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Montana Department of Public Health and Human Services  
Immunization Program

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# Montana COVID-19 Vaccination Program Provider Handbook

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*Version 12 Updated September 1, 2021*

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# 1. SUMMARY OF CHANGES

Recent changes are highlighted below and in each section.	Date of Change	Page
Section 1–Summary of Changes		
<ul style="list-style-type: none"> <li>Added Summary of Changes Section</li> </ul>	December 17, 2020	Pg. 4
Section 2–Introduction		
Section 3–Emergency Use Authorization and FDA Licensing		
<ul style="list-style-type: none"> <li>Added link to Moderna EUA Fact Sheet for Healthcare Providers</li> </ul>	December 20, 2020	Pg. 5
<ul style="list-style-type: none"> <li>Added link to Janssen EUA Fact Sheet for Healthcare Providers</li> </ul>	March 2, 2021	Pg. 5
<ul style="list-style-type: none"> <li>Added information on full FDA licensing of Pfizer vaccine for 16 years and older</li> </ul>	September 1, 2021	Pg. 6
Section 4–Vaccine Manufacturer Information and Training Resources		
<ul style="list-style-type: none"> <li>Added link to Moderna website and medical information 800 numbers</li> </ul>	December 20, 2020	Pg. 5
<ul style="list-style-type: none"> <li>Added section on determining Moderna vaccine expiration date</li> </ul>	January 7, 2021	Pg. 6
<ul style="list-style-type: none"> <li>Added link to Janssen website and medical information number</li> </ul>	March 2, 2021	Pg. 5
<ul style="list-style-type: none"> <li>Added Janssen and Janssen expiration date lookup tool to Moderna exp date paragraph</li> </ul>	March 2, 2021	Pg. 5
<ul style="list-style-type: none"> <li>Changed heading to “Expiration Dates” and added that imMTrax is a source for current dates</li> </ul>	June 7, 2021	Pg. 5
<ul style="list-style-type: none"> <li>Added information on Pfizer expiration date extension</li> </ul>	September 1, 2021	Pg. 6
Section 5–Vaccine Prioritization and ACIP recommendations - Required		
<ul style="list-style-type: none"> <li>Changed to reflect CDC-amended provider agreement language about following priority populations from health jurisdictions and not just ACIP recommendations.</li> </ul>	December 17, 2020	Pg. 5
<ul style="list-style-type: none"> <li>Added link to January 6, 2021 HAN updating phases and critical populations</li> </ul>	February 16, 2021	Pg. 5
<ul style="list-style-type: none"> <li>Removed link to January 6 HAN and replaced with link to March 24, 2021 HAN</li> </ul>	April 1, 2021	Pg. 5
<ul style="list-style-type: none"> <li>Changed the allocation process to include county unified commands</li> </ul>	April 9, 2021	Pg. 8
<ul style="list-style-type: none"> <li>Updated link to May 14, 2021 HAN describing ages and eligible populations</li> </ul>	August 6, 2021	Pg. 6
Section 6–Provider Enrollment - Required		
Section 7–Key Staff		
Section 8–Provider Training - Required		
Section 9–imMTrax - Required		
Section 10–Vaccine Allocations and Ordering Vaccine		
<ul style="list-style-type: none"> <li>Removed references to specific phases and added link to HAN</li> </ul>	February 16, 2021	Pg. 8
<ul style="list-style-type: none"> <li>Added sub-section on 1<sup>st</sup> and 2<sup>nd</sup> dose allocations</li> </ul>	February 16, 2021	Pg. 8
<ul style="list-style-type: none"> <li>Removed section on allocations and added to refer to recent emails for instructions on ordering</li> </ul>	June 7, 2021	Pg. 8
<ul style="list-style-type: none"> <li>Added to notify the Immunization Program if 2<sup>nd</sup> doses are not needed</li> </ul>	June 7, 2021	Pg. 9
<ul style="list-style-type: none"> <li>Updated process of ordering vaccine to direct ordering in imMTrax.</li> </ul>	August 6, 2021	Pg. 8
<ul style="list-style-type: none"> <li>Changed guidance on 2<sup>nd</sup> dose orders to the provider’s responsibility</li> </ul>	August 6, 2021	Pg. 9
Section 11–Receiving Vaccine in imMTrax		
Section 12–VaccineFinder – Reporting Daily Inventory - Required		
<ul style="list-style-type: none"> <li>Added how to handle vial overfill doses in VaccineFinder</li> </ul>	January 7, 2021	Pg. 9
<ul style="list-style-type: none"> <li>Added information on public display function in VaccineFinder</li> </ul>	April 9, 2021	Pg. 10
Section 13–Reconciling Vaccine in imMTrax		
<ul style="list-style-type: none"> <li>Added instructions on reconciling discrepancies in imMTrax inventory</li> </ul>	June 7, 2021	Pg. 10
Section 14–Vaccine Shipments and Ancillary Supplies		

Recent changes are highlighted below and in each section.	Date of Change	Page
<ul style="list-style-type: none"> <li>Added Moderna information and link to Product Guide</li> </ul>	December 20, 2020	Pg. 10
<ul style="list-style-type: none"> <li>Added links to manufacturer/distributor guidance on receiving shippers</li> </ul>	February 16, 2021	Pg. 10
<ul style="list-style-type: none"> <li>Added sub-section on general guidance when receiving vaccine</li> </ul>	February 16, 2021	Pg. 10
<ul style="list-style-type: none"> <li>Created a space for Janssen shipper handling guidelines, when available</li> </ul>	March 2, 2021	Pg. 11
<ul style="list-style-type: none"> <li>Added addition of regular frozen storage allowance for Pfizer</li> </ul>	March 2, 2021	Pg. 11
<ul style="list-style-type: none"> <li>Added Janssen product specifications</li> </ul>	March 2, 2021	Pg. 12
<ul style="list-style-type: none"> <li>Changed dose size of Moderna from ~10 to a range of 10-11 and 11 maximum</li> </ul>	April 9, 2021	Pg. 12
<ul style="list-style-type: none"> <li>Added Pfizer 450 dose order size and allowance at refrigerated temps expanded to 31 days</li> </ul>	June 7, 2021	Pg.11-12
<ul style="list-style-type: none"> <li>Added Moderna 13-15 dose MDVs</li> </ul>	June 7, 2021	Pg. 12
<ul style="list-style-type: none"> <li>Removed Pfizer 1170 shipments and Moderna 10 MDVs from Vaccine Shipment Contents</li> </ul>	August 6, 2021	Pg.11-12
<b>Section 15–Patient Education - Required</b>		
<ul style="list-style-type: none"> <li>Added link to Moderna EUA for Recipients and Caregivers</li> </ul>	December 20, 2020	Pg. 11
<ul style="list-style-type: none"> <li>Added link to Janssen EUA for Recipients and Caregivers</li> </ul>	March 2, 2021	Pg. 13
<b>Section 16–Vaccination Record Cards (required) and Second Dose Reminders</b>		
<ul style="list-style-type: none"> <li>Removed reference to digital version of card on website</li> </ul>	February 16, 2021	Pg. 13
<b>Section 17–Temperature Monitoring - Required</b>		
<ul style="list-style-type: none"> <li>Removed information on using the Pfizer shipper for on-site storage</li> </ul>	August 6, 2021	Pg. 14
<b>Section 18–Reporting Temperature Excursions - Required</b>		
<ul style="list-style-type: none"> <li>Changed primary contact for reporting excursions to the manufacturer medical information line rather than submitting a VIR to the Immunization Program. Report to IZ Program after contacting the manufacturer for guidance.</li> </ul>	December 17, 2020	Pg. 13
<ul style="list-style-type: none"> <li>Added Moderna medical information 800 number</li> </ul>	December 20, 2020	Pg. 13
<ul style="list-style-type: none"> <li>Removed information added on December 17<sup>th</sup> (see first bullet this section). Added that guidance on temperature excursions was forthcoming from the CDC and updated instructions with the current interim process.</li> </ul>	December 24, 2020	Pg. 14
<ul style="list-style-type: none"> <li>Removed the statement that guidance was forthcoming from the CDC</li> </ul>	February 16, 2021	Pg. 14
<ul style="list-style-type: none"> <li>Added Janssen to the paragraph on how to handle issues with shipments</li> </ul>	March 2, 2021	Pg. 15
<ul style="list-style-type: none"> <li>Added to contact the IZ Program by submitting a Vaccine Incident Report</li> </ul>	March 2, 2021	Pg. 16
<b>Section 19–Vaccine Redistribution – Required (if applicable to your facility)</b>		
<ul style="list-style-type: none"> <li>Added instructions on how to seek approval for a redistribution by submitting a transfer in imMTrax.</li> </ul>	December 24, 2020	Pg. 15
<ul style="list-style-type: none"> <li>Added note to redistribute 2<sup>nd</sup> doses following 1<sup>st</sup> dose redistribution</li> </ul>	February 16, 2021	Pg. 16
<b>Section 20–Vaccine Transport – Required (if applicable to your facility)</b>		
<ul style="list-style-type: none"> <li>Removed statement about transporting opened, MDVs and underlined for emphasis that all transport must follow manufacturer’s guidance.</li> </ul>	December 17, 2020	Pg.14
<b>Section 21–Vaccine Wastage and Loss</b>		
<ul style="list-style-type: none"> <li>Updated with current information on reporting and disposing of wasted doses</li> </ul>	January 7, 2021	Pg. 17
<ul style="list-style-type: none"> <li>Added link to COVID-19-specific Wasted and Expired Form</li> </ul>	June 6, 2021	Pg. 18
<b>Section 22–VAERS Adverse Event Reporting - Required</b>		
<b>Section 23–Reporting Administered Doses to imMTrax - Required</b>		
<b>Section 24–Coverage and Billing</b>		
<b>Section 25–Inventory Management Special Circumstances</b>		
<ul style="list-style-type: none"> <li>Added section with guidance on using vial overfill and expiring vaccine</li> </ul>	December 20, 2020	Pg. 18
<ul style="list-style-type: none"> <li>Added information on managing vial overfill doses in imMTrax</li> </ul>	January 7, 2021	Pg. 19

Recent changes are highlighted below and in each section.	Date of Change	Page
<ul style="list-style-type: none"> <li>Renamed section</li> </ul>	February 16, 2021	Pg. 19
<ul style="list-style-type: none"> <li>Added information on change to 6-dose MDV for Pfizer</li> </ul>	February 16, 2021	Pg. 19
<ul style="list-style-type: none"> <li>Added cautionary note on giving a 1<sup>st</sup> dose from a second dose allocation</li> </ul>	February 16, 2021	Pg. 20
<ul style="list-style-type: none"> <li>Added Janssen information on vial overfill and extra doses</li> </ul>	March 2, 2021	Pg. 20
<ul style="list-style-type: none"> <li>Changed Moderna information on vial overfill to account for a 10-11 dose MDV. No extras.</li> </ul>	April 9, 2021	Pg. 20
<ul style="list-style-type: none"> <li>Standardized information and added Moderna 13-15 dose MDV and a summary table</li> </ul>	June 6, 2021	Pg. 20
<ul style="list-style-type: none"> <li>Removed section on first-dose/second-dose cadence</li> </ul>	June 6, 2021	Pg. 20
<ul style="list-style-type: none"> <li>Removed reference to Pfizer 1170 shipments and Moderna 10 MDVs</li> </ul>	August 6, 2021	Pg. 19

## 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](mailto: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 Vaccine EUA Fact Sheet for Healthcare Providers](#)

[Moderna Vaccine EUA Fact Sheet for Healthcare Providers](#)

[Janssen Vaccine 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 EUA remains in effect for administering Pfizer vaccine to individual 12 through 15 years and a third dose to individuals 12 years and older who have certain immunocompromised conditions.

The full licensure language is captured in the current [EUA Fact Sheet 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 Vaccine under EUA have the same formulation and 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 on their shelves.

## 4. VACCINE MANUFACTURER INFORMATION

Pfizer Vaccine:	<a href="http://cvdvaccine.com">cvdvaccine.com</a>	800-438-1985
Moderna Vaccine:	<a href="#">Moderna COVID-19 Vaccine</a>	866-663-3762
Janssen Vaccine:	<a href="#">Janssen COVID-19 Vaccine Official Website</a>	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**

Lots of Pfizer vaccine 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:

<u>Printed Expiry Date</u>	<u>Updated Expiry Date</u>
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

## 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. 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

Providers must administer COVID-19 vaccine in accordance with prioritization groups determined by appropriate public health authorities. (i.e., CDC/ACIP, state health dept in coordination with the state governor, Indian Health Service, Tribal Health, Urban Indian organizations, and freely Associated States.)

See the [Health Alert Network \(HAN\) message dated May 14, 2021](#) for details on the current vaccination phases and priority groups in Montana.

See our [Required Training webpage](#) for ACIP recommendations for COVID-19 vaccines.

## 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](mailto:covidvax@mt.gov) or call 406-444-5580 for information on how to enroll.

## 7. KEY STAFF

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.

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. 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 they deem appropriate.
3. Completing the online attestation form on the webpage attesting to the completion of the activities.

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. We will notify primary vaccine coordinators by email when changes are made and additional information is available. 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 was 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](mailto: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.

### 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 will 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 vial overfill.)

Providers enrolled in the COVID-19 Vaccination Program will receive an email from the “COVID Locating Health Provider Portal” ([vaccinefinder@auth.castlighthouse.com](mailto:vaccinefinder@auth.castlighthouse.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*

#### **Pfizer Product**

The Pfizer vaccine arrives in a dry-ice thermal shipper containing:

- 3 trays each containing 25 MDVs (6 doses per vial). Minimum dose order is 450 doses.

The Pfizer vaccine ships at ultra-cold temperature (-90 to -60°C) and upon arrival 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.

### **Moderna Product**

Each carton of Moderna vaccine contains:

10 MDVs (13-15 doses per vial) for a total of 130-150) doses per carton. Minimum dose order is 140 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.

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](mailto: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 Vaccine EUA Fact Sheet for Recipients and Caregivers](#)

[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**

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](mailto: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](mailto: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](mailto: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.

## 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 \(mt.gov\)](https://www.mt.gov/COVID-19-Vaccine)
- *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***

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

### **Pfizer**

You should obtain 6 doses out of each 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.

### **Moderna**

Moderna comes in only one vial size at this time:

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

- Report anything less than 14 doses to the Immunization Program on a [Wasted and Expired Form](#).
- 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 1 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 MDV	6	6	6	6
Moderna 13–15 Dose MDV	13	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.