

**BULLETIN**

**What Massachusetts COVID-19 Vaccine Providers Need to Know**

**Week of 9/3/21**

**Latest Numbers**

* As of 9/3/21 **4,517,107** people in Massachusetts have been fully vaccinated.

**Who to Vaccinate this Week**

* **Reminder** Effective 8/13/21, [CDC recommends](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#considerations-additional-vaccine-dose) 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 On 8/30/2021 ACIP unanimously recommended** use of the [FDA approved Pfizer-BioNTech COVID-19 Vaccine](https://www.fda.gov/media/150386/download), which will now be marketed as Comirnaty, for people aged 16 years and older.

* [Presentation slides](https://www.cdc.gov/vaccines/acip/meetings/slides-2021-08-30.html) from the meeting are available online.
* ACIP’s recommendation follows FDA’s approval, and included a careful examination of available data.
* The Pfizer-BioNTech COVID-19 vaccine also remains recommended under an Emergency Use Authorization (EUA) as:
* a 2-dose primary series for adolescents 12 through 15 years old; and
* 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 [Vaccine Information Fact Sheet for Recipients and Caregivers](https://www.fda.gov/media/144414/download) 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.
* Data presented:
* Severe allergic reaction (e.g., anaphylaxis): an estimated rate following vaccination with mRNA vaccines of about 5 per 1,000,000 doses administered.
* Myocarditis and myopericarditis following COVID-19 vaccination: rare instances, consistent with earlier estimates
* highest risk in males 12 through 49 years
* follow-up studies of longer-term outcomes are underway
* 75% had already recovered at the time of the report.
* benefits from vaccination in preventing hospitalization, ICU admission, and death greatly outweighed any risk from vaccination in all age groups analyzed
* surveillance reports continue to strongly support the overall acceptable safety of currently available COVID-19 vaccines.
* Booster doses of COVID-19 vaccine for immunocompetent people who have completed a primary series:
* Not yet authorized or recommended.
* COVID-19 vaccines continue to maintain a high level of protection against severe disease, hospitalization, and death
* ACIP will continue to evaluate the ability of booster doses to improve protection, the impact of variants on vaccine effectiveness, and available safety data.
* ACIP anticipates reconvening in mid-September to consider additional data on safety and effectiveness of a booster dose for immunocompetent people in preparation for a future vote.
* After FDA regulatory action on booster doses, ACIP will meet to make recommendations on the use of a booster dose, after thoroughly reviewing the evidence.
* CDC has a new [COVID-19 Vaccine Booster Shot](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html) webpage

**NEW** On August 25th, CDC updated the [Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html) to include information on [people vaccinated for COVID-19 as part of a clinical trial in the United States](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#vaccinated-part-clinical-trail). Some people in the United States have completed a COVID-19 vaccination series as part of a U.S.-based clinical trial involving a vaccine that is not currently authorized by FDA. There is information regarding:

* people who received the full series of an active COVID-19 vaccine as part of a U.S.-based clinical trial that is not authorized by FDA but is listed for emergency use by WHO
* people who received the full series of an active COVID-19 vaccine candidate as part of a U.S.-based clinical trial that is neither authorized by FDA nor listed for emergency use by WHO
* specific recommendations for people who received the AstraZeneca COVID-19 vaccine and the Novavax COVID-19 vaccine during a clinical trial

**NEW**  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.
	+ Vaccines are transferred in the refrigerated temperature range.
	+ Upon delivery, vaccines must be placed in the refrigerator for 30 days.

**Reminder**  **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](https://www.fda.gov/vaccines-blood-biologics/comirnaty)
* [press release](https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine)
* [frequently asked questions](https://www.fda.gov/vaccines-blood-biologics/qa-comirnaty-covid-19-vaccine-mrna)
* 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](https://www.fda.gov/media/144414/download) 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)

**Reminder Updated Standing Orders, Prep & Admin Summaries, and Prevaccination Screening Form**

* [Prevaccination Screening Form](https://www.cdc.gov/vaccines/covid-19/downloads/pre-vaccination-screening-form.pdf)
* [Pfizer Standing Orders](https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/standing-orders.pdf)
* [Pfizer Prep and Admin Summary](https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/prep-and-admin-summary.pdf)
* [Moderna Standing Orders](https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/standing-orders.pdf)
* [Moderna Prep and Admin Summary](https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/prep-and-admin-summary.pdf)

**Reminder 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](https://urldefense.com/v3/__https%3A/www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html__;!!CUhgQOZqV7M!y3QBMl1wDBgmNSyeaTRiKD74ovS_36Lf9kZR5XAzmG_SgHO3oIBIT1Zud2AenSk7Aew$) of CDC, the [Advisory Committee on Immunization Practices](https://urldefense.com/v3/__https%3A/www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html__;!!CUhgQOZqV7M!y3QBMl1wDBgmNSyeaTRiKD74ovS_36Lf9kZR5XAzmG_SgHO3oIBIT1Zud2AeWH5ldwk$), and [FDA](https://urldefense.com/v3/__https%3A/www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines__;!!CUhgQOZqV7M!y3QBMl1wDBgmNSyeaTRiKD74ovS_36Lf9kZR5XAzmG_SgHO3oIBIT1Zud2AeXocNhzI$). 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)](https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-vaccine-dose-certain-immunocompromised) 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](https://www.fda.gov/media/144413/download) and [recipients](https://www.fda.gov/media/144414/download)
* Moderna EUA fact sheets for [providers](https://www.fda.gov/media/144637/download) and [recipients](https://www.fda.gov/media/144638/download)
* New section in the [CDC Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#considerations-additional-vaccine-dose). 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](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/immunocompromised-patients.html)
* For the public: [COVID-19 Vaccines for Moderately to Severely Immunocompromised People](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html)

**Reminder *Recommendations For People Who Are Pregnant, Lactating, or Trying to Get Pregnant:*** On 8/11/21, CDC updated its [Interim Clinical Considerations](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#pregnant) 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](https://urldefense.com/v3/__https%3A/www.immunizationmanagers.org/resource/collection/49107373-8424-42C5-9A82-882C58A2CC10/PartnerKM_COVID-19vax_Pregnancy.pdf__;!!CUhgQOZqV7M!zypMbcJFFNMKBgYzDfHoxz53VrE5vzFs1rKtTATmOX6OPfRZ-ssBMu6mKHWXQxbt-jw$).

* The American College of Obstetricians and Gynecologists (ACOG) also issued an [updated practice advisory](https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/covid-19-vaccination-considerations-for-obstetric-gynecologic-care?fbclid=IwAR0PM1UqSezzkxT7a8RCa49SDR_6pXM7KNXT1HCrbKdYuXBsukSywFG5wEo)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.

**Reminder*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 27th.
* 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.](https://urldefense.com/v3/__https%3A/www.fda.gov/media/144413/download__;!!CUhgQOZqV7M!x2jKzq8ClkO_yt_G9jkFC5_UgYMjPS13laaQXtwVZgcmqTCR-OsBS025r5rlxE6tM-abqog$)
* Additional information on Pfizer storage and handling may be found at:  [Administration Overview for Pfizer-BioNTech COVID-19 Vaccine | CDC](https://urldefense.com/v3/__https%3A/www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html__;!!CUhgQOZqV7M!x2jKzq8ClkO_yt_G9jkFC5_UgYMjPS13laaQXtwVZgcmqTCR-OsBS025r5rlxE6tAVoryPk$)

**Reminder 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)](https://urldefense.com/v3/__https%3A/www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/bud-tracking-labels.pdf__;!!CUhgQOZqV7M!1sCQOw2VnmWBIvWhV7PZnpvFsUqK6WoZ76pkLLeouYfs5Cn3vFk1yhG9Sis7TUG9R4s$)
* [Pfizer-BioNTech COVID-19 Beyond Use Date/Time (BUD) Tracking Labels for Vaccine During Freezer or Refrigerator Storage (cdc.gov)](https://urldefense.com/v3/__https%3A/www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/bud-tracking-labels.pdf__;!!CUhgQOZqV7M!1sCQOw2VnmWBIvWhV7PZnpvFsUqK6WoZ76pkLLeouYfs5Cn3vFk1yhG9Sis7LmM8Ft8$)
* 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)](https://urldefense.com/v3/__https%3A/www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/storage-summary.pdf__;!!CUhgQOZqV7M!1sCQOw2VnmWBIvWhV7PZnpvFsUqK6WoZ76pkLLeouYfs5Cn3vFk1yhG9Sis7AmblAc8$)
* [Pfizer-BioNTech COVID-19 Vaccine Storage and Handling Summary (cdc.gov)](https://urldefense.com/v3/__https%3A/www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/storage-summary.pdf__;!!CUhgQOZqV7M!1sCQOw2VnmWBIvWhV7PZnpvFsUqK6WoZ76pkLLeouYfs5Cn3vFk1yhG9Sis7A5Rj9I4$)

**Resources & Learning Opportunities**

**Reminder** COVID-19 vaccine flyers and EUA factsheets are available in [26 different languages](https://medlineplus.gov/languages/covid19vaccines.html).

**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](https://www.cdc.gov/mmwr/covid19_vaccine_safety.html) to help people find the latest information on COVID-19 vaccine effectiveness and safety.

**New** CDC MMWRs

* Early Release 8/31/2021 [Association Between COVID-19 and Myocarditis Using Hospital-Based Administrative Data — United States, March 2020–January 2021](https://www.cdc.gov/mmwr/volumes/70/wr/mm7035e5.htm?s_cid=mm7035e5_w)
* Early Release 8/27/2021 [Outbreak Associated with SARS-CoV-2 B.1.617.2 (Delta) Variant in an Elementary School — Marin County, California, May–June 2021](https://urldefense.com/v3/__https%3A/t.emailupdates.cdc.gov/r/?id=h4fcb4ea9,14be89ee,14bfc3a7&ACSTrackingID=USCDC_921-DM64558&ACSTrackingLabel=MMWR*20Early*20Release*20-*20Vol.*2070*2C*20August*2027*2C*202021__;JSUlJSUlJSUlJQ!!CUhgQOZqV7M!0DjXm62AHAFmay4SzqC-yzJaL98gv54Se-s_hS4kP8Q4hl_tRCOMofbISMS-Bd-wsc3WMt_l$)
* Early Release 8/27/2021 [COVID-19 Vaccination Coverage Among Adolescents Aged 12–17 Years — United States, December 14, 2020–July 31, 2021](https://urldefense.com/v3/__https%3A/t.emailupdates.cdc.gov/r/?id=h4fcb4ea9,14be89ee,14bfc3a8&ACSTrackingID=USCDC_921-DM64558&ACSTrackingLabel=MMWR*20Early*20Release*20-*20Vol.*2070*2C*20August*2027*2C*202021__;JSUlJSUlJSUlJQ!!CUhgQOZqV7M!0DjXm62AHAFmay4SzqC-yzJaL98gv54Se-s_hS4kP8Q4hl_tRCOMofbISMS-Bd-wsVhvP_ff$)
* Early Release 8/27/2021 [COVID-19 Case Rates in Transitional Kindergarten Through Grade 12 Schools and in the Community — Los Angeles County, California, September 2020–March 2021](https://urldefense.com/v3/__https%3A/t.emailupdates.cdc.gov/r/?id=h4fcb4ea9,14be89ee,14bfc3a9&ACSTrackingID=USCDC_921-DM64558&ACSTrackingLabel=MMWR*20Early*20Release*20-*20Vol.*2070*2C*20August*2027*2C*202021__;JSUlJSUlJSUlJQ!!CUhgQOZqV7M!0DjXm62AHAFmay4SzqC-yzJaL98gv54Se-s_hS4kP8Q4hl_tRCOMofbISMS-Bd-wsQQm-1U2$)

**Reminder** MDPH Immunization Division is pleased to present [free accredited COVID-19 Vaccine content](https://macovidvax.populationhealthexchange.org/). These training sessions are designed for health care providers, vaccine coordinators, and all health care personnel who handle and/or administer COVID-19 vaccines.