manufacturer and lot number of the vaccine used.



**Vaccine Information Statements (VISs)** are information sheets produced by the Centers for Disease Control and Prevention (CDC). VISs explain both the benefits and risks of a vaccine to adult vaccine recipients and the parents or legal representatives of vaccinees who are children and adolescents.

Federal law requires that VISs be handed out whenever certain vaccinations are given (before each dose).

### **Out-of-date translations**

The translations for some VISs on our website are from previously published English-language versions that have since been updated. Unfortunately, IAC is not always able to obtain translations as updates are issued. Please ensure that your patients receive information consistent with the current **English-language version** of the following VISs.

# You Must Provide Patients with Vaccine Information Statements (VISs) – It’s Federal Law!

## What are Vaccine Information Statements (VISs)?

Vaccine Information Statements (VISs) are documents produced by the Centers for Disease Control and Prevention (CDC), in consultation with panels of experts and parents, to properly inform vaccinees (or their parents/legal representatives) about the risks and benefits of each vaccine. VISs are not meant to replace interactions with healthcare providers, who should address any questions or concerns that the vaccinee (or parent/legal representative) may have.

## Using VISs is legally required!

Federal law (under the National Childhood Vaccine Injury Act) requires a healthcare professional to provide a copy of the current VIS to an adult patient or to a child’s parent/legal representative before vaccinating an adult or child with a dose of the following vaccines: 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).

## Where to get VISs

All available VISs can be downloaded from the websites of Immunize.org at [www.immunize.org/vis](http://www.immunize.org/vis) or CDC at [www.cdc.gov/vaccines/hcp/vis/index.html](http://www.cdc.gov/vaccines/hcp/vis/index.html). Ready-to-copy versions may also be available from your state or local health department.

**Translations:** You can find VISs in more than 40 languages on the Immunize.org website at [www.immunize.org/vis](http://www.immunize.org/vis).

To obtain translations of VIS in languages other than English, go to [www.immunize.org/vis](http://www.immunize.org/vis).

According to CDC, the appropriate VIS must be given:

- Prior to the vaccination (and prior to each dose of a multi-dose series);
- Regardless of the age of the vaccinee;
- Regardless of whether the vaccine is given in a public or private healthcare setting.

## Top 10 Facts About VISs

**FACT 1** It’s federal law! You must provide current\* VISs to all your patients before vaccinating them.

Federal law requires that VISs must be used for patients of **ALL ages** when administering these vaccines:

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

For the vaccines not covered under the National Childhood Vaccine Injury Act (i.e., adenovirus, anthrax, dengue, ebola, Japanese encephalitis, pneumococcal polysaccharide, rabies, smallpox/monkeypox, typhoid, yellow fever, and zoster), providers are not required by federal law to use VISs unless they have been purchased under CDC contract. However, CDC recommends that VISs be used whenever these vaccines are given.

\*Federal law allows up to 6 months for a new VIS to be used.

**FACT 2** VISs can be given to patients in a variety of ways.

In most medical settings, VISs are provided to patients (or their parents/legal representatives) in paper form. However, VISs also may be provided using electronic media. Regardless of the format used, the goal is to provide a current VIS just prior to vaccination.

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## Most current versions of VISs (table)

As of June 30, 2022, the most recent versions of the VISs are as follows:

<b>Adenovirus</b> .....	1/8/20	<b>MMRV</b> .....	8/6/21
<b>Anthrax</b> .....	1/8/20	<b>Multi-vaccine</b> .....	10/15/21
<b>Cholera</b> .....	10/30/19	<b>PCV</b> .....	2/4/22
<b>Dengue</b> .....	12/17/21	<b>PPSV23</b> .....	10/30/19
<b>DTaP</b> .....	8/6/21	<b>Polio</b> .....	8/6/21
<b>Ebola</b> .....	6/30/22	<b>Rabies</b> .....	6/2/22
<b>Hepatitis A</b> .....	10/15/21	<b>Rotavirus</b> .....	10/15/21
<b>Hepatitis B</b> .....	10/15/21	<b>Smallpox/monkeypox</b> ..	6/1/22
<b>Hib</b> .....	8/6/21	<b>Td</b> .....	8/6/21
<b>HPV</b> .....	8/6/21	<b>Tdap</b> .....	8/6/21
<b>Influenza</b> .....	8/6/21	<b>Typhoid</b> .....	10/30/19
<b>Japanese enceph</b> .....	8/15/19	<b>Varicella</b> .....	8/6/21
<b>MenACWY</b> .....	8/6/21	<b>Yellow fever</b> .....	4/1/20
<b>MenB</b> .....	8/6/21	<b>Zoster</b> .....	2/4/22
<b>MMR</b> .....	8/6/21		

A handy list of current VIS dates is also available at [www.immunize.org/catg.d/p2029.pdf](http://www.immunize.org/catg.d/p2029.pdf).

(For information on special circumstances involving vaccination of a child when a parent/legal representative is not available at the time of vaccination, see CDC’s *VIS Frequently Asked Questions* at [www.cdc.gov/vaccines/hcp/vis/about/vis-faqs.html](http://www.cdc.gov/vaccines/hcp/vis/about/vis-faqs.html).)

Prior to vaccination, VIS may be:

- Provided as a paper copy
- Offered on a permanent, laminated office copy
- Downloaded by the vaccinee (parent/legal representative) to a smartphone or other electronic device (VISs have been specially formatted for this purpose)
- Made available to be read before the office visit, e.g., by giving the patient or parent a copy to take home during a prior visit, or telling them how to download or view a copy from the Internet. These patients must still be offered a copy in one of the formats described previously to read during the immunization visit, as a reminder.

Regardless of the way the patient is given the VIS to read, providers must still offer a copy (which can be an electronic copy) of each appropriate VIS to take home following the vaccination. However, the vaccinee may decline.

**FACT 3** VISs are required in both public and private sector healthcare settings.

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

**FACT 4** You must provide a current VIS *before* a vaccine is administered to the patient.

A VIS provides information about the disease and the vaccine and must be given to the patient **before** a 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 a current VIS right before administering vaccines.

**FACT 5** You must provide a current VIS for *each* dose of vaccine you administer.

The most current VIS must be provided before **each dose** of vaccine is given, including vaccines given as a series of doses. For example, if 5 doses of a single vaccine are required (e.g., DTaP), the patient (parent/legal representative) must have the opportunity to read the information on the VIS before each dose is given.

**FACT 6** You must provide VISs whenever you administer combination vaccines.

If you administer a combination vaccine that does not have a stand-alone VIS (e.g., Kinrix, Quadracel, Pediarix, Pentacel, Twinrix) you should provide the patient with individual VISs for the component vaccines, or use the Multi-Vaccine VIS.

The Multi-Vaccine VIS may be used in place of the individual VISs for DTaP, Hib, hepatitis B, polio, and pneumococcal when two or more of these vaccines are administered during the same visit. It may be used for infants as well as children through 6 years of age. The Multi-Vaccine VIS should not be used for adolescents or adults.

**FACT 7** VISs should be given in a language /format that the recipient can understand, whenever possible.

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. To obtain VISs in more than 40 languages, visit the Immunize.org website at [www.immunize.org/vis](http://www.immunize.org/vis). Providers can supplement VISs with visual presentations or oral explanations as needed.

**FACT 8** Federal law does not require signed consent in order for a person to be vaccinated.

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

**FACT 9** To verify that a VIS was given, providers must record in the patient’s medical record (or permanent office log or file) the following information:

- The edition date of the VIS (found on the back at the right bottom corner)
- The date the VIS is provided (i.e., the date of the visit when the vaccine is administered)
- The office address and name and title of the person who administers the vaccine
- The date the vaccine is administered
- The vaccine manufacturer and lot number

In addition, providers must record:

**FACT 10** VISs should not be altered before giving them to patients, but you can add some information.

Providers should not change a VIS or write their own VISs. However, it is permissible to add a practice’s name, address, and contact information to an existing VIS.

**Additional resources on VISs and their use are available from the following organizations:**

**Immunization Action Coalition**

- VIS general information and translations in more than 40 languages: [www.immunize.org/vis](http://www.immunize.org/vis)
- Current Dates of Vaccine Information Statements: [www.immunize.org/catg.d/p2029.pdf](http://www.immunize.org/catg.d/p2029.pdf)

**Centers for Disease Control and Prevention**

- VIS website: [www.cdc.gov/vaccines/hcp/vis](http://www.cdc.gov/vaccines/hcp/vis)
- VIS Facts: [www.cdc.gov/vaccines/hcp/vis/about/facts-vis.html](http://www.cdc.gov/vaccines/hcp/vis/about/facts-vis.html)
- VIS FAQs: [www.cdc.gov/vaccines/hcp/vis/about/vis-faqs.html](http://www.cdc.gov/vaccines/hcp/vis/about/vis-faqs.html)

## Frequently Asked Questions (FAQ) about Immunization Registries (Health Care Providers)

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### **What is an immunization registry? What is CAIR?**

An immunization registry is a secure web-based database that can store your patients' immunization records. A registry helps medical practices keep their patients vaccinated on time, avoiding under- or overimmunization. All 50 states have immunization registries. Our California Immunization Registry is also known as CAIR. California has 10 regional CAIR affiliates that cover the state. CAIR users pay nothing for software, training and help desk support.

### **Who can use CAIR?**

CAIR can only be used by authorized medical office staff, hospitals, and public health departments for the purposes of evaluating shot records, sending reminders, billing, and protecting the public health. Programs such as WIC, child care, schools, foster care, and CalWORKS may also be authorized to view shot histories for the children they serve.

### **What can CAIR do for my practice? Will it increase my staff's busy workload?**

CAIR reduces the staff time needed to:

- ❖ search for or replace patient immunization records
- ❖ provide records ("yellow cards" and "blue cards,") for school, camp, or other activities
- ❖ forecast which vaccines are due
- ❖ give "just-in-case" immunizations when earlier shot records are missing
- ❖ request shot records from other providers
- ❖ prepare reminder notices, and
- ❖ track vaccine inventory—including separate tracking for VFC vaccine supplies.

Immunization registry software works quickly and efficiently in a variety of clinic settings. The software has a high satisfaction rate. [Testimonials from medical office staff](#) affirm these advantages. Your regional CAIR representative can help assess your office workflow to maximize CAIR benefits for your practice.

## What if our immunization rates are high already, should my practice join the registry?

CAIR:

- saves staff time and helps your patients
- consolidates records when children have been immunized by different providers.
- keeps children up-to-date by making rapid, accurate assessments of the increasingly complex vaccine schedule.
- accurately tracks your practice's coverage rates.
- improves immunization rates, whether high or low.

## What computer equipment is needed?

Most computers with high-speed Internet access are adequate for registry use. Ask the CAIR Help Desk to help you evaluate your current system technology, identify any gaps.

## Who will train our staff to use the registry?

[CAIR training](#) is available online. In some areas of the state, CAIR representatives can schedule free in-person training for your staff. [CAIR software is very user-friendly](#), requiring no prior computer skills. Free Help Desk services are available to answer questions during normal business hours. Call 800-578-7889.

## How do we ensure data accuracy?

CAIR software has built-in quality assurance features. Validation procedures identify inaccurate or missing data entered into the registry. The CAIR Help Desk can help you correct data.

## How does CAIR integrate with your existing EMR/EHRs?

CAIR is currently able to receive immunization data from EMR/EHRs in HL7 format. Only HL7 data submission qualifies under the [EHR Incentive Program](#). Data exchange file specifications are available on the [5 Steps to Data Exchange](#) page or from the CAIR Data Exchange staff at [CAIRDataExchange@cdph.ca.gov](mailto:CAIRDataExchange@cdph.ca.gov). Providers interested in data exchange with CAIR should view the [5 Steps to Data Exchange](#) page to receive general instructions on the data submission process then register at the [CDPH Gateway/CAIR IZ Portal](#)

## Are patients' records in CAIR kept secure?

[CAIR complies with HIPAA and state law](#) to protect patient privacy. Providers and CAIR staff must abide by confidentiality agreements in order to share patient records. Each viewing of patient records is tracked to maintain an "audit trail." Moreover, CAIR software has security features to protect confidential data from being seen by unauthorized sources.

## Some families might not like the idea of a registry. What are their options?

Families have the choice of whether their children's records are shared with other CAIR users. [All parents or guardians must be notified](#) before their children's records are entered into CAIR. In practice, few families have chosen to not participate after this notification. Participating families also have the choice whether to receive reminders and to inspect their children's registry records for accuracy.

## Can I access patient records from another part of California?

Yes. While the CAIR system currently has three distinct regional registries that are not connected ([CAIR regions](#)), the CAIR Help Desk can assist providers to obtain patient records outside of their region. In 2019, data sharing among the CAIR registries will begin and participating providers will have access to patient immunization data from anywhere in the state.

## How do we maintain control of our patients' records? Will other practices be able lure away our patients?

Your patients' immunization records are protected by security measures as well as by agreements signed by all providers participating in CAIR. Providers must use specific identifying information to search for children in the registry and cannot browse through all records.

## Where can I learn more about CAIR?

Visit [cairweb.org](http://cairweb.org) or contact the CAIR Help Desk at 800-578-7889 or your [Local CAIR Representative](#).