



ALABAMA *Vaccines for Children* PROGRAM

Administered by
The Alabama Department of Public Health
Immunization Division

Provider Resource

Revised
02/15/2006



Overview

In October 1993, the Omnibus Budget Reconciliation Act (OBRA) created the Vaccines for Children (VFC) Program as part of the Social Security Act. The VFC Program has become a critical element of the President's Childhood Immunization Initiative. Funds for the Program are annually transferred from the Centers for Medicare and Medicaid Services (CMS) to the Centers for Disease Control and Prevention (CDC) and awarded to 61 immunization projects. The VFC Program, which began October 1, 1994, represents an unprecedented approach to improving vaccine availability nationwide. The Program provides free vaccine to VFC-eligible children through public and private providers.

The OBRA Act, which is included behind this manual, provides guidance for the implementation of the VFC Program, including sections on eligibility, VFC-enrolled providers, and negotiation of contracts with vaccine manufacturers. The legislation also notes that the VFC Program will only be "terminated beginning on the date . . . that provides for immunization services for all children as part of a broad-based reform of the national health care system."



Benefits of the VFC Program

1. Provides public purchased vaccine, for eligible children, at no charge to public and private providers in all 50 states and 11 additional projects.
2. Automatically covers vaccine recommended by the Advisory Committee on Immunization Practices (ACIP) and approved by the CDC, including new vaccines, new vaccine combinations, and revised guidelines for vaccine use.
3. Saves parents and enrolled providers out-of-pocket expenses for vaccinations.
4. Saves money by negotiating federal vaccine contracts at lower prices.
5. Eliminates vaccine cost as a barrier to eligible children.
6. Reduces the practice of referring children from the private sector to the public sector for vaccination, thereby keeping children in their medical home for comprehensive health care.
7. Provides access to ImmPRINT, the Alabama immunization registry.



Policies and Procedures

The policies and procedures are based on the premise that the VFC Program should -

1. Keep provider enrollment, patient access and administrative accountability procedures simple by keeping forms and other documentation to a minimum while still allowing for vaccine accountability and program evaluation.
2. Be easily integrated into existing immunization service delivery systems.
3. Promote increased participation by private providers, and cooperation between the public and private medical communities.
4. Promote close coordination among public agencies, including Alabama Department of Public Health and Alabama Medicaid Agency, and other programs serving families and children.

The VFC Program marks the first time private providers nationwide can receive public purchased vaccine. By eliminating cost as a barrier to vaccinating children, and providing opportunities for vaccinations at more health care provider locations, the VFC Program supports improved immunization coverage levels among eligible children. The goal is to ensure that no VFC-eligible child contracts a vaccine preventable disease because of his or her parent's inability to pay for the vaccine administration.

VFC Accountability

Vaccine accountability is one of the high priorities and is an essential component of the VFC Program. Our primary responsibility is to develop and maintain vaccine accountability systems which -

1. Ensure that vaccine and wastage is minimized.
2. Protect against fraud and abuse.
3. Ensure that vaccines purchased with VFC funds are administered only to VFC-eligible children.

Systems have been implemented in Alabama to base provider profiles on actual data concerning populations that are vaccinated (bench marking process) instead of estimates. Also, the Alabama VFC Program conducts VFC site visits to provide technical assistance and education to providers to ensure accountability. All VFC providers will be visited by a public health representative.

Provider Requirements and Responsibilities

All VFC enrolled providers have agreed to the following:

1. Submit a completed Provider Enrollment Form and a Provider Profile Form to the Alabama VFC Program for review, approval, and record storage.
2. At a minimum, the Provider Profile is updated annually with data. It may be revised more frequently if the provider's practice size or vaccine supply needs change or at the Program's discretion.
3. Screen children and only administer VFC vaccine to VFC-eligibles. The provider also agrees to maintain Screening Records for a period of three years.
4. Offer VFC-eligible children vaccine at no cost, charge no more than \$14.26 for administration, comply with ACIP recommendations, and ensure no VFC-eligible child is denied a vaccination because of parents' inability to pay the administration fee.
5. Distribute written Vaccine Information Statements and maintain records according to the National Childhood Injury Act, and report adverse events following vaccination as they occur.
6. Adhere to other accountability reporting requirements of the State of Alabama.

Who Is Eligible for VFC Vaccine?

Any child, newborn-18 years of age that meet at least one of the following criteria is eligible for VFC vaccine:

1. Medicaid enrolled - a child who is enrolled in the Medicaid program.
2. Uninsured - a child who has no health insurance coverage.
3. American Indian or Alaskan Native - as defined by the Indian Health Services Act.

If your practice is a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC), there is an additional population that you can receive free vaccine for and administer free vaccine to, which is the

4. Underinsured - a child whose health insurance benefit plan does not include vaccinations.

So, for all VFC providers, except FQHC or RHC, if a child has any type of health insurance, they are not eligible for VFC vaccine.



Covered Vaccine

The OBRA of 1993 assigns the ACIP the responsibility of determining which vaccines are provided to VFC-eligible children. The ACIP is an advisory group composed of members representing a broad range of public and private health organizations. The ACIP meets quarterly. At these meetings they vote on the inclusion of new vaccines into the VFC program or the modification of existing resolutions. Usually, a VFC resolution takes effect after a CDC contract for the purchase of that vaccine is established.

VFC vaccine must be administered according to the recommendations outlined by the ACIP in the VFC resolutions. Deviation is not permitted and is considered abuse of VFC vaccine.

Vaccine Ordering

All providers enrolled in the Alabama VFC Program are responsible for the proper maintenance of their vaccine inventory and ordering vaccine in the appropriate amounts. To lower administrative and shipping costs, a reasonable goal is to process no more than four vaccine shipments per provider site per year. In other words, all providers should order all needed vaccines for a 3-month supply and reorder when they are down to a 2-week supply.

To order vaccine, a provider must first enroll in the Alabama VFC Program. After enrollment, a provider may order vaccine by faxing the Vaccine Order Form to the Alabama VFC Program on a toll-free fax line at 1-800-706-8507 or the provider may order on-line via the Alabama VFC Program Web site, which is www.adph.org/immunization. Your vaccine will be shipped to you within two weeks after your order is received. Please call 1-800-469-4599 regarding any discrepancies.

Private providers must continue to purchase vaccine from their usual sources for insured, underinsured, and CHIPS children. The Alabama VFC Program requires that VFC vaccine be maintained separately from your private-purchased vaccines. Maintaining separate stocks enables providers and the Alabama VFC Program to establish and monitor vaccine accountability. The Alabama VFC Program will provide VFC yellow stickers for providers' use to identify vaccines received through the Program to assist providers with maintaining separate stocks. These stickers will be shipped with your vaccine shipments and can be ordered for your medical records.

To order vaccine, please complete the Vaccine Order Form and fax to: 1-800-706-8507.

Instructions for Completing the Vaccine Order Form

As stated under "Vaccine Ordering" providers should order vaccine every three months and allow two weeks for shipping. The most current version of the Vaccine Order Form must be used to ensure VFC providers are up-to-date on available vaccine.

The form must be completed as follows:

1. **Date:** Indicates the day the vaccine order is placed.
2. **Vaccine Provider Name:** Please use the name the practice was enrolled in.
3. **Shipping Address:** Enter physical address.
4. **Contact Person:** Enter current contact person.
5. **Phone #:** Enter an accurate telephone and fax number.
6. **Vaccine types and order in doses:** All provider orders are subject to approval by the Alabama VFC Program. Always order in doses, not vials or boxes.
7. **Special Delivery Instructions/Backup System:** Because vaccines are very expensive, we ask that providers let the Program know when their offices are closed. Also we ask that you develop a backup system, in the event that vaccine is delivered when the office is closed.

Vaccine Storage

To ensure purity, potency, and unnecessary loss of vaccine, each clinic site should have one individual who is responsible for the following procedures to reduce wastage and possible liability:

Train your personnel

1. Designate one person and a backup person to be responsible for vaccine.
2. All staff who works with vaccine should know office protocols.
3. All staff should view the *Protect Your Patients: Storage & Handling of Vaccines* videotape.

Be ready to receive vaccines

1. Let staff know when you order vaccine and to open boxes immediately and inspect contents.
2. If any vaccine seems warm, if the ice pack is completely melted, or if the vaccine has a different lot number than what is recorded on the invoice, call the Alabama VFC Program immediately.
3. Refrigerate or freeze the vaccine immediately according to temperature guidelines.

Store and manage vaccines properly

1. Proper storage and handling guidelines should be posted for all staff to see.
2. Check expiration dates regularly.
3. Rotate stock, use shortest expiration date first regardless of arrival dates.
4. Never use outdated vaccine, call the Alabama VFC Program to return expired/spoiled vaccine.
5. Indicate on the label of each multi-dose vial the date & time first opened.

Use reliable refrigerators and freezers

1. Store vaccines in the best refrigerator /freezer in the building.

2. Keep in temperature range, 2-8°C (35-46°F) in the refrigerator and -15°C (+5°F) or colder in the freezer.
3. Don't use outlets with built-in circuit switches or outlets activated by wall switch.
4. Use a plug guard to prevent anyone from unplugging the vaccine refrigerator/freezer.
5. Post a warning sign: "Warning. Don't Unplug! Expensive vaccine inside!"
6. Store refrigerated vaccine far enough away from the freezer air circulation vent to prevent freezing.
7. Store all opened vials together and away from other drugs.
8. Store only Varicella and MMRV (MMR + Varicella) in the freezer.
9. Use Varicella and MMRV only with diluent supplied.
10. Place ice packs in the freezer and filled plastic water jugs in the refrigerator to help stabilize temperatures.
11. Do not store food or drinks in a refrigerator/freezer with vaccines.
12. Never store vaccine in the door of refrigerator or freezer.

Place thermometers inside refrigerators and freezers that store vaccine

1. Put Fisher Scientific thermometer that is supplied to you by the Alabama VFC Program in both refrigerator and freezer.
2. Check thermometer and record temperature twice a day.
3. Keep a daily temperature log on the door of the refrigerator.
4. Analyze temperatures to keep track of how long out of range.
5. Check refrigerator/freezer over holidays.

How to handle and store live vaccines

1. MMR - refrigerate, do not use warm and protect from light.
2. Varicella - freeze, must be administered within 30 minutes after reconstitution.
3. MMRV - freeze, must be administered within 30 minutes after reconstitution.

4. Never freeze reconstituted vaccine and protect from light.

How to handle and store inactivated vaccines

1. All other vaccines must be refrigerated and never frozen.
2. Refrigerate immediately after receiving.

Transport vaccines safely

1. Never transport Varicella and MMRV without dry ice.
2. All other vaccine may be transported in an insulated container with cold packs on top to maintain proper temperature and prevent freezing.

What to do if there is a mishap in vaccine storage or handling

1. Publicize to all staff the importance of reporting any violation of handling protocol or any accidental storage problem.
2. Contact the Alabama VFC Program immediately to determine if vaccine is good.
3. Do not assume vaccines cannot be salvaged.
4. Record the temperature of refrigerator or freezer at the time of the incident.
5. Mark affected vaccine until guidance is provided by the Alabama VFC Program.

Expired/Spoiled Vaccine

1. Transfer vaccine to another refrigerator or freezer , if necessary.
2. Call the Alabama VFC Program at 1-800-469-4599 to determine if vaccine is good.
3. Mail a completed Expired/Spoiled Vaccine Report using the business-reply label (shipped with vaccine) if it is determined that the vaccine is not good.
4. Watch the *Protect Your Patients: Storage & Handling of Vaccines* video again to learn more about proper vaccine storage and handling.



Evaluation

CDC will routinely review VFC Program operations during technical assistance visits to the States. States are required to visit providers' offices in both the public and private health care sectors. When your practice is visited, records of children who are being immunized through the Alabama VFC Program will be reviewed, and your record keeping and vaccine storage procedures will be evaluated. The site visit will also entail evaluation of your fee schedules, tracking and screening methods, and the availability of immunization literature. We will also provide needed education and solicit comments and suggestions from you to ensure that the Alabama VFC Program is the best program it can be.

Thank you for your efforts to ensure that Alabama's most vulnerable populations are vaccinated against vaccine-preventable diseases through the Alabama VFC Program.



Questions

Please call the Alabama VFC Program for vaccine information, shipments, or deliveries at 1-800-469-4599.

Providers who have questions about reimbursement for the administration of vaccine to specific patients, or concerns about the reimbursement process should call the Electronic Data Systems (EDS) customer relations service line at 1-800-999-3371.

Providers who would like more information about the Alabama Medicaid Agency should call (334) 242-5000.