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| **BULLETIN****What Massachusetts COVID-19 Vaccine Providers Need to Know****Week of 4/20/2023** |

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| **As of April 18, 2023, the monovalent Moderna and Pfizer COVID-19 vaccines are no longer authorized for use in the U.S.****LATEST NUMBERS*** As of 4/20/2023 **5,942,979** people in Massachusetts have completed primary series of monovalent vaccine. However, only 2,024,432 Massachusetts residents have received the recommended bivalent booster dose.

**LATEST NEWS****CDC simplifies COVID-19 vaccine recommendations** **and allows some flexibility for people at higher risk** Following [FDA regulatory action](https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-changes-simplify-use-bivalent-mrna-covid-19-vaccines) on April 18th, [CDC](https://www.cdc.gov/media/releases/2023/s0419-covid-vaccines.html) has taken steps to simplify COVID-19 vaccine recommendations and allow more flexibility for people at higher risk who want the option of added protection from an additional COVID-19 vaccine dose.CDC’s Advisory Committee on Immunization Practices (ACIP) met April 19th to discuss these COVID-19 vaccine recommendation changes, and the associated implications and implementation. Although there was no vote at this meeting, ACIP members expressed their support for these recommendations.These changes include:* Monovalent (original) COVID-19 mRNA COVID-19 vaccines will no longer used in the United States.
* CDC recommends that everyone ages 6 years and older be up to date with their vaccines, which includes receiving a bivalent booster dose.
* For those who have not yet received a monovalent primary series, CDC now recommends a single bivalent dose.
* **Individuals ages 6 years and older who have already received an updated mRNA vaccine do not need to take any action unless they are 65 years or older or immunocompromised.**
* For young children (6 months through 5 years), multiple doses continue to be recommended and will vary by age, vaccine, and which vaccines were previously received.
* CDC’s new recommendations allow an additional updated (bivalent) vaccine dose for adults ages 65 years and older and additional doses for people who are immunocompromised. This allows more flexibility for healthcare providers to administer additional doses to immunocompromised patients as needed.

Alternatives to mRNA COVID-19 vaccines remain available for people who cannot or will not receive an mRNA vaccine. CDC’s recommendations for use of (monovalent) Novavax or Johnson & Johnson’s Janssen COVID-19 vaccines were not affected by recent changes.CDC and ACIP will continue to monitor COVID-19 disease levels and vaccine effectiveness in the months ahead and look forward to additional discussion around potential updates this fall.In the coming days, CDC will update it’s website, including the [Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States](https://urldefense.com/v3/__https%3A/www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html__;!!CUhgQOZqV7M!mL44pfnFY3RjPzB3GHzrKwd0aJvzXnVTSr9FiFoarpvUo-_ycIqkA0K1qdKPSHuWxOY3ATPjarq0rh8B9nrxm07yPA$) and additional [COVID-19 vaccine webpages](https://urldefense.com/v3/__https%3A/www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html__;!!CUhgQOZqV7M!mL44pfnFY3RjPzB3GHzrKwd0aJvzXnVTSr9FiFoarpvUo-_ycIqkA0K1qdKPSHuWxOY3ATPjarq0rh8B9noT_A3t8A$).**Vaccine Management - Storage and handling for expired and wasted doses**Monovalent COVID-19 vaccine is no longer available for ordering in the MIIS. Expiration dates for monovalent vaccines have been updated in the MIIS to April 18,2023. All monovalent doses are now expired. Please process a storage and handling issue in the MIIS to report the wasted doses. Discard all expired or wasted doses in medical waste. **COVID-19 Vaccine Reconciliation and Inventory Cleanup**By signing the Massachusetts COVID-19 Vaccination Program (MCVP) provider agreement, providers agreed to comply with all data reporting requirements. These requirements include reporting administered doses as well as processing storage and handling issues for all expired and wasted vaccines in the MIIS. Consistently check the expiration and Beyond Use Dates (BUD) to ensure expired and/or nonviable doses are not administered to patients. A storage and handling issue should be entered into MIIS to account for all expired and wasted doses. Please discard any expired or wasted COVID-19 doses in medical waste at your facility, as these do not need to be returned.During the month of April, the MDPH Vaccine Management Unit will be working with sites to reconcile inventory in the MIIS. To ensure that your MIIS inventory counts align appropriately with your physical counts, your site must take the following actions:* Ensure that all COVID-19 vaccine doses administered are reported to the MIIS as required by law. Your site must account for all administered doses by your facility.
* Review your [Inventory Decrementing Tool](https://urldefense.com/v3/__https%3A/r20.rs6.net/tn.jsp?f=001-fgkEojohXW2BThMqXJhRW69pPtGRfsqOAol5OW6nzBZKwa2qq8oPowGP7rTaEGXj_tCrStmQVQDlArmmYRNTmQwChA-YCZVEpntOySTRqlecTC0UKU3gy8cRrkWd6NzNvvtMX-MJQZsN992lvqXh8WTb8lFN9qrX4LhNy5rCjVaRfRCsrammFw6SSDKWVW3DVKwa43Q75fc-ct3ZllUITreSPEZnAfeO0fULCGsf3N3z8iNesL1_HxYTUcB6UY5NplYaeMGoFA=&c=kvVRibmWHiGtHSQnyZ8AGOMqtfXurGysmSpU-wx_R-uQoKx6np6y1A==&ch=k-cDUAfeY1gJdXkpsy8QVEoXSztHJfqS_e2sS-8wB8bY6aVjEd0bjg==__;!!CPANwP4y!Rr9L4nBMAJjuUQSmdwApaXiAl7O2sx1cwCrW7qda6DvQIHrjiMJr8_sTSPVgIG4WPo5XuanbFDYtZZo_RMqWTZCQSc2yxJQ$) to ensure that all reported doses have decremented out of your MIIS inventory appropriately.
* Submit [storage and handling](https://urldefense.com/v3/__https%3A/r20.rs6.net/tn.jsp?f=001-fgkEojohXW2BThMqXJhRW69pPtGRfsqOAol5OW6nzBZKwa2qq8oPsLWekD_mIaY6HBHnPm1LIHkreuUHd1mlklotbXnNssbMt4E6rB21rM6wx0K1tRF54wbMGTXzdeDgAdNwCDcceRft1mEwF4m8j_rSBYYdp0JkossD6MxkIEhT2q6LtmpmB2x1I-0J0XRl983YAkGvbvsHv8BxaeN1NP3AO36P82vlVbe4MQrGDsfqeiS32rCeHud6aAF9kd_uPSKJrbNd-o=&c=kvVRibmWHiGtHSQnyZ8AGOMqtfXurGysmSpU-wx_R-uQoKx6np6y1A==&ch=k-cDUAfeY1gJdXkpsy8QVEoXSztHJfqS_e2sS-8wB8bY6aVjEd0bjg==__;!!CPANwP4y!Rr9L4nBMAJjuUQSmdwApaXiAl7O2sx1cwCrW7qda6DvQIHrjiMJr8_sTSPVgIG4WPo5XuanbFDYtZZo_RMqWTZCQ1P2VHeQ$) issues in MIIS for any wasted, spoiled (including lots that have reached their Beyond Use Date) or expired doses of COVID vaccines that are still appearing in your MIIS inventory.
* As part of the reporting requirements all wasted, spoiled, and expired doses must be accounted for in the MIIS system. As is noted in our [updated guidance](https://urldefense.com/v3/__https%3A/r20.rs6.net/tn.jsp?f=001-fgkEojohXW2BThMqXJhRW69pPtGRfsqOAol5OW6nzBZKwa2qq8oPhoPB_tAOBInWIq6ewMBD1fp1MmZ9UOMZBsPH2wdH4z3YBgSFq-P95vmHXJYdZNiViyGUZ-clyXu2GcXH_rn_H8MS59EsF9RWJcKWFFYsIHFI1fzoy2unI7aMsKuyZtCtHyv22GXM_irvZumCzugZGYaIHAyULwaG4tzcnnAzmHiuEtgtU1kX_x-EbtR-Aa5JIoZXxb-7DdkKe-wQnJmoZfnuWIT0HsQZAC1pKyr8sRk&c=kvVRibmWHiGtHSQnyZ8AGOMqtfXurGysmSpU-wx_R-uQoKx6np6y1A==&ch=k-cDUAfeY1gJdXkpsy8QVEoXSztHJfqS_e2sS-8wB8bY6aVjEd0bjg==__;!!CPANwP4y!Rr9L4nBMAJjuUQSmdwApaXiAl7O2sx1cwCrW7qda6DvQIHrjiMJr8_sTSPVgIG4WPo5XuanbFDYtZZo_RMqWTZCQCzk_z-Q$) regarding allowable wastage for COVID-19 vaccines, there are no penalties for sites wasting doses. Sites should take every opportunity to vaccinate a potential patient, even if it results in the remaining doses in the open multi-dose vial being wasted.

To ensure that all administered, transferred and wasted doses are reported accurately into MIIS, please conduct a full review of your MIIS COVID-19 vaccine inventory by April 30, 2023. On May 1, 2023, the Vaccine Management Unit will be auto-clearing out any COVID-19 vaccine lots listed as expired in your MIIS inventory on or before April 1, 2023.In addition to reviewing your MIIS COVID inventory, please keep a close eye on the expiration dates on the ancillary supplies your site received with your COVID vaccine shipments. Please note that all ancillary kit materials have expiration dates, and they may not align to the same date. Any expired ancillary supplies should be disposed of by your site and never used for vaccine administration. If you have any questions, please reach out to the Vaccine Management Unit at 617-983-6828 or dph-vaccine-management@mass.gov. **COVID-19 Public Health Emergency Ending on May 11th** The Department of Health and Human Services has announced that the Federal Public Health Emergency for COVID-19 is planned to end on May 11, 2023. Please note that the Public Health Emergency ending will not have any immediate impacts on your site’s ability to continue to order COVID-19 vaccines. COVID-19 vaccines will still be available to order via the MIIS system for all enrolled sites with a signed MCVP Agreement. The associated EUA’s for the COVID formulations will still be active and hold true, even after the official Public Health Emergency ends. **QUESTION OF THE WEEK** Q: Where do I go to find the correct information about what vaccine doses I should be administering?A: For the most up-to-date, correct information, you should be frequently checking the CDC’s ‘[Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html)’. In the coming days, CDC will be updating all documents and webpages, so check back frequently.**WHO TO VACCINATE** ***CDC will be providing tables and detailed guidance describing various scenarios. Please watch the*** [***Clinical Considerations***](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html) ***for this.***COVID-19 vaccination is recommended for everyone ages 6 months and older in the United States for the prevention of COVID-19. There is currently no FDA-approved or FDA-authorized COVID-19 vaccine for children younger than age 6 months.As of April 19, 2023, * All persons 6 years and older are considered up to date with their COVID-19 vaccination if they have received one dose of bivalent mRNA vaccine. Once they had/have a bivalent mRNA dose, they are complete/up to date, with no further doses indicated at this time.
* Children under 6 years of age have a more detailed/customized recommendation, depending on their age, product used, and previous vaccination status.
* Adults over 65 years, and those who are immunocompromised may now receive an optional additional bivalent mRNA dose, once a minimal interval is met.
* If you are unable or choose not to get a recommended bivalent mRNA vaccine, you will be up to date if you got the Novavax COVID-19 vaccine doses approved for your age group. CDC’s recommendations for use of (monovalent) Novavax or Johnson & Johnson’s Janssen COVID-19 vaccines were not affected by these changes.

**VACCINE ADMINISTRATION RECOMMENDATIONS*** 6+ years old: 1 bivalent mRNA dose. Regardless of vaccine history.
* 6 months through <6 years old:
	+ Moderna: at least 2 doses, including at least 1 bivalent dose.
	+ Pfizer:
		- 5 years: 1 bivalent dose.
		- 6 months through < 5 years old: at least 3 doses, including at least 1 bivalent dose.

In addition, people ***may***now choose to receive an additional optional spring dose if: * 65 years of age and older and got a first bivalent (updated) COVID-19 vaccine booster 4 or more months ago.
* Moderately or severely immunocompromised and received a bivalent (updated) COVID-19 vaccine booster 2 or more months ago.
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| **VACCINE MANAGEMENT** **Moderna <6 Bivalent Minimum Order Quantity**The minimum order quantity for Moderna <6 Bivalent (NDC # 80777-0283-99) vaccines has been reduced from 100 doses to 20 doses. Sites are now able order Moderna <6 Bivalent vaccines by increments of 20 doses. Please note that if your site orders 20 doses of Moderna <6 Bivalent vaccine, you will receive one carton, containing 20 doses in 10 two-dose vials. **Pfizer 12+ bivalent single dose vials now available for ordering by Primary Care Provider (PCP) Sites**The Pfizer bivalent vaccine formulation for 12+ is now available in single dose vials. Due to limited quantities of this formulation, it is currently being made available only to PCP sites (pediatricians, family practices, internal medicine offices, community health centers). To add this vaccine formulation/packaging click on the “[add a vaccine](https://resources.miisresourcecenter.com/trainingcenter/New%20Order_2018_Mini%20Guide.pdf)” button in the lower left-hand corner of the ordering screen.See below for additional information about the SDV presentation of the Pfizer (12+) Bivalent COVID-19 Vaccine: * The order quantity is 50 doses.
	+ All single-dose vials, plan to use every single dose.
* Product dimensions: 1.47in x 1.535in x 3.504in
	+ Storage space required equals that of a 300-dose MDV order
* **SDVs will not include ancillary kits**. SDVs do not require the use of low-dead-volume syringes.
* This product is new packaging, not a new vaccine. Storage and handling requirements remain the same as the Pfizer bivalent multi-dose vial. (Store at ultra-low temperature until expiry, may refrigerate up to 10 weeks within the expiry period).

**Watch for Expired Vaccine**We continue to encourage you to properly manage and report your inventory:* Practice first in/first out inventory management.
* Store older vaccines to the front of the refrigerator or freezer unit.
* Continually monitor vaccines to help reduce administration errors.
* Verify expiry dates using the manufacturers’ online checkers:
	+ **Pfizer:** [https://lotexpiry.cvdvaccine.com](https://urldefense.com/v3/__https%3A/lotexpiry.cvdvaccine.com__;!!CUhgQOZqV7M!g1Yw5s9rP2l4dkC-7CD1gxNax-9_NEnMVlrrMsI7fKtol4z38iBzCVOWymrfdx2hFKkXG21JexZO0BFcRHYFXWo$)
	+ **Moderna:** [https://modernacovid19global.com/vial-lookup](https://urldefense.com/v3/__https%3A/modernacovid19global.com/vial-lookup__;!!CUhgQOZqV7M!g1Yw5s9rP2l4dkC-7CD1gxNax-9_NEnMVlrrMsI7fKtol4z38iBzCVOWymrfdx2hFKkXG21JexZO0BFc0u-dkYA$)
	+ **Novavax:** [https://us.novavaxcovidvaccine.com/hcp](https://urldefense.com/v3/__https%3A/us.novavaxcovidvaccine.com/hcp__;!!CUhgQOZqV7M!g1Yw5s9rP2l4dkC-7CD1gxNax-9_NEnMVlrrMsI7fKtol4z38iBzCVOWymrfdx2hFKkXG21JexZO0BFcSHj6TOA$)
	+ **Johnson and Johnson/Janssen:** [https://vaxcheck.jnj/](https://urldefense.com/v3/__https%3A/vaxcheck.jnj/__;!!CUhgQOZqV7M!g1Yw5s9rP2l4dkC-7CD1gxNax-9_NEnMVlrrMsI7fKtol4z38iBzCVOWymrfdx2hFKkXG21JexZO0BFcjMhtgo4$)
* Ensure your inventory is up to date by reporting administered doses and processing storage and handling for expired or wasted vaccine.
* Dispose of any expired or wasted vaccine.

**Expiry Date vs Beyond Use Date (BUD)** The **expiration date** is set by the manufacturer and is the date by which the vaccine should be used. The expiration date assumes that the vaccine has been stored and handled according to the manufacturer’s guidance. Expiration dates cannot change based on how vaccine is being stored or when a vial is punctured. However, on occasion, the expiration date may be updated by the manufacturer as additional stability data become available. **Beyond Use Date (BUD)** is the date of when the vaccine can no longer be used due to a change in storage temperature, reconstitution, puncturing the vial, etc. It is recommended to place a label with the BUD and the initials of the person making the calculation whenever a vaccine vial or box is moved to a different temperature storage unit, reconstituted, or had a vial punctured resulting in a chance in the BUD.   You can find BUD guidance and labels for [Moderna,](https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/storage-handling-label.pdf) [Novavax](https://www.cdc.gov/vaccines/covid-19/info-by-product/novavax/downloads/novavax-bud-tracking-labels.pdf), [Janssen](https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/downloads/janssen-storage-handling-label.pdf), and [Pfizer](https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/storage-handling-label.pdf) from the CDC’s U.S. COVID-19 Vaccine Product Information webpage.**COVID Vaccines Available for ordering in the MIIS**All providers enrolled Massachusetts COVID-19 Vaccine Program (MCVP) are able to place routine orders for all of the following COVID-19 vaccine formulations through the Massachusetts Immunization Information System (MIIS).

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| Brand | NDC | NDC Description | Minimum ordering size |
| - | 59267-0304-02 | COVID-19 (Pfizer);BIVALENT;MDV6; 10-pack | 180 |
| - | 59267-1404-02 | COVID-19(Pfizer);BIVALENT;SDV;10pk | 50 |
| - | 59267-0565-02 | COVID-19 (Pfizer);BIVALENT;(PED 5-11) MDV10;10pk | 100 |
| - | 59267-0609-02 | COVID-19 (Pfizer);BIVALENT;(PED 6m-4y) MDV10; 10-pack | 100 |
| - | 80777-0282-99 | COVID-19 (Moderna);BIVALENT;MDV5; 10-pack | 100 |
| - | 80777-0283-99 | COVID-19 (Moderna); BIVALENT;(PED 6m-5y) MDV2;10-pack | 20 |
| - | 80631-0102-10 | COVID-19 (Novavax); MDV5; 10-pack | 50 |

* Initial shipments of the Pfizer-BioNTech vaccine for children aged 6m–4 years may state “2y to <5y” or “6m to <5y” on the vial or carton labels. Please note that vials or cartons with labels that state “2y to <5y” can be used for children aged 6m through 4 years.
* Pfizer-BioNTech vaccine vial labels and cartons may also state that a vial should be discarded 6 hours after the first dilution however as stated in the EUA Fact Sheet the timeframe for use post-dilution is actually 12 hours just like orange and gray cap Pfizer vaccine formulations.

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| **RESOURCES & LEARNING OPPORTUNITIES** **Commercialization of COVID-19 products**HHS recently published a [question-and-answer document](https://urldefense.com/v3/__https%3A/immunizationmanagers.us16.list-manage.com/track/click?u=13b4fdc9ac0078e4c57522c2b&id=c4349edb49&e=4f158a4069__;!!CUhgQOZqV7M!mOJ1HacJneXLSjQ5ZfhT0d9FRTQ70-wNRhMBaNIFv3Zzh-ju5wb8TNlskW5-iCHlfrsxXy2c4hkRTipWdV-sypc0DJ6wA9E$) with frequently asked questions on the commercialization of COVID-19 medical countermeasures.**Moderna’s COVID-19 Vaccine Training**Moderna is having live 10-minute presentations, followed by Q&A, available at <https://app.livestorm.co/moderna-na-medical/regional-medical-affairs-office-hours-simplified-dosing-schedules-for-moderna-covid-19-vaccine-bivalent> **Pfizer’s COVID-19 Vaccine Training**Pfizer has live medical update sessions<https://www.pfizermedicalinformation.com/en-us/medical-updates> **EUA Fact Sheets**Once a new EUA Fact Sheet is issued, it must be used. Previous ones no longer contain accurate information.* Moderna EUAscan be found on the FDA website[here](https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccines)
* Pfizer EUAs can be found on the FDA website [here](https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccines)
* Novavax EUAscan be found on the FDA website[here](https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/novavax-covid-19-vaccine-adjuvanted)
* Janssen EUAscan be found on the FDA website[here](https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine)

**Standing Orders** * Watch for updated standing orders: <https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html>
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**MDPH RESOURCES****Immunization Division Main Number**For questions about immunization recommendations, disease reporting, etc.Phone: 617-983-6800 (24/7 MDPH Epi line)Fax: 617-983-6840Website: <https://www.mass.gov/topics/immunization> **MIIS Help Desk**Phone: 617-983-4335Fax: 857-323-8321 Email questions to: miishelpdesk@mass.gov Website: <https://www.mass.gov/massachusetts-immunization-information-system-miis>**MDPH Vaccine Unit**Phone: 617-983-6828Email questions to: dph-vaccine-management@mass.gov Website: <https://www.mass.gov/service-details/vaccine-management> **Color Help**Email questions to: colorhelp@mass.govWebsite: <https://www.mass.gov/info-details/vaccine-clinic-management-platform>**COVID-19 Email Box**Email questions to: COVID-19-Vaccine-Plan-MA@mass.gov  |

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