Massachusetts Department of Public Health
Division of Epidemiology and Immunization
Vaccines for Children Program (VFC)

Guidelines for Compliance with Federal and State Vaccine Administration Requirements

The following requirements regarding vaccine storage and handling, administration, documentation, reporting and information are in accordance with Section 317 of the Public Health Service Act, federal vaccine contract terms, the specification of the National Childhood Vaccine Injury Act (NCVIA) of 1986 (Section 2125, of the Public Health Service Act), the Vaccines for Children Program (VFC) (Section 1928 of the Social Security Act), and the Massachusetts Department of Public Health (MDPH) Immunization Program requirements.

A. Appropriate Use of State-Supplied Vaccine

A-1. Providers will use state-supplied vaccine only for those children and adults determined eligible as defined in the most recent versions of the Childhood Vaccine Availability Table, the Adult Vaccine Availability Table and the Summary of the Advisory Committee on Immunization Practices Recommended Groups for Vaccination (available on the MDPH Immunization Program website by visiting http://www.mass.gov/dph/imm and selecting "Vaccine Management.")

A-2. VFC-only vaccines (see Childhood Vaccine Availability Table) will be offered only to VFC-eligible children. Children < 19 years of age in the following categories are eligible for VFC vaccine:

- Enrolled in Medicaid, or
- Without health insurance, or
- American Indian (Native American) or Alaska Native or
- Underinsured children seen at federally qualified health centers (FQHC) and rural health centers (RHC).

A-3. Providers will screen all children, as outlined in the Provider Enrollment Form, to determine eligibility to receive vaccine purchased with VFC funds. VFC-only vaccines will not be used for children who are not eligible for VFC. VFC Screening Forms must be retained in the medical record or on file in the office for at least 3 years after service to the patient has been completed. MDPH allows patient eligibility screening for VFC to be recorded electronically, if all information requested on the VFC Patient Eligibility form is both recorded and retrievable in the event of an audit. To obtain permission, call the Vaccine Management Unit @ 617-983-6828.

A-4. VFC-enrolled providers are expected to maintain an adequate inventory of vaccine for their non-VFC-eligible patients. VFC vaccine cannot be used as a replacement system for a provider's privately purchased vaccine inventory. If the provider must borrow VFC vaccine to administer to non-VFC eligible children because private stock vaccine is unexpectedly unavailable, the provider must:

- Assure that VFC vaccine supply is adequate to meet the needs of the provider's VFC-eligible patients and that borrowing VFC vaccine will not prevent a VFC-eligible child from receiving a needed vaccination.

- Assure that borrowing occurs only when there is lack of private-stock vaccine due to unexpected circumstances such as a delayed vaccine shipment, vaccine spoiled in-transit to provider, or new staff that calculated ordering time incorrectly.
- Complete and submit to MDPH the MDPH VFC Vaccine Borrowing Report Form whenever VFC vaccine is administered to non-VFC eligible children.
- Agree to provide to MDPH a copy of the invoice for the private stock vaccine used to replenish the borrowed VFC vaccine should MDPH request such documentation.

Borrowing of VFC vaccine should be rare and not a routine occurrence and should only occur to avoid a missed opportunity to provide a needed vaccine for a child who might otherwise not receive vaccine.

A-5. Fraud and Abuse: Improper use of VFC vaccine may constitute fraud and abuse and is punishable by law (Medicaid regulation: 42 CFR §455.15 and applicable state law). Please see section H (Provider-Based Assessments) for information about assessment and follow-up of fraud and abuse according to CDC guidelines.

Fraud is defined by the Centers for Disease Control and Prevention (CDC) as an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to him/herself or some other person. It includes any act that constitutes fraud under applicable federal or state law.

Abuse is defined by CDC as provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in unnecessary cost to the Medicaid program, (and/or including actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient); or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary cost to the Medicaid program.

These same parameters also apply to state-funded vaccines.

A specific federal algorithm must be followed when problems are identified in provider's offices. This algorithm shall also be followed for problems related to state-purchased vaccines.

You must keep all privately purchased vaccine separate from state-supplied vaccine. Fraud and abuse can include (but not be limited to):

- Selling or otherwise misdirecting VFC or other state-supplied vaccine.
- Billing a patient or third party for VFC or other state-supplied vaccine.
- Charging more than the established maximum regional charge for administration of a VFC vaccine to a federally vaccine-eligible child. (See section C-2.)
- Not providing VFC-eligible children VFC vaccine because of parents' inability to pay for the administration fee.
- Not implementing provider enrollment requirements of the VFC program.
- Failing to screen patients for VFC eligibility.
- Failing to maintain VFC records and comply with other requirements of the VFC program.
- Failing to fully account for VFC or other state-supplied vaccine.

- Failing to properly store and handle VFC or other state-supplied vaccine.
- Ordering VFC vaccine in quantities or patterns that do not match provider profile or otherwise involve over-ordering of VFC doses.
- Wastage of VFC or other state-supplied vaccine.

Please see section H (Provider-Based Assessments) for information about assessment and follow-up of fraud and abuse according to CDC guidelines.

B. Vaccine Management

B-1. Providers will have written procedures for vaccine management, which include:

- Designation of a Vaccine Manager and another staff person to be a back up.
- Proper storage and handling.
- Vaccine receiving.
- Procedures for vaccine relocation in the event of a power or equipment failure.
- Vaccine ordering and inventory control.
- Handling lost and expired vaccine.
- Protocols for response when vaccine is stored out of temperature range.

B-2. The provider agrees to follow the manufacturer's specifications and the guidelines established by the MDPH Immunization Program for the storage and handling of vaccines. Proper vaccine management includes:

- All vaccines, with the exception of varicella, MMRV, and Zostavax vaccine must be stored refrigerated at 2° to 8° C (35° to 46° F).
- Varicella, MMRV, and Zostavax vaccine must be stored frozen at $\leq -15^{o}$ C ($\leq 5^{o}$ F).
- Inventory will be clearly marked or identified so that providers can differentiate between state-supplied and privately purchased vaccine.
- The use of a small combination refrigerator/freezer unit that is outfitted with one external door is **not** acceptable for proper storage of vaccines.
- Vaccines should **not** be stored on the refrigerator or freezer door or in storage bins.
- Vaccines should be organized in refrigerator to maximize space and allow proper air flow.
- Using a certified, calibrated, product temperature thermometer, temperatures must be recorded twice daily (AM and PM) for all vaccine storage units. Logs must be reviewed for completeness and out-of-range temperatures. Immediate action must be taken if temperatures are out of range. Report all vaccine storage and handling issues to the Vaccine Management Unit at 617-983-6828.
- Temperature logs must be maintained for 3 years.
- All providers are required to submit current temperature logs whenever vaccines are ordered with their vaccine order form and usage report to the Vaccine Management Unit.
- All vaccine stock must be rotated so vaccine with shortest shelf life is used first.

- Stabilize refrigerator and freezer temperatures with proper placement and use of water bottles and frozen packs.

B-3. Most state-supplied vaccines will be shipped directly to providers by a third party distributor. There may be times when some state-supplied vaccine might be distributed from a local or regional depot. Providers must transport vaccine back to their offices from their local or regional distributor in an insulated cooler.

B-4. The provider will maintain an accurate record of vaccines received from the MDPH Immunization Program. This record must include:

- Type of vaccine
- Manufacturer
- Lot number
- Expiration date
- Number of doses received.

B-5. Providers must accurately complete MDPH's vaccine order forms and usage reports, which include inventory, lost and expired doses. All vaccine with the exception of varicella, MMRV, and Zostavax vaccine, will be shipped to you by McKesson Specialty Distribution. Varicella MMRV, and Zostavax vaccine will be shipped to you by Merck & Co., Inc.

- The usage report form and current temperature logs must accompany every order form to receive vaccine. These 3 forms should be faxed to the Vaccine Management Unit at 617-983-6924.
- Providers with computerized vaccine usage and inventory systems may submit data directly to the MDPH Immunization Program electronically. All computerized reporting systems must be pre-approved by the MDPH Immunization Program. For approval, call 617-983-6828.

B-6. Providers must complete a physical inventory of state-supplied vaccines, prior to submitting vaccine orders, and document this inventory on the vaccine order form.

- Providers must call the Vaccine Management Unit at 617-983-6828 for instructions and approval before returning expired, damaged or contaminated state supplied vaccine. Account for all wasted state supplied vaccine on the approved Vaccine Return Request Form.
- Do not use mishandled or damaged vaccine.
- Determine vaccine ordering levels for each vaccine so that orders for all vaccines are placed at the same time. Depending on the quantity of vaccine you administer during the year, vaccine shipments could be as frequent as every month, every 2-3 months or as needed. Expect order delivery no later than 14 days after order placement.
- Open box of vaccine immediately. Check the two transit temperature monitors. You must contact the Vaccine Management Unit within 2 hrs of receipt of vaccine if temperature monitors indicate a possible temperature variation. Check to see if the packing list matches your vaccine order. If there are any problems or inconsistencies between your order and the vaccine received, contact the Vaccine Management Unit immediately at 617-983-6828.

B-7. Providers agree to use state-supplied vaccines only within their own office/clinic setting. They further agree not to sell, distribute or transfer vaccines provided by the MDPH Immunization

Program to any other person, clinic or organization. Redistributing state-supplied vaccine may take place only with permission from the MDPH Vaccine Management Unit.

C. Billing and Charging for State-Supplied Vaccine

C-1. Providers may not impose a charge for the cost of state-supplied vaccine to a patient or a third-party (e.g., insurance company or Medicaid).

C-2. Providers may charge an administration fee of not more than $15.78 per dose for non-Medicaid (uninsured or underinsured) VFC-eligible patients. For Medicaid VFC-eligible children, accept the reimbursement for vaccine administration set by the Massachusetts Medicaid agency or the contracted Medicaid health plans. Providers may bill administration fees to third party payers in accordance with the terms of their contracts. Any administration fee must be waived if a patient is unable to pay. MDPH recommends a sign that states **NO ELIGIBLE CHILD MAY BE DENIED STATE-SUPPLIED VACCINE DUE TO INABILITY TO PAY FEE** be posted in the provider's office. This sign is available from the MDPH Immunization Program in English and Spanish.

D. Vaccine Information Statements (VIS) and Consent

D-1. All providers, including public clinics and private offices, are required to provide a copy of the relevant, current edition of the Vaccine Information Statement (VIS) produced by the Centers for Disease Control and Prevention (CDC) before administering each dose of vaccine (NCVIA: 42 U.S.C. Section 300aa-26). VISs provide risk-benefit information. VISs must be given for all vaccines and toxoids covered by the NCVIA, whether the vaccine was state-supplied or privately purchased. Each patient or parent/legal representative receiving vaccine must receive a copy of the VIS prior to administration of vaccine. There are additional requirements relating to the use of VISs in school-based or other programs where the parent or legal representative is not likely to be present at the time of immunization. Please see item D4 below.

D-2. VISs must be used for the vaccines and toxoids specified in the NCVIA: measles, mumps and rubella containing vaccines (MMR, MR, M, R); diphtheria and tetanus toxoids (DT); tetanus and diphtheria toxoids (Td); tetanus toxoid (T); diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP); tetanus toxoids, diphtheria and acellular pertussis (Tdap); pertussis vaccine (P); inactivated polio virus vaccine (IPV); hepatitis B vaccine (HBV); *Haemophilus influenzae* type B vaccine (Hib); varicella vaccine; pneumococcal conjugate 7-valent vaccine, hepatitis A vaccine (HAV); trivalent influenza vaccine (both inactivated influenza vaccine [TIV] and live, attenuated influenza vaccine[LAIV]); rotavirus vaccine; meningococcal vaccines (MCV4 and MPSV4) and human papillomavirus vaccine (HPV).

VISs should also be used for vaccines not currently specified in the NCVIA: hepatitis B immune globulin (HBIG); pneumococcal polysaccharide 23-valent vaccine; shingles vaccine and other vaccines/toxoids. Information about the National Vaccine Injury Compensation Program can be found at http://www.hrsa.gov/vaccinecompensation.

D-3. It is the provider's responsibility to maintain copies of the most up to date VISs in their office. All VISs, in many languages, are available in print and audio format. We recommend you assign someone in your office to be the VIS coordinator. Subscribe to CDC's e-mail update for Vaccine

Information Statements (VIS) at http://www.cdc.gov/vaccines/pubs/vis/default.htm, click on "Get E-Mail Updates," and enter your e-mail address.

D-4. In school-based programs, or other programs where the parent or legal representative is not likely to be present at the time of immunization, the parent or legal representative may:

- Sign individual consent forms for the administration of each dose in the series which include acknowledging receipt of the VIS; or
- Sign a single consent form for the administration of the series which includes acknowledging receipt of the VIS.

It is important to consult with your institution's legal counsel about policies or requirements specific to your institution regarding consent and consent forms.

VISs for additional doses in the series may be mailed or sent home with the student prior to administration of the next dose. If the school-based program chooses to use only one consent form, the additional VISs must be accompanied by a statement notifying the parent that based on their earlier permission the next dose will be given (list the date), unless the parent withdraws permission for the child to receive the following doses. School-based programs must maintain the original consent signature or any "veto statements" in the patient's medical record. A record of the dates that the VIS was mailed or sent home with the student must also be maintained.

In addition, procedures must be established for responding to questions by telephone or mail in cases of a school-based program, or other programs where the VISs are read and signed by the parent or legal representative, who will not be present at the immunization site when the immunization is given.

D-5. **There is no federal or state requirement that providers, public or private, obtain the signature of parents or legal representative acknowledging the receipt of the VIS. However, providers may choose to obtain these signatures.**

E. Documentation of Vaccine Administration

E-1. Providers must ensure that the permanent medical record of the recipient (or a permanent office log or file) contains all the required documentation. This documentation shall consist of the following:

- Date of administration of the vaccine
- Vaccine manufacturer and lot number of the vaccine
- Name, address and title of person administering the vaccine
- Edition date printed on the appropriate VIS, and
- Date the VIS was given to the vaccine recipient, or the parents/legal representative.

We also recommend that the vaccine type, dose, site and route of administration be documented. Copies of vaccine administration records which can be used in your office are available by visiting http://www.mass.gov/dph/imm and selecting "Guidelines and Schedules."

E-2. Requirements for retention of written documentation vary and depend on licensing requirements:

- Clinics and hospitals: Must retain documentation for a period of *20 years* after the discharge or final treatment of the patient. State law was recently amended to require providers to

notify MDPH before destroying records. MDPH will promulgate regulations in 2009 to implement the new law, including procedures for notifying MDPH of a provider's intent to destroy records. (105 CMR: 140.302C, 105 CMR: 130.370A, MGL c111, s70).

- All other facilities, e.g., doctor offices, BOHs, VNAs, nursing homes, etc.: Must retain documentation for a period of *10 years* following the end of the calendar year in which the documentation occurred (NCVIA 1986).

State regulations regarding record retention and destruction (including new regulations pertaining to clinics/hospitals) can be found at the Division of Healthcare Quality website by visiting http://www.mass.gov/dph/dhcq, selecting "Regulations, Amendments and Public Hearings" in the Health care Quality Topics section, and then selecting "Amendments and Revisions to Regulations."

An additional requirement applies to all categories of providers. If a notice of a claim or lawsuit has been made, the VIS, Provider Enrollment Form and other types of approved documentation pertaining to the matter must be retained until a final disposition of the claim or litigation (including appeals) has been made.

F. Reporting Adverse Events

F-1. Provider must report events as outlined in the *Vaccine Injury Table* (http://www.hrsa.gov/vaccinecompensation/table.htm). Also included as reportable are events listed in the vaccine manufacturer's package insert as contraindications to receiving additional doses of vaccine and any other serious or unusual event. Adverse events should be reported via the Vaccine Adverse Events Reporting System (VAERS). All providers except boards of health should obtain and forward the VAERS forms to:

VAERS
C/o ERC BioServices Corporation, A Division of Ogden Biomedical Service Group
First Street, Rockville, MD 20850

Board of health clinics and clinics run by visiting nurse associations (VNAs) for boards of health in Massachusetts should obtain and forward their VAERS forms to:

MDPH Immunization Program
State Laboratory Institute
305 South Street, Jamaica Plain, MA 02130
617-983-6800

VAERS forms and instructions are available in the FDA Drug Bulletin, the Physician's Desk Reference, or by calling VAERS at 1-800-822-7967. Providers can also report adverse events on line by utilizing the VAERS web site at http://www.vaers.hhs.gov.

F-2. Each vaccine recipient or the vaccine recipient's parent/legal representative will be furnished with a personal immunization record listing the type, dosage, and the date (month, day, and year) of each vaccination. The *Lifetime Health and Vaccination Record* (the Blue Book) is recommended (available from the MDPH Immunization Program). Information on the required immunization schedules, the vaccine injury compensation program, and claim filing should also be made available.

F-3. The requirements contained in these guidelines must be communicated to any other health care personnel administering vaccine under the supervision of the physician signing this agreement.

G. Responsibilities of the Medical Director

G-1. The Medical Director, on behalf of himself or herself and all practitioners associated with the entity, is responsible for ensuring that state-supplied vaccine, including VFC vaccine, is administered in compliance with federal requirements for administration of vaccine. Failure to comply with federal requirements as outlined in this document may constitute fraud and abuse, and may be punishable by law (Medicaid regulation: 42 CFR §455.15).

G-2. The Medical Director is responsible for signing the *Provider Enrollment Form* and *Agreement to Comply with Federal and State Requirements for Vaccine Administration*, providing the MDPH Immunization Program with an accurate *Practice Profile* and providing the names of all physicians, physician assistants and nurse practitioners in the practice/clinic, with their corresponding medical license number.

G-3. MDPH Immunization Program staff are required to make an initial educational site visit to a provider who is enrolling in the VFC Program for the first time. The enrollment visit ensures that the provider and office staff are educated on the VFC Program requirements and have appropriate resources to implement these requirements.

G-4. The Medical Director understands and agrees that MDPH Immunization Program staff are required to make site visits to evaluate vaccine handling and storage, VFC screening and record keeping, and to assess immunization levels.

G-5. The Medical Director is responsible for the staff who order, store, administer and report on vaccine usage. Any change in Medical Director must be reported to the MDPH Immunization Program within ten (10) days.

G-6. The Medical Director is responsible for assuring that:

- Immunization policies and practices are in compliance with the *Standards for Child and Adolescent Immunization Practices* (Pediatrics October 2003;Vol.112, No.4, p.958-963) and
- The immunization schedule, dosage, and contraindications followed are in compliance with those established by the Advisory Committee on Immunization Practices (ACIP).[1]

G-7. Non-compliance with any of the above shall be cause to exclude the provider from continued participation in the MDPH Immunization Program/VFC Program.

H. Provider-Based Assessments

H-1. Providers will be assessed for compliance with VFC and other federal requirements in accordance with MDPH guidelines.

H-2. If any problems are identified with VFC compliance, the provider will be entered into an educational follow-up process in accordance with CDC fraud/abuse guidelines.

[1] The ACIP immunization schedule is compatible with the AAP and AAFP recommendations.