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Memorandum

TO: Long-Term Care Facilities
Pharmacies that Service Long-Term Care Facilities

FROM: Elizabeth Kelley, MBA, MPH, Director, Bureau of Health Care Safety and Quality
David Sencabaugh, R.Ph., Executive Director, Board of Registration in Pharmacy

SUBJECT: COVID-19 Booster Dose Vaccination Guidance

DATE: November 09, 2021

The Massachusetts Department of Public Health (DPH) continues to work with state, federal and local partners on the Coronavirus Disease 2019 (COVID-19) pandemic, and we continue to appreciate the essential role you have in responding to this evolving situation.

Vaccinating long-term care facility residents, staff, and visitors against COVID-19 is a crucial step in preventing the spread of COVID-19. The purpose of this memorandum is to outline the roles of long-term care facilities and pharmacies in preparing for and administering COVID-19 booster doses. A “booster dose” refers to a subsequent dose of a vaccine that is given to someone who has built enough protection after full vaccination, but then that protection decreases over time (this is called waning immunity). At this time, booster doses are available to those who have previously received a complete series of Pfizer-BioNTech or Moderna vaccine and it has been at least 6 months since the second dose; or received the single dose Johnson and Johnson/Janssen vaccine and it has been at least 2 months since the dose.

DPH is working with licensed pharmacies that service long-term care facilities to distribute COVID-19 vaccine booster doses. The Centers for Disease Control and Prevention’s (CDC) has recommended a single Pfizer-BioNTech COVID-19 or a single Moderna COVID-19 vaccine booster to be administered at least 6 months after the primary series under FDA Emergency Use Authorization for several populations, including:

- persons age 65+ and long-term care facility residents
- individuals 18-64 years of age who are at increased risk for COVID-19 because of occupational or institutional settings

On October 22, 2021, the CDC also recommended an additional single Johnson and Johnson/Janssen vaccine booster dose to be administered at least 2 months after the initial dose for all individuals aged 18 years or older.

For booster doses, the use of the same vaccine as the primary series or of a heterologous vaccine (a COVID-19 vaccine booster that is different from the primary series) is authorized. There is evidence to support the use of either mRNA vaccine (Moderna or Pfizer) in boosting any primary vaccine series. Long-term care facilities should also note that the Moderna booster dose, regardless of what primary series vaccine was administered, is 50 micrograms or one-half of the Moderna primary series dose.

Based on the CDC recommendations, long-term care facilities should work to ensure that all eligible residents and staff receive a COVID-19 vaccine booster dose no later than November 30, 2021. DPH will follow up with any facilities that do not meet this important deadline.

Pharmacies have indicated that they have the capacity to store and allocate COVID-19 vaccine booster doses and will be distributing them to their long-term care facility clients. Some long-term care facilities have reported that they need support to administer booster doses to their staff and residents onsite; DPH has identified resources to help vaccinate either through long-term care pharmacy partners, mobile vaccine providers or the Rapid Response Team (RRT).

Long-term Care Facilities Choosing Self-Vaccination of COVID-19 Booster Doses:

Long-term care facilities may elect to vaccinate their staff and residents. Prior to administering the vaccines, long-term care facilities that are storing any COVID-19 vaccine onsite should review and complete the Vaccine Management Standard Operating Procedure found here: <https://www.mass.gov/doc/covid-19-vaccine-management-standard-operating-procedure-sop-template/download>

Long-term care facilities that choose to act as the vaccinator for their residents and staff should complete booster dose administration to all eligible individuals no later than November 30, 2021.

Planning for Vaccination of COVID-19 Booster Doses:

To prepare and plan for vaccination of COVID-19 booster doses for residents and staff, all long-term care facilities should:

- Communicate to their pharmacy partner how many eligible residents and staff they estimate will be receiving booster doses.
- Ensure that the medical director or another licensed independent provider has signed Pfizer, Moderna, or Johnson and Johnson/Janssen COVID-19 vaccination and Emergency Management Standing Orders and have them readily available.
- Have copies of the Vaccine Information Statement (VIS) or Emergency Use Authorization (EUA) Fact Sheet for Recipients and screening forms for each individual being vaccinated.

- The current screening form may be found here (Note only page 1 is needed): <https://www.cdc.gov/vaccines/covid-19/downloads/pre-vaccination-screening-form.pdf>
- An updated VIS or EUA Fact Sheet for Recipients will be available once ACIP provides their recommendations. The latest versions can be found here: <https://www.cdc.gov/vaccines/covid-19/eua/index.html>
- Print Vaccine Administration Record to track vaccines given to each individual being vaccinated. An example may be found here: <https://www.mass.gov/doc/immunization-clinic-vaccine-administration-record/download>
- Confirm PPE is available for any vaccinators, including pharmacy staff or RRT coming onsite (eye protection and facemask)
- Ensure that the following supplies are available:
 - Sharp containers
 - Writing utensil
 - Gloves
 - Bandages
 - Chux
 - Alcohol Based Hand Rub (ABHR)
 - Sani-wipes or other surface cleaning supply
 - Emergency- kit (Epi-pens and Benadryl)
 - Blood pressure cuff and stethoscope
 - Trash receptacle
- Verify each individual's first doses of Pfizer-BioNTech, Moderna, or Johnson and Johnson/Janssen vaccines are documented in MIIS.
- For each individual who received both doses of Pfizer-BioNTech or Moderna vaccine, ensure that the last dose has been administered at least 6 months prior to administering the booster.
- For each individual who received the single dose of Johnson and Johnson/Janssen, ensure that it has been administered at least 2 months prior to administering the booster.

Immediately prior to Booster Vaccination or the Day Before the Booster Vaccine Clinic:

- Ensure the individual's CDC screening form is completed (one per individual being vaccinated) and vaccination card or MA Immunization Information System (MIIS) vaccination status is readily available.
- Set up a location for the vaccinator (either the long-term care facility, pharmacy, or RRT staff) to prepare and administer the COVID-19 booster dose. Residents may be vaccinated in their rooms if they can be directly observed for 15-30 minutes afterwards.
- Create a space for staff to be vaccinated. Mark socially distanced areas for vaccine recipients to remain for the observation period following vaccination.

At the time of Booster Vaccination or Day of Vaccine Clinic:

- Ensure vaccination cards/MIIS verification are in place for everyone who will be receiving a booster dose.

- Ensure that the CDC screening form is completed prior to receiving the booster dose.
- Provide a space for the vaccinator to reconstitute, prepare, and administer the vaccines. A quick reference guide is available here: <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/prep-and-admin-summary.pdf>
- Provide the vaccinator with a rolling cart (if they are going to administer the vaccine on different units) or a table (if vaccine will be administered in a central location) with the following supplies:
 - Sharp containers
 - Writing utensil
 - Gloves
 - Bandages
 - Blue chux
 - Alcohol Based Hand Rub (ABHR)
 - Sani-wipes or other surface cleaning supply
 - Emergency- kit (Epi-pens and Benadryl)
 - Blood pressure cuff and stethoscope
 - Trash receptacle
- Once the vaccine is administered, there must be a 15 or 30-minute observation time to ensure there are no adverse events. The long-term care facility, pharmacy, or RRT should determine who is responsible for observing the vaccine recipients.
- If vaccine is being administered in a central location, ensure social distancing can be maintained during the observation period.
- The vaccinator will complete the vaccination card for the recipient and fill out the Clinic Vaccination Administration Record (VAR) with the booster dose information (lot information, expiration date, etc.). The facility will be asked to make a copy of the VAR for their records.

Report vaccine side effects to FDA/CDC Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or online reporting is available at the following page: <https://vaers.hhs.gov/reportevent.html>

If adverse reaction occurs, the long-term care facility is responsible for reporting to VAERS:

- Information you need to complete a VAERS form:
 - Patient information (age, DOB, sex)
 - Vaccine information (manufacturer, dosage, lot number, expiration date)
 - Date, time, and location administered
 - Date and time when adverse event(s) started
 - Symptoms and outcome
 - Provider's contact information

After Vaccine Administration

Input vaccination data in the MIIS database within 24 hours of administration. Facilities may choose to upload the spreadsheet found in Appendix A if they have vaccinated multiple individuals. Instructions for how to upload a clinic roster may be found here:

https://resources.miisresourcecenter.com/trainingcenter/Clinic%20Rosters_Mini%20Guide.pdf

Please review the step-by-step guidance found in the above link regarding how to input residents' information.

Pharmacies and long-term care facilities that will be vaccinating should review the Weekly COVID-19 Vaccine Provider Bulletin and comply with its contents. The most recent bulletin may be found at: <https://www.mass.gov/info-details/massachusetts-covid-19-vaccine-program-mcyp-guidance-for-vaccine-providers-and-organizations#weekly-provider-bulletins>

Nursing homes must use the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) to report cumulative weekly COVID-19 vaccination for residents and personnel, including booster doses, through the Long-Term Care Facility Component. Rest homes must use DPH's Health Care Facility Reporting System (HCFRS) to report cumulative monthly COVID-19 vaccination, including booster doses, for residents and personnel through the COVID-19 Vaccination Module.

Please visit DPH and CDC's websites that provide up-to-date information on COVID-19 and vaccine efforts in Massachusetts: <https://www.mass.gov/2019coronavirus> and <https://www.mass.gov/vaccine> <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Interchangeability>:

Booster Dose Table

Vaccine manufacturer	Booster dose	Booster volume
Pfizer-BioNTech	30 mcg	0.3 ml
Moderna	50 mcg	0.25 ml
Janssen/Johnson & Johnson	5×10^{10} viral particles	0.5 ml

Pfizer-BioNTech: 30 micrograms (mcg) in a volume of 0.3 ml (same as the primary series and additional doses)

NOTE: The Moderna booster dose of 50 mcg (0.25 ml) is half the amount used for the primary series.

Janssen: 5×10^{10} viral particles in a volume of 0.5ml (same as the primary series doses).