NEW YORK STATE OF OPPORTUNITY. Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

LISA J. PINO, M.A., J.D.
Executive Deputy Commissioner

March 5, 2021

Dear Vaccine Provider,

Please see the attached COVID-19 vaccination program document package, where you will find updated forms, templates, and instructions regarding the Janssen (Johnson & Johnson) vaccine.

You will find the following documents attached:

1. Guidance for the New York State COVID-19 Vaccination Program (Effective 3/5/21)
2. Janssen (Johnson & Johnson) EUA Letter of Authorization (Issued 3/1/21 - Revised)
3. New York State COVID-19 Immunization Screening and Consent Form
4. Information for Health Care Professionals about the Screening Checklist for the COVID-19 Vaccine
5. New York State COVID-19 Vaccine Provider Storage and Handling Overview
6. New York State COVID-19 Vaccine Program Temperature Excursion Report
7. New York State COVID-19 Vaccine Program Guidance for Vaccine Transport and Tracking Sheet
8. New York State COVID-19 Vaccine Program Redistribution and Q&A

Also attached separately: Janssen (Johnson & Johnson) Non-Patient Specific Standing Order Template

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Guidance for
The New York State COVID-19 Vaccination Program

Effective March 5, 2021

Purpose and Background:

Limited amounts of COVID-19 vaccine are available for New York's COVID-19 Vaccination Program. The amount of vaccine the state receives is based upon the allocation made to New York by the federal government. The New York State Department of Health (NYSDOH) then determines state allocations to providers and entities who have enrolled to administer vaccine. Executive Order 202.91, as extended, also sets forth mandatory prioritization for vaccination by provider type.

Hospitals must continue to prioritize unvaccinated healthcare workers. Hospitals were allocated vaccine until the end of Week 9 (February 14, 2021) to vaccinate ALL eligible hospital employees who currently desire vaccination, after which time any allocation to the hospital is open to all populations eligible for vaccination at hospitals, prioritizing all Phase 1A individuals who are not employed at the hospital, and OPWDD congregate care populations, then individuals age 65 and older. Eligible hospital employees who were not vaccinated by the end of Week 9 (e.g., new eligible employees, employees who changed their mind) may still be vaccinated out of such allocation.

Retail pharmacies or physician network or practice groups, after vaccinating their own patient-facing staff, should only vaccinate persons aged 65 years or older.

Local Health Departments must continue to prioritize the essential worker population in phase 1B and residents and staff of congregate settings operated or certified by the Office for People With Developmental Disabilities (OPWDD). Individuals with comorbidities and underlying conditions are eligible for vaccination at State-operated mass vaccination sites (MVS), and other locations as designated by the local health department (LHD). LHDs can work with health care providers in their counties to determine where individuals with comorbidities and underlying conditions can be vaccinated. A list of eligible comorbidities and underlying conditions is included in Appendix A. LHDs may also receive a week-to-week supplemental allocation to vaccinate the 65+ population.

Beginning in Week 12, public-facing hotel workers are now eligible at state mass vaccination sites, and may be eligible for vaccination at Local Health Departments, if the county opts to vaccinate such population.

New York is mandating social equity and fair distribution among the priority groups now eligible to ensure fair treatment and proportionate allocations both by eligibility group and by region.

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 regarding vaccine prioritization, as well as any other relevant directives.

Eligible individuals:

Appendix A summarizes populations eligible to be vaccinated.

Vaccine Provider Responsibilities:

- COVID-19 vaccine must be given according to the prioritization plan established by the NYSDOH. The vaccine cannot be used for any other populations or groups other than those listed as eligible in NYSDOH guidance.
- All facilities, entities, and practices receiving vaccine doses have an obligation to quickly utilize all doses, per New York's "Use it or Lose it" policy and Executive Order 202.88. If any vaccine is not administered within seven days of receipt, remaining doses may be removed, and entities may not be allocated future vaccine doses.
- Any provider or entity not on track to administer all received doses to eligible populations within the week of receipt, must notify the state no later than the fifth day after receipt, at CovidVaccineNotUsed@health.ny.gov, pursuant to Executive Order 202.88.
- Vaccine cannot be redistributed to another facility, provider, practice, or department without prior approval and consent of the NYSDOH. Facilities needing to redistribute vaccine 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 must 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 6 hours of filling; Janssen 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 NYS Vaccine Tracker.

Each facility that receives vaccine:

- **MUST ensure that for each individual they vaccinate:**

    - The individual displays evidence of completed NYS COVID-19 Vaccine Form and attestation,
    - The individual displays proof of eligibility, and
    - The provider reports all relevant information in the NYS Vaccine Tracker and NYSIIS/CIR, as applicable.
- Will be notified about how much vaccine will be received.
- Must use all vaccine doses in the week received by rapidly deploying it to the eligible populations.
- Must prioritize which of their own staff receives vaccination first (if you are a new provider).
- Must prioritize vaccinating those who are administering the vaccine (if you are a new provider).
- May be required to schedule and accommodate other priority populations for vaccination within the facility.
- 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 on a daily basis** using the COVID-19 Vaccine Tracker.

Vaccinating individuals from outside your facility or practice:

The NYSDOH will clearly communicate to all facilities or practices as to the allocation of vaccine (e.g. if a certain vaccine allocation is for the purpose of vaccinating individuals outside of the facility or practice). If you are unsure as to the intended priority population for any vaccine allocation, you should email the NYSDOH at COVID19Vaccine@health.ny.gov. All providers must ensure that all individuals they are vaccinating are eligible to receive the vaccine as required by Executive Order 202.86 and this guidance.

The Second COVID-19 Vaccine Dose:

Pfizer-BioNTech and Moderna vaccines require two doses, whereas Janssen 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**. Those who receive the vaccine must return to the same location to receive the second dose, unless NYSDOH approves an alternative due to extenuating circumstances. 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 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 (https://www.cdc.gov/vaccines/covid-19/vaccine-inventory-management.html).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. The State is encouraging that individuals 65 plus be prioritized, however, 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 such 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 may contain extra doses of vaccine. Vaccine administrators may use any extra vaccine that can be easily drawn up in a syringe to meet the dose requirements. Extra vaccine fluid from more than one vial **CANNOT** be combined to produce extra doses. This is particularly important because the vaccination doesn't 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.

Remaining COVID-19 Vaccine Doses:

All vaccine providers must plan accordingly to ensure every dose of vaccine is administered. Proper planning to avoid waste includes confirming the exact number of recipients from a priority population available to be vaccinated before drawing the first dose from a new vial.

All providers must keep a daily list of "stand by" eligible individuals to be notified 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. However, there may be times due to inclement weather, cancellations, or extra doses in vial, that there are doses of vaccine that remain at the close of business or the end of a vaccine clinic and no one from the priority population can come in before the doses expire. ("Stand by" lists must include individuals eligible for first and second doses.)

At these times and **only** under these circumstances, providers are authorized by the NYSDOH to administer vaccine first to other eligible individuals, and if no eligible individuals are able to be vaccinated, vaccinate any consenting adult. Providers must report any vaccine administered pursuant to this authority to NYS DOH. As an example, commercial pharmacists in this situation who had already vaccinated eligible populations, everyone public facing in the pharmacy department and the "stand by" list they can then move on to vaccinate any other eligible individual, rather than letting doses expire. This exception is **ONLY** for the purpose of ensuring vaccine is not wasted and must be reported to NYSDOH.

As the NYS COVID-19 Vaccination Program opens to more populations, the need for this exception should greatly diminish. If this exception is utilized, providers must:

- Require anyone receiving the COVID-19 vaccine to complete the New York State COVID-19 Vaccine Form pursuant to Executive Order 202.86, as extended.
- Record any vaccine dose administered in NYSIIS/CIR within 24 hours of administration.
- Maintain a separate tracking sheet so that the amount of vaccine used for different groups is clearly documented, as well as to whom it was administered.
- Schedule a second dose at the time of administration.

Under all circumstances, providers must contact the local Department of Health to determine if any eligible individuals can be contacted to receive the vaccine before discarding any vaccine.

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

Proof of Occupation or Eligibility:

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

If an individual is eligible due to their work or employment status, they must prove they work or are employed **in** the State of New York, regardless of where they reside. Additionally, if an individual resides in New York but is employed or works in another state, such individual must show proof of residence in New York and proof of work or employment, regardless of where such work or employment occurs.

Proof of work or employment may include:

- an employee ID card or badge,
- a letter from an employer or affiliated organization,
- a pay stub, depending on the specific priority status, or
- display proof of work via an application (e.g., Uber, Lyft, DoorDash, etc.).

If an individual is eligible due to their age, they must produce proof of age and proof of residence in New York. To prove New York residence, an individual must show:

- One of the following: State or government-issued ID; consulate ID (if New York address is displayed); Statement from landlord; Current rent receipt or lease; Mortgage records; or
- Two of the following: Statement from another person; Current mail; School records.
- For age, such proof 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.

Alternatively, employers or organizations can provide a list of staff who meet the eligibility criteria for vaccination. Do not vaccinate any person who does not have proof of their occupation, age, or priority status, as applicable, as well as proof of residence or employment. Executive Order 202.86 imposes monetary penalties for any provider vaccinating an individual who has not certified eligibility or for whom the provider otherwise has knowledge the individual is not a member of a priority group.

Public-facing hotel workers are eligible beginning on March 1, 2021.

For individuals with certain comorbidities or underlying conditions, at state-operated mass vaccination sites, any of the following proof is acceptable to prove eligibility:

- Doctor's Letter, or
- Medical Information Evidencing Comorbidity, or
- Signed Certification.

Local health departments are authorized to determine what forms, or combination thereof, of the proof options listed above, are required in their jurisdiction for this population. Providers must be aware of the LHD policy for proof of comorbidity and must require individuals being vaccinated to show proof consistent with such policy.

The Department of Health will audit local compliance with the above to ensure ALL providers are complying with the proof requirements in the jurisdiction.

The mandatory New York State COVID-19 Vaccine Form includes a self-attestation regarding eligibility for vaccination and New York residence or employment in New York, which must be completed prior to vaccination.

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:

All workers who meet the eligibility criteria must be included, regardless of job title, location, or other status. For example, in a hospital, frontline workers include doctors, registered nurses, licensed practical nurses, certified nursing assistants, personal care assistants, environmental workers, ward clerks, dietary workers, and others who work on the same floor, ward, clinic or office and who have direct contact with COVID-19 patients must all be eligible for vaccination at the same time.

Effort must be made to do outreach to persons 65 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.

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
Priority Groups Eligible to be Vaccinated

New Eligible Priority Groups for Week 12 (beginning Monday, March 1, 2021)

Beginning March 1, public-facing hotel workers are eligible to receive COVID-19 vaccine.

Individuals with one of the below comorbidities or underlying conditions are eligible to receive COVID-19 vaccine. The list is subject to change as additional scientific evidence is published and as New York State obtains and analyzes additional state-specific data. Adults over the age of 16 with the following conditions due to increased risk of moderate or severe illness or death from the virus that causes COVID-19 are eligible:

- Cancer (current or in remission, including 9/11-related cancers);
- Chronic kidney disease;
- Pulmonary Disease, including but not limited to, COPD (chronic obstructive pulmonary disease), asthma (moderate-to-severe), pulmonary fibrosis, cystic fibrosis, and 9/11 related pulmonary diseases;
- Intellectual and Developmental Disabilities including Down Syndrome;
- Heart conditions, including but not limited to heart failure, coronary artery disease, cardiomyopathies, or hypertension (high blood pressure);
- Immunocompromised state (weakened immune system) including but not limited to solid organ transplant or from blood or bone marrow transplant, immune deficiencies, HIV, use of corticosteroids, use of other immune weakening medicines, or other causes;
- Severe Obesity (BMI 40 kg/m2), Obesity (body mass index [BMI] of 30 kg/m2 or higher but < 40 kg/m2);
- Pregnancy;
- Sickle cell disease or Thalassemia;
- Type 1 or 2 diabetes mellitus;
- Cerebrovascular disease (affects blood vessels and blood supply to the brain);
- Neurologic conditions, including but not limited to Alzheimer's Disease or dementia; and
- Liver disease.

Priority Groups Continuing to Be Eligible:

- Healthcare Workers
    - High-risk hospital and FQHC staff, including OMH psychiatric centers.
    - Health care or other high-risk essential staff who come into contact with residents/patients working in LTCFs and long-term, congregate settings overseen by OPWDD, OMH, OCFS and OASAS, and residents in congregate living situations, run by the OPWDD, OMH, OCFS and OASAS.
    - Staff of urgent care provider.
    - Staff who administer COVID-19 vaccine.
    - All Outpatient/Ambulatory front-line, high-risk health care workers of any age who provide direct in-person patient care, or other staff in a position in which they have direct contact with patients (i.e., intake staff),
        - This includes, but is not limited to, individuals who work in private medical practices; hospital-affiliated medical practices; public health clinics; specialty medical practices of

all types; dental practices of all types; dialysis workers; diagnostic and treatment centers; occupational therapists; physical therapists; speech therapists; phlebotomists and blood workers; behavioral health workers; midwives and doulas; and student health workers.
    - All front-line, high-risk public health workers who have direct contact with patients, including those conducting COVID-19 tests, handling COVID-19 specimens and COVID-19 vaccinations.
- Certified NYS EMS provider, including but not limited to Certified First Responder, Emergency Medical Technician, Advanced Emergency Medical Technician, Emergency Medical Technician – Critical Care, Paramedic, Ambulance Emergency Vehicle Operator, or Non-Certified Ambulance Assistant.
- County Coroner or Medical Examiner, or employer or contractor thereof who is exposed to infectious material or bodily fluids.
- Licensed funeral director, or owner, operator, employee, or contractor of a funeral firm licensed and registered in New York State, who is exposed to infectious material or bodily fluids.
- Home care workers and aides, hospice workers, personal care aides, and consumer-directed personal care workers.
- Staff and residents of nursing homes, skilled nursing facilities, and adult care facilities.

New York residents age 65 and older[1]

- First Responder or Support Staff for First Responder Agency
    - Fire
        - State Fire Service, including firefighters and investigators (professional and volunteer)
        - Local Fire Service, including firefighters and investigators (professional and volunteer)
    - Police and Investigations
        - State Police, including Troopers
        - State Park Police, DEC Police, Forest Rangers
        - SUNY Police
        - Sheriffs' Offices
        - County Police Departments and Police Districts
        - City, Town, and Village Police Departments
        - Transit of other Public Authority Police Departments
        - State Field Investigations, including DMV, SCOC, Justice Center, DFS, IG, Tax, OCFS, SLA
    - Public Safety Communications
        - Emergency Communication and PSAP Personnel, including dispatchers and technicians
    - Other Sworn and Civilian Personnel
        - Court Officer
        - Other Police or Peace Officer
        - Support or Civilian Staff for Any of the Above Services, Agencies, or Facilities
- Corrections
    - State DOCCS Personnel, including correction and parole officers
    - Local Correctional Facilities, including correction officers
    - Local Probation Departments, including probation officers
    - State Juvenile Detention and Rehabilitation Facilities
    - Local Juvenile Detention and Rehabilitation Facilities

[1] **Pharmacies are vaccinating only individuals from this population.**

- P-12 Schools
    - P-12 school (public or non-public) or school district faculty or staff (includes all teachers, substitute teachers, student teachers, school administrators, paraprofessional staff, and support staff including bus drivers)
    - Contractor working in a P-12 school (public or non-public) or school district (including contracted bus drivers)
    - Licensed, registered, approved or legally exempt group childcare
- In-Person College Faculty and Instructors
- Employees or Support Staff of Licensed, Registered, Approved or Legally Exempt Group Childcare Settings
- Licensed, Registered, approved or legally exempt group Childcare Provider
- Public Transit
    - Airline and airport employee
    - Passenger railroad employee
    - Subway and mass transit employee (i.e., MTA, LIRR, Metro North, NYC Transit, Upstate transit)
    - Ferry employee
    - Port Authority employee
    - Public bus employee
- Public Facing Grocery Store Workers, including convenience stores, bodegas, regional food banks, food pantries, and permitted home-delivered meal programs,
- Incarcerated individuals age 65+ or those with comorbidities or underlying conditions.
- Individual living in a homeless shelter where sleeping, bathing or eating accommodations must be shared with individuals and families who are not part of your household.
- Individual working (paid or unpaid) in a homeless shelter where sleeping, bathing or eating accommodations must be shared by individuals and families who are not part of the same household, in a position where there is potential for interaction with shelter residents.
- Restaurant employees, including workers in permitted soup kitchen and congregate meal programs,
- Restaurant delivery workers,
- Public facing hotel workers, and
- For-hire vehicle drivers, including taxi, livery, black car, and transportation network company drivers

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March 1, 2021 -- Revised

Dear Emergency Response Stakeholder/Vaccine Provider:

As you are aware, on February 27, 2021, the U.S. Food & Drug Administration issued an Emergency Use Authorization ("EUA") for emergency use of Janssen Biotech, Inc. COVID-19 Vaccine for the prevention of Coronavirus Disease 2019 (COVID-19) for individuals 18 years of age and older.[1] If you have not already, it is crucial that you carefully review the EUA and the terms therein.

In accordance with the EUA, I wish to remind you that all vaccination providers must:

- Carefully review the Fact Sheet for Healthcare Providers Administering Vaccine[2] and administer the vaccine in accordance with that Fact Sheet.
- The Department will notify you of any amendments to the EUA.
- Participate and comply with the terms and training required by CDC's COVID-19 Vaccination Program.
- Provide the Fact Sheet for Recipients and Caregivers[3] to each individual receiving vaccination.

I cannot overemphasize the vital role that vaccines will play as we turn the tide of COVID-19 infections and bring hope for a brighter future in New York State. Your continued efforts to ensure proper vaccine storage, handling, and administration are of paramount importance. Thank you for your efforts to protect New Yorkers from COVID-19.

Sincerely,

Howard Zucker M.D.

Howard A. Zucker, M.D., J.D.
Commissioner of Health

[1] https://www.fda.gov/media/146303/download
[2] https://www.fda.gov/media/146304/download
[3] https://www.fda.gov/media/146305/download

New York State Department of Health
Bureau of Immunization

COVID-19 Immunization Screening and Consent Form*

Recipient Name (please print)		Preferred Name	
DOB	Current Gender ID Indicate ID Below:	**Key:** W – Woman/Girl TW – Transgender Woman/Girl M – Man/Boy TM – Transgender Man/Boy NB – Non-Binary Person GNC – Gender Non-Conforming Q – Not Sure/Questioning NR – Chose not to Respond GNL – Gender not Listed (write-in) * Gender Pronouns: write-in by client's name	
Sex Assigned at Birth Indicate Sex Below:	**Key:** M – Male F – Female I – Intersex NR – Chose not to Respond SNL – Sexual Orientation not Listed (write-in)	Marital Status Indicate Status Below:	**Key:** S – Single D – Divorced M – Married W – Widowed V – Civil Union U – Unknown SEPARATED – Legally Separated PARTNER – Life Partner
Address City State Zip			Email Address
Parent/Guardian/ Surrogate (if applicable, please print)		Phone	Preferred Language
Ethnicity Indicate Ethnicity Below:	**Ethnicity Key:** DECL – Declined HIS – Hispanic Origin NHL – Non-Hispanic Origin UNK – Unknown	Race Indicate Race Below:	**Race Key:** AIA – Native American or Alaskan ASN – Asian BAA – African American or Black DECL – Declined NHP – Native Hawaiian or Pacific Islander WHT – White OTH – Other or Multiracial
Primary Insurance Name		Primary Insurance ID#	Subscriber Name/DOB / Subscriber Relation to Patient
Primary Insurance Address		Primary Insurance Group #	Primary Insurance Phone #
Secondary Insurance Name		Secondary Insurance ID#	Subscriber Name/DOB / Subscriber Relation to Patient
Secondary Insurance Address		Secondary Insurance Group #	Secondary Insurance Phone #
Clinic/Office Site Where Vaccine is Administered		Primary Care Physician Address/Phone Number	

Screening Questionnaire

1.	Are you feeling sick today?	□ Yes	□ No	
2.	In the last 10 days, have you had a COVID-19 test because you had symptoms and are still awaiting your test results or been told by a health care provider or health department to isolate or quarantine at home due to COVID-19 infection, exposure or travel?	□ Yes	□ No	□ Unknown
3.	Have you been treated with antibody therapy or convalescent plasma for COVID-19 in the past 90 days (3 months)? *If yes, when did you receive the last dose?* Date: _____	□ Yes	□ No	□ Unknown
4.	Have you ever had an immediate allergic reaction (e.g., hives, facial swelling, difficulty breathing, anaphylaxis) to any vaccine, injection, or shot or to any component of the COVID-19 vaccine, or a severe allergic reaction (anaphylaxis) to anything?	□ Yes	□ No	□ Unknown
5.	Have you had any vaccines in the past 14 days (2 weeks) including flu shot? *If yes, how long ago was your most recent vaccine?* Date: _____	□ Yes	□ No	□ Unknown
6.	Are you pregnant or considering becoming pregnant?	□ Yes	□ No	□ Unknown

7.	Do you have cancer, leukemia, HIV/AIDS, a history of autoimmune disease or any other condition that weakens the immune system?	□ Yes	□ No	□ Unknown
8.	Do you take any medications that affect your immune system, such as cortisone, prednisone or other steroids, anticancer drugs, or have you had any radiation treatments?	□ Yes	□ No	□ Unknown
9.	Do you have a bleeding disorder or are you taking a blood thinner?	□ Yes	□ No	□ Unknown
10.	Have you received a previous dose of the COVID-19 vaccine? If yes, which vaccine? □ Moderna □ Pfizer		□ No	Date: _____ (if applicable)

Emergency Use Authorization

The FDA has made the COVID-19 vaccine available under an emergency use authorization (EUA). The EUA is used when circumstances exist to justify the emergency use of drugs and biological products during an emergency, such as the COVID-19 pandemic. This vaccine has not undergone the same type of review as an FDA-approved or cleared product. However, the FDA's decision to make the vaccine available is based on the totality of scientific evidence available, showing that known and potential benefits of the vaccine outweigh the known and potential risks.

Consent

I have read, or had explained to me, the information sheet about the COVID-19 vaccination. I understand that if my vaccine requires two doses, I will need to be administered (given) two doses of this vaccine in order for it to be effective. I have had a chance to ask questions which were answered to my satisfaction (and ensured the person named above for whom I am authorized to provide surrogate consent was also given a chance to ask questions). I understand the benefits and risks of the vaccination as described.

I request that the COVID-19 vaccination be given to me (or the person named above for whom I am authorized to make this request and provide surrogate consent). I understand there will be no cost to me for this vaccine. I understand that any monies or benefits for administering the vaccine will be assigned and transferred to the vaccinating provider, including benefits/monies from my health plan, Medicare or other third parties who are financially responsible for my medical care. I authorize release of all information needed (including but not limited to medical records, copies of claims and itemized bills) to verify payment and as needed for other public health purposes, including reporting to applicable vaccine registries.

Recipient/Surrogate/Guardian (Signature) recipient	Date / Time	Print Name	Relationship to Patient (if other than recipient)
Telephonic Interpreter's ID # **OR**	Date / Time		
Signature: Interpreter	Date/ Time	Print: Interpreter's Name and Relationship to Patient	

Area Below to be Completed by Vaccinator

Which vaccine is the patient receiving today?

Vaccine Name	Administration		EUA Fact Sheet Date	Manufacturer & Lot Number
Pfizer/ BioNTech	□ First Dose	□ Second Dose		
Moderna	□ First Dose	□ Second Dose		
Astra-Zeneca	□ First Dose	□ Second Dose		
Janssen	□ Single Dose			

Administration Site □ Left Deltoid □ Right Deltoid □ Left Thigh □ Right Thigh

Dosage □ 0.5 ml □ 0.3 ml

□ I have provided the patient (and/or parent, guardian or surrogate, as applicable) with information about the vaccine and consent to vaccination was obtained.

Vaccinator Signature: _____

Use of this form is optional. In the ongoing effort to address health disparities it is essential that all demographic information is collected at the time of COVID-19 vaccination including sex/gender identity and race/ethnicity.* **Updated January 20, 2021

NEW YORK STATE OF OPPORTUNITY. Department of Health

ANDREW M. CUOMO
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Information for Health Care Professionals about the Screening Checklist for the COVID-19 Vaccine

Updated: March 5, 2021

Note: For summary information on contraindications an precautions to vaccines, go to the ACIP's General Best Practice Guidelines for Immunization at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html.

1. **Are you feeling sick today?**
   If yes, refer to the vaccination site health care provider for assessment of current health status. If patient is feeling moderately or severely ill, do not vaccinate at this time. Ask the patient to return when symptoms improve.

2. **In the last 10 days, have you had a COVID-19 test because you had symptoms and are still awaiting your test results or been told by a health care provider or health department to isolate or quarantine at home due to COVID-19 infection, exposure or travel?**
   If yes, advise patient to return to isolation or quarantine and reschedule for after isolation/quarantine ends.
   If the patient was diagnosed with COVID-19 greater than 10 days ago and has been asymptomatic for 72 hours or more, patient may be vaccinated.
   If the patient has had a test in the last 10 days, ask for the result. If positive, send them home. If negative, they can proceed to vaccination. If the result is unsure or unknown, advise the patient to return once a negative test has been confirmed or 10 days have passed since a positive test.

3. **Have you been treated with antibody therapy or convalescent plasma for COVID-19 in the past 90 days (3 months)? If yes, when did you receive the last dose?**
   If yes, reschedule at least 90 days after last dose of antibody therapy.

4. **Have you ever had an immediate allergic reaction, such as hives, facial swelling, difficulty breathing, anaphylaxis to any vaccine, injection, or shot or to any component of the COVID-19 vaccine, or a severe allergic reaction (anaphylaxis) to anything?**
   If yes, then refer to the vaccination site health care provider for assessment of allergic reaction.
   Review the ingredient lists at https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Appendix-C

   Contraindications to COVID-19 vaccine:
   - Severe allergic reaction (e.g., anaphylaxis) or immediate allergic reaction of any severity after a previous dose or to a component of the COVID-19 vaccine

- People with a contraindication to one of the mRNA COVID-19 vaccines should not receive doses of either of the mRNA COVID-19 vaccines (Pfizer or Moderna)

Precautions to COVID-19 vaccine: (Refer to your organization's protocol to see whether individuals with a precaution to vaccination warrant further evaluation.)

- Immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies excluding subcutaneous immunotherapy for allergies)
- Individuals with a contraindication to one type of COVID-19 vaccine (e.g., mRNA) have a precaution to the other (e.g., Janssen viral vector)
    - Consultation with an allergist-immunologist should be considered to help determine if the patient can safely receive vaccination, and vaccination of these individuals should only be undertaken in an appropriate clinical setting under the supervision of a health care provider experienced in the management of severe allergic reactions.
    - Note: These individuals should not be administered COVID-19 vaccine at State-operated vaccination sites.

For patients who are determined eligible for COVID-19 vaccination after assessment of allergy history, a 30-minute post-vaccination observation period is needed for the following:

- Patients with a history of an immediate allergic reaction of any severity to any other vaccine or injectable therapy
- Patients with a contraindication to a different type of COVID-19 vaccine (e.g., mRNA vs. Janssen viral vector)
- Patients with a history of anaphylaxis due to any cause

5. **Have you had any vaccines in the past 14 days (two weeks) including a flu shot? If yes, how long ago was your most recent vaccine?**
   If yes, then reschedule at least 14 days after the most recent vaccine.

6. **Are you pregnant or considering becoming pregnant?**
   If yes, ask the patient if they would like to have a discussion with a health care provider at site for counseling on the risks and benefits of COVID-19 vaccine during pregnancy. Patient may be vaccinated if they choose and does not need to go to medical evaluation if they choose.

7. **Do you have cancer, leukemia, HIV/AIDS, a history of autoimmune disease or any other condition that weakens the immune system?**
   If yes, refer to the vaccination site health care provider to discuss what is known and not yet known about COVID-19 vaccine for immunocompromised people. You can tell the patient that if they are immunocompromised or are on a medicine that affects their immune system, they may have a less strong immune response to the vaccine but may still get vaccinated. They should continue to follow current guidance to protect themselves against COVID-19.

8. **Do you take any medications that affect your immune system, such as cortisone, prednisone or other steroids, anticancer drugs, or have you had any radiation treatments?**
   If yes, refer to the vaccination site health care provider to discuss what is known and not yet known about COVID-19 vaccine for immunosuppressed people. You can tell the patient that if they are immunocompromised or are on a medicine that affects their immune system, they may have a less strong immune response to the vaccine but may still get vaccinated. They should continue to follow current guidance to protect themselves against COVID-19.

9. **Do you have a bleeding disorder or are you taking a blood thinner?**
   If yes, refer to health care provider to assess the patient's bleeding risk. If cleared for vaccination, then administer vaccine using a 23-gauge or smaller caliber needle and apply firm pressure on the site of vaccination, without rubbing, for at least 2 minutes after vaccination.

10. **Have you received a previous dose of the COVID-19 vaccine?**
    If yes, verify that the second dose of mRNA COVID-19 vaccine is from the same manufacturer as the previous dose and that the second dose is being administered within the correct timeframe (21 days from first dose for Pfizer; 28 days from first dose for Moderna). If patient does not recall previous COVID-19 vaccine received, check medical records, NYSIIS, CIR, and vaccination record cards to help determine the initial product received. The second dose of an mRNA COVID-19 vaccine should be administered as close to the recommended interval as possible. The Janssen COVID-19 vaccine only requires one dose.

    At State-operated vaccination sites: If a person presents for a Janssen COVID-19 vaccine after previously having received one dose of the Pfizer or Moderna COVID-19 vaccine, they should not be administered the Janssen COVID-19 vaccine.

*** Anyone answering "Unknown" to any screening question should be referred to the medical director or responsible health care provider at the POD or clinic to further assess their answer to that question. (E.g., the person might not have understood the question and the health care provider could explain it further).**

New York State COVID-19 Vaccination Provider Storage and Handling - Overview

A cold chain is a temperature-controlled supply chain that includes all vaccine-related equipment and procedures. As part of the agreement for COVID-19 vaccination providers, providers are required to:

- Store and handle COVID-19 vaccines under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with EUA or vaccine package insert, manufacturer guidance, and CDC Guidance.
- Monitor storage unit temperatures at all times, using equipment and practices that comply with guidance in the CDC Vaccine Storage and Handling Toolkit.
- Comply with immunization program guidance for handling temperature excursions (contact the manufacturer and also report to vaccinetempexcursion@health.ny.gov).
- Monitor and comply with COVID-19 vaccine expiration dates.
- Preserve all records related to COVID-19 vaccine management for a minimum of three years.
- Comply with federal instructions and timelines for disposing of COVID-19 vaccine and diluent, including unused doses.

COVID-19 vaccination providers must have proper storage and temperature monitoring equipment to meet the specific needs of the COVID-19 vaccine product(s) they have in their inventory. This includes the correct vaccine storage unit(s), whether a refrigerator, regular freezer, or ultra-cold freezer.

- Purpose-built, also referred to as “pharmaceutical-grade,” units are preferred and designed specifically for storage of biologics, including vaccines.
- Household-grade units can be an acceptable alternative in some situations.
- Most standard freezer units do not meet ultra-cold freezer requirements for storing vaccine between -60° C and -80° C. However, at this time, CDC does not recommend COVID-19 vaccination providers purchase ultra-cold storage units because vaccines requiring these storage conditions are expected to be shipped in containers that can maintain ultra-cold temperatures for an extended period.
- Dorm style refrigerators are NOT permitted for vaccine storage.
- Food and beverages should never be stored in the unit with vaccines.
- It is essential for each vaccine storage unit to have a temperature monitoring device (TMD) to ensure that vaccines are stored within the correct temperature range. CDC recommends a specific type of TMD called a “digital data logger” (DDL).
- Providers must notify New York State DOH regarding any compromised doses or suspected compromise doses at COVID19vaccine@health.ny.gov along with the required to reporting to the New York State Immunization Information System (NYSIIS) or Citywide Immunization Registry (CIR).
- Reach out to your regional hospital hub or local health department if doses are going to expire to see if they can be used.

Upon arrival, shipments of refrigerated and frozen vaccine must be immediately examined for signs of damage, for indication of a temperature excursion during transit, and to guarantee receipt of the appropriate vaccine types and quantities. Before opening ultra-cold vaccine shipments, make sure the vaccine can be quickly placed in an ultra-cold freezer or that dry ice is available for re-icing the shipping container to ensure vaccine remains at the appropriate ultra-

cold temperature. Vaccines and diluents must be carefully examined, stored at recommended temperatures, and documented using your facility's vaccine inventory management process immediately after they arrive.

As part of the COVID-19 Vaccination Program, a minimum order size of COVID-19 vaccine, diluent, and ancillary supplies will be shipped directly to enrolled COVID-19 vaccination providers. In most instances, vaccine will be delivered directly to the facility where it will be administered to maintain the vaccine cold chain. However, there may be circumstances where COVID-19 vaccine needs to be redistributed or transported. In these cases, approval must be requested and granted prior to any redistribution or transport of vaccine.

Providers must adhere to all CDC and NYS COVID-19 Vaccination Program requirements, including, but not limited to, all storage and handling requirements, and failure to adhere to such requirements can result in termination from the program as well as any other penalties available under federal or New York State law.

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New York State COVID-19 Vaccination Program
Temperature Excursion Report
March 5, 2021

An *out-of-range temperature incident,* also called a *temperature excursion* is any temperature outside the recommended range for a vaccine. The TOTAL amount of time a vaccine is stored at an out-of-range temperature affects the viability of the vaccine.

Complete this report to gather information vaccine manufacturers will need to make a stability determination. For vaccines in question, ***label the vaccine "DO NOT USE"*** and if applicable, move it to a unit where it can be stored at the correct temperature. Download your digital data logger data to gather information on duration of excursion. Do not administer any affected vaccine until you have determined its efficacy with the manufacturer and report the excursion to the New York State Department of Health Vaccine Program at vaccinetempexcursion@health.ny.gov.

Recommended Temperature Ranges				
MANUFACTURER	**REFRIGERATOR**	**FREEZER**	**ULT FREEZER**	**THERMAL SHIPPER**
PFIZER	**2°C to 8°C (36°F to 46°F) 120 hours**	**-25°C to -15°C (-13°F to 5°F) 2 weeks cumulative**	**-80ºC to -60ºC (-112ºF and -76ºF) Until expiration date**	**-90ºC to -60ºC * (-130ºF to -76ºF)**
MODERNA	**2°C to 8°C (36°F to 46°F) 30 days**	**-25°C to -15°C (-13°F to 5°F) Until expiration date**	**N/A**	**N/A**
Janssen	**2°C to 8°C (36°F to 46°F) Until expiration date**	**N/A**	**N/A**	**N/A**

* Storage within this temperature range is not considered an excursion from the recommended storage condition.

Step 1: Record the temperature excursion details.

Select affected vaccine: ☐ Pfizer ☐ Moderna ☐ Janssen

Temperatures out of range: ☐ too cold ☐ too warm

Excursion start date: _____ **Excursion end date:** _____

Affected vaccines stored in:
☐ refrigerator ☐ freezer ☐ ULT freezer ☐ thermal shipper ☐ transport container

Check if related to:
☐ redistribution ☐ off-site/mobile clinic ☐ emergency transport

What was the warmest temperature: _____

What was the coldest temperature: _____

Total duration of excursion: _____ (hrs./mins.)

Description of incident: _____

_____

Were affected vaccines involved in a previous temperature excursion? ☐ No ☐ Yes, date: _____
This information must be communicated to the manufacturer as part of the viability determination.

Step 2: Record manufacturer's stability determination.

- Contact the vaccine manufacturer using phone information below.
- Request a case number/reference number for your call and document the number provided.
- Communicate information about this and any prior excursions affecting these doses
- Request stability letters of electronic reports from the manufacturers; keep for your records for three years.
- Document the manufacturer's resolution on this form.

MANUFACTURER	Phone	Doses Administered?	Stability Determination	Case or Reference #
PFIZER	**800-666-7248 option 8**	☐ **Yes** ☐ **No**	☐ **May use** ☐ **May not use**	
MODERNA	**833-272-6635**	☐ **Yes** ☐ **No**	☐ **May use** ☐ **May not use**	
JANSSEN	**1-800-565-4008**	☐ **Yes** ☐ **No**	☐ **May use** ☐ **May not use**	

Resolution: _____

_____

_____

Step 3: Determine viability.
If manufacturer determines vaccines are okay to use:

- Remove "DO NOT USE" sign and alert your supervisor. Vaccines are okay to administer.

If manufacturer determines vaccines **may not** be viable and are NOT okay to use:

- Dispose of the non-viable vaccine as medical waste, such as by placing in a sharps container.
- Document wasted doses in NYSIIS.

Step 4: Contact Information

Facility/Provider Name: _____

NYSIIS COVID PIN#: _____

Name of Person Submitting: _____

Phone Number: _____

Email: _____

Step 5: Submit the Temperature Excursion Report and attach relevant documents.

- Submit this report to vaccinetempexcursion@health.ny.gov and include any supporting documentation such as data logger summary report (or section showing excursions), vaccine transport log, temperature log, etc.

New York State COVID-19 Vaccine Program
Guidance for Vaccine Transport

Routine transport of vaccine is not recommended. Each transport increases the risk of exposing vaccine to inappropriate storage conditions, which compromises the viability of vaccines. However, in certain situations transporting vaccine may be necessary. Opened vials cannot be transported.

Any time vaccine is transported, return the completed Transport Tracking Form(s) (final page of this guidance) to the NYS COVID-19 Vaccine Program via email at covid19vaccine@health.ny.gov

Each receiving location with storage capacity must be enrolled in the COVID-19 Vaccine Program and must follow all NYS Department of Health guidance and directives, including storage and handling requirements.

How should vaccine be transported?

1. **Portable vaccine refrigerator and freezer units** are considered the **best option** for vaccine transport. Portable vaccine refrigerator/freezer units are preferred because they use built-in temperature regulation, controlled by a thermostat, to maintain the temperature and do not require the use of packout methods to maintain appropriate temperatures.
2. **Use a continuous temperature monitoring device** or digital data logger to monitor temperatures during transport.
3. **Qualified containers and packouts** are tested under laboratory conditions and are acceptable to use for emergency or short-term vaccine transport, when portable vaccine refrigerator units are not available.
   A. Qualified containers do not have built-in temperature regulation to maintain temperature but are known to maintain appropriate temperatures when a qualified packout method is also used.
   B. Polystyrene coolers or intact Styrofoam vaccine shipping containers are examples of qualified containers. Soft-sided or collapsible coolers are never acceptable.
   C. Qualified packouts require specific supplies and packing procedures to minimize temperature excursions. Refer to the instructions in the ***CDC's: Packing Vaccines for Transport during Emergencies*** on pages 3 and 4.
   D. A **hard-sided insulated cooler** may be used for short-term or emergency transport when portable or qualified containers are not available.
4. **To transport refrigerated vaccine**:
   A. Temperatures during transport are to be maintained between 36ºF and 46ºF (2ºC and 8ºC). Janssen, Moderna and Pfizer vaccine may be transported refrigerated.
   B. Use portable refrigerator unit or qualified container and packout with a digital data logger. Properly maintained packouts can hold appropriate temperatures for up to 8 hours if left undisturbed.
   C. Keep vaccines out of direct sunlight.
   D. Protect vaccines as much as possible from drops, shocks, and vibration. Transport in the original carton whenever possible. If individual vials are transported vials should be placed with dunnage (padding material like bubble wrap or similar padding). Transport container must be secured.
   E. Transport only full, unpunctured vials.
   F. Take care to ensure vaccine does not refreeze during transport.

G. Include hours used for transport when calculating the beyond use date (BUD) for vaccines. For more information and sample BUD tracking labels, see https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/bud-tracking-labels.pdf and https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/bud-tracking-labels.pdf

5. **To transport frozen vaccine**:

A. As of March 2021, the Moderna vaccine and the Pfizer vaccine may be stored or transported in a frozen state (-25°C to -15°C or -13°F to 5°F). Frozen transport is preferred, if Moderna or individual vials of Pfizer vaccine must be transported and have not been thawed.

B. Use a portable freezer unit or qualified container and packout and a digital data logger acceptable for frozen temperatures.

C. Immediately upon arrival at the destination, unpack the vaccines and place them in a freezer or refrigerator at an acceptable temperature range.

D. If individual vials of Pfizer are transported frozen, any hours used for transport count against the 2-week limit for storage at -25° C to -15° C. Frozen vials transported at -25° C to -15° C may be returned one time to the recommended storage condition of -80° C to -60° C.

E. Never transport or store Moderna vaccine on dry ice or below -40°C (40°F).

F. Keep vials out of direct sunlight.

G. **If frozen vaccine begins to thaw during transport, store in a refrigerator at receiving location. Do NOT refreeze vaccine that has started to thaw.**

6. **To transport ultra-frozen vaccine**:

A. As of February 2021, the Pfizer vaccine is the only COVID vaccine that can be stored or transported in an ultra-frozen state (-80°C to -60°C or -112°F to -76°F).

B. Use the original thermal shipping container with dry ice or aportable ultra-cold freezer that can maintain a temperature of -80°C.

C. **Transport only full trays of vaccine**; partial trays or individual vials must be transported at -25° C to -15° C unless already thawed, which requires refrigerated transport. Partially used vials cannot be transferred between providers under any circumstances.

D. Keep tray(s) in original packaging to protect vaccine from light.

E. Do not open trays or remove any vials until ready to thaw.

F. Place trays in ultra-cold storage within five minutes of unpacking.

G. Once Pfizer COVID-19 vaccine is removed from ultra-cold storage, it must be used within 120 hours (5 days).

H. Never refreeze thawed vaccine.

If temperature goes above or below the appropriate range during transport, report as soon as vaccine arrives at the receiving location by emailing vaccinetempexcursion@health.ny.gov.

Resources

Centers for Disease Control (CDC), Packing Vaccines for Transport during Emergencies, http://www.cdc.gov/vaccines/recs/storage/downloads/emergency-transport.pdf

Centers for Disease Control (CDC), Vaccine Storage and Handling Toolkit, https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf pages 21-24 and 49-62

Packing Vaccines for Transport during Emergencies

Be ready BEFORE the emergency

Equipment failures, power outages, natural disasters—these and other emergency situations can compromise vaccine storage conditions and damage your vaccine supply. **It's critical to have an up-to-date emergency plan with steps you should take to protect your vaccine.** In any emergency event, activate your emergency plan immediately, and if you can do so safely, follow the emergency packing procedures for refrigerated vaccines.

1 Gather the Supplies

Hard-sided coolers or Styrofoam™ vaccine shipping containers

- Coolers should be large enough for your location's typical supply of refrigerated vaccines.
- Can use original shipping boxes from manufacturers if available.
- Do NOT use soft-sided collapsible coolers.

Conditioned frozen water bottles

- Use 16.9 oz. bottles for medium/large coolers or 8 oz. bottles for small coolers (enough for 2 layers inside cooler).
- Do NOT reuse coolant packs from original vaccine shipping container, as they increase risk of freezing vaccines.
- Freeze water bottles (can help regulate the temperature in your freezer).
- Before use, you must condition the frozen water bottles. Put them in a sink filled with several inches of cool or lukewarm water until you see a layer of water forming near the surface of bottle. The bottle is properly conditioned if ice block inside spins freely when rotated in your hand.

Insulating material — You will need two of each layer

- **Insulating cushioning material** – Bubble wrap, packing foam, or Styrofoam™ for a layer above and below the vaccines, at least 1 in thick. Make sure it covers the cardboard completely. Do NOT use packing peanuts or other loose material that might shift during transport.
- **Corrugated cardboard** – Two pieces cut to fit interior dimensions of cooler(s) to be placed between insulating cushioning material and conditioned frozen water bottles.

Temperature monitoring device – Digital data logger (DDL) with buffered probe. Accuracy of +/-1°F (+/-0.5°C) with a current and valid certificate of calibration testing. Pre-chill buffered probe for at least 5 hours in refrigerator. Temperature monitoring device currently stored in refrigerator can be used, as long as there is a device to measure temperatures for any remaining vaccines.

Why do you need cardboard, bubble wrap, and conditioned frozen water bottles?

Conditioned frozen water bottles and corrugated cardboard used along with one inch of insulating material such as bubble wrap keeps refrigerated vaccines at the right temperature and prevents them from freezing. **Reusing vaccine coolant packs from original vaccine shipping containers can freeze and damage refrigerated vaccines.**

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Distributed by

CS249276-I August 2015

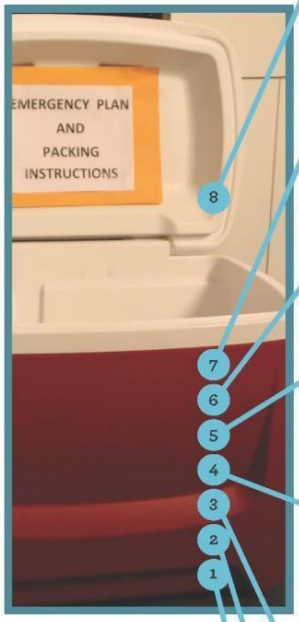
Visit www.cdc.gov/vaccines/SandH for more information, or your state health department.

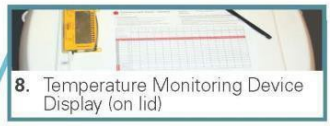
Packing Vaccines for Transport during Emergencies

2 Pack for Transport

Conditioning frozen water bottles

- Put frozen water bottles in sink filled with several inches of cool or lukewarm water or under running tap water until you see a layer of water forming near surface of bottle.
- The bottle is properly conditioned if ice block inside spins freely when rotated in your hand.
- If ice "sticks," put bottle back in water for another minute.
- Dry each bottle.
- Line the bottom and top of cooler with a single layer of conditioned water bottles.
- Do NOT reuse coolant packs from original vaccine shipping container.




8. Temperature Monitoring Device Display (on lid)

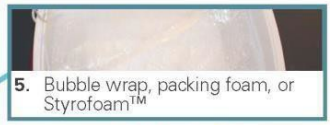
Close lid – Close the lid and attach DDL display and temperature log to the top of the lid.


7. Conditioned Water Bottles

Conditioned frozen water bottles – Fill the remaining space in the cooler with an additional layer of conditioned frozen water bottles.


6. Cardboard Sheet

Insulating material – Another sheet of cardboard may be needed to support top layer of water bottles.


5. Bubble wrap, packing foam, or Styrofoam™

Insulating material – Cover vaccines with another 1 in. layer of bubble wrap, packing foam, or Styrofoam™


4. Vaccines, Diluents, and Temperature Monitoring Device Probe

Vaccines – Add remaining vaccines and diluents to cooler, covering DDL probe.
Temperature monitoring device – When cooler is halfway full, place DDL buffered probe in center of vaccines, but keep DDL display outside cooler until finished loading.
Vaccines – Stack boxes of vaccines and diluents on top of insulating material.


3. Bubble wrap, packing foam, or Styrofoam™

Insulating material – Place a layer of bubble wrap, packing foam, or Styrofoam™ on top (layer must be at least 1 in. thick and must cover cardboard completely).


2. Cardboard Sheet

Insulating material – Place 1 sheet of corrugated cardboard over water bottles to cover them completely.


1. Conditioned Water Bottles

Conditioned frozen water bottles – Line bottom of the cooler with a single layer of conditioned water bottles.

NOTE:
This packout can maintain appropriate temperatures for up to 8 hours, but the container should not be opened or closed repeatedly.

3 Arrive at Destination

Before opening cooler – Record date, time, temperature, and your initials on vaccine temperature log.

Storage – Transfer boxes of vaccines quickly to storage refrigerator.

Troubleshooting – If there has been a temperature excursion, contact vaccine manufacturer(s) and/or your immunization program before using vaccines. Label vaccines "Do Not Use" and store at appropriate temperatures until a determination can be made.

COVID-19 Vaccine Transport Tracking Sheet

Providers must email completed Vaccine Transport Tracking Sheet to covid19vaccine@health.ny.gov

Date of transport:_____ Name of provider releasing vaccine:_____ PIN:_____

Name of contact person at *releasing* provider:_____ Phone number of contact person: _____

Temperature of *releasing* storage unit on day of transport:_____ ☐°C ☐°F Time placed in transport container:_____ ☐AM ☐PM

Vaccines will be transported (*Select one*):

☐ **Refrigerated**
2°C to 8°C (36°F to 46°F)

- **Moderna, Pfizer, and Janssen vaccines**
- Use portable refrigerator unit or qualified container and packout with DDL
- Keep vaccines out of direct sunlight
- Transport only full, unpunctured vials
- Minimize shocks and vibrations during transport
- Include hours used for transport when calculating the beyond use date (BUD) for Moderna and Pfizer vaccines
- **Never refreeze thawed vaccine**

☐ **Frozen**
-25°C to -15°C (-13°F to 5°F)

- **Moderna and Pfizer vaccine**
- Use a portable freezer unit or qualified container and packout with DDL
- Never transport or store Moderna vaccine on dry ice or below -40°C (40°F)
- Keep vaccine out of direct sunlight
- Include hours of transport in 2-week limit for Pfizer frozen storage
- Pfizer vaccine transported frozen may be returned to ULT storage one time
- **Never refreeze thawed vaccine**

☐ **Ultra-frozen**
-80°C to -60°C (-112°F to -76°F)

- **Pfizer vaccine only**
- Use original thermal shipping container with dry ice or a portable ultra-cold freezer that can maintain a temperature of -80°C
- **Transport only full trays of Pfizer vaccine at ultra-frozen temperatures**
- Keep tray(s) in original packaging to protect vaccine from light
- Do not open trays or remove any vials until ready to thaw
- Place trays in ultra-cold storage within five minutes of unpacking
- **Once removed from ultra-cold storage, vaccine must be used within 120 hours (5 days)**
- **Never refreeze thawed vaccine**

Vaccines included in this transport *(Attach additional sheets if needed)*:

Manufacturer	Lot #	Expiration Date	Beyond Use Date (BUD)[1]	# of Doses[2]	Dose in Sequence (1 or 2)	Cold Chain Maintained (Y/N)[3]	Comments

[1] *The BUD for Moderna vaccine will be 30 days after thawing begins. The BUD for Pfizer vaccine will be 120 hours (5 days) after thawing begins.*

[2] *After 2/16/2021, count six doses per vial for Pfizer vaccine.*

[3] *If temperature goes out of range during transport, report immediately to vaccinetempexcursion@health.ny.gov*

Name of provider receiving vaccine (or alternate storage location):_____ PIN:_____

Name of contact person at *receiving* provider:_____ Phone number of contact person: _____

Time arrived at receiving location:_____ ☐AM ☐PM

Temperature of transport container upon arrival:_____ ☐°C ☐°F

Temperature of *receiving* storage unit on day of transport: _____ ☐°C ☐°F

Maximum temperature reached during transport:_____ ☐°C ☐°F

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New York State COVID-19 Vaccination Program Redistribution

March 5, 2021

WHAT IS VACCINE REDISTRIBUTION?

- Vaccine redistribution is the process by which vaccine is physically moved and possession is transferred from the enrolled provider that first received the vaccine shipment, to another enrolled provider, who will store and administer the doses.
- If an enrolled provider receives vaccine, and brings the vaccine to a satellite, temporary, or off-site clinic controlled by such provider for administration the same day, this is **NOT** vaccine redistribution.

WHAT ARE THE REQUIREMENTS TO REDISTRIBUTE COVID-19 VACCINE?

- The facility that is redistributing the vaccine must have a signed CDC Redistribution Agreement, as well as a completed NYSDOH Request to Redistribute Vaccine Between Locations (see attached), that has been approved by NYS DOH after submission to CovidVaccineRedistribution@health.ny.gov. The facility must maintain all redistribution records as indicated in the agreement.
- The provider site receiving the vaccine from the provider site redistributing it must be enrolled as a COVID-19 Vaccination Program Provider.
- After the facility that is redistributing the vaccine submits a completed CDC Redistribution Agreement and NYSDOH Request to Redistribute Vaccine Between Locations, if the request is approved, both the redistributing AND receiving sites will be asked to complete and submit a single Vaccine Transport Tracking Sheet. This form includes facility site names (sending and receiving facilities), dates and time of redistribution, vaccine lot numbers, vaccine expiration dates, temperature of vaccine during transport, and number of doses.
- Inventory in the New York State Immunization Information System (NYSIIS) or in the Citywide Immunization Registry (CIR) must be updated by both participating providers. The receiving site should update the inventory before administering any doses and no later than 24 hours after receiving the redistributed vaccine. The facility redistributing the vaccine should ensure inventory is updated within 24 hours of the transaction.

HOW DO I REQUEST APPROVAL TO REDISTRIBUTE VACCINE?

- Submission of CDC Redistribution Agreement; and
- Submission of a completed NYSDOH Request to Redistribute Vaccine Between Locations form that includes detailed, relevant information for review.

Note: NYSDOH approval must be obtained before the vaccine may be redistributed. Submission of a request to redistribute does not constitute approval.

- NYSDOH may expressly direct enrolled providers to redistribute vaccine through a directed re-allocation, or in the case of emergency (such as equipment failure). Prior approval is not required in these instances, and the NYSDOH Request to Redistribute Vaccine Between Locations form is not needed. However, the CDC Redistribution Agreement and the Vaccine Transport Tracking Sheet must still be submitted and NYSIIS or CIR Inventory updated appropriately.

HOW DO I SAFELY TRANSPORT VACCINE?

- Please visit NYSDOH Guidance for COVID-19 Vaccine Transport for details on vaccine transport.
- Individual vials of Pfizer vaccine may be transported at refrigerated temperatures (2° C to 8° C) or frozen temperatures (-25°C to -15°C). Full trays of Pfizer vaccine may be transported in an ultra-cold shipper or ultra-cold portable freezer at -90°C to -60°C or frozen temperatures (-25° C to -15° C).
- Moderna vaccine may be transported at frozen (-25°C to -15° C) or refrigerated temperatures (2°C to 8° C).
- Janssen vaccine may only be transported at refrigerated temperatures (2° C to 8° C).
- Every time vaccine leaves the storage unit the cold chain is at risk, therefore redistributions should be limited to the extent possible. Vaccine must not be redistributed more than once, pursuant to COVID-19 vaccine manufacturer guidance.

NEW YORK STATE | Department of Health

New York State COVID-19 Vaccination Program
Request to Redistribute Vaccine Between Locations

Providers must submit this form to NYSDOH to request approval to redistribute COVID-19 vaccine between locations. Submission of a request to redistribute vaccine does not guarantee approval. Providers must NOT redistribute vaccine prior to receiving approval. Submit this form with all fields completed to CovidVaccineRedistribution@health.ny.gov.

Redistribution is when vaccine physically moves from the enrolled provider that received the vaccine shipment to another enrolled provider, who will store and administer the doses. Redistribution of vaccine product from one location to another is strongly discouraged (due to cold chain considerations), requires pre-approval, and should be extremely rare.

- This form must be completed by the facility (location) that will be **releasing** vaccine from their inventory. This facility must have a signed CDC Redistribution Agreement on file with their jurisdiction (NYSDOH for facilities outside NYC and NYCDOHMH for facilities within NYC).
- Redistribution between New York City and Rest of State (ROS; i.e. outside New York City) is NOT permitted.
- The receiving location must be an enrolled COVID-19 Vaccination Provider within the same jurisdiction as the location distributing (New York State or New York City).
- Rather than requesting re-distribution (i.e., shipping or physical transfer) of vaccine supply between locations, facilities should conduct outreach to the target priority population groups to be vaccinated at the facility who received the original vaccine shipment. This will help to prevent vaccine wastage.
- Only full, unpunctured vials can be transported and must follow safe transport guidelines for cold-chain integrity.

RELEASING FACILITY INFORMATION

Releasing Facility Location Name and Address (including County):	**Releasing Provider COVID PIN #:**	**Date of Submission:** xx/xx/xx
Facility Contact Name and email: enter here	**Contact Phone #:** enter phone number **Extension:** enter if applicable	

RECEIVING FACILITY INFORMATION: Complete one row for each site receiving vaccine from your inventory

		Receiving Provider COVID PIN #	Manufacturer and # of Doses	Target date of transfer
Receiving Facility Location Name and Address (including County)	**Contact Name and Email**		**Check if 2nd Doses** ☐	Click or tap to enter a date.
Receiving Facility Location Name and Address (including County)	**Contact Name and Email**		**Check if 2nd Doses** ☐	Click or tap to enter a date.
Receiving Facility Location Name and Address (including County)	**Contact Name and Email**		**Check if 2nd Doses** ☐	Click or tap to enter a date.

Justification (explain in detail the **reason for re-distribution** and **the target population to be vaccinated in accordance with state guidelines**):

I hereby certify, under penalty of law, that I represent the facility named herein, and that such facility is in compliance with all State and federal laws, regulations, and agreements concerning COVID-19 vaccine distribution, including but not limited to such facility's *CDC COVID-19 Vaccination Provider Agreement* executed with the Centers for Disease Control, and such facility's *Memorandum of Understanding Regarding COVID-19 Vaccine Administration* executed with the NYS Department of Health.

Signature: **Date:**

I agree that by typing my name above, I am hereby affixing my electronic signature as if I had physically signed this certification.

CDC Supplemental COVID-19 Vaccine Redistribution Agreement

The Centers for Disease Control and Prevention (CDC) plans to ship a minimum order size of COVID-19 vaccine, constituent products, and ancillary supplies at no cost directly to enrolled COVID-19 vaccination providers throughout the United States. The federally contracted vaccine distributor uses validated shipping procedures to maintain the vaccine cold chain and minimize the likelihood of vaccine loss or damage during shipment. There may be circumstances where COVID-19 vaccine needs to be redistributed beyond the identified primary CDC ship-to sites (i.e., for orders smaller than the minimum order size or for large organizations whose vaccine is shipped to a central depot and requires redistribution to additional clinic locations). In these instances, vaccination provider organizations/facilities, third-party vendors, and other vaccination providers may be allowed to redistribute vaccine, if approved by the jurisdiction's immunization program and if validated cold chain procedures are in place in accordance with the manufacturer's instructions and CDC's guidance on COVID-19 vaccine storage and handling. There must be a signed *CDC Supplemental COVID-19 Vaccine Redistribution Agreement* for the facility/organization conducting redistribution and a fully completed *CDC COVID-19 Vaccination Provider Profile Information* form (Section B of the CDC COVID-19 Vaccination Program Provider Agreement) for each receiving vaccination location.

The parties to this agreement are CDC and healthcare organizations, third-party vendors, and vaccination providers that redistribute COVID-19 vaccine. CDC cannot reimburse costs of redistribution beyond the initial designated primary CDC ship-to site(s), or for purchase of any vaccine-specific refrigerators or qualified containers. Therefore, organizations planning for redistribution of COVID-19 vaccine must carefully assess the associated risks and costs (e.g., vaccine loss due to temperature excursions, purchase of vaccine-specific portable refrigerators and/or containers) before planning this activity.

Organization information

Organization/facility name:

FOR OFFICIAL USE ONLY

VTrckS ID:

Unique COVID-19 Organization ID (from Section A):

Primary address and contact information of COVID-19 vaccination organization

Street address 1: Street address 2:

City: County: State: ZIP:

Telephone: Fax:

Responsible officers

Medical Director (or Equivalent) Information

Last name: First name: Middle initial:

Title: Licensure state: Licensure number:

Telephone: Email:

Street address 1: Street address 2:

City: County: State: ZIP:

Chief Executive Officer (or Chief Fiduciary) Information

Last name: First name: Middle initial:

Telephone number: Email:

Street address 1: Street address 2:

City: County: State: ZIP:

CDC Supplemental COVID-19 Vaccine Redistribution Agreement

Primary point of contact responsible for receipt of COVID-19 vaccine
(if different than medical director listed above)

Last name: First name: Middle initial:

Telephone number: Email:

Secondary point of contact for receipt of COVID-19 vaccine

Last name: First name: Middle initial:

Telephone number: Email:

COVID-19 vaccination organization redistribution agreement requirements

To redistribute COVID-19 vaccine, constituent products, and ancillary supplies to secondary sites, this organization agrees to:

1. Sign and comply with all conditions as outlined in the CDC COVID-19 Vaccination Program Provider Agreement.
2. Ensure secondary locations receiving redistributed COVID-19 vaccine, constituent products, or ancillary supplies also sign and comply with all conditions in the CDC COVID-19 Vaccination Program Provider Agreement.
3. Comply with vaccine manufacturer instructions on cold chain management and CDC guidance in CDC's *Vaccine Storage and Handling Toolkit*, which will be updated to include specific information related to COVID-19 vaccine, for any redistribution of COVID-19 vaccine to secondary locations.
4. Document and make available any rrecords of COVID-19 vaccine redistribution to secondary sites to jurisdiction's immunization program as requested, including dates and times of redistribution, sending and receiving locations, lot numbers, expiration dates, and numbers of doses.
   Neither CDC nor state, local, or territorial health departments are responsible for any costs of redistribution or equipment to support redistribution efforts.

By signing this form, I understand this is an agreement between my Organization and CDC, implemented and maintained by my jurisdiction's immunization program. I also certify on behalf of myself, my medical practice, or other legal entity with staff authorized to administer vaccines, and all the practitioners, nurses, and others associated with this Organization that I have read and agree to the COVID-19 vaccine redistribution agreement requirements listed above and understand my Organization and I are accountable for compliance with these requirements. Non-compliance with the terms of this Redistribution Agreement may result in suspension or termination from the CDC COVID-19 Vaccination Program and criminal and civil penalties under federal law, including but not limited to the False Claims Act, 31 U.S.C. § 3729 et seq., and other related federal laws, 18 U.S.C. §§ 1001, 1035, 1347, 1349.

Organization Medical Director (or equivalent)

Last name: First name: Middle initial:

Signature: Date:

Chief Executive Officer (chief fiduciary role)

Last name: First name: Middle initial:

Signature: Date:

[1] *Requirements incorporated by reference; refer to* www.cdc.gov/vaccines/hcp/admin/storage-handling.html.

SUBMIT FORM