NEW YORK STATE OF OPPORTUNITY. | Department of Health

ANDREW M. CUOMO
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HOWARD A. ZUCKER, M.D., J.D.
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NYSIIS/CIR Reporting Requirements for the COVID-19 Vaccination Program

NYSIIS or CIR access is required to submit requests for vaccine, manage COVID vaccine inventory, and report doses administered.

As a condition of receiving federally funded vaccine, all providers must report:

"*Within 24 hours of administering a dose of COVID-19 Vaccine and adjuvant (if applicable), Organization must record in the vaccine recipient's record and report required information to the relevant state, local, or territorial public health authority.*

Organization must submit Vaccine-Administration Data through either (1) the immunization information system (IIS) of the state and local or territorial jurisdiction or (2) another system designated by CDC according to CDC documentation and data requirements."

For providers administering vaccine in New York State, submitting data to NYSIIS and CIR satisfies the federal reporting mandate. Providers should continue to submit this data to the NYSIIS and CIR within 24 hours of vaccination.

Please continue to ensure you are entering all patient demographic and vaccine information completely and without errors.

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Guidance for
The New York State COVID-19 Vaccination Program
June 24, 2021

Purpose and Background:

All individuals **12 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 accurately and completely report doses administered to the appropriate immunization information system (NYSIIS or CIR) within 24 hours of vaccine administration per Executive Order 202.82 as extended by 202.89, and must maintain up-to-date inventory in such system.

Accurate and timely reporting to NYSIIS/CIR is critical, as this information can be used to allow individuals to display proof of vaccination, such as the Excelsior Pass.

Eligible individuals:

All individuals age 12 years of age and older that reside in the United States are eligible to be vaccinated.

On May 12, following the New York State Clinical Advisory Task Force's recommendation and CDC's adoption of the Advisory Committee on Immunization Practices' (ACIP) endorsement in response to the U.S. Food and Drug Administration's expansion of the emergency use authorization (EUA) for the Pfizer-BioNTech COVID-19 Vaccine to include adolescents 12 through 15 years of age, Governor Cuomo authorized all providers enrolled in the NYS COVID-19 vaccination program to expand eligibility for the Pfizer COVID-19 vaccine to 12 through 15-year olds, effective immediately.

Minors must present identification to verify that they are at least 12 years of age or have a parent/guardian attest on their behalf. See Appendix A for guidance regarding necessary consent for individuals under 18 years of age.

The mandatory New York State COVID-19 Vaccine Form includes demographic questions and a self-attestation and must be completed by all individuals prior to vaccination.

Updates to Johnson & Johnson COVID-19 Vaccine Expiration Dates:

On June 10, 2021, the FDA authorized an extension of the shelf life for the Johnson & Johnson's Janssen single-shot COVID-19 vaccine (J&J vaccine) from 3 months to 4.5 months (an additional 6 weeks). The decision is based on data from ongoing stability assessment studies, which have demonstrated that the vaccine is stable at 4.5 months when refrigerated at temperatures of 36 to 46 degrees Fahrenheit (2 to 8 degrees Celsius).

Vaccine providers that have J&J vaccine in storage should visit https://vaxcheck.jnj and enter the lot number to confirm the latest expiration dates of vaccine, including those currently available for administration throughout the U.S. This extension applies to refrigerated vials of J&J COVID-19 vaccine that have been held in accordance with the manufacturer's storage conditions.

The vials and carton must be marked with the new date displayed and the date must also be updated in the NYSIIS or CIR inventory module. If providers have vaccine in storage that expired prior to June 10, 2021, those vials should be disposed of as medical waste and reported as wastage in NYSIIS/CIR (see NYSIIS wastage reporting guidance here and NYCIR here).

COVID-19 vaccines that are authorized under an EUA do not have fixed expiration dates, and their expiration dates may be extended as the FDA receives and reviews additional stability data. Vaccine providers should check the manufacturer's website to obtain the most up-to-date expiration dates for COVID-19 vaccines they have on hand.

No Minimum Interval Between COVID-19 Vaccine and Other Vaccines:

On May 14, the CDC updated its "Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States," to recommend that "COVID-19 vaccines and other vaccines **may now be administered without regard to timing**. This includes simultaneous administration of COVID-19 vaccines and other vaccines on the same day, as well as coadministration within 14 days." Although COVID-19 vaccines were previously recommended to be administered a minimum of 14 days before or after other vaccines, that previous recommendation was out of an abundance of caution and not due to any known safety or immunogenicity concerns, and is no longer in effect. When deciding whether to co-administer another vaccine(s) with COVID-19 vaccines, providers should consider whether the patient is behind or at risk of becoming behind on recommended vaccines, their risk of vaccine-preventable disease (e.g., during an outbreak or occupational exposures), and the reactogenicity profile of the vaccines.

Vaccine Provider Responsibilities:[1]

- Vaccine can be redistributed to another facility, provider, practice, or local health department that is enrolled in the COVID-19 vaccination program, with prior notice to the NYSDOH. Prior to redistributing vaccine, facilities must submit a completed completed redistribution form to COVIDVaccineRedistribution@health.ny.gov and can proceed with the redistribution once submitted.
    - 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

[1] Individuals identified under COVID-19 Public Readiness and Emergency Preparedness Act (PREP Act) declarations are authorized to administer COVID-19 vaccinations in accordance with the PREP Act declaration requirements and subject to any additional guidance or training issued or identified by the New York State Department of Health.

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.

- When managing vaccine inventory, vaccines should always follow a first-in, first-out process in which vials that have the earliest expiration date are used first.

- All vaccine providers should minimize the amount of vaccine that goes unused, consistent with CDC guidance, which states that while enrolled providers must continue to follow best practices to use every dose possible, it should not be at the expense of missing an opportunity to vaccinate every eligible person when they are ready to get vaccinated. (See page 4 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 directed by your agency or organization.

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 administering it to eligible individuals.
- All vaccine administered must be accurately and completely reported, using NYSIIS or CIR, within 24 hours of administration, and providers must maintain up-to-date inventory in such system. This is critically important to allow an individual to prove vaccination status.
- With respect to **pharmacies,** pharmacists are authorized to vaccinate individuals 12 years of age and older for COVID-19, pursuant to the Seventh Amendment to Declaration Under the Public Readiness and Emergency Preparedness [PREP] Act for Medical Countermeasures Against COVID–19.

In addition, to ensure all New Yorkers can find vaccination locations close to them, **vaccine providers are strongly encouraged to have their facility/facilities opt-in to the CDC's online VaccineFinder tool (Vaccines.gov).** To do so, providers should set the display field in the COVID-19 Locating Health Portal to "display" if the facility is currently providing vaccinations to the general public. This will allow patients in the local area to see in real-time whether the facility has doses of each brand available, enabling vaccination access for a broader population.

- NYSDOH reports inventory to the CDC every Monday through Friday for each organization. Therefore, organizations do not need to report inventory to VaccineFinder (despite having access).
- Additional information on the VaccineFinder tool can be found here.

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**.

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.

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 local health department.

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 local health department 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's VaccineFinder. 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.

Special Considerations for Individuals Receiving COVID-19 Vaccine Outside the United States:

The CDC guidance for fully vaccinated people states that "this [CDC] guidance can also be applied to COVID-19 vaccines that have been authorized for emergency use by the World Health Organization (WHO) (e.g., AstraZeneca/Oxford)."

For COVID-19 vaccines not authorized by the FDA but listed for emergency use by the WHO:

- People who have received all recommended doses of a COVID-19 vaccine that is listed for emergency use by the WHO **do not need** any additional doses with an FDA-authorized COVID-19 vaccine.
- People who have not received all the recommended doses of a COVID-19 vaccine listed for emergency use by the WHO may be offered a complete FDA-authorized COVID-19 vaccine series.

For COVID-19 vaccines neither authorized by FDA nor listed for emergency use by the WHO:

- People who received all or some of the recommended doses of a COVID-19 vaccine that is neither authorized by FDA nor listed for emergency use by the WHO may be offered a complete FDA-authorized COVID-19 vaccine series.

COVID-19 Vaccines Listed for Emergency Use by the WHO:

As of June 15, 2021, the WHO has listed the following COVID-19 vaccines for emergency use:

- Pfizer-BioNTech COVID-19 vaccines (e.g., COMIRNATY, Tozinameran)*
- Janssen (Johnson & Johnson) COVID-19 vaccine*
- Moderna COVID-19 vaccine*
- AstraZeneca-Oxford COVID-19 vaccines (e.g., Covishield, Vaxzevria)
- Sinopharm COVID-19 vaccine
- Sinovac COVID-19 vaccine

*Also authorized by the FDA for Emergency Use in the United States

Universal Doses:

Effective May 11th, New York State moved to a "Universal Dose" administration process for all multi-dose COVID-19 vaccine types. All doses are now considered universal doses, which means that doses can be used as either a first dose or a second dose, regardless if they were originally shipped to providers as a first dose or a second dose. <u>This does NOT eliminate the obligation of the provider to schedule second dose appointments at the time the first dose is administered.</u>

First and second doses may also be drawn interchangeably from the same vial. With all doses considered a universal dose, please utilize a first in, first out rule to manage inventory. This includes storing newly received vaccine in the freezer until it is needed. **COVID-19 vaccine providers should continue to follow their jurisdiction's (NYC or NYS) vaccine ordering and inventory guidance to request their weekly vaccine allocations.**

Extra Doses of Pfizer-BioNTech and Moderna:

Vials of both Pfizer-BioNTech and Moderna may 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.

Responsible Wastage:

The CDC released guidance on May 11th regarding wastage with the critical message to "take every opportunity to vaccinate every eligible person." As more vaccination opportunities are created, the likelihood of leaving unused doses in a vial may increase. While enrolled providers must continue to follow best practices to use every dose possible, it should not be at the expense of missing an opportunity to vaccinate every eligible person when they are ready to get vaccinated.

To ensure providers do not miss an opportunity to vaccinate every eligible person:

- Providers must follow clinical best practice for vaccination as well as best practices when managing inventory to maximize vaccination and minimize dose wastage.
- Providers should not miss any opportunities to vaccinate every eligible person who presents at a vaccination site.
    - Consider establishing and promoting standing vaccination days or half-days to increase likelihood of larger numbers of people presenting for vaccination on the same day.
    - Vaccinate family members or friends who accompany patients to medical visits even if they are not established patients at the vaccinating practice.
    - Continue outreach to employers or other community partners that have a large membership or network to arrange vaccination events.
    - As contingency plan, vaccine providers should attempt to contact additional persons (i.e., from a standby list or through personal contacts of persons being vaccinated) to use as many vaccine doses as possible.
    - Once punctured, multidose vials must be used within:
        - 12 hours (Moderna)
        - 6 hours (Pfizer)
        - 6 hours (refrigerated) or up to 2 hours at room temperature (J&J/Janssen)

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. All practices, providers, and entities must confirm adherence to this requirement at the time of vaccine administration.

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 and Access:

Effort must be made to do outreach to persons 12 years of age 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. Every effort should be made to increase their access to vaccination opportunities.

Communicating the Plan:

Please be sure to clearly communicate this critical guidance to all staff involved in the vaccination program.

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 12 years of age and older that reside in the United States are eligible to be vaccinated. **However, minors 12 through 17 are NOT authorized to receive the Janssen/Johnson & Johnson or Moderna COVID-19 vaccines. They may ONLY receive Pfizer at this time pursuant to the FDA Emergency Use Authorization (EUA). Children under 12 years of age are not yet authorized to receive ANY COVID-19 vaccine.**

It is important to verify the age of individuals who appear to be a minor to confirm eligibility and ensure the administration of the proper COVID-19 vaccine.

Proof of age should be requested but is not required where the parent or guardian is available to attest to the minor's age. Documentary proof may include (but is not limited to):

- 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
- Parent/Guardian attestation

Minor Consent:

16 and 17-year olds:

For all minors, a parent or legal guardian must provide consent for vaccination. For minors 16 or 17 years of age, such consent should be provided either in person or by phone, at the time of vaccine appointment. 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.

12 through 15-year olds:
For minors who are 12 through 15 years of age, additionally, an adult caregiver should accompany the minor. If the adult caregiver is not the parent/guardian, the adult caregiver should be designated by the parent/guardian. The parent/guardian must still provide consent to the vaccination.