NEW YORK STATE OF OPPORTUNITY. Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

LISA J. PINO, M.A., J.D.
Executive Deputy Commissioner

December 23, 2020

Dear Colleagues,

The New York State Department of Health (NYSDOH) has learned that COVID-19 vaccine providers have consistently been able to withdraw more than 10 doses from one vial of the Moderna vaccine. Vials have yielded 11 doses in some cases.

The NYSDOH is providing the following guidance after consulting with the FDA:

- Vaccinators may withdraw more than 10 doses from a single 10-dose vial.
- **Extra vaccine fluid from more than one vial CANNOT be combined to produce extra doses.** This is particularly important since the vaccine does not contain preservatives.
- Use any extra vaccine that can easily be drawn up into a syringe to meet the 0.5 ml dose requirement. This could be 11 doses.
- Enter all vaccines given into NYSIIS, including any additional vaccines given.
- Inventory as shown and managed in NYSIIS may have to be modified, per the attached guidance.

This guidance applies to the Moderna vaccine only.

Thank you for your hard work as vaccinators and recipients of COVID-19 vaccines.

Sincerely,

Howard Zucker M.D.

Howard A. Zucker, M.D., J.D.
Commissioner

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Moderna COVID-19 Vaccine Vial Extra Doses- Guidance on the use of the New York State Immunization Information System (NYSIIS)

December 23, 2020

The New York State Department of Health has learned that COVID-19 vaccine providers have been able to withdraw more than 10 doses from one vial of the Moderna vaccine. As a result, the New York State Department of Health (NYSDOH) provides the following guidance after consulting with the FDA and the manufacturer:

- Vaccinators may withdraw more than 10 doses from a single 10-dose vial.
- **Extra vaccine fluid from more than one vial CANNOT be combined to produce extra doses**. This is particularly important because the vaccination doesn't contain preservatives.
- Use any extra vaccine that can easily be drawn up in a syringe to meet the 0.5 ml dose requirement. This may be 11 doses.
- Enter all vaccines given into NYSIIS, including any additional vaccines given.
- Inventory as shown and managed in NYSIIS will have to be modified, as below.

How does a site manage the reporting of this additional dose to NYSIIS?

NYSIIS will be able to accept the reporting of all COVID-19 doses administered, and this potential for additional doses will be accepted by NYSIIS without any modification needed. The impact will be on an organization's Moderna inventory in NYSIIS. As doses are reported, inventory in NYSIIS will automatically decrease, reflecting usage. This is dependent on an organization having accepted the inventory in NYSIIS and accurately reporting lot number.

Do not modify inventory until doses have been used! In other words, don't increase the inventory in NYSIIS in anticipation of using more doses. This is NOT best practice.

How to Manually Modify Inventory in NYSIIS

If necessary, inventory can be manually modified in NYSIIS. If you need to modify inventory, log into NYSIIS Production, access your organization and click on Manage Inventory, however, **do not increase inventory in anticipation of additional doses**.

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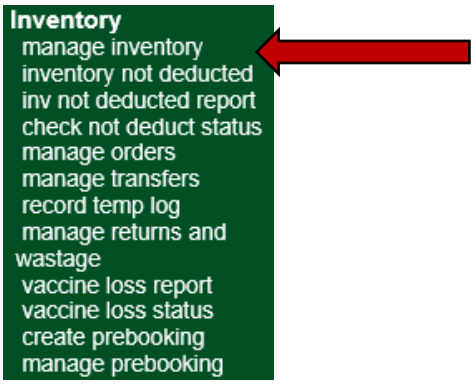
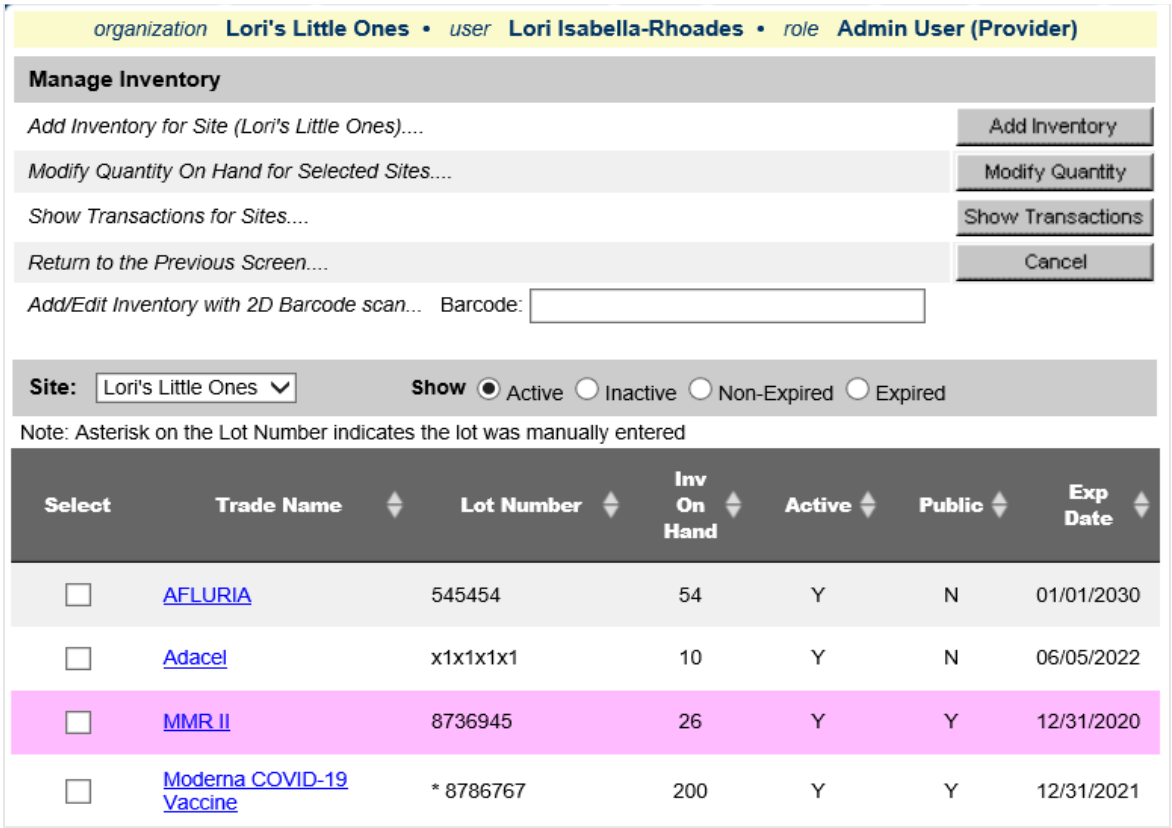
Note: You must have Administrative User access in NYSIIS to view the Inventory panel.

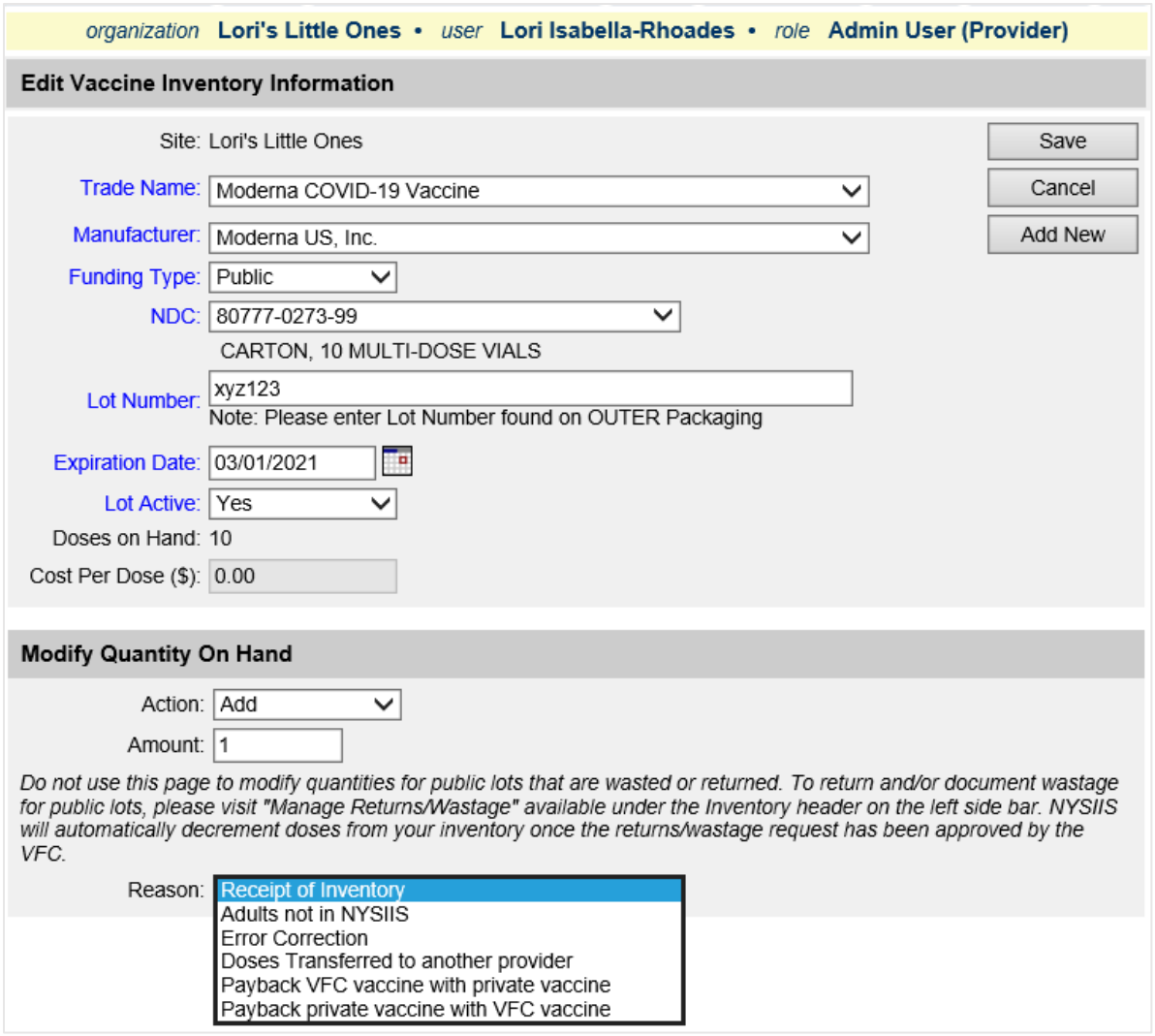


Next, click the Show Inventory button at the top right of the screen. You will be directed to the Manage Inventory Screen.



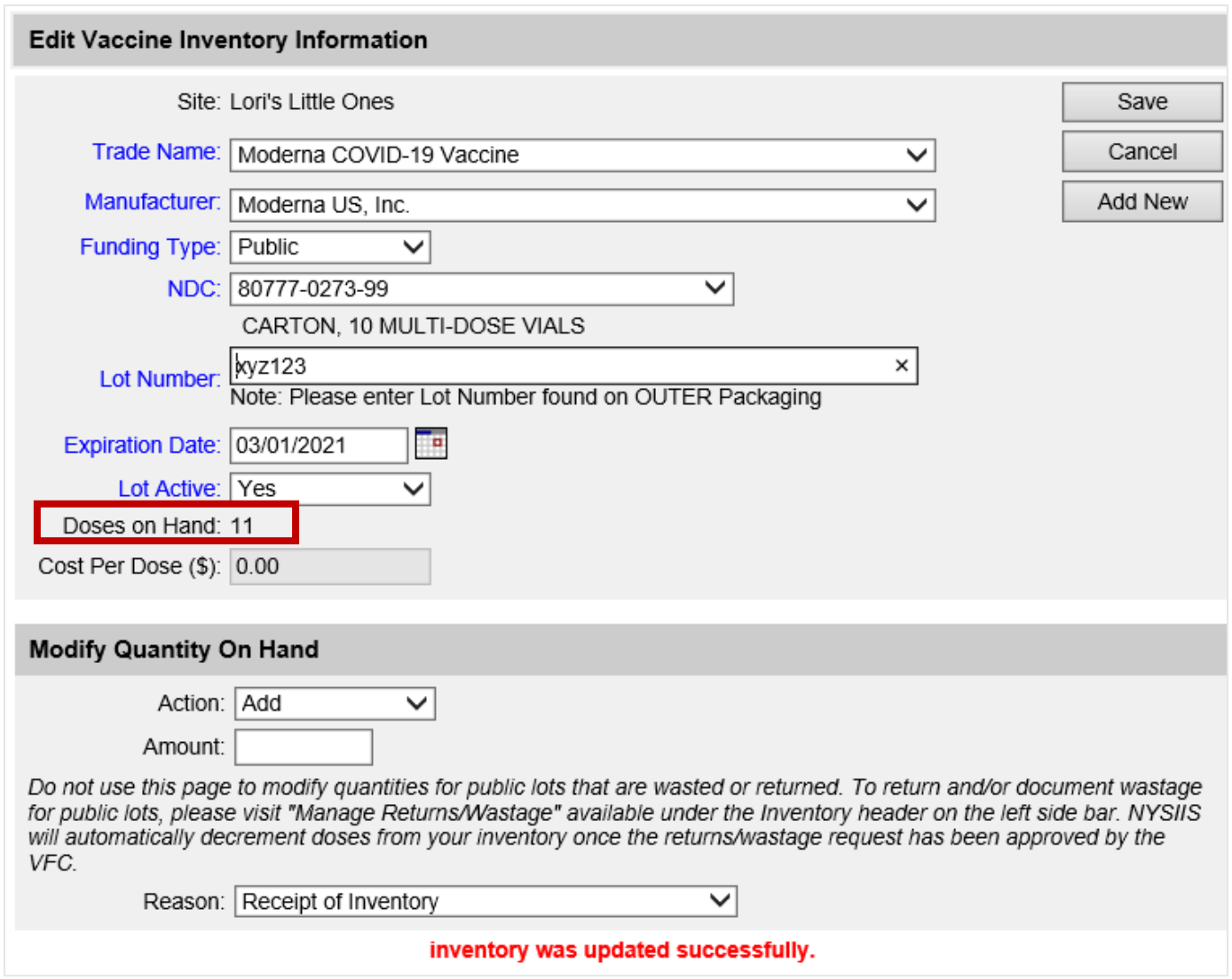
Choose the vaccine lot you want to edit, either by clicking the Trade Name hyperlink, or clicking the Select checkbox to the left of the Trade Name, then click the Modify Quantity button on the top right of the screen.

NYSIIS will direct you to the Edit Inventory Screen.



Towards the bottom of the screen, under the Modify Quantity on Hand header, choose an action. The choices are Add or Subtract. Next, enter the number of doses you want to modify in the Amount field.

Last, choose your reason for modifying, from the Reason drop down and click Save.



You will be alerted that your inventory was updated successfully, and your Doses on Hand will update.

Non Patient-Specific Standing Order for the Administration of the Moderna COVID-19 Vaccination for the Initial Phase of the COVID-19 Vaccination Program

Purpose: To reduce morbidity and mortality from COVID-19 by administering the Moderna COVID-19 vaccination as permitted by its Emergency Use Authorization (EUA) to individuals in accordance with the Centers 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,

insert clinical staff titles

who are

employees, volunteers, [and/or] contractors

of the

insert organization name

who have satisfied all applicable training requirements for vaccination as set forth in law and by Executive Order 202.82 may administer the Moderna COVID-19 vaccination to

insert description of the group of individuals being vaccinated, including age ranges

, as permitted by its Emergency Use Authorization (EUA) to individuals in accordance with the CDC's Vaccination Program and recommendations issued by ACIP.

Procedure:

1. **Assess for vaccine eligibility**
    a. Persons 18 years of age or older and in one or more of the current priority groups designated by the NYSDOH.

2. **Screen for contraindications and precautions**
    a. **Contraindications**: Do not administer the Moderna vaccine to anyone with a known history of a severe allergic reaction (e.g., anaphylaxis) to a prior dose of the Moderna vaccine or to polyethylene glycol or any other vaccine component listed in the prescribing information at https://www.fda.gov/media/144637/download. Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.5 mL of the Moderna COVID-19 Vaccine.

b. **Precautions:**

i. In persons who report a history of a severe allergic reaction (e.g., anaphylaxis) to any vaccine or injectable therapy (intramuscular, intravenous, or subcutaneous) conduct a risk assessment to determine the type of reaction and certainty of information. For example, whether the medication was administered via injection and whether the reaction constituted a severe allergic reaction (e.g., required use of epinephrine and/or hospitalization). Counsel these patients about the unknown risks of developing a severe allergic reaction and the benefits of COVID-19 vaccination, including the patient's current personal risks of COVID-19 and current COVID-19 transmission in their community. This precaution does not apply to persons with a mild allergic reaction, such as urticaria alone without signs or symptoms of anaphylaxis, nor to allergic reactions not related to vaccines or injectable therapy (e.g., pet, venom, environmental, food, latex or medications given orally).

ii. Defer administering the Moderna vaccine to people who are moderately to severely ill with an acute illness until they have recovered.

iii. Defer administering the Moderna vaccine for at least 90 days after receipt of antibody therapy for COVID-19 infection in order to avoid interference of antibody therapy with vaccine-induced immune responses.

iv. Defer administration of the Moderna vaccine to anyone who has received a different vaccine in the last 14 days.

3. Provide information on the Moderna 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 Moderna COVID-19 Vaccine, including: (1) FDA has authorized the emergency use of the Moderna COVID-19 Vaccine, which is not an FDA-approved vaccine; (2) The recipient or their caregiver has the option to accept or refuse Moderna COVID-19 Vaccine; (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.

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 https://www.modernatx.com/covid19vaccine-eua/ 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 consent to administer the vaccine from the patient or the patient's legal guardian, as applicable.

insert how the Organization will be documenting consent and what forms will be used

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

4. Storage and Handling of Vaccine

a. The Moderna COVID-19 Vaccine multiple-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.

b. Moderna 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 ten patients.

c. Thawing under refrigeration: Thaw in the refrigerator between 2 ^{0}C to 8 ^{0}C (36 ^{0}F to 46 ^{0}F) for 2 hours and 30 minutes. After thawing, let stand at room temperature for 15 minutes before administering. Vials can be in the refrigerator for up to 30 days prior to first use.

d. Thawing at room temperature: Vials will thaw at room temperature between 15 ^{0}C to 25 ^{0}C (59 ^{0}F to 77 ^{0}F) in 1 hour. Unpunctured vials may be stored between 8° to 25°C (46° to 77°F) for up to 12 hours. Do not thaw a vial at room temperature unless you are prepared to vaccinate 10 persons within 12 hours.

e. Do not refreeze vials once thawed.

5. Prepare to administer vaccine

a. Moderna 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. Swirl vial gently after thawing and between each withdrawal. Do not shake. Do not dilute 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 or translucent particulates. Do not use if liquid is discolored or if other particles are observed. Notify the NYSDOH at 1-800-543-7468 if you need to discard vaccine.

e. 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)**.

f. Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.5 mL of the Moderna COVID-19 Vaccine.

g. After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Record the date and time of first use on the Moderna COVID-19 Vaccine vial label. Discard vial after 6 hours. Do not refreeze.

6. Administer vaccine

a. Visually inspect each dose in the dosing syringe prior to administration.

a. Verify the final dosing volume of 0.5 mL.

b. Confirm there are no particulates and that no discoloration is observed.

c. Do not administer if vaccine is discolored or contains particulate matter.

d. Call the manufacturer and the NYSDOH if the vaccine is discolored or contains particulate matter.

b. Administer the Moderna COVID-19 Vaccine, 0.5 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 (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 person administering the vaccine, the publication date of the EUA fact sheet and the date it was given to the patient is documented in CDMS. 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.

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. Request the patient to attest, in writing on the certificate of immunization, that they will provide a copy of the certificate to their primary care provider, if one exists.

New York State Immunization Information System (NYSIIS) and City Immunization Registry (CIR): Report all doses administered to NYSIIS or CIR within 24 hours of administration. [If using CDMS] 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

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. RNs 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

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 Multisystem Inflammatory Syndrome in children and adults

iv. Cases of COVID-19 that result in hospitalization or death

[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.

Order: In accordance with Governor Cuomo's Executive Order No. 202.82, and subject to the Purpose, Policy and Procedure set forth herein, I am hereby prescribing this non patient-specific order to administration of Moderna COVID-19 Vaccine on

insert dates of testing and locations

Specifically,

insert staff titles

who are employees, volunteers, or contractors of the

insert Organization

may administer Moderna COVID-19 Vaccine as permitted by its Emergency Use Authorization (EUA) to

insert description of the group of individual being vaccinated, including age ranges

, in accordance with the CDC Vaccination Program and recommendations issued by the ACIP.
This non patient-specific order shall remain in effect for the vaccination of any individuals as set forth herein, beginning on insert date through insert date .

In the event that I discontinue this non patient-specific order prior to insert end date as listed above , notice of such discontinuance shall be provided to those

insert Organization

employees and contractors permitted to execute under this Order via

insert how employees and contractors will be notified of a discontinuance

Signature: _____ Date: _____

Name of Physician: _____

Title: _____

Institution: _____

NYS License No.: _____

Effective Date of Order: _____