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Guidance for
The New York State COVID-19 Vaccination Program

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Purpose and Background:

On October 21, 2021, following the Food and Drug Administration's amended emergency use authorizations (EUAs) for the Moderna and Janssen (Johnson & Johnson) COVID-19 vaccines, the Centers for Disease Control and Prevention (CDC) endorsed the CDC's Advisory Committee on Immunization Practice's (ACIP's) recommendation for a booster shot of COVID-19 vaccines in the populations specified below. This recommendation follows the CDC's September 24 recommendation of booster doses for certain individuals who received the Pfizer-BioNTech vaccine.

For individuals who received the Pfizer-BioNTech or Moderna COVID-19 Vaccines, the CDC issued recommendations for a single booster dose six months or more after initial series for the following individuals:

- Age 65 years of age and older
- Age 18 and older who live in long-term care settings
- Age 18 and older who have underlying medical conditions
- Age 18 and older who work or live in high-risk settings

Long-term care setting, underlying conditions and high-risk settings are further defined using the link above or in **Appendix A** below.

The CDC has also issued recommendations for a single booster dose for those individuals who previously received a primary dose of the Janssen (Johnson & Johnson) vaccine, at least two months after the administration of the first dose.

The booster dose should be given using the same vaccine manufacturer that the person received for the primary series. If the same product used for the primary series is no longer available, or a different COVID-19 vaccine is desired, any FDA-approved COVID-19 vaccine can be used for the booster dose, according to FDA and CDC guidance.

In August, the FDA approved, and CDC recommended the Pfizer-BioNTech COVID-19 Vaccine for use in individuals 16 years of age and older, under the FDA's Biologics License Application (BLA) approval. This vaccine will now be marketed as Comirnaty (koe-mir'-na-tee). This vaccine continues to be available and recommended under emergency use authorization (EUA) for individuals 12 through 15 years of age, for the administration of an additional third dose in certain immunocompromised individuals, and a booster dose in specified populations.

The FDA-approved Pfizer-BioNTech product Comirnaty (COVID-19 Vaccine, mRNA) and the FDA-authorized Pfizer-BioNTech COVID-19 Vaccine under EUA have the same formulation and can be used

interchangeably to provide the COVID-19 vaccination series without presenting any safety or effectiveness concerns. Therefore, providers can use doses distributed under the EUA to administer the vaccination series for those seeking the approved vaccine. The updated Fact Sheet for Recipients provides additional information about both the approved and authorized vaccine. Providers should continue to use the vaccines on their shelves.

Moderna, which also has an mRNA COVID vaccine similar to Pfizer's, has started the process to seek full approval in the U.S. and began submitting data on a rolling basis on June 1. Johnson & Johnson (Janssen) has not yet submitted its application for full approval, though it is expected to this year. Both vaccines have been authorized for emergency use in the U.S.

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 both EUA and FDA approved COVID-19 vaccines. Accordingly, use of these products outside of those that have been approved and authorized by FDA (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: 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: 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).

Booster Doses for Specified Individuals:

All providers enrolled in the NYS COVID-19 vaccination program are authorized to expand eligibility for the following individuals, effective immediately.

Among those who received a primary series of the Pfizer-BioNTech or Moderna vaccines:

Under the U.S. Food and Drug Administration's (FDA's) updated emergency use authorizations (EUA), the CDC issued recommendations for a single booster dose six months after completion of the primary series of the Pfizer-BioNTech COVID-19 Vaccine and Moderna COVID-19 Vaccine for the following individuals:

- Age 65 years of age and older
- Age 18 and older who live in long-term care settings
- Age 18 and older who have underlying medical conditions
- Age 18 and older who work or live in high-risk settings

Please see **Appendix A** for a detailed list of individuals who are eligible for a booster dose following receipt of a primary series of an mRNA vaccine.

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 reported as 6 doses and 8 doses wasted).

Among those who received a primary series of the Janssen (Johnson & Johnson) vaccine:

Under the FDA's updated EUA for the Janssen (Johnson & Johnson) vaccine, the CDC has also recommended a single booster dose of any FDA-authorized vaccine for individuals age 18 and older who previously received a primary dose of the Janssen vaccine, at least two months after the administration of the primary dose.

Heterologous or "mixed" dosing

The same product that was used for the primary series should be used for the booster dose. If that product is not available or another product is preferred, heterologous boosting or "mixed" dosing with a single dose of any of the authorized COVID-19 vaccine boosters is acceptable, according to FDA and CDC guidance. Although cases of myocarditis related to mRNA vaccines (mostly in young men), and cases of GBS (mostly in middle aged adults) and Thrombosis with thrombocytopenia (mostly in young women) related to the Janssen vaccine continue to remain very rare, this information should be considered as clinicians and recipients determine individual risk and benefits of booster doses and product preferences.

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

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.

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.

According to the CDC, an estimated 2.7 percent of adults in the United States are immunocompromised. This proportionally equates to approximately 425,000 adults in NYS. Persons with immunocompromising conditions are more likely to get severely ill from COVID-19, are at a higher risk for prolonged SARS-CoV-2 infection and viral shedding, have increased viral evolution during infection and treatment (hospitalized patients), have low antibody/neutralization titers to SARS-CoV-2 variants, are more likely to transmit SARS-CoV-2 to household contacts, and are more likely to have breakthrough infection. **Therefore, certain people who are moderately or severely immunocompromised due to a medical condition or receipt of immunosuppressive medications or treatments, should consult with their healthcare provider to discuss the benefits of an additional dose of an mRNA vaccine, and receive the additional vaccine dose if indicated.**

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.

Eligible Individuals:

Eligibility for Additional Doses of Pfizer-BioNTech or Moderna COVID-19 Vaccines effective August 13, 2021:

For public health purposes, immunocompromised people who have completed a primary vaccine series (i.e., 2-dose mRNA vaccine series [Pfizer-BioNTech and Moderna] or single dose of the Janssen vaccine) are considered fully vaccinated ≥2 weeks after completion of the series. However, an additional dose of an mRNA COVID-19 vaccine (at least 28 days following the last dose of the primary COVID-19 vaccine series) should be considered for people with moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments. For a list of conditions or treatments eligible for receipt of an additional dose, please see **Appendix A**.

Factors to consider in assessing the general level of immune competence in a patient include disease severity, duration, clinical stability, complications, comorbidities, and any potentially immune-suppressing treatment.

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.

Ongoing Eligibility for Primary (Initial) Series

In addition to the immunocompromised population listed above, all individuals 12 years of age and older continue to be eligible to be vaccinated. However, minors 12 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 12 years of age are not yet authorized to receive ANY COVID-19 vaccine. Minors must present identification to verify that they are at least 12 years of age or have a parent/guardian attest on their behalf. See **Appendix B** for guidance regarding necessary consent for individuals under 18 years of age.

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

On May 14, the CDC updated its "Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States," to recommend that "COVID-19 vaccines and other vaccines **may now be administered without regard to timing**. This includes simultaneous administration of COVID-19 vaccines and other vaccines on the same day, as well as coadministration within 14 days." 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. When deciding whether to co-administer another vaccine(s) with COVID-19 vaccines, providers should consider whether the patient is behind or at risk of becoming behind on recommended vaccines, their risk of vaccine-preventable disease (e.g., during an outbreak or occupational exposures), and the reactogenicity profile of the vaccines.

Vaccine Provider Responsibilities:[1]

- COVID-19 vaccine must be given according to eligibility and criteria established by the ACIP recommendations as well as EUAs and associated fact sheets 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.

[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.

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.

- With respect to pharmacies, pharmacists are authorized to vaccinate individuals 12 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 second 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 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 guidance for fully vaccinated people states that "this [CDC] guidance can also be applied to COVID-19 vaccines that have been authorized for emergency use by the World Health Organization (WHO) (e.g., AstraZeneca/Oxford)."

For COVID-19 vaccines not authorized by the FDA but listed for emergency use by the WHO:

- People who have received all recommended doses of a COVID-19 vaccine that is listed for emergency use by the WHO **do not need** any additional doses with an FDA-authorized COVID-19 vaccine.
- People who have not received all the recommended doses of a COVID-19 vaccine listed for emergency use by the WHO may be offered a complete FDA-authorized COVID-19 vaccine series.

For COVID-19 vaccines neither authorized 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 FDA-authorized COVID-19 vaccine series.

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

As of August 13, 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

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

Universal Doses:

Effective May 11th, New York State moved to a "Universal Dose" administration process for all multi-dose COVID-19 vaccine types. All doses are now considered universal doses, which means that doses can be used as either a first dose or a second dose, regardless if they were originally shipped to providers as a first dose or a second dose. This does NOT eliminate the obligation of the provider to schedule second dose appointments at the time the first dose is administered.

First, second, and booster doses may also be drawn interchangeably from the same vial. With all doses considered a universal dose, please utilize a first in, first out rule to manage inventory. This includes storing newly received vaccine in the freezer until it is needed. **COVID-19 vaccine providers should continue to follow their jurisdiction's (NYC or NYS) vaccine ordering and inventory guidance to request vaccine.**

Extra Doses of Moderna:

The Moderna COVID-19 Vaccine is supplied in two multiple-dose vial presentations:

- A multiple-dose vial containing a maximum of 11 doses: range 10-11 doses (0.5 mL each).
- A multiple-dose vial containing a maximum of 15 doses: range 13-15 doses (0.5 mL each).

Depending on the syringes and needles used for each dose, there may not be sufficient volume to extract more than 10 primary doses from the maximum of 11 doses vial or more than 13 primary doses from the maximum of 15 doses vial. Irrespective of the type of syringe and needle:

- Each full dose must contain 0.5 mL of vaccine, and must be administered for the primary vaccine series.
    - A half-dose (0.25 mL), must be administered as a booster dose only.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.5 mL or half dose of 0.25mL for a booster dose, discard the vial and contents. Do not pool excess vaccine from multiple vials.
- Pierce the stopper at a different site each time.

This is particularly important because the vaccination does not 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 Moderna guidance for extra doses. Extra doses are not supported in the EUAs for Pfizer-BioNTech or Janssen (Johnson & Johnson) beyond the labeled doses per vial.

Responsible Wastage:

The CDC released guidance on May 11th 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.

New York State COVID-19 Vaccination Program Guidance
Appendix A
Individuals Eligible to be Vaccinated

Eligible Individuals for Booster Doses After Receiving a Primary Series of the Pfizer-BioNTech or Moderna COVID-19 Vaccine:

As noted above, the following individuals are eligible for a single mRNA vaccine booster dose of any FDA approved or authorized COVID-19 vaccine, at least six months after completion of a primary series of either the Pfizer-BioNTech COVID-19 Vaccine or the Moderna COVID-19 Vaccine:

- Age 65 years of age and older
- Age 18 and older who live in long-term care settings
- Age 18 and older who have underlying medical conditions
- Age 18 and older who work or live in high-risk settings

Long-term care settings include any location where older adults, people with disabilities or chronic health conditions, or people otherwise needing assistance with activities of daily living receive services or supports. These can include both medical care and non-medical care. Examples of long-term care settings include, but are not limited to:

- Skilled nursing and nursing facilities (also known as nursing homes);
- Intermediate care facilities for individuals with intellectual disabilities (ICFs-IID);
- Inpatient psychiatric settings, including psychiatric residential treatment facilities (PRTFs);
- Inpatient substance use disorder facilities and residential settings for people with substance use disorders;
- Assisted living settings for older adults and people with disabilities, including assisted living facilities, independent living facilities, residential care and continuing care retirement communities, personal care homes, and board and care homes;
- Senior housing, including Section 202 and other HUD-assisted housing that primarily serves older adults;
- Housing for people with disabilities, including Section 811 HUD-assisted housing, Housing Opportunities for People living With AIDS (HOPWA), and other HUD-assisted housing that primarily serves people with disabilities;
- Residential settings for people with disabilities and older adults, including group homes, shared living, adult foster care, and transitional housing;
- Congregate day programs, including adult day programs, PACE programs, day habilitation programs, and other community-based day service programs; and
- Senior center programs and congregate nutrition programs.

For the purposes of mRNA vaccine booster dose eligibility, underlying conditions include:

- Cancer (current or in remission, including 9/11-related cancers)
- Chronic kidney disease*
- Pulmonary disease, limited to chronic obstructive pulmonary disease (COPD), asthma (moderate to severe), pulmonary fibrosis, cystic fibrosis, tuberculosis, 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: body mass index ((BMI) 40 kg/m2 or higher)*, obesity: (BMI of 30 kg/m2 or higher but < 40 kg/m2)*, overweight (BMI of 25 kg/m2 or higher but < 30kg/m2)
- Pregnant or recently pregnant
- 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
- Liver disease limited to cirrhosis, non-alcoholic fatty liver disease, alcoholic liver disease, or autoimmune hepatitis.
- Current or former smoker
- Substance use disorder
- Mental health disorders limited to mood disorders including depression, schizophrenia spectrum disorders.

* indicates underlying conditions with evidence for pregnant and non-pregnant people

For the purposes of booster dose eligibility, ACIP gave the following examples of high-risk occupational and institutional settings:

- Essential workers (frontline and non-frontline) https://www.cisa.gov/publication/guidance-essential-critical-infrastructure-workforce
- Unpaid caregiver of a frail or immunocompromised person
- Paid and unpaid workers who interact within <6ft of others
- Live in a congregate setting (e.g. homeless shelter, correctional facility)

Eligibility for Additional Doses of Pfizer-BioNTech or Moderna COVID-19 Vaccines effective August 16, 2021:

For public health purposes, immunocompromised people who have completed a primary vaccine series (i.e., 2-dose mRNA vaccine series [Pfizer-BioNTech and Moderna] or single dose of the Janssen vaccine) are considered fully vaccinated ≥2 weeks after completion of the series. However, an additional dose of an mRNA COVID-19 vaccine after an initial 2-dose primary mRNA COVID-19 vaccine series, at least 28 days following the last dose of the primary COVID-19 vaccine series, should be considered for people with moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments. These conditions and treatments include but are not limited to:

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection

- Active treatment with high-dose corticosteroids (i.e., ≥20mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory.

New York State COVID-19 Vaccination Program Guidance
Appendix B

All individuals 12 years of age and older are eligible to be vaccinated. **However, minors 12 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 12 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.

12 through 15-year olds:

For minors who are 12 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.