1. COVID-19 Vaccine Order Placement

- Hawaii COVID-19 Vaccine providers must submit orders via the Hawaii Department of Health COVID-19 Vaccine Order Form. Orders must be submitted via email to DOH.C19VaccineOrder@doh.hawaii.gov.
- Providers are required to:
  - Have current COVID-19 Vaccination Program enrollment status.
  - Document the core data elements for COVID-19 vaccine administration in the provider's medical record system within 24 hours of administration and report COVID-19 vaccine administration data to VAMS or data exchange with the Hawaii Immunization Registry as soon as practical and no later than 72 hours after administration.
  - Regularly report COVID-19 vaccine inventory to Vaccines.gov (VaccineFinder).
  - Report the number of all COVID-19 vaccine doses currently on hand with each vaccine order submitted.
    - If the space available on the COVID-19 Vaccine Order Form is insufficient for complete inventory reporting, please use separate supplemental forms (use COVID-19 Vaccine Inventory Sheet supplied with order form).
  - Report the number of vaccine doses used since the item was last ordered. Vaccine usage must be reported to provide necessary justification for fulfillment of new vaccine requests.

Note: Requests for vaccines may be fulfilled via redistributions from other Hawaii COVID-19 vaccination providers who have excess supply available, rather than direct shipments from CDC/McKesson or vaccine manufacturers.

2. How to Ensure Vaccine Orders are Received in a Timely Manner:

- If any of the elements in section 1 (above) are missing, provider order processing will be delayed.
- Providers should ensure that their delivery address and hours of operation are up to date. Please be sure to indicate if the provider office will be closed for holidays or other reasons within the next month.

3. COVID-19 Vaccine Order Components

- Moderna Monovalent and Bivalent vaccines:
  - Vaccine (in thermal shipper container), delivered by FedEx or UPS.
  - Ancillary kit containing administration supplies sufficient to administer primary and booster doses of vaccine, delivered by FedEx or UPS. Arrival to occur within 24 hours of receipt of vaccine. Note:
    - Providers requesting the Moderna Bivalent vaccines may indicate whether they would like to receive ancillary supplies to support pediatric (0.25 mL dose) or adult (0.5 mL

dose) populations. Be sure to check the corresponding "Adult Kit" or "Ped Kit" box on the HDOH COVID-19 Vaccine Order Form.
    - Alternatively, providers may "Opt-Out" of receipt of Moderna ancillary supplies if none are needed. To do so, please be sure to check the "Opt-out" box on the HDOH COVID-19 Vaccine Order Form.
- Pfizer Adult/Adolescent Monovalent and Bivalent vaccines ("Gray Cap"):
    - Vaccine (in thermal shipping container), delivered by FedEx or UPS.
    - Ancillary kit containing administration supplies sufficient to administer primary and booster doses of vaccine, delivered by FedEx or UPS. Arrival to occur within 24 hours of receipt of vaccine.
        - Providers may "Opt-Out" of receipt of Pfizer Adult/Adolescent ("Gray Cap") ancillary supplies if none are needed. To do so, please be sure to check the "Opt-out" box on the HDOH COVID-19 Vaccine Order Form.
- Pfizer Pediatric Monovalent and Bivalent vaccines ("Orange Cap" and "Maroon Cap"):
    - Vaccine (in thermal shipping container), delivered by FedEx or UPS.
    - Ancillary kit containing administration and mixing supplies sufficient to prepare and administer vaccine, delivered by FedEx or UPS. Arrival to occur within 24 hours of receipt of vaccine. *Note: Providers may not opt out of Pfizer Pediatric ancillary supplies as diluent for these vaccines are included in ancillary supply shipments.*
- Janssen and Novavax Vaccines:
    - CDC has discontinued regular allocations of Janssen (Johnson and Johnson) and Novavax vaccines to the Department of Health. Janssen and Novavax vaccines have limited use/applicability and may be requested as "Special Order" vaccines only. Contact HDOH at DOH.C19VaccineOrder@doh.hawaii.gov if you wish to request Janssen or Novavax vaccines.

4. COVID-19 providers will receive notices via the following email addresses:

- Moderna/Janssen/Novavax:
    - Order acknowledgement and/or vaccine shipment notification: CDCNotifications@mckesson.com or CDCCustomerService@mckesson.com
    - Ancillary kit shipment notification: SNSSupport@mckesson.com

- Pfizer:
    - Vaccine shipment notification: pfizer.logistics@controlant.com
    - Ancillary kit shipment notification: donotreply@pfizer.com

5. Timing of Vaccine Shipments

- Shipment timelines vary by manufacturer. Please allow for at least 7 – 10 days from order placement to receipt of vaccine shipments.
- Vaccine shipments will not arrive on weekends or State/Federal holidays.

- If an expected vaccine shipment has not arrived, please contact the Hawaii Immunization Branch at (808) 586-8300, 1-800-933-4832 (toll-free), or DOH.C19VaccineOrder@doh.hawaii.gov.

6. FedEx/UPS Signature Release

- **It is strongly recommended that you do <u>not</u> have a signature release on file.**
  - Having a FedEx/UPS signature release on file allows FedEx/UPS to drop off any FedEx/UPS package, including vaccine shipments, without a signature, regardless of office hours.
  - If vaccine shipment arrives without staff being present to receive the vaccine, temperature monitors could trigger before a vaccine shipment is discovered.
- **If you do have a signature release on file, please ensure that your provider office has procedures in place to ensure proper receipt of all vaccine shipments.**
- CDC/McKesson will not replace vaccine that has spoiled under these circumstances.

7. Receipt of COVID-19 Vaccine Shipments

- Providers should **<u>never</u>** refuse vaccine shipments under any circumstances including delivery after provider hours (i.e., suspected "warm"/spoiled vaccines) or damage to the exterior package. If there is damage to the exterior package, be sure to take a photo for documentation purposes.
- Open vaccine shipments **immediately**, check the temperature monitor reading, inspect the vaccine, compare the vaccine received with the vaccine products indicated on the packing list, and store at the appropriate temperature.
- If you suspect that vaccine viability has been compromised, vaccines should be separated from non-affected vaccine stock (e.g., placed in a paper or zip-top bag), labelled "Do Not Use," and stored at appropriate temperatures until vaccine viability is determined. Follow the procedures below based on where the vaccine was shipped from:

Shipments from McKesson (**Moderna, Janssen, Novavax, all ancillary kits**):

- **Moderna: COVID-19 providers must contact McKesson directly on <u>the same day</u> that delivery has occurred to report the shipping incident and inquire about vaccine viability.**
  - Phone: 1-833-272-6635, Monday – Friday, 8:00 am – 8:00 pm EST.
  - **Send an email to:** <u>COVIDVaccineSupport@McKesson.com if reporting a shipping incident to McKesson after 8:00 pm Eastern Time.</u>
- McKesson may request that you supply photos of the shipping container, packaging, and any activated temperature monitors. Take photos for documentation purposes and avoid disposal of shipping boxes/packaging, packing slips, and temperature monitors until the situation is resolved.
- Contact the HDOH Immunization Branch at (808) 586-8300, 1-800-933-4832 (toll-free), or DOH.C19VaccineOrder@doh.hawaii.gov to report the incident.

Shipments from Pfizer (Pfizer COVID-19 vaccines only):

- Contact Pfizer Customer Service at (800) 666-7248 (toll free) or via email at cvgovernment@pfizer.com.
- Take photos for documentation purposes and avoid disposal of shipping boxes/packaging, packing slips, and temperature monitors until the situation is resolved.
- Contact the HDOH Immunization Branch at (808) 586-8300, 1-800-933-4832 (toll-free), or DOH.C19VaccineOrder@doh.hawaii.gov to report the incident.

8. Ancillary Kits (Moderna/Janssen/Novavax and Pfizer)

- **Ancillary kits must be opened immediately to inspect for damage and to check the package against the packing list. If products are damaged or do not match the packing list, take photos for documentation and contact McKesson at:**
  - **Pfizer kits**: (833) 272-6634 (toll-free) or SNSSupport@McKesson.com
  - **Moderna/Janssen/Novavax kits:** (833) 343-2703 (toll-free) or COVIDVaccineSupport@McKesson.com

9. Over Shipments and Mis-Shipments

- "Over Shipments" are defined as situations in which the vaccine quantity shipped to a provider exceeds the amount that was ordered.
- "Mis-Shipments" are defined as situations in which shipments include at least one vaccine product that was not ordered.
- **The preferred action is for the provider to keep the additional vaccine and use it.**
- Contact the Immunization Branch at (808) 586-8300 or 1-800-933-4832 (toll-free) to report the incident.

10. Delivery Shortage

- A delivery shortage has occurred if the amount of product supplied is less than the amount listed on the packing slip.

Shipments from McKesson (Moderna):

- **Delivery shortage reports must be made on the same day that delivery has occurred.**
- Take a photo of the delivered vaccines for documentation.
- Contact the Immunization Branch at (808) 586-8300 or 1-800-933-4832 (toll-free) to report the incident and request additional vaccine. Immunization Branch staff will report the incident to McKesson.
- Please be prepared to provide the following information and answer the following questions:
  - Provider COVID-19 PIN

- Provider Name
- Order Delivery Date
- NDC
- Number of missing doses
- Is the packing slip for the correct provider?
- Does the product that was shipped match the packing slip?
- Does the delivery number on the packing slip match the delivery number on the shipping label affixed to the outside of the shipping container?

Shipments from Pfizer:

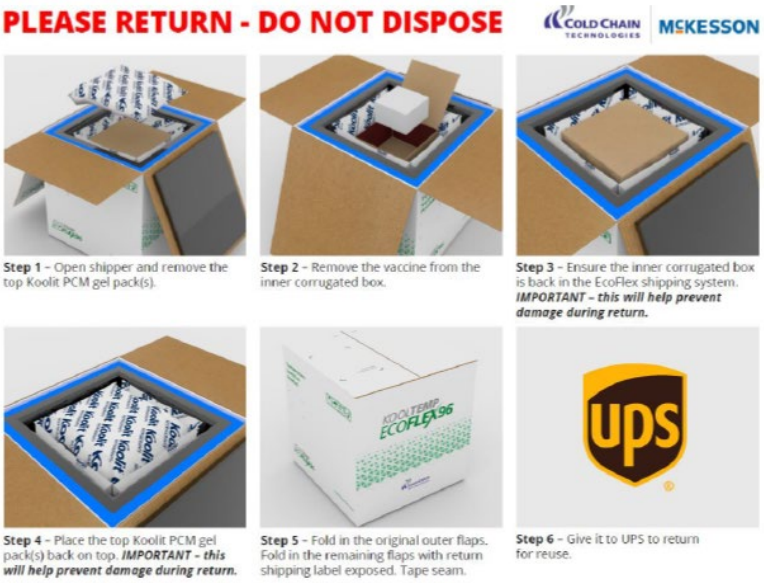
- Contact Pfizer Customer Service at:
  - Tel. (800) 666-7248 (option 8)
  - Email: CVGovernment@pfizer.com

11. Concealed Shortage

- A concealed shortage is defined as product shortages that are found within the manufacturer's packaging (e.g., a box of 10 multidose vials contains only 8 multidose vials).
- For all concealed shortages or damages, contact the vaccine manufacturer directly (see item 14 for manufacturer contact information).

12. Return of Vaccine Thermal Shippers and Controlant Temperature Monitors

- Moderna: Frozen (-20°C) Shippers



- Keep the SensiTech TagAlert temperature monitor that arrived with the shipment. Do not return.
- **DO NOT** enclose anything in the box (e.g., no empty vaccine vials, syringes, needles, etc.).

- Give the box to UPS personnel when they are already at your facility to deliver items. Note: You may be charged a fee if you schedule a pick-up specifically to return the shipping container.
    - Please contact McKesson Customer Care if you have questions about returning the EcoFlex shipper:
        - Phone: (833) 343-2703, Monday – Friday, 8:00 am – 8:00 pm, ET
        - Email: COVIDVaccineSupport@McKesson.com
- Pfizer Adult/Adolescent and Pediatric Formulations: Ultra-Cold (-80°C) Shippers
    - Follow the Pfizer return instructions included in the box

13. Vaccine Lot Management, Wastage, and Expiration

As access to COVID-19 vaccine increases, it is important for providers to not miss any opportunity to vaccinate every eligible person who presents at vaccination clinics. CDC and the Hawaii Department of Health recognize that as more opportunities for vaccination become available, it may increase the likelihood of leaving unused doses in a vial. While COVID-19 providers are expected to follow best practices to use every dose possible, this should not be at the expense of missing an opportunity to vaccinate every eligible person when they are ready to be vaccinated.

In order to minimize the number of unused expired doses and manage expired doses correctly, HDOH encourages providers to:

- Monitor expiration dates weekly, rotate stock as needed, and follow a "first in, first out" strategy to manage inventory.
- If nearing expiration, check posted manufacturer information for the most up to date expiration/extension information for vaccine lots.
    - Expiry Look-up Pages:
        - Pfizer: https://lotexpiry.cvdvaccine.com/
        - Moderna: https://eua.modernatx.com/covid19vaccine-eua/providers/vial-lookup
        - Novavax: https://us.novavaxcovidvaccine.com/hcp
        - Johnson and Johnson/Janssen: https://vaxcheck.jnj/
- Based on the latest expiration information, REMOVE expired vaccine from the storage unit IMMEDIATELY. Do not give staff opportunity to administer expired vaccine.
    - If expired vaccine is inadvertently administered, it is considered a vaccine administration error. This requires remediation including submitting a VAERS report and contacting the recipient to inform them of the error. Administering an expired vaccine may or may not require revaccination based on the manufacturer's guidance. Guidance on vaccine administration errors can be found in Appendix A of the Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States.
- Vaccine disposal: Dispose of the vaccine vial (with any remaining vaccine) and packaging as medical waste according to facility policies and state regulations. HDOH strongly recommends disposal of COVID-19 vaccine vials in sharps containers to avoid potential misuse of discarded vials. Do NOT return vaccine in the thermal shipping container.

Report Wasted/Expired Vaccine

Providers must promptly report any wasted or expired vaccines. This helps CDC/HDOH 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/HDOH recognizes that unused expired vaccine is a normal part of any vaccination program, especially one of this scope and size. **Note: Hawaii COVID-19 vaccine providers must report expiration and wastage of doses received from HDOH allocations via the "COVID-19 Vaccine Loss Reporting Form."**

Wastage Reporting Table

The table below serves as CDC guidance to determine if a dose should be reported as waste. Wastage does not negatively impact a provider but serves as means of accounting for inventory.

Manufacturer	Dose	Was the dose extracted in full?	Is it counted as waste?
Pfizer	6th dose	Yes	No
		No	Yes
Moderna 11 dose vial	10th dose	Yes	No
		No	Yes
	11th dose	Yes	No
		No	No
Moderna 15 dose vial	13th dose	Yes	No
		No	Yes
	14th dose	Yes	No
		No	Yes
	15th dose	Yes	No
		No	No
J&J/Janssen	5th dose	Yes	No
		No	Yes

When reporting wastage for bivalent boosters in children, always report wastage in full doses based on the volume identified on the label. Never report wastage in half doses. The table below is provided to assist with wastage reporting. Additional information on the identification, disposal and reporting of wastage can be found at Identification, Disposal, and Reporting of COVID-19 Vaccine Wastage | CDC

Product Label	Authorized For	Approved Administration	Dose Per Volume	Doses Per Vial	Max Reportable Inventory (Unopened Vials Only)	Max Reportable Wastage
Bivalent Vaccines						
Pfizer-BioNtech COVID-19 Vaccine Bivalent Booster	12 years and older	Booster	30mcg per 0.3mL	6	6	6
Pfizer-BioNtech COVID-19 Vaccine Bivalent Booster	5-11 y/o	Booster	10mcg per 0.2 mL	10	10	10
Moderna COVID-19 Bivalent Booster	12 years and older	Booster	50mcg per 0.5 mL	5	5	5
	6 – 11 y/o	Booster	25mcg per 0.25 mL	10	5	5

Moderna Bivalent Booster Wastage Reporting on HDOH COVID-19 Vaccine Loss Reporting Form

Wastage should be reported only as whole doses. Each dose administered, whether it is a half dose or a full dose, counts against the total possible wastage of 5 doses. Once 5 administrations occur *in any combination of dose sizes from a single vial*, *even if vaccine remains in the vial*, no wastage should be reported.

- ***For example***:
  - *During a full day in a clinic, 1 adult (0.5 mL) dose is administered, and 2 pediatric half-doses (0.25 mL) are administered from a Moderna Bivalent Booster vial.*
  - *COUNT the **total** number of doses administered (3), regardless of volume or series and subtract this from the total number of identified doses in the vial (5).*
  - *A total of 3 people were vaccinated (1 adult and 2 children); 5 – 3 = 2 doses wasted.*

14. Temperature Excursions After Shipment; During Provider Storage

Temperature excursions within the Clinic/Site	Call the Manufacturer
	Moderna: 1-866-MOD-ERNA or 1-866-663-3762 excursions@modernatx.com **Pfizer:** Pfizer US Medical Information 1-800-438-1985 **Janssen:** 1-800-565-4008 or 1-908-455-9922 JSCCOVIDTEMPEXCURSION@its.jnj.com **Novavax**: 1-844-NOVAVAX (M-F 8:00 am – 8:00 pm ET) or https://us.novavaxmedinfo.com/request-medical-information

- Contact the Immunization Branch at (808) 586-8300, 1-800-933-4832 (toll-free), or DOH.C19VaccineOrder@doh.hawaii.gov to report the incident.
- Quarantine vaccines and store at appropriate temperature ranges until resolution of the temperature excursion by the vaccine manufacturer.
- Should vaccine spoilage occur, COVID-19 providers must report the incident to the HDOH Immunization Branch via the HDOH Immunization Branch COVID-19 Vaccine Loss Reporting Form as soon as possible.

15. Documentation of Vaccine Transfers

- Transfer or redistribution (i.e., shipping or physical transfer) of vaccine product from one location to another is strongly discouraged due to cold chain considerations and should be an extremely rare occurrence.
- In general, transfers or redistribution may be considered for large health care systems that need to store vaccine supply for smaller affiliated clinics.
- Authorized, enrolled COVID-19 providers may ONLY transfer vaccine to other authorized, enrolled COVID-19 providers.
- The transferring site (i.e., sending facility) must have a completed “CDC Supplemental COVID-19 Vaccine Redistribution Agreement” on file at the HDOH Immunization Branch prior to initiating vaccine transfers if “ownership” of COVID-19 vaccine will be transferred to a COVID-19 provider/facility outside of their organization.
- Transfer of vaccine must strictly adhere to CDC and manufacturer-specified storage, handling, and transport guidelines. See:

https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf for specific CDC guidance.

- Authorized transfers must be documented and reported to the HDOH Immunization Branch via the COVID-19 Vaccine Transfer Form.

16. Conclusion

- This document will be updated as information evolves.
- Please pay close attention to COVID-19 Vaccination Program communications (emailed notices) to stay current with program updates as well as any changes to current policy/procedures.
- You are encouraged to share this resource with other staff members.
- The Hawaii Immunization Branch values your input. If you have any comments or questions pertaining to COVID-19 vaccine deliveries, please contact us at (808) 586-8300, 1-800-933-4832 (toll-free), or DOH.C19VaccineOrder@doh.hawaii.gov.