

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

The U.S. Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) have authorized a single booster dose of the three COVID-19 vaccines available in the United States (Pfizer/Comirnaty, Moderna, and Johnson & Johnson/Janssen) to strengthen protection against serious outcomes from COVID-19 and/or against COVID-19 infection.

Ohioans age 16 years and older are now eligible to receive booster doses. Dosage and timing of booster shots vary by COVID-19 vaccine product. *Please read eligibility information by product in the guidance below.*

Fully vaccinated individuals 18 years old and older are eligible to receive a booster dose of the COVID-19 vaccine of their choice (Pfizer/Comirnaty, Moderna or Johnson & Johnson & Johnson vaccine recipients are eligible two months following their original dose; Pfizer/Comirnaty and Moderna vaccine recipients are eligible six months following their second dose (or third dose if immunocompromised).

Fully vaccinated individuals ages 16-17 years are now eligible to receive a booster dose of the Pfizer vaccine, as it is the only COVID-19 vaccine authorized for people younger than 18 years.

It's important to note the top priority for vaccine providers remains continued vaccination of unvaccinated individuals to protect against serious illness, hospitalization, and death from COVID-19.

PROOF OF ELIGIBILITY

BOOSTER DOSE ELIGIBILITY REQUIREMENTS

At this time, fully vaccinated people who are 16 years old and older are eligible for a booster dose. The timing of booster doses varies by vaccine product (see below). Children ages 15 years and younger are not eligible to receive a booster dose at this time. Children ages 12-15 years who have an immunocompromising condition are eligible to receive an <u>additional/third dose of the Pfizer vaccine</u> to strengthen protection.

Pfizer-BioNTech/Comirnaty

Eligibility: If an individual received the Pfizer/Comirnaty vaccine for the primary series, booster doses can be given to fully vaccinated people age 16 years and older.

Dosage: The Pfizer/Comirnaty booster dose is the same dosage given for the primary series.

Mix-and-match booster: People age 18 years or older who received the primary series of the Pfizer/Comirnaty vaccine may get a booster dose of <u>any</u> COVID-19 vaccine approved or authorized for use in the United States. People ages 16 or 17 years who received the primary series of the Pfizer/Comirnaty vaccine may get a booster dose of only the Pfizer/Comirnaty vaccine, as it is the only COVID-19 vaccine available for people younger than 18.

Booster dose timing: At least six months after the completion of the initial series.

Booster doses for people who are immunocompromised: Pfizer vaccine recipients 12 years and older who are moderately to

severely immunocompromised can receive a third dose for the primary vaccine series at least 28 days following the second dose. Those 16 years and older also are eligible for a single COVID-19 booster dose (Pfizer/Comirnaty, Moderna or Janssen) at least six months after completing the third mRNA vaccine dose.

More info: Pfizer-BioNTech COVID-19 Vaccine Fact Sheet for Healthcare Providers

Moderna

Eligibility: If an individual received the Moderna vaccine for the primary series, booster doses can be given to <u>fully vaccinated</u> people age 18 years and older.

Dosage: The Moderna booster dose is NOT the same dosage given for the primary series (0.5 mL). The booster dose is a half-dose (0.25 mL).

- 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 deadvolume 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.

Mix-and-match booster: Someone who received the primary series of the Moderna vaccine may get a booster dose of <u>any</u> COVID-19 vaccine approved or authorized for use in the United States (Pfizer/Comirnaty, Moderna, or Johnson & Johnson).

Booster dose timing: At least six months after completion of mRNA series.

Booster doses for people who are immunocompromised: Moderna vaccine recipients who are moderately to severely immunocompromised can add a third dose to their primary vaccine series at least 28 days following the second dose. These individuals also will be eligible for a single COVID-19 booster dose (Pfizer/Comirnaty, Moderna or Janssen) at least six months after completing their third mRNA vaccine dose.

More info: Moderna COVID-19 Vaccine Fact Sheet for Healthcare Providers

Johnson & Johnson/Janssen

Booster doses are authorized for all recipients of the single-dose Johnson & Johnson/Janssen COVID-19 vaccine. Anyone age 18 years or older who received a Johnson & Johnson vaccine can get a booster dose at least two months following the initial dose.

Dosage: The Johnson & Johnson booster dose is the same formulation and dosage given for the first dose.

Mix-and-match booster: Someone who received the Johnson & Johnson vaccine may get a booster dose of <u>any</u> COVID-19 vaccine approved or authorized for use in the United States.

Booster dose timing: At least two months following the first dose of the Johnson & Johnson vaccine.

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

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 how to mail a request for your vaccination records to the Ohio Department of Health. Replacement vaccine cards are not available from the Ohio Department of Health. If a vaccine recipient does not have their original vaccine card, that should not be a barrier to prevent them from being vaccinated.

MIX-AND-MATCH BOOSTER DOSES

Eligible 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 means:

- A person who originally received the Johnson & Johnson vaccine can receive a booster dose of the Johnson & Johnson, Pfizer, or Moderna vaccine.
- A person who originally received the Moderna primary vaccine series can receive a booster dose of the Moderna,
 Pfizer, or Johnson & Johnson vaccine.
- A person who originally received the Pfizer primary vaccine series can receive a booster dose of the Pfizer, Moderna, or Johnson & Johnson vaccine.

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.

This mix-and-match approach applies only to booster doses for adults. People ages 16-17 years may only receive a Pfizer vaccine booster.

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 Interim Clinical Considerations for Use of the COVID-19 Vaccines.

BOOSTER DOSE AVAILABILITY

Eligible Ohioans will have many opportunities to receive a booster dose, including at pharmacies, federally qualified health centers, doctor's offices, community vaccination sites, and local health departments.

While it will be important for providers to administer booster doses to eligible Ohioans, there are still many Ohioans who have not yet received their first dose of vaccine. Please continue to prioritize vaccination for new vaccine recipients while administering booster doses.

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 can start programming 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.

DIRECT ORDERING

There will be no changes to the standard ordering process as a result of the start of booster dose administration. 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 1,170 doses, available in increments of 1,170 doses.
- The ODH Receipt, Store, and Stage (RSS) warehouse will break down Pfizer shipments into smaller sizes.
 - Minimum order quantity is 120 doses, available in increments of 120.
 - o In rare cases, smaller increments of 30 doses are available for small providers such as pediatric practices or primary care providers with special approval.

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 140 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

- **Timing of booster doses:** Booster doses can be administered six months or longer after completion of the primary series for people who received Pfizer or Moderna shots. For those who had Johnson & Johnson/Janssen, the boosters may be given after two months.
- 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.
 - 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). <u>This includes the reporting of booster doses.</u>

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.

<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 U.S. Food and Drug Administration (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 Centers for Disease Control and Prevention (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 VAERS for a complete listing of requirements and step-by-step instructions on how to submit a report.

MESSAGING

Primary care providers are asked to recommend booster doses to eligible patients to boost their immunity to help prevent severe outcomes from COVID-19, including hospitalization or death.

KEY MESSAGES

- The COVID-19 vaccines continue to be incredibly effective. There is a natural tendency for immunity to wane over time, whether natural immunity or immunity from a vaccine, and many immunizations require at least one booster dose, including hepatitis A; hepatitis B; Haemophilus influenzae type B (Hib); measles-mumps-rubella (MMR); tetanus, diphtheria, and pertussis (Tdap); and varicella (chickenpox).
- Millions of Americans are now eligible for COVID-19 booster shots.
 - For people who received the Pfizer/Comirnaty primary series: People who are age 16 and older can get a booster dose at least six months after the second dose (or third dose if immunocompromised).
 - For people who received the Moderna primary series: People who are age 18 and older can get a booster dose at least six months after the second dose (or third dose if immunocompromised).
 - For people who received the Johnson & Johnson single dose: People who are age 18 and older can get a booster dose at least two months after the first dose.
- Who is eligible for a booster dose? Fully vaccinated recipients 16 years and older are eligible to receive a booster dose
 of COVID-19 vaccine. Recipients 18 years and older can receive the vaccine product of their choice, and timing and
 dosage are based on the chosen vaccine.

- We are focused on staying ahead of the virus by making sure people have optimal protection against COVID-19
 infection, severe illness, and death. A booster dose will help provide continued protection against severe disease,
 including hospitalization and death.
- The U.S. Food and Drug Administration and Centers for Disease Control and Prevention have determined these
 booster shots are safe and effective, based on the latest data and evidence, after a thorough, independent, and
 transparent review process. They will continue to evaluate data as it is available to determine when people younger
 than age 16 may become eligible for booster shots.
- Side effects, which are expected with any vaccination, were similar to those from second COVID-19 vaccine doses, and were mostly mild, moderate, and short-lived.
- The COVID-19 vaccines approved and authorized in the United States continue to be highly effective in reducing risk
 of severe disease, hospitalization, and death, even against the widely circulating Delta variant. Booster shots may
 result in increases in antibody levels, and may result in increased effectiveness.
 - Although we don't have all the answers on the new Omicron variant, initial data suggests that COVID-19 boosters help strengthen the protection against Omicron and other variants. We are closely monitoring new data and emerging research as it is released.
 - While we still have much to learn about Omicron, this variant's arrival underscores the importance of our best prevention tool – choosing to be vaccinated and getting a booster dose when eligible.
- For fully vaccinated adults, getting a booster shot is convenient, and as simple as visiting your local pharmacy, health department, or doctor's office.
 - Additionally, if a patient is eligible, both flu and COVID-19 vaccines can be administered at the same visit.
 - o A COVID-19 vaccine can be given with other vaccines, such as shingles and pneumonia, as well.

PATIENT REMINDER MESSAGE TEMPLATE

COVID-19 boosters are now available for fully vaccinated recipients 16 years old and older. [Call to action, such as "Walk-in appointments available every day from 8 a.m. to 6 p.m." or "Call XXX-XXXX or visit www.ourwebsite.com to make an appointment."]

[Provider name] is now offering #COVID19 booster doses to eligible Ohioans for the Pfizer, Moderna, and Johnson & Johnson vaccines. [Call to action, such as "Walk-in appointments available every day from 8 a.m. to 6 p.m." or "Call XXX-XXXX or visit www.ourwebsite.com to make an appointment."]

SOCIAL MEDIA POSTS

We are now offering #COVID19 booster doses to fully vaccinated recipients ages 16 or older. Those who received the Pfizer or Moderna vaccines can get a booster dose 6 months after the second dose (or third dose if immunocompromised). All Johnson & Johnson vaccine recipients can get a booster dose at least 2 months after the first dose. [Call to action, such as "Walk-in appointments available every day from 8 a.m. to 6 p.m." or "Call XXX-XXXX or visit www.ourwebsite.com to make an appointment."]

EMAIL OR WEBSITE ARTICLE

At this time, fully vaccinated recipients 16 years and older are eligible to receive a booster dose of the COVID-19 vaccine of their choice. Booster doses can now be given using any available COVID-19 vaccine if you are at least18 years old (those age 16-17 years can only receive the Pfizer/Comirnaty vaccine).

Pfizer/Comirnaty and Moderna vaccine recipients can receive a booster dose at least six months after the second dose (or third dose if immunocompromised). Johnson & Johnson vaccine recipients can receive a booster dose at least two months after the first dose.

There is ample supply of vaccine for boosters, as well as first and second doses, for Ohioans. Vaccinations are available at [Provider name] either by making an appointment or by walking in [insert details including days of the week and start time and end time]. While you do not have to get your booster dose at the same location where you received your first and second doses, you are welcome to continue to visit [Provider name] for your COVID-19 vaccine needs.

You are encouraged to bring your COVID-19 vaccine card, and if you cannot find your vaccine card, please review this fact sheet from the Ohio Department of Health for options to access to your vaccination records. In short, you should first contact

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Eligible Ohioans have many opportunities to be vaccinated in their local community, whether they walk in to get their booster dose or make an appointment with a nearby provider.

Updated Dec. 10, 2021.

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>.