Interim COVID-19 Vaccine Provider Guide

INFORMATION FOR HANDLING AND ADMINISTERING COVID-19 VACCINE

Updated 05/11/2023

The COVID-19 vaccine response can change periodically. Please make sure you have the most current version of this document, which can be found at [COVID-19 Vaccine Providers](https://www.health.state.mn.us/diseases/coronavirus/vaccine/provider.html).
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Background

In March 2020, the World Health Organization (WHO) declared COVID-19 a global pandemic. Immunization with a safe and effective COVID-19 vaccine is critical to reduce COVID-19-related illnesses, hospitalizations, and deaths.

Initial vaccines were authorized by emergency use authorizations (EUA) from the Food and Drug Administration (FDA) when enough preliminary data on their effectiveness and safety was collected. In a global health pandemic, an EUA allows the FDA to review information from a vaccine manufacturer to determine if a vaccine can be released early. They weigh the benefits of early release against the known and unknown risks of a vaccine. Information about effectiveness and safety continues to be collected. If at any time vaccine data shows more risk than benefit, an EUA is re-evaluated.

Providers are responsible for adhering to all requirements outlined in the CDC COVID-19 Vaccination Program Provider agreement. Specifically, providers must administer COVID-19 vaccines in accordance with all program requirements and recommendations of CDC, the Advisory Committee on Immunization Practices (ACIP), and FDA. This applies to both EUA and FDA approved COVID-19 vaccines. Accordingly, use of these products outside of those that have been approved and authorized by FDA is a violation of the provider agreement and could expose providers to the following risks:

- Administration of the product may not be covered under the PREP Act or the PREP Act declaration; therefore, providers may not have immunity from claims.
- Individuals who receive doses may not be eligible for compensation under the Countermeasures Injury Compensation Program after a possible adverse event.
- CDC has defined the scope of the CDC COVID-19 Vaccination Program in terms of how vaccines provided by the United States government (USG) may be used. Providers administering doses outside the published recommendations are violating the CDC Program provider agreement potentially impacting their ability to remain a provider.
- Administration fees may not be reimbursable by third party payers.

Use of this guide

Anyone who handles and/or administers COVID-19 vaccine should read this guide. Bookmark this guide for easy reference and check back often for updates. Updates are highlighted in the weekly COVID-19 vaccine provider bulletin. Sign up at COVID-19 Vaccine Provider Updates (www.health.state.mn.us/diseases/coronavirus/vaccine/vaxbulletin.html).

Training requirements

The vaccine coordinator and back-up coordinator at each registered site are required to read this COVID-19 vaccine provider guide and watch MDH’s online COVID-19 Vaccination Providers Training. These individuals are identified during the registration process. Other people storing, handling, and administering COVID-19 vaccines are highly encouraged to complete the training and read this guide to strengthen their competency in using these vaccines. Access the training at COVID-19 Vaccine Trainings for Health Professionals (www.health.state.mn.us/diseases/coronavirus/vaccine/training.html).
Roles and responsibilities

- The vaccine coordinator, at every enrolled provider site, is responsible for ensuring that staff handling and administering vaccine are properly trained and fully competent on storage, handling, preparation, and administration of the vaccine as applicable to their role.

- The coordinator can host an internal training and/or require all staff to complete the trainings that can be found at COVID-19 Vaccine Trainings for Health Professionals (www.health.state.mn.us/diseases/coronavirus/vaccine/training.html).

- Staff new to vaccinating may need additional hands-on training provided by the vaccine coordinator or other clinical staff at the registered site.

Providers should track, maintain documentation, and monitor the training status of staff.

COVID-19 vaccine ordering and distribution

- Registered COVID-19 providers directly request COVID-19 vaccines in the Minnesota Immunization Information Connection (MIIC). Learn more on how to request special event vaccine in MIIC User Guidance and Training Resources (www.health.state.mn.us/people/immunize/miic/train/index.html) under "Vaccine Ordering and Management." If you do not have staff with that role, contact health.mdhvaccine@state.mn.us for assistance.

Determining your COVID-19 vaccine order

COVID-19 vaccine requests need to be made in specific multiples of the following shipment packaging sizes:

- **Pfizer-BioNTech COVID-19 vaccines**
  - Pfizer-BioNTech COVID-19 – 12+ yrs. – Bivalent – Gray Cap **single dose vial** DO NOT DILUTE: requests must be made in 50 dose increments. Less than 50 doses cannot be shipped.
  - Pfizer-BioNTech COVID-19 – 5-11 yrs. – Bivalent – Orange Cap - 10 multi-dose vials of 10 doses: requests must be made in 100 dose increments. Less than 100 doses cannot be shipped.
  - Pfizer-BioNTech COVID-19-6m-4years—Bivalent—Maroon Cap - 10 multi-dose vials of 10 doses: requests must be made in 100 dose increments. Less than 100 doses cannot be shipped.

- **Moderna COVID-19 vaccines**
  - Moderna COVID-19 – 6+ yrs. – Bivalent – Blue Cap Gray Border - 20 multi-dose vials of 5 doses: requests must be made in 100 dose increments. Less than 100 doses cannot be shipped.
  - Moderna COVID-19-6m-5years – Bivalent – Dark Pink Cap Yellow Border - 10 multi-dose vials of 2 doses: requests must be made in 20 dose increments. Less than 20 doses cannot be shipped.

- **Novavax COVID-19 vaccine**
  - Novavax COVID-19 – 12+ yrs. - 10 multi-dose vials of 5 doses - DO NOT DILUTE: requests must be made in 100 dose increments. Less than 100 doses cannot be shipped.

The person who places the vaccine order, as well as the primary and back-up contacts will receive an order confirmation email from MIIC when the order is created and a vaccine shipment confirmation email when vaccine doses ship. The vaccine manufacturer will send details on shipment tracking to the primary contact as soon as the package leaves their warehouse. If you would like to update the contacts for your site, please email health.mdhvaccine@state.mn.us. Enrolled and approved sites do not need to complete any additional registration with the vaccine manufacturer or distributor to receive doses.
COVID-19 vaccine providers do not need to be enrolled in the Minnesota Vaccines for Children (MnVFC) program to vaccinate people ages 6 months through 18 years with COVID-19 vaccine.

**Redistribution**

If you redistribute COVID-19 vaccine, you must sign a redistribution agreement. To receive a redistribution agreement or to determine if your site is covered by an agreement, please email health.mdhvaccine@state.mn.us. Sites must strictly follow the components of the agreement during redistribution and off-site vaccination. Providers can request redistributed doses or list excess inventory using the COVID-19 Vaccine Redistribution Dashboard (https://app.smartsheet.com/b/publish?EQBCT=356419d9e62a427991faa57d6d17c0f2).


**COVID-19 vaccine supplies**

COVID-19 vaccines and supplies for administration are distributed at no cost to providers registered for COVID-19 vaccination. Ancillary supply kits are automatically ordered in amounts to match vaccine orders.

Pediatric ancillary kits are available with the same supplies as adult kits, except they include 1-inch needles only. Diluent, mixing needles and syringes, and extra alcohol pads will be included in the ancillary kit for vaccines requiring reconstitution. Note: kits do not include sharps containers, gloves, or bandages.

Providers can opt out of getting ancillary kits for vaccines that do not require diluent for vaccine shipments coming from MDH. For vaccines that require reconstitution, a combined kit will be included that contains administration supplies (as noted above), mixing supplies, and diluent vials. If you redistribute vaccine, you also need to redistribute the ancillary supplies. Single dose vial vaccines do not come with ancillary kits. In order to opt out of ancillary kits, please note this in the shipping information section in MIIC.

For questions or problems related to ancillary supply kits (e.g., missing supplies, etc.), contact:

- Pfizer vaccine: McKesson MedSurg to report by email SNSSupport@McKesson.com.
- Moderna/Novavax vaccine: McKesson Specialty at 833-343-2703 or by email COVIDVaccineSupport@McKesson.com.

To report defective or faulty medical equipment (e.g., syringes, needles), visit the FDA’s MedWatch Online Voluntary Reporting Form (www.accessdata.fda.gov/scripts/medwatch/) and complete FDA Form 3500 for health professionals.

**COVID-19 vaccine products and recommendations**

Several COVID-19 vaccines are currently available. Having multiple products makes COVID-19 vaccine more accessible, but it also increases the risk of medication errors and can lead to vaccine waste. Sites are encouraged to only store and administer one COVID-19 mRNA vaccine product. Double check the product specific EUA provider fact sheet or package insert for age indication, route, dosage, and storage and handling requirements. The currently FDA-approved or FDA-authorized COVID-19 vaccines are summarized below. None of the current vaccines are live-virus vaccines or contain any preservatives. Any COVID-19 vaccine can be used when indicated.
### Pfizer-BioNTech-Bivalent COVID-19 vaccines

<table>
<thead>
<tr>
<th>Description</th>
<th>Maroon cap-Bivalent</th>
<th>Orange cap-Bivalent</th>
<th>Gray cap-Bivalent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age indication</td>
<td>6 months-4 years</td>
<td>5-11 years</td>
<td>12 years and older</td>
</tr>
<tr>
<td>Dose and route</td>
<td>0.2 mL (3mcg) IM</td>
<td>0.2 mL (10 mcg) IM</td>
<td>0.3 mL (30 mcg) IM</td>
</tr>
<tr>
<td>Amount of diluent* needed per vial</td>
<td>2.2 mL</td>
<td>1.3 mL</td>
<td>NO DILUTION</td>
</tr>
<tr>
<td>Doses per vial</td>
<td>10 doses</td>
<td>10 doses per vial</td>
<td>6 doses per vial</td>
</tr>
</tbody>
</table>

**Storage Conditions**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Maroon cap-Bivalent</th>
<th>Orange cap-Bivalent</th>
<th>Gray cap-Bivalent</th>
</tr>
</thead>
<tbody>
<tr>
<td>ULT Freezer (-90°C to -60°C/-130°F to -76°F)</td>
<td>Until expiration date</td>
<td>Until expiration date</td>
<td>Until expiration date</td>
</tr>
<tr>
<td>Freezer (-25°C to -15°C/-13°F to 5°F)</td>
<td>DO NOT STORE</td>
<td>DO NOT STORE</td>
<td>DO NOT STORE</td>
</tr>
<tr>
<td>Refrigerator (2°C to 8°C/35°F to 46°F)</td>
<td>10 weeks or until expiration date</td>
<td>10 weeks or until expiration date</td>
<td>10 weeks or until expiration date</td>
</tr>
<tr>
<td>Room Temperature (8°C to 25°C/46°F to 77°F)</td>
<td>12 hours (including thaw time)</td>
<td>12 hours (including thaw time)</td>
<td>12 hours (including thaw time)</td>
</tr>
<tr>
<td>After First Puncture (2°C to 25°C/36°F to 77°F)</td>
<td>Discard after 12 hours</td>
<td>Discard after 12 hours</td>
<td>Discard after 12 hours</td>
</tr>
</tbody>
</table>

**Comments**

* Diluent sterile 0.9% Sodium Chloride Injection USP. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.

### Moderna Bivalent COVID-19 vaccines

<table>
<thead>
<tr>
<th>Description</th>
<th>Dark pink cap-Bivalent (booster)</th>
<th>Dark blue cap-Bivalent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age indication</td>
<td>6 months through 5 years</td>
<td>6 months through 11 years or 12 years and older</td>
</tr>
<tr>
<td>Dose and route</td>
<td>0.2mL (20mcg)</td>
<td>0.25 mL (25 mcg) IM (6 months – 11 years) or 0.5 mL (50 mcg) IM (12 years and older)</td>
</tr>
<tr>
<td>Amount of diluent* needed per vial</td>
<td>Do not mix with any diluent.</td>
<td>Do not mix with any diluent.</td>
</tr>
<tr>
<td>Doses per vial</td>
<td>2 doses per vial**</td>
<td>5 to 10 doses per vial**</td>
</tr>
</tbody>
</table>

**Storage Conditions**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Maroon cap-Bivalent</th>
<th>Orange cap-Bivalent</th>
<th>Gray cap-Bivalent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freezer (-25°C to -15°C/-13°F to 5°F)</td>
<td>Until expiration date</td>
<td>Until expiration date</td>
<td>Until expiration date</td>
</tr>
<tr>
<td>Refrigerator (2°C to 8°C/35°F to 46°F)</td>
<td>30 days or until expiration date</td>
<td>30 days or until expiration date</td>
<td>30 days or until expiration date</td>
</tr>
<tr>
<td>Room Temperature (8°C to 25°C/46°F to 77°F)</td>
<td>Up to 24 hours (unpunctured vials)</td>
<td>Up to 24 hours (unpunctured vials)</td>
<td>Up to 24 hours (unpunctured vials)</td>
</tr>
<tr>
<td>After First Puncture (2°C to 25°C/36°F to 77°F)</td>
<td>Discard after 8 hours</td>
<td>Discard after 12 hours</td>
<td>Discard after 12 hours</td>
</tr>
</tbody>
</table>

**Comments**

Do not refreeze

*If a full dose cannot be withdrawn from the vial, discard the vial and contents. Never “pool” or combine excess vaccine from multiple vials to obtain a dose.
Novavax COVID-19 vaccine

<table>
<thead>
<tr>
<th>Age indication</th>
<th>Primary dose route</th>
<th>Primary schedule</th>
<th>Booster</th>
<th>Presentation/preparation</th>
<th>Storage and handling</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 years and older</td>
<td>0.5 mL (5 mcg/50 mcg adjuvant) IM</td>
<td>0, 3-8 weeks**</td>
<td>at least 6 months after completion of any primary series***</td>
<td>Multi-dose vial: 5 doses per vial Do not mix with any diluent.</td>
<td>Refrigerator: 2°C to 8°C (36°F to 46°F)</td>
<td>Recommended to use the same vaccine product to complete the primary series.</td>
</tr>
</tbody>
</table>

** An 8-week interval is suggested between dose one and two for some people ages 6 months to 64 years of age, especially for males ages 12 to 39 years. A shorter interval (3 weeks for Novavax and Pfizer-BioNTech; 4 weeks for Moderna) between the first and second doses remains the recommended interval for: people who are moderately to severely immunocompromised; adults ages 65 years and older; and others who need rapid protection due to increased concern about community transmission or risk of severe disease.

*** A monovalent Novavax booster dose may be used in limited situations in people ages 18 years and older who completed any FDA-approved or FDA-authorized monovalent primary series, have not received any previous booster dose(s), and are unable to receive an mRNA vaccine (i.e., mRNA vaccine contraindicated or not available) or unwilling to receive an mRNA vaccine and would otherwise not receive a booster dose. The monovalent Novavax booster dose is administered至少 6 months after completion of any primary series.

COVID-19 vaccination guidance for people NOT moderately or severely immunocompromised

CDC recommends that people ages 6 months and older receive at least one bivalent mRNA COVID-19 vaccine. The number of bivalent doses varies by age, vaccine, previous COVID-19 vaccines received, and the presence of moderate or severe immune compromise. Refer to [CDC: Interim Clinical Considerations for Use of COVID-19 Vaccines: Guidance for people who are not moderately or severely immunocompromised](www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#immunocompromised) for detailed schedules.

COVID-19 vaccination guidance for people moderately or severely immunocompromised

People who are moderately or severely immunocompromised have the option to receive one additional dose of a homologous bivalent mRNA vaccine at least two months following the last recommended bivalent mRNA COVID-19 vaccine dose. Further additional homologous bivalent dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances. Any further additional doses should be administered at least two months after the last COVID-19 vaccine dose. Refer to: [CDC: Interim Clinical Considerations for Use of COVID-19 Vaccines: Guidance for people who are moderately or severely immunocompromised](www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#immunocompromised) for more specific information on this population, including detailed schedules.

Considerations for people ages 65 years and older to receive an additional bivalent mRNA dose

People ages 65 years and older have the option to receive one additional bivalent mRNA vaccine dose if it has been at least four months after their first bivalent mRNA dose. The option to receive one additional bivalent mRNA dose may be informed by the clinical judgement of a healthcare provider, a person’s risk for severe COVID-19 due to the presence of underlying medial conditions and age, and personal preference and circumstances.
COVID-19 vaccine storage and handling

COVID-19 vaccine products are temperature-sensitive and must be stored and handled correctly to ensure efficacy and maximize shelf life. Proper storage and handling practices are critical to minimize vaccine loss and limit risk of administering COVID-19 vaccine with reduced effectiveness.


Vaccine must be stored in dedicated refrigeration/freezer units. Find more information on CDC’s storage and handling recommendations at Vaccine Storage and Handling Toolkit (www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html). Storing vaccine in the freezer of a combination household unit is not recommended. If your facility provides frozen vaccine, you must have a separate freezer.

Refer to Vaccination at Satellite, Temporary, or Off-site Locations (www.health.state.mn.us/diseases/coronavirus/vaccine/guideappd.pdf) for storage and handling guidance, including many helpful resources for transporting vaccine and monitoring temperatures.

Providers new to vaccine storage and handling, should view CDC’s, You Call the Shots module. Learn more at CDC: CE Instructions for WB4417: Immunization: You Call the Shots-Module Ten-Storage and Handling—2021 (www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp).

Expiration date and beyond-use date (BUD)

In certain conditions vaccines must be used before the actual expiration date. This is referred to as the beyond-use date (BUD). The BUD is determined based on the storage conditions and the time a vial is first punctured for COVID-19 vaccines. The person that performs the step in the administration process that changes the BUD (e.g., punctures the vial, reconstitutes it, moves it from the freezer to refrigerator, etc.) must document the new BUD on a label. BUD tracker labels are available on CDC’s website.

Check expiration dates and beyond-use dates closely. Discard the vaccine based on the earliest date, whether that is the manufacturer’s labeled expiration date or the BUD.

Example: Undiluted Pfizer 5-11 years vaccine (orange cap) can be stored for 10 weeks in the refrigerator. If it was placed in the refrigerator on December 20, its BUD is February 28. However, if the vaccine vial’s expiration date is February 8, then it needs to be discarded at the end of the day on February 8.

Keep in mind that COVID-19 vaccine products do not contain any preservative and therefore can’t be used after a certain number of hours after the vial is first punctured. Carefully read and follow the EUA fact sheet for health care providers and/or manufacturers’ websites for each vaccine product regarding expiration and beyond-use dates.

Managing out-of-range temperatures (excursions)

As with all vaccines, if COVID-19 vaccines are exposed to out-of-range temperatures, take immediate action. Mark the vaccine “do not use” until its usability is determined. If vaccine thaws, do not re-freeze.

Contact MDH’s Immunization Program Monday through Friday between 8:00 a.m. and 4:30 p.m. at 651-201-5414 to determine your next steps. Make sure to have specific information about temperatures, duration of excursion, etc. available.

Contact information for vaccine manufacturers:
Modern: Phone: 1-866-MOD-ERNA or 1-866-663-3762 Email: excursions@modernatx.com

Pfizer: Pfizer U.S. Medical Information Phone: 1-800-438-1985

Novavax: Phone: 1-844-668-2829 Email: Fill out our contact form (www.novavax.com/contact-us/email-us)

Some vaccine manufacturers have online temperature excursion tools you may use:


Contact MDH even if you have contacted the vaccine manufacturer or used their online temperature excursion tool and the issue was resolved.

Information to include when reporting a vaccine excursion

- Your email address and phone number.
- Storage condition at the time of excursion (e.g., frozen storage, refrigerated storage, or room temperature).
- Duration of excursion.
- Interim disposition of affected vials (e.g., returned to freezer or refrigerator, moved to another storage unit, or maintained at room temperature).
- Visual inspection, noting any change in the vaccine’s state (e.g., frozen vials that thawed or thawed vials that were re-frozen).
- If the vaccine is determined to be nonviable (not usable) it should be discarded immediately. Report these doses as nonviable vaccine to MDH in the Minnesota Immunization Information Connection (MIIC). Refer to the section below on reporting vaccine wastage and spoilage for instructions.

Clinical considerations for authorized vaccines

ACIP has issued interim recommendations for the use of COVID-19 vaccines for the prevention of COVID-19. These recommendations are published in CDC: Use of COVID-19 Vaccines in the United States (www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html). CDC is updating these recommendations frequently as new vaccines are authorized and information changes. A summary of recent changes and the date they were last updated is at the top of the webpage.

Resources for screening patients before COVID-19 vaccination

Verify patient COVID-19 immunization data

Prior to administering a dose of COVID-19 vaccine, please review the patient’s immunization history. The primary source of COVID-19 vaccine administration data should be the Minnesota Immunization Information Connection (MIIC). If the data for a patient is not in MIIC, other acceptable sources include:

1. Their CDC vaccination card.
2. An official document from a health care provider or another state’s Immunization Information System (IIS) with day, month, year, and product administered as well as the patient’s name and date of birth.
3. Electronic documentation from a health care provider or another state’s Immunization Information System (IIS) such as the MyChart app or another consumer access application (app) that includes day, month, year, and product administered as well as the patient’s name and date of birth.
4. A patient’s U.S. Department of State’s Vaccination Documentation form DS-3025 that includes a patient’s verified past immunizations.

Verbal presentations of data are not acceptable. Please enter immunization data from these acceptable sources into a patient’s record in your electronic health record (EHR) or directly into MIIC.

Remember that in addition to Minnesota data, MIIC regularly receives data for Minnesota residents for doses administered in Iowa, Wisconsin, and North Dakota. A patient may not yet be in MIIC because they have recently moved to Minnesota or do not have any recent immunizations administered in Minnesota. If a patient is found in MIIC, their associated immunization data still may not be in MIIC for several reasons, including: they received an immunization in another state/country that does not regularly send data to MIIC, the provider who administered the dose didn’t enter it into their systems or MIIC, the data was entered by the provider into their systems but has not yet been sent to MIIC, the patient has opted out of MIIC, or the patient has locked their record to another provider.

For more information, review MIIC user guidance for looking up a client at Client Search and Printing Immunization Records (www.health.state.mn.us/people/immunize/miic/train/clientsearch.html) and entering immunization data at Adding Immunizations Not Using Inventory (www.health.state.mn.us/people/immunize/miic/train/addnoinv.html).

COVID-19 vaccine administration

Based on their scope of practice, all people who administer vaccines should receive comprehensive, competency-based staff training and education, including the “rights of vaccine administration,” patient care before, during, and after vaccine administration, vaccine preparation, and skill validation.

- Vaccine administration resources for all people who vaccinate, including staff who are new to vaccination and staff who need a refresher:
  - CDC: Immunization Education and Training (www.cdc.gov/vaccines/ed/index.html)
  - CDC: You Call the Shots (www.cdc.gov/vaccines/ed/youcalltheshots.html)
    Watch the “Vaccine Administration” e-Learn
  - CDC: Epidemiology and Prevention of Vaccine-Preventable Diseases (www.cdc.gov/vaccines/pubs/pinkbook/index.html)
    Known as the “Pink Book”
  - How to Administer IM (Intramuscular) Injections (www.health.state.mn.us/people/immunize/hcp/admim.pdf)
Emergency use authorization (EUA) fact sheets and vaccine information sheets (VISs)

EUA fact sheets

EUA fact sheets for vaccination providers are product-specific information sheets that replace the usual package insert. The fact sheet for vaccine recipients is similar to a licensed product’s VIS.

The EUA fact sheet for vaccine recipients explains the vaccine risks and benefits, specific vaccine product information and its use, and information from clinical trials that support the FDA’s emergency use authorization.

- You are legally required to give an EUA fact sheet to each recipient/parent/legal representative prior to vaccination. Be prepared to answer questions about the vaccine.

EUA fact sheets for providers and recipients are available on FDA, CDC, MDH, and vaccine manufacturer websites. Translated fact sheets in multiple languages are on the FDA website:

- Pfizer Healthcare Provider Fact Sheet (www.fda.gov/media/167211/download)
- Moderna Healthcare Provider Fact Sheet (www.fda.gov/media/167208/download)
- Novavax COVID-19 Vaccine Healthcare Provider Fact Sheet (www.fda.gov/media/159897/download)

Vaccine information sheets (VIS)

Vaccines licensed through the FDA and added to the vaccine injury table are required to have a vaccine information sheet. Federal law requires that patients receive a vaccine information sheet prior to administration of a licensed vaccine.

COVID-19 vaccine reminders

Most people aged 6 years and older now only need one dose of the bivalent vaccine. For those under 6 years old or who are immunocompromised and need more than one dose for a primary series, it is important that people receive all doses, and that doses are the same vaccine product. Make an effort to keep doses within the recommended interval. If the interval is missed, the dose should be given as soon as possible, and the series does not need to be restarted. Providers should refer to: CDC: Interim Clinical Considerations for Use of COVID-19 Vaccines: Overview of COVID-19 vaccination (www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#covid-vaccines) to understand the schedule for situations that require more than one dose.

Vaccination reminders are critical to ensure compliance with vaccine dosing intervals and to achieve optimal vaccine effectiveness. Use these tips for COVID-19 vaccine reminders:
Make sure each person getting vaccinated knows if they need additional doses and schedule an appointment for the next dose.

Complete a COVID-19 vaccination record card (vaccine manufacturer, lot number, date of dose received, and the date the next dose is due) for each person who is vaccinated. Encourage them to keep the card and bring it to the next dose appointment.

If the patient has a smartphone, ask them to take a photo of their vaccination card and/or enter the date when the next vaccine is due into their electronic calendar.

Using Minnesota Immunization Information Connection (MIIC) for vaccine reminders:

- Record all vaccinations in MIIC within 7 days after vaccine administration.
- Pull lists of people overdue/recommended for COVID-19 vaccine using the MIIC client follow-up functionality in MIIC. Information on client follow-up is available at Client Follow-Up (www.health.state.mn.us/people/immunize/miic/train/followup.html).
- Partner with MDH to text your clients who have not received any COVID-19 vaccine or are kids overdue for routine immunizations. This program is free to the participating provider and does not take a lot of resources to implement. Typically, a 30-minute conference call is all that’s needed to set up the texting activity. For more information, please email the MIIC Help Desk at health.miictexting@health.state.mn.us. Please find more information on this project here at Reminder/Recall Using Text Messages (www.health.state.mn.us/diseases/coronavirus/vaccine/remindrecall.pdf).
- Look at your electronic health record or vaccine management tool to identify if there is a next dose reminder function already built in (e.g., patient portal).
- Use other methods, such as text messaging, phone calls, email, and mail.

Post-vaccination care

Vaccine efficacy

All COVID-19 vaccines currently approved or authorized in the United States (Pfizer-BioNTech, Moderna, Novavax, and Janssen) are effective at preventing severe disease, hospitalizations, and death from COVID-19.

Post-vaccination instructions

Preparing people for what to expect after vaccination and when to follow up with a health care provider is a best practice and expectation. Patient instructions should include information specific to the product they are receiving. This information should include:

- Common side effects (listed in the EUA fact sheet).
- When to contact their health care provider (such as signs of an allergic reaction or medical concerns that may or may not be related to vaccination).
- For vaccine(s) requiring more than one dose, the importance of receiving all recommended dose(s) of vaccine to build an adequate immune response.
- What it means to be up to date with your COVID-19 Vaccines refer to: CDC: Stay Up to Date with Your COVID-19 Vaccines (www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html)

Treatment of post-vaccination symptoms

After receiving a COVID-19 vaccine dose, over the counter fever, or pain medication (e.g., acetaminophen, non-steroidal anti-inflammatory drugs) may be used for local or systemic symptoms, if medically appropriate. Refer to the applicable EUA fact sheet for recipients to view side effects listed for each vaccine product.
It is not recommended to routinely take over-the-counter fever or pain medication prior to vaccination to prevent symptoms following vaccination.

**Allergic reaction (anaphylaxis)**

Anaphylactic reactions in people receiving the COVID-19 vaccine outside of clinical trials have been reported. While rare, these events highlight the importance of a quick and competent response. Antihistamines should not be taken before vaccination to prevent allergic reactions, as they do not prevent anaphylaxis and might mask cutaneous (skin) symptoms. Refer to [CDC: Interim Clinical Considerations for Use of COVID-19 Vaccines: Contraindications and precautions](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Contraindications) for more information regarding adverse reactions.

**Appropriate medical treatment used to manage immediate allergic reactions (e.g., epinephrine) must be immediately available in the event an acute anaphylactic reaction occurs following administration of the vaccine.**

An allergic reaction to a vaccine can be a life-threatening event. Know the early signs of anaphylaxis: throat closing sensation, swelling of throat, face or lips, hives or itching, stridor (high-pitched whistling sound), wheezing, coughing, dizziness, fainting, fast heart rate, low blood pressure, nausea, vomiting, diarrhea, and/or abdominal pain. CDC has a helpful poster on [Recognizing and Responding to Anaphylaxis](https://www.cdc.gov/vaccines/covid-19/downloads/recognizing-responding-to-anaphylaxis-508.pdf).

**Observation periods following vaccination**

Syncope (fainting) might occur in association with any injectable vaccine, especially in adolescents. In accordance with [general best practice guidelines for immunization (GBPG)](https://www.cdc.gov/vaccines/covid-19/downloads/recognizing-responding-to-anaphylaxis-508.pdf), vaccination providers, particularly when vaccinating adolescents, should consider observing vaccine recipients for 15 minutes after vaccination.

Additionally, providers should consider observing people with the following medical histories for 30 minutes after COVID-19 vaccination to monitor for allergic reactions:

- Allergy-related contraindication to a different type of COVID-19 vaccine.
- Non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of COVID-19 vaccine.
- Anaphylaxis after non-COVID-19 vaccines or injectable therapies.

See also [CDC: Interim Clinical Considerations for Use of COVID-19 Vaccines: Contraindications and precautions](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Contraindications)

**Emergency preparation**

Administer vaccines in settings where staff are trained to recognize and respond to reactions. Immediate systemic reactions can include fainting (syncope) and severe allergic reaction (anaphylaxis). Learn more about how to prepare for anaphylactic reactions at [CDC: Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html).

Some considerations:

- Staff should be trained in CPR and be familiar with the signs, symptoms, and treatment of anaphylaxis.
- Have the appropriate equipment and medication on hand. Have trained staff available to administer epinephrine and maintain an airway in settings where vaccinations are given.
  - COVID-19 vaccination locations should have at least three doses of epinephrine available at all times and a way to quickly replace doses.
Have a signed hard copy of a plan and age-appropriate protocols for the medical management of a vaccine reaction. Ensure staff review the plan and protocol and are ready to carry it out before giving vaccinations or providing related services.

- Immunization Action Coalition (IAC): Vaccine Information for Health Care Professionals (immunize.org) has examples of emergency plans. Refer to Medical Management of Vaccine Reactions in Children and Teens in a Community Setting (www.immunize.org/catg.d/p3082a.pdf) and Medical Management of Vaccine Reactions in Adults in a Community Setting (www.immunize.org/catg.d/p3082.pdf) for more information.

Report vaccine adverse events and administration errors

As with licensed vaccines, vaccines under an Emergency Use Authorization have the same requirements to report to the Vaccine Adverse Event Report System (VAERS) any situations, including serious adverse events, that occurred after vaccination. This is regardless of determination of cause. As part of the CDC COVID-19 Vaccination Program Provider Agreement, vaccination providers are required to report the following to VAERS:

- Vaccine administration errors, even if they did not involve an adverse effect.
- Serious adverse events:
  - Death.
  - A life-threatening adverse event.
  - An event requiring hospitalization or prolonged hospitalization.
  - Prolonged impact on a person’s ability to perform daily activities.
  - A congenital anomaly/birth defect.
  - A significant medical event that may cause harm to a person and may require medical or surgical intervention to prevent one of the outcomes listed above.
- Cases of Multisystem Inflammatory Syndrome (MIS) in children and adults.
- Cases of myocarditis or pericarditis.
- Cases of COVID-19 (including vaccine breakthrough cases) that result in hospitalization or death.

Learn more about VAERS at CDC: Vaccine Adverse Event Reporting System (VAERS): How VAERS works (www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html#anchor_1616772696807). To submit an event, go to VAERS: Report an Adverse Event (vaers.hhs.gov/reportevent.html). There is a checklist on this page to help gather information needed when submitting a report (VAERS 2.0 Checklist [vaers.hhs.gov/docs/VAERS 2.0_Checklist.pdf]).

HIPAA permits reporting of vaccine adverse events and medical documentation to VAERS for public health purposes under 45 CFR, section 164.512(b), as authorized by 42 USC 300aa-25.

Resources to assist clinicians in possible COVID-19 vaccine-related adverse events

Urgent consults: Health care providers can contact the CDC Emergency Operations Center at 770-488-7100 if they need an urgent COVID-19 vaccine safety consultation. In case of a health emergency, providers should call 911.

Complex health situations following COVID-19 vaccination: For complex vaccine safety questions, health care providers or health departments in the United States can request a consultation from the CDC: Clinical Immunization Safety Assessment (CISA) Project (www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html) COVIDvax clinicians. For non-urgent concerns, providers may Contact CDC-INFO (www.cdc.gov/DCS/ContactUs/Form).

Document administered doses
Give the vaccinated person (and caregiver, if applicable), a completed COVID-19 vaccination record card that includes the name of the vaccine given, the lot number, the date administered, and the name and location of the administering clinic. Providers should follow their usual documentation processes in the patient’s permanent medical record. Record vaccine administration information such as:

- Vaccine name.
- Date of administration.
- Vaccine manufacturer and lot number.
- Vaccination site and route.
- Name and title of the person who administered the vaccine.

If a vaccinated person misplaces their COVID-19 vaccination record card, providers that administered the vaccine should replace their card if requested.

**COVID-19 vaccine reporting requirements**

The [Minnesota Immunization Information Connection (MIIC)](www.health.state.mn.us/miic) is a statewide immunization information system that stores electronic immunization records for Minnesota health service providers and for the public. MIIC combines immunizations a person has received into a single record, even if the shots were given by different health care providers in the state.

Per the CDC provider agreement, product-specific COVID-19 vaccination data must be reported within 24 hours of vaccine administration. Data reported to MIIC in a timely manner will be routinely sent to the CDC in de-identified form to meet their data requirements and in a manner consistent with Minnesota laws. There are a number of data elements for each COVID-19 vaccination that is administered.

**Data elements for COVID-19 vaccination reporting**

These data elements are subject to change.

**Vaccine recipient data**

- First name
- Middle name
- Last name
- Date of birth
- Sex
- Full address (street, street 2, city, county, state, ZIP code)
- Race/ethnicity*

*MDH requires providers to enter available race/ethnicity information into MIIC as part of their regular reporting for all patients who are getting vaccinated.

**Vaccine administration data**

- Administration date
- CVX code
- CPT code (note: For Moderna boosters to be reported as a booster and not a third dose, the corresponding CPT code **MUST** be included)
- NDC (if known)
- MVX code
- Lot number
- Expiration date
- Body site
- Route of administration
- Responsible organization
- Administered at location
- Vaccination refusal (when appropriate)

Become familiar with MIIC. If your organization already submits data to MIIC via one of the following ways, please implement these steps.
- **Electronic data exchange**: Review your messages to ensure you are sending timely messages and that those messages contain a CVX/CPT code pair or an NDC code, as well as an MVX code. Verify that your organization has a process to routinely review rejection (ACK) messages.

- **Uploaded file via the user interface**: Ensure you are submitting a CVX/CPT code pair, as well as the manufacturer code. A new spreadsheet template is available in MIIC, and the latest user guide can be found at [General Immunization Upload Using the Spreadsheet Template](www.health.state.mn.us/people/immunize/miic/data/spreadsheet.pdf). Please download the template from MIIC each time you use it. Consider creating an electronic interface with MIIC to reduce staff burden and help ensure timely data reporting.

- **Direct data entry in the user interface**: Ensure staff are selecting the correct option from the “Trade Name” drop-down menu. Strongly consider using one of the above reporting methods. Connecting to MIIC for electronic data exchange can reduce staff burden, especially during high-volume times.

Minnesota Statutes, chapter 144.3351 allows vaccine providers to share immunization data, which is defined in the statute, with MDH without patient consent. This data includes race and ethnicity. MIIC is a tool that providers can use to share this information. Find Vaccine Administration Codes from CDC at [Data Code Sets](www.cdc.gov/vaccines/programs/iis/code-sets.html). For more information on entering correct COVID-19 product information into MIIC, please review this resource: [Entering COVID-19 Product Information in MIIC](www.health.state.mn.us/people/immunize/miic/train/entercovidproduct.pdf).

If you have any questions, please contact the MIIC Help Desk at [health.miichelp@state.mn.us](mailto:health.miichelp@state.mn.us).

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### Managing vaccine inventory

#### Reporting vaccine inventory

MDH reports inventory to CDC weekly. To facilitate this reporting and identify inventory across the state, all COVID-19 vaccine that is redistributed needs to be reported to MDH within one week of redistribution. Learn more about COVID-19 vaccine redistribution at [COVID-19 Vaccine: Redistribution and Off-site Vaccination Guide](www.health.state.mn.us/diseases/coronavirus/vaccine/vaxredistribution.pdf).

#### Tracking vaccine wastage and spoilage

Tracking vaccine wastage is part of vaccine inventory. Sites are asked to report wastage or spoilage of vaccine doses (e.g., exposure to out-of-range temperatures, vaccines in refrigerator past the allowed time, doses drawn up and not used, doses remaining in vials at the time of the beyond use date (BUD) expiration, vaccine discoloration or particulates, unable to get the recommended number of doses out of a vial, etc.). Any vaccine determined to be nonviable (not usable) should be discarded immediately.

Registered COVID-19 providers must report vaccine wastage in MIIC within one week of wastage. There are two ways to report wastage/spoilage. Choose one method of reporting:

- **Preferred**: Submit this information in MIIC. More information is available at [Reporting Nonviable COVID-19 Vaccine to MIIC](www.health.state.mn.us/diseases/coronavirus/vaccine/nonviablereport.pdf).

- **If your organization is not able to use the preferred method of reporting via MIIC, you may use the PDF form, [Minnesota Department of Health COVID-19 Nonviable Vaccine Form](www.health.state.mn.us/diseases/coronavirus/vaccine/nonviableform.pdf).

To report wasted vaccine to MIIC, you need to be set up with a MIIC user role that has ordering privileges. Please contact [health.mdhvaccine@state.mn.us](mailto:health.mdhvaccine@state.mn.us) with questions about getting set up to access this feature in MIIC.
Expired or spoiled COVID-19 vials are not being returned to the manufacturer or McKesson. When entering nonviable COVID-19 vaccine into MIIC, you may receive an email about returning vaccine. Please disregard the email. Returning vaccine is our process only for other, non-COVID-19 vaccines.

Billing and reimbursement

COVID-19 vaccine administration fee

- There is no cost for COVID-19 vaccine for vaccine providers or for vaccine recipients. Per the CDC provider agreement, vaccine providers must administer COVID-19 vaccine, regardless of the vaccine recipient’s ability to pay COVID-19 vaccine administration fees or their insurance coverage status. There should be no out-of-pocket costs for COVID-19 vaccine.
- Insurance plans should reimburse providers for the administration fee. Vaccine providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient.
- For patients who have a Minnesota Health Care Plan (MHCP), providers will be reimbursed. As a reminder, COVID-19 vaccines are exempt from cost-sharing. MHCP also covers vaccine counseling that occurs during visits and for those COVID-19 vaccines they can administer. For details, refer to the MHCP Provider Manual: Immunizations and Vaccinations (www.dhs.state.mn.us/main/idcplg?IdcService=GET_DYNAMIC_CONVERSION&RevisionSelectionMethod=LatestReleased&dDocName=dhs16_136660). Please contact the MHCP Provider Call Center at 651-431-2700 with any related questions.

CDC will consider taking appropriate measures, including the possibility of rescinding the CDC provider agreement if a provider engages in any of the following:

- Administering COVID-19 vaccine at any out-of-pocket cost to the recipient.
- Denying anyone vaccination, or differentially reducing appointment access, based on the vaccine recipient’s coverage status or network status.
- Charging an office visit or other fee if COVID-19 vaccination is the sole medical service provided.
- Requiring additional medical services to receive COVID-19 vaccination.
- Seeking any reimbursement, including through balance billing, from the vaccine recipient.

Additional resources:

- For more information on provider requirements visit CDC COVID-19 Vaccination Program Provider Requirements and Support (www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html).
- Find vaccine administration codes from CDC at Data Code Sets (www.cdc.gov/vaccines/programs/iis/code-sets.html).

The Minnesota Department of Health wants to thank all health care workers who have worked tirelessly during this pandemic. Thank you for your dedication and efforts in working to overcome the devastating effects of COVID-19.