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Guidance for Administration of the Second Dose of COVID-19 Vaccine January 11, 2021

Background:

There are currently two COVID-19 vaccines authorized for emergency use in the United States: BNT-162b2, produced by Pfizer-BioNTech; and mRNA-1273, produced by Moderna. Each of these vaccines have been granted Emergency Use Authorization by the FDA based on a two-dose series. Recipients of the Pfizer-BioNTech vaccine are to receive the doses 21 days apart, and recipients of the Moderna vaccine are to receive the doses 28 days apart.

Receipt of the second dose of COVID-19 vaccine is necessary and critical to ensuring optimal protection against COVID-19, based on the high degree of effectiveness demonstrated in phase 3 clinical trials of each of the vaccines currently authorized for emergency use.

Plan immediately for the second COVID-19 vaccine dose:

The second dose must be administered 21 days (Pfizer vaccine) or 28 days (Moderna vaccine) after the first dose. To facilitate this, all providers **must** schedule the second dose appointment for recipients **at the time the first dose is administered**. Those who receive the first vaccine must return to the same location to receive the second dose. It is important to send frequent reminders about when and where to receive the second dose. Individuals must receive two doses of the same vaccine (e.g., you must receive two doses of the Pfizer vaccine or two doses of the Moderna vaccine). They are **not** interchangeable.

Planning for a second dose, including making an appointment for the second dose, will need to occur for all facility staff and those coming from outside the facility. However, please note the initial allocation is for the first dose of the vaccine. **Do not reserve first dose vaccine for the second dose.** A second dose allocation will be shipped to your facility in time for administration of the second dose at the required interval. **The second shipment must be reserved for second doses.** Facilities will be notified of the timing and quantity of the second dose shipment so that it can be separated from first doses in your inventory.

Provider Responsibilities:

Providers must report to NYSIIS/CIR every time a dose is administered. <u>Executive Order 202.89</u> and the CDC COVID-19 Vaccination Program Provider Agreement require providers to submit all COVID-19 vaccination information fields within 24 hours of vaccine administration, for both the first and second dose of vaccine.

Entities that administered the first dose of COVID-19 vaccine are responsible for administering the second dose to all vaccine recipients.

Managing vaccine inventory:

It is the responsibility of the administering facility to track and manage inventory for first and second dose administration.

Vaccine designated for the second dose will automatically be allocated and delivered to each site.

Shipments of COVID-19 vaccine are not differentiated into first doses and second doses. NYSDOH will inform providers when an order has been placed for second doses, but the shipment will not be labeled as such. If a provider is receiving a new allocation of first doses combined with second doses for patients previously vaccinated, such doses may all come in one shipment, depending on when the orders were placed.

Providers should consider separating first and second dose inventory, to ensure that first dose from second dose supplies are not inadvertently mixed.

Additional considerations when planning second dose management:

- Facilities administering vaccine may want to consider specific days or clinic hours for second dose administration.
- Second dose appointments must be made at the time the first dose is administered, for a day either 21 days later (Pfizer-BioNTech vaccine) or 28 days later (Moderna vaccine).
- NYSDOH will be sending second dose reminders to all individuals, Providers should send frequent reminders about specific appointment information for the second dose.

Other information about second doses of the Pfizer-BioNTech and Moderna COVID-19 vaccines:

- There is a grace period for receiving the second dose that allows individuals to receive the
 vaccine if it is inadvertently given up to four days before the second dose administration date
 recommended by the FDA.
 - However, it is preferable to plan to administer the second dose as close to the recommended date as possible.
- The second dose may be administered after the 21- or 28-day window for the Pfizer-BioNTech
 or Moderna vaccine, respectively. Although it is optimal to receive the second dose as close as
 possible to the correct day, second doses should be administered even if an individual presents
 to receive their second dose after that time period. The vaccine series does not need to be
 restarted even if the second dose is administered late.
- COVID-19 vaccine products are NOT interchangeable. Persons who received the first dose with one COVID-19 vaccine product must receive the second dose with the same vaccine product. However, if a different vaccine is inadvertently given, the second dose does not need to be repeated.

Pfizer-BioNTech COVID-19 Vaccine:

- The second dose of the Pfizer-BioNTech vaccine is due to be administered 21 days after the first dose was administered.
- There is a 4-day grace period, so that if a dose is inadvertently given on days 17-20 after the first vaccination, that second dose is considered valid.
- A dose given 5 or more days before the due date is not considered valid, and that second dose (but not the first dose) must be repeated.
- Additional ancillary kits ("mega kits") will be sent with orders of the Pfizer-BioNTech vaccine to support using 6th doses. The "mega kit" contains supplies for 1,024 doses. Two additional boxes with supplies for 105 doses each will also be shipped, for a total supply to give 1,234 doses.
- Please see the <u>FDA fact sheet for health care providers administering the Pfizer-BioNTech</u> <u>COVID-19 vaccine</u> for more information.

Moderna COVID-19 Vaccine:

- The second dose of the Moderna vaccine is due to be administered 28 days after the first dose was administered.
- There is a 4-day grace period, so that if a dose is inadvertently given on days 24-27 after the first vaccination, that second dose is considered valid.
- A second dose given 5 or more days before the due date is not considered valid, and that second dose (but not the first dose) must be repeated.
- Please see the <u>FDA fact sheet for health care providers administering the Moderna COVID-19</u> vaccine for more information.