FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)
EMERGENCY USE AUTHORIZATION (EUA) OF THE MODERNA COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, **MODERNA COVID-19 VACCINE,** for active immunization to prevent COVID-19 in individuals 18 years of age and older.

SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS
Vaccination providers enrolled in the federal COVID-19 Vaccination Program must report all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults, and cases of COVID-19 that result in hospitalization or death following administration of the Moderna COVID-19 Vaccine. See "MANDATORY REQUIREMENTS FOR THE MODERNA COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION" for reporting requirements.

The Moderna COVID-19 Vaccine is a suspension for intramuscular injection administered as a series of two doses (0.5 mL each) 1 month apart.

See this Fact Sheet for instructions for preparation and administration. This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.modernatx.com/covid19vaccine-eua.

For information on clinical trials that are testing the use of the Moderna COVID-19 Vaccine for active immunization against COVID-19, please see www.clinicaltrials.gov.

DESCRIPTION OF COVID-19
Coronavirus disease 2019 (COVID-19) is an infectious disease caused by the novel coronavirus, SARS-CoV-2, that appeared in late 2019. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have reported a wide range of symptoms, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle and body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

DOSAGE AND ADMINISTRATION

Storage and Handling
The storage and handling information in this Fact Sheet supersedes the storage and handling information on the vial and carton labels.

Storage Prior to Use

As Displayed on the Vial Labels and Cartons

The Moderna COVID-19 Vaccine multiple-dose vials are stored frozen between -25º to -15ºC (-13º to 5ºF). Store in the original carton to protect from light.

Additional Storage Information Not Displayed on the Vial Labels and Cartons

Do not store on dry ice or below -40ºC (-40ºF).

Vials can be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use.

Unpunctured vials may be stored between 8° to 25°C (46° to 77°F) for up to 12 hours.

Do not refreeze once thawed.

Storage After First Puncture of the Vaccine Vial

After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Discard vial after 6 hours. Do not refreeze.

Dosing and Schedule
The Moderna COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.5 mL each) 1 month apart.

There are no data available on the interchangeability of the Moderna COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of the Moderna COVID-19 Vaccine should receive a second dose of the Moderna COVID-19 Vaccine to complete the vaccination series.

Dose Preparation
- The Moderna COVID-19 Vaccine multiple-dose vial contains a frozen suspension that does not contain a preservative and must be thawed prior to administration.
- Remove the required number of vial(s) from storage and thaw each vial before use.
- Thaw in refrigerated conditions between 2° to 8°C (36° to 46°F) for 2 hours and 30 minutes. After thawing, let vial stand at room temperature for 15 minutes before administering.
- Alternatively, thaw at room temperature between 15° to 25°C (59° to 77°F) for 1 hour.
- After thawing, do not refreeze.
- Swirl vial gently after thawing and between each withdrawal. **Do not shake.** Do not dilute the vaccine.
- The Moderna COVID-19 Vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates. Visually inspect the Moderna COVID-

19 Vaccine vials for other particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
- Each dose is 0.5 mL.
- 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.

Administration
Visually inspect each dose of the Moderna COVID-19 Vaccine in the dosing syringe prior to administration. The white to off-white suspension may contain white or translucent product-related particulates. During the visual inspection,
- verify the final dosing volume of 0.5 mL.
- confirm there are no other particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains other particulate matter.

Administer the Moderna COVID-19 Vaccine intramuscularly.

CONTRAINDICATION
Do not administer the Moderna COVID-19 Vaccine to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 Vaccine *(see Full EUA Prescribing Information)*.

WARNINGS
Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Moderna COVID-19 Vaccine.

Monitor Moderna COVID-19 vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/).

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Moderna COVID-19 Vaccine.

The Moderna COVID-19 Vaccine may not protect all vaccine recipients.

ADVERSE REACTIONS
Adverse reactions reported in a clinical trial following administration of the Moderna COVID-19 Vaccine include pain at the injection site, fatigue, headache, myalgia, arthralgia, chills, nausea/vomiting, axillary swelling/tenderness, fever, swelling at the injection site, and erythema at the injection site. *(See Full EUA Prescribing Information)*

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Moderna COVID-19 Vaccine.

USE WITH OTHER VACCINES

There is no information on the co-administration of the Moderna COVID-19 Vaccine with other vaccines.

INFORMATION TO PROVIDE TO VACCINE RECIPIENTS/CAREGIVERS

As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the "Fact Sheet for Recipients and Caregivers" (and provide a copy or direct the individual to the website www.modernatx.com/covid19vaccine-eua to obtain the Fact Sheet) prior to the individual receiving the Moderna COVID-19 Vaccine, including:

- FDA has authorized the emergency use of the Moderna COVID-19 Vaccine, which is not an FDA-approved vaccine.
- The recipient or their caregiver has the option to accept or refuse the Moderna COVID-19 Vaccine.
- The significant known and potential risks and benefits of the Moderna COVID-19 Vaccine, and the extent to which such risks and benefits are unknown.
- Information about available alternative vaccines and the risks and benefits of those alternatives

For information on clinical trials that are evaluating the use of the Moderna COVID-19 Vaccine to prevent COVID-19, please see www.clinicaltrials.gov.

Provide a vaccination card to the recipient or their caregiver with the date when the recipient needs to return for the second dose of Moderna COVID-19 Vaccine.

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.

MANDATORY REQUIREMENTS FOR MODERNA COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION

In order to mitigate the risks of using this unapproved product under EUA and to optimize the potential benefit of the Moderna COVID-19 Vaccine, the following items are required. Use of unapproved Moderna COVID-19 Vaccine for active immunization to prevent COVID-19 under this EUA is limited to the following (all requirements **must** be met):

1. The Moderna COVID-19 Vaccine is authorized for use in individuals 18 years of age and older.

2. The vaccination provider must communicate to the individual receiving the Moderna COVID-19 Vaccine or their caregiver, information consistent with the "Fact Sheet for Recipients and Caregivers" prior to the individual receiving the Moderna COVID-19 Vaccine.

3. The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system.

4. The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):
    - vaccine administration errors whether or not associated with an adverse event,
    - serious adverse events* (irrespective of attribution to vaccination),
    - cases of Multisystem Inflammatory Syndrome (MIS) in adults, and
    - cases of COVID-19 that result in hospitalization or death.

    Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. For further assistance with reporting to VAERS, call 1-800-822-7967. The reports should include the words "Moderna COVID- 19 Vaccine EUA" in the description section of the report.

5. The vaccination provider is responsible for responding to FDA requests for information about vaccine administration errors, adverse events, cases of MIS in adults and cases of COVID-19 that result in hospitalization or death following administration of the Moderna COVID-19 Vaccine to recipients.

*Serious adverse events are defined as:
- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- 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.

OTHER ADVERSE EVENT REPORTING TO VAERS AND MODERNATX, INC.
Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to ModernaTX, Inc. using the contact information below or by providing a copy of the VAERS form to ModernaTX, Inc.

Email	Fax number	Telephone number
ModernaPV@modernatx.com	1-866-599-1342	1-866-MODERNA (1-866-663-3762)

ADDITIONAL INFORMATION
For general questions, visit the website or call the telephone number provided below.

To access the most recent Moderna COVID-19 Vaccine Fact Sheets, please scan the QR code or visit the website provided below.

Website	Telephone number
www.modernatx.com/covid19vaccine-eua 	1-866-MODERNA (1-866-663-3762)

AVAILABLE ALTERNATIVES
There is no approved alternative vaccine to prevent COVID-19. There may be clinical trials or availability under EUA of other COVID-19 vaccines.

AUTHORITY FOR ISSUANCE OF THE EUA
The Secretary of the Department of Health and Human Services (HHS) has declared a public health emergency that justifies the emergency use of drugs and biological products during the COVID-19 Pandemic. In response, the FDA has issued an EUA for the unapproved product, Moderna COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 18 years of age and older.

FDA issued this EUA, based on ModernaTX, Inc.'s request and submitted data.

Although limited scientific information is available, based on the totality of the scientific evidence available to date, it is reasonable to believe that the Moderna COVID-19 Vaccine may be effective for the prevention of COVID-19 in individuals as specified in the *Full EUA Prescribing Information*.

This EUA for the Moderna COVID-19 Vaccine will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.

For additional information about Emergency Use Authorization visit FDA at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

COUNTERMEASURES INJURY COMPENSATION PROGRAM
The Countermeasures Injury Compensation Program (CICP) is a federal program that has been created to help pay for related costs of medical care and other specific expenses to compensate people injured after use of certain medical countermeasures. Medical countermeasures are

specific vaccines, medications, devices, or other items used to prevent, diagnose, or treat the public during a public health emergency or a security threat. For more information about CICP regarding the vaccines to prevent COVID-19, visit http://www.hrsa.gov/cicp, email cicp@hrsa.gov, or call: 1-855-266-2427.

Patent(s): www.modernatx.com/patents
Revised: 12/2020

END SHORT VERSION FACT SHEET
Long Version (Full EUA Prescribing Information) Begins On Next Page

FULL EMERGENCY USE AUTHORIZATION (EUA)
PRESCRIBING INFORMATION

MODERNA COVID-19 VACCINE

FULL EUA PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed

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FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

1 AUTHORIZED USE

Moderna COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

2 DOSAGE AND ADMINISTRATION

For intramuscular injection only.

2.1 Preparation for Administration

- The Moderna COVID-19 Vaccine multiple-dose vial contains a frozen suspension that does not contain a preservative and must be thawed prior to administration.
- Remove the required number of vial(s) from storage and thaw each vial before use.
- Thaw in refrigerated conditions between 2° to 8°C (36° to 46°F) for 2 hours and 30 minutes. After thawing, let vial stand at room temperature for 15 minutes before administering.
- Alternatively, thaw at room temperature between 15° to 25°C (59° to 77°F) for 1 hour.
- After thawing, do not refreeze.
- Swirl vial gently after thawing and between each withdrawal. **Do not shake.** Do not dilute the vaccine.
- The Moderna COVID-19 Vaccine is a white to off-white suspension. It may contain

white or translucent product-related particulates. Visually inspect the Moderna COVID-19 Vaccine vials for other particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.

- Each dose is 0.5mL.
- 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.

2.2 Administration

Visually inspect each dose of the Moderna COVID-19 Vaccine in the dosing syringe prior to administration. The white to off-white suspension may contain white or translucent product-related particulates. During the visual inspection,

- verify the final dosing volume of 0.5 mL.
- confirm there are no other particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains other particulate matter.

Administer the Moderna COVID-19 Vaccine intramuscularly.

2.3 Dosing and Schedule

The Moderna COVID-19 Vaccine is administered as a series of two doses (0.5 mL each) 1 month apart.

There are no data available on the interchangeability of the Moderna COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Moderna COVID-19 Vaccine should receive a second dose of Moderna COVID-19 Vaccine to complete the vaccination series.

3 DOSAGE FORMS AND STRENGTHS

Moderna COVID-19 Vaccine is a suspension for intramuscular injection. A single dose is 0.5 mL.

4 CONTRAINDICATIONS

Do not administer the Moderna COVID-19 Vaccine to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 Vaccine *[see Description (13)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Management of Acute Allergic Reactions

Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Moderna COVID-19 Vaccine.

Monitor Moderna COVID-19 vaccine recipients for the occurrence of immediate adverse

reactions according to the Centers for Disease Control and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/).

5.2 Altered Immunocompetence
Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished response to the Moderna COVID-19 Vaccine.

5.3 Limitations of Vaccine Effectiveness
The Moderna COVID-19 Vaccine may not protect all vaccine recipients.

6 OVERALL SAFETY SUMMARY

It is MANDATORY for vaccination providers to report to the Vaccine Adverse Event Reporting System (VAERS) all vaccine administration errors, all serious adverse events, cases of Multi-inflammatory Syndrome (MIS) in adults, and hospitalized or fatal cases of COVID-19 following vaccination with the Moderna COVID-19 Vaccine. To the extent feasible, provide a copy of the VAERS form to ModernaTX, Inc. Please see the REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS section for details on reporting to VAERS and ModernaTX, Inc.

In clinical studies, the adverse reactions in participants 18 years of age and older were pain at the injection site (92.0%), fatigue (70.0%), headache (64.7%), myalgia (61.5%), arthralgia (46.4%), chills (45.4%), nausea/vomiting (23.0%), axillary swelling/tenderness (19.8%), fever (15.5%), swelling at the injection site (14.7%), and erythema at the injection site (10.0%).

6.1 Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared with rates in the clinical trials of another vaccine and may not reflect the rates observed in practice.

Overall, 15,419 participants aged 18 years and older received at least one dose of Moderna COVID- 19 Vaccine in three clinical trials (NCT04283461, NCT04405076, and NCT04470427).

The safety of Moderna COVID-19 Vaccine was evaluated in an ongoing Phase 3 randomized, placebo-controlled, observer-blind clinical trial conducted in the United States involving 30,351 participants 18 years of age and older who received at least one dose of Moderna COVID-19 Vaccine (n=15,185) or placebo (n=15,166) (NCT04470427). At the time of vaccination, the mean age of the population was 52 years (range 18-95); 22,831 (75.2%) of participants were 18 to 64 years of age and 7,520 (24.8%) of participants were 65 years of age and older. Overall, 52.7% were male, 47.3% were female, 20.5% were Hispanic or Latino, 79.2% were White,10.2% were African American, 4.6% were Asian, 0.8% were American Indian or Alaska Native, 0.2% were Native Hawaiian or Pacific Islander, 2.1% were Other, and 2.1% were Multiracial. Demographic characteristics were similar among participants who received Moderna COVID-19 Vaccine and those who received placebo.

Solicited Adverse Reactions

Data on solicited local and systemic adverse reactions and use of antipyretic medication were collected using standardized diary cards for 7 days following each injection (i.e., day of vaccination and the next 6 days) among participants receiving Moderna COVID-19 Vaccine (n=15,179) and participants receiving placebo (n=15,163) with at least 1 documented dose. Solicited adverse reactions were reported more frequently among vaccine participants than placebo participants.

The reported number and percentage of the solicited local and systemic adverse reactions by age group and dose by subject are presented in Table 1 and Table 2, respectively.

Table 1: Number and Percentage of Participants With Solicited Local and Systemic Adverse Reactions Within 7 Days* After Each Dose in Participants 18-64 Years (Solicited Safety Set, Dose 1 and Dose 2)

	Moderna COVID-19 Vaccine		**Placebo[a]**	
	Dose 1 (N=11,406) n (%)	**Dose 2** (N=10,985) n (%)	**Dose 1** (N=11,407) n (%)	**Dose 2** (N=10,918) n (%)
Local Adverse Reactions				
Pain	9,908 (86.9)	9,873 (89.9)	2,177 (19.1)	2,040 (18.7)
Pain, Grade 3[b]	366 (3.2)	506 (4.6)	23 (0.2)	22 (0.2)
Axillary swelling/tenderness	1,322 (11.6)	1,775 (16.2)	567 (5.0)	470 (4.3)
Axillary swelling/tenderness, Grade 3[b]	37 (0.3)	46 (0.4)	13 (0.1)	11 (0.1)
Swelling (hardness) ≥25 mm	767 (6.7)	1,389 (12.6)	34 (0.3)	36 (0.3)
Swelling (hardness), Grade 3[c]	62 (0.5)	182 (1.7)	3 (<0.1)	4 (<0.1)
Erythema (redness) ≥25 mm	344 (3.0)	982 (8.9)	47 (0.4)	43 (0.4)
Erythema (redness), Grade 3[c]	34 (0.3)	210 (1.9)	11 (<0.1)	12 (0.1)
Systemic Adverse Reactions				
Fatigue	4,384 (38.4)	7,430 (67.6)	3,282 (28.8)	2,687 (24.6)
Fatigue, Grade 3[d]	120 (1.1)	1,174 (10.7)	83 (0.7)	86 (0.8)
Fatigue, Grade 4[e]	1 (<0.1)	0 (0)	0 (0)	0 (0)
Headache	4,030 (35.3)	6,898 (62.8)	3,304 (29.0)	2,760 (25.3)
Headache, Grade 3[f]	219	553	162	129

	Moderna COVID-19 Vaccine		Placebo[a]	
	Dose 1 (N=11,406) n (%)	**Dose 2** (N=10,985) n (%)	**Dose 1** (N=11,407) n (%)	**Dose 2** (N=10,918) n (%)
	(1.9)	(5.0)	(1.4)	(1.2)
Myalgia	2,699 (23.7)	6,769 (61.6)	1,628 (14.3)	1,411 (12.9)
Myalgia, Grade 3[d]	73 (0.6)	1,113 (10.1)	38 (0.3)	42 (0.4)
Arthralgia	1,893 (16.6)	4,993 (45.5)	1,327 (11.6)	1,172 (10.7)
Arthralgia, Grade 3[d]	47 (0.4)	647 (5.9)	29 (0.3)	37 (0.3)
Arthralgia, Grade 4[e]	1 (<0.1)	0 (0)	0 (0)	0 (0)
Chills	1,051 (9.2)	5,341 (48.6)	730 (6.4)	658 (6.0)
Chills, Grade 3[g]	17 (0.1)	164 (1.5)	8 (<0.1)	15 (0.1)
Nausea/vomiting	1,068 (9.4)	2,348 (21.4)	908 (8.0)	801 (7.3)
Nausea/vomiting, Grade 3[h]	6 (<0.1)	10 (<0.1)	8 (<0.1)	8 (<0.1)
Fever	105 (0.9)	1,908 (17.4)	37 (0.3)	39 (0.4)
Fever, Grade 3[i]	10 (<0.1)	184 (1.7)	1 (<0.1)	2 (<0.1)
Fever, Grade 4[j]	4 (<0.1)	12 (0.1)	4 (<0.1)	2 (<0.1)
Use of antipyretic or pain medication	2,656 (23.3)	6,292 (57.3)	1,523 (13.4)	1,248 (11.4)

* 7 days included day of vaccination and the subsequent 6 days. Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary).

[a] Placebo was a saline solution.

[b] Grade 3 pain and axillary swelling/tenderness: Defined as any use of prescription pain reliever; prevents daily activity.

[c] Grade 3 swelling and erythema: Defined as >100 mm / >10 cm.

[d] Grade 3 fatigue, myalgia, arthralgia: Defined as significant; prevents daily activity.

[e] Grade 4 fatigue, arthralgia: Defined as requires emergency room visit or hospitalization.

[f] Grade 3 headache: Defined as significant; any use of prescription pain reliever or prevents daily activity.

[g] Grade 3 chills: Defined as prevents daily activity and requires medical intervention.

[h] Grade 3 nausea/vomiting: Defined as prevents daily activity, requires outpatient intravenous hydration.

[i] Grade 3 fever: Defined as ≥39.0 – ≤40.0°C / ≥102.1 – ≤104.0°F.

[j] Grade 4 fever: Defined as >40.0°C / >104.0°F.

Table 2: Number and Percentage of Participants With Solicited Local and Systemic Adverse Reactions Within 7 Days* After Each Dose in Participants 65 Years and Older (Solicited Safety Set, Dose 1 and Dose 2)

	Moderna COVID-19 Vaccine		Placebo[a]	
	Dose 1 (N=3,762) n (%)	**Dose 2** (N=3,692) n (%)	**Dose 1** (N=3,748) n (%)	**Dose 2** (N=3,648) n (%)
Local Adverse Reactions				
Pain	2,782 (74.0)	3,070 (83.2)	481 (12.8)	437 (12.0)
Pain, Grade 3[b]	50 (1.3)	98 (2.7)	32 (0.9)	18 (0.5)
Axillary swelling/tenderness	231 (6.1)	315 (8.5)	155 (4.1)	97 (2.7)
Axillary swelling/tenderness, Grade 3[b]	12 (0.3)	21 (0.6)	14 (0.4)	8 (0.2)
Swelling (hardness) ≥25 mm	165 (4.4)	400 (10.8)	18 (0.5)	13 (0.4)
Swelling (hardness), Grade 3[c]	20 (0.5)	72 (2.0)	3 (<0.1)	7 (0.2)
Erythema (redness) ≥25 mm	86 (2.3)	275 (7.5)	20 (0.5)	13 (0.4)
Erythema (redness), Grade 3[c]	8 (0.2)	77 (2.1)	2 (<0.1)	3 (<0.1)
Systemic Adverse Reactions				
Fatigue	1,251 (33.3)	2,152 (58.3)	851 (22.7)	716 (19.6)
Fatigue, Grade 3[d]	30 (0.8)	254 (6.9)	22 (0.6)	20 (0.5)
Headache	921 (24.5)	1,704 (46.2)	723 (19.3)	650 (17.8)
Headache, Grade 3[e]	52 (1.4)	106 (2.9)	34 (0.9)	33 (0.9)
Myalgia	742 (19.7)	1,739 (47.1)	443 (11.8)	398 (10.9)
Myalgia, Grade 3[d]	17 (0.5)	205 (5.6)	9 (0.2)	10 (0.3)
Arthralgia	618 (16.4)	1,291 (35.0)	456 (12.2)	397 (10.9)
Arthralgia, Grade 3[d]	13 (0.3)	123 (3.3)	8 (0.2)	7 (0.2)
Chills	202 (5.4)	1,141 (30.9)	148 (4.0)	151 (4.1)
Chills, Grade 3[f]	7 (0.2)	27 (0.7)	6 (0.2)	2 (<0.1)
Nausea/vomiting	194 (5.2)	437 (11.8)	166 (4.4)	133 (3.6)
Nausea/vomiting,	4	10	4	3

	Moderna COVID-19 Vaccine		Placebo[a]	
	Dose 1 (N=3,762) n (%)	**Dose 2** (N=3,692) n (%)	**Dose 1** (N=3,748) n (%)	**Dose 2** (N=3,648) n (%)
Grade 3[g]	(0.1)	(0.3)	(0.1)	(<0.1)
Nausea/vomiting, Grade 4[h]	0 (0)	1 (<0.1)	0 (0)	0 (0)
Fever	10 (0.3)	370 (10.0)	7 (0.2)	4 (0.1)
Fever, Grade 3[i]	1 (<0.1)	18 (0.5)	1 (<0.1)	0 (0)
Fever, Grade 4[j]	0 (0)	1 (<0.1)	2 (<0.1)	1 (<0.1)
Use of antipyretic or pain medication	673 (17.9)	1,546 (41.9)	477 (12.7)	329 (9.0)

* 7 days included day of vaccination and the subsequent 6 days. Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary).

[a] Placebo was a saline solution.

[b] Grade 3 pain and axillary swelling/tenderness: Defined as any use of prescription pain reliever; prevents daily activity.

[c] Grade 3 swelling and erythema: Defined as >100 mm / >10 cm.

[d] Grade 3 fatigue, myalgia, arthralgia: Defined as significant; prevents daily activity.

[e] Grade 3 headache: Defined as significant; any use of prescription pain reliever or prevents daily activity.

[f] Grade 3 chills: Defined as prevents daily activity and requires medical intervention.

[g] Grade 3 Nausea/vomiting: Defined as prevents daily activity, requires outpatient intravenous hydration.

[h] Grade 4 Nausea/vomiting: Defined as requires emergency room visit or hospitalization for hypotensive shock.

[i] Grade 3 fever: Defined as ≥39.0 – ≤40.0°C / ≥102.1 – ≤104.0°F.

[j] Grade 4 fever: Defined as >40.0°C / >104.0°F.

Solicited local and systemic adverse reactions reported following administration of Moderna COVID-19 Vaccine had a median duration of 2 to 3 days.

Grade 3 solicited local adverse reactions were more frequently reported after Dose 2 than Dose 1. Solicited systemic adverse reactions were more frequently reported by vaccine recipients after Dose 2 than after Dose 1.

Unsolicited Adverse Events

Participants were monitored for unsolicited adverse events for up to 28 days following each dose and follow-up is ongoing. Serious adverse events and medically attended adverse events will be recorded for the entire study duration of 2 years. As of November 25, 2020, among participants who had received at least 1 dose of vaccine or placebo (vaccine=15,185, placebo=15,166), unsolicited adverse events that occurred within 28 days following each vaccination were reported by 23.9% of participants (n=3,632) who received Moderna COVID-19 Vaccine and 21.6% of participants (n=3,277) who received placebo. In these analyses, 87.9% of study participants had at least 28 days of follow-up after Dose 2.

Lymphadenopathy-related events that were not necessarily captured in the 7-day e-Diary were reported by 1.1% of vaccine recipients and 0.6% of placebo recipients. These events included lymphadenopathy, lymphadenitis, lymph node pain, vaccination-site lymphadenopathy,

injection-site lymphadenopathy, and axillary mass, which were plausibly related to vaccination. This imbalance is consistent with the imbalance observed for solicited axillary swelling/tenderness in the injected arm.

Hypersensitivity adverse events were reported in 1.5% of vaccine recipients and 1.1% of placebo recipients. Hypersensitivity events in the vaccine group included injection site rash and injection site urticaria, which are likely related to vaccination.

Throughout the same period, there were three reports of Bell's palsy in the Moderna COVID-19 Vaccine group (one of which was a serious adverse event), which occurred 22, 28, and 32 days after vaccination, and one in the placebo group which occurred 17 days after vaccination. Currently available information on Bell's palsy is insufficient to determine a causal relationship with the vaccine.

There were no other notable patterns or numerical imbalances between treatment groups for specific categories of adverse events (including other neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Moderna COVID-19 Vaccine.

Serious Adverse Events

As of November 25, 2020, serious adverse events were reported by 1.0% (n=147) of participants who received Moderna COVID-19 Vaccine and 1.0% (n=153) of participants who received placebo, one of which was the case of Bell's palsy which occurred 32 days following receipt of vaccine.

In these analyses, 87.9% of study participants had at least 28 days of follow-up after Dose 2, and the median follow-up time for all participants was 9 weeks after Dose 2.

There were two serious adverse events of facial swelling in vaccine recipients with a history of injection of dermatological fillers. The onset of swelling was reported 1 and 2 days, respectively, after vaccination and was likely related to vaccination.

There was one serious adverse event of intractable nausea and vomiting in a participant with prior history of severe headache and nausea requiring hospitalization. This event occurred 1 day after vaccination and was likely related to vaccination.

There were no other notable patterns or imbalances between treatment groups for specific categories of serious adverse events (including neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Moderna COVID-19 Vaccine.

8 REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS

See Overall Safety Summary (Section 6) for additional information.

The vaccination provider enrolled in the federal COVID-19 Vaccination Program is responsible for the MANDATORY reporting of the listed events following Moderna COVID-19 Vaccine to

the Vaccine Adverse Event Reporting System (VAERS)

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events* (irrespective of attribution to vaccination)
- Cases of multisystem inflammatory syndrome (MIS) in adults
- Cases of COVID-19 that results in hospitalization or death

*Serious Adverse Events are defined as:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- 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.

Instructions for reporting to VAERS

The vaccination provider enrolled in the federal COVID-19 Vaccination Program should complete and submit a VAERS form to FDA using one of the following methods:

- Complete and submit the report online: https://vaers.hhs.gov/reportevent.html, or
- If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366. If you need additional help submitting a report, you may call the VAERS toll-free information line at 1-800-822-7967 or send an email to info@vaers.org.

IMPORTANT: When reporting adverse events or vaccine administration errors to VAERS, please complete the entire form with detailed information. It is important that the information reported to FDA be as detailed and complete as possible. Information to include:

- Patient demographics (e.g., patient name, date of birth)
- Pertinent medical history
- Pertinent details regarding admission and course of illness
- Concomitant medications
- Timing of adverse event(s) in relationship to administration of Moderna COVID-19 Vaccine
- Pertinent laboratory and virology information
- Outcome of the event and any additional follow-up information if it is available at the time of the VAERS report. Subsequent reporting of follow-up information should be completed if additional details become available.

The following steps are highlighted to provide the necessary information for safety tracking:

1. In Box 17, provide information on Moderna COVID-19 Vaccine and any other vaccines administered on the same day; and in Box 22, provide information on any other vaccines received within one month prior.

2. In Box 18, description of the event:
    a. Write "Moderna COVID-19 Vaccine EUA" as the first line
    b. Provide a detailed report of vaccine administration error and/or adverse event. It is important to provide detailed information regarding the patient and adverse event/medication error for ongoing safety evaluation of this unapproved vaccine. Please see information to include listed above.
3. Contact information:
    a. In Box 13, provide the name and contact information of the prescribing healthcare provider or institutional designee who is responsible for the report.
    b. In Box 14, provide the name and contact information of the best doctor/healthcare professional to contact about the adverse event.
    c. In Box 15, provide the address of the facility where vaccine was given (NOT the healthcare provider's office address).

Other Reporting Instructions

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to ModernaTX, Inc. using the contact information below or by providing a copy of the VAERS form to ModernaTX, Inc.

Email	Fax number	Telephone number
ModernaPV@modernatx.com	1-866-599-1342	1-866-MODERNA (1-866-663-3762)

10 DRUG INTERACTIONS

There are no data to assess the concomitant administration of the Moderna COVID-19 Vaccine with other vaccines.

11 USE IN SPECIFIC POPULATIONS

11.1 Pregnancy

Pregnancy Exposure Registry
There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Moderna COVID-19 Vaccine during pregnancy. Women who are vaccinated with Moderna COVID-19 Vaccine during pregnancy are encouraged to enroll in the registry by calling 1-866-MODERNA (1-866-663-3762).

Risk Summary
All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically

recognized pregnancies is 2% to 4% and 15% to 20%, respectively. Available data on Moderna COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

In a developmental toxicity study, 0.2 mL of a vaccine formulation containing the same quantity of nucleoside-modified messenger ribonucleic acid (mRNA) (100 mcg) and other ingredients included in a single human dose of Moderna COVID-19 Vaccine was administered to female rats by the intramuscular route on four occasions: 28 and 14 days prior to mating, and on gestation days 1 and 13. No vaccine-related adverse effects on female fertility, fetal development or postnatal development were reported in the study.

11.2 Lactation

Risk Summary
Data are not available to assess the effects of Moderna COVID-19 Vaccine on the breastfed infant or on milk production/excretion.

11.3 Pediatric Use
Safety and effectiveness have not been assessed in persons less than 18 years of age. Emergency Use Authorization of Moderna COVID-19 Vaccine does not include use in individuals younger than 18 years of age.

11.4 Geriatric Use
Clinical studies of Moderna COVID-19 Vaccine included participants 65 years of age and older receiving vaccine or placebo, and their data contribute to the overall assessment of safety and efficacy. In an ongoing Phase 3 clinical study, 24.8% (n=7,520) of participants were 65 years of age and older and 4.6% (n=1,399) of participants were 75 years of age and older. Vaccine efficacy in participants 65 years of age and older was 86.4% (95% CI 61.4, 95.2) compared to 95.6% (95% CI 90.6, 97.9) in participants 18 to <65 years of age *[see Clinical Trial Results and Supporting Data for EUA (18)]*. Overall, there were no notable differences in the safety profiles observed in participants 65 years of age and older and younger participants *[*see *Clinical Trials Experience (6.1)]*.

13 DESCRIPTION

Moderna COVID-19 Vaccine is provided as a white to off-white suspension for intramuscular injection. Each 0.5 mL dose of Moderna COVID-19 Vaccine contains 100 mcg of nucleoside-modified messenger RNA (mRNA) encoding the pre-fusion stabilized Spike glycoprotein (S) of SARS-CoV-2 virus.

Each dose of the Moderna COVID-19 Vaccine contains the following ingredients: a total lipid content of 1.93 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), 0.31 mg tromethamine, 1.18 mg tromethamine hydrochloride, 0.043 mg acetic acid, 0.12 mg sodium acetate, and 43.5 mg sucrose.

Moderna COVID-19 Vaccine does not contain a preservative.

The vial stoppers are not made with natural rubber latex.

14 CLINICAL PHARMACOLOGY

14.1 Mechanism of Action

The nucleoside-modified mRNA in the Moderna COVID-19 Vaccine is formulated in lipid particles, which enable delivery of the nucleoside-modified mRNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits an immune response to the S antigen, which protects against COVID-19.

18 CLINICAL TRIAL RESULTS AND SUPPORTING DATA FOR EUA

A Phase 3 randomized, placebo-controlled, observer-blind clinical trial to evaluate the efficacy, safety, and immunogenicity of the Moderna COVID-19 Vaccine in participants 18 years of age and older is ongoing in the United States (NCT04470427). Randomization was stratified by age and health risk: 18 to <65 years of age without comorbidities (not at risk for progression to severe COVID-19), 18 to <65 years of age with comorbidities (at risk for progression to severe COVID-19), and 65 years of age and older with or without comorbidities. Participants who were immunocompromised and those with a known history of SARS-CoV-2 infection were excluded from the study. Participants with no known history of SARS-CoV-2 infection but with positive laboratory results indicative of infection at study entry were included. The study allowed for the inclusion of participants with stable pre-existing medical conditions, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 3 months before enrollment, as well as participants with stable human immunodeficiency virus (HIV) infection. A total of 30,420 participants were randomized equally to receive 2 doses of the Moderna COVID-19 Vaccine or saline placebo 1 month apart. Participants will be followed for efficacy and safety until 24 months after the second dose.

The primary efficacy analysis population (referred to as the Per-Protocol Set), included 28,207 participants who received two doses (at 0 and 1 month) of either Moderna COVID-19 Vaccine (n=14,134) or placebo (n=14,073), and had a negative baseline SARS-CoV-2 status. In the Per-Protocol Set, 47.4% were female, 19.7% were Hispanic or Latino; 79.5% were white, 9.7% were African American, 4.6% were Asian, and 2.1% other races. The median age of participants was 53 years (range 18-95) and 25.3% of participants were 65 years of age and older. Of the study participants in the Per Protocol Set, 18.5% were at increased risk of severe COVID-19 due to at least one pre-existing medical condition (chronic lung disease, significant cardiac disease, severe obesity, diabetes, liver disease, or HIV infection) regardless of age. Between participants who received Moderna COVID-19 Vaccine and those who received placebo, there were no notable differences in demographics or pre-existing medical conditions.

Efficacy Against COVID-19

COVID-19 was defined based on the following criteria: The participant must have experienced at least two of the following systemic symptoms: fever (≥38ºC), chills, myalgia, headache, sore throat, new olfactory and taste disorder(s); or the participant must have experienced at least one of the following respiratory signs/symptoms: cough, shortness of breath or difficulty breathing, or clinical or radiographical evidence of pneumonia; and the participant must have at least one NP swab, nasal swab, or saliva sample (or respiratory sample, if hospitalized) positive for SARS-CoV-2 by RT-PCR. COVID-19 cases were adjudicated by a Clinical Adjudication Committee.

The median length of follow up for efficacy for participants in the study was 9 weeks post Dose 2. There were 11 COVID-19 cases in the Moderna COVID-19 Vaccine group and 185 cases in the placebo group, with a vaccine efficacy of 94.1% (95% confidence interval of 89.3% to 96.8%).

Table 3: Primary Efficacy Analysis: COVID-19* in Participants 18 Years of Age and Older Starting 14 Days After Dose 2 per Adjudication Committee Assessments – Per-Protocol Set

Moderna COVID-19 Vaccine			Placebo			% Vaccine Efficacy (95% CI)†
Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	
14,134	11	3.328	14,073	185	56.510	94.1 (89.3, 96.8)

* COVID-19: symptomatic COVID-19 requiring positive RT-PCR result and at least two systemic symptoms or one respiratory symptom. Cases starting 14 days after Dose 2.
† VE and 95% CI from the stratified Cox proportional hazard model

The subgroup analyses of vaccine efficacy are presented in Table 4.

Table 4: Subgroup Analyses of Vaccine Efficacy: COVID-19* Cases Starting 14 Days After Dose 2 per Adjudication Committee Assessments – Per- Protocol Set

Age Subgroup (Years)	Moderna COVID-19 Vaccine			Placebo			% Vaccine Efficacy (95% CI)*
	Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	
18 to <65	10,551	7	2.875	10,521	156	64.625	95.6 (90.6, 97.9)
≥65	3,583	4	4.595	3,552	29	33.728	86.4 (61.4, 95.2)

* COVID-19: symptomatic COVID-19 requiring positive RT-PCR result and at least two systemic symptoms or one respiratory symptom. Cases starting 14 days after Dose 2.
† VE and 95% CI from the stratified Cox proportional hazard model

Severe COVID-19 was defined based on confirmed COVID-19 as per the primary efficacy endpoint case definition, plus any of the following: Clinical signs indicative of severe systemic illness, respiratory rate ≥30 per minute, heart rate ≥125 beats per minute, SpO2 ≤93% on room air at sea level or PaO2/FIO2 <300 mm Hg; or respiratory failure or ARDS, (defined as needing high-flow oxygen, non-invasive or mechanical ventilation, or ECMO), evidence of shock (systolic blood pressure <90 mmHg, diastolic BP <60 mmHg or requiring vasopressors); or significant acute renal, hepatic, or neurologic dysfunction; or admission to an intensive care unit or death.

Among all participants in the Per-Protocol Set analysis, which included COVID-19 cases confirmed by an adjudication committee, no cases of severe COVID-19 were reported in the Moderna COVID-19 Vaccine group compared with 30 cases reported in the placebo group (incidence rate 9.138 per 1,000 person-years). One PCR-positive case of severe COVID-19 in a vaccine recipient was awaiting adjudication at the time of the analysis.

19 HOW SUPPLIED/STORAGE AND HANDLING

Moderna COVID-19 Vaccine Suspension for Intramuscular Injection, Multiple-Dose Vials are supplied as a carton of 10 multiple-dose vials (NDC 80777-273-99).

Store frozen between -25º to -15ºC (-13º to 5ºF). Store in the original carton to protect from light. Do not store on dry ice or below -40ºC (-40ºF).

Vials can be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use. Do not refreeze.

Unpunctured vials may be stored between 8° to 25°C (46° to 77°F) for up to 12 hours. Do not refreeze.

After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Discard vial after 6 hours. Do not refreeze.

20 PATIENT COUNSELING INFORMATION

Advise the recipient or caregiver to read the Fact Sheet for Recipients and Caregivers.

The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system. Advise recipient or caregiver that more information about IISs can be found at: https://www.cdc.gov/vaccines/programs/iis/about.html.

21 CONTACT INFORMATION

For general questions, send an email or call the telephone number provided below.

Email	Telephone number
medinfo@modernatx.com	1-866-MODERNA (1-866-663-3762)

This EUA Prescribing Information may have been updated. For the most resent Full EUA Prescribing Information, please visit www.modernatx.com/covid19vaccine-eua.

Patent(s): www.modernatx.com/patents
Revised: 12/2020

Updating Inventory in NYSIIS

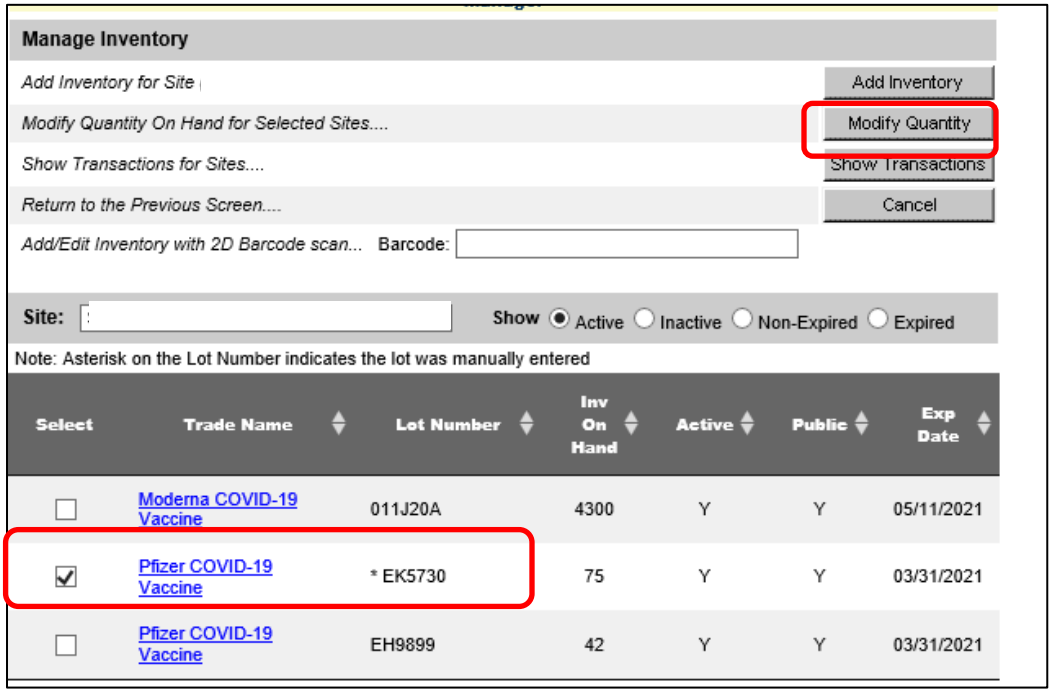
When vaccine inventory is transferred from one facility to another, both the releasing facility and the receiving facility must manually update their vaccine inventory amounts in NYSIIS.

Releasing facility: Subtracting Doses from Inventory

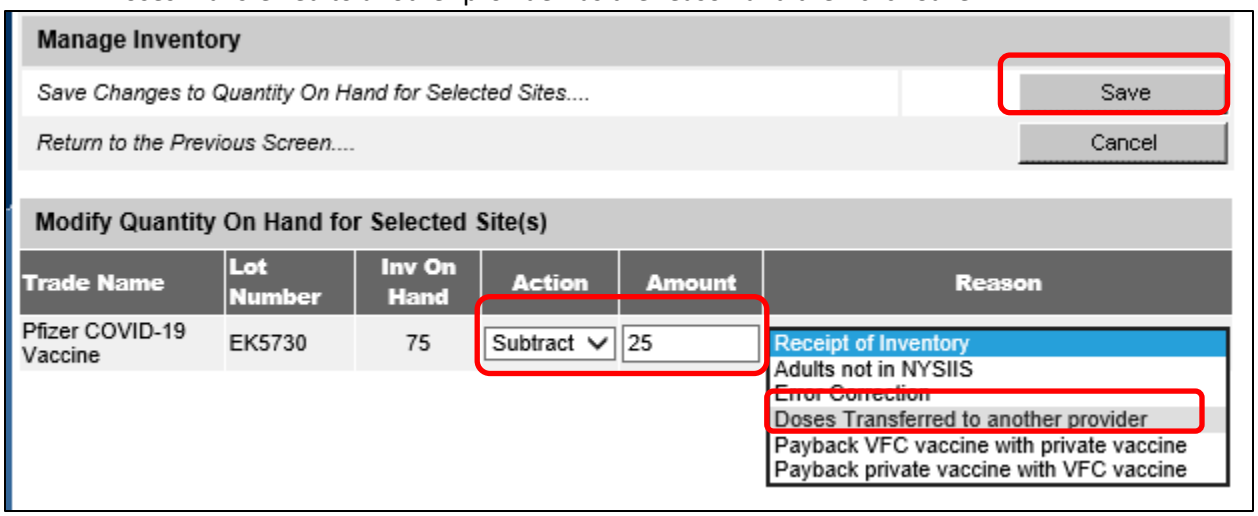
1. Navigate to Manage Inventory screen from the left menu bar.

2. Click Show Inventory

3. Check the box next to the vaccine/lot that was released and click Modify Quantity.

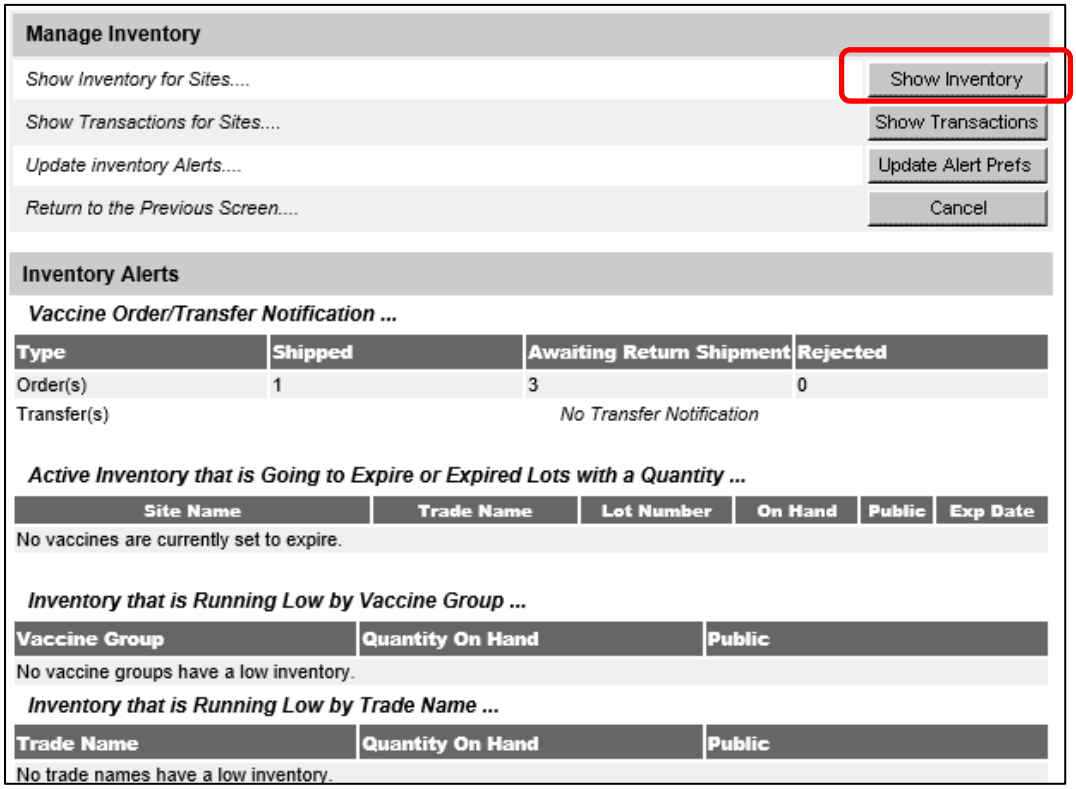


4. In the Action column choose Subtract, enter the number of doses transferred, and choose 'Doses Transferred to another provider' as the reason and then click Save.

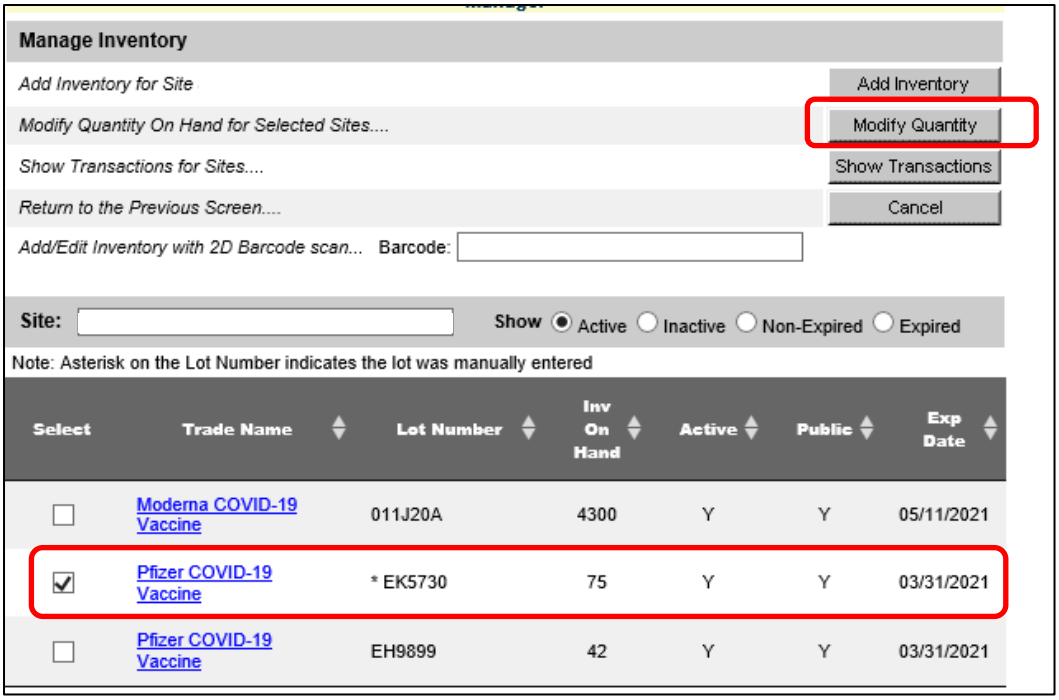


Receiving facility: Adding Doses to Inventory

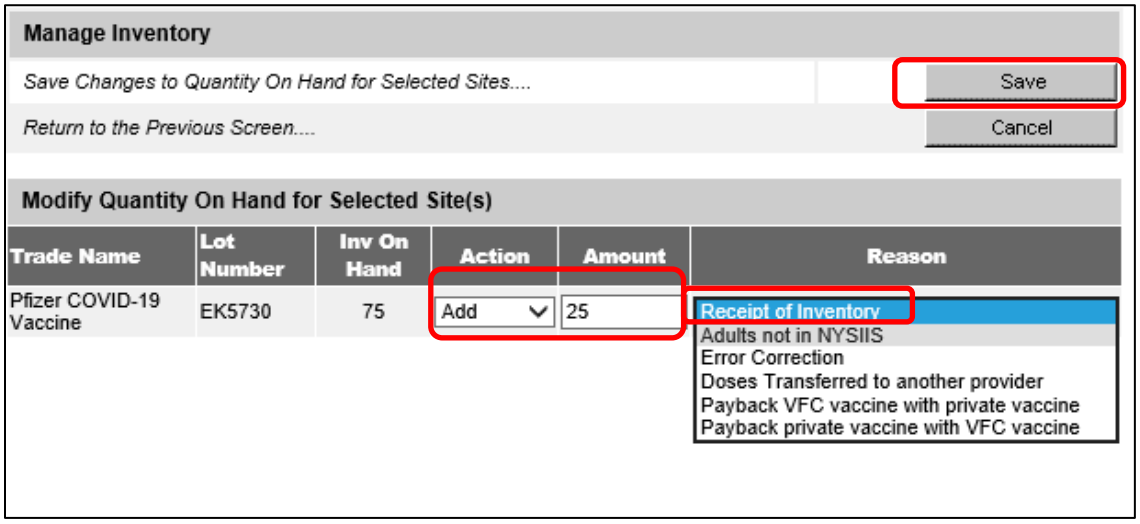
1. Navigate to Manage Inventory screen (see same step as #1 for releasing facility). Click Show Inventory



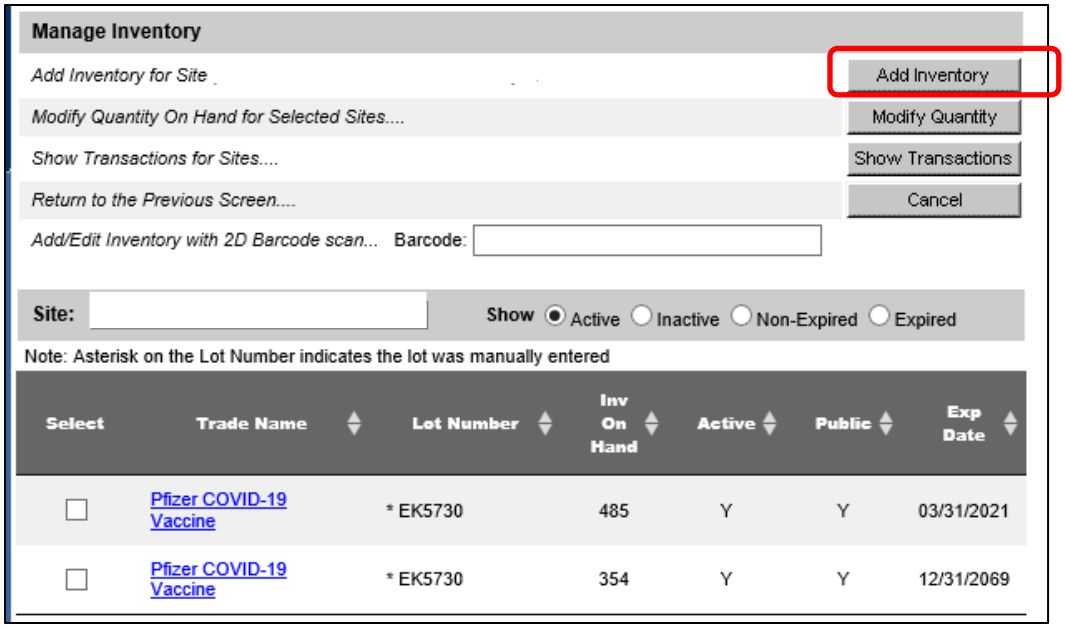
2. If there is already the **same** manufacturer, lot number, fund type (Public) and expiration date in inventory click the box next to it and choose Modify Quantity. If not skip to step 4.



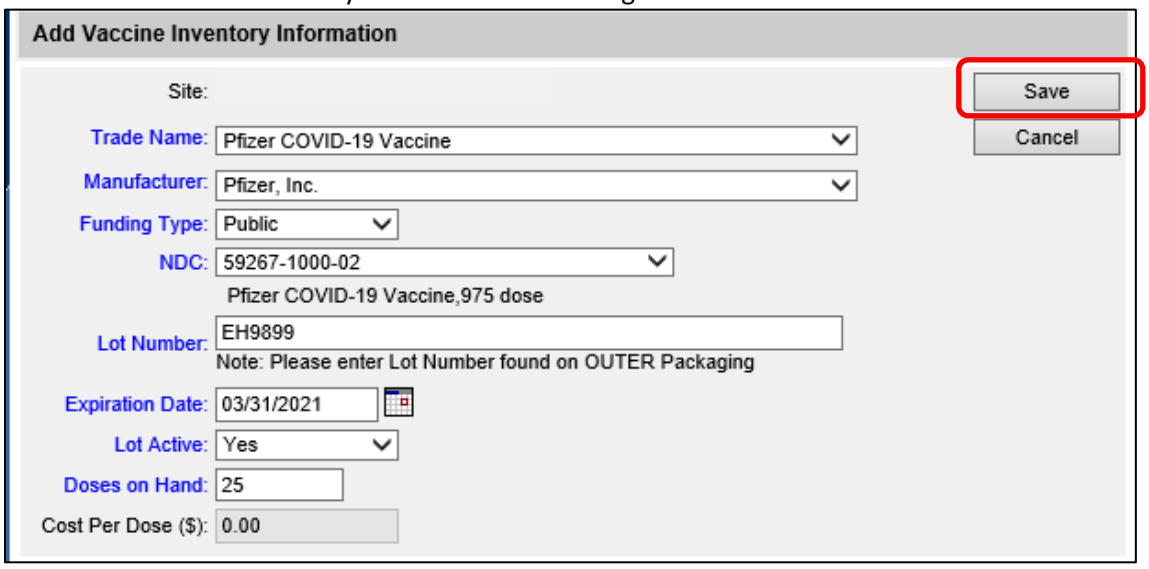
3. In the Action column choose Add, enter the number of doses transferred, and choose 'Receipt of Inventory' as the reason and then click Save.



4. If the vaccine manufacturer, lot number, funding type (Public) and expiration date does not already exist in your inventory, click Add Inventory from the Manage Inventory screen.



5. Add the Vaccine Inventory Information* including the number of doses and click Save.



*All COVID-19 vaccine is Funding Type 'Public'

New York State Department of Health
Bureau of Immunization

COVID-19 Immunization Screening and Consent Form*

Recipient Name (please print)		Preferred Name	
DOB	Current Gender ID Indicate ID Below:	**Key:** W – Woman/Girl TW – Transgender Woman/Girl M – Man/Boy TM – Transgender Man/Boy NB – Non-Binary Person GNC – Gender Non-Conforming Q – Not Sure/Questioning NR – Chose not to Respond GNL – Gender not Listed (write-in) * Gender Pronouns: write-in by client's name	
Sex Assigned at Birth Indicate Sex Below:	**Key:** M – Male F – Female I – Intersex NR – Chose not to Respond SNL – Sexual Orientation not Listed (write-in)	Marital Status Indicate Status Below:	**Key:** S – Single D – Divorced M – Married W – Widowed V – Civil Union U – Unknown SEPARATED – Legally Separated PARTNER – Life Partner
Address City State Zip			Email Address
Parent/Guardian/ Surrogate (if applicable, please print)		Phone	Preferred Language
Ethnicity Indicate Ethnicity Below:	**Ethnicity Key:** DECL – Declined HIS – Hispanic Origin NHL – Non-Hispanic Origin UNK – Unknown	Race Indicate Race Below:	**Race Key:** AIA – Native American or Alaskan ASN – Asian BAA – African American or Black DECL – Declined NHP – Native Hawaiian or Pacific Islander WHT – White OTH – Other or Multiracial
Primary Insurance Name		Primary Insurance ID#	Subscriber Name/DOB / Subscriber Relation to Patient
Primary Insurance Address		Primary Insurance Group #	Primary Insurance Phone #
Secondary Insurance Name		Secondary Insurance ID#	Subscriber Name/DOB / Subscriber Relation to Patient
Secondary Insurance Address		Secondary Insurance Group #	Secondary Insurance Phone #
Clinic/Office Site Where Vaccine is Administered		Primary Care Physician Address/Phone Number	

Screening Questionnaire

1.	Are you feeling sick today?	□ Yes	□ No	
2.	In the last 10 days, have you had a COVID-19 test because you had symptoms and are still awaiting your test results or been told by a health care provider or health department to isolate or quarantine at home due to COVID-19 infection, exposure or travel?	□ Yes	□ No	□ Unknown
3.	Have you been treated with antibody therapy or convalescent plasma for COVID-19 in the past 90 days (3 months)? *If yes, when did you receive the last dose?* Date: _____	□ Yes	□ No	□ Unknown
4.	Have you ever had an immediate allergic reaction (e.g., hives, facial swelling, difficulty breathing, anaphylaxis) to any vaccine, injection, or shot or to any component of the COVID-19 vaccine, or a severe allergic reaction (anaphylaxis) to anything?	□ Yes	□ No	□ Unknown
5.	Have you had any vaccines in the past 14 days (2 weeks) including flu shot? *If yes, how long ago was your most recent vaccine?* Date: _____	□ Yes	□ No	□ Unknown
6.	Are you pregnant or considering becoming pregnant?	□ Yes	□ No	□ Unknown

7.	Do you have cancer, leukemia, HIV/AIDS, a history of autoimmune disease or any other condition that weakens the immune system?	□ Yes	□ No	□ Unknown
8.	Do you take any medications that affect your immune system, such as cortisone, prednisone or other steroids, anticancer drugs, or have you had any radiation treatments?	□ Yes	□ No	□ Unknown
9.	Do you have a bleeding disorder or are you taking a blood thinner?	□ Yes	□ No	□ Unknown
10.	Have you received a previous dose of the COVID-19 vaccine? If yes, which vaccine? □ Moderna □ Pfizer		□ No	Date: _____ (if applicable)

Emergency Use Authorization

The FDA has made the COVID-19 vaccine available under an emergency use authorization (EUA). The EUA is used when circumstances exist to justify the emergency use of drugs and biological products during an emergency, such as the COVID-19 pandemic. This vaccine has not undergone the same type of review as an FDA-approved or cleared product. However, the FDA's decision to make the vaccine available is based on the totality of scientific evidence available, showing that known and potential benefits of the vaccine outweigh the known and potential risks.

Consent

I have read, or had explained to me, the information sheet about the COVID-19 vaccination. I understand that if my vaccine requires two doses, I will need to be administered (given) two doses of this vaccine in order for it to be effective. I have had a chance to ask questions which were answered to my satisfaction (and ensured the person named above for whom I am authorized to provide surrogate consent was also given a chance to ask questions). I understand the benefits and risks of the vaccination as described.

I request that the COVID-19 vaccination be given to me (or the person named above for whom I am authorized to make this request and provide surrogate consent). I understand there will be no cost to me for this vaccine. I understand that any monies or benefits for administering the vaccine will be assigned and transferred to the vaccinating provider, including benefits/monies from my health plan, Medicare or other third parties who are financially responsible for my medical care. I authorize release of all information needed (including but not limited to medical records, copies of claims and itemized bills) to verify payment and as needed for other public health purposes, including reporting to applicable vaccine registries.

Recipient/Surrogate/Guardian (Signature) recipient	Date / Time	Print Name	Relationship to Patient (if other than recipient)
Telephonic Interpreter's ID # **OR**	Date / Time		
Signature: Interpreter	Date/ Time	Print: Interpreter's Name and Relationship to Patient	

Area Below to be Completed by Vaccinator

Which vaccine is the patient receiving today?

Vaccine Name	Administration		EUA Fact Sheet Date	Manufacturer & Lot Number
Pfizer/ BioNTech	□ First Dose	□ Second Dose		
Moderna	□ First Dose	□ Second Dose		
Astra-Zeneca	□ First Dose	□ Second Dose		
Janssen	□ Single Dose			

Administration Site □ Left Deltoid □ Right Deltoid □ Left Thigh □ Right Thigh

Dosage □ 0.5 ml □ 0.3 ml

□ I have provided the patient (and/or parent, guardian or surrogate, as applicable) with information about the vaccine and consent to vaccination was obtained.

Vaccinator Signature: _____

Use of this form is optional. In the ongoing effort to address health disparities it is essential that all demographic information is collected at the time of COVID-19 vaccination including sex/gender identity and race/ethnicity.* **Updated January 20, 2021

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

Guidance for
The New York State COVID-19 Vaccination Program

Effective March 1, 2021

Purpose and Background:

Limited amounts of COVID-19 vaccine are available for New York's COVID-19 Vaccination Program. The amount of vaccine the state receives is based upon the allocation made to New York by the federal government. The New York State Department of Health (NYSDOH) then determines state allocations to providers and entities who have enrolled to administer vaccine. Executive Order 202.91, as extended, also sets forth mandatory prioritization for vaccination by provider type.

Hospitals must continue to prioritize unvaccinated healthcare workers. Hospitals were allocated vaccine until the end of Week 9 (February 14, 2021) to vaccinate ALL eligible hospital employees who currently desire vaccination, after which time any allocation to the hospital is open to all populations eligible for vaccination at hospitals, prioritizing all Phase 1A individuals who are not employed at the hospital, and OPWDD congregate care populations, then individuals age 65 and older. Eligible hospital employees who were not vaccinated by the end of Week 9 (e.g., new eligible employees, employees who changed their mind) may still be vaccinated out of such allocation.

Retail pharmacies or physician network or practice groups, after vaccinating their own patient-facing staff, should only vaccinate persons aged 65 years or older.

Local Health Departments must continue to prioritize the essential worker population in phase 1B and residents and staff of congregate settings operated or certified by the Office for People With Developmental Disabilities (OPWDD). Individuals with comorbidities and underlying conditions are eligible for vaccination at State-operated mass vaccination sites (MVS), and other locations as designated by the local health department (LHD). LHDs can work with health care providers in their counties to determine where individuals with comorbidities and underlying conditions can be vaccinated. A list of eligible comorbidities and underlying conditions is included in Appendix A. LHDs may also receive a week-to-week supplemental allocation to vaccinate the 65+ population.

Beginning in Week 12, public-facing hotel workers are now eligible at state mass vaccination sites, and may be eligible for vaccination at Local Health Departments, if the county opts to vaccinate such population.

New York is mandating social equity and fair distribution among the priority groups now eligible to ensure fair treatment and proportionate allocations both by eligibility group and by region.

All vaccine providers in New York State, including those located in the City of New York and those participating in federal programs, must follow New York State Department of Health (NYSDOH) guidance regarding vaccine prioritization, as well as any other relevant directives.

Eligible individuals:

Appendix A summarizes populations eligible to be vaccinated.

Vaccine Provider Responsibilities:

- COVID-19 vaccine must be given according to the prioritization plan established by the NYSDOH. The vaccine cannot be used for any other populations or groups other than those listed as eligible in NYSDOH guidance.
- All facilities, entities, and practices receiving vaccine doses have an obligation to quickly utilize all doses, per New York's "Use it or Lose it" policy and Executive Order 202.88. If any vaccine is not administered within seven days of receipt, remaining doses may be removed, and entities may not be allocated future vaccine doses.
- Any provider or entity not on track to administer all received doses to eligible populations within the week of receipt, must notify the state no later than the fifth day after receipt, at CovidVaccineNotUsed@health.ny.gov, pursuant to Executive Order 202.88.
- Vaccine cannot be redistributed to another facility, provider, practice, or department without prior approval and consent of the NYSDOH. Facilities needing to redistribute vaccine must submit a completed redistribution form to COVIDVaccineRedistribution@health.ny.gov and must not redistribute until NYSDOH approval.
- A provider may transport vaccine to another location for the purpose of holding a limited duration vaccination clinic without prior approval from the NYSDOH; if the provider is administering the doses and reporting doses administered against their own inventory in NYSIIS, all unused vaccine must be transported back to the original location at the conclusion of the clinic that day. The provider must retain possession and control of the vaccine for the duration of the transport and administration.
- Those who are administering the vaccine should be prioritized to receive vaccine as soon as doses are available.
- All providers must keep a daily list of "standby" eligible individuals to be notified of open appointments for vaccine administration on short notice. As soon as providers are aware that there are more doses than people to be vaccinated, "standby" eligible individuals should be called, or other steps must be taken to bring additional eligible recipients to the facility or clinic before the acceptable use period expires. Standby lists must include eligible individuals for first and second doses. (See page 3 for further guidance.)
- Providers should not prefill more syringes than they can use within one hour. Prefilled syringes must be used within 6 hours of filling. Excess prefilling can lead to waste if a clinic must end early or an excessive number of recipients fail medical screening or do not show up for their appointment. Please see Guidance on Use of COVID-19 Vaccine Doses Remaining at End of Day or Clinic for Providers Participating in the New York State COVID-19 Vaccination Program for more information.
- All facilities or practices are required to track vaccine uptake among their staff and must furnish uptake data to the NYSDOH via HERDS survey, or as part of the NYS Vaccine Tracker.

Each facility that receives vaccine:

- **MUST ensure that for each individual they vaccinate:**
    - The individual displays evidence of completed NYS COVID-19 Vaccine Form and attestation,

    - The individual displays proof of eligibility, and
    - The provider reports all relevant information in the NYS Vaccine Tracker and NYSIIS/CIR, as applicable.
- Will be notified about how much vaccine will be received.
- Must use all vaccine doses in the week received by rapidly deploying it to the eligible populations.
- Must prioritize which of their own staff receives vaccination first (if you are a new provider).
- Must prioritize vaccinating those who are administering the vaccine (if you are a new provider).
- May be required to schedule and accommodate other priority populations for vaccination within the facility.
- All vaccine administered must be reported, using the New York State Immunization Information System (NYSIIS) or the Citywide Immunization Registry (CIR) in New York City, within 24 hours of administration.
- Vaccine Administrators **must also report additional information on all those vaccinated on a daily basis** using the COVID-19 Vaccine Tracker.

Vaccinating individuals from outside your facility or practice:

The NYSDOH will clearly communicate to all facilities or practices as to the allocation of vaccine (e.g. if a certain vaccine allocation is for the purpose of vaccinating individuals outside of the facility or practice). If you are unsure as to the intended priority population for any vaccine allocation, you should email the NYSDOH at COVID19Vaccine@health.ny.gov. All providers must ensure that all individuals they are vaccinating are eligible to receive the vaccine as required by Executive Order 202.86 and this guidance.

The Second COVID-19 Vaccine Dose:

The second dose must be administered 21 days (Pfizer-BioNTech vaccine) or 28 days (Moderna vaccine) after the first dose. To facilitate this, all providers **must** schedule the second dose appointment for recipients **at the time the first dose is administered**. Those who receive the vaccine must return to the same location to receive the second dose, unless NYSDOH approves an alternative due to extenuating circumstances. Individuals must receive two doses of the same vaccine (e.g., you must receive two doses of the Pfizer-BioNTech vaccine or two doses of the Moderna vaccine). They are **not** interchangeable. Please see Guidance for Administration of the Second Dose of COVID-19 Vaccine for additional information regarding administration of the second dose.

Do not reserve first dose vaccine for the second dose. A second dose allocation will be shipped to your facility in time for administration of the second dose at the required interval. **The vaccine included in the second shipment must be reserved for second doses.** Facilities will be notified of the timing and quantity of the second dose shipment so that it can be separated from first doses in your inventory.

New York State has adopted the Centers for Disease Control's (CDC's) Vaccine Inventory Management Guidance (https://www.cdc.gov/vaccines/covid-19/vaccine-inventory-management.html).This guidance requires providers, on a weekly basis, to review all missed appointments, as well as any other reason for a second dose to be unused after 42 days, and to repurpose any remaining doses as first doses.

Frozen second doses that are not beyond the 42-day window for scheduled administration must NOT be used as first doses. The only second doses that may be administered as first doses are those doses that are approaching their expiration or beyond use date, and providers must follow the process outlined in the Second Dose Guidance.

Any frozen second doses that are currently beyond the 42-day window should immediately be used as first doses. The State is encouraging that individuals 65 plus be prioritized, however, these doses can be administered to any eligible individual in accordance with NYS Vaccine Program Guidance. If an individual requests a second dose after missing the 42-day window, they should still be administered such a second dose. There is no need to restart the series, pursuant to CDC guidance. Providers who have insufficient vaccine to administer a second dose that was delayed beyond the 42 DAY window should work with their Lead Hub Hospital, which maintains a second dose waiting list.

Extra Doses of Pfizer-BioNTech and Moderna:

Vials of both Pfizer-BioNTech and Moderna may contain extra doses of vaccine. Vaccine administrators may use any extra vaccine that can be easily drawn up in a syringe to meet the dose requirements. 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. Enter all vaccines given into NYSIIS/CIR, including any additional vaccines given, however do not modify inventory in anticipation of extra doses. For additional information please see Pfizer-BioNTech guidance and Moderna guidance for extra doses.

Remaining COVID-19 Vaccine Doses:

All vaccine providers must plan accordingly to ensure every dose of vaccine is administered. Proper planning to avoid waste includes confirming the exact number of recipients from a priority population available to be vaccinated before drawing the first dose from a new vial.

All providers must keep a daily list of "stand by" eligible individuals to be notified for vaccine administration on short notice. As soon as providers are aware that there are more doses than people to be vaccinated, "standby" eligible individuals should be called, or other steps must be taken to bring additional eligible recipients to the facility or clinic before the acceptable use period expires. However, there may be times due to inclement weather, cancellations, or extra doses in vial, that there are doses of vaccine that remain at the close of business or the end of a vaccine clinic and no one from the priority population can come in before the doses expire. ("Stand by" lists must include individuals eligible for first and second doses.)

At these times and **only** under these circumstances, providers are authorized by the NYSDOH to administer vaccine first to other eligible individuals, and if no eligible individuals are able to be vaccinated, vaccinate any consenting adult. Providers must report any vaccine administered pursuant to this authority to NYS DOH. As an example, commercial pharmacists in this situation who had already vaccinated eligible populations, everyone public facing in the pharmacy department and the "stand by" list they can then move on to vaccinate any other eligible individual, rather than letting doses expire. This exception is **ONLY** for the purpose of ensuring vaccine is not wasted and must be reported to NYSDOH.

As the NYS COVID-19 Vaccination Program opens to more populations, the need for this exception should greatly diminish. If this exception is utilized, providers must:

- Require anyone receiving the COVID-19 vaccine to complete the New York State COVID-19 Vaccine Form pursuant to Executive Order 202.86, as extended.
- Record any vaccine dose administered in NYSIIS/CIR within 24 hours of administration.
- Maintain a separate tracking sheet so that the amount of vaccine used for different groups is clearly documented, as well as to whom it was administered.
- Schedule a second dose at the time of administration.

Under all circumstances, providers must contact the local Department of Health to determine if any eligible individuals can be contacted to receive the vaccine before discarding any vaccine.

Mandatory Vaccine Form:

All individuals receiving the COVID-19 vaccine **must** complete the New York State COVID-19 Vaccine Form for the first dose, and attest that they are eligible to be vaccinated. Pursuant to Executive Order 202.86, as extended, practices, providers, and entities must confirm adherence to this requirement at the time of vaccine administration.

Proof of Occupation or Eligibility:

Individuals being vaccinated **must** provide proof of eligibility.

If an individual is eligible due to their work or employment status, they must prove they work or are employed **in** the State of New York, regardless of where they reside. Additionally, if an individual resides in New York but is employed or works in another state, such individual must show proof of residence in New York and proof of work or employment, regardless of where such work or employment occurs.

Proof of work or employment may include:

- an employee ID card or badge,
- a letter from an employer or affiliated organization,
- a pay stub, depending on the specific priority status, or
- display proof of work via an application (e.g., Uber, Lyft, DoorDash, etc.).

If an individual is eligible due to their age, they must produce proof of age and proof of residence in New York. To prove New York residence, an individual must show:

- One of the following: State or government-issued ID; consulate ID (if New York address is displayed); Statement from landlord; Current rent receipt or lease; Mortgage records; or
- Two of the following: Statement from another person; Current mail; School records.
- For age, such proof may include:
    - Driver's license or non-driver ID;
    - Birth certificate issued by a state or local government;
    - Consulate ID;
    - Current U.S passport or valid foreign passport;
    - Permanent resident card;
    - Certificate of Naturalization or Citizenship;
    - Life insurance policy with birthdate; or
    - Marriage certificate with birthdate.

Alternatively, employers or organizations can provide a list of staff who meet the eligibility criteria for vaccination. Do not vaccinate any person who does not have proof of their occupation, age, or priority status, as applicable, as well as proof of residence or employment. Executive Order 202.86 imposes monetary penalties for any provider vaccinating an individual who has not certified eligibility or for whom the provider otherwise has knowledge the individual is not a member of a priority group.

Public-facing hotel workers are eligible beginning on March 1, 2021.

For individuals with certain comorbidities or underlying conditions, at state-operated mass vaccination sites, any of the following proof is acceptable to prove eligibility:

- Doctor's Letter, or
- Medical Information Evidencing Comorbidity, or
- Signed Certification.

Local health departments are authorized to determine what forms, or combination thereof, of the proof options listed above, are required in their jurisdiction for this population. Providers must be aware of the LHD policy for proof of comorbidity and must require individuals being vaccinated to show proof consistent with such policy.

The Department of Health will audit local compliance with the above to ensure ALL providers are complying with the proof requirements in the jurisdiction.

The mandatory New York State COVID-19 Vaccine Form includes a self-attestation regarding eligibility for vaccination and New York residence or employment in New York, which must be completed prior to vaccination.

Vaccine Safety:

Post-vaccination monitoring is an essential part of the COVID-19 vaccination program. The Centers for Disease Control and Prevention (CDC) is promoting and encouraging all those being vaccinated to participate in V-Safe, a smart-phone based application that will allow those vaccinated to enter their symptoms in the days after vaccination using text messaging. V-Safe also provides reminders for the second dose and telephone follow up for anyone who reports medically significant adverse events. V-Safe materials can be found at http://www.cdc.gov/vsafe, including a V-Safe information sheet. Please print out the information sheet and hand to each person vaccinated. You must report any adverse events that occur after vaccination to the Vaccine Adverse Events Reporting System (VAERS) at info@VAERS.org or by calling 1-800-822-7967.

Equity:

All workers who meet the eligibility criteria must be included, regardless of job title, location, or other status. For example, in a hospital, frontline workers include doctors, registered nurses, licensed practical nurses, certified nursing assistants, personal care assistants, environmental workers, ward clerks, dietary workers, and others who work on the same floor, ward, clinic or office and who have direct contact with COVID-19 patients must all be eligible for vaccination at the same time.

Effort must be made to do outreach to persons 65 years of age and older in all communities and settings. Persons in areas that have a high social vulnerability index are particularly vulnerable to COVID-19 and should be notified about how they can receive vaccine.

Communicating the Plan:

Please be sure to clearly communicate prioritization to all staff.

This guidance is in effect from the date of issuance until it is updated, or additional guidance is issued by NYSDOH. For questions, please contact the New York State Department of Health, Bureau of Immunization at COVID19vaccine@health.ny.gov.

New York State Vaccination Program Guidance
Appendix A
Priority Groups Eligible to be Vaccinated

New Eligible Priority Groups for Week 12 (beginning Monday, March 1, 2021)

Beginning March 1, public-facing hotel workers are eligible to receive COVID-19 vaccine.

Individuals with one of the below comorbidities or underlying conditions are eligible to receive COVID-19 vaccine. The list is subject to change as additional scientific evidence is published and as New York State obtains and analyzes additional state-specific data. Adults over the age of 16 with the following conditions due to increased risk of moderate or severe illness or death from the virus that causes COVID-19 are eligible:

- Cancer (current or in remission, including 9/11-related cancers);
- Chronic kidney disease;
- Pulmonary Disease, including but not limited to, COPD (chronic obstructive pulmonary disease), asthma (moderate-to-severe), pulmonary fibrosis, cystic fibrosis, and 9/11 related pulmonary diseases;
- Intellectual and Developmental Disabilities including Down Syndrome;
- Heart conditions, including but not limited to heart failure, coronary artery disease, cardiomyopathies, or hypertension (high blood pressure);
- Immunocompromised state (weakened immune system) including but not limited to solid organ transplant or from blood or bone marrow transplant, immune deficiencies, HIV, use of corticosteroids, use of other immune weakening medicines, or other causes;
- Severe Obesity (BMI 40 kg/m2), Obesity (body mass index [BMI] of 30 kg/m2 or higher but < 40 kg/m2);
- Pregnancy;
- Sickle cell disease or Thalassemia;
- Type 1 or 2 diabetes mellitus;
- Cerebrovascular disease (affects blood vessels and blood supply to the brain);
- Neurologic conditions, including but not limited to Alzheimer's Disease or dementia; and
- Liver disease.

Priority Groups Continuing to Be Eligible:

- Healthcare Workers
    - High-risk hospital and FQHC staff, including OMH psychiatric centers.
    - Health care or other high-risk essential staff who come into contact with residents/patients working in LTCFs and long-term, congregate settings overseen by OPWDD, OMH, OCFS and OASAS, and residents in congregate living situations, run by the OPWDD, OMH, OCFS and OASAS.
    - Staff of urgent care provider.
    - Staff who administer COVID-19 vaccine.
    - All Outpatient/Ambulatory front-line, high-risk health care workers of any age who provide direct in-person patient care, or other staff in a position in which they have direct contact with patients (i.e., intake staff),
        - This includes, but is not limited to, individuals who work in private medical practices; hospital-affiliated medical practices; public health clinics; specialty medical practices of

all types; dental practices of all types; dialysis workers; diagnostic and treatment centers; occupational therapists; physical therapists; speech therapists; phlebotomists and blood workers; behavioral health workers; midwives and doulas; and student health workers.
    - All front-line, high-risk public health workers who have direct contact with patients, including those conducting COVID-19 tests, handling COVID-19 specimens and COVID-19 vaccinations.
- Certified NYS EMS provider, including but not limited to Certified First Responder, Emergency Medical Technician, Advanced Emergency Medical Technician, Emergency Medical Technician – Critical Care, Paramedic, Ambulance Emergency Vehicle Operator, or Non-Certified Ambulance Assistant.
- County Coroner or Medical Examiner, or employer or contractor thereof who is exposed to infectious material or bodily fluids.
- Licensed funeral director, or owner, operator, employee, or contractor of a funeral firm licensed and registered in New York State, who is exposed to infectious material or bodily fluids.
- Home care workers and aides, hospice workers, personal care aides, and consumer-directed personal care workers.
- Staff and residents of nursing homes, skilled nursing facilities, and adult care facilities.

New York residents age 65 and older[1]

- First Responder or Support Staff for First Responder Agency
    - Fire
        - State Fire Service, including firefighters and investigators (professional and volunteer)
        - Local Fire Service, including firefighters and investigators (professional and volunteer)
    - Police and Investigations
        - State Police, including Troopers
        - State Park Police, DEC Police, Forest Rangers
        - SUNY Police
        - Sheriffs' Offices
        - County Police Departments and Police Districts
        - City, Town, and Village Police Departments
        - Transit of other Public Authority Police Departments
        - State Field Investigations, including DMV, SCOC, Justice Center, DFS, IG, Tax, OCFS, SLA
    - Public Safety Communications
        - Emergency Communication and PSAP Personnel, including dispatchers and technicians
    - Other Sworn and Civilian Personnel
        - Court Officer
        - Other Police or Peace Officer
        - Support or Civilian Staff for Any of the Above Services, Agencies, or Facilities
- Corrections
    - State DOCCS Personnel, including correction and parole officers
    - Local Correctional Facilities, including correction officers
    - Local Probation Departments, including probation officers
    - State Juvenile Detention and Rehabilitation Facilities
    - Local Juvenile Detention and Rehabilitation Facilities

[1] **Pharmacies are vaccinating only individuals from this population.**

- P-12 Schools
    - P-12 school (public or non-public) or school district faculty or staff (includes all teachers, substitute teachers, student teachers, school administrators, paraprofessional staff, and support staff including bus drivers)
    - Contractor working in a P-12 school (public or non-public) or school district (including contracted bus drivers)
    - Licensed, registered, approved or legally exempt group childcare
- In-Person College Faculty and Instructors
- Employees or Support Staff of Licensed, Registered, Approved or Legally Exempt Group Childcare Settings
- Licensed, Registered, approved or legally exempt group Childcare Provider
- Public Transit
    - Airline and airport employee
    - Passenger railroad employee
    - Subway and mass transit employee (i.e., MTA, LIRR, Metro North, NYC Transit, Upstate transit)
    - Ferry employee
    - Port Authority employee
    - Public bus employee
- Public Facing Grocery Store Workers, including convenience stores, bodegas, regional food banks, food pantries, and permitted home-delivered meal programs,
- Incarcerated individuals age 65+ or those with comorbidities or underlying conditions.
- Individual living in a homeless shelter where sleeping, bathing or eating accommodations must be shared with individuals and families who are not part of your household.
- Individual working (paid or unpaid) in a homeless shelter where sleeping, bathing or eating accommodations must be shared by individuals and families who are not part of the same household, in a position where there is potential for interaction with shelter residents.
- Restaurant employees, including workers in permitted soup kitchen and congregate meal programs,
- Restaurant delivery workers,
- Public facing hotel workers, and
- For-hire vehicle drivers, including taxi, livery, black car, and transportation network company drivers