

2025-26 COVID-19 Vaccine Administration Protocol/Standing Order for Pharmacists

VACCINE PROTOCOL FOR CHILDREN AGE 3 TO 11 YEARS

This protocol/standing order is effective September 22, and shall remain in effect until September 21, 2026, or when rescinded by the Minnesota Department of Health's (MDH) State Epidemiologist and Medical Director or her designee, whichever occurs first. MDH retains the right to modify, rescind, or supplement this protocol/standing order as needed.

Condition for protocol/standing order

To reduce incidence of morbidity and mortality of COVID-19 disease, this protocol/standing order offers a mechanism to facilitate accessibility of COVID-19 vaccines by authorizing qualified health care professionals, as defined below, to administer 2025-26 COVID-19 vaccines to eligible individuals who meet the criteria established below by MDH.

This protocol/standing order is intended to supplement the authority that currently exists under Minnesota state and federal law for qualified health professionals to administer COVID-19 vaccines.

Authority

This non-patient specific protocol/standing order is issued by the MDH's State Epidemiologist and Medical Director in her official capacity and authorizes qualified health professionals, practicing in the State of Minnesota and in accordance with their respective scopes of practice, to assess eligibility and administer the most updated versions of the FDA-approved 2025-26 COVID-19 vaccine appropriate for age and health status as described below.

As defined in this protocol/standing order, qualified health care professionals are pharmacists who hold an active Minnesota license and are legally permitted to administer immunizations. Pharmacists may delegate the administration of vaccines to qualified pharmacy personnel (including nurses supporting pharmacists in administration of vaccines in pharmacy settings) in accordance with the laws and rules governing their scope of practice.

Policy

Participating pharmacists will implement this protocol/standing order for COVID-19 vaccination using the 2025-26 Pfizer-BioNTech and Moderna COVID-19 vaccine products for 3 through 11 years of age consistent with the criteria and eligibility described below.

The indications in this protocol/standing order are based on recommendations from the American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP), and the Infectious Diseases Society of America (IDSA).

Condition-specific criteria and prescribed actions

2025-26 COVID-19 VACCINE ADMINISTRATION PROTOCOL/STANDING ORDER FOR PHARMACISTS

Indications

Criteria	Prescribed action
<p>Child is currently healthy and aged 3 through 11 years, and is one or more of the following:</p> <ul style="list-style-type: none"> ▪ At high risk for severe COVID-19 due to an underlying medical condition*. <ul style="list-style-type: none"> ▪ Includes moderate to severe immune compromise (see below). ▪ A resident of a long-term care facility or congregate setting. ▪ Has never been vaccinated for COVID-19. ▪ A person whose household contacts are at high risk for severe COVID-19. ▪ A person whose parent or guardian desires protection from COVID-19 for their child. 	<p>Proceed to vaccinate.</p>
<p>Child with moderate to severe immunocompromise**</p>	<p>Proceed to vaccinate using schedule for children with immunocompromising conditions. Counsel the individual and/or parent/guardian about:</p> <ol style="list-style-type: none"> 1) The potential for reduced immune responses. 2) The need to continue to follow current guidance for COVID-19 prevention (visit COVID-19: Protect Yourself and Others (www.health.state.mn.us/diseases/coronavirus/prevention.html) for prevention strategies). <p>Refer to primary care provider and/or specialist if additional doses may be indicated.</p>
<p>Child is under 3 years of age.</p>	<p>Do not vaccinate. Refer to primary care provider for vaccination.</p>
<p>Person is 12 years or older.</p>	<p>Do not vaccinate under this protocol. Refer to the <i>2025-26 COVID-19 Vaccine Administration Protocol/Standing Order for Pharmacists</i> for persons 12-64 years of age.</p>

*Visit [AAP: 2025-2026 COVID-19 Vaccine Recommendations: FAQ \(www.aap.org/en/patient-care/covid-19/covid-19-vaccine-frequently-asked-questions/\)](https://www.aap.org/en/patient-care/covid-19/covid-19-vaccine-frequently-asked-questions/) and [CDC: Underlying Conditions and the Higher Risk for Severe COVID-19 \(www.cdc.gov/covid/hcp/clinical-care/underlying-conditions.html\)](https://www.cdc.gov/covid/hcp/clinical-care/underlying-conditions.html) for lists of high-risk underlying conditions or treatments. **Note these lists are not exhaustive.** Patients (or their parents or guardians) may self-attest to their underlying condition.

Visit [CDC: COVID-19 Vaccination Guidance for People Who Are Immunocompromised \(www.cdc.gov/covid/hcp/vaccine-considerations/immunocompromised.html\)](https://www.cdc.gov/covid/hcp/vaccine-considerations/immunocompromised.html) for a description of moderate and severe immunocompromising conditions and treatments. **Note this list is not exhaustive. Patients (or their parents or guardians) may self-attest to their underlying immunocompromising condition or treatment.

Contraindications

Criteria: Allergies	Prescribed action
<p>Child had a severe allergic reaction (e.g., anaphylaxis) to a previous dose of mRNA COVID-19 vaccine or any of its components.</p>	<p>Do not vaccinate.</p>

Precautions

Criteria	Prescribed action
<p>Child has a moderate to severe acute illness with or without fever (defined as temperature 100.4°F/38°C or higher).</p>	<p>Defer vaccination and refer to their primary care provider for assessment.</p>

2025-26 COVID-19 VACCINE ADMINISTRATION PROTOCOL/STANDING ORDER FOR PHARMACISTS

Criteria	Prescribed action
Child was diagnosed with non-severe allergy (e.g., urticaria beyond the injection site) to a component of an mRNA COVID-19 vaccine; or non-severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of an mRNA COVID-19 vaccine.	Defer vaccination and refer to their primary care provider to receive an assessment of their current health condition and assessment of individual benefits and risks.
History of severe allergic reaction (e.g., anaphylaxis) to any other vaccine or injectable therapy (e.g., intramuscular, intravenous, or subcutaneous). <i>This precaution includes allergies related to vaccines or injectable therapies. It does not include other kinds of allergies, e.g., food, pets, environmental allergies, latex allergies, or oral medications (including the oral equivalents of injectable medications).</i>	Defer vaccination and refer to their primary care provider to receive an assessment of their current health condition and assessment of individual benefits and risks.
Child has a history of Multisystem Inflammatory Syndrome in Children (MIS-C).	Defer vaccination and refer to their primary care provider to receive an assessment of their current health condition and assessment of individual benefits and risks.
Child has a history of myocarditis or pericarditis within 3 weeks after a previous dose of any COVID-19 vaccine.	Defer vaccination and refer to their primary care provider to receive an assessment of their current health condition and assessment of individual benefits and risks.
Child had a delayed local allergic reaction (e.g., erythema, induration, pruritis at the injection site).	Proceed to vaccinate. Give vaccine in the opposite arm from where the previous dose was given if known.

Prescription

Give any of the following products using the same vaccine product to complete the initial series and according to the schedule below:

- 2025-26 Pfizer-BioNTech Comirnaty COVID-19 vaccine for 5 through 11 years old (vials with blue caps and labels with blue borders); 10 mcg, **0.3 mL**, intramuscular (IM).
- 2025-26 Moderna Spikevax COVID-19 vaccine 3 through 11 years old (red label); 25 mcg, **0.25 mL**, intramuscular (IM).

Vaccination for 3 through 4-year-olds

- **Unvaccinated, incomplete initial vaccination series (with one or more doses of Moderna or Pfizer BioNTech), or previously completed an initial series:**
 - Give one dose of 2025-26 Moderna Spikevax vaccine at least 8 weeks after the most recent dose.

Vaccination for 5 through 11-year-olds

- **Unvaccinated:** Give one dose of 2025-26 Moderna Spikevax or Pfizer Comirnaty vaccine.
- **Previously vaccinated before 2025-26 vaccine:** Give one dose 2025-26 Moderna Spikevax or Pfizer vaccine at least 2 months following any previous COVID-19 vaccine dose.

Vaccination for persons aged 3 through 4 years old with immunocompromising conditions:

2025-26 COVID-19 VACCINE ADMINISTRATION PROTOCOL/STANDING ORDER FOR PHARMACISTS

Unvaccinated

- Give four doses Moderna Spikevax: A 3-dose initial series at 0, 4 weeks, and at least 4 weeks after dose two, followed by a fourth dose 6 months later (minimum interval 2 months).*

Incomplete initial three-dose vaccination series

- Previous vaccination with Moderna:
 - One dose of Moderna: Complete initial series with two doses Moderna Spikevax at least 4 weeks apart (administer dose one 4 weeks after most recent dose), followed by one dose 6 months later (minimum interval 2 months).*
 - Two doses of Moderna: Complete initial series with one dose of Moderna Spikevax at least 4 weeks after most recent dose, followed by one dose 6 months later (minimum interval 2 months).*
- Previous vaccination with Pfizer-BioNTech:
 - One dose Pfizer-BioNTech: Complete initial series with two doses Moderna Spikevax at least 8 weeks apart (administer dose one Moderna Spikevax 4 weeks after most recent dose), followed by one dose Moderna Spikevax 6 months later (minimum interval 2 months). *
 - Two doses Pfizer-BioNTech: complete initial series with 1 dose Moderna at least 8 weeks after most recent dose, followed by 1 dose Moderna 6 months later (minimum interval 2 months).
- Previously completed initial 3-dose vaccination series:
 - Three or more doses Moderna: Give two doses Moderna Spikevax 6 months apart (minimum interval 2 months). Administer dose one at least 8 weeks after the most recent dose.*
 - Three or more doses Pfizer-BioNTech: Give two doses Moderna Spikevax 6 months apart (minimum interval 2 months). Administer dose one at least 8 weeks after the most recent dose.*

*Additional doses of COVID-19 vaccine for moderately or severely immunocompromised may be given based on shared clinical decision making and administered at least 2 months after the most recent dose. Refer patient to health care provider.

Vaccination for persons aged 5 through 11 years old with immunocompromising conditions:

Unvaccinated*

- Give four doses (three-dose initial series Moderna Spikevax at 0, 4 weeks, and at least 4 weeks after dose two, followed by one dose Moderna Spikevax or Pfizer-BioNTech 6 months later [minimum interval 2 months]).**

OR

- Give four doses (3-dose initial series Pfizer-BioNTech at 0, 3 weeks, and at least 4 weeks after dose two, followed by one dose Moderna Spikevax or Pfizer-BioNTech 6 months later [minimum interval 2 months]).**

Incomplete initial 3-dose vaccination series

- Previous vaccination with Moderna:
 - One dose Moderna Spikevax: Give two doses Moderna Spikevax at least 4 weeks apart (administer dose one Moderna Spikevax 4 weeks after most recent dose), followed by one dose Moderna Spikevax or Pfizer-BioNTech 6 months later (minimum interval 2 months). **

2025-26 COVID-19 VACCINE ADMINISTRATION PROTOCOL/STANDING ORDER FOR PHARMACISTS

- Two doses Moderna Spikevax: Give one dose Moderna Spikevax at least 4 weeks after most recent dose, followed by one dose Moderna Spikevax or Pfizer-BioNTech 6 months later (minimum interval 2 months). **
- Previous vaccination with Pfizer-BioNTech:
 - One dose Pfizer-BioNTech: Give two doses Pfizer-BioNTech at least 4 weeks apart (administer dose one Pfizer-BioNTech 3 weeks after most recent dose), followed by one dose Moderna Spikevax or Pfizer-BioNTech 6 months later (minimum interval 2 months).**
 - Two doses Pfizer-BioNTech: Give one dose Pfizer-BioNTech at least 4 weeks after most recent dose, followed by one dose Moderna Spikevax or Pfizer-BioNTech 6 months later (minimum interval 2 months).**
- Completed initial 3-dose vaccination series
 - Three or more doses Moderna or three or more doses Pfizer BioNTech: Give two doses Moderna or Pfizer-BioNTech 6 months apart (minimum interval 2 months). Administer dose one at least 8 weeks after the most recent dose.**

*Use vaccine from the same manufacturer for all doses in the initial vaccination series.

**Additional doses of COVID-19 vaccine for moderately or severely immunocompromised may be given based on shared clinical decision making and administered at least 2 months after the most recent dose. Patient should talk to health care provider regarding additional doses.

Medical emergency or anaphylaxis

Vaccinators should be prepared to recognize and manage vaccine reactions and medical emergencies related to the administration of vaccines, including anaphylaxis. Follow your organization's pre-established protocol for anaphylaxis or refer to these suggested resources:

- [CDC: Preventing and Managing Adverse Reactions \(www.cdc.gov/vaccines/hcp/imz-best-practices/preventing-managing-adverse-reactions.html\)](https://www.cdc.gov/vaccines/hcp/imz-best-practices/preventing-managing-adverse-reactions.html)
- [Immunize.org: Medical Management of Vaccine Reactions in Children and Teens in a Community Setting \(www.immunize.org/wp-content/uploads/catg.d/p3082a.pdf\)](https://www.immunize.org/wp-content/uploads/catg.d/p3082a.pdf)

Provide Vaccine Information Statements (VIS)

Provide all patients with a copy of the most current federal vaccine information statement (VIS). Provide non-English speaking patients with a copy of the VIS in their native language, if one is available.

- [CDC: COVID-19 Vaccine VIS \(www.cdc.gov/vaccines/hcp/current-vis/covid-19.html\)](https://www.cdc.gov/vaccines/hcp/current-vis/covid-19.html)

Report adverse events to VAERS

Report all adverse events following the administration of COVID-19 vaccine to the federal Vaccine Adverse Event Reporting System (VAERS).

- [VAERS: Report an Adverse Event \(https://vaers.hhs.gov/reportevent.html\)](https://vaers.hhs.gov/reportevent.html)

Record keeping and documentation

- Qualified health professionals that are using this document must keep a copy of it on site at all locations administering vaccines pursuant to this protocol/standing order.

2025-26 COVID-19 VACCINE ADMINISTRATION PROTOCOL/STANDING ORDER FOR PHARMACISTS

- Document each patient's vaccine administration information in the Minnesota Immunization Information Connection (MIIC).

Insurance and billing

This protocol/standing order does not guarantee insurance coverage of the COVID-19 vaccine. Coverage for the COVID-19 vaccine is dependent upon and may vary based on insurance policies and individual plans.

Name of prescriber: Dr. Ruth Lynfield MD, State Epidemiologist and Medical Director, Minnesota Department of Health

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Prescriber signature:



Date:

Ingredient list

- 2025-26 Pfizer-BioNTech Comirnaty COVID-19 vaccine for age 5 through 11 years (single dose vials with blue caps and labels with blue borders): [Package Insert and Patient Package Insert - COMIRNATY \(https://www.fda.gov/media/151707/download?attachment\)](#)
- 2025-26 Moderna Spikevax COVID-19 vaccine for age 3 through 11 years (red label): [Package Insert - SPIKEVAX \(https://www.fda.gov/media/155675/download?attachment\)](#)