NEW YORK STATE OF OPPORTUNITY. Department of Health

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Non Patient-Specific Standing Order for the Administration of the Pfizer-BioNTech COVID-19 Vaccination in New York Retail Pharmacies for the Initial Phase of the COVID-19 Vaccination Program

Purpose: To reduce morbidity and mortality from COVID-19 by administering the Pfizer-BioNTech COVID-19 vaccination as permitted by its Emergency Use Authorization (EUA) to individuals in accordance with the Center for Disease Control and Prevention's (CDC) Vaccination Program and recommendations issued by the Advisory Committee on Immunization Practices (ACIP).

Policy: Under this non patient-specific standing order, licensed pharmacists and other authorized vaccinators employed by or under contract with a pharmacy and possessing a certificate to administer immunizations by the New York State Education Department who meet and/or have satisfied all applicable requirements to administer vaccination as set forth in law and by Executive Order 202.82, and any other relevant Executive Orders that may extend, modify, add to, or expand upon the provisions in EO 202.82, may administer the Pfizer-BioNTech COVID-19 vaccination to individuals age 16 years and older who are eligible for COVID-19 vaccine at the time they are vaccinated, in connection with their employment or contract with said pharmacy, and as permitted by its Emergency Use Authorization (EUA) to individuals in accordance with the CDC's Vaccination Program and recommendations issued by ACIP, as well as with any requirements set forth in EO 202.82 and such other relevant Executive Orders.

Procedure:

1. Assess persons 16 years of age or older for eligibility for Pfizer-BioNTech COVID-19 vaccine based on the following criteria:

    a. No COVID-19 vaccine: Administer the first dose of Pfizer-BioNTech COVID-19 vaccine according to the procedure described herein.
    b. One (1) previous dose of Pfizer-BioNTech COVID-19 vaccine administered 21 or more days prior to the date of vaccine administration: Administer the second dose of Pfizer-BioNTech COVID-19 vaccine according to the procedure described herein.
    c. Pfizer-BioNTech COVID-19 vaccine should not be administered at the same time as other vaccines. Separate Pfizer-BioNTech COVID-19 vaccine from other vaccines by 14 days before or after the administration of Pfizer-BioNTech COVID-19 vaccine.
    d. Pfizer-BioNTech COVID-19 vaccine should be deferred for at least 90 days for persons who received passive antibody therapy (monoclonal antibodies or convalescent plasma) as part of COVID-19 treatment in order to avoid interference of antibody therapy with vaccine-induced immune responses.

2. Screen for contraindications and precautions

    a. **Contraindications:** Do not administer the Pfizer-BioNTech COVID-19 vaccine to anyone with a known history of:
        i. a severe allergic reaction (e.g., anaphylaxis) to a prior dose of an mRNA COVID-19 vaccine (i.e., Moderna or Pfizer-BioNTech COVID-19 vaccines) or to any vaccine component (including polyethylene glycol) listed in the prescribing information at https://www.fda.gov/media/144637/download; or
        ii. immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components (including polyethylene glycol), unless they have been evaluated by an allergist-immunologist and it is determined that the person can safely receive the vaccine; or
        iii. immediate allergic reaction of any severity to polysorbate, unless they have been evaluated by an allergist-immunologist and it is determined that the person can safely receive the vaccine.

    b. **Precautions:**

        i. In persons who report a history of an immediate allergic reaction (defined as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress, or anaphylaxis that occur within 4 hours following exposure to a vaccine or medication) to any vaccine or injectable therapy (intramuscular, intravenous, or subcutaneous), counsel about the unknown risks of developing a severe allergic reaction and the risks and benefits of COVID-19 vaccination, and consider deferral of vaccination until further information on risk of anaphylaxis is available and/or consultation with an allergist-immunologist. This precaution does not apply to allergic reactions not related to vaccines or injectable therapy (e.g., pet, venom, environmental, food, latex or oral medications).
        ii. Defer administering the Pfizer-BioNTech vaccine to people who are moderately to severely ill with an acute illness until they have recovered.

3. Provide information on the Pfizer-BioNTech COVID-19 vaccine and obtain consent.

    a. Prior to vaccine administration:

        i. Inform each patient or or a patient's legal guardian, as applicable, of the risks, benefits, and alternatives of receiving the COVID-19 vaccine.
            – As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the "Fact Sheet for Recipients and Caregivers" prior to the individual receiving Pfizer-BioNTech COVID-19 Vaccine, including: **(1)** FDA has authorized the emergency use of the Pfizer-BioNTech

COVID-19 Vaccine, which is not an FDA-approved vaccine; **(2)** The recipient or their caregiver has the option to accept or refuse Pfizer-BioNTech COVID-19 Vaccine; **(3)** The significant known and potential risks and benefits of Pfizer-BioNTech COVID-19 Vaccine, 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.

ii. Provide each patient or patient's legal guardian, as applicable, a copy of the "Fact Sheet for Recipients and Caregivers," or direct the individual to the website www.cvdvaccine.com to obtain the Fact Sheet.

iii. Provide the v-safe information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in v-safe. V-safe is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. V-safe also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information, visit: www.cdc.gov/vsafe.

iv. Obtain verbal consent to administer the vaccine from the patient or the patient's legal guardian, as applicable. If verbal consent is received, then document consent in the patient's medication profile or medical record. The New York State Department of Health Screening and Consent Form, which is optional, also is available on the Department of Health COVID-19 Vaccination Program webpage for providers at https://covid19vaccine.health.ny.gov.

b. Provide necessary information on receiving the second dose of vaccine.

i. When administering the first dose of Pfizer-BioNTech COVID-19 vaccine, provide a vaccination card to the recipient or their caregiver with the location and date in 21 days when the recipient needs to return for the second dose of Pfizer-BioNTech COVID-19 Vaccine.

4. Storage and Handling of Vaccine

a. Pfizer-BioNTech COVID-19 vaccines contain preservative-free frozen suspension that must be stored at appropriate temperatures to preserve efficacy. Consult CDC, NYSDOH and Pfizer guidance on storage and handling of Pfizer-BioNTech COVID-19 vaccines.

b. Pfizer-BioNTech COVID-19 vaccines must be thawed prior to dilution and administration. Only thaw the number of vials that you believe you will need. Thawed vials cannot be refrozen. Each multi-dose vial contains enough suspension for five patients.

c. Thawing under refrigeration: A full tray of 25 or 195 vials may take up to 2 or 3 hours, respectively, to thaw in the refrigerator. A smaller number of vials will thaw in less time. Undiluted vials may remain in the refrigerator for up to 5 days.
d. Thawing at room temperature: Vials will thaw at room temperature (up to 25 ºC [77 ºF]) in 30 minutes. Undiluted vials may be stored at room temperature for no more than 2 hours. Do not thaw a vial at room temperature unless you are prepared to vaccinate 5 persons within two hours.
e. Pfizer-BioNTech COVID-19 vaccine vials must reach room temperature prior to dilution.
f. Store diluent vials at room temperature.

5. Prepare to administer vaccine

a. Pfizer-BioNTech COVID-19 vaccine vials do not contain preservatives. Strict adherence of aseptic technique during dilution and administration must be followed.
b. Ensure the vaccine vial has thawed to room temperature prior to dilution. If a vial feels cold to the touch, then it has not thawed enough.
c. Gently invert the vaccine vial ten (10) times to mix. Do not shake. Shaking can impair the efficacy of the vaccine.
d. Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles. Do not use if liquid is discolored or if other particles are observed.
e. Dilution:
    i. Use only sterile 0.9% Sodium Chloride Injection, USP as diluent. Do not use bacteriostatic 0.9% Sodium Chloride Injection as this may impair the efficacy of the vaccine.
    ii. Using aseptic technique, withdraw 1.8 mL of 0.9% Sodium Chloride diluent into a 3 mL or 5 mL transfer syringe, using a 21-gauge or narrower needle.
    iii. Cleanse the vaccine vial stopper with a single-use antiseptic swab.
    iv. Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.
    v. Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe.
    vi. Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix. Do not shake.
    vii. Inspect the vaccine in the vial. The vaccine will be an off-white suspension. 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.
    viii. Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label. Store diluted vaccine between 2°C to 25°C (35°F to 77°F) for a maximum of 6 hours after dilution. Discard any unused diluted vaccine 6 hours after dilution. Notify the NYSDOH at 1-800-543-7468 if you need to discard vaccine.

f. Visually assess patient weight and select a needle for vaccine administration based on the following chart:

Patient Gender	Patient Weight	Needle Length
Female	< 130 lbs	5/8* – 1”
	130–152 lbs	1"
	153–200 lbs	1–1½"
	200+ lbs	1½"
Male	< 130 lbs	5/8* – 1”
	130–152 lbs	1"
	153–260 lbs	1–1½"
	260+ lbs	1½"

*Some experts recommend a 5/8-inch needle for men and women who weigh less 130 pounds. If used, skin must be stretched tightly (**do not bunch subcutaneous tissue**).

g. 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.

6. Administer vaccine

a. Visually inspect each dose in the dosing syringe prior to administration.
   i. Verify the final dosing volume of 0.3 mL.
   ii. Confirm there are no particulates and that no discoloration is observed.
   iii. Do not administer if vaccine is discolored or contains particulate matter.
   iv. Call the manufacturer and the NYSDOH if the vaccine is discolored or contains particulate matter.

b. Administer the Pfizer-BioNTech COVID-19 Vaccine, 0.3 mL, in the deltoid muscle via the intramuscular (IM) route.

7. Document vaccination

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

Medical Record System: 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 pharmacist administering the vaccine, the publication date of the EUA fact sheet and the date it was given to the patient is documented in the patient’s medication profile. In instances where a patient medication profile is not required, this information must be recorded on a separate form retained by the pharmacist 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 12 hours of administration. This information, whether in a patient medication profile 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)**:** Record the patient's name, date of vaccination, name/location of the administering clinic, administering nurse, 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 NYSIIS or CIR within 12 hours of administration.

8. Licensed pharmacists must inform their 16 and 17-year-old vaccination patients and the adult caregiver accompanying such patient of the importance of a well-child visit with a pediatrician or other licensed primary care provider and refer patients as appropriate.

9. Management of medical emergencies

Observe all patients for a minimum of 15 minutes following vaccination to monitor for the occurrence of immediate adverse reactions. Observe patients with a history of anaphylaxis for 30 minutes following vaccination.

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. Pharmacist immunizers 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, 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/info-by-product/pfizer/anaphylaxis-management.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 Adults in a Community Setting" at https://www.immunize.org/catg.d/p3082.pdf.

10. Reporting of adverse events

    a. Report the following information associated with the administration of Pfizer BioNTech COVID-19 vaccine 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 Multisystem Inflammatory Syndrome in children and adults
iv. Cases of COVID-19 that result in hospitalization or death

b. Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html or by calling 1-800-822-7967. The VAERS reports should include the words "Pfizer-BioNTech COVID-19 Vaccine EUA" in the description section of the report. To the extent feasible, report to Pfizer Inc. by contacting 1-800-438-1985 or by providing a copy of the VAERS form to Pfizer Inc.; Fax: 1-866-635-8337.

c. Conduct any follow-up requested by the U.S government, including CDC, FDA, or other designee, regarding adverse events to the extent feasible given the emergency circumstances.

Order: In accordance with Governor Cuomo's Executive Order No. 202.82, (and any other relevant Executive Orders that may extend, modify, add to, or expand upon the provisions in EO 202.82), sections 6527, 6801, and 6802, 6909 of the New York State Education Law and associated regulations, as applicable, any other relevant laws for authorized vaccinators permitted to administer vaccinations under this Order, and subject to the Purpose, Policy and Procedure set forth herein, I am hereby prescribing this non patient-specific order for the administration of Pfizer-BioNTech COVID-19 Vaccine statewide beginning January 12, 2021 Specifically, licensed pharmacists and other authorized vaccinators, employed by or under contract with a pharmacy and possessing a certificate to administer immunizations by the New York State Education Department may administer Pfizer-BioNTech COVID-19 Vaccine in connection with their employment or contract with said pharmacy, and as permitted by its Emergency Use Authorization (EUA) to individuals age 16 years and older who are eligible for COVID-19 vaccine at the time they are vaccinated, in accordance with the CDC Vaccination Program and recommendations issued by the ACIP, and such other relevant Executive Orders.

This non patient-specific order will expire at the earlier of (i) the expiration of Executive Order 202.82, and any further extension thereof; or (ii) my discontinuance of this non patient-specific order, which I may do at my discretion. In the event that I discontinue this non patient-specific order prior to the expiration of Executive Order No. 202.82, and any further extension thereof,

[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.

notice of such discontinuance shall be provided on the New York State Department of Health website.

Signature:  Date: 01/12/2021

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