

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**

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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).

Please note, children enrolled in sCHIP or the Children's Medical Security Plan (CMSP) are also covered with state funds.

- 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 can 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 a VFC Site Visit.
- 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 protocol must be followed when problems are identified in providers' offices. This protocol 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. The Massachusetts Department of Public Health (MDPH) may require providers to make restitution for any doses of federal or state-purchased vaccines that have been wasted due to the provider's failure to properly receive, store, or use vaccine inventory. See section A-6 below for additional information about the restitution policy. Examples of provider negligence include (but are not limited to):
 - Failure to open vaccine shipments from McKesson or Merck immediately which results in damage to the vaccines
 - Failure to rotate vaccine stock which results in expired vaccine
 - Allowing vaccine to expire. You must contact the Vaccine Unit 2 months prior to vaccine expiration.
 - Freezing vaccines meant to be refrigerated
 - Refrigerating vaccines meant to be frozen
 - Refrigerator or freezer left unplugged, or electrical breaker switched off by provider staff, contractor or any other individual
 - Refrigerator or freezer door left opened or ajar by provider staff, contractor, or any other individual.
 - Vaccine that is left out of the refrigerator unit and becomes non-viable (Always call the Vaccine Management Unit @ 617-983-6828 to determine if vaccines can be identified as viable.)
 - Any power outages in which the provider fails to act according to their vaccine storage back up plan
 - Ordering VFC vaccine in quantities or patterns that do not match provider profile or otherwise involve over-ordering of VFC or state-supplied vaccine doses.

- Wastage of VFC or other state-supplied vaccine.
- Any other handling and storage mistakes by provider staff.

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

- A-6 MDPH will require providers to make restitution for any doses of federal or state-purchased vaccines that have been lost due to the provider's failure to properly receive, store, or use vaccines (as outlined in section A-5 above) if:
- a. it is the 1st incident and the total loss is over \$10,000, or
 - b. it is the 2nd incident (or greater) regardless of total value, or
 - c. it is due to a failure to immediately open a vaccine shipment from McKesson or Merck resulting in damaged vaccine regardless of total value.

NEW

MDPH will notify the provider in writing concerning the number of doses of each vaccine that must be replaced. Vaccine orders from the provider will not be processed by the Vaccine Management Unit until a copy of the invoice for the replacement vaccine has been received by MDPH, reviewed, and determined to be adequate.

Providers may also propose to MDPH to purchase new vaccine storage and/or monitoring equipment (i.e. refrigerator, temperature monitoring devices, alarms) in lieu of or in addition to replacement vaccine. The cost of the new equipment will be deducted from the total amount of replacement vaccine that will need to be purchased. All purchases must be preapproved by MDPH and evidence of the new purchase (i.e. invoice and/or packing slip) must be sent to the Vaccine Management Unit.

Please note that the MDPH will only hold providers accountable in situations of provider negligence as outlined above and will not seek restitution for a vaccine loss that occurred due to a circumstance not in the provider's control (i.e. act of nature). Providers will be given due process to dispute cases of avoidable loss. Procedures for appealing a restitution decision will be included in the formal restitution notification given to practices. However, MDPH retains the right to make final determinations regarding vaccine restitution.

B. Vaccine Management

B-1. Providers will have written procedures for vaccine management which are reviewed or updated annually or when there's a change in responsible staff, 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.

NEW

- Protocols for response when vaccine is stored out of temperature range.

A sample copy of MDPH's *SOP for Vaccine Management* can be found on DPH website at: www.mass.gov/eohhs/docs/dph/cdc/immunization/vaccine-management-sop-sample.pdf.

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. For more information on storing, transporting, and handling of vaccines see the CDC Vaccine Storage and Handling Guide at: www.cdc.gov/vaccines/recs/storage/default.htm.

. Proper vaccine management includes:

- All vaccines, with the exception of varicella, MMRV, and Zostavax vaccine must be stored refrigerated between 2°C and 8°C (35°F and 46°F).
- Varicella, MMRV, and Zostavax vaccine must be stored frozen between -50°C and -15°C (-58°F and 5°F). DO NOT store the diluent in the freezer. The diluent for these vaccines may be stored in the refrigerator or at room temperature.
- MMR may be stored in the freezer to reduce the likelihood of a vaccine loss due to a refrigeration issue since MMR is much more temperature sensitive than other vaccines. Storing MMR in the freezer can also free up storage space in the refrigerator for other refrigerated vaccines. DO NOT store the diluent in the freezer. The diluent may be stored in the refrigerator or at room temperature.
- 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. If a practice is discovered to be using this type of unit as their main vaccine storage unit, they will be suspended from ordering vaccines until the unit is replaced and the invoice faxed to the vaccine unit.
- Stand alone refrigerator and stand alone freezer units are the preferred units for storage of vaccines. The size of the refrigerator should be able to accommodate your largest vaccine supply. Combination household style refrigerator units with 2 thermostats are acceptable. The use of combination household refrigerator units with one thermostat is strongly discouraged.
- "DO NOT DISCONNECT" signs should be placed on the refrigerator/freezer electrical outlet and circuit breakers.
- Vaccines should **not** be stored on the refrigerator or freezer door or in storage bins.
- Food or beverages should **not** be stored in vaccine storage units.
- 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 preferably at the start of the work day and at the end of the work day. 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.

- All inventory must be checked for short-dated (2-3 month shelf life) product that might not be used before expiring. This product needs to be moved to another facility so that the vaccine is not wasted and you will not have to make restitution by replacing the doses. Call the Vaccine Management Unit @ 617-983-6828 to help facilitate this process.
 - Stabilize refrigerator and freezer temperatures with proper placement and use of water bottles and frozen packs.
 - Should the temperature of the vaccine storage unit need adjusting, it should only be done after vaccines have been removed and stored in a temporary storage unit. Please call the Vaccine Unit for consultation before attempting to do this.
- 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. In such circumstances, 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, doses administered, 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 checking expiration dates, 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 McKesson Specialty at 877-836-7123 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.

B-8. Providers will maintain all records related to the VFC Program for at least a period of 3 years. These records include the authorized representative's response about a child's eligibility, temperature logs, and receipt of all state provided vaccines. Release of such records will be bound by the privacy protection of Federal Medicaid law. If requested, I will make such records available to the MDPH Immunization Program or the federal Department of Health and Human Services (DHHS).

B-9. For additional guidance about vaccine storage and handling please refer to Section E of MDPH's *General Protocols for Vaccine Storage, Administration, Standing Orders and Mass Immunization Clinics* available at: http://www.mass.gov/Eeohhs2/docs/dph/cdc/immunization/mso_protocols_general.pdf .

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, underinsured or who are American Indian or Alaskan Native) 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). Either a paper or electronic copy of the VIS must be available to read during the immunization visit. A paper copy must also be offered to the patients to take home. If they prefer to take home an electronic version, patients may be directed to CDC's patient download webpage (<http://www.cdc.gov/vaccines/pubs/vis/vis-downloads.htm>) to download the appropriate VIS onto their mobile device.

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 13-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. Copies of the most recent VISs (including in foreign languages) are available online and can be downloaded from the Immunization Action Coalition website (www.immunize.org/vis). They are also available on the CDC website (www.cdc.gov/vaccines/publications/VIS) and can be downloaded directly into a personal mobile device. You can also subscribe for email notification when a VIS is updated or a new VIS becomes available at <http://www.cdc.gov/vaccines/pubs/vis/default.htm>, click on "Get E-Mail Updates," and enter your e-mail address.

Appropriate materials and information may be substituted only if VISs are unavailable. This information should be culturally and linguistically appropriate and written at a reading level that can be easily understood. The National Childhood Vaccine Injury Act requires providers to supplement the VISs with "visual presentations" or "oral explanations" as needed. If patients are unable to read the VISs, it is up to the provider to ensure that they have access to the information they contain. VISs can be read to these patients, or videotapes can be used as supplements. Audio files and versions of VISs that are compatible with screen reader devices are available on CDC's VIS website.

- 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 an individual consent form for the administration of each dose of vaccine, which includes acknowledging receipt of the VIS prior to each dose; or
 - Sign a single consent form for the administration of an entire vaccine series (e.g. hepatitis B vaccine), if permissible by the institution's legal counsel. Single signature consent forms must:

- Have a place for the parent/legal representative acknowledging the receipt of the VIS and give permission for their child to be vaccinated with the complete series.
- Describe the future process whereby the VIS shall be sent home prior to each subsequent dose.
- State that a “Withdrawal of Permission Form” will be sent home with the VIS prior to each subsequent dose. This statement notifies the parent or legal representative that, based on their earlier permission, the next dose will be given (list the date), unless the parent or legal representative signs the “Withdrawal of Permission Form”.

Establish procedures for responding to questions from parent or legal representative by telephone or mail.

In the patient’s medical record, maintain the original consent signature(s), any “Withdrawal of Permission Forms”, and dates the VISs were sent home to the parent or legal representative.

Consult with the institution’s legal counsel about any policies or requirements specific to the institution regarding consent and consent forms.

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.

Regardless of the setting or whether you are vaccinating children or adults, all providers are encouraged to consult with their legal counsel and/or follow their institution’s policies regarding consent.

**D-6. For additional guidance about required patient education and consent please refer to Sections C and D of MDPH’s *General Protocols for Vaccine Storage, Administration, Standing Orders and Mass Immunization Clinics* available at:
http://www.mass.gov/Eeohhs2/docs/dph/cdc/immunization/mso_protocols_general.pdf .**

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 and title of person administering the vaccine
- Address of clinic where vaccine was given
- 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. You may record the initials of the vaccinator in place of the full name and title as

long as the vaccine administration record contains a legend that has the full name and title and its corresponding initials.

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.

E-3. For additional guidance about vaccine administration and documentation policies and procedures please refer to Sections F and G of MDPH’s *General Protocols for Vaccine Storage, Administration, Standing Orders and Mass Immunization Clinics* available at: http://www.mass.gov/Eeohhs2/docs/dph/cdc/immunization/mso_protocols_general.pdf .

F. Vaccine Safety

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.
- F-4. In addition to reporting adverse events, MDPH also recommends reporting medication errors to the Institute for Safe Medication Practices (ISMP), a non-profit organization, educating the healthcare community and consumers about safe medication practices

Errors, near-errors or hazardous conditions to be reported include, but are not limited to, administering the wrong drug, strength, or dose of medications; confusion over look-alike drugs; incorrect route of administration; calculation or preparation errors; misuse of medical equipment; and errors in prescribing, transcribing, dispensing, and monitoring of medications. Providers can report medication errors by utilizing the ISMP website at: <http://www.ismp.org>.

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). The Medical Director must ensure that all communications from MDPH regarding immunizations or vaccine preventable diseases are disseminated to all relevant staff within his or her facility. MDPH recommends each practice or agency have a communication plan and identify a person responsible for disseminating information.
- G-2. The Medical Director is responsible for signing and initialing 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 and Medicaid number where applicable.

- 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 biannual 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 identifying an Immunization Contact Person. The Immunization Contact Person is responsible for communicating vaccine policy, vaccine availability, updates, and alerts to all pertinent staff.
- G-7. 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-8. 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 biannually.
- 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.

I. Additional Guidance

For additional information about the policies and procedures for vaccine administration, screening for contraindications and precautions, guidelines for busy providers offices and mass vaccination clinics, including polices related to pre-filled syringes, please refer to Section I of MDPH's *General Protocols for Vaccine Storage, Administration, Standing Orders and Mass Immunization Clinics* available at:
http://www.mass.gov/Eeohhs2/docs/dph/cdc/immunization/mso_protocols_general.pdf .

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