



HDOH Vaccines For Children (VFC) Program

VACCINE LOSS

(Expired, Spoiled and Wasted Vaccines)

April 9, 2024

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HOUSEKEEPING



Please ensure you are muted throughout the presentation unless you are speaking.

Reminder for QA Team:

Please monitor the chat for questions you may be able to answer.



Reminder to Attendees:

Today's session is being recorded. Slides and webinar recordings will be uploaded to:
<https://health.hawaii.gov/docd/for-healthcare-providers/vaccination-resources/vaccines-for-children-program-vfc/>



To be added to the Hawaii VFC Program email list, please email your request to HawaiiVFC@doh.Hawaii.gov. In the subject line of the email, please write **EMAIL LIST**.

QUESTIONS?



- During today's webinar, please use the chat to ask your questions so the Hawaii VFC Program subject matter experts can respond directly.
- We will be answering your questions at the end of the presentation

Objectives

By the end of the presentation, providers are able to:


- ▶ Identify and describe the types of vaccine loss
- ▶ Identify reasons for negligence resulting to vaccine loss
- ▶ Understand what to do and how to report expired, spoiled and wasted vaccines

Vaccine Accountability

Vaccine Accountability is one of CDC's highest priorities and an essential component of the VFC program. The VFC program has the primary responsibility for developing and maintaining vaccine accountability systems which:

- Ensure that vaccine loss and wastage is minimized;
- Protect against fraud and abuse;
- Ensure that vaccines purchased with VFC funds are administered only to VFC-eligible children; and
- Ensure the proper apportionment of vaccine purchases based on the VFC-eligibility data for population.





It is important that VFC providers account for and store VFC vaccine appropriately to avoid loss of vaccine due to expiration, storage and handling issues, and administration errors.

Reasons of negligence include but are not limited to the following:

- ◆ *Not being available to accept/receive a vaccine delivery during stated vaccine delivery hours*
- ◆ *Failure to store vaccine promptly upon arrival*
- ◆ *Storing vaccine in a refrigerator or freezer unit that cannot consistently maintain the required temperature range*
- ◆ *Freezing vaccine intended to be refrigerated and/or refrigerating vaccine intended to be frozen*
- ◆ *Failure to check and document vaccine storage temperatures twice per workday*
- ◆ *Failure to download and review DDL data for any out-of-range temperature*
- ◆ *Failure to follow vaccine storage alarm response protocol for power outage or unit failure*
- ◆ *Failure to rotate vaccine stock, resulting in preventable expired vaccine*
- ◆ *Any other preventable incidents made by providers*

Hawaii VFC Vaccine Loss

During Federal Fiscal Year 2023, **over 8700 doses** of routine VFC vaccines, valued at **over \$540,000**, were reported as expired, wasted, or spoiled by Hawai'i VFC vaccine providers.

Note: This figure represents **only** routinely administered vaccines and does not include seasonal/allocated VFC vaccines like influenza and COVID-19, for which wastage is expected to occur on a yearly basis as new formulations become available.



Types of Vaccine Loss

► Spoiled or Expired Vaccine (Returnable)

Any intact (i.e., vials/prefilled syringes must be capped and unused), nonviable VFC vaccine vials and prefilled syringes, including expired vaccine or vaccine that has been spoiled as a result of the following:


- Vaccine expiration date exceeded
- Failure to store properly upon receipt
- Refrigerator/Freezer too cold
- Refrigerator/Freezer too warm
- Natural Disaster: Power outage, hurricane, etc.
- Spoiled in transit (Cold/Frozen, Warm/Defrosted)
- Spoiled – Other (provider must state “other” reason)
- Mechanical Failure/Technical issue
- Recall (provider must state reason for recall)
- Other (provider must state “other” reason)

► Wasted Vaccine (Non-Returnable)

Any nonviable vaccine that cannot be returned to the Hawaii VFC program is considered “wasted” vaccine. These vaccines should be reported to the Hawaii VFC program but cannot be returned to the CDC-contracted vaccine distributor (McKesson). The following wasted vaccine products are not available for federal excise tax credit and should be disposed of as medical waste by the provider:

- Broken vial/syringe
- Vaccine drawn up into syringe but not administered
- Lost or unaccounted for vaccine
- Non-vaccine product (e.g. IG, HBIG, vaccine diluent)
- Open multi-dose vial but all doses not administered
 - NOTE: Open, expired multidose vials of IPOL must be reported as wastage and disposed of at the provider office.
- Other (provider must state “other” reason)

NOTE: Opened vaccine vials and prefilled syringes (i.e., caps have been removed) cannot be returned to McKesson, should be reported as wastage, and disposed of at the provider’s office.



**What can you do about
expiration, wastage and
spoilage?**

- 1. Plan***
- 2. Know***
- 3. Act***

1. PLAN your VFC orders.

- a) Do not go on ordering “autopilot” and continue to request the same amounts of vaccines if they are no longer regularly administered.
- b) With the greater availability of combination vaccines, the Hawaii VFC program has observed a sharp increase in wastage of DTaP and Hib products. If your office primarily administers combination vaccines, reduce orders for the individual vaccine components accordingly.
- c) Td vaccine supply is currently constrained and should now only be ordered for administration to persons contraindicated to receive pertussis-containing vaccines. See: [Diphtheria, Tetanus, and Pertussis Vaccine Recommendations | CDC](#) for more information. For most persons, Tdap should be administered instead.

2. Know when vaccine is truly spoiled/wasted.

- a) Do not discard open multidose IPV vials after 30 days. With the exception of COVID-19, vaccines in multidose vials (MDVs) that do not require reconstitution contain preservatives and can be used through the expiration date printed on the label as long as the vaccine is not contaminated, unless otherwise indicated by the manufacturer. See [Package Insert - IPOL \(fda.gov\)](#): 30-day BUD is not indicated by the manufacturer.

- b) If a temperature excursion occurs, do not assume all affected vaccines are spoiled. Activate your emergency vaccine storage plan and continue to store affected vaccines at appropriate storage temperatures. Label “Do Not Use” and follow-up with vaccine manufacturers and the Hawaii VFC Quality Assurance team to determine viability.

3. Act.

- a) If you do have expired or spoiled VFC vaccine on hand, report it to the Hawaii VFC program and initiate a return to McKesson within 6 months. The Hawaii VFC Program receives excise tax credits for each vial returned which allows for recovery of a portion of the funds lost due to expiration and spoilage.

- b) Note, all unused/intact (i.e., caps have not been removed) expired and spoiled VFC vaccines are returnable, including VFC influenza and COVID-19 vaccines.



Reporting expired, spoiled and wasted vaccines

Hawaii VFC vaccine return instructions are available here:
[VFC-Vaccine-Return-Instructions.pdf \(hawaii.gov\)](#)

HAWAII DEPARTMENT OF HEALTH
IMMUNIZATION BRANCH

VACCINE LOSS REPORTING FORM

Reset Form

INSTRUCTIONS: Report VFC VACCINES that have expired, spoiled, or were wasted **WITHIN 6 MONTHS** after loss. Fax Reporting Form to: (808) 586-8302 or E-mail Reporting Form to: doh.hawaii.vfc@doh.hawaii.gov
Do NOT return expired and spoiled vaccines to the Hawaii Immunization Branch. A return label will be sent via email from United Parcel Service (UPS). Enclose a copy of this form with the return shipment. Keep a copy for your records.

EXPIRED VACCINES

VACCINE TYPE	MANUFACTURER	NDC NUMBER	LOT NUMBER	EXPIRATION DATE	NUMBER OF DOSES

SPOILED VACCINES

VACCINE TYPE	MANUFACTURER	NDC NUMBER	LOT NUMBER	EXPIRATION DATE	NUMBER OF DOSES	REASON (SELECT CODE)
						1-Failure to store properly upon receipt 2-Refrigerator/Freezer too cold 3-Refrigerator/Freezer too warm 4-Natural Disaster: Power outage, Hurricane, etc. 5-Spoiled in transit (Cold/Frozen, Warm/Defrosted) 6-Spoiled: (other reason) 7-Mechanical failure/Technical issue 8-Recall: (reason) 9-Other: (state reason with detailed information)

WASTED VACCINES (DISPOSE OF WASTED VACCINES AFTER REPORTING. DO NOT SHIP TO CDC'S VACCINE DISTRIBUTOR/MCKESSON)

VACCINE TYPE	MANUFACTURER	NDC NUMBER	LOT NUMBER	EXPIRATION DATE	NUMBER OF DOSES	REASON (SELECT CODE)
						1-Broken vial/syringe 2-Drawn up, but not administered 3-Lost or unaccounted for 4-Open vial, but all doses not administered 5-Non-vaccine product (e.g., HBIG, Ig, Diluent, etc.) 6-Other: (state reason with detailed information)

NAME OF PHYSICIAN'S OFFICE, PRACTICE, CLINIC _____ VFC PIN NO. _____ DATE _____
 ADDRESS _____ CITY _____ ZIP _____
 CONTACT PERSON _____ PRIMARY VACCINE COORDINATOR E-MAIL ADDRESS ONLY (WHERE RETURN LABEL WILL BE SENT) _____ PHONE NO. _____

Entered in

 Date: _____
 Revised 10/2023
 GRANTEE CODE: HIA

1. Report vaccine expiration, spoilage and/or wastage either through:

a) Hawaii Immunization Registry (see: [VFC Vaccine Returns and Wastage in the Hawaii Immunization Registry \(HIR\) | Disease Outbreak Control Division](#))

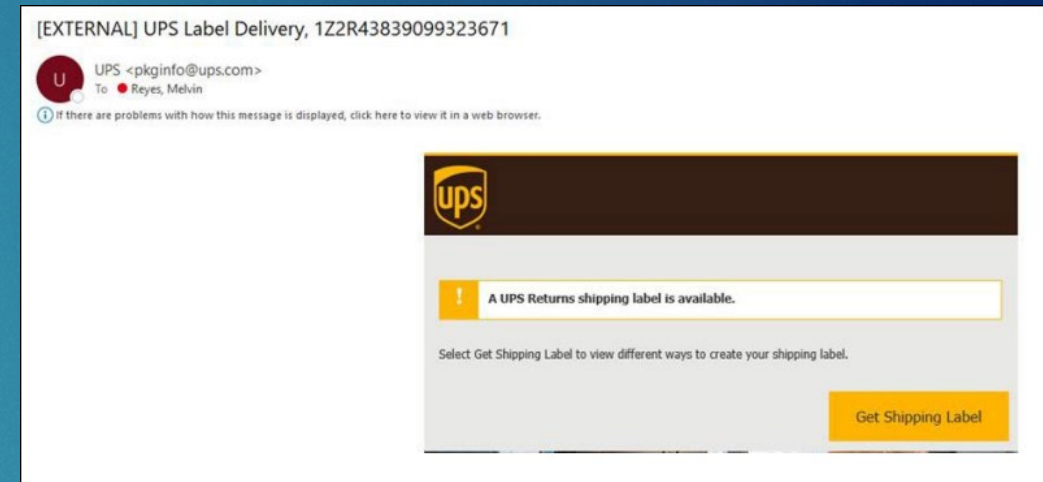
or

b) Completing and submitting the Vaccine Loss Reporting Form to HawaiiVFC@doh.hawaii.gov

NOTE: Returnable vaccines should always be sent to the CDC-contracted vaccine Distributor (McKesson). DO NOT return vaccines to the Hawaii VFC Program.

2. Hawaii VFC Program staff will submit your vaccine return and/or wastage information to the CDC. CDC will then transmit RETURNABLE vaccine information to the CDC-contracted vaccine distributor (McKesson). Upon receipt, McKesson will have UPS send an email to the provider with a link to a UPS Returns Shipping Label. The email will be sent to the email address providers specify in HIR or on the Vaccine Loss Reporting Form.

3. Providers must check their specified email inbox for an email from UPS that contains the link to the UPS Returns Shipping Label. Please be sure to monitor “spam” and “junk” email inboxes as well since the email originates from a general UPS account. Provider should then click on the “Get Shipping Label” link to print their label(s).



4. Pack returnable vaccines as follows:

- Note: spoiled or expired vaccines do not need to be packed in a cooler with ice.
- Vaccines should be placed inside a zip-top or plastic bag to prevent leakage during transportation.
- Place the zip-top or plastic bag containing the returnable vaccines in either a padded mailing envelope or box. If re-using a box, please ensure it does not contain any printed shipping warning labels (e.g., “Contains Bleach,” “Contains Batteries,” etc.)
- Enclose a copy of the HIR Return List or Vaccine Loss Reporting form in the box or padded envelope along with the returnable vaccines.
- Affix the printed UPS Returns Shipping Label to the outside of the box.



5. Either hand the box/envelope to a UPS driver visiting your facility to make a regular delivery or drop the package off at a UPS retail location. Do not schedule a UPS pick-up as your office will be charged for the service





Key Takeaway:

Vaccine loss is both costly and preventable. VFC providers must ensure accountability for publicly-funded vaccines and are responsible for maintaining vaccine quality from the time a shipment arrives at a facility until a dose is administered. Therefore, sound vaccine management practices related to ordering, inventory maintenance, and storage and handling are critical to minimizing vaccine loss and waste and potentially putting VFC children at risk from compromised vaccine.

Contact Information

For HIR technical/login issues, please contact Registry Help Desk at (808) 586-4665, 1-888-447-1023 (toll-free), or registryhelp@doh.hawaii.gov.

For VFC Vaccine Ordering questions/concerns, you may contact:

Melvin Reyes	melvin.reyes@doh.hawaii.gov	808-586-8316
Elizabeth Ricon	elizabeth.ricon@doh.hawaii.gov	808-586-8301
Heather Winfield-Smith	h.winfield-smith@doh.hawaii.gov	808-586-8348
Ji Hyun Choi	jihyun.choi@doh.hawaii.gov	808-586-4585

For any VFC-related questions/concerns, you may contact:

Josephine Araki, RN	josephine.araki@doh.hawaii.gov	808-723-1601
Loraine Lim, RN	loraine.lim@doh.hawaii.gov	808-723-0018
Kealohi Corpos	kealohi.corpos.nsw@doh.hawaii.gov	808-723-0091
Jennifer Dean	jennifer.dean.nsw@doh.hawaii.gov	808-723-0366
Sisilia Meli	sisilia.meli.nsw@doh.hawaii.gov	808-587-6588
Heather Winfield-Smith	h.winfield-smith@doh.hawaii.gov	808-586-8348

Thank you for joining us today!

POST-WEBINAR SATISFACTION SURVEY

Please use the following link to complete the satisfaction survey:

<https://forms.office.com/g/XStX9ewn6e>