

Maine Immunization Program COVID-19 Policy and Procedure Manual



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INTRODUCTION TO THE MAINE IMMUNIZATION PROGRAM PROVIDER POLICY AND PROCEDURE MANUAL

I. 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.

II. 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

III. COVID Provider Manual Information

The purpose of the Maine Immunization Program (MIP) COVID Provider Manual is to consolidate the Federal COVID and State of Maine policies and information into one source. Throughout the year, MIP will announce new policies via official letters and memorandums. Notice of these will be done through the email notification system govDELIVERY and postings on the Maine Immunization Information System, ImmPact. 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 <u>www.immunizeme.org</u>.

IV. Public Health Law Establishing the COVID Provider Eligibility

Laws and Regulations

The Public Readiness and Emergency Preparedness Act (PREP Act) added new legal authorities to the Public Health Service (PHS) Act to provide liability immunity related to the manufacture, testing, development, distribution, administration and use of medical countermeasures against chemical, biological, radiological, and nuclear agents of terrorism, epidemics, and pandemics. It also added authority to establish a program to compensate eligible individuals who suffer injuries from

administration or use of products covered by the PREP Act's immunity provisions.

The Prep Act and DHHS Secretary declarations provide immunity for the administration or use of a covered countermeasure (which includes vaccines) to, among others, "a qualified person who prescribed, administered, or dispensed such countermeasure" and their agents and employees. 42 U.S.C. sec. 247d-6d.

Acts or omissions which are willful are not protected by immunity. The federal law specifically defines willful as a standard for liability that is more stringent than a standard of negligence in any form or recklessness. Willful acts or omissions are those intentionally done to achieve a wrongful purpose; knowingly without legal or factual justification; and in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.

V. Countermeasures Injury Compensation Program (CICP)

The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the CICP to provide benefits to certain individuals or estates of individuals who sustain a covered serious physical injury as the direct result of the administration or use of the covered countermeasures. The CICP can also provide benefits to certain survivors of individuals who die as a direct result of the administration or use of covered countermeasures identified in a PREP Act declaration. The PREP Act declaration for medical countermeasures against COVID-19 states that the covered countermeasures are any antiviral medication, any other drug, any biologic, any diagnostic, any other device, or any vaccine used to treat, diagnose, cure, prevent, or mitigate COVID-19, the transmission of SARS-CoV–2 or a virus mutating from SARS-CoV-2, or any device used in the administration of and all components and constituent materials of any such product.

The CICP is administered by the Health Resources and Services Administration within the Department of Health and Human Services. Information about the CICP and filing a claim is available by calling 1-855-266-2427 or visiting <u>CICP</u>.

CHAPTER 1: MIP SITE ELIGIBILITY AND ENROLLMENT

Requirements for Participating in the COVID-19 Vaccination Program

At this time, all COVID-19 vaccine in the United States has been purchased by the federal government for administration exclusively by <u>enrolled providers</u> through the CDC COVID-19 Vaccination Program.

I. Signing Provider Eligibility Requirements

• Providers that wish to receive COVID-19 vaccines must enroll in the COVID-19 Vaccination Program (CoVP). The enrollment process is described on the <u>COVID-19 Vaccination Clinical &</u> <u>Professional Resources</u> webpage.

- Enrolled COVID-19 vaccination providers must be legally licensed and authorized to administer vaccines in the jurisdiction where they will be practicing. Your health system or you, as an independent provider, are required to sign and abide by the terms of the CDC COVID-19 Vaccination Program Provider Agreement.
- COVID-19 vaccination providers participating in the CDC COVID-19 Vaccination Program are required to sign a CDC <u>COVID-19 Vaccination Program Provider Agreement</u>.
- Providers are responsible for adhering to all requirements outlined in the agreement, including updated recommendations, requirements, and other guidance provided in the footnoted web links incorporated in the agreement.
- Vaccination providers and organizations must check the <u>CDC COVID-19 Vaccine Program</u> <u>Provider Requirements and Support</u> link regularly. A <u>sign-up</u> is available to receive emails any time page is updated.

Clinicians administering specific COVID-19 vaccines should follow manufacturer instructions and the recommendations of ACIP.

Under the COVID-19 vaccine program:

- Providers of COVID-19 vaccine are required to report all doses administered electronically directly to or indirectly via the ImmPact platform.
- COVID-19 vaccine providers must administer COVID-19 vaccine regardless of the vaccine recipient's ability to pay any COVID-19 vaccine administration fees.
- When administering COVID-19 vaccine under the FDA Emergency Use Authorization (EUA), providers must make available an <u>EUA fact sheet</u> to each vaccine recipient or legal guardian accompanying the recipient. The fact sheet may be made available as a hard copy or via a website URL.

II. Enrollment Requirements

To become a COVID-19 vaccination provider, you must be licensed to administer vaccines in the state of Maine. Your health system or you, as an independent provider, are required to sign and abide by the terms of the CDC COVID-19 Vaccination Program Provider Agreement. The agreement requires that you follow best practices for storing, handling, and administering vaccine and that you collect and report certain vaccination-related information.

A. Specific Terms of Agreement

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

- Submit a profile representing populations served by the facility annually.
- Screen for and eligibility and contraindications at each immunization encounter.
- Administer COVID-19 vaccine to all children and adults 5 years of age and older.

- Comply with appropriate vaccination schedules, dosages, and contraindications that are established by the Advisory Committee on Immunization Practices (ACIP).
- Maintain all records related to MIP COVID-19 vaccine for at least 3 years and upon request, make these records available for review.
- Immunize COVID-19 vaccine at no charge to the patient for the vaccine.
- Provide a copy of the most current FDA Emergency Use Authorization (EUA) for each vaccine at the time of administration
- Operate in a manner intended to avoid fraud and abuse.
- Comply with MIP requirements for vaccine management, including ordering and proper storage and handling.
- Participate in MIP compliance visits, including unannounced visits and other education opportunities, as required.
- Do not charge an administration fee per vaccine administration
- Do not deny administration of 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 COVID-19 administration fee.
- 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.
- ImmPact User Agreements MIP requires Primary and Backup vaccine coordinators to provide a signed ImmPact User Administration Agreement in order to continue to have access to the system.
 - All individuals within your organization with active log-in credentials for ImmPact must have a signed <u>ImmPact Individual User Agreement</u> on file. These individual user agreements should be kept on file at your facility and be made available to MIP if necessary.

These do NOT need to be sent to MIP.

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

B. Vaccine Coordinator Responsibilities

Vaccine Coordinator Role and Responsibilities

The CoVP requires enrolled COVID-19 vaccination providers to designate a vaccine coordinator role at each location as well as a back-up vaccine coordinator. A vaccine coordinator is the point of contact with Department of Health (DPH) and is responsible for receiving vaccine shipments, monitoring storage unit temperatures, managing vaccine inventory, etc. The coordinator responsibilities may be completed by the coordinator or delegated to appropriate staff. The

coordinator must ensure that all delegated staff have been trained appropriately for all tasks assigned to them. <u>CDC Storage and Handling Toolkit</u>.

The back-up coordinator would assist or assume the vaccine coordinator role when the vaccine coordinator is not available. (Note: This person will be responsible for ensuring all vaccines are stored and handled correctly and should be an expert on your facility's storage and handling Standard Operating Procedures.)

MIP requires that the signing healthcare provider designate a primary and backup 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 patients receive age appropriate COVID-19 vaccine and dosage.
- Assist with set up of data loggers in storage units.
- Ensure staff are familiar with the operations of the dataloggers including how to download data.
- Monitor, read and record the minimum and maximum temperatures of the units (refrigerators and freezers) at the beginning of each workday (if not monitoring min/max temperatures must be read and recorded twice a day).
- Monitor the operation of storage equipment and systems.
- Maintain all documentation, such as inventory and temperature logs for a minimum of three years (documentation in ImmPact meets this requirement, with the exception of temperature logs. Sites must keep the most current month of paper temperature logs on hand in case of a temperature discrepancy or site visit.)
- Reconcile inventory in ImmPact every 14 days (recommended daily). Track and document doses administered. COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration and use their best efforts to report administration data to the relevant system for the jurisdiction [i.e., <u>Immunization Information Systems (IIS)</u>] as soon as practicable and no later than 72 hours after administration.
- Oversee proper receipt and storage of vaccine deliveries.
- Organize vaccines to monitor expiration dates.
- Ensure vaccine is stored and handled appropriately to safeguard vaccine viability.
- Respond to out-of-range temperature excursions or respond in the event of an emergency (unit failure, power outage, disaster, etc.)

- Oversee proper vaccine transport when necessary.
- Ensure other staff are trained in the proper storage and handling of vaccines.
- Notify MIP COVID-19 team of staff changes immediately (primary or backup vaccine coordinators or signing healthcare provider). For Primary and backup coordinators a

Primary and Back-Up Vaccine Coordinator ImmPact Administrator Agreement will need to be filled out and submitted.

CoVP Provider Responsibilities for Temperature Monitoring

- 1. Ensure there is a digital data logger (DDL) monitoring and recording device for each vaccine storage unit storing COVID-19 vaccine.
- 2. Assess and record temperatures once per day (See log sheets below).
- 3. Document minimum/maximum temperature at least once a day.
- 4. Name (or initials) of the person who assessed/and recorded these temperature readings, time, and date of each reading.
- 5. Download DDL Data Report, Evaluate Daily, Weekly and Monthly temperatures; for any changes in temperature trends that might require corrective action.
- 6. If a temperature excursion occurs:
 - a. Document information about any excursion and what steps were taken to correct any issues.b. Contact the Immunization Program/or Manufacturers for guidance on vaccine viability.

C. Initial Enrollment

The first step in enrolling to become a Covid-19 Provider is to complete the CDC <u>COVID-19</u> <u>Vaccination Program Provider Agreement</u>.

Provider Agreement. The COVID-19 Vaccination Program Provider Agreement should be updated when there is a change in contact information or Section B. There are no requirements to update/renew the Provider Agreement on a particular schedule. 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 at the facility who have prescribing authority must be listed on the COVID Provider Agreement. The listing must also include the signing healthcare provider's information. Information required for all licensed healthcare staff include the following:

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

The profile section of the COVID 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.

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 "Vaccine Storage and Handling" training modules upon initial enrollment. The educator will provide education by conducting an initial enrollment visit with the primary and backup vaccine coordinators. MIP-enrolled sites must also enroll in the Maine Immunization Information System, ImmPact. The educator and ImmPact Help Desk will provide necessary education on ImmPact.

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

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

D. 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:

- Covid vaccines are administered to everyone at no charge for vaccine
- Vaccine loss and waste are minimized and documented
- Fraud and abuse does not occur
- Covid vaccine inventory is accurately reported at least every 14 days (recommended daily)

E. Provider Change of Information

It is the responsibility of the staff at the MIP-enrolled site to maintain correct demographics, days and hours available to receive vaccine shipments, and profile information in ImmPact. MIP must be contacted immediately if there is a new signing healthcare provider or a change in staff that are assigned the duties as a primary or backup vaccine coordinator. In addition, it is the MIP-enrolled site staff's responsibility to update ImmPact with that current information. Coordinators are responsible for completed required trainings that can be found on the Maine Immunization Program website.

The COVID Provider Agreement and profile must be updated if the 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.

F. Re-Enrollment

Provider Agreements should be updated when there is a change in contact information or Section B. There are no requirements to update/renew the Provider Agreement on particular schedule.

G. Withdrawal from MIP

MIP must be contacted if a MIP-enrolled site chooses to withdraw from the program. MIP will arrange to pick up COVID-19 vaccine and will assist with final paperwork. Prior to withdrawal, it is requested that the site staff complete a withdrawal form and submit to MIP.

H. Suspension from MIP

If it is determined that the COVID Provider Agreement or accountability requirement have been violated, the enrolled site may temporarily lose program privileges.

Suspension is dependent upon the severity of the non-compliance issues and/or failure to complete the MIP required corrective action plans. MIP corrective action plans are set in place to correct failures in vaccine management and non- compliance issues, including, but not limited to: failure to complete re-enrollment in a timely manner, failure in vaccine management, failure of required patient eligibility screening, improper storage and handling practices, or failure to complete monthly reporting requirements. Staff at suspended sites may be required to complete additional training as part of a corrective action plan.

I. 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.

J. Re-enrollment after Termination

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

Sites that are terminated may be considered for re-enrollment after one year.

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

K. 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. <u>Patient Eligibility Requirements</u>

Enrollees must complete CDC <u>COVID-19 Vaccination Program Provider Agreement</u>. Failure of any enrolled COVID-19 vaccine provider organization or vaccination location under its authority to meet the conditions of the agreement may impact whether COVID-19 vaccine product orders are fulfilled and may result in legal action by the federal government. A Provider Profile indicating key attributes of the organization is also required to accompany the Agreement (see Section B of the CDC COVID-19

Vaccination Program Provider Agreement). The Provider profile will be retained on file for a minimum of 3 years and made available to CDC upon request.

- COVID-19 vaccines are 100% free for the patient. No administration fees, copays, or coinsurance can be charged. However, vaccination providers may seek reimbursement for vaccine administration fees from a patient's health coverage program or plan. For further information on reimbursement requirements, please see the <u>CDC COVID-19 Vaccination Program Provider</u> <u>Requirements and Support webpage</u>.
- You must administer COVID-19 vaccines in accordance with all <u>program requirements and</u> <u>recommendations</u>, including those of CDC, the <u>Advisory Committee on Immunization</u> <u>Practices</u>, and the <u>U.S Food and Drug Administration</u>
- You must be able to administer COVID-19 vaccines under proper conditions to maintain the vaccine cold chain.
- COVID-19 vaccine preparation differs among COVID-19 vaccine products and is different from that of routinely recommended vaccines. Therefore, vaccine preparation training is essential.
- Comply with appropriate vaccination schedules, dosages, and contraindications that are established by the Advisory Committee on Immunization Practices (ACIP).
- Follow best practices for storing, handling, and administering vaccine.
- Collect and report certain vaccination-related information.
- Maintain all COVID-19 records related to MIP for at least 3 years and upon request, make these records available for review.
- Immunize COVID-19 vaccine at no charge to the patient for the vaccine.
- Provide a copy of the most current <u>FDA Emergency Use Authorization (EUA)</u> for each vaccine at the time of administration
- Provide <u>a V-safe Information Sheet</u> to each COVID-19 vaccine recipient or legal guardian accompanying the recipient. The fact sheet may be made available as a hard copy or via website URL.
- 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 COVID compliance visits, including unannounced visits and other education opportunities, as required.
- To not charge an administration fee in excess of \$21.58 per vaccine dose (maximum regional cap established by FederalCDC).
- To not deny administration of Covid vaccine to anyone because of
- the inability to pay the administration fee.
- To not send a patient to collections or charge additional fees for non- payment of Covid administration fee.
- To not send a patient to collections or charge additional fees for non- payment of

Covid administration fee.

Acknowledge that MIP may terminate the agreement at any time for failure to comply with established vaccine requirement.

CHAPTER 3: VACCINE MANAGEMENT

I. Approved COVID-19 Vaccines

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

a. Pfizer-BioNTech/COMIRNATY

- Pediatric Pfizer for ages 6 mos-4 years (maroon cap)
- Pfizer-BioNTech ages 5-11 years (orange cap)
- Pfizer-BioNTech ages 12 years and older (purple cap)
- Pfizer-BioNTech ages 12 years and older (gray cap)

b. Moderna/SPIKEVAX

- Moderna for 12 and older (Red cap with light blue border)
- Moderna for 6 11 years (Dark Blue Cap with purple border)
- Moderna Booster for 18 and older (Dark Blue Cap with Purple border)
- Moderna for ages 6 mos 5 years (Dark Blue Cap with Magenta border)

c. Johnson and Johnson's Janssen ages 18 and older

For additional information on dosing and intervals for primary and booster doses follow updated <u>COVID-19 Reference Guide for Healthcare Professionals</u>. A complete list of available vaccines including trade names and manufacturers can be found on the Maine CDC website here: <u>Stay Up to</u> <u>Date with Your COVID-19 Vaccines | CDC</u>

II. Vaccine Ordering

A. Vaccine Choice

Maine Immunization Program providers who have an approved COVID-19 agreement will have the ability to order COVID-19 vaccine through the Pandemic Vaccine Ordering tool in ImmPact. Providers will be able to order the following minimum quantities of COVID-19 vaccine:

Pandemic Vaccine								
# Doses	Intent		Vaccine	Trade Name	Manufacturer	Packaging	NDC	Min Order Qty
	ADU	COVID-19 vaccine, vector-nr, rS- Ad26, PF, 0.5 mL		Janssen COVID-19 Vaccine	Janssen Products, LP	2 Cartons of 10 Multidose Vials - 5 dose vial	59676-0580-15	100
	PED	COVID-19 pediatric 25	, mRNA, LNP, PF, i mcg/0.25 mL dose	Moderna COVID-19 Pediatric 6mo-<6 y	Moderna US, Inc.	MDV10 10pk	80777-0279-99	100
	ADU	COVID-19, m mcg/	RNA, LNP-S, PF, 100 0.5 mL dose	Moderna COVID-19 Vaccine	Moderna US, Inc.	10 dose vial	80777-0273-99	100
	PED	COVID-19, n mcg	RNA, LNP-S, PF, 50 .50 mL dose	Moderna COVID-19 Vaccine Booster	Moderna US, Inc.	MDV 5	80777-0275-99	100
	PED	Tris-sucrose mL for age	formula, 10 mcg/0.2 es 5 yrs to < 12 yrs	Pfizer-BioNTech COVID-19 Vaccine 5 yrs to < 12 yrs	Pfizer-Wyeth	10 Dose Vial	59267-1055-04	100
	PED	Tris-sucrose formula, 3 mcg/0.2 mL for ages 6m to < 5 yrs		Pfizer-BioNTech COVID-19 Vaccine 6m to < 5 yrs	Pfizer-Wyeth	MDV10 10pk	59267-0078-04	100
	ADU	Tris-sucrose formula, 30 mcg/0.3 mL for ages 12+		Comirnaty TS	Pfizer-Wyeth	MDV6 10 pack	00069-2025-10	300
	ADU	Tris-sucrose mL f	formula, 30 mcg/0.3 for ages 12+	Pfizer-BioNTech COVID-19 Vaccine 12yrs+	Pfizer-Wyeth	6 dose vial	59267-1025-04	300
Pandem	nic Vac	cine						
Trade Name Max Order Oty			x der /					
Jassen Covid-19 Vaccine 500)					
Moderna Covid 19 Pediatric 500 6mo-<6y)					
Moderna Co	ovid -19 Va	iccine 100	00					
Moderna Covid-19 Vaccine 300 Booster)					

Providers must order at least the minimum amount listed. For questions about ordering minimums or maximums contact: <u>C19Allocations.MECDC@Maine.gov</u>. Please ensure that the following information is entered into ImmPact, prior to placing a vaccine order:

- Verification of days and hours of operation that the staff at MIP-enrolled sites are available to receive vaccine.
- Site's delivery address.

Prizer-BioNTech Covid-19

Vaccine 5 yrs to <12 yrs Pfizer BioNTech Covid-19

Pfizer-BioNTech Covid-19

Vaccine 6m to <5ys Comirnaty TS

Vaccine 12year+

- Primary and backup point of contact information.
- Up-to-date temperature logs for all units.

1000

500

1000

1200

- Doses administered are required to be entered in the client record within 24-hours of administration.
- Reconciliation within the past fourteen days to include the following:
 - 1. A physical count of all vaccines by brand, presentation, lot number, and expiration date.
 - 2. Any expired, spoiled, or ruined/wasted vaccine doses

Pandemic Vaccine Ordering in ImmPact

- From the menu panel (green column on the left)
- Under Inventory heading
- Click the Pandemic Vaccine Request link



This will open the Order Request screen:

Pandemic Or	der Reque	st						
VFC PIN Initiating Organization Initiating User Org Phone Org Fax Order Date		7050 SHAD PANDEMIC Sherri Dunton (207) 555-5555 (207) 555-5555 05/19/2021			Delivery Contact Delivery Address Delivery Days/Hours Delivery Days/Hours Wednesday 7 AM 5 Ph Tuesday 7 AM 5 Ph Tuesday 7 AM 5 Ph Friday 7 AM 5 Ph		Submit Request Cancel	
Pandemic Va	ccine							
#Doses	Intent	Vaccine	Trade Name	Manufacturer	Prokaging	NDC	Min Order Qty	Doses on Hand
	ADU	COVID-19 vaccine, vector-nr, rS- Ad26, PF, 0.5 mL	Janssen COVID-19 Vaccine	Janssen Products, LP	o pack 5 dose via	Is 59676-0580-15	50	51
	ADU	COVID-19, mRNA, LNP-S, PF, 100 mcg/ 0.5 mL dose	Moderna COVID-19 Vaccine	Moderna US, Ir c.	14 dose vial	80777-0273-98	140	0
	ADU	COVID-19, mRNA, LNP-S, PF, 30 mcg/0.3 mL dose	Pfizer COVID-19 Vaccine	Pfizer wyeth	6 dose vial	59267-1000-02	1170	2337

- Enter the quantity of doses for the vaccines wanted
- Note: You will need to order in increments of the minimum order (i.e. you cannot order 1000 or 2000 doses of Pfizer you would need to order 1170, 2340, 3510 etc.)
- Click the Submit Request tab
- A message will show at the top of the screen: Your vaccine request has been successfully submitted

B. Vaccine Inventory Plan

Once orders are submitted through ImmPact, they will ship the following business day. Please allow five-days for shipping.

Important Reminders

• The Maine Immunization Program will no longer be ordering on provider's behalf for 2nd doses.

All COVID-19 vaccination providers must report COVID-19 vaccine inventory by reconciling inventory within ImmPact a minimum of once every 14 days. Federal CDC has required that all COVID 19 vaccine administration be documented within 24 hours of administration of vaccine. This data will be used to determine state uptake on vaccine and the need for further allocations.

C. Short-Dated Vaccine

Short-dated vaccines are those that are within 30 days of expiration. 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.

All COVID-19 vaccine must either be used prior to expiration OR transferred to another facility; returns will not be accepted.

- Excess vaccine may also be posted to the "Vaccine Available" page on ImmPact
- No vaccine will be posted with an expiration date of less than 30 days

Vaccine diluents, the liquid mixed with a freeze-dried vaccine to reconstitute it, must be managed in the same manner as vaccines. The expiration date of diluents must be checked prior to every reconstitution. The diluent must be rotated to use the shortest expiration date first. If providers are interested in opting out of ancillary kits for COVID vaccine, they should contact the ImmPact support team.

D. Storage Capacity for Vaccine Orders

Sites must have adequate refrigeration and/or freezer space to accommodate a supply of inventory on hand. 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, ImmPact, for vaccine ordering. ImmPact allows MIP-enrolled sites to manage vaccine inventory online. All vaccine orders will be placed in ImmPact. Sites may be held responsible for vaccine loss that is a result of incorrect information entered into ImmPact. Prior to placing a vaccine order, the following information must be entered into ImmPact:

- Verification of days and hours of operation that the staff at MIP-enrolled sites are available to receive vaccine.
- Site's delivery address.
- Primary and backup point of contact information.
- Up-to-date temperature logs for all units.
- Doses administered are required to be entered in the client record within five days of administration.
- Reconciliation within the past fourteen days to 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 of reconciliation and temperature logs is required for all COVID-19 enrolled sites, whether or not a vaccine order is placed.

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

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

III. Vaccine Distribution

A. Vaccine Distributors

MIP uses two vaccine distribution centers.

• McKesson Specialty, a third-party distributor that ships the majority of MIP-supplied vaccines that are refrigerated.

B. Receiving Vaccine Orders

Vaccine Deliveries

- Maintaining the cold chain is the first step in vaccine inventory management. Staff members who might accept vaccine deliveries should be trained to immediately notify the vaccine coordinator or alternate coordinator when deliveries arrive.
- Vaccines must always be immediately checked and stored properly upon arrival.
 - Check DDL upon shipment to ensure cold chain.
 - Check for discoloration of vial/contamination.

- Check invoice against what is shipped.
- COVID-19 vaccine diluent and ancillary supplies will be shipped separately.
- The practice needs to make sure that someone is available to accept the shipment during the days and hours you have designated for deliveries under your COVID-19 Vaccination Program Provider Agreement.
- If the practice will be closed for any day or time other than what is listed on your provider profile, it is the responsibility of the provider to contact the Immunization Program to let them know.
- Ensure adequate amount of diluent is included for those vaccines that require reconstitution. Diluent will arrive separately.
- Determine the length of time the vaccine was in transit by looking at the ship date and time on the packing.
- Immediately contact MIP when:
 - The appropriate quantity and type of vaccine or diluent is not received,
 - Vaccines have been received in error, or
 - Vaccines appear to be compromised.
- Appropriately store all vaccines immediately upon receipt regardless of any errors in quantity, shipping, or transport.
- Check expiration dates and rotate stock to ensure short-dated vaccines are used first.
- Immediately accept receipt of the vaccines in ImmPact.

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

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

C. Manufacturer and Distributor Maintenance of the Cold Chain

The manufacturer and distributor pack the vaccine using qualified pack-outs and containers that have been tested to maintain appropriate temperatures.

Refrigerated vaccine is packed to maintain the cold chain for 72 hours. The vaccine will be shipped using high quality cardboard boxes with Styrofoam inserts.

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

D. Vaccines Received Warm or Questionable

Vaccines must always be stored properly, even if viability is questionable. Vaccines that are received too warm, damaged, or in an otherwise questionable state require immediate contact to the vaccine manufacturers. Questionable

vaccine cannot be identified visually and must be labeled "Do not Use" and placed into the storage unit until viability can be determined.

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

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

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

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

NOTE: Vaccine returns due to shipping issues are required to be returned to McKesson within 48 hours.

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 discarded. 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 as a result 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 freezerunit
- 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 notadministered.
- 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 and discarded in the biohazard waster bin. 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). Expired vaccine must be disposed of and cannot be used for any other reason.

B. Procedures for Vaccine Loss

Every dose of vaccine that is lost due to expiration or spoilage must be reported when reconciling inventory in ImmPact. Reconciliation is required at least once every 14 days but recommended to be done daily. Expired or spoiled vaccine must be discarded.

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

- Remove expired or spoiled vaccine from the vaccine storage unit and discard.
- Reconcile the vaccine loss in ImmPact.

MIP-enrolled sites who have lost vaccine as a result of improper temperature storage must assess how long the vaccines were stored improperly and how many recipients may have received the affected vaccines. The signing healthcare provider must work with MIP and the distributor to determine if recipients must be revaccinated.

Properly dispose of the unused vaccine as biohazard waste in a sharp's container. <u>Never</u> return unused or expired vaccines with the shipping containers back to the manufacturer. Additionally, promptly report any expired or unused vaccine. This helps CDC accurately monitor the amount of vaccine in the field. Keep in mind that there are no negative consequences for reporting waste, and it will not negatively impact future allocations. CDC recognizes that unused expired vaccine is a normal part of any vaccination program, especially one of this scope and size.

C. Negligent Vaccine Loss

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

- Failure to store vaccine properly
- Refrigerator temperature too cold
- Storage temperature unit too warm including:
 - Unit that was unplugged
 - Unit door left open
- Temperatures were not documented or monitored properly
- Expired vaccines in excess of a full box due to overordering
- Vaccines left out of appropriate storage unit
- Vaccine not stored properly upon receipt

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

Vaccine Storage Units

- Provider sites are required to have appropriate equipment that can store vaccine and maintain proper conditions.
- Refrigerator/freezer units must be large enough to hold the years largest inventory without crowding.
- Two types of storage units are acceptable for storage: a refrigerator that has a separate freezer compartment with a separate exterior door and separate thermostat controls for the refrigerator and freezer compartments (refrigerator use only) or stand-alone purpose refrigerators and freezers. Stand-alone units are preferred.
- Small combination refrigerator-freezer units outfitted with a single external door and dormstyle refrigerators are never allowed for the storage of state-supplied vaccine.
- The refrigerator unit must maintain temperatures between 36F and 46F (2C and 8C) for vaccine viability.
- 1. Moderna viable for 31 days in refrigerator, unpunctured or until expiration date
- 2. Pfizer viable 10 weeks in refrigerator, unpunctured or until expiration date
 - The freezer unit must maintain temperatures
- 1. Between -5 8F and +5F (-50C and-15C) for Moderna
- 2. Between -13°F and +5F (-25C to -15C) for Pfizer

Moderna's COVID-19 vaccine must be stored in a freezer between -50°C and -15°C.

Pfizer-BioNTech COVID-19 vaccine for children ages 5 through 11 years (orange cap), Pfizer-BioNTech COVID-19 vaccine for persons ages 12 years and older (gray cap), Pfizer-BioNTech COVID-19 vaccine for persons ages 6 months through 4 years (magenta cap) may NOT be stored in a standard freezer.

- Ultra-cold freezers must maintain temperatures between -112°F to-76°F (-80°C to-60°C).
- Place water bottles (labeled "Do Not Drink") on the top shelf by the cold air vent, floor, and indoor racks of the refrigerator.
- Place frozen coolant packs along walls, back, and bottom of freezer and inside the door racks.
- Diluents that are not packaged with vaccine may be stored in the door of the refrigerator and can provide extra insulation much like bottles of water.
- Refrigerators and freezers storing vaccine must be plugged directly into a wall outlet with a plug guard. Multi-strip outlets must not be used.
- Do Not Unplug sticker should be on all units that store vaccine and near outlet
- It is never acceptable to store food or drinks in the same refrigerator or freezer as vaccine.

B. Covid-19 Vaccine Temperature Ranges/Excursions

• Temperature Log for Refrigerator Vaccine Storage

Store COVID-19 vaccines between 36°F and 46°F. Using a digital data logger (DDL), check and record the temperature daily using one of the options below. Save this record for 3 years, unless your state/local jurisdiction requires a longer time period

• Temperature Log for Frozen Vaccine Storage

Store Moderna COVID-19 vaccine between -58°F and 5°F. Using a digital data logger (DDL), check and record the temperature daily using one of the options below. Save this record for 3 years, unless your state/local jurisdiction requires a longer time period.

• Temperature Log for Ultra-Cold Vaccine Storage

Store COVID-19 vaccine (Pfizer) between -130°F and -76°F, using a digital data logger (DDL), check and record the temperature daily using one of the options below. Save this record for 3 years, unless your state/local jurisdiction requires a longer time period

Temperature Log Sheets

- <u>Refrigerator Temperature Log</u>
- Freezer Temperature Log

Temperature Excursions

A temperature excursion refers to when a storage device goes out of the temperature range required for the storage of vaccine. If a storage unit experiences a temperature excursion, corrective action

must be taken as soon as it is detected.

Temperature excursions or inappropriate storage conditions for any vaccine require immediate action. Any temperature reading outside the recommended ranges is considered a temperature excursion. Responses to temperature excursion reports are dependent on information given by the provider to the manufacturer. Completing the Vaccine Troubleshooting Record can help provide needed information for manufacturers to determine the viability of the vaccine.

Providers must document information about all excursions and what steps were taken to correct any issues on the <u>Temperature Troubleshooting Record</u>. These corrective actions include but are not limited to the following:

1. Quarantine and label vaccines exposed to an excursion as "DO NOT USE".

2. Place vaccines in a unit where they can be stored under proper conditions.

3. Contact the Immunization Program to report a temperature excursion (207-287-2586) or toll-free at (1-800-867-4775)

4. Contact the vaccine manufacturer to obtain documentation supporting the usability of the vaccine.

5. Document all steps taken on temperature paper log and in ImmPact

C. Approved COVID-19 Storage Units

- Thermal Shipper
- Ultra-Cold Freezer
- Standard Freezer
- Refrigerator
- Portable Storage Unit

Additional storage and Handling information can be found here

D. Placement of Storage Unit

The following guidelines are recommended for placement of your storage unit:

- Good air circulation around the outside of the storage units is important.
- Storage units should be in a well-ventilated room, leaving space between the unit, ceiling, and any wall. Nothing should block the cover of the motor compartment.
- Most units work best when placed in an area with standard indoor room temperature between 68° F and 77° F (20° C and 25° C).
- Comply with the manufacturer-supplied owner's manual for additional guidance on placement and spacing.
- Each vaccine storage unit MUST be plugged directly into a wall outlet. It may be plugged into an outlet controlled by a light switch or into a surge protector with an on/off switch extension cord.

E. Data Logger Requirements

Digital Data Loggers

COVID-19 Vaccination and VFC providers should obtain DDLs at this time. With an understanding that this process can take time, there is an expectation that <u>all</u> provider locations where COVID-19 or VFC vaccine is stored or administered, including during transport, have and appropriately use DDLs in their facilities for COVID-19 and VFC vaccines, in accordance with CDC's <u>Vaccine Storage and Handling Toolkit (cdc.gov)</u> (COVID-19 Addendum) and the VFC Operations Guide.

All COVID-19 vaccine providers **MUST** use a working, digital, downloadable, continuous temperature monitoring device (e.g. data logger) with a current and valid certificate of calibration in all storage units that are used to store vaccine. The data logger must be calibrated to monitor at the intended temperature of the storage device.

• Having a DDL provides valuable data that can save vaccine, prevent ineffective vaccine from being administered, and prevent the need to revaccinate affected patients.

When selecting a digital data logger, CDC/CT Immunization Program recommends the following features:

- A detachable, buffered probe (i.e., glycol, ethanol, glycerin, sand, glass beads or a solid block of Teflon or aluminum)
- Alarm for out-of-range temperatures
- Current, minimum, and maximum temperature displays
- Low battery indicator
- Accuracy of +/- 1°F (0.5°C)
- Memory storage of at least 4,000 readings
- User programmable logging interval (or reading rate)

MIP requires a data logger in each storage unit that stores COVID-19 vaccine and ONE backup data logger on site for COVID-19 vaccines.

Units that store MIP-supplied vaccines must contain a centrally located data logger probe with a current and valid Certificate of Calibration Testing, also known as a Report of Calibration, set at a minimum recording interval of at least every 30 minutes.

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

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

The following are requirements for data loggers:

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

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

MIP does **<u>NOT</u>** allow the following temperature devices:

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

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

The following are requirements for data logger probes:

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

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

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

A valid certificate of calibration matching the serial number of the data logger in use must be readily available for review and is recommended to be posted on or near the refrigerator and/or freezer. Calibration testing should be done everyone to two years or according to the manufacturer's suggested timeline. A

continuous-read temperature recording device does not replace the requirement for a certified data logger.

Data logger certificates of calibration must contain the following:

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

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

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

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

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

In addition, a room thermometer is recommended to record the room temperature when a temperature excursion occurs in a vaccine storage unit. This is important for making vaccine viability determinations, if necessary.

F. Protective Equipment

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

- Plug unit(s) directly into a wall outlet.
- Plug only one unit into an outlet.
- Plug guards are recommended to be used on all units that store MIP vaccines. Plug guards are effective tools in preventing the accidental or intentional unplugging of equipment.
- Post a "Do Not Unplug" sign on or near all outlets where units are plugged in.
- Post a "Do Not Disconnect" sign on or near each circuit breaker

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

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

G. 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.

1. The assigned primary and backup vaccine coordinators are required to complete the "Vaccines for Children" training each year. <u>Annual Education Requirement | Immunization</u> <u>MeCDC | Maine DHHS</u> 2. All new primary and backup vaccine coordinators must participate in a "Vaccine Coordinator Education" webinar. These are conducted twice a month. The schedule for these webinars is available at <u>https://www.maine.gov/dhhs/mecdc/infectious-disease/immunization/</u>

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.

What training is available to learn how to prepare and administer COVID-19 vaccines? CDC offers a variety of training resources for preparing and administering COVID-19 vaccines. Visit <u>Training and Education for COVID-19 Vaccination</u> for training information and core competencies for healthcare professionals. At a minimum, CDC recommends all providers complete the training module for the vaccine(s) they will be administering. The training modules can be found at <u>COVID-19 Vaccine</u> <u>Training Modules</u>. Additional vaccine preparation and administration resources can be found on CDC's web pages for each vaccine product at <u>U.S. COVID-19 Vaccine Product Information</u>. Providers who are enrolled in the VFC program may already have completed some of the training recommended to become a COVID-19 vaccination provider.

H. Routine and Emergency Storage and Handling Plan

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

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

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

- Identify a responsible primary and backup person to carry out the contingency plan. Contact information such as email addresses and home, office, and cell phone numbers for both persons must be included. Contact information must be updated annually or when changes occur.
- Identify an alternative location to take MIP-suppled vaccine for storage in the event of an emergency. A location with a power generator or other alternate source of power

such as a hospital or pharmacy is preferable. Ideally, this facility must be located within a reasonable distance from the site and can maintain the cold chain during any period when the MIP- enrolled site's refrigerator or freezer is out of service, as well as have adequate space to accommodate the largest vaccine inventory. Temperatures for these temporary storage units are required to be monitored and minimum and maximum temperatures recorded each morning.

- Adequate supplies in amounts sufficient for packing and transporting the entire MIP-supplied vaccine inventory must be available, in case of an emergency.
- Contact with staff at the emergency storage location is important to gain their approval before including them as part of the plan. List their contact person(s) and phone number(s) on the plan. An alternative backup location must be considered in the event that the primary alternative location is unavailable or unable to store the vaccine inventory for any reason.

The most current Emergency Vaccine Storage and Handling Plan will be reviewed during MIP Compliance Site Visits and Unannounced Storage and Handling Visits. The documents must be posted on or near the refrigerator or freezer that contains MIP-supplied vaccine. The site staff involved with vaccine management must be aware of this plan.

I. COVID-19 Storage Back Up Plan in an Event of an Emergency

Every facility that administers vaccines **MUST** have an <u>Emergency Vaccine Storage and Handling</u> <u>Plan</u> in place to protect the vaccines when there is a temperature excursion, loss of power to the refrigerator and /or freezer unit(s) that houses the vaccines. An emergency vaccine storage vaccine plan template can be seen in the Appendix. This plan should be posted on or near vaccine storage unit or where it can be easily accessed in the event of an emergency. All office staff should know the emergency back-up procedure to follow and where/how the individual vaccines are to be stored.

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

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

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

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

- Document the time of the emergency situation/poweroutage.
- 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 Checklistis available for documenting this process.

J. 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.

The <u>CDC Vaccine Storage and Handling Toolkit</u> outlines CDC recommendations for vaccine storage and handling. Proper storage and handling practices are critical to minimize vaccine loss and limit risk of administering COVID-19 vaccine with reduced effectiveness. A vaccine provider is responsible for maintaining appropriate cold chain storage, monitoring, and handling from the time the vaccine arrives at the facility until it is administered.

Vaccines must be stored and handled properly from the time they are manufactured until they are administered to maintain the cold chain, thus protecting the potency and effectiveness of the vaccine and ensuring vaccine recipients are fully and safely protected from vaccine-preventable diseases.

As part of the COVID-19 Vaccination Provider Agreement, providers are required to:

- Store and handle COVID-19 vaccines under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with an EUA or vaccine package insert, manufacturer guidance, and CDC guidance in the Vaccine Storage and Handling Toolkit.
- Monitor storage unit temperatures at all times, using equipment and practices that comply with guidance in the toolkit.
- Comply with immunization program guidance for handling temperature excursions.
- Monitor and comply with COVID-19 vaccine expiration dates.
- Preserve all records related to COVID-19 vaccine management for a minimum of three years, or longer as required by the agreement or law of the jurisdiction.
- Comply with CDC instructions and timelines for disposing of COVID-19 vaccine and diluent, including used doses.

Find detailed information regarding COVID-19 Vaccine storage and handling requirements at <u>CDC</u> <u>Vaccine Storage and Handling Toolkit</u>.



Refrigerated Vaccine Transport

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

- Using a hard-sided cooler, Styrofoam vaccine shipping container, orother 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 was removed from the permanent storage unit.

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

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

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

- Insulating material two each of the following layers is needed:
 - Corrugated cardboard two pieces cut to fit the internal dimensions of the coolers(s) and placed between the insulating cushioning material and the conditioned water bottles.
 - Insulating cushioning material such as bubble wrap, packing foam, or Styrofoam for a layer at least 2-inches thick above and below the vaccines. Ensure this layer covers the cardboard completely.

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

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

MIP recommends the following packing assembly for refrigerated vaccines:

- Line the bottom of the cooler with a single layer of conditioned water bottles.
- Place a sheet of corrugated cardboard over the water bottles.
- Place at least a 2-inch layer of insulating material (i.e., bubble-wrap, packing

foam, or Styrofoam) over the cardboard.

- Stack boxes of vaccines on top of the insulating material.
- When cooler is halfway full, place the data logger buffered probe in the center of the vaccines, but keep the display outside the cooler.
- Cover vaccines with another 2-inch layer of insulating material.
- Add the second layer of corrugated cardboard.
- Fill the remaining space in the cooler with conditioned water bottles.
- Close the lid of the cooler securely and attach the data logger display and a temperature log to the top of the lid to record and monitor the temperature during transport.
- Use the temperature recording form to record the time and temperature inside of the storage unit at the time the vaccines were removed.
- If vaccines are kept in a transport container for longer than an hour, record the temperatures hourly.
- As soon as the destination site is reached, check and record the vaccine temperature.

As long as the vaccine temperature is 36°F to 46°F (2°C to 8°C), place the vaccine in the refrigerator.

If the vaccine is below 36°F (below 2°C) or above 46°F (above 8°C), label the vaccine as "Do Not Use", place in the refrigerator, and immediately contact the vaccine manufacturer to determine viability.

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

Frozen Vaccine Transport

Some COVID vaccines are fragile and must be kept frozen. Transportation of COVID vaccine is not recommended. If these vaccines must be relocated in an emergency, the following steps must be taken:

- Portable Freezer MIP recommends transport with a portable freezer unit that maintains the temperature between -58°F to +5°F (-50°C to -15°C). Portable freezers may be available for rent. Label the portable freezer with the facility name and "Fragile Vaccines Keep Frozen" and the date and time the vaccine was removed from the permanent storage unit.
- Temperature Monitoring Device Use a certified and calibrated data logger with a current and valid certificate of calibration testing. Prepare the data logger by placing it in a freezer unit at least 2 hours before packing the vaccine.

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

VI. Vaccine Transfers

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

statewide vaccine shortage).

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

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

VII. Reporting Requirements

Monthly 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 MIPsupplied 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.

At least once every 14 days, the following must be completed:

• Vaccine Reconciliation.

Additionally, all MIP-supplied doses must be entered into the client record within 24 hours of administration. Failure to submit required documents will result in future vaccine orders placed on hold.

A. Temperature Recording Form

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

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

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

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

All temperatures recorded on the Temperature Recording Forms must match the temperatures match the information downloaded from the DDL. MIP-enrolled sites are required to keep paper Temperature Recording Forms on file in the event they are chosen for a site visit or there is a discrepancy for three years.

B. Vaccine Reconciliation & Doses Administered

All MIP-supplied vaccine must be recorded in the client record within 24 hours, 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 to ensure 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 COVID enrolled sites, vaccine is not free. Reconciliation is done to ensure inventory on hand and ImmPact inventory match and vaccine has not been lost.

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

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

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

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

If quantities match after modifying has been done, submit the reconciliation. If vaccine inventories still do not match, vaccine may have to be "subtracted" in ImmPact as lost or unaccounted for vaccine.

CHAPTER 4: BILLING AND ADMINISTRATION

I. Billing for Vaccine

All organizations and providers participating in the CDC COVID-19 Vaccination Program:

- must administer COVID-19 vaccine at no out-of-pocket cost to the recipient
- may **not** deny anyone vaccination based on the vaccine recipient's coverage status or network status
- may **not** charge an office visit or other fee if COVID-19 vaccination is the sole medical service provided

- may **not** require additional medical services to receive COVID-19 vaccination
- **may** seek appropriate reimbursement from a program or plan that covers COVID-19 Vaccine administration fees for the vaccine recipient, such as:
 - vaccine recipient's private insurance company
 - Medicare or Medicaid reimbursement
- may **not** seek any reimbursement, including through balance billing, from the vaccine recipient

COVID-19 vaccine is provided at 100% no cost to recipients

II. Administration Fee

COVID-19 vaccines are provided at 100% no cost to the vaccine recipient. COVID-19 vaccination providers cannot charge vaccine recipients for the vaccine (which is provided free to enrolled providers by the U.S. government) or for any administration fees, copays, or coinsurance. COVID-19 vaccination providers cannot deny vaccination to anyone who does not have health coverage, is underinsured, or is out of network.

COVID-19 vaccination providers cannot charge recipients for an office visit or any other fee if the only service provided is a COVID-19 vaccination. Additional healthcare services can be provided at the same time and billed as appropriate. However, providers cannot require additional services for a person to receive a COVID-19 vaccine.

If a vaccine recipient has health coverage, providers may seek appropriate reimbursement from the recipient's plan or program (e.g., private health insurance, Medicare, Medicaid) for a vaccine administration fee. However, providers cannot bill the recipient for the balance not covered by the recipient's plan or program.

CHAPTER 5: PROGRAM EVALUATION

I. COVID-19 Enrolled Compliance Site Visits

By signing the MIP COVID Provider Agreement, the signing authority agrees to allow MIP quality assurance (QA) reviewers to conduct site visits at least every other year at their site.

COVID-19 compliance site visits are conducted as deemed necessary by Federal and Maine CDC. The purpose of the compliance visit is to assess, support, and educate the staff regarding MIP policies and procedures and if necessary, assist practices with course corrections. If areas of concern are identified, the educator will provide a follow-up phone call or visit to assist the clinic with any changes or questions.

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

- Appropriate staff to answer questions regarding day-to-day operations, screening/documentations procedures, billing polices, storage and handling practices
- The need for a space to work and a power source if laptop is used.
- Current and previous temperature logs or data for a minimum of the last month, or all temperature logs if less than one month since initial COVID-19 vaccine supply was received
- Access to all vaccine storage units and areas where COVID-19 vaccine is stored
- Access to the circuit breaker, if applicable—the provider location should be informed maintenance staff may need to be available during the site visit to gain access to the circuit breaker
- Immpact reconciliation of 14 days

II. Follow-up Activities

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

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

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

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

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

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

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

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

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.

- Sell or otherwise misdirect MIP-supplied vaccine
- Bill a patient or third party for MIP-supplied vaccine
- Charge an administration fee of a MIP-supplied COVID-19 vaccine
- Failure to meet licensure requirements for enrolled physicians
- Deny vaccine because of the inability to pay the administration fee
- Send a patient or charge additional fees for non-payment of the administration fee
- Failure to implement MIP enrollment requirements
- Failure to maintain MIP records for three years
- Failure to fully account for MIP-supplied vaccine
- Failure to properly store and handle and document MIP-supplied vaccine
- Order MIP-supplied vaccine in quantities or patterns that do not match population profile or otherwise involve over-ordering of MIP doses
- Loss of MIP-supplied vaccine due to negligence

IV. Failure to Comply with MIP Requirements

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

A. Intentional Non-Compliance

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

B. Unintentional Non-Compliance

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

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

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

- Identification of Non-Compliance When non-compliance is identified, either at a site visit or another way, the site will be given 30 days to remediate the non-compliance. Education and guidance will be provided to ensure the site understands steps to take to become fully compliant.
- If, after 30 days, the site continues to be non-compliant, a certified letter will be sent to the signing physician of the site. The letter will explain the non-compliance and the site's failure to remediate the issue.
- If, after 45 days, the site continues to be non-compliant, the site will be suspended from ordering vaccine. A probation agreement will be sent certified mail to the signing physician. The probation agreement will include adherence to all MIP requirements including the non-compliance at hand. This probation document must be signed and returned to MIP within five business days.
 - If the probation document is signed and returned, MIP reviewer will continue to work with the practice to ensure their non-compliance is corrected and remains that way for six months. Ordering suspension will be lifted. After six months of full compliance the site probation will be removed.
 - Failure to comply with all probation requirements will result in termination from MIP.
- If, after 50 days, the probation document is not signed and returned the site will be terminated from MIP. A certified letter will be sent to the signing physician.

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

V. Fraud and Abuse Prevention

MIP actively works with enrolled sites to help prevent fraud and abuse. The best methods to prevent fraud and abuse are strong educational components discussed during the initial enrollment process and during the MIP compliance visits. Both occasions provide the opportunity to identify and prevent situations

that may develop into fraud and abuse. MIP offers monthly webinars to review all MIP requirements. This allows vaccine managers and site staff to ask any questions they may have regarding program requirements.

VI. Reporting Fraud and Abuse

Suspected fraud or abuse can be reported to MIP via email, telephone, fax, or letter. Furthermore, newspaper articles and internet pages that promote potential fraudulent situations are also investigated.

MIP site visit reviewers must report all cases of alleged or suspected fraud or abuse. Reports received by MIP in any form that merit further investigation may be referred to the Centers for Medicare and Medicaid Services (CMS), and/or Medicaid Integrity Group (MIG) Field Office. The state Medicaid agency will conduct preliminary investigations and as warranted, refer appropriate cases to the state's Medicaid Fraud Control Unit.

CHAPTER 7: DOCUMENTATION REQUIREMENTS

I. Vaccine Record Keeping Requirements

COVID-19 vaccination providers, after administering a dose of COVID-19 vaccine, must record all information marked by an asterisk below (if it is not already recorded in the vaccine recipient's record) and report the following required vaccine administration data, or other data elements if revised by CDC, to the appropriate entity noted in the agreement, within 24 hours of administering the vaccine:

- 1. Administered at location/facility name/ID
- 2. Administered at location type
- 3. Administration address (including company)*
- 4. Recipient name and ID*
- 5. Recipient date of birth*
- 6. Recipient sex*
- 7. Recipient race
- 8. Recipient ethnicity
- 9. Recipient address*
- 10. Administration date*
- 11. CVX (product)*
- 12. NDC (national drug code)
- 13. Dose number*
- 14. Lot number (Unit of Use [UoU] or Unit of Sale [UoS])*
- 15. MVX (manufacturer)*
- 16. Sending organization (name of the agency submitting the report)
- 17. Vaccine administering provider's name and suffix*
- 18. Administering provider's address, if different from the administration address*
- 19. Vaccine administration site (on the body)*
- 20. Vaccine expiration date*
- 21. Vaccine route of administration*
- 22. Vaccine series

Find more information about vaccine administration and reporting requirements.

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 seventy- two 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 the majority of people believe in the benefits of immunizations and are vaccinated themselves or have one of their children vaccinated, some have concerns about the safety of vaccines. The concerns about vaccine safety are preventing some people/parents from being immunized and/or having their children immunized.

When a parent or patient initiates the discussing regarding a vaccine concern, discuss the specific concern and provide factual information. The EUA provides an outline for discussing vaccine benefits and risks. Reinforce key point regarding each vaccine, including safety, and emphasize risks encountered by the unimmunized population. Conversations stating facts might reduce any potential liability if a vaccine-preventable disease occurs in an unimmunized patient.

IV. Vaccine Adverse Events/VAERS Reporting

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.

Vaccine Adverse Event Reporting System

The <u>Vaccine Adverse Event Reporting System</u> (VAERS) is a program for vaccine safety, co-managed by the U.S. Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). VAERS accepts and analyzes reports of adverse events (possible side effects) after a person has received a vaccination. Anyone can report an adverse event to VAERS. Reports should be submitted online under the circumstances listed below. Healthcare providers are **required by law** to report to VAERS:

- Any adverse event listed in the <u>VAERS Table of Reportable Events</u> Following Vaccination that occurs within the specified time period after vaccinations.
- An adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine.
- Healthcare providers are strongly **encouraged** to report to VAERS:
- Any adverse event that occurs after the administration of a vaccine licensed in the United States, whether it is or is not clear that a vaccine caused the adverse event.
- Vaccine administration errors.

The VAERS table of Reportable Events and the list of contraindications are vaccine specific and will be updated to include COVID-19 when a vaccine has been authorized or approved by the FDA. Adverse events to COVID-19 vaccines should be reported electronically through VAERS.

Other reporting requirements specific to COVID-19 vaccines may be put in place when they become available

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

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

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

V. Reminder/Recall

Using reminder/recall systems within COVID provider site is important for several reasons, not only to improve immunization rates but also overall health care.

- A public health outbreak
- Reconciliation is overdue (reconciliation required every 14 days)

- ImmPact Fix tool has unresolved items that requiring updating
- A patient has received compromised vaccine (ie. due to vaccine exposed to temperature excursion, a vaccine administration error, or expired vaccine given) and needs to be contacted for revaccination-

CHAPTER 8: EMERGENCY USE AUTHORIZATION (EUA)

COVID-19 Vaccine Emergency Use Authorization (EUA) Fact Sheets for Recipients and Caregivers

For each COVID-19 vaccine authorized under an Emergency Use Authorization (EUA), the Food and Drug Administration (FDA) requires that vaccine recipients or their caregivers are provided with certain vaccine-specific EUA information to help make an informed decision about vaccination. This is accomplished by providing an EUA Fact Sheet for Recipients and Caregivers. The Fact Sheet is similar in purpose and content to vaccine information statements (VISs) for licensed vaccines but differs in that the EUA Fact Sheet is specific to each authorized COVID-19 vaccine, is developed by the manufacturer of the vaccine, and is authorized by the FDA.

There is no VIS for COVID-19 vaccines authorized under an EUA. Instead, the FDA-issued EUA Fact Sheet for Recipients and Caregivers for each COVID-19 vaccine must be used.

To help facilitate documentation of having provided the EUA Fact Sheet in electronic medical records/immunization information systems, CDC is leveraging the existing <u>VIS Code Set</u> infrastructure, barcoding, and URLs to provide the information needed for various systems, analogous to electronic system and workflow documentation of VISs.

An EUA may be provided as a paper copy or in the following ways:

- A permanent, laminated, office copy of each EUA, which must be read prior to vaccination.
- A computer monitor or video display where the EUA 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 EUA must be offered to take away following the vaccination.

Reasonable steps must be taken to provide information in the appropriate languages to ensure patients with limited English proficiency are effectively informed. All EUA's can be downloaded from the CDC website at <u>COVID-19 Vaccine EUA Recipient/Caregiver</u> <u>Fact Sheets | CDC</u>

CHAPTER 9: SYMPTOMS OF COVID

People with COVID-19 have had a wide range of symptoms reported – ranging from mild symptoms to severe illness. Symptoms may appear 2-14 days after exposure to the virus. Anyone can have mild to severe symptoms. People with these symptoms may have COVID-19:

- Fever or chills
- Cough
- Shortness of breath or difficulty breathing
- Fatigue
- Muscle or body aches
- Headache
- New loss of taste or smell
- Sore throat
- Congestion or runny nose
- Nausea or vomiting
- Diarrhea

This list does not include all possible symptoms. CDC will continue to update this list as we learn more about COVID-19. Older adults and people who have severe underlying medical conditions like heart or lung disease or diabetes seem to be at higher risk for developing more serious complications from COVID-19 illness.

What do I do if I am feeling sick?

Visit the <u>CDC Coronavirus Self-Checker</u> Page

A tool to help you make decisions on when to seek testing and medical care: What to Do IF You are Sick

If you test positive and are an older adult or someone who is at <u>high risk</u> of getting very sick from COVID-19, <u>treatment may be available</u>. Contact a healthcare provider right away after a positive test to determine if you are eligible, even if your symptoms are mild right now. You can also visit <u>Test to Treat</u> and, if eligible, receive a prescription from a provider. Don't delay: Treatment must be started within the first few days to be effective.

If you have a fever, cough, or <u>other symptoms</u>, you might have COVID-19. Most people have mild illness and are able to recover at home. If you are sick:

- Keep track of your symptoms.
- If you have <u>an emergency warning sign</u> (including trouble breathing), call 911.
 - a. Where can I get a Covid -19 test?
 - <u>Self-Testing</u>
 - <u>Community-Based Testing Sites</u>

For additional COVID-19 Testing Resources please click link here.

b. What are the quarantine guidelines if I have COVID

- <u>Isolation</u>- is used to separate people with confirmed or suspected COVID-19 from those without COVID-19. People who are in isolation should stay home until it's safe for them to be around others.
- <u>Quarantine</u> and stay away from others when you have been in <u>close contact</u> with someone who has COVID-19.
- **c.** What are guidelines for Healthcare Worker?
 - <u>Requirements</u>
 - Caring for Patients
- d. Additional COVID FAQ's

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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