

Governor

MARY T. BASSETT, M.D., M.P.H. Commissioner

KRISTIN M. PROUD
Acting Executive Deputy Commissioner

# Guidance for the New York State COVID-19 Vaccination Program: Vaccination of Children Ages 6 Months to 11 Years

June 22, 2022

**Note:** This document applies specifically to health care providers offering COVID-19 vaccinations to children ages 6 months to 11 years. Guidance for the New York State COVID-19 Vaccination Program pertaining to individuals ages 5 and older can be found on the <a href="New York State COVID-19 Vaccine Information for Providers">New York State COVID-19 Vaccine Information for Providers</a> page.

#### **Table of Contents**

- 1. Summary of Recent Changes
- 2. Key Points About the COVID-19 Vaccine for Children 6 months 11 years old
- 3. Scheduling Second Dose
- 4. Special Considerations for Individuals Receiving their Primary Series Doses Outside New York State
  - a. Outside of New York State
  - b. Outside of the United States
- 5. COVID-19 Vaccines Listed for Emergency Use by the WHO
- 6. Vaccine Safety
- 7. Consent for Minors
- 8. EUAs, FDA Vaccine Approval Status, and Appropriate Use of Vaccines in New York State
- 9. Vaccine Management
  - a. Ordering Instructions
  - b. Storage and Handling Requirements
  - c. Updates to Pediatric mRNA COVID-19 Vaccine Expiration
  - d. Vaccine Redistribution
  - e. Responsible Wastage
- 10. Equity and Access
- 11. Communicating the Plan
- 12. Resources

# **Summary of Recent Changes**

- Update as of June 18, 2022: Everyone ages 6 months and older in the United States should receive a COVID-19 primary series vaccination for the prevention of COVID-19. This current provider guidance has expanded the age range to 6 months-11 years of age accordingly.
- On June 18, 2022, the CDC authorized **BOTH** the Pfizer-BioNTech COVID-19 Vaccine for use as a 3-dose primary series in children 6 months through 4 years of age, AND the Moderna COVID-19 Vaccine for use as a 2-dose primary series in individuals 6 months through 5 years of age.
- Additionally, on June 18, 2022, the CDC updated the COVID-19 vaccine schedule for those eligible to receive a COVID-19 vaccine, by age, immunocompetency status and vaccine product. An at-a-glance schedule can be found here.
- The CDC's interim clinical considerations note that children ages 6 months—4 years who receive different
  mRNA products for the first 2 doses of an mRNA COVID-19 vaccine series should follow a 3-dose
  schedule. A third dose of either mRNA vaccine should be administered at least 8 weeks after the second
  dose to complete the 3-dose primary series. This is considered a <u>vaccination administration error</u> and
  should be reported to <u>VAERS</u>.
- There are special considerations for the immuno<u>competent</u> population for an <u>extended interval of 3-8</u> weeks between Dose 1 & 2 depending on the vaccine product. The moderately & severely immunocompromised have a set <u>interval of 3 weeks</u> or 4 weeks between Dose 1 & 2.
- Individuals should receive the recommended age-appropriate vaccine dosage based on their age on the
  day of vaccination. According to the CDC, if a child moves from a younger group to an older age group
  during the primary series or between primary series and receipt of a booster dose, they should receive
  the vaccine product and dosage for their older age group for all subsequent doses. However, FDA
  authorization allows for different dosing for certain age transitions; more information regarding
  transitions from a younger to older group can be found here.
- Regarding preterm infants (infants born before 37 weeks' gestation) as a <u>special population</u>, regardless
  of birth weight, should receive COVID-19 vaccination at their chronological age and according to the
  same schedule and guidance as for full-term infants and children.
- Content regarding NYS Wastage Guidance has been updated to reflect updated guidance.
- Content regarding Storage and Handling Guidance has been updated to reflect updated guidance.

2

# Key points about COVID-19 Vaccine for Children Ages 6 months – 11 years old

- All children ages 6 months to 11 years old are eligible to receive an age-appropriate COVID-19 primary series. The same mRNA vaccine product should be used for all doses of the primary series (see <u>Interchangeability of COVID-19 vaccine products</u>).
- Additionally, children 6 months to 11 years old with certain immunocompromising conditions are
  eligible for a third primary dose. Further information on this 3<sup>rd</sup>primary dose for immunocompromised
  children aged 6 months to 11 years old can be found in CDC's Interim Clinical Considerations document,
  section entitled <u>Guidance for COVID-19 vaccination for people who are moderately or severely
  immunocompromised</u>. To note:
  - o Immunocompromised children ages **5 to 11** who received 2 doses of Pfizer-BioNTech COVID-19 vaccine at least 28 days prior should receive a 3<sup>rd</sup> primary dose of the Pfizer-BioNTech vaccine.
  - Regardless of immunocompetency, both immuno<u>competent</u> & immuno<u>compromised</u> children 6 months to 4 years old, can receive a 3 dose primary series of Pfizer-BioNTech COVID019 vaccine. Immunocompromised children ages 6 months 4 years old who receive the standard 3-dose Pfizer primary series, do not need an extra primary dose as for other immunocompromised age groups.
  - o Immunocompromised children ages **6 months to 5 years** old who received 2 doses of Moderna primary series, should receive a 3<sup>rd</sup> primary dose of the Moderna vaccine.
  - Immunocompromised children ages 5 to 11 who received a primary series of a <a href="non-FDA">non-FDA</a>
    <a href="mailto:authorized or approved">authorized or approved</a> COVID-19 vaccine at least 28 days prior should receive an additional dose of an age-appropriate mRNA COVID-19 vaccine (i.e. Pfizer-BioNTech or Moderna). More information can be found within the <a href="mailto:CDC clinical Considerations">CDC clinical Considerations</a>.
  - An at-a-glance vaccination schedule for immunocompromised children can be found <u>here</u>.
- The Pfizer-BioNTech vaccine for ages 6 months to 4 years has a different pediatric formulation (3 µg per dose), packaging, preparation, and national drug code (NDC) from the Pfizer-BioNTech COVID-19 vaccine for ages 5-11 and ages 12 years and older. The Pfizer vaccine formulations for adults and adolescents (purple cap and gray cap; 30 µg per dose) CANNOT be used in children ages 6 months to 11 years old. Children ages 6 months to 11 years old should receive the age-appropriate vaccine formulation regardless of their size or weight. The vaccine dosage should be based on the child's age on the day of vaccination. For more information regarding the dosing and pediatric formulation please visit the CDC's clinical considerations.
  - The Pfizer-BioNTech COVID-19 Vaccine for use in children 6 months through 4 years of age is supplied in multiple dose vials with maroon caps and labels with a maroon border. After dilution each multiple dose vial contains ten doses of 0.2 mL with 10 mcg modRNA each.
- The Moderna vaccine for ages 6 months to 4 years has a different pediatric formulation (0.25 μg), packaging, preparation, and NDC from the Moderna vaccines for ages 18 years and older. The Moderna vaccine formulations for adults and adolescents (red cap with blue border; 0.5 μg) CANNOT be used in children ages 6 months to 5 years of age.
  - O Moderna COVID-19 Vaccine supplied in multiple-dose vials 0.25mL dose with 25 μg mRNA with a dark blue cap and a label with a magenta border intended for use in individuals 6 months through 5 years of age should not be used in individuals 6 years of age and older because of the potential for vaccine administration errors, including dosing errors. Children ages 6 months to 11 years old should receive the age-appropriate vaccine formulation regardless of their size or weight. For more information regarding the dosing and pediatric formulation please visit the CDC's clinical considerations.
- There is no minimum interval between COVID-19 vaccine and other vaccines. CDC states that "COVID-19 vaccines may be administered without regard to timing of other vaccines. This includes simultaneous

3

administration of COVID-19 vaccine and other vaccines on the same day." For more information, see CDC's <u>Interim Clinical Considerations</u> sections entitled <u>Coadministration of COVID-19 vaccines with other vaccines and Time</u>, Spacing, and Interchangeability of COVID-19 Vaccines.

- Regarding potential for local and systematic reactions among younger children, particularly younger than ages 3 years, systematic reactions can include irritability, crying, sleepiness, and loss of appetite in addition to common local reactions (i.e., pain, swelling, erythema at the injection site).
  - Febrile seizures can occur in infants and young children ages 6 months 5 years with ANY condition that causes a fever, including COVID-19. Febrile seizures are uncommon after vaccination and were rare in COVID-19 vaccine trials for young children.
  - No cases of myocarditis or pericarditis were reported in children in the pre-authorization clinical trials of Pfizer-BioNTech (ages 6 months-4 years) or Moderna (ages 6 months-5 years) vaccines.

# Scheduling the Second or Third COVID-19 Vaccine Dose

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 should 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 **should** either schedule a second (or third) dose for these individuals elsewhere or must supply information on how/where to obtain a second (or third) dose of vaccine. Vaccine availability can be located using the <a href="CDC's VaccineFinder">CDC's VaccineFinder</a>. 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

Children 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 child's COVID-19 Vaccination Record Card OR advise the parent that they ask their primary care provider to enter their primary series doses 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 <u>CDC guidance</u> 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)."

Children ages 6 months to 11 years old who received only the first dose of a two-dose or three-dose mRNA COVID-19 vaccine are not considered fully vaccinated in the United States. They should be offered an age-appropriate second dose of an mRNA vaccine (i.e., Pfizer-BioNTech COVID-19 Vaccine formulation for children ages 6 months-11 years old).

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

 Please visit the <u>CDC's guidance on vaccines listed for emergency use by the WHO but not</u> approved/authorized by the FDA.

4

• Children 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.

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

For children 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 (i.e., PfizerBioNTech or Moderna COVID-19 Vaccine formulation). For more information, please visit the <a href="CDC's guidance">CDC's guidance</a> on these vaccines.

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

As of May 1, 2022, the WHO has listed a number of COVID-19 vaccines for emergency use. There are several vaccines on this list that are also authorized by the FDA for Emergency Use in the United States. These include:

- Pfizer-BioNTech COVID-19 vaccines (e.g., COMIRNATY, Tozinameran)\*
- Janssen (Johnson & Johnson) COVID-19 vaccine\*
- Moderna COVID-19 vaccine (Spikevax)\*

For more information regarding other vaccines listed for emergency use by the WHO, please visit the <u>WHO</u> <u>website</u>.

Please note that the minimum interval between receipt of the non-FDA-approved/authorized vaccine and initiation of the FDA-approved/authorized COVID-19 vaccine primary series is at least 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 <a href="http://www.cdc.gov/vsafe">http://www.cdc.gov/vsafe</a>, 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 <a href="mailto:info@VAERS.org">info@VAERS.org</a> 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 <u>Selected Adverse Events Reported after COVID-19 Vaccination</u>. Additional information can be found in CDC's Interim Clinical Considerations:

- Section entitled <u>Safety considerations for mRNA COVID-19 vaccines: Pfizer-BioNTech and Moderna</u> (including considerations surrounding myocarditis and pericarditis), and
- Section entitled <u>COVID-19 vaccination and SARS-CoV-2 infection including MIS-C and MIS-A</u> (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 <u>CDC's Facts webpage</u> and New York State's webpage <u>Combatting</u> 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 months through 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.

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

Providers must administer COVID-19 vaccines in accordance with all <u>program requirements and recommendations</u> of NYSDOH and the CDC, the <u>Advisory Committee on Immunization Practices</u>, and the U.S Food and Drug Administration (<u>FDA</u>). 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.

6

 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 <u>NYSDOH COVID-19 Vaccine Information for Providers</u> page for more information on ordering pediatric Pfizer-BioNTech and Moderna COVID-19 vaccine in NYSIIS. Providers in New York City should follow instructions from NYC DOHMH and CIR.

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 <a href="CDC Vaccine Storage">CDC Vaccine Storage</a> and Handling Toolkit. A storage and handling summary for the Pediatric Pfizer vaccine is available <a href="https://example.com/herealth/hardling-toolkit">here</a>.

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 <u>record</u> 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.

# Updates to mRNA Pediatric COVID-19 Vaccine Expiration

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.

Pfizer-BioNTech COVID-19 vaccine for ages 6 months – 4 years old (vials have maroon caps) and Pfizer-BioNTech COVID-19 vaccine for ages 5-11 (vials have orange caps): Expiration dates for both pediatric Pfizer-BioNTech products can be found here.

7

• The date printed on the Pfizer-BioNTech COVID-19 vaccine for ages 6 months – 4 years old (vials have maroon caps) and Pfizer-BioNTech COVID-19 vaccine for ages 5-11 (vials have orange caps) indicate the

manufacture date and **NOT** the expiration date. **The expiration date for both formulations is 12 months** from manufacture date (while held at ULT frozen).

- Vials may also be stored up to 10 weeks in the refrigerator at 2-8° C (see beyond use dates, below).
   Once thawed, vials CANNOT be refrozen.
- No standard freezer storage is approved for the Pfizer-BioNTech pediatric formulations.
- Regardless of storage conditions, Pfizer-BioNTech orange cap and maroon cap vaccines should not be
  used after 12 months from the date of manufacture printed on the vial and cartons. Therefore, vaccine
  must be used by the expiration date, or the 10-week beyond use date for refrigerator storage,
  whichever comes first. The updated expiry dates for the orange cap and maroon cap vials based on 12
  months from the date of manufacture are provided below.

Printed Manufacturing Date	12-Month Expiry Date*
06/2021	31-May-2022
07/2021	30-Jun-2022
08/2021	31-Jul-2022
09/2021	31-Aug-2022
10/2021	30-Sep-2022
11/2021	31-Oct-2022
12/2021	30-Nov-2022
01/2022	31-Dec-2022
02/2022	31-Jan-2023

<sup>\*</sup>Date of expiration always falls on the last day of the month.

Moderna COVID-19 vaccine for 6 months through 5 years: 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 <u>website</u> 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.

# 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 Pediatric (Maroon Cap): <u>Beyond-Use Date (BUD) Tracking Labels for Vaccine During Refrigerator Storage</u>
  - o Refrigerator (2° C to 8° C): 10 weeks
  - o NOTE: NO standard freezer (-25° C to -15° C) storage allowed
  - o Room temperature (8 ° C to 25° C): 12 hours prior to first puncture

8

- o After Puncture: 2° C to 25° C for up to 12 hours. Vial labels and cartons may state that a vial should be discarded 6 hours after the first puncture. The information in the EUA Fact Sheet (12 hours) supersedes the number of hours printed on vial labels and cartons.
- Pfizer Pediatric Tris (Orange Cap): <u>Beyond-Use Date (BUD) Tracking Labels for Vaccine During</u> Refrigerator Storage
  - o Refrigerator (2° C to 8° C): 10 weeks
  - o NOTE: NO standard freezer (-25° C to -15° C) storage allowed
  - o Room temperature (8 ° C to 25° C): 12 hours prior to first puncture
  - After Puncture: 2° C to 25° C for up to 12 hours. Vial labels and cartons may state that a vial should be discarded 6 hours after the first puncture. The information in the EUA Fact Sheet (12 hours) supersedes the number of hours printed on vial labels and cartons.
- Moderna: <u>Moderna COVID-19 Vaccine Beyond-Use Date (BUD) Tracking Label for Vaccine During</u> Refrigerator Storage
  - Refrigerator (2° C to 8° C): 30 days
  - o After Puncture: 2° C to 25° C for up to 12 hours

# 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 <u>inventory</u> to VaccineFinder (despite having access). Providers must
maintain accurate inventory in NYSIIS or CIR. Additional information on the VaccineFinder tool can be
found here.

# **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

9

must submit a completed <u>redistribution form</u> to <u>COVIDVaccineRedistribution@health.ny.gov</u> and can proceed with the redistribution once submitted. Redistributions must follow the <u>New York State COVID-19 Vaccine</u> <u>Program Guidance for Vaccine Transport</u>, 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: Pfizer ages 5-11 orange cap and Pfizer ages 6 months through 4 years (maroon cap)
  - 12 hours: Moderna ages 6 months through 5 years (blue cap with magenta border)

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 <a href="https://www.vaccines.gov/">https://www.vaccines.gov/</a> 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

- Moderna EUA for 6 months through 5 years of age
- Pfizer EUA for 6mo through 4 years of age
- Pfizer fact Sheet for instructions for preparation and administration
- Communication resourcse 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
- Patient friendly vaccine chart
- 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.