



**Guidance for  
The New York State COVID-19 Vaccination Program for Individuals 12 Years of Age or Older**

**January 6, 2022**

**Note:** This guidance document applies specifically to healthcare providers offering COVID-19 vaccinations to adolescents and adults age 12 and older. Guidance specific to COVID-19 vaccination of children ages 5-11 may be found on the [New York State COVID-19 Vaccine Information for Providers](#) page.

**Purpose and Background:**

On January 4, 2022, the Centers for Disease Control and Prevention (CDC) updated the recommendation for receipt of a booster dose of the COVID-19 vaccine following receipt of the Pfizer-BioNTech primary series. CDC now recommends receipt of a booster dose at least five months after completing their Pfizer-BioNTech primary series. This previously recommended interval was at least six months.

On January 5, 2022, the CDC endorsed the Advisory Committee on Immunization Practice's (ACIP) recommended expansion of booster dose eligibility for the Pfizer-BioNTech COVID-19 to individuals ages 12 to 15. CDC now recommends that all adolescents ages 12 to 17 should receive a booster dose five months after their initial Pfizer-BioNTech vaccination series.

More information can be found under **Booster Dose Eligibility**, beginning on page 2 of this document.

**Clinical Preference for mRNA COVID-19 Vaccine:**

On December 16, 2021, the CDC endorsed the recommendations of its Advisory Committee on Immunization Practices (ACIP) for a clinical preference for individuals aged 18 years and older to receive an mRNA COVID-19 vaccine over the Janssen (also known as Johnson & Johnson) COVID-19 vaccine.

As part of a pre-vaccination discussion with a vaccination provider, all persons who elect to receive a Janssen COVID-19 Vaccine primary series or booster dose should be informed about the risk and symptoms of thrombosis with thrombocytopenia syndrome (TTS), and the need to seek immediate medical care should TTS symptoms develop. The highest rates of TTS occur among females 30-49 years. The FDA also added a contraindication for people who experienced TTS after their first shot of the Janssen COVID-19 vaccine, or from other COVID-19 vaccines based on a similar adenovirus vector technology such as the one developed by AstraZeneca, from getting a booster shot from the same type of vaccine. Current recommendations are for urgent medical evaluation for TTS if any of the following symptoms develop 4 to 30 days after vaccination:

- severe headache,
- visual changes,
- abdominal pain,
- nausea and/or vomiting,

- backache,
- shortness of breath,
- leg pain or swelling, or
- petechiae or easy bruising.

In limited, exceptional situations where an individual received the first dose of an mRNA COVID-19 vaccine but is unable to complete the series with either the same or different mRNA COVID-19 vaccine (e.g., due to contraindication), a single dose of Janssen COVID-19 Vaccine may be considered at a minimum interval of 28 days from the mRNA COVID-19 vaccine dose if the person is aged  $\geq 18$  years.

The CDC also noted: “Given the current state of the pandemic both here and around the world, the ACIP reaffirmed that receiving any vaccine is better than being unvaccinated. Individuals who are unable or unwilling to receive an mRNA vaccine will continue to have access to Johnson & Johnson’s COVID-19 vaccine. The benefits of using the Ad26.COV2.S vaccine still outweigh the risks involved with Covid-19 infection. Previous studies suggest that thrombotic complications are far more likely following infection with COVID-19.”

#### **New Pfizer Adult/Adolescent Formulation:**

On December 23, 2021 a new formulation of Pfizer adult/adolescent vaccine is being introduced. This formulation is being referred to as Pfizer Adult/Adolescent Tris (Gray Cap, age 12+, no diluent). This formulation contains the Tris Sucrose buffer, **does not require dilution** at administration sites, may be stored at refrigerated temperature (2-8° C) for up to 10 weeks, and can be used on individuals 12 years of age and older. The vials will have a gray cap and label with gray border. Individuals who received a previous dose or doses of the Pfizer 12+ “purple cap” vials may receive the Pfizer Adult/Adolescent Tris (Gray Cap, age 12+, no diluent) formulation for primary, additional, or booster doses.

Pfizer Adult/Adolescent Tris (Gray Cap, age 12+, no diluent) is a multiple dose vial that contains a volume of 2.25 mL and is supplied as a frozen suspension that does not contain preservative. Each vial must be thawed prior to administration. **DO NOT DILUTE** prior to use. One vial contains 6 doses of 0.3 mL. Even though the vaccine does not require dilution, the vial must be mixed by gently inverting the vial 10 times before puncture.

Vaccination providers should maximize using inventory of all Pfizer 12+ purple cap vials prior to using Pfizer Adult/Adolescent Tris (Gray Cap, age 12+, no diluent) vials and should ideally carry only one Pfizer adult formulation at a time. Provider sites utilizing the Pfizer thermal shipping containers for temporary storage must prepare for use of an ULT freezer -or- refrigerator moving forward; the shipping containers used for this formulation are single use and cannot be used for temporary storage with dry ice or for vaccine transport. **To avoid mistakes during this period of transition when both adult formulation products may be in circulation, these products should not be offered/administered at the same time.**

#### **Booster Dose Eligibility:**

Per CDC recommendation on January 5, 2022, adolescents ages 12 to 17 should receive a booster dose of the Pfizer-BioNTech COVID-19 vaccine. Additionally, per CDC Interim Guidance as recently as of December 20, 2021, all persons aged 18 years and older should receive a booster dose of COVID-19 vaccine, even if they were less than 18 years of age at the time of the primary series. Use of an mRNA

COVID-19 vaccine for a booster dose is preferred even for those who received Janssen COVID-19 Vaccine for their single dose primary series. However, offering the Janssen COVID-19 Vaccine as a booster is preferable to not providing any COVID-19 vaccine booster in most situations.

The interval for booster vaccination should follow the interval recommended for the primary series. Persons aged 18 years and older who received Janssen primary vaccination should receive a COVID-19 vaccine booster dose at least 2 months (8 weeks) later. Following updated CDC recommendations as recently as January 5, recipients of the Pfizer-BioNTech COVID-19 vaccine primary series ages 12 and older should receive a single booster dose at least **5 months** after the last dose administered. Recipients of the Moderna COVID-19 vaccine primary series, or those who received two doses of different mRNA vaccine products, should receive a single booster dose at least 6 months after the last dose administered. For persons aged 18 years and older, an mRNA COVID-19 vaccine is preferred over the Janssen COVID-19 Vaccine for booster vaccination. However, recipients of an mRNA vaccine primary series aged 18 years and older who are unable to receive an mRNA booster dose can be offered a Janssen vaccine booster dose at least 5 months later (Pfizer-BioNTech primary series) or 6 months later (Moderna primary series), after discussion of the benefits and risks. If the booster dose is given more than 4 days before the dose is due, the booster dose does not need to be repeated.

The following vaccine-specific booster dose and volume should be administered regardless of whether the vaccine is homologous (same dose as primary series) or heterologous (different than primary series):

- Pfizer-BioNTech: 30 ug in a volume of 0.3 mL (same dose as the primary series dose and additional primary dose).
- Moderna: 50 µg in a volume of 0.25 mL. This is a different dose than what is used for the primary series dose and the additional primary dose.
- Janssen: 5×10<sup>10</sup> viral particles in a volume of 0.5 mL (same dose as the primary series dose)

#### **Additional Doses of mRNA COVID-19 Vaccines for Immunocompromised Persons:**

On November 17, 2021, the CDC issued an Emergency Use Instructions (EUI) for Pfizer BioNTech COVID-19 vaccine for use by individuals that received a completed primary series of a non-FDA authorized or approved COVID-19 vaccine including the following:

- COVID-19 vaccines that are not FDA-approved or FDA-authorized
- COVID-19 vaccines that are not listed for emergency use by WHO but for which a U.S. data and safety monitoring board or equivalent has independently confirmed efficacy (e.g., Novavax).

On August 12 and 13, 2021, the FDA amended the EUAs and the CDC adopted the ACIP recommendations for both the [Pfizer-BioNTech](#) and the [Moderna](#) COVID-19 vaccines to allow for the administration of an additional (i.e., third) dose at least 28 days after completion of the two dose primary series for certain people who are **moderately or severely immunocompromised** due to a medical condition or receipt of immunosuppressive medications or treatments.

Eligible persons for a third additional dose of an mRNA vaccine due to being moderately to severely immunocompromised include:

- Individuals 18 years or older, who received a primary series of an FDA-approved or FDA authorized mRNA vaccine at least 28 days prior, may receive a 3<sup>rd</sup> dose of EITHER the Pfizer or Moderna vaccine.

- Individuals 5 years or older, who received a primary series of an FDA-approved or FDA authorized mRNA vaccine at least 28 days prior, may receive a 3<sup>rd</sup> dose of ONLY the Pfizer vaccine.
- Individuals 5 years or older, who received a primary series of a non-FDA authorized or approved COVID-19 vaccine at least 28 days prior, may receive a 3<sup>rd</sup> dose of ONLY the Pfizer vaccine.

Recommendations for booster doses of an mRNA vaccine for moderately to severely immunocompromised people:

- Individuals who are ≥18 years of age and received an additional dose (third dose) due to a moderately to severely immunocompromising condition should get a booster dose 6 months after their 3<sup>rd</sup> dose. Moderately or severely immunocompromised people aged 16 or 17 years who received the Pfizer-BioNTech COVID-19 vaccine primary series and an additional primary Pfizer-BioNTech vaccine dose may receive a single Pfizer-BioNTech COVID-19 booster dose at least 6 months after completing their additional primary dose.
- In such situations, people who are moderately and severely immunocompromised and are 16 years or older may receive a total of four COVID-19 vaccine doses (i.e., 2 primary vaccine doses, 1 dose at 28 days due to immunocompromising condition, and 1 dose at 6 months as a booster).

Due to insufficient data at this time, the EUA amendment for a 28-day additional dose does not apply to the Janssen/Johnson & Johnson COVID-19 vaccine. However, all Janssen/Johnson & Johnson vaccine recipients are now eligible to receive a booster at least two months following their primary dose.

Due to the risk of COVID-19 infection in this population, immunocompromised people should continue to be counseled regarding the potential for a reduced immune response after vaccination and the importance of additional protective measures, regardless of the decision to receive an additional dose of the COVID-19 vaccine. Prevention measures include wearing a mask, staying six feet apart from others they don't live with, and avoiding crowds and poorly ventilated indoor spaces until advised otherwise by their healthcare provider. Close contacts of immunocompromised people should be strongly encouraged to be vaccinated against COVID-19.

The EUA amendment for additional doses is not intended for persons with chronic conditions such as diabetes or heart disease, for which there might be mild associated immunosuppression, nor for residents of long-term care facilities who do not otherwise meet the moderate to severe immunocompromised criteria.

Additional information about the level of immune suppression associated with a range of medical conditions and treatments can be found in [general best practices for vaccination of people with altered immunocompetence](#), the [CDC Yellow Book](#), and the [Infectious Diseases Society of America policy statement, 2013 IDSA Clinical Practice Guideline for Vaccination of the Immunocompromised Host](#).

Whenever possible, mRNA COVID-19 vaccination doses (including the primary series and an additional dose) should be completed at least two weeks before initiation or resumption of immunosuppressive therapies, but timing of COVID-19 vaccination should take into consideration current or planned immunosuppressive therapies and optimization of both the patient's medical condition and response to vaccine.

A patient's clinical team is best positioned to determine the degree of immune compromise and appropriate timing of vaccination.

The [utility of serologic testing](#) or cellular immune testing to assess immune response to vaccination and guide clinical care (e.g., as part of need assessment for an additional dose) has not been established. Serologic testing or cellular immune testing outside of the context of research studies is **not recommended at this time**.

The age groups authorized to receive the additional dose are unchanged from those authorized to receive the primary vaccination series. For those with qualifying immunocompromising conditions, Pfizer-BioNTech COVID-19 vaccine may be administered down to 5 years of age, and Moderna may be administered down to 18 years of age.

**Attempts should be made to match the additional dose type to the mRNA primary series, however if that is not feasible, a heterologous additional dose is permitted.**

There is no requirement for proof or prescription from the individual's health care provider. This is to prevent additional barriers to vaccination for this vulnerable population. The mandatory [New York State COVID-19 Vaccine Form](#), discussed below under "Vaccine Provider Responsibilities," includes a self-attestation regarding eligibility for vaccination and must be completed prior to vaccination.

#### **EUAs, FDA Vaccine Approval Status, and Appropriate Use of Vaccines in New York State:**

All authorized COVID-19 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. Providers are responsible for adhering to all requirements outlined in the COVID-19 Vaccination Program agreement. Specifically, providers must administer COVID-19 vaccines in accordance with all [program requirements and recommendations](#) of NYSDOH and the CDC, the [Advisory Committee on Immunization Practices](#), and the U.S Food and Drug Administration (FDA). This applies to vaccines administered in accordance with an EUA or EUI, as well as FDA approved COVID-19 vaccines. Accordingly, use of these products outside of those that have been approved and authorized by FDA or in accordance with a CDC EUI (often referred to as "**off-label use**") **is not recommended**. It would violate the provider agreement and could expose providers to the following risks:

- Administration of the product off label may not be covered under the PREP Act or the PREP Act declaration; therefore, providers may not have immunity from claims.
- Individuals who receive an off-label dose may not be eligible for compensation under the Countermeasures Injury Compensation Program after a possible adverse event.
- CDC has defined the scope of the CDC COVID-19 Vaccination Program in terms of how the USG-provided vaccines may be used in the program. Providers giving off-label doses would be in violation of the CDC Program provider agreement potentially impacting their ability to remain a provider in the CDC program.
- Administration fees may not be reimbursable by payers.

Accurate and timely reporting to NYSIIS/CIR is critical, as this information can be used to allow individuals to display proof of vaccination, such as the Excelsior Pass or Excelsior Pass Plus.

## Updates to COVID-19 Vaccine Expiration and Beyond Use Dates:

### Expiration Dates:

Determining when a vaccine expires is a critical step in proper storage and handling. The expiration date should always be checked prior to preparing or administering vaccine. Expired vaccine or diluent should NEVER be used. As additional stability data become available, the expiration dates for some products may change. Follow the instructions below to determine the expiration date:

- Pfizer-BioNTech COVID-19 vaccine for ages 12 and older (vials have purple caps): FDA approved an amendment to the EUA for Pfizer-BioNTech COVID-19 vaccine extending the expiration dates of COVID-19 Vaccine from six to nine months. Cartons and vials of Pfizer-BioNTech COVID-19 Vaccine with an expiry date of August 2021 through February 2022 printed on the label may remain in use for 3 months beyond the printed date as long as authorized storage conditions between -90°C to -60°C (-130°F to -76°F) have been maintained. Please note: the ultra-cold temperature range has been broadened to include -90° C (-130°F). Frozen vials stored at -25°C to -15°C and refrigerated vials (2°C to 8°C) are NOT eligible for a three-month use extension. Updated expiry dates for vaccine maintained in ultra-cold storage are shown below. The extended expiration date is effective immediately for all currently available batches that have not yet expired.

The extension of Pfizer-BioNtech COVID-19 vaccine expiration applies to any vaccine that has been stored in a manner consistent with the storage guidelines that have been in place to this point. Specifically:

- Vaccine moved from ultra-cold storage to standard frozen storage and back once to ultra-cold storage
- Vaccine in a standard freezer for a total of up to 14 days
- Vaccine in a refrigerator for a total of up to 31 days, including vaccine that was previously in a standard freezer for 14 days

All of the above conditions are consistent with the existing storage guidance. **Vaccine stored under these conditions can be used until the [correct beyond-use date](#), based on the vaccine storage conditions, or the updated expiration date, whichever occurs first.** Vaccine cannot be used after the new expiration date, even if the storage-determined beyond-use date would be after the updated expiration date.

Printed Expiry Date	Updated Expiry Date
October 2021	January 2022
November 2021	February 2022
December 2021	March 2022
January 2022	April 2022
February 2022	May 2022

- Pfizer Adult/Adolescent Tris (Gray Cap, age 12+, no diluent): The date printed on the Pfizer Adult/Adolescent Tris (Gray Cap, age 12+, no diluent) vaccine vials indicate the manufacture date and NOT the expiration date. Originally, the expiration date was 6 months from the manufacture date, when stored in ultra-cold freezer temperatures (-90 to -60° C). **The**

**expiration date for Pfizer gray cap vaccine has now been extended to 9 months (while held at ULT frozen.)** Vials may also be stored up to 10 weeks in the refrigerator (2-8° C). **No standard freezer storage is approved for the Pfizer Adult/Adolescent Tris (Gray Cap, age 12+, no diluent) formulation.** Once thawed, vials CANNOT be refrozen.

The Fact Sheet for the Pfizer Adult/Adolescent Tris (Gray Cap, age 12+, no diluent) provided by the FDA now reads, “regardless of storage conditions, vaccines should not be used after 9 months from the date of manufacture printed on the vial and cartons”. Therefore, vaccine must be used by the expiration date, or [the 10-week beyond use date](#) for refrigerator storage, whichever comes first. The updated expiry dates for the gray cap vials based on 9 months from the date of manufacture are provided below.

Printed Manufacturing Date	9-Month Expiry Date*
06/2021	Feb. 28, 2022
07/2021	Mar. 31, 2022
08/2021	Apr. 30, 2022
09/2021	May 31, 2022
10/2021	Jun. 30, 2022
11/2021	July. 31, 2022
12/2021	Aug. 31, 2022
01/2022	Sept. 30, 2022
02/2022	Oct. 31, 2022

\*Date of expiration always falls on the last day of the month

- Moderna COVID-19 vaccine: The expiration date is NOT printed on the vaccine vial or carton. To obtain the expiration date of the lot number received, providers can scan the QR code located on the vial or carton or access the manufacturer’s [website](#) directly, enter) the lot number and the expiration date will be displayed.
  - In September 2021, Moderna submitted data to support the extension of certain lot number expiration dates. Prior to discarding expired lots of Moderna vaccine, it is important to re-check the manufacturer’s website to determine if the lot number’s expiration date has been extended. If an extension was made, providers need to ensure the expiration date on the vials/packages and in NYSIIS/CIR are updated.
- Janssen/Johnson & Johnson COVID-19 vaccine: The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date:
  - Scan the QR code located on the outer carton, or
  - Call 1-800-565-4008, or
  - Go to [vaxcheck.jnj/](https://vaxcheck.jnj/), enter the lot number and the expiration date will be displayed.

For Moderna and Janssen/J&J COVID-19 vaccines it is important to write the expiration date on the carton or vials since it is not printed. Orders of Moderna and Janssen/J&J received in NYSIIS or CIR will contain a placeholder date of 12/31/2069. The actual expiration date must be updated in NYSIIS or CIR, as well as part of inventory management. Vaccines should always follow a first in, first out process in which vials that have the earliest expiration date are used first. CDC’s <https://www.cdc.gov/vaccines/covid-19/downloads/expiration-tracker.pdf> can help providers keep

track of the expiration date by lot number. Vaccine inventory should be managed using a “first in first out” tracking process to limit the potential for wastage.

### Beyond Use Dates (BUDs):

All vaccines have expiration dates, and some routinely recommended vaccines have a beyond use date (BUD), which is calculated based on the date the vial is first punctured and the storage information in the package insert. Whenever a vial of COVID-19 vaccine is moved to storage conditions that affect BUD or a multidose vial is punctured, label the vial(s) with the beyond use date/time. The BUD must never exceed the labeled expiration date. Once the vaccine has reached its expiration or beyond use date/time, unused doses must be disposed of as medical waste and [reported as wastage in NYSIIS or CIR](#). A summary of COVID-19 vaccine beyond use dates and resources are listed below.

- Pfizer age 12 and older (vials have purple caps): [Pfizer-BioNTech COVID-19 Vaccine Beyond-Use Date \(BUD\) Tracking Labels for Vaccine During Freezer or Refrigerator Storage](#)
  - Freezer (-25° C to -15° C): Two weeks
  - Refrigerator (2° C to 8° C): 31 days
  - After Puncture: 2° C to 25° C for up to 6 hours
  
- Pfizer Adult/Adolescent Tris (Gray Cap, age 12+, no diluent): [Beyond-Use Date \(BUD\) Tracking Labels for Vaccine During Refrigerator Storage](#)
  - Refrigerator (2° C to 8° C): 10 weeks
  - **NOTE: NO standard freezer (-25° C to -15° C) storage allowed**
  - Room temperature (8° C to 25° C): 12 hours prior to first puncture
  - After Puncture: 2° C to 25° C for up to 12 hours. Vial labels and cartons may state that a vial should be discarded 6 hours after the first puncture. The information in the EUA Fact Sheet (12 hours) supersedes the number of hours printed on vial labels and cartons.
  
- Moderna: [Moderna COVID-19 Vaccine Beyond-Use Date \(BUD\) Tracking Label for Vaccine During Refrigerator Storage](#)
  - Refrigerator (2° C to 8° C): 30 days
  - After Puncture: 2° C to 25° C for up to 12 hours
  
- Janssen/J&J: [Janssen COVID-19 Vaccine Preparation and Administration Summary](#)
  - After Puncture: 2° C to 8° C up to 6 hours OR 9° C to 25° C for up to 2 hours. These times are NOT cumulative (i.e., you cannot store a punctured vial for 6 hours at refrigerated temperatures and then another 2 hours at room temperature).

### **Moderna Booster Dose:**

#### Moderna Booster Dose Volume and Vial Presentation:

It is important to note that the volume of a Moderna booster dose is **0.25 mL** (half the volume of a primary dose). The Moderna COVID-19 Vaccine is supplied in two multiple-dose vial presentations:

- A multiple-dose vial containing 5.5 mL (i.e., Moderna 10-dose)



- A multiple-dose vial containing 7.5 mL (i.e., Moderna 14- dose)

Both primary series doses of 0.5 mL and booster doses of 0.25 mL may be extracted from either vial presentation. When extracting only booster doses or a combination of primary series and booster doses, the maximum number of doses that may be extracted from either vial presentation should not exceed 20 doses. **Do not puncture the vial stopper more than 20 times.**

Despite the volume of the booster dose being 0.25 mL, providers should still report a full dose as administered in NYSIIS. Reporting of half doses is not allowed and inventory must only be reported in whole doses. Continue to maintain reporting of wastage in whole doses. Wastage should only be reported if the total doses administered from a vial, regardless of volume or series, is less than the vial dose count (i.e., 1 primary and 5 booster doses from a 14-dose vial would be reported as 6 doses and 8 doses wasted).

#### Moderna Booster Dose Inventory Considerations:

**Reporting:** Despite the volume of the booster dose being **0.25 mL**, providers must still **report a full dose as administered in NYSIIS**. Reporting of half doses is not allowed and **inventory must only be reported in whole doses**. Half doses in NYSIIS inventory will prevent a provider from entering new vaccine orders.

**Maximum vial puncture:** Providers may extract both primary series doses (0.5mL) and booster doses (0.25 mL) from the same vial. When extracting only booster doses or a combination of primary series and booster doses, **the maximum number of doses that may be extracted from either vial presentation should not exceed 20 doses. Do not puncture the vial stopper more than 20 times.**

- When ordering vaccine for booster doses, consider that an order of 140 doses (ten 14-dose vials) can support a maximum of 200 booster and/or primary doses.
- After the vial has been punctured 20 times, the vial must be discarded, even if there is vaccine remaining in the vial and the beyond use date/time has not been reached (see more info below on when to report wastage in NYSIIS).
- The use of vial adapters, dispensing pins, or strategies where a needle is inserted into the vial septum for multiple medication withdraws is not allowed due to contamination risk.

**NYSIIS inventory:** Due to the reporting of full doses for boosters and the maximum of 20 punctures for each vial, the number of doses reported may exceed the number of doses recorded in NYSIIS inventory (i.e., 140 dose order = up to 200 booster doses). This means NYSIIS inventory may be depleted before physical inventory. Best practice would be to [modify inventory](#) to add doses to the lot number BEFORE ADMINISTRATION. Do a vial count of physical inventory at the end of the day and multiply your full, unopened vials times the number of labeled doses in the vial (10 or 14 doses) and manually modify your NYSIIS inventory to reflect this count. If you report vaccine administration data via data exchange, additional doses beyond the NYSIIS doses on hand will go to the Inventory Not Deducted module. If this happens, manually add doses to the lot number and then [update non-deducted inventory](#).

**Vaccine Finder:** NYSIIS inventory is used to populate Vaccine Finder product availability through a daily data upload. If you have physical inventory and you do not modify inventory to add doses once it is depleted in NYSIIS, your location will not show as having Moderna vaccine available on Vaccine Finder.

**Ancillary Supplies:** Current Moderna inventory may be used for booster doses and is encouraged to be used. Please be aware that there is no mechanism to provide additional ancillary supplies for existing

inventory. Providers may need to purchase additional supplies. Ancillary kits for Moderna 14 (140 doses) that were sent for existing inventory contain a combination of 1mL and 3mL syringes. While the 3mL syringes are adequate for extracting a primary series dose (0.5 mL), they do not support extraction of the booster dose (0.25 mL). The 1 mL syringes allow for better visualization and extraction of the smaller 0.25 mL booster dose. To assure providers have an adequate supply of 1 mL syringes to support extraction of booster doses (0.25 mL) from a Moderna 14 vial, CDC will ship an additional ancillary kit that contains all 1 mL syringes with all Moderna 14 orders. **When possible, please use 3 mL syringes for extraction of primary series doses to ensure you have an adequate supply of 1 mL syringes to support extraction of booster doses from a Moderna vial.**

**Wastage:** Continue to maintain reporting of wastage in whole doses. Wastage should only be reported if the total doses administered from a vial, regardless of volume or series, is less than the vial dose count (i.e., 1 primary and 5 booster doses from a 14-dose vial would be reported as 6 doses used and 8 doses wasted). Once 14 doses are given from a 14-dose vial, regardless of whether primary or booster doses, no wastage needs to be reported even if there is vaccine remaining in the vial.

#### **No Minimum Interval Between COVID-19 Vaccine and Other Vaccines:**

The CDC's "[Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States](#)," current recommendations state that "COVID-19 vaccines **may be administered without regard to timing of other vaccines**. This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day."

#### **Vaccine Provider Responsibilities:**

- COVID-19 vaccine must be given according to eligibility and criteria established by the ACIP recommendations as well as EUAs and associated fact sheets or emergency use instruction, as applicable, for immunocompromising conditions that would benefit from an additional dose of Pfizer-BioNTech or Moderna COVID-19 vaccines.
- As the ordering quantities and the storage conditions have become more practical, providers are encouraged to place direct orders in NYSIIS and avoid redistribution whenever possible, even if all doses cannot be used. Vaccine may be redistributed to another facility, provider, practice, or local health department that is enrolled in the COVID-19 vaccination program, with proper notice to the NYSDOH. Prior to redistributing vaccine, facilities must submit a completed [redistribution form](#) to [COVIDVaccineRedistribution@health.ny.gov](mailto:COVIDVaccineRedistribution@health.ny.gov) and can proceed with the redistribution once submitted. Direct orders are the preferred and safest way to receive vaccine.
  - A provider may transport vaccine to another location for the purpose of holding a limited duration vaccination clinic without notifying 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.
- When managing vaccine inventory, vaccines should always follow a first-in, first-out process in which vials that have the earliest expiration or beyond use date are used first.

- All vaccine providers should minimize the amount of vaccine that goes unused, consistent with CDC guidance, which states that while enrolled providers must continue to follow best practices to use every dose possible, it should not be at the expense of missing an opportunity to vaccinate every eligible person when they are ready to get vaccinated. (See Responsible Wastage section below for further guidance.)
- Providers should not prefill more syringes than they can use within 30 minutes. 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.
- All facilities or practices are required to track vaccine uptake among their staff and must furnish uptake data to the NYSDOH via HERDS survey upon request, or as directed by your agency or organization.

**Each provider that receives vaccine:**

- Must ensure all individuals receiving the COVID-19 vaccine complete the [New York State COVID-19 Vaccine Form](#) for the first dose, and attest that they are eligible to be vaccinated. All practices, providers, and entities must confirm adherence to this requirement at the time of vaccine administration.
- Must make best efforts to use all vaccine doses before expiration or reaching beyond use dates based on temperature storage requirements by assessing the COVID-19 vaccination status of each patient and offering the vaccine to all eligible individuals.
- Providers should continue to report all doses administered to NYSIIS and CIR, including third vaccine doses and booster doses as appropriate based on ACIP recommendations. It is critical that providers follow the appropriate intervals and product combinations in order for these doses to be considered valid. Providers should fully utilize both NYSIIS and CIR to confirm patients' previous dose dates and vaccine type. Full contact information for the individual receiving the vaccination, including phone number, email and zip code, should be entered as well.
- With respect to pharmacies, pharmacists are authorized to vaccinate individuals 5 years of age and older for COVID-19, pursuant to [current COVID-19 PREP Act declarations](#).

In addition, to ensure all New Yorkers can find vaccination locations close to them, **vaccine providers are strongly encouraged to have their facility/facilities opt-in to the CDC's online VaccineFinder tool ([Vaccines.gov](#))**. To do so, providers should set the display field in the [COVID-19 Locating Health Portal](#) to "display" if the facility is currently providing vaccinations to the general public. This will allow patients in the local area to see in real-time whether the facility has doses of each brand available, enabling vaccination access for a broader population.

- NYSDOH reports inventory to the CDC every Monday through Friday for each organization. Therefore, organizations do not need to report inventory to VaccineFinder (despite having access).
- Additional information on the VaccineFinder tool can be found [here](#).

### **Message for COVID-19 Vaccine Clinical Trial Sites:**

As a reminder, all COVID-19 vaccines administered in the State of New York must be entered in to NYSIIS or CIR. This includes any doses administered as part of an experimental arm of a clinical trial as well as doses offered and administered to participants in the control group (originally received placebo) after the clinical trial ended or at other time points per trial protocol. Staff at the participating site of the clinical trial must provide participants with a vaccination card and enter participant's immunization history into NYSIIS/CIR as applicable. Please note that only vaccines that have been issued an Emergency Use Authorization or that have been approved by the United States Food and Drug Administration (FDA) can be entered.

**The Second COVID-19 Vaccine Dose:** (Note: The following ONLY applies to the primary series, NOT for booster/additional third doses, as discussed above.)

Pfizer-BioNTech and Moderna vaccines require two doses, whereas Janssen (Johnson & Johnson) vaccine requires only a single 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**.

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.

If an individual requests a second dose after missing the 42-day window, they should still be administered 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 local health department.

Circumstances may arise where individuals need to receive their second dose at a different location than their first. Providers who have determined that the individual cannot return to the location where they received their first dose should schedule a second dose for these individuals or coordinate with the local health department to find a provider who has extra doses of the appropriate vaccine to vaccinate the individual. Vaccine availability can also be located using the [CDC's VaccineFinder](#). Individuals should not be tasked with locating second dose appointments. This obligation is on the provider who administered the first dose.

### **Special Considerations for Individuals Receiving Their First Dose within the United States but Outside New York State:**

Individuals who received their first dose of COVID-19 vaccine outside of New York State will not have a record of this dose in NYSIIS or CIR. Providers administering a second dose should either enter the first dose in NYSIIS/CIR as part of the historical record using data listed on the individual's COVID-19 Vaccination Record Card OR advise the patient that they should ask their primary care provider to enter their first dose into NYSIIS/CIR so the state has a full record of both doses of COVID-19 vaccine.

### **Special Considerations for Individuals Receiving COVID-19 Vaccine Outside the United States:**

The [CDC's Interim Clinical Considerations for Use of COVID-19 Vaccine](#) states as follows:

People who completed all of the recommended doses of an WHO-EUL [Emergency Use Listing] COVID-19 vaccine not approved or authorized by FDA, or people who completed a heterologous (mix and match) series composed of any combination of FDA-approved, FDA-authorized, or WHO-EUL COVID-19 vaccines:

- Are considered fully vaccinated.
- Under the [EUI](#), moderately or severely immunocompromised people aged  $\geq 12$  years should receive an additional primary dose of Pfizer-BioNTech COVID-19 vaccine (30  $\mu\text{g}$  formulation [purple cap]) at least 28 days after receiving the second vaccine dose of their primary series as detailed in [Considerations for COVID-19 vaccination in moderately or severely immunocompromised people](#).
- Under the [EUI](#), people aged  $\geq 18$  years (including moderately or severely immunocompromised people who received an additional primary dose) are eligible to receive a single booster dose of Pfizer-BioNTech COVID-19 vaccine (30  $\mu\text{g}$  formulation [purple cap]) at least 6 months after completing their primary series, as detailed in [Considerations for use of a COVID-19 vaccine booster dose](#).

Further, pursuant to the CDC's Interim Clinical Considerations, "people who received only the first dose of a multidose WHO-EUL COVID-19 primary series that is not FDA-approved or FDA-authorized, or who received all or some of the recommended doses of a COVID-19 vaccine primary series that is not listed for emergency use by WHO:

- Should be offered primary vaccination with an FDA-approved or FDA-authorized COVID-19 vaccine (i.e., 2-dose mRNA series or single Janssen dose), with a minimum interval of at least 28 days since receipt of the last dose of a non-FDA-approved/authorized vaccine.
- After completion of primary vaccination with an FDA-approved or FDA-authorized COVID-19 vaccine, these individuals are considered fully vaccinated, and are not recommended to receive an additional primary or booster dose at this time.

For COVID-19 vaccines neither authorized or approved by FDA nor listed for emergency use by the WHO:

- People who received all or some of the recommended doses of a COVID-19 vaccine that is neither authorized by FDA nor listed for emergency use by the WHO may be offered a complete age-appropriate, FDA-authorized or approved COVID-19 vaccine series.

#### **COVID-19 Vaccines Listed for Emergency Use by the WHO:**

As of December 20, 2021, the WHO has listed the following COVID-19 vaccines for emergency use:

- Pfizer-BioNTech COVID-19 vaccines (e.g., COMIRNATY, Tozinameran)\*
- Janssen (Johnson & Johnson) COVID-19 vaccine\*
- Moderna COVID-19 vaccine (Spikevax)\*
- AstraZeneca-Oxford COVID-19 vaccines (e.g., Covishield, Vaxzevria)
- Sinopharm Beijing Institute of Biological Products (BIBP) COVID-19 vaccine

- Sinopharm Wuhan Institute of Biological Products (WIBP) is a separate vaccine from Sinopharm BIBP and has not been listed for emergency use by the WHO as of August 13, 2021
- Sinovac-Coronavac COVID-19 vaccine
- Bharat Biotech BBV152 COVID-19 Vaccine (COVAXIN)
- Novavax (Covovax, Nuvaxovid)

\*Also authorized by the FDA for Emergency Use in the United States

The WHO maintains a list of COVID-19 vaccines listed for emergency use at <https://extranet.who.int/pqweb/vaccines/vaccinescovid-19-vaccine-eul-issued>.

### **Responsible Wastage:**

The CDC released guidance on May 11, 2021, regarding wastage with the critical message to “take every opportunity to vaccinate every eligible person.” As more vaccination opportunities are created, the likelihood of leaving unused doses in a vial may increase. While enrolled providers must continue to follow best practices to use every dose possible, it should not be at the expense of missing an opportunity to vaccinate every eligible person when they are ready to get vaccinated.

To ensure providers do not miss an opportunity to vaccinate every eligible person:

- Providers must follow [clinical best practice for vaccination as well as best practices when managing inventory](#) to maximize vaccination and minimize dose wastage.
- Providers should not miss any opportunities to vaccinate every eligible person who presents at a vaccination site.
  - Consider establishing and promoting standing vaccination days or half-days to increase likelihood of larger numbers of people presenting for vaccination on the same day.
  - Vaccinate family members or friends who accompany patients to medical visits even if they are not established patients at the vaccinating practice.
  - Continue outreach to employers or other community partners that have a large membership or network to arrange vaccination events.
  - As contingency plan, vaccine providers should attempt to contact additional persons (i.e., from a standby list or through personal contacts of persons being vaccinated) to use as many vaccine doses as possible.
  - Once punctured, multidose vials must be used within:
    - 12 hours [Moderna and Pfizer Adult/Adolescent Tris (Gray Cap, age 12+, no diluent)]
    - 6 hours (Pfizer-BioNTech 12+ purple cap vials)
    - 6 hours (refrigerated) **or** up to 2 hours at room temperature (J&J/Janssen). These times are NOT cumulative (i.e., you cannot store a punctured vial for 6 hours at refrigerated temperatures and then another 2 hours at room temperature).

### **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](mailto:info@VAERS.org) or by calling 1-800-822-7967.

**Equity and Access:**

Effort must be made to do outreach to persons 12 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. Every effort should be made to increase their access to vaccination opportunities.

**Communicating the Plan:**

Please be sure to clearly communicate this critical guidance to all staff involved in the vaccination program.

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](mailto:COVID19vaccine@health.ny.gov).

## New York State COVID-19 Vaccination Program Guidance Appendix A

All individuals 5 years of age and older are eligible to be vaccinated. **However, minors 5 through 17 are NOT authorized to receive the Janssen/Johnson & Johnson or Moderna COVID-19 vaccines. They may ONLY receive Pfizer-BioNTech at this time pursuant to the FDA EUA. Children under 5 years of age are not yet authorized to receive ANY COVID-19 vaccine.**

It is important to verify the age of individuals who appear to be a minor to confirm eligibility and ensure the administration of the proper COVID-19 vaccine.

Proof of age should be requested but is not required where the parent or guardian is available to attest to the minor's age. Documentary proof may include (but is not limited to):

- 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
- Parent/Guardian attestation

### **Minor Consent:**

#### **16 and 17-year olds:**

For all minors, a parent or legal guardian must provide consent for vaccination. For minors 16 or 17 years of age, such consent should be provided either in person or by phone, at the time of vaccine appointment. Providers may elect whether to accept a written statement of consent from the parent or guardian, where the parent or guardian is not available by phone to provide consent to vaccinate an unaccompanied minor. The [NYS COVID-19 Immunization Screening and Consent Form](#) may be considered for this purpose.

#### **5 through 15-year-olds:**

For minors who are 5 through 15 years of age, additionally, an adult caregiver should accompany the minor. If the adult caregiver is not the parent/guardian, the adult caregiver should be designated by the parent/guardian. The parent/guardian must still provide consent to the vaccination.