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Guidance for the New York State COVID-19 Vaccination Program: Vaccination of Individuals Ages 6 Months to Adult

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Summary of Recent Changes

- Effective April 18, 2023: The Food and Drug Administration (FDA) amended the Emergency Use Authorizations (EUAs) of the Pfizer-BioNTech and Moderna bivalent mRNA vaccines to simplify the vaccination schedule by authorizing ONLY bivalent vaccines to be used for all doses administered to individuals 6 months and older. The monovalent Moderna and Pfizer-BioNTech COVID-19 vaccines are no longer authorized for use in the United States. Dispose of any monovalent Moderna and Pfizer-BioNTech vaccine doses that are in inventory as medical waste and report unused doses as wastage in NYSIIS.
- On April 22, 2023: The Centers for Disease Control and Prevention (CDC) updated its interim clinical considerations with respect to bivalent COVID-19 vaccine recommendations for individuals 6 months and older.
- On April 22 and May 1, 2023: The CDC updated vaccine schedules for those eligible to receive a COVID-19 vaccine, by age, immunocompetency status, and vaccine product. These changes were made to reflect recent FDA EUAs for bivalent formulations of the Pfizer-BioNTech and Moderna COVID-19 mRNA vaccines.
    - For immunocompetent individuals aged 6 months and older who previously received both a monovalent mRNA vaccination series and a bivalent mRNA dose, their vaccination is complete. No additional doses are indicated at this time.
    - Individuals aged 65 years and older without immunocompromise have the option to receive 1 additional bivalent mRNA vaccine dose at least 4 months after their first dose of bivalent mRNA.
    - Immunocompromised individuals who previously received a bivalent COVID-19 mRNA vaccine have the option to receive an additional bivalent COVID-19 mRNA vaccine dose 2 months after their first. Further additional dose(s) may be administered as determined by individual's healthcare providers, personal preference, and clinical scenario. Any additional doses should be administered at least 2 months after their last bivalent vaccine dose.
    - Unvaccinated and immunocompromised individuals ages 6 months and older are recommended to receive 3 bivalent mRNA doses at this time.
    - For more information regarding any of the scenarios above please visit the CDC's Interim Clinical Considerations.
- Storage and handling guidance has been updated to reflect updated guidance regarding mRNA bivalent vaccines.
- As of May 6, 2023, all Janssen COVID-19 vaccine purchased by the United States Government has expired. Janssen vaccines may no longer be administered.
- For detailed clinical guidelines regarding the administration of the COVID-19 vaccines, providers should refer to the CDC Interim Clinical Considerations here: Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC.
- **NOTICE: As of May 23, 2023, NYSDOH will discontinue updating this guidance document for the New York State COVID-19 Vaccination Program. Providers should stay up-to-date on COVID-19 vaccination guidance by visiting the CDC's** Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC.

Key Points about Currently Available COVID-19 Vaccines

Moderna and Pfizer BioNTech COVID-19 Bivalent mRNA vaccine

For individuals 6 months of age and older who are either immunocompetent or immunocompromised, please refer to the CDC's Interim Clinical Considerations.

- Individuals >5 years, who are unvaccinated and receive Moderna Bivalent COVID-19 vaccine as a second dose following a first dose of Pfizer-BioNTech COVID-19 bivalent vaccine: (1) If immunoCOMPETENT, do

not administer any more vaccine doses as this is considered a single-dose Pfizer-BioNTech bivalent vaccination series. (2) If immunoCOMPROMISED, a third dose of either mRNA bivalent vaccine should be administered at least 4 weeks after the second dose.

- Individuals 6 months to 4 years of age, if different bivalent vaccines are used for the two doses in unvaccinated, then follow a 3-dose schedule. Either Pfizer-BioNTech or Moderna bivalent doses can be administered 8 weeks after the 2nd dose.
- Individuals receiving the Pfizer-BioNTech bivalent vaccine who turn 4 to 5 years old during the 3 dose vaccine series, should follow dosing recommendations based on age at the start of the vaccine series (3 dose of 0.2 mL/3ug, Maroon Cap).
- Unvaccinated individuals receiving the Moderna Bivalent mRNA vaccine who turn 5 to 6 years should receive 2 doses of Moderna COVID-19 vaccine (0.25mL/25ug; dark blue cap and label with gray border).
- There are 3 scenarios in which an individual should receive the Moderna bivalent mRNA vaccine dose from the Dark Pink Cap with Yellow Label Border vial: (1) immunoCOMPETENT individuals ages 6 months to 5 years of age who were previously vaccinated with 2 doses of monovalent Moderna mRNA vaccine (2) immunoCOMPROMISED individuals age 6 months to 4 years of age who were previously vaccinated with 3 doses of monovalent Moderna mRNA vaccine (3) when immunocompromised individuals ages 6 months to 5 years of age receive further additional bivalent doses as determined by the healthcare provider.

Novavax (NUVAXOVID) COVID-19 vaccine

For individuals 12 years and older:

- Individuals who are NOT immunocompromised:
  - 2-dose Novavax primary series followed by either bivalent mRNA dose
- Individuals who ARE immunocompromised:
  - 2-dose Novavax primary series followed by either bivalent mRNA booster dose. There is no 3rd primary dose. Immunocompromised individuals 12 years and older, have the option to receive an additional dose of a bivalent mRNA vaccine at least 8 weeks after their last bivalent dose.

For individuals 18 years and older:

- For both individuals who are NOT immunocompromised & those who ARE immunocompromised
  - It is preferred that these individuals receive either a Moderna or Pfizer-BioNTech mRNA bivalent vaccine as a booster at least 2 months after their 2nd Novavax primary dose. In limited situations, a 1-dose monovalent Novavax booster dose may be used (instead of a bivalent mRNA bivalent booster dose) the individual is unable to receive an mRNA vaccine (i.e., contraindicated) or unwilling to receive an mRNA vaccine and would otherwise remain unvaccinated. Please refer to the Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC for more information.

All COVID-19 vaccines

- An 8-week interval between the first and second primary doses of Novavax, Moderna Bivalent, and Pfizer-BioNTech Bivalent COVID-19 vaccines may be optimal for some individuals 6 months to 64 years of age, as it may reduce the small risk of myocarditis and pericarditis associated with these vaccines. A 3-4-week interval continues to be recommended for individuals who are moderately or severely immunocompromised, adults ages 65 years and older, and in scenarios where fullest possible protection is required sooner due to risk of severe disease or community spread.
- In general, COVID-19 vaccine from the same manufacturer should be used for the primary series. There is limited data on the safety and efficacy of a mixed series composed of any combination of Moderna, Novavax, and Pfizer-BioNTech COVID-19 vaccines. Please refer to the Interim Clinical Considerations for

Use of COVID-19 Vaccines | CDC for more information regarding the interchangeability of COVID-19 vaccines.

- As before, there is no minimum interval between COVID-19 vaccine and other routine vaccines. CDC states 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." For more information, see CDC's Interim Clinical Considerations, section entitled "Coadministration of COVID-19 vaccines with other vaccines".
    - Additional considerations for the orthopoxvirus vaccination: If an orthopoxvirus vaccine is administered first, the individual might consider waiting 4 weeks before receiving a Moderna, Novavax, or Pfizer-BioNTech vaccine. If Moderna, Novavax, or Pfizer-BioNTech is administered first, then there is no minimum interval necessary before receiving orthopoxvirus vaccination for prophylaxis in the setting of an outbreak.

Scheduling Subsequent COVID-19 Vaccine Doses

All providers **should** schedule the second (or third) dose appointment for recipients **at the time the first (or second) dose is administered**. If scheduling a second (or third) dose appointment is not possible at the time of the first (or second) dose, providers **must** supply information on how/where to obtain a subsequent dose(s) of vaccine.

Circumstances may arise where individuals need to receive their second (or third) 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 (or second) dose **must** either schedule a second (or third) dose for these individuals elsewhere or supply information on how/where to obtain a second (or third) dose of vaccine. Vaccine availability can be located using the CDC's VaccineFinder. Please ensure all individuals are informed on how to locate second (or third) dose appointment.

Special Considerations for Individuals Receiving Their Primary Series Doses Outside New York State

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

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

The WHO maintains a list of COVID-19 vaccines that it has authorized for emergency use globally. This list includes products currently authorized by the FDA for Emergency Use in the United States (Pfizer BioNTech, Novavax, Moderna) as well as other COVID-19 vaccines not currently available in the U.S. A complete list of these vaccines can be found on the WHO website.

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)."

Individuals who received a partial monovalent mRNA COVID-19 (i.e., Moderna or Pfizer-BioNTech) or partial Novavax COVID-19 vaccine primary series are not considered fully vaccinated in the United States. These

individuals do not need to restart the primary series. They should complete the series as close to the recommended time as possible with a bivalent mRNA dose as per CDC's Interim Clinical Considerations Appendix B.

Whether an individual who received COVID-19 vaccines outside the USA is "up-to-date" depends on which COVID-19 vaccine and how many doses they received. More information about when individuals vaccinated outside the USA are considered fully vaccinated and/or "up-to-date" can be found here.

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

- Please visit the CDC's guidance on vaccines listed for emergency use by the WHO but not approved/authorized by the FDA.
- Individuals who have received all recommended doses of a COVID-19 vaccine that is listed for emergency use by the WHO, administer 1 bivalent mRNA dose if ages 6 years and older. If individuals are 6 months to 5 years of age, please follow recommendations within CDC's Interim Clinical Considerations Table 1 or Table 2 (immunocompromised).

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

- For individuals 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, the CDC does NOT consider these persons to be fully vaccinated. They should be offered an age-appropriate COVID-19 mRNA vaccine according to the United States vaccination schedule. For more information, please visit the CDC's guidance on these vaccines.

The minimum interval between receipt of a non-FDA-approved/authorized vaccine and initiation of the FDA-approved/authorized COVID-19 vaccine series is 28 days.

Vaccine Safety

Post-vaccination monitoring is an essential part of the COVID-19 vaccination program. The 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. For a list of administration errors and deviations and what action to take after an error or deviation has occurred, please refer to this CDC resource: Appendix C. Vaccine Administration Errors and Deviations.

Information on COVID19 vaccine safety signals that have been assessed by one or more of these mechanisms can be found in CDC's Selected Adverse Events Reported after COVID-19 Vaccination. Additional information can be found in CDC's Interim Clinical Considerations:

- Section entitled Safety considerations for mRNA COVID-19 vaccines: Pfizer-BioNTech and Moderna (including considerations surrounding myocarditis and pericarditis), and
- Section entitled COVID-19 vaccination and SARS-CoV-2 infection including MIS-C and MIS-A (including considerations for vaccination after MIS-C).

Regarding vaccine demand and hesitancy—serious safety problems associated with COVID-19 vaccines are rare. Still, patient perception of COVID19 vaccine safety, often fueled by false reports on social media, can impact public trust in vaccination. Information on common myths about COVID-19 vaccine safety (including impact on fertility and DNA) can be found at the CDC's Facts webpage and New York State's webpage Combatting Misinformation about the COVID-19 Vaccines.

Consent for Vaccination of Minors

Entities operating vaccination sites may use the following verification methods as a model for securing consent for vaccination of minors, in consultation with counsel as needed. It is important to verify the age of any individual who appears to be a minor to ensure consent is obtained, 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 US passport or valid foreign passport
- Permanent resident card
- Certificate of Naturalization or Citizenship
- Life insurance policy with birthdate
- Parent/guardian attestation

For all minors, a parent or legal guardian must provide consent for vaccination.

6 month–5-year-olds: For minors who are 6 months through 5 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.

16 and 17-year-olds: For minors 16 or 17 years of age, consent should be provided either in person or by phone, at the time of vaccine appointment. Providers may elect 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.

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

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 Emergency Use Instruction (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 Public Readiness and Emergency Preparedness (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.

Ordering Instructions

Please see the NYSDOH COVID-19 Vaccine Information for Providers page for more information on ordering COVID-19 vaccines in NYSIIS. Providers in New York City should follow instructions from NYC DOHMH and CIR. As of August 2022, Novavax COVID-19 vaccine is not orderable for all providers in NYSIIS or CIR. Providers in NYC that are interested in ordering Novavax vaccine should email covidvax@health.nyc.gov and providers outside NYC that are interested in ordering Novavax vaccine should email COVID19Vaccine@health.ny.gov.

NYSDOH COVID-19 vaccination program providers are able to request bivalent booster doses through routine ordering in NYSIIS.

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.

Storage and Handling Requirements

Vaccines must be stored and handled properly from the time they are manufactured until they are administered to maintain the cold chain, thus protecting the potency and effectiveness of the vaccine, and ensuring vaccine recipients are fully and safely protected from vaccine-preventable diseases. Detailed information regarding COVID-19 vaccine storage and handling requirements is available at CDC Vaccine Storage and Handling Toolkit.

CDC storage and handling summaries for the COVID-19 vaccines by age for each product can be found here:

- Pfizer COVID-19 Vaccine Storage and Handling
- Moderna COVID-19 Vaccine Storage and Handling
- Novavax COVID-19 Vaccine Storage and Handling

As part of the COVID-19 Vaccination Provider Agreement, providers are required to:

- Store and handle vaccines under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with an EUA or vaccine package insert, manufacturer guidance, and CDC guidance in the Vaccine Storage and Handling Toolkit.
- Monitor storage unit temperatures at all times, using equipment and practices that comply with guidance in the toolkit. Every storage unit that holds COVID-19 vaccines must have a digital data logger (DDL). Staff must check and record temperatures each workday and regularly check the DDL temperature data.
- If the temperature of the storage unit goes outside of the recommended temperature range, the temperature excursion must be reported immediately. Providers located outside NYC must complete the COVID-19 Vaccination Program Temperature Excursion Report.

- Monitor and comply with COVID-19 vaccine expiration and beyond use dates.
- Preserve all records related to COVID-19 vaccine management, including temperature records, for a minimum of three years.
- Comply with CDC instructions and timelines for disposing of COVID-19 vaccine and diluent, including used doses.

COVID-19 Vaccine 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. Prior to discarding COVID-19 vaccine, recheck the expiry date to determine if an extension has been made.

1. **Pfizer-BioNTech COVID-19 vaccines (all formulations):** The vial may contain the expiration date or the manufacture date. However, some expiration dates have received extensions from when the label was printed.
    - To obtain the current expiration date of the lot number received, providers can access the manufacturer website at https://lotexpiry.cvdvaccine.com/, enter the lot number and the expiration date will be displayed.
    - Pfizer purple cap: All Pfizer purple cap COVID-19 vaccine is now expired. Any remaining supply must be disposed of according to state and local regulations and report as wastage in NYSIIS.
    - Pfizer vaccines may be stored in ultra-cold temperatures between -90° and -60° C (-130° and -76° F) until expiration date. If vaccine is stored in a refrigerator, beyond use dates must be tracked.

2. **Moderna COVID-19 vaccines (all formulations):** The expiration date is NOT printed on the vaccine vial or carton.
    - In December 2022, Moderna COVID-19 vaccines have once again received a shelf-life extension by lot number. It is important to regularly monitor expiration dates of all vaccines, as dates are subject to change.
    - 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.
    - Moderna vaccines may be stored in standard freezer at temperatures between -50°C and -15°C (-58°F and 5°F) until expiration date. If vaccine is stored in a refrigerator, beyond use dates must be tracked.

3. **Novavax COVID-19 vaccine:** The expiration date is not printed on the vaccine vial or carton. To find the expiration date:
    - Visit www.NovavaxCovidVaccine.com. Navigate to the United State Healthcare Professional section of the website. Type the lot number printed on the vial or carton into the Expiry Date Checker tool.
    - Novavax vaccine may be stored at refrigerated temperatures of 2°–8° Celsius (36°–46° Fahrenheit) until expiration date.

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.

1. Pfizer-BioNTech (all formulations): Pfizer-BioNTech COVID-19 Vaccine Storage and Beyond Use Date Tracking Labels
    - 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 (36°F to 77°F) 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.

2. Moderna: Moderna COVID-19 Vaccine Storage and Beyond-Use Date (BUD) Tracking Labels
    - Refrigerator (2° C to 8° C): 30 days
    - After Puncture:
        - Moderna Bivalent for ages 6 months through 5 years, 2 dose vials, may be stored at 2° C to 25° C (36°F to 77°F) for up to **8** hours following puncture.
        - All other Moderna products (Monovalent for ages 6 months through 5 years, Monovalent for ages 6 years through 11 years, Monovalent for ages 12 and older, and Bivalent for ages 6 and older) may be stored at 2° C to 25° C (36°F to 77°F) for up to 12 hours following puncture.

3. Novavax: Novavax COVID-19 Vaccine Storage and Beyond-Use Date Tracking Labels
    - ONLY store in refrigerator up to expiration date.
    - After Puncture: 2° C to 25° C (36°F to 77°F) up to 6 hours

Moderna Bivalent Booster Dose Inventory Considerations

It is important to note that the volume of a Moderna bivalent booster dose for individuals ages 6-11 is **0.25 mL** (half the volume of a bivalent booster dose for ages 12+). This means that up to 10 doses may be drawn from a 2.5 mL vial despite the order quantity accounting for 5 doses per vial. Please see the Dear Healthcare Provider Letter for additional info: https://www.fda.gov/media/162249/download.

Reporting: Despite the volume of the booster dose for individuals ages 6-11 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.

NYSIIS inventory: Due to the volume of the bivalent booster dose varying by age, the number of doses reported may exceed the number of doses recorded in NYSIIS inventory (i.e., 100 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 (5 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.

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 bivalent vaccine available on Vaccine Finder.

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, is less than the vial dose count (i.e., 1 booster and 5 booster doses from a 5-dose vial would be reported as 6 doses used and 2 doses wasted). Once 10 doses are given from a 10-dose vial, regardless of whether primary or booster doses, no wastage needs to be reported even if there is vaccine remaining in the vial. Post-puncture times must still be tracked and remaining doses discarded as medical waste.

Each provider that receives vaccine:

- 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 parent/guardian of the child receiving the vaccination, including phone number, email and zip code, should be entered, as well.

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). Providers must maintain accurate inventory in NYSIIS or CIR. Additional information on the VaccineFinder tool can be found here.

As of August 31, 2022, Moderna Red Cap Vials (Moderna 10-dose) are no longer allowed to be administered for booster doses.

Vaccine Redistribution

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 and can proceed

with the redistribution once submitted. Redistributions must follow the New York State COVID-19 Vaccine Program Guidance for Vaccine Transport, including use of a digital data logger to monitor temperatures during transport. 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.

Responsible Wastage

The CDC released guidance on May 11, 2021, regarding wastage along with a 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 clinical 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.

As the ordering quantities and the storage conditions have become more practical, we are encouraging providers to place direct orders whenever possible, even if you cannot use all doses. This is the safest way for providers to receive vaccine and reduces the risk of temperature excursions and the burden of continued redistribution.

- Currently available COVID-19 vaccine products are all multidose vials. Vaccine vials must often be punctured without using the full number of doses printed on the label. Do not turn anyone away because you do not have additional people to vaccinate with remaining doses in a vial. Discarding the remaining doses is acceptable wastage (and needs to be reported as wastage in NYSIIS). Doses not administered within the limits below post-puncture must be wasted:
    - 12 hours: All formulations of Pfizer and all formulations of Moderna except the Moderna Bivalent for ages 6 months through 5 years (2-dose vials)
    - 8 hours: Moderna Bivalent for ages 6 months through 5 years (2-dose vials)
    - 6 hours: Novavax

Please note: **Any vial of vaccine that exceeds the shelf life indicated by the manufacturer (expiration date OR beyond use date) must be disposed of as regulated medical waste and reported as wastage** in consultation with the manufacturer.

Equity and Access

Efforts must be made to conduct outreach to families in all communities and settings. Children and families 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. Encourage families to look for the vaccine through https://www.vaccines.gov/ or call 1-800-232-0233 (TTY 1-888-720-7489). Locations, types of vaccine available, age range for vaccination and appointment scheduling information can be found here.

Communicating the Plan

Please be sure to clearly communicate this critical guidance to all staff involved in the vaccination program. Even front desk staff can be champions to promote the vaccine.

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.

Resources

1. **CDC Resources**
    - CDC's Presentation on the Updates to the Interim Clinical Considerations for the Use of COVID-19 Vaccines
    - Guidance for people who are **not** immunocompromised
    - Guidance for people who **are** immunocompromised
    - Timing, spacing, age transitions, and co-administration of COVID-19 vaccines
    - Vaccine Interchangeability
    - Contraindications and Precautions
    - Reporting of Adverse Events
    - Special Populations: Pregnancy, Lactation and Fertility
    - Vaccine administration errors and deviations (Appendix D)

2. **Resources for Pediatric Populations**
    - Communication resources for pediatrics
    - Vaccine Administration Resource Library for Healthcare Professionals (CDC)
    - Epidemiology and Prevention of Vaccine-Preventable Diseases: Vaccine Administration (CDC)
    - COVID-19 Vaccine Webinar Series (CDC)
    - COVID-19 Vaccination Clinical and Professional Resources (CDC)
    - How to Administer Intramuscular and Subcutaneous Vaccine Injections (Immunization Action Coalition)
    - Medical Management of Vaccine Reactions in Children and Teens in a Community Setting (Immunization Action Coalition)
    - Updated toolkit for pediatirc COVID vaccines

3. **General Resources**
    - Protective Measures for Vaccinating During the COVID-19 Pandemic (Immunization Action Coalition)
    - Skills Checklist for Vaccine Administration (Immunization Action Coalition)
    - Supplies You May Need at an Immunization Clinic (Immunization Action Coalition)
    - Ask the Experts: COVID-19 Specific Information (Immunization Action Coalition)
    - Ask the Experts: Administering Vaccines (Immunization Action Coalition)
    - 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.