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| **BULLETIN****What Massachusetts COVID-19 Vaccine Providers Need to Know****Special Notice - 4/18/2023** |

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| **Monovalent Moderna and Pfizer COVID-19 vaccines are no longer authorized for use in the United States**Today, the U.S. Food and Drug Administration [amended the emergency use authorizations](https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-changes-simplify-use-bivalent-mrna-covid-19-vaccines) (EUAs) of the Moderna and Pfizer COVID-19 bivalent mRNA vaccines. **The monovalent Moderna and Pfizer-BioNTech COVID-19 vaccines are no longer authorized for use in the United States.** Administration of monovalent Moderna and Pfizer-BioNTech COVID-19 vaccines must stop immediately.Monovalent COVID-19 vaccine is no longer available for ordering in the MIIS. All outstanding orders in the MIIS have been canceled. Further instructions on processing wastage will be forthcoming.**ACIP is meeting tomorrow, April 19**. We expect significant more detail and clinical guidance following that meeting. We will follow up with a more detailed Provider Bulletin as quickly as we can.What we know at present:* Following the FDA’s actions, as clinicians we wait for approval from the CDC Director to inform the clinical guidance and our clinical actions.
* The FDA action is meant to simplify the vaccination schedule for most individuals.

Pending recommendation by ACIP and approval by the CDC, today’s FDA authorization includes:* **Most individuals, depending on age, previously vaccinated with a monovalent COVID-19 vaccine** who have not yet received a dose of a bivalent vaccine may receive a single dose of a bivalent vaccine.
* **Most individuals who have already received a single dose of the bivalent vaccine** are not currently eligible for another dose. The FDA intends to make decisions about future vaccination after receiving recommendations on the fall strain composition at an FDA advisory committee in June.
* **Individuals 65 years of age and older who have received a single dose of a bivalent vaccine** may receive one additional dose at least four months following their initial bivalent dose.
* **Most individuals with certain kinds of immunocompromise who have received a bivalent COVID-19 vaccine** may receive a single additional dose of a bivalent COVID-19 vaccine at least 2 months following a dose of a bivalent COVID-19 vaccine, and additional doses may be administered at the discretion of, and at intervals determined by, their healthcare provider. However, for immunocompromised individuals 6 months through 4 years of age, eligibility for additional doses will depend on the vaccine previously received.
* **Most unvaccinated individuals** may receive a single dose of a bivalent vaccine, rather than multiple doses of the original monovalent mRNA vaccines.
* **Children 6 months through 5 years of age who are unvaccinated** may receive a two-dose series of the Moderna bivalent vaccine (6 months through 5 years of age) OR a three-dose series of the Pfizer-BioNTech bivalent vaccine (6 months through 4 years of age). Children who are 5 years of age may receive two doses of the Moderna bivalent vaccine or a single dose of the Pfizer-BioNTech bivalent vaccine.
* **Children 6 months through 5 years of age who have received one, two or three doses of a monovalent COVID-19 vaccine** may receive a bivalent vaccine, but the number of doses that they receive will depend on the vaccine and their vaccination history.
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