

COVID-19 Vaccine Program Interim Provider Guidance for Pfizer-BioNTech COVID-19 Vaccines for Children Ages 5-11

Ohio’s goal is to ensure fair, equitable distribution across the state so that this important COVID-19 vaccine for younger Ohioans is available in all counties. The U.S. Food and Drug Administration’s (FDA’s) Vaccines and Related Biological Products Advisory Committee (VRBPAC) is scheduled to meet on this topic Oct. 26, and the Centers for Disease Control and Prevention’s (CDC’s) Advisory Committee on Immunization Practices (ACIP) is scheduled to meet Nov. 2-3, 2021. Providers should be ready to vaccinate children 5-11 years old shortly thereafter, pending FDA authorization and CDC recommendations. Orders of the Pfizer-BioNTech pediatric vaccine formulation will not be shipped until authorization has been granted by the FDA. **Doses cannot be administered until the CDC makes a recommendation.**

COVID-19 VACCINE PLANNING FOR CHILDREN AGES 5-11

- The Pfizer-BioNTech COVID-19 vaccine for 5-11-year-olds will be a new product configuration with new packaging, new preparation, and a new national drug code (NDC). **The current product for adults and adolescents should not be used in children.** Details about the pediatric formulation:
 - It will have a vial with an orange cap.
 - The dose is 10 micrograms (mcg) (compared with the adult/adolescent formulation of 30 mcg.)
 - It will contain 10 doses per vial.
 - It will require dilution.
- Preliminary temperature storage information, pending FDA authorization, is as follows. The product will be delivered in a newly updated product shipper at -80°C. **Ultracold storage units are not required.** If you do not have ultracold storage, plan to order only what you believe can be administered in the first 10 weeks following FDA authorization.

Storage Conditions	Temperature	Maximum Storage Time After Arrival at Provider Site
Ultracold (ULT) freezer	-90°C to -60°C	Up to 6 months
Refrigerator	2°C to 8°C	Up to 10 weeks

- The current adult/adolescent formulation (with a purple cap) **cannot** be used to vaccinate children ages 5-11. The future pediatric formulation (orange cap) **must** be used only for this age group.
- Administration details are forthcoming following an emergency use authorization. At this time, preliminary information suggests that, once open, doses in vials should be used within six hours.

Clinics should consider vial size (10 doses) and a six-hour timeframe when scheduling children for vaccination, especially early in the program, to minimize waste and optimize use of supply.

- Providers should encourage parents or guardians to enroll their children in the [v-safe](#) program.
- Upon authorization, it is anticipated that the Pfizer-BioNTech COVID-19 vaccine can be co-administered with influenza and routine childhood vaccines. Best practices for administering more than one vaccine, including COVID-19 vaccines and influenza vaccines, include:
 - When preparing more than one vaccine, label each with the name and dosage (amount) of vaccine, lot number, the initials of the preparer, and the exact beyond-use time, if applicable.
 - Always use different injection sites.
 - Separate injection sites by 1 inch or more, if possible, so that any local reactions can be differentiated. Each muscle (deltoid, vastus lateralis) has multiple injection sites.
 - If administered at the same time, COVID-19 vaccines and vaccines that might be more likely to cause a local injection site reaction (for example, Dtap or Tdap vaccines) should be administered in different arms (or legs), if possible.

ADDITIONAL PEDIATRIC CONSIDERATIONS

- In order to be vaccinated, consent from a parent or guardian is required for those under age 18 (emancipated teens may sign their own consent).
- State law allows those ages 7 and older to receive a COVID-19 or influenza vaccine at a pharmacy without a prescription; **prescriptions are still required for all other routine childhood vaccinations** for this age group. Those under age 7 years will not be able to receive COVID-19 vaccines at a pharmacy per Ohio law.

VACCINE WASTAGE

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. The Ohio Department of Health recognizes that current vaccine supply, demand, and administration strategies may present an increased risk of vaccine wastage. The goal should always be to administer COVID-19 vaccines to those who choose to be vaccinated. Vaccine providers should make all reasonable efforts to minimize vaccine wastage and continue to vaccinate and reduce missed opportunities.

VACCINE MANAGEMENT SOLUTION: GETTHESHOT.CORONAVIRUS.OHIO.GOV

Eligible Ohioans will be able to schedule an appointment through Ohio's Vaccine Management Solution (VMS), at gettheshot.coronavirus.ohio.gov. Providers may offer walk-in availability as appropriate.

PLANNING FOR PEDIATRIC FORMULATION ORDERING

- Providers can now order the Pfizer-BioNTech Pediatric Formulation. Initial orders are due at noon **on Wednesday, Oct. 20**. Providers can request vaccine through the Vaccine Ordering Management System (VOMS) in the Impact Statewide Immunization Information System (ImpactSIIS). VOMS is open for providers to place orders 24 hours a day, 7 days a week.

- Only plan to order the Pfizer-BioNTech Pediatric Formulation if you will administer pediatric vaccines. Not all providers are expected to administer vaccines to children ages 5-11.
- During the initial ordering period, providers will be required to order a minimum of 300 doses. In later weeks, you will be able to order in increments of 100.
 - Your order quantity should include first doses only; there will not be a separate automatic allocation for second doses. You will be responsible for placing your own order for second doses in later weeks.
 - Smaller providers should plan to form regional partnerships if needed to transfer vaccine during the early distribution phase. If you need assistance with the transfer process, please reach out to the Ohio Department of Health (ODH) Provider Call Center at 1-844-9ODHVAX (1-844-963-4829), available between 8 a.m. and 7 p.m. Mondays through Fridays, or email COVIDVACCINE@odh.ohio.gov.
- Ancillary kits – containing needles, syringes, diluent, alcohol pads, vaccination cards, and surgical masks/face shields for vaccinators – are shipped separately.

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.
 - Select "COVID-19 Pfizer" order set. After selecting that order set, you will be able to enter a quantity on the line for "COVID-19 Pfizer (300 doses) - Peds" to request Pfizer-BioNTech pediatric formulation for ages 5-11.
 - During the initial phase of ordering, the minimum order quantity is 300 doses.
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.** *Pfizer orders will need freezer and refrigerator temperatures.*
 - Enter any additional notes for ODH, such as requests for a special clinic or event. 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.

CONSIDER PARTNERING WITH ANOTHER PROVIDER OR ORGANIZATION

If you are not ready to receive vaccine at your location, consider starting out by building a partnership with other providers or groups in your community, including schools or community organizations supporting youth, for vaccination clinics set up to meet the needs of children.

If you have any questions about enrolling as a COVID-19 vaccination provider, please call the ODH Provider Call Center, available between 8 a.m. and 7 p.m. Monday through Friday, at 1-844-9ODHVAX (1-844-963-4829) or email COVIDVACCINE@odh.ohio.gov.

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.

MESSAGING

The CDC currently offers tips on [how to talk to parents about COVID-19 vaccines](#) for adolescents ages 12 years and older, including:

- Encourage vaccine confidence by being a trusted provider of accurate information. Right now, patients and families may be wading through a lot of information – and misinformation – to make decisions about COVID-19 vaccinations. Consider ways in which patients and families like to receive information and use these mechanisms to debunk common myths and answer frequently asked questions.

- Be prepared to address questions and misinformation about the COVID-19 vaccine with your patients and their parents. The CDC has developed some [useful tips for talking about COVID-19 vaccines](#).
- Share important information including:
 - [Adolescent Vaccines](#) – What parents/guardians need to know when preparing for vaccination for their adolescent child, what to expect during the visit, side effects, and more.
 - [Benefits of Getting a COVID-19 Vaccine](#) – Share the benefits of vaccination with parents and guardians and that it is a safe way to build protection. Getting all eligible family members vaccinated can protect other family members around them.
 - [Coadministration of Vaccines](#) – COVID-19 vaccines and other vaccines may now be administered without regard to timing. This includes simultaneous administration of COVID-19 vaccines and other vaccines on the same day, as well as coadministration within 14 days.
 - [Myths and Facts about COVID-19 Vaccines](#) – Accurate information is critical and can help stop common vaccine myths and rumors. This page has information for talking with parents/guardians about common vaccine myths. Reassure parents that there is **no evidence** that any vaccines, including COVID-19 vaccines, can cause female or male fertility problems.
 - [V-safe After Vaccination Checker](#) – **V-safe** is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you or your child receive a COVID-19 vaccine.

KEY MESSAGES

- The COVID-19 vaccine for children ages 5-11 years is likely to be authorized by the U.S. Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) in the coming weeks.
- Topline data for the COVID-19 vaccine for children ages 5-11 years old showed the vaccine was safe and generated robust antibody response.
- The Pfizer-BioNTech vaccine for 5-11-year-olds is a new product configuration of the existing Pfizer-BioNTech COVID-19 vaccine that has been successfully administered to millions of people ages 12 and up across the country. The new pediatric formulation is a lower dose that has been clinically tested for administration in young children.
- The clinical trial included 2,268 children, two-thirds of whom had received two doses of the vaccine spaced three weeks apart. The remaining volunteers were injected with two doses of a saltwater placebo.
- While children are less likely than adults to get severely ill from COVID-19, they are not invincible. Children most certainly can, and do, become ill. Just like adults, when children become sick from COVID-19, they spread it to others, and can suffer severe health outcomes, or even death.
- COVID-19 is a very bad virus, even for children. COVID-19 vaccines provide the best protection and immunity from the disease.

- According to the American Academy of Pediatrics, as of Oct. 7, 2021, [more than 6 million Americans younger than 18](#) had been infected with COVID-19, and 542 had died. In Ohio, more than 193,000 children have contracted COVID-19, and 15 Ohio residents under age 18 have died.
- It is likely that two doses of the vaccine will be required for children ages 5-11, similar to what is required for older recipients. This means it would take several weeks for your child to achieve full protection. Scheduling an appointment now will ensure your child is protected as soon as possible.
- Ohioans should choose to be vaccinated regardless of whether they already had COVID-19. Evidence is emerging that people **get better protection by being fully vaccinated** compared with having had COVID-19. [One study](#) showed that unvaccinated people who already had COVID-19 are more than two times as likely than fully vaccinated people to get COVID-19 again.
- COVID-19 is still a threat to people who are unvaccinated. Some people who get COVID-19 can become severely ill, which could result in hospitalization, and some people have ongoing health problems several weeks or even longer after getting infected. Even people who did not have symptoms when they were infected can have these ongoing health problems.
- COVID-19 can cause otherwise healthy children to suffer multisystem inflammatory syndrome in children (MIS-C), a potentially life-threatening condition causing inflammation of multiple vital organs. Pediatric hospitals have reported an increase in cases of MIS-C in Ohio.
- The Delta variant is making children sicker than previous COVID-19 variants, resulting in more children requiring hospitalization.

PATIENT MESSAGE TEMPLATE

Upon authorization, [Provider name] will be offering COVID-19 vaccines for children ages 5-11 years. These vaccines are safe, effective, and can be co-administered at the same time as a flu shot or other routine childhood vaccinations. Contact us for more information to give your child the best protection from COVID-19. [Call to action, such as “Check back after FDA authorization to make an appointment. Call XXX-XXX-XXXX or visit [www.ourwebsite.com](#) to make an appointment.”]

SOCIAL MEDIA POSTS

Following @US_FDA & @CDCgov authorization, we will be offering #COVID19 vaccines for children 5-11 years old. Learn more about the safety & efficacy of COVID-19 vaccines, so you can make the best decision possible to protect the children in your life. <https://bit.ly/3j7KEc5>

Upon authorization, we will be offering #COVID19 vaccines for children 5-11 years old. These vaccines are safe, effective, and can be administered at the same visit as a flu shot or other childhood vaccination. Contact us for more information on protecting your child from COVID-19.

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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 7 p.m. Mondays through Fridays or email COVIDVACCINE@odh.ohio.gov.