Janet T. Mills
Governor

Jeanne M. Lambrew, Ph.D.
Commissioner

Maine Department of Health and Human Services
Maine Center for Disease Control and Prevention
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To: Maine Immunization Program Providers
From: Maine Immunization Program
Subject: Vaccine Preventable Wastage Procedure
Date: April 5, 2023

The Maine Immunization Program (MIP) is continuing to work towards reducing vaccine wastage. As part of this effort MIP will be reinstating the Vaccine Replacement Procedure for July 2023. MIP will make sure that you are well informed to make this transition as easy as possible. The program will host webinar information sessions closer to July.

MIP will be generating the threshold reports to notify practices what their 3% and 5% thresholds are for July 2023 – June 2024. MIP will also be calculating the quarter Vaccine Usage Reports that will show you the wastage and distribution for the past quarter. You can expect to receive both reports by the end of May.

You will find a copy of the Vaccine Preventable Wastage Procedure below. Thank you in advance for your cooperation and support.

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Vaccine Replacement Procedure

Purpose:

To ensure that Mainers will continue to have access to an adequate supply of vaccines. The Maine Immunization Program (MIP) provides approximately $27 million annually in vaccines at no cost for people of Maine. As a Universal State, Maine provides all vaccines recommended by the federal Advisory Committee on Immunization Practices (ACIP), US Centers for Disease Control and Prevention (US CDC) for children under 19 years of age and select vaccine for adults.

Vaccine Replacement Procedure:

The vaccine replacement procedure applies to providers actively enrolled with MIP who receive publicly funded vaccines. As set out in the Provider Agreement, enrolled providers are required to report all wasted, expired, spoiled, lost or unaccounted for vaccines, as well as, any unauthorized administration of vaccines to MIP within 30 days of incident. Under the vaccine replacement procedure, dose-for-dose replacement for public vaccine is required for wastage as defined below that exceeds 5% of total vaccine distribution. The provider is responsible for the replacement of vaccines. MIP will review all vaccine loss and determine the dose-for-dose replacement of vaccines. Replacement is required for activities identified in Appendix A.

1. When a provider's wastage is greater than or equal to 3%, MIP will send to the provider, via certified mail, a notice of 3 % wastage.
    a. The provider has 10 days from the date of the notice to contact MIP to review the wastage calculation.
    b. The provider will need to satisfy a storage and handling education requirement.
        i. The provider has an additional 10 days to provide proof of storage and handling education requirement.
        ii. The provider's ordering status may be put on hold until proof of educational requirement is provided.
2. When a provider's wastage meets or exceeds 5%, the provider will be sent a Notice for Replacement via certified mail and will be required to replace the wasted vaccines. At this time, the provider's ordering status will be put on hold until MIP receives proof of replacement.
    a. Providers will be required to submit a Corrective Action Plan within 90 days of receiving the Notice of Replacement. These forms will be provided by MIP.
    b. Replacement vaccine must be placed in the provider's stock within 90 days of receiving the Notice for Replacement. Proof of purchase must be sent to MIP. Acceptable proof of purchase is a packing list or paid invoice showing type, amount, lot number, National Drug Code (NDC) and expiration date of privately purchased vaccine.
    c. MIP will enter data into ImmPact and identify it as public supplied.
3. If proof of replacement is not received within 90 days, MIP may terminate the Provider Agreement.
4. If wastage meets or exceeds 15%, the provider's enrollment status will be reviewed to determine if enrollment should be continued.

5. While it is not required, MIP strongly recommends that a provider contact their insurance company to verify that they have adequate coverage to cover any type of vaccine loss. This coverage should be evaluated and updated on an annual basis as vaccine usage and vaccine prices change.
6. If public vaccine is administered to individuals not eligible for the vaccine, such as adults or out-of-state residents, this vaccine must be replaced.
    a) The provider must contact MIP as soon as the unauthorized administered vaccination is discovered.
    b) Replacement vaccine is due within 90 days. Acceptable proof of replacement is a packing list or paid invoice showing type, amount, lot number, National Drug Code (NDC) and expiration date of privately purchased vaccine. This vaccine will then be marked in ImmPact as public supplied vaccine.
    c) If it is found that unauthorized administration has occurred at a practice and the practice had not previously contacted MIP, MIP will contact the practice to make arrangements for replacement. The provider will also be required to complete the Corrective Action plan.

Definitions:

- **Dose-for-dose Replacement:** replenishing public vaccine supply, at the provider's expense, with the same amount, trade name, and National Drug Code (NDC) of the vaccine needing to be replaced.
- **ImmPact:** the MIP online immunization registry that is a repository for accurate and up-to-date records concerning the distribution, use and return of wastage of publicly funded vaccines and allows for data and communication exchange between MIP and providers.
- **Publicly funded Vaccine:** all vaccines supplied by the State of Maine through multiple funding sources. Private Vaccine: any vaccine purchased on the open market and not government subsidized.
- **Unauthorized Administration:** any public vaccine given to individuals who are not eligible for public vaccine.
- **Universal State:** a state which provides all ACIP recommended pediatric vaccines to all enrolled providers to vaccinate all children in their jurisdiction regardless of insurance status.
- **Vaccines for Children (VFC) Program**: a federally funded program that provides vaccines at no cost to qualifying children.
- **Wastage:** vaccine that is non-viable for any reason including, but not limited to, the following:
    - **Expired:** any vaccine that has passed its expiration date and is eligible to be returned for excise tax credit.
    - **Spoiled:** any vaccines that have been deemed non-viable due to temperature excursion, recall, or other safety reasons and able to be returned for excise tax credit.
    - **Unaccounted for vaccines:** any publicly supplied vaccine that is lost or cannot be tracked through ImmPact.
    - **Waste:** any nonviable vaccine that is <u>not</u> able to be returned for excise tax credit (e.g., vaccine drawn into syringe but not administered, broken vials).
- **Wastage Allowance:** permissible margin of wastage before is required.
    - The 5% wastage allowance is based on the average distribution during the previous two years.
      {[(Current year-1) distribution] + [(Current year-2) distribution)]/2} x .05 = 5% wastage allowance

Appendix A: Required Vaccine Replacement Examples

Required Vaccine Replacement Examples	
Expired	Failure to rotate stock. Failure to transfer expiring vaccines and work with MIP within a reasonable time frame. Over ordering vaccines.
Spoiled	Failure to immediately open vaccine shipments. Pre-drawn vaccine that is not used. Please note the MIP strongly discourages the practice of pre-drawing vaccine. Vaccine that is left out of the refrigerator or freezer and becomes non-viable. Vaccine stored in dorm style refrigerators. Freezing vaccine that is supposed to be refrigerated. Refrigerating vaccine that is supposed to be frozen. Refrigerator/freezer left unplugged. Refrigerator/freezer door left open or ajar. Refrigerator/freezer equipment problems where proof of repair or equipment replacement is not provided to the MIP within 30 days from the date you became aware of the situation. Power outages in which the provider fails to follow the facility's vaccine storage and emergency response plan. Vaccine that is considered spoiled due to the provider not checking, reviewing and recording refrigerator and freezer temperatures or failing to use currently certified calibrated thermometers to check temperatures twice daily. Vaccine that is considered spoiled because a provider did not take immediate or appropriate action on out-of-range temperatures. Revaccination due to negligence to keep vaccine viable or improper administration. Transporting vaccines inappropriately (e.g. not on ice packs or not using a thermometer during transportation) between practices. Failure to notify the MIP when a provider's office hours change or the practice moves, resulting in vaccines being undeliverable and consequently spoiled. Discarding vaccine before the manufacturer's expiration date (includes multi-dose vials discarded after 30 days).
Unaccounted For	Failure to document doses administered. Failure to document patient eligibility. Failure to report inventory. Inaccurate reporting of inventory or doses administered. Failure to report expired/wasted vaccine.

Unauthorized Administration	All unauthorized administered vaccines.
Other	Situations not listed above that MIP deems to be wastage due to provider negligence.