

COVID-19 Vaccine Program Guidance for Vaccine Providers for Administering Booster Doses

COVID-19 vaccines offer the best protection against serious illness and death from COVID-19. The vaccines are safe and effective at reducing risk for serious illness and death from COVID-19. But that protection weakens over time. Booster doses can help restore and maintain that protection from severe COVID-19 outcomes.

The U.S. Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) recommend a **single COVID-19 booster dose for people age 12 years and older**. The timing of booster doses varies by vaccine product (see product specific guidance below). Booster doses are not authorized for anyone younger than age 12 at this time.

In addition, the FDA and CDC have authorized a **second booster dose for those people who are at the highest risk for severe illness or death from COVID-19**. This authorization gives people who are at increased risk the choice to add another layer of protection.

People who may choose to receive a second booster dose, based on their individual benefits and risks, include:

- People age 50 and older who received an initial mRNA booster dose (Pfizer-BioNTech or Moderna) at least four months ago MAY RECEIVE a second booster dose of an mRNA COVID-19 vaccine. A second booster dose may be most beneficial for people who are age 65 and older, or who are age 50-64 with certain underlying medical conditions.
- People age 12 and older who are <u>moderately to severely immunocompromised</u> who received an initial mRNA booster dose (Pfizer or Moderna) <u>at least four months ago</u> MAY RECEIVE a second booster dose of an mRNA COVID-19 vaccine (Pfizer, age 12+; Moderna, age 18+). This means individuals age 12 years and older who are moderately to severely immunocompromised may receive as many as five doses the recommended three-dose primary series for people who are immunocompromised, plus two booster doses.
- In addition, <u>based on a newly published CDC report</u>, adults who received a primary vaccine and booster dose of the
 Johnson & Johnson (Janssen) COVID-19 vaccine <u>at least 4 months ago</u> MAY RECEIVE a second booster dose
 using an mRNA COVID-19 vaccine (Pfizer or Moderna).

People who are now eligible to receive a second booster dose are encouraged to talk to their healthcare providers to assess individual risks and the benefits of another dose in strengthening ongoing protection.

Eligibility, dosage, and timing of booster shots vary by COVID-19 vaccine product, and other factors including age and medical condition. *Please read eligibility information by product in the guidance below.*

<u>Vaccine providers should continue to prioritize efforts to vaccinate unvaccinated individuals to protect against severe illness and death from COVID-19.</u>

BOOSTER DOSE ELIGIBILITY REQUIREMENTS BY PRODUCT

IF YOU RECEIVED PFIZER-BIONTECH FOR THE PRIMARY SERIES:

Booster dose eligibility: A single booster dose is recommended for Pfizer vaccine recipients age 12 and older at least five months after the last dose.

Second booster dose eligibility: A second booster dose may be given to people at the highest risk for severe illness or death from COVID-19 at least four months after the first booster. People in the following higher-risk categories may choose to receive a second booster dose to strengthen protection, based on their individual benefits and risks:

- People age 50 and older who received an initial mRNA booster dose (Pfizer or Moderna) at least four months ago may receive a second booster dose of an mRNA COVID-19 vaccine. A second booster dose may be most beneficial for people who are age 65 and older, or who are age 50-64 with certain underlying medical conditions.
- People age 12 and older who are <u>moderately to severely immunocompromised</u> who received an initial mRNA booster dose (Pfizer or Moderna) <u>at least four months ago may receive</u> a second booster dose of an mRNA COVID-19 vaccine (Pfizer, age 12+; Moderna, age 18+). This means individuals age 12 years and older who are moderately to severely immunocompromised may receive as many as five doses the recommended three-dose primary series for people who are immunocompromised, plus two booster doses.

Booster doses are not authorized for children younger than 12 years. Children ages 5-11 who are moderately to severely immunocompromised are eligible to receive a third dose in their Pfizer primary vaccine series at least 28 days after the second dose to strengthen the original immune response.

More info: Pfizer-BioNTech COVID-19 Vaccine Fact Sheet for Healthcare Providers (must dilute purple cap formulation for 12+); Pfizer BioNTech COVID-19 Vaccine Face Sheet for Healthcare Providers (no dilution gray cap formulation for 12+)

IF YOU RECEIVED MODERNA FOR THE PRIMARY SERIES:

Booster dose eligibility: A booster dose is recommended for Moderna vaccine recipients age 18 years and older at least five months after the last dose.

Second booster dose eligibility: A second booster dose may be given to people at the highest risk for severe illness or death from COVID-19 at least four months after the first booster. People in the following higher-risk categories may choose to receive a second booster dose to strengthen protection, based on their individual benefits and risks:

- People age 50 and older who received an initial mRNA booster dose (Pfizer or Moderna) at least four months ago may receive a second booster dose of an mRNA COVID-19 vaccine. A second booster dose may be most beneficial for people who are age 65 and older, or who are age 50-64 with certain underlying medical conditions.
- People age 12 and older who are <u>moderately to severely immunocompromised</u> who received an initial mRNA booster dose (Pfizer or Moderna) <u>at least four months ago <u>may receive</u> a second booster dose of an mRNA COVID-19 vaccine (Pfizer, age 12+; Moderna, age 18+). This means individuals age 12 years and older who are moderately to severely immunocompromised may receive as many as five doses the recommended three-dose primary series for people who are immunocompromised, plus two booster doses.
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More info: Moderna COVID-19 Vaccine Fact Sheet for Healthcare Providers (labels with purple borders); Moderna COVID-19 Vaccine Fact Sheet for Healthcare Providers (labels with light blue borders)

IF YOU RECEIVED JOHNSON & JOHNSON FOR THE PRIMARY SERIES:

Booster dose eligibility: A booster dose is recommended for Johnson & Johnson vaccine recipients age 18 years and older at least two months after the initial dose. Most patients should consider an mRNA booster dose due to the remarkable safety and efficacy of the mRNA vaccines. Individuals who are unable to receive an mRNA vaccine may receive a Johnson & Johnson booster dose.

Second booster dose eligibility: <u>Based on a newly published CDC report</u>, adults who received a primary vaccine and booster dose of the Johnson & Johnson (Janssen) COVID-19 vaccine <u>at least 4 months ago</u> may consider a second booster dose using an mRNA COVID-19 vaccine.

More info: Johnson & Johnson/Janssen COVID-19 Vaccine Fact Sheet for Healthcare Providers

PROOF OF ELIGIBILITY AND CONSENT

IDENTIFICATION REQUIREMENTS

- Providers should ask to see identification that proves name, age, and identity.
 - Ask for identification to verify only the patient's identity, name, and age. Patients do not need to show
 proof of citizenship or residency status. Identification should still be accepted if it is expired or from another state
 or country.
 - Acceptable forms of identification are listed below:
 - Driver's license or any photo ID, regardless of expiration date or place of origin.
 - Active/retired military ID.
 - Physician statement (including shot records).
 - Census records.
 - Adoption records.
 - Naturalization certificate.
 - Birth certificate: Birth record, either original or certified copy.
 - Consulate ID or matricula consular.
 - Passport or a passport card.
 - Certificate of citizenship.
 - Permanent resident card.
 - Application for replacement naturalization/citizenship document.
 - Department of State forms.
 - Military service records (DD-214)
 - Certification of Birth Abroad of a Citizen of the United States (FS-545)
 - Certification of Report of Birth Abroad of a United States Citizen (DS-1350)
 - Consular Report of Birth Abroad of a Citizen of the United States of America (FS-240)
 - Employment Authorization Document (I-766/EAD)
 - Transportation letter (I-797F)

PARENTAL CONSENT

Children younger than age 18 who are not emancipated must have parental or legal guardian consent for any vaccine. A parent or legal guardian generally should accompany the minor to receive the vaccine, unless the administration of the vaccine occurs in a physician's office, school-based or school-associated clinic setting or similar setting.

VACCINE CARDS

Eligible Ohioans are encouraged to bring their COVID-19 vaccine card to their booster appointment. If they cannot find their vaccine card, they should first contact their original vaccine provider to see if their records can be located. If the original vaccine provider is unable to assist, they should contact their local health department. The final available option is to review this information on <a href="https://www.how.no.in/wort.no

MIX-AND-MATCH BOOSTER DOSES

Fully vaccinated individuals ages 18 years and older who have completed the primary vaccination series can receive a booster dose of any authorized or approved COVID-19 vaccine, regardless of the vaccine used for initial vaccination. This mix-and-match approach applies only to booster doses for adults. People ages 12-17 years may only receive a Pfizer vaccine booster.

People may consider the benefits and risks of each product and discuss with their healthcare provider which product is most appropriate for them based on their age, gender, medical history, reactions after past vaccinations, or overall allergy history.

NOTE: In most situations, mRNA COVID-19 vaccines (Pfizer-BioNTech or Moderna) are preferred over the Johnson & Johnson COVID-19 vaccine for primary and booster vaccination, based on ongoing vaccine safety and effectiveness studies. Most patients should now consider an mRNA primary vaccine series or booster dose due to the remarkable safety and efficacy of these vaccines. Individuals who are unable to receive an mRNA vaccine or would prefer not to receive an mRNA vaccine may receive the Johnson & Johnson's COVID-19 vaccine, after a discussion of the benefits and risks.

It's important to note, the half-dose Moderna booster dose should be given to all booster recipients, even if the primary series was different.

Additional recommendations around mix-and-match booster doses, including data and studies around homologous (same vaccine as primary series) or heterologous (different vaccine from primary series) boosters, are included in the CDC's <u>Interim Clinical Considerations for Use of the COVID-19 Vaccines and a new study of effectiveness of homologous and heterologous COVID-19 booster doses following Johnson & Johnson vaccination.</u>

BOOSTER DOSE AVAILABILITY

Vaccines are widely available at many locations across the state, including local health departments, pediatricians, family physicians, community health centers, adult and children's hospitals, and pharmacies. Ohioans are encouraged to call their provider for more information or 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.

VACCINE MANAGEMENT SOLUTION (VMS): GETTHESHOT.CORONAVIRUS.OHIO.GOV

Eligible Ohioans will be able to determine their eligibility for booster doses and, if determined to be eligible, schedule an appointment at <u>gettheshot.coronavirus.ohio.gov</u>. Providers may continue to offer walk-in availability as appropriate.

Providers should program appointment availability in VMS now. 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 are encouraged to offer all COVID-19 vaccine products, and should ensure that VMS displays which vaccine products are available. Providers are also encouraged to share available vaccine products on their websites and social media pages so people can find an appointment for their preferred product.

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

VACCINE LOCATIONS

Eligible Ohioans can find a provider and schedule an appointment online at <u>gettheshot.coronavirus.ohio.gov</u> or by calling <u>1-833-427-5634.</u>

- Most retail and independent pharmacies will offer either walk-in or scheduled appointments.
- Local health departments in some of our largest cities will offer special community vaccination sites, and health departments in virtually every county are prepared to offer booster doses, including to homebound individuals.
- Community health centers and participating primary care providers will also offer booster doses.
- Participating long-term care facilities will offer doses of the Pfizer vaccine to residents through Ohio's COVID-19
 Vaccine Maintenance Program, and state agencies and state-owned veterans homes will vaccinate eligible staff and residents.

Affordable senior housing communities will work with local partners to host special vaccination opportunities for booster
doses. Ohio will have ample supply of vaccine for boosters and for first and second doses. It may take 2-3 weeks, or
more, for every eligible person who wants a booster to receive one.

BOOSTER DOSE ORDERS/SHIPPING

DIRECT ORDERING

Vaccine providers should factor booster dose supply into current ordering cadences. All Ohio COVID-19 vaccine providers are responsible for placing vaccine orders through the ImpactSIIS Vaccine Ordering Management System (VOMS). VOMS is open for providers to place orders 24 hours a day, seven days a week. Providers can order COVID-19 vaccine at their convenience. ODH is committed to getting COVID-19 vaccines to our 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.

MINIMUM ORDER/SHIPPING QUANTITIES

Pfizer (adult/adolescent formulation)

- Minimum order quantity for direct shipment from the manufacturer is 300 doses, available in increments of 300 doses.
- The ODH Receipt, Store, and Stage (RSS) warehouse will break down Pfizer shipments into smaller sizes.
 - o Minimum order quantity is 60 doses, available in increments of 60.

Moderna

- Moderna booster doses will not be packaged or distributed separately. Vaccine providers will draw the appropriate booster dosage from existing inventories (vials include the equivalent of 14 full doses).
- Minimum order quantity for direct shipment from the CDC/McKesson Distribution Center is 100 doses.

Johnson & Johnson

Minimum order quantity for direct shipment from the CDC/McKesson Distribution Center is 100 doses.

COVID-19 orders processed through the ODH RSS Warehouse will be delivered Tuesdays, Thursdays, and Fridays. The Friday delivery option is only available to 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. Moderna ancillary kits will be doubled to ensure adequate supply.

VACCINE ADMINISTRATION

- **Booster dosage:** All booster doses are the same formulation as the primary series; however, the amount varies from the primary series in the case of the Moderna vaccine.
 - A Pfizer booster dose is the same dosage given for the primary series.
 - A Moderna booster dose is NOT the same dosage given for the primary series (0.5 mL). The booster dose and second booster dose is a half-dose (0.25 mL).
 - The half-dose Moderna booster dose should be given to all booster recipients, even if the primary series was different.
 - Moderna booster doses will not be packaged or distributed separately.
 - Primary series doses (0.5 mL) or booster doses (0.25 mL) may be extracted from a vial, preferentially using low dead-volume syringes and/or needles.
 - When extracting only primary series doses, depending on the syringes and needles used, a
 maximum of 11 doses (range: 10-11 doses) may be extracted from the vial containing 5.5 mL or a

- maximum of 15 doses (range: 13-15 doses) may be extracted from the vial containing 7.5 mL.
- When extracting only booster doses or a combination of primary series and booster doses, the maximum number of doses that may be extracted from either vial presentation should not exceed 20 doses. Do not puncture the vial stopper more than 20 times.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.5 mL or 0.25 mL, discard the vial and contents. Do not pool excess vaccine from multiple vials.
- Ancillary kits will be doubled to ensure adequate supply.
- The Johnson & Johnson booster dose is the same dosage given for the first dose.
- No out-of-pocket costs: There is no out-of-pocket cost for a COVID-19 vaccine. Providers may ask for insurance, Medicare, or Medicaid information and can charge an administration fee to insurance. Patients do not have to pay a fee directly.
- Coadministration: Booster doses may be given with other vaccines without regard to timing. This includes simultaneous administration of COVID-19 and other vaccines on the same day. 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 inject vaccines into 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.
 - o 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, high-dose and adjuvanted inactivated influenza vaccines) should be administered in different arms (or legs), if possible.
- Contraindications and precautions for a booster dose are the same as for the primary series.
- For individuals who had myocarditis and myopericarditis, it is recommended to defer a subsequent dose until
 myocarditis and myopericarditis has completely resolved.

View the CDC's Interim Clinical Considerations for use of COVID-19 vaccines for more detailed guidance for vaccine providers.

DATA REPORTING

The Ohio Department of Health (ODH) is committed to releasing data to inform the public in the midst of the COVID-19 crisis 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 <u>COVID-19 Vaccination Dashboard</u> at coronavirus.ohio.gov displays the most recent data reported to the Ohio Department of Health (ODH) regarding the number of individuals that have started and completed the COVID-19 vaccination series by various demographics and county of residence.

To ensure timely data reporting and sharing, <u>all COVID-19 vaccine providers must report all vaccinations within 24 hours</u> through the Ohio Impact Statewide Immunization Information System (ImpactSIIS). **This includes the reporting of booster doses.**

VACCINE ADMINISTRATION ERRORS AND ADVERSE EVENTS

As part of ongoing vaccine safety monitoring efforts, vaccine providers are required to report any adverse events, including vaccine administration errors, to the <u>Vaccine Adverse Event Reporting System</u>. <u>VAERS</u> 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 conduct follow-up studies. Visit <u>VAERS</u> for a complete listing of requirements and step-by-step instructions on how to submit a report.

Ohio Department of Health

MESSAGING

Healthcare providers are asked to share facts about the safe and effective COVID-19 vaccines, remind patients eligible for booster doses to stay up to date on their vaccinations, and answer any patient questions about the vaccines.

COMMUNICATIONS TOOLKIT

As part of Ohio's ongoing work to encourage Ohioans to get their COVID-19 booster shot, the Ohio Department of Health has developed a communications toolkit to provide tools that may be used to help promote key messages.

The toolkit includes resources such as graphics, printable flyers, website and newsletter language, patient reminders, and social media posts:

- COVID-19 Vaccine Boosters Communications Toolkit for Vaccine Providers
- COVID-19 Vaccine Boosters Communications Toolkit for Local Health Departments
- COVID-19 Vaccine Boosters Communications Toolkit for Community Partners

Updated March 30, 2022.

For additional information, visit coronavirus.ohio.gov.

The <u>Ohio Department of Health COVID-19 Provider website</u> 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 <u>COVIDVACCINE@odh.ohio.gov</u>.