NEW YORK STATE OF OPPORTUNITY. Department of Health

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Non Patient-Specific Standing Order for the Administration of the Pfizer-BioNTech Updated COVID-19 Vaccine (2024-2025 Formula) for Persons 3 Years to 4 Years of Age by Pharmacists (Updated 09/17/2024)

Purpose: To reduce morbidity and mortality from COVID-19 by administering the Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) vaccination as permitted by the policy and order sections of this Order. Pursuant to 8 NYCRR § 63.9, the Commissioner of Health is authorized to issue a statewide standing order where he finds that there is an outbreak of disease, or that there is imminent threat of an outbreak of disease.

Policy: Under this non patient-specific standing order, pharmacists who are employees, volunteers, and/or contractors of all pharmacies licensed in New York State and who are pharmacists authorized to administer vaccines pursuant to a certificate of administration from the Department of Education under non-patient specific standing orders in New York State and who are certified in cardio-pulmonary resuscitation, may administer the Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) as permitted by its Biologics License Application (BLA) approval or Emergency Use Authorization, as applicable, by the U.S. Food and Drug Administration (FDA), state and federal laws, Executive Orders, COVID-19 Public Health Readiness and Emergency Preparedness (PREP) Act declarations, and the recommendations of the Advisory Committee on Immunization Practices (ACIP).

The 2024–2025 Pfizer formulation has been updated as a monovalent vaccine based on the Omicron KP.2 strain of SARS-CoV-2 and will be referred to as the "Pfizer COVID-19 Vaccine (2024-2025 Formula)" in this standing order. For ages 3-4 years, the product comes in a multiple dose vial with a yellow label and yellow cap.

NOTE: Pharmacists must follow the requirements set forth in 8 NYCRR 63.9, including providing patients with requisite information, maintaining adequate records and adhering to reporting requirements.

Procedure: This standing order is for use of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) multidose vials for persons 3 years to 4 years of age administered intramuscularly.

1. Assess children 3 years to 4 years of age *who are NOT moderately to severely immunocompromised* for eligibility for Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) based on the following criteria and administer dose(s) according to the table below:

COVID-19 Vaccination history	Number of Pfizer-BioNTech COVID-19 (2024-2025	Dosage (mL/ug)	Interval between doses

	Formula) doses indicated		
Unvaccinated	3	0.3 mL/3 ug	**Dose 1**: Day 0 **Dose 2**: -8 weeks after dose 1* **Dose 3**: At least 8 weeks after dose 2
1 dose of any Pfizer-BioNTech Vaccine	2	0.3 mL/3 ug	**Dose 2**:3-8 weeks after dose 1* **Dose 3**: At least 3-8 weeks after dose 2
2 previous doses of any Pfizer-BioNTech Vaccine	1	0.3 mL/3ug	**Dose 3**: At least 8 weeks after Dose 2
3 or more doses any Pfizer-BioNTech Vaccine NOT including at least 1 dose of 2024-2025 Pfizer-BioNTech COVID-19 Vaccine	1	0.3 mL/3ug	At least 8 weeks after last dose
3 or more doses of any Pfizer-BioNTech Vaccine INCLUDING at least 1 dose of 2024-2025 COVID-19 vaccine	No further doses indicated		

*An **8-week** interval between the first and second COVID-19 vaccine doses might be optimal for some people as it might reduce the rare risk of myocarditis and pericarditis associated with these vaccines.

2. Assess individuals aged 3 years to 4 years *who are moderately to severely immunocompromised* and administer Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) dose(s) according to the table below:

COVID-19 Vaccination history	**Number of Pfizer-BioNTech COVID-19 (2024-2025 Formula)**	**Dosage (mL/ug)**	**Interval between doses**

	doses indicated		
Unvaccinated	3	0.3 mL/3ug	**Dose 1**: Day 0 **Dose 2**: 3 weeks after Dose 1 **Dose 3**: At least 8 weeks after Dose 2 **See additional doses**
1 dose any Pfizer-BioNTech Vaccine	2	0.3 mL/3ug	**Dose 2**: 3 weeks after Dose 1. **Dose 3**: At least 8 weeks after Dose 2 **See additional doses**
2 doses any Pfizer-BioNTech Vaccine	1	0.3 mL/3ug	**Dose 3**: At least 8 weeks after dose 2 **See additional doses**
3 or more doses any Pfizer-BioNTech Vaccine NOT including at least 1 dose of 2024-2025 Pfizer-BioNTech COVID-19 vaccine	1	0.3 mL/3ug	At least 8 weeks after last dose **See additional doses**
3 or more doses of Pfizer-BioNTech Vaccine, INCLUDING at least 1 dose of 2024-2025 COVID-19 vaccine	**See additional doses**		
ADDITIONAL DOSES: Children in this age group may receive 1 additional dose of 2024–2025 mRNA COVID-19 vaccine from the same manufacturer as the initial series at least 2 months after the last 2024–2025 mRNA vaccine dose indicated in the table. Further additional 2024–2025 mRNA dose(s) may be administered from the same manufacturer, informed by the clinical judgment of a healthcare provider and personal preference and circumstances. Any further additional doses should be administered at least 2 months after the last 2024–2025 mRNA vaccine dose.			

Additional Clinical Considerations

- Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) may be simultaneously administered with other routinely recommended vaccines. There are additional

considerations for simultaneous administration of an orthopoxvirus vaccine and COVID-19 vaccine.

- Administration of COVID-19 vaccines should not be delayed in patients taking immunosuppressive therapies. Whenever possible, COVID-19 vaccines should be administered at least 2 weeks before initiation or resumption of immunosuppressive therapies. For patients who receive B-cell-depleting therapies on a continuing basis, COVID-19 vaccines should be administered approximately 4 weeks before the next scheduled therapy.
- Revaccinate persons who received doses of COVID-19 vaccine prior to or during hematopoietic cell transplantation (HCT) or chimeric antigen receptor T-cell (CAR-T-cell) therapy, following the current COVID-19 vaccination schedule. Revaccination should start at least 3 months (12 weeks) after transplant or CAR-T-cell therapy. For additional details and all clinical considerations, see Interim Clinical Considerations for Use of COVID-19 Vaccines

3. Screen for contraindications and precautions
    a. **Contraindications:** History of a severe allergic reaction (e.g., anaphylaxis) after a previous dose of Pfizer-BioNTech vaccine to a component of the Pfizer-BioNTech COVID-19 vaccine.
    b. **Precautions:**
        i. A diagnosed non-severe allergy to a component of the COVID-19 vaccine.
        ii. Non-severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of COVID-19, if receiving the same vaccine type.
        iii. Moderate to severe acute illness, with or without fever
        iv. Multisystem inflammatory syndrome in children (MIS-C).
        v. Myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine.
4. Provide information on the Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) and obtain consent.
    a. Prior to vaccine administration:
        i. Inform each patient or a patient's legal guardian, as applicable, of the risks, benefits, and alternatives of receiving the Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula).
        ii. As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the information for recipients and caregivers prior to the individual receiving Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) including: **(1)** FDA has approved the use of the Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) for ages 12 and older; there is an Emergency Use Authorization in place for ages 6 months-11years. **(2)** The recipient or their caregiver has the option to accept or refuse Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula); **(3)** The significant known and potential risks and benefits of Pfizer-BioNTech

COVID-19 Vaccine (2024-2025 Formula), and the extent to which such risks and benefits are unknown; and **(4)** Information about available alternative vaccines and the risks and benefits of those alternatives.

b. **For those aged 3 years to 4 years of age:** Provide each patient's legal guardian, as applicable, the package insert, or direct the individual to the website to obtain the fact sheet for the EUA.
c. Obtain consent to administer the vaccine from the patient or the patient's legal guardian, as applicable following the pharmacy's policies for consent.
d. Provide written instructions to the parent or legal guardian regarding appropriate course of action in the event of adverse reactions.
e. Provide necessary information on receiving the next dose of vaccine, if applicable.

5. Prepare to administer vaccine
   a. Administration of multi-dose vials
      i. Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) multi-dose vials do not contain preservatives. Strict adherence of aseptic technique during administration must be followed.
      ii. **Carefully inspect the vial prior to preparation**. The Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) multi-dose dose vial for children 6 months to 4 years of age, has a **yellow cap** and a **yellow label border**.
      iii. Inspect the vaccine in the vial. Prior to mixing the vial, the thawed vaccine may contain white to off-white opaque amorphous particles.
      iv. For multi-dose vials with yellow caps and yellow label border, dilute prior to use.
         a. Add 1.1 mL of sterile 0.9% Sodium Chloride injection, USP, into the vaccine vial.
         b. Before removing the needle from the vial, equalize vial pressure by withdrawing air into the syringe.
         c. Record the date and time of dilution on the vial label.
      v. Before use, mix the vial by inverting vaccine vial gently 10 times. Do not shake.
      vi. After mixing, the vaccine should appear as an off-white suspension with no visible particles. Do not use if vaccine is discolored or contains particulate matter. Call the manufacturer and the New York State Department of Health (NYSDOH) if this occurs.
      vii. Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3 mL of the Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula). If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials.

6. Administer vaccine:
   i. For children 3 through 4 years of age, use a 22-25 gauge, 1 inch needle. Give the vaccination in the deltoid muscle in the upper arm.

ii. Administer Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) by intramuscular injection, 0.3mL/3ug.

7. Document Vaccination

Document each patient's vaccine administration information and follow-up in the following places:

Medical Record System (including CDMS, as applicable) : Ensure that the patient's name, the date the vaccine was administered, the name of the vaccine, the manufacturer and lot number, the vaccination site and route, address of administering site, and the name and title of the authorized person administering the vaccine, and the date it was given to the patient is documented in the patient's medical record or on a separate form retained by the authorized vaccinator who has administered the immunization, and in a retrievable format available to the State Education Department and the patient. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, refusal). Documentation must be completed within 24 hours of administration. This information, whether in a medical record or separately kept, must be recorded and maintained in accordance with 8 NYCRR section 29.2 (a) (3).

Signed Certificate of Immunization (given to the patient's parent or legal guardian)**:** Record the patient's name, date of vaccination, name/location of the administering pharmacy, administering pharmacist (name or signature), name of vaccine, manufacturer and lot number, and recommendations for future immunizations.

New York State Immunization Information System (NYSIIS) and City Immunization Registry (CIR): Report all doses administered to those 18 years of age and younger to NYSIIS or CIR within 14 days of administration. With respect to NYSIIS, if the dose was documented in the Countermeasure Data Management System (CDMS), then the NYSDOH shall transmit data from CDMS to NYSIIS for all patients ages 18 and younger and for those who are 19 and older, with consent.

8. Management of medical emergencies

A post vaccination observation period should be considered to monitor patients for the occurrence of immediate adverse reactions:

- 30 minutes:
  - History of non-severe, immediate (less than 4 hours) allergic reaction after a previous dose of COVID-19 vaccine
  - History of-allergy-related contraindication to a different type of COVID-19 vaccine
  - History of anaphylaxis after non-COVID-19 vaccines or injectable therapies
- 15 minutes: All other people

Be prepared for management of a medical emergency related to the administration of vaccine by maintaining written copies of the standing orders and protocols for administration of epinephrine and diphenhydramine. Pharmacists shall be responsible for having emergency anaphylaxis treatment agents, related syringes and needles at the immunization site, including at least 3 epinephrine prefilled syringes or autoinjectors appropriate for age, H1 antihistamine, blood pressure cuff, and a stethoscope and timing device to assess pulse. To prevent syncope, vaccinate patients while they are seated or lying down and assess for signs of syncope such as extreme paleness, sweating, coldness of the hands and feet, nausea, lightheadedness, dizziness, weakness or visual disturbances.

For more information, please see:

- Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination sites at: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html
- CDC's General Best Practice Guidelines for Immunization, "Preventing and Managing Adverse Reactions," at https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.pdf
- Immunization Action Coalition's "Medical Management of Vaccine Reactions in Children and Teens in a Community Setting" at https://www.immunize.org/catg.d/p3082a.pdf

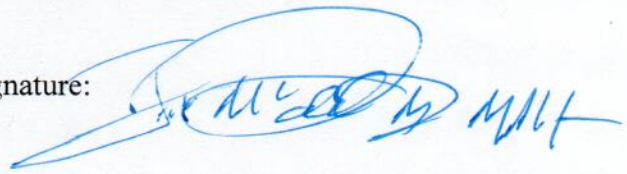
9. Reporting of adverse events
    a. Report the following information associated with the administration of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) of which they become aware to Vaccine Adverse Events Electronic Reporting System (VAERS) in accordance with the "Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers)" including:
        i. Vaccine administration errors whether or not associated with an adverse event
        ii. Serious adverse events (irrespective of attribution to vaccination)[1]
        iii. Cases of myocarditis or pericarditis after vaccine
        iv. Cases of Multisystem Inflammatory Syndrome in children and adults
        v. Cases of COVID-19 that result in hospitalization or death
        vi. Any additional adverse events and revised safety requirements per the Food and Drug Administration's conditions for use of an authorized vaccine
    b. Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html or by calling 1-800-822-7967.

[1] Serious adverse events are defined as: (1) Death; (2) A life-threatening adverse event; (3) Inpatient hospitalization or prolongation of existing hospitalization; (4) A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions; (5) A congenital anomaly/birth defect; or (6) An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

10. Storage and Handling of Vaccine for Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula)
    a. For storage and handling details, please refer to the fact sheet: Fact Sheet for Healthcare Providers Administering Vaccine: Emergency Use Authorization of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula), located here: https://www.fda.gov/media/167211/download?attachment

Order: I am hereby prescribing this non patient-specific order to administration of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula). Specifically, pharmacists who are employees, volunteers, or contractors of the pharmacy licensed in New York State may administer Pfizer-BioNTech COVID-19 Vaccine, as permitted by its BLA approval or its Emergency Use Authorization (EUA), as applicable, state and federal laws, Executive Orders, COVID-19 Public Health Readiness and Emergency Preparedness (PREP) Act declarations, ACIP recommendations, and the CDC's and New York State's Vaccination Program.

This non patient-specific order shall remain in effect for the vaccination of any individuals as set forth herein, beginning on September 19, 2024 through December 31, 2024. In the event that I discontinue this non patient-specific order prior to December 31, 2024, notice of such discontinuance shall be provided to those employees, volunteers, and contractors of the pharmacy licensed in New York State permitted to execute under this Order via using the usual methods of communication.

Signature: 

Date: September 19, 2024

Name of Physician: James V. McDonald MD MPH

Title: Commissioner

Institution: New York State Department of Health

NYS License No.: 186383

Effective Date of Order: September 19, 2024

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