NEW YORK STATE OF OPPORTUNITY. Department of Health

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Guidance for
The New York State COVID-19 Vaccination Program

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Purpose and Background:

This guidance reflects the Centers for Disease Control and Prevention (CDC)'s November 29, 2021 recommending booster doses for anyone 18 years or older either 6 months after their primary vaccine series of Pfizer BioNTech, or 2 months after their primary vaccine series of Janssen/Johnson & Johnson.

The COVID-19 vaccine by Pfizer-BioNTech is an FDA-approved COVID-19 vaccine (brand name Comirnaty, mRNA) to prevent COVID-19 in persons 16 years of age and older. On November 17, 2021, CDC issued an EUI to provide information about use of this vaccine for individuals who received **a non-FDA authorized or approved COVID-19 vaccine**[1] as follows:

- A 3rd additional primary dose for moderately to severely immunocompromised persons aged ≥12 years; and
- A booster dose in certain adults aged ≥18 years after completion of primary vaccination.

Note: On November 2, the CDC endorsed the CDC's Advisory Committee on Immunization Practice's (ACIP's) recommendation for children ages 5-11 to receive the Pfizer-BioNTech COVID-19 vaccine. Guidance specific to this pediatric age group may be found on the New York State COVID-19 Vaccine Information for Providers page. This guidance document applies specifically to healthcare providers offering COVID-19 vaccinations to adolescents and adults age 12 and older.

(See below for individuals receiving COVID-19 vaccination outside the U.S.)

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

[1] Individuals identified under COVID-19 Public Readiness and Emergency Preparedness Act (PREP Act) declarations are authorized to administer COVID-19 vaccinations in accordance with the PREP Act declaration requirements and subject to any additional guidance or training issued or identified by the New York State Department of Health.

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 3rd dose of EITHER the Pfizer or Moderna vaccine.
- Individuals 12 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 3rd dose of ONLY the Pfizer vaccine.
- Individuals 12 years or older, who received a primary series of a non-FDA authorized or approved COVID-19[1] vaccine at least 28 days prior, may receive a 3rd dose of ONLY the Pfizer vaccine.
- In such situations, people who are moderately and severely immunocompromised and are 18 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).
- Individuals <18 years of age are not eligible for booster doses at this time.

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.

Heterologous or "mixed" dosing:

Individuals recommended to receive a booster should speak with their healthcare provider about which vaccine is best for their booster dose. If they choose a different vaccine booster, according to FDA and CDC guidelines, they can select from any FDA-approved or authorized COVID-10 vaccine for which they are eligible. Please see CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines for more information on booster dosing and considerations for clinicians regarding the different vaccine products.

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. **NOTE:** Expiration dates extension does NOT apply to vials dated July 2021 and earlier.

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
August 2021	November 2021
September 2021	December 2021
October 2021	January 2022
November 2021	February 2022
December 2021	March 2022
January 2022	April 2022
February 2022	May 2022

- 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/, 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

- 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.

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 12 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.

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." Although COVID-19 vaccines were previously recommended to be administered a minimum of 14 days before or after other vaccines, that previous recommendation was out of an abundance of caution and not due to any known safety or immunogenicity concerns and is no longer in effect.

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.

- Vaccine can 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 and can proceed with the redistribution once submitted.
    - 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 one hour. Prefilled syringes of Pfizer-BioNTech and Moderna vaccines must be used within six hours of filling; Janssen (Johnson & Johnson) vaccine must be used within two 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.

- 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 ≥12 years should receive an additional primary dose of Pfizer-BioNTech COVID-19 vaccine (30 µg 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 ≥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 µg 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 November 11, 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*
- 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)

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

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)
        - 6 hours (Pfizer-BioNTech)
        - 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 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.

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.