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то:	Points of Dispensing participating in the COVID-19 Vaccination Program
FROM:	Judith M. Persichilli, R.N., B.S.N., M.A. Commissioner
SUBJECT:	Provision of Pfizer mRNA Vaccine Booster Dose for Certain Individuals

Effective Friday, September 24, Points of Dispensing (PODs) can begin administration of a booster dose of the Pfizer-BioNTech COVID-19 vaccine to certain persons as defined by the Centers for Disease Control and Prevention (CDC) who completed their initial Pfizer vaccination series at least six months ago.

On Wednesday, September 22, the Food and Drug Administration (FDA) issued a revised Emergency Use Authorization (EUA). On Thursday, September 23, the CDC's Advisory Committee on Immunization Practices' (ACIP) offered recommendations for certain populations to be eligible to receive a booster dose of the Pfizer-BioNTech COVID-19 Vaccine. On Friday, September 24, the CDC offered final recommendations endorsing boosters for selected populations.

This memo serves to alert you to the amended use of the Pfizer in New Jersey's COVID-19 vaccination effort. **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. <u>https://www.state.nj.us/health/cd/topics/covid2019\_vaccination.shtml</u>. Points of Dispensing may contact the New Jersey Department of Health Vaccine Operations Center at <u>Vax.Operations@doh.nj.gov</u> with any further questions.

# Eligible population

Effective immediately, the following populations are eligible to receive a booster dose of Pfizer-BioNTech's COVID-19 vaccine at least six months after their Pfizer-BioNTech primary series:

- People aged 65 years or older,
- Residents of long-term care settings,
- People aged 18 through 64 years with <u>underlying medical conditions</u>, and
- People aged 18 through 64 years who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting.

Please review the EUA Fact Sheet for Healthcare Providers: <u>https://www.fda.gov/media/144413/download</u>. All points of dispensing are advised to make the Pfizer booster 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.

Six months after primary series means a person who received their second Pfizer dose at least six months ago. For example, on September 24, 2021, this would mean anyone who completed their initial two-dose Pfizer series on March 24, 2021 or earlier. To establish the six month timing, if a person does not present with a vaccination record or the Docket app, providers can query the New Jersey Immunization Information System (NJIIS).

Underlying medical conditions included in this booster authorization are found at this CDC website: <u>https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-</u>

<u>conditions.html</u>. Note: The list below does not include all potential medical conditions that could make an individual more likely to get severely ill from COVID-19. Rare medical conditions may not be included below. However, a person with a condition that is not listed may still be in more danger from COVID-19 than persons of similar age who do not have the condition and should talk with their healthcare provider.

As of September 24, 2021, this list includes:

- Cancer
- Chronic kidney disease
- Chronic lung diseases, including COPD (chronic obstructive pulmonary disease), asthma (moderate-to-severe), interstitial lung disease, cystic fibrosis, and pulmonary hypertension
- Dementia or other neurological conditions
- Diabetes (type 1 or type 2)
- Down syndrome
- Heart conditions (such as heart failure, coronary artery disease, cardiomyopathies or hypertension)
- HIV infection
- Immunocompromised state (weakened immune system)
- Liver disease
- Overweight and obesity
- Pregnancy
- Sickle cell disease or thalassemia
- Smoking, current or former
- Solid organ or blood stem cell transplant
- Stroke or cerebrovascular disease, which affects blood flow to the brain
- Substance use disorders (such as alcohol, opioid, and cocaine use disorders)

The Centers for Disease Control and Prevention has recommended that those 18 through 49 with underlying medical conditions and those eligible due to their occupational/institutional risk of exposure and transmission should consider their individual risks and benefits when deciding whether or not to seek a COVID-19 booster dose. Vaccine recipients may make this individual self-assessment through their

consideration of their own medical, occupational, or institutional risks; may weigh information in the EUA Fact Sheet for Recipients and Caregivers: <a href="https://www.fda.gov/media/144414/download">https://www.fda.gov/media/144414/download</a>; 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.

Nonexhaustive examples of occupational and institutional settings with potential increased risk for COVID-19 exposure and transmission include those identified during New Jersey's Phased Rollout of COVID-19 Vaccination where Phase 1A, 1B, and 1C groups were identified due to COVID-19 risks at that time.

Additional populations may be recommended to receive a booster shot as more data becomes available. At this time, federal agencies have not yet issued a booster recommendation for other populations nor for people who completed a primary series with the Moderna or Johnson & Johnson COVID-19 vaccines.

Meanwhile, the following remain eligible:

- All persons ages 12 through 17 are eligible for the Pfizer-BioNTech COVID-19 two-dose series.
- All persons 18 and older are eligible for the Pfizer-BioNTech and Moderna two-dose series, and for the Johnson & Johnson one-dose vaccine.
- Persons who are moderately to severely immune compromised are eligible for an additional dose of the Pfizer-BioNTech or Moderna vaccines.

### Vaccine types

The booster Pfizer-BioNTech COVID-19 vaccine dose is the same product and dosage as the initial twodose mRNA COVID-19 primary vaccine series. PODs may use the currently available Pfizer-BioNTech vaccine for primary, second, and third dose recipients.

### Administration timeline

The booster dose of the Pfizer-BioNTech COVID-19 vaccine should be administered no sooner than six months following the second dose of the Pfizer vaccine.

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

ACIP now recommends that 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 12 years old), and those due for their second dose of an initial two-dose mRNA vaccine series. All appointment schedulers should be updated to account for booster dose needs and intervals. Points of dispensing must continue to be listed on the <u>New Jersey COVID-19 Information</u> <u>Hub</u> and your POD must update NJDOH in a timely manner if any information on the state website is incomplete or out-of-date.

The New Jersey Vaccine Scheduling System (NJVSS) is still undergoing upgrades to accommodate booster scheduling and this is expected to be completed in the next week. Until the upgrade is completed, NJVSS providers should:

- Accommodate booster vaccine recipients as walk-ins through NJVSS functionality that will automatically report to NJIIS, and
- Document booster dose recipients in an ancillary system and ensure reporting to NJIIS via either (a) manual Excel upload to NJIIS or (b) direct entry by provider into NJIIS.

PODs must use recall and reminder methods to message eligibility for boosters to your Pfizer vaccine recipients who received their second dose at least six months ago.

# Site Readiness

To accommodate as many eligible vaccine recipients as soon as possible, all Pfizer-BioNTech-capable active sites should prepare to have additional Pfizer-BioNTech 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 (<u>https://covid19.nj.gov/finder</u>), and share information with NJDOH about pop-up vaccination clinics to be included in the COVID-19 Community Calendar (<u>https://covid19.nj.gov/pages/communitycalendar</u>). 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 NJ must be reported to NJIIS. Doses reported to NJIIS will then be available for display in the vaccine recipient's Docket app upon app refresh.

# Federal recommendation

On Wednesday, September 22, the FDA issued revised EUA for the Pfizer BioNTech vaccine with updated fact sheets.

- FDA statement: <u>https://www.fda.gov/news-events/press-announcements/fda-authorizes-booster-dose-pfizer-biontech-covid-19-vaccine-certain-populations</u>
- For Pfizer-BioNTech vaccine:
  - Updated EUA: <u>https://www.fda.gov/media/150386/download</u>
  - Updated EUA Fact Sheet for Healthcare Providers: https://www.fda.gov/media/144413/download
  - Updated EUA Fact Sheet for Recipients and Caregivers: <u>https://www.fda.gov/media/144414/download</u>

 Translations of the Fact Sheet for Recipients and Caregivers: <u>https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-</u>2019-covid-19/pfizer-biontech-covid-19-vaccine

On Friday, September 24, the CDC adopted recommendations for the booster dose.

CDC statement: <u>https://www.cdc.gov/media/releases/2021/p0924-booster-recommendations-.html</u>

## 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 P https://www.cdc.gov/vaccines/covid-19/index.html. Please see CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized United States: in the 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: <u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html</u>

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