Non Patient-Specific Standing Order for the Administration of the Moderna COVID-19 Vaccine (2023-2024 Formula) for Persons 5 Years of Age and Older by Pharmacists (Updated 10/18/2023)

Purpose: To reduce morbidity and mortality from COVID-19 by administering the Moderna COVID-19 Vaccine (2023-2024 Formula) 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 orders in New York State and who are certified in cardio-pulmonary resuscitation, may administer the Moderna COVID-19 Vaccine (2023-2024 Formula), to individuals ages 5 years and older, 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 2023–2024 Moderna formulation has been updated to a monovalent vaccine based on the Omicron XBB.1.5 sublineage of SARS-CoV-2 and will be referred to as the "Moderna COVID-19 Vaccine (2023-2024 Formula)" in this standing order. For ages 5 years to 11 years, the product is under Emergency Use Authorization. The product comes in single-dose vials with dark blue cap and green label border. For ages 12 years and older, the product is called SPIKEVAX and is available in single dose vials with a blue cap and a blue label border. SPIKEVAX is also available in a prefilled, single-dose syringe for people ages 12 years and older, with a dark blue border on the label.

Moderna COVID-19 bivalent vaccine is no longer permitted to be used in any circumstance.

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 Moderna COVID-19 Vaccine (2023-2024 Formula) single dose vials or prefilled, single-dose syringes for persons 5 years and older administered intramuscularly.

1. **Assess** individuals ages 5 years and above who *are NOT moderately to severely immunocompromised* for eligibility for Moderna COVID-19 Vaccine (2023-2024 Formula), based on the following criteria and administer dose(s) according to the table below.

COVID-19 Vaccination history prior to updated (2023-2024 Formula)	**Number of Moderna (2023-2024 Formula) doses indicated**	**Dosage**	**Vaccine vial cap and label border colors***	**Interval between doses***
Unvaccinated	1	Ages ≥ 12 years: 0.5 mL/50 ug OR ≥ 5 years to 11 years: 0.25 mL/25ug	Ages ≥ 12 years: dark blue cap; blue label border or single dose syringe OR Ages ≥5 years to 11 years: dark blue cap; green label	--
1 or more doses any mRNA vaccine	1	Ages ≥ 12 years: 0.5 mL/50 ug OR ≥ 5 years to 11 years: 0.25mL/25ug	Ages ≥ 12 years: dark blue cap; blue label border or single dose syringe OR Ages ≥5 years to 11 years: dark blue cap; green label border	At least 8 weeks after last dose
1 or more doses Novavax of Janssen, including in combination with any mRNA vaccine dose(s)	1	Ages ≥ 12 years: 0.5 mL/50 ug OR ≥ 5 years to 11 year 0.25 mL/25ug	Ages ≥ 12 years: dark blue cap; blue label border or single dose syringe OR Ages ≥5 years to 11 years: dark blue cap; green label	At least 8 weeks after last dose

*Vials come with dark blue cap and dark blue label border for those ages 12 and older. For those 5-11, the vials come with a dark blue cap and green label border. Moderna COVID-19 Vaccine (2023-2024 Formula) is also available in a prefilled, single-dose syringe for people ages 12 years and older with dark blue border on the label.

Note 1: Children who transition from age 11 years to age 12 years during the Moderna initial vaccination series are recommended to receive updated (2023–2024 Formula) Moderna COVID-19 Vaccine, 0.5 mL/50 ug (dark blue cap; dark blue label border) for all doses received on or after turning age 12 years. However, the FDA EUA provides that they may also receive the dosage for children ages 5–11 years (0.25mL/25ug, dark blue cap and green label border)

For more information, please see CDC's Interim Clinical Considerations:
https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

- Assess individuals aged 5 years and older who *are moderately to severely immunocompromised* and administer Moderna COVID-19 Vaccine (2023-2024

COVID-19 Vaccination history prior to updated (2023-2024 Formula)	**Number of Moderna COVID-19 (2023-2024 Formula) doses indicated**	**Dosage**	**Vaccine vial cap and label border colors***	**Interval between doses**
Unvaccinated	3	Ages ≥ 12 years: 0.5 mL/50 ug OR ≥ 5 years to 11 years: 0.25 mL/25ug	Ages ≥ 12 years: dark blue cap; blue label border or single dose syringe OR ages ≥5 years to 11 years: dark blue cap; green label border	Dose 1 and Dose 2: 4 weeks Dose 2 and Dose 3: At least 4 weeks
1 dose any Moderna	2	Ages ≥ 12 years: 0.5 mL/50 ug OR ≥ 5 years to 11 years: 0.25 mL/25ug	Ages ≥ 12 years: dark blue cap; blue label border or single dose syringe OR ages ≥5 years to 11 years: dark blue cap; green label Dark blue cap; blue label (ages ≥12) OR dark blue cap; green label (ages ≥5-11)	Dose 1: 4 weeks after last dose Dose 1 and Dose 2: At least 4 weeks
2 doses any Moderna	1	Ages ≥ 12 years: 0.5 mL/50 ug OR ≥ 5 years to 11 years: 0.25 mL/25ug	Ages ≥ 12 years: dark blue cap; blue label border or single dose syringe OR ages ≥5 years to 11 years: dark blue cap; green label	At least 4 weeks after last dose
3 or more doses any mRNA vaccine	1	Ages ≥ 12 years: 0.5 mL/50 ug OR ≥ 5 years to 11 years: 0.25 mL/25ug	Ages ≥ 12 years: dark blue cap; blue label border or single dose syringe OR ages ≥5 years to 11 years: dark blue cap; green label border	At least 8 weeks after last dose
1 or more doses of Novavax of	1	Ages ≥ 12 years: 0.5	Ages ≥ 12 years: dark blue cap; blue	At least 8 weeks after last dose

Janssen, including in combination with any mRNA vaccine dose(s)		mL/50 ug OR ≥ 5 years to 11 years: 0.25 mL/25ug	label border or single dose syringe OR ages ≥5 years to 11 years: dark blue cap; green label border	

*Children who transition from age 11 years to age 12 years during the Moderna initial vaccination series are recommended to receive updated (2023–2024 Formula) Moderna COVID-19 Vaccine, 0.5 mL/50ug (dark blue cap; blue label border) for all doses received on or after turning age 12 years. However, the FDA EUA provides that they may also receive the dosage for children ages 5–11 years, 0.25 mL/25ug (dark blue cap; green label border).

*People ages 12 years and older who are moderately or severely immunocompromised have the option to receive 1 additional dose Moderna COVID-19 Vaccine (2023-2024 Formula) dose at least 2 months following the last recommended updated (2023-2024 Formula) mRNA vaccine dose. Further additional 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 2 months after the last COVID-19 vaccine dose.

Additional Clinical Considerations

- Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) may be simultaneously administered with other routinely recommended vaccines. There are additional consideration for simultaneous administration of an orthopoxvirus vaccine and COVID-19 vaccine.
- 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" (links to clinical considerations)

For more information, please see CDC's Interim Clinical Considerations: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

2. Screen for contraindications and precautions

    a. **Contraindications:** History of a severe allergic reaction (e.g., anaphylaxis) after a previous dose of Moderna COVID-19 vaccine or to a component of the Moderna 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. Multisystem inflammatory syndrome in children (MIS-C) or adults (MIS-A).
iv. Myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine.
v. Moderate to severe illness with or without fever.

4. Provide information on the Moderna COVID-19 Vaccine (2023-2024 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 Moderna COVID-19 Vaccine (2023-2024 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 Moderna COVID-19 Vaccine (2023-2024 Formula) including: **(1)** FDA has approved the use of the adolescent and adult formulation of the Moderna COVID-19 Vaccine for ages 12 years and older. There is an Emergency Use Authorization in place for ages 5-11 **(2)** The recipient or their caregiver has the option to accept or refuse Moderna COVID-19 Vaccine (2023-2024 Formula); **(3)** The significant known and potential risks and benefits of Moderna 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.
b. **For those aged 5 to 11 years of age:** Provide each patient or 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. **For those aged 12 years or older:** There is currently no VIS. Once a VIS is available it should be used; but vaccination should not be delayed because of the absence of a VIS. See additional information below for alternative information materials that can be provide. Check for the VIS here: https://www.cdc.gov/vaccines/hcp/vis/current-vis.html.
d. Obtain consent to administer the vaccine from the patient or the patient's legal guardian, as applicable following the pharmacy's policies for consent.
e. Provide necessary information on receiving the next dose of vaccine, if applicable.

5. Prepare to administer vaccine

a. Administration of single dose vials
   i. Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.25 mL of the Moderna COVID-19

Vaccine (2023-2024 Formula). If the amount of vaccine remaining in the vial cannot provide a full dose of 0.25 mL, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials.

ii. Moderna COVID-19 Vaccine single dose vials contain a frozen suspension that does not contain a preservative and must be thawed prior to administration.
iii. Swirl vial gently after thawing. Do not shake. Do not dilute the vaccine.
iv. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.
v. Moderna COVID-19 Vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates. Do not administer if vaccine is discolored or contains other particulate matter.
vi. Each single dose vial contains one dose of 0.25 mL for ages 5 years through 11 years or 0.5 mL for ages 12 years and older.
vii. Each vial or syringe is single use only. Discard after single use.

b. Administration of single dose, prefilled syringes
   i. Moderna COVID-19 Vaccine single dose syringes contain a frozen suspension that does not contain a preservative and must be thawed prior to administration.
   ii. Do not shake. Do not dilute the vaccine.
   iii. Use a sterile needle of the appropriate size for intramuscular injection.
   iv. With tip cap upright, remove tip cap by twisting counterclockwise until tip cap releases. Remove tip cap in a slow, steady motion. Avoid pulling tip cap while twisting.
   v. Attach the needle by twisting in a clockwise direction until the needle fits securely on the syringe.
   vi. Each syringe contains 0.5 mL for ages 12 years and older.
   vii. Administer the entire dose intramuscularly.
   viii. Discard syringe after use.11.

6. Administer vaccine:

   i. Choose the correct needle gauge, needle length and injection site.
   ii. Visually assess patient weight and select a needle for vaccine administration based on the following:

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"

*For administration in the deltoid 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**).

Administer Moderna COVID-19 Vaccine (2023-2024 Formula) by intramuscular injection:

5-11 years: 0.25 mL/25ug

12 years of age and older: 0.50 mL /50ug

Administer the Moderna COVID-19 Vaccine (2023-2024 Formula) in the deltoid muscle via the intramuscular (IM) route. Alternately, the anterolateral thigh can be used. A 1.5-inch needle is typically used for adults if administering vaccine in this site. More information about choice of needle length can be found at https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.html#t6_2

a. For vials: Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.25 or 0.50 mL of the Moderna COVID-19 Vaccine (2023-2024 Formula). If the amount of vaccine remaining in the vial cannot provide a full dose, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials.

b. For syringes: Administer the entire volume to deliver a single dose. For the prefilled syringe, remove tip cap and attach a sterile needle. Do not shake. Administer the entire volume to deliver a single 0.5 mL dose.

c. For single dose vials and syringes, discard immediately after use.

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)**:** Record the patient's name, date of vaccination, name/location of the administering pharmacy, administering pharmacist (can be a signature or printed name), 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 24 hours of administration. Report all doses administered to those 19 years of age and older to NYSIIS and CIR after obtaining consent. With respect to NYSIIS, if the dose was documented in CDMS, then the NYSDOH shall transmit data from CDMS to NYSIIS for all patients.

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 an 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, particularly when vaccinating adolescents

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, 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 Adults in a Community Setting" at https://www.immunize.org/catg.d/p3082.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 Moderna 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 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 approval

    b. Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html or by calling 1-800-822-7967.

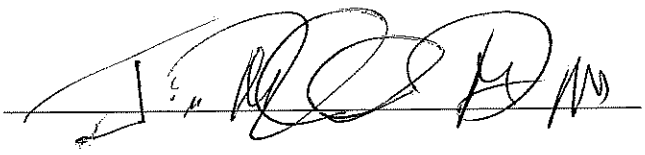
10. Storage and Handling of Vaccine for Moderna COVID-19 Vaccine (2023-2024 Formula)

    a. Storage of Single Dose Vials and Prefilled Syringes prior to use:

i. The Moderna COVID-19 Vaccine single dose vial contains a frozen suspension that does not contain a preservative. Consult CDC, NYSDOH and Moderna guidance on storage and handling of Moderna COVID-19 vaccines.
ii. Moderna COVID-19 Vaccine single dose vials may be stored frozen between -50° to -15°C (-58° to 5°F) until expiration date.
iii. Unpunctured vials can be in the refrigerator between 2 °C to 8 °C (36 °F to 46 °F) for up to 30 days prior to first use, not to exceed the expiration date. Use CDC's beyond-use date labels for this vaccine to track storage time at refrigerated temperatures.
iv. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.
v. Moderna COVID-19 vaccines must be thawed in the refrigerator or at room temperature prior to administration. Only thaw the number of vials that you believe you will need. Thawed vials cannot be refrozen.
vi. Thawing under refrigeration: Thaw in the refrigerator between 2 °C to 8 °C (36 °F to 46 °F) for 45 minutes. After thawing, let stand at room temperature for 15 minutes before administering.
vii. Alternatively, thaw at room temperature: Vials will thaw at room temperature between 15 °C to 25 °C (59 °F to 77 °F) within 15 minutes.
viii. Vials may be stored between 8° to 25°C (46° to 77°F) for up to 24 hours total.
ix. After first puncture, doses must be used within 12 hours after which any remaining doses must be discarded.
x. Do not refreeze vials once thawed.

Order: I am hereby prescribing this non patient-specific order to administration of Moderna COVID-19 Vaccine (2023-2024 Formula). Specifically, pharmacists who are employees, volunteers, or contractors of the pharmacy licensed in New York State may administer Moderna COVID-19 Vaccine, as permitted by its Biologics License Application (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 October 19, 2023 through October 19, 2024. In the event that I discontinue this non patient-specific order prior to October 19, 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 using the usual methods of communication.

Signature:  Date: 10/19/23

Name of Physician: James V. McDonald, MD, MPH

Title: Commissioner of Health

Institution: New York State Department of Health

NYS License No.: 186383

Effective Date of Order: October 19, 2023