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

COVID-19 vaccine booster doses have been authorized for certain recipients of the Pfizer-BioNTech/Comirnaty vaccine to prevent serious outcomes from COVID-19 illness. Eligibility for booster doses is currently limited to individuals at the highest risk for severe COVID-19 based upon their age, certain underlying medical conditions, or occupational/institutional settings as outlined below. A booster dose is recommended <u>at least six months</u> following completion of the original Pfizer-BioNTech/Comirnaty vaccine series.

Following required actions by the U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC), Ohio's more than 3,500 enrolled COVID-19 vaccine providers can begin administering booster doses to eligible individuals as outlined below. It is important to note that the FDA will review data and determine if and when booster doses are needed by vaccine product. Right now, recipients of the Moderna and Johnson & Johnson (Janssen) vaccines do not need booster doses, but evaluation of safety, effectiveness, and immunity will continue and recommendations will be updated as needed.

As booster dose administration begins, it's important to note the top priority for vaccine providers should be continued vaccination of unvaccinated individuals to protect against serious illness, hospitalization and death from COVID-19.

Booster doses can be given immediately. It is important to note that the CDC is expected to share additional guidance and resources for providers on booster dose administration in its <u>Interim Clinical Considerations for Use of the COVID-19 Vaccines</u>, and its <u>Morbidity and Mortality Weekly Report (MMWR)</u>.

PROOF OF ELIGIBILITY

BOOSTER DOSE ELIGIBILITY REQUIREMENTS

A single booster dose for the **Pfizer-BioNTech/Comirnaty COVID-19 vaccine** can be given to the following populations <u>at least</u> six months or more after completion of the primary vaccine series:

- People 65 years and older or residents in long-term care settings SHOULD receive a booster shot.
- People ages 50 to 64 with certain underlying medical conditions SHOULD receive a booster shot.
- People ages 18 to 49 with <u>certain underlying medical conditions MAY</u> receive a booster shot based on their individual benefits and risks.
- People age 18 and older who are at increased risk for COVID-19 exposure and transmission because of their job or living in an institutional setting <u>MAY</u> receive a booster shot based on their individual benefits and risks. The CDC has indicated that this is a determination to be made by the vaccine recipient.

At this time, booster doses are authorized only for the Pfizer vaccine and the defined populations above. Eligibility criteria for Pfizer recipients could be expanded in the future following further evaluation.

View the CDC's list of applicable underlying medical conditions: <u>https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html</u>

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.
 - <u>Acceptable forms of identification</u> 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 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.

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: 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.

65 AND OLDER, ELIGIBLE INDIVIDUALS WITH CERTAIN UNDERLYING MEDICAL CONDITIONS AND THOSE WHO LIVE OR WORK IN HIGH-RISK OCCUPATIONAL OR INSTITUTIONAL SETTINGS NOT LISTED SEPARATELY BELOW

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

LONG-TERM CARE FACILITIES

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.

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

- 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.

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.

VACCINE ADMINISTRATION

- **Timing of booster doses:** Booster doses can be administered 6 months or longer after completion of the primary series. Immunity wanes gradually over time, therefore a booster may be given at an interval greater than 6 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.
 - o 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.
- Data on the safety and efficacy of a mixed-product series are limited. Both doses of the primary series and any additional or booster doses should be completed with the same product.
- 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 <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 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 <u>VAERS</u> 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.

Please specify that eligibility, at this time, is only for individuals who received the Pfizer primary vaccine series.

KEY MESSAGES

- With the Delta variant surging and cases of COVID-19 increasing significantly, a booster dose will help provide continued protection against severe disease in these populations who are especially at risk for severe COVID-19. For example:
 - 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. This is why CDC recommends that individuals 50 to 64 with underlying medical conditions receive a Pfizer-BioNTech booster shot. Individuals 18-49 with underlying medical conditions may also receive a booster if they determine the personal benefits outweigh the risks.
 - 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 the Pfizer booster based on their individual benefits and risks.
 - The COVID-19 vaccines approved and authorized in the United States continue to be 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 Pfizer vaccine series. Vaccine booster doses have been authorized for those 65+, those with underlying medical conditions, or those 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-XXX-XXXX or visit <u>www.ourwebsite.com</u> to make an appointment."]

[Provider name] is now offering #COVID19 booster doses to eligible Ohioans. If you received the Pfizer vaccine series and are either 65 or older, have underlying medical conditions, or live or work in a setting that puts you at risk for exposure, you can get a booster dose six months after you completed the series. [Call to action, such as "Walk-in appointments available every day from 8 a.m. to 6 p.m." or "Call XXX-XXX-XXXX or visit <u>www.ourwebsite.com</u> to make an appointment."]

SOCIAL MEDIA POSTS

We are now offering #COVID19 booster doses to eligible Ohioans. If you received the Pfizer vaccine series and are either 65 or older, or 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. [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 <u>www.ourwebsite.com</u> to make an appointment."]

Did you get the Pfizer #COVID19 vaccine series? Ohioans age 65+, those with underlying conditions, or those live or work in a setting that puts them at risk for exposure, are now eligible for booster doses, six months following their second dose. Check eligibility and find a shot near you at https://gettheshot.coronavirus.ohio.gov, or call 1-833-427-5634.

EMAIL OR WEBSITE ARTICLE

The following groups of Ohioans who originally received the Pfizer 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 in:

- People 65 years or older or residents in long-term care settings should receive a booster shot.
- People ages 50 to 64 with certain underlying medical conditions should receive a booster shot.
- People ages 18 to 49 with <u>certain underlying medical conditions may</u> receive a booster shot based on their individual benefits and risks. The CDC has indicated that this is a determination made by the vaccine recipient.
- People age 18 and older who are at increased risk for COVID-19 exposure and transmission because of their job or living in an institutional setting <u>may</u> receive a booster shot based on their individual benefits and risks. The CDC has indicated that this is a determination made by the vaccine recipient.

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.

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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>.