

MASSACHUSETTS COVID-19 VACCINE PROGRAM

BULLETIN

What Massachusetts COVID-19 Vaccine Providers Need to Know Week of 4/22/21

Latest Numbers

• As of 4/22, 6,465,170 doses of COVID-19 vaccine have shipped to Massachusetts, and 5,397,052 doses (83.5%) have been administered.

Who to Vaccinate this Week

- Anyone age 16 and older who lives, works, or studies in Massachusetts is eligible for a vaccine.
- Sites should maintain wait lists of individuals they can call if they have extra vaccine they can administer by the end of the day to prevent wastage.

What to Know this Week

- New Consent for vaccination for minors younger than 18: Vaccine providers are responsible for obtaining appropriate consent from patients before administering vaccines. For minors younger than 18 years of age, consent is obtained from a legally authorized representative on behalf of the child (usually a parent or guardian) by completing a written consent form that the minor can bring to their vaccination appointment. The parent or guardian does not need to go with the minor to their vaccination appointment to give consent. Currently, people younger than 18 can only get the Pfizer vaccine.
 - For more information, including copies of the consent form in multiple languages, see COVID-19 vaccinations for people under age 18 | Mass.gov.
- New Patient rights regarding access to COVID-19 vaccine: Across the U.S., some immigrants are facing documentation requests prior to COVID-19 vaccination, and individuals are being inappropriately billed for COVID-19 vaccine fees. HRSA developed fact sheets to help patients and providers better understand their rights and responsibilities regarding access to COVID-19 vaccines. COVID-19 vaccines are free to all individuals. Please ensure that all signage and other messaging on site makes it clear that an ID and insurance card are not required for vaccination.
 - Patient Fact Sheet (<u>English</u> | <u>Spanish</u>)
 - Provider Fact Sheet (<u>English</u> | <u>Spanish</u>)
- New Withdraw only the authorized number of doses from a vial of COVID-19 vaccine: This is indicated in the vaccine-specific EUA provider fact sheet. CDC will update its guidance if the EUA and ancillary supply kits support additional doses per vial in the future. Additional guidance:
 - Never combine or "pool" partial doses from 2 or more vials to obtain one full dose.
 - Withdraw only the number of doses <u>authorized</u> for the specific vaccine.
 - Discard vaccine vial and remaining vaccine in sharps container if the amount of vaccine left in the vial is not a full dose, or you have withdrawn the maximum number of doses authorized for that vaccine.

- Updated *Pausing use of Johnson & Johnson (J&J) vaccine*: The FDA and CDC have recommended a pause in the use of the J&J COVID-19 vaccine out of an abundance of caution, after 6 people who received the vaccine developed a rare but serious cerebral venous sinus thrombosis with thrombocytopenia. DPH has notified all Massachusetts providers to pause administration of the J&J vaccine until federal health experts investigate this matter.
 - DPH Health Alert Cases of Cerebral Venous Thrombosis with Thrombocytopenia after Receipt of Johnson & Johnson COVID-19 vaccine (attached to this bulletin)
 - CDC slides: Johnson & Johnson/Janssen COVID-19 Vaccine and Cerebral Venous Sinus Thrombosis with Thrombocytopenia – Update for Clinicians on Early Detection and Treatment
- Management of J&J vaccine during pause: If you have J&J vaccine on hand, implement the following CDC guidance until further notice:
 - Mark any Janssen/J&J vaccine in your inventory "Do not use. Awaiting guidance."
 - Continue to store the vaccine in the refrigerator between 2°C and 8°C (36°F and 46°F).
 - Follow <u>vaccine storage practices</u> and continue to monitor and document storage unit temperatures.
- Updated *Pfizer EUA fact sheets updated 4/6/21:* The following adverse reactions have been identified during post-authorization use of Pfizer-BioNTech COVID-19 Vaccine: 1) immune system disorders (severe allergic reactions, including anaphylaxis, and other hypersensitivity reactions [e.g., rash, pruritus, urticaria, angioedema]); 2) gastrointestinal disorders (diarrhea, vomiting); and 3) musculoskeletal and connective tissue disorders (pain in extremity [arm]). Because these reactions are reported voluntarily, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure.
 - Pfizer EUA Fact Sheet for Providers
 - Pfizer EUA Fat Sheet for Vaccine Recipients
- Moderna EUA fact sheets updated 3/31/21: Key updates to the EUA factsheet for healthcare providers include:
 - Moderna COVID-19 Vaccine Vials Contain 10 11 Doses
 - It is possible to extract 11 doses using low dead-volume (LDV) needles/syringes.
 - Moderna ancillary supply kits include enough supplies to administer 10 doses per vial. Moderna kits do NOT contain low dead-volume needles/syringes.
 - Given the limited supply of LDV syringes, sites should still plan to reliably extract 10 doses. The 11th dose does not count as waste.
 - Do NOT "borrow" low dead-volume needles/syringes from Pfizer kits.
 - Needles/syringes from the provider's supply used to withdraw an 11th dose cannot be replaced.
 - Moderna Vaccine Storage
 - Unpunctured vials Moderna vials can now be stored frozen between -50° to -15°C (-58° to 5°F). This is a new, wider temperature range that is consistent with other recommended vaccines stored in the freezer.
 - Vials may be stored between 8° to 25°C (46° to 77°F) for a total of 24 hours. This is an increase from 12 hours to 24 hours.
 - Unchanged: Vials may be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use.

- Punctured vials After the first dose has been withdrawn, the vial can be held between 2° to 25°C (36° to 77°F) for up to 12 hours. Vials should be discarded 12 hours after the first puncture. This is an increase from 6 hours.
- USP's factsheet on <u>Beyond use date in vial or syringe for COVID-19</u>
 <u>Vaccines</u> reflects the changes in the Moderna beyond use dates.
- Use the Moderna <u>Temperature Excursion Tool</u> to see what to do with vials that may have experienced a temperature excursion prior to administering.
- How and where to refer patients for COVID-19 vaccine. Even if you are not administering COVID-19 vaccine, as your patients' most-trusted source of information on vaccines, you play a critical role in helping your patients understand the importance of COVID-19 vaccination. Key messaging includes helping your patients understand that all three COVID-19 vaccines are safe and effective, and they all prevent severe illness, hospitalization and death. To help you with these conversations, please see these resources:
 - Making a Strong Recommendation for COVID-19 Vaccination
 - <u>Trust the Facts, Get the Vax campaign materials</u> in multiple languages.
 - <u>COVID-19 Vaccination Locations</u> to help your patients find out where to get vaccinated.
- Revised COVID-19 Vaccine Management Standard Operating Procedure Template & Redistribution Guidance: Revised documents are posted on the mass.gov provider page.
- Provider sites are responsible for informing patients about the MIIS and for managing data sharing: This 10 minute MIIS Kick Off Video explains the duty to inform and data sharing.
 - The following materials may also help sites comply: MIIS Fact Sheets, MIIS Posters, MIIS Language Templates, MIIS Sample Workflow for Duty to Inform and Data Sharing.
 - The <u>Data Sharing Mini Guide</u> provides step-by-step instructions for managing data sharing in the MIIS. Read the <u>MIIS legislation</u> to ensure your organization understands all its responsibilities. Contact the <u>miishelpdesk@mass.gov</u> with any questions.
- Ensure patient safety at vaccination clinics: Use the <u>CDC COVID-19 Patient Safety Checklist for Vaccination Clinics</u> to ensure your clinic is following the best practices for patient safety and vaccine handling and administration.
- Ensure vaccinators have the following at their station: 1) Standing Orders, 2) Prevaccination Checklist (screening form), 3) Vaccine Preparation and Administration Summary, and 4) COVID-19 Vaccine Quick Reference Guide for Healthcare Professionals. The product-specific Standing Orders and Vaccine Preparation and Administration Summaries, as well as the Prevaccination Checklist (in English and 6 additional languages), can be found under the Administration Resources section of each product page (Pfizer, Moderna, and Janssen/J&J). These pages also have product-specific training modules.
- Assess staff and volunteer competencies: CDC and IAC have tools for self-assessment and supervisor review of skills, techniques, and procedures.
 - COVID-19 Vaccine Administration Competency Assessment Form
 - IAC Skills Checklist for Vaccine Administration
- *Maximize doses per vial of Pfizer vaccine*: This informational <u>USP video</u> helps healthcare providers maximize doses per vial of the Pfizer COVID-19 vaccine.
- **Return Pfizer thermal shipping containers:** Shipping containers may be used as temporary storage of Pfizer vaccine for up to 30 days from delivery. After use, <u>follow these instructions</u> to return the container, including the temperature-monitoring device, to the supplier.

Resources & Learning Opportunities

- New Clinical information (including FAQs, contraindications and precautions) and administration resources can be found for each vaccine on their own product webpage. Scroll to the bottom of each vaccine specific webpage to see Storage and Handling Resources.
 - Pfizer-BioNTech COVID-19 vaccine
 - Moderna COVID-19 vaccine
 - Janssen/J&J COVID-19 vaccine
- CDC is offering a series of brief (15-20 minute) webinars with CE credit:
 - Preventing Vaccine Administration Errors: A Primer for Healthcare Workers
 - A Primer for Healthcare Workers on Storing and Transporting Vaccines
- COVID-19 Vaccine Guidance for MCVP Providers: information on becoming a COVID-19 vaccine
 provider, information about each COVID-19 vaccine product, requesting vaccine and reporting to
 the MIIS, storage and handling, clinical considerations, and who to contact with questions.
- V-safe After Vaccination Health Checker | CDC
- CDC Interim Clinical Considerations reference materials:
 - Interim Clinical Consideration Summary
 - Vaccine Administration Errors and Deviations table
- USP COVID-19 Vaccine Handling Toolkit. Download the latest toolkit
 - Maximizing Doses of Pfizer-BioNTech COVID-19 Vaccine
 - Transporting COVID-19 Vaccines Off-Site
 - Beyond-use Date in Vial or Syringe for COVID-19 Vaccines