

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 for 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.

Eligibility, dosage, and timing of booster doses vary by individual COVID-19 vaccine product. Not all Ohioans are eligible to receive a booster dose at this time, including people who are younger than 18. Factors that determine booster dose eligibility include age, health conditions, and work or living settings. Please read eligibility requirements by product below.

Following required actions by the U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) for each vaccine product, Ohio COVID-19 vaccine providers can administer booster doses, as soon as practical and people are determined eligible, to individuals as outlined below.

Eligible vaccine recipients may now receive a <u>booster dose of any available COVID-19 vaccine product</u>. The booster dose does not have to match the original dose/series.

The CDC is expected to share additional guidance and resources for providers about booster dose administration in its Interim Clinical Considerations for Use of the COVID-19 Vaccines, and its Morbidity and Mortality Weekly Report (MMWR). That guidance will include considerations for mix-and-match boosters. This guidance is forthcoming.

As booster dose administration expands, 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

Eligibility for booster doses is determined based upon the vaccine product used for the primary series, and in the cases of the two messenger RNA (mRNA) vaccines (Pfizer-BioNTech/Comirnaty and Moderna), age, health conditions, and living/work settings.

Pfizer-BioNTech/Comirnaty

If an individual received the Pfizer/Comirnaty vaccine for the primary series, booster doses can be given to <u>adults</u> who are at high risk for severe disease and complications from COVID-19 or high risk for exposure to COVID-19.

Eligibility includes those who meet any of the following criteria:

- 65 years and older.
- Age 18 and older who live in <u>long-term care settings</u>.
- Age 18 and older who have <u>underlying medical conditions</u>.
- Age 18 and older who work or live in high-risk settings.

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

Mix-and-match booster: Someone who received the primary series of the Pfizer/Comirnaty vaccine and is eligible to receive a

booster dose may get a booster dose of any COVID-19 vaccine approved or authorized for use in the United States.

Booster dose timing: At least six months following completion of the standard primary Pfizer series (two doses spaced at least 21 days apart).

Additional dose for people who are immunocompromised: A third dose can be added to the primary vaccine series at least 28 days following the second dose for individuals at least 12 years of age who have had a solid organ transplant or a condition that results in moderate to severe immunocompromise. At this time, the maximum number of doses of an mRNA vaccine that can be given to any individual is three. Therefore, if someone received an additional dose because they are immunocompromised, they should not receive a fourth booster dose.

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

Moderna

If an individual received the Moderna vaccine for the primary series, booster doses can be given to adults who are at high risk for severe disease and complications from COVID-19 or high risk for exposure to COVID-19.

Eligibility includes those who meet any of the following criteria:

- 65 years and older.
- Age 18 and older who live in long-term care settings.
- Age 18 and older who have <u>underlying medical conditions</u>.
- Age 18 and older who work or live in high-risk settings.

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 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.
- More info: Moderna letter to healthcare providers (Oct. 20, 2021)

Mix-and-match booster: Someone who received the primary series of the Moderna vaccine and is eligible to receive a booster dose 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 six months following completion of the primary Moderna series (two doses spaced at least 28 days apart).

Additional dose for people who are immunocompromised: A third dose can be added to the primary vaccine series at least 28 days following the second dose for individuals at least 18 years of age who have had a solid organ transplant or a condition that results in moderate to severe immunocompromise. At this time, the maximum number of doses of an mRNA vaccine that can be given to any individual is three. Therefore, if someone received an additional dose because they are immunocompromised, they should not receive a fourth booster 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 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)

PROOF OF ELIGIBILITY

Eligible booster recipients will be asked to attest they meet one of the eligibility requirements, but specific proof will not be required. Individuals ages 18 to 49 with certain <u>underlying medical conditions</u> or who live/work in high-risk institutional or occupational settings are encouraged to discuss the benefits and risks of getting a booster dose with their healthcare providers.

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 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 who have completed the primary vaccination series can receive a booster dose of a different authorized or approved COVID-19 vaccine. 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.

This mix-and-match approach applies only to booster doses. The primary series of the two-dose mRNA vaccines must be from the same product.

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 how individuals can assess their own benefits and risks, and how healthcare providers can best offer advice to patients, will be published in the CDC's final clinical recommendations. Those recommendations will be published soon in the CDC's Interim Clinical Considerations for Use of the COVID-19 Vaccines, and its Morbidity and Mortality Weekly Report (MMWR).

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.

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, 7 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 7 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.
 - 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. These products are available for distribution from the ODH RSS Warehouse:

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 6 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. Immunity wanes gradually over time, therefore a booster may be given at the appropriate interval.
- 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

- A booster dose will help provide continued protection against severe disease, including hospitalization and death, in populations who are especially at risk for severe COVID-19.
 - Because residents in long-term care (LTC) settings live closely together in group settings and are often older adults and/or have underlying medical conditions, they are at increased risk of infection and severe illness from COVID-19.
 - The risk of severe illness from COVID-19 increases with age, and can also increase for adults of any age with certain underlying medical conditions.
 - And while COVID-19 vaccine effectiveness against severe disease remains high for healthcare personnel and other essential workers, those with even mild illness often cannot work. In addition, some individuals may care for or live with at-risk people, such as the immunocompromised, and others may live in a congregate setting such as a homeless shelter or correctional facility where there is higher risk for transmission. For these reasons as well as continued strain on the U.S. healthcare infrastructure due to the widely circulating Delta variant CDC recommends that adults at high risk of disease from occupational and institutional exposures to COVID-19 get a booster based on their individual benefits and risks.
 - 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.

PATIENT REMINDER MESSAGE TEMPLATE

COVID-19 boosters are now available for select Ohioans who completed the primary vaccine series. Vaccine booster doses have been authorized for all Johnson & Johnson vaccine recipients. Booster doses have been authorized for Pfizer or Moderna vaccine recipients if they are 65+, or if they are 18+ and have an underlying medical condition, or live or work in a setting that puts them at risk for exposure. [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 eligible Ohioans. If you received the Pfizer or Moderna vaccine series and are either 65 or older, or if you are 18 or older and have underlying conditions, or live or work in a setting that puts you at risk for exposure, you can get a booster dose 6 months after your second dose. 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

The following groups of Ohioans who originally received the Pfizer or Moderna COVID-19 vaccine series are now eligible to receive a single booster dose, to be administered at least six months after completion of the primary series:

Eligibility includes those who meet any of the following criteria:

- 65 years and older.
- Age 18 and older who live in <u>long-term care settings</u>.
- Age 18 and older who have <u>underlying medical conditions</u>.
- Age 18 and older who work or live in high-risk settings.

Ohioans who received the Johnson & Johnson COVID-19 vaccine are eligible for a booster dose if it has been at least two months since the first dose.

Booster doses can now be given using any available COVID-19 vaccine. Booster doses do not have to be the same product given during the primary vaccine series.

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 your original vaccine provider to see if they can locate your records. If they are unable to assist, please contact your local health department. If they are unable to assist, please review this information on how to mail a request for your vaccination records to the Ohio Department of Health.

Eligible Ohioans should allow 2-3 weeks to get their booster dose, with many opportunities to be vaccinated in their local community, whether they walk in to get their third dose or make an appointment with a nearby provider.

Updated Oct. 22, 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>.