VFC Program Overview

Vaccines for Children (VFC) Program

Congress created the federal Vaccines for Children (VFC) Program in 1993. The goal of the VFC Program is to prevent vaccine-preventable diseases by removing or reducing cost barriers.

The VFC program is funded by federal entitlement money guaranteed to each state to buy vaccine for children who are Medicaid eligible, uninsured, underinsured (defined in this case as a health insurance policy that will not cover vaccination services), Alaskan native or native American.

The Vermont Department of Health ensures that private providers and district health departments have access to vaccine and abide by the rules and regulations of the VFC program. VFC requirements include:

1. Screening patients for VFC eligibility.
2. Maintain immunizations records for a period of at least three years.
3. Make immunization records available to the VDH, when requested.
4. Representatives of VDH Immunization Program are permitted access to facilities and records.
5. Administer vaccines according to the Advisory Committee on Immunization Practices (ACIP) current schedule, unless compliance would be medically inappropriate.
6. Vaccine Information Statements (VIS) are provided in accordance with the National Childhood Vaccine Injury Act and date VIS given is documented on the immunization record.
7. Not imposing a charge for the cost of vaccine provided through state and federal funding
8. Not imposing a charge higher than the maximum fee established by the Center for Medicaid Services for Vermont ($13.86) for non- Medicaid, VFC eligible children.
9. Vaccine usage, wastage and inventory is reported to VDH Immunization Program.

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VFA Program Overview

Vaccines for Adults (VFA) Program

Vermont Department of Health initiated an adult (age 19 and up) vaccine program in 2007. Primary care and OB/GYN providers are invited to enroll.

See the VDH website for vaccine availability:
http://healthvermont.gov/hc/imm/provider.aspx#schedule.

Goal: Protect the health of Vermonters by increasing adult coverage with ACIP recommended vaccinations.

Access: Vaccine is free of charge to the medical home, thus reducing access and cost barriers for patients. There is no residency requirement for adults who receive state supplied vaccine.

To participate the provider must:

- Submit the completed Vermont Immunization Program Vaccines for Children (VFC) and/or the Vaccines for Adults (VFA) Enrollment form found at http://healthvermont.gov/hc/imm/documents/VFC_VFA_Enrollmentform.pdf
- Allow VDH program staff to visit yearly for the purpose of educational support and to assure adherence to program requirements.

Enrolled practices agree to follow:

1. ACIP recommended schedule
2. CDC recommendations for vaccine storage and handling
3. VDH and federal guidelines for immunization documentation and inventory management systems
4. VDH Vaccine Purchasing Pool pilot implementation procedures related to charging insurers, found on the VDH immunization web page: http://healthvermont.gov/hc/imm/VaccinePurchasingPoolPilotProgram.aspx#procedures

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Vaccine Management Plan

Vaccine Ordering and Accountability

Vaccine Ordering Schedule (EOQ)

- Practices have a vaccine economic order frequency (EOQ: i.e., **monthly, bimonthly, quarterly** and **as-needed**). EOQ allows practices a two-week order window (first half of the month 1-15th and second half of the month 16-31st) schedule.
- If you do not have a copy of your schedule, call the Immunization Program at (802) 863-7638 to request an EOQ calendar showing your order schedule.
- If you anticipate running out of vaccines before your next scheduled order, call to discuss placing an additional order.

Completing the Vaccine Accountability & Order form

- Complete the form by filling out *Contact Person*, *Ending Inventory D*ate, *Delivery Days* and *Delivery Hours* information on top of the form.
- In the column titled *Total Doses Given,* list number of doses administered. In the column, *Ending Inventory,* enter the number of doses left in your fridge.
- *Expiration Dates* must be filled in the column next to *Ending Inventory.*
- *New Doses Ordered* and *New Inventory Balance* columns: **leave blank** unless you need a vaccine that you have never previously ordered.
- Submitting an incomplete form may result in a delay of vaccine order.
- Fax the completed form to (802) 863-7395 along with temperature logs from prior order date to current order date.
- Please do not send copies of packing slips. They are **not required.**
- The Immunization Program will fax a new *Vaccine Accountability & Order Form*, confirming that your order has been received.
- If you do not receive the new *Vaccine Accountability and Order Form* within three business days please call (802) 863-7395.

Receipt of Vaccine Shipments

- Vaccines are shipped from McKesson Specialty Distribution and only freezer stable vaccine (VARICELLA) is shipped by the manufacturer, Merck.
- Verify that packing slip amounts agree with the content of the shipment. Date and sign the packing slip.
- You may want to keep packing slips for your records, but do not fax it to the Immunization Program.
- If you find a discrepancy between the packing slip and the amount or type of the vaccine ordered, or if temperature monitor inside the box indicates that vaccine has been exposed to out-of-range temperatures, please call the Immunization Program instantly.
- Store vaccine promptly in the appropriate refrigerator or freezer based on the required storage temperature for the vaccine.
- Varicella vaccine is shipped in a box with frozen packs and the lid of the box contains diluent. Please ensure you remove diluent from the lid before you discard it.
- Rotate your vaccine stock to ensure use the shorter expiration dates first
- Notify the Immunization Program if you have vaccine approaching its expiration date within 6 to 8 weeks and you are unable to use it. We will assist you in redistributing it to a practice that can use it.

Returning Expired or Non-viable Vaccines

- All expired and non-viable vaccines (with caps intact) must be sent back to McKesson.
- Record the expired and non-viable vaccines on the *Vaccine Accountability and Order Form* with lot number, expiration date and number of doses.
- When you place your next order and submit that information, a *Return Authorization Form* and shipping label will be mailed to you.
- Ship the vaccine in any sturdy box packed to prevent vial breakage.

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Vaccines for Children and Vaccine for Adults Vaccine Availability and Eligibility – *Effective July 22, 2011*

VACCINE	AVAILABILITY	SPECIFICS FOR USE OF STATE SUPPLIED VACCINE
DTaP Diphtheria and tetanus toxoids, and acellular pertussis	VFC only	None
DTaP-HepB-IPV	VFC only	None
DTaP-IPV	VFC only	None
DTaP-IPV/Hib	VFC only	None
Hib Haemophilus influenzae type b	VFC only	None
HepA Hepatitis A	VFC/VFA	None
HepB Hepatitis B	VFC/VFA	None
HepA-HepB	VFA only	None
HPV4 Human papillomavirus	VFC/VFA	None
IPV Inactivated poliovirus	VFC only	None
Influenza	VFC only	None
MMR Measles, mumps and rubella	VFC/VFA	None
MCV4 Meningococcal conjugate	VFC/VFA	Routinely: one dose at age 11-12 with one booster dose at age 16. For those given one dose at age 13-15, give one booster dose at age 16-18. Those given one dose at age 16 or older, no booster dose needed. Not routinely recommended after age 21. For 9 months through 10 years with certain high risk conditions, see complete ACIP recommendations.
PCV13 Pneumococcal conjugate	VFC only	None
PPSV23 Pneumococcal polysaccharide	VFC/VFA	Routine for adults age 65 and older. Also for adults age 19 - 64 with asthma, cigarette smokers, and those with certain chronic medical conditions. For 2 through 18 years with certain high risk conditions, see complete ACIP recommendations.
RV1 Rotavirus	VFC only	None
Td Tetanus and diphtheria toxoid (adult formulation)	VFC only	Only for 7 – 18 year olds with 1) a true medical contraindication to accelular pertussis vaccine; or 2) to complete the primary series if previously unvaccinated, or 3) for wound management if a Tdap has been previously administered.
Tdap Tetanus and diphtheria toxoids, and acellular pertussis	VFC/VFA	None
VAR Varicella	VFC/VFA	Routine for pediatrics. For 19 years and older with a negative history of vaccine and disease, and a negative titer.

For the Vermont Recommended Immunization Schedules and current Vaccine Availability and Eligibility please go to: http://healthvermont.gov/hc/imm/provider.aspx

Documentation Requirements

As required by federal law (42 US Code 300aa-25), the following information is to be documented for each vaccination:

1. Date of administration
2. Vaccine manufacturer and lot number
3. Signature and title of the person administering the vaccine
4. Address where the vaccine was given
5. Vaccine refusal should be documented

As required by The National Childhood Vaccine Injury Act of 1986

1. Patient or the parent/legal representative must be given the most current Vaccine Information Statement (VIS) prior to the administration of the vaccine.
2. The date the VIS was given is to be documented if different from the date the vaccination was given.
3. The publication date of the VIS must also be recorded in the patient record. The date appears at the bottom of the VIS.

Screening for VFC eligibility and recording this information in the patient chart is required by federal mandate. It is suggested that vaccine administrator record VFC eligibility screening as follows:

1: Medicaid / Dr. Dynasaur= has this insurance and is eligible for VFC vaccines

2: Alaskan Native or Native American= people can self identify and are eligible for VFC vaccines

3: No insurance= are eligible for VFC vaccines. Children with no insurance, children who are Alaskan Native or Native American cannot be charged more than $13.86 for vaccine administration fee

4: Not VFC Eligible- means anyone with insurance other than Medicaid/Dr. Dynasaur *(at this time individuals in this category can get state supplied vaccine as long as Vermont remains a universal provider of vaccines, this is subject to change due to funding issues)*

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Instructions for the Use of
Vaccine Information Statements

Required Use

1. 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† 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.

2. 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.

Applicability of State Law

Health care providers should consult their legal counsel to determine additional State requirements pertaining to immunization. The Federal requirement to provide the vaccine information materials supplements any applicable State laws.

Availability of Copies

Copies are available in English and many other languages from CDC's website at www.cdc.gov/vaccines/pubs/vis. Single camera-ready copies may also be available from State health departments.

Current VIS Editions

DTaP/DT: 5/17/07
Hib: 12/16/98
Hepatitis A: 3/21/06
Hepatitis B: 7/18/07†
HPV (Cervarix): 5/3/10†
HPV (Gardasil): 5/3/10†
Influenza (inactivated): 8/10/10†
Influenza (live): 8/10/10†
MMR: 3/13/08†
MMRV: 5/21/10†
Meningococcal: 1/28/08†
Pneumococcal (PCV7): 12/9/08†
Pneumococcal (PCV13): 4/16/10†
Polio: 1/1/00
Rotavirus: 5/14/10†
Tdap/Td: 11/18/08†
Varicella: 3/13/08†
Multi-Vaccine*: 9/18/08†

*An optional alternative when two or more routine childhood vaccines (i.e., DTaP, hepatitis B, Hib, pneumococcal, polio, or rotavirus) are administered at the same visit.
†Interim

Reference 42 U.S.C. §300aa-26
May 4, 2011

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/pubs/vis/vis-facts.htm

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/pubs/vis/default.htm. 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 May 2011, the most recent versions of the VISs are as follows:

DTaP/DT/DTP	5/17/07
Hepatitis A	3/21/06
Hepatitis B	7/18/07
Hib	12/16/98
HPV (H. papillomavirus)	
Cervarix	5/3/11
Gardasil	5/3/11
Influenza (inactive)	8/10/10
Influenza (live)	8/10/10
Japanese encephalitis	
JE-Ixiaro	3/1/10
Meningococcal	1/28/08
MMR	3/13/08
MMRV	5/21/10
PCV7	12/9/08
PCV13	4/16/10
PPSV	10/6/09
Polio	1/1/00
Rabies	10/6/09
Rotavirus	12/6/10
Shingles	10/6/09
Td/Tdap	11/18/08
Typhoid	5/19/04
Varicella	3/13/08
Yellow fever	3/30/11

Multi-vaccine VIS 9/18/08
(for 6 vaccines given to infants/children: DTaP, IPV, Hib, Hep B, PCV, RV)

Technical content reviewed by the Centers for Disease Control and Prevention, June 2011.

www.immunize.org/catg.d/p2027.pdf • Item #P2027 (6/11)

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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/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), polio (IPV), or rotavirus (RV). The multi-vaccine VIS can also be used when giving combination vaccines (e.g., Pediarix, Pentacel, Comvax) 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: www.cdc.gov/vaccines/Pubs/vis/vis-downloads.htm

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 English-language VISs to all patients (even if the patient's first language is not English)

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

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.

www.immunize.org/catg.d/p2027.pdf • Item #P2027 (6/11)