

BULLETIN

What Massachusetts COVID-19 Vaccine Providers Need to Know Week of 9/24/21

Latest Numbers

• As of 9/24, **4,605,562** people in Massachusetts have been fully vaccinated.

Who to Vaccinate this Week

- New Effective 9/24/2021, CDC recommends a Pfizer-BioNTech booster for certain people who
 received the two-dose Pfizer-BioNTech COVID-19 vaccine at least 6 months ago. See below for
 more information.
- Anyone age 12 and older who lives, works, or studies in Massachusetts is eligible for a vaccine. Health care providers can also vaccinate their patient panels regardless of place of residency.
- Effective 8/13/21, <u>CDC recommends</u> that people who are moderately to severely immunocompromised receive an additional dose of an mRNA COVID-19 Vaccine (Pfizer-BioNTech or Moderna) at least 28 days after the completion of the initial mRNA COVID-19 vaccine series.

What to Know this Week

New Pfizer-BioNTech boosters

These recommendations are ONLY for those who originally received the two-dose series of Pfizer's COVID vaccine. Booster doses might be recommended in the future for those who received COVID vaccines manufactured by Moderna or Janssen (Johnson & Johnson), but there isn't enough research available yet to make that call.

9/17/2021 FDA authorized the use of Pfizer-BioNTech's COVID-19 Vaccine to be administered as boosters at least six months after completion of the primary Pfizer-BioNTech series in certain populations. Ordering additional doses needed to implement these booster recommendations can begin immediately.

9/23/2021 CDC endorsed the ACIP recommendation for a booster shot of the Pfizer-BioNTech COVID-19 vaccine in certain populations and also recommended a booster dose for those in high risk occupational and institutional settings.

New CDC recommendations:

people 65 years and older and residents in long-term care settings should receive a booster shot
of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary
series,

- people aged 50–64 years with <u>underlying medical conditions</u> **should** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series,
- people aged 18–49 years with <u>underlying medical conditions</u> may receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series, based on their individual benefits and risks, and
- people aged 18-64 years who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting may receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series, based on their individual benefits and risks.

Pfizer-BioNTech COVID-19 Vaccine can now be given under EUA for:

- a two-dose primary series in individuals 12 years of age and older;
- a third primary series dose in individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise; and
- a single booster dose in certain populations and high risk occupational and institutional settings

Comirnaty COMIRNATY (COVID-19 Vaccine, mRNA), the FDA-approved Pfizer-BionTech COVID-19 vaccine is approved for, and can be given to:

• individuals 16 years of age and older, as a 2-dose primary series for the prevention of COVID-19 in individuals 16 years of age and older.

Comirnaty can also be given under EUA for:

- a two-dose primary series in individuals 12 through 15 years;
- a third primary series dose in individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise; and
- a single booster dose in certain populations and high risk occupational and institutional settings

The **FDA-approved COMIRNATY** (COVID-19 Vaccine, mRNA) and the **EUA-authorized Pfizer-BioNTech** COVID-19 Vaccine have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series.

Updated Pfizer resources

- CDC's COVID-19 Vaccine Booster Shot webpage will be updated to reflect these updates.
- Watch the CDC <u>Pfizer webpage</u> for updated Pfizer <u>standing orders</u>, screening form, and other documents.
- Pfizer EUA/Fact Sheet updated September 22
 Providers https://www.fda.gov/media/144413/download
 Recipients https://www.fda.gov/media/144414/download

NEW <u>COCA Call</u> Tuesday, September 28, 2-3 pm, What Clinicians Need to Know About the Latest CDC Recommendations for Pfizer-BioNTech COVID-19 Booster Vaccination

This CDC COCA Call will give clinicians an overview of the Pfizer-BioNTech COVID-19 booster vaccination.

Clinicians will learn about the vaccine booster recommendations, safety of booster dose, and clinical guidance for using the Pfizer-BioNTech COVID-19 booster vaccine.

Reminder CDC guidance supports <u>coadministration of COVID-19 vaccines</u> with other vaccines, including influenza vaccines, without regard to timing.

- o ACIP 2021/2022 flu recommendations:
 - Full report: <u>Prevention and Control of Seasonal Influenza with Vaccines:</u> <u>Recommendations of the Advisory Committee on Immunization Practices, United</u> States, 2021–22 Influenza Season.
 - o Full report pdf: https://www.cdc.gov/mmwr/volumes/70/rr/pdfs/rr7005a1-H.pdf
 - o Summary https://www.cdc.gov/flu/professionals/acip/summary/summary-recommendations.htm
 - Summary pdf: https://www.cdc.gov/flu/pdf/professionals/acip/acip-2020-21-summary-of-recommendations.pdf

Vaccines for Kids FDA Statement, 9/10/2021: FDA press statement from Dr. Woodcock and Dr. Marks: <u>FDA Will Follow The Science On COVID-19 Vaccines For Young Children.</u>

On 8/30/2021 ACIP unanimously recommended use of the FDA approved Pfizer-BioNTech COVID-19 Vaccine, which will now be marketed as Comirnaty, for people aged 16 years and older.

- The Pfizer-BioNTech COVID-19 vaccine also remains recommended under an Emergency Use Authorization (EUA) as:
 - o a 2-dose primary series for adolescents 12 through 15 years old; and
 - o an additional (third) dose for people 12 years of age and older who are moderately to severely immunocompromised.
- This decision doesn't affect how the Pfizer-BioNTech COVID-19 Vaccine is given, but it reinforces the safety and effectiveness of the vaccine shown in clinical studies and by the millions who have already received the vaccine.
- This decision does not affect CDC's recommendations for using the Moderna and Johnson & Johnson's Janssen COVID-19 vaccines for people 18 years and older.
- Comirnaty is in the identical formulation and presentation as the Pfizer-BioNTech COVID-19
 Vaccine already authorized under the EUA. Therefore, clinicians may use currently available
 inventory as licensed or authorized. The updated FDA <u>Vaccine Information Fact Sheet for
 Recipients and Caregivers</u> should continue to be given to all approved age groups before
 vaccination. CDC is not releasing a Vaccine Information Statement (VIS) for Comirnaty at this
 time.

J&J/Janssen Vaccine: Available for Ordering. To best utilize this vaccine in the field, please order this product for use in populations in which it is most needed.

There are currently no allocations or order caps for this vaccine. Please be good stewards of this important public health resource and follow these guidelines for managing your inventory:

• Use what you currently have on hand, re-order only what you need based on your current administration data, use what you order, and reorder small quantities when you need more.

CDC has launched the <u>SmartFind COVID-19 Vaccine ChatBot</u>, a new resource to quickly connect healthcare providers and others to clear, consistent, and credible information about COVID-19 vaccines. The automated ChatBot features include:

- Answers to common questions and answers about COVID-19 vaccines that are authorized and recommended, or undergoing large-scale (Phase 3) clinical trials in the United States
- 24-7 access to COVID-19 vaccine information on web-based devices, including mobile phones and tablets
- Links to additional resources, such as where to find a COVID-19 vaccination location

Reminder *CDC COVID-19 Vaccination Record Cards:* As a reminder, COVID-19 Vaccination Record Cards remain property of the U.S. Government until provided to the vaccine recipient following vaccination. Unauthorized use and reproduction of the cards constitute fraud. Healthcare providers are encouraged to keep ample supply of vaccination record cards on site for those patients requesting replacements. Healthcare providers can order extra print copies from the MA Health Promotion Clearinghouse.

The Pfizer tray of 1170 ordering cadence has changed from a 1-day to a 3-day window once the order is approved and submitted to CDC. Supplemental dry ice will no longer be supplied by Pfizer or CDC. Sites are required to secure dry ice if the shipper is used to store the Pfizer vaccines.

- The Pfizer box of 450 is no longer available to order from the CDC.
- Order request less than 1170 will be fulfilled by transfer from another provider site.
 - o Vaccines are transferred in the refrigerated temperature range.
 - o Upon delivery, vaccines must be placed in the refrigerator for 30 days.

Adherence to MCVP Agreement: As a reminder, providers are responsible for adhering to all requirements outlined in the MCVP. Specifically, providers must administer COVID-19 vaccines in accordance with all <u>program requirements and recommendations</u> of CDC, the <u>Advisory Committee on Immunization Practices</u>, and <u>FDA</u>. This applies to both EUA and FDA approved COVID-19 vaccines. Accordingly, use of these products outside of those that have been approved and authorized by FDA (often referred to as "off-label use") is not recommended. It would violate the provider agreement and could expose providers to the following risks:

- Administration of the product off label may not be covered under the PREP Act or the PREP Act declaration; therefore, providers may not have immunity from claims.
- Individuals who receive an off-label dose may not be eligible for compensation under the Countermeasures Injury Compensation Program after a possible adverse event.
- CDC has defined the scope of the CDC COVID-19 Vaccination Program in terms of how the USG-provided vaccines may be used in the program. Providers giving off-label doses would be in violation of the CDC Program provider agreement potentially impacting their ability to remain a provider in the CDC program.
- Administration fees may not be reimbursable by payers.

Resources & Learning Opportunities

COVID-19 vaccine flyers and EUA factsheets are available in 26 different languages.

CDC's primary publication for disseminating the science it produces is the *Morbidity and Mortality Weekly Report*, better known as MMWR. The staff at MMWR have launched a new <u>landing page</u> to help people find the latest information on COVID-19 vaccine effectiveness and safety.

New CDC MMWRs

September 24, 2021

- Decreased Incidence of Infections Caused by Pathogens Transmitted Commonly Through Food
 During the COVID-19 Pandemic Foodborne Diseases Active Surveillance Network, 10 U.S.

 Sites, 2017–2020
- Comparative Effectiveness of Moderna, Pfizer-BioNTech, and Janssen (Johnson & Johnson)
 Vaccines in Preventing COVID-19 Hospitalizations Among Adults without Immunocompromising
 Conditions United States, March–August 2021
- <u>Use of Pfizer-BioNTech COVID-19 Vaccine in Persons Aged ≥16 Years: Recommendations of the</u> Advisory Committee on Immunization Practices — United States, September 2021
- Outbreak of SARS-CoV-2 B.1.617.2 (Delta) Variant Infections Among Incarcerated Persons in a Federal Prison — Texas, July–August 2021

September 17, 2021

- Post-Acute Sequelae of SARS-CoV-2 Infection Among Adults Aged ≥18 Years Long Beach,
 California, April 1-December 10, 2020
- Monitoring Incidence of COVID-19 Cases, Hospitalizations, and Deaths, by Vaccination Status —
 13 U.S. Jurisdictions, April 4–July 17, 2021
- Interim Estimates of COVID-19 Vaccine Effectiveness Against COVID-19—Associated Emergency
 Department or Urgent Care Clinic Encounters and Hospitalizations Among Adults During SARS-CoV-2 B.1.617.2 (Delta) Variant Predominance Nine States, June—August 2021
- Effectiveness of COVID-19 mRNA Vaccines Against COVID-19—Associated Hospitalization Five Veterans Affairs Medical Centers, United States, February 1—August 6, 2021
- Correction and Republication: New COVID-19 Cases and Hospitalizations Among Adults, by Vaccination Status — New York, May 3–July 25, 2021

Reminder MDPH Immunization Division is pleased to present <u>free accredited COVID-19 Vaccine content</u>. These training sessions are designed for health care providers, vaccine coordinators, and all health care personnel who handle and/or administer COVID-19 vaccines.

MDPH Resources

Immunization Division Main Number

For questions about immunization recommendations, disease reporting, etc.

Phone: 617-983-6800 (24/7 MDPH Epi line)

Fax: 617-983-6840

Website: https://www.mass.gov/topics/immunization

MIIS Help Desk

Phone: 617-983-4335 Fax: 857-323-8321

Email questions to: miishelpdesk@mass.gov

Website: https://www.mass.gov/service-details/massachusetts-immunization-information-system-miis

MDPH Vaccine Unit

Phone: 617-983-6828

Email questions to: dph-vaccine-management@mass.gov

Website: https://www.mass.gov/service-details/vaccine-management

COVID email box:

Email questions to: <u>COVID-19-Vaccine-Plan-MA@mass.gov</u>