



Maine Immunization Program Provider Policy and Procedure Manual



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Introduction to the Maine Immunization Program

Provider Policy and Procedure Manual

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 Universal Immunization 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 (<https://www11.maine.gov/dhhs/mecdc/health-professionals/immunization/program-updates-announcements>). 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.

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. 2025 Maine Public Law 440 expanded this program to include adults aged 19 to 64.

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 residents ages 0 – 64. 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

I. Signing Provider Eligibility Requirements

To be eligible to enroll as an 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:

- Submit a vaccine profile(vaccine need) representing populations served by the facility annually.
- Screen for and document vaccine eligibility of all children and adults at each immunization encounter.
- Administer state supplied vaccine to age-appropriate individuals 0 – 64 years of age who meet the established eligibility criteria.
- Comply with appropriate vaccination schedules, dosages, and contraindications that are established by the [Advisory Committee on Immunization Practices \(ACIP\)](#), including the [American Academy of Pediatrics \(AAP\)](#) and the [American Academy of Family Physicians \(AAFP\)](#).

- Maintain all records related to MIP for at least 3 years and made available upon request. Digital or electronic storage of records is allowable.
- Immunize eligible individuals 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.
- Do not charge an administration fee more than \$21.58 per VFC eligible vaccine dose (maximum regional cap established by Federal CDC).
 - Providers may charge a vaccine administration fee at a reasonable rate determined by each MIP enrolled provider.
- Do not deny administration of a vaccine to an eligible individual because of
- the inability to pay the administration fee.
- Do not send a patient to collections or charge additional fees for non-payment of an administration fee.
- Do not be cited or terminated from MaineCare.
- 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 VFC800 Wi-Fi data loggers in storage units attach them to the online cloud.
- Ensure staff are familiar with the operations of the data loggers including how to configure and review uploaded data in LogTag Online..
- 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. Digital or electronic storage or records are allowable. Handwritten temperature logs from the past three months must be made available for compliance site visits and as requested.
- Place orders for MIP vaccine in ImmPact. Reconciliation must be completed on the same day, prior to placing an order
- Reconcile inventory in ImmPact at least 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, same day is recommended).
- 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 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 and enrollment forms. 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 includes the following:

- Name
- Title
- Maine Medical License Number
- National Provider Identifier (NPI) 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 VFC eligible children 0-18 years of age, privately insured children 0-18 years of age, and adults 19 to 64 years of age (who are underinsured, uninsured, privately insured, or enrolled in MaineCare) 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 Maine Immunization Program educational training module upon initial enrollment. Additional education will be provided during the initial enrollment visit with the primary and backup vaccine coordinators.

MIP-enrolled sites must also enroll in the Maine Immunization Information System (IIS), ImmPact. The educator and ImmPact Help Desk will provide necessary education on how to utilize 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 enrollment 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. MIP will provide a certified and calibrated digital data logger (DDL) that must be in all units that will store MIP-supplied vaccines. Minimum and maximum temperatures must be documented at the beginning of each day for seven operational days before any MIP-supplied vaccine can be ordered. The initial enrollment visit typically takes up to ninety minutes 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 storage units are available to store MIP vaccine.
- Digital data loggers are in place to monitor temperatures and connected to LogTag Online.
- The staff understands how to properly monitor, store and handle, MIP-supplied vaccine.
- The staff know 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
 - How to review temperature data in LogTag Online.
 - Proper vaccine storage and handling
 - Vaccine quarantine and how to respond to excursions
 - 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 and adults 0 – 64 years of age.
 - Eligibility screening must be documented at every vaccine encounter
 - VFC eligibility is met through the following conditions:
 - Children must be 18 years of age or younger AND one of the following:
 - MaineCare enrolled
 - Alaskan Native/American Indian
 - Uninsured
 - Non-U.S. Citizen (not intended for temporarily traveling or visiting)
 - State-supplied eligibility is met through the following conditions:
 - Must be state of Maine resident and one of the following:
 - Children must be 18 years of age or younger with commercial insurance
 - Adults must be 19-64 years of age with commercial insurance OR underinsured
 - Vaccine loss and waste are minimized and documented
 - Fraud and abuse do 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 information in Impact including demographics, days/hours available to receive vaccine shipments, and profile information. 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. New primary or backup vaccine coordinators are required to complete the Maine Immunization Program Educational Training.

The educational module can be found on the MIP website.

<https://www.maine.gov/dhhs/mecdc/health-professionals/immunization/required-training>.

The MIP Provider Agreement and provider profile (vaccine need) 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 every other year (biennial). 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:

➤ **Due One-time Only**

- ImmPact User Agreements- MIP requires all users to provide a signed [ImmPact user agreement](#) in order to have access to the ImmPact system. All accounts must complete a one-time-only signed and dated user agreement. Completed user agreements must be kept on file and provided to MIP upon request.

➤ **Annual - every year (Due by July 1st)**

- 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 1st. The Vaccine Need can be found under the “maintenance” section in ImmPact.

➤ **Annual - every year (Due July 1st - July 31st)**

- Education Requirement – The assigned primary and backup vaccine coordinators are required to complete the Maine Immunization Program Educational Training each year.
- The required training will become available on the MIP website starting
- July 1 and must be completed by July 31st of each year.
- Any newly assigned primary or secondary vaccine coordinators should complete the training upon being added to their provider agreement and prior to their first order.
 - Any training completed prior to July 1st* will not count towards satisfying the requirement in the upcoming fiscal year.

➤ **Biennial - every other year (Due by July 1st)**

- 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.

*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 it to MIP.

IV. Suspension from MIP

If it is determined that the MIP Provider Agreement or accountability requirements 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 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

I. Patient Eligibility Requirements

Maine is a universal vaccine state. This means that any individual 0 – 64 years of age can receive MIP-supplied vaccine including Maine receives funding from both the Federal VFC program and from Maine health insurers to purchase vaccines from the CDC federal contract at no cost to the providers

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.

A. Eligibility Screening for Patients 0 – 64 Years of Age

i. State Vaccine Eligible: 0 – 64 years of age

- Any individual **0 – 64** years of age and meet the criteria below:
 - Maine resident and privately insured
 - Adults **19 – 64** years of age with secondary insurance which covers vaccinations
- Adults **19 – 64** years of age and meets at least one of the criteria below:
 - Uninsured (no insurance coverage)
 - Underinsured (coverage does not include vaccines or whose insurance covers only selected vaccines)

ii. Federal VFC Eligible: 0 – 18 years of age

- 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 **federal VFC** vaccine:
 - Medicaid – (child has MaineCare)
 - Uninsured (no insurance coverage)
 - Underinsured (coverage does not include vaccines or a child whose insurance covers only selected vaccines)
 - American Indian or Alaskan Native (in accordance with 25USC1603)
 - Non-U.S. Citizen Children (Not intended for temporary travel or visiting)

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.

II. Patient Eligibility Screening Record

Screening for patient eligibility is the foundation for MIP supplied vaccine accountability. Screening and documenting all individuals at every immunization encounter is the only way to ensure that MIP-supplied vaccine is used only for eligible children and adults and that correct funding is used to purchase these vaccines. Full compliance with screening for eligibility is required prior to vaccination. If 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 resident, patients 19 -64 with Medicare only for insurance coverage, and/or patients 65 years and older, regardless of insurance coverage.

Eligibility documentation of each individual receiving MIP-supplied vaccine is required at every vaccination visit. During a patient's initial visit, eligibility must be documented per MIP guidelines. Every subsequent visit must contain the patient'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 (EHR). Eligibility screening must be completed/updated for all patients at every visit prior to vaccine administration. Even those patients with a previous record on file, must be confirmed and re-documented prior to vaccine administration.

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 at the time of each visit

Eligibility screening records must be kept on file for a minimum of three years after the last date of service and must be easily retrievable. Digital or electronic storage of records is allowable if anyone in the office can access them.

It is acceptable for sites to utilize an EMR/EHR system to capture and save information from

the patient eligibility screening record if 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

I. Approved Vaccines

All vaccines and toxoids recommended by the Advisory Committee on Immunization Practices (ACIP) are available from MIP to enrolled sites. All vaccines should be given to patients based on age indication and current vaccine recommendations.

- A.** COVID-19 - (Not available for adults 19 – 64 during 2026-2027, except for underinsured and uninsured)
- B.** Diphtheria-Tetanus toxoids and acellular Pertussis(DTaP)
- C.** Diphtheria-Tetanus toxoids and acellular Pertussis, Hepatitis B, and inactivated polio (DTaP-Hep B- IPV)
- D.** Diphtheria-Tetanus toxoids and acellular Pertussis, inactivated polio, and Haemophilus influenzae type b(DTaP-IPV-Hib)
- E.** Diphtheria-Tetanus toxoids and acellular Pertussis and inactivated polio (DTaP-IPV)
- F.** Diphtheria-Tetanus toxoids and acellular Pertussis, inactivated polio, Haemophilus influenzae type b, and Hepatitis B (DTaP-IPV-Hib-Hep B)
- G.** Hepatitis A (Hep A)
- H.** Hepatitis B (Hep B)
- I.** Hepatitis A and Hepatitis B (Hep A-Hep B)
- J.** Haemophilus influenzae type b (Hib)
- K.** Human Papillomavirus (HPV)
- L.** Influenza (Flu) - *(Not available for adults 19 – 64 during 2026-2027 season, except for those uninsured or underinsured are eligible under adult 317)*
- M.** Inactivated polio (IPV)
- N.** Measles, Mumps, and Rubella (MMR)
- O.** Measles, Mumps, Rubella, and Varicella (MMRV)
- P.** Meningococcal Conjugate (MCV4)
- Q.** Meningococcal Serogroup B (MenB)
- R.** Meningococcal Pentavalent (MenABCWY)
- S.** Mpox (Jynneos)
- T.** Pneumococcal Conjugate (PCV15)
- U.** Pneumococcal Conjugate (PCV20)
- V.** Pneumococcal Polysaccharide 23-valent vaccine (PPSV23)
- W.** Respiratory Syncytial Virus (RSV)
- X.** Rotavirus (RV)
- Y.** Tetanus and diphtheria toxoids (Td)
- Z.** Tetanus and diphtheria toxoids and acellular pertussis (Tdap)

AA.Varicella

BB.Zoster

A complete list of available vaccines including trade names and manufacturers can be found on the Maine Vaccine Board website here: <https://www.mevaccine.org/ui/providers>

II. Vaccine Ordering

A. Vaccine Choice

All vaccines recommended by 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 and COVID-19 vaccine.

The signing healthcare provider at MIP-enrolled sites may choose vaccine brands and presentations. For new sites enrolling in MIP, staff at MIP can 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. Vaccine coordinators 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 to choose from.

If 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.

B. Vaccine Inventory Management

Vaccine inventory management requires all enrolled sites to maintain a 4 - 6-week supply of vaccine inventory. . MIP recommends placing a vaccine order while still having a four-week supply of vaccines available , to ensure there is enough stock to allow for any potential delays. Place smaller, more frequent orders rather than large orders to minimize vaccine loss should an incident take place during shipment or in the vaccine storage unit. 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.

The vaccine need may be increased or decreased at any time if the number of MIP-supplied

eligible individual changes, or if there are any applicable changes to the status of the facility that might affect vaccine usage. The assigned vaccine coordinators for the enrolled site must update their vaccine need 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 vaccine need.

C. Short-Dated Vaccine

Short-dated vaccines are those that are within 60 – 90 days of expiration. Placing vaccine orders according to the vaccine need 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 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/node/236>.

Vaccine diluents, the liquid mixed with a lyophilized (freeze-dried) vaccine powder 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 vaccine replacement procedure.

D. 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.

E. Vaccine Ordering in ImmPact

MIP uses the Maine Immunization Information System (IIS), 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 staff at MIP-enrolled sites are available to receive vaccine.
- Site's delivery address.
- Primary and backup vaccine coordinators point of contact information.
- Up-to-date temperature logs for all units.
- Doses administered is 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. All orders placed in ImmPact will be reviewed and approved by MIP staff 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 dose 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 most 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.

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 vaccine coordinators 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 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.
 - 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*.

Assigned vaccine coordinators for the enrolled site 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.

- A.** 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.
- B.** 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.

- C. 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 or Merck). 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.

A. 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.

Process vaccines for return using the “Manage Returns” module in ImmPact. The primary vaccine coordinator will receive a shipping label via email for returning expired or spoiled vaccine within 24 hours of the Manage Returns module being completed and submitted. Depending on the number of doses lost, multiple shipping labels may be received. The return authorization must be printed from ImmPact and 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 patients may have received the affected vaccines. The signing healthcare provider must work with MIP to determine if children must be revaccinated if applicable.

B. 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 more than 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.

A. Refrigerator and Freezer Requirements

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

- A.** MIP recommends the following types of units, listed in preferential order:
Pharmaceutical/purpose-built units,
- B.** Stand-alone, single-purpose refrigerator and stand-alone single-purpose freezer, and
- C.** 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 not allowed.

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:

- D.** 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)
- E.** 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).
- F.** The freezer compartment must maintain temperatures between -58°F and
- G.** +5°F (-50°C and -15°C) for vaccine viability.
- H.** An alarm system to help reduce vaccine loss when unexpected temperature fluctuations occur.
- I.** Refrigerators and freezer storing vaccines must be plugged directly into a wall outlet. A plug guard is recommended to be used/installed to prevent accidental or intentional unplugging.
- J.** 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.
- K.** 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.

- L. 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:

- A. Ensure the door closes completely.
- B. Replace crisper bins with water bottles to help maintain a consistent temperature (unless used for other medical equipment or supplies).
- C. Label water bottles “Do Not Drink”.
- D. Post “Do Not Unplug” signs on the refrigerator, at the electrical outlet, and at the circuit breaker.
- E. Place water bottles in unit doors carefully so they do not dislodge and
- F. place water bottles on the top shelf of the refrigerator under the fan (if present).
- G. Leave 2-3 inches between all vaccine (if possible) and the refrigerator walls.
- H. Store each type of vaccine or diluent in a separate container with holes to allow for air flow unless the diluent is contained in the same box as the vaccine, then they must be kept together.
- I. Place vaccines with the earliest expiration dates in front of those with later expiration dates.
- J. Whenever possible, store diluent with the corresponding refrigerated vaccine. Diluents must not be frozen.
- K. 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.
- L. Label the formulation “pediatric” or “adult” if applicable.
- M. Always store vaccines in their original packaging with lids closed until ready for administration.
- N. 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.
- O. Vaccines must be centrally stored within the unit.
- P. Do not store loose vials or manufacturer-filled syringes outside their packaging.
- Q. Do not use the top shelf or floor of unit for vaccine storage.
- R. Do not store food or beverages in the refrigerator with vaccines.
- S. Do not put vaccines in the doors or on the floor of the refrigerator.
- T. Do not drink from or remove water bottles.
- U. Do not pack a storage unit too tightly. This may result in restricted air circulation and impact the unit’s temperature.

For the freezer:

- A. Ensure the door closes completely.
- B. Use frozen water bottles to help maintain a consistent temperature.

- C. Place water bottles against the walls, in the back, on the floor, and in the door racks.
- D. Place water bottles in unit doors carefully so they cannot dislodge and prevent the doors from closing or weighing down the door so much that it does not seal tightly.
- E. Post “Do Not Unplug” signs on the freezer and by the electrical outlet.
- F. Leave 2-3 inches between all vaccines and the freezer walls.
- G. 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.
- H. Store each type of vaccine in a separate container.
- I. Vaccines must be centrally stored within the unit.
- J. Place vaccines with the earliest expiration dates in front of those with later expiration dates.
- K. Attach labels to shelves and containers to clearly identify each type of vaccine.
- L. Store vaccines with similar packaging or with both pediatric and adult formulations on different shelves to minimize the risk of administration errors.
- M. 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.
- N. Clearly label the formulation “pediatric” or “adult” if applicable.
- O. Always store vaccines in their original packaging with lids closed until ready for administration.
- P. Do not store food or drinks in the freezer.
- Q. Do not store vaccines in the freezer doors.
- R. Do not store loose vials or manufacturer-filled syringes outside of their packaging.
- S. Do not store diluent in the freezer. Diluent must never be frozen.
- T. Do not pack a storage unit too tightly. This can restrict air circulation and impact vaccine temperature.

B. New or Repaired Units:

Prior to using a new or newly repaired unit to store vaccines, the MIP requires seven operational days of refrigerator or freezer temperature recordings that are in the recommended range.

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 are necessary, read the instructions carefully and verify that the temperatures did not change overnight. It is recommended that you e post instructions on who to contact for this 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. A temperature recording paper log is required to be located on or near all units that store

MIP vaccines.

- B.** Freezer and/or refrigerator temperatures are required to be checked, recorded, and initialed. This includes recording time the temperatures were taken. Minimum and maximum temperatures must be recorded on the temperature recording form once at the beginning of each business day.
- C.** Temperatures must be recorded manually on temperature recording forms, even when using a data logger
- D.** Temperature recording forms must be maintained for at least three years and made easily available.

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

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

C. Data Logger Requirements

MIP supplies the amount of data loggers each enrolling provider location needs for storing MIP supplied vaccines, including one back-up logger. It is required that one primary [VFC-800 Wi-Fi data logger with smart probe](#) be in use for each unit that contains MIP-supplied vaccines, regardless of what may be in use for existing temperature monitoring devices. In addition, MIP provides one back-up data logger that must be available on site.

Each VFC 800-WiFi data logger with smart probe comes 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.

The VFC-800 Wi-Fi data logger with smart probe provides more accurate and comprehensive monitoring of temperature excursions to which vaccines may be exposed. The data logger helps reduce vaccine loss by providing necessary data via email and text messages to alert the need for immediate action, when the vaccine would otherwise be lost.

MIP-enrolled sites are required to use the data loggers supplied by MIP and must comply with the daily minimum and maximum temperature recording requirements. It is recommended that staff review LogTag Online at least once per week to ensure that any notifications are identified and acknowledged in a timely manner.

The following requirements are included with the VFC800-Wifi data loggers with smart probe:

- 1.** An active temperature display that can be easily read by all staff from outside of the unit without having to open the door.
- 2.** Alarm for out-of-range temperatures.

3. A display that shows the current temperature, as well as ability to access daily minimum and maximum temperatures.
4. Low battery indicator.
5. Accuracy of $\pm 1^{\circ}\text{F}$ ($\pm 0.5^{\circ}\text{C}$).
6. Detachable probe in buffered material.
7. Memory storage of at least 16,000 readings
8. User-programmable logging interval of at least every 30 minutes.

Data logger 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. Each MIP supplied VFC800-WiFi data logger comes with a smart probe offering superior accuracy. Each probe is independently calibrated, resulting in highly reliable and precise measurements.

MIP does **NOT** allow the following temperature devices to be used for transport or back up temperature monitoring:

- 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:

1. Placed in the center of the unit.
2. Placed as close to the vaccine as possible.
3. 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.

A valid certificate of calibration matching 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.

Each MIP-enrolled site is responsible for maintaining valid certificates of calibration for each MIP supplied data logger. Replacements smart probes can be ordered directly online at: <https://www.vfcdataloggers.com/product/vfc800wifi-replacement-probe/>

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 and cannot be utilized as primary temperature monitoring device

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.

D. 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, IPV, MCV4, MenB, MMR, MMRV, Rotavirus, and Varicella.

- All MIP-supplied vaccines, except for 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.

E. Protective Equipment

- The power supply for vaccine storage units must be protected by ensuring these practices are as follows: 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 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.

F. 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 MIP online educational module. Due July 1st – July 31st of each year, available at <https://www.maine.gov/dhhs/mecdc/health-professionals/immunization/required-training>

All new primary and backup vaccine coordinators are recommended to participate in a Vaccine Coordinator 101 Educational webinar. These are conducted quarterly and as

needed. MIP education staff will accommodate individual one-on-one training upon request. The schedule for these webinars and/or request for personal training can be requested by emailing ImmunizeME.DHHS@maine.gov.

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.

G. Routine and Emergency Storage and Handling Plan

All MIP-enrolled sites must have plans for routine and emergency vaccine management. Templates are provided for the Routine and Emergency Vaccine Storage and Handling Plan, including a Checklist for Safe Storage and Handling. . The plan and checklist templates contain comprehensive information on best practices and the most current information about the storage and handling of vaccines.. staff at the site can develop their own routine and emergency vaccine management plans if it includes all the information on the templates provided by MIP.

MIP routine and emergency vaccine storage and handling plan 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 coordinators must be included. Contact information must be updated annually, or sooner if 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 sources 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 if 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. All staff must be aware of this plan.

In the event of an emergency that includes out of range temperatures, 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.
- Lot # and 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/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.

H. 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.

I. 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 if 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 always be used as a temperature monitoring device during transport.
 - 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).

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.
- If 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.

J. Frozen Vaccine Transport

Varicella and MMRV vaccines are fragile and must be kept frozen and protected from light. 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).
- 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.
- **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.
- **Temperature Monitoring Device** – Use a certified and calibrated datalogger 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.

- 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 travel 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 remove the vaccine from appropriate storage conditions or waste out in ImmPact without contacting the manufacturer and MIP first Viability determination will be made on a case-by-case basis.

VI. Vaccine Transfers

The routine re-distribution of MIP-supplied vaccine is discouraged. 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:

- A.** 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).
- B.** Ensure the vaccine is being transferred to another MIP-enrolled site.
- C.** Both MIP-enrolled sites (the site transferring vaccine and the site accepting the vaccine transfer) must have up-to-date temperatures entered in ImmPact.
- D.** 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.
- E.** 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.
- F.** Include a travel 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 need a copy of the temperature recording form from the transfer as well as the past three months of the transferring site's monthly temperature recording forms.
- G.** 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 must offer all vaccines recommended for their patient population. While keeping every vaccine in stock is not required, any requested vaccine must be ordered and made available to MIP-eligible patients age 0 – 64. .

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 for the following:

- 1.** Non-Maine resident, regardless of insurance coverage
- 2.** Adults 19 – 64 with Medicare only for insurance coverage
- 3.** Any adult aged 65 years of age or older, regardless of insurance coverage.

For example, MIP-supplied flu vaccine must not be administered to an adult over 65 years old 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 patient, the following steps must be completed within thirty days:

- A. 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 the ImmPact Help Desk at 1-800-906-8754.
- B. 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.
- C. Replace the vaccine immediately with privately purchased vaccine and account for the replacement in ImmPact. All vaccines must be replaced dose for dose; a different vaccine may not be used.

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.

If a site does not follow corrective actions in response to borrowing procedure, the vaccine ordering privileges may be suspended if not completed within thirty days. 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.

Reconciliation is also required prior to placing an order.

A. Temperature Recording Log

A temperature log 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 always maintained at proper storage temperatures. 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 initial by the staff member conducting the check.

Completed temperature must be submitted in ImmPact 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 Log and included in the notes section in ImmPact:

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

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

B. 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 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

I. Billing for Vaccine

MIP-enrolled sites are prohibited from charging any MIP-eligible individual for the cost of vaccines. MIP-supplied vaccines are provided at no cost to clinics to vaccinate eligible individual. 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 patient to another healthcare facility for MIP-supplied vaccines if the site already accepted that individual into their practice as their patient, unless directed by MIP.

II. Administration Fee

MIP enrolled provider's vaccine administration fee for non-Medicaid, VFC-eligible children must not exceed the state/territory vaccine administration fee cap established by the Centers for Medicare & Medicaid Services (CMS). A fee may be charged for administering MIP-supplied vaccine to eligible children and adults. The maximum administration fee cap for Maine is no more than \$21.58.

MIP-eligible children 0 – 18 years old will fall into two categories.

- **VFC-eligible** includes all MaineCare, American Indian, Alaskan native, uninsured, or underinsured children.
- **State-eligible** includes all privately insured children residing in Maine.

MIP-eligible adults include:

- Adults 19 - 64 years of age who are privately insured, uninsured, or underinsured and a Maine resident

Adults 65 and over age not eligible for MIP supplied vaccines.

There is no maximum administration fee required for State-eligible children or adults, 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 for the separate administration of each Infanrix (DTaP) and IPOL (IPV).

Children and adults with MaineCare must not be charged the administration fee for receiving vaccines. 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.

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>

Vaccines must be made available to all MIP-eligible patients. Services cannot be denied due to the parent/guardian/patient's inability to pay the administration fee. The administration fee 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 individuals 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 and adults, Medicaid should be billed for the vaccine administration fee.

Effective January 1, 2020, providers who choose to bill for the vaccine administration fee of a non-Medicaid, VFC-eligible child age 0 – 18, or eligible adult age 19 – 64 after the date of service, may issue only a single bill to the patient within 90 days of vaccine administration. Administration fees can never be sent to collections.

CHAPTER 5: PROGRAM EVALUATION

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 3 –12 months after initial enrollment. MIP enrolled sites that received a virtual enrollment visit are required to receive a QA visit within 3 – 6 months of enrollment. For those sites that received an in-person enrollment visit are required to receive a QA visit within 6 – 12 months of 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 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
- Handwritten temperature logs data for the last three months
- Calibration certificates for the primary and back up digital data loggers (DDL)
- Vaccine borrowing forms for any occurrences since last site visit
- 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/excessive preventable wastage
- Improper documentation on temperature logs
- Vaccine orders are inconsistent with population profile data
- 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 participating 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 (AOR) 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 are identified by the reviewer and 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 the 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. Immunization Quality Improvement for Providers (IQIP)

Immunization Quality Improvement for Providers (IQIP) is the CDC's national, Vaccines for Children (VFC) provider-level immunization quality improvement (QI) program. IQIP serves to assist and support health care providers by identifying opportunities to improve vaccine uptake and to help providers be:

- Motivated to try new vaccination service delivery strategies and incorporate changes into their current practices
- Supported in sustaining changes and improvement to their vaccination service delivery
- Aware of and knowledgeable about vaccination coverage and missed opportunities to vaccinate
- Able to use available data from the IIS to improve services and coverage

The purpose of IQIP is to promote and support the implementation of provider-level strategies designed to help increase vaccination across Maine.

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 individuals 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 .
- Failure to meet licensure requirements for enrolled physicians.
- Deny MIP-supplied vaccine to MIP eligible individuals because of the inability to pay the administration fee.
- Send a patient's fee 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 intentionally 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 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 do 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 remain 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

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/health-professionals/immunization/vaccine-education-materials>

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. Digital and electronic storage of records is allowable.

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.

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 most 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 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 <https://www.maine.gov/dhhs/mecdc/diseases->

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 welcomed from all concerned individuals, including the following:

- Patients
- Parents
- Healthcare professionals
- Pharmacists
- 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, 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 healthcare.

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 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)

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.

Current Vaccine Information Statements (VIS) must be presented to parents at every vaccination prior to the vaccine being administered. An [Immunization Information Statement \(IIS\)](#) should be provided prior to administration of Respiratory Syncytial Virus (RSV) preventive antibody.

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.

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. VIS's are also available in more than 20 languages and can be downloaded from the IAC website at www.immunize.org/vis.

CONCLUSION

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*

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