State of New Jersey
DEPARTMENT OF HEALTH
PO BOX 360
TRENTON, N.J. 08625-0360
www.nj.gov/health

PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

JUDITH M. PERSICHILLI, RN, BSN, MA
Commissioner

January 4, 2022

TO: Points of Dispensing participating in the COVID-19 Vaccination Program

FROM: Judith M. Persichilli, R.N., B.S.N., M.A. Commissioner

SUBJECT: Modification of Pfizer COVID-19 Vaccine Booster Dose Interval to Five Months for Persons Aged 16 and Older. Expansion of Third Dose to Immunocompromised Persons Aged 5 and Older

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Effective January 4, 2022, Pfizer-BioNTech recipients aged 16 and older may receive a booster at least five months after primary series. Additionally, moderately or severely immunocompromised persons aged five years and older are recommended to receive an additional primary dose of vaccine 28 days after their second mRNA vaccine dose. At this time, only the Pfizer-BioNTech COVID-19 vaccine is authorized and recommended for children aged 5 through 17.

Moderna recipients continue to be eligible to receive a booster at least six months after primary series. Janssen recipients continue to be eligible to receive a booster at least two months after primary dose.

On Tuesday, January 4, the Centers for Disease Control and Prevention (CDC) updated its recommendation for when many people can receive a booster shot, shortening the interval from 6 months to 5 months for people who received a primary series using the Pfizer-BioNTech COVID-19 vaccine.

Everyone aged 18 years and older who completed their initial vaccination series with Moderna at least six months ago continues to be recommended to receive a booster dose. Everyone aged 18 years and older who received a Johnson & Johnson/Janssen vaccine continues to be recommended to receive a booster at least two months after their primary dose.

While adolescents aged 16 through 17 years old may only receive a Pfizer-BioNTech booter, adults aged 18 and older may receive any of the FDA-authorized or approved COVID-19 vaccines (Pfizer-BioNTech, Moderna, and Johnson & Johnson/Janssen) as a booster.

This memo serves to alert you to the amended use of the Pfizer, Moderna, and Johnson & Johnson COVID-19 vaccines in New Jersey. Please share this information with appropriate staff in your program. Thank you for your partnership in this initiative. This memo supplements the other materials circulated by the New Jersey Department of Health (NJDOH) regarding the provision, delivery, and administration of COVID-19 vaccines. https://www.state.nj.us/health/cd/topics/covid2019_vaccination.shtml. Points of

Dispensing may contact the New Jersey Department of Health Vaccine Operations Center at Vax.Operations@doh.nj.gov with any further questions.

Eligible population

Effective immediately, all adolescents and adults aged 16 years and older are eligible and recommended to receive a booster dose:

- All adolescents and adults (aged 16 and older) who received a primary series with Pfizer-BioNTech COVID-19 vaccine at least five months ago.
- All adults (aged 18 and older) who received a primary series with Moderna COVID-19 vaccine at least six months ago.
- All adults (aged 18 and older) who received one Johnson & Johnson/Janssen vaccine at least two months ago.

Meanwhile, the following remain eligible for the primary vaccine series:

- All persons aged five through 11 years are eligible for the Pfizer-BioNTech pediatric formulation COVID-19 two-dose series.
- All persons aged 12 through 17 years are eligible for the Pfizer-BioNTech adolescent/adult formulation COVID-19 two-dose series.
- All persons aged 18 and older are eligible for the Pfizer-BioNTech and Moderna two-dose series, and for the Johnson & Johnson/Janssen one-dose vaccine.
- Persons aged five and older who are moderately to severely immune compromised are eligible for an additional (third) dose of the Pfizer-BioNTech or Moderna vaccines 28 days after their second dose. Minors (aged five through 17) may only receive the Pfizer-BioNTech vaccine.

Also, pursuant to CDC's Emergency Use Instructions (EUI), the Pfizer-BioNTech vaccine may be used as an additional (third) dose in certain immunocompromised persons aged 12 years and older and as a booster dose in certain adults aged 18 years and older after completion of primary vaccination with certain non-FDA authorized or approved COVID-19 vaccines administered outside of the United States.

All points of dispensing are advised to make booster doses available to those who self identify as eligible under the above criterion. Providers must accept self-reported eligibility from the vaccine recipient as sufficient and are not permitted to require individuals to present documentation or a note from a medical provider to demonstrate eligibility. To establish the interval, if a person does not present with a vaccination record or the Docket app, providers can query the New Jersey Immunization Information System (NJIIS).

Vaccine types

For adolescents aged 16 through 17, the only booster dose authorized at this time is the Pfizer-BioNTech vaccine. For adults aged 18 and older, federal authorizations and recommendations allow for mix and match (heterologous) dosing for booster shots. To offer choice at point of dispensing and while maintaining proper vaccine stewardship, sites are encouraged to carry as many types of COVID-19 vaccines as capable.

Eligible adults may choose which vaccine they receive as a booster dose. Some people may have a preference for the vaccine type that they originally received and others may prefer to get a different

booster. However, the mRNA vaccines (Pfizer-BioNTech and Moderna) are recommended over the Johnson & Johnson/Janssen vaccine. Vaccine recipients may make this individual self-assessment through their consideration of their own risks, may weigh information in the EUA Fact Sheets for Recipients and Caregivers, may consult a healthcare provider, or may seek out other sources of guidance. Points of dispensing must not add barriers to access for anyone who presents at a vaccination site and self-identifies as eligible.

PODs may use the currently available Pfizer-BioNTech and Moderna vaccines for primary, second, and third dose recipients. Currently available Johnson & Johnson/Janssen vaccine may be used for primary and second dose recipients.

- The booster Pfizer-BioNTech COVID-19 vaccine dose is the same product and dosage as the initial two-dose mRNA COVID-19 primary vaccine series.
- The booster Moderna vaccine dose is the same product and half the dosage as the initial two-dose mRNA COVID-19 primary vaccine series.
- The booster Johnson & Johnson/Janssen is the same product and dosage as the initial COVID-19 primary vaccine.

Administration timeline

If the individual received a Pfizer-BioNTech primary series, a booster may be admistered at least five months after the primary series. If the individual received a Moderna primary series, a booster may be admistered at least six months after the primary series. If the individual received a Johnson & Johnson/Janssen primary series, a booster may be administered at least two months after the first dose. If the individual is an immunocompromised mRNA vaccine recipient, an additional dose may be administered 28 days after the second dose.

Note: "Fully vaccinated" remains defined as at least two weeks after their second dose in a two-dose series, such as the Pfizer-BioNTech or Moderna vaccines, or two weeks after a single-dose vaccine, such as the Johnson & Johnson/Janssen vaccine. This definition applies to all people, including those who receive an additional dose as recommended for moderate to severely immunocompromised people and those who receive a booster dose.

Co-administration

COVID-19 and other vaccines (e.g., influenza vaccines, childhood vaccines) may be administered without regard to timing. This includes administration of COVID-19 and other vaccines on the same day, as well as co-administration within 14 days.

Scheduling

During the initial booster rollout, in addition to appointments, walk-ins should still be accommodated. This is especially important to ensure timely access without barriers for those who are unvaccinated, those newly eligible (e.g. just turned five years old), and those due for their second dose of an initial two-dose mRNA vaccine series.

Update all appointment schedulers to account for updated booster dose eligibility. Points of dispensing must continue to be listed on the New Jersey COVID-19 Information Hub and your POD must update NJDOH in a timely manner if any information on the state website is incomplete or out-of-date.

PODs must use recall and reminder methods to message eligibility for boosters to your Pfizer-BioNTech and Moderna vaccine recipients who received their second dose at least six months ago. PODs also must use recall and reminder methods to message eligibility for boosters to your Johnson & Johnson/Janssen vaccine recipients who received their first dose at least two months ago.

Site Readiness

To accommodate as many eligible vaccine recipients as soon as possible, all active sites should prepare to have additional vaccines on hand at all vaccine events, provide night and weekend hours, accommodate walk-ins, update appointment availability reflected on the New Jersey Vaccine Appointment Finder (https://covid19.nj.gov/finder), and share information with NJDOH about pop-up vaccination clinics to be included in the COVID-19 Community Calendar (https://covid19.nj.gov/pages/communitycalendar). Sites are also encouraged to actively promote the availability of booster doses. If additional vaccine supply is needed at a site, please be in touch with New Jersey Department of Health to arrange for allocation and/or transfer.

To the extent possible while maintaining approproriate vaccine stewardship, all points of dispensing are expected to optimize use of all COVID-19 vaccines. No vaccination opportunity should be missed, so sites should request and carry sufficient inventory to vaccinate at capacity.

Reporting

The New Jersey Immunization Information System (NJIIS) has been upgraded to accept booster doses in vaccine recipients' records.

All doses of COVID-19 vaccine administered in New Jersey must be reported to NJIIS. Doses reported to NJIIS will then be available for display in the vaccine recipient's Docket app upon application refresh.

Federal recommendation

On Monday, January 3, the FDA issued revised EUAs with updated fact sheets for the Pfizer-BioNTech booster vaccines:

- FDA statement: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-multiple-actions-expand-use-pfizer-biontech-covid-19-vaccine
- For Pfizer-BioNTech vaccine:
    - Updated EUA: https://www.fda.gov/media/150386/download
    - Updated EUA Fact Sheet for Healthcare Providers:
    - https://www.fda.gov/media/153713/download
    - Updated EUA Fact Sheet for Recipients and Caregivers: https://www.fda.gov/media/153716/download
    - Translations of the Fact Sheet for Recipients and Caregivers: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine

On Tuesday, January 4, the CDC adopted recommendations for the booster dose:

- CDC statement: https://www.cdc.gov/media/releases/2022/s0104-Pfizer-Booster.html

Current revised EUAs with updated fact sheets for the Moderna and Janssen booster vaccines:

- For Moderna vaccine:

    - Updated EUA: https://www.fda.gov/media/144636/download
    - Updated EUA Fact Sheet for Healthcare Providers: https://www.fda.gov/media/144637/download
    - Updated EUA Fact Sheet for Recipients and Caregivers: https://www.fda.gov/media/144638/download
    - Translations of the Fact Sheet for Recipients and Caregivers: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine
- For Johnson & Johnson/Janssen vaccine:
    - Updated EUA: https://www.fda.gov/media/146303/download
    - Updated EUA Fact Sheet for Healthcare Providers: https://www.fda.gov/media/146304/download
    - Updated EUA Fact Sheet for Recipients and Caregivers: https://www.fda.gov/media/146305/download
    - Translations of the Fact Sheet for Recipients and Caregivers: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine

On Wednesday, November 17, the CDC issued Emergency Use Instructions (EUI) for certain people who completed a vaccine primary series with certain COVID-19 vaccines that are not authorized or approved by the U.S. Food and Drug Administration. Current fact sheets:

- EUI Fact Sheet for Healthcare Providers: https://www.cdc.gov/vaccines/covid-19/eui/downloads/EUI-HCP.pdf
- EUI Fact Sheet for Recipients and Caregivers: https://www.cdc.gov/vaccines/covid-19/eui/downloads/EUI-Caregiver.pdf

Additional guidance

- Interim Clincal Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html
- World Health Orgainization Emergency Use List: https://extranet.who.int/pqweb/vaccines/vaccinescovid-19-vaccine-eul-issued

Provider education

Please ensure vaccination providers are trained and well versed in the updated vaccine information, provider fact sheet, and clinical considerations. We expect providers to be prepared to address questions from their patients and their families about the recommended booster dose. Information about COVID-19 vaccines and training materials is available through the CDC website at https://www.cdc.gov/vaccines/covid-19/index.html. Please see CDC's 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

Consumer education

Points of dispensing play a critical role in building trust in vaccination. Please note CDC's dedicated webpage with information on the COVID-19 Vaccine Booster Shot: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html

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