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Guidance for The New York State COVID-19 Vaccination Program May 6, 2021

Purpose and Background:

All individuals 16 years of age and older that reside in the United States are eligible to be vaccinated. See Appendix A for guidance regarding necessary consent for individuals under 18 years of age.

Performance, throughput, effort, and effective administration of vaccines by providers continue to be key factors in making future vaccine allocations, along with equity, access, and regional positivity rates.

All vaccine providers in New York State, including those located in the City of New York and those participating in federal programs, must follow New York State Department of Health (NYSDOH) guidance and directives, including the requirement to report to the NYS [COVID-Vaccine Tracker](#) on Mondays and Thursdays.

Eligible individuals:

All individuals age 16 years of age and older that reside in the United States are eligible to be vaccinated.

Vaccine Provider Responsibilities:

- Vaccine can be redistributed to another facility, provider, practice, or department, with prior approval and consent of the NYSDOH. To redistribute vaccine, facilities must submit a [completed redistribution form](#) to COVIDVaccineRedistribution@health.ny.gov and must not redistribute until NYSDOH approval.
 - A provider may transport vaccine to another location for the purpose of holding a limited duration vaccination clinic without prior approval from the NYSDOH. If the provider is administering the doses and reporting doses administered against their own inventory in NYSIIS, all unused vaccine must be transported back to the original location at the conclusion of the clinic that day. The provider must retain possession and control of the vaccine for the duration of the transport and administration.
- Those who are administering the vaccine should be prioritized to receive vaccine as soon as doses are available.
- All providers should keep a daily list of “standby” eligible individuals to be notified of open appointments for vaccine administration on short notice. As soon as providers are aware that there are more doses than people to be vaccinated, “standby” eligible individuals should be called, or other steps must be taken to bring additional eligible recipients to the facility or clinic before the acceptable use period expires. Standby lists must include eligible individuals for first and second doses. (See page 3 for further guidance.)

- Providers should not prefill more syringes than they can use within one hour. Prefilled syringes of Pfizer-BioNTech and Moderna vaccines must be used within six hours of filling; Janssen (Johnson & Johnson) vaccine must be used within two hours of filling. Excess prefilling can lead to waste if a clinic must end early or an excessive number of recipients fail medical screening or do not show up for their appointment. Please see [Guidance on Use of COVID-19 Vaccine Doses Remaining at End of Day or Clinic for Providers Participating in the New York State COVID-19 Vaccination Program](#) for more information.
- All facilities or practices are required to track vaccine uptake among their staff and must furnish uptake data to the NYSDOH via HERDS survey, or as part of the daily NYS COVID Vaccine Tracker.

Each provider that receives vaccine:

- MUST ensure that each individual they vaccinate displays evidence of completed [NYS COVID-19 Vaccine Form](#) and attestation.
- Must make best efforts to use all vaccine doses within seven days of receipt by rapidly deploying it to eligible individuals.
- All vaccine administered must be reported, using the New York State Immunization Information System (NYSIIS) or the Citywide Immunization Registry (CIR) in New York City, within 24 hours of administration.
- Vaccine Administrators **must also report additional information on all those vaccinated every Monday and Thursday** using the [COVID Vaccine Tracker](#).
- With respect to **pharmacies**, pharmacists are authorized to vaccinate individuals age 16 and older for COVID-19 only, pursuant to the Seventh Amendment to Declaration Under the Public Readiness and Emergency Preparedness [PREP] Act for Medical Countermeasures Against COVID-19.

Message for COVID-19 Vaccine Clinical Trial Sites:

As a reminder, all COVID-19 vaccines administered in the State of New York must be entered in to NYSIIS or CIR. This includes any doses administered as part of an experimental arm of a clinical trial as well as doses offered and administered to participants in the control group (originally received placebo) after the clinical trial ended or at other time points per trial protocol. Staff at the participating site of the clinical trial must provide participants with a vaccination card and enter participant's immunization history into NYSIIS/CIR as applicable. Please note that only vaccines that have been issued an Emergency Use Authorization or that have been approved by the United States Food and Drug Administration (FDA) can be entered.

The Second COVID-19 Vaccine Dose:

Pfizer-BioNTech and Moderna vaccines require two doses, whereas Janssen (Johnson & Johnson) vaccine requires only a single dose. The second dose must be administered 21 days (Pfizer-BioNTech 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**.

Circumstances may arise where individuals need to receive their second dose at a different location than their first. Providers who have determined that the individual cannot return to the location where they received their first dose should schedule a second dose for these individuals or coordinate with the Regional Hub Lead Hospital to find a provider who has extra second doses of the appropriate vaccine to vaccinate the individual. Vaccine availability can also be located using the [CDC Vaccine Finder Tool](#). Individuals should not be tasked with locating second dose appointments. This obligation is on the provider who administered the first dose.

Special Considerations for Individuals Receiving Their First Dose Outside New York State:

Individuals who received their first dose of COVID-19 vaccine outside of New York State will not have a record of this dose in NYSIIS or CIR. Providers administering a second dose should either enter the first dose in NYSIIS/CIR as part of the historical record using data listed on the individual's COVID-19 Vaccination Record Card OR advise the patient that they should ask their primary care provider to enter their first dose into NYSIIS/CIR so the state has a full record of both doses of COVID-19 vaccine.

Individuals must receive two doses of the same vaccine (e.g., you must receive two doses of the Pfizer-BioNTech vaccine or two doses of the Moderna vaccine). They are **not** interchangeable. Please see [Guidance for Administration of the Second Dose of COVID-19 Vaccine](#) for additional information regarding administration of the second dose.

Do not reserve first dose vaccine for the second dose. A second dose allocation will be automatically shipped to your facility in time for administration of the second dose at the required interval. **The vaccine included in 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.

New York State has adopted the [Centers for Disease Control's \(CDC's\) Vaccine Inventory Management Guidance](#). This guidance requires providers, on a weekly basis, to review all missed appointments, as well as any other reason for a second dose to be unused after 42 days, and to repurpose any remaining doses as first doses.

Frozen second doses that are not beyond the 42-day window for scheduled administration must NOT be used as first doses. The only second doses that may be administered as first doses are those doses that are approaching their expiration or beyond use date, and providers must follow the process outlined in the Second Dose Guidance.

Any frozen second doses that are currently beyond the 42-day window should immediately be used as first doses. These doses can be administered to any eligible individual in accordance with NYS Vaccine Program Guidance. If an individual requests a second dose after missing the 42-day window, they should still be administered a second dose. There is no need to restart the series, pursuant to CDC guidance. Providers who have insufficient vaccine to administer a second dose that was delayed beyond the 42-day window should work with their Lead Hub Hospital, which maintains a second dose waiting list.

Extra Doses of Pfizer-BioNTech and Moderna:

Vials of both Pfizer-BioNTech and Moderna are expected to contain at least one extra dose of vaccine. Depending on the type of needle and syringes used, additional vaccine may remain in the vial. Vaccine administrators may use any extra vaccine that can be easily drawn up in a syringe to meet the full dose requirements. Extra vaccine fluid from more than one vial **CANNOT** be combined to produce extra doses. This is particularly important because the vaccination does not contain preservatives. Enter all vaccines given into NYSIIS/CIR, including any additional vaccines given, however do not modify inventory in anticipation of extra doses. For additional information please see [Pfizer-BioNTech](#) guidance and [Moderna](#) guidance for extra doses. Extra vaccine has not been observed in the Janssen (Johnson & Johnson) vials beyond the expected five doses.

Remaining COVID-19 Vaccine Doses:

All vaccine providers must plan accordingly to make best efforts to ensure every dose of vaccine is administered.

All providers should attempt to keep a daily list of “stand by” eligible individuals to be notified for vaccine administration on short notice. “Stand by” lists must include individuals eligible for first and second doses. As soon as providers are aware that there are more doses than people to be vaccinated, “stand by” eligible individuals should be called, or other steps should be taken to bring additional eligible recipients to the facility or clinic before the acceptable use period expires. Each provider should contact their regional hub hospital to help facilitate the use of extra doses at the end of the clinic day.

Mandatory Vaccine Form:

All individuals receiving the COVID-19 vaccine **must** complete the [New York State COVID-19 Vaccine Form](#) for the first dose, and attest that they are eligible to be vaccinated. Pursuant to [Executive Order 202.86](#), as extended, all practices, providers, and entities must confirm adherence to this requirement at the time of vaccine administration.

Proof of Eligibility:

Individuals being vaccinated **must** provide proof of age.

Proof of age may include:

- Driver’s license or non-driver ID;
- Birth certificate issued by a state or local government;
- Consulate ID;
- Current U.S passport or valid foreign passport;
- Permanent resident card;
- Certificate of Naturalization or Citizenship;
- Life insurance policy with birthdate; or
- Marriage certificate with birthdate.

The mandatory [New York State COVID-19 Vaccine Form](#) includes demographic questions and a self-attestation and must be completed prior to vaccination. Minors must present identification to verify that they are at least 16 years of age or have a parent present to attest on their behalf.

Vaccine Safety:

Post-vaccination monitoring is an essential part of the COVID-19 vaccination program. The Centers for Disease Control and Prevention (CDC) is promoting and encouraging all those being vaccinated to participate in V-Safe, a smart-phone based application that will allow those vaccinated to enter their symptoms in the days after vaccination using text messaging. V-Safe also provides reminders for the second dose and telephone follow up for anyone who reports medically significant adverse events. V-Safe materials can be found at <http://www.cdc.gov/vsafe>, including a V-Safe information sheet. Please print out the information sheet and hand to each person vaccinated. You must report any adverse events that occur after vaccination to the Vaccine Adverse Events Reporting System (VAERS) at info@VAERS.org or by calling 1-800-822-7967.

Equity:

Effort must be made to do outreach to persons age 16 and older in all communities and settings. Persons in areas that have a high social vulnerability index are particularly vulnerable to COVID-19 and should be notified about how they can receive vaccine.

Communicating the Plan:

Please be sure to clearly communicate prioritization to all staff.

This guidance is in effect from the date of issuance until it is updated, or additional guidance is issued by NYSDOH. For questions, please contact the New York State Department of Health, Bureau of Immunization at COVID19vaccine@health.ny.gov.

New York State Vaccination Program Guidance Appendix A

All individuals age 16 and older that reside in the United States are eligible to be vaccinated. **However, minors ages 16 and 17 are NOT authorized to receive the Janssen or Moderna COVID-19 Vaccines. Children under 16 years of age are not yet authorized to receive ANY COVID-19 vaccine.**

Minor Consent

For the purposes of this document, a minor is defined as an individual under the age of 18. Minors need parental or guardian consent to receive a COVID-19 vaccine, except in the rare instance where the minor is part of a group to whom the law gives the right to consent to their own care (e.g., married minors, minors who are parents or pregnant, and minors in the military).

In general, it is strongly encouraged that a parent or legal guardian accompany a minor age 16 or 17 to provide in-person consent for vaccination at each dose. Vaccine Support/Medical Documentation Staff must document in the CDMS Notes section the name of the person providing consent for the minor. Verbal consent is allowed.

If a minor is unaccompanied, the provider should attempt to contact the parent or guardian by phone at the time of the minor's vaccination to provide consent to the provider. Providers may elect whether to accept a written statement of consent from the parent or guardian, where the parent or guardian is not available by phone to provide consent to vaccinate an unaccompanied minor. The [NYS COVID-19 Immunization Screening and Consent Form](#) may be considered for this purpose.