

**Vaccine Storage & Handling and
VFC Compliance Training
MIAP, October 2016**

Massachusetts Department of Public Health
Immunization Program

Presenter Disclosure Information

- I, Robert Morrison, have been asked to disclose any significant relationships with commercial entities that are either providing financial support for this program or whose products or services are mentioned during my presentations.
 - I have no relationships to disclose
- I may/will discuss the use of vaccines in a manner not approved by the U.S. Food and Drug Administration.
 - But in accordance with ACIP recommendations.

2

Introduction

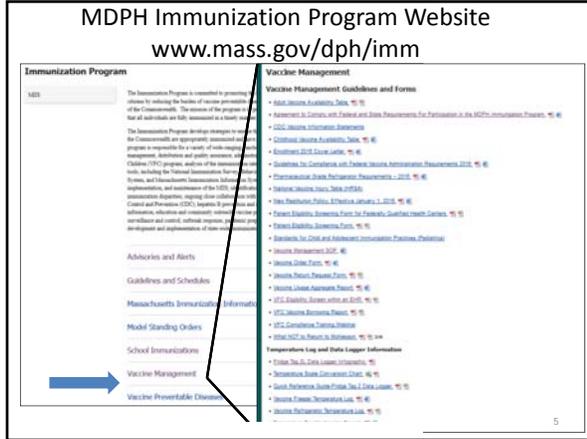
- The Vaccine Coordinator and back-up Vaccine Coordinator at each VFC provider site must receive an annual educational training covering VFC requirements including proper vaccine storage and handling. This requirement will be met by attending today's presentation.
- It can also be met by:
 - VFC compliance site visit
 - Webinar training
 - In-person training
 - Other Workshops (i.e. Immunization Updates in spring)

3

Introduction

- All vaccine storage and handling and VFC requirements and recommendations are detailed in the Guidelines for Compliance with Federal and State Vaccine Administration Requirements.
- Available on our website: www.mass.gov/dph/imm and click on 'Vaccine Management'

MDPH Immunization Program Website www.mass.gov/dph/imm



Annual Enrollment

- **In December, providers must complete their annual enrollment in the MIIS. The Medical Director “signs” and agrees to be responsible for**
 - Following the requirements outlined in the Agreement to Comply with Federal and State Requirements for Vaccine Administration.
 - Complying with ACIP recommended immunization schedule.
 - Providing the MDPH with an accurate Practice Profile.
 - Identifying a Vaccine Coordinator and back-up, who will be responsible for all vaccine storage and handling.
 - Reporting any change in the Vaccine Coordinator or back-up to the MDPH within ten (10) days.

Updating Standard Operating Procedure (SOP)

- After enrolling, providers can use the template provided on the MDPH website to update and customize their SOP, including
 - Proper storage and handling of vaccines
 - Vaccine receiving
 - Procedure for vaccine relocation in the event of power or equipment failure
 - Vaccine ordering and inventory control
 - Handling damaged or expired vaccines
 - Protocols for response and documentation when vaccine is stored out of temperature range

7

Vaccine Management

- Each provider must designate one staff member to be the Vaccine Coordinator and one back up person who is able to perform the same responsibilities.
- The Vaccine Coordinator must train other staff responsible for managing the vaccine supply.
- Training certificates given during immunization program site visits or from attendance of immunization program trainings/webinars must be kept on file.
- MDPH must be notified within 10 days when there is a change in Vaccine Coordinators so that a training can be scheduled.

8

Updating SOP

- The Vaccine Coordinator must ensure that
 - all staff who handle or administer vaccines read the updated SOP and sign and date the last page.
 - post the SOP on the vaccine refrigerator or another convenient location.
 - the SOP will be updated annually or with any changes.



9

Appropriate Use of State-Supplied Vaccine

- 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, or
 - Adult Vaccine Availability Table



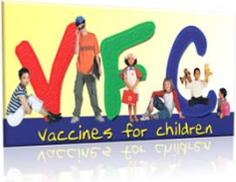
10

VFC Eligibility Screening

- Providers must screen all children at every immunization visit to determine VFC-eligibility.
- These results must be documented at every visit.
- Results can be recorded electronically if it can be retrieved in the event of a VFC compliance site visit.

11

VFC Eligibility



Birth through 18 years of age:

- Enrolled in Medicaid
- Without health insurance
- Under-insured and seen at federally qualified community health center
- American Indian (Native American) or Alaska Native

12

VFC Eligibility

- If recorded electronically only the following categories are acceptable:
 - VFC eligible – Medicaid
 - VFC eligible – uninsured
 - VFC eligible – American Indian (Native American) or Alaska Native
 - VFC eligible – under-insured (ONLY for use at FQHC)
 - Not VFC eligible – private insurance

13

Vaccine Inventory & Borrowing

- Providers must not borrow state-supplied vaccine for an adult patient.
- Vaccine borrowing should be rare and only as a last resort to avoid a missed opportunity.
- If a provider borrows state-supplied vaccine, a Vaccine Borrowing Report Form must be completed.
 - The borrowing report is available on-line: mass.gov/dph/imm, click on Vaccine Management.
- A copy of the invoice for the privately purchased vaccine must be kept on file.
- Borrowing reports must be available for review during a site visit.

14

Fraud (as defined by CDC)

- Fraud is as an intentional deception or misrepresentation made by a person with the knowledge that it could result in some unauthorized benefit to him/herself or some other person.
- Improper use of VFC vaccine may constitute fraud and is punishable by law (Medicaid regulation: 42 CFR §455.2 and applicable state law).

15

Abuse (as defined by CDC)

- Abuse is provider practice that is inconsistent with sound fiscal, business, or medical practices and result in unnecessary cost to the Medicaid program, and/or including:
 - actions that result in unnecessary cost to the immunization program, or
 - 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.

16



Restitution Policy



- 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 if:
 - 1st incident and the total loss is over \$10,000
 - 2nd incident (or greater) regardless of total value
 - Due to a failure to immediately open a vaccine shipment from McKesson or Merck resulting in damaged vaccine regardless of total value.
 - Due to a failure to store refrigerated vaccine in a refrigerator or failure to store frozen vaccine in a freezer.

17

Vaccine Storage

- Maintain refrigerator temperature between 2°C to 8°C (36°F and 46°F).
- Maintain freezer temperature between -50°C and -15°C (-58°F and +5°F) for varicella and MMRV vaccine storage.
- Place temperature data logger vial in a central area of the storage unit adjacent to the vaccines and away from any air vents.

18

Temperature Adjustment

- Never adjust the refrigerator temperature control with vaccine in the unit.
- Remove refrigerated vaccine to another refrigerator before adjusting temperature.
- Wait until you have successive readings one hour apart before returning vaccine to the unit.
- If you have questions, call the Vaccine Management Unit.

19

Stabilize Your Refrigerator

Stabilize your refrigerator temperatures by placing water bottles where vaccine should not be stored (on the bottom shelf in the refrigerator).



Store cold packs in the refrigerator and ice packs in your freezer as part of your emergency plan in case you need to transport vaccine during an emergency.

20

Vaccine Storage Units

- MDPH now requires pharmacy grade refrigerators for all primary and co-primary vaccine storage units for pediatric vaccines.
 - Co-primary is a second refrigerator used for bulk vaccine storage
- Pharmacy grade refrigerators are strongly recommended for all secondary vaccine storage units.
- A stand alone freezer that can maintain the proper temperatures will be acceptable.

21

Pharmaceutical Grade Refrigerator

- Although there is no clear description of a pharmaceutical refrigerator, we have identified the following characteristics:
 - Internal fans to disperse cold air throughout the unit, eliminating cold pockets of air
 - Wire racks to allow better air flow
 - No storage bins, or shelves on door
 - Typically, pharmaceutical grade refrigerators have a narrow operating range (less than 2 Celsius degrees or 3 Fahrenheit degrees)

22

Loading vaccines

- Keep vaccines in original manufacturer packaging →
 - Don't remove individual vials from cardboard boxes
- Place vaccine boxes in trays
- Organize vaccines by type, state/private, to facilitate quick retrieval and minimize time with refrigerator door open
- Avoid over-filling refrigerator and hindering air circulation →



23

Appropriate Temperature Monitoring & Documentation

- NIST certified calibrated digital data loggers for continuous 24-hour temperature monitoring for all vaccine storage units at all pediatric providers (any site that administers vaccines to those <19 years of age) will be required by MDPH in 2017.
- These data loggers should have a biosafe glycol-encased detachable temperature probe.
- The data logger must record the minimum and maximum temperature each day.
- Providers must still physically acknowledge the high/low temperatures at least twice daily.

24

Appropriate Temperature Monitoring & Documentation

- Immediate action must be taken if temperatures are out of range.
- Report all vaccine storage issues, including temperature excursions, to:
 - Vaccine Management Unit at 617-983-6828.
- Record your contact with the Vaccine Unit
 - Date, time, name of the person you talked with, steps and outcome.
 - Providers are responsible to keep a log of their contact with the Vaccine Unit following temperature excursions.
 - There is a “temperature troubleshooting document” on our web site for documentation.

25

MDPH-Supplied Data Loggers

- All Fridge-tag®2 refrigerator and freezer data loggers have been replaced by Fridge-tag®2L data loggers



26

Data Logger Replacements

- Fridge-tag®2L data loggers have a 3-year battery life and calibration
- Data logger reports have pdf and txt files to allow temperature reporting in 5-minute intervals
- Graphs are available for determining the length and frequency of freezer defrost cycles
- MDPH plans to supply Fridge-tag®2L data loggers for all secondary vaccine storage units at pediatric sites before the end of 2016

27

Vaccine Ordering

- Providers must place vaccine orders using the Vaccine Management Module of the MIIS.
- Vaccine should be ordered on a replacement basis. Typically when there is a one-month inventory remaining.
- Inventory and usage for each vaccine must be identified by lot number and expiration date.
- Data logger reports must be submitted with each order and uploaded electronically in the MIIS.

31

Vaccine Shipments



32

Expired or Damaged Vaccines

- Providers must complete a physical inventory of all state-supplied vaccines checking expiration dates prior to submitting vaccine orders.
- Vaccines should be transferred to another site 2-3 months prior to expiration.
- Any expired, damaged, or contaminated vaccine must be reported in the MIIS when placing your vaccine order.
- Any expired, damaged, or contaminated vaccine should be:
 - Immediately removed from the refrigerator;
 - labeled "Do Not Use"; and
 - packaged for return to McKesson.

33

Record Maintenance

- Accurate record of all vaccines received from MDPH:
 - type, manufacturer
 - lot number
 - expiration date
 - total doses
 - This information is on the packing list from McKesson and Merck
- Patient Eligibility Screening documentation
- Temperature logs
- All records must be maintained for at least 3 years and most of this information can be maintained electronically in your electronic health record (EHR) or and/or the MIIS

34

Billing & Administration Fees

- Providers may not bill for the cost of any state-supplied vaccines.
- Providers may charge an administration fee of not more than \$23.29 per dose for non-Medicaid VFC-eligible children.
- Providers may not deny state-supplied vaccine to an established patient due to the inability to pay the administration fee.

35

Complying with ACIP Immunization Schedule

- The Medical Director of the practice is responsible for assuring that:
 - Immunization policies and practices are in compliance with the Standards for Child and Adolescent Immunization Practices, and
 - The immunization schedule, dosage, and contraindications followed are in compliance with those established by the ACIP.
- Non-compliance may result in exclusion from continued participation in the MDPH Immunization Program/VFC Program.

36

Vaccine Information Statements (VIS)



- All providers, including public clinics and private offices, are required to provide a copy of the relevant, current edition of the VIS produced by the CDC before administering a dose of vaccine (NCVIA: 42 U.S.C. Section 300aa-26).
- Copies of the most recent VIS can be found at www.immunize.org/vis or on the CDC website at www.cdc.gov/vaccines/hcp/vis/index.html

37

Vaccine Safety

- Providers must report events as outlined in the Vaccine Injury Table.
- Adverse events should be reported via the Vaccine Adverse Events Reporting System (VAERS).
- VAERS forms and instructions are available in the FDA Drug Bulletin, the Physician's Desk Reference, or by calling VAERS at 800-822-7967.
- Providers can also report adverse events on line by utilizing the VAERS web site at www.vaers.hhs.gov

38

Massachusetts Immunization Information System

MIIS

- The MIIS Vaccine Management Module has been online since summer 2013. All practices are **required** to register. Make sure at least two people have a user name and password.
- The Vaccine Management Module allows for:
 - Provider enrollment
 - Inventory management
 - Vaccine ordering functionality
- Contact the MIIS Help Desk at **617-983-4335** or www.miishelpdesk@state.ma.us with any questions regarding registration.

39

VFC Compliance Site Visits

- Providers will be assessed for compliance with VFC and other federal requirements in accordance with MDPH guidelines biannually.
- If any problems are identified with VFC compliance, the provider will be entered into an educational follow-up process in accordance with the CDC guidelines.
- MDPH may conduct unannounced provider visits to serve as “spot checks” for proper storage and handling practices.

40

Provider Follow-up Plan

- All sites will receive a Provider Follow-up Plan summarizing the results of the assessment which both MDPH and Medical Director (or staff authorized to sign on behalf of the organization) must sign.
- Some type of follow up (visit, phone call, written) may be required depending on the problems identified.

41

Worried about your site visit?

- Use the Guidelines for Compliance with Federal and State Vaccine Administration Requirements as a tool.
- This document outlines all of the program requirements and recommendations. If you’re following it—you’re all set!

42

Help

- Please contact the Vaccine Management Unit at 617-983-6828 with any issue relating to vaccine availability, storage, or handling.
- Please contact the MIIS Help Desk at 617-983-4335 with any questions regarding the registry.



43
