Montana Department of Public Health and Human Services

Immunization Program

Montana
COVID-19 Vaccination Program
Provider Handbook

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2. INTRODUCTION

The Montana Immunization Program implements the national COVID-19 Vaccination Program within the state of Montana.

This handbook contains Montana-specific information for enrolled providers and is a component of the provider training program. It, combined with the documents on our Required Training webpage, prepares providers for receiving, managing, and administering COVID-19 vaccine.

Throughout this document, required activities are indicated in the section headings. The handbook and our COVID-19 Vaccine Provider Resource webpage will be updated as information changes and more vaccines are authorized. The primary vaccine coordinator at your facility will be notified of significant changes.

For Montana COVID-19 Vaccination Program support, email covidvax@mt.gov or call 406-444-5580.

3. EMERGENCY USE AUTHORIZATION AND FDA LICENSING

Emergency Use Authorization

COVID-19 vaccines are initially authorized under an Emergency Use Authorization or EUA. An EUA allows the US Food and Drug Administration (FDA) to authorize the use of unapproved medical products such as a vaccine during an emergency based on certain criteria. The EUA outlines how the COVID-19 vaccine must be used and any required conditions of authorized use. Until full licensure, the EUA is the primary source of information on each authorized COVID-19 vaccine.

Use the link(s) below to access COVID-19 vaccine EUA fact sheets for healthcare providers:

Pfizer-BioNTech EUA Fact Sheet for Healthcare Providers—12 years of age and older (purple cap, must dilute-retired December 23, 2021)

Pfizer-BioNTech EUA Fact Sheet for Healthcare Providers—12 years of age and older (gray cap, DO NOT DILUTE—Introduced December 23, 2021)

Pfizer-BioNTech EUA Fact Sheet for Healthcare Providers—5–11 years of age (orange cap, must dilute)

Moderna EUA Fact Sheet for Healthcare Providers

Janssen EUA Fact Sheet for Healthcare Providers

Full FDA Licensing

On Monday, August 23, 2021, FDA approved the Pfizer BioNTech COVID-19 vaccine for use as a two-dose series for individuals 16 years of age and older. The new tradename is Comirnaty®. The FDA licensure applies to purple-cap Pfizer-BioNTech vaccine (retired on December 23, 2021, but still in inventory in the state) and the gray-cap Pfizer-BioNTech product (introduced on December 23, 2021) for use as a 2-dose primary series in individuals 16 years of age and older. The EUA remains in effect for administering Pfizer-BioNTech purple cap and gray cap vaccine as follows:

- A 2-dose primary series to individuals 12 through 15 years of age
- A third primary series dose to individuals 12 years of age and older who have certain kinds of immunocompromise
- A single booster dose to individuals 16 years of age and older who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or Comirnaty®

- A single booster dose to individuals 18 years of age and older who have completed primary vaccination with a different authorized COVID-19 vaccine.

The full licensure language is captured in the current EUA Fact Sheets for Healthcare Providers and in the prescribing information (product insert).

Interchangeability of FDA authorized (EUA) and FDA approved COVID-19 Products: The FDA-approved Pfizer-BioNTech product COMIRNATY (COVID-19 Vaccine, mRNA) and the FDA-authorized Pfizer-BioNTech COVID-19 under EUA can be used interchangeably to provide the COVID-19 vaccination series without presenting any safety or effectiveness concerns. Therefore, providers can use doses distributed under the EUA to administer the vaccination series for those seeking the approved vaccine. The Fact Sheet for Recipients provides additional information about both the approved and authorized vaccine. Providers should continue to use the vaccines in their inventory to their expiration or beyond use dates.

The pediatric Pfizer-BioNTech vaccine (orange cap) is only authorized under an EUA at this time.

4. VACCINE MANUFACTURER INFORMATION

Pfizer Vaccine:	cvdvaccine.com	800-438-1985
Moderna Vaccine:	Moderna COVID-19 Vaccine	866-663-3762
Janssen Vaccine:	Janssen COVID-19 Vaccine Official Website	800-565-4008

Vaccine Expiration Dates

As stability data is collected on COVID-19 vaccines, manufacturers may extend the expiration date on a particular lot. Always confirm that an expiration date is still valid before discarding expired vaccine.

Pfizer-BioNTech

Pfizer Product—12 years of age and older (Purple cap. Must dilute)

Lots of Pfizer vaccine for 12 years of age and older (purple cap) come with labeled expiration dates. However, on August 23, 2021, FDA approved an extension to the Pfizer expiration dates for particular lots. Cartons and vials of Pfizer-BioNTech COVID-19 vaccine with a printed expiration date of August 2021 through February 2022 may remain in use for 3 months beyond the printed date as long as they have been kept in ultra-cold storage between -90°C to -60°C (-130°F to -76°F). We maintain current expiration dates in imMTrax.

See table below for guidance:

Table 1 Pfizer-BioNTech Purple Cap Expiration Date Extensions (Source: CDC)

Printed Expiry Date	Updated Expiry Date
August 2021	November 2021
September 2021	December 2021
October 2021	January 2022
November 2021	February 2022
December 2021	March 2022
January 2022	April 2022
February 2022	May 2022

Pfizer Product—12 years of age and older (Gray cap. DO NOT DILUTE) and 5–11 years of age (Orange cap. Must dilute)

The Pfizer gray cap and orange cap vaccines come with the manufacture month and year printed on the vial and carton. The vaccine expires 9 months after the manufacture date including the month of manufacture. The actual expiration date is the last day of that ninth month. imMTrax lists accurate expiration dates and not manufacture dates. You can refer to imMTrax for the accurate expiration dates. See table below for guidance:

Table 2 Pfizer-BioNTech Gray Cap Expiration Date Calculation (Source: CDC)

Printed Manufacturing Date	9-Month Expiry Date*
06/2021	Feb. 28, 2022
07/2021	Mar. 31, 2022
08/2021	Apr. 30, 2022
09/2021	May 31, 2022
10/2021	Jun. 30, 2022
11/2021	July. 31, 2022
12/2021	Aug. 31, 2022
01/2022	Sept. 30, 2022
02/2022	Oct. 31, 2022

*Date of expiration always falls on the last day of the month

Moderna and Janssen

Lots of Moderna and Janssen vaccine do not come with labeled expiration dates. You can find the expiration date by entering the lot number printed on the carton into the manufacturers respective websites listed below or scanning the QR code on the vaccine. You can also check imMTrax for current expiration dates:

Moderna online expiration date lookup tool

Janssen online expiration date lookup tool

imMTrax-Web Main Page

5. VACCINE PRIORITIZATION AND ACIP RECOMMENDATIONS - REQUIRED

Montana currently follows the recommendations of the Advisory Committee on Immunization Practices (ACIP) for administering COVID-19 vaccines. ACIP recommendations are captured in the CDC-published "Clinical Considerations" documents linked below.

Clinical Considerations for Use of COVID-19 vaccines Currently Approved or Authorized in the US

Summary of Clinical Considerations for COVID-19 Vaccine Authorized in the US

6. PROVIDER ENROLLMENT - REQUIRED

Healthcare facilities must enroll with the Montana Immunization Program by submitting a *CDC COVID-19 Vaccination Program Provider Agreement* (Provider Agreement) in order to receive, store, and administer COVID-19 vaccine.

The Immunization Program will confirm the following before approving an enrollment:

- Storage unit and temperature monitoring capabilities meet minimum CDC standards
- Medical licenses for prescribing providers listed on the Provider Agreement are current
- That we have the necessary information to enter your location into our vaccine distribution system.

Contact covidvax@mt.gov or call 406-444-5580 for information on how to enroll.

7. KEY STAFF & COVID-19 VACCINE MANAGEMENT PLAN

You listed three points of contact on your Provider Agreement: an organization email (Section A), and a location-specific primary and backup vaccine coordinator (Section B). Please refer to your Provider Agreement and be aware of who your points of contact are.

Using the specific primary and back-up coordinators, an up-to-date COVID-19 Vaccine Management Plan must be completed and posted at your location (Appendix A). Enrolled VFC providers may use their Section 12 VFC vaccine management plan if the contacts and location information is the same.

All state, federal, and contracted entities involved in the COVID-19 Vaccination Program will use these email addresses to communicate with your facility. Please ensure these email addresses are actively monitored, emailed information is read carefully, and instructions are followed accurately.

Please keep your POCs up to date. Contact the Immunization Program if you need to update the points of contact at your facility.

8. PROVIDER TRAINING - REQUIRED

The Montana Immunization Program is required to train providers on the COVID-19 Vaccination Program. Our required training program is located here:

COVID-19 Vaccine Provider Required Training

It consists of the primary vaccine coordinator at your facility doing the following:

1. Clicking the links on the Required Training webpage and reading the required information.
2. Sharing this information with staff at your facility as you deem appropriate.
3. Completing the online attestation form on the webpage attesting to the completion of the activities and keep a log of other employees who have completed the trainings (Appendix B).

Downloading the documents is optional but recommended so you have off-line versions but be aware that the Required Training webpage and handbook will be updated frequently as information changes and more vaccines are authorized and approved. Primary coordinators should keep up with and share changes with other staff but are not required to attest to their training after the original attestation.

Although only the primary vaccine coordinator is required to attest to training completion, we encourage all staff at your facility involved in COVID-19 vaccination to read and understand the training contents.

Additional Resources

The Montana COVID-19 Vaccine Provider Resources webpage has links to additional (not required) COVID-19 vaccine trainings and resources.

9. *IMMTRAX* - REQUIRED

imMTrax, is Montana's Immunization Information System. *imMTrax* consolidates immunization records from healthcare providers and "shot cards" to form one complete, digital record. *imMTrax* is the platform used to order and manage public vaccines, including COVID-19 vaccines. All providers enrolled in the COVID-19 Vaccination Program must participate in *imMTrax*, and *imMTrax* onboarding is part of the enrollment process.

Access to *imMTrax* is restricted. Staff needing access to *imMTrax* must submit an *imMTrax* Access Request Form and be assigned a role commensurate with their activities in the system. Your primary and backup vaccine coordinators must have a vaccine management role in order to manage COVID-19 vaccine inventory in the system. If you need *imMTrax* access or have questions about your assigned role, email hhsphsiis@mt.gov or call 406-444-5580.

10. ORDERING VACCINE

As of August 1, 2021, COVID-19 vaccine supply exceeds demand, and enrolled providers can order vaccine as needed in imMTrax. However, to prevent wastage, we encourage you to inquire locally about receiving a transfer of vaccine already in the state before placing a new direct-ship order especially if the minimum quantity for a direct-ship order is more than you need.

Ordering Vaccine in imMTrax

- Before placing a vaccine order, you must have reconciled your inventory within the last 30 days. See Section 13 – Reconciling Vaccine in imMTrax for details on how to reconcile your inventory.
- Place orders in imMTrax by using the order form found at **VOMS**>>>**Orders & Returns**>>>**Orders & Transfers**>>>**New Order**. Click the drop-down arrow next to **Choose an Order Set:** and select **COVID-19**.
- Order vaccine by putting the number of doses in the **Doses Requested** column next to the product you wish to order. The quantity ordered must be divisible by the minimum dose order. A red callout box will appear with the minimum dose order requirement if your doses requested do not conform to the rules.
- DO NOT enter anything in the Comments box. We do not use or monitor that field. Click **Next.**
- On the next page, confirm your shipping address and Primary Vaccine Coordinator. Contact the Immunization Program if you need to make changes. DO NOT worry about the delivery hours or enter any Delivery Instructions. We manage delivery hours in another program and do not use or monitor the Delivery Instructions field.
- When your order is ready, click **Submit Order**. DO NOT just Save your order. Saved orders are not sent to the Immunization Program. You must SUBMIT ORDER.
- You can monitor the status of your order by going to **VOMS**>>>**Orders & Returns**>>>**Orders & Transfers.** Your order should show in the list with the status in the last column.
- You should receive your order within 1-3 days of submitting your order. Please call the Immunization Program (406-444-5580) if you do not receive your order within 5 days of placing your order.

First and Second Doses

For vaccines with two-dose regimens, providers are responsible for acquiring second doses to vaccinate recipients on time. Second doses no longer automatically ship in time for administration. Providers can either reserve second doses from current inventory or place another order for their second doses.

11. RECEIVING VACCINE IN *IMMTRAX*

You will receive an email from us the morning of the day your vaccine is scheduled to arrive at your facility, and your COVID-19 vaccines will automatically appear in your *imMTrax* inventory. You do not need to do anything.

To view your inventory in *imMTrax*:

1. Log in to *imMTrax*.

2. Select **Vaccine Management VOMS 2.0** from the left-hand menu.
3. Once in VOMS 2.0, select **Inventory** and then either **Reconciliation** or **Add/Search.**
4. You should see your COVID-19 vaccine listed in your inventory under the **Private** tab.

12. VACCINEFINDER – REPORTING DAILY INVENTORY - REQUIRED

VaccineFinder is a national online repository of vaccine inventory that is being used to track COVID-19 vaccine doses at provider locations. Once you receive vaccine, vaccine providers are required to report COVID-19 vaccine inventory on hand in VaccineFinder each day your facility is open. Inventory on hand should be based on the doses in each multi-dose vial (MDV) as described in the EUA. (See Section 25 for more information on doses per vial and tracking inventory.)

Providers enrolled in the COVID-19 Vaccination Program will receive an email from the "COVID Locating Health Provider Portal" (vaccinefinder@auth.castlighthealth.com) with instructions for enrolling in VaccineFinder. The initial email will be sent to the organization email entered on page 1 of your Provider Agreement. Multi-location organizations will have the choice of having one contact (org email on page 1 of your Provider Agreement) report inventory for all locations or having each location report inventory separately. Providers have two options for reporting inventory: manual entry or upload using a spreadsheet. Contact the Immunization Program if you do not receive an email onboarding your facility to VaccineFinder or if you have issues enrolling.

In addition to inventory reporting, VaccineFinder has a public display function where you can opt to display your COVID-19 vaccine availability and services to the public in an easy-to-use, searchable interface. Using the public display feature in VaccineFinder is optional, but we encourage you to use it if it makes sense in your vaccination efforts.

The following link has more information on VaccineFinder including downloadable handouts and training videos: VaccineFinder Provider Support

13. RECONCILING VACCINE IN *IMMTRAX*

Once a month, you must reconcile your vaccine inventory in *imMTrax*. This involves accounting for the doses administered or otherwise removed from inventory since your last reconciliation. If you participate in other public vaccine programs such as the Vaccines for Children program, you should reconcile your COVID-19 vaccines at the same time you reconcile your other public vaccines.

The process differs depending on how you report administered vaccines to the system. See below for brief descriptions of the reconciliation process. Quick reference guides and videos on reconciling inventory can be found here: *imMTrax* Training. See Section 25 for information on accounting for extra doses due to vial overfill.

Aggregate Providers

If you do not hand-key (direct enter) shots into *imMTrax* and shots come in through a data feed, you are an "aggregate provider" and should reconcile your inventory using the following steps:

1. Log in to *imMTrax*.
2. Select **Vaccine Management VOMS 2.0** from the left-hand menu.
3. Once in VOMS, click the arrow next to **Inventory** in the left-hand menu. Then select **Reconcile**.
4. Physically count the doses of each lot in your storage unit and enter the number in the **Physical Counts** column for each vaccine lot. The **Discrepancy** column will display the doses removed from inventory since your last reconciliation.
5. Click the **Adjust** button and enter the discrepancy amounts in the **Doses** box.
    a. For administered doses, select **Administered** from the **Adjust** dropdown list and **System Non-User Aggregate Reporting Only** as the reason.
    b. To remove extra doses added to accommodate vial overfill (Moderna only), select **Correction** from the **Adjust** dropdown list and **Correction of invalid entry** as the reason.
    c. For doses drawn up and not used, select **Wasted** from the **Adjust** dropdown list and **Drawn up, not used** as the reason.
6. Click **Save**. You will be returned to the main reconciliation list.
7. Scroll to the bottom and click **Submit Inventory**.

Integrated Providers

If you hand-key or directly enter shots into *imMTrax* and deduct the shots from your vaccine inventory you are an "integrated provider" and should reconcile using the following step:

1. Log in to *imMTrax*.
2. Select **Vaccine Management VOMS 2.0** from the left-hand menu.
3. Once in VOMS, click the arrow next to **Inventory** in the left-hand menu. Then select **Reconcile**.
4. Physically count the doses of each lot in your storage unit and enter the number in the **Physical Counts** column for each vaccine lot.
5. Since doses were removed from inventory as the shots were recorded in the system, the **Inventory on Hand** and **Physical Counts** column should be the equal. If they are not, doses should appear in the **Discrepancy** column. You should investigate to account for the discrepancy.
8. Adjust for any discrepancies by selecting **Adjust** and entering the **Dose(s**).
    a. To remove extra doses added to accommodate vial overfill (Moderna only), select **Correction** from the **Adjust** dropdown list and **Correction of invalid entry** as the reason.
    b. For doses drawn up and not used, select **Wasted** from the **Adjust** dropdown list and **Drawn up, not used** as the reason.
6. Click **Save**. You will be returned to the main reconciliation list.
7. Scroll to the bottom and click **Submit Inventory**.

14. VACCINE SHIPMENTS AND ANCILLARY SUPPLIES

Specific instructions on unpacking vaccine shipments at your facility are covered in the manufacturer's vaccine-specific information in the shipping containers.

Receiving Vaccine at your Facility

Follow the instructions in the shipper and contact the Immunization Program to report issues with shipments.

Below are general best practices on receiving shipments:

- Inform front desk and supply personnel when vaccine deliveries are expected.
- DO NOT leave vaccine deliveries unattended. Check all deliveries immediately to determine if they are perishable vaccine and handle them accordingly.
- Contact the primary or backup vaccine coordinator when shipments arrive.
- Place vaccine in an approved storage unit holding proper temperatures as soon as possible.
- Follow the instructions in the shipping container when unpacking vaccines.
- Confirm that:
  - The package is not damaged or leaking
  - The temperature monitors are within acceptable limits
  - The vaccine and ancillary supply quantities, diluents, lot numbers, and expiration dates (if present) match the packing list and imMTrax inventory.
- Compare expiration dates to current stock to ensure short-dated vaccines are used first.

Vaccine Shipment Contents

Products listed below may not be available at any given time. Check the imMTrax order form (order set "COVID-19") for currently available products.

Pfizer Product—12 years of age and older (Purple cap. Must dilute—Retired on December 23, 2021)

On December 23, 2021, the Pfizer vaccine for 12 years of age and older (purple cap) vaccine was retired and can no longer be ordered. However, doses may still remain in inventory around the state and can be used to their expiration or beyond use dates. The purple-cap vaccine arrived in dry-ice thermal shippers containing either:

- 3 trays each containing 25 MDVs (6 doses per vial). Minimum dose order is 450 doses, OR
- 1 tray containing 195 MDVs (6 doses per vial). Minimum dose order is 1170 doses.

The Pfizer purple-cap vaccine shipped at ultra-cold temperature (-90 to -60°C) and can be stored three ways:

- Ultra-cold freezer until expiration (-80° to -60°C)
- Frozen for a cumulative two weeks (-25° to -15°C). Can go back into ultra-cold storage one time.
- Refrigerated if used within 31 days (2° to 8°C). Do not re-freeze.

Pfizer Product—12 years of age and older (Gray cap. DO NOT DILUTE—Introduced on December 23, 2021)

The Pfizer vaccine for 12 years of age (gray cap) comes in one shipment size and arrives in a dry-ice thermal shipper containing:

- 1 carton containing 10 MDVs (6 doses per vial). Minimum dose order is 300 doses (5 cartons).

The Pfizer vaccine for 12 years of age (gray cap) ships at ultra-cold temperature (-90 to -60°C) and upon arrival can be stored two ways:

- Ultra-cold freezer until expiration (-80° to -60°C)
- Refrigerated for use within 10 weeks (2° to 8°C). Do not re-freeze.

PLEASE NOTE: This product should not be stored in a regular freezer

The Pfizer vaccine for 5–11 years of age (orange cap) expires 9 months after the manufacturing date printed on the carton regardless of storage regimen.

Pfizer Product—5–11 years of age (Orange cap. Must dilute)

The Pfizer vaccine for 5–11 years of age (orange cap) comes in one shipment size and arrives in a dry-ice thermal shipper containing:

- 1 carton containing 10 MDVs (10 doses per vial). Minimum dose order is 100 doses.

The Pfizer vaccine for 5–11 years of age (orange cap) ships at ultra-cold temperature (-90 to -60°C) and upon arrival can be stored two ways:

- Ultra-cold freezer until expiration (-80° to -60°C)
- Refrigerated for use within 10 weeks (2° to 8°C). Do not re-freeze.

PLEASE NOTE: This product should not be stored in a regular freezer

The Pfizer vaccine for 5–11 years of age (orange cap) expires 9 months after the manufacturing date printed on the carton regardless of storage regimen.

Moderna Product

Each carton of Moderna vaccine contains:

10 MDVs (10-11 doses per vial) for a total of 100-110 doses per carton. Minimum dose order is 100 doses.

The Moderna vaccine ships at frozen temperature (-25 to -15°C) and upon arrival can be stored two ways:

- Frozen until expiration (-25° to -15°C)
- Refrigerated for up to 30 days prior to first use (2° to 8°C). Do not re-freeze.

Janssen Product

Each carton of Janssen vaccine contains 10 MDVs (5 doses per vial) for a total of 50 doses per carton. A minimum order is two cartons or 100 doses. The Janssen vaccine ships refrigerated (2° to 8°C) and upon arrival should be stored refrigerated. Do not freeze.

Ancillary Supplies

You will receive an ancillary supply kit with each shipment of vaccine. The kits ship separately and should arrive before or on the same day as the vaccine. In general, for each 100 doses of vaccine, the following will be provided in the ancillary kit:

- 105 Needles 22–25-gauge, 1-1.5" (adult)
- 105 Syringes (ranging from 1–3 mL)
- Alcohol prep pads
- 4 surgical masks and 2 face shields for vaccinators
- COVID-19 Vaccination Record Cards for vaccine recipients
- Vaccine needle guide detailing the appropriate length/gauge for injections based on route, age, gender, and weight
- Diluent for the Pfizer product.

With the authorization of a Moderna half-dose (0.25mL) booster, Moderna vaccine shipments now come with an extra pediatric ancillary kit to provide additional supplies to administer double the number of doses per vial.

Ancillary kit dimensions:

- Pfizer product: 24in x 20in x 24in. This provides supplies needed to administer 450 doses of vaccine.
- Moderna product: 1in x 13in x 9in. This provides supplies needed to administer 100 doses of vaccine.
- Janssen product: 1in x 13in x 9in. This provides supplies needed to administer 100 doses of vaccine.

Please report any issues with ancillary kits to the Immunization Program (406-444-5580 covidvax@mt.gov)

15. PATIENT EDUCATION - REQUIRED

Providers must provide an EUA Fact Sheet for Recipients and Caregivers to each vaccine recipient prior to each vaccination.

Links to EUA Fact Sheets for Recipients and Caregivers are listed below and are also on our Required Training webpage:

Pfizer-BioNTech EUA Fact Sheet for Recipients and Caregivers — 12 years of age and older (purple cap)

Pfizer-BioNTech EUA Fact Sheet for Recipients and Caregivers — 12 years of age and older (gray cap)

Pfizer-BioNTech EUA fact Sheet for Recipients and Caregivers — 5–11 years of age

Moderna Vaccine EUA Fact Sheet for Recipients and Caregivers

Janssen Vaccine EUA Fact Sheet for Recipients and Caregivers

16. Vaccination Record Cards (Required) and Second Dose Reminders

Providers must provide an accurately filled-out COVID-19 Vaccination Record Card to each vaccine recipient. Vaccination Record Cards are part of the ancillary kit included with each vaccine shipment. Providers must complete all required information (i.e., manufacturer, lot number, date of first dose, and second dose due date) including the second-dose appointment field, if possible.

Contact the Immunization Program if you need additional Vaccination Record Cards. Please keep paper and digital versions of the Vaccination Record Card in a secure place.

Providers should encourage the vaccine recipients to:

- Keep the card in a safe place and present it when they receive their second dose.
- Take a picture of their card with their Smartphone as a backup
- Enter their second-dose due date on any digital or paper calendars or reminder systems they use.

For redundancy, providers should use any system available to them to remind vaccine recipients about their second dose including scheduling an appointment for the second dose, if possible.

V-safe - After Vaccination Health Checker

V-safe is a smartphone app that uses text messaging and web surveys to check-in with patients after they receive a COVID-19 vaccination. Through *v-safe*, patients can quickly tell CDC of post-vaccination side effects. Depending on what is reported to *v-safe*, CDC may follow up with the patient. *V-safe* will also remind patients to get their second dose, if indicated.

Please encourage your patients to participate in *v-safe* by distributing *a v-safe* patient information sheet (linked below) to all vaccine recipients.

The v-safe Patient Information Sheet and a poster to display at your facility can be found on our COVID-19 Vaccine Provider Resources webpage.

17. Temperature Monitoring - Required

COVID-19 vaccine providers are expected to follow the standards of practice for vaccine storage and handling as described in the COVID-19 Addendum to the CDC Vaccine Storage and Handling Toolkit (starts on page 49). Digital and paper temperature records must be kept for a minimum of three years.

Continuous Monitoring

COVID-19 vaccine providers must continuously monitor the temperature of vaccine storage units using a device called a data logger. Data loggers are digital thermometers capable of continuously recording temperatures on a predetermined schedule. Vaccine providers must have a data logger in each vaccine storage unit and transport cooler used for COVID-19 vaccine.

At a minimum, data loggers must:

- Be continuous recording devices that take readings at least every 30 minutes
- Be calibrated to accurately monitor the temperature range it is used for (i.e., refrigerator 2 to 8°C, frozen -25 to -15°C, ultra-cold -90 to -60°C)
- Read temperatures from a buffered probe.
- Display the current, minimum, and maximum temperatures on the outside of the storage unit or transport container
- Generate historic data that is able to be archived, reviewed, and sent to the Immunization Program.

Daily Monitoring

In addition to continuous monitoring, providers also must manually check storage unit temperatures once per day preferably in the morning before beginning to vaccinate and record:

- Minimum/maximum temperature (If the data logger cannot display a min/max temperature, the current temperature must be recorded twice daily, morning and evening.)
- Date and time
- Name of person checking and recording temperature
- Actions taken and resolution if a temperature excursion occurred.

18. REPORTING TEMPERATURE EXCURSIONS - REQUIRED

A temperature excursion occurs whenever vaccine is exposed to temperatures outside those allowed by the EUA and/or prescribing information. Refer to the EUA Fact Sheet for Healthcare Providers for each vaccine for the exact storage conditions and any allowed deviations. Incidents within the confines of an allowed deviation are not considered excursions.

Incidents Involving Vaccine Shipments

Pfizer Vaccine (Purple, Gray, and Orange Cap Products)

Controlant® is contracted to monitor Pfizer vaccine shipments. Controlant® should know of any issues with your vaccine while it is in route to your facility and will contact you if they are aware of issues. Once the thermal shipper arrives at your facility, press the Stop button on the data logger embedded in the thermal shipper for 5 seconds. You will receive an email from Controlant® with instructions. If you have questions about the condition

of the thermal shipper or temperatures upon arrival at your facility, immediately call Pfizer customer support at 877-829-2619 and follow the instructions in the shipper.

Moderna and Janssen Vaccines

Follow the instructions that come with your Moderna and Janssen vaccine shipments and contact the phone number in the instructions if you have questions about the condition or temperatures of the shipment upon arrival at your facility. Either the Immunization Program or McKesson will follow up with you with next steps.

Incidents Involving Storage and Handling at your Facility

While vaccine is in your custody, you must respond to temperature excursions involving COVID-19 vaccine immediately by taking the following steps:

1. Stop vaccinating and quarantine (place a "DO NOT USE" designation) on the affected vaccine.
2. Notify the primary or backup vaccine coordinator at your facility.
3. If possible, stabilize the situation by placing the vaccine into appropriate storage temperatures. (DO NOT re-freeze thawed vials.)
4. Download the temperature data for the timeframe of the excursion and ascertain the duration and extent (minimum or maximum temperature achieved).
5. Contact the Immunization Program at by submitting an online Vaccine Incident Report. You can also contact the Immunization Program at covidvax@mt.gov or 406-444-5580. We will help you with next steps in resolving the issue.
6. Continue to quarantine the vaccines under appropriate temperatures (if possible) until the incident is resolved and your Vaccine Incident has been closed.

19. VACCINE REDISTRIBUTION – REQUIRED (IF APPLICABLE TO YOUR FACILITY)

Whenever possible, COVID-19 vaccine will be directly shipped to the end-use facility. Under certain circumstances it may be necessary to redistribute COVID-19 vaccine beyond the direct ship locations. For instance, providers capable of storing large amounts of vaccine may be asked to redistribute vaccine to those with less capacity. Large healthcare organizations may wish to redistribute vaccine to other locations within their organization.

Providers redistributing vaccine outside of their location must:

1. Have a *CDC Supplemental COVID-19 Vaccine Redistribution Agreement* on file.

2. Only redistribute vaccine to facilities enrolled in the COVID-19 Vaccination Program
3. Obtain approval from the Immunization Program before physically moving the vaccine by submitting a transfer in imMTrax (see process below).

To submit a transfer in imMTrax:

4. Navigate to **VOMS 2.0**. Then select **Orders & Returns**>>>**Orders & Transfers**>>>**New Transfer**. Pick the receiving organization and facility from the drop-down lists and enter the doses of vaccine to be transferred. Enter a comment in the comment box (required). Click **Submit Transfer**.
5. Immediately after submitting the transfer, email kgrady-selby@mt.gov that a transfer is ready for approval (required).
6. Once approved, the sending and receiving clinic will receive an email that the transfer is ready to be received in imMTrax by the receiving clinic.
7. Before receiving the transfer in imMTrax, the receiving clinic must confirm the vaccine, lot numbers, expiration dates, and number of doses physically transferred match what is transferred in imMTrax. If it does not, do not accept the transfer and contact kgrady-selby@mt.gov 406-444-1613. If it does, receive the transfer in imMTrax by navigating to **VOMS 2.0** then selecting **Orders & Returns**>>>**Orders & Transfers**.

DO NOT redistribute vaccine to another location without notifying the Immunization Program and obtaining approval. We will ensure the conditions of redistribution are met and provide instructions on transporting vaccine (see section below) and adjusting your inventory.

DO NOT redistribute opened (punctured) MDVs or vaccine that has experienced a temperature excursion.

Contact the Immunization Program if you need a *Redistribution Agreement*.

20. VACCINE TRANSPORT – REQUIRED (IF APPLICABLE TO YOUR FACILITY)

"Transport" is defined as the physical movement of vaccine using coolers where the expected duration out of regular storage is less than eight hours or a regular business day. Vaccine transport will be necessary during redistribution.

Vaccine transport should comply with the standards of practice as outlined in the CDC Vaccine Storage and Handling Toolkit including the following:

- Vaccine must be transported following the manufacturer's guidance on transport and redistribution.
- The cold chain must be maintained during transport by:
  - Using appropriate pack-out methods and qualified containers
  - Monitoring temperatures with a digital data logger
  - Recording temperatures when vaccines are loaded, unloaded, and every hour during transport.
- The following cold chain documentation must be maintained during transport:

- Transport-specific inventory list
- Container-specific temperature log
- Data logger data

Temperature excursions during transport must be reported according to Section 18 Reporting Temperature Excursion.

Providers are prohibited from "shipping" vaccine, which the CDC defines as moving vaccine using a commercial carrier over a longer timeframe than eight hours.

21. VACCINE WASTAGE AND LOSS

There is currently no vaccine return policy for COVID-19 vaccine. All wasted doses must be reported to the Immunization Program on our COVID-19 Vaccine Wasted and Expired Vaccine Report, and then securely discarded according to your facility guidelines for medication waste in a manner that renders the vials and external packaging unusable.

See Section 25 for product-specific information on reporting wastage.

22. VAERS ADVERSE EVENT REPORTING - REQUIRED

The Vaccine Adverse Event Reporting System (VAERS) is a nation-wide reporting system for adverse events following vaccination. It can detect possible safety problems requiring additional investigation.

COVID-19 vaccine providers are required to report the following to VAERS:

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events* (irrespective of attribution to vaccination)
- Cases of Multisystem Inflammatory Syndrome (MIS) in adults and children
- Cases of COVID-19 that result in hospitalization or death.

Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html or by calling 1-800-822-7967.

Vaccine providers must respond to FDA requests for more information about vaccine administration errors, adverse events, cases of MIS in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of a COVID-19 vaccine.

*Refer to the EUA Fact Sheet for Healthcare Providers for each vaccine for more details on adverse event reporting including the definition of serious adverse events.

23. REPORTING ADMINISTERED DOSES TO *IMMTRAX* - REQUIRED

Enrolled providers are required to report patient and vaccine-level COVID-19 vaccination data within 24 hours of administration. Reporting is completed by submitting information to *imMTrax* through direct entry or through an existing HL7 connection from the location's electronic health record (EHR).

Montana has an opt-in IIS (*imMTrax*), requiring consent be obtained and applied to a patient record in order for immunization information to be accessible. Designated Data Reporting Coordinators will be provided instructions on how to report information for persons who decline to participate in *imMTrax* based on their reporting method. Limited and non-identifiable demographic information, along with full vaccine information will be used to satisfy CDC reporting requirements. Contact the Immunization Program immediately to report any changes in Data Reporting Coordinators assigned at your location.

Additional Resources on Data Reporting:

- COVID-19 Vaccine Provider Resources: COVID-19 Vaccine (mt.gov)
- *imMTrax* Training Resources and Guides: *imMTrax* Training

24. COVERAGE AND BILLING

COVID-19 vaccine providers must not sell or seek reimbursement for COVID-19 vaccine and any adjuvant, syringes, needles, or other constituent products and ancillary supplies that the federal government provides without cost to the provider.

Providers agree to administer vaccine regardless of a recipient's ability to pay and regardless of their coverage status, and may not seek any reimbursement, including through balance billing, from a vaccine recipient.

Providers who have questions about billing or reimbursement of vaccine administration for patients covered by private insurance or Medicaid should contact the respective health plan or state Medicaid agency.

Center for Medicare Services and Medicaid Toolkits

To ensure adequate reimbursement for COVID-19 vaccine administration, CMS has the following webpage with information and toolkits: (https://www.cms.gov/covidvax-provider)

To ensure broad and consistent coverage, the CMS toolkits have specific information for several programs, including:

- **Medicare:** Beneficiaries with Medicare pay nothing for COVID-19 vaccines, and their copayment/coinsurance and deductible are waived.
- **Medicaid:** State Medicaid agencies must provide vaccine administration with no cost sharing for most beneficiaries during the public health emergency.

- **Private Plans**: CMS, along with the Departments of Labor and the Treasury, is requiring most private health plans and issuers to cover a recommended COVID-19 vaccine and its administration, both in-network and out-of-network, with no cost sharing. The rule also provides that out-of-network rates cannot be unreasonably high, and references CMS's reimbursement rates as a potential guideline for insurance companies.
- **Uninsured:** Providers will be able to be reimbursed for administering COVID-19 vaccine to individuals without insurance through the Provider Relief Fund, administered by the Health Resources and Services Administration (HRSA). (full link: https://www.hrsa.gov/CovidUninsuredClaim).

Vaccine Codes and Crosswalk

Refer to the CDC webpage COVID-19 Vaccine Related Codes for COVID-19 vaccine codes.

25. INVENTORY MANAGEMENT SPECIAL CIRCUMSTANCES

Expected Vial Fill and Extra Doses and Wastage

Partial doses from separate vials should never be pooled to create a full dose.

Pfizer-BioNTech 12 years of age and older (purple cap)

You should obtain 6 doses out of each purple-cap Pfizer MDV.

- Report anything less than 6 doses to the Immunization Program on a Wasted and Expired Form.
- Your imMTrax inventory is based on a 6-dose MDV, and you should report inventory on hand in VaccineFinder based on a 6-dose MDV.
- Extra doses beyond 6 doses are not allowed.

Pfizer-BioNTech 12 years of age and older (gray cap)

You should obtain 6 doses out of each gray-cap Pfizer MDV.

- Report anything less than 6 doses to the Immunization Program on a Wasted and Expired Form.
- Your imMTrax inventory is based on a 6-dose MDV, and you should report inventory on hand in VaccineFinder based on a 6-dose MDV.
- Extra doses beyond 6 doses are not allowed.

Pfizer-BioNTech 5–11 years of age (orange cap)

You should obtain 10 doses out of each orange-cap Pfizer MDV.

- Report anything less than 10 doses to the Immunization Program on a Wasted and Expired Form.
- Your imMTrax inventory is based on a 10-dose MDV, and you should report inventory on hand in VaccineFinder based on a 10-dose MDV.
- Extra doses beyond 10 doses are not allowed.

Moderna

Moderna comes in two vial sizes although both may not be available at any given time. Moderna also has two dose sizes a full dose (primary series 0.5mL) and a half dose (booster 0.25mL). See below for guidance on reporting wastage for Moderna:

Moderna 10–11 dose MDV (tracked in inventory as a 10-dose MDV)

- Report wastage based on the ratio of full and half doses given from each vial as indicated in the table below (white cells indicate doses to waste). Report wastage on a Wasted and Expired Form.

Table 3 Moderna 10 Wastage to Report per Vial Based on Ratio of Full and Half Doses Administered
(Source: CDC National Center for Immunization and Respiratory Diseases)

Half Doses \ Full doses	0	1	2	3	4	5	6	7	8	9	10
0	10	9	8	7	6	5	4	3	2	1	0
1	9	8	7	6	5	4	3	2	1	0	
2	8	7	6	5	4	3	2	1	0		
3	7	6	5	4	3	2	1	0			
4	6	5	4	3	2	1	0				
5	5	4	3	2	1	0					
6	4	3	2	1	0						
7	3	2	1	0							
8	2	1	0								
9	1	0									
10	0										
11											
12											
13											
14				No Waste Reported							
15											
16											
17											
18											
19											
20											

Green Area = No Waste Reported

- Your imMTrax inventory is based on a 10-dose MDV*, and you should report inventory on hand in VaccineFinder based on a 10-dose MDV.
- Extra doses beyond 15 doses are not allowed.

Moderna 13–15 dose MDV (tracked in inventory as a 14-dose MDV)

- Report wastage based on the ratio of full and half doses given from each vial as indicated in the table below (white cells indicate doses to waste). Report wastage on a Wasted and Expired Form.

Table 4 Moderna 14 Wastage to Report per Vial Based on Ratio of Full and Half Doses Administered
(Source: CDC National Center for Immunization and Respiratory Diseases)

Half Doses \ Full doses	0	1	2	3	4	5	6	7	8	9	10	11	12	13
0	14	13	12	11	10	9	8	7	6	5	4	3	2	1
1	13	12	11	10	9	8	7	6	5	4	3	2	1	0
2	12	11	10	9	8	7	6	5	4	3	2	1	0	
3	11	10	9	8	7	6	5	4	3	2	1	0		
4	10	9	8	7	6	5	4	3	2	1	0			
5	9	8	7	6	5	4	3	2	1	0				
6	8	7	6	5	4	3	2	1	0					
7	7	6	5	4	3	2	1	0						
8	6	5	4	3	2	1	0							
9	5	4	3	2	1	0								
10	4	3	2	1	0									
11	3	2	1	0										
12	2	1	0											
13	1	0				No Waste Reported								
14	0													
15														
16														
17														
18														
19														
20														

Green Area = No Waste Reported

- Your imMTrax inventory is based on a 14-dose MDV*, and you should report inventory on hand in VaccineFinder based on a 14-dose MDV.
- Extra doses beyond 15 doses are not allowed.

Janssen

You should obtain 5 doses out of each Janssen MDV.

- Report anything less than 5 doses to the Immunization Program on a Wasted and Expired Form.
- Your imMTrax inventory is based on a 5-dose MDV, and you should report inventory on hand in VaccineFinder based on a 5-dose MDV.
- Extra doses beyond 5 doses are not allowed.

Table 5 Inventory Tracking and Wastage Reporting

Vaccine	Report as Wastage Anything Less than X.	imMTrax Inventory Tracked as X.	VaccineFinder Inventory Tracked as X.	Doses Beyond X Not Allowed.
Pfizer 6-dose (purple and gray cap)	6	6	6	6
Pfizer 10-dose (orange cap)	10	10	10	10
Moderna 10–11 Dose MDV	See tables above	10	10	11
Moderna 13–15 Dose MDV	See tables above	14*	14	15
Janssen 5-dose MDV	5	5	5	5

*Your actual doses administered may not match your imMTrax inventory exactly. After reconciling your doses administered, you can reconcile out any extra doses. Please refer to Section 13 for details on reconciling your imMTrax inventory.

APPENDICES

APPENDIX A - VACCINE MANAGEMENT PLAN

COVID vaccine providers must have a written vaccine management plan that covers routine and emergency situations. Enrolled VFC providers may use their Section 12 VFC vaccine management plan if the contacts and location information is the same.

Customize and Review your Plan

- Complete the vaccine management plan template below. You can hand-write the information or use a computer-fillable version obtained by request from the Immunization Program.
- Review the plan with your staff involved in immunization services.
- Document the completion and review by filling in the table at the end of the document.
- Post a copy of the completed plan on or near your COVID vaccine storage units.

Keep Your Plan Up to Date

- Review your plan with staff at least annually. Document the reviews in the table at the end of the document.
- Any time the information in this plan changes, update the plan, review with staff, and re-post on or near your storage units.

Vaccine Management Plan Template

Create your plan by filling in the information below and posting a copy of this section on or near your vaccine storage units. A computer-fillable version is available from the Immunization Program.

Facility Information

Provider/Facility Name	PIN #

Designated Vaccine Managers

Designate one person primarily responsible for COVID vaccine management and one alternate for when the primary is not available.

Vaccine Manager	Phone
Alternate Vaccine Manager	Phone

Important Phone Numbers and Emails

As appropriate for your facility, provide important phone numbers and email addresses below.

Montana Immunization Program	**406-444-5580** hhsiz@mt.gov	Data Logger Calibration	
Utility Company		Vaccine Transport	
Facility Maintenance/Landlord		Other	
Appliance Repair		Other	
Alarm Company		Other	
Data Logger Support		Other	

Power Supply

Circuit Breaker Location

Contact person if access to circuit breaker is restricted	Phone/Email

DO NOT DISCONNECT Signs

Posted to:

☐ Refrigerator Outlet(s) ☐ Freezer Outlet(s) ☐ Ultra-Cold Freezer ☐ Circuit Breaker(s)

Backup Generator

Does your facility have a backup generator?

☐ Yes (Provide contact information below) ☐ No (Provide alternate vaccine storage locations, next section).

Contact person for generator testing/maintenance	Phone/Email
Date and Result of Last Test (e.g., pass/fail, issues, repairs)	

Emergency Plan

Alternate Vaccine Storage Locations

Identify at least one alternate vaccine storage facility that has compliant storage and backup power where vaccines can be stored in the event of a power outage or equipment failure. We recommend signing a Memorandum of Agreement (MOU) with the alternate location. Designate two locations, if possible.

Alternate Location #1	Contact Name	Phone	MOU/Agreement Date

Alternate Location #2 (Optional)	Contact Name	Phone	MOU/Agreement Date

Location of Emergency Transport/Pack-out Materials

Location of Emergency Transport/Pack-Out Materials

Storage Units and Data Loggers

Inventory

Storage Unit Make/Model/Identifier	Ref, Std Freezer, UC Freezer	Location	Data Logger Make/Model/Identifier	Calibration Due Date

Location of Storage Unit User Manuals

Location of Backup Data Logger

Location of Data Logger Accessories

User Manual

Calibration Certificates
Computers with Software or System Access
Archived Temperature Logs and Trouble-shooting Logs
Archived Temperature Data Files or Reports (NA if using cloud or centralized server storage)

Vaccine Inventory Management

Receiving Shipments

Describe the process for receiving vaccine shipments at your facility.

Rotating Stock and Removing Expired Vaccine

Describe the process for ensuring short-dated vaccines are used first and expired vaccines are removed from storage.

Responsible Persons

Vaccine Ordering	Responsible Person	Phone/Email
Receiving Shipments	Responsible Person	Phone/Email
Organizing/Managing Storage Units	Responsible Person	Phone/Email
Rotating Stock so Short-dated Vaccines are Used First	Responsible Person	Phone/Email
Accounting for Doses Administered	Responsible Person	Phone/Email

Removing Expired Vaccine from Storage Units	Responsible Person	Phone/Email
Returning/Disposing of Wasted, Spoiled, and Expired Vaccine	Responsible Person	Phone/Email
Managing Data Loggers	Responsible Person	Phone/Email
Handling and Reporting Temperature Excursions	Responsible Person	Phone/Email

Vaccine Management Plan Updates and Reviews

Document updates and staff reviews in the table below. Anytime the information in your plan changes, repost the most curet version on or near your vaccine storage units.

Updates		**Staff Reviews**	
Completion/Update Date	Staff Signature and Title	Staff Review Date	Staff Initials
Completion/Update Date	Staff Signature and Title	Staff Review Date	Staff Initials
Completion/Update Date	Staff Signature and Title	Staff Review Date	Staff Initials
Completion/Update Date	Staff Signature and Title	Staff Review Date	Staff Initials
Completion/Update Date	Staff Signature and Title	Staff Review Date	Staff Initials
Completion/Update Date	Staff Signature and Title	Staff Review Date	Staff Initials
Completion/Update Date	Staff Signature and Title	Staff Review Date	Staff Initials
Completion/Update Date	Staff Signature and Title	Staff Review Date	Staff Initials
Completion/Update Date	Staff Signature and Title	Staff Review Date	Staff Initials
Completion/Update Date	Staff Signature and Title	Staff Review Date	Staff Initials
Completion/Update Date	Staff Signature and Title	Staff Review Date	Staff Initials

APPENDIX B – COVID VACCINATION STAFF TRAINING LOG

Document completion of required training in the columns below by listing the date and the signature and title of the staff.

By signing below I confirm that I have completed all the required training located at COVID-19 Vaccine Provider Required Training.

Completion Date	Staff Signature and Title
Completion Date	Staff Signature and Title
Completion Date	Staff Signature and Title
Completion Date	Staff Signature and Title
Completion Date	Staff Signature and Title
Completion Date	Staff Signature and Title
Completion Date	Staff Signature and Title
Completion Date	Staff Signature and Title
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