



# Maine Immunization Program Provider Policy and Procedure Manual



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# Introduction to the Maine Immunization Program Provider Policy and Procedure Manual

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## I. Provider Manual Information

The purpose of the Maine Immunization Program (MIP) Provider Manual is to consolidate the federal Vaccines for Children (VFC) and State of Maine policies and information into one source. Throughout the year, MIP will announce new policies via official letters and memorandums. Notice of these will be done through the email notification system govDELIVERY and postings on the Maine Immunization Information System, ImmPact. To sign up to receive email updates, visit our website ([www.Immunizeme.org](http://www.Immunizeme.org)) and enter your email address in the box on the top-left side of our homepage. This manual will undergo a comprehensive review annually. Consultation on the policies in this manual are conducted routinely with the Centers for Disease Control and Prevention (CDC), the Center for Medicare and Medicaid Services (CMS), and other organizations. Both the provider manual and latest updates can be found on the MIP website at [www.Immunizeme.org](http://www.Immunizeme.org).

**Email Updates**  
Sign up below to receive program updates, our monthly newsletter and other communications.

\*Email Address

## II. Public Health Law Establishing the VFC Program and Maine Universal Vaccine Distribution

The federal VFC Program is authorized by the Omnibus Budget Reconciliation Act (OBRA), Section 1928 of the Social Security Act.

Maine Public Law 595 authorizes the universal purchase of vaccines for the children of Maine through the established Maine Vaccine Board covering all privately insured Maine children.

Funding from the federal VFC program is supplemented with both federal 317 funds and Maine private insurance companies. Section 317 of the Public Health Service Act authorized the federal purchase of vaccines to vaccinate children, adolescents, and adults. Section 317 discretionary funding also supports immunization program operations at the local, state, and national levels. The

Maine Vaccine Board facilitates the purchase of vaccines by collecting money from health plans and insurers and remitting these funds to MIP. This allows for Maine to be a universal state and provide vaccines at no cost for all Maine children through 18 years of age. The Maine Immunization Program is a voluntary program.

### **III. Vision and Mission of MIP**

The Maine Immunization Program (MIP) strives to ensure full protection of all Maine children and adults from vaccine-preventable disease. Through cooperative partnerships with public and private health practitioners and community members, MIP provides vaccine, comprehensive education and technical assistance, vaccine-preventable disease tracking and outbreak control, accessible population-based management tools, and compassionate support services that link individuals into comprehensive health care systems.

### **IV. MIP Goals**

- Raise and sustain vaccine coverage levels for infants and children
- Improve adolescent vaccine coverage levels
- Improve adult vaccine coverage levels
- Prevent and reduce cases of vaccine-preventable diseases
- Promote and practice the safe handling of vaccines and ensure the accountability of all program components

## **CHAPTER 1: MIP SITE ELIGIBILITY AND ENROLLMENT**

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### **I. Signing Provider Eligibility Requirements**

To be eligible to enroll as a MIP site, the provider agreement must be signed by one of the following types of healthcare providers:

- Medical Doctor (MD)
- Doctor of Osteopathy (DO)
- Nurse Practitioner (NP)
- Certified Nurse Midwife (CNM)

- Physician Assistant (PA)

## **II. Enrollment Requirements**

### **A. Specific Terms of Agreement**

In order to participate as a MIP site, each signing health care provider must agree to the following program requirements. By signing the provider agreement, the office and all practitioners associated with the medical site agree to the following:

- Submit a profile representing populations served by the facility annually.
- Screen for and document VFC or state eligibility of all children at each immunization encounter.
- Administer VFC and state eligible vaccine to all children 18 years of age or younger who meet the established eligibility criteria.
- Comply with appropriate vaccination schedules, dosages, and contraindications that are established by the Advisory Committee on Immunization Practices (ACIP).
- Maintain all records related to MIP for at least 3 years and upon request, make these records available for review. Digital or electronic storage of records is allowable.
- Immunize eligible children with state-supplied vaccine at no charge to the patient for the vaccine.
- Provide a copy of the most current Vaccine Information Statements (VIS) for each vaccine prior to administration of each vaccine
- Comply with MIP requirements for vaccine management, including ordering and proper storage and handling practices.
- Operate in a manner intended to avoid fraud and abuse.
- Participate in MIP compliance visits, including unannounced visits and other education opportunities, as required.
- To not charge an administration fee in excess of \$21.58 per vaccine dose (maximum regional cap established by Federal CDC).
- To not deny administration of VFC vaccine to an eligible child because of the inability of the child's parent or guardian to pay the administration fee.

- To not send a patient to collections or charge additional fees for non-payment of a VFC administration fee.
- To not be cited or terminated from MaineCare or CHIP.
- Acknowledge that MIP may terminate the agreement at any time for failure to comply with established requirements. If the agreement is terminated, the office and/or facility agrees to return all state-supplied vaccines.

## **B. Site Coordinator Responsibilities**

MIP requires that the signing healthcare provider designate a primary vaccine coordinator at the site who will be responsible for ensuring all vaccines are stored and handled correctly. It is also required that a second staff member at the facility be named to serve as the alternate in the absence of the primary coordinator. Both coordinators must be physically located at the clinic site and must be fully trained in routine and emergency policies and procedures.

The primary and backup vaccine coordinators are required to implement, oversee, and monitor the following MIP requirements:

- Ensure only eligible patients receive MIP vaccines.
- Set up data loggers in storage units.
- Ensure staff are familiar with the operations of the data loggers including how to download data (monthly download required, recommended weekly).
- Monitor, read and record the minimum and maximum temperatures of the units (refrigerators and freezers) at the beginning of each workday.
- Monitor the operation of storage equipment and systems.
- Maintain all documentation, such as inventory and temperature logs for a minimum of three years (documentation in ImmPact meets this requirement, with the exception of temperature logs. Sites must keep the most current three months of paper temperature logs on hand in case of a temperature discrepancy or site visit.)
- Place orders for additional MIP vaccine in ImmPact.
- Reconcile inventory in ImmPact every 14 days (recommended weekly).

- Track and document doses administered (all state-supplied vaccine must be recorded in the client record in ImmPact within 5 days of administration).
- Oversee proper receipt and storage of vaccine deliveries.
- Organize vaccines to monitor expiration dates.
- Ensure vaccine is stored and handled appropriately to safeguard vaccine viability.
- Respond to out-of-range temperature excursions or respond in the event of an emergency (unit failure, power outage, disaster, etc.)
- Oversee proper vaccine transport when necessary.
- Ensure other staff are trained in the proper storage and handling of vaccines.
- Notify MIP of staff changes immediately (primary or backup vaccine coordinators or signing healthcare provider).

### **C. Initial Enrollment**

The first step in enrolling with MIP is to complete the MIP Provider Agreement. The MIP Provider Agreement must be completed and updated every two years. The agreement includes basic information about the facility and outlines the signing healthcare provider's responsibilities. The signed agreement must be received and processed by MIP before the enrolled site receives state and federally funded vaccines.

All licensed healthcare providers (MD, DO, NP, CNM, or PA) at the facility who have prescribing authority must be listed on the MIP Provider Agreement. The listing must also include the signing healthcare provider's information.

Information required for all licensed healthcare staff include the following:

- Name
- Title
- Maine Medical License Number

If the signing healthcare provider leaves the practice, the MIP Provider Agreement must be updated and signed by a new signing healthcare provider.

The profile section of the MIP Provider Agreement requests information about the site's patient population, which includes the projection and identification of clients the site will serve in the upcoming year. Existing sites must provide accurate data from the previous 12 months for both VFC eligible children and privately insured children served by the enrolled site. These numbers must be specific to the site and not be combined with other site's patient numbers if part of a larger organization. Data sources may come from the following:

- ImmPact
- Benchmarking
- Billing data
- Client encounter data

An educator from MIP will assist staff through the enrollment process. Two staff members at each provider site must be designated as primary and backup vaccine coordinators. The two staff members will be educated on how to complete the required "Vaccines for Children" training module upon initial enrollment. The educator will provide education by conducting an initial enrollment visit with the primary and backup vaccine coordinators.

MIP-enrolled sites must also enroll in the Maine Immunization Information System, ImmPact. The educator and ImmPact Help Desk will provide necessary education on ImmPact.

All licensed healthcare providers and clinicians listed on the MIP Provider Agreement will be checked against the Office of the Inspector General's (OIG) List of Excluded Individuals or Entities to ensure that all licensed healthcare professionals listed on an enrollment form are eligible to participate with MIP.

Once the forms are approved, a Provider Identification Number (PIN) is issued. The PIN will be the site's vaccine account number for the duration of the site's enrollment in MIP. The PIN is required to be included on all MIP forms and communications.

## **D. Enrollment Visit**

All new MIP sites must receive an enrollment visit prior to receiving vaccine. This enrollment visit will cover all state and federal policies. When the educator visits the new site, a review of all storage units in the office is performed to ensure adequate and approved storage units are being used. A certified and calibrated data logger must be in all units that will store MIP-supplied vaccines. Minimum and maximum temperatures must be documented at the beginning of the day for five operational days before any MIP-supplied vaccine is received. The initial enrollment visit typically takes a minimum of two hours to complete. The primary and backup vaccine coordinator must both be available to meet with the educator for the duration of the initial enrollment visit. Training for new MIP-enrolled sites will review and confirm that the staff understand and will implement all MIP requirements.

- Confirm the following:
  - Proper equipment is available to store MIP vaccine.
  - The staff understands how to properly store, handle, and monitor MIP-supplied vaccine.
  - The staff knows whom to contact if problems arise.
- Verification of the following:
  - Facility information provided on the initial enrollment form to include:
    - Shipping address
    - Phone numbers
    - Email address of primary vaccine coordinator
  - A primary and backup coordinator has been identified.
  - A plan for routine vaccine management is in place.
  - Placement of data loggers, probes, and calibration certificates.
  - Vaccine storage units have enough storage space to accommodate the maximum capacity of vaccine especially during back-to-school flu season, and anticipated new vaccines
  - “Do Not Unplug” signs are present on both the storage units and circuit breaker.

- Training also includes a review of the following:
  - MIP Provider Policy and Procedure Manual
  - Vaccine ordering and accounting in ImmPact
  - Recording temperatures in ImmPact
  - Proper vaccine storage and handling
  - Vaccine quarantine
  - Immunization guidelines and schedules
  - Maine school and daycare requirements
  - ImmPact, Maine Immunization Registry
  - Vaccine Information Statements (VIS)
  - Vaccine Adverse Events Reporting System (VAERS)
  - Vaccine safety and other resources
  - Vaccine types
  - Administering vaccines
  - Schedule and intervals of vaccines
  - Contraindications and precautions

## **E. Vaccine Accountability**

Vaccine accountability is the cornerstone of the MIP program and one of the highest priorities for a MIP-enrolled site. When a site enrolls in MIP, the staff agree to the accountability requirements as a condition of participation.

All MIP-enrolled sites must ensure the following:

- MIP-supplied vaccines are administered to eligible children or adults (317) only
  - Eligibility screening must be done at every vaccine encounter
  - Eligibility must be documented at every vaccine encounter
  - VFC eligibility is met through the following conditions:
    - Children must be 18 years of age or younger
    - MaineCare enrolled
    - Alaskan Native/American Indian
    - Uninsured
  - State-supplied eligibility is met through the following conditions:
    - Children must be 18 years of age or younger
    - Privately insured

- Underinsured
  - Adult 317 eligibility is met through the following conditions:
    - Uninsured or underinsured (insurance does not cover immunizations) adults aged 19 years and older
    - Fully insured individuals 19 years and older, seeking vaccines during public health response activities including:
      - i. Outbreak response
      - ii. Post-exposure prophylaxis
      - iii. Disaster relief efforts
      - iv. Mass vaccination campaigns or exercises for public health preparedness
      - v. Individuals in correctional facilities and jails
- Vaccine loss and waste are minimized and documented
- Fraud and abuse does not occur
- MIP vaccine inventory is accurately reported at least every 14 days (recommended weekly)

## **F. Provider Change of Information**

It is the responsibility of the staff at the MIP-enrolled site to maintain correct demographics, days, and hours available to receive vaccine shipments, and profile information in ImmPact. MIP must be contacted immediately if there is a new signing healthcare provider or a change in staff that are assigned the duties as a primary or backup vaccine coordinator. In addition, it is the MIP-enrolled site staff's responsibility to update ImmPact with that current information. New primary or backup vaccine coordinators are required to complete the "Vaccines for Children" education module on the MIP website.

The MIP Provider Agreement and profile must be updated if the MIP-enrolled site's patient population changes or when the healthcare provider that signed the agreement is no longer associated with the site.

Failure to properly update current site information may result in vaccine delays and possible negligent vaccine loss.

## **G. Annual Re-Enrollment**

MIP's re-enrollment is required on a biannual basis. However, some documents will be required annually. MIP will send communication through the govDELIVERY listserv and post announcements on ImmPact to notify sites of any upcoming required documents. The following documents and timeline will be followed to maintain enrollment:

### **Annually (Due by July 1st)**

- ImmPact User Agreements- MIP requires all users to provide a signed [ImmPact user agreement](#) in order to continue to have access to the ImmPact system. All accounts without an updated user agreement by July 1<sup>st</sup> will be terminated until a completed form has been submitted.
- Vaccine Need – The “Vaccine Need” represents populations served by the MIP-enrolled site during the most recent 12 months and helps MIP determine how much vaccine to supply to each site. Each site must submit the vaccine need in ImmPact, by July 1<sup>st</sup>. The Vaccine Need can be found under the “maintenance” section in ImmPact.

### **Biannually (Due by July 1\*)**

- Provider Agreement – MIP requires that the MIP Provider Agreement be submitted every two years. The provider agreement will be available during the month of June to complete and obtain a healthcare provider signature.
- MIP-enrolled sites must also submit a copy of their calibration certificates for all primary and backup data loggers that are used to monitor the temperatures in units that store MIP vaccine.

Vaccine shipments may be interrupted for sites without current enrollment information on file.

### **Annually (Due by October 1)**

- Education Requirement – The assigned primary and backup vaccine coordinators are required to complete the “Vaccines for Children” training each year.
  - The required training will become available on the MIP website by July 1

- and must be completed by October 1 of each year.
- Any new primary or secondary coordinators should complete the training upon being added to their provider agreement and prior to their first order.
    - If you are a new vaccine coordinator and need to complete your post-test prior to July 1, you may contact 207-287-3746 or email [ImmunizeME.DHHS@maine.gov](mailto:ImmunizeME.DHHS@maine.gov) to request a copy.
  - Any trainings completed prior to July 1 (with the exception of new providers) will not count towards satisfying the requirement in the upcoming fiscal year.

\*July 1 signifies the beginning of Maine's cooperative agreement year. Maine's cooperative agreement year runs from July 1 to June 30.

### **III. Withdrawal from MIP**

MIP must be contacted if a MIP-enrolled site chooses to withdraw from the program. MIP will arrange to pick up MIP-supplied vaccine and will assist with final paperwork. Prior to withdrawal, it is requested that the site staff complete a withdrawal form and submit to MIP.

### **IV. Suspension from MIP**

If it is determined that the MIP Provider Agreement or accountability requirement have been violated, the enrolled site may temporarily lose program privileges. Suspension is dependent upon the severity of the non-compliance issues and/or failure to complete the MIP required corrective action plans. MIP corrective action plans are set in place to correct failures in vaccine management and non-compliance issues, including, but not limited to; failure to complete re-enrollment in a timely manner, failure in vaccine management, failure of required patient eligibility screening, improper storage and handling practices, or failure to complete bi-weekly reporting requirements. Staff at suspended sites may be required to complete additional training as part of a corrective action plan.

## **V. Termination from MIP**

A site may be terminated from MIP for continued non-compliance with MIP requirements, such as failure to complete required corrective actions associated with non-compliance.

A site may also be terminated for instances of fraud and abuse as described in *Chapter 6: Fraud and Abuse*, of this manual.

All MIP-enrolled sites will be notified of termination from the program via a signed letter from the MIP Director. Terminated sites will be removed from MIP for a period of at least one year. Sites seeking re-enrollment following the minimum termination period must seek approval to re-enroll from the MIP Director and the VFC Manager.

## **VI. Re-enrollment after Termination**

In the event that a terminated site is approved for re-enrollment in MIP, completion of a MIP-enrollment visit is required. Primary and backup vaccine coordinators must participate in this on-site education and confirm that any outstanding issues have been resolved through a focused site review and assessment.

Sites that are terminated may be considered for re-enrollment after one year, and only if the signing healthcare provider is actively enrolled in MaineCare at that time and is not listed on OIG's List of Excluded Individuals and Entities.

The MIP Director and VFC Manager have the authority to determine whether a site is eligible to re-enroll in MIP.

## **VII. Provider Code of Conduct**

Providers must communicate with Maine Immunization Program staff and others in a courteous and respectful manner. Using intimidating, threatening, vulgar, demeaning, disrespectful, discourteous and/or abusive language and/or behaviors toward, or in the presence of Maine Immunization Program staff will not be tolerated. The Maine Immunization Program reserves the right to terminate a

provider site based on these terms.

## **CHAPTER 2: PATIENT ELIGIBILITY AND SCREENING**

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### **I. Patient Eligibility Requirements**

Maine is a universal vaccine state. This means that any child 18 years of age or younger can receive MIP-supplied vaccine, with the only exception being privately insured children that are NOT Maine residents. Maine receives funding from both the Federal VFC program and from Maine health insurers to make this possible. To ensure that Maine continues to be a universal vaccine state, eligibility screening should be a top priority at all sites. An outline of the types of eligibility criteria and the requirements for screening and documentation are covered in this chapter.

Maine also provides a limited number of adult vaccines (HPV, Hepatitis A, Hepatitis A/B, Tdap, MenACWY, MenB, Pneumococcal 20, Shingles, MMR, and Varicella) to Maine residents through 317 funding. Any adult who is 19 years or older and either uninsured or underinsured can receive 317-funded adult vaccine.

#### **A. State-Supplied Vaccine Patient Eligibility Criteria**

Any child who is a Maine resident, 18 years of age or younger, and meets at least one of the eligibility criteria listed below is eligible to receive state-supplied vaccine:

- Insured
- Under-insured
  - A child who has commercial (private) health insurance, but coverage does not include vaccines; or
  - A child whose insurance covers only selected vaccines

#### **B. VFC Vaccine Patient Eligibility Criteria**

Any child who is 18 years of age or younger and meets at least one of the

eligibility criteria listed below is eligible to receive VFC vaccine:

- Enrolled in MaineCare, or is MaineCare-eligible
- Uninsured
- American Indian or Alaskan Native (in accordance with 25USC1603)

If a child is VFC-eligible in more than one category, select and document the eligibility category that will require the least out-of-pocket expense for the parent or guardian.

Immigration and/or residency status does not affect a child's eligibility for VFC vaccines.

### **C. Children's Health Insurance Program (CHIP)**

Maine has an insurance program called CHIP. An agreement between MIP and CHIP stipulates those vaccines for eligible CHIP enrollees are purchased through the federal contract. Since children with CHIP are not eligible for the federal VFC Program, MIP is reimbursed for doses administered to CHIP children based on CHIP enrollment data. MIP-enrolled sites that administer vaccines to CHIP children must actively participate in CHIP.

### **D. MaineCare as Secondary Insurance**

Children with private health insurance and MaineCare as a secondary insurance are eligible for VFC vaccines. MaineCare can be billed for the administration fee. The parent or guardian of a child with MaineCare as secondary insurance should never be billed a vaccine administration fee.

### **E. Adult Section 317 Funding**

Adults 19 years of age or older that are uninsured or under-insured are eligible for the Adult 317 funded vaccine. The 317 funded vaccine cannot be administered to insured adults with unmet high deductibles.

## **II. Patient Eligibility Screening Record**

Screening for patient eligibility is the foundation for MIP supplied vaccine accountability. Screening and documenting all children at every immunization

encounter is the only way to ensure that MIP-supplied vaccine is used only for eligible children or adults and that correct funding is used to purchase these vaccines. As such, full compliance on screening for eligibility is required. In the event improper screening results in the administration of MIP-supplied vaccine to a patient that is ineligible, staff are responsible for documenting the error on a vaccine borrowing form and immediately replacing the improperly used vaccine with private stock. Examples of ineligibility include vaccines given to privately insured non-Maine residents and patients 19 years of age or older (for VFC) or under 19 years of age (for 317).

Eligibility documentation of each child receiving MIP-supplied vaccine at every visit is required. During a child's initial visit, eligibility must be documented per MIP guidelines. Every subsequent visit must contain the child's eligibility information.

The Patient Eligibility Screening Record may be used, or staff may electronically store patient demographic information in the MIP-enrolled site's Electronic Medical Record (EMR) or Electronic Health Record (HER). Eligibility screening must be completed/updated for all children at every visit, even children with a previous record on file and must be documented prior to vaccine administration. The screening form is completed by the parent/guardian and is a self-declaration. Verification of parent/guardian response is not required.

Eligibility screening must include all the following elements:

- Date of screening
- Patient's name
- Patient's date of birth
- Parent/guardian's name
- Site name
- Eligibility status for each visit

Eligibility screening records must be kept on file with the patient's record, for a minimum of three years after the last date of service to the patient and must be easily retrievable. Digital or electronic storage of records is allowable.

It is acceptable for sites to utilize an EMR/EHR system to capture and save the information from the patient eligibility screening record as long as the EMR/EHR captures all the required eligibility elements. It is also required that vaccine eligibility be entered into the patient's record in ImmPact for every dose of vaccine given at each encounter. This vaccine eligibility must match the eligibility on file for that patient in their medical record.

## **CHAPTER 3: VACCINE MANAGEMENT**

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### **I. Approved Vaccines**

All vaccines and toxoids recommended by the Advisory Committee on Immunization Practices (ACIP) are available from MIP to enrolled sites.

- COVID-19 (18 years and under only)
- Diphtheria-Tetanus toxoids and acellular Pertussis (DTaP)
- Diphtheria-Tetanus toxoids and acellular Pertussis, Hepatitis B, and inactivated polio (DTaP-Hep B-IPV)
- Diphtheria-Tetanus toxoids and acellular Pertussis, inactivated polio, and Haemophilus influenzae type b (DTaP-IPV-Hib)
- Diphtheria-Tetanus toxoids and acellular Pertussis and inactivated polio (DTaP-IPV)
- Hepatitis A (HepA)\*
- Hepatitis A and Hepatitis B (Hep A-HepB)\*
- Haemophilus influenzae type b (Hib)
- Human Papillomavirus (HPV)\*
- Influenza (Flu)
- Inactivated polio (IPV)
- Measles, Mumps, and Rubella (MMR)\*
- Measles, Mumps, Rubella, and Varicella (MMRV)
- Meningococcal conjugate (MCV4) \*
- Meningococcal Serogroup B (MenB)\*
- Pneumococcal Conjugate (PCV13)
- Pneumococcal Polysaccharide 23-valen vaccine (PPSV23)

- Pneumococcal Conjugate (PCV20) \*
- Rotavirus (RV)
- Tetanus and diphtheria toxoids (Td)
- Tetanus and diphtheria toxoids and acellular pertussis (Tdap)\*
- Varicella \*
- Zoster\* (adult 317 only)

A complete list of available vaccines including trade names and manufacturers can be found on the Maine Vaccine Board website here:

<http://www.mevaccine.org/mevaccine.nsf/pages/for-providers.html>

*Vaccines with an \* in the above list are available through the 317 Adult Program.*

## **II. Vaccine Ordering**

### **Vaccine Choice**

All vaccines and toxoids recommended by the ACIP are available from MIP to enrolled sites. MIP-enrolled sites are required to offer all ACIP-recommended vaccines to the eligible populations they serve, including influenza vaccine.

The signing healthcare provider at MIP-enrolled sites may choose vaccine brands and presentations. For new sites enrolling in MIP, MIP education staff can help assist in creating an initial vaccine order. Orders should reflect vaccine choices, populations served, and adequate quantity on hand. Changes or adjustments to specific vaccines brands, presentations, and choices within each vaccine “family” (i.e., DTaP) can be made at any time an order is placed, or sites can decide to maintain current selections. Staff at MIP-enrolled sites are encouraged to review all choice selections on a quarterly basis.

The primary or backup vaccine coordinator may complete the vaccine ordering process; however, the signing authority must be consulted and must agree to the vaccine choices. Only vaccines supplied by the Centers for Disease Control and Prevention (CDC) that have been approved by the Maine Vaccine Board will be available for vaccine choice.

In the event that a chosen vaccine is not available, MIP will assist the MIP-enrolled site to replace the unavailable vaccine with a comparable substitution until the chosen vaccine becomes available.

#### **A. Vaccine Inventory Plan**

The vaccine inventory plan requires all enrolled sites to maintain a 4 - 6-week supply of vaccine inventory. Staff at MIP-enrolled sites should place vaccine orders monthly. MIP recommends placing a vaccine order when there is a four-week supply of vaccine available at the site, to ensure there is enough vaccine in stock to allow for any potential delays. MIP also recommends smaller, more frequent orders rather than larger orders to minimize the amount of vaccine loss if an incident occurs during shipment or in the vaccine storage unit. Vaccine orders are not required each month but should be entered as needed to maintain an adequate supply of vaccine. Current inventory and unit storage capacity must be considered when vaccine orders are placed to ensure adequate storage for all vaccine is available, especially during influenza season, including anticipated new vaccines.

Vaccine need may be increased or decreased at any time if the number of MIP-supplied eligible children changes, or if there are any applicable changes to the status of the facility that might affect vaccine usage. Staff at MIP-enrolled sites must update their Provider Profile to reflect these new eligibility changes before placing an order. All orders are reviewed by MIP staff prior to approval to ensure the amount and type of vaccine is appropriate to the Provider Profile.

#### **Short-Dated Vaccine**

Short-dated vaccines are those that are within 60-90 days of expiration. Placing vaccine orders according to the Provider Profile and rotating vaccines so that short-dated vaccines are used first will help prevent losses due to expiration. Clinic staff must note vaccine expiration dates when physically counting inventory during reconciliation. Short-dated vaccine must be used first. Vaccine surplus kept in inventory increases the risk of vaccine expiration and increases the amount of loss in the event of unit failure.

If a site feels any or all of the vaccine cannot be administered prior to expiration, MIP encourages the site to transfer the vaccine to another MIP-enrolled site. MIP can help assist with posting a notice of short-dated vaccines available on ImmPact, or a site can find a list of participating MIP-enrolled sites in their area

here: <https://www.maine.gov/dhhs/mecdc/infectious-disease/immunization/active-vfc-provider-sites.shtml>

Vaccine diluents, the liquid mixed with a freeze-dried vaccine to reconstitute it, must be managed in the same manner as vaccines. The expiration date of diluents must be checked prior to every reconstitution. The diluent must be rotated to use the shortest expiration date first.

If vaccines are allowed to expire, they are considered non-viable. Expired vaccines must be clearly labeled “Do not use” and removed from the storage units.

All expired vaccines are subject to the [MIP Replacement Procedure](#).

## **B. Storage Capacity for Vaccine Orders**

Sites must have adequate refrigeration and/or freezer space to accommodate a four to six-week supply of inventory on hand, including maximum quantity times such as influenza season, back-to-school, and anticipated new vaccines. Space needed for private stock vaccine must be taken into consideration when calculating storage capacity.

## **C. Vaccine Ordering in ImmPact**

MIP uses the Maine Immunization Information System, ImmPact, for vaccine ordering. ImmPact allows MIP-enrolled sites to manage vaccine inventory online. All vaccine orders will be placed in ImmPact. Sites may be held responsible for vaccine loss that is a result of incorrect information entered into ImmPact.

Prior to placing a vaccine order, the following information must be entered into ImmPact:

- Verification of days and hours of operation that the staff at MIP-enrolled sites are available to receive vaccine.
- Site’s delivery address.
- Primary and backup point of contact information.
- Up-to-date temperature logs for all units.
- Doses administered are required to be entered in the client record within five days of administration.

- Reconciliation with each vaccine order must include the following:
  - A physical count of all vaccines by brand, presentation, lot number, and expiration date.
  - Any expired, spoiled, or ruined/wasted vaccine doses.

Bi-weekly reporting (at least every 14 days) of reconciliation and temperature logs is required for all MIP- enrolled sites, whether or not a vaccine order is placed.

All orders placed in ImmPact will be reviewed and approved by MIP staff. Orders will be reviewed to ensure quantity on hand is not exceeded, that both reconciliation and temperature logs have been entered into ImmPact, and that the site has not been suspended from ordering for compliance issues.

If a discrepancy is found between orders placed, the packing list, or the doses received, staff at MIP-enrolled sites must immediately contact MIP for resolution. All vaccines must be appropriately stored immediately upon receipt regardless of the errors in the order.

### **III. Vaccine Distribution**

#### **A. Vaccine Distributors**

MIP uses two vaccine distribution centers:

- McKesson Specialty, a third-party distributor that ships the majority of MIP-supplied vaccines that are refrigerated.
- Merck, the manufacturer of frozen vaccines, which ships directly to MIP-enrolled sites.

#### **B. Receiving Vaccine Orders**

MIP requires vaccine shipments always be accepted and never refused or returned without specific instruction from MIP.

In order for sites to receive vaccine shipments, appropriate staff must be on site and available at least one day a week other than Monday and for at least four consecutive hours during the hours of 8:00 a.m. to 5:00 p.m. Each site establishes

the hours available to accept vaccine shipments when the initial vaccine order is submitted in ImmPact. The vaccine will be shipped so that it will arrive when staff are available to accept the vaccine. The staff at the MIP-enrolled site may not change available hours in ImmPact once an order is placed. The signing healthcare provider is responsible for incomplete or erroneous information entered into ImmPact which can result in vaccine loss.

Sites can expect their approved orders approximately one to two weeks after placing the order in ImmPact but can be as long as three weeks. It is important to recognize and store vaccine shipments immediately upon receipt to ensure vaccine viability. All of the staff at MIP-enrolled sites should be educated on what a vaccine shipment looks like, and sites must maintain a completed vaccine management plan to ensure that vaccine is stored quickly and correctly upon arrival.

The following steps are required when a vaccine shipment arrives:

- Check vaccines against the packing list to verify all vaccines have been received.
- Inspect the vaccines and check the temperature strip or other temperature reading device.
- Ensure adequate amount of diluent is included for those vaccines which require reconstitution (e.g., MMR, Varicella).
- Determine the length of time the vaccine was in transit by looking at the ship date and time on the packing.
- Immediately contact MIP when:
  - The appropriate quantity and type of vaccine or diluent is not received,
  - Vaccines have been received in error, or
  - Vaccines appear to be compromised.
- Appropriately store all vaccines immediately upon receipt regardless of any errors in quantity, shipping, or transport.
- Check expiration dates and rotate stock to ensure short-dated vaccines are used first.
- Immediately accept receipt of the vaccines in ImmPact.

Each package shipped from McKesson comes with a temperature monitoring strip(s). If the monitor strip(s) indicates, or if staff suspects the cold chain has been compromised., staff must immediately follow the instructions in subsection D, *Vaccines Received Warm or Questionable*.

Staff at MIP-enrolled sites are required to accept the vaccine at the time of receipt in ImmPact to maintain correct on hand vaccine inventory.

### **C. Manufacturer and Distributor Maintenance of the Cold Chain**

The manufacturer and distributor pack the vaccine using qualified pack-outs and containers that have been tested to maintain appropriate temperatures. Refrigerated vaccine is packed to maintain the cold chain for 72 hours. The vaccine will be shipped using high quality cardboard boxes with Styrofoam inserts.

Packages from McKesson are imprinted with “Temperature Sensitive Product” and include stickers reading “Refrigerate upon Arrival” to alert clinic staff to refrigerate contents immediately upon arrival.

Varicella and MMRV are shipped directly from Merck. Merck products are shipped frozen with a four-day pack-out. If the vaccine arrives within four days of the pack date on the packaging slip, then the vaccine is viable. Staff must immediately place all vaccines in proper storage. If the vaccine arrives outside of the four-day pack-out, the staff must immediately label the vaccines as “Do Not Use”, store the vaccine properly, and contact the vaccine manufacturer to determine vaccine viability.

### **D. Vaccines Received Warm or Questionable**

Vaccines must always be stored properly, even if viability is questionable. Vaccines that are received too warm, damaged, or in an otherwise questionable state require immediate contact to the vaccine manufacturers. Questionable vaccine cannot be identified visually and must be labeled “Do not Use” and placed into the storage unit until viability can be determined.

Examples are below of questionable (potentially non-viable) vaccines.

- Vaccine shipment received with temperature indicator strip showing out of range.
- Vaccine is warm to touch.
- Ice/gel packs are melted.
- Ice/gel packs are missing.
- Vaccine is received damaged.

If vaccine viability is questionable upon receipt, staff must follow the steps below.

- Separate the questionable vaccine, label as “Do not Use”, and place the questionable vaccines in the refrigerator or freezer, as applicable, until viability can be determined. Do not write on the vaccine itself.
- Contact MIP on the same day the vaccine arrived. Calls received after the day of delivery may result in liability for vaccine replacement, regardless of the cause of the temperature excursion.
- MIP may direct the staff to contact the distributor(s) to determine if a shipping issue has occurred.
- MIP may direct the staff to contact the vaccine manufacturer(s) to determine if vaccines are still viable.
- Vaccines must be kept quarantined until instructions for viability, replacement, reporting loss, etc. are received.

NOTE: Vaccine returns due to shipping issues are required to be returned to McKesson within 48 hours. Merck requires that frozen vaccine be returned within fifteen days of the original shipment.

#### **E. Vaccines Received in Error**

MIP must be contacted immediately upon receipt of vaccines that are received in error. Staff at the MIP-enrolled site may choose to keep the vaccine if storage capacity is sufficient and the vaccine doses will be administered. If vaccine was ordered by the site incorrectly, it is the site’s responsibility to keep the vaccine. If the site cannot absorb the vaccine due to storage capacity; MIP may assist in redistributing the vaccine to other sites to prevent vaccine wastage.

#### **IV. Vaccine Loss**

## **A. Expired, Spoiled, and Ruined/Wasted Vaccine**

MIP requires all unopen or unused vials and syringes of expired MIP-supplied vaccines be returned to the third-party distributor (McKesson). Staff must not discard MIP-supplied vaccine unless specifically directed by MIP. In the event of a cold chain failure, staff are immediately required to contact the vaccine manufacturer(s) to determine vaccine viability.

Expired or spoiled vaccine is any non-viable vaccine in its original container such as a vial or syringe. This includes expired vaccine or vaccine that has been spoiled because of the following:

- Natural disaster/power outage
- Refrigerator temperature too warm or too cold
- Freezer too warm
- Vaccine was not stored properly upon receipt
- Vaccine was spoiled in transit
- Mechanical failure of a refrigerator or freezer unit
- Vaccine recall

Ruined/wasted vaccine is non-viable vaccine that cannot be returned. Below are examples of ruined/wasted vaccines:

- Vaccine drawn into the syringe but was not administered.
- Vaccine in an opened multi-dose vial where all doses have not been administered.
- Compromised vial (due to a drop causing damage to vial integrity or sterility).
- Lost vial.
- Vaccine drawn into the syringe but refused by the patient.
- Incorrect vaccine that has been prepared for patient.
- Incorrect diluent was drawn or used for vaccine reconstitution.

Expired or spoiled vaccines must be removed from the storage unit, labeled “Do Not Use”, and stored pending return to distributor. Expired diluents do not need to be returned. Lost vials must be adjusted in ImmPact.

Vaccine loss must be documented in ImmPact no later than five days past the date of the incident(s). All vaccine returns to McKesson must occur within six months of the loss.

## **B. Procedures for Vaccine Loss**

Every dose of vaccine that is lost due to expiration or spoilage must be reported when reconciling inventory in ImmPact. Reconciliation is required at least once every fourteen days but recommended to be done weekly. Expired or spoiled vaccine must be returned to the distributor within six months of vaccine loss.

Staff must follow the procedures listed below when a vaccine loss occurs.

- Remove expired or spoiled vaccine from the vaccine storage unit and mark do not use.
- Reconcile the vaccine loss in ImmPact.
- Contact MIP's Vaccine Management (207-287-3006) for a return authorization.

The primary vaccine coordinator will receive a shipping label via email or mail for returning expired or spoiled vaccine. Depending on the number of doses lost, multiple shipping labels may be received. The return authorization must be included with the returned vaccine. MIP-enrolled sites who have lost vaccine because of improper temperature storage must assess how long the vaccines were stored improperly and how many children may have received the affected vaccines. The signing healthcare provider must work with MIP to determine if children must be revaccinated.

## **C. Negligent Vaccine Loss**

The signing healthcare provider at any MIP-enrolled site is responsible for any negligent vaccine losses. The following are examples of vaccine negligence:

- Failure to store vaccine properly
- Refrigerator temperature too cold
- Storage temperature unit too warm including:
  - Unit that was unplugged
  - Unit door left open
- Temperatures were not documented or monitored properly

- Expired vaccines in excess of a full box due to overordering
- Vaccines left out of appropriate storage unit
- Vaccine not stored properly upon receipt

Please refer to [MIP's Vaccine Replacement Procedure](#) for additional information on replacing vaccine that was lost due to negligence.

## **V. Vaccine Storage and Handling**

Proper receipt and storage of a vaccine delivery is important to maintain the vaccine cold chain.

The cold chain, or temperature monitoring, begins with the cold storage unit at the manufacturing plant, extends through transport of vaccines to the distributor, and continues through the delivery to and storage at the enrolled facility, and ends with the administration of vaccine to the patient. Exposure to heat, cold, or light at any step in the cold chain can damage vaccines, resulting in loss of potency.

Failure in the cold chain can be costly. If there is a failure in the cold chain, the result can mean extra doses for patients, increased cost for sites, and damage to public confidence in vaccines. A loss of public confidence in vaccines can lead patients to refuse revaccination and remain unprotected from serious vaccine-preventable diseases.

Maintaining the vaccine cold chain will prevent a site from incurring additional costs associated with loss and replacement of vaccines, as well as the need to recall patients for revaccination.

### **Refrigerator and Freezer Requirements**

MIP-enrolled sites are required to have appropriate equipment that can store vaccine and maintain proper conditions.

MIP recommends the following types of units, listed in preferential order:

- Pharmaceutical/purpose-built units,
- Stand-alone, single-purpose refrigerator and stand-alone single-purpose freezer, and

- Combination household refrigerator/freezer unit, using only the refrigerator compartment to store vaccines—a separate stand-alone freezer should then be used to store frozen vaccines. Use of the freezer compartment of a household combination unit is discouraged.

**NOTE:** Dorm-style and small combination refrigerator and freezer units with a single external door are **NEVER** allowed for the storage of MIP-supplied vaccine.

The following are MIP storage unit requirements:

- Refrigerator and freezer units must be large enough to hold the year's largest inventory without crowding (such as influenza season or back-to-school)
- The refrigerator compartment must maintain temperatures between 36°F and 46°F (2°C and 8°C) for vaccine viability. The refrigerator temperature should be set at 40°F (4°C).
- The freezer compartment must maintain temperatures between -58°F and +5°F (-50°C and -15°C) for vaccine viability.
- An alarm system to help reduce vaccine loss when unexpected temperature fluctuations occur.
- Refrigerators and freezer storing vaccines must be plugged directly into a wall outlet with a plug guard installed to prevent accidental or intentional unplugging.
- Units containing MIP-supplied vaccine must not be plugged into a multi-strip power outlet, surge protector, or an extension cord. In addition, units must not be plugged into an outlet that is controlled by a wall switch, or GFCI outlets.
- Each refrigerator and freezer should contain enough water bottles to help maintain proper storage temperature during peak usage of the unit or during a power outage. Peak usage is when there is frequent opening and closing of the unit. Water bottles serve as a physical barrier to prevent placing vaccines in areas where there is greater risk for temperature excursions.
  - Gel packs (thawed or frozen), ice packs, and coolant packs from

vaccine shipments are NOT recommended to be used in units to maintain temperatures during peak usage or power outages.

**NOTE:** Water bottles should not be used in pharmaceutical/purpose-built units if the manufacturer indicates that water bottles negatively impact the functionality of the unit.

For the refrigerator:

- Ensure the door closes completely.
- Replace crisper bins with water bottles to help maintain a consistent temperature (unless used for other medical equipment or supplies).
- Label water bottles “Do Not Drink”.
- Post “Do Not Unplug” signs on the refrigerator, at the electrical outlet, and at the circuit breaker.
- Place water bottles in unit doors carefully so they do not dislodge and place water bottles on the top shelf of the refrigerator under the fan (if present).
- Leave 2-3 inches between all vaccine (if possible) and the refrigerator walls.
- Store each type of vaccine or diluent in a separate container unless the diluent is contained in the same box as the vaccine, then they must be kept together.
- Place vaccines with the earliest expiration dates in front of those with later expiration dates.
- Whenever possible, store diluent with the corresponding refrigerated vaccine. Diluents must not be frozen.
- Attach labels to shelves and containers to clearly identify where each type of vaccine and diluent is stored. If diluent is stored separately from the corresponding vaccine, label the container where it is stored. Store vaccines and diluents with similar packaging or names (e.g., DTaP and Tdap or Hib and Hep B) or with both pediatric and adult formulations on different shelves to minimize the risk of administration errors.
- Label the formulation “pediatric” or “adult” if applicable.
- Always store vaccines in their original packaging with lids closed until ready for administration.

- Store privately purchased vaccine on different shelves from MIP vaccine to minimize the risk of administering MIP vaccine to non-eligible patients. MIP vaccines must be clearly marked to differentiate them from privately-purchased vaccines.
- Vaccines must be centrally stored within the unit.
- Do not store loose vials or manufacturer-filled syringes outside their packaging.
- Do not use the top shelf for vaccine storage.
- Do not store food or beverages in the refrigerator with vaccines.
- Do not put vaccines in the doors or on the floor of the refrigerator.
- Do not drink from or remove water bottles.
- Do not pack a storage unit too tightly. This may result in restricted air circulation and impact the unit's temperature.

For the freezer:

- Ensure the door closes completely.
- Use frozen water bottles to help maintain a consistent temperature.
- Place water bottles against the walls, in the back, on the floor, and in the door racks.
- Place water bottles in unit doors carefully so they cannot dislodge and prevent the doors from closing or weigh down the door so much that it does not seal tightly.
- Post "Do Not Unplug" signs on the freezer and by the electrical outlet.
- Leave 2-3 inches between all vaccines and the freezer walls.
- Avoid storing vaccines in any part of the unit that may not provide stable temperatures or sufficient airflow, such as directly under cooling vents or shelves on the door.
- Store each type of vaccine in a separate container.
- Vaccines must be centrally stored within the unit.
- Place vaccines with the earliest expiration dates in front of those with later expiration dates.
- Attach labels to shelves and containers to clearly identify each type of vaccine.

- Store vaccines with similar packaging or with both pediatric and adult formulations on different shelves to minimize the risk of administration errors.
- Store privately purchased vaccine in a clearly marked container separate from MIP vaccine to ensure MIP vaccine is not inadvertently administered to a non-eligible patient.
- Clearly label the formulation “pediatric” or “adult” if applicable.
- Always store vaccines in their original packaging with lids closed until ready for administration.
- Do not store food or drinks in the freezer.
- Do not store vaccines in the freezer doors.
- Do not store loose vials or manufacturer-filled syringes outside of their packaging.
- Do not store diluent in the freezer. Diluent must never be frozen.
- Do not pack a storage unit too tightly. This can restrict air circulation and impact vaccine temperature.

### **New or Repaired Units:**

Prior to using a new or newly repaired unit to store vaccines, the MIP requires five operational days of refrigerator or freezer temperature recordings. Minimum and maximum temperatures are required to be recorded once daily, at the beginning of each business day, to ensure temperatures are within appropriate ranges. Submit the recordings to MIP for review and approval before placing vaccine in the storage unit.

If adjustments to a unit’s temperature control is necessary, read the instructions carefully and verify that the temperatures did not change overnight. Some manufacturers recommend resetting the controls in the summer and winter. If so, post instructions on the unit door.

Refrigerators and freezers that store MIP-supplied vaccines are to be dedicated to storing vaccine only. Food or drinks in the same refrigerator or freezer as vaccines is not allowed. If other biologics must be stored in the same unit, store them below the vaccines to avoid contamination.

Maintaining MIP temperature logging requirements is mandatory for all MIP-enrolled sites. The required steps are listed below:

- A temperature recording paper log is required to be located on or near all units that store MIP vaccines.
- Freezer and/or refrigerator temperatures are required to be checked, recorded, and initialed. Minimum and maximum temperatures must be recorded on the temperature recording form once at the beginning of each business day.
- Temperatures must be recorded manually on temperature recording forms, even when using a data logger.
- Temperature recording forms must be maintained for at least three years and made easily available. (If facility is entering temperatures into ImmPact, they must keep at least three months of paper temperature logs on hand and demonstrate how to retrieve the past three years in ImmPact.)

If an out-of-range temperature excursion is observed, the clinic staff must document all excursions and take the following actions immediately:

- Label the vaccines “Do Not Use”.
- Store vaccines in a unit where they can be kept under appropriate conditions.
- Generate a report from the data logger for discussion with the vaccine manufacturer.
- Contact the vaccine manufacturer to obtain documentation for the viability of the vaccine.
- Document all steps taken on temperature recording paper log and in ImmPact.

### **Data Logger Requirements**

MIP requires that one primary data logger be in use for each unit that contains MIP-supplied vaccines. In addition, one back-up data logger must be available on site.

Units that store MIP-supplied vaccines must contain a centrally located data

logger probe with a current and valid Certificate of Calibration Testing, also known as a Report of Calibration, set at a minimum recording interval of at least every 30 minutes.

A data logger provides more accurate and comprehensive monitoring of temperature excursions to which vaccines may be exposed. Using a datalogger may reduce vaccine loss by providing necessary data when the vaccine would otherwise be lost.

Staff at MIP-enrolled sites that use data loggers must comply with the daily minimum and maximum temperature recording requirements. It is recommended that staff download the data from their data loggers at least once per week to ensure that any excursions are identified and addressed in a timely manner.

The following are requirements for data loggers:

- An active temperature display that can be easily read by all staff from outside of the unit without having to open the door.
  - If your unit does not have an outside temperature display it is also acceptable to retrieve these temperatures from a nearby computer only if ALL staff has easy access to the data logger temperatures.
- Alarm for out-of-range temperatures.
- A display that shows the current temperature, as well as minimum and maximum temperatures.
- Low battery indicator.
- Accuracy of +/-1°F (+/-0.5°C).
- Detachable probe in buffered material.
- Memory storage of at least 4,000 readings (device must not rewrite over old data and must stop recording when the memory is full).
- User-programmable logging interval of at least every 30 minutes.

Probes must be in buffered material so that they measure temperatures that are more representative of the temperature of the vaccine in the vial rather than the air temperature of the storage unit. Examples of buffers include a vial filled with liquid (glycol, ethanol, glycerin), a vial filled with loose media (sand, glass beads), or a solid block of material (Teflon, aluminum).

MIP does **NOT** allow the following temperature devices:

- Alcohol or mercury thermometers, even if placed in fluid filled bio-safe liquid vial.
- Bi-metal stem temperature monitoring devices.
- Food temperature monitoring devices.
- Household mercury temperature monitoring devices.
- Chart recorders.
- Infrared temperature monitoring devices.

These devices can have significant limitations, can be difficult to read, and generally only provide information on the temperature at the precise time they are read. Therefore, temperature fluctuations outside the recommended range may not be detected.

The following are requirements for data logger probes:

- Placed in the center of the unit.
- Placed as close to the vaccine as possible.
- Placed away from walls, ceilings, cooling vents, doors, floor, and back of the unit

NOTE: In pharmaceutical or purpose-built units, the data logger probe is recommended to be placed in a central location; however, other placements may be suitable because these units maintain more consistent temperatures throughout the unit.

MIP-enrolled sites are required to have a calibrated data logger in each unit that store MIP-supplied vaccine that is either International Laboratory Accreditation Cooperation (ILAC) laboratory accredited or has a valid up-to-date certificate issued by an ILAC laboratory.

A valid certificate of calibration matching the serial number of the data logger in use must be readily available for review and is recommended to be posted on or near the refrigerator and/or freezer. Calibration testing should be done every two years or according to the manufacturer's suggested timeline. A continuous-read temperature recording device does not replace the requirement for a certified

data logger.

Data logger certificates of calibration must contain the following:

- Model number.
- Serial number.
- Date of calibration.
- Measurement results that indicate the unit passed the test and the documented uncertainty is within suitable limits( $\pm 1^{\circ}\text{F}$ [ $\pm 0.5^{\circ}\text{C}$ ]).
- A statement indicating that it meets International Organization for Standardization/International Electronic Commission (ISO/IEC) 17025 standards.

All MIP-enrolled sites must have at least one backup data logger with a valid and current certificate of calibration. Backup data loggers must be readily available in the event the primary data logger that is in use is no longer working appropriately, in the event of an emergency transport of vaccine, or if calibration testing of the current equipment is required.

The backup data logger must be stored outside of the storage unit until needed to avoid vaccine space issues and differing temperature readings leading to potential confusion.

It is recommended that the backup data logger have a different calibration retesting date. If both data loggers have the same calibration date, they will need to be sent out for recalibration at the same time. By having different calibration dates there will always be one data logger available for use.

Refrigerators and freezers that are manufactured with built-in temperature monitoring capabilities are required to be accompanied by a certificate of calibration, and the thermostat must be capable of being adjusted as needed to maintain proper temperature. These units must meet all MIP data logger requirements.

In addition, a room thermometer is recommended to record the room

temperature when a temperature excursion occurs in a vaccine storage unit. This is important for making vaccine viability determinations, if necessary.

## **Vaccine Storage Requirements**

Some vaccines are sensitive to light and their efficacy could be compromised if exposed to light. The following vaccines must be protected from light: Hib, HPV, MCV4, MMR, MMRV, Rotavirus, and Varicella.

All MIP-supplied vaccines, with the exception of Varicella and MMRV, are to be stored in the refrigerator and must never be frozen. Varicella and MMRV must be stored in the freezer in a continuously frozen state between -58°F and +5°F (-50°C and -15°C). MMR vaccine may be stored in either a refrigerator or freezer.

All vaccines must be stored in the central area of the refrigerator and/or freezer, not in the vegetable bins, meat drawers, in the door, or on the floor. Storing vaccines in the central body of the refrigerator and/or freezer helps maintain proper temperatures for the vaccines.

Vaccines must be stored and/or stacked to allow cold air to circulate freely.

All MIP-supplied vaccines must be stored separately from privately purchased vaccines and must be labeled accordingly.

MIP-enrolled sites that are also receiving MIP-supplied vaccines for their underinsured adult populations must label and separate pediatric doses from adult doses. Sufficient alternate space to store vaccines and maintain the cold chain during any period when the refrigerator/freezer is out of service must be identified.

## **Protective Equipment**

The power supply for vaccine storage units must be protected by ensuring these practices are followed:

- Plug unit(s) directly into a wall outlet.
- Plug only one unit into an outlet.
- Plug guards are recommended to be used on all units that store MIP

vaccines. Plug guards are effective tools in preventing the accidental or intentional unplugging of equipment.

- Post a “Do Not Unplug” sign on or near all outlets where units are plugged in.
- Post a “Do Not Disconnect” sign on or near each circuit breaker.

Do not use the following for units that contain MIP-supplied vaccine:

- Extension cords.
- Multi-outlet power strips.
- Power outlets that can be activated by a wall switch.
- Outlets with built-in circuit switches (ground fault interrupt receptacles).
- Surge protectors.

## **Personnel**

Vaccine viability depends on the knowledge and habits of the site staff. All staff who handle MIP-supplied vaccine must be trained on proper storage, handling, and administration of vaccine as well as, aware of and familiar with the written procedures for emergency situations to assure continued viability of the vaccines. The site is required to designate a primary and at least one backup vaccine coordinator to ensure that MIP-supplied vaccines are handled and stored properly.

The following are training requirements for vaccine coordinators.

- All new primary and backup vaccine coordinators must complete the online education module, “Vaccines for Children” available at: <https://www.maine.gov/dhhs/mecdc/infectious-disease/immunization/annual-education-requirement.shtml>
  - New vaccine coordinators must also complete a post-test which is only available online after July 1.
  - To request a copy prior to July 1, new providers may contact 207-287-3746 or email [ImmunizeME.DHHS@maine.gov](mailto:ImmunizeME.DHHS@maine.gov).
- All new primary and backup vaccine coordinators must participate in a “Vaccine Coordinator Education” webinar. These are conducted twice

a month. The schedule for these webinars is available at:

<https://www.maine.gov/dhhs/mecdc/infectious-disease/immunization/>

Although only primary and backup coordinators are required to complete the online education modules, MIP strongly encourages that all staff handling vaccines at a site complete these modules as well.

### **Routine and Emergency Storage and Handling Plan**

All MIP-enrolled sites must have plans for routine and emergency vaccine management. MIP provides templates for the Vaccine Management Plan and the Emergency Storage and Handling Plan Checklist. The plan and checklist templates contain comprehensive information on best practices and the most current information about the storage and handling of vaccines. Sites are not required to use these templates, but they are valuable tools should assistance be needed when developing an emergency plan. If the templates are not used, staff at the site must develop routine and emergency vaccine management plans that include all of the information on the templates provided by MIP.

The Vaccine Management Plan and the Emergency Vaccine Storage and Handling Plan Checklist must be reviewed and updated annually. The signature, name, and title of the preparer as well as the date the documents were reviewed must be documented.

The following items must be addressed in the Emergency Vaccine Storage and Handling Plan:

- Identify a responsible primary and backup person to carry out the contingency plan. Contact information such as email addresses and home, office, and cell phone numbers for both persons must be included. Contact information must be updated annually or when changes occur.
- Identify an alternative location to take MIP-supplied vaccine for storage in the event of an emergency. A location with a power generator or other alternate source of power such as a hospital or pharmacy is preferable. Ideally, this facility must be located within a reasonable distance from the site and can maintain the cold chain during any period when the MIP- enrolled site's refrigerator or

freezer is out of service, as well as have adequate space to accommodate the largest vaccine inventory. Temperatures for these temporary storage units are required to be monitored and minimum and maximum temperatures recorded each morning.

- Adequate supplies in amounts sufficient for packing and transporting the entire MIP-supplied vaccine inventory must be available, in case of an emergency.
- Contact with staff at the emergency storage location is important to gain their approval before including them as part of the plan. List their contact person(s) and phone number(s) on the plan. An alternative backup location must be considered in the event that the primary alternative location is unavailable or unable to store the vaccine inventory for any reason.
- The most current Emergency Vaccine Storage and Handling Plan will be reviewed during MIP Compliance Site Visits and Unannounced Storage and Handling Visits. The documents must be posted on or near the refrigerator or freezer that contains MIP-supplied vaccine. The site staff involved with vaccine management must be aware of this plan. Vaccine Protection in the Event of an Emergency

As noted above, every facility maintaining an inventory of MIP vaccine is required to develop and display an Emergency Vaccine Storage and Handling Plan in the event of emergencies that could result in the loss of vaccine. This plan must be reviewed and updated annually or more frequently if there are any changes to the plan or changes in staff responsible for vaccine management, storage, and handling.

In the event of an emergency, the manufacturers must be contacted immediately to determine if the vaccine is still viable.

Staff at enrolled sites must be prepared to provide the following information:

- Temperature of the vaccine.
- Amount of vaccine.
- Expiration dates of the vaccine.
- Amount of time the vaccine was exposed to inappropriate temperatures.

If vaccines are determined to be viable, vaccine must be transported to an alternative site. The following information must be collected when transporting vaccine to the alternate location.

- Document the time of the emergency situation/power outage.
- Document the temperature of the refrigerator and freezer before removing any vaccine for transportation.
- Indicate which containers are being used and how the refrigerated vaccine will be packed for transportation (e.g., conditioned water bottles separated from the vaccine by layered packing materials to prevent freezing and damage).
- If frozen vaccine is being transported, indicate whether a portable freezer or cooler will be used and what packing materials will be used.
- Take inventory of the vaccine as it is moved into the transport container, documenting the number of doses of each vaccine, and the expiration dates.
- Ensure the Emergency Vaccine Storage and Handling Plan Checklist is available for documenting this process.

### **Cold Chain Management and Vaccine Transport**

MIP requires vaccines to be stored properly from the time they are manufactured until the time they are administered. The system used to maintain and distribute vaccines in optimal condition is called the cold chain.

Sufficient alternative space to store MIP-supplied vaccines and maintain the cold chain during any period when the refrigerator or freezer is out of service must be identified. Adequate supplies for packing and transporting the entire MIP vaccine supply/inventory must be available in case of an emergency.

Avoid prolonged temperature extremes inside vehicles by taking the quickest route possible. Do not leave vaccines unattended in vehicles. Do not place vaccines in the trunk of a vehicle.

Pack refrigerated vaccines first. If followed, the directions below will help maintain the cold chain for up to eight hours during transport of refrigerated

vaccines.

## **Refrigerated Vaccine Transport**

MIP recommends transporting refrigerated vaccines with a portable refrigeration unit. If this type of unit is not available, a hard-sided insulated cooler with at least 2-inch walls, a Styrofoam vaccine shipping container, or other qualified container may be used as long as it maintains the recommended temperature range (36°F to 46°F [2°C to 8°C]).

- Using a hard-sided cooler, Styrofoam vaccine shipping container, or other qualified container requires the following:
  - Coolers should be large enough to hold the MIP supply of refrigerated vaccines.
  - Label the container with the facility name, “Fragile Vaccines – Do NOT Freeze”, and the date and time the vaccines were removed from the permanent storage unit.

**NOTE:** Do not use soft-sided collapsible coolers for transporting vaccine.

- Conditioned frozen water bottles are recommended for keeping vaccines cold.
  - Use 16.9 oz. bottles for medium/large coolers and 8 oz. bottles for small coolers
  - Before use, condition the frozen water bottles. This is done by placing them in a sink filled with several inches of cool or lukewarm water until there is a layer of water forming near the inner surface of the bottle. The bottle is properly conditioned when the ice block spins freely within the bottle when rotated.

**NOTE:** Do not reuse coolant packs from original vaccine shipping containers.

- Insulating material – two each of the following layers is needed:
  - Corrugated cardboard – two pieces cut to fit the internal dimensions of the coolers(s) and placed between the insulating cushioning material and the conditioned water bottles.
  - Insulating cushioning material such as bubble wrap, packing foam,

or Styrofoam for a layer at least 2-inches thick above and below the vaccines. Ensure this layer covers the cardboard completely.

**NOTE:** Do not use packing peanuts or other loose material that may shift during transport.

- A data logger with a buffered probe must be used as a temperature monitoring device.
  - Prepare the probe by pre-chilling it in the refrigerator for at least 5 hours prior to transport.
  - Ensure the data logger has a current and valid certificate of calibration testing.
  - Ensure the data logger certificate is documented to be accurate within +/- 1°F (+/- 0.5°C).
  - The data logger currently stored in the refrigerator can be used for transport, as long as there is a device in place to measure the temperature for any remaining vaccines.

MIP recommends the following packing assembly for refrigerated vaccines:

- Line the bottom of the cooler with a single layer of conditioned water bottles.
- Place a sheet of corrugated cardboard over the water bottles.
- Place at least a 2-inch layer of insulating material (i.e., bubble-wrap, packing foam, or Styrofoam) over the cardboard.
- Stack boxes of vaccines on top of the insulating material.
- When cooler is halfway full, place the data logger buffered probe in the center of the vaccines, but keep the display outside the cooler.
- Cover vaccines with another 2-inch layer of insulating material.
- Add the second layer of corrugated cardboard.
- Fill the remaining space in the cooler with conditioned water bottles.
- Close the lid of the cooler securely and attach the data logger display and a temperature log to the top of the lid to record and monitor the temperature during transport.
- Use the temperature recording form to record the time and temperature inside of the storage unit at the time the vaccines were removed.

- If vaccines are kept in a transport container for longer than an hour, record the temperatures hourly. As soon as the destination site is reached, check, and record the vaccine temperature.
- As long as the vaccine temperature is 36°F to 46°F (2°C to 8°C), place the vaccine in the refrigerator.
- If the vaccine is below 36°F (below 2°C) or above 46°F (above 8°C), label the vaccine as “Do Not Use”, place in the refrigerator, and immediately contact the vaccine manufacturer to determine viability.

**NOTE:** Always keep vaccine properly stored until otherwise instructed by the vaccine manufacturer or MIP.

### **Frozen Vaccine Transport**

Varicella and MMRV vaccines are fragile and must be kept frozen. MIP and the vaccine manufacturer do not recommend transporting varicella or MMRV. If these vaccines must be relocated in an emergency, the following steps must be taken:

- **Portable Freezer** – MIP recommends transport with a portable freezer unit that maintains the temperature between -58°F to +5°F (-50°C to -15°C). Portable freezers may be available for rent. Label the portable freezer with the facility name and “Fragile Vaccines – Keep Frozen” and the date and time the vaccine was removed from the permanent storage unit.
- **Temperature Monitoring Device** – Use a certified and calibrated data logger with a current and valid certificate of calibration testing. Prepare the data logger by placing it in a freezer unit at least 2 hours before packing the vaccine.
- **Cooler** – If a portable freezer is unavailable, a hard-sided insulated cooler with at least 2-inch walls, a Styrofoam vaccine shipping container, or other qualified container may be used if temperatures between -58°F to +5°F (-50°C to -15°C) can be maintained. Label the container with the facility name and “Fragile Vaccines – Keep Frozen” and the date and time the vaccine was removed from the permanent storage unit.
- Use frozen water bottles in the cooler. Dry ice is not allowed to be used for transporting vaccines, even for temporary storage or emergency transport.

Dry ice may allow the vaccine to be exposed to temperatures colder than -58°F (-50°C).

- Line the bottom of the cooler with a single layer of frozen water bottles.
- Place at least a 2-inch layer of insulating material (i.e., bubble-wrap, packing foam, or Styrofoam) over the frozen water bottles.
- Stack boxes of vaccines and diluents on top of the insulating material.
- When cooler is halfway full, place the data logger buffered probe in the center of the vaccines, but keep the display outside the cooler.
- Cover vaccines with another 2-inch layer of insulating material.
- Fill the remaining space in the cooler with frozen water bottles.
- Close the lid of the cooler securely and attach the data logger display and a temperature log to the top of the lid to record and monitor the temperature during transport.
- Use the temperature recording form to record the time and temperature inside of the storage unit at the time the vaccines were removed.
- If vaccines are kept in a transport container for longer than an hour, record the temperatures hourly.
- As soon as the destination site is reached, check, and record the vaccine temperature.
- Place the vaccines in a freezer that maintains a temperature range between -58°F to +5°F (-50°C to -15°C).
- Document the time and temperature the vaccine was removed from the transport container and placed in the alternate storage unit.
- Immediately contact the vaccine manufacturer for viability data and guidance when frozen vaccine has been exposed to a temperature above +5°F (-15°C). Do not discard the vaccine without contacting the manufacturer. Viability determination will be made on a case-by-case basis.

## **VI. Vaccine Transfers**

The routine re-distribution of MIP-supplied vaccine is not allowed. However, a vaccine transfer can be allowed when necessary to avoid vaccine loss (i.e., vaccines close to expiration or statewide vaccine shortage).

To conduct a vaccine transfer, the site transferring the vaccine must complete the following:

- Ensure the vaccine transfer is occurring for one of the following reasons:
  - Short-dated vaccine (vaccine close to expiration).
  - Withdrawal, suspension, or termination of a clinic from MIP.
  - Vaccine shortage.
  - Other (emergency situations).
- Ensure the vaccine is being transferred to another MIP-enrolled site.
- Both MIP-enrolled sites (the site transferring vaccine and the site accepting the vaccine transfer) must have up-to-date temperatures entered into ImmPact.
- Ensure that the vaccine is packaged using proper cold chain management as detailed in Section V – Vaccine Storage and Handling, subsection H – Cold Chain Management and Vaccine Transport and a certified calibrated data logger is enclosed with the vaccine.
- Include a list of all vaccines being transported. This list must include the following:
  - Vaccine type.
  - National Drug Code (NDC).
  - Lot number.
  - Expiration date.
  - Number of doses being transferred.
- Include a temperature recording form to document temperatures before, during, and upon conclusion of the vaccine transfer. The MIP-enrolled site taking possession of the vaccine will attach the temperature recording form from the transfer to the site’s monthly temperature recording form.
- Document the transfer in ImmPact.

## **VII. Vaccine Borrowing**

Vaccine borrowing is the utilization of MIP-supplied vaccines as a replacement system for filling the vaccine needs of non-MIP eligible patients.

MIP does **NOT** allow vaccine borrowing between MIP-eligible and non-eligible patients.

All MIP-enrolled sites are expected to maintain an adequate inventory of vaccine for both MIP-eligible and non-MIP-eligible patients. Vaccines supplied by MIP must not be provided to an ineligible patient. Undocumented borrowing and administration of MIP-supplied vaccines to an ineligible patient is considered fraud. MIP-supplied vaccines must not be used as a replacement system for filling the vaccine needs of out of state privately insured children or any adults aged 19 years or older. For example, MIP-supplied flu vaccine must not be administered to an adult even if MIP-supplied flu vaccine arrived in the office prior to the arrival of privately purchased flu vaccine.

If an MIP dose is accidentally administered to an ineligible MIP patient, the following steps must be completed:

- Document the incident by completing the MIP Vaccine Borrowing Form. Each MIP-supplied vaccine that was administered to an ineligible patient must be listed on a separate row on the form. The form is available by contacting an MIP Health Educator.
- Report the incident by faxing a copy of the MIP Vaccine Borrowing Form to MIP at 208-287-8127. The MIP Vaccine Borrowing Form must be kept as part of MIP records for a minimum of three years and be made easily available.
- Replace the vaccine immediately with privately purchased vaccine and account for the replacement in ImmPact.

It is the responsibility of the staff at the MIP-enrolled site to ensure that all staff members are familiar with MIP requirements. Adequate vaccine supply must be maintained in accordance with the clinic's patient population. The MIP-supplied vaccine and private vaccine must be kept separate and clearly labeled as such. All vaccine usage must be tracked, and all doses of MIP-supplied vaccine must be accounted for in ImmPact.

Continued non-compliance with MIP policies and procedures may be considered fraud and abuse. Referral may be made to the CMS Medicaid Integrity Group (MIG) Field Office.

## **VIII. Reporting Requirements**

**Bi-weekly vaccine management and reporting is required in ImmPact regardless of whether an order is submitted or not.**

MIP requires the monitoring of the temperatures of all refrigerators and freezers containing MIP-supplied vaccines and the documentation of all administered MIP-supplied vaccine.

All records related to MIP are required to be maintained for three years and made easily available. Digital or electronic storage of records is allowable.

At least once every 14 days, the following must be completed and submitted in ImmPact:

- Temperature Recording Forms.
- Vaccine Reconciliation.

Additionally, all MIP-supplied doses must be entered into the client record within five days of administration

Failure to submit required documents will result in future vaccine orders placed on hold. Clinic staff must ensure that all reporting is completed and submitted to ImmPact in a timely manner. Although required bi-weekly, it is recommended to enter temperatures and complete reconciliation weekly.

### ***Temperature Recording Form***

A temperature recording form is to be maintained on all refrigerators and freezers that store MIP-supplied vaccine (including temporary day storage units). A Fahrenheit or Celsius form is required to be used to monitor temperatures.

All MIP-supplied vaccines are required to be maintained at proper storage temperatures at all times. To ensure proper temperatures are maintained, MIP requires the recording of refrigerator and/or freezer temperatures daily for all units that store MIP-supplied vaccine. The minimum and maximum temperatures are to be recorded in the morning of each business day. Results of each check must be documented on the temperature recording form and the form must be

initialed by the staff member conducting the check.

Completed temperature forms must be submitted at least once every 14 days but recommended to be entered weekly. Temperatures must be up to date in ImmPact when placing a vaccine order.

In the event of a temperature excursion, immediate notification to the manufacturer is necessary and all information must be documented on the Temperature Recording Form and included in the notes section in ImmPact:

- Date and time of event.
- Storage unit temperature.
- Name of person completing the report.
- Description of event.
- Actions taken, including the case number(s) and instructions given from the manufacturers and the individual(s) spoken to.
- The results.

All temperatures recorded on the Temperature Recording Forms must match the temperatures entered into ImmPact. MIP-enrolled sites are required to keep at least three months of paper Temperature Recording Forms on file in the event they are chosen for a site visit or there is a discrepancy.

### ***Vaccine Reconciliation & Doses Administered***

All MIP-supplied vaccine must be recorded in the client record within five days of administration to a patient. ImmPact is a tool used in many different settings from the primary care physician's office to Maine schools. Timely documentation of vaccines is important to ensure office medical records match ImmPact, children are not re-immunized for a dose already received, and that all inventory is accounted for.

It is important that physical inventory on hand in the storage unit(s) match the inventory listed in ImmPact. Although vaccine is provided free of charge to MIP enrolled sites, vaccine is not free. Reconciliation is done to ensure inventory on hand and ImmPact inventory match and vaccine has not been lost.

ImmPact continuously tracks vaccine quantities in the practice. When a site receives an order, they must review the packing slip, ensure the correct vaccine and quantity is received, and accept the order into their inventory in ImmPact. This will “add” to the dose quantity for the vaccine in ImmPact.

When a dose is administered to a patient, the site must enter that vaccine administered into the client record. Choosing a particular vaccine and lot number from the site’s inventory and saving the administration will cause a dose to be “subtracted” from the dose quantity for the vaccine in ImmPact.

This addition and subtraction of inventory in ImmPact should reflect the physical count of inventory in the storage unit. To complete the bi-weekly reconciliation requirement, the site must first ensure that all doses administered have been entered into the client record. Then the site must complete a physical count of all doses of vaccine in the storage units. All reconciliation is done by vaccine lot number. Once all inventory is counted, the site must ensure that the quantity on hand matches the quantity listed in ImmPact. If the quantities match, submit the reconciliation. If the quantities do not match, the quantities in ImmPact must be changed to reflect the actual physical dose count on hand.

During the month, any vaccine that is removed from the storage unit and not administered must be documented. There are a variety of reasons vaccine may be removed, vaccine could have expired, vaccine may have been drawn up and not administered and vaccine may have spoiled due to a temperature excursion. Any documented of inventory changes must be reflected in ImmPact by modifying the vaccine quantity.

If quantities match after modifying has been done, submit the reconciliation. If vaccine inventories still do not match, vaccine may have to be “subtracted” in ImmPact as lost or unaccounted for vaccine. Please keep in mind that any lost or unaccounted for vaccine is subject to the MIP Vaccine Replacement Procedure.

## **CHAPTER 4: BILLING AND ADMINISTRATION**

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### **I. Billing for Vaccine**

MIP-enrolled sites are prohibited from charging any MIP-eligible child for the cost

of vaccines. MIP-supplied vaccines are provided at no cost to clinics in order to vaccinate eligible children. Charging for the cost of vaccines supplied by MIP constitutes fraudulent behavior. Fraud in MIP will be handled in the same manner as Medicaid fraud.

Private clinics may not refer a MIP-eligible child to another healthcare facility for MIP-supplied vaccines if the site already accepted that child into their practice as their patient, unless directed by MIP.

## **II. Administration Fee**

Sites are required to enroll in MIP to obtain vaccines at no cost to vaccinate MIP-eligible children and have the option to enroll into the 317 Adult Program. MIP-eligible children will fall into two categories. VFC-eligible includes all MaineCare, CHIP, Alaskan native, American Indian, and uninsured children. State-eligible includes all privately insured children residing in Maine. Adults are eligible for the 317 funded vaccine through MIP if they uninsured or underinsured.

A fee for administered MIP-supplied vaccine to MIP-eligible children or 317 eligible adults may be charged. The maximum administration fee is \$21.58. There is no maximum administration fee for State-eligible children, but MIP encourages sites to charge a reasonable fee. The fee is per dose of vaccine, not per antigen. Example: A practice can only charge \$21.58 for one dose of Kinrix (DTaP-IPV combination vaccine) but is allowed to charge \$43.16 for the separate administration of Infanrix (DTaP) and IPOL (IPV).

MaineCare and CHIP children must not be charged the administration fee for receiving vaccines. For MaineCare children, the MIP-enrolled site must accept the reimbursement for immunization administration fee set by MaineCare.

Sites are reimbursed the lesser of the billed amount or the maximum allowable fee.

MaineCare has the discretion to pay any amount up to the maximum amount allowed for the State of Maine, \$21.58.

Children 0-18 years of age who are enrolled in Medicaid as their secondary insurance are considered VFC-eligible.

As stated in the MaineCare Provider Manual, clinics should bill their usual and

customary fee except for vaccines obtained from MIP. For more information on Medicaid reimbursement, please refer to the MaineCare Provider Manual located at: <https://www.maine.gov/sos/cec/rules/10/ch101.htm>

Children 0-18 years of age who are enrolled in CHIP are eligible to receive MIP-supplied vaccines from active CHIP participating sites. Sites must bill CHIP for the administration of a vaccine to a CHIP-enrolled child.

Vaccines must be made available to all MIP-eligible children or 317 eligible adults. Services cannot be denied due to the parent/guardian or adult's inability to pay the administration fee and the parent/guardian or adult must not be sent to collections. Penalties for the inability to pay administration fees must not be charged.

### **III. Eligibility – Billing Practices**

MIP-enrolled sites must adhere to proper billing practices for vaccine administration fees and clearly understand that MIP-supplied vaccine is provided at no cost to the site and to eligible children. At no time should billing occur for the cost of MIP-supplied vaccine. When administering MIP-supplied vaccine, providers should never bill two different “payers” (i.e., patient, Medicaid, insurance) for the same vaccine administration fee amount.

For Medicaid-eligible children, Medicaid should be billed for the vaccine administration fee.

For all other VFC/317 adult eligible populations, the patient may be billed for an amount within the state/territory cap established by the Centers for Medicare and Medicaid Services (CMS); however, patients cannot be turned away or reported to collections for inability to pay the administration fee.

Effective January 1, 2020, providers who choose to bill for the vaccine administration fee of a non-Medicaid, VFC-eligible child, or 317-eligible adult after the date of service may issue only a single bill to the patient within 90 days of vaccine administration.

## **CHAPTER 5: PROGRAM EVALUATION**

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## **I. MIP-Enrolled Site Visits**

By signing the MIP Provider Agreement, the signing physician agrees to allow MIP quality assurance (QA) reviewers to conduct site visits at least every other year at their site. Newly enrolled sites must receive an enrollment site visit prior to ordering any MIP-supplied vaccine. Newly enrolled sites will also receive a QA site visit between 6-12 months after initial enrollment.

### **A. Compliance Site Visits**

Compliance site visits are conducted every 24 months. The purpose of the compliance visit is to assess, support, and educate the staff regarding MIP policies and procedures and if necessary, assist practices with course corrections. If areas of concern are identified, the educator will provide a follow-up phone call or visit to assist the clinic with any changes or questions.

MIP-enrolled site staff will be contacted prior to a scheduled compliance site visit and will receive a confirmation letter via email or fax that includes the date, time, materials needed, and summary of the site visit process.

During a compliance site visit, the reviewer will need access to the following:

- Internet connectivity (if available)
- Patient records
- Temperature logs or data for the last three months
- Calibration certificates for the primary and back up digital data loggers (DDL)
- Vaccine borrowing forms for the previous 12months
- Circuit breaker
- Admin and billing personnel to clarify eligibility screening and billing processes
- All vaccine storage units where MIP-supplied vaccine is stored

### **B. Unannounced Storage and Handling Visits**

Unannounced storage and handling visits may be conducted to serve as “spot checks” for proper vaccine storage and handling.

MIP may prioritize sites for unannounced visits based on the following criteria:

- Vaccine loss
- Improper storage of vaccine
- Improper documentation on temperature logs
- Vaccine orders are inconsistent with population profile data
- Newly enrolled sites
- Determination of the clinic's compliance with corrective actions

During the unannounced storage and handling visits, the reviewer will need access to the following:

- Internet connectivity (if available)
- Circuit breaker
- All vaccine storage units where MIP-supplied vaccine is stored

## **II. Follow-up Activities**

Upon completion of the site visit, the reviewer will discuss the outcomes of the visit with the vaccine coordinator. The discussion will include a review of the site visit findings and a formal follow-up plan with a timeline that addresses issues of non-compliance or opportunities for improvement.

The vaccine coordinator must sign an Acknowledgement of Receipt following the visit. This document attests to the fact that a site visit was completed, the results of the visit were received, and that both the reviewer and the vaccine coordinator understand all non-compliance issues identified and the actions necessary to address them.

The reviewer will conduct all required follow-up activities. The purpose of follow-up activities is to ensure that areas for improvement identified by the reviewer are understood by the site's staff and corrective actions have been identified and implemented.

Follow-up activities are conducted as necessary to address all issues and are dependent upon the severity of the non-compliance issues and the follow-up action plan.

Follow up activities can include, but are not limited to the following:

- Visiting the clinic to observe corrective actions.
- Calling the vaccine coordinator at the clinic.
- Sending an email or letter to address the deficient items identified during the site visit.
- Determining the staff's compliance with the corrective action plans, if applicable.

The reviewer works with clinic staff on non-compliance issues by providing education and guidance regarding corrective actions, including monitoring. Unless otherwise stated on action plan, all follow up activities are due within 30 days of the site visit.

If a site exhibits habitual non-compliance and does not follow corrective actions in response to education, the vaccine ordering privileges may be suspended. If non-compliance continues, termination from MIP may be implemented.

### **III. IQIP Site Visits**

IQIP is the CDC quality improvement program conducted by immunization programs to support the VFC Program throughout the United States. The goal of IQIP is to increase vaccination rates of children and adolescents with all ACIP-recommended vaccines by reducing missed opportunities to vaccinate and improving immunization delivery practices at the clinic level.

IQIP serves to assist and support staff by identifying low immunization rates, determining opportunities for improving immunization delivery practices, and ensuring that staff are:

- Aware of and knowledgeable about their immunization rates and missed opportunities to vaccinate.
- Motivated to incorporate changes into their current practices.
- Ready to try new immunization service strategies.
- Capable of sustaining improvements to their vaccination delivery services.

IQIP visits are conducted at least every four years by the MIP education staff, however, larger sites will often receive a visit every year. The core component of

this visit is the assessment and review of immunization records on children 24-35 months of age, adolescents 13 & 17 years of age.

## **CHAPTER 6: FRAUD AND ABUSE/NON-COMPLIANCE**

### **I. Fraud and Abuse**

As the complexity of immunizations and immunization-related programs grow, MIP-enrolled sites may become more vulnerable to unintentionally committing acts that could be construed as fraud and/or abuse. Fraud and abuse, whether intentional or not, is subject to all federal fraud and abuse laws.

### **II. Definitions**

A working understanding of what constitutes fraud and abuse is critical for all persons working with MIP. The following are definitions of terms related to fraud and abuse.

**Fraud** – An intentional deception or misrepresentation made by a person with the knowledge that the deception could result in an unauthorized benefit to himself or another person. It includes any act that constitutes fraud under applicable federal or state laws.

**Abuse** – Practices that are inconsistent with sound fiscal, business, or medical practices and result in an unnecessary cost to MaineCare (and/or including actions that result in an unnecessary cost to MIP, 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 healthcare. It also includes recipient practices that result in unnecessary costs to MaineCare.

**Oversight** – The act of training, monitoring, and providing assistance to site staff on MIP policies and procedures.

**Enforcement** – Identifying rules and policy violations and ensuring corrective action is taken.

**Termination** – Action taken when a site or signing authority is no longer eligible for MIP due to fraud, abuse, or non-compliance.

**Waste** – The careless, inefficient, or unnecessary use of MIP resources.

### **III. Examples**

Fraud or abuse can occur in many ways. Some types of fraud and abuse are easier to prevent or detect than others. All staff at MIP-enrolled sites should familiarize themselves with the examples below, as they illustrate common practice errors that could result in fraud or abuse allegations. **This list provides examples only and should not be considered an exhaustive list of situations that would constitute fraud or abuse.**

- Provide MIP-supplied vaccine to ineligible children/317 adults
- Sell or otherwise misdirect MIP-supplied vaccine
- Bill a patient or third party for MIP-supplied vaccine (other than administration fees)
- Charge more than \$21.58 per dose for administration of a MIP-supplied vaccine to a VFC-eligible child/317-eligible adult
- Failure to meet licensure requirements for enrolled physicians
- Deny MIP-eligible children/317-eligible adult MIP-supplied vaccine because of the inability to pay the administration fee
- Send a parent/guardian or adult to collections or charge additional fees for non-payment of the administration fee
- Failure to implement MIP enrollment requirements
- Failure to screen for and document MIP-supplied vaccine eligibility at every visit
- Failure to maintain MIP records for three years
- Failure to fully account for MIP-supplied vaccine
- Failure to properly store and handle and document MIP-supplied vaccine
- Order MIP-supplied vaccine in quantities or patterns that do not match population profile or otherwise involve over-ordering of MIP doses
- Loss of MIP-supplied vaccine due to negligence

### **IV. Failure to Comply with MIP Requirements**

Enrolling in MIP is an agreement to comply with all the requirements of the

program. Lack of adherence to MIP requirements by an enrolled site could lead to fraud and abuse of the program by that site. Non-compliance with MIP requirements may occur due to an unintentional understanding of the requirements. Behavior may also be intentional.

#### **A. Intentional Non-Compliance**

If the non-compliance appears intentional and the clinic staff or signing authority has received financial benefits from the behavior, the situation may result in immediate referral for investigation of suspected MIP fraud and abuse. Based on the severity of the non-compliance, the site may be suspended or terminated immediately.

#### **B. Unintentional Non-Compliance**

If non-compliance is a result of lack of understanding of MIP policies and procedures, MIP will work with the site staff by providing education and guidance. MIP will provide a timeline to ensure that all corrective actions will be addressed and corrected.

If a site exhibits habitual non-compliance or does not follow corrective actions in response to education, the vaccine ordering privileges may be suspended. If non-compliance continues, termination from MIP may be implemented.

Non-compliance must be addressed on a timely basis to ensure fraud and abuse does not occur. The following timeline will be adhered to if non-compliance is identified:

- Identification of Non-Compliance – When non-compliance is identified, either at a site visit or another way, the site will be given 30 days to remediate the non-compliance. Education and guidance will be provided to ensure the site understands steps to take to become fully compliant.
- If, after 30 days, the site continues to be non-compliant, a certified letter will be sent to the signing physician of the site. The letter will explain the non-compliance and the site's failure to remediate the issue.
- If, after 45 days, the site continues to be non-compliant, the site will be

suspended from ordering vaccine. A probation agreement will be sent certified mail to the signing physician. The probation agreement will include adherence to all MIP requirements including the non-compliance at hand. This probation document must be signed and returned to MIP within five business days.

- If the probation document is signed and returned, MIP reviewer will continue to work with the practice to ensure their non-compliance is corrected and remains that way for six months. Ordering suspension will be lifted. After six months of full compliance the site probation will be removed.
- Failure to comply with all probation requirements will result in termination from MIP.
- If, after 50 days, the probation document is not signed and returned the site will be terminated from MIP. A certified letter will be sent to the signing physician.

MIP-enrolled sites that have been terminated from the program may seek permission to re-enroll after one year has passed since the effective termination date. If agreed, MIP will enroll the site on a probationary six-month period. During that time, the site will agree to follow all MIP requirements. If the site remains compliant for six months, the probation will be removed. If the site demonstrates any non-compliance within the six months, the site will be terminated and will not be eligible to re-enroll with MIP again.

## **V. Fraud and Abuse Prevention**

MIP actively works with enrolled sites to help prevent fraud and abuse. The best methods to prevent fraud and abuse are strong educational components discussed during the initial enrollment process and during the MIP compliance visits. Both occasions provide the opportunity to identify and prevent situations that may develop into fraud and abuse. MIP offers monthly webinars to review all MIP requirements. This allows vaccine managers and site staff to ask any questions they may have regarding program requirements.

## **VI. Reporting Fraud and Abuse**

Suspected fraud or abuse can be reported to MIP via email, telephone, fax, or letter. Furthermore, newspaper articles and internet pages that promote potential fraudulent situations are also investigated. MIP site visit reviewers must report all cases of alleged or suspected fraud or abuse. Reports received by MIP in any form that merit further investigation may be referred to the Centers for Medicare and Medicaid Services (CMS), and/or Medicaid Integrity Group (MIG) Field Office. The state Medicaid agency will conduct preliminary investigations and as warranted, refer appropriate cases to the state’s Medicaid Fraud Control Unit.

## **CHAPTER 7: DOCUMENTATION REQUIREMENTS**

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### **I. Vaccine Record Keeping Requirements**

The 1986 National Childhood Vaccine Injury Act (NCVIA) requires all vaccinators nationwide to record the following specific information in the medical record each time a vaccine is administered.

- Name of vaccine administered
- Date vaccine was administered (month, day, year)
- Date vaccine information statement (VIS) was given
- Publication date on VIS
- Name of vaccine manufacturer
- Vaccine lot number
- Name and title of the health care professional administering the vaccine
- Address of the clinic where the vaccine was administered

If needed, the Immunization Action Coalition provides immunization records for children and adults that are designed to capture all information that is required when a vaccine is administered. Immunization records for clinics can be found at this location: <http://www.immunize.org/handouts/document-vaccines.asp>

MIP also provides State of Maine Childhood Immunization Record cards “Gold Cards” that can be ordered free for clients at this location:

<https://www.maine.gov/dhhs/mecdc/infectious-disease/immunization/order-form-immunization.shtml>

MIP suggests the following recommendations regarding record keeping.

- Designate a specific staff member to answer immunization questions for staff and parents.
- File patient records, keeping the immunization record and MIP Eligibility forms together.
- Place immunization records at the front of each patient's chart and make immunizations a priority.
- Encourage parents to bring their children's immunization record with them to facilitate complete documentation in the child's record of previous immunization history.
- If a child presents with no immunization record, obtain the history through ImmPact if available, or call previous medical facility to obtain the history.
- Empower all staff to become "Immunization Advocates" and have them assess each child's immunization status at every encounter.
- Give a personal immunization record to each vaccine recipient showing the date (month, day, and year) of when each vaccine was administered. These "Gold Cards" are available on the MIP website.

Copies of all MIP documents must be maintained for three years and made available on request by MIP.

## **II. The Maine Immunization Information System(ImmPact)**

ImmPact is operated by MIP and is an important component of Maine's strategy to improve immunization coverage rates. Maine Law requires all MIP-supplied vaccine be recorded in the client record in ImmPact within five days of administration of the vaccine. ImmPact is designed to consolidate immunization records from multiple sources throughout the state. ImmPact allows authorized organizations easy access to immunization histories of participating clients and has "Reminder/Recall" capabilities.

ImmPact is not only for children but designed to store immunization for a lifetime. MIP-enrolled sites have the capability to enter their private vaccine inventory and record immunizations for their adult populations or out of state

client's that may not be eligible for MIP-supplied vaccine.

### **III. Addressing and Documenting Vaccine Hesitancy**

Maintaining public confidence in immunizations is critical for preventing a decline in vaccination rates that can result in disease outbreaks. While the majority of parents believe in the benefits of immunizations and have their children vaccinated, some have concerns about the safety of vaccines. The concerns about vaccine safety are preventing some parents from having their children immunized.

When a parent or patient initiates the discussing regarding a vaccine concern, discuss the specific concern and provide factual information. The VIS provides an outline for discussing vaccine benefits and risks. Reinforce key point regarding each vaccine, including safety, and emphasize risks encountered by unimmunized children. Parents should be informed about Maine State laws pertaining to school or childcare entry, which might require unimmunized children to stay home from school during outbreaks. Documentation of these discussions in the patient's record might reduce any potential liability if a vaccine-preventable disease occurs in an unimmunized patient.

Maine State Immunization Laws can be accessed at [www.ImmunizeME.org](http://www.ImmunizeME.org).

### **IV. Vaccine Adverse Events**

The Vaccine Adverse Event Reporting System (VAERS) is a national vaccine safety surveillance program co-sponsored by the Food and Drug Administration (FDA) and the CDC. The purpose of VAERS is to detect possible signals of adverse events associated with vaccines. VAERS collects and analyzes information from reports of adverse events that occur after the administration of U.S. licensed vaccines.

Reports of adverse events are welcome from all concerned individuals, including the following:

- Patients,

- Parents,
- Healthcare professionals,
- Pharmacists, and
- Vaccine manufacturers.

Use the VAERS Reporting Website at <https://vaers.hhs.gov> to report adverse events. All information requested on VAERS should be completed. It is very important to record the vaccine manufacturer, lot number, and injection site on VAERS. VAERS also requests the types of vaccine received, the timing of vaccination and onset of the adverse event, a description of the event, current illness and medication, past history of adverse events following vaccination, and demographic information about the recipient (e.g., age, gender, etc.).

## **V. Reminder/Recall**

Using reminder/recall systems within a medical home is important for several reasons, not only to improve immunization rates but also overall health care. The reminder/recall function helps in determining vaccination status, including vaccine evaluation and forecasting, determining which vaccines are due, past due, or due in the future, and also recalling patients if the following should occur:

- A public health outbreak
- Follow-up when additional doses of vaccine are needed after a public health clinic is held
- A patient has received compromised vaccine (i.e. due to vaccine exposed to temperature excursion, a vaccine administration error, or expired vaccine given) and needs to be contacted for revaccination
- When children are added to the Maine IIS, the option to notify a patient for reminder/recall is the only mechanism MIP has to flag a patient, should one of these situations occur.
- A provider site is not authorized to select the “do not notify” option on the patient’s behalf. This may ONLY be done on an individual basis AND upon patient request.

## CHAPTER 8: VACCINE INFORMATION STATEMENT (VIS)

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All immunization clinic sites are required by the National Vaccine Childhood Injury Act (NCVIA-42 U.S.C. § 300ss-26) to provide a patient, parent, guardian, or other responsible adult a current Vaccine Information Statement (VIS). The appropriate VIS must be given prior to administration of each vaccine and must also be distributed prior to each dose of a multi-dose series.

The VIS informs the client and their parent, guardian, or other responsible adult about the benefits and risks of the vaccine the child/patient is receiving. The most current version of each VIS must be provided prior to administration of each vaccine. A list of current VIS dates for each vaccine can be found on the Immunization Action Coalition (IAC) website at [www.immunize.org/vis](http://www.immunize.org/vis).

A VIS may be provided as a paper copy or in the following ways:

- A permanent, laminated, office copy of each VIS, which must be read prior to vaccination.
- A computer monitor or video display where the VIS can be reviewed.
- As a downloadable document that can be accessed via a smartphone or other electronic device by the client, parent, guardian, or other responsible adult.

The parent/patient must be offered a copy in one of the formats mentioned above to be read during the immunization visit. A copy (which can be an electronic copy) of each appropriate VIS must be provided prior to administration of each vaccine.

Reasonable steps must be taken to provide information in the appropriate languages to ensure patients with limited English proficiency are effectively informed. All VIS's are available on the CDC website at [www.cdc.gov/vaccines/hcp/vis](http://www.cdc.gov/vaccines/hcp/vis). VIS's are also available in more than 20 languages and can be downloaded from the IAC website at [www.immunize.org/vis](http://www.immunize.org/vis).

## CONCLUSION

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As a Maine Immunization Program enrolled provider, we thank you for helping to protect, promote, and improve the health of all people in Maine through integrated state, county, and community efforts.

Thank you for your contribution to our program and help keeping Maine free from vaccine preventable disease.

*-Maine Immunization Program*

Phone: (207) 287-3746 or (800) 867-4775

Fax: (207) 287-8127

Email: [www.ImmunizeME.org](http://www.ImmunizeME.org)

Address: 11 State House Station, Augusta, ME 04330

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