



# MASSACHUSETTS COVID-19 VACCINE PROGRAM

## BULLETIN

### What Massachusetts COVID-19 Vaccine Providers Need to Know Week of 8/26/21

#### Latest Numbers

- As of 8/26/21 **4,472,630** people in Massachusetts have been fully vaccinated.

#### Who to Vaccinate this Week

- **Reminder** Effective 8/13/21, [CDC recommends](#) 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.
- 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.

#### What to Know this Week

- **NEW August 23, 2021 FDA approves Comirnaty** (COVID-19 Vaccine, mRNA), which was previously known as Pfizer-BioNTech COVID-19 Vaccine, for the prevention of COVID-19 disease in individuals 16 years of age and older
  - [Comirnaty information](#)
  - [press release](#)
  - [frequently asked questions](#)
- We are in an interim phase, where Pfizer is available both by EUA and approval/licensure. Rather than the traditional Vaccine Information Statements (VIS), we now see an interim combined EUA/VIS. *Please note that previously published hyperlinks should take you directly to the new August 23 versions.*
  - For [Recipients](#) it is called: VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS ABOUT COMIRNATY (COVID-19 VACCINE, mRNA) AND PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)
  - For [Healthcare Providers](#) it is called: FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS) / EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)
- Both Fact Sheets include the following language, clarifying what is under approval and what is under EUA:

- **COMIRNATY** (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech.
    - It is approved as a 2-dose series for prevention of COVID-19 in individuals 16 years of age and older.
    - It is also authorized under EUA to be administered to:
      - prevent COVID-19 in individuals 12 through 15 years, and
      - provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
  - The **Pfizer-BioNTech COVID-19 Vaccine** has received EUA from FDA to:
    - prevent COVID-19 in individuals 12 years of age and older, and
    - provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
  - 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.
- **NEW Updated Standing Orders, Prep & Admin Summaries, and Prevacination Screening Form**
    - [Prevaccination Screening Form](#)
    - [Pfizer Standing Orders](#)
    - [Pfizer Prep and Admin Summary](#)
    - [Moderna Standing Orders](#)
    - [Moderna Prep and Admin Summary](#)
  - **NEW 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 [program requirements and recommendations](#) of CDC, the [Advisory Committee on Immunization Practices](#), and [FDA](#). 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.
  - **Reminder FDA Authorizes Additional Vaccine Dose for Certain Immunocompromised People:** On 8/12/21, the [FDA amended the emergency use authorizations \(EUAs\)](#) for both the Pfizer-BioNTech COVID-19 Vaccine and the Moderna COVID-19 Vaccine to allow for the use of an additional dose in certain immunocompromised individuals, specifically, solid organ transplant recipients or those who are diagnosed with conditions that are considered to have an equivalent

level of immunocompromise. Other fully vaccinated individuals do not need an additional vaccine dose right now.

- Updated EUA factsheets
  - Pfizer EUA fact sheets for [providers](#) and [recipients](#)
  - Moderna EUA fact sheets for [providers](#) and [recipients](#)
- New section in the [CDC Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States](#). The clinical considerations for use of an additional dose of an mRNA COVID-19 vaccine apply only to people who are moderately or severely immunocompromised.
- For providers: [Talking with Patients Who Are Immunocompromised](#)
- For the public: [COVID-19 Vaccines for Moderately to Severely Immunocompromised People](#)
- **Reminder Recommendations For People Who Are Pregnant, Lactating, or Trying to Get Pregnant:** On 8/11/21, CDC updated its [Interim Clinical Considerations](#) to recommend COVID-19 vaccination for people who are pregnant, lactating, trying to get pregnant now, or might become pregnant in the future and shared [key messages and talking points](#).
  - The American College of Obstetricians and Gynecologists (ACOG) also issued an [updated practice advisory](#) on COVID-19 vaccination. The advisory summarizes the latest COVID-19 vaccine safety data in pregnancy and states unequivocally that all eligible people, including pregnant and lactating individuals, should receive COVID-19 vaccination.
- **NEW Pfizer-BioNTech Vaccine Expiration Extension:** The FDA has approved an amendment to the EUA for Pfizer-BioNTech extending the expiration dates of COVID-19 Vaccine from six to nine months.
  - Cartons and vials of Pfizer-BioNTech COVID-19 Vaccine with an expiry date of August 2021 through February 2022 printed on the label may remain in use for 3 months beyond the printed date **as long as authorized storage conditions between -90°C to -60°C (-130°F to -76°F) have been maintained**. Please note: the ultra cold temperature range has been broadened to include -90° C (-130°F). **Frozen vials stored at -25°C to -15°C and refrigerated vials (2°C to 8°C) are NOT eligible for extension.**
  - Updated expiry dates for vaccine maintained in ultra-cold storage are shown below.

**Printed Expiry Date - Updated Expiry Date**

**August 2021 - November 2021**

**September 2021 - December 2021**

**October 2021 - January 2022**

**November 2021 - February 2022**

**December 2021 - March 2022**

**January 2022 - April 2022**

**February 2022 - May 2022**

- The extended expiration date is effective immediately for all currently available batches that have not yet expired. **NOTE: Expiration dates extension does NOT apply to vials dated July 2021 and earlier**
- Pfizer vaccine expiration dates will be automatically update in the MIIS on August 27<sup>th</sup>.

- No changes have been made to the vaccine itself to enable extension of expiry dating. This change is based on stability data generated on batches manufactured over approximately the past nine months of COVID-19 vaccine development, from the batches that supplied early clinical trials through the commercial scale batches currently in production.
- Currently available vaccine will not have an updated NCD. Please refer to the current [EUA Fact Sheet for information](#).
- Additional information on Pfizer storage and handling may be found at: [Administration Overview for Pfizer-BioNTech COVID-19 Vaccine | CDC](#)
- **NEW COVID-19 Vaccine and Beyond-use Dates (BUDs)** With all of the changes in COVID-19 vaccine expiration dates and the differing requirements for cold storage for each vaccine, it can be difficult to keep track of expiration and Beyond-Use Dates (BUDs). CDC has developed tracking labels for your refrigerators and freezers to help monitor and document cold storage dates. There are also labels available to assist with documenting transportation time and temperature. These labels and supporting materials are available for both Moderna and Pfizer vaccines. We hope you will find these tools useful.
  - [Moderna COVID-19 Vaccine: Beyond Use Date/Time \(BUD\) Tracking Label for Vaccine During Refrigerator Storage \(cdc.gov\)](#)
  - [Pfizer-BioNTech COVID-19 Beyond Use Date/Time \(BUD\) Tracking Labels for Vaccine During Freezer or Refrigerator Storage \(cdc.gov\)](#)
  - There are also summaries available on the CDC website for storage and handling of each vaccine.
    - [Moderna COVID-19 Vaccine: Storage and Handling Summary \(cdc.gov\)](#)
    - [Pfizer-BioNTech COVID-19 Vaccine Storage and Handling Summary \(cdc.gov\)](#)
- **Reminder MassHealth Coverage for Services Related to COVID-19 Vaccine Counseling:** Effective for dates of service on or after 7/26/21, MassHealth will reimburse physicians and acute outpatient hospitals for providing clinically appropriate, medically necessary COVID-19 counseling services. Learn more in the [MassHealth All Provider Bulletin](#).
- **Reminder Transporting COVID-19 Vaccines:** DPH recommends using the [CDC - Packing Vaccines for Transport during Emergencies](#) guide when transporting vaccines. Sites must have on hand or have ready access to the following supplies needed for transport:
  - Portable vaccine refrigerator/freezer unit that does not rely on a power source **OR**
  - Qualified containers and packouts which include hard-sided insulated containers or Styrofoam™
    - Conditioned frozen water bottles
    - Insulating materials such as bubble wrap and corrugated cardboard—enough to form two layers per container
  - Temperature monitoring device/digital data logger for each container
- **DPH COVID-19 Vaccine Website for Providers:** DPH has a [COVID-19 vaccine website for providers](#). Here you will find information about storage and handling, detailed guidance for healthcare providers and organizations, answers to frequently asked questions by providers, links to CDC and FDA resources, and other relevant information about vaccination efforts. DPH recommends checking the website frequently to stay up to date with the latest information.

## Resources & Learning Opportunities

- **Reminder** COVID-19 vaccine flyers and EUA factsheets are available in [26 different languages](#).
- **Reminder** 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 [landing page](#) to help people find the latest information on COVID-19 vaccine effectiveness and safety.
- **New** CDC MMWRs
  - 8/20: [Disparities in Excess Mortality Associated with COVID-19 — United States, 2020 | MMWR \(cdc.gov\)](#)
  - 8/18: [New COVID-19 Cases and Hospitalizations Among Adults, by Vaccination Status — New York, May 3–July 25, 2021](#)
  - 8/18: [Sustained Effectiveness of Pfizer-BioNTech and Moderna Vaccines Against COVID-19 Associated Hospitalizations Among Adults — United States, March–July 2021](#)
  - 8/18: [Effectiveness of Pfizer-BioNTech and Moderna Vaccines in Preventing SARS-CoV-2 Infection Among Nursing Home Residents Before and During Widespread Circulation of the SARS-CoV-2 B.1.617.2 \(Delta\) Variant — National Healthcare Safety Network, March 1–August 1, 2021](#)
- MDPH Immunization Division is pleased to present [free accredited COVID-19 Vaccine content](#). These training sessions are designed for health care providers, vaccine coordinators, and all health care personnel who handle and/or administer COVID-19 vaccines.