COVID-19 Vaccine Program Provider Guidance for COVID-19 Vaccines for Infants, Children, and Teens

COVID-19 vaccines are now recommended for infants, children, and teenagers 6 months through 17 years to protect against serious illness from COVID-19 disease. Parents of infants, toddlers, and preschoolers – who did not have access to vaccine protection until now – can choose to vaccinate their children for protection against the most serious impacts of COVID-19, including hospitalization and death.

The Ohio Department of Health (ODH) offers guidance and resources for providers to vaccinate Ohio children across different age groups in alignment with the guidance provided by the U.S. Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC). This guidance is organized by product and age range and includes product-specific information about ordering, storage, handling, and administration.

COVID-19 vaccine products manufactured by Pfizer-BioNTech and Moderna using messenger RNA (mRNA) technology are available for infants/toddlers/preschoolers, children, and adolescents/teens. **These products are not interchangeable across age groups.** Vaccine formulations by both manufacturers are age-specific with different dosages for different age groups. In addition, storage, handling, and administration requirements also vary by product.

Consent from a parent or guardian is required for youth younger than age 18 years to be vaccinated, unless emancipated.

LATEST UPDATES ON FEDERAL APPROVAL PROCESS

MODERNA COVID-19 VACCINE

The FDA amended the emergency use authorization (EUA) for Moderna COVID-19 vaccine on June 17, 2022, to include use of the vaccine in individuals 6 months through 17 years of age. The vaccine had previously been authorized for use in adults 18 years of age and older and has received full FDA approval for adults.

The CDC recommended use of the vaccine in children ages 6 months through 5 years on June 18, 2022, and in children ages 6 years through 17 years on June 24, 2022.

PFIZER COVID-19 VACCINE

The FDA amended the EUA for the Pfizer COVID-19 vaccine on June 17, 2022, to include use of the vaccine in individuals 6 months through 4 years of age. The vaccine had previously been authorized for use in individuals 5 years of age and older.

The CDC recommended use of the vaccine in children ages 6 months through 4 years on June 18, 2022.

KEY MESSAGES TO SHARE WITH PARENTS

Parents are urged to have conversations with their child's doctor or a qualified healthcare provider to discuss the benefits and risks of COVID-19 vaccination. A child's healthcare provider is the top trusted source for the facts about COVID-19 and vaccination; therefore, healthcare providers can play a crucial role in giving parents the information they need to make an informed decision about what is best for their child.

Why are vaccinations in children beneficial?

According to information provided by the CDC:

- Children who get COVID-19 can get very sick, can require treatment in a hospital, and in rare situations, can die.
  - COVID-19 was one of the top five leading causes of death among children during the pandemic – and the only infectious disease that was a leading cause.
  - Even though deaths are rare in this age group, they can be prevented with vaccination.
  - Children who are otherwise healthy can get very sick from COVID-19, requiring hospital care. Approximately 1 in 3 children younger than 18 years old, hospitalized with COVID-19, have no underlying conditions.
  - COVID-19 associated hospitalizations among children ages 6 months to 4 years have similar or increased severity compared to older children and adolescents.
  - Hospitalizations for all children reached a pandemic high during the Omicron surge at the beginning of 2022, with the steepest rise from the youngest age group not eligible for vaccination at the time.
  - More children have died from COVID-19 than other pediatric vaccine preventable diseases, including hepatitis, meningitis, varicella, rubella, and rotavirus.
- Vaccines offer the best protection against serious illness from COVID-19. COVID-19 vaccines, much like other vaccines for illnesses including influenza, are not intended to prevent infection and minor illness, but to protect against more serious disease progression.
- Children who have had COVID-19 should still get vaccinated after infection. Prior infection does not prevent reinfection, especially against new variants.
  - Reinfection occurs more frequently in those previously infected and not vaccinated compared to those who were previously infected and vaccinated. Vaccination leads to a broader and more robust neutralizing antibody response.
  - For children who have been infected with COVID-19, the next dose can be delayed 3 months from when symptoms started or, if they did not have symptoms, when they received a positive test result.
- Future COVID-19 surges and variants will continue to impact children, with unvaccinated children remaining at higher risk of severe outcomes.
- COVID-19 vaccines are being administered under the most intensive vaccine safety effort in U.S. history. The FDA and CDC have rigorously reviewed the safety and effectiveness of the COVID-19 vaccines and determined the benefits of vaccination outweigh any known potential risks. CDC and FDA continue to monitor vaccines for safety and effectiveness.
- Vaccination in children may also provide parents with increased confidence to return to pre-pandemic activities, improving social interactions and well-being for children.

Common side effects

Some people experience mild side effects from the vaccine, which are normal signs that their body is building protection. These side effects are common and should go away in a few days. Some people have no side effects, and allergic reactions and severe reactions are rare.

The most common side effects after vaccination include redness, swelling, and pain/tenderness at the injection site. Other side effects include tiredness, headache, muscle pain, chills, fever, nausea/vomiting, decreased appetite, and irritability.

Parents should talk to a doctor about taking over-the-counter medications such as ibuprofen or acetaminophen to reduce symptoms. To reduce pain at the injection site, apply a clean, cool, wet washcloth. Drinking plenty of fluids can help reduce discomfort from fever.

Parents should also be instructed on side effects that would require medical attention.

PFIZER-BIONTECH COVID-19 VACCINES FOR CHILDREN, TEENS

OVERVIEW

Pfizer offers three different product configurations for different age groups with different packaging and national drug codes (NDC). Pfizer COVID-19 products are age specific and are not interchangeable.

- **AVAILABLE UNDER FULL FDA APPROVAL/EUA –** 12 years and older
  - The currently available adult/adolescent formulation (purple cap/gray cap), packaged as Comirnaty, has received full FDA approval for use in people age 16 years and older.
    - *Full FDA approval granted Aug. 23, 2021; EUA issued Dec. 11, 2020.*
    - *Dose: 30 mcg/0.3 mL, two-dose primary series with boosters*
  - The same formulation, same dose is available for safe use in children ages 12 years through 15 years under EUA. *EUA issued May 10, 2021*
- **AVAILABLE UNDER EUA –** 5 years through 11 years
  - A pediatric formulation (orange cap) that is one-third of the dose used for adults/adolescents is available for use in children ages 5 years through 11 years under EUA.
    - *EUA issued Oct. 29, 2021.*
    - *Dose: 10 mcg/0.2 mL, two-dose primary series with boosters*
- **AVAILABLE UNDER EUA –** 6 months through 4 years
  - A pediatric formulation (maroon cap) that is a lower dose than that used for children ages 5 years through 11 years and one-tenth of the dose used for adults/adolescents is available for safe use in infants and children ages 6 months through 4 years under EUA.
    - *EUA issued June 17, 2022.*
    - *Dose: 3 mcg/0.2 mL, three-dose primary series with no boosters authorized at this time.*

PFIZER PEDIATRIC FORMULATION (6 MONTHS – 4 YEARS)

PRODUCT DETAILS

Summary information about the new pediatric formulation (6 months through 4 years):

- Vaccination schedule: Unlike other Pfizer COVID-19 products, this product is administered as a three-dose primary series, which is different from other Pfizer products***. It's important to note that all three doses are necessary for protection.*** The second dose should be given 3-8 weeks after the first dose. The third dose should be given at least 8 weeks after the second dose. For immunocompromised individuals the second dose should be given 3 weeks after the first dose, an additional dose is not authorized at this time. Booster doses are also not authorized for this age group.
- Dilution: Requires dilution of 2.2 mL preservative free 0.9% Sodium Chloride Injection, USP before use.
- Dose: 3 mcg/0.2 mL after dilution. *Note: this is one-tenth of the dose given to adults.*
- Doses per vial: 10 doses per vial (after dilution).
- Packaging: Maroon vial cap and maroon label border.

- *The vial labels may state "Age 2y to < 5y" or "Age 6m to < 5y" and carton labels may state "For age 2 years to < 5 years" or "For age 6 months to < 5 years".* ***Vials with either printed age range can be used for individuals 6 months through 4 years of age.***
- *The labels may state vaccine should be discarded 6 hours after dilution.* ***The EUA supersedes this guidance, and vaccine should be discarded 12 hours after dilution.***
- *CDC resource: Pfizer (6 months through 4 years) updated label information*

- Minimum order: 10 vials per carton (and 10 doses per vial) for a total of 100 doses.
- Ancillary kits will support 100 doses and will include 1-inch needles and syringes and diluent.

STORAGE

- The product will be delivered in an ultra-low thermal shipper at minus 80 degrees Celsius.
  - The ultra-low thermal shipper may not be used for storage.
- Ultracold storage units are not required to order this vaccine. The vaccine can be stored in an ultracold freezer or a standard refrigerator. **DO NOT STORE IN A STANDARD FREEZER.**
- The vaccine must be unpacked ***immediately*** and moved to an ultracold freezer OR a refrigerator within five minutes of unpacking.
- Provider locations without ultracold storage should plan to order only what you believe can be administered over 10 weeks.

STORAGE SUMMARY: PFIZER PEDIATRIC FORMULATION (6 MONTHS – 4 YEARS)

Storage Conditions	Temperature	Maximum Storage Time After Arrival at Provider Site
Ultracold (ULT) freezer	-90ºC to -60ºC (-130ºF to -76ºF)	Up to 12 months
Freezer	-25ºC to -15ºC (-13ºF to 5ºF)	***DO NOT STORE***
Refrigerator	2°C to 8°C (36ºF to 46ºF)	Up to 10 weeks
Room Temperature	8°C to 25°C (46ºF to 77ºF)	12 hours prior to first puncture, including any thaw time
After first puncture	2°C to 25°C (36ºF to 77ºF)	Discard after 12 hours

PFIZER PEDIATRIC FORMULATION (5 YEARS THROUGH 11 YEARS)

PRODUCT DETAILS

Information about the pediatric formulation (5 years through 11 years):

- Vaccination schedule: Two-dose primary series, with 3-8 weeks between doses; a booster dose can be given at least 5 months after the last dose. Adjusted vaccination schedule for children who are moderately to severely immunocompromised.
- Dilution: Requires dilution of 1.3 mL preservative free 0.9% Sodium Chloride Injection, USP before use.
- Dose: 10 mcg/0.2 mL after dilution. *Note: This is one-third of the dose given to adults.*
- Doses per vial: 10 doses per vial (after dilution).
- Packaging: Orange vial cap and orange label border.
- Minimum order: 10 vials per carton (and 10 doses per vial) for a total of 100 doses.
- Ancillary kits support 100 doses and includes required diluent.

STORAGE

- The product is delivered in an ultra-low thermal shipper at minus 80 degrees Celsius.
- The ultra-low thermal shipper may not be used for storage. Ultracold storage units are not required to order this vaccine. The vaccine can be stored in an ultracold freezer or a standard refrigerator. **DO NOT STORE IN A STANDARD FREEZER.**
- The vaccine must be unpacked ***immediately*** and moved to an ultracold freezer OR a refrigerator within five minutes of unpacking.

STORAGE SUMMARY: PFIZER PEDIATRIC FORMULATION (5 – 11 YEARS)

Storage Conditions	Temperature	Maximum Storage Time After Arrival at Provider Site
Ultracold (ULT) freezer	-90ºC to -60ºC (-130ºF to -76ºF)	Up to 12 months
Freezer	-25ºC to -15ºC (-13ºF to 5ºF)	***DO NOT STORE***
Refrigerator	2°C to 8°C (36ºF to 46ºF)	Up to 10 weeks
Room Temperature	8°C to 25°C (46ºF to 77ºF)	12 hours prior to first puncture, including any thaw time
After first puncture	2°C to 25°C (36ºF to 77ºF)	Discard after 12 hours

PFIZER ADULT/ADOLESCENT FORMULATION (12 YEARS AND OLDER)

PRODUCT DETAILS

Information about the adult and adolescent formulation (12 years and older):

- Vaccination schedule: Two-dose primary series, with 3-8 weeks between doses; a booster dose can be given at least 5 months after the last dose. Adjusted vaccination schedule for children who are moderately to severely immunocompromised.
- Dilution: Do not dilute.
- Dose: 30 mcg/0.3 mL. *Note: This is the same dose and product given to adults.*
- Doses per vial: 6 doses per vial.
- Packaging: Gray vial cap and gray label border. *Note, the purple cap formulation has been phased out and is no longer available for orders. Providers should continue to use any remaining purple cap product first.*
- Minimum order: 5 cartons with 10 vials per carton (and 6 doses per vial) for a total of 300 doses. Smaller increments of 60 doses are available, repackaged and shipped through the Ohio Department of Health's Receipt, Store, and Stage (RSS) Warehouse.
- Ancillary kits from the manufacturer support 300 doses, with smaller kits available through the RSS for those sites that order through RSS.

STORAGE

- The product is delivered in an ultra-low thermal shipper at minus 80 degrees Celsius.
    - The ultra-low thermal shipper may not be used for storage.
- Ultracold storage units are not required to order this vaccine. The vaccine can be stored in an ultracold freezer or a standard refrigerator. **DO NOT STORE IN A STANDARD FREEZER.**
- The vaccine must be unpacked ***immediately*** and moved to an ultracold freezer OR a refrigerator within five minutes of unpacking.

STORAGE SUMMARY: PFIZER ADULT/ADOLESCENT FORMULATION (12 YEARS AND OLDER)		
Storage Conditions	**Temperature**	**Maximum Storage Time After Arrival at Provider Site**
Ultracold (ULT) freezer	-90ºC to -60ºC (-130ºF to -76ºF)	Up to 12 months
Freezer	-25ºC to -15ºC (-13ºF to 5ºF)	***DO NOT STORE***
Refrigerator	2°C to 8°C (36ºF to 46ºF)	Up to 10 weeks
Room Temperature	8°C to 25°C (46ºF to 77ºF)	12 hours prior to first puncture, including any thaw time
After first puncture	2°C to 25°C (36ºF to 77ºF)	Discard after 12 hours

PFIZER RESOURCES FOR PROVIDERS

- Pfizer Gray Cap Vaccine Preparation and Administration Summary
- Pfizer COVID-19 Vaccine Dosage Chart
- Pfizer Standing Orders for Administering Vaccine (12 years and older, gray cap)
- Pfizer Standing Orders for Administering Vaccine (5 -11 years, orange cap)
- Pfizer Standing Orders for Administering Vaccine (6 months through 4 years, maroon cap)
- Fact Sheet for Healthcare Providers (12 years and older, gray cap)
- Fact Sheet for Recipients and Caregivers (12 years and older)
- Fact Sheet for Healthcare Providers (5-11 years)
- Fact Sheet for Recipients and Caregivers (5-11 years)
- Fact Sheet for Healthcare Providers (6 months through 4 years)
- Fact Sheet for Recipients and Caregivers (6 months through 4 years)
- Pfizer-BioNTech COVID-19 Vaccine Products
- CDC: Vaccine Storage, Handling, Preparation, and Administration Materials (Pfizer)
- CDC: Pfizer Vaccine Preparation

MODERNA

Moderna will offer three different product configurations based on age, with different packaging and national drug codes (NDC). Moderna COVID-19 products are age specific and are not interchangeable.

- **AVAILABLE NOW UNDER FULL FDA APPROVAL/EUA** – Adults/adolescents ages 12 years and older
    - The same formulation for adults can now be given to adolescents ages 12 years through 17 years (red cap/light blue label border, 100 mcg/0.5mL). *Full FDA approval for ages 18+ granted Jan. 31, 2022; EUA 18+ issued Dec. 18, 2020; EUA 12-17 years issued June 17, 2022.*
    - This formulation can be given for the primary series for people ages 12 years and older (100 mcg/0.5 mL) or for booster doses for people age 18 years and older (half dose: 50 mcg/0.25 mL).
- **AVAILABLE NOW UNDER FDA EUA** – Children ages 6 years through 11 years
    - The FDA issued an EUA on June 17, 2022, for a new product configuration for children ages 6 years through 11 years (50 mcg/0.5 mL). *EUA issued June 17, 2022*

- **A product with new labeling will be manufactured soon for this age group. For now, children in this age group should receive the vaccine labeled as BOOSTER DOSES ONLY (dark blue vial cap/purple label border), which is the equivalent dose (50 mcg/0.5mL).**
- This formulation can be given as the primary series for children ages 6 years through 11 years and as boosters for people ages 18 years and older.

- **AVAILABLE NOW UNDER FDA EUA** – Children ages 6 months through 5 years
  - The FDA issued an EUA on June 17, 2022, for a new product configuration (dark blue vial cap, magenta label border) for children ages 6 months through 5 years (25 mcg/0.25 mL). *EUA issued June 17, 2022.*

MODERNA PEDIATRIC FORMULATION (AGES 6 MONTHS THROUGH 5 YEARS)

PRODUCT DETAILS

Information about the new pediatric formulation (6 months through 5 years):

- Two-dose primary series with 4-8 weeks between the first and second dose. A third dose can be given to children in this age group who are immunocompromised at least 4 weeks after the second dose. No booster doses are authorized for this age group at this time.
- Do not dilute.
- Dose: 25 mcg/0.25 mL
- Doses per vial: 10
- Packaging: Dark blue vial cap; label includes a magenta border and age label.
- Minimum order includes 100 doses.
- Ancillary kits will support 100 doses.

STORAGE

- The product will be delivered in a product shipper at minus 20 degrees Celsius.
- The vaccine can be stored only in a standard freezer or a standard refrigerator. No ultra-cold storage required.

STORAGE SUMMARY: MODERNA PEDIATRIC FORMULATION (6 MONTHS TO 4 YEARS)

Storage Conditions	Temperature	Maximum Storage Time After Arrival at Provider Site
Ultracold (ULT) freezer	-90ºC to -60ºC (-130ºF to -76ºF)	DO NOT STORE
Freezer	-50ºC to -15ºC (-58ºF to 5ºF)	Until Expiry
Refrigerator	2°C to 8°C (36ºF to 46ºF)	Up to 30 days; Until Expiry
Room Temperature	8°C to 25°C (46ºF to 77ºF)	A total of 24 hours if unpunctured
After first puncture	2°C to 25°C (36ºF to 77ºF)	Discard after 12 hours

AGES 6 YEARS THROUGH 11 YEARS

PRODUCT DETAILS

Information about the new pediatric formulation (6 years through 11 years):

- Two-dose primary series with 4-8 weeks between the first and second dose. A third dose can be given to children in this age group who are immunocompromised at least 4 weeks after the second dose. No booster doses are authorized for this age group at this time.

- Do not dilute.
- Dose: 50 mcg/0.5 mL
- Doses per vial: 5
- Packaging: Dark blue cap vial; label includes a purple border and purple label.
    - This product is available for two purposes – primary series for children ages 6-11 years and booster doses for ages 18 years and older.
    - The product is labeled "BOOSTER DOSES ONLY" but can also be used for primary series for children ages 6years through11 years.
    - Note: The primary dose series for children 6years through11 years will be manufactured and packaged separately with a dark blue vial cap and teal label, but that product is not yet available.
- Minimum order includes 100 doses.
- Ancillary kits will support 100 doses.

STORAGE

- The product will be delivered in a product shipper at minus 20 degrees Celsius.
- The vaccine can be stored in a standard freezer or a standard refrigerator.

Storage Conditions	Temperature	Maximum Storage Time After Arrival at Provider Site
Ultracold (ULT) freezer	-90ºC to -60ºC (-130ºF to -76ºF)	DO NOT STORE
Freezer	-50ºC to -15ºC (-58ºF to 5ºF)	Until Expiry
Refrigerator	2°C to 8°C (36ºF to 46ºF)	Up to 30 days; Until Expiry
Room Temperature	8°C to 25°C (46ºF to 77ºF)	A total of 24 hours if unpunctured
After first puncture	2°C to 25°C (36ºF to 77ºF)	Discard after 12 hours

AGES 12 YEARS AND OLDER

PRODUCT DETAILS

Information about the adult/adolescent formulation (12 years and older):

- Adolescents ages 12years through17years receive the same formulation and dose given to adults.
- Two-dose primary series, with 4-8 weeks between doses. A third dose can be given to people in this age group who are immunocompromised at least 4 weeks after the second dose. Booster doses can be given at least 5 months after the last dose to people ages 18 years and older.
- Do not dilute.
- Red cap vial; label includes a red border.
- Dose: Primary series 100 mcg/0.5 mL; booster 50 mcg/0.25 mL
- Doses per vial: Can draw primary series and booster doses from same vial for a maximum of 20 punctures per vial.
- Packaging: Minimum order includes 100 doses.
- Ancillary kits will support 100 doses.

STORAGE

- The product will be delivered in a product shipper at minus 20 degrees Celsius.
- The vaccine can be stored in a standard freezer or a standard refrigerator.

Storage Conditions	Temperature	Maximum Storage Time After Arrival at Provider Site
Ultracold (ULT) freezer	-90ºC to -60ºC (-130ºF to -76ºF)	DO NOT STORE
Freezer	-50ºC to -15ºC (-58ºF to 5ºF)	Until Expiry
Refrigerator	2°C to 8°C (36ºF to 46ºF)	Up to 30 days; Until Expiry
Room Temperature	8°C to 25°C (46ºF to 77ºF)	A total of 24 hours if unpunctured
After first puncture	2°C to 25°C (36ºF to 77ºF)	Discard after 12 hours

MODERNA RESOURCES FOR PROVIDERS

- Moderna COVID-19 Vaccine Presentations
- Fact Sheet for Healthcare Providers (6 months through 5 years)
- Fact Sheet for Recipients and Caregivers (6 months through 5 years)
- Fact Sheet for Healthcare Providers (6-11 years)
- Fact Sheet for Recipients and Caregivers (6-11 years)
- Fact Sheet for Healthcare Providers (12 years and older)
- Fact Sheet for Recipients and Caregivers (12 years and older)
- Moderna Standing Orders for Administering Vaccine (18 years and older)
- Moderna Standing Orders for Administering Vaccine (12 years through 17 years)
- Moderna Standing Orders for Administering Vaccine (6 years through 11 years)
- Moderna Standing Orders for Administering Vaccine (6 months through 5 years)
- CDC: Vaccine Storage, Handling, Preparation, and Administration Materials (Moderna)
- CDC: Moderna COVID-19 Vaccine At-A-Glance
- CDC: Moderna (6 years through 11 years) Updated Label Information
- FDA: Moderna COVID-19 Presentations Wall Chart
- CDC: Self-paced training module (Moderna) | Moderna job aids

ADDITIONAL RESOURCES

- CDC: Interim Clinical Considerations for Use of COVID-19 Vaccines | Summary Document
- CDC: COVID-19 Vaccination Schedule
- CDC: COVID-19 Vaccine Product Information
- CDC: Vaccine Recipient Education
- CDC: COVID-19 Vaccination for Children
- CDC Operational Planning Guide
- CDC: Resources to promote COVID-19 vaccine for children and teens
- CDC: Web-on-demand “mini” webinar
- CDC: Vaccine Administration: Preventing Vaccine Administration Errors

CLINICAL CONSIDERATIONS

EXTENDED INTERVALS BETWEEN DOSE 1 AND DOSE 2

The interval between the first and second doses of the Pfizer and Moderna vaccines can be extended up to eight weeks. Consult with a qualified healthcare provider for individual guidance.

A shorter interval of 3 weeks for Pfizer or 4 weeks for Moderna is recommended for:

- People who are immunocompromised
- People who are at high risk for severe disease
- People who live with people who are at high risk for severe disease
- People who live in communities with high COVID-19 community spread

A longer interval may be considered to:

- Reduce the risk for myocarditis, especially for adolescent and young adult males
- Optimize vaccine effectiveness

VACCINE INTERCHANGEABILITY

COVID-19 vaccines are not interchangeable. The same mRNA vaccine product should be used for all doses of the primary series. In exceptional situations in which the mRNA vaccine product administered for a previous dose(s) of the primary series cannot be determined or is not available, either age-appropriate available mRNA COVID-19 vaccine product may be administered at a minimum interval of 28 days between doses to complete the mRNA COVID-19 primary vaccination series.

VACCINE DOSAGE

Children should receive the age-appropriate vaccine formulation and follow the schedule based on their age on the day of vaccination, regardless of their size or weight.

If a person moves from a younger age group to an older age group during the primary series or between the primary series and receipt of the booster dose(s), they should receive the vaccine dosage for the older age group for all subsequent doses.

COADMINISTRATION WITH OTHER VACCINES

According to the CDC, COVID-19 vaccines may be administered without regard to timing of other vaccines.

Extensive experience with non-COVID 19 vaccines has demonstrated that immunogenicity and adverse event profiles are generally similar when vaccines are administered simultaneously as when they are administered alone. Data assessing the outcomes of simultaneous administration of COVID-19 vaccines with other vaccines are limited currently.

In accordance with general best practices, routine administration of all age-appropriate doses of vaccines simultaneously is recommended for children for whom no specific contraindications exist at the time of the healthcare visit.

When deciding whether to co-administer another vaccine(s) with COVID-19 vaccine, providers and parents/guardians may consider:

- Whether a child is behind or at risk of becoming behind on immunizations.
- Likelihood of the child returning for another vaccination.
- Risk of vaccine-preventable diseases.

Best practices for multiple injections include:

- Label each syringe.
- Administer each injection in a different injection site; separate injection sites by 1 inch or more, if possible.
- Administer the COVID-19 vaccine and vaccines that may be more likely to cause a local reaction in different limbs.

COVID-19 VACCINE ORDERING

Ohio vaccine providers are responsible for placing their own orders for COVID-19 vaccines, with support and oversight by ODH. Vaccine providers should factor current supply into current ordering cadences. Providers can place orders through the ImpactSIIS Vaccine Ordering Management System (VOMS) 24 hours a day, seven days a week.

ODH is committed to getting COVID-19 vaccines to providers as quickly as possible. To ensure adequate inventory levels, providers should anticipate a window of seven days from the date your order is entered into VOMS to the date the vaccine is delivered to your facility. Orders for products that are shipped directly from the manufacturer will be approved and processed Monday through Friday.

HOW TO PLACE AN ORDER IN VOMS

*Note, it may be necessary to reconcile your inventory before ordering. Reconciling **only** your COVID-19 vaccine is acceptable.*

1. Log into your VOMS account.
2. Select your site (if applicable).
3. Click Orders & Returns in the left navigation menu.
4. Click Orders & Transfers.
5. Click New Order.
6. Choose Order Set.
    - Note, all formulations of a specific vaccine product can be accessed from a single order set. Choose ODH-RSS for smaller repackaged options.
7. Input your order.
    - Enter the total quantity of doses needed in the "Doses Requested" field.
    - **Enter high and low temperatures for your vaccine storage unit in the Comments box.**
    - Enter any additional notes for ODH, such as requests for a special clinic or event or to opt out of ancillary supplies. Providers can also use the Comments box for internal notes or reminders for that order.
    - Click Next.
8. Verify your location's shipping address, contact information, and delivery hours. If any information is incorrect, please contact the ODH Immunization Program team at the email address listed below.
9. Click Submit Order.

Providers are encouraged to order only one of the two vaccine options to avoid administration and/or storage errors, as each vaccine has different and unique criteria for storage and handling. The ability to use all 10 doses within 12 hours once a vial is opened should be a planning consideration for initial orders. Sites should consider currently configured vial size (10-dose vials) in planning when scheduling children for vaccination, especially early in the program, to optimize use of supply.

A "soft-cap" maximum of 1,000 doses will be placed on each order at this time to help with the equitable distribution of the vaccine. Please order only what you plan to use in the near future. Please call the ODH Provider Call Center at 1-844-9ODHVAX (1-844-963-4829) if you have a special request for a local vaccination effort that would require more than 1,000 doses, and we will work with you.

Due to national demand, placing an order through VOMS in this instance does not guarantee delivery of these new vaccine products for young children. Orders will be processed in the order received. ODH has the discretion to adjust orders to ensure equitable distribution of this supply.

SHIPPING

COVID-19 orders processed through the ODH RSS Warehouse will be delivered Tuesdays, Thursdays, and Fridays. The Friday delivery option is only available to hospitals and pharmacies.

Federal holidays that occur on weekdays may interrupt the delivery schedule.

Ancillary kits – containing needles, syringes, alcohol pads, vaccination cards and surgical masks/face shields for vaccinators – are shipped separately.

PLANNING CONSIDERATIONS

As vaccine supply, demand, and administration strategies continue to evolve, providers must use new approaches to make vaccine readily available to the people in their communities. ODH recognizes that current vaccine supply, demand, and administration strategies may present an increased risk of vaccine wastage.

Because vaccine must be used in a short time frame once the vial is punctured, best practices should include scheduling appointments whenever possible to help minimize waste. However, providers should also allow the flexibility of walk-ins if possible.

Vaccine providers should make all reasonable efforts to minimize vaccine wastage and reduce missed opportunities. But the primary goal should always be to administer COVID-19 vaccines to those who choose to be vaccinated. **Don't waste an opportunity to vaccinate.**

PARENTAL CONSENT

Consent from a parent or guardian is required before youth under age 18 years can be vaccinated. (Emancipated teens may sign their own consent.)

PHARMACY VACCINATIONS

The U.S. Department of Health and Human Services (HHS) released guidance authorizing the administration of COVID-19 vaccines under the PREP Act. This guidance authorizes state-licensed pharmacists to order and administer – and state-licensed or registered pharmacy interns acting under the supervision of the qualified pharmacist to administer – COVID-19 vaccinations to persons ages 3 years or older, subject to certain requirements.

ODH is encouraging Ohioans to check with their pharmacy regarding its minimum age for vaccination and vaccine availability. More information on state and federal requirements can be found in the following guidance documents from the Ohio Board of Pharmacy:

- For pharmacists and interns: www.pharmacy.ohio.gov/COVIDvaccine.
- For qualified techs: www.pharmacy.ohio.gov/TechAdmin.

VACCINE AVAILABILITY

COVID-19 vaccines will become available through pediatricians, family physicians, health departments, children's hospitals, hospitals, health systems, community health centers and clinics, and pharmacies.

Ohioans are encouraged to first call their primary provider for more information about vaccine availability. Ohioans may also visit **gettheshot.coronavirus.ohio.gov** or call 1-833-4-ASK-ODH (1-833-427-5634) to locate a provider or make an appointment. Many providers offer walk-in appointments.

Providers may also choose to partner with school districts, health departments, pharmacies and other community healthcare providers and organizations to hold vaccine clinics for children who may not have a healthcare home or otherwise have access.

VACCINE MANAGEMENT SOLUTION: GETTHESHOT.CORONAVIRUS.OHIO.GOV

Eligible Ohioans can determine eligibility, find a provider, and schedule an appointment online at **gettheshot.coronavirus.ohio.gov** or by calling 1-833-427-5634. Providers may offer walk-in availability as appropriate.

For those providers who are scheduling appointments and whose schedulers can accommodate, please open schedulers at least three weeks out for future appointments if possible. Providers should ensure that VMS displays all vaccine products available at your location.

Providers are also encouraged to share age groups who can receive COVID-19 vaccines at their location and all available vaccine products on their websites and social media pages so people can find an appointment for their preferred product.

View training materials on the Ohio Department of Health VMS training page.

DATA REPORTING

The Ohio Department of Health (ODH) is committed to releasing data to keep the public informed on the COVID-19 pandemic while also protecting the privacy rights of Ohioans. ODH has developed several online data dashboards reflecting information from multiple sources, including vaccination data provided by all enrolled providers.

VACCINE ADMINISTRATION DATA

The COVID-19 Vaccination Dashboard at coronavirus.ohio.gov displays the most recent data reported to the Ohio Department of Health (ODH) regarding the number of individuals who have started and completed the COVID-19 vaccination series. Data is provided by various demographics and county of residence.

To ensure timely data reporting and sharing, all COVID-19 vaccine providers must report all vaccinations within 24 hours through the Ohio Impact Statewide Immunization Information System (ImpactSIIS).

VACCINE ADMINISTRATION ERRORS AND ADVERSE EVENTS

As part of essential ongoing vaccine safety monitoring efforts, vaccine providers are required to report any adverse events, including vaccine administration errors, to the Vaccine Adverse Event Reporting System. VAERS is the nation's early warning system that monitors the safety of vaccines after they are authorized or licensed for use by the FDA.

VAERS is part of the larger vaccine safety system in the United States that helps make sure vaccines are safe. The system is co-managed by the CDC and FDA. VAERS accepts and analyzes reports of possible health problems – also called "adverse events" – after vaccination. If VAERS detects a pattern of adverse events following vaccination, other vaccine safety monitoring systems will conduct follow-up studies. Visit VAERS for a complete listing of requirements and step-by-step instructions on how to submit an online report.

Vaccine recipients can also report through VAERS, as well as V-Safe, a smartphone app that provides personalized and confidential health check-ins via text messages and web surveys following vaccination.

Updated June 30, 2022.

For additional information, visit coronavirus.ohio.gov.

The Ohio Department of Health COVID-19 Provider website is a hub for a variety of resources for vaccine providers. Vaccine providers with questions may call the ODH Provider Call Center at 1-844-9ODHVAX (1-844-963-4829) between 8 a.m. and 5:30 p.m. Mondays through Fridays or email COVIDVACCINE@odh.ohio.gov.