Guidance and Standing Orders for New Hampshire State-Managed COVID-19 Vaccination Clinics

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New Hampshire Department of Health & Human Services

Division of Public Health Services

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STATE OF NEW HAMPSHIRE

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Interim Guidance for NH State-Managed COVID-19 Vaccination Clinics

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The Regional Public Health Networks (RPHN) and NH National Guard will support the New Hampshire Department of Health and Human Services (DHHS) to vaccinate residents of New Hampshire with the new Coronavirus Disease 2019 (COVID-19) vaccines. In the early phases of vaccine availability, limited vaccine will be targeted to health workers and people at highest risk of severe COVID-19; as vaccine becomes more readily available mass vaccination of the public will be required. This guidance is intended for NH State-managed COVID-19 vaccination clinics and must be followed by clinics and vaccinators operating under the medical direction and standing orders from the State of NH. Other organizations can adopt this guidance and/or modify to fit local organizational context and policies as appropriate.

This guidance will be updated as new information and resources become available, including as new vaccines become available for use under a Food and Drug Administrations (FDA) Emergency Use Authorization (EUA), and after the U.S. Centers for Disease Control and Prevention (CDC) and their Advisory Committee on Immunization Practices (ACIP) provides medical recommendations for appropriate use of the vaccines.

If questions or issues arise during vaccine clinic operations, staff of RPHN vaccination clinics should contact the NH DHHS Immunization Program at 603-271-4482 (during normal business hours). Any vaccine clinic issues that arise after hours should be directed to the public health nurse at 603-271-5300, and ask for the public health nurse on-call.

General Guidance:

Review CDC's Infection Control Guidance for Healthcare Professionals

All persons involved in handling, preparing or administering COVID-19 vaccine must read and be familiar with these NH COVID-19 vaccine clinic protocols and standing orders, and the following manufacturer-specific COVID-19 vaccine fact sheets from the FDA:

- **Pfizer-BioNTech vaccine for persons 5-11 years of age: Fact Sheet for Healthcare Providers Administering Vaccine**

- **Pfizer-BioNTech vaccine for persons 12 years of age or older: Fact Sheet for Healthcare Providers Administering Vaccine**
- **Moderna vaccine: Fact Sheet for Healthcare Providers Administering Vaccine**
- **Janssen vaccine: Fact Sheet for Healthcare Providers Administering Vaccine**

Review CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States

All persons involved in handling, preparing or administering COVID-19 vaccines must have been provided and reviewed vaccination training material developed by the NH Department or Health and Human Services, or a comparable/equivalent training.

Face Mask Use:

- All healthcare providers and staff supporting the COVID-19 vaccination clinic must wear a surgical face mask over their nose and mouth at all times when within the vaccination clinic facility (including in breakrooms and other indoor spaces where they might encounter co-workers), when entering a facility or person's home, and when outdoors and around other people.
    - Staff should be given routine mask breaks as needed (ideally outside if weather permits) where staff are separated from others and can safely remove (and store) their face mask.
    - Staff must sanitize hands before and after removing and putting on face masks.
    - Avoid touching face or adjust face covering without first sanitizing hands. After touching a person's face or adjusting face coverings, hands must again be sanitized.
- All vaccine recipients (VRs) and visitors to a COVID-19 vaccination clinic who are 2 years of age and older must wear a face mask or cloth face covering over their nose and mouth when within the vaccination facility or outdoors and around other people, unless there is a valid medical or developmental reason a child or adult cannot wear a face mask (per CDC guidance), or if a young child is unable to be compliant with face mask use even after parents/guardians and staff work to gain compliance.
- Even if a mobile vaccine clinic is operating in another facility that doesn't require face masks (e.g., a school or workplace), all staff, VRs, and visitors should wear face masks to enter the clinic area, per guidance above. The vaccination clinic is considered a medical clinic and must follow this guidance and all best medical and public health practices.

Personal Protective Equipment (PPE) During a Vaccine Recipient (VR) Care Encounter:

- During VR encounters, or when interacting with members of the public, vaccination clinic staff should wear appropriate PPE, including the following:
    - Surgical face mask

    - Eye protection: face shield (preferred) or googles (note: eye protection is optional for vaccinators operating in areas that have a low or moderate level of Community transmission of COVID-19, but should be worn in areas of "substantial" community transmission)
    - Gloves are optional for healthcare workers delivering vaccine
- Staff going into a long-term care facility (LTCF) experiencing an outbreak or with concern for facility transmission must follow the facility's PPE guidance and infection control procedures.
- The above specified articles of PPE should be appropriately donned and doffed (put on and taken off) per CDC guidance on using PPE.
- Masks and face shields can be re-used between VRs at fixed site (non-mobile) vaccination clinics as long as they are not contaminated; gloves should be changed in-between VRs.
    - Masks should be discarded, at a minimum, at the end of each shift, or if the mask becomes saturated or soiled.
    - Face shields and goggles can be re-used and should be cleaned and disinfected at the end of each shift, or if they become soiled/contaminated; gloves should be used when cleaning and disinfecting (see cleaning and disinfection guidance below).
- For mobile clinics, or teams traveling going between facilities or households, vaccinators and staff must doff all PPE between vaccination sites – disposable masks and eye protection should be discarded after use at each vaccination site; reusable eye protection (i.e. face shield or goggles) must be cleaned and disinfected at a minimum after use at each site before traveling to the next site where clean PPE should be put on.
- Healthcare workers should practice hand hygiene immediately before AND after each VR care encounter.

Hand Hygiene:

- Alcohol-based hand sanitizer should be made readily available at the walk-in facility entrances, exists, throughout the facility, and at points of vaccination. Drive-thru clinics should also have alcohol-based hand sanitizer readily available, especially at points of vaccination for use by staff. Mobile vaccination teams should carry portable containers of alcohol-based hand sanitizer.
- All staff, visitors, and VRs should be asked to practice hand hygiene upon entry to the facility and upon exiting (even for drive-thru clinics). All household members should be asked to practice hand hygiene before a mobile vaccination team enters a household.
- All healthcare personnel delivering vaccination must practice hand hygiene immediately before and after vaccinating each person.
- All staff should frequently perform hygiene throughout the day, including before and after taking a break or eating, before and after restroom use, etc.

Maintaining Social Distancing:

- Limit and monitor points of entry to the facility.
- Drive through vaccine clinics should have personnel managing traffic flow and ensure roads and entrances/exits are not blocked. VRs and visitors to drive-thru clinics should not get out of their vehicles.
- Limit/avoid unnecessary visitors; each child/minor should be accompanied by a single parent/guardian, for example, unless others in a family are being vaccinated.
- Assign a person (e.g., a safety officer) to monitor compliance with face mask use, social distancing, clinic flow, etc.
- Maintain a unidirectional flow through the facility so people are entering and exiting through different locations to avoid close contact between VRs and visitors.
- Avoid close physical contact between staff, visitors, and VRs (i.e., avoid people coming within 6 feet of each other) unless delivering vaccine to a VR.
- Check-in and check-out process should avoid physical or prolonged close contact between VRs/visitors and staff. Consider a physical barrier (e.g., a plastic partition or barrier) at check-in/check-out separating staff and VRs, if feasible (more applicable to walk-in clinics).
- Any waiting areas at walk-in clinics should have seating for VRs and visitors spaced 6 feet or more apart. Drive-thru clinics should have people waiting in cars.
- Waiting lines should have clearly demarcated spacing for people to stand/wait 6 feet or more apart.
- Multiple vaccine delivery areas should have appropriate spacing between areas to ensure that staff, VRs, and visitors in one area are not in close contact to people in another vaccination area.
- Mobile clinics going into a household (e.g., vaccinating a homebound person) should request that a minimum number of people be present in the household at the time of vaccination as is necessary to support vaccination of an individual in order to limit close contacts.

Screening for fever, symptoms, and risk factors for COVID-19:

- Each staff member must have their temperature taken and be screened for symptoms of COVID-19, recent diagnosis of active SARS-CoV-2 infection (the novel coronavirus that causes COVID-19), and risk factors for COVID-19 prior to each shift/clinic (see screening questions below) – temperatures and responses to questions do not need to be documented or recorded
- Each VR and visitor entering a clinic (including drive thru clinics), or any household contact present for vaccination of a homebound individual should have their temperature taken and be screened for symptoms of COVID-19, recent diagnosis of active SARS-CoV-2 infection (the novel coronavirus that causes COVID-19), and risk factors for COVID-19 immediately prior, or upon entry, to the facility (see screening

questions below); temperatures and responses to questions do not need to be documented or recorded.

- Staff, VRs, visitors, and household contacts who screen positive for any new or unexplained symptoms of COVID-19, have recently been diagnosed with COVID-19 in the prior 10 days, or who report household contact to a person with COVID-19 in the prior 5 days requiring quarantine* should not be allowed into the vaccination facility, or a mobile team should not enter that person's household.

  * People who previously tested positive for COVID-19 by PCR or antigen testing in the 90 days prior to an exposure, or who are up to date on all recommended vaccine doses (including booster doses) at the time of an exposure are not required to quarantine. These persons can be allowed into vaccination clinics as long as they remain asymptomatic and wear a face mask.

- Anybody with new or unexplained symptoms of COVID-19 (including fever of 100.4°F or higher) should be instructed to contact their healthcare provider for COVID-19 testing, or seek out COVID-19 testing any one of the many options for testing around the State.
- All staff, VRs, visitors, and household contacts should have their temperature taken with a touchless thermometer prior to entry to the facility (or prior to a vaccination team entering a person's home) and be asked the following screening questions (people can be asked verbally, or provided the questions in writing and asked to identify any "yes" or affirmative answers to the screening questions):
  - Do you have any symptoms of COVID-19 that are new for you, including:
    - Fever, chills, or feeling feverish;
    - Respiratory symptoms such as runny nose, nasal congestion, sore throat, cough, or shortness of breath;
    - General body symptoms such as muscle aches or severe fatigue;
    - Nausea, vomiting, or diarrhea, or
    - Changes in your sense of taste or smell?
  - Have you recently tested positive for, or been diagnosed with, active COVID-19 in the prior 10 days?
  - Has anyone in your household recently tested positive for COVID-19 that you have been in close contact with in the prior 5 days?

Cleaning and Disinfection:

- Review CDC's cleaning and disinfection guidance under their Infection Prevention and Control Recommendations for Healthcare Personnel (see "Environmental Infection Control" section), and general community Cleaning and Disinfecting guidance.
- Commonly touched surfaces should be routinely cleaned and disinfected.
- Shared tools and equipment, especially shared non-disposable medical equipment used during VR care, must be cleaned and disinfected according to manufacturer's instructions between each VR use.

- Use an EPA-approved disinfectant effective against the novel SARS-CoV-2 coronavirus (EPA List N disinfectant).
- Use disposable gloves to clean and disinfect.
- Follow manufacturer instructions on PPE use, and application and contact time needed for disinfectant.

Building Ventilation (if applicable):

- Building ventilation systems should be evaluated to increase room and overall building ventilation to the extent possible. This includes increasing the number of air exchanges, increasing outdoor air ventilation, limiting internal air circulation, and improving central air filtration. Ventilation systems' filters must be routinely replaced and other necessary maintenance should be performed as needed.

Messaging and Communication:

- All healthcare workers and supporting staff and volunteers should be informed and educated about the infection control and COVID-19 mitigation measures outlined in this and other supporting guidance documentation.
- VRs and visitors should also be informed (e.g., through use of signage) that they should not enter the facility if they have any new or unexplained symptoms of COVID-19, have traveled internationally or on a cruise ship in the prior 10 days, or been in close contact to someone with COVID-19 in their household in the prior 10 days (unless the person is not required to quarantine after travel or an exposure to COVID-19 due to previous infection or being fully vaccinated – see above).
- VRs, visitors, and household contacts should be instructed to wear a face mask, practice hand hygiene, and socially distance upon entering the facility, or when a mobile vaccination team enters a person's home.

Environmental Safety:

- Clinic managers and safety officers should ensure walkways and drive-up areas are safe and free of ice and snow to prevent slips and falls.
- Vaccination areas in outdoor drive-thru clinics should have space where staff can shelter from weather in a safe, socially-distanced space, and also provide a warm space for breaks and snack/lunch if needed due to cold weather.
- In the case of unsafe inclement weather (e.g., snow storm or Nor'easter), clinics should have plans for cancelling and re-scheduling VRs and have a plan/process in place for notification of staff.

Vaccination Clinic Work-Flow:

- Recommendations for COVID-19 vaccination are increasingly complicated. All clinics must develop work-flows with quality assurance checks to ensure that eligible vaccine

recipients (VR) are receiving the right COVID-19 vaccine product, at the right time interval, for the appropriate indication, and with the right vaccine dose. COVID-19 vaccination clinics should identify VRs early in the process (e.g., at registration) who are presenting for the following reasons, to ensure the VR is connected with the appropriate COVID-19 vaccine formulation and dose:

- Primary vaccination series (i.e., 2-dose Pfizer-BioNTech or Moderna COVID-19 vaccine series, or 1-dose J&J Janssen COVID-19 vaccine) – the specific vaccine product that is able to be administered will depend on the age of the VR. The Pfizer-BioNTech COVID-19 vaccine now comes in two different formulations (a "pediatric vaccine" for VRs 5-11 years of age, and another for VRs 12 years of age and older). Because VRs 5-11 years of age require a lower dose, clinics should develop processes to ensure the right vaccine product at the right dosage is administered based on the age of the VR.
- 3rd additional primary series vaccine dose for VRs who are moderately to severely immunocompromised – this 3rd dose is only allowable for people who got their primary series with the Pfizer-BioNTech or Moderna COVID-19 vaccines AND who are 5 years of age or older (for receipt of the Pfizer-BioNTech vaccine), or 18 years of age or older (for receipt of the Moderna vaccine). Third doses should be administered at least **28 days** after completion of the initial 2-dose mRNA COVID-19 primary vaccine series.
- Booster dose for people who got their primary series with the Pfizer-BioNTech, Moderna, or Janssen COVID-19 vaccines. Guidance on the timing of booster dose administration is based on which vaccine the VR received for their primary vaccine series. VRs must be 12 years of age or older to receive a booster dose. For VR's 18 years of age or older, any of the COVID-19 vaccines can be used for booster doses regardless of the vaccine product used for a VR's primary vaccination. For VR's 12-17 years of age, only the Pfizer-BioNTech COVID-19 vaccine can be used.

- The mRNA COVID-19 vaccines (i.e., Pfizer-BioNTech or Moderna) are preferred and recommended over the J&J Janssen vaccine. Therefore, the Pfizer-BioNTech and Moderna vaccines should preferentially be made available and offered to all VRs both for primary series vaccination, and as a booster dose (regardless of which vaccine product a VR received for their primary series). The J&J Janssen vaccine can still be administered if a person has a contraindication to receipt of an mRNA COVID-19 vaccine, or if the VR wants/requests the J&J Janssen vaccine, but they must be informed of the rare but serious risk of Thrombosis with Thrombocytopenia Syndrome (TTS) associated with the vaccine (see FDA Fact Sheet, Vaccinator Checklist, and standing orders below for more information).

- Pre-Registration: If possible, vaccine recipients (VR) should be provide the necessary documents listed below* so the VR has a chance to review before their vaccine appointment.

  * Documents that need to be provided to all VR's BEFORE vaccination include:
    - NH DHHS Notice of Privacy Practices
    - NH DHHS general consent for treatment/vaccination (unless VR already consented during online registration) – which must be signed before vaccination
    - FDA COVID-19 vaccine "Fact Sheet for Recipients and Caregivers" (provide the specific fact sheet for the vaccine that will be administered):
      - Pfizer-BioNTech vaccine for people **5-11 years of age**: Fact Sheet for Recipients and Caregivers (for other language translations of the Fact Sheet, see the FDA website)
      - Pfizer-BioNTech vaccine for people **12 years of age or older**: Fact Sheet for Recipients and Caregivers (for other language translations of the Fact Sheet, see the FDA website)
      - Moderna vaccine: Fact Sheet for Recipients and Caregivers (for other language translations of the Fact Sheet, see the FDA website)
      - Janssen vaccine: Fact Sheet for Recipients and Caregivers (for other language translations of the Fact Sheet, see the FDA website)
    - V-safe information sheet that contains background on the v-safe program and instructions for enrolling; V-safe is a new smartphone-based tool that uses text messaging and web surveys to check-in with vaccinated individuals to monitor for adverse events after a COVID-19 vaccination.

- Entry Screening: Before entry into the COVID-19 vaccination clinic, staff should take the temperature of all VRs and visitors using a touchless thermometer, and ask (or provide in writing) the screening questions above, to which the VR and visitors should provide an answer.

- Registration: Direct VRs to the registration area where the following should occur:
  - If VR has pre-registered and has a vaccination appointment, then registration staff verify VR's identity based on at least 2 personal identifiers (e.g., name and date of birth), verify the VR's information in the Vaccine Management System (VMS), and "check-in" the VR. If VR has NOT pre-registered, then staff registers VR on-site in the VMS (it is recommended that fixed-vaccination sites require pre-registration).
  - Ensure all VR demographic and contact information is entered and accurate in VMS, including name, date of birth, phone number, and mailing address. This is important in case VR needs to be contacted after the appointment.

- Identify and verify whether the VR is being vaccinated for the first time or is presenting for an additional dose:
  - Ask if the VR has previously been vaccinated with a COVID-19 vaccine.
  - If previously vaccinated:
    - Ask which vaccine product was used in the past and what dose number they are seeking at the current clinic visit (i.e., second, third, or fourth dose).
    - Verify past vaccination in the VMS and/or using the VR's "COVID-19 Vaccine Record Card".
  - If the VR requires a specific formulation of the vaccine, then alert the vaccinator about the specific vaccine product requirement – this "alert" can be verbal, electronic in the VMS, or using a visual signal (e.g., a color-coded card), but whatever process is developed the staff should be trained and the process should be consistent.
  - Provide the VR (or the parent/guardian of VRs 5-17 years of age) the age-appropriate Pre-Vaccination Medical Screening Questionnaire (there is a general questionnaire for all ages, and a separate questionnaire specifically for VRs 5-17 years of age to be implemented during school-based vaccination clinics that are administering only the Pfizer-BioNTech vaccine). If the questionnaire "General Pre-Vaccination Screening Questions for All Ages" is used, then check the box on the form for the VR highlighting the "COVID-19 Vaccine Being Administered" and ensure the VR has access to the appropriate FDA Fact Sheet.
- Provide necessary documents outlined above*****, if not already provided.
- If the VR (or the VR's parent or guardian) has not been given or not reviewed the above information before the clinic, staff should direct the VR to a waiting area to review the provided information before vaccination. After reviewing the information, if the VR elects not to be vaccinated, registration staff should cancel the clinic appointment.
- If VR elects vaccination, staff should direct the VR to the vaccination area where the vaccinator identifies the VR in the "Manage Appointments" section of the VMS.

- Pre-Vaccination: Vaccinator should 1) verify the VR's identify using at least 2 personal identifiers (e.g., name and date of birth), 2) verify whether the VR is being vaccinated for the first time or presenting for an additional COVID-19 vaccine dose, 3) identify the appropriate vaccine formulation to be administered, 4) review information entered into the Medical Screening Questionnaire with the VR, and 5) follow the directions in the vaccinator's checklist and COVID-19 vaccine standing orders to screen/review for any contraindications, precautions or other health conditions, and to ensure the VR receives the appropriate vaccine.

- 3rd additional primary series dose for people who are moderately or severely immunocompromised: People seeking a 3rd primary series dose of the Pfizer-BioNTech or Moderna COVID-19 vaccines are able to self-attest that they qualify for a 3rd dose by reviewing and signing the form "Third Dose Vaccine Administration for People Who Are Immunocompromised"; vaccinator should also document self-attestation in VMS.
    - This signed form needs to be saved and securely sent to the Immunization Program at the NH Division of Public Health Services (DPHS) for storage and record keeping.
- Age Eligibility, and Consent for Minors and Persons Who Lack Decision Making Capacity:
    - Vaccinator should verify VR's age.
    - All VRs (regardless of age) should have received and completed a general NH DHHS Consent for Treatment/Vaccination form either through the online registration process or have been given a paper-based consent form at the clinic.
    - If VR is 5 – 17 years of age, they can only currently be given the Pfizer-BioNTech vaccine (there are different Pfizer-BioNTech formulations based on age of VR), and need to also have either 1) a parent/guardian present who is able to fill out the appropriate Medical Screening Questionnaire and give verbal consent to vaccination which is then documented in the VMS, or 2) the Medical Screening Questionnaire and "Consent to Administer the COVID-19 Vaccine to a Person Under the Age of 18 Years" form (i.e., "medical consent form") needs to be filled out and signed by the VR's parent or legal guardian (note: this vaccination consent form is in addition to the NH DHHS general Consent for Treatment/Vaccination), and brought with the VR at the time of vaccine administration (note: this is most applicable to vaccination of minors at dedicated clinics, such as at schools). A new signed (and dated) medical consent form for persons under the age of 18 years and Medical Screening Questionnaire is needed for any new vaccine dose administration (e.g., if a VR receives a 2-dose series at a school-based clinic, then two separate signed consent forms are needed, one before each dose administered). Any signed consent forms and Medical Screening Questionnaires need to be sent to the Immunization Section at the NH Division of Public Health Services for storage and record keeping. Emancipated minors do not require the consent of a parent or legal guardian, but documentation is needed when an unaccompanied minor states they are emancipated.

        - If a medical consent form for persons under the age of 18 years is used for a vaccination clinic dedicated to vaccinating people under the age of 18 (e.g., a school-based clinic), the clinic needs to develop a process by which the parent or legal guardian of the minors being vaccinated are provided with the necessary documentation to review BEFORE filling out, signing and returning the consent form and Medical Screening Questionnaire.
        - If a VR is 18 years of age or older but lacks decision making capacity and cannot legally consent to vaccination, then the VR must be accompanied by their medical decision maker (e.g., a legal guardian) to give verbal consent to vaccination, which should then be documented in the VMS. Alternatively, if the vaccination is taking place at a long-term care facility the facility should gain consent and provide the vaccinator with proof of consent, which should then be documented in the VMS; the Medical Screening Questionnaire also needs to be completed.
    - Check for Contraindications, Precautions, or other health conditions requiring follow-up: review information entered into the Medical Screening Questionnaire with the VR, and use the vaccinator's checklist to screen/review for any contraindications or precautions to vaccination and to identify other health conditions that may require further attention or follow-up.
        - Also review any prior vaccination encounters in the VMS to ensure no adverse/allergic reactions occurred after the previous dose that would be a contraindication to vaccination with an additional dose, or require additional monitoring or precautions.

- Vaccination: If no contraindications, administer the appropriate COVID-19 vaccine per standing order protocols (see attached protocols) using safe vaccination and infection prevention technique.
    - Vaccinators should follow General Best Practice Guidelines for Vaccine Administration.
    - Sharps and syringes should be appropriately disposed of in a sharps container immediately after vaccination.
    - Sharps containers should be monitored and replaced when nearing capacity to prevent needle sticks when disposing of sharps.
    - Vaccination should occur while a VR is seated or lying down to prevent falling or syncope injuries.
    - "Log Vaccination" and enter the necessary information in the "Vaccine Administration" section of the VMS.
    - Document that the Medical Screening Questionnaire was completed and reviewed prior to vaccination and that no contraindications to vaccination were

noted. Also document any consent form or verbal consent obtained from parents/guardians for VRs 5-17 years of age.

- Post-Vaccination:
  - Schedule follow-up, if applicable.
  - Provide the following documents to all VR's AFTER vaccination:
    - The "After Visit Summary (AVS) Recommendations for Vaccine Recipients" (note: this can also be provided with the information packet provided prior to vaccination if easier to implement into clinic flow).
    - "COVID-19 Vaccine Record Card" documenting the following:
      - VR's name and date of birth
      - Vaccine clinic site
      - Vaccine manufacturer and lot number
      - Date of vaccination
      - Second dose due date (if applicable)
  - Encourage VRs to enroll in CDC's v-safe monitoring system.
  - Educate the VR that they should expect some side effects from the vaccine in the following few days (refer VR to the "After Visit Summary"), and instruct the VR to contact their primary care provider if they experience any concerning adverse reactions after leaving the vaccine clinic. If a VR doesn't have a primary care provider, they should seek medical care at a local urgent care or emergency department if they have any concerning signs/symptoms after vaccination, or call 9-1-1 for serious life-threatening symptoms or reactions (e.g., chest pains, difficulty breathing, face or throat swelling, confusion, body rash or hives, etc.).
  - Observation: Direct the VR to wait in an observation area for at least 15 minutes after vaccination to ensure there are no immediate serious adverse vaccine reactions (e.g., anaphylaxis) – it is not mandatory that someone wait 15 minutes, but it is strongly recommended. Persons with a history of a severe allergic reaction (e.g., anaphylaxis) due to any cause, a history of a non-severe immediate (i.e., onset less than 4 hours) allergic reaction after a previous dose of a COVID-19 vaccine, or a history of any immediate allergic reaction of any severity to other non-COVID-19 vaccines or injectable medication therapies that does not meet criteria as a contraindication should be instructed to wait for 30 minutes after vaccination.
    - Waiting areas should be large rooms (for walk-in clinics) with seating spaced more than 6 feet apart, and everybody must wear masks.
    - VRs should be seated or lying down during the observation period to decrease the risk for injury should they faint.
    - For drive-thru clinics, waiting areas should have enough space for cars to park spaced apart so that someone can walk up to a window to check on

the person without coming within 6 feet of another vehicle (e.g., space waiting vehicles so that every-other space is empty).
    - Clinic staff should monitor the waiting area wearing appropriate PPE and periodically check on VRs.
    - For vaccination of homebound persons, mobile vaccination teams should identify an area within the home where the VR can be safely observed for the appropriate time frame while the vaccination staff maintains appropriate social distance from the VR and other household members (while continuing to wear appropriate PPE).
  - Manage and Report Adverse Reactions or Events:
    - Any adverse vaccine reactions should be managed according to the "Medical Management of Vaccine Reactions" protocols.
    - Adverse events should be reported to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 or online at https://vaers.hhs.gov/reportevent.html.
    - Any adverse reactions after vaccination should also be documented in the VMS free-text field.

Additional Considerations for Vaccinating Children Under the Age of 18 Years:

The additional guidance should be considered when developing clinic plans for vaccinating younger pediatric VRs who may need more privacy and/or emotional and social support during the vaccination process. Many pediatric VRs may be able to be vaccinated through the normal process, but plans should be in place for those who need additional support.

- Identify vaccinators who are comfortable and/or have experiencing vaccinating younger children.
- Consider having increased clinical staff on-site when vaccinating larger numbers of pediatric VRs in case some VRs require additional vaccination support.
- Make clinic dates/times available for vaccinating pediatric VRs that allow access after school and/or on weekends.
- Consider dedicated pediatric vaccination clinics, or have areas for vaccinating pediatric VRs that are separate from the general adult vaccination locations for those pediatric VRs that are needle-phobic or need additional support; this could involve deployment of screens or barriers between vaccination stations for more privacy.
- A supporting parent/guardian should be requested accompany a pediatric VR at fixed-site locations, especially for those who have difficulty receiving vaccinations (not necessary for school-based targeted vaccination clinics).
- If a pediatric VR is having difficulty accepting COVID-19 vaccination, and the vaccinator and parent/guardian are unable to get voluntary compliance, then the vaccinator and

clinic staff can make the decision to decline vaccination and recommend vaccination in a more suitable healthcare setting.

Additional Guidance for School-Based Vaccination Clinics:

School-based COVID-19 vaccination clinics will be logistically more complicated to implement than school-based influenza vaccination clinics because of the need for increased medical screening, delivery of a multi-dose vaccine series, increased paperwork and information that needs to be shared with parents/guardians before vaccination, the need to consent children and adolescents before each vaccine dose administration, and the different vaccine formulations and doses that will need to be administered based on the age of the VR. All of these factors increase the chance for medical errors, so there needs to be close attention to clinic processes and to verify a VR's identity, personal health information, consent forms, and eligibility before vaccination. Below is additional guidance for conducting school-based clinics when a parent or guardian is NOT in attendance.

- A new signed/dated (and filled out) medical consent form for persons under the age of 18 years is needed before each new vaccine dose administration.
- A "Medical Screening Questions for Persons 5-17 Years of Age" form needs to be filled out and signed by a parent or legal guardian before each new vaccine dose administration.
- The Medical Screening Questionnaire should be used to screen children for any serious adverse reactions or side effects that might have occurred after a prior dose. The vaccinator should also verify and inquire of the VR whether they had any serious adverse side effects after a prior dose of the vaccine. If a parent/guardian reports on the consent form that their child did experience serious/severe side effects or allergic reactions after an earlier vaccine dose, then the vaccinator should seek additional information from the parent/guardian to clarify (if needed), or decline vaccination if it is not medically appropriate.
- For VRs who are 5 years of age or older who are seeking a 3rd additional dose because they are moderate-severely immunocompromised, in addition to the consent form, the form "Third Dose Vaccine Administration for People who are Immunocompromised" also needs to be filled out, signed, and returned with the consent form prior to dose #3 administration.
- The following documents should be sent to the parent/guardian of the pediatric VR **BEFORE** the vaccine clinic with clear instructions on the purpose of each form, which forms need to be reviewed before vaccination, and which forms need to be signed, dated, and returned before vaccination can occur:
    - NH DHHS Notice of Privacy Practices

- NH DHHS general consent for treatment/vaccination (unless VR already consented during online registration) – which must be signed before vaccination
- Age-appropriate Pfizer-BioNTech FDA "Fact Sheet for Recipients and Caregivers":
  - For children 5-11 years of age being vaccinated with the Pfizer-BioNTech COVID-19 pediatric vaccine, review this Fact Sheet for Recipients and Caregivers
  - For children and adolescents 12 years of age or older being vaccinated with the Pfizer-BioNTech COVID-19 vaccine, review this Fact Sheet for Recipients and Caregivers
- The "Consent to Administer COVID-19 Vaccine to a Person Under the Age of 18 Years" needs to be reviewed, filled out, signed, dated, and returned prior to each vaccine administration
- The form "Medical Screening Questions for Persons 5-17 Years of Age" which needs to be filled out, signed, dated, and returned prior to each vaccine administration.
- Attestation form for people who are seeking a 3rd vaccine dose because they are moderately-severely immunocompromised ("Third Dose Vaccine Administration for People Who are Immunocompromised") – this form only needs to be reviewed, filled out, signed, dated, and returned if a vaccine recipient is 5 years of age or older AND is seeking a 3rd vaccine dose because they are moderately-severely immunocompromised
- V-safe information sheet that contains background on the v-safe program and instructions for enrolling (people should enroll in this after they are vaccinated).
- The "After Visit Summary (AVS) Recommendations for Vaccine Recipients" – this contains information for parents/guardians after their child is vaccinated

- Develop a process where each VR presenting to a school-based vaccination clinic is verified to have an appropriately filled out and signed the necessary consent forms and Medical Screening Questionnaire before vaccination. This is important to ensure that a child is not given the vaccine if there is not consent to do so, and to ensure vaccine is not given to a child who had a severe/serious adverse event or allergic reaction after an earlier dose.

- A medical consent form for persons under the age of 18 years and a Medical Screening Questionnaire should be completely filled out before each dose. If there is needed information that is missing, then the vaccinator can attempt to contact the parent/guardian (see phone number listed on the consent form or in the VMS) to clarify medical information, but if parent/guardian is unable to be reached then vaccination should be declined, and the parent/guardian should be contacted after the vaccination clinic and informed as to the reason for declining vaccination.

- Document any conversations or discussions with a parent/guardian in the VMS.

- Document in VMS that the consent form and the Medical Screening Questionnaire were received, complete, reviewed and that and no medical contraindications were noted prior to vaccination.

To give parents/guardians the option of being in attendance during vaccination (which will also be logistically easier to implement), community-based pediatric COVID-19 vaccination clinics should be strongly considered during after-school hours or during evening/weekend times in addition to school-based clinics (which occur during the school day). If a RPHN has additional capacity to conduct vaccination clinics, community-based pediatric clinics should be prioritized over community/facility-specific booster clinics.

Additional Guidance for Vaccination Clinics in Long-Term Care Facilities:

- See recommendations below on "COVID-19 Testing for Vaccinators and COVID-19 Vaccine Clinic Staff Entering Long-Term Care and Assisted Living Facilities"
- In order to efficiently provide COVID-19 vaccination to long-term care facility (LTCF) or assisted living facility (ALF) residents, the required information and documents outlined above should be provided prior to a scheduled vaccination clinic, and at least verbal agreement (assent) should be obtained prior to the date of the clinic. LTCFs/ALFs should assist in sharing of information and obtaining consent for vaccination.
- Prior to a scheduled clinic, LTCFs/ALFs should provide the vaccination clinic staff the list of residents who have agreed, or whose legal surrogates have agreed, to vaccination, and should indicate this on the provided vaccination list. Provide this list by secure fax or e-mail to the appropriate Regional Public Health Network contact.
- The LTCFs/ALFs should document in the resident's chart or medical record that the required information was provided to residents or healthcare powers of attorney, and that consent was obtained prior to vaccination.

COVID-19 Testing for Vaccinators and COVID-19 Vaccine Clinic Staff Entering Long-Term Care and Assisted Living Facilities (LTCFs and ALFs):

The guidance below apply to any vaccinator or staff associated with a State-Managed COVID-19 Vaccination Clinic entering a long-term care facility (LTCF) or Assisted Living Facility (ALF) for the purpose of administering the COVID-19 vaccine to staff and/or residents.

NH State-Managed COVID-19 Vaccination Clinic staff and vaccinators are reasonably considered "facility staff" because of their role vaccinating LTCF residents and staff and should be tested for COVID-19 per CMS guidance, and if required by CMS or the facility, before entering a LTCF/ALF. If testing is not required by a facility or by CMS, then a fully vaccinated person (a person who has received all doses of a recommended COVID-19 vaccine regimen and is at least 14 days beyond receipt of the last dose) is not required to undergo testing by NH DHHS before entering a facility to conduct COVID-19 vaccination:

- Specimen collection to test for active SARS-CoV-2 infection should occur in the week before a person enters a LTCF/ALF, ideally within 3 days before the vaccination clinic/event, and results should be back before the vaccination clinic occurs.
- For staff that are regularly going into LTCFs/ALFs on a weekly basis, testing should be routine and recurring based on CMS guidance.
- Testing should preferentially occur with PCR-based testing due to increased sensitivity and likely lower false-positive rate; however, if PCR testing is not immediately available, antigen testing can be considered if the only options are to not vaccinate (or delay vaccination), or not test staff for COVID-19.
    - For first responders taking part in the First Responder Optional Screening Testing (FROST) program, weekly antigen testing is acceptable to meet the LTCF/ALF vaccination clinic testing requirement.
    - When antigen testing is used, a positive antigen test in an asymptomatic person needs to be confirmed immediately with a PCR-based test, per NH DPHS guidance.
- Regardless of any recent negative PCR- or antigen-based test, any staff identified as symptomatic with new or unexplained symptoms of COVID-19 should immediately isolate, be excluded from entering any facility, and tested for COVID-19.

Additional Guidance for Vaccination of Homebound Persons:

Mobile COVID-19 vaccination teams may be required to vaccinate homebound individuals. Vaccinators and staff conducting mobile vaccination clinics for homebound persons must review and follow CDC's guidance for vaccinating homebound persons with COVID-19 vaccine, and must also review and apply the guidance in these documents and standing orders to vaccinating homebound individuals, including the following additional guidance:

- Vaccinations teams that are moving from home-to-home to vaccinate homebound individuals must plan out their routes ahead of time, including estimating time intervals of travel between vaccinations, to ensure the appropriate number of vaccine doses are available, vaccine is stored and transported at necessary temperatures, and that the vaccine is used in the necessary time period to avoid vaccine wastage.
- To efficiently vaccinate homebound individuals, the required information and documents outlined above should be provided prior to a scheduled vaccination clinic, and consent should be obtained from the vaccine recipient or guardian and documented in VMS.
- Per CDC guidance and best immunization practice, vaccine should ideally be transported in vials and not in pre-drawn syringes; vaccination teams should plan route and schedules with this in mind. However, there may be instances when the only option is to transport vaccine in a pre-drawn syringe, which can be considered in certain situations, but vaccination teams must follow the guidance for transporting pre-drawn vaccine in

syringes found in the COVID-19 Vaccine Handling Toolkit: Operational Considerations for Healthcare Practitioners; this includes appropriate labeling of containers transporting pre-drawn syringes, and labeling of each individual pre-drawn syringe. Transporting pre-drawn syringes, however, should NOT be considered routine practice due to increased risk of administration errors.

- Before the vaccination team enters a person's home, everybody present in the home should be screened for fever, symptoms or risk factors for COVID-19 per guidance in the section above "Screening for fever, symptoms, and risk factors for COVID-19".
- Vaccination teams should request ahead of time that the minimum number of people be present in the household at the time of vaccination as is necessary to support vaccination of a homebound person.
- Everybody in the house should be asked to practice hand hygiene and everybody 2 years of age and older should wear a face mask over their nose and mouth before the vaccination team enters the home.
- Vaccination teams must develop a process for appropriate monitoring of the VR after vaccination (15 or 30 minutes), and be prepared with the necessary equipment and supplies to manage and allergic reaction, including anaphylaxis (a minimum of 3 doses of epinephrine should be on-hand when administering vaccine).

List of Medical Providers Approved to Administer COVID-19 Vaccine through NH State-Managed Vaccination Clinics

All persons administering vaccinations through the NH State-managed COVID-19 vaccination clinics should have training and/or experience in administering vaccinations. All persons should be trained in the necessary processes and procedures outlined in this document, and provided vaccination refresher training. Any trainees (e.g., pharmacy interns, nursing students, medical students, etc.), must operate under the direct supervision of a provider/preceptor in their respective profession who is onsite, trained, experienced, and licensed/certified to provide vaccination. If pharmacists and pharmacy interns are being utilized as vaccinators, that they need to have an "immunization endorsement" which is offered through the NH Office of Professional Licensure and Certification (OPLC).

The following licensed medical providers or trainees are allowed to administer COVID-19 vaccines through NH State-managed COVID-19 vaccination clinics:

MD – Doctor of Medicine
DO – Osteopathic Medicine
PA – Physician Assistant
DMD – Doctor of Dental Medicine
DDS – Doctor of Dental Surgery
RDH – Registered Dental Hygienists
DPM – Doctor of Podiatric Medicine
ND – Naturopathic Doctor
APRN – Advanced Practice Registered Nurse
RN – Registered Nurse
LPN – Licensed Practical Nurse
RMA – Registered Medical Assistant
CMA – Certified Medical Assistant
Paramedic
Advanced-EMT
EMT – Emergency Medical Technician (including EMT-basic)*
68W and 4N – Military Medics
Pharmacist†
Pharmacy interns†*
Nursing, Medical, and PA Students*

** Interns and students must operate under the direct supervision of a provider/preceptor in their respective profession who is onsite, trained, experienced, and licensed/certified to provide vaccination. These individuals must all receive training on clinic processes and protocols, and training in injection safety and technique. EMTs must also conduct any training required through the NH Bureau of EMS.*

† Pharmacists & pharmacy interns require an immunization endorsement offered through OPLC.

Bureau of Infectious Disease Control

Consent to Administer COVID-19 Vaccine to a Person Under the Age of 18 Years

INFORMATION AND INSTRUCTIONS:

The parent or legal guardian of the child or teenager being vaccinated should review the additional information below about the COVID-19 vaccine and follow the instructions.

You will be asked some medical questions about the health of your child to make sure they do not have any allergies that would prevent them from getting the COVID-19 vaccine. Right now, the only COVID-19 vaccine available for people under the age of 18 years is the Pfizer-BioNTech COVID-19 vaccine (sometimes just called the "Pfizer vaccine"). There are two different formulations of this vaccine – a lower-dose vaccine for children 5-11 years of age, and a higher-dose vaccine for people 12 years of age and older. The dose your child or teenager will receive is based on their age and NOT their size or weight. Both formulations of the Pfizer COVID-19 vaccine have been shown to be safe and effective when used within the intended age group. Regardless of age, however, this vaccine requires two doses to be given about 21 days apart in order for a person to be considered fully vaccinated and have the best protection against COVID-19. So if this is your child's first COVID-19 vaccine, they will need to get a second shot about 21 days after the first shot. Also, people who have a weakened immune system may be able to get a third shot as part of their primary vaccination series to improve their protection. This additional third shot is given at least 28 days after the second shot, but it's only for people who have a moderately or severely compromised immune system. More information about who may benefit from this additional third shot can be found on CDC's website: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html. Finally, all persons 12 years of age or older are able to get a "booster" shot after completing their 2-dose or 3-dose primary vaccination series (a 3-dose primary vaccine series is for people with a moderately or severely compromised immune system). For 12-17 year olds, this booster dose is given starting at least 5 months after completing the primary vaccination series.

Before your child can be given the COVID-19 vaccine, you need to review the information in a FDA Fact Sheet which should have been provided to you already. There are different Fact Sheets for the different Pfizer vaccines, which can also be found online. The Fact Sheet for vaccinating children 5-11 years old can be found here: https://www.fda.gov/media/153717/download. The Fact Sheet for vaccinating people 12 years of age and older can be found here: https://www.fda.gov/media/153716/download.

If you agree to have your child vaccinated with the age-appropriate Pfizer COVID-19 vaccine and if there is not a medical reason why your child cannot get the vaccine, then please answer the questions on the next page and follow the instructions to agree (consent) to have your child vaccinated. Then sign and date the form and return the form to the vaccine clinic staff. If you do not want your child to be vaccinated, then do not sign or return the form, and your child will not be given the COVID-19 vaccine.

Name of Person Receiving the Vaccine: _____

Date of Birth: _____ **Age:** _____

- **Check the box below for the COVID-19 vaccine dose that is to be given to your child:**
  - ☐ **Dose #1**
  - ☐ **Dose #2**
  - ☐ **Dose #3** (this third dose is only for people 5 years of age or older who are moderately or severely immunocompromised)
  - ☐ **Booster Dose** (a booster dose is only able to be given to people 12 years of age or older who have completed a primary vaccination series)

CONSENT FOR MY CHILD TO RECEIVE THE COVID-19 VACCINE:

☐ I have been given and reviewed the age-appropriate FDA Fact Sheet for people receiving the Pfizer-BioNTech COVID-19 vaccine. I have also been given and reviewed the NH Department of Health and Human Services' Notice of Privacy Practices. By checking the box and signing below, I am acknowledging that I have received and reviewed the information provided, I confirm that the information entered on this form is accurate, and **I GIVE CONSENT** for my child named above to be vaccinated with the age-appropriate Pfizer-BioNTech COVID-19 vaccine.

Signature of Parent/Legal Guardian: _____

Printed Name of Parent/Legal Guardian: _____

Date: _____

Phone Number of Parent/Legal Guardian (Emergency Contact Number):_____
(Note: vaccine clinic staff may contact you at this number if there are questions about the information you provided on this form.)

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Third Dose Vaccine Administration for People Who Are Immunocompromised

(A third additional primary series vaccine dose is recommended only for people who got their first two doses of a COVID-19 vaccine with either the Pfizer-BioNTech or Moderna vaccine)

INFORMATION and INSTRUCTIONS:

Please review the information in this form carefully and follow the instructions. For people under the age of 18 years, the parent or legal guardian should review the information and follow the instructions.

The CDC recommends that people who have a weakened immune system and are "moderately to severely immunocompromised" should get a third primary series vaccine dose of either the Pfizer-BioNTech vaccine (for people 5 years of age or older) or Moderna vaccine (for people 18 years of age or older) after completing the first two recommended doses. This additional third dose should be given at least 28 days after the second dose. A third dose has been found to increase protection against COVID-19 for people who may not have developed full protection from the first two doses. This third additional dose for people who have a weakened immune system is different from a "booster dose". Even after getting this third primary series dose, you will still qualify for a booster dose after the recommended time period has gone by.

We recommend you talk to your healthcare provider about your particular health situation and whether you might benefit from a third dose. The CDC currently recommends a third vaccine dose for people who:

- Are receiving active treatment for cancers (including solid organ tumors or cancers of the blood)
- Received an organ transplant and are taking medicines that weaken the immune system
- Received a stem cell transplant within the last 2 years, or are taking medicine that weaken the immune system after a stem cell transplant
- Have moderate or severe primary immunodeficiency disorders (such as DiGeorge syndrome and Wiskott-Aldrich syndrome)
- Have advanced or untreated HIV infection
- Are receiving active treatment with high-dose corticosteroids or other drugs that weaken the immune system, such as transplant-related immunosuppressive drugs, cancer chemotherapy, tumor-necrosis factor (TNF) blockers, etc.

There are other health conditions not included in this list that could cause a person to be "moderately to severely immunocompromised". So if you are unsure about whether you should get a third additional primary series vaccine dose, please talk with your healthcare provider.

Also, because of your weakened immune system, even if you get a third vaccine dose you still may not develop a full protective immune response. So it is recommended that you still take steps to protect yourself from COVID-19.

If you qualify for a third vaccine dose then please fill out the information below, check the box to acknowledge you have reviewed the information provided and that you believe you meet criteria to receive a third primary series vaccine dose, then sign and date this form and return to vaccine clinic staff.

Name of Person Receiving the Vaccine: _____

Date of Birth: _____ **Age:** _____

☐ I have reviewed and understand the information provided in this form, and I confirm that I (or my child) meet criteria to receive a third primary series vaccine dose of either the Pfizer-BioNTech or Moderna COVID-19 vaccine because of a health condition which causes me (or my child) to have a moderate or severely weakened immune system.

Signature of Vaccine Recipient: _____

Signature of Parent/Legal Guardian (if applicable): _____

Printed Name of Parent/Legal Guardian: _____

Date: _____

NH DIVISION OF Public Health Services
Department of Health and Human Services

Bureau of Infectious Disease Control

COVID-19 Vaccination Clinic After Visit Summary (AVS)
Recommendations for Vaccine Recipients

Thank you for getting the COVID-19 vaccine. **Please wait in the clinic area for 15 minutes after getting the vaccine in case you have any immediate side effects to the vaccine**. **If you have had any type of allergic reaction within several hours after being given another vaccine or injectable medication therapy, or if you have had a severe allergic reaction (like anaphylaxis) to anything in the past, you should wait and be monitored for 30 minutes after vaccination.** Serious reactions are rare, but we want to be careful. You can use that time to read this and other papers we gave you.

You likely will notice some symptoms after vaccination; this means that the vaccine is working and your body is developing protection against COVID-19. The most common symptoms are pain, redness, and swelling where the vaccine was injected, and some people experience swelling and pain in the armpit on the side where the injection took place. People also commonly have symptoms like headache, feeling very tired, having muscle or joint pains, feeling sick and throwing up, or even fever and chills. Most of the time these symptoms are mild, start 1-2 days after vaccination, and then go away on their own soon after. You can use acetaminophen or ibuprofen (medications like Tylenol, or Advil or Motrin) to help you feel better if you have any of these symptoms. You should also enroll in CDC's "v-safe" smartphone tool to tell the CDC if you have any side effects after getting the COVID-19 vaccine (you should have received separate instructions about how to sign up). This is important so we can track side effects people may be having from these new vaccines.

If you have symptoms that are severe, last longer than 2-3 days, or get worse, you should call your primary care provider to be evaluated, and you might need testing for COVID-19 depending on your symptoms. The COVID-19 vaccines can't give you COVID-19, but you could have been infected before, or soon after vaccination before the vaccine had a chance to work. If you don't have a healthcare provider, go to your local emergency department, urgent care center, or local community health clinic (please call ahead).

Serious reactions are rare, but can happen with any vaccine, even hours or days after a vaccine is given. If you have serious symptoms (like chest pains, a hard time breathing, feelings of a fast-beating or irregular/fluttering heart, face or throat swelling, a bad rash or hives, severe and persistent abdominal pain or headache, seizures, difficulty with speech or vision, leg swelling, or any other concerning symptoms) please get medical attention right away or call 9-1-1.

Please make sure you get all the recommended doses of your COVID-19 vaccine so that you are fully protected from COVID-19. Check with your healthcare provider if you have any questions about how many doses of a COVID-19 vaccine you should receive. Thank you again for doing your part to stop the spread of COVID-19 and protect yourself and your community. If you have questions or concerns about the vaccine, or experience any concerning side effects, please talk with your primary care provider. Other vaccine and COVID-19 information is on the CDC website: www.cdc.gov/coronavirus/2019-ncov.

NH DIVISION OF Public Health Services
Department of Health and Human Services

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Medical Screening Questions for Persons 5-17 Years of Age Receiving the Pfizer-BioNTech Vaccine

The following questions will help us determine if there is any reason your child should not get the COVID-19 vaccine. If you answer "yes" to any of the questions, it does not necessarily mean your child should not be vaccinated. It just means additional information may be needed. Please answer the questions below for your child who is receiving the vaccine.

Name of Person Receiving the Vaccine: _____

Date of Birth: _____ **Age:** _____

	Yes	No	Don't Know
1. Are you feeling sick today?	☐	☐	☐
2. Have you ever received a dose of a COVID-19 vaccine before? **If yes**, which COVID-19 vaccine product(s) were you previously given? ☐ Pfizer-BioNTech ☐ Moderna ☐ Janssen (Johnson & Johnson)	☐	☐	☐
3. Did you have an allergic reaction after a prior dose of any COVID-19 vaccine? (*Allergic reactions can include symptoms like rash, hives, swelling of the face or mouth, wheezing and difficulty breathing, etc.*) **If yes**, please specify the specific vaccine AND your allergic reaction: _____	☐	☐	☐
4. Do you have a known allergy to an ingredient in the Pfizer-BioNTech COVID-19 vaccine? *(See the provided age-appropriate FDA Fact Sheet for a list of vaccine ingredients)*	☐	☐	☐
5. Do you have a known allergy to polyethylene glycol (PEG)?	☐	☐	☐
6. Do you have a known allergy to polysorbate?	☐	☐	☐
7. Have you ever had any allergic reaction within 4 hours of receiving a non-COVID-19 vaccine or other injectable medication (including medications injected into a muscle, vein, or under the skin)?	☐	☐	☐
8. Have you ever had a severe allergic reaction (like anaphylaxis) due to any other cause, including to medications taken by mouth, food, or other substances?	☐	☐	☐
9. Did you develop myocarditis or pericarditis after receiving a prior dose of either the Pfizer-BioNTech or Moderna COVID-19 vaccine?	☐	☐	☐
10. Do you have a bleeding disorder or are you taking blood thinners?	☐	☐	☐
11. In the last 90 days, have you been given a COVID-19 antibody therapy to either treat COVID-19, or to prevent COVID-19 from developing after you were exposed to another person with COVID-19? (*Antibody therapies include monoclonal antibodies or a blood product called "convalescent plasma"*)	☐	☐	☐

Please sign below to confirm that the information on this form is accurate to the best of your knowledge:

Signature of Parent/Legal Guardian: _____

Printed Name of Parent/Legal Guardian: _____

Date: _____

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General Medical Screening Questions for All Ages

The following questions will help us determine if there is any reason you should not get the COVID-19 vaccine. If you answer "yes" to any of the questions, it does not necessarily mean you should not be vaccinated. It just means additional information may be needed. Please answer the questions below for the person who is receiving the vaccine.

Name of Person Receiving the Vaccine: _____

Date of Birth: _____ **Age:** _____

COVID-19 Vaccine Being Administered: ☐ Pfizer-BioNTech ☐ Moderna ☐ Janssen (Johnson & Johnson)

		Yes	No	Don't Know
1.	Are you feeling sick today?	☐	☐	☐
2.	Have you ever received a dose of a COVID-19 vaccine before? **<u>If yes</u>**, which COVID-19 vaccine product(s) were you previously given? ☐ Pfizer-BioNTech ☐ Moderna ☐ Janssen (Johnson & Johnson) ☐ Other	☐	☐	☐
3.	Did you have an allergic reaction after a prior dose of any COVID-19 vaccine? (*Allergic reactions can include symptoms like rash, hives, swelling of the face or mouth, wheezing and difficulty breathing, etc.*) **<u>If yes</u>**, please specify the specific vaccine AND your allergic reaction: _____	☐	☐	☐
4.	Do you have a known allergy to an ingredient in the COVID-19 vaccine that you will be receiving today? *(See the provided FDA Fact Sheet for a list of vaccine ingredients)*	☐	☐	☐
5.	Do you have a known allergy to polyethylene glycol (PEG)?	☐	☐	☐
6.	Do you have a known allergy to polysorbate?	☐	☐	☐
7.	Have you ever had any allergic reaction within 4 hours of receiving a non-COVID-19 vaccine or other injectable medication (including medications injected into a muscle, vein, or under the skin)?	☐	☐	☐
8.	Have you ever had a severe allergic reaction (like anaphylaxis) due to any other cause, including to medications taken by mouth, food, or other substances?	☐	☐	☐
9.	Did you develop myocarditis or pericarditis after receiving a prior dose of either the Pfizer-BioNTech or Moderna COVID-19 vaccine?	☐	☐	☐
10.	Do you have a bleeding disorder or are you taking blood thinners?	☐	☐	☐
11.	In the last 90 days, have you been given a COVID-19 antibody therapy to either treat COVID-19, or to prevent COVID-19 from developing after you were exposed to another person with COVID-19? (*Antibody therapies include monoclonal antibodies or a blood product called "convalescent plasma"*)	☐	☐	☐
12.	In the last 90 days, did you develop an immune-related health condition that caused blood clotting AND low platelet blood counts? (*The most common example of this is called "heparin-induced thrombocytopenia"*)	☐	☐	☐
13.	Did you develop a health condition called "Thrombosis with Thrombocytopenia Syndrome" (TTS) after receiving a prior dose of the Janssen or AstraZeneca COVID-19 vaccines? (*People with TTS develop blood clotting and low platelet blood counts after COVID-19 vaccination*)	☐	☐	☐
14.	Did you develop Guillain-Barré syndrome (GBS) after receiving a prior dose of the Janssen vaccine?	☐	☐	☐

Please sign below to confirm that the information on this form is accurate to the best of your knowledge:

Signature of Vaccine Recipient: _____

Date: _____

Vaccination Screening Checklist (For Vaccinators)

This screening checklist is to help vaccinators identify important information which may impact the ability of a person to receive the vaccine or affect vaccine selection or management of a person after vaccination.

Review vaccine recipient (VR) information and verify information with VR prior to vaccination:

☐ **Is the VR starting or completing their primary COVID-19 vaccination series (i.e., 2-doses of either Pfizer-BioNTech or Moderna, or 1-dose of the J&J Janssen vaccine)?**

- The Pfizer-BioNTech and Moderna vaccines are preferred/recommended over the J&J Janssen vaccine. The Janssen vaccine can still be administered if the VR has a contraindication to mRNA COVID-19 vaccines, or if VR requests the Janssen vaccine (see Question below about Janssen vaccine).
- Verify if the VR previously received a dose of a COVID-19 vaccine in the past.
- If VR has received a single-dose of the Janssen vaccine in the past, no further vaccine is needed to complete their primary vaccine series.
- If VR is receiving their second dose of an mRNA COVID-19 vaccine (Pfizer or Moderna), it should be with the same age-appropriate brand/manufacturer as their first dose. If vaccine recipient has already received two doses of an mRNA vaccine in the past, no further vaccine is needed to complete their primary vaccine series.
- If two doses of different mRNA vaccines are inadvertently administered in the past, no additional doses of either vaccine/product are recommended to complete the primary vaccine series.
- If VR received the first dose of an mRNA vaccine in the past but is unable to complete the series with the second dose (due to a contraindication), a single dose of the Janssen COVID-19 vaccine may be given at a minimum interval of 28 days from receipt of the mRNA vaccine, but additional precautions apply (see below).
- Verify the VR's age to ensure they are receiving the correct vaccine product at the right dose (see below).

☐ **Is the VR receiving a 3rd additional primary series dose of an mRNA vaccine because they are moderately or severely immunocompromised?**

- See CDC clinical guidance for conditions and treatments that may cause a person to be moderately or severely immunocompromised; this is not an all-inclusive list. If it is unclear if a person is "moderately or severely" immunocompromised, they should discuss with their healthcare provider.
- People who are moderately or severely immunocompromised are recommended to get a 3rd dose of either the Pfizer-BioNTech vaccine (for persons ≥ 5 years) or Moderna vaccine (for persons ≥18 years), after they receive a primary 2-dose mRNA vaccine series (note: this does not apply to the Janssen vaccine, or to people who received the Janssen vaccine as a primary series).
- Verify the VR's age to ensure they are receiving the correct vaccine product at the right dose (see below).
- Persons seeking a 3rd dose of the Pfizer-BioNTech or Moderna vaccine (or their parent/guardian) should be provided the self-attestation form ("Third Dose Vaccine Administration for People Who Are

Immunocompromised") to review and sign before being given a 3rd dose – the signed form should be saved and securely sent to NH DPHS Immunization Section for record keeping. Also document self-attestation in VMS.

- The 3rd dose should be with the same mRNA vaccine as the primary series, but an alternate mRNA product can be given if the primary series product is unknown or not available.
- The 3rd dose should be administered at least 28 days after completion of the 2nd dose in the primary mRNA vaccine series.
- The vaccine may be less effective due to their immune system, even after a 3rd dose. Counsel person to continue to take steps to protect themselves from COVID-19. If questions or concerns, recommend they discuss with their health care provider.

☐ **Is the VR receiving a booster vaccine dose?**

- Booster doses are recommended for everybody 12 years of age or older who completed a primary COVID-19 vaccination series, regardless of VR's risk factors or underlying medical conditions.
- Recommendations for the timing of booster dose administration is based on which vaccine the VR received for their primary vaccine series.
- For VRs 18 years of age or older: heterologous (mix-and-match) booster dosing is allowed, so any of COVID-19 vaccines can be used regardless of the vaccine product a VR received for their primary vaccination series. However, the Pfizer-BioNTech and Moderna vaccines are preferred/recommended over the J&J Janssen vaccine for booster vaccination. The Janssen vaccine can still be administered if the VR has a contraindication to mRNA COVID-19 vaccines, or if VR requests the Janssen vaccine (see Question below about Janssen vaccine).
- For VRs 12-17 years of age: only the Pfizer-BioNTech COVID-19 vaccine may be administered.
- Verify that the VR is eligible to receive a booster dose by meeting <u>all of the following criteria</u>:
  - The VR is 12 years of age or older
  - The VR completed a primary vaccine series with either the Pfizer-BioNTech, Moderna, or Janssen COVID-19 vaccines
  - The VR is either:
    - at least 5 months beyond completion of their primary COVID-19 vaccine series with the Pfizer-BioNTech or Moderna vaccine (including any 3rd dose administered because a VR is moderately or severely immunocompromised)

    OR

    - at least 2 months (8 weeks) beyond completion of the single-dose Janssen COVID-19 vaccine
- Verify the vaccine product being given and verify the vaccine dose being administered – the **Moderna booster is a half-dose (50 mcg, or 0.25 mL)** compared to the Moderna dose for the primary series.

☐ **Is the VR under 18 years of age?**

- Verify the VR's age.
- No vaccine is authorized yet to be used in children under the age of 5 years.
- VRs who are 5 – 17 years of age are only able to be given the Pfizer-BioNTech COVID-19 vaccine.

- The Pfizer-BioNTech COVID-19 pediatric vaccine formulation for 5-11 year olds is a different formulation (orange cap vial) than the Pfizer-BioNTech COVID-19 vaccine for VRs 12 years of age and older (gray cap vials).
- See CDC information on the different Pfizer-BioNTech COVID-19 vaccines by age and cap color
- For VRs 5-11 years of age, refer to this FDA Fact Sheet for Healthcare Providers Administering Vaccine (Fact Sheet for orange cap vials)
- For VR's 12 years of age or older, refer to this FDA Fact Sheet for Healthcare Providers Administering Vaccine (Fact Sheet for gray cap vials)

- Ensure the appropriate FDA Fact Sheet is provided to the VR or their parent/guardian:
  - Use this FDA Fact Sheet for Recipients and Caregivers when vaccinating persons 5-11 years of age
  - Use this FDA Fact Sheet for Recipients and Caregivers when vaccinating persons 12 years of age or older
- Verify the vaccine dose being administered:
  - The Pfizer-BioNTech vaccine dose for 5-11 year olds is **10 micrograms** (0.2 mL of vaccine after ORANGE cap multi-dose vial is appropriately diluted)
  - The Pfizer-BioNTech vaccine dose for 12-17 year olds is **30 micrograms** (0.3 mL of vaccine from GRAY cap multi-dose vial – do NOT dilute gray cap vials prior to use)
- Vaccine and dose selection is based on the age of the VR at the time of vaccine dose administration and NOT a VR's size or weight – If VR is 11 years old on date of dose #1 administration but turns 12 years old by date of dose #2 administration, then the VR should be given the 10 microgram vaccine dose for dose #1, and then the higher 30 microgram vaccine dose for dose #2.
- VR's under the age of 18 must have either 1) a parent/legal guardian present who gives verbal consent to vaccination of the minor, which then should be documented in VMS, or 2) have a medical consent form signed by the VR's parent or guardian (note: this is most applicable to vaccination of minors at dedicated clinics, such as at schools). Signed consent forms need to be sent to the Immunization Section at the NH Division of Public Health Services (DPHS) for storage and record keeping. Emancipated minors do not require the consent of a parent or legal guardian.
  - Any new vaccine dose administered requires a new consent form (if the parent/guardian is not in attendance); for example, a 2-dose vaccine series would require 2 separate consent forms to be filled out and signed (one prior to each dose administration).

☐ Is VR receiving the J&J Janssen COVID-19 Vaccine?

- The Pfizer-BioNTech or Moderna COVID-19 vaccines are recommended over the J&J Janssen vaccine because of the rare, but serious risk of blood clots with low platelets that can occur after vaccination, called Thrombosis with Thrombocytopenia Syndrome (TTS).
- The risk of TTS after receiving the Janssen vaccine is highest for females in their 30's and 40's (about 10 cases per million vaccine doses administered), but a low risk has also been found for females in other age groups, and in males.
- If no contraindications, the J&J Janssen vaccine can be administered to people who have a contraindication to the mRNA COVID-19 vaccines, and to people who request the J&J Janssen vaccine after being informed of the risks and the recommendations.

☐ **Is the VR feeling sick today?**

- Moderate or Severe Illness: vaccination should be delayed for any person with moderate-to-severe acute illness until their illness has improved.
- Symptoms of COVID-19: A person with any new or unexplained symptoms of COVID-19 (even mild cold symptoms) should be declined vaccination, instructed to isolate at home, and seek testing for COVID-19 (person should be screened for symptoms of COVID-19 before reaching the vaccinator).

☐ **Did the VR develop myocarditis or pericarditis after receiving an earlier dose of an mRNA COVID-19 vaccine (Pfizer-BioNTech or Moderna)?**

- Myocarditis refers to inflammation of the heart muscle, and pericarditis refers to inflammation of the pericardial sac surrounding the heart muscle. Symptoms of myocarditis or pericarditis can include acute chest pain, shortness of breath, and palpitations; often symptoms are severe enough to require clinical evaluation and hospitalization. Myocarditis or pericarditis has occurred rarely in some people after receiving an mRNA COVID-19 vaccine – this has occurred predominantly in males aged 12-29 years of age within a week after receiving the second dose of vaccine.
- If "yes", then do NOT give an additional dose of an mRNA vaccine or the Janssen vaccine at a State-run vaccination clinic.
- The Janssen vaccine has not been associated with development of myocarditis/pericarditis. Therefore, VR could be considered for the Janssen vaccine to either complete their primary vaccine series or receive a booster, if VR is eligible. However, before administration of the Janssen vaccine after an episode of myocarditis/pericarditis associated with receipt of an mRNA COVID-19 vaccine, the VR should be fully recovered with no evidence of ongoing heart inflammation, as determined by a VR's clinical team. Therefore, in a VR who developed myocarditis/pericarditis after receipt of an mRNA vaccine, such persons should be referred to their healthcare provider for further assessment and administration of additional COVID-19 vaccine doses (including Janssen vaccine) to ensure appropriate counseling and risk assessment, monitoring, and to ensure that signs/symptoms of myocarditis/pericarditis have completely resolved before another dose is given.
- People with a history of myocarditis or pericarditis that is NOT related to receipt of a prior dose of an mRNA COVID-19 vaccine may receive either the Pfizer-BioNTech, Moderna, or Janssen vaccines after their episode of myocarditis/pericarditis has completely resolved.

☐ **Does the VR have a history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose of the COVID-19 vaccine, or a component of the vaccine?**

OR

Does the VR have a known/diagnosed allergy to a specific component of the vaccine?

- If "yes" to either, this is a vaccine **Contraindication**: Do NOT give that specific COVID-19 vaccine.
- See CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines, Appendix C for a list of ingredients included in COVID-19 vaccines.
- See CDC's guidance on COVID-19 vaccine contraindications and precautions, including Appendix B, for details on what qualifies as a "severe" vs. "non-severe" allergic reaction.

- A person with a contraindication to one mRNA vaccine should not receive doses of either mRNA vaccine (Pfizer or Moderna).

☐ **Did the VR develop Thrombosis with Thrombocytopenia Syndrome (TTS) after a prior dose of the Janssen or AstraZeneca COVID-19 vaccines?**

- If "yes", this is a vaccine **Contraindication** to receipt of the Janssen vaccine: Do NOT give the Janssen COVID-19 vaccine.
- The VR should be offered a Pfizer-BioNTech or Moderna vaccine, assuming no contraindications to mRNA vaccination.

☐ **Does the VR have a history of any immediate allergic reaction to other non-COVID-19 vaccines or injectable medication therapies (including intramuscular, intravenous, or subcutaneous injections)?**

OR

Does the VR have a history of a non-severe, immediate allergic reaction after a previous dose of a COVID-19 vaccine?

- If "yes", this is a vaccine **Precaution**. Vaccine may be given, but VRs with a vaccine "precaution" are recommended to discuss their allergy histories with their primary care provider so their provider can help perform a risk assessment and discuss the potential risks/benefits of the COVID-19 vaccines with the VR. If the VR chooses not to discuss their allergy history with their primary care provider before vaccination, the VR can still be administered the vaccine (see exceptions below). Inform the VR about the potential increased risk of an allergic reaction to the COVID-19 vaccine. VR must be monitored for at least 30 minutes after vaccination.
- An "immediate allergic reaction" is defined as any hypersensitivity related signs or symptoms consistent with urticaria (hives), angioedema, respiratory distress, or anaphylaxis that occurs within 4 hours following administration.
- Allergic reactions after vaccination should be differentiated from non-allergic reactions, such as vasovagal episodes and normal vaccine side effects. CDC has created a table (Appendix D) to assist providers in differentiating.
- See CDC's guidance on COVID-19 vaccine contraindications and precautions, including Appendix B, for details on what qualifies as a "severe" vs. "non-severe" allergic reaction.
- If there is any question about whether a VR has a COVID-19 vaccine contraindication vs. precaution, consult with vaccine clinic medical lead to help determine if vaccination is appropriate. If there are concerns about whether a VR is appropriate to be vaccinated with available COVID-19 vaccines, then the VR should be declined vaccination, and instructed to seek assessment and vaccination in a more appropriate medically monitored setting.

☐ **If VR is receiving the Janssen vaccine:**

1.) Did the VR have a severe allergic reaction after a previous dose of either the Pfizer or Moderna COVID-19 vaccine?

2.) Does the VR have a known/diagnosed allergy to polyethylene glycol (PEG)?

- If "yes" to either question, this is a vaccine **Precaution** for the VR getting the Janssen vaccine; above Precautions information and recommendations apply.
- However, the CDC also recommends referral to an allergist-immunologist be considered before administration of the Janssen vaccine. This is because of potential allergic cross-reactivity between polyethylene glycol (an ingredient in both the Pfizer and Moderna vaccines), and polysorbate (an ingredient in the Janssen vaccine).
- If VR has consulted with their primary care provider and/or an allergist-immunologist, and vaccination was determined to be appropriate based on provider's risk assessment, and if patient is aware of risks and desires to be vaccinated, then the Janssen vaccine may be given; document in VMS. VR must be monitored for at least 30 minutes after vaccination.
- If Janssen vaccine is given, it should be at least 28 days after a previous mRNA vaccine dose (if applicable).
- If VR has not consulted with their primary care provider or an allergist-immunologist, consult with vaccine clinic medical lead to determine if vaccination is appropriate based on VR's allergy history. Consider declining vaccination until patient is evaluated by their primary care provider or an allergist-immunologist if any concerning history.

☐ **If VR is receiving the Pfizer or Moderna vaccine:**

1.) Did the VR have a severe allergic reaction after a previous dose of the Janssen COVID-19 vaccine?

2.) Does the VR have a known/diagnosed allergy to polysorbate?

- If "yes", this is a vaccine **Precaution** for the VR receiving an mRNA vaccine; above Precautions information and recommendations apply.
- However, the CDC also recommends referral to an allergist-immunologist be considered before administration of the Pfizer-BioNTech or Moderna vaccine. This is because of potential allergic cross-reactivity between polysorbate (an ingredient in the Janssen vaccine) and polyethylene glycol (an ingredient in both the Pfizer and Moderna vaccines).
- If VR has consulted with their primary care provider and/or an allergist-immunologist, and vaccination was determined to be appropriate based on provider's risk assessment, and if patient is aware of risks and desires to be vaccinated, then the Pfizer or Moderna vaccine may be given; document in VMS. VR must be monitored for at least 30 minutes after vaccination.
- If VR has not consulted with their primary care provider or an allergist-immunologist, consult with vaccine clinic medical lead to determine if vaccination is appropriate based on VR's allergy history. Consider declining vaccination until patient is evaluated by their primary care provider or an allergist-immunologist if any concerning history.

☐ **Does the VR have a history of a severe allergic reaction (e.g., anaphylaxis) due to any other cause that does not qualify as a vaccine contraindication or precaution (including oral medications, foods, substances, environmental exposures, etc.)?**

- If "yes", vaccine may be given, but it is recommended that the VR discuss their allergy history with their primary care provider before vaccination. Even if VR did not discuss with their primary care

provider, vaccine can be given. Vaccine recipient must be monitored for at least 30 minutes after vaccination.

☐ **Does the VR have a bleeding disorder or is VR taking a blood thinner?**

- If "yes", vaccine may be given, but use a fine-gauge needle (23 gauge or smaller caliber), followed by firm pressure on the site (without rubbing) for at least 2 minutes.

☐ **Has VR received a passive antibody therapy to treat COVID-19 in the last 90 days, or received passive antibody therapy for post-exposure prophylaxis to prevent COVID-19 after an exposure? (passive antibody therapy includes convalescent plasma and monoclonal antibodies)?**

- If "yes", vaccination should be deferred for at least 90 days after receipt of a passive antibody therapy for treatment for COVID-19, and deferred for at least 30 days after receipt of a passive antibody therapy for post-exposure prophylaxis. This is a precautionary measure to avoid interference of the antibody treatment with the vaccine-induced immune response.
- If it is unclear whether a VR received passive antibody therapy as treatment for COVID-19 or for post-exposure prophylaxis, then defer vaccination for at least 90 days.

☐ **Is the VR moderately or severely immunocompromised?***

- If "yes", vaccine may be given; it is safe for the VR to be vaccinated.

☐ **Is the VR currently pregnant or breastfeeding?**

- If "yes", vaccine may be given; it is safe for the VR to be vaccinated.
- Vaccination is recommended for pregnant and breastfeeding women by the CDC and by professional medical societies like the American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal and Fetal Medicine (SMFM). Vaccine is also recommended for people who are trying to get pregnant, might become pregnant, or who were recently pregnant.
- Pregnant women are at increased risk for severe COVID-19 and adverse pregnancy outcomes (e.g., preterm birth, stillbirth, preeclampsia) if they become infected with SARS-CoV-2, and vaccination will help protect both mother and baby from COVID-19 and related complications.
- Safety data on use of the mRNA COVID-19 vaccines (Pfizer-BioNTech and Moderna vaccines) in pregnant women haven't identified any safety concerns for the mother or infant.
- The Janssen COVID-19 vaccine has less data on use in pregnant women, so information on Janssen vaccine safety and effectiveness during pregnancy is limited, but we believe that the risk of the vaccine to the VR and unborn baby is low.
- If the person has questions or concerns, recommend they discuss with their pregnancy provider before vaccination.

☐ **Does the VR have a history of an immune-mediated health condition that caused thrombosis (blood clotting) AND thrombocytopenia (low platelet counts), such as "heparin-induced thrombocytopenia" (HIT), which they have recovered from in the last 90 days?**

- These persons should NOT be given the J&J Janssen vaccine

- Such persons should be given either the Pfizer-BioNTech or Moderna COVID-19 vaccines
- If more than 90 days have passed since recovery from their health condition, they can still receive the J&J Janssen vaccine after informing that person of the potential risks associated with the J&J Janssen vaccine. But the Pfizer-BioNTech and Moderna vaccines are still preferred/recommended over the Janssen vaccine.

☐ **Did the VR develop Guillain-Barré syndrome (GBS) after their first Janssen vaccine?**

- Guillain-Barré syndrome (GBS) is a neurological disorder where the body's immune system damages nerve cells causing muscle weakness and sometimes paralysis.
- GBS has occurred rarely within 42 days after receiving the Janssen vaccine. No increased risk of GBS has been identified with the mRNA vaccines.
- VRs with a history of GBS (unrelated to COVID-19 vaccination) can receive any COVID-19 vaccine.
- A VR who developed GBS within 42 days following the first dose of the Janssen vaccine should not receive a Janssen booster – the VR should be offered either a Pfizer-BioNTech or Moderna vaccine booster instead, assuming no contraindications.
- If VR also has a contraindication to mRNA vaccination, then a Janssen booster may still be able to be administered (i.e., GBS that occurs after receiving the Janssen vaccine is not an absolute contraindication to receiving another dose), but it should NOT be administered at a State-managed COVID-19 vaccination clinic; such VRs should be referred to their healthcare provider for further evaluation for booster dose administration.

☐ **Are other vaccines being administered with the COVID-19 vaccine?**

- All COVID-19 vaccines may be coadministered with other vaccines (including the influenza vaccine) on the same day, or within 14 days of each other (see CDC guidance on coadministration of vaccines).
- If multiple vaccines are administered during a single visit, administer each injection in a different location, ideally in opposite shoulder/deltoid locations.

STATE OF NEW HAMPSHIRE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DIVISION OF PUBLIC HEALTH SERVICES

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Blood Borne Pathogen (BBP) Exposure Guidance

Blood-borne pathogens (BBPs) include Human Immunodeficiency Virus (HIV), hepatitis C virus (HCV), and hepatitis B virus (HBV). A healthcare worker can be exposed to these viral pathogens when exposed to an infected person's blood or other potentially infectious body fluids* through a percutaneous exposure (i.e., needle stick), or when blood or body fluids are exposed to a break in the skin or mucous membranes (i.e., eyes, nose, and mouth). In the setting of a COVID-19 vaccination clinic, the primary route of exposure to BPPs is from a contaminated needle stick; the risk of mucous membrane exposure should be minimal given brief patient contact, limited care targeting vaccine delivery, and the provider and clinic staff wearing eye protection (full face shield preferred over goggles). Clinic staff should follow the *Interim Guidance for NH State-Managed COVID-19 Vaccination Clinics* and follow the Advisory Committee on Immunization Practices (ACIP) General Best Practice Guidelines for Vaccine Administration to minimize the risk for a needle stick and BBP exposure.

In the event of a potential exposure to a source patient's (i.e., the person who is the source of exposure) blood or other potentially infectious body fluid, the healthcare provider or clinic staff should take the following steps:

1. Immediately and thoroughly wash with soap and water any needle stick, other sharps wounds, or broken skin that has been exposed to another person's blood or body fluids.
2. Copiously flush and irrigate any exposed mucous membranes with clean water or sterile saline.
3. Once wound is cleaned or mucous membranes are flushed, immediately report any exposure to the onsite clinical lead/supervisor.
4. Clinical lead/supervisor shall discuss the situation with the source patient and ask if the source patient can get blood borne pathogen testing to help inform care/management of the staff member who was stuck with a needle. If there is a local ConvenientMD Urgent Care by the vaccine clinic (or close to where the source patient lives) they should be provided with the ConvenientMD brochure and informational sheet that will be provided to the vaccine clinics, and the source patient should be instructed to call the ConvenientMD Telehealth number to set up an appointment for testing; there should be no charge to the source patient for the visit or blood testing (costs are covered by the State of NH under a contract with ConvenientMD). If there is not a locally accessible ConvenientMD location, the source patient should be instructed that they may be getting a follow-up call from public health to discuss and help coordinate BBP testing.
5. The exposed staff member should also be instructed to seek medical evaluation immediately. If there is a local ConvenientMD Urgent Care by the vaccine clinic, they should be provided with the ConvenientMD brochure and informational sheet, and the staff member should be instructed to immediately call the ConvenientMD Telehealth number to set up a same-day appointment for evaluation; there should be no charge to the staff member for the visit or blood testing (costs are covered by the State of NH under a

contract with ConvenientMD). If there is not a locally accessible ConvenientMD location, then the staff member should be instructed to seek medical evaluation through the staff member's primary care provider, agency occupational medicine group, or a local emergency department (if primary care or occupational medicine is not immediately available) for consideration of BBP testing and possible need for post-exposure prophylaxis (PEP).

6. Fill out the attached "Incident Report Form" below. This is critical to complete to ensure appropriate coordination between public health, ConvenientMD, the staff member, and the source patient. Be sure to document:
    a. Staff name, date of birth, and contact information (including phone number and e-mail address)
    b. Date, time, and clinic location of incident and exposure
    c. Description of the exposure, including:
        i. Nature of the exposure (i.e., percutaneous needle stick, non-intact skin, mucosal, human bite, etc.)
        ii. Type of body fluid involved
        iii. Body location of exposure and contact time with the body fluid
        iv. For percutaneous needle stick injuries, include a description of the injury including, type of needle used (solid vs. hollow bore needle), depth of wound, use in source patient
        v. Actions taken after the exposure
    d. Source patient's name, date of birth, and contact information (including phone number, mailing address, and e-mail)
    e. Source patient's pertinent medical history (including known HIV, HBV, or HCV infection status)
7. A worker's compensation claim, if applicable, should be submitted through standard employer processes. National Guard Service Members are covered under TRICARE Prime. Service Members should initiate Line of Duty (LOD) paperwork and receive further post-exposure instructions:
    a. ARMY MEMBERS, notify the State Surgeon Office at 603-545-8091
    b. AIR MEMBERS, notify 157th MDG at 603-973-2200

8. Supervisor should notify the NH Division of Public Health Services (DPHS) Immunization Program by phone, and submit the Incident Report Form by secure fax (phone: 603-271-4482; fax: 603-271-3850; e-mail: immunization@dhhs.nh.gov). All staff and source patient information must be kept confidential; National Guard Service Members and other staff are not allowed to retain a personal copy of the Incident Report Form, nor submit the Form as supporting documentation for Line of Duty determination or worker's compensation claims (because it contains confidential source patient information).

9. Based on the clinical assessment of the exposed staff member, if a ConvenientMD Urgent Care is not available to send a source patient for BBP testing, then DPHS can help to get source patient tested for BBP testing, if necessary. If BBP testing of the source patient is recommended, DPHS would work with the source patient to have them tested for the following (the DPHS BBP testing protocol may differ from the ConvenientMD testing protocol):
    a. HIV 4th generation Ag/Ab screening test
    b. HCV RNA viral load (or HCV antibody with reflex to RNA viral load if antibody is positive, but HCV RNA viral load is preferred)
    c. HBV surface antigen (SAg), surface antibody (SAb), and core antibody (CAb)

(*Note: there are no assurances DPHS can obtain BBP testing on the source patient. NH DPHS cannot compel a source patient to get tested, although NH RSA 141-G does outline a legal process by which a source patient can be compelled to be tested*.)

10. Additional post-exposure follow-up shall be conducted by the service member's military service (i.e., Army or Air National Guard) in accordance with each component's needle stick or BBP exposure policy. Non-National Guard staff should follow-up with their agency occupational medicine group or primary care provider.

**Body fluids considered potentially infectious include: blood, semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, amniotic fluid, or any body fluid contaminated with visible blood. HBV and HCV can be detected in saliva, so these viruses could potentially be transmitted through bite wounds, although uncommon. Fluids generally NOT considered infectious (unless they contain blood) include feces, nasal secretions, sputum, sweat, urine, and vomit.*

NH COVID-19 Vaccination Clinic: *Incident Report Form*

(Call 603-271-4482 to report incident and then Fax form to 603-271-3850)

Date of Incident: ____ /____ /____ **Time of Incident:** ____:____ pm/am

Clinic Name/Location: _____

Staff Information

Name: _____ Date of Birth: ____ / ____ / ____

Phone Number (Home): _____ - _____ - _____ Phone Number (Cell): _____ - _____ - _____

E-mail Address: _____

Employer/Staff Type (circle all that apply):

National Guard **RPHN** **Hospital** **Fire/EMS** **Volunteer** **Other**_____

Clinic Supervisor Name and Contact Information: _____

Phone Number (Cell): _____ - _____ - _____ E-mail Address: _____

Description of Exposure/Incident

Type of Exposure (circle all that apply):

Needle stick **Non-intact skin** **mucous membrane** **Bite** **Other**: _____

Type of Body Fluid (circle all that apply): **Blood** **Other**: _____

Body Location of Exposure: _____

Estimated Contact Time: _____

Describe the Injury (for a needle stick: describe the type of needle, depth of wound, etc.):

_____

_____

Actions Taken: _____

Location of Medical Evaluation: _____

Name & contact information of healthcare provider following staff after needle stick:

_____

Source Patient Information (person who is the source of the exposure)

Name: _____ Date of Birth: ____ / ____ / ____

Phone Number (Home): _____ - _____ - _____ Phone Number (Cell): _____ - _____ - _____

Mailing Address: _____

E-mail Address: _____

Source Patient Has a Known History of Infection with (circle all that apply):

HIV **Hepatitis C Virus** **Hepatitis B Virus** **None** **Unknown**

Lori A. Shibinette
Commissioner

Patricia M. Tilley
Interim Director

STATE OF NEW HAMPSHIRE

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Standing Order for Administering the Pfizer-BioNTech COVID-19 mRNA Vaccine

PURPOSE: To reduce the burden of disease and associated morbidity and mortality from Coronavirus Disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the U.S. Food and Drug Administration (FDA) and the U.S. Centers for Disease Control and Prevention (CDC).

POLICY: This standing order enables eligible healthcare professionals to assess and vaccinate persons who meet the criteria outlined below and are seeking COVID-19 vaccination through the New Hampshire Department of Health & Human Services' State-managed COVID-19 vaccine clinics without the need for clinician examination or direct order from the attending provider at the time of the interaction.

PROCEDURE:

1. **Follow the "*Interim Guidance for NH State-Managed COVID-19 Vaccination Clinics*"**. Be familiar with CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines.

2. **Identify the following individuals for vaccination (i.e., the vaccine recipient, or VR)**:

   - Primary vaccination series: Any person 5 years of age or older who has not already received two prior doses of an mRNA COVID-19 vaccine (i.e., Pfizer-BioNTech or Moderna), a single dose of the J&J Janssen COVID-19 vaccine, or all recommended doses of another World Health Organization (WHO) Emergency Use listed vaccine. If administering mRNA COVID-19 vaccine dose #2, the same age-appropriate brand/manufacturer should be administered that the person received for dose #1, and doses of the Pfizer-BioNTech COVID-19 vaccine should be separated by at least 21 days (second doses given between day 17 and 21 after the first dose are considered valid, but should not be routine). If dose #2 is given earlier than 17 days after dose #1 (i.e., earlier than the 4-day grace period), then dose #2 should be repeated and the repeat dose should be administered at least 21 days after the improperly spaced dose (see Appendix A in CDC's clinical guidance for more recommendations about vaccine administration errors). If more than 21 days have elapsed since the first dose, the second dose should be given as soon as possible and is still valid. Verify the person's age to ensure they are receiving the correct Pfizer-BioNTech vaccine formulation and dose for their age (see administration instructions below).

- 3rd additional primary series dose for persons who are moderately or severely immunocompromised: Any person 5 years of age or older who is moderately or severely immunocompromised (see CDC guidance for examples of persons who qualify; note this is NOT an all-inclusive list), and who has already received 2-doses of either the Pfizer-BioNTech or Moderna COVID-19 vaccines. This additional 3rd dose for people who are moderately or severely immunocompromised is only for VRs who received the Pfizer-BioNTech or Moderna vaccines for their primary series. Vaccine dose #3 for this indication should be administered at least 28 days after dose #2. If the 3rd dose is administered fewer than 24 days after the second dose (i.e., earlier than the 4-day grace period), then the 3rd additional dose should be repeated and the repeat dose should be administered at least 28 days after the improperly spaced dose (see Appendix A in CDC's clinical guidance for more recommendations about vaccine administration errors). The third dose should ideally be with the same mRNA vaccine product used for the first two doses, but if the same product is not available or not known, then the alternate mRNA vaccine product can be used (i.e., the Moderna COVID-19 vaccine can be used in place of the Pfizer-BioNTech COVID-19 vaccine, and vice versa). Verify the person's age to ensure they are receiving the correct Pfizer-BioNTech vaccine formulation and dose for their age (see administration instructions below). Persons seeking a third dose of the Pfizer-BioNTech or Moderna COVID-19 vaccine should be provided the self-attestation form ("Third Dose Vaccine Administration for People Who Are Immunocompromised") to review and sign before administration of a third dose. The signed form should be saved and securely sent to NH DPHS Immunization Section for record keeping. Self-attestation should also be documented in the Vaccine Management System (VMS).

- Booster dose: Any person 12 years of age or older (regardless of risk factors or underlying medical conditions, and including those who were 11 years of age or younger at the time they completed their primary vaccine series) who is either:
    1. At least 5 months beyond completion of a primary COVID-19 vaccine series with the Pfizer-BioNTech or Moderna vaccine (including any 3rd dose administered because the person is moderately or severely immunocompromised),

    OR

    2. At least 2 months (8 weeks) beyond completion of the single-dose Janssen COVID-19 vaccine.

  For person 18 years of age or older, heterologous (i.e., mix-and-match) booster dosing is allowed, so any of the COVID-19 vaccines can be used for booster doses regardless of the vaccine product used for a VR's primary vaccination. For persons 12-17 years of age, only the Pfizer-BioNTech COVID-19 vaccine may be used. Recommendations about the timing of booster dose administration is based on which vaccine the VR received for their primary vaccine series. If a booster dose is given earlier than the recommended time period, the booster dose does NOT need to be repeated. Verify the person is receiving the correct Pfizer-BioNTech vaccine formulation and dose for their age (see administration instructions below).

3. **Screen for any contraindications or precautions to vaccination (refer to the "*Vaccination Screening Checklist*" for vaccinators).**

Contraindications: Do NOT give the Pfizer-BioNTech COVID-19 vaccine to any person who has a history of either: **1)** A severe allergic reaction (e.g., anaphylaxis) after a previous dose of the Pfizer-BioNTech COVID-19 vaccine or a component of the vaccine, or **2)** A known (diagnosed) allergy to a component of the vaccine.

- See CDC's "Interim Clinical Considerations for Use of COVID-19 Vaccines", Appendix C for a list of COVID-19 vaccine ingredients.
- Allergic reactions after vaccination should be differentiated from non-allergic reactions, such as vasovagal episodes and normal vaccine side effects. CDC has created a table (Appendix D) to assist providers in differentiating.
- See CDC's guidance on COVID-19 vaccine contraindications and precautions, including Appendix B, for details on what qualifies as a "severe" vs. "non-severe" allergic reaction.
- A person with a contraindication to one mRNA COVID-19 vaccine (Pfizer-BioNTech or Moderna) should not receive doses of either of the mRNA vaccines.

Precautions: Take additional precautions if a person has a history of either: **1)** An immediate allergic reaction to other non-COVID-19 vaccines or injectable medication therapies (including intramuscular, intravenous, or subcutaneous injections), or **2)** A non-severe, immediate allergic reaction after a previous dose of a COVID-19 vaccine.

- An "immediate allergic reaction" is defined as any hypersensitivity related signs or symptoms consistent with urticaria (hives), angioedema, respiratory distress, or anaphylaxis that occurs within 4 hours following administration.
- Allergic reactions after vaccination should be differentiated from non-allergic reactions, such as vasovagal episodes and normal vaccine side effects. CDC has created a table (Appendix D) to assist providers in differentiating.
- See CDC's guidance on COVID-19 vaccine contraindications and precautions, including Appendix B, for details on what qualifies as a "severe" vs. "non-severe" allergic reaction.
- Vaccine may be given, but persons with a vaccine "precaution" are recommended to discuss their allergy histories with their primary care provider so their provider can help perform a risk assessment and discuss the potential risks/benefits of the COVID-19 vaccines with the VR. If the VR chooses not to discuss their allergy history with their primary care provider before vaccination, the VR can still be administered the vaccine. Inform the VR about the potential increased risk of an allergic reaction to the COVID-19 vaccine. VR must be monitored for at least 30 minutes after vaccination.
- If VR either 1) had a severe allergic reaction after a previous dose of the Janssen vaccine, or 2) has a known/diagnosed allergy to polysorbate, then VR has a contraindication to the Janssen vaccine

and the CDC recommends referral to an allergist-immunologist be considered before administration of the Pfizer-BioNTech or Moderna vaccines. This is because of potential allergic cross-reactivity between polysorbate (an ingredient in the Janssen vaccine) and polyethylene glycol (an ingredient in both the Pfizer and Moderna vaccines).

  - If VR has consulted with their primary care provider and/or an allergist-immunologist, and vaccination was determined to be appropriate based on provider's risk assessment, and if patient is aware of risks and desires to be vaccinated, then the Pfizer-BioNTech vaccine may be given; document in the Vaccine Management System (VMS).
  - If VR has not consulted with their primary care provider or an allergist-immunologist, consult with vaccine clinic medical lead to determine if vaccination is appropriate based on VR's allergy history. Consider declining vaccination until patient is evaluated by their primary care provider or an allergist-immunologist.

- If there is any question about whether a VR has a COVID-19 vaccine contraindication vs. precaution, consult with vaccine clinic medical lead to help determine if vaccination is appropriate. If there are concerns about whether a VR is appropriate to be vaccinated with available COVID-19 vaccines, then the VR should be declined vaccination, and instructed to seek assessment and vaccination in a more appropriate medically monitored setting.

4. **Screen for other health conditions listed below (refer to the "*Vaccination Screening Checklist*" for vaccinators).**

- **Development of myocarditis or pericarditis after receiving an earlier dose of an mRNA COVID-19 vaccine (Pfizer-BioNTech or Moderna)**: If the VR developed myocarditis or pericarditis after receipt of an earlier dose of the Pfizer-BioNTech or Moderna vaccine, then the VR should not receive an additional dose of an mRNA vaccine or the Janssen vaccine at a State-managed vaccination clinic. The Janssen vaccine has not been associated with development of myocarditis/pericarditis. Therefore, VR could be considered for the Janssen vaccine to either complete their primary vaccine series or receive a booster, if VR is eligible. However, before administration of the Janssen vaccine after an episode of myocarditis/pericarditis associated with receipt of an mRNA COVID-19 vaccine, the VR should be fully recovered with no evidence of ongoing heart inflammation, as determined by a VR's clinical team. Therefore, in a VR who developed myocarditis/pericarditis after receipt of an mRNA vaccine, such persons should be referred to their healthcare provider for further assessment and administration of additional COVID-19 vaccine doses (including Janssen vaccine) to ensure appropriate counseling and risk assessment, monitoring, and to ensure that signs/symptoms of myocarditis/pericarditis have completely resolved before another dose is given. People with a history of myocarditis or pericarditis that is NOT related to receipt of a prior dose of an mRNA COVID-19 vaccine may receive either the Pfizer-BioNTech or Moderna vaccines after their episode of myocarditis/pericarditis has completely resolved.

- **Severe allergic reaction (e.g., anaphylaxis) due to any cause that does not qualify as a vaccine contraindication or precaution (including to other oral medications, food, environmental exposures, etc.)**: Vaccine may be given. It is recommended that the VR discuss their allergy history with their primary care provider before vaccination, but even if the VR did not discuss with their primary care provider, vaccine can be given. VR must be monitored for at least 30 minutes after vaccination.
- **Receipt of passive antibody therapy (e.g., convalescent plasma or monoclonal antibody therapy) as <u>treatment</u> for COVID-19 in the prior 90 days, or as <u>post-exposure prophylaxis</u> in the prior 30 days**: As a precautionary measure to avoid interference of the antibody treatment with the vaccine-induced immune response, COVID-19 vaccination should be deferred for:
    - At least 90 days after receipt of a passive antibody therapy for COVID-19 <u>treatment</u>
    - At least 30 days after receipt of passive antibody therapy for <u>post-exposure prophylaxis</u> (i.e., to prevent COVID-19 after an exposure)

  If it is unclear whether a VR received passive antibody therapy as treatment for COVID-19 or for post-exposure prophylaxis, then defer vaccination for at least 90 days.
- **Moderate or Severe Immunosuppression:** Vaccine may be given. Vaccine should be safe for VR to receive, but the vaccine may be less effective due to their immune system. Counsel the person to continue to take steps to protect themselves from COVID-19 after vaccination. If questions or concerns, recommend the VR discuss with their health care provider.
- **Pregnancy/Breastfeeding:** Vaccine is recommended for pregnant and breastfeeding women by the CDC and by professional medical societies like The American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal and Fetal Medicine (SMFM). Vaccine is also recommended for people who are trying to get pregnant, might become pregnant in the future, or who were recently pregnant. If a pregnant or breastfeeding woman has concerns, counsel VR that pregnant women are at increased risk for severe COVID-19 and adverse pregnancy outcomes (e.g., preterm birth, stillbirth, preeclampsia) if they become infected with SARS-CoV-2, and the vaccine will help protect both mother and baby from COVID-19 and related complications. Additionally, safety data on use of the mRNA COVID-19 vaccines (Pfizer-BioNTech and Moderna vaccines) in pregnant women haven't identified any safety concerns for the mother or infant. If the person has concerns recommend they discuss their concerns with their pregnancy provider.
- **Bleeding disorder or taking blood thinner**: Vaccine may be given, but use a fine-gauge needle (23 gauge or smaller caliber), followed by firm pressure on the site (without rubbing) for at least 2 minutes.

5. **Provide required documents listed in the "*Interim Guidance for NH State-Managed COVID-19 Vaccination Clinics*" (or ensure vaccine recipient has already received the documents)**: Provide all vaccine recipients (or, in the case of minors or people who lack decision making capacity, their parent or legal representative) with a copy of the most current required information (or verify the person,

parent/guardian, or legal representative received and had the opportunity to review the information), including, but not limited to:

- This FDA Fact Sheet for Recipients and Caregivers when vaccinating persons 5-11 years of age.
- This FDA Fact Sheet for Recipients and Caregivers when vaccinating persons 12 years of age or older.
- Fact Sheet translations into other languages can be found on the FDA's Pfizer-BioNTech COVID-19 Vaccine Website.

6. **Obtain consent for vaccination from a legal guardian for vaccine recipients under the age of 18 years, and for vaccine recipients 18 years of age or older who lack decision making capacity and cannot legally consent to vaccination themselves:** Follow instructions outlined in the "*Interim Guidance for NH State-Managed COVID-19 Vaccination Clinics*". Any new vaccine dose administration requires a new consent form (if the parent/guardian is not in attendance).

7. **Prepare to administer vaccine**: Choose the needle gauge, needle length, and injection site as outlined below. Follow manufacturer's instructions for storing and handling vaccine, and ensure the multi-dose vials of the Pfizer-BioNTech vaccine have been appropriately prepared for administration based on the following instructions:
   - For Pfizer-BioNTech COVID-19 pediatric vaccine for vaccine recipients 5-11 years of age (vial has an **orange cap**), follow the instructions outlined in this FDA Fact Sheet for Healthcare Providers Administering Vaccine.
   - For Pfizer-BioNTech COVID-19 vaccine for vaccine recipients 12 years of age or older (vial has a **gray cap**), following the instructions outlined in this FDA Fact Sheet for Healthcare Providers Administering Vaccine.

Children and Adolescents (5-18 years of age): Use a 1-inch needle (22-25 gauge) and administer in the deltoid muscle of the arm. Alternatively, the anterolateral thigh muscle can also be used with needle gauge and length according to the table below.

Age	Needle Gauge	Needle Length	Preferred Injection Site
Children, 5-10 years	22-25	5/8* – 1"	Deltoid muscle of arm (preferred)
	22-25	1 – 1¼"	Anterolateral thigh (alternate)
Children, 11-18 years	22–25	5/8* – 1"	Deltoid muscle of arm (preferred)
	22–25	1 – 1½"	Anterolateral thigh (alternate)

** A 5/8" needle may be used in children/adolescents weighing less than 130 lbs for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle to the skin.*

Adults (19 years of age and older): Use needle size, gauge, and injection location as outlined in the table below based on a person's sex and weight. The deltoid muscle of the arm/shoulder is the preferred injection site, but if necessary due to a medical condition, the anterolateral thigh muscle can also be used for injection (use a 1½ inch needle length for males and females of any weight when injecting the anterolateral thigh).

Sex and Weight	Needle Gauge	Needle Length	Preferred Injection Site
Female or male <130 lbs	22–25	5/8* – 1”	Deltoid muscle of arm
Female or male 130–152 lbs	22–25	1”	Deltoid muscle of arm
Female 153–200 lbs	22–25	1 – 1½”	Deltoid muscle of arm
Male 153–260 lbs	22–25	1 – 1½”	Deltoid muscle of arm
Female 200+ lbs	22–25	1½”	Deltoid muscle of arm
Male 260+ lbs	22–25	1½”	Deltoid muscle of arm

** A 5/8” needle may be used in patients weighing less than 130 lbs (<60 kg) for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle to the skin.*

8. **Administer the Pfizer-BioNTech COVID-19 vaccine as follows**:
   a. **Dose #1**:
      - For vaccine recipients 5-11 years of age: Give a 10 microgram dose (i.e., 0.2 mL of vaccine after ORANGE cap multi-dose vial is appropriately diluted) by intramuscular (IM) injection.
      - For vaccine recipients 12 years of age or older: Give a 30 microgram dose (i.e., 0.3 mL of vaccine from GRAY cap multi-dose vial – do NOT dilute gray cap vials prior to use) by intramuscular (IM) injection.

   b. **Dose #2**:
      - For vaccine recipients 5-11 years of age: Give a 10 microgram dose (i.e., 0.2 mL of vaccine after ORANGE cap multi-dose vial is appropriately diluted) at least 21 days after dose #1 of the Pfizer-BioNTech vaccine by intramuscular (IM) injection.
      - For vaccine recipients 12 years of age or older: Give a 30 microgram dose (i.e., 0.3 mL of vaccine from GRAY cap multi-dose vial – do NOT dilute gray cap vials prior to use) at least 21 days after dose #1 of the Pfizer-BioNTech vaccine by intramuscular (IM) injection.

   c. **Dose #3** (additional primary series dose for moderately or severely immunocompromised):
      - For vaccine recipients 5-11 years of age who self-attest that they are moderately or severely immunocompromised: Give a 10 microgram dose (i.e., 0.2 mL of vaccine after ORANGE cap multi-dose vial is appropriately diluted) at least 28 days after dose #2 of an mRNA vaccine by intramuscular (IM) injection.
      - For vaccine recipients 12 years of age or older who self-attest that they are moderately or severely immunocompromised: Give a 30 microgram dose (i.e., 0.3 mL of vaccine from GRAY cap multi-dose vial – do NOT dilute gray cap vials prior to use) at least 28 days after dose #2 of an mRNA vaccine by intramuscular (IM) injection.

   d. **Booster Dose**: If a person is 12 years of age or older and meets criteria outlined above for booster dose administration, then give a 30 microgram dose (i.e., 0.3 mL of vaccine from GRAY cap multi-dose vial – do NOT dilute gray cap vials prior to use) by intramuscular (IM) injection at the following time interval after the person completed their primary series:
      - If the VR completed their primary series with either the Pfizer-BioNTech or Moderna COVID-19 vaccine, then given the Pfizer-BioNTech booster dose at least 5 months after the

person completed their primary mRNA COVID-19 vaccine series (including any 3rd dose administered because the person is moderately or severely immunocompromised).

- If the VR completed their primary series with the Janssen COVID-19 vaccine, then give the Pfizer-BioNTech booster dose at least 2 months (8 weeks) after the VR completed their single-dose Janssen COVID-19 vaccine.

9. **Document vaccination**: Document each person's vaccine administration immediately in the Vaccine Management System (VMS) and enter required information.

10. **Give vaccine recipient the required post-vaccination documents listed in the "*Interim Guidance for NH State-Managed COVID-19 Vaccination Clinics*"** (including the "*COVID-19 Vaccine Record Card*" and "*After Visit Summary (AVS) Recommendations for Vaccine Recipients*").

11. **Be prepared to manage medical emergencies**: Be prepared to manage medical emergencies related to the administration of vaccine by following the emergency medical protocols ("*Medical Management of Vaccine Reactions*"). To prevent syncope, vaccinate patients while they are seated. Observe vaccine recipient for at least 15 minutes after vaccination; persons with a history of a severe allergic reaction (e.g., anaphylaxis) due to any cause, a history of a non-severe immediate (onset less than 4 hours) allergic reaction after a previous dose of a COVID-19 vaccine, or a history of any immediate allergic reaction of any severity to other non-COVID-19 vaccines or injectable medication therapies that do not qualify as a vaccine contraindication should be observed for 30 minutes after vaccination.

12. **Report adverse events to VAERS**: Report adverse events following administration of vaccine to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 or online at https://vaers.hhs.gov/reportevent.html.

Standing Order Authorization for Pfizer-BioNTech COVID-19 Vaccine Administration

This policy and procedure shall remain in effect for all vaccine recipients of the **NH State-Managed COVID-19 Vaccine Clinic**, and is effective **1/10/2022** until rescinded, replaced, or until **6/30/2022**. Updates to vaccination guidance and this standing order may occur. Therefore, this current order supersedes any previous standing orders for administration of the Pfizer-BioNTech vaccine.

Medical Director Signature/Date: _____ _____ / __**1/10/2022**__

(Benjamin P. Chan, MD, MPH)

Lori A. Shibinette
Commissioner

Patricia M. Tilley
Interim Director

STATE OF NEW HAMPSHIRE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Standing Order for Administering the Moderna COVID-19 mRNA Vaccine

PURPOSE: To reduce the burden of disease and associated morbidity and mortality from Coronavirus Disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the U.S. Food and Drug Administration (FDA) and the U.S. Centers for Disease Control and Prevention (CDC).

POLICY: This standing order enables eligible healthcare professionals to assess and vaccinate persons who meet the criteria outlined below and are seeking COVID-19 vaccination through the New Hampshire Department of Health & Human Services' State-managed COVID-19 vaccine clinics without the need for clinician examination or direct order from the attending provider at the time of the interaction.

PROCEDURE:

1. **Follow the "*Interim Guidance for NH State-Managed COVID-19 Vaccination Clinics*"**. Be familiar with CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines.

2. **Identify the following individuals for vaccination (i.e., the vaccine recipient, or VR)**:

   - Primary vaccination series: Any person 18 years of age or older who has not already received two prior doses of an mRNA COVID-19 vaccine (i.e., Pfizer-BioNTech or Moderna), a single dose of the J&J Janssen COVID-19 vaccine, or all recommended doses of another World Health Organization (WHO) Emergency Use listed vaccine. If administering mRNA COVID-19 vaccine dose #2, the same age-appropriate brand/manufacturer should be administered that the person received for dose #1, and doses of the Moderna COVID-19 vaccine should be separated by at least 28 days (second doses given between day 24 and 28 after the first dose are considered valid, but should not be routine). If dose #2 is given earlier than 24 days after dose #1 (i.e., earlier than the 4-day grace period), then dose #2 should be repeated and the repeat dose should be administered at least 28 days after the improperly spaced dose (see Appendix A in CDC's clinical guidance for more recommendations about vaccine administration errors). If more than 28 days have elapsed since the first dose, the second dose should be given as soon as possible and is still valid.

   - 3rd additional primary series dose for persons who are moderately or severely immunocompromised: Any person 18 years of age or older who is moderately or severely immunocompromised (see CDC guidance for examples of persons who qualify; note this is NOT an

all-inclusive list), and who has already received 2-doses of either the Pfizer-BioNTech or Moderna COVID-19 vaccines. This additional 3rd dose for people who are moderately or severely immunocompromised is only for VRs who received the Pfizer-BioNTech or Moderna vaccines for their primary series. Vaccine dose #3 for this indication should be administered at least 28 days after dose #2. If the 3rd dose is administered fewer than 24 days after the second dose (i.e., earlier than the 4-day grace period), then the 3rd additional dose should be repeated and the repeat dose should be administered at least 28 days after the improperly spaced dose (see Appendix A in CDC's clinical guidance for more recommendations about vaccine administration errors). The third dose should ideally be with the same mRNA vaccine product used for the first two doses, but if the same product is not available or not known, then the alternate mRNA vaccine product can be used (i.e., the Moderna COVID-19 vaccine can be used in place of the Pfizer-BioNTech COVID-19 vaccine, and vice versa). Persons seeking a third dose of the Pfizer-BioNTech or Moderna COVID-19 vaccine should be provided the self-attestation form ("Third Dose Vaccine Administration for People Who Are Immunocompromised") to review and sign before administration of a third dose. The signed form should be saved and securely sent to NH DPHS Immunization Section for record keeping. Self-attestation should also be documented in the Vaccine Management System (VMS).

- Booster dose: Any person 18 years of age or older (regardless of risk factors or underlying medical conditions) who is either:
    1. At least 5 months beyond completion of a primary COVID-19 vaccine series with the Pfizer-BioNTech or Moderna vaccine (including any 3rd dose administered because the person is moderately or severely immunocompromised),

    OR

    2. At least 2 months (8 weeks) beyond completion of the single-dose Janssen COVID-19 vaccine.

  Heterologous (i.e., mix-and-match) booster dosing is allowed, so any of the COVID-19 vaccines can be used for booster doses regardless of the vaccine product used for a VR's primary vaccination. However, recommendations about the timing of booster dose administration is based on which vaccine the VR received for their primary vaccine series. If a booster dose is given earlier than the recommended time period, the booster dose does NOT need to be repeated. Verify the correct Moderna vaccine booster dose is being given (see administration instructions below).

3. Screen for any contraindications or precautions to vaccination (refer to the "*Vaccination Screening Checklist*" for vaccinators).

Contraindications: Do NOT give the Moderna COVID-19 vaccine to any person who has a history of either: **1)** A severe allergic reaction (e.g., anaphylaxis) after a previous dose of the Moderna COVID-19 vaccine or a component of the vaccine, or **2)** A known (diagnosed) allergy to a component of the vaccine.

- See CDC's "Interim Clinical Considerations for Use of COVID-19 Vaccines", Appendix C for a list of COVID-19 vaccine ingredients.

- Allergic reactions after vaccination should be differentiated from non-allergic reactions, such as vasovagal episodes and normal vaccine side effects. CDC has created a table (Appendix D) to assist providers in differentiating.
- See CDC's guidance on COVID-19 vaccine contraindications and precautions, including Appendix B, for details on what qualifies as a "severe" vs. "non-severe" allergic reaction.
- A person with a contraindication to one mRNA COVID-19 vaccine (Pfizer-BioNTech or Moderna) should not receive doses of either of the mRNA vaccines.

Precautions: Take additional precautions if a person has a history of either: **1)** An immediate allergic reaction to other non-COVID-19 vaccines or injectable medication therapies (including intramuscular, intravenous, or subcutaneous injections), or **2)** A non-severe, immediate allergic reaction after a previous dose of a COVID-19 vaccine.

- An "immediate allergic reaction" is defined as any hypersensitivity related signs or symptoms consistent with urticaria (hives), angioedema, respiratory distress, or anaphylaxis that occurs within 4 hours following administration.
- Allergic reactions after vaccination should be differentiated from non-allergic reactions, such as vasovagal episodes and normal vaccine side effects. CDC has created a table (Appendix D) to assist providers in differentiating.
- See CDC's guidance on COVID-19 vaccine contraindications and precautions, including Appendix B, for details on what qualifies as a "severe" vs. "non-severe" allergic reaction.
- Vaccine may be given, but persons with a vaccine "precaution" are recommended to discuss their allergy histories with their primary care provider so their provider can help perform a risk assessment and discuss the potential risks/benefits of the COVID-19 vaccines with the VR. If the VR chooses not to discuss their allergy history with their primary care provider before vaccination, the VR can still be administered the vaccine. Inform the VR about the potential increased risk of an allergic reaction to the COVID-19 vaccine. VR must be monitored for at least 30 minutes after vaccination.
- If VR either 1) had a severe allergic reaction after a previous dose of the Janssen vaccine, or 2) has a known/diagnosed allergy to polysorbate, then VR has a contraindication to the Janssen vaccine and the CDC recommends referral to an allergist-immunologist be considered before administration of the Pfizer-BioNTech or Moderna vaccines. This is because of potential allergic cross-reactivity between polysorbate (an ingredient in the Janssen vaccine) and polyethylene glycol (an ingredient in both the Pfizer and Moderna vaccines).
    - If VR has consulted with their primary care provider and/or an allergist-immunologist, and vaccination was determined to be appropriate based on provider's risk assessment, and if patient is aware of risks and desires to be vaccinated, then the Moderna vaccine may be given; document in the Vaccine Management System (VMS).

- If VR has not consulted with their primary care provider or an allergist-immunologist, consult with vaccine clinic medical lead to determine if vaccination is appropriate based on VR's allergy history. Consider declining vaccination until patient is evaluated by their primary care provider or an allergist-immunologist.

- If there is any question about whether a VR has a COVID-19 vaccine contraindication vs. precaution, consult with vaccine clinic medical lead to help determine if vaccination is appropriate. If there are concerns about whether a VR is appropriate to be vaccinated with available COVID-19 vaccines, then the VR should be declined vaccination and instructed to seek assessment and vaccination in a more appropriate medically monitored setting.

4. **Screen for other health conditions listed below (refer to the "*Vaccination Screening Checklist*" for vaccinators).**

   - **Development of myocarditis or pericarditis after receiving an earlier dose of an mRNA COVID-19 vaccine (Pfizer-BioNTech or Moderna)**: If the VR developed myocarditis or pericarditis after receipt of an earlier dose of the Moderna or Pfizer-BioNTech vaccine, then the VR should not receive an additional dose of an mRNA vaccine or the Janssen vaccine at a State-managed vaccination clinic. The Janssen vaccine has not been associated with development of myocarditis/pericarditis. Therefore, VR could be considered for the Janssen vaccine to either complete their primary vaccine series or receive a booster, if VR is eligible. However, before administration of the Janssen vaccine after an episode of myocarditis/pericarditis associated with receipt of an mRNA COVID-19 vaccine, the VR should be fully recovered with no evidence of ongoing heart inflammation, as determined by a VR's clinical team. Therefore, in a VR who developed myocarditis/pericarditis after receipt of an mRNA vaccine, such persons should be referred to their healthcare provider for further assessment and administration of additional COVID-19 vaccine doses (including Janssen vaccine) to ensure appropriate counseling and risk assessment, monitoring, and to ensure that signs/symptoms of myocarditis/pericarditis have completely resolved before another dose is given. People with a history of myocarditis or pericarditis that is NOT related to receipt of a prior dose of an mRNA COVID-19 vaccine may receive either the Pfizer-BioNTech or Moderna vaccines after their episode of myocarditis/pericarditis has completely resolved.

   - **Severe allergic reaction (e.g., anaphylaxis) due to any cause that does not qualify as a vaccine contraindication or precaution (including to other oral medications, food, environmental exposures, etc.)**: Vaccine may be given. It is recommended that the VR discuss their allergy history with their primary care provider before vaccination, but even if the VR did not discuss with their primary care provider, vaccine can be given. VR must be monitored for at least 30 minutes after vaccination.

   - **Receipt of passive antibody therapy (e.g., convalescent plasma or monoclonal antibody therapy) as treatment for COVID-19 in the prior 90 days, or as <u>post-exposure prophylaxis</u> in**

the prior 30 days: As a precautionary measure to avoid interference of the antibody treatment with the vaccine-induced immune response, COVID-19 vaccination should be deferred for:

- At least 90 days after receipt of a passive antibody therapy for COVID-19 treatment
- At least 30 days after receipt of passive antibody therapy for post-exposure prophylaxis (i.e., to prevent COVID-19 after an exposure)

If it is unclear whether a VR received passive antibody therapy as treatment for COVID-19 or for post-exposure prophylaxis, then defer vaccination for at least 90 days.

- **Moderate or Severe Immunosuppression:** Vaccine may be given. Vaccine should be safe for VR to receive, but the vaccine may be less effective due to their immune system. Counsel the person to continue to take steps to protect themselves from COVID-19 after vaccination. If questions or concerns, recommend the VR discuss with their health care provider.
- **Pregnancy/Breastfeeding:** Vaccine is recommended for pregnant and breastfeeding women by the CDC and by professional medical societies like The American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal and Fetal Medicine (SMFM). Vaccine is also recommended for people who are trying to get pregnant, might become pregnant in the future, or who were recently pregnant. If a pregnant or breastfeeding woman has concerns, counsel VR that pregnant women are at increased risk for severe COVID-19 and adverse pregnancy outcomes (e.g., preterm birth, stillbirth, preeclampsia) if they become infected with SARS-CoV-2, and the vaccine will help protect both mother and baby from COVID-19 and related complications. Additionally, safety data on use of the mRNA COVID-19 vaccines (Pfizer-BioNTech and Moderna vaccines) in pregnant women haven't identified any safety concerns for the mother or infant. If the person has concerns recommend they discuss their concerns with their pregnancy provider.
- **Bleeding disorder or taking blood thinner**: Vaccine may be given, but use a fine-gauge needle (23 gauge or smaller caliber), followed by firm pressure on the site (without rubbing) for at least 2 minutes.

5. **Provide required documents listed in the "*Interim Guidance for NH State-Managed COVID-19 Vaccination Clinics*" (or ensure vaccine recipient has already received the documents)**: Provide all vaccine recipients (or, in the case of minors or people who lack decision making capacity, their parent or legal representative) with a copy of the most current required information (or verify the person, parent/guardian, or legal representative received and had the opportunity to review the information), including, but not limited to, the FDA's Fact Sheet for Recipients and Caregivers (for Moderna COVID-19 vaccine). Fact Sheet translations into other languages can be found on the FDA's Moderna COVID-19 Vaccine Website.

6. **Obtain consent for vaccination from a legal guardian for vaccine recipients 18 years of age or older who lack decision making capacity and cannot legally consent to vaccination themselves:** Follow

instructions outlined in the "*Interim Guidance for NH State-Managed COVID-19 Vaccination Clinics*". Any new vaccine dose administration requires a new consent form (if the parent/guardian is not in attendance).

7. **Prepare to administer vaccine**: Choose the needle gauge, needle length, and injection site as outlined below. Ensure the multi-dose vials of the Moderna vaccine have been appropriately prepared for administration, as outlined in the FDA's Fact Sheet for Healthcare Providers Administering Vaccine (for Moderna COVID-19 vaccine). Follow manufacturer's instructions for storing and handling vaccine.

   Adolescents (18 years of age): Use a 1-inch needle (22-25 gauge) and administer in the deltoid muscle of the arm. Alternatively, the anterolateral thigh can also be used (use a 1 – 1½ inch needle length when injecting the anterolateral thigh).

   Adults (19 years of age and older): Use needle size, gauge, and injection location as outlined in the table below based on a person's sex and weight. The deltoid muscle of the arm/shoulder is the preferred injection site, but if necessary due to a medical condition, the anterolateral thigh can also be used for injection (use a 1½ inch needle length for males and females of any weight when injecting the anterolateral thigh).

Sex and Weight	Needle Gauge	Needle Length	Preferred Injection Site
Female or male <130 lbs	22–25	5/8* – 1"	Deltoid muscle of arm
Female or male 130–152 lbs	22–25	1"	Deltoid muscle of arm
Female 153–200 lbs	22–25	1 – 1½"	Deltoid muscle of arm
Male 153–260 lbs	22–25	1 – 1½"	Deltoid muscle of arm
Female 200+ lbs	22–25	1½"	Deltoid muscle of arm
Male 260+ lbs	22–25	1½"	Deltoid muscle of arm

** A 5/8" needle may be used in patients weighing less than 130 lbs (<60 kg) for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle to the skin.*

8. **Administer the Moderna COVID-19 vaccine as follows**:

   a. **Dose #1**: Give a 100 microgram dose (i.e., 0.5 mL of vaccine) by intramuscular (IM) injection.

   b. **Dose #2**: Give a 100 microgram dose (i.e., 0.5 mL of vaccine) at least 28 days after dose #1 of the Moderna vaccine by intramuscular (IM) injection.

   c. **Dose #3** (additional primary series dose for moderately or severely immunocompromised): After the vaccine recipient self-attests that they are moderately or severely immunocompromised, give a 100 microgram dose (i.e., 0.5 mL of vaccine) at least 28 days after dose #2 of an mRNA vaccine by intramuscular (IM) injection.

   e. **Booster dose** (note the different dose): If a person is 18 years of age or older and meets criteria outlined above for booster dose administration, then give a **50 microgram dose** (i.e., **0.25 mL of**

vaccine) by intramuscular (IM) injection at the following time interval after the person completed their primary series:

- If the VR completed their primary series with either the Pfizer-BioNTech or Moderna COVID-19 vaccine, then given the Moderna booster dose at least 5 months after the person completed their primary mRNA COVID-19 vaccine series (including any 3rd dose administered because the person is moderately or severely immunocompromised).
- If the VR completed their primary series with the Janssen COVID-19 vaccine, then give the Moderna booster dose at least 2 months (8 weeks) after the VR completed their single-dose Janssen COVID-19 vaccine.

9. **Document vaccination**: Document each person's vaccine administration immediately in the Vaccine Management System (VMS) and enter required information.
10. **Give vaccine recipient the required post-vaccination documents listed in the "*Interim Guidance for NH State-Managed COVID-19 Vaccination Clinics*"** (including the "*COVID-19 Vaccine Record Card*" and "*After Visit Summary (AVS) Recommendations for Vaccine Recipients*").
11. **Be prepared to manage medical emergencies**: Be prepared to manage medical emergencies related to the administration of vaccine by following the emergency medical protocols ("*Medical Management of Vaccine Reactions*"). To prevent syncope, vaccinate patients while they are seated. Observe vaccine recipient for at least 15 minutes after vaccination; persons with a history of severe allergic reaction (e.g., anaphylaxis) due to any cause, a history of a non-severe immediate (onset less than 4 hours) allergic reaction after a previous dose of a COVID-19 vaccine, or a history of any immediate allergic reaction of any severity to other non-COVID-19 vaccines or injectable medication therapies that do not qualify as a vaccine contraindication should be observed for 30 minutes after vaccination.
12. **Report adverse events to VAERS**: Report adverse events following administration of vaccine to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 or online at https://vaers.hhs.gov/reportevent.html.

Standing Order Authorization for Moderna COVID-19 Vaccine Administration

This policy and procedure shall remain in effect for all vaccine recipients of the **NH State-Managed COVID-19 Vaccine Clinic**, and is effective **1/10/2022** until rescinded, replaced, or until **6/30/2022**. Updates to vaccination guidance and this standing order may occur. Therefore, this current order supersedes any previous standing orders for administration of the Moderna vaccine.

Medical Director Signature/Date: _____ _____ / **1/10/2022**

(Benjamin P. Chan, MD, MPH)

Lori A. Shibinette
Commissioner

Patricia M. Tilley
Interim Director

STATE OF NEW HAMPSHIRE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DIVISION OF PUBLIC HEALTH SERVICES

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Standing Order for Administering the J&J Janssen COVID-19 Adenovirus Vector Vaccine

PURPOSE: To reduce the burden of disease and associated morbidity and mortality from Coronavirus Disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the U.S. Food and Drug Administration (FDA) and the U.S. Centers for Disease Control and Prevention (CDC).

POLICY: This standing order enables eligible healthcare professionals to assess and vaccinate persons who meet the criteria outlined below and are seeking COVID-19 vaccination through the New Hampshire Department of Health & Human Services' State-managed COVID-19 vaccine clinics without the need for clinician examination or direct order from the attending provider at the time of the interaction.

PROCEDURE:

1. **Follow the "*Interim Guidance for NH State-Managed COVID-19 Vaccination Clinics*"**. Be familiar with CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines.

2. **Identify the following individuals for vaccination (i.e. the vaccine recipient, or VR)**:
   - Primary vaccination series: Any person 18 years of age or older who has not already received two prior doses of an mRNA COVID-19 vaccine (i.e., Pfizer-BioNTech or Moderna), a single dose of the Janssen COVID-19 vaccine, or all recommended doses of another World Health Organization (WHO) Emergency Use listed vaccine. A person who has received one prior dose of an mRNA vaccine but has an allergic reaction which prevents that person from receiving their second dose of the mRNA vaccine (i.e., person has a contraindication to receiving an mRNA COVID-19 vaccine) may be given the single-dose Janssen vaccine after at least 28 days have passed from receipt of the mRNA vaccine dose #1 to complete a primary COVID-19 vaccine series (with appropriate assessment, counseling, and precautions as outlined below).

   - Booster dose: Any person 18 years of age or older (regardless of risk factors or underlying medical conditions) who is either:
     1. At least 5 months beyond completion of a primary COVID-19 vaccine series with the Pfizer-BioNTech or Moderna vaccine (including any 3rd dose administered because the person is moderately or severely immunocompromised),

     OR

2. At least 2 months (8 weeks) beyond completion of the single-dose Janssen COVID-19 vaccine.

Heterologous (i.e., mix-and-match) booster dosing is allowed, so any of the COVID-19 vaccines can be used for booster doses regardless of the vaccine product used for a VR's primary vaccination. However, recommendations about the timing of booster dose administration is based on which vaccine the VR received for their primary vaccine series. If a booster dose is given earlier than the recommended time period, the booster dose does NOT need to be repeated.

- For both primary series and booster dose vaccination, the Pfizer-BioNTech or Moderna COVID-19 vaccines should be offered to a person first before vaccination with the Janssen vaccine; the Pfizer-BioNTech or Moderna COVID-19 vaccines are recommended over the Janssen vaccine because of the rare risk of Thrombosis with Thrombocytopenia Syndrome (TTS) that can occur after Janssen vaccination. However, the Janssen vaccine can be administered to people who meet the above criteria and who have a contraindication to the mRNA COVID-19 vaccines or who request the Janssen vaccine after being informed of the risks and the recommendations (see "Vaccination Screening Checklist").

3. Screen for any contraindications or precautions to vaccination (refer to the "*Vaccination Screening Checklist*" for vaccinators).

Contraindications: Do NOT give the Janssen COVID-19 vaccine to any person who has a history of any of the following: **1)** A severe allergic reaction (e.g., anaphylaxis) after a previous dose of the Janssen COVID-19 vaccine or a component of the vaccine, **2)** A known (diagnosed) allergy to a component of the vaccine, or **3)** Thrombosis with Thrombocytopenia Syndrome (TTS) development after receiving a prior dose of the Janssen or AstraZeneca COVID-19 vaccines.

- See CDC's "Interim Clinical Considerations for Use of COVID-19 Vaccines", Appendix C for a list of COVID-19 vaccine ingredients.
- Allergic reactions after vaccination should be differentiated from non-allergic reactions, such as vasovagal episodes and normal vaccine side effects. CDC has created a table (Appendix D) to assist providers in differentiating.
- See CDC's guidance on COVID-19 vaccine contraindications and precautions, including Appendix B, for details on what qualifies as a "severe" vs. "non-severe" allergic reaction.

Precautions: Take additional precautions if a person has a history of either: **1)** An immediate allergic reaction to other non-COVID-19 vaccines or injectable medication therapies (including intramuscular, intravenous, or subcutaneous injections), or **2)** A non-severe, immediate allergic reaction after a previous dose of a COVID-19 vaccine.

- An "immediate allergic reaction" is defined as any hypersensitivity related signs or symptoms consistent with urticaria (hives), angioedema, respiratory distress, or anaphylaxis that occurs within 4 hours following administration.

- Allergic reactions after vaccination should be differentiated from non-allergic reactions, such as vasovagal episodes and normal vaccine side effects. CDC has created a table (Appendix D) to assist providers in differentiating.
- See CDC's guidance on COVID-19 vaccine contraindications and precautions, including Appendix B, for details on what qualifies as a "severe" vs. "non-severe" allergic reaction.
- Vaccine may be given, but persons with a vaccine "precaution" are recommended to discuss their allergy histories with their primary care provider so their provider can help perform a risk assessment and discuss the potential risks/benefits of the COVID-19 vaccines with the VR. If the VR chooses not to discuss their allergy history with their primary care provider before vaccination, the VR can still be administered the vaccine. Inform the VR about the potential increased risk of an allergic reaction to the COVID-19 vaccine. VR must be monitored for at least 30 minutes after vaccination.
- If VR either 1) had a severe allergic reaction after a previous dose of the Pfizer or Moderna COVID-19 vaccine, or 2) has a known/diagnosed allergy to polyethylene glycol (PEG), then the VR has a contraindication to the mRNA COVID-19 vaccines and the CDC recommends referral to an allergist-immunologist be considered before administration of the Janssen vaccine. This is because of potential allergic cross-reactivity between polyethylene glycol (an ingredient in both the Pfizer and Moderna vaccines) and polysorbate (an ingredient in the Janssen vaccine).
    - If VR has consulted with their primary care provider and/or an allergist-immunologist, and vaccination was determined to be appropriate based on provider's risk assessment, and if patient is aware of risks and desires to be vaccinated, then the Janssen vaccine may be given; document in the Vaccine Management System (VMS). If Janssen vaccine is given, it should be at least 28 days after a previous mRNA vaccine dose (if applicable).
    - If VR has not consulted with their primary care provider or an allergist-immunologist, consult with vaccine clinic medical lead to determine if vaccination is appropriate based on VR's allergy history. Consider declining vaccination until patient is evaluated by their primary care provider or an allergist-immunologist.
- If there is any question about whether a VR has a COVID-19 vaccine contraindication vs. precaution, consult with vaccine clinic medical lead to help determine if vaccination is appropriate. If there are concerns about whether a VR is appropriate to be vaccinated with available COVID-19 vaccines, then the VR should be declined vaccination, and instructed to seek assessment and vaccination in a more appropriate medically monitored setting.

4. **Screen for other health conditions listed below (refer to the "*Vaccination Screening Checklist*" for vaccinators).**
    - **Development of myocarditis or pericarditis after receiving an earlier dose of an mRNA COVID-19 vaccine (Pfizer-BioNTech or Moderna)**: If the VR developed myocarditis or pericarditis after

receipt of an earlier dose of the Moderna or Pfizer-BioNTech vaccine, then the VR should not receive an additional dose of an mRNA vaccine or the Janssen vaccine at a State-managed vaccination clinic. The Janssen vaccine has not been associated with development of myocarditis/pericarditis. Therefore, VR could be considered for the Janssen vaccine to either complete their primary vaccine series or receive a booster, if VR is eligible. However, before administration of the Janssen vaccine after an episode of myocarditis/pericarditis associated with receipt of an mRNA COVID-19 vaccine, the VR should be fully recovered with no evidence of ongoing heart inflammation, as determined by a VR's clinical team. Therefore, in a VR who developed myocarditis/pericarditis after receipt of an mRNA vaccine, such persons should be referred to their healthcare provider for further assessment and administration of additional COVID-19 vaccine doses (including Janssen vaccine) to ensure appropriate counseling and risk assessment, monitoring, and to ensure that signs/symptoms of myocarditis/pericarditis have completely resolved before another dose is given. People with a history of myocarditis or pericarditis that is NOT related to receipt of a prior dose of an mRNA COVID-19 vaccine may receive the Janssen vaccine after their episode of myocarditis/pericarditis has resolved.

- **Severe allergic reaction (e.g., anaphylaxis) due to any cause that does not qualify as a vaccine contraindication or precaution (including to other oral medications, food, environmental exposures, etc.)**: Vaccine may be given. It is recommended that the VR discuss their allergy history with their primary care provider before vaccination, but even if the VR did not discuss with their primary care provider, vaccine can be given. VR must be monitored for at least 30 minutes after vaccination.

- **Receipt of passive antibody therapy (e.g., convalescent plasma or monoclonal antibody therapy) as treatment for COVID-19 in the prior 90 days, or as post-exposure prophylaxis in the prior 30 days**: As a precautionary measure to avoid interference of the antibody treatment with the vaccine-induced immune response, COVID-19 vaccination should be deferred for:
    - At least 90 days after receipt of a passive antibody therapy for COVID-19 treatment
    - At least 30 days after receipt of passive antibody therapy for post-exposure prophylaxis (i.e., to prevent COVID-19 after an exposure)

  If it is unclear whether a VR received passive antibody therapy as treatment for COVID-19 or for post-exposure prophylaxis, then defer vaccination for at least 90 days.

- **Moderate or Severe Immunosuppression:** Vaccine may be given. Vaccine should be safe for VR to receive, but the vaccine may be less effective due to their immune system. Counsel the person to continue to take steps to protect themselves from COVID-19 after vaccination. If questions or concerns, recommend the VR discuss with their health care provider.

- **Pregnancy/Breastfeeding:** Vaccine is recommended for pregnant and breastfeeding women by the CDC and by professional medical societies like The American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal and Fetal Medicine (SMFM). Vaccine is also

recommended for people who are trying to get pregnant, might become pregnant in the future, or who were recently pregnant. If a pregnant or breastfeeding woman has concerns, counsel VR that pregnant women are at increased risk for severe COVID-19 and adverse pregnancy outcomes (e.g., preterm birth, stillbirth, preeclampsia) if they become infected with SARS-CoV-2, and the vaccine will help protect both mother and baby from COVID-19 and related complications. Additionally, safety data on use of the mRNA COVID-19 vaccines (Pfizer-BioNTech and Moderna vaccines) in pregnant women haven't identified any safety concerns for the mother or infant. The Janssen COVID-19 vaccine has less data on use in pregnant women, so information on Janssen vaccine safety and effectiveness during pregnancy is limited, but we believe that the risk of the vaccine to the VR and unborn baby is low. If the person has concerns recommend they discuss their concerns with their pregnancy provider.

- **Bleeding disorder or taking blood thinner**: Vaccine may be given, but use a fine-gauge needle (23 gauge or smaller caliber), followed by firm pressure on the site (without rubbing) for at least 2 minutes.
- **History of an immune-mediated clinical syndrome characterized by thrombosis (blood clotting) AND thrombocytopenia (low platelet counts), such as "heparin-induced thrombocytopenia" (HIT):** Persons who are within 90 days after recovery from an immune-mediated syndrome characterized by thrombosis and thrombocytopenia should not be given the Janssen COVID-19 vaccine; such persons should be offered either the Pfizer-BioNTech or Moderna COVID-19 vaccines. If more than 90 days have passed since recovery from their clinical condition, they can still receive the Janssen vaccine after informing that person of the potential risks associated with the Janssen vaccine and Thrombosis with Thrombocytopenia Syndrome (TTS), but the Pfizer-BioNTech or Moderna COVID-19 vaccines are still preferred.
- **Development of Guillain-Barré syndrome (GBS) after the first dose of the Janssen vaccine**: A VR who developed GBS within 42 days following the first dose of the Janssen vaccine should not receive a Janssen booster. The VR should be offered either a Pfizer-BioNTech or Moderna vaccine booster instead, assuming no contraindications (development of GBS has not been associated with the mRNA COVID-19 vaccines). If VR also has a contraindication to mRNA vaccination, then a Janssen booster may still be able to be administered, but not at a State-managed COVID-19 vaccination clinic; such VRs should be referred to their healthcare provider for further evaluation for booster dose administration.

5. **Provide required documents listed in the "*Interim Guidance for NH State-Managed COVID-19 Vaccination Clinics*" (or ensure vaccine recipient has already received the documents)**: Provide all vaccine recipients (or, in the case of minors or people who lack decision making capacity, their parent or legal representative) with a copy of the most current required information (or verify the person, parent/guardian, or legal representative received and had the opportunity to review the information), including, but not limited to, the FDA's Fact Sheet for Recipients and Caregivers (for Janssen COVID-19 vaccine). Fact Sheet translations into other languages can be found on the FDA's Janssen COVID-19 Vaccine Website.

6. **Obtain consent for vaccination from a legal guardian for vaccine recipients 18 years of age or older who lack decision making capacity and cannot legally consent to vaccination themselves:** Follow instructions outlined in the "*Interim Guidance for NH State-Managed COVID-19 Vaccination Clinics*". Any new vaccine dose administration requires a new consent form (if the parent/guardian is not in attendance).

7. **Prepare to administer vaccine**: Choose the needle gauge, needle length, and injection site as outlined below. Ensure the multi-dose vials of the Janssen vaccine have been appropriately prepared for administration, as outlined in the FDA's Fact Sheet for Healthcare Providers Administering Vaccine (for Janssen COVID-19 vaccine). Follow manufacturer's instructions for storing and handling vaccine.

   Adolescents (18 years of age): Use a 1-inch needle (22-25 gauge) and administer in the deltoid muscle of the arm. Alternatively, the anterolateral thigh can also be used (use a 1 – 1½ inch needle length when injecting the anterolateral thigh).

   Adults (19 years of age and older): Use needle size, gauge, and injection location as outlined in the table below based on a person's sex and weight. The deltoid muscle of the arm/shoulder is the preferred injection site, but if necessary due to a medical condition, the anterolateral thigh can also be used for injection (use a 1½ inch needle length for males and females of any weight when injecting the anterolateral thigh).

Sex and Weight	Needle Gauge	Needle Length	Preferred Injection Site
Female or male <130 lbs	22–25	5/8* – 1"	Deltoid muscle of arm
Female or male 130–152 lbs	22–25	1"	Deltoid muscle of arm
Female 153–200 lbs	22–25	1 – 1½"	Deltoid muscle of arm
Male 153–260 lbs	22–25	1 – 1½"	Deltoid muscle of arm
Female 200+ lbs	22–25	1½"	Deltoid muscle of arm
Male 260+ lbs	22–25	1½"	Deltoid muscle of arm

** A 5/8" needle may be used in patients weighing less than 130 lbs (<60 kg) for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle to the skin.*

8. **Administer the Janssen COVID-19 vaccine as follows**:

   a. **Dose #1**: Give a single 0.5 mL dose of vaccine by intramuscular (IM) injection.

   b. **Booster Dose**: If a person is 18 years of age or older and meets criteria outlined above for booster dose administration, then give a 0.5 mL dose of vaccine by intramuscular (IM) injection at the following time interval after the person completed their primary series:

      - If the VR completed their primary series with either the Pfizer-BioNTech or Moderna COVID-19 vaccine, then given the Janssen booster dose at least 5 months after the person completed their primary mRNA COVID-19 vaccine series (including any 3rd dose administered because the person is moderately or severely immunocompromised).

- If the VR completed their primary series with the Janssen COVID-19 vaccine, then give the Janssen booster dose at least 2 months (8 weeks) after the VR completed their single-dose Janssen COVID-19 vaccine.

9. **Document vaccination**: Document each person's vaccine administration immediately in the Vaccine Management System (VMS) and enter required information.

10. **Give vaccine recipient the required post-vaccination documents listed in the "*Interim Guidance for NH State-Managed COVID-19 Vaccination Clinics*"** (including the "*COVID-19 Vaccine Record Card*" and "*After Visit Summary (AVS) Recommendations for Vaccine Recipients*").

11. **Be prepared to manage medical emergencies**: Be prepared to manage medical emergencies related to the administration of vaccine by following the emergency medical protocols ("*Medical Management of Vaccine Reactions*"). To prevent syncope, vaccinate patients while they are seated. Observe vaccine recipient for at least 15 minutes after vaccination; persons with a history of severe allergic reaction (e.g., anaphylaxis) due to any cause, a history of a non-severe immediate (onset less than 4 hours) allergic reaction after a previous dose of a COVID-19 vaccine, or a history of any immediate allergic reaction of any severity to other non-COVID-19 vaccines or injectable medication therapies that do not qualify as a vaccine contraindication should be observed for 30 minutes after vaccination.

12. **Report adverse events to VAERS**: Report adverse events following administration of vaccine to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 or online at https://vaers.hhs.gov/reportevent.html.

Standing Order Authorization for Janssen COVID-19 Vaccine Administration

This policy and procedure shall remain in effect for all vaccine recipients of the **NH State-Managed COVID-19 Vaccine Clinic**, and is effective **1/10/2022** until rescinded, replaced, or until **6/30/2022**. Updates to vaccination guidance and this standing order may occur. Therefore, this current order supersedes any previous standing orders for administration of the Janssen vaccine.

Medical Director Signature/Date: _____ _____ / **1/10/2022**

(Benjamin P. Chan, MD, MPH)

Medical Management of Vaccine Reactions in Adults

All vaccines have the potential to cause an adverse reaction. In order to minimize adverse reactions, patients should be carefully screened for precautions and contraindications before vaccine is administered (see www.immunize.org/catg.d/p3072.pdf, guidance in provided clinic protocols, and vaccine standing orders). Even with careful screening, reactions may occur. These reactions can vary from minor (e.g., soreness, itching) to severe and life threatening (e.g., anaphylaxis). Vaccine providers should be familiar with identifying allergic reactions, including anaphylaxis, and must be competent in managing these vaccine events at the site of vaccine administration. Providers should also have a plan in place to immediately contact emergency medical services (EMS) in the event of a severe vaccine reaction. Maintenance of the airway, oxygen administration, and administration of intravenous medications might be necessary. The table below describes procedures to follow if various reactions occur.

REACTION	SIGNS and SYMPTOMS	MANAGEMENT
Localized	Soreness, redness, itching, or swelling at the injection site	Apply a cold compress to the injection site. Consider giving an analgesic (pain reliever) or antipruritic (anti-itch) medication.
	Slight bleeding	Apply pressure and an adhesive compress over the injection site.
	Continuous bleeding	Place thick layer of gauze pads over site and maintain direct and firm pressure; raise the bleeding injection site (e.g., arm) above the level of the patient's heart.
Psychological fright and syncope (fainting)	Fright before injection is given	Have patient sit or lie down for the vaccination.
	Patient feels "faint" or has paleness, sweating, nausea, lightheadedness, dizziness, weakness, or visual disturbances	Have patient lie flat. Loosen any tight clothing and maintain an open airway. Apply cool, damp cloths to patient's face and neck. Keep them under close observation until full recovery.
	Fall, without loss of consciousness	Examine the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated.
	Loss of consciousness	Check the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated. Call 911 if patient does not recover immediately.
Anaphylaxis	**Skin and mucosal symptoms** such as generalized hives, itching, or flushing; swelling of lips, face, throat, or eyes. **Respiratory symptoms** such as change in voice, sensation of throat closing, stridor, shortness of breath, wheeze, or cough. **Gastrointestinal symptoms** such as nausea, vomiting, diarrhea, cramping abdominal pain. **Cardiovascular symptoms** such as collapse, dizziness, tachycardia, hypotension.	See "Emergency Medical Protocol for Management of Anaphylactic Reactions in Adults" on the next page for detailed steps to follow in treating anaphylaxis.

Adapted from www.immunize.org and online.lexi.com by the New Hampshire Division of Public Health Services (DPHS)
Updated 12/20/2020

Suggested medications for a community immunization clinic

First-line medication

- **Epinephrine** aqueous solution 1.0 mg/mL (1:1,000 dilution), in ampules, vials of solution, or prefilled syringes, including epinephrine autoinjectors (e.g., EpiPen and Auvi-Q). If autoinjectors are stocked, at least three should be available at all times (both pediatric and adult formulations).

Optional medication: H_1 antihistamines

- **Diphenhydramine** (e.g., Benadryl) oral 12.5 mg/5 mL liquid, 25 or 50 mg capsules/tablets.

Suggested supplies for a community immunization clinic

- Syringes (1 and 3 cc) and needles (22 and 25 g, 1", 1½", and 2") for epinephrine. For ampules, use filtered needles.
- Alcohol wipes
- Tourniquet
- Pediatric and adult airways (small, medium, and large)
- Pediatric and adult size pocket mask with one-way valve
- Oxygen (if available)
- Stethoscope
- Sphygmomanometer (blood pressure measuring device) with child, adult, and extra-large cuff sizes
- Tongue depressors
- Flashlight with extra batteries (for examination of the mouth and throat)
- Wrist watch with a second hand or other timing device
- Cell phone or access to onsite phone

Emergency Medical Protocol for Management of Anaphylactic Reactions in Adults

1. If itching and swelling are confined to the injection site where the vaccination was given, observe patient closely for the development of generalized symptoms.
2. If symptoms are generalized, activate the emergency medical system (i.e., call 911). This should be done by a second person, while the primary healthcare professional assesses the airway, breathing, circulation, and level of consciousness of the patient. Vital signs should be monitored continuously.
3. **Drug dosing information: The first-line and most important therapy in anaphylaxis is epinephrine. There are NO absolute contraindications to epinephrine in the setting of anaphylaxis.**
   a. **First-line treatment:** Use **epinephrine** 1.0 mg/mL aqueous solution (1:1,000 dilution). Administer 0.01 mg/kg per dose intramuscularly (adult dose ranges from 0.2 mg to 0.5 mg; maximum single dose is 0.5 mg). Prefilled autoinjector use is preferred. Repeat every 5-15 minutes in the absence of clinical improvement. Administration should preferably occur in the mid-outer thigh; administer through clothing if necessary. Follow manufacturer instructions for autoinjector use – hold the device/needle in the thigh for at least 3 seconds. Never re-insert needle. Do not administer repeated injections at the same site.
   b. **Optional treatment: H_1 antihistamines** – for hives or itching use **diphenhydramine**. Administer 25 mg orally every 4–6 hours or 50 mg every 6-8 hours (maximum single dose is 50 mg). H_1 antihistamines do NOT relieve upper or lower airway obstruction, hypotension, or shock.
4. Monitor the patient closely until EMS arrives. Perform cardiopulmonary resuscitation (CPR), if necessary, and maintain airway. Keep patient in supine position (flat on back) unless he or she is having breathing difficulty. If breathing is difficult, patient's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs. Monitor blood pressure and pulse at least every 5 minutes.
5. If EMS has not arrived and symptoms are still present, repeat dose of epinephrine every 5–15 minutes for up to 3 doses, depending on patient's response.
6. Record the patient's reaction (e.g., hives, anaphylaxis) to the vaccine, all vital signs, medications administered to the patient, including the time, dosage, response, and the name of the medical personnel who administered the medication, and other relevant clinical information. Report the incident to the Vaccine Adverse Event Reporting System (VAERS).
7. Notify the patient's primary care physician.

These standing orders for the medical management of vaccine reactions in adult patients shall remain in effect for patients of the **NH State-Managed Vaccine Clinic** until rescinded, or until **6/30/2022**

Name of Clinic — Date

Medical Director's Signature (Benjamin P. Chan, MD, MPH) — **12/21/2021** Date of Signing

Adapted from www.immunize.org and online.lexi.com by the New Hampshire Division of Public Health Services (DPHS)
Updated 12/20/2020

Medical Management of Vaccine Reactions in Children & Teens

All vaccines have the potential to cause an adverse reaction. In order to minimize adverse reactions, patients should be carefully screened for precautions and contraindications before vaccine is administered (see www.immunize.org/catg.d/p3072.pdf, guidance in provided clinic protocols, and vaccine standing orders). Even with careful screening, reactions may occur. These reactions can vary from minor (e.g., soreness, itching) to severe and life threatening (e.g., anaphylaxis). Vaccine providers should be familiar with identifying allergic reactions, including anaphylaxis, and must be competent in managing these vaccine events at the site of vaccine administration. Providers should also have a plan in place to immediately contact emergency medical services (EMS) in the event of a severe vaccine reaction. Maintenance of the airway, oxygen administration, and administration of intravenous medications might be necessary. The table below describes procedures to follow if various reactions occur.

REACTION	SIGNS and SYMPTOMS	MANAGEMENT
Localized	Soreness, redness, itching, or swelling at the injection site	Apply a cold compress to the injection site. Consider giving an analgesic (pain reliever) or antipruritic (anti-itch) medication.
	Slight bleeding	Apply pressure and an adhesive compress over the injection site.
	Continuous bleeding	Place thick layer of gauze pads over site and maintain direct and firm pressure; raise the bleeding injection site (e.g., arm) above the level of the patient's heart.
Psychological fright and syncope (fainting)	Fright before injection is given	Have patient sit or lie down for the vaccination.
	Patient feels "faint" or has paleness, sweating, nausea, lightheadedness, dizziness, weakness, or visual disturbances	Have patient lie flat. Loosen any tight clothing and maintain an open airway. Apply cool, damp cloth to patient's face and neck. Keep them under close observation until full recovery.
	Fall, without loss of consciousness	Examine the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated.
	Loss of consciousness	Check the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated. Call 911 if patient does not recover immediately.
Anaphylaxis	**Skin and mucosal symptoms** such as generalized hives, itching, or flushing; swelling of lips, face, throat, or eyes. **Respiratory symptoms** such as change in voice, sensation of throat closing, stridor, shortness of breath, wheeze, or cough. **Gastrointestinal symptoms** such as nausea, vomiting, diarrhea, cramping abdominal pain. **Cardiovascular symptoms** such as collapse, dizziness, tachycardia, hypotension.	See "Emergency Medical Protocol for Management of Anaphylactic Reactions in Children and Teens" on the next page for detailed steps to follow in treating anaphylaxis.

Adapted from www.immunize.org and online.lexi.com by the New Hampshire Division of Public Health Services (DPHS)
Updated 12/20/2020

Suggested medications for a community immunization clinic

First-line medication

- **Epinephrine** aqueous solution 1.0 mg/mL (1:1,000 dilution), in ampules, vials of solution, or prefilled syringes, including epinephrine auto injectors (e.g., EpiPen and Auvi-Q). If autoinjectors are stocked, at least three should be available at all times (both pediatric and adult formulations).

Optional medication: H_1 antihistamines

- **Diphenhydramine** (e.g., Benadryl) oral 12.5 mg/5 mL liquid, 25 or 50 mg capsules/tablets.

Suggested supplies for a community immunization clinic

- Syringes (1 and 3 cc) and needles (22 and 25 g, 1", 1½", and 2") for epinephrine. For ampules, use filtered needles.
- Alcohol wipes
- Tourniquet
- Pediatric and adult airways (small, medium, and large)
- Pediatric and adult size pocket masks with one-way valve
- Oxygen (if available)
- Stethoscope
- Sphygmomanometer (blood pressure measuring device) with child, adult, and extra-large cuff sizes
- Tongue depressors
- Flashlight with extra batteries (for examination of the mouth and throat)
- Wrist watch with a second hand or other timing device
- Cell phone or access to onsite phone

Emergency Medical Protocol for Management of Anaphylactic Reactions in Children and Teens

1. If itching and swelling are confined to the injection site where the vaccination was given, observe patient closely for the development of generalized symptoms.

2. If symptoms are generalized, activate the emergency medical system (i.e., call 911). This should be done by a second person, while the primary healthcare professional assesses the airway, breathing, circulation, and level of consciousness of the patient. Vital signs should be monitored continuously.

3. **Drug dosing information: The first-line and most important therapy in anaphylaxis is epinephrine. There are NO absolute contraindications to epinephrine in the setting of anaphylaxis.**

   a. **First-line treatment:** Use **epinephrine** 1.0 mg/mL aqueous solution (1:1,000 dilution). Administer 0.01 mg/kg per dose intramuscularly (maximum single dose is 0.3 mg in prepubertal children, and 0.5 mg in adolescents); see dosing chart on page 3. Prefilled autoinjector use is preferred, if available for patient age and weight. Repeat dosing every 5-15 minutes in the absence of clinical improvement. Administration should preferably occur in the mid-outer thigh; administer through clothing if necessary. Follow manufacturer instructions for autoinjector use – hold the device/needle in the thigh for at least 3 seconds. Never re-insert needle. Do not administer repeated injections at the same site.

   b. **Optional treatment: H_1 antihistamines** – for hives or itching use **diphenhydramine**. Administer 1–2 mg/kg of body weight orally every 4-6 hours (maximum single dose is 50 mg, but may be less based on age). See dosing charts on page 3. H_1 antihistamines do NOT relieve upper or lower airway obstruction, hypotension, or shock.

4. Monitor the patient closely until EMS arrives. Perform cardiopulmonary resuscitation (CPR), if necessary, and maintain airway. Keep patient in supine position (flat on back) unless he or she is having breathing difficulty. If breathing is difficult, patient's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs. Monitor blood pressure and pulse at least every 5 minutes.

5. If EMS has not arrived and symptoms are still present, repeat dose of epinephrine every 5–15 minutes for up to 3 doses, depending on patient's response.

6. Record the adverse event (e.g., hives, anaphylaxis) to the vaccine, all vital signs, medications administered to the patient, including the time, dosage, response, and the name of the medical personnel who administered the medication, and other relevant clinical information. Report the incident to the Vaccine Adverse Event Reporting System (VAERS).

7. Notify the patient's primary care physician.

These standing orders for the medical management of vaccine reactions in pediatric patients shall remain in effect for patients of the **NH State-Managed Vaccine Clinic** until rescinded, or until **6/30/2022**

Name of Facility — Date

Medical Director's Signature (Benjamin P. Chan, MD, MPH) — **12/21/2021** Date of Signing

Adapted from www.immunize.org and online.lexi.com by the New Hampshire Division of Public Health Services (DPHS)
Updated 12/20/2020

For your convenience, approximate dosages based on weight and age are provided in the following charts. Please confirm that you are administering the correct dose for your patient.

First-Line Treatment: Epinephrine					Epinephrine Dose	
Recommended dose is 0.01 mg/kg body weight up to 0.5 mg maximum dose. May be repeated every 5–15 minutes for a total of 3 doses.		**Age group**	**Range of weight (lbs)**	**Range of weight (kg)***	1.0 mg/mL aqueous solution (1:1000 dilution); intramuscular. Minimum dose is 0.05 mg	Epinephrine autoinjector (0.1 mg 0.15 mg or 0.3 mg)
	Infants and children	1–6 months	9–19 lbs	4–8.5 kg	0.05 mg (or mL)	Off label
		7–36 months	20–32 lbs	9–14.5 kg	0.1 mg (or mL)	0.1 mg†
		37–59 months	33–39 lbs	15–17.5 kg	0.15 mg (or mL)	0.15 mg/dose
		5–7 years	40–56 lbs	18–25.5 kg	0.2–0.25 mg (or mL)	0.15 mg/dose
		8–10 years	57–76 lbs	26–34.5 kg	0.25–0.3 mg (or mL)	0.15 mg or 0.3 mg/dose
	Teens	11–12 years	77–99 lbs	35–45 kg	0.35–0.4 mg (or mL)	0.3 mg/dose
		13 years & older	100+ lbs	46+ kg	0.5 mg (or mL) – max. dose	0.3 mg/dose

Note: If body weight is known, then dosing by weight is preferred. If weight is not known or not readily available, dosing by age is appropriate.
* *Rounded weight at the 50th percentile for each age range*
† 0.1 mg autoinjector is licensed for use in 7.5 kg to 14 kg infants and children

Optional Treatment: Diphenhydramine					Diphenhydramine Dose
Commonly known as Benadryl		**Age group**	**Range of weight (lb)**	**Range of weight (kg)***	Liquid: 12.5 mg/5 mL Tablets: 25 mg or 50 mg
Recommended dose is 1-2 mg/kg body weight every 4-6 hours	**Infants and children**	7–36 months	20–32 lbs	9–14.5 kg	10 –15 mg/dose
		37–59 months	33–39 lbs	15–17.5 kg	15–20 mg/dose
		5–7 years	40–56 lbs	18–25.5 kg	20–25 mg/dose
		8–12 years	57–99 lbs	26–45 kg	25–50 mg/dose
	Teens	13 years & older	100+ lbs	46+ kg	50 mg/dose (single dose maximum is 50 mg)

Note: If body weight is known, then dosing by weight is preferred. If weight is not known or not readily available, dosing by age is appropriate.
* *Rounded weight at the 50th percentile for each age range*

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