This document provides administrative guidance on vaccinating North Carolinians with a COVID-19 vaccine. This guidance is applicable for all vaccine providers in North Carolina, including hospitals, health systems, local health departments, federally qualified health centers, pharmacies, primary care providers, occupational health, and any other vaccine providers. As North Carolina moves through COVID-19 vaccine implementation, this guidance will be updated.

The administrative guidance is organized in the following sections:

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1.0 Executive Summary

1.1 Purpose

The purpose of this COVID-19 vaccine provider guidance document for North Carolina COVID-19 vaccine providers is to serve as a collection of key resources for vaccine providers who are on the front lines of implementing a safe and effective COVID-19 vaccination campaign in North Carolina. This guidance aims to meet the specific needs of COVID-19 vaccination planning and administration for the full spectrum of COVID-19 vaccine providers.

1.2 Organization of Guidance

This document is organized to serve as a step-by-step guide for vaccine providers to prepare for and administer COVID-19 vaccines to eligible populations in North Carolina. Additional content links are included throughout the document. Additional key resources are available in a technical appendix found here.

1.3 Updating of Guidance

This interim guidance will be distributed on a regular cadence to enrolled vaccine provider organizations. We will update the guidance as federal and state health officials receive additional COVID-19 vaccination information. When revisions are released, new changes will be highlighted in yellow.

1.4 Revision Log and Document Live Link

The most recent version of the document will be posted on the NCDHHS website. The link will be provided once available.

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| • Changed the title of the document  
Section 2: Overview of NC’s COVID-19 Vaccination Plan [updated]  
• Section 3: Group 1 [minor updates]  
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• Section 6: Guidance for Vaccine Providers [updated]  
• Section 7: Scenario Planning [updated]  
• Appendix 2 [minor updates]  
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• Appendix 8. COVID-19 Community Based Vaccination Events: Best Practices [New] |
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| Combined with LHD Vaccine Toolkit with several new sections noted below  
Section 3: Group 1 [minor updates]  
Section 4: Group 2 [Updated]  
Section 5: Group 3 [Updated]  
Section 9: Communicating with Patients about Vaccines [Updated]  
Section 10: Who Can Be A COVID Vaccine Provider? [New]  
Section 11: Readiness Checklist for Newly Enrolled Providers (Abbreviated) [Updated]  
Section 12: Guidance for Collaboration Among Vaccine Providers [Updated and renamed]  
Section 13: COVID-19 Vaccination Legal Considerations [New]  
Section 14: COVID-19 Vaccine Management System (CVMS) [Renamed and updated]  
Section 15: COVID-19 Vaccine Clinical Information and Guidance [New]  
Section 16: Orders to Administer COVID-19 Vaccine [New]  
Section 17: Administration of Vaccine [New]  
Section 18: Vaccine Storage and Handling [New]  
Section 20: Planning and Running Vaccination Clinics and Events [Updated]  
Section 21: Promoting Equitable Vaccine Distribution [Updated]  
Section 22: Payment and Billing of COVID-19 Vaccine [New] |
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| Section 3.0: Overview of North Carolina’s COVID-19 Vaccine Plan [Updated Infographic]  
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| Version 7.0 | March 26, 2021 | Sections 4.4 and 4.5: Updated dates of eligibility for Group 4 and 5 |
| Version 8.0 | April 16, 2021 | Section 4.0: [Updated and New Resources in Subsections 4.4 and 4.5 about Groups 4 and 5]  
Section 5.0: Special Populations [Added Subsection 5.3 Vaccination of Pregnant and Lactating Women]  
Section 6.0 [New Subsection 6.3 Johnson & Johnson (Janssen) COVID-19 Vaccine Pause Guidance]  
Section 7.0: CVMS [Updates to Several Subsections]  
Section 8: Who Can Be a COVID-19 Vaccine Provider [Updates to Subsection 8.2]  
Section 12: COVID-19 Vaccine Clinical Information and Guidance [Added New Subsection 12.9 and Updates to Subsections 12.2.3 and 12.10]  
Section 14: Vaccine Storage and Handling [Updated Subsection 14.2 Moderna with storage and EUA changes]  
Section 17: Planning and Running Vaccination Clinics and Events [Updates to Several Subsections] |
| Version 9.0 | April 30, 2021 | Section 5.0: Special Populations to Consider [Moderna Updates, New NCDHHS Resource, New Subsection 5.4 People Vaccinated With COVID-19 Vaccines Not Authorized in the US]  
Section 6.0 [Updates and Information About Bringing Summer Back Campaign 6.4.1 and Healthier Together Effort 6.4.2]  
Section 9: Newly Enrolled Providers [Renamed and Updated Section]  
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Section 12: COVID-19 Vaccine Clinical Information and Guidance [Updates on Janssen (Johnson & Johnson)]  
Section 17: Planning and Running Vaccination Clinics and Events [Vaccine Allocation Subsection 17.1 Updated and Addition of Subsection 17.10 Walk-In Vaccinations]  
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<p>| Version 10.0 | May 17, 2021 | Section 4.0: Vaccination Eligibility [Updated to Include Pfizer COVID-19 vaccine authorization to 12 years] |</p>
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PLEASE NOTE: Section 10.0: Guidance For Collaboration Among Vaccine Providers was removed and the sections that follow have been renumbered

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Recommendation About Pregnant and Lactating Women, and Added New Subsection 5.4 Vaccination of People Who Are Moderately to Severely Immunocompromised

Section 6.0: Communication and Outreach With Patients About Vaccines [Updated Subsection 6.3 Key Messages Related to Adolescents About FDA Approved and Authorized Pfizer Vaccine, Added New Subsection 6.4 Key Messages Related to People Who Are Immunocompromised, Updates to Section 6.5.3 Incentives for Vaccination, Added to Section 6.6 Examples of Additional Vaccine Resources: NC DHHS Teen, Friends and Families Sites and Resources and Updated Vaccine Site Locator]

Section 7.0: COVID-19 Vaccine Management System (CVMS) [Reorganized and Renumbered Added Subsections 7.6-7.9 and Added to 7.12 CVMS Updates]

Section 10: COVID-19 Vaccination Legal Considerations [Updates to Subsections 10.2.2 and 10.2.3 Related to Minor’s Consent General Statute]

Section 11: COVID-19 Vaccine Clinical Information and Guidance [Substantial Edits throughout Section: Added Information About Approved Pfizer Vaccine and Authorized Pfizer Vaccine, New Information Throughout and Subsection 11.2.6 About Additional Dose of mRNA Vaccine for People Who Are Moderately to Severely Immunocompromised, Updated Subsection 11.6 Warnings GBS with Johnson&Johnson COVID-19 Vaccine, New Subsection 11.11 Vaccinated People and Interpretation of SARS-CoV-2 Results]

Section 12: Orders to Administer COVID-19 Vaccine [Edits and Updates]

Section 13: Storage and Handling [Updates to Subsections 13.5 and 13.6 About Expiration of Vaccines With Extension of Expiry Dates for Pfizer and Shelf Life for Johnson&Johnson and Disposal]

Section 14.0 Administration of Vaccine [Edits to Subsection 14.6 and Addition of Information on Vaccinated People Who Subsequently Develop COVID-19]

Section 15.0: Vaccine Transfer Guidance [Added Information about Diluent Vials and Updated Information About Transfers]

Section 16.0: Planning and Running Vaccination Clinics and Events [Added to Subsection 16.2 About the Vaccine at Home Program]

Appendix/Reference Material [Added Appendices 59 and 60]
2.0 Guiding Principles

North Carolina’s COVID-19 Vaccine Plan is guided by a set of core principles rooted in equity, inclusivity, transparency, data-driven decision-making, and responsibility. Below, we outline how those principles inform the North Carolina Department of Health and Human Service’s guidance for vaccinating North Carolinians.

- **Equity:** All North Carolinians have equitable access to vaccines based on risk of exposure and risk of severe illness.
- **Inclusivity:** Vaccine planning and distribution is inclusive; actively engages state and local government, public and private partners; and draws upon the experience and expertise of leaders from historically marginalized populations.
  - Coordination is facilitated by state and local entities to ensure all priority populations can be reached. Vaccine and health care providers have a responsibility to take intentional action to reach and engage historically marginalized communities.
- **Transparency:** Transparent, accurate, and frequent public communications is essential to building trust
  - All North Carolinians, including vaccine providers and the public, understand what to expect in the vaccination campaign.
- **Data-Driven Decision-Making:** Data is used to promote equity, track progress and guide decision-making
  - Data will be used to prioritize vaccine allocations to reach populations at the highest risk of being hospitalized or dying, and those at high risk of exposure to COVID-19.
- **Responsibility:** Appropriate stewardship of resources and continuous evaluation and improvement drive successful implementation
  - Vaccinations will be administered in a way that protects the safety of all North Carolinians. All North Carolinians are able to receive their vaccine in as timely a manner as possible, recognizing the limited vaccine supply and that limited vaccine supply does not go unused.

3.0 Overview of North Carolina’s COVID-19 Vaccine Plan

After months of planning, North Carolina began providing COVID-19 vaccinations on December 14, 2020. To save lives and slow the spread of COVID-19, independent state and federal public health advisory committees made recommendations for who to vaccinate first based on limited supplies of vaccine being available. In North Carolina, the NC Institute of Medicine (NCIOM) convened a Vaccine Advisory Committee of more than 65 people representing diverse constituencies across the state. These committees recommended first protecting health care workers caring for patients with COVID-19, people at the highest risk of being hospitalized or dying, and those at high risk of exposure to COVID-19.

Our goal is to vaccinate as many people as quickly as possible given with the available supply of vaccines. North Carolina moved through vaccination groups by aligning to federal priorities and working with local vaccine providers to understand their local demand and available supply. North Carolina initially prioritized vaccination in simplified groups to remove barriers to identifying eligible individuals.

Since April 7, 2021, all North Carolinians age 16 and over have been eligible to be vaccinated. In May 2021, both the US Food and Drug Association (FDA) authorized and the Advisory Committee on Immunization Practices (ACIP)
recommended the use of Pfizer-BioNTech COVID-19 vaccine in individuals from 12-15 years of age. As a result, all North Carolinians ages 12 and older are eligible to be vaccinated with the Pfizer-BioNTech COVID-19 vaccine.

North Carolina has made a commitment to equity. Equity is embedded in every aspect of vaccine operations, beginning with holding ourselves and our vaccine providers publicly accountable. A top priority for the state is to distribute vaccine as quickly and equitably as possible. All vaccine providers are expected to ensure that vaccine is equitably administered within each group. NCDHHS has a specific focus on building trust with historically marginalized populations. Longstanding and continuing racial and ethnic injustices in our health care system contribute to lack of trust in vaccines. We hope you will join us in partnering with trusted leaders and organizations to provide accurate information about the vaccine.

4.0 Vaccination Eligibility : Individuals Ages 12 Years and Older

Everyone who wants a safe and effective COVID-19 vaccination. Since April 7, 2021, FDA authorized COVID-19 vaccines have been available in North Carolina to everyone ages 16 and older. Since May 13, 2021, the FDA authorized Pfizer-BioNTech COVID-19 vaccine has been available in North Carolina for use among adolescents 12-15 years of age.

NEW: Starting August 13, 2021, individuals who are moderately to severely immunocompromised are eligible under Pfizer-BioNTech COVID-19 vaccine Emergency Use Authorization(EUA) and the Moderna COVID-19 Vaccine EUA by the FDA to receive an additional dose of mRNA COVID-19 vaccine after an initial 2-dose primary mRNA COVID-19 vaccine series. People will be asked to self-attest to being moderately to severely immunocompromised. See Section 11.2.6 for more information which includes examples of conditions and treatments associated with moderate and severe immunocompromise.

NEW: On August 23, 2021, the U.S. Food and Drug Administration approved the first COVID-19 vaccine. The FDA approved Pfizer-BioNTech COVID-19 Vaccine which is being marketed as COMIRNATY (koe-mir’-na-tee). COMIRNATY is approved for use as a 2-dose primary series for the prevention of COVID-19 disease in individuals 16 years of age and older. The Pfizer-BioNTech vaccine continues to be available under EUA by the FDA for use in individuals 12 through 15 years of age and also for use under EUA by the FDA for the administration of a third dose in certain immunocompromised individuals 12 years and older. (See Section 11.0 for more information)

What you should know:

• The vaccine is free everywhere in North Carolina.
• No photo ID or insurance is needed.
• Only Pfizer vaccine is currently approved or authorized for use in people 12 years and older
• Depending on where you get your vaccine, you may need to make an appointment.
• U.S. citizenship is not required or checked.
• Find out the answers to frequently asked questions about who can get a COVID-19 vaccine at: https://covid19.ncdhhs.gov/vaccines/frequently-asked-questions-about-covid-19-vaccinations
In response to concerns of access barriers some people are facing regarding documentation requests prior to receiving COVID-19 vaccine, the Health Resources and Services Administration (HRSA) developed and posted two fact sheets to help both patients and providers better understand their rights and responsibilities regarding access to COVID-19 vaccines.

Fact Sheets:
- Patient Fact Sheet (English | Spanish)
- Provider Fact Sheet (English | Spanish)

5.0 Special Populations to Consider

5.1 Vaccination of Homebound Persons

5.1.1 Identifying homebound persons.
Homebound persons are those that need the help of another person or medical equipment such as crutches, a walker, or a wheelchair to leave their home, or their medical provider believes that their health or illness could get worse if they leave their home. In North Carolina, there are estimated to be as many as over 97,000 homebound persons. Vaccine providers should coordinate with other health care providers, community-based organizations, and community healthcare workers to identify homebound persons in your community. Examples include:
- Medicaid/Medicare-Sponsored Organizations
- Home Health Agencies
- Veterans Associations
- Area Aging Agencies
- Community-Based Organizations
- Agencies Serving People with Disabilities
- Health Insurance Companies

NCDHHS has engaged with more than 300 homebound serving agencies, many of which have said they can help identify homebound persons for vaccination. NCDHHS has distributed this list by county to vaccine providers to facilitate partnerships, and will continue to distribute it periodically.

5.1.2 Vaccination Models to Consider for Homebound Persons

- **Onboard New Providers to Vaccinate Homebound Persons**: Examples of providers include but are not limited to hospice and home care agencies, palliative care organizations, Long Term Care or independent pharmacies, and EMS. These providers are allocated vaccine to deliver to homebound persons in their communities
- **Events Allocation to Vaccinate Homebound Persons**: Partner existing vaccine providers with community-based organizations that can identify and reach homebound persons. Apply to host a vaccination event, one time or recurring, until demand is met.
- **Existing Vaccine Providers Vaccinate Homebound Persons on an Ongoing Basis**: Existing providers set aside a portion of allocated vaccines or use left-over doses from missed appointments to vaccinate homebound persons
Vaccine Providers Can Participate in the Vaccines at Home Program: The North Carolina Department of Health and Human Services is partnering with Piedmont Triad Regional Council Area Agency on Aging (PTRC AAA) to provide free COVID-19 vaccinations to people with limited mobility who cannot leave their home. This new initiative expands PTRC AAA’s successful local at-home vaccination program to communities across the state. There is also an At-Home Vaccination Hotline at 1-866-303-0026 which allows caregivers, providers and individuals across North Carolina to schedule an at-home vaccination. An online registration form is also available at www.ptrc.org/covid. A PTRC Vaccination Specialist will follow up to schedule an at-home vaccination. For more information about how the Vaccine at Home Program, please see Section 7.7 and Section 16.2

5.1.3 Planning Vaccinations for Homebound Persons with Partners

Requirements for local medical providers to administer the vaccine to homebound individuals:

- Enrolled and onboarded to CVMS to be a COVID-19 vaccine provider and meet all storage and handling requirements (See Section 7.7)
- **Vaccinating workforce**
  - Licensed health professionals or other individuals authorized by the federal PREP act or the state to administer COVID-19 vaccines
  - Trained in vaccine administration of COVID-19 vaccine product they have available
  - Trained and able to provide emergency management of severe allergic reactions and anaphylaxis
  - **Vaccinator workforce options include, but are not limited to**
    - Paramedics
    - Home Health and Hospice Staff
    - Individual Pharmacists
    - Home health nurses
    - Dentists
    - Students (e.g., nurses)
- Have a medical provider order vaccine or use the appropriate statewide standing order
- Liability protection is available at federal level through PREP Act and through state Executive Order 193, Section 3B

A list of vaccine providers who are providing or interested in providing vaccinations to homebound individuals can be found on NCDHHS’s website at: https://covid19.ncdhhs.gov/vaccines/homebound-vaccine-providers or on myspot.nc.gov.

5.1.4 Best Practices for Vaccinating Homebound Persons

1. **Best Practice #1: Plan to maximize efficiency of vaccinations**
   - Estimate the number of doses needed as accurately as possible
   - Map out travel plans to increase efficiency within the approved time frame specified for the vaccine product, factoring in pre-vaccination preparation time and post-vaccine observation
   - Ensure readiness to maintain, monitor, & report temperature of vaccine from the time vaccine is taken out of a clinic facility, during transportation & up to the time that vaccine is administered
   - Providers may also administer vaccine to caretakers and family members
2. **Best Practice #2: Follow transport guidance for the specific vaccine product**
   • **Temperature:** A digital data logger should be used to monitor the temperature of the vaccine. Place the probe near the vaccine. Document the min/max temperatures and time when transport begins, every time the container is opened, and upon return to the facility using the transport temperature log (retain for a minimum of three years).
   • **Vials vs Pre-Drawn Syringe:**
     - **Vials**: Recommended by CDC. Punctured vial may be transported from one home to another by the same health care professional if the cold chain is properly maintained. A partially used vial cannot be transferred from one provider to another or across state lines.
     - **Pre-Drawn Syringe**: If only option, [U.S. Pharmacopeia](https://www.uspharmacopoeia.org) includes guidance for transporting pre-drawn vaccine in syringes
   • **General Information:**
     - If using a company or personal vehicle, only transport vaccines inside the passenger compartment (not in the trunk or bed of a truck, which may be too hot or too cold).
     - Move transport containers directly to a vehicle that is already at a comfortable temperature—neither too hot nor too cold.
     - Keep containers out of direct sunlight.
     - Pack loose vials carefully to prevent them from breaking.
     - Never leave the container unattended in the vehicle.
     - The total time for transport plus vaccine administration should not exceed 8 hours (unless stated otherwise by the vaccine manufacturer).

See [Section 13.0](#) for more information on storage, handling, and transporting COVID-19 vaccine.

3. **Best Practice #3: Data Entry for Homebound Vaccinations**
   • **Registration in CVMS**
     - Pre-registration: Requires individuals or caregiver to complete process after receiving email
     - On-site registration
       - Online with tablet, laptop, or other mobile device
       - Paper form – Use CVMS Recipient Registration and COVID-19 Vaccine Administration Form (English / [Spanish](https://www.uspharmacopoeia.org))
     - Online registration forms should not require for people to submit ID, SSN, or insurance information to be able to register for an appointment. These fields should be made optional or should not be included on registration forms at all. The form should allow for people to proceed to register even if they do not have these documents.
     - Asking for SSN or ID information in a registration form presents a special barrier since many people will see the questions and elect to simply not register for the event, without an opportunity to speak to the vaccine provider about whether the documents are actually required.
   • **Vaccine Administration**: Providers should fully enter vaccine administrations into CVMS within 24 hours, but no later than 72 hours

4. **Best Practice #4: Plan for Accessibility Issues**
• Include training on accessibility-specific issues. Examples:
  o Working with people who are blind or have limited vision
  o Those who are deaf or hard of hearing
  o Those who work with service animals
  o Those with various language, physical, social, or sensory needs
• Providing information in a variety of accessible formats (e.g., American Sign Language, multiple languages, braille, large font, low literacy, materials with pictures or visual cues)
• NCDHHS has an Accessibility Checklist with additional resources: https://covid19.ncdhhs.gov/media/2259/download

5. Best Practice #5: Whenever possible, transport of the vaccine to homebound persons is preferred to ensure the safety of the homebound persons. However, an alternative can be to bring homebound people to vaccination sites if needed. Transportation options to consider:

• People who need transportation assistance to receive a COVID-19 vaccine should reach out to their local transit agency. You can find your local transit agency online at North Carolina Public Transit (https://www.ncdot.gov/divisions/public-transit/Documents/NC_public_transit.pdf). Local transit agencies serve all 100 North Carolina counties.
• Coordinate with trusted partners such as places of worship or community centers to arrange for people to safely transport homebound persons to and from vaccination appointments
• Consider partnering with Uber to provide homebound persons with discounted or free ride vouchers to and from vaccination events.
• Partner with local EMS to provide transportation for medically fragile homebound persons.
• Consider coordinating with service providers who have existing contracts with a variety of private transportation providers (this is targeted primarily to those who are 60+ and are receiving services funded by DHHS-DAAS).

For additional in-depth guidance, see CDC guidance on vaccinating homebound persons at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/homebound-persons.html.

5.2 Vaccination of Minors

There is now an approved COVID-19 vaccine recommended for use among adolescents 16 and 17 years of age.

On August 23, 2021, FDA-approved the Pfizer-BioNTech COVID-19 vaccine (being marketed as COMIRNATY) as a 2-dose series for the prevention of COVID-19 in individuals 16 years of age and older. Pfizer-BioNTech COVID-19 vaccine continues to be available under EUA for the prevention of COVID-19 in individuals 12 through 15 years. Moderna and Janssen (J&J) are authorized only for adults (18 years and older) at this time. NCDHHS recommends that vaccine providers put practices in place to ensure only Pfizer-BioNTech COVID-19 vaccine is given to individuals under 18 years of age at the time of this release. This could include practices, such as:

• Sharing which brands of vaccines are offered and for which specific age groups when opening up appointments to schedule
• Utilize scheduling notes to ensure that only appointments with Pfizer vaccine are offered to adolescents younger than 18 years of age
Review scheduled appointments ahead of time to identify individuals that are younger than 18 years of age and ensure Pfizer vaccine is available or refer the individual to another community provider with Pfizer

Review age as part of pre-screening for COVID-19 vaccine to ensure only Pfizer vaccine is given to those under 18 years of age

Leverage EHR Order Sets (i.e., SmartSets) to incorporate decision logic for Pfizer COVID-19 vaccine if less than 18 years of age

Starting August 20, 2021, a new state law (Session Law 2021-110 Section 9) requires health care providers to “obtain written consent from a parent or legal guardian prior to administering any vaccine that has been granted emergency use authorization and is not yet fully approved by the United States Food and Drug Administration to an individual under 18 years of age.”

However, on August 23, 2021, when Pfizer-BioNTech COVID-19 vaccine (marketed as COMIRNATY) received full FDA approval for use in individuals 16 years and older, according to SL 2021-110, 16 and 17 year old individuals have the legal authority to consent to receive the Pfizer-BioNTech COVID-19 Vaccine (COMIRNATY) if they demonstrate the decisional capacity to do so (See Section 10.2.2). Since Pfizer-BioNTech COVID-19 vaccine continues to only be available under emergency use authorization for individuals 12 through 15 years, health care providers are required to obtain written consent from a parent or legal guardian prior to administration of the Pfizer-BioNTech COVID-19 vaccine in this age group. For more information around minor’s consent, see Section 10.2.2.

States do not need to take any additional steps to permit pharmacists, pharmacy interns, or pharmacy technicians to administer COVID-19 vaccines to children in the age range specified by an EUA, in accordance with the Secretary’s Declaration. Any State or local laws or requirements that would prohibit, or effectively prohibit, the pharmacists, pharmacy interns, and pharmacy technicians from administering COVID-19 vaccines are preempted by the PREP Act.

Vaccine manufacturers continue to work to include younger children in their trials to determine safety and efficacy.

**5.3 Vaccination of Pregnant and Lactating Women**

- The following is updated and stronger language provided by CDC: COVID-19 vaccination is recommended for all people 12 years and older, including people who are pregnant, breastfeeding, trying to get pregnant now, or might become pregnant in the future. Evidence about the safety and effectiveness of COVID-19 vaccination during pregnancy has been growing.” Detailed information from CDC and more can be found at COVID-19 Vaccines While Pregnant or Breastfeeding: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html

- Vaccination for those who are pregnant or wanting to become pregnant is recommended by the American College of Obstetricians and Gynecologists (ACOG), the Society for Maternal-Fetal Medicine (SMFM), the American Society for Reproductive Medicine (ASRM), and the Society for Male Reproduction and Urology.
5.4 Vaccination of People Who Are Moderately to Severely Immunocompromised

- People who are moderately to severely immunocompromised make up about 3% of the adult population and are especially vulnerable to COVID-19 because they are more at risk of serious, prolonged illness.
- FDA modified the Emergency Use Authorizations (EUAs) and ACIP added recommendations for use of an additional dose of Pfizer-BioNTech COVID-19 vaccine (for persons aged ≥12 years) or Moderna COVID-19 vaccine (for persons aged ≥18 years) after an initial 2-dose primary mRNA COVID-19 vaccine series for people who are moderately to severely immunocompromised.
- Starting August 13, 2021, vaccine providers in North Carolina may begin administering an additional dose of mRNA COVID-19 vaccine to people with moderately to severely compromised immune systems after an initial two-dose vaccine series.
- Please see Section 11.2.6 for more details about the clinical guidance which includes some examples of conditions and treatments associated with moderate and severe immune compromise.
- Patients may self-attest to having one or more medical conditions or treatments associated with moderate or severe immune compromise.

5.5 Vaccination of All Employees

Guidance for employers of frontline essential workers and all other employees suggest that they take the following steps:

- Encourage all of their employees to get vaccinated.
- Share information and resources with all of their employees on how they can find their spot to take their shot
- Offer to work with their local vaccination providers
- Consider what type of vaccination model would work best for the organization and their employees.

Vaccine providers may choose to partner or vaccinate frontline essential workers and all other employees in a way that matches their existing infrastructure. Vaccine providers may choose to use one of following vaccination models for employees, though the list is not exhaustive of potential approaches.
<table>
<thead>
<tr>
<th>Model</th>
<th>Description</th>
</tr>
</thead>
</table>
| Occupational health                       | • Company or contracted clinics for employers and facilities with their own occupational health providers who are enrolled and onboarded onto the COVID-19 Vaccine Management System (CVMS).  
• Now that vaccine supply is more available, enrolled and onboarded occupational health providers can be directly allocated vaccines. Occupational health providers are held to the same expectations as all other vaccine providers. |
| Onsite vaccination event                  | • Local vaccine provider partners with employer who have a large workforce and are committed to supporting efforts to vaccinate their employees.  
• Vaccine providers may choose to invite an employer to assist with employee registration and bulk upload employees using the Organizational Portal in the COVID-19 Vaccine Management System (CVMS) (See Section 7.3 for more information) |
| Vaccination event with local vaccine provider | • Local vaccine provider partners with employer who have a large workforce and are committed to supporting efforts to vaccinate their employees. For example, the vaccine provider can host a vaccine clinic with appointments made available first to a certain employer group, such as meat processing or childcare workers.  
• Vaccine providers may choose to invite an employer to assist with employee registration and bulk upload employees using the Organizational Portal in the COVID-19 Vaccine Management System (CVMS)  
• The employer role for these events held at a clinic or other community-based site can include the following:  
  o Identifying eligible employees and assisting with employee registration in the COVID-19 Vaccine Management System (CVMS)  
  o Scheduling employees into pre-specified appointment slots |

The employer role for these onsite events can include the following:
- Providing and arranging the onsite vaccination clinic space, including space for patient registration, vaccination, and post-vaccine monitoring
- Identifying eligible employees and assisting with employee registration in the COVID-19 Vaccine Management System (CVMS)
- Scheduling employees into pre-specified appointment slots
- Notifying employees of their assigned appointment slot
- Staffing to assist with registration or traffic control
- Supporting vaccination clinic needs, such as Wi-Fi, toilet and handwashing facilities, basic beverage and food provision, eating location away from vaccination locations, clear identification for vaccination site staff
22

- Notifying employees of their assigned appointment slot
- Staffing to assist with registration or traffic control
- Supporting vaccination clinic needs, such as basic beverage and food provision
- Providing transportation to the vaccination sites for employees
- Providing paid time off for the employee to be vaccinated

Employee independently seeks vaccination
- The employee finds a spot for vaccination independently of their employer, such as through the Find My Spot online tool, their health care provider, or community vaccination events.

School-Located Vaccination Clinics Web Resources
- Webpage for planning and implementing school-located vaccination (SLV) clinics for any routinely-recommended vaccine as well as COVID-19 vaccine. The target audiences for this guidance are public and private entities interested in planning and implementing SLV clinics, including staff from state and local public health departments, community health care clinics, pharmacies, pediatric practices, and health systems.

5.6 People Vaccinated with COVID-19 Vaccines Not Authorized in the United States

Some people may have received a COVID-19 vaccine that is not currently approved or authorized in the United States (i.e., Astrazeneca or Sinovac). No data are available on the safety or efficacy of receiving a COVID-19 vaccine currently approved or authorized in the United States after receipt of a non-FDA-authorized COVID-19 vaccine. However, in some circumstances people who received a COVID-19 vaccine not currently approved or authorized in the United States may be offered revaccination with an FDA-approved or authorized vaccine:

- COVID-19 vaccines not approved or authorized by FDA but authorized for emergency use by WHO
  - People who completed a COVID-19 vaccination series with a vaccine that has been authorized for emergency use by the World Health Organization (WHO) do not need any additional doses with an FDA-approved or authorized COVID-19 vaccine.
  - People who are partially vaccinated with a COVID-19 vaccine series authorized for emergency use by WHO may be offered an FDA-approved or authorized COVID-19 vaccine series.

- COVID-19 vaccines not approved or authorized by FDA or not authorized for emergency use by WHO
  - People who completed or partially completed a COVID-19 vaccine series with a vaccine that is not approved or authorized by FDA or not authorized for emergency use by WHO may be offered an FDA-approved or authorized COVID-19 vaccine series.

- Administration of an FDA-approved or authorized COVID-19 vaccine in these people should comply with all conditions of use specified under the EUA for the vaccine being used. The minimum interval between the last dose of a non-FDA-authorized vaccine and an FDA-approved or authorized COVID-19 vaccine is 28 days.
- More information from the CDC can be found here.
authorized vaccines seen by vaccine providers in North Carolina are listed below with their status as of August 23, 2021:

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Doses</th>
<th>WHO Approved</th>
<th>FDA Approved</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>AstraZeneca</td>
<td>2</td>
<td>✓</td>
<td>×</td>
<td>Adenovirus Vector</td>
</tr>
<tr>
<td>Sinovac (CoronaVac)</td>
<td>2</td>
<td>✓</td>
<td>×</td>
<td>Killed Virus</td>
</tr>
<tr>
<td>CanSinoBio (Convidencia)</td>
<td>1</td>
<td>×</td>
<td>×</td>
<td>Adenovirus Vector</td>
</tr>
<tr>
<td>Gamaleya (Sputnik V)</td>
<td>2</td>
<td>×</td>
<td>×</td>
<td>Adenovirus Vector</td>
</tr>
<tr>
<td>Gamaleya (Sputnik Light)</td>
<td>1</td>
<td>×</td>
<td>×</td>
<td>Adenovirus Vector</td>
</tr>
<tr>
<td>Covaxin</td>
<td>2</td>
<td>×</td>
<td>×</td>
<td>Inactivated Virus</td>
</tr>
<tr>
<td>BBIBP-CorV/Sinopharm</td>
<td>2</td>
<td>✓</td>
<td>×</td>
<td>Inactivated Virus</td>
</tr>
</tbody>
</table>

× = not approved  ✓ = approved

6.0 Communication and Outreach with Patients about Vaccines

6.1 Overview

North Carolina is committed to providing early, transparent, consistent, and frequent communications so that North Carolinians:

- Trust the information that they receive from NCDHHS and vaccine providers about COVID-19 vaccinations
- Understand the benefits and risks of COVID-19 vaccinations
- Make informed decisions about COVID-19 vaccinations
- Know how and when to get a COVID-19 vaccine

North Carolinians are eager for information about COVID-19 vaccination. With the principle of “no wrong door” for public education, it is imperative that health care providers, local health departments, other enrolled providers, and trusted messengers in the community are equipped with clear, fact-based information and talking points to respond to inquiries. Organizations can consider creating email signatures or auto-responses containing key vaccine messages. Inquiries may come in via phone, email, social media, webinars, live Q&A, and many other channels. To date, inquiries have largely fallen into the following categories, outlined below.
6.2 Key Messaging to North Carolinians

- All vaccines were found to help prevent COVID-19 and are effective in preventing hospitalization and death, with no serious safety concerns noted in the clinical trials.
- **Tested, safe, and effective, COVID-19 vaccine** will help us get back in control of our live and back to the people and places we love.
- **Scientists had a head start and thousands of volunteers helped with clinical trials.** Researchers have been studying the technology used in the COVID-19 vaccines for decades.
- **You cannot get COVID-19 from the vaccine.** Vaccines safely increase your body’s natural ability to fight the virus before the virus attacks you.
- **The vaccines are available to all—for free.** You are able to get a vaccine for free, even if you don’t have health insurance.
- **Your privacy and personal information are protected at all times.** We do not send any personal information to the CDC or ICE.
- **After you are fully vaccinated,** you can get back to many activities you enjoyed before the pandemic, but for some activities you should still wear a mask.

6.3 Key Messages Related to Adolescents

- **Pfizer-BioNTech COVID-19 vaccine (marketed as COMIRNATY) now has full approval by the FDA for use as a 2-dose series to prevent COVID-19 in individuals 16 years and older.**
- **Pfizer-BioNTech COVID-19 vaccine continues to be available under Emergency Use Authorization by the FDA for use as a 2-dose series to prevent COVID-19 in individuals 12-15 years of age.**
  - At this time according to current state statute, written consent from a parent or a legal guardian is required for any vaccine under EUA, including teens ages 12 to 15 year receiving a Pfizer-BioNTech COVID-19 vaccine or an adolescent eligible for an additional dose with certain immunocompromised conditions.
- Adolescents ages 12-15 represent approximately 17 million people in the United States.
- At least 1.5 million 12-17-year-olds have gotten COVID-19 during the pandemic.
- While fewer children have been sick with COVID-19 compared to adults, children can be infected with COVID-19, and there is no way to tell in advance if your adolescent will get a severe or mild case. Without vaccination, your adolescent may be at risk for getting seriously ill and suffering pain, disability, and even death from COVID-19.
- **COVID-19 vaccines are safe and effective in adolescents.**
  - Thousands of adolescents received COVID-19 vaccines during clinical trials and tens of millions of adults in the United States have received COVID-19 vaccines under the most intense safety monitoring in U.S. history.
  - This vaccine can help protect your adolescent from getting infected or sick from COVID-19.
  - Adolescents, like adults, may have some side effects, which are normal signs that their body is building protection. These side effects may affect your adolescent’s ability to do daily activities, but they should go away in a few days.
Parents/caregivers can enroll their adolescent in v-safe, a free, smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins. Through v-safe, you can report any side effects your adolescent may have after vaccination. (See Section 11.10.3 for more information on v-safe).

- Getting your adolescent vaccinated can bring them one step closer to enjoying the activities they have missed.
- We can protect our adolescents by helping them make a lifetime of healthy choices. We can also protect adolescents by simply getting them vaccinated against COVID-19.
  - COVID-19 vaccination is COVID-19 prevention.
  - Widespread vaccination is critical to helping us end this unprecedented pandemic.

### 6.4 Key Messages Related to People Who Are Immunocompromised

- People who are moderately to severely immunocompromised are especially vulnerable to COVID-19 because they are more at risk of serious, prolonged illness.
- People who have compromised immune systems may benefit from an additional dose to make sure they have enough protection against COVID-19.
- CDC recommends people who are moderately to severely immunocompromised should receive an additional dose of mRNA COVID-19 vaccine after the initial 2 doses.
- CDC recommends that people with moderately to severely compromised immune systems receive an additional dose of mRNA COVID-19 vaccine at least 28 days after a second dose of Pfizer-BioNTech COVID-19 vaccine or Moderna COVID-19 vaccine.
- Immunocompromised people (including those who receive an additional mRNA dose) should be counseled about the potential for reduced immune response to COVID-19 vaccination and need to follow prevention measures
  - Wear a mask
  - Stay 6 feet apart from others they don’t live with
  - Avoid crowds and poorly ventilated indoor spaces until advised otherwise by their healthcare provider
- Close contacts of immunocompromised people should be strongly encouraged to be vaccinated against COVID-19.

### 6.5 Outreach and Communication Campaigns

#### 6.5.1 Bringing Summer Back Initiative
COVID-19 vaccines are our best shot to bring back summer and get everyone safely back to the people, places and activities they love. NCDHHS has launched the Bringing Summer Back initiative, a fun, flexible, community-centered approach to help every organization and individual stop the spread of COVID-19 by urging friends and neighbors to get vaccinated.

Bringing Back Summer campaign ran during the following weeks:
- May 16-21
- June 6-12
June 20-26

More information is available at: https://covid19.ncdhhs.gov/BringSummerBack.

6.5.2 Healthier Together

The Health Equity Action Network, also known as Healthier Together, is a public private partnership to increase the number of individuals who are Black, Indigenous, and People of Color (BIPOC) and from other historically marginalized populations receiving COVID-19 vaccinations across the state of North Carolina.

NCDHHS is committed to maximizing the speed and efficiency of North Carolina’s COVID-19 vaccine distribution in a way that adheres to our strong commitment to equity. To do that, NCDHHS is continuing to build a grassroots mobilization strategy to help overcome centuries of health inequities by investing in state, regional and community partners led by and serving BIPOC and other historically marginalized populations by:

- Building and earning trust on the ground with BIPOC and other historically marginalized communities and the organizations that are led by and support them
- Co-creating strategies in collaboration with nonprofit, grassroots, and community partners rooted in BIPOC and other historically marginalized communities
- Using data on vaccination efforts to inform planning and investment of resources

NCDHHS has partnered with the NC Counts Coalition to implement the Healthier Together initiative. NC Counts Coalition is a nonpartisan, nonprofit 501(c)(3) organization committed to building a healthy, just and equitable North Carolina through cross-sector partnerships that advance systemic solutions for communities facing systemic barriers, including BIPOC communities, LGBTQ+, low wealth, immigrant, and other communities.

Healthier Together is implementing strategies to drive demand and increase access to vaccines to BIPOC and other historically marginalized populations by conducting outreach and education efforts, coordinating local vaccine events at trusted and accessible locations, helping people schedule and get to vaccine appointments, providing on-site translation services, and helping ensure people get to second dose appointments.

As part of this initiative, Healthier Together is providing e grants to community-based organizations to do this work and hire regional health equity teams to support community-based organizations in their outreach and education efforts, help match vaccine providers with community-based organizations, and work with NCDHHS to ensure that communities have the vaccine supply, outreach, and transportation resources they need to get people vaccinated. As we move from COVID-19 response to recovery, we will extend this program’s infrastructure as a foundation for a longer-term framework for health equity. The program is funded by federal COVID-19 dollars. For more information about Healthier Together please click on this link.

6.5.3 Incentives for Vaccination

NCDHHS is offering various incentive programs to encourage COVID-19 vaccination. These include the following:

- **Summer Card Program:** A pilot program launched in May in four counties (Mecklenburg, Guilford, Rowan and Rockingham). Anyone 18 years and older who got their first dose of a COVID-19 vaccine, or drove someone to a vaccination at a participating provider received a $25 Summer Card at participating locations. In addition, from Aug. 4 through Aug. 31, $100 Summer Cards in the form of a Prepaid Mastercard are available at a limited
number of participating sites in some counties to anyone 18 and older who gets their first dose of a COVID-19 vaccine—while supplies last. Anyone who drives someone to get their first dose will continue to be able to receive a $25 Summer Card at participating locations.* Drivers will receive one Summer Card* per first-dose visit. Those interested in the program can visit https://covid19.ncdhhs.gov/vaccines/covid-19-vaccine-incentives or call 888-675-4567 to find a participating location. All locations accept walk-ins unless otherwise noted.

*Summer Card is in the form of a Prepaid Mastercard®. Prepaid card is issued by MetaBank®, N.A., Member FDIC.

- **Summer Cash Drawings:**
  - On June 10, Governor Cooper announced the $4 Million Summer Cash and Summer Cash 4 College Drawings to motivate those who have not yet been vaccinated—and thank those who have. Four North Carolinians 18 and older won $1 million each, and four North Carolinians ages 12 to 17 won tuition for post-secondary education.
  - Winners were selected through a series of four drawings, from June 23 through August 4. Drawings took place every other week on Wednesdays. New entries closed at midnight on the Sunday prior to that week’s Wednesday drawing. Winners were verified and then announced.
  - Entries were drawn from the state’s COVID-19 vaccination records. To be entered in the drawing, a record of at least one dose of vaccine must be available in CVMS by 11:59pm on the Sunday prior to the drawing. Those vaccinated on or after June 10, were entered twice for each drawing.
  - For more information go to: https://covid19.ncdhhs.gov/summervaxcash and the Governor’s Executive Order 219 at: https://files.nc.gov/governor/documents/files/Executive-Order-No.-219-FAQ.pdf

### 6.5.4 Vaccinating North Carolinians Ages 12 and Older

NCDHHS has developed materials to help you spread the word and stay informed about the availability of vaccine for this younger age group. Please visit the communications toolkit and select the tab labeled “Vaccine for Teens.” Teens and their families can also visit TeenVaxFacts for more information. Please also see this resource related to minors and parental consent.

CDC also has COVID-19 vaccine resources for parents, adolescents, healthcare providers, and community partners. See below for multiple CDC resources:

**Information for Parents and Adolescents:**

- **Web page:** [COVID-19 Vaccines for Children and Teens](https://www.cdc.gov/vaccines/parents/children/index.html) provides information about the benefits of COVID-19 vaccines for adolescents ages 12 and older, how to find a vaccination provider for adolescents, and what to expect during and after vaccination. provides information about the benefits of COVID-19 vaccines for adolescents ages 12 and older, how to find a vaccination provider for adolescents, and what to expect during and after vaccination.

- **Fact sheet:** [COVID-19 Vaccines for Preteens and Teens](https://www.cdc.gov/vaccines/parents/preteens/index.html) is a printable fact sheet for parents that explains the benefits of a COVID-19 vaccine for their children, safety information, and what to expect during and after vaccination. is a printable fact sheet for parents that explains the benefits of a COVID-19 vaccine for their children, safety information, and what to expect during and after vaccination.
• **Frequently asked questions:** Two new FAQs have been posted to address questions about the safety and benefits of COVID-19 vaccination for adolescents ages 12 and older. have been posted to address questions about the safety and benefits of COVID-19 vaccination for adolescents ages 12 and older.

• **Myth-buster about menstrual cycles:** Your menstrual cycle cannot be affected by being near someone who received a COVID-19 vaccine. This question and answer explains why.

• **Myth-buster about infertility:** It is safe for people who would like to have a baby one day to get a COVID-19 vaccine. This question and answer explains why.

• **Key things to know:** The web pages Key Things to Know about COVID-19 Vaccines and About COVID-19 Vaccines have been updated to include the recommendation that adolescents ages 12 and older get vaccinated.

• **Vaccine information for specific groups:** The web page COVID-19 Vaccine Information for Specific Groups has been updated to help the public find information about vaccination for adolescents.

Information for Healthcare and Vaccine Providers

• **Pediatric toolkit:** The Pediatric Healthcare Professionals COVID-19 Vaccination Toolkit provides materials to help healthcare providers give parents clear and accurate information about COVID-19 vaccines. The toolkit includes answers to common questions, an explanation of how mRNA vaccines work, and printable materials to give to parents. provides materials to help healthcare providers give parents clear and accurate information about COVID-19 vaccines. The toolkit includes answers to common questions, an explanation of how mRNA vaccines work, and printable materials to give to parents.

• **FAQs about consent for minors:** FAQs have been posted on the Pfizer-BioNTech product page for providers with information about consent, prescreening questions, and other issues related to the vaccination of minors.

• **Recipient education page:** The Vaccine Recipient Education page has been updated to include resources about COVID-19 vaccination for adolescents.

Information for Community Groups and Health Departments

• **Toolkit for community-based organizations:** The Community-Based Organizations COVID-19 Vaccine Toolkit has been updated to include information and resources on COVID-19 vaccination for adolescents ages 12 and older.

### 6.6 Examples of Additional Communication Resources

Any vaccine provider’s leadership and staff potentially responding to inquiries should be familiar with and stay up to date on the following topics:

<table>
<thead>
<tr>
<th>Training Program / Reference Material</th>
<th>Description</th>
</tr>
</thead>
</table>
| NC DHHS COVID-19 Vaccine Communications Toolkit ([https://covid19.ncdhhs.gov/vaccines/covid-19-vaccine-communications-toolkit](https://covid19.ncdhhs.gov/vaccines/covid-19-vaccine-communications-toolkit)) | The most up-to-date materials will be posted on the NC DHHS COVID-19 vaccine landing page:  
<table>
<thead>
<tr>
<th><strong>NC DHHS Vaccination Sites for Teens and Their Friends and Families</strong></th>
<th><strong>Information, Tools and Resources in English and Spanish to help educate about the benefits of COVID-19 vaccines which include:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Spanish</strong>&lt;br&gt;<a href="https://covid19.ncdhhs.gov/vacunasparajovenes">https://covid19.ncdhhs.gov/vacunasparajovenes</a></td>
<td></td>
</tr>
</tbody>
</table>

| **Vaccine Site Locator**<br>[(https://myspot.nc.gov/map-view)](https://myspot.nc.gov/map-view) | Easy to use online tool to help individuals find their spot to get a vaccination in NC, including vaccine provider locations and contact information. |

| **Vaccine Site Locator**<br>(Vaccines.gov) | **Vaccines.gov** helps people find the latest information on COVID-19 vaccine availability at certain providers and pharmacies. |

| **NC COVID-19 Vaccine Help Center**<br>1-888-675-4567 | Call center to respond to constituent questions. |

| **How Nurses and Medical Assistants Can Foster a Culture of Immunization in the Practice video** | Research shows that healthcare professionals are patients’ most trusted source of information when it comes to vaccines. By highlighting key points before, during, and after a patient’s visit, this presentation will support vaccine conversations and reinforce best practices for improving vaccination coverage. |

| **“#HowIRecommend” vaccination video series** | These videos explain the importance of vaccination, how to effectively address questions from patients about vaccine safety and effectiveness, and how clinicians routinely recommend same day vaccination for their patients. |

<p>| <strong>Provider Resources for COVID-19 Vaccine Conversations with Patients</strong> | Information for healthcare providers on how to talk to patients about COVID-19 vaccines, including giving strong recommendations, setting expectations about |</p>
<table>
<thead>
<tr>
<th>Epidemiology and Prevention of Vaccine-Preventable Diseases</th>
<th>Comprehensive information on routinely used vaccines and the diseases they prevent. Chapter 3, discusses essential strategies healthcare professionals can use when talking to patients about vaccines (updated 2020).</th>
</tr>
</thead>
<tbody>
<tr>
<td>NC DHHS COVID-19 Vaccine site <a href="https://covid19.ncdhhs.gov/vaccines">https://covid19.ncdhhs.gov/vaccines</a></td>
<td>COVID-19 vaccine guidance, resources, tools, data dashboard, etc.</td>
</tr>
</tbody>
</table>

### 7.0 COVID-19 Vaccine Management System (CVMS)

#### 7.1 Overview

**What is CVMS?**

CVMS, COVID-19 Vaccine Management System, is a secure, cloud-based vaccine management solution for COVID-19 that enables vaccine management and data sharing across NC providers, hospitals, agencies, pharmacies outside of the federal program and local, state, and federal governments on one common platform. NC providers enrolled in the CDC COVID-19 Vaccination Program will need to self-register for an NCID user account and password in order to log in to CVMS.

CVMS includes scheduling, inventory management, Spanish language translation, and the opportunity for EHR integration through the Health Information Exchange (HIE). Work towards an integration with the North Carolina Immunization Registry (NCIR) for one complete vaccine record is also underway. Providers wishing to capture vaccination records for the purposes of clinical documentation, billing, or other data capture, must do so separately in the EHR. Of note, there should be no out-of-pocket cost to vaccination for any patient, regardless of insurance coverage.

Many North Carolinians can view and print their COVID-19 vaccine information in the COVID-19 Vaccine Portal, including anyone who received their COVID-19 vaccine from a North Carolina enrolled provider, and provided an email address to their provider. The Vaccine Information PDF will also include a QR code that can be scanned to provide vaccine information for the recipient for whom it was generated. However, if the recipient received their COVID-19 vaccine from a pharmacy participating in the Federal Retail Pharmacy Program (such as CVS or Walgreens) or from another federal vaccine provider such as the Department of Defense, that individual will have to work directly with their vaccinating provider for a copy of their COVID-19 Vaccine information.

The Vaccine Marketplace has launched in CVMS. The Vaccine Marketplace streamlines the transfer process by enabling providers to check all on-hand inventory and transfer opportunities in a centralized database. Please see Section 7.10 for more details.
Why CVMS?
CVMS provides a flexible approach for managing, delivering, and administering vaccine programs. It is a scalable, integrated platform with configurable modules. This will allow for quicker updates to the system in order to meet business needs. In addition, built-in automation features mean less time spent on routine tasks and more time for high-value activities.

Documentation in CVMS.
CVMS remains the state’s system of record as well as the federal government’s reference point for North Carolina vaccination progress. All vaccine doses administered in North Carolina must be documented in CVMS. At this time, providers should fully enter administrations into CVMS within 24 hours as often as possible, but must enter administration data within 72 hours of administration. Providers should plan capacity for real-time or simultaneous data entry during vaccine efforts and identify local support or request help with staffing or centralized data entry immediately if they are not certain they can get the data entered within the timeframe.

CVMS in the COVID-19 Vaccine Journey

Below you will find the direct links and details on the username to use for each CVMS Portal.

- **CVMS Provider Enrollment Portal**: [https://covid-enroll.ncdhhs.gov](https://covid-enroll.ncdhhs.gov) – Use your Provider Enrollment username, which is the email address you registered with, and password you created.
- **CVMS Provider Portal**: [https://covid-vaccine-provider-portal.ncdhhs.gov](https://covid-vaccine-provider-portal.ncdhhs.gov) – Use your NCID username and password you created when registering for your NCID.
- **CVMS COVID-19 Vaccine Portal (for vaccine recipients)**: [https://covid-vaccine-portal.ncdhhs.gov/](https://covid-vaccine-portal.ncdhhs.gov/) – Use your COVID-19 Vaccine Portal username, which is the email address that was used to register you with plus.covid19vaccine (e.g., emailaddress.covid19vaccine), and password you created. For additional information, you may also reference [CVMS learning materials for recipients](https://www.covid19vaccine.va.gov).
- **CVMS Help Desk Portal**: [https://ncgov.servicenowservices.com/csm_vaccine](https://ncgov.servicenowservices.com/csm_vaccine) – Use your Help Desk username, which is a custom ID sent via email upon registration. Registration Link:
https://covid19.ncdhhs.gov/media/3055/download?attachment. The virtual agent can answer common questions on demand 24/7. The CVMS Help Desk Portal is located on the bottom right corner of the CVMS Help Desk Portal homepage.

- CVMS Organization Portal: https://covid-vaccine-employer-portal.ncdhhs.gov - Healthcare Location Managers- Use your CVMS Provider Portal username and password to access the portal in order to create a user account for an organization. Organization Point of Contact’s username will be the email address used by the healthcare location manager who sent the invite to register with .cvms.org added (e.g. first.last@email.com.cvms.org ). Please see Section 7.3 for additional information.

### 7.2 Online Resources: CVMS

<table>
<thead>
<tr>
<th>Training Program / Reference Material</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CVMS Provider Portal 101</td>
<td>101: An overview of CVMS, setting up profiles, logging in, checking in and verifying recipient eligibility for the vaccine, documenting vaccine administration, and conducting point of care registration.</td>
</tr>
<tr>
<td>CVMS Provider Portal 201</td>
<td>201: An overview of CVMS, receiving and processing vaccine inventory, changing inventory status, requesting allocation adjustments, documenting insufficient quantities, recording vaccine wastage events, and managing vaccine transfer requests.</td>
</tr>
<tr>
<td>CVMS Provider Portal 102</td>
<td>102: An overview of CVMS scheduling feature in CVMS.</td>
</tr>
<tr>
<td>CVMS Provider Portal 202</td>
<td>202: An overview of CVMS, account management, exploring reports, updating recipient information, recipient bulk uploads, and recipient portal overview.</td>
</tr>
<tr>
<td>CVMS Provider Portal 203</td>
<td>203: An overview of CVMS, scheduling from the perspective of a recipient and the CVMS appointment scheduling process.</td>
</tr>
<tr>
<td>CVMS Provider Portal 204</td>
<td>204: An overview of CVMS Vaccine Marketplace for Location Managers</td>
</tr>
<tr>
<td><strong>CVMS Provider Enrollment Demo</strong></td>
<td>A recorded walk-through of the steps needed for Providers to complete enrollment in CVMSMS.</td>
</tr>
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<td>----------------------------------</td>
<td>---------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>CVMS Readiness Training</strong></td>
<td>This readiness training will cover key actions you can do right now to prepare for CVMS and administering the COVID-19 vaccine. We will also review important upcoming dates to keep in mind as we prepare for CVMS go-live.</td>
</tr>
<tr>
<td><strong>CVMS Visual Road maps:</strong></td>
<td>NC DHHS has designed a visual representation of a Healthcare Provider's CVMS journey from program enrollment to facilitating a recipient's vaccination. The following downloadable placemats are interactive with live links to portals, tools, and templates as well as step-by-step instructions to better support Provider readiness to manage and administer the COVID-19 vaccine.</td>
</tr>
<tr>
<td>CVMS User Guides, Recorded trainings and Upcoming Trainings</td>
<td></td>
</tr>
<tr>
<td><strong>Vaccine Locator Tool</strong></td>
<td>Allows Healthcare Location Managers to maintain information on their permanent location and short term community vaccination events in CVMS to automatically be published on the NCDHHS Vaccine Site Locator Website (MySpot.nc.gov), including ability to display vaccine brands (e.g. Pfizer, J&amp;J, Moderna) available for locations that are receiving state allocations based on current CVMS inventory levels. Healthcare Location Managers have the ability to manually edit what vaccine brands are displayed on the Vaccine Site Locator website for their location.</td>
</tr>
<tr>
<td><strong>CVMS Display on Vaccine Site Locator One Pager.</strong></td>
<td></td>
</tr>
<tr>
<td><strong>CVMS Scheduling Feature/Site Locator on (Vaccines.gov)</strong></td>
<td>Vaccine providers enrolled in the COVID-19 Vaccine Management System (CVMS) have access to a free vaccine appointment scheduling feature that: ✓ Enables recipients to self-register ✓ Makes available appointments easy for recipients to find, including on the CDC’s Vaccine Site Finder website (Vaccines.gov)</td>
</tr>
</tbody>
</table>
✓ Allows people to use the scheduling feature in both English and Spanish
✓ Makes it easy for recipients to cancel appointments, which reduces no-shows

| CVMS COVID-19 Vaccination Registration | Uploaded recipients can complete their registration and view their proof of vaccination once they are vaccinated. |

7.3 CVMS Organization Portal

To facilitate collaboration for employee vaccination events, an Organization Portal was developed as part of the COVID-19 Vaccine Management System (CVMS). The Organization Portal allows vaccine providers to invite organizations to bulk upload files of eligible vaccine recipients. This portal is a potential tool that can be used to assist vaccine providers in collaboration with community organizations.

Access to Organization Portal is available to vaccine providers. An organization, such as an employer, will only be able to access the Organization Portal with an invitation from a vaccine provider. The Organization Portal was first piloted among a small group of vaccine providers on February 15th and is now open to vaccine providers who choose to use this tool to facilitate partnerships and vaccination events with community organizations. We recommend vaccine providers take the following steps to use the Organization Portal:

- **Step 1: Identify a point of contact for the employer/organization.** NCDHHS strongly encourages partnerships with employers/organizations based on equity (i.e., worker groups with higher proportions of historically marginalized populations; see Section 17.0 for additional suggestions on promoting equitable vaccine distribution), and work environments where social distancing is most challenging (e.g., food processing, migrant farm camps). Identify the representative from the employer/organization (“Organization Point of Contact”) who will be responsible for bulk upload of employees or members. You will need this Organization Point of Contact’s first name, last name, organization, email address, and phone number to add them to the CVMS Organization Portal. You can add more than one point of contact, but we do not recommend adding more than 5 points of contact.

- **Step 2: Talk to the Organization Point of Contact.** Let them know about this resource (the Organization Portal), that you (the vaccine provider) will be adding them to the CVMS Organization Portal as the point of contact to bulk upload employees, and they will receive an email to access the Organization Portal. Any uploaded employees will receive an invitation email to complete registration in CVMS. Preregistration is not a required step to receive a COVID-19 vaccine but may help facilitate a more efficient vaccination event by reducing on-site registration time.

- **Step 3: Invite an employer/organization to upload their employees/members to the Organization Portal.** NCDHHS recommends that providers invite those organizations with whom they have established a partnership
and working to coordinate an event or set of appointments for the organization. The Organization Portal is accessible by invitation only. A vaccine provider must first add the organization into CVMS. Please see the simplified instructions for adding an organization into CVMS below. For more in-depth instructions, please review the CVMS Provider Portal Account and Organization Management User Guide.

- To add the employer/organization to the CVMS Organization Portal, see the following instructions.
  
  Note: Only users assigned as a “Healthcare Location Manager” in CVMS can add organizations and invite them to access the CVMS Organization Portal.

  1. Log into the CVMS Provider Portal and navigate to the Organization Management tab.
  2. Confirm that the organization has not already been added by first performing a search for that organization.
  3. Click “Create New Organization.” Complete the information and save the New Organization record. You will be required to enter the organization’s name, industry, and address.

- Create the Organization Point of Contact by clicking “Create Org Point of Contact”. You will be required to enter the first name, last name, email address and select the Organization you created. After you create the Organization and Organization Point of Contact, an email will be sent automatically to the Organization Point of Contact. The email will explain what the Organization Portal is, provide their login information for the Organization Portal and specific instructions on next steps.

Trainings are available to help vaccine providers walk through the steps listed above. Once you have added the Organization and Point of Contact, we recommend sending the email template provided in Appendix 45, to the Organization Point of Contact so they know what to expect, in addition to communicating with the partner organization the details of a specified vaccination event for those employees/members or about how those individuals should schedule their vaccine appointment in addition to CVMS registration. Appendix 46 also includes a sample email template to send to the Organization’s designated employees as part of vaccination preparation.

7.4. CVMS Scheduling

CVMS scheduling capability is available to providers as an optional tool for allowing recipients to self-schedule vaccine appointments. The CVMS scheduling includes the following functionality:

- Ability for recipients to manage (schedule/cancel) vaccination appointments with participant providers and receive email and SMS notifications
- Ability for Location Managers to manage appointments for each of their locations, and create new locations as needed for clinics or vaccination events
- Ability for Healthcare Providers to manage location data within the CVMS Provider Portal that will be displayed on MySpot.nc.gov, used by recipients to find vaccine providers

- To make your vaccination location and location data viewable by recipients on the Vaccine Site Locator Website, follow the steps below in the CVMS Provider Portal:
  - Click on the Locations tab
  - Select the location to edit
  - Check the Display on Vaccine Site Locator checkbox
• Providers can schedule the 2nd dose appointment directly following the 1st dose appointment OR from the Provider Portal Appointments tab once the 1st dose is administered.
• User Guide: How to Use Scheduling in CVMS

7.5 CVMS Direct

CVMS Direct is an integration solution offering for Providers to connect COVID-19 vaccination records with CVMS. Providers submit a standardized flat file from their Electronic Health Records (EHRs) that pass through the Health Information Exchange (HIE) and are loaded directly to CVMS. This NC COVID-19 Vaccine Reporting file (NCVR) contains patient information that complies with today’s CVMS workflow across patient registration and vaccination recording, along with appropriate inventory reduction. Each organization will need to finalize legal agreements with the HIE, establish connectivity, complete file validations, and pass testing criteria before they can use the CVMS Direct integration. Please reach out to hiea@nc.gov if you are interested in using CVMS Direct.

7.6 CVMS Data Entry Tool

The Division of Public Health’s Centralized Remote Data Entry Team (CRDET) launched a new automated data entry tool that will accelerate the submission of handwritten COVID-19 vaccine administration form data into the COVID-19 Vaccine Management System (CVMS). By simply scanning accurate, complete forms and uploading them to our server, our team can get your form data entered quickly and hassle free.

What is the Centralized Remote Data Entry Team (CRDET)?
CRDET has been supporting various providers to reduce their COVID-19 vaccination form data entry backlogs since early in the pandemic by entering in associated data within CVMS.

What is the automation tool?
The automated data entry tool scans handwritten vaccine forms and pulls data from them. The data is validated by a CRDET member and then uploaded to CVMS. This tool will expand the capacity and increase the efficiency of CRDET allowing it to better help providers across North Carolina.

How do providers access these services?
If you are interested in receiving assistance with COVID-19 vaccination form data entry, contact the team at CVMS_DES@dhhs.nc.gov.

Note: The automated data entry tool is specifically designed to process the standard “COVID-19 Vaccine Administration Form,” which is listed below. While the CRDET can support data entry requests using other formats, using a standard form will assist us in accelerating processing this data.

- Recipient Registration and COVID-19 Vaccine Administration Form (English)
- Recipient Registration and COVID-19 Vaccine Administration Form (Spanish)
7.7 Vaccinating During the CVMS Outage

If you plan to administer vaccines during scheduled maintenance outages, you must collect the CVMS required information offline and add it to the system when it is available again, within 72 hours from vaccine administration. Offline operations forms can be found on the NC DHHS COVID-19 CVMS website (under the section “CVMS Offline Operations – How to Proceed”). Direct links to the forms can also be found in the instructions below.

Recipient Registration & Vaccine Administration in CVMS

Providers need to follow proper procedures when checking in COVID-19 vaccine recipients. Please use the CVMS Recipient Registration Form and COVID-19 Vaccine Administration Form (English) or the Spanish version and follow these instructions:

- Ask the recipient to manually fill out the form. Please note that providers are responsible for confirming recipient eligibility based on the recipient’s responses.
- Collect the completed form from the recipient.
- Capture the required vaccine administration data elements in the “Office Use Only” section. While CVMS is offline you will not have access to recipient information. If the recipient is returning for a second dose, please confirm information related to the first dose with recipient using CDC vaccination card, photo of vaccination card, electronic health record or other mechanism. If an appointment has been made, we recommend you also consider looking up recipient information prior to the CVMS outage.

While CVMS is offline you will not have access to recipient information. If the recipient is returning for a dose beyond their first (second or third), please confirm information related to the first dose with recipient using CDC vaccination card, photo of vaccination card, electronic health record or other mechanism. If an appointment has been made, we recommend you also consider looking up recipient information prior to the CVMS outage.

Vaccine Inventory Levels

For the vaccine inventory levels, a team member must capture the required data elements identified in CVMS Inventory Levels Sheet. This form also mirrors the user experience of CVMS. Providers should enter the data captured offline into the CVMS as soon as possible when the CVMS is back online or providers have access to a connected device.

7.8 CVMS and Vaccine at Home Providers

CVMS now has an option for providers to mark themselves as Vaccine at Home providers. Any provider who has previously indicated that they would to be a Vaccine at Home provider will automatically have this option turned on. To opt out of this program, please follow the steps in the job aid.

7.9 Vaccine Marketplace

The Vaccine Marketplace streamlines the transfer process by enabling providers to check all on-hand inventory and transfer opportunities in a centralized database. We encourage all providers to post and manage their available excess inventory they are willing to transfer on Vaccine Marketplace. This will allow providers who wish to obtain vaccine to identify locations closest to them with the vaccine type and quantity they need. Best practice is to locate the closest provider in the Vaccine Marketplace with excess available vaccine inventory that may be used for your patient
population. Next, contact that provider via email or phone to coordinate a transfer. Please see Section 15 Vaccine Transfer Guidance. We truly appreciate your flexibility and willingness to facilitate transfers, as the State tries to utilize as much on-hand inventory as possible.

Please see the job aids for instructions on how to post available vaccine doses to the Marketplace and request vaccines through the Marketplace:

- CVMS Provider Portal Offer Vaccine Through Vaccine Marketplace Job Aid
- CVMS Provider Portal Request Vaccine Through Vaccine Marketplace Job Aid

This COVID-19 Transport Guidance document details how to safely transport vaccines being transferred between provider locations.

7.10 CVMS Support

If you have any questions, please use the CVMS Help Desk Portal. To submit a question, issue, or request, please follow the instructions below:

- Go to CVMS Help Desk Portal
- Click on ‘Vaccine Provider’
- Login using your username and password
  - If you already registered, use your Service Now username and password (not your NCID)
  - If this is your first time registering for the CVMS Help Desk Portal, refer to this knowledge article to register
- Open a ticket by selecting relevant Request Type drop down menu (e.g., CVMS access or login issue, Request CVMS provider enrollment assistance, Manage CVMS provider agreement).
- Explicitly write the question, issue, or request in the description field
- Submit case

In addition to submitting questions or issues via the CVMS Help Desk Portal, providers can also search the CVMS Help Desk Portal for knowledge articles to help immediately address questions or issues.

The COVID-19 Vaccine Provider Help Center is available for providers and organizations to call and receive live support for COVID-19 vaccine and CVMS-related questions, issues, or requests. To reach the Help Center, call (877) 873-6247 and select option 1 for COVID-19 questions. The COVID-19 Vaccine Provider Help Center is available:

- Monday – Friday 7:00 AM – 7:00 PM ET
- Saturday – Sunday 10:00 AM – 6:00 PM ET

Providers can connect with the Virtual Agent to resolve common questions and inquiries about COVID-19 vaccine and the COVID-19 vaccination program. Here you can receive immediate support 24 hours a day, 7 days a week. To engage with the Virtual Agent, please go to the CVMS Help Desk Portal and click on the chat icon in the bottom right of the page.

- User Guide: Provider Help Desk Submission -- Process Summary
The COVID-19 Vaccine Management System (CVMS) has implemented additional functionality to further streamline the provider and recipient experiences, in addition to future planned enhancements:

- Ability to identify federal vaccine allocations used by some Federally Qualified Health Centers (FQHCs) and the Federal Emergency Management Agency (FEMA)
- Spanish translation of the COVID-19 Vaccine Portal for recipients
- Streamlined recipient registration process that removed the need for recipients to indicate Priority Group (since all recipients 16 years or older are now eligible)
- Ability for Healthcare Location Managers to maintain information on their permanent location and short term community vaccination events in CVMS to automatically be published on the NCDHHS Vaccine Site Locator website (MySpot.nc.gov), including ability to display vaccine brands (e.g., Pfizer, J&J, Moderna) available for locations that are receiving state allocations based on current CVMS inventory levels. Healthcare Location Managers have ability to manually edit what vaccine brands are displayed on the Vaccine Site Locator website for their location. For instructions on how to edit the vaccine brands for your location or any of your information in CVMS that will be displayed on the Vaccine Site Locator website, please see the CVMS Display on Vaccine Site Locator One Pager.
- Ability for providers to use the optional scheduling feature in CVMS to allow recipients to self-schedule vaccine appointments (see Section 7.4 above).
- Ability for providers to submit COVID-19 vaccination administrations from their system to CVMS through direct integration (CVMS Direct, see Section 7.5 above).

Some of the key functionality with CVMS Version 6.0 included:

- Provider Enrollment Portal enhancements:
  - Addition of a new provider type for Dentists
  - As a part of the Provider Enrollment process, ability to enter the first Location Manager’s profile information so that the location user activation process can be initiated immediately once a location is approved
  - Ability to generate automated email notifications to Org Admins and Vaccine Coordinators when additional locations have been approved
  - Additional guidance for Storage and Handling requirements
  - Enhanced Provider Portal experiences for providers with CVMS Scheduling enabled

- Health Care Provider Portal enhancements:
  - Ability for Healthcare Location Managers to self-enable CVMS Scheduling functionality for current and future locations through a series of self-attestation questions
  - Ability for providers to mark Recipient record as “deceased” to ensure record is up to date and no further communications are sent
  - New routine email to remind Location Managers to mark Vaccine Inventory status as “Complete” when inventory has 0 doses available
  - Additional automatic validation when Healthcare Location Managers are manually creating Vaccine Inventory records
Automatic CVMS appointment cancellation for:

- All appointments with no check-in after 24 hours
- Any duplicate appointments created by providers reporting vaccine administrations through CVMS Direct.
- Previously scheduled appointments after intended recipient received vaccine elsewhere.

Updated Vaccine Consent language prior to documenting Vaccine Administration

COVID-19 Vaccine (Recipient) Portal enhancements:

- New Recipient data collection fields to allow for optional identification of recipient disabilities and preferred language
- Updated consent language prior to completing Recipient Registration

Some of the key functionality with CVMS Version 7.0 included:

- **Inventory Management enhancements:**
  - To align with the updated process of ordering and tracking vaccine doses, the designation between 1\textsuperscript{st} vs. 2\textsuperscript{nd} doses will be removed within CVMS.

- **Recipient Management enhancements:**
  - Vaccine Information – This release will enhance the Vaccine Information PDF to include a QR code that can be scanned to provide vaccine information regarding the recipient for whom it was generated.

- **CVMS Provider enhancements:**
  - A new “Read-Only” profile will be added for users of pharmacies participating in the Federal Retail Pharmacy Program. They will be able to verify the vaccine information of recipients that received their first dose from a provider using CVMS.
  - Providers will be able to quickly access the Virtual Agent chatbot directly from the CVMS Provider Portal.
  - Values in the ‘Injection Site’ dropdown will be reordered so the most used injection sites are easier to select.

- **Scheduling enhancements:**
  - Recipient Call Center agents have the ability to perform vaccine appointment scheduling activities on behalf of recipients using CVMS scheduling.
  - Location Managers are able to generate new appointment scheduling reports that provide more insight into appointments booked vs. appointments still available.
  - There are three types of new reports available to you. Once you log in to the CVMS Provider Portal, click “More” in the Navigation bar and select “Reports”.
    - *Dose 1 Vaccine Supply Report and Dose 2 Vaccine Supply Report:* As you receive additional vaccine inventory and wish to release more appointments to the appointment booking tool, these Reports inform you how many appointments have been booked and you can, therefore, determine by how much you should increase the Current Stock for your location to supply the first does and second dose Vaccine Appointments.
    - *Availability Report:* The Availability Report informs providers of the number of appointment slots that are released, reserved for first dose and second dose appointments respectively, and the remaining appointment slots available by day.
  - Scheduling in CVMS now supports the creation of non-regular scheduling availability, which gives you the flexibility to extend your appointment offering window. For example, you may now create a schedule with:
• No availability in situations of an office closure, such as a holiday.
• Changed availability for a day on which there are different operating hours or staffing.
• Increased availability for day(s) on which there will be a vaccination event.
• Note: any previously scheduled appointment will remain scheduled even if you change your schedule availability.
  o Scheduling Feature: Upcoming Holiday Support
  o For more information on the scheduling enhancements, please reference this CVMS Provider Portal Manage Appointment Scheduling User Guide.

• Provider Enrollment enhancements:
  o Organization Admins have the ability to review a “Read-Only” page of submitted Section A agreement without changing the status.
  o To prevent providers from accidentally overwriting existing organization information, a warning notification will appear before an Organization Admin can update the Organization Enrollment portion of Section A.
  o Vaccine Coordinators can indicate a Resubmission Reason in Section B.

The system will allow a deactivated location status to be submitted upon completion of Section B, which enables the Immunization Branch to distinguish between a deactivated location submitting enrollment application for the first time and a deactivated location that has already been approved, but resubmitting their application due to a change.

Some of the key functionality with CVMS Version 8.0 included:

• Vaccine Inventory enhancements:
  o Enable the “Vaccine Marketplace” for providers to self-identify vaccine needs and match with other providers, preventing potential wastage due to dose expiration.

• Vaccines.gov and CVMS Scheduling enhancements:
  o Migration of all provider location details, including pop-up location details, to the CDC Vaccines.gov site (https://www.vaccines.gov) instead of MySpot site (https://MySpot.nc.gov). Recipients selecting CVMS Scheduling locations in the CDC Vaccine.gov site will be redirected to the CVMS Scheduling site (https://takemyshot.nc.gov).
  Note: After June 17th, users connecting to https://MySpot.nc.gov will be automatically redirected to https://www.vaccines.gov.
  o Enable Healthcare Location Managers to capture CDC requested data, to support CDC Vaccines.gov site (i.e., location offering of walk-ins, language support, in-home vaccinations, and additional hours of operations), in the “Location” tab of the CVMS Provider Portal.
  o Change automatic cancellations for “no-shows” to 72 hours after the scheduled appointment instead of 24 hours to allow more time to document administration data in CVMS.

• Other CVMS Provider Portal enhancements:
  o User Account Management functionality is modified to enable single location deactivation for a user while maintaining access to other locations if applicable.
  o To support data privacy requirements, users will be required to review and agree to a data Confidentiality Agreement when logging into the CVMS Provider Portal for the first time after release.
  o Help text is enhanced to remind providers to capture recipient email address to enable future access of Vaccine Information records.
• COVID-19 Vaccine Portal for Recipients access enhancements:
  o For recipients vaccinated by CVMS Direct providers (EHR) and who provided email address, changes will enable recipients to access their COVID-19 Vaccination Information in the COVID-19 Vaccine Portal.

Some of the key functionality with CVMS Version 9.0 included:

• Vaccine Marketplace enhancements
  o Addition of Vaccine Hub locations sites displayed in the “Seek Transfer Match” screen
  o The Marketplace will be able to display providers as a “Hub” in the search function to display/prioritize Hubs when providers search for Extra Vaccine Inventory.
    ▪ What is a Hub?
      • Hubs are locations contracted by the State, serving as vaccine repositories. Hubs consolidate vaccine inventories that are dispersed among multiple providers.
      • These designated “Hubs” are also able to deliver and/or facilitate vaccine pickups if a transfer is requested.
  o Ability to associate several Vaccine Inventory records sharing the same lot number to a single listing.
  o Ability to opt-in and out of the “Auto-Update Available Doses” functionality, so that the listing will be automatically updated if the associated inventory is consumed.
  o Listing will auto-lapse after 21 days instead of 7.
  o Listing will auto-lapse when their Expiration Date has passed, or when a site location's doses availability reaches zero.

• Inventory Management enhancements
  o System validation to only allow entering an Expiration Date within one year from vaccine inventory creation date.
  o Following the latest CDC Guidance, enable a warning message to prevent users from entering “Extra Doses” for the Pfizer 6-dose vials
  o Provide additional options for “Wastage Event” reason so providers can better document wastage.

• Recipient Record enhancements
  o Addition of the “Address 2” field for Recipients to capture Apartment/Unit numbers and enable better data matching

Some of the key functionality with CVMS Version 10.0 included:

• Vaccine Administration enhancements:
  o Ability to record and manage a third vaccine administration when necessary, including displaying the third administration on the Vaccine Info PDF
  o Ability to retroactively log a Dose 1 vaccine administration after a Dose 2 administration has already been logged

• Vaccine Marketplace Updates:
  o Ability to create, view, and update/close Marketplace Inquiries
    ▪ Creating an inquiry allows providers to quickly fill in information about what they need and send it to the provider who has extra vaccine.
Those requests are not only immediately emailed to the provider who is offering vaccine, but also kept as a record within CVMS.

- New Transfer Warning box to serve as visual warning for cross-hub inquiries
- Ability to include additional details for temperature/storage history when creating Seek Transfer Match – Extra requests
- Ability to capture justification for closing a Seek Transfer Match request
- New validation in place for HCP Contact Phone Number

Other enhancements:
- Provide users of the CVMS Provider Enrollment and Organization Portals access to a virtual agent using the virtual chatbot to provide system support of functionality

Key functionality with CVMS 10.0.2 Minor release included

**Bulk Upload:**
- The CVMS Provider Portal will enable providers to create up to 100 CVMS Provider Portal Users at a time in bulk via a drag and drop process. Location managers will fill out a .CSV file with all the relevant information including name, email, NCID, and profile. The template and instructions will be in the Account Management tab of the CVMS Provider Portal. Please access the user guide deck (slides 19-28) here.

With the updates in CVMS Version 10.0.2, the impacts to your location include:

- **Adjustment to Master Location Settings:** With the minor release, the CVMS Provider Portal made a one-time adjustment to location settings for master locations that receive federal allocations. Healthcare Location Managers overseeing these master locations should see the "Display on Vaccine Site Locator" field has now been set to "NO" for the master location.

- **Managing Visibility on the Vaccine Site Locator:** The master location will still be visible on the Vaccine Site Locator, Vaccines.gov, as the location’s listing was created by the CDC, rather than by CVMS. To edit location details as displayed on the Vaccine Site Locator for these federally allocated master locations, the Healthcare Location Manager must do so from https://covid.locating.health. The location details for these master locations cannot be edited within the CVMS Provider Portal.

Note: Healthcare Location Managers must still create and manage pop-up locations through the CVMS Provider Portal, as this option is not available on Vaccines.gov.

For more information on how to manage location details for a master location displayed on the Vaccine Site Locator, refer to this CDC Vaccine Site Locator User Guide.

**8.0 Who Can Be A COVID-19 Vaccine Provider?**

**8.1 North Carolina COVID-19 Vaccine Providers**

All eligible North Carolina healthcare providers who are interested in administering the COVID-19 vaccine can submit an enrollment application for their organization in the COVID Vaccine Management System (CVMS). COVID-19 vaccine
providers must be qualified under the CDC agreement to prescribe COVID-19 vaccines and authorized under the appropriate NC licensing authority. Vaccine providers already enrolled through the federal vaccine programs, such as the Pharmacy Partnership for Long-Term Care Program or the Federal Retail Pharmacy Program, do not have to enroll through CVMS.

The enrollment application in CVMS is an electronic version of the required CDC COVID-19 Vaccine Program Provider Agreement. The agreement should be reviewed prior to beginning the enrollment process to ensure understanding of program requirements. The CDC also provides additional information for COVID-19 vaccine provider requirements and support. Providers who will not be able to fully adhere to all aspects of the agreement should not begin enrollment. One critical aspect of the vaccine program is the provider’s ability to properly store and handle vaccine, ensuring vaccine being administered to North Carolinians is viable and offers the protection needed to prevent COVID-19 infection. As part of the COVID-19 Vaccination Provider Agreement, providers are required to:

- Store and handle COVID-19 vaccines under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with an EUA or vaccine package insert, manufacturer guidance, and CDC guidance in the Vaccine Storage and Handling Toolkit.
- Monitor storage unit temperatures at all times, using equipment and practices that comply with guidance in the toolkit*.
- Comply with immunization program guidance for handling temperature excursions**.
- Monitor and comply with COVID-19 vaccine expiration dates.
- Preserve all records related to COVID-19 vaccine management for a minimum of three years, or longer as required by the agreement or law of the jurisdiction.
- Comply with CDC instructions and timelines for disposing of COVID-19 vaccine and diluent, including used doses.

*Providers are required to store vaccine in appropriate storage units (i.e., purpose-built or pharmaceutical-grade units designed to either refrigerate or freeze). Household combination units are acceptable for the refrigerated component only. If frozen vaccine storage is needed, a separate, stand-alone freezer must be used. Dormitory-style or bar-style combined refrigerator/freezer units cannot be used to store vaccine under any circumstances. Temperatures must be continuously monitored using a Digital Data Logger that meets the specifications as noted in the Vaccine Storage and Handling Toolkit*. Providers are required to document the minimum and maximum temperature reading each workday. Product specific temperature logs can be obtained from the CDC.

**Temperature excursions must be reported immediately to the respective vaccine manufacturer. Label any vaccine exposed to out of range temperatures as “DO NOT USE”, separate the doses from non-exposed vaccine, but continue to keep the vaccine stored under proper conditions until further guidance is obtained from the vaccine manufacturer on viability. Do not discard the doses prior to receiving manufacturer guidance. Be prepared to document the event. The Immunization Action Coalition’s Vaccine Storage Troubleshooting Record can be utilized to document excursion events. Before enrolling in CVMS, it is recommended that a representative from your organization:

- Attend a live CVMS Provider Enrollment Training Session (CVMS Training Schedule)
- Review and complete the COVID-19 Vaccine Readiness Checklist
- Enrollment can be initiated at https://covid-enroll.ncdhhs.gov.
8.2 Federal COVID-19 Vaccine Providers

8.2.1 Federal Retail Pharmacy Program.
The Federal Retail Pharmacy Program for COVID-19 Vaccination is a collaboration between the federal government, states and territories, and 21 national pharmacy partners and independent pharmacy networks to increase access to COVID-19 vaccination across the United States. The program is being implemented incrementally based on the available vaccine supply, with select retail pharmacy locations providing COVID-19 vaccine to eligible individuals. As vaccine availability increases over time, the program will expand to ultimately include all 40,000+ pharmacies. Additional details from the CDC can be found here.

Several federal retail pharmacy partners have been activated in North Carolina. These vaccine providers can be found on the vaccine site locator at https://myspot.nc.gov/.

8.2.2 Federally Qualified Health Centers Program.
To ensure our nation’s underserved communities and those disproportionately affected by COVID-19 are equitably vaccinated against COVID-19, the Health Resources and Services Administration (HRSA) and the Centers for Disease Control and Prevention (CDC) launched a program in mid-February to directly allocate a limited supply of COVID-19 vaccine to select HRSA-funded health centers. FQHCs allocated vaccine in this federal program will not receive allocations from NCDHHS. Additional details on the program can be found here.

8.2.3 Federally Supported Vaccination Site in North Carolina
Guilford County was selected for a vaccination site by FEMA and the CDC as an area with significant underserved or marginalized populations, using a range of criteria including the Centers for Disease Control Social Vulnerability Index, historical COVID-19 community impacts, and the current rate and pace of equitable community vaccinations. The site was staffed by federal personnel, mostly from the Department of Defense. It was supported with resources and personnel from Guilford County, the North Carolina Department of Public Safety, to include the Division of Emergency Management and the North Carolina National Guard, and the North Carolina Department of Health and Human Services. Support services included logistics, information technology, data entry, emergency medical services and security. The first site launched on March 10, 2021 and operated through May 27.

9.0 Newly Enrolled Providers
For providers not yet enrolled, currently enrolled providers can share this one-pager on how to get started or route them to the CVMS Provider Enrollment Portal. If there is a critical partner in the community that should be prioritized for enrollment, please reach out to your Immunization Branch Regional Nurse Consultant. Information about new provider orientation is available here: CVMS User Guides, Recorded Trainings and Upcoming Trainings. There is also a COVID-19 Vaccine Provider Toolkit available (you can also find it, along with other materials, at the NC DHHS site under Reference Materials for Serving as a Vaccine Provider). The COVID-19 Vaccine Provider Toolkit provides a step by step walk through of becoming a vaccine provider, all the way from considerations to think about at the outset through onboarding, training, receiving vaccines and administration, and reaching out to your population to encourage vaccination.
Detailed steps to share about how to enroll as a new provider in CVMS can be found [here](#) on the NCDHHS website. A high-level overview of the steps a new provider location will need to take to enroll are below:

- **Step 1**: Register your organization in the CVMS Provider Enrollment Portal.
- **Step 2**: Register each vaccine location and all prescribing providers who will administer vaccine.
- **Step 3**: Obtain NCID credentials.
- **Step 4**: Onboard your organization’s first healthcare location manager user.
  - This step is optional to complete in Step 1, while entering your location details in the CVMS Provider Enrollment Portal. If a Location Manager user was provided during enrollment, it does not need to be repeated.
- **Step 5**: Log into the CVMS Provider Portal.
  - Step 5 can only be done once all previous steps have been completed and your organization has been approved as a COVID-19 vaccination provider.

The process to become enrolled and activated can take up to two weeks depending on the completeness of the application, so now is a great time to encourage new providers to get started. Please see the [CVMS Enrollment and Activation Process Roadmap](#) for a condensed version of all steps a new provider location needs to take. Once a new practice is enrolled and activated in CVMS, the location will be able to request doses via local transfers using the Vaccine Marketplace in CVMS or via the NC DHHS Vaccination Allocation Request Form. See [Section 16.1](#) for more information on vaccine allocations.

Using all doses in the multi-dose vial can be a barrier to primary care. Every effort should be made to minimize leaving unused doses in a COVID vaccine vial. However, our top priority is to make vaccines easily accessible to North Carolinians in settings they trust, so that as many people as possible are vaccinated as quickly as possible. Providers are also encouraged to accommodate walk-in appointments and to offer vaccines as part of a regular patient visits to provide the greatest flexibility and access to people wanting the vaccine. In these circumstances, getting vaccine to people who want the vaccine should be prioritized over ensuring that every dose is used in an open vial. CDC acknowledges that vaccine wastage may increase as the vaccine rollout continues. To ensure providers do not miss an opportunity to vaccinate every eligible person, CDC recommends:

- Providers follow [clinical best practice for vaccination as well as best practices when managing inventory](#) to maximize vaccination and minimize dose wastage.
- Providers should not miss any opportunities to vaccinate every eligible person who presents at a vaccination site, even if it means puncturing a multidose vial to administer vaccine without having enough people available to receive each dose.
  - Consider establishing and promoting standing vaccination days or half-days to increase likelihood of larger numbers of people presenting for vaccination on the same day.
  - Vaccinate family members or friends who accompany patients to medical visits even if they are not established patients at the vaccinating practice
  - Continue outreach to employers or other community partners that have a large membership or network to arrange vaccination events.
  - As contingency plan, vaccine providers should attempt to contact additional persons (i.e., from a waitlist or through personal contacts of persons being vaccinated) to use as many vaccine doses as possible.
  - Once punctured, multidose vials must be used within:
    - 12 hours (Moderna)
6 hours (Pfizer)
2 hours (J&J/Janssen)

The more Americans who get vaccinated, the fewer COVID-19 cases, hospitalizations, outbreaks, and deaths that will occur.

In addition, a primary care or other outpatient practice may not have the capacity to receive and store shipments of Pfizer vaccine in the quantities in which it is ordered. We encourage practices to reach out to other enrolled providers in the community to establish partnerships to share or transfer vaccine. To further support practices, especially those who serve adolescents for whom Pfizer is currently the only option, NCDHHS will be assisting with matchmaking and looking to engage community partners to help facilitate the ability for smaller practices to receive vaccine in lesser quantities than the current minimum shipment size. Providers will receive information via “vaccineinfo” email on next steps to request smaller vaccine quantities than shipment amounts. The State will make every effort to honor provider requests for smaller vaccine amounts.

This checklist contains recommended action items to help enrolled providers ensure their readiness to receive and administer COVID-19 vaccine. Please see Appendix 7: COVID-19 Vaccine Readiness Checklist for long form.

Onboarding

◊ Identify internal single point of contact for your employees to send questions or provide feedback related to the administration of COVID-19 vaccine

◊ Identify your organization’s users that need access to CVMS and confirm that these users have a valid NCID. Instruct users that do not have an NCID to create an NCID and provide it to you. Complete the HCP User Onboarding Template and submit on the CVMS Help Desk Portal at https://ncgov.servicenowservices.com/csm_vaccine.

Training

◊ Vaccine Coordinators: Provide orientation and training materials to your organization’s designated primary and back-up vaccine coordinators. At a minimum the primary and back-up Immunization Coordinators must complete these vaccine trainings:
  o Review the CDC Storage and Handling Toolkit, including the COVID-19 vaccine addendum https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf
  o Complete the You Call The Shots: Storage and Handling module
  o Complete the vaccine brand specific training(s) from CDC for each vaccine product being offered at your location.

◊ Receipt of COVID-19 vaccine: Train your staff that are designated to receive COVID-19 vaccine shipments and manage inventory levels in CVMS on how to receive vaccines in CVMS, document
received quantities, contact CVMS help desk, return shipping containers, etc. Please reference Section 7.0 for CVMS, Appendix 8 for Pfizer Storage and Handling Checklist and Appendix 13 for Moderna Storage and Handling Summary Guidance.

◊ **Storage and Handling**: Train your staff that are designated to store and handle COVID-19 vaccines on how to (a) properly store and handle COVID-19 vaccines according to CDC and each respective vaccine manufacturer as noted within each product’s EUA Fact Sheet for Healthcare Providers, (b) monitor and document the storage temperature for COVID-19 vaccines, and (c) for Pfizer vaccine, recharge COVID-19 vaccine shipping containers with dry ice pellets if they are being used to store COVID-19 vaccines. Please see Section 13.0 for additional information on storage and handling.

◊ **Other CVMS Training**: Train your staff that are designated to check-in eligible vaccine recipients prior to administration of COVID-19 vaccine on how to use CVMS to complete their responsibilities. Please reference Section 7.1 for CVMS overview and Section 7.2 for Online Resources: CVMS Communication

◊ **FAQ**: Consider developing internal FAQs for your organization to help employees understand the COVID-19 vaccination process.

◊ **Operational Communications**: Develop and distribute the communications to identified employees or individuals on the process, timing, and logistics to receive the COVID-19 vaccine.

### Vaccine Administration Prep

◊ **Prioritizing and scheduling**: Determine process for prioritizing and scheduling employees or individuals to receive the COVID-19 vaccine and logistics on where employees or individuals will need to go to receive the COVID-19 vaccine.

◊ **CVMS and shipments**: Understand how to view status of COVID-19 vaccine shipments to your organization in CVMS.

◊ **Pfizer vaccine storage**: If storing the Pfizer vaccine in an ultra-cold freezer, ensure proper equipment and processes are being used with adequate capacity. Each tray contains 195 vials and is roughly 9”x9”x1.6”. (See Appendix 8 and 9) Please see the updated EUA Fact Sheet for Health Care Providers – Pfizer (See Appendix 2) which added an alternative option for frozen storage and transportation. In May 2021, the FDA amended the Pfizer EUA to allow for a 450-dose order configuration and changes in storage to allow undiluted, thawed Pfizer vaccine vials to be stored in the refrigerator at 2 degrees to 8 degrees for up to 1 month (31 days). See Section 13.0 for more information on storage and handling. This vaccine does require mixing with a diluent before administration.

◊ **Moderna vaccine Storage**: Moderna vaccine vials may be stored in the refrigerator or freezer. Each box contains 10 multidose vials (100 doses). There is a maximum of 11 extractible doses from the vials that are currently available. There are new 15 dose vials that will be phased in to replace the current 10 dose vials.
vials. Depending on the syringes and needles used for each dose, there may not be sufficient volume to extract more than 10 doses from the maximum of 11 doses vial or more than 13 doses from the maximum of 15 doses vial. This vaccine does not need to be mixed with a diluent before administration. (See Appendix 13). See Section 13.0 for more information on storage and handling.

◊ **Johnson & Johnson (Janssen) vaccine storage**: J&J (Janssen) vaccine should be protected from light and stored in the refrigerator and not stored frozen. Unpunctured vials of Janssen COVID-19 Vaccine may be stored between 9°C to 25°C (47°F to 77°F) for up to 12 hours. Each carton contains 50 doses in ten 5-dose vials, with shipment quantity of 2 carto or 100 doses. Carton dimension 93 mm x 38 mm x 54 mm (approximately 3.66 in x 1.50 in x 2.13 in). This vaccine does not need to be mixed with a diluent before administration. See Section 13 for more information on storage and handling.

◊ **Vaccine Information/EUA fact sheet**: Obtain copies of Vaccine Information/Emergency Use Authorization Fact Sheets for each COVID-19 vaccine product your organization receives and establish a process to provide a printed most current copy of the Fact Sheet for Recipients and Caregivers to each recipient prior to administration of the vaccine (both first and second dose, as applicable) and ensure each individual administering vaccine in your organization has reviewed the Fact Sheet for Healthcare Providers Administering Vaccine. (See Appendix 1, 2, 11, 12, 42, 43)

◊ **V-SAFE information sheet**: Obtain copies of the V-safe Information Sheet to also provide to vaccine recipients (See Appendix 4). Resources from CDC are available in multiple languages at: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe/printresources.html

**North Carolina Identification (NCID) Account Registration**
As part of the readiness checklist, you are required to have an NCID user account in order to access COVID-19 Vaccine Management System (CVMS) for scheduling and entering vaccine administrative data or inventory. If you are only a vaccine recipient, then you do not need an NCID. If you do not already have an NCID, please follow the steps below to register for one (for step #2, refer to the Readiness Checklist in Appendix 7):

2. Click **Register!** (in the bottom right corner of the blue box)
3. Click **Business** user type option
4. Complete the required fields to create an NCID user account
5. An e-mail will be sent to the e-mail address that was used to create the NCID with a link to verify your new user ID
6. Click the link and verify your NCID; Once verified, you will be prompted to log-in to NCID with the NCID and password you created
7. Select and answer the 5 security questions; After finalizing the 5 security questions, you will be routed to the NCID homepage

Please ensure anyone at your facility who will enter vaccine administration and/or inventory data completes this action. Individuals who are vaccine recipients only do not need an NCID user account.
10.0 COVID-19 Vaccination Legal Considerations

10.1 NC Immunization Law

COVID-19 vaccine is not required by Federal or State law. The NCDHHS Immunization Branch website has extensive information regarding NC Immunization law and links to the North Carolina General Statutes and Administrative Code. North Carolina immunization law has not changed.

- NC Immunization Laws (link)
  - NC Minor’s consent (link)

10.2 Consent for Vaccination

10.2.1 Informed Consent

Informed consent for medical treatment must be obtained prior to anyone being vaccinated with any of the COVID-19 vaccines. That consent can be verbal, but a provider may choose to have patients provide written consent for vaccines per their facility policy. For each COVID-19 vaccine authorized under an Emergency Use Authorization (EUA) or approved by the Food and Drug Administration (FDA), the FDA requires that vaccine recipients or their caregivers are provided with vaccine-specific information consistent with the approval or EUA to help make an informed decision about vaccination.

10.2.2 Consent for Individuals Under 18 Years of Age

On August 23, 2021, the FDA approved the Pfizer-BioNTech COVID-19 mRNA vaccine (marketed as COMIRNATY) for the prevention of COVID-19 in individuals 16 years of age and older. At this time, Pfizer COVID-19 vaccine continues to be available under emergency use authorization for use in 12-15 year old individuals. For individuals under 18 years who present to local health department clinics, practices and other locations for a COVID-19 vaccine without a parent/guardian, there are changes related to minor’s consent law (N.C.G.S. 90-21.5) per SL 2021-110 to keep in mind:

- N.C.G.S. 90-21.5 gives minors the legal authority to consent for the prevention, diagnosis, and treatment of reportable communicable diseases. As COVID-19 is a reportable communicable disease, under N.C.G.S. 130A-135 and 10A NCAC 41A .0101, .0107, it has been permissible for minors to consent to receive the COVID-19 vaccine for themselves, if they have decisional capacity, meaning that they are able to understand and make decisions about their health.
- However, on August 20, 2021, SL 2021-110, S.9, made a change to the minor’s consent law. Pursuant to a new paragraph added to N.C.G.S. 90-21.5(a1), health care providers are now required to "obtain written consent from a parent or legal guardian prior to administering any vaccine that has been granted emergency use authorization and is not yet fully approved by the United States Food and Drug Administration to an individual under 18 years of age."
- Starting August 23, 2021, when Pfizer-BioNTech COVID-19 vaccine received full FDA approval for individuals 16 years and above, these individuals once again have the legal authority to consent to receive the Pfizer-BioNTech vaccine in accordance with the minor’s consent law. Adolescents 16 and 17 years of age have the ability to make certain health decisions, including the choice to get an approved COVID-19 vaccine, if they show the decisional capacity to do so. Decisional capacity is a person’s ability to understand their health and health care needs and options, and to make decisions about them. However, it is expected that for most teens, information about vaccination with parents and guardians and parental/guardian consent will be obtained for COVID-19
vaccination. Pfizer COVID-19 vaccine continues to be available under emergency use authorization for use in 12-15 year old individuals and for those who may be eligible for an additional dose due to certain immunocompromised conditions. Therefore, written consent from parent or a legal guardian is required for teens ages 12 to 15 year or youth under 18 receiving an additional dose if immunocompromised. Approval for this age group is expected at a later date as Pfizer was authorized for teens ages 12 to 15 years, six months after it was authorized for people 16 and older.

- For each COVID-19 vaccine authorized under an EUA or approved, the Food and Drug Administration (FDA) requires that vaccine recipients or their caregivers are provided with vaccine-specific information consistent with the Vaccine Information/EUA to help make an informed decision about vaccination.

### 10.2.3 Students presenting for COVID-19 Vaccine in School Settings

Many North Carolina Schools have been excellent partners in efforts to provide COVID-19 vaccines to school staff, often on school grounds, in a manner similar to past influenza clinics. CDC has developed considerations for planning school-located vaccination clinics available at for interested public and private agencies at: [https://www.cdc.gov/vaccines/covid-19/planning/school-located-clinics.html](https://www.cdc.gov/vaccines/covid-19/planning/school-located-clinics.html). Current FDA approval of Pfizer-BioNTech COVID vaccine for 16 years and above, FDA emergency use authorization of the Pfizer vaccine for people 12-15 years of age, and anticipated future authorization for lower age groups, makes now a good time to work with your local school districts on school located opportunities for qualifying high school students, their families, and school staff. Please see Sections 10.2.1 and 10.2.2 for more details about informed consent for vaccination for minors. The provision of COVID-19 vaccine on school grounds will present a need to partner with the school district about language and procedures related to student/parent consent.

### 10.3 Vaccinating Outside Jurisdiction

COVID-19 is a global, national, and statewide pandemic. SARS-CoV-2 (the virus that causes COVID-19) is a highly contagious respiratory virus that is widespread in North Carolina and easily crosses jurisdictional boundaries as people move across county borders and in and out of North Carolina. The CDC has stated that to achieve the public health objectives of ensuring the health, safety, and welfare of all Americans, states and providers must distribute or administer vaccine without discriminating on non-public-health grounds within a prioritized group. As such, it is permissible to allow limitations to vaccine based on public-health grounds. The core public health goals for North Carolina are to: 1) Protect the health of North Carolinians by preventing transmission of SARS-CoV-2 within North Carolina. To achieve this, we must vaccinate as many people who reside or spend time in North Carolina. 2) Promote equity in vaccine distribution. To achieve this, we must ensure we have a vaccine supply for reaching priority populations, including historically marginalized populations in North Carolina.

Therefore, to protect the health of North Carolinians and promote equity in vaccine distribution, people who spend significant time in North Carolina and are able to spread the virus in North Carolina should be vaccinated when and where they have access to vaccine. People who can be vaccinated in North Carolina and considered to spend significant time in North Carolina include, but are not limited to, persons who have a residence and/or live in North Carolina, work in North Carolina, or receive on-going health care in North Carolina. Jurisdictions should continue to not put restrictions on administering vaccinations based on North Carolina county of residence.
Operational Considerations

Vaccination eligibility documentation: The State of North Carolina and NCDHHS do not require individuals to present identification or proof of residency to be vaccinated or to schedule an appointment for vaccination. The need for an identification card presents a barrier for many populations within our state, including older adults, particularly those from racial and ethnic minority groups, immigrants, and homeless individuals. Providers should not ask people for photo identification (this includes government IDs, such as drivers licenses). Recognizing the need to confirm names, addresses and dates of birth, vaccine providers are encouraged to adopt practices that do not include requesting a photo ID; instead, for example, they can ask people to pre-register, allow people to complete a form on-site with their name, address and date of birth, or ask for a bill with a name and address. Vaccine providers should not withhold vaccinations because an individual could not or refused to present identification or proof of residency. The COVID-19 vaccine should be made available to everyone, whether or not they have health insurance and regardless of their immigration status.

Appointment strategies: Providers can employ strategies in their appointment system to promote access for priority populations in North Carolina. For example, providers can: 1) Have an appointment system instead of a first-come, first serve system and 2) Open appointments first or set aside blocks of appointments to filled by community health workers, community members, or community organizations with priority populations in their local area.

10.4 Limited English Proficiency

Title VI of the Civil Rights Act of 1964 requires recipients of Federal financial assistance to take reasonable steps to make their programs, services, and activities accessible by eligible persons with limited English proficiency. Since the vaccine is funded by the federal government and they can bill an administrative fee to Medicare and Medicaid providers would need to abide by this federal law. Under the regulations implementing Section 1557, recipients, such as health care providers, must take reasonable steps to provide meaningful access to individuals with LEP eligible to be served or likely to be encountered in their health programs and activities. This longstanding obligation is not waived during a National Emergency. Reasonable steps may include written translations of documents, or oral language assistance from a qualified interpreter, either in-person or using remote communication technology. https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/index.html https://www.hhs.gov/sites/default/files/lep-bulletin-5-15-2020-english.pdf

Please see Section 17.4 for important examples of strategies of reasonable steps for providers to ensure meaningful access for persons with LEP to COVID-19 vaccine information which includes assistance with phone, onsite and online registration and enrollment. https://www.hhs.gov/sites/default/files/lep-bulletin-5-15-2020-english.pdf

A service email address is available for vaccine providers requesting assistance with connections to resources to better serve individuals with communications needs, including for those with limited English proficiency: communication.access@dhhs.nc.gov

10.5 Americans with Disabilities Act (ADA) and Accessibility

Title II of the Americans with Disabilities Act (ADA) considers states and local governments to be “public entities,” and that law specifically says that “no qualified individual with a disability shall, by reason of such disability, be excluded from participation in or be denied the benefits of the services, programs, or activities of a public entity, or be subjected
to discrimination by any such entity.” 42 U.S.C. § 12132. The corresponding regulation makes it clear that states must effectively communicate with individuals who have disabilities. “A public entity shall take appropriate steps to ensure that communications with applicants, participants, members of the public, and companions with disabilities are as effective as communications with others.” 28 C.F.R. § 35.160(1). This requires that facilities, activities, services, and programs be accessible to individuals with disabilities. Ensuring effective communication and provision of auxiliary aids (i.e., qualified ASL interpreters, TDD, alternate formats) is just as important as providing facilities that are accessible to individuals with disabilities under the ADA.

In addition inclusive and accessible outreach about accessing COVID-19 vaccine information must be used for those patients with disabilities such as those individuals who may be blind or have low vision who are using digital methods (i.e., web sites and social media). Accommodations for point-of-care registration for people with disabilities must be made available to enroll and register people in CVMS by phone prior to the vaccination encounter or onsite. Additional accommodations need to be available to assist people during the onsite registration process in order to complete registration forms and questionnaires in hardcopy or electronically.

For more information about ways to ensure access for individuals with disabilities, the following resources can be helpful:

- NCDHHS Covid-19 Vaccination Site Accessibility Checklist (English) (Spanish)
- Tips for Effective Communication with Individuals Who Have Hearing Loss at a Mass Vaccination Event
- Accessibility at Drive-Thru Medical Sites
- A service email address is available for vaccine providers requesting assistance with connections to resources to better serve individuals with communications needs: communication.access@dhhs.nc.gov

**10.6 Immigration Status**

The COVID-19 vaccine is available to everyone for free, whether or not they have health insurance and regardless of their immigration status. Information is kept confidential and won’t be shared with ICE for immigration enforcement. Getting the vaccine does not have a negative impact on people’s chances of adjusting their immigration status. The Department of Homeland Security released a statement on equal access to COVID-19 vaccines and vaccine distribution sites. Vaccine providers should not withhold vaccinations or appointments for vaccinations because you cannot present identification

**11.0 COVID-19 Vaccine Clinical Information and Guidance**

**11.1 Overview**

Currently information is available for FDA approved Pfizer-BioNTech COVID-19 vaccine marketed as COMIRNATY, and authorized vaccines, including Pfizer-BioNTech COVID-19 Vaccine, Moderna COVID-19 Vaccine, and the Janssen (Johnson & Johnson) COVID-19 vaccine. Once information on other vaccines become available, this document will be updated. The Product Information Guide for COVID-19 Vaccines and Associated Products (See Appendix 6) provides an overview of COVID-19 vaccine products. Any COVID-19 vaccine can be used when indicated with no product preference.
11.2 Approved and Authorized Vaccines

11.2.1 Pfizer-BioNTech COVID-19 Vaccine

Pfizer-BioNTech COVID-19 vaccine (marketed as COMIRNATY) now has full approval by the FDA for use in individuals 16 years and above and Emergency Use Authorization by the FDA for use in individuals 12-15 years of age.

On August 23, 2021, FDA approved COMIRNATY (COVID-19 Vaccine, mRNA) made by Pfizer for BioNTech as a 2-dose series for the prevention of COVID-19 in individuals 16 years of age and older. EUA-authorized Pfizer-BioNTech COVID-19 vaccine continues to be available for use as a 2-dose series in 12-15 year old individuals. The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series.

On August 12, 2021, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) to permit the emergency use of Pfizer-BioNTech COVID-19 Vaccine to provide a third dose to individuals 12 years of age and older after an initial 2-dose primary vaccine series who have been determined to have certain kinds of immunocompromise. See Section 11.2.6 for more information.

Updated CDC interim clinical considerations for use of the Pfizer-BioNTech COVID-19 vaccine which are pertinent to adolescents can be found in several sections and more information can be found at the following site.

11.2.2 Moderna COVID-19 Vaccine

On December 18, 2020, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for the second vaccine for the prevention of coronavirus disease 2019 (COVID-19). The emergency use authorization allows the Moderna COVID-19 Vaccine to be distributed in the U.S for use in individuals 18 years of age and older.

On August 12, 2021, a third dose of the Moderna COVID-19 Vaccine (0.5 mL) administered at least 28 days following the first two doses of this vaccine was authorized by FDA for administration to individuals at least 18 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise. See Section 11.2.6 for more information.

11.2.3 Johnson & Johnson (Janssen) COVID-19 Vaccine

On February 27, 2021, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for the third vaccine for the prevention of coronavirus disease 2019 (COVID-19). The emergency use authorization allows the Janssen (Johnson & Johnson) COVID-19 Vaccine to be distributed in the U.S for use in individuals 18 years of age and older.

11.2.4 Brands of COVID-19 vaccine are currently NOT interchangeable

Always use the same manufacturer of COVID-19 vaccine to complete a series if there is more than one dose recommended. In exceptional situations in which the vaccine product given for the first dose cannot be determined or is no longer available, any available mRNA COVID-19 vaccine may be administered at a minimum interval of 28 days between doses to complete the mRNA COVID-19 vaccination series. In situations where the same mRNA vaccine product is temporarily unavailable, it is preferable to delay the 2nd dose (up to 6 weeks) to receive the same product than to receive a mixed series using a different product. If two doses of different mRNA COVID-19 vaccine products are administered in these situations (or inadvertently), no additional doses of either product are recommended at this time.
Always refer to the package insert of the product you are using for licensure information or the EUA Fact Sheet for each vaccine and the ACIP Recommendations for COVID-19 vaccines before administering a COVID-19 vaccine. See the EUA Fact Sheet section below for specific information on the vaccines currently available.

11.2.5 EUA Fact Sheets

Vaccine Information/EUA Fact Sheets for each approved or authorized vaccine are available [here](#). The Vaccine Information/EUA Fact Sheet for Recipients and Caregivers for the appropriate vaccine is required to be given to each patient before administration of COVID-19 vaccine. There is no federal or state requirement to document that the patient fact sheet was received or to document a publication date. The EUA also requires the Fact Sheet for Healthcare Providers Administering Vaccine (Pfizer / Moderna / Johnson & Johnson (Janssen)) be provided to vaccination providers.

Please note that the Pfizer-BioNTech COVID-19 EUA Fact Sheet for Recipients and the Pfizer-BioNTech COVID-19 Vaccine Fact Sheet for Caregivers and for Healthcare Providers Administering Vaccine have been updated to include information related to use of the vaccine in people down to 12 years of age and new precautions around syncope. The most current fact sheets should be used and accessed at the links above.

Per the EUA, the vaccination provider must communicate to the recipient or their caregiver, information consistent with the “Fact Sheet for Recipients and Caregivers” (and provide a copy or direct the individual to the website [www.cvdvaccine.com](http://www.cvdvaccine.com) to obtain the Fact Sheet) prior to the individual receiving either the Pfizer-BioNTech COVID-19 Vaccine, the Moderna COVID-19 Vaccine or the Johnson & Johnson (Janssen) COVID-19 vaccine, including:

- FDA has approved COMIRNATY COVID-19 mRNA vaccine made by Pfizer for BioNTech as a 2-dose series to prevent COVID-19 for use in individuals 16 years and older.
- FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine for a 2-dose series to prevent COVID-19 in individuals 12-15 years of age and use for an additional dose in individuals 16 years and above with moderate to severe immunocompromise.
- FDA has authorized the emergency use of the Moderna COVID-19 Vaccine and the Johnson & Johnson (Janssen) COVID-19 vaccine, which are not FDA-approved vaccines.
- The recipient or their caregiver has the option to accept or refuse any of the approved or authorized COVID-19 vaccines. The significant known and potential risks and benefits of each of the approved or authorized COVID-19 vaccines and the extent to which such risks and benefits are unknown.
- Information about available alternative approved or authorized vaccines and the risks and benefits of those alternatives.
- Consent for medical treatment must be obtained prior to being vaccinated. That consent can be verbal. Please see Section 11.2 for more information about consent for minors.
- COVID-19 vaccination provider must provide the necessary information for receiving the second dose to every vaccine recipient receiving the Pfizer or Moderna COVID-19 vaccines.

Currently there is no VIS for any of the COVID-19 vaccines. Federal law (under the National Childhood Vaccine Injury Act) requires a healthcare professional to provide a copy of the current VIS to an adult patient or to a child’s parent/legal representative before vaccinating an adult or child with other routine vaccines (e.g., diphtheria, tetanus, pertussis, measles, mumps, rubella) that are FDA-approved vaccines. Because no COVID-19 vaccines have full FDA approval, this requirement does not include any of the COVID-19 vaccines.
Resources in Technical Appendix:

- Appendix 1: EUA Fact Sheet for Recipients and Caregivers for Pfizer-BioNTech COVID-19 Vaccine.
- Appendix 60: FDA Letter of Approval for COMIRNATY (COVID mRNA vaccine made by Pfizer for BioNTech).
- Appendix 11: EUA Fact Sheet for Recipients and Caregivers for Moderna COVID-19 Vaccine.
- Appendix 43: EUA Fact Sheet for Health Care Providers Administering Vaccine for Janssen (Johnson & Johnson) COVID-19 Vaccine.

**11.2.6 Clinical Guidance About Additional Dose of mRNA Vaccine in People Who Are Moderately to Severely Immunocompromised**

- On August 12, 2021 FDA modified the Emergency Use Authorizations (EUAs) for Pfizer-BioNTech COVID-19 vaccine and Moderna COVID-19 vaccine to allow for administration of an additional dose (i.e., a third dose) of an mRNA COVID-19 vaccine after an initial 2-dose primary mRNA COVID-19 vaccine series for certain people who are immunocompromised.
- On August 13, 2021, ACIP met and reviewed the data for use of an additional dose of mRNA COVID-19 vaccine for immunocompromised people within the Evidence to Recommendation Framework. ACIP made an interim recommendation for emergency use of an additional dose of Pfizer-BioNTech COVID-19 vaccine (for persons aged ≥12 years) or Moderna COVID-19 vaccine (for persons aged ≥18 years) after an initial 2-dose primary mRNA COVID-19 vaccine series for moderately to severely immunocompromised people.
- Based on ACIP recommendations, the CDC Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States were updated and can be found here: [https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html) Changes include considerations for use of an additional mRNA COVID-19 vaccine dose after an initial 2-dose primary mRNA COVID-19 vaccine series for immunocompromised people. The clinical considerations for use of an additional dose of an mRNA COVID-19 vaccine apply only to people who are moderately or severely immunocompromised.
- **Currently there are insufficient data to support the use of an additional mRNA COVID-19 vaccine dose after a single-dose Janssen COVID-19 vaccination series in immunocompromised people.**
- **There is not enough data at this time to determine whether immunocompromised people who received the Johnson & Johnson’s Janssen COVID-19 vaccine also have an improved antibody response following an additional dose of the same vaccine.**
- Conditions and treatments associated with moderate and severe immune compromise include but are not limited to:
  - Active treatment for solid tumor and hematologic malignancies
  - Receipt of solid-organ transplant and taking immunosuppressive therapy
  - Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
  - Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids (i.e., ≥20mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory.

- Healthcare professionals and public health officials should consider the following for use of an additional mRNA COVID-19 vaccine dose after an initial 2-dose primary mRNA COVID-19 vaccine series for people who are moderately to severely immunocompromised people:
  - The currently FDA-approved or authorized COVID-19 vaccines are not live vaccines and therefore can be safely administered to immunocompromised people.
  - Studies indicate some immunocompromised people don’t always build the same level of immunity after vaccination the way non-immunocompromised people do, and may benefit from an additional dose to ensure adequate protection against COVID-19. In small studies, fully vaccinated immunocompromised people have accounted for a large proportion of hospitalized post-vaccination cases.
  - Studies have further demonstrated that including an additional mRNA COVID-19 vaccine dose after an initial 2-dose primary mRNA COVID-19 vaccine series in some immunocompromised populations may enhance immune response.
  - The clinical benefit of an additional mRNA vaccine dose after an initial 2-dose primary mRNA COVID-19 vaccine series for immunocompromised people is not precisely known. However, for people with moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments, the potential to increase immune response coupled with an acceptable safety profile, support the recommendation for an additional mRNA vaccine dose after an initial 2-dose primary mRNA COVID-19 vaccine series.
  - There is limited information about the risks of receiving an additional dose of vaccine, and the safety, efficacy, and benefit of additional doses of COVID-19 vaccine in immunocompromised people continues to be evaluated. So far, reactions reported after the third mRNA dose were similar to that of the two-dose series: fatigue and pain at injection site were the most commonly reported side effects, and overall, most symptoms were mild to moderate. However, as with the two-dose series, serious side effects are rare, but may occur.
  - The additional dose should be administered at least 28 days after the completion of the initial mRNA COVID-19 vaccine series.
  - The additional mRNA COVID-19 vaccine dose should be the same vaccine product as the initial 2-dose mRNA COVID-19 primary vaccine series (Pfizer-BioNTech or Moderna). If the mRNA COVID-19 vaccine product given for the first two doses is not available, the other mRNA COVID-19 vaccine product may be administered. A person should not receive more than three mRNA COVID-19 vaccine doses.
  - Whenever possible, mRNA COVID-19 vaccination primary series and additional dose should be given at least two weeks before initiation or resumption of immunosuppressive therapies, but timing of COVID-19 vaccination should take into consideration immunosuppressive therapies and optimization of both the patient’s medical condition and response to vaccine
    - Patient’s clinical team is best situated to determine the degree of immune compromise and appropriate timing of vaccination
    - Factors to consider in assessing the general level of immune competence of patients include disease severity, duration, clinical stability, complications, comorbidities, and any potentially immune-suppressing treatment
Utility of serologic testing or cellular immune testing to assess immune response to vaccination and guide clinical care (e.g., need for an additional dose) has not been established and is not recommended at this time.

11.2.7 Clinical Guidance About Johnson & Johnson (Janssen) COVID-19 Vaccine

“FDA has added a warning to the Janssen COVID-19 vaccine EUA and fact sheets regarding rare clotting events that have been reported among vaccine recipients. Updated patient education and communication materials reflecting this warning are critical to ensure that women aged <50 years are aware of the increased risk for TTS and that other COVID-19 vaccines are available (i.e., mRNA vaccines). The EUA fact sheet should be provided to all vaccine recipients and their caregivers (as relevant) for careful review before vaccination with any authorized COVID-19 vaccine.

“Treatment for TTS that occurs after receipt of the Janssen COVID-19 vaccine is different from the treatment typically administered for blood clots; notably, heparin should not be administered, and consultation with hematology specialists is strongly recommended. A Health Alert Network notification published on April 13, 2021 provided additional information and recommendations concerning the identification and treatment of suspected cases of TTS after Janssen COVID-19 vaccination for clinicians, public health officials, and the public. Additional clinical considerations for use of COVID-19 vaccines are available at: [https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html).”

“CDC and FDA will continue to closely monitor reports of TTS after receipt of the Janssen COVID-19 vaccine and will bring any additional data needed to guide benefits and risks to ACIP for consideration. The risk-benefit analysis can be updated as needed to reflect changes in the COVID-19 pandemic and additional information on the risk for TTS after COVID-19 vaccination. The ACIP recommendation for use of the Janssen COVID-19 vaccine under an EUA is interim and will be updated as additional information becomes available.”

The above information was published on April 27 by the CDC in the Morbidity and Mortality Weekly Report (MMWR) Updated Recommendations from the Advisory Committee on Immunization Practices for Use of the Janssen (Johnson & Johnson) COVID-19 Vaccine After Reports of Thrombosis with Thrombocytopenia Syndrome Among Vaccine Recipients — United States, April 2021. For more detailed information and references please go to: [https://www.cdc.gov/mmwr/volumes/70/wr/mm7017e4.htm](https://www.cdc.gov/mmwr/volumes/70/wr/mm7017e4.htm)

For Healthcare Providers

- Review the revised [Janssen COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers)](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html), which has been revised to include a warning about the risk TTS.
- Read the official CDC health alert, [Cases of Cerebral Venous Sinus Thrombosis with Thrombocytopenia after Receipt of the Johnson & Johnson COVID-19 Vaccine](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html), which includes details about how to assess and care for a patient that presents with thrombosis or thrombocytopenia.
- Report adverse events to the [Vaccine Adverse Event Reporting System](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html). (see Section 11.10.1)

For Vaccine Providers

- Vaccine providers may resume use of the Janssen COVID-19 Vaccine.
- Review the [Janssen COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers)](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html), which has been revised to include a warning about the risk of TTS that has occurred in a small number of people who have received the Janssen COVID-19 Vaccine.
• CDC encourages vaccine providers to promote the use of v-safe among vaccine recipients using CDC’s free print resources. See information on CDC’s webpage: [CDC Recommends Use of Johnson & Johnson’s Janssen COVID-19 Vaccine Resume](#)

If you have any questions, please submit a ticket to the CVMS Help Desk Portal or call the COVID-19 Vaccine Provider Help Center at (877) 873-6247 and select option 1 for COVID-19 questions (Monday – Friday 7:00 AM – 7:00 PM ET and Saturday – Sunday 10:00 AM – 6:00 PM ET), or call the COVID-19 Vaccine Provider Help Center at (877) 873-6247 and select option 1 for COVID-19 questions (Monday – Friday 7:00 AM – 7:00 PM ET and Saturday – Sunday 10:00 AM – 6:00 PM ET).

### 11.3 Contraindications and Precautions for mRNA COVID-19 Vaccines

**Contraindications:**

CDC considers a history of the following to be a contraindication to vaccination with the Pfizer-BioNTech and Moderna COVID-19 vaccines:

1. Severe allergic reaction (e.g., anaphylaxis) after a previous dose of a COVID-19 vaccine or any of its components
2. Immediate allergic reaction of any severity to a previous dose of a COVID-19 vaccine or any of its components (including polyethylene glycol [PEG])* CDC for this purpose defines “immediate allergic reaction” as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g. wheezing, stridor), or anaphylaxis that occur within 4 hours following administration.
3. Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)* Update: Known polysorbate allergy is no longer a contraindication to mRNA vaccination; however, known polysorbate allergy is a contraindication to Janssen COVID-19 vaccine and thus, a precaution to mRNA COVID-19 vaccination.

Note: It is very important to report all adverse reactions after the receipt of a COVID-19 vaccine. See [Section 11.10.1](#) for information on the Vaccine Adverse Event Reporting System (VAERS).

**Precautions:**

1. CDC considers a history of any immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies not related to a component of mRNA COVID-19 vaccines or polysorbate) as a precaution but not a contraindication to vaccination for both the Pfizer-BioNTech and Moderna COVID-19 vaccines.
2. Persons with a contraindication to Johnson & Johnson (Janssen) COVID-19 vaccine have a precaution for mRNA COVID-19 vaccine.

### 11.4 Contraindications and Precautions for Johnson & Johnson/ Janssen COVID-19 vaccine

**Contraindications:**

Do not administer the Janssen COVID-19 Vaccine to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Janssen COVID-19 Vaccine.
Precautions:
Persons with a contraindication to mRNA COVID-19 vaccines have a precaution to Johnson & Johnson/ Janssen vaccine.

- **People with a contraindication to mRNA COVID-19 vaccines** (including due to a known PEG allergy): Consideration may be given to vaccination with Janssen COVID-19 vaccine. People who have received one mRNA COVID-19 vaccine dose but for whom the second dose is contraindicated should wait at least 28 days after the mRNA vaccine dose to receive Janssen COVID-19 vaccine.

- **People with a contraindication to Janssen COVID-19 vaccine** (including due to a known polysorbate allergy): Consideration may be given to mRNA COVID-19 vaccination. Of note, polysorbate allergy is no longer a contraindication to mRNA COVID-19 vaccination; however, it remains a precaution.

Because of potential cross-reactive hypersensitivity between ingredients in mRNA and Janssen COVID-19 vaccines, consultation with an allergist-immunologist should be considered to help determine if the patient can safely receive vaccination. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax project. Vaccination of these individuals should only be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions. As a change from previous versions of the guidance, known polysorbate allergy is no longer a contraindication to mRNA vaccination; however, known polysorbate allergy is a contraindication to Janssen COVID-19 vaccine and thus, a precaution to mRNA COVID-19 vaccination.
# 11.5 Triage of Persons Presenting for COVID-19 Vaccination

<table>
<thead>
<tr>
<th>CONTRAINICATION TO VACCINATION</th>
<th>PRECAUTION TO VACCINATION</th>
<th>MAY PROCEED WITH VACCINATION</th>
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<tbody>
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<td>History of the following:</td>
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<td>Among people without a</td>
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<tr>
<td>• Severe allergic reaction</td>
<td>contraindication, a history of:</td>
<td>contraindication or precaution,</td>
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<td>(e.g., anaphylaxis) after a</td>
<td>• Any immediate allergic</td>
<td>a history of:</td>
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<td>previous dose or to component</td>
<td>reaction* to other vaccines</td>
<td>• Allergy to oral medications</td>
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<td>of the vaccine†</td>
<td>or injectable therapies‡</td>
<td>(including the oral</td>
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<tr>
<td>• Immediate allergic</td>
<td>Note: people with a</td>
<td>equivalent of an injectable</td>
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<td>reaction* of any severity</td>
<td>contraindication to mRNA</td>
<td>medication)</td>
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<td>after a previous dose or</td>
<td>COVID-19 vaccines have a</td>
<td>• History of food, pet,</td>
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<tr>
<td>known (diagnosed) allergy</td>
<td>precaution to Janssen</td>
<td>insect, venom, environmental,</td>
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<td>to a component of the vaccine</td>
<td>COVID-19 vaccine, and vice versa.</td>
<td>latex, etc., allergies</td>
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<td>†</td>
<td></td>
<td>• Family history of allergies</td>
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| Actions:                       | Actions:                   | Actions:                     |
|                               |                           | • 30-minute observation      |
| • Do not vaccinate.           | • Risk assessment         | period: people with history   |
| • Consider referral to        | • Consider referral to    | of anaphylaxis (due to any   |
| allergist-immunologist.      | allergist-immunologist    | cause)                      |
| • Consider other vaccine      | • 30-minute observation    | • 15-minute observation      |
| alternative.†                 | period if vaccinated      | period: all other people     |

† See Appendix C for a list of ingredients. People with a contraindication to one of the mRNA COVID-19 vaccines should not receive doses of either of the mRNA vaccines (Pfizer-BioNTech or Moderna).

* Immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms consistent with urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.

‡ Includes people with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is a vaccine component, but in whom it is unknown which component elicited the immediate allergic reaction.

# Polyethylene glycol (PEG) is an ingredient in both mRNA COVID-19 vaccines, and polysorbate 80 is an ingredient in Janssen COVID-19 vaccine. PEG and polysorbate are structurally related, and cross-reactive hypersensitivity between these compounds may occur. People with a contraindication to mRNA COVID-19 vaccines (including due to a known allergy to PEG) have a precaution to Janssen COVID-19 vaccine. Among people who received one mRNA COVID-19 dose but for whom the second dose is contraindicated, consideration may be given to vaccination with Janssen COVID-19 vaccine (administered at least 28 days after the mRNA COVID-19 dose). People with a contraindication to Janssen COVID-19 vaccine (including due to a known allergy to polysorbate) have a precaution to mRNA COVID-19 vaccines. For people with these precautions, referral to an allergist-immunologist should be considered. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment.
COVIDvax project. In patients with these precautions, vaccination should only be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions. Additional information from CDC included in the Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States.

11.6 Warnings for the Pfizer-BioNTech COVID-19 Vaccine, Moderna COVID-19 Vaccine, and Johnson & Johnson/ Janssen COVID-19 Vaccine

CDC recommends the following observation periods after any COVID-19 vaccination:

- 30 minutes:
  - History of an immediate allergic reaction of any severity to a vaccine or injectable therapy
  - People with a contraindication to a different type of COVID-19 vaccine (for example, people with a contraindication to mRNA COVID-19 vaccines who receive Janssen viral vector vaccine should be observed for 30 minutes following Janssen vaccination).
  - History of anaphylaxis due to any cause
- 15 minutes: All other people

With the expanded authorization of Pfizer-BioNTech to include adolescents 12 years and older, the FDA included precautions around syncope. Syncope may occur in association with administration of vaccines, in particular in adolescents, and procedures should be in place to avoid injury from fainting.

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine, Moderna COVID-19 Vaccine, and Johnson & Johnson/ Janssen COVID-19 Vaccine. CDC provides guidance on Preparing for the Potential Management of Anaphylaxis After COVID-19 Vaccination.

People with a history of thrombosis or risk factors for thrombosis

Although the etiology of TTS associated with the Janssen COVID-19 vaccine is unclear, it appears to be similar to another rare immune-mediated syndrome, heparin-induced thrombocytopenia (HIT). Until more information becomes available, experts advise that persons with a history of an episode of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as HIT, should be offered another FDA-approved or authorized COVID-19 vaccine (i.e., mRNA vaccine) if it has been ≤90 days since their illness resolved. After 90 days, patients may be vaccinated with any FDA-approved or authorized COVID-19 vaccine.

People with a history of multisystem inflammatory syndrome in children (MIS-C) or adults (MIS-A)

Currently, there are no data on the safety and efficacy of COVID-19 vaccines in people with a history of multisystem inflammatory syndrome in children (MIS-C) or in adults (MIS-A). The mechanisms of MIS-C and MIS-A are not well understood but include a dysregulated immune response to SARS-CoV-2 infection. It is unclear if people with a history of MIS-C or MIS-A are at risk of recurrence of the same dysregulated immune response following reinfection with SARS-CoV-2 or in response to vaccination. These theoretical concerns should be weighed against the known risks of COVID-19 from reinfection and the benefits of protection from a COVID-19 vaccine. Children with MIS-C have high antibody titers to SARS-CoV-2; however, it is unknown if this correlates with protection against reinfection and for how long protective antibody levels persist. People with a history of MIS-C or MIS-A may choose to be vaccinated. Considerations for vaccination may include:
• Clinical recovery from MIS-C or MIS-A, including return to normal cardiac function
• Personal risk of severe acute COVID-19 (e.g., age, underlying conditions)
• Level of COVID-19 community transmission and personal risk of reinfection
• Lack of safety data of COVID-19 vaccines following these illnesses
• Timing of any immunomodulatory therapies (ACIP’s general best practice guidelines for immunization can be consulted for more information)

A conversation between the patient, their guardian(s), and their clinical team or a specialist may assist with decisions about the use of a COVID-19 vaccine, though a conversation with a healthcare provider is not required before vaccination.

Current evidence suggests that the risk of SARS-CoV-2 reinfection is low in the months after initial infection but may increase with time due to waning immunity. Thus, people with a history of MIS-C or MIS-A should consider delaying vaccination until they have recovered from their illness and for 90 days after the date of diagnosis of MIS-C or MIS-A, recognizing that the risk of reinfection and, therefore, the benefit from vaccination, might increase with time following initial infection.

For people who develop MIS-C or MIS-A that is associated with a confirmed SARS-CoV-2 infection but occurs after receipt of a COVID-19 vaccine, referral to a specialist in infectious diseases, rheumatology, or cardiology should be considered. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax. In addition, information about these cases should be reported to VAERS.

mRNA COVID-19 Vaccines and Risk of Myocarditis and Pericarditis

On June 23, 2021, ACIP met to review reported cases of myocarditis or pericarditis in mRNA COVID-19 vaccine (Pfizer-BioNTech and Moderna) recipients. Cases of myocarditis or pericarditis have occurred predominantly in males aged 12-29 years, with symptoms typically developing within a few days after receipt of the second dose of vaccine. ACIP reviewed the benefits and risks of mRNA COVID-19 vaccines in the United States and determined that the benefits of using mRNA COVID-19 vaccines under the Food and Drug Administration’s (FDA) Emergency Use Authorization (EUA) clearly outweigh the risks of myocarditis and pericarditis in all people aged 12 years or older. The FDA updated the EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and the Fact Sheet for Recipients and Caregivers for Pfizer-BioNTech COVID-19 vaccine and Moderna COVID-19 vaccine to include information about the occurrence of myocarditis or pericarditis in some people following use of the vaccine. Based on the benefit-risk assessment, COVID-19 vaccination continues to be recommended for everyone aged 12 years and older under the FDA’s EUAs.

ACIP highlighted the need for continued monitoring of cases of myocarditis or pericarditis after receipt of mRNA COVID-19 vaccines, as well as patients’ clinical course and long-term outcomes. The benefit-risk analysis may be updated, as needed, to reflect changes in COVID-19 disease trends and additional information on the risk for myocarditis or pericarditis after mRNA COVID-19 vaccination.

Patient and vaccination provider education about the risk of myocarditis or pericarditis occurring after receipt of COVID-19 mRNA vaccines, especially among males aged 12–29 years, is important to ensure timely diagnosis and treatment. A vaccine-specific EUA fact sheet should be provided to all vaccine recipients, parents or guardians, and caregivers (when relevant) before vaccination with any FDA-approved or authorized COVID-19 vaccine.
Clinicians should consult current clinical guidance for information on the evaluation and management of myocarditis or pericarditis. Healthcare professionals should report all cases of myocarditis or pericarditis after COVID-19 vaccination to VAERS.

Updated interim clinical considerations, including COVID-19 vaccination of people with a history of myocarditis or pericarditis and patient counseling information about the risk of myocarditis or pericarditis after receipt of mRNA COVID-19 vaccines, can be found in this document as follows:

- Considerations for vaccination of people with certain underlying medical conditions
- Patient counseling

Additional resources include:

- Myocarditis and Pericarditis Following mRNA COVID-19 Vaccination
- Clinical Considerations: Myocarditis and Pericarditis after Receipt of mRNA COVID-19 Vaccines Among Adolescents and Young Adults

**Janssen (Johnson & Johnson) Vaccine and Guillain-Barré Syndrome**

On July 12, 2021, the Food and Drug Administration (FDA) attached a warning to the Johnson & Johnson vaccine health care provider and recipient/caregiver factsheets highlighting the increased possibility of a rare nerve condition, Guillain-Barré syndrome (GBS).

GBS is a condition in which the body’s immune system damages nerve cells, causing muscle weakness, or in severe cases, paralysis. Approximately, 3,000 to 6,000 people in the United States develop GBS; it is typically developed as a result of a respiratory or gastrointestinal infection. Most people fully recover from GBS.

According to the CDC, approximately 100 preliminary reports out of 12.8 million doses Janssen/J&J COVID-19 vaccines administered. Many of these cases have been reported about two weeks after vaccination in males age 50 and older. Increased reports of GBS have not been observed with the mRNA vaccines Pfizer or Moderna after 321 million doses administered in the United States. The CDC states that the risk of developing GBS after receiving the Johnson & Johnson COVID-19 vaccine is low.

- Revised Provider and Recipient factsheets for the Janssen (patient and provider)
- FDA Statement
- Johnson & Johnson Statement

**11.7 Expected Reactions and How to Prepare Your Patients**

Prior to vaccination, all COVID-19 vaccine administrators should counsel vaccine recipients about expected systemic and local reactions that can occur with the COVID-19 vaccine. These expected reactions have been seen and experienced with vaccine recipients during the clinical trials and are described in each EUA Fact Sheet. Unless a person develops a contraindication to vaccination, they should be encouraged to complete the series even if they develop post-vaccination symptoms in order to optimize protection against COVID-19. Antipyretic or analgesic medications if not otherwise contraindicated may be taken for treatment of post-vaccination symptoms. Preparing your patients and community
members for temporary reactions that could occur will help to decrease anxiety and vaccine hesitancy in individual patients and your community. Please see the following CDC resource for additional information: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html

11.8 Adverse Reactions Reported During the Clinical Trials

In clinical trials, hypersensitivity-related adverse events were observed in 0.63% of participants who received the Pfizer-BioNTech COVID-19 vaccine and 1.5% of participants who received the Moderna COVID-19 vaccine. In the Johnson & Johnson/ Janssen trial, there was 1 reported hypersensitivity reaction but no reports of anaphylaxis. The most common adverse reactions to COVID-19 vaccines include soreness at the injection site, fatigue, headache, muscle aches, chills, joint pain, and fever. Side effects can last from 24-48 hours.

Among adolescent vaccine recipients ages 12–15 years in the clinical trials, reactogenicity symptoms during the 7 days after vaccination were frequent (90.9% of vaccine recipients reported any local reaction and 90.7% reported any systemic reaction) and mostly mild to moderate. Pain at the injection site was the most common local reaction. Systemic adverse reactions (e.g., fever, fatigue, headache, muscle pain) were more commonly reported after the second dose than after the first dose. The local and systemic reactions were similar to those reported in persons aged ≥ 16 years. No specific safety concerns were identified among adolescent vaccine recipients.

An immediate or severe allergic reaction to any component or previous dose of a COVID-19 vaccine is a contraindication to vaccination. If an individual had a severe allergic reaction after getting the first dose of an mRNA COVID-19 vaccine, the CDC recommends the individual not get the second dose. The following is a list of ingredients for the Pfizer-BioNTech and Moderna COVID-19 vaccines, as reported in the prescribing information for each vaccine. If the first dose of mRNA COVID-19 vaccine was received but patient unable to complete series with same or different mRNA vaccine (e.g., contraindication), a single dose of Janssen (Johnson & Johnson) vaccine may be administered at minimum interval of 28 days from mRNA dose.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the COVID-19 vaccines. For guidance on responding to and management of vaccine reactions, see Medical Management of Vaccine Reactions in Adults in a Community Setting Appendix 28.

<table>
<thead>
<tr>
<th>Description</th>
<th>Pfizer-BioNTech (mRNA)</th>
<th>Moderna (mRNA)</th>
<th>Janssen (viral vector)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active ingredient</td>
<td>Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2</td>
<td>Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2</td>
<td>Recombinant, replication-incompetent Ad26 vector, encoding a stabilized variant of the SARS-CoV-2 Spike (S) protein</td>
</tr>
</tbody>
</table>
### 11.9 Interim Recommendations for COVID-19 Vaccine Administration Errors and Deviations

A vaccine administration error is any preventable event that may cause or lead to inappropriate use of vaccine causing the patient to receive an ineffective immunization or patient harm.

**For all vaccine administration errors:**
- Inform the recipient of the vaccine administration error.
- Consult with the state immunization program (Regional Immunization Nurse Consultant) to determine how the dose should be entered into the COVID-19 Vaccine Management System (CVMS).
- Contact the COVID-19 Vaccine Provider Help Center to receive support for COVID-19 vaccine management and CVMS questions. The North Carolina Immunization Branch Help Desk 877-873-6247.
- Providers are required to report all COVID-19 vaccine administration errors—even those not associated with an adverse event to VAERS.
- Determine how the error occurred and implement strategies to prevent it from happening again.
- All vaccine administration errors secondary to a medical device malfunction must follow the steps for ancillary kit deficiency reporting noted in Section 11.10.2.
- **If an additional dose is intentionally (or inadvertently) administered, appropriate documentation in CVMS of the administration is still required, regardless of the reason.**

Note: Although CDC guidance refers to the NC Immunization Information System IIS, North Carolina is currently using the CVMS for COVID-19 vaccine management and data sharing across recipients, care providers, hospitals, agencies and local, state, and federal governments. The CVMS program is currently used for state COVID-19 vaccines. Refer to the
CVMS Provider Portal Inventory Depreciation, Transfer and Distribution User guide for assistance with inventory management.

The CDC provides a table listing resources for preventing and reporting COVID-19 vaccine administration errors, as well as actions to take after an error has occurred. Please see COVID-19 Vaccine Administration Errors and Deviations

11.10 Safety Monitoring – VAERS and V-safe

It is very important to report all adverse reactions after the receipt of a COVID-19 vaccine. Providers should use Vaccine Adverse Event Reporting System (VAERS) and also provide V-safe information to the recipient so that recipients can self-enroll for a post-vaccination health check-in, as well as a 2nd dose reminder. These two systems are described below:

11.10.1 VAERS

Vaccine Adverse Event Reporting System (VAERS) is a national early warning system to detect possible safety problems with vaccine by continuously monitoring the safety of vaccines given to children and adults in the United States. Please go to the VAERS home page for information about how to report an adverse event at: https://vaers.hhs.gov/reportevent.html There are certain situations stated below where reporting to VAERS is required by the EUA for providers. Vaccination providers are required to report the following to VAERS:

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events (irrespective of attribution to vaccination)
  - Serious adverse events are defined as:
    - Death;
    - A life-threatening adverse event;
    - Inpatient hospitalization or prolongation of existing hospitalization;
    - A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
    - A congenital anomaly/birth defect;
    - An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.
- Cases of Multisystem Inflammatory Syndrome in children and adults (See Section 11.6)
- Cases of COVID-19 that result in hospitalization or death
- Any additional select adverse events and/or any revised safety reporting requirements per FDA’s conditions of authorized use of vaccine(s) throughout the duration of any COVID-19 vaccine being authorized under an Emergency Use Authorization

Health care providers are encouraged to report any adverse event they think is medically important or clinically significant, even if they think the event might not be related to the vaccine. Please go to the VAERS home page at: https://vaers.hhs.gov/reportevent.html
11.10.2 V-safe
V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins to vaccine recipients following COVID-19 vaccination. V-safe also provides second dose vaccine reminders, if needed. This program is only for COVID-19 vaccine and serves as an important active surveillance system for adverse events. All providers who administer COVID-19 vaccine are asked to provide printed hard copies of the v-safe information sheet to each vaccinated individual and counsel them on the importance of enrolling in v-safe. Please take advantage of the post-vaccination observation period to encourage V-safe participation.

See Appendix 4 for the v-safe information sheets to give to patients who receive COVID-19 vaccine and Appendix 5 for a poster for your clinic. V-safe information sheets are available in multiple languages from CDC: https://www.cdc.gov/coronavirus/2019ncov/vaccines/safety/vsafe.html

Parents/caregivers can enroll their adolescent in v-safe, a free, smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins. Through v-safe, parents or caregivers can report any side effects their adolescent may have after vaccination. Modifications to V-safe have been made to allow parents and guardians the ability to complete health surveys on behalf of their adolescents, describing symptoms and health events after vaccination. Participation in V-safe will help CDC continue to monitor the safety of COVID-19 vaccines as use is expanded into younger populations.

11.10.3 Pregnancy Exposure Registry
CDC established the v-safe COVID-19 Vaccine Pregnancy Registry to learn more about the safety of COVID-19 vaccines in people who are pregnant. The information is critical to helping individuals and their healthcare providers make informed decisions about COVID-19 vaccination. The v-safe COVID-19 Vaccine Pregnancy Registry is for v-safe participants who self-identify as pregnant at the time of vaccination or shortly thereafter (within 30 days of vaccination). The registry activities are in addition to the v-safe after vaccination health check-ins that participants receive via text message. People who choose to enroll in the registry will be contacted several times throughout their pregnancy for additional health check-ins. During these check-ins, they will be asked questions about their pregnancy and medical history. After delivery, participants might be contacted when their babies are about three months old. Participants will also be asked for permission to review their medical records to get a more comprehensive picture of their pregnancies. Personal information and responses in v-safe are confidential and will be protected to the full extent allowed by law. Participation in the registry is voluntary, and participants may opt out at any time. Women who receive COVID-19 vaccine during pregnancy are also encouraged to enroll in the registry by visiting https://c-viper.pregistry.com.

11.11 Vaccinated People and Interpretation of SARS-CoV-2 Test Results

Prior receipt of a COVID-19 vaccine will not affect the results of SARS-CoV-2 viral tests (nucleic acid amplification or antigen tests). Currently available antibody tests for SARS-CoV-2 assess IgM and/or IgG to one of two viral proteins: spike or nucleocapsid. Because COVID-19 vaccines are constructed to encode the spike protein, a positive test for spike protein IgM/IgG could indicate prior infection and/or vaccination. To evaluate for evidence of prior infection in an individual with a history of COVID-19 vaccination, a test that specifically evaluates IgM/IgG to the nucleocapsid protein should be used.

Antibody testing is not currently recommended to assess for immunity to SARS-CoV-2 following COVID-19 vaccination because the clinical utility of post-vaccination testing has not been established. Antibody tests currently authorized
under an EUA have variable sensitivity, specificity, as well as positive and negative predictive values, and are not authorized for the assessment of immune response in vaccinated people. Furthermore, the serologic correlates of protection have not been established, and antibody testing does not evaluate the cellular immune response, which may also play a role in vaccine-mediated protection. Finally, antibody testing against nucleocapsid will not detect immune responses resulting from vaccination, but patients may not always know what type of antibody test was used. If antibody testing was performed following vaccination, additional doses of the same or different COVID-19 vaccines are not recommended based on antibody test results at this time. If antibody testing was done after the first dose of an mRNA vaccine, the vaccination series should be completed regardless of the antibody test result. For more information please go to the statement from FDA.

**11.12 Online Resources: Vaccine Clinical Information and Guidance**

<table>
<thead>
<tr>
<th>Training Program / Reference Material</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare Providers</strong></td>
<td>A web-based training course outlining best practices and principles for healthcare providers when preparing to administer COVID-19 vaccine. It is a high-level overview of the following topics with links to detailed information: vaccine development and safety, safety monitoring programs, Emergency Use Authorizations (EUAs), vaccine storage and handling, preparation, administration, PPE, scheduling, documentation, and reporting adverse events. Information on each vaccine product will be added as each is approved or authorized by FDA.</td>
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<tr>
<td><em>Required</em></td>
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<tr>
<td><strong>You Call the Shots: Vaccine Administration</strong></td>
<td>An interactive, web-based vaccine administration course that provides training using videos, job aids, and other resources.</td>
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<tr>
<td><strong>Vaccine administration videos</strong></td>
<td>Short, skill-based demonstration videos of vaccine administration activities, including injection techniques based on age and medication preparation.</td>
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<tr>
<td><strong>Skills Checklist for Vaccine Administration</strong></td>
<td>This checklist from the Immunization Action Coalition is a self-assessment tool for healthcare professionals who administer vaccines.</td>
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<tr>
<td><strong>CDC Guidance by COVID-19 Vaccine Product</strong></td>
<td>The CDC website provides Clinical Information and Guidance by product.</td>
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<tr>
<td><strong><a href="mailto:No-reply@emailupdates.cdc.gov">No-reply@emailupdates.cdc.gov</a></strong></td>
<td>To receive auto-generated email updates for COVID-19 Lot Number Expiration Date Reporting registration</td>
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<tr>
<td><strong>Moderna Trainings</strong></td>
<td>Moderna Online training Module Moderna EUA Fact Sheet for HCP</td>
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<td><strong>Fact sheet for vaccination providers</strong></td>
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<td><strong>Fact sheet for vaccine recipients and caregivers</strong></td>
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<td><strong>Pfizer Trainings</strong></td>
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<td><strong>Pfizer Online Training Module</strong></td>
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<td><strong>Pfizer EUA Fact Sheet for HCP</strong></td>
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<td><strong>Fact sheet for vaccine recipients and caregivers</strong></td>
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<tr>
<td><strong>Vaccine preparation and administration summary</strong></td>
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<td><strong>Storage and handling summary</strong></td>
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<tr>
<td><strong>Temperature log for ultra-cold freezer units, including online fillable PDF version</strong></td>
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<td><strong>Beyond use date tracker labels for refrigerator storage</strong></td>
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<td><strong>Clinical Materials</strong></td>
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<td><strong>COVID-19 vaccine screening form for contraindications and precautions</strong></td>
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<tr>
<td><strong>Expiration date tracker</strong></td>
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<td><strong>Reporting a temperature excursion</strong></td>
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<tr>
<td><strong>IIS off-line vaccine administration documentation tool</strong></td>
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<tr>
<td><strong>Guide to ancillary supplies kit (for staff helping providers order vaccine)</strong></td>
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<tr>
<td><strong>COVID-19 vaccine frequently asked clinical questions web page</strong></td>
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<tr>
<td><strong>Quick Reference Guide for Healthcare Professionals</strong>: provides basic information on proper storage, preparation, and administration of all three vaccines</td>
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<td><strong>Janssen (J&amp;J) Trainings</strong></td>
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<td><strong>Janssen Online Training</strong></td>
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<tr>
<td><strong>Janssen COVID-19 Webinar: Information for Healthcare Providers</strong></td>
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<tr>
<td><strong>Janssen EUA Fact Sheet for HCP</strong></td>
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<tr>
<td><strong>Janssen EUA Fact Sheet for vaccine recipients and caregivers</strong></td>
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12.0 Orders to Administer COVID-19 Vaccine

- Prior to February 25, 2021 when Dr. Betsey Tilson, State Health Director/Chief Medical Officer received the authority to write a statewide standing order via North Carolina Executive Order 193, standing order templates for COVID-19 vaccines were encouraged. Local health departments could then adopt the state-approved standing order templates for use by their medical director and nursing staff. A statewide Standing Order for Pharmacists was issued December 28th, 2020. Upon Dr. Tilson receiving the authority to write the North Carolina statewide standing order, the previous standing order and templates have not been maintained and should be retired.

- A statewide Standing Order for COVID-19 vaccines was authorized under Executive Order 193 and was effective February 25, 2021 for Pfizer-BioNTech and Moderna vaccines. This standing order was most recently revised August 16, 2021 and authorizes any North Carolina healthcare provider, in accordance with the conditions of their licensure, or pursuant to orders issued under North Carolina Executive Order 193, or as a covered person under the federal PREP Act, functioning as vaccinating providers (collectively “vaccinators”) to administer COVID-19 Vaccines authorized by the FDA through an Emergency Use Authorization (EUA) and per conditions of the order for the Pfizer and Moderna vaccine. (See Appendix 44)

- A separate statewide Standing Order for Johnson & Johnson (Janssen) COVID-19 vaccine was effective March 4, 2021 and latest revision August 16, 2021 at the time of the release of this document. (Appendix 50)

- For most current standing orders, please visit https://covid19.ncdhhs.gov/guidance#vaccination-info-for-providers

13.0 Vaccine Storage and Handling

Providers are required to store vaccine in appropriate storage units (i.e., purpose-built or pharmaceutical-grade units designed to either refrigerate or freeze). Household combination units are acceptable for the refrigerated component only. If frozen vaccine storage is needed, a separate, stand-alone freezer must be used. Dormitory-style or bar-style combined refrigerator/freezer units cannot be used to store vaccine under any circumstances. Temperatures must be continuously monitored using a Digital Data Logger that meets the specifications as noted in the Vaccine Storage and Handling Toolkit. Providers are required to document the minimum and maximum temperature reading each workday. Product specific temperature logs can be obtained from the CDC.

*Temperature excursions must be reported immediately to the respective vaccine manufacturer. Label any vaccine exposed to out of range temperatures as “DO NOT USE”, separate the doses from non-exposed vaccine, but continue to keep the vaccine stored under proper conditions until further guidance is obtained from the vaccine manufacturer on viability. Do not discard the doses prior to receiving manufacturer guidance. Be prepared to document the event. The Immunization Action Coalition’s Vaccine Storage Troubleshooting Record can be utilized to document excursion events.

Stability studies for COVID-19 vaccines have been on-going as each manufacturer seeks to increase flexibility in storage allowances, while also ensuring potency is maintained. Such studies have resulted in evolving storage and handling requirements. The information in this section reflect current recommendations as of the “updated” date noted at the beginning of this provider guidance document. Please ensure staff who are responsible for any duties related to storage
and handling of COVID-19 vaccine have read and understand the most current guidance as noted in each product’s EUA Fact Sheet for Healthcare Providers Administering Vaccine and according to CDC’s Vaccine Storage and Handling Toolkit with the COVID-19 vaccine addendum and CDC’s product specific guidance.

Each product has its own storage and handling requirements. Please read all requirements for the product carefully before removing from packaging.

Ancillary Kits

Ancillary kits will be shipped separately from each vaccine product (see Appendix 6 for more information). The kits contain a 5% overage of supplies from CDC. If vaccine needs to be transported to another enrolled provider location, be sure to pack equal amounts of vaccine administration supplies from the ancillary kits (e.g., diluents (Pfizer only), needles, syringes, vaccination record cards, alcohol prep pads) to ensure the receiving site has sufficient quantities to vaccinate their patients.

Vaccine providers are encouraged to report any issues with equipment in the ancillary kits that are shipped with their federal vaccine orders. There are four steps to reporting to ensure enough information is gathered to ensure problem trends in packaging and shipping can be identified.

- **Report deficiencies to McKesson** the customer service desk is charged with responding to problems and identifying trends.
- **Report deficiencies to the State Department of Health** or clinic/hospital leadership who may then contact the Operation Regional LNO. This helps identify trends in problem equipment.
- **Report adverse events to VAERS.** Adverse events involving vaccines should be reported to the Vaccine Adverse Event Reporting System (VAERS).
- **Mandatory reporting of medical device adverse events.** Because syringes are a medical device, complete FDA form 3500.

Reporting to McKesson: Report all deficiencies with ancillary supplies immediately to McKesson by calling or emailing McKesson Customer Service: Phone- 833-272-6634 or Email- SNSSupport@McKesson.com.

**Reporting deficiencies to the State Department of Health:** Complete a ServiceNow ticket using the “Ancillary Kit Deficiency Reporting” tab. A ServiceNow team member will follow up to ensure all required reporting is complete.

**Reporting to Vaccine Adverse Event Reporting System (VAERS):** Vaccination providers are required to report vaccine administration errors and serious adverse events. The CDC has also requested all deficiencies with ancillary supplies (e.g. syringes) to be reported to VAERS as well. Enter this information into VAERS online at https://vaers.hhs.gov/reportevent.html. For additional information or assistance with filing a VAERS report, call 1-800-822-7967.

**Reporting of Medical Device Adverse Event:** Because syringes are a medical device, complete form 3500. Please refer to the instructions for completing form FDA 3500A. https://www.accessdata.fda.gov/scripts/medwatch/

- Per the FDA guidelines: If the case report involves more than one (1) faulty medical device, please prepare a complete copy of Form FDA 3500 that identifies one device and attach an additional copy of Form FDA 3500, with only Section E filled in, for each additional device.
  - Link to FDA form 3500: https://www.accessdata.fda.gov/scripts/medwatch/
ii. Information on how to file the report: https://www.fda.gov/safety/reporting-serious-problemsfda/how-consumers-can-report-adverse-event-or-serious-problem-fda

Be prepared to provide photos, lot number, order number, date ordered, and dates received when filing a report for a deficient ancillary kit.

13.1 Pfizer

The Pfizer COVID-19 vaccine is shipped from the manufacturer in a thermal shipper as an ultra-cold product (-90°C to -60°C). The vaccine should be stored in the original tray or box in one of the storage unit options listed below and protected from light at all times. The vaccine must be thawed prior to use (either in the refrigerator or at room temperature if needed for immediate use). Unpunctured vials cannot be kept at room temperature for longer than two hours (including thaw time). When mixing the vaccine with diluent, gently invert the vial 10 times. DO NOT shake. If the vial is shaken, contact the manufacturer prior to use. Please see Appendix 9 for an overview of Pfizer vaccine storage and handling. Refer to the S.T.E.P.S document for your guide to proper storage, handling, administration and disposal/wastage of the Pfizer-BioNTech COVID-19 Vaccination.

Storage Unit Options:

- **Ultra-Cold Storage (-80°C to -60°C) (Before mixing):**

  The thermal shipper can be used to store the product if appropriate equipment is not available for up to 30 days with dry ice refills every 5 days, the first of which will arrive the day after vaccine is received. If using the thermal shipping container to store vaccine, replenish the container with dry ice pellets (sized 10 mm to 16 mm) within 24 hours of delivery. Unless you have opted out of receiving dry ice when the order was placed, dry ice will be provided for the **first re-icing**. Close the container using packing tape. If the first dry ice refill will not be needed, please see below figure for CDC information about the Dry Ice Kit Opt Out from Pfizer. The provider is responsible for the remaining dry ice refills after the first one as needed. The Pfizer COVID-19 vaccine can last up to 5 days at refrigerated temperatures. It is recommended that the thermal shipping container not be opened more than 2 times a day and should not be opened for more than 3 minutes at a time.

  An Ultra-Cold Freezer that is able to maintain temperatures between -80°C to -60°C can be used for long-term storage of the Pfizer COVID-19 vaccine (up to the expiration date).

- **Freezer Storage (-25°C to -15°C):**

  Before mixing, vaccine may be stored in a freezer between -25°C and -15°C (-13°F to 5°F) for up to 2 weeks. The total time vials are stored at these temperatures should be tracked and should not exceed 2 weeks. Vials stored in the freezer can be transferred to the refrigerator for an additional 31 days. Once thawed, they cannot be refrozen. Vials stored in the freezer can be returned one time to ultra-cold temperature storage. Once returned, the 2-week time frame is suspended, and vaccines can be stored at ultra-cold temperatures until the expiration date.

- **Refrigerator Storage (2°C to 8°C):**
Before mixing, the vaccine may be stored in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to 1 month (31 days). After 31 days, remove any remaining vials from the refrigerator and discard following manufacturer guidance on proper disposal.

After mixing, the vaccine can be used for up to six hours when held at temperatures between 2°C and 25°C. Any unused vaccine must be discarded after six hours.

Pfizer Update January 2021
In January, the FDA amended the Emergency Use Authorization to reflect that healthcare workers administering the Pfizer-BioNTech vaccine can extract six doses from the vials originally labeled for five doses.

Supplies
Ancillary kits contain supplies necessary to deliver the additional dose. While the number of syringes in each ancillary box will increase to support six doses, this does not necessarily guarantee that every vial will yield six doses. Only low dead-volume syringes and/or needles will consistently ensure extraction of six doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.

As a reminder, irrespective of the type of syringe and needle, each dose must contain 0.3 mL of vaccine. If the amount in the vial cannot provide a full sixth dose of 0.3 mL, the vial and content should be discarded. Excess vaccine should never be pooled from multiple vials to make up a full dose.

Reporting
Changes should not be made to inventory already received or orders placed prior to January 26. Product on hand and product in-transit should still be inventoried as a 5-dose vial. Providers can begin accepting inventory ordered at 6 doses per vial on or after February 16, 2021. Pfizer has prepared a checklist for storage and handling. Please see Appendix 8. This document is also available at https://www.cvdvaccine-us.com. This document is imperative to read prior to handling the product.

FDA May 19, 2021 EUA Updates: Pfizer 450-Dose Configuration
The US Food and Drug Administration amended the Pfizer-BioNTech COVID-19 Emergency Use Authorization(EUA) to include a new Pfizer 450-dose order configuration.

Key facts about the 450-dose pack:
- The new 450-dose pack includes 3 trays of 25 vials each
- Vials will be shipped in the same container as the 1170-dose orders and will include the same Controlant temperature monitor
- The newly extended refrigerator storage temperatures should decrease the need for dry ice
  - Therefore, Pfizer asks the the shippers and Controlant monitors be returned within 10 days
  - There will be no dry ice replenishment for the 450-dose pack
- The minimum order size is 450 doses
- Both the 1170 dose and 450 dose product configurations will be in circulation and available

Ancillary Kits:
- Ancillary kits have been created to support the 450-dose minimum order size
• When placing orders, you should select an order intention of Adult or Pediatric for the Pfizer 450 order. This information will determine which ancillary kit is shipped with the vaccine. This is a change from COVID-19 vaccine ordering since the program first started, for which all vaccines had to be ordered with an Adult order intention
• The Adult ancillary kits contain the same ratio of 1” to 1.5” needles as the 1170 kit
• The Pediatric ancillary kit contains only 1” needles

13.2 Moderna

The Moderna COVID-19 Vaccine multiple-dose vials are stored frozen between -50º to -15ºC (-58º to 5ºF). Store in the original carton to protect from light. Do not store on dry ice or below -50ºC (-58ºF). Use of dry ice may subject vials to temperatures colder than -50ºC (-58ºF). Vials can be stored refrigerated between 2º to 8ºC (36º to 46ºF) for up to 30 days prior to first use. Unpunctured vials may be stored between 8º to 25ºC (46º to 77ºF) for up to 24 hours. Do not refreeze once thawed. After the first dose has been withdrawn, the vial should be held between 2º to 25ºC (36º to 77ºF). Record the date and time of first use on the Moderna COVID-19 Vaccine vial label. Vials should be discarded 12 hours after the first puncture. Thawed vials can be handled in room light conditions.

Dose Preparation
The Moderna COVID-19 Vaccine is currently being supplied in two multiple-dose vial presentations:
• A multiple-dose vial containing a maximum of 11 doses: range 10-11 doses (0.5 mL each).
• A multiple-dose vial containing a maximum of 15 doses: range 13-15 doses (0.5 mL each).
• The Moderna COVID-19 Vaccine multiple-dose vials contain a frozen suspension that does not contain a preservative and must be thawed prior to administration.
• Remove the required number of vial(s) from storage and thaw each vial before use following the instructions below.

<table>
<thead>
<tr>
<th>Vial</th>
<th>Thaw in Refrigerator</th>
<th>Thaw at Room Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Maximum 11-Dose Vial (range: 10-11 doses)</strong></td>
<td>Thaw in refrigerated conditions between 2º to 8ºC for 2 hours and 30 minutes. Let each vial stand at room temperature for 15 minutes before administering.</td>
<td>Alternatively, thaw at room temperature between 15º to 25ºC for 1 hour.</td>
</tr>
<tr>
<td><strong>Maximum 15-Dose Vial (range: 13-15 doses)</strong></td>
<td>Thaw in refrigerated conditions between 2º to 8ºC for 3 hours. Let each vial stand at room temperature for 15 minutes before administering.</td>
<td>Alternatively, thaw at room temperature between 15º to 25ºC for 1 hour and 30 minutes.</td>
</tr>
</tbody>
</table>

Potential tinting with Moderna vaccine vials: With the addition of new vial suppliers, a portion of the vials recently entering distribution may appear thicker and display a slight green tint as a result of the vial sterilization process during manufacturing. This tinting is strictly visual and has no impact on the vaccine. A range of vial colors under various lighting conditions may be encountered in the field and over time, vial tinting may fade naturally, resulting in a faint yellow color. Please continue to inspect each dose of the Moderna COVID-19 Vaccine prior to administration in
accordance with the Administration section of the Fact Sheet for Healthcare Providers for Administering Vaccine – Moderna (See Appendix 12).

### 13.3 Johnson & Johnson / Janssen

Janssen vaccine is the first of the COVID-19 vaccines that do not require freezing for storage and transportation. Janssen vials will arrive refrigerated and can be stored at 2°C – 8°C until the expiration date. Each vial provides for 5 doses. The Johnson & Johnson/Janssen vaccine is shipped in quantities of 100 doses.

**Storage Prior to First Puncture of the Vaccine Vial**
- Store unpunctured multi-dose vials of the Janssen COVID-19 Vaccine at 2°C to 8°C (36°F to 46°F) and protect from light. Do not store frozen.
- Unpunctured vials of Janssen COVID-19 Vaccine may be stored between 9°C to 25°C (47°F to 77°F) for up to 12 hours.
- The Janssen COVID-19 Vaccine is initially stored frozen by the manufacturer, then shipped at 2°C to 8°C (36°F to 46°F). If vaccine is still frozen upon receipt, thaw at 2°C to 8°C (36°F to 46°F). If needed immediately, thaw at room temperature (maximally 25°C/77°F). At room temperature (maximally 25°C/77°F), a carton of 10 vials will take approximately 2 hours to thaw, and an individual vial will take approximately 1 hour to thaw. Do not refreeze once thawed.

**Storage After First Puncture of the Vaccine Vial**
- After the first dose has been withdrawn, hold the vial between 2°C to 8°C (36°F to 46°F) for up to 6 hours or at room temperature (maximally 25°C/77°F) for up to 2 hours. Discard the vial if vaccine is not used within these times.

(See Section 13.4 on the next page)
13.4 Transport Guidance

In order to reduce vaccine wastage and meet vaccine needs across the state, COVID-19 vaccine may be transported between two providers enrolled in the CDC COVID-19 Vaccination Program using the guidance below.

**Items required for transporting COVID-19 vaccine:**

1) **Portable vaccine refrigerator and/or freezer**
   - If a portable vaccine unit is not available, thermal shippers (Pfizer only), and qualified containers and packouts may be used. Information regarding qualified containers and packouts may be found in the CDC Storage and Handling Toolkit linked below.
   - Manufacturer-supplied packaging may also be used in accordance with the directions in the manufacturer's labeling.

2) **Digital Data Logger (DDL) Thermometer**
   - Must be placed with the vaccine in the transport container.

3) **Sufficient coolant (phase change materials or conditioned water bottles) and insulating materials (bubble wrap and corrugated cardboard)**
   - If using a qualified packout with a hard-sided insulated container or Styrofoam™ cooler, ensure the coolant/phase change material being used is appropriate for the desired storage conditions (i.e. frozen or refrigerated). When transporting under refrigerated conditions, conditioned water bottles can be used as an alternative as noted in CDC's Emergency Transport Guidance document. Ensure the packout can maintain the appropriate temperature prior to placing vaccines inside for transport.

4) **Adequate ancillary supplies for preparation and administration**
   - Include all ancillary supplies (and diluent, if applicable) to correspond with the number of doses being transported.

**Temperature Monitoring**

Using the required DDL, the **time** and **temperature (min/max)** should be recorded at each of the below times during the transport:

- **Start of transport**
- **Upon opening the storage container**
- **When transport is completed**

**Important Reminders:**
- The total time for transport should be minimized to reduce potential risk for a temperature excursion.
- Vaccine vials may be transported more than once.
- When transport is complete, vaccine should **immediately** be placed in an appropriate storage unit.
- CDC recommends transporting vaccine in vials. However, there may be instances when the only option is to transport pre-drawn vaccine in a syringe. The USP COVID-19 Vaccine Toolkit: Operational Considerations for Healthcare Practitioners includes guidance for transporting pre-drawn vaccine in syringes.
- It is not recommended to transfer pre-drawn syringes or punctured vials outside of your provider organization.
- When transporting mRNA vaccines (Pfizer-BioNTech and Moderna), please follow these best practices:
- Protect vaccines as much as possible from drops, shocks, and vibration.
- To minimize movement, transport vials in the carton whenever possible.
- If individual vials must be transported:
  - Place vials with padding material like bubble wrap or similar materials to prevent breaking.
  - Secure storage containers during transport.
  - Keep vaccine vials upright whenever possible.

**Additional Resources:**
- CDC Storage and Handling Toolkit
- CDC Refrigerator Transport Temperature Log
- USP COVID-19 Vaccine Handling Toolkit
- CDC Emergency Transport Guidance
- Pfizer-BioNTech COVID-19 Vaccine: Transporting Vaccine
- Moderna COVID-19 Vaccine: Transporting Vaccine
- Johnson & Johnson (Janssen) COVID-19 Vaccine: Transporting Vaccine

**Pfizer-BioNTech COVID-19 Vaccine**

**Vaccine Temperature Ranges:**
- Ultra-cold (ULC): -80°C to -60°C (-112°F to -76°F)
- Frozen: -25°C to -15°C (-13°F to 5°F) for up to 2 weeks
- Refrigerated: 2°C to 8°C (36°F to 46°F) for up to one month (31 days)

**Vaccine Storage Unit(s):**
- Ultra-cold freezer until the expiration date
- Thermal shipping container (for up to 30 days, following manufacturer's guidance and dry ice recharges)
- Freezer (for up to two weeks)
- Refrigerator (for up to 31 days)

**Vaccine Transport:**

- **Ultra-cold transport** (-80°C to -60°C; -112°F to -76°F): Only full trays of vaccine may be transported at ultra-cold temperatures.
  - ULC vaccine may be transported using the thermal shipping containers with dry ice or in a portable ultra-cold freezer.
- **Frozen transport** (-25°C to -15°C; -13°F to 5°F): If local redistribution is needed and full cartons containing vials cannot be transported at ULC temperatures, vials may be transported at -25°C to -15°C (-13°F to 5°F).
  - Any hours used for storage or transport at -25°C to -15°C count against the 2-week limit for storage at -25°C to -15°C.
  - **Frozen vials transported** at -25°C to -15°C may be returned one time to the recommended storage condition of -80°C to -60°C (-112°F to -76°F).
- **Refrigerated transport** (2°C to 8°C; 36°F to 46°F): Individual vials or partially filled trays must be transported at refrigerated temperatures.
  - Once vaccine vials are removed from the tray, the thawing process has begun, and the vaccines require refrigerated transport. Once vials have been thawed, they cannot be refrozen.
  - Unpunctured vials can be transported for up to 12 hours.
  - Punctured vials can be transported at refrigerated temperatures. Once punctured, the refrigerated vials must be used within 6 hours. Transport time counts as part of the 6-hour time limit.
  - Vaccines may be stored at refrigerated temperatures for up to 31 days.
    - Any time used for transport counts against the 31-day limit.
Modern COVID-19 Vaccine

<table>
<thead>
<tr>
<th>Vaccine Temperature Ranges:</th>
<th>Vaccine Storage Unit(s):</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Frozen: -50°C to -15°C (-58°F to 5°F)</td>
<td></td>
</tr>
<tr>
<td>• Refrigerated: 2°C to 8°C (36°F to 46°F) for up to 30 days</td>
<td>• Freezer until the expiration date</td>
</tr>
<tr>
<td>• Refrigerator (for up to 30 days)</td>
<td></td>
</tr>
</tbody>
</table>

**Vaccine Transport:**

**Frozen transport** (-50°C to -15°C; -58°F to 5°F): *Preferred method of transport.*
- Only unpunctured vials may be transported frozen.
- Do not freeze thawed vaccine.

**Refrigerated transport** (2°C to 8°C; 36°F to 46°F):
- Vaccines that will be transported in a refrigerated state should begin transport in a frozen state if possible.
- Take care to ensure vaccine does not refreeze during transport.
- **Unpunctured** vials may be transported for up to 12 hours. This time is cumulative, including the amount of time to and from clinics. Transport time is also included in the 30-day time frame.
- **Punctured** vials can be transported at refrigerated temperatures. Once punctured, the vials must be refrigerated and used within 12 hours. Time used for transport counts as part of the 12-hour time limit.

Johnson & Johnson (Janssen) COVID-19 Vaccine

<table>
<thead>
<tr>
<th>Vaccine Temperature Ranges:</th>
<th>Vaccine Storage Unit(s):</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Refrigerated: 2°C to 8°C (36°F to 46°F)</td>
<td>• Refrigerator until the expiration date</td>
</tr>
</tbody>
</table>

**Vaccine Transport:**

**Refrigerated transport** (2°C to 8°C; 36°F to 46°F):
- Take care to ensure vaccine does not freeze during transport.
- CDC recommends the total time for transport alone or transport plus clinic workday should be a maximum of 8 hours.
- **Punctured** vials can be transported at refrigerated temperatures. Once punctured, the refrigerated vials must be used within 6 hours. Transport time counts as part of the 6-hour time limit.
13.5 Expiration of Vaccine

Over the next two months, several lots of Pfizer, Moderna, and Johnson & Johnson (Janssen) vaccines are set to expire. It is recommended to check for expiration dates at least weekly for each COVID-19 vaccine in the following ways:

- **For Pfizer COVID-19 vaccine**, the vaccine product has an expiration date located on the vaccine vial.
  - On August 23, 2021, the FDA amended the Pfizer-BioNTech Fact Sheet for Health Care Providers with the following information, “cartons and vials of Pfizer-BioNTech COVID-19 Vaccine with an expiry date of August 2021 through February 2022 printed on the label may remain in use for 3 months beyond the printed date as long as approved storage conditions between -90°C to -60°C (-130°F to -76°F) have been maintained.” Please see page 3 of the Fact Sheet for Health Care Providers for Updated Expiry Dates at: [https://www.fda.gov/media/144413/download](https://www.fda.gov/media/144413/download) (Appendix 2)
  - With this change in motion, location managers are responsible for monitoring inventory records in the CVMS Provider Portal. Please update the expiration dates for your on-hand Pfizer COVID-19 doses currently in ultra-cold freezing storage in CVMS. Please reference the COVID-19 Vaccine Expiration Date Job Aid (See Appendix 59 for a Listing of Job Aids) for steps on how to change expiration dates in CVMS. Since CVMS does not show a particular vaccines storage conditions and beyond use date, NCDHHS will not be able to update expiration dates on the backend since it only applies to vaccines stored at ultra-cold temperatures. Continue to follow the beyond-use date guidance for doses being stored at frozen (-25°C to -15°C) or refrigerated (2°C to 8°C) temperatures.

- **To check Moderna COVID-19 vaccine expiration**, providers can scan the QR code located on the vial or carton or access the manufacturer’s website directly, enter the lot number and the expiration date will be displayed.

- **For Johnson & Johnson COVID-19 vaccine**, the expiration date can be obtained by entering the lot number from the carton or vial using the website [www.vaxcheck.jnj](http://www.vaxcheck.jnj) or by phone using an automated response system at 1-800-565-4008.
  - NC DHHS has updated expiration dates of the Janssen COVID-19 vaccine for provider locations. All dates have been updated based on information provided to the State via the CDC.
  - Location Managers are responsible for monitoring inventory records in the CVMS Provider Portal and should double check all updated expiration dates. If a Location Manager finds an incorrect expiration date, they should manually edit the vaccine inventory.

With vaccine inventory on provider shelves, it is critical that providers have controls and processes in place to monitor the expiration dates of on-hand inventory and pull lots that have the earliest expiration dates for administering doses first. Best practice strategies for management of vaccine include:

- Designate a Point of Contact (POC)s responsible for managing inventory
- Providers should view inventory data in CVMS to identify expiration dates of lots in inventory. Sort data by expiration date to identify lots with earliest expiration date(s).
• Inventory Point of Contact (POC) and/or POC responsible for pulling and thawing doses in preparation for upcoming appointments should coordinate the lots that need to be prioritized based on earliest expiration date.

• Rotate vaccine stock and check for expired doses expiration weekly as well as whenever a shipment is received. Follow a “first in, first out” strategy to manage inventory.

• Conduct weekly analysis of available inventory and expiration date compared with forecasted demand (appointments plus estimated walk-ins) to assess whether vaccines can be used before reaching expiration date(s)

• If analysis indicates that doses expiring within 30-60 days cannot be used, reach out to enrolled providers in your local area or utilize the Vaccine Marketplace in CVMS to coordinate a transfer. Escalate to NC DHHS if the number of doses forecasted to expire exceeds 1000 doses.

• If nearing expiration, check posted manufacturer information for the most up to date expiration/extension information for vaccine lots.

• Arrange stock so doses with earliest expiration dates are physically in front of those with later expiration dates or use visible marking for easy identification

• Based on the latest expiration information, REMOVE expired vaccine from the storage unit IMMEDIATELY. Do not give staff opportunity to administer expired vaccine.
  
  • If expired vaccine is inadvertently administered, it is considered a vaccine administration error and requires remediation including a VAERS report, contacting the recipient to inform them of the error, and may or may not require revaccination based on the manufacturers’ guidance. Guidance on vaccine administration errors can be found in Appendix A of the CDC document (which was not updated at the time of this release to include information about the FDA approved Pfizer-BioNTech COVID vaccine) Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States.

• Log expired vaccine under wastage in CVMS. Use these user guide instructions (also see Appendix 59) to help you accurately log doses in CVMS. There are no negative consequences for reporting waste and it will not negatively affect future allocations. This helps NCDHHS and CDC accurately monitor the amount of vaccine in the field. CDC recognizes that unused expired vaccine is a normal part of any vaccination program, especially one of this scope and size.

13.6 Unused Doses, Wastage, and Disposal of Vaccine and Related Materials

As access to COVID-19 vaccine increases, it is important for providers to not miss any opportunity to vaccinate every eligible person who presents at vaccine clinics. We recognize that as we continue to create more opportunities to vaccinate more people, it may increase the likelihood of leaving unused doses in a vial. While we want to continue to follow best practices to use every dose possible, we do not want that to be at the expense of missing an opportunity to vaccinate every eligible person when they are ready to get vaccinated.

• Vaccine wastage is increasing as the vaccine rollout continues because:
  
  • more providers, including smaller provider sites, are now receiving vaccine,
  • vial sizes for some vaccines have increased,
  • vaccine vials may be opened without every dose being used

• To ensure providers do not miss an opportunity to vaccinate every eligible person, CDC recommends:
o Providers follow clinical best practice for vaccination as well as best practices when managing inventory to maximize vaccination and minimize dose wastage.
o Providers should not miss any opportunities to vaccinate every eligible person who presents at a vaccination site, even if it means puncturing a multidose vial to administer vaccine without having enough people available to receive each dose.
o Consider establishing and promoting standing vaccination days or half-days to increase likelihood of larger numbers of people presenting for vaccination on the same day.
o Vaccinate family members or friends who accompany patients to medical visits even if they are not established patients at the vaccinating practice.
o Continue outreach to employers or other community partners that have a large membership or network to arrange vaccination events.
o As contingency plan, vaccine providers should attempt to contact additional persons (i.e., from a waitlist or through personal contacts of persons being vaccinated) to use as many vaccine doses as possible.
o Please see Section 16.9 for more strategies about walk-in clinics.

- Dispose of any expired vaccine vials and packaging following your agency’s policies.
o Empty vaccine vials are usually not considered hazardous or pharmaceutical waste and do not require disposal in a biomedical waste container, however, to reduce the risk of fake or counterfeit COVID-19 vaccines, the CDC recommends providers “dispose of vials and packaging as medical waste by placing vials in a sharps container and packaging in a red medical waste bag. If medical waste containers are in short supply, deface or safely crush packaging materials so they cannot be reintroduced or reproduced. After the products are sufficiently defaced or destroyed, dispose with regular waste”.
o There are currently no vaccine return programs. Do NOT return vaccine in the thermal shipping container.
o Do not dispose of the ancillary kit supplies received to administer the vaccine(s) that has since expired.
o Please also refer to the CDC document about the Identification, Disposal, and Reporting of COVID-19 Vaccine Wastage here.

13.7 Satellite, Temporary, and Off-Site Clinics Guidance

Satellite, temporary, or off-site clinics in collaboration with community or mobile vaccinators may assist jurisdictions in providing equitable access for COVID-19 vaccination. However, these situations require additional oversight and enhanced storage and handling practices, including:

- Before making any vaccine movements / transports, please refer to the product-specific transport guidelines and limitations from the manufacturer. See Section 13.4 for more information on vaccine transport.

- The quantity of COVID-19 vaccines transported to a satellite, temporary, or off-site clinic should be based on the anticipated number of COVID-19 vaccine recipients and the ability of the vaccination provider to store, handle, and transport the vaccine appropriately in order to minimize vaccine wastage and spoilage.

- COVID-19 vaccines may be transported—not shipped—to a satellite, temporary, or off-site COVID-19 vaccination clinic using vaccine transportation procedures outlined in the COVID-19 addendum to CDC’s Vaccine Storage and Handling Toolkit.
Upon arrival at the COVID-19 vaccination clinic site, vaccines must be stored correctly to maintain appropriate temperature throughout the clinic day.

Temperature data must be reviewed and documented according to guidance in the COVID-19 addendum to CDC’s Vaccine Storage and Handling Toolkit.

As with all vaccines, if COVID-19 vaccines are exposed to temperature excursions at any time, the temperature excursion is required to be documented and reported immediately to the vaccine manufacturer for further guidance. Exposed vaccines must be labeled “do not use” and stored at the required temperature range until further information on usability can be obtained by the manufacturer. Providers must document all actions taken.

Temperature records, including daily temperature logs and information for each temperature excursion event must be kept for a minimum of three years.

### 13.8 Online Resources: Storage and Handling

<table>
<thead>
<tr>
<th>Training Program / Reference Material</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pfizer COVID-19 Resources for HCP</strong></td>
<td>This Pfizer vaccine website is intended for healthcare professionals. Resources include training videos, administration guidance, and storage and handling resources.</td>
</tr>
<tr>
<td><strong>Moderna COVID-19 Resources for HCP</strong></td>
<td>This Moderna vaccine website is intended for healthcare professionals. Resources include training videos, administration guidance, and storage and handling resources.</td>
</tr>
<tr>
<td><strong>Moderna COVID-19 Training</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Janssen (J&amp;J) COVID-19 Resources for HCP</strong></td>
<td>This Janssen vaccine website is intended for healthcare professionals. This will be updated as additional resources are available.</td>
</tr>
<tr>
<td><strong>CDC COVID-19 Information by Product</strong></td>
<td>The CDC website has detailed storage and handling documentation for each available product.</td>
</tr>
<tr>
<td><strong>COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare Providers</strong></td>
<td>A web-based training course outlining best practices and principles for healthcare providers when preparing to administer COVID-19 vaccine. It is a high-level overview of the following topics with links to detailed information: vaccine development and safety, safety monitoring programs, Emergency Use Authorizations (EUAs), vaccine storage/handling, preparation, administration, PPE, scheduling, documentation, and reporting adverse events. Information on each vaccine product will be added as each is approved and authorized by FDA.</td>
</tr>
<tr>
<td>Resource</td>
<td>Description</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>You Call the Shots: Vaccine Storage and Handling</strong></td>
<td>An interactive, web-based immunization training course on storage and handling best practices and principles.</td>
</tr>
<tr>
<td><strong>“Keys to Storing and Handling Your Vaccine Supply” video</strong></td>
<td>This video is designed to decrease vaccine storage and handling errors by demonstrating recommended best practices and addressing frequently asked questions.</td>
</tr>
<tr>
<td><strong>Vaccine Storage and Handling Toolkit</strong></td>
<td>Comprehensive guide that reflects best practices for vaccine storage and handling from Advisory Committee on Immunization Practices (ACIP) recommendations, product information from vaccine manufacturers, and scientific studies.</td>
</tr>
<tr>
<td><strong>Vaccine Storage and Handling Toolkit, COVID-19 Vaccine Addendum</strong></td>
<td>The Vaccine Storage and Handling Toolkit, COVID-19 Vaccine Addendum, provides information, recommendations, and resources on storage and handling best practices to help safeguard the COVID-19 vaccine supply and ensure patients receive safe and effective vaccines.</td>
</tr>
<tr>
<td><strong>Epidemiology and Prevention of Vaccine-Preventable Diseases</strong></td>
<td>Comprehensive information on routinely used vaccines and the diseases they prevent. Chapter 5 is dedicated to vaccine storage and handling (updated 2020).</td>
</tr>
<tr>
<td><strong>Pfizer Storage and Handling Label</strong></td>
<td><strong>Pfizer-BioNTech COVID-19 Beyond Use Date/Time (BUD) Tracking Label (cdc.gov)</strong></td>
</tr>
<tr>
<td><strong>Moderna Storage and Handling Label</strong></td>
<td><strong>Moderna COVID-19 Vaccine Storage and Handling Label (cdc.gov)</strong></td>
</tr>
<tr>
<td><strong>J&amp;J/Janssen Storage and Handling Label</strong></td>
<td><strong>Janssen COVID-19 Vaccine Storage and Handling Label (cdc.gov)</strong></td>
</tr>
<tr>
<td><strong>COVID-19 Vaccine Transport Guidance</strong></td>
<td>In order to reduce vaccine wastage and meet vaccine needs across the state, COVID-19 may be transported between two providers enrolled in the CDC COVID-19 Vaccination Program using this guidance.</td>
</tr>
</tbody>
</table>

# 14.0 Administration of Vaccine

## 14.1 Dosing
14.1.1 Pfizer-BioNTech COVID-19 Vaccine
Pfizer-BioNTech COVID-19 vaccine is approved for 0.3mL in a 2-dose series administered intramuscularly 21 days apart. 

**Pfizer-BioNTech COVID-19 vaccine (marketed as COMIRNATY) now has full approval by the FDA for use in individuals 16 years and above and Emergency Use Authorization by the FDA for use in individuals 12-15 years of age.**

14.1.2 Moderna COVID-19 Vaccine
Moderna COVID-19 vaccine is approved for 0.5mL in a 2-dose series administered intramuscularly 28 days apart. The Moderna COVID-19 vaccine is authorized for use in individuals **18 years of age and older**.

14.1.3 Johnson & Johnson/ Janssen COVID-19 Vaccine
Janssen COVID-19 vaccine is approved for 0.5ml in a **single dose** administered intramuscularly. The Janssen COVID-19 vaccine is authorized for use in individuals **18 years of age and older**.

**Reminder:** Never combine or “pool” vaccine from multiple vials. Although no one wants to waste vaccine, it is crucial for infection control and patient safety to administer vaccine properly. Combining vaccine from multiple vials can result in cross-contamination, potentially causing serious bacterial infection in patients. CDC recommends the following practices:

- Never combine or “pool” partial doses from two or more vials to obtain a full dose of vaccine.
- Withdraw only the number of doses authorized for the specific vaccine.
- Discard vaccine vial and remaining vaccine if the amount of vaccine left in the vial is not a full dose.

**Vaccine Dosage Reminder:**

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Dose/vial</th>
<th>Volume</th>
<th>Ancillary Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer</td>
<td>6</td>
<td>0.3 mL</td>
<td>6 doses/vial</td>
</tr>
<tr>
<td>Moderna</td>
<td>11</td>
<td>0.5 mL</td>
<td>10-11 doses/vial</td>
</tr>
<tr>
<td>Moderna</td>
<td>15</td>
<td>0.5 mL</td>
<td>13-15 doses/vial</td>
</tr>
<tr>
<td>J&amp;J</td>
<td>5</td>
<td>0.5 mL</td>
<td>5 doses/vial</td>
</tr>
</tbody>
</table>

Rules

- Administer only full doses
- Never try to pool vials to make a full dose
- Do not refreeze any COVID vaccines

CDC recommends healthcare providers follow the dosing guidance from the manufacturer and outlined in the EUA. CDC will update its guidance if the EUA and ancillary supply kits support additional doses per vial in the future.

**Vaccine Administration: Needle Gauge and Length**
Vaccines must reach the desired tissue to provide an optimal immune response and reduce the likelihood of injection-site reactions. Needle selection should be based on the route, age, gender and weight for adults (19 years and older) and injection site. You call the shots vaccine administration: Needle Gauge and Length outlines recommended needle gauges and lengths. In addition, clinical judgment should be used when selecting needles to administer injectable vaccines.
14.2 Intervals between the first and second doses of Pfizer-BioNTech COVID-19 and Moderna COVID-19 vaccines

- Patients should not be scheduled to receive the second dose earlier than recommended (i.e., 21 days [Pfizer-BioNTech] or 28 days [Moderna]). However, second doses administered within a grace period of 4 days earlier than the recommended date for the second dose are still considered valid. Doses inadvertently administered earlier than the grace period should not be repeated.
- The second dose for either vaccine should be administered as close to the recommended interval as possible. However, if it is not feasible to adhere to the recommended interval, the second dose of Pfizer-BioNTech and Moderna COVID-19 vaccines may be scheduled for administration up to 6 weeks (42 days) after the first dose. There are currently limited data on efficacy of mRNA COVID-19 vaccines administered beyond this window. If the second dose is administered beyond these intervals, there is no need to restart the series.

14.3 Recommendations on interchangeability of vaccine two dose products

- mRNA COVID-19 vaccines (Pfizer-BioNTech and Moderna) are not interchangeable. These are suggested strategies to help ensure patients receive the second dose with the appropriate product and interval between doses including:
  - Providing COVID-19 vaccination record cards to vaccine recipients, asking recipients to bring their card to their appointment for the second dose, and encouraging recipients to make a backup copy (e.g., by taking a picture of the card on their phone).
  - Encouraging vaccine recipients to enroll in VaxText, a free text message-based platform to receive COVID-19 vaccination second-dose reminders.
  - Recording each recipient’s vaccination in the immunization information system (IIS) (e.g. CVMS).
  - Recording vaccine administration information in the patient’s medical record.
  - Making an appointment for the second dose before the vaccine recipient leaves, to increase the likelihood that patients will return to the same vaccination site for the second dose.
- Using the above strategies, every effort should be made to determine which vaccine product was received as the first dose in order to ensure completion of the vaccine series with the same product.
- In exceptional situations in which the first-dose vaccine product cannot be determined or is no longer available, any available mRNA COVID-19 vaccine may be administered at a minimal interval of 28 days between doses to complete the mRNA COVID-19 vaccination series. If two doses of different mRNA COVID-19 vaccine products are administered in these situations (or inadvertently), no additional doses of either product are recommended at this time.
- The safety and efficacy of Janssen COVID-19 vaccine administered after an mRNA COVID-19 vaccine has not been established. However, in limited, exceptional situations where a patient received the first dose of an mRNA COVID-19 vaccine but is unable to complete the series with either the same or different mRNA COVID-19 vaccine (e.g., due to contraindication), a single dose of Janssen COVID-19 vaccine may be considered at a minimum interval of 28 days from the mRNA COVID-19 vaccine dose.
14.4 Second COVID-19 Vaccination Doses for Pfizer-BioNTech and Moderna COVID-19 Vaccines

14.4.1 Scheduling Second Dose Appointments and Managing Second Dose Inventory
With abundant supply, NCDHHS moved to a ‘dose is a dose’ philosophy to allow more flexibility for providers to request doses and manage inventory as needed with no first or second dose differentiation in allocation.

Second Dose Scheduling Suggested Practices

- Schedule second dose appointments at the same time that you schedule first-dose appointments, or schedule second dose appointments when the recipient completes their first dose appointment.
- Create a priority phone number for second-dose scheduling or appointment changes to reduce confusion and increase likelihood of vaccine series completion.
- Consider how you will handle second-doses when planning one-time events or via mobile vaccine sites. This could be by repeating the event or returning to the community in 3 or 4 weeks.
- Use auto-dialers, text messages, email, staff outreach, or other means to remind individuals of appointments.

14.4.2 Providing second doses to individuals who received first doses elsewhere
In some instances, individuals may have received a first dose from a different provider (e.g., out of state, previously long-term care resident, etc.). Previously, individuals were encouraged to return to the provider or location where they received their first dose. With increased supply and the ability for providers to request second doses, providers are encouraged to offer second doses to any individual requesting vaccination, even if that person did not receive the first dose at that site.

For Long Term Care residents and staff that received first doses from Walgreens or CVS through the Federal Long Term Care Pharmacy program and are not able to get a second dose, a list of Long Term Care Pharmacies is available to provide second doses. Long Term Care facilities needing second dose supports should contact their long term care pharmacy partners, or can contact Patrick Brown at patrick.brown@dhhs.nc.gov to receive the full list.

14.5 Coadministration With Other Vaccines

COVID-19 vaccines were previously recommended to be administered alone, with a minimum interval of 14 days before or after administration of any other vaccines. This was out of an abundance of caution and not due to any known safety or immunogenicity concerns. However, substantial data have now been collected regarding the safety of COVID-19 vaccines currently approved by FDA or authorized by FDA for use under EUA. Although data are not available for COVID-19 vaccines administered simultaneously with other vaccines, extensive experience with non-COVID-19 vaccines has demonstrated that immunogenicity and adverse event profiles are generally similar when vaccines are administered simultaneously as when they are administered alone.
COVID-19 vaccines and other vaccines may be administered without regard to timing. This includes simultaneous administration of COVID-19 vaccines and other vaccines on the same day, as well as coadministration within 14 days. It is unknown whether reactogenicity of COVID-19 vaccine is increased with coadministration, including with other vaccines known to be more reactogenic, such as adjuvanted vaccines or live vaccines. When deciding whether to coadminister another vaccine(s) with COVID-19 vaccines, providers should consider whether the patient is behind or at risk of becoming behind on recommended vaccines, their risk of vaccine-preventable disease (e.g., during an outbreak or occupational exposures), and the reactogenicity profile of the vaccines.

If multiple vaccines are administered at a single visit, administer each injection in a different injection site. For adolescents and adults, the deltoid muscle can be used for more than one intramuscular injection.

Best practices for multiple injections include:

- Label each syringe with the name and the dosage (amount) of the vaccine, lot number, the initials of the preparer, and the exact beyond-use time, if applicable.
- Separate injection sites by 1 inch or more, if possible.
- Administer the COVID-19 vaccines and vaccines that may be more likely to cause a local reaction (e.g., tetanus-toxoid-containing and adjuvanted vaccines) in different limbs, if possible.

For the most updated CDC information on coadministration go to: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Coadministration

14.6 Additional Vaccine Administration Considerations for COVID-19 Vaccines

- Vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection
- Viral testing for current infection, or serologic testing for prior infection, is NOT recommended for vaccine decision-making purposes.
- Vaccination should be deferred until recovery from acute illness (if person had symptoms) AND criteria have been met to discontinue isolation.
- For persons with a known SARS-CoV-2 exposure in the community, defer vaccination until quarantine period has ended to avoid exposing health care personnel or other persons during vaccination visit. For residents of congregate health care settings (e.g. long-term care facilities) or other congregate settings (e.g., correctional facilities, homeless shelters), person may be vaccinated.
- There is no minimum interval between infection and vaccination. However, current evidence suggests reinfection is uncommon in the months after initial infection, and thus while vaccine supply remains limited, persons with recent documented infection may choose to temporarily delay vaccination. However, the risk of reinfection, and therefore the need for vaccination, may increase with time following initial infection.
- COVID-19 vaccines should not be delayed because of testing for TB infection. Testing for TB infection with one of the immune-based methods, either the tuberculin skin test (TST) or an interferon release assay (IGRA) can be done before or during the same encounter as COVID-19 vaccination. When testing with TST or IGRA cannot be done at the same time as COVID-19 vaccination, these tests should be delayed ≥4 weeks after the completion of COVID-19 vaccination but generally should not be cancelled. See Laboratory Testing section under Interim
Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States from the CDC at: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#laboratory-testing

**Vaccinated People Who Subsequently Develop COVID-19**

For people who have received one or more doses of COVID-19 vaccine and subsequently experience COVID-19, prior receipt of a COVID-19 vaccine should not affect treatment decisions (including use of monoclonal antibodies, convalescent plasma, antiviral treatment, or corticosteroid administration) or timing of such treatments. If a person who has SARS-CoV-2 RNA or antigen detected on a respiratory specimen collected ≥14 days after they complete all recommended doses of an FDA-approved or authorized COVID-19 vaccine (defined as a COVID-19 vaccine breakthrough case), CDC encourages local health departments, healthcare professionals, and clinical laboratories to:

- Request the respiratory specimen be held for further testing
- Report the case to the state health department where the individual resides for further investigation and reporting to the national system
- COVID-19 vaccine breakthrough cases that result in hospitalization or death should be reported to VAERS

**15.0 Vaccine Transfer Guidance**

- NCDHHS recognizes that redistribution or transfer of vaccine may be necessary in some instances.
  - **Redistribution** is the planned and scheduled movement of inventory between two enrolled sites within the same organization with an approved redistribution agreement.
  - **Transfer** is the unplanned and unscheduled movement of inventory between two enrolled sites (move inventory between those who have vaccine to the those who do not)

**Vaccine Inventory, Diluent Vials, and Process Update Related to Transfer Requests**

- If you need additional vaccine at your provider location, we encourage you to facilitate transfers on your own. We currently have an ample supply of vaccine doses within North Carolina and our goal is to move as many of these unused and on-hand doses within the State. **Best practice is to locate the closest provider in the Vaccine Marketplace with excess available vaccine inventory that may be used for your patient population. Next, contact that provider via email or phone to coordinate a transfer.** Please visit the Vaccine Marketplace in CVMS to find local providers with excess on-hand inventory. **See Section 7.8 for additional information on the Vaccine Marketplace.** If you are unable to identify a transfer, please utilize the always-open Allocation Request Form to request vaccine doses (inclusive of first and second doses), **NC DHHS Vaccination Allocation Request Form.** Please note that allocation requests to the State will likely be fulfilled via transfer to ensure our on-hand vaccine supply is utilized.
- All requests to the State will be confirmed via direct phone call to identify the best course of action. Following that conversation, providers will be notified of their final allocation and the necessary details. Given the new process, final allocation confirmations may be delayed as we solution the best course of action to fulfill requests. We appreciate your patience and understanding.
When transporting vaccine between providers, proper storage and handling must be maintained to ensure potency is not compromised. See Section 13.0 for information on safe transport of COVID-19 vaccine for each available product.

- Please be sure to include the diluent vials supplied with your order when redistributing or transporting Pfizer COVID-19 vaccine. Diluent is critical to the administration of Pfizer vaccine and must be included to ensure proper administration.

- If the diluent vials have been lost, misplaced, or are no longer useable, CDC recommends the following actions:
  - Determine how the diluent was lost and develop strategies to prevent this from happening again. Replacing diluent must be done at the expense of the provider or jurisdiction. Replacement diluent increases the risk of vaccine administration errors and may impact the safety of the vaccine if managed incorrectly.
  - All COVID-19 vaccines are preservative free. When replacing diluent for Pfizer vaccine, only 0.9% preservative-free sodium chloride can be used. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent as they contain preservatives. This information is included in the manufacturer’s fact sheet for healthcare providers.
  - Diluent vials can only be used once and cannot be repeatedly punctured for multiple vials. Once diluent has been withdrawn from a vial it MUST be discarded, even if excessive saline is still available in the vial. Do not be tempted to re-puncture a diluent vial and withdraw additional diluent, even if mixing multiple vials for a mass vaccination clinic. Use only 1 vial of diluent with 1 vial of Pfizer vaccine. Failure to follow this practice may impact the safety of the vaccine. Additional information may be found at: Questions about Single-dose/Single-use Vials | Injection Safety | CDC
  - A full list of approved Pfizer distributors can be found at: Pfizer Distributors | pfizeruscom

- Vaccine-specific storage and handling guidance must be followed. All transfers must be documented and approved in CVMS. CVMS inventory will be adjusted appropriately following transfers.

- Transfer requests require NCDHHS IMMUNIZATION BRANCH APPROVAL to ensure proper storage capabilities and tracking of COVID-19 Vaccine Inventory movements. There are three scenarios that transfer requests will fall under.
  - If a provider requests a redistribution between two CVMS Provider locations within the same organization, who have an existing redistribution agreement, THE TRANSFER IS AUTOMATICALLY APPROVED BY NCDHHS IMMUNIZATION BRANCH
  - If a provider requests a redistribution between two locations within the same organization, but there is no existing redistribution agreement, the TRANSFER MUST BE MANUALLY APPROVED BY NCDHHS IMMUNIZATION BRANCH
  - If a provider requests a transfer to a location that is outside their location’s organization, the TRANSFER MUST BE MANUALLY APPROVED BY NCDHHS IMMUNIZATION BRANCH

- Please see pages 74-94 in the Step 6 – Receive and Manage Vaccine Inventories Job Aid for an overview of the transfer process for COVID-19 vaccines. There are also specific notification processes that must be followed by health centers that transfer HRSA-allocated vaccine doses to other health centers or external partners. Any interested health centers should reach out to Health Center Program Support or call 877-464-4772, option 2, 7:00 a.m. to 8:00 p.m. ET, Monday-Friday (except federal holidays).
16.0 Planning and Running Vaccination Clinics and Events

In order to vaccinate increasing numbers of people, enrolled vaccinating providers should set up vaccination clinics and events. Experience from planning testing events across the state has shown that pre-planning and publicizing (e.g., through Facebook, on your website, through community listservs) these events promote more widespread access and efficiently connects residents to services. In order to ensure that you are best able to reach residents from your community, consider providing scheduling information through trusted community leaders. Additional best practices for Community Vaccine Events are found in Appendix 38.

16.1 Vaccine Allocation

North Carolina’s allocation guidance has changed to accommodate the softening of vaccine demand from recipients and to give more flexibility to providers. The NC allocation strategy has shifted from an allocation method based on percentage of people unvaccinated in the county to provider requests. Providers can now request doses using the always-open Allocation Request Form (inclusive of first and second doses).* As this is a request-based model, providers will no longer have to accept or decline allocation doses. Providers are now allowed to request doses in general for their provider location, rather than first and second doses separately. Requested doses should include all doses your provider location intends to administer for the coming week, including scheduled appointments, walk-ins, and community events.

*Due to the amount of on-hand inventory in NC, please attempt to secure vaccine doses via local transfers from other enrolled providers utilizing the Vaccine Marketplace in CVMS prior to submitting an allocation request. See Section 7.10 for more information on the Vaccine Marketplace.

Only one request from each provider location should be submitted. If there are multiple responses for your location, we will use the most recent form response submitted. Similar to the current notification process, providers will be notified of their fulfilled allocation request prior to the vaccine shipment or transfer as appropriate. The provided allocation number will be final, no further action will be required from providers and no changes can be made.

Allocation Expectations – providers must be ready to follow these expectations to request allocation:

• Providers are no longer held to the expectation to administer all allocated doses within seven days of receipt.
• Providers can take more than one week to administer doses, as long as providers exhaust 50% or more of their allocation before requesting more doses through the allocation request process.
  o For example, if a provider cannot administer 100 Moderna doses within a week, they will not be penalized. Providers in this situation are asked not to request more doses through the request process until at least 50 of those 100 doses are administered and recorded in CVMS.
• Providers are encouraged to accommodate walk-in vaccination requests and to offer vaccines as part of regular patient visits to provide the greatest flexibility and access to people wanting the vaccine.
• Because of how COVID-19 vaccines are packaged and their storage and use requirements, using every dose in a vial before it expires can be challenging in some settings.
• In these circumstances, getting vaccine to people who want the vaccine easily should be prioritized over ensuring that every dose is used in an open vial.
• Providers should fully enter vaccine administrations into CVMS within 24 hours, but no later than 72 hours.
• If you are experiencing difficulty entering data into CVMS and need assistance clearing a data backlog, please reach out to your County Emergency Manager to request assistance through WebEOC.
• COVID-19 vaccine can only be transferred to other COVID-19 vaccination providers in CVMS. Physical transfer of vaccine in accordance with vaccine-specific storage and handling requirements must not be initiated until the transfer has been approved in CVMS. **Best practice is to locate the closest provider in the Vaccine Marketplace with excess available vaccine inventory that may be used for your patient population. Next, contact that provider via email or phone to coordinate a transfer. See Section 7.10 for additional information on the Vaccine Marketplace.** Further details on vaccine transfer can be found in Section 15.0.
• Providers who are unable to receive or administer the current large allotments of vaccine (1170 or 450 for Pfizer, 100 for Moderna and Janssen) can work with nearby providers to transfer vaccine in smaller quantities.
  o For example, transfers of small amounts of Pfizer to providers who care for adolescents (e.g., Family Medicine or Pediatric Primary Care) are a great way to help vaccinate youth 12 years and older.
  o Providers can utilize the Vaccine Marketplace in CVMS to locate smaller quantities of vaccine. (See Section 7.8 for more information)
• The percentage of vaccine administered to historically marginalized and minority populations should meet or exceed the population estimates of these communities in their county and region. Providers should engage in partnerships and targeted outreach to vaccinate historically marginalized populations and meet this goal.
• Vaccine cannot be restricted based on county of residency. People should not be required to present identification to verify age or residency.

16.2 Identify Vaccine Sites and Those Who Would Benefit from The Vaccine at Home Initiative

Meet people where they are. Marginalized communities often lack access to transportation. Selecting an accessible site (e.g., on a common bus route, centrally located within the town) and/or one that is well-known to the population needing to be vaccinated (e.g., a senior center for the 65+ population) can improve the likelihood that more North Carolinians can equitably access vaccination services. Partnerships with large public venues, such as sports arenas, parks, or convention centers, should be explored to allow for large volume vaccine distribution centers. Given the storage, handling, and administration requirements of currently approved or authorized vaccines, vaccination sites should also be selected to maximize throughput of prioritized populations while minimizing transport, and without compromising vaccine stability. Sites must be equipped to respond to rare but potentially life-threatening reactions that may occur following vaccine administration, including the availability of epi pens (epinephrine) and clear protocols for managing severe reactions. Site planning should include logistics for maintaining social distancing and considering traffic or crowd control. In order to meet the requirements of Title II, the Americans with Disabilities Act, vaccination settings must be made accessible to those with disabilities. For more information about ways to ensure access for individuals with disabilities, see Section 10.5.

The Vaccine at Home initiative is able to help more North Carolinians with the efforts of providers. If a provider has signed up as a Vaccine at Home provider, the provider may begin to receive referrals for patients who stand to benefit from that provider’s in-home vaccine services.
Below is the general process:

- Individuals or caregivers may request Vaccine at Home support through a web form (on the PTRC COVID-19 Information Site) or by calling 866-303-0026
- Once potential recipients are in the system, the NCDHHS Vaccine at Home referral partner (Piedmont Triad Council, or PTRC) will match recipients to a provider based on location, and may provide route mapping assistance if necessary
- PTRC will contact providers that are flagged as offering in-home vaccinations to refer possible recipients and confirm provider capability to provide vaccinations
- Providers will be asked to contact recipients to schedule a vaccination appointment
- Upon completing vaccination, providers will be asked to confirm completed vaccination (dose one if giving a two-dose product) to PTRC

16.3 Identify Local Partners

Local community partners are strongly encouraged to work together to plan and host vaccination events. Experience from large-scale testing events has shown that collaboration among health care providers, local health departments, emergency management, law enforcement, municipal government, community-based organizations, schools, large venues, local businesses, and others can lead to smoother, more successful operations. It is also important to work with trusted partners, particularly in communities with high levels of vaccine hesitancy and/or distrust.

NCDHHS has developed a Survey for Organizations Interested in Hosting or Supporting Vaccine Events for organizations that are interested in hosting a community vaccine event or supporting a vaccine event by contributing volunteers, equipment, or other resources. The survey results are collected into a Database of Organizations Interested in Hosting or Support Vaccine Events (which is a read-only Google Document that will update in real-time).

Vaccine providers are strongly encouraged to:

- Share the link to the survey with organizations that are offering to host or support vaccine events
- Use the database to learn which organizations in your county want to help with either 1) hosting a vaccine event, 2) contributing volunteers, facilities, equipment, or resources to support another organization’s vaccine event. You can filter column C to see which organizations are in your county, and you can filter column K to see whether organizations are offering to host a vaccine event or contribute resources.
- Reach out directly to organizations to form partnerships for vaccine events, using contact information from the database.

16.4 Identify Dates and Times

Well-publicized dates and times, particularly when consistent week over week, allows the public to know exactly when and where to get vaccinated. This clarity can decrease confusion and build trust in the vaccination process. To increase access to vaccinations, hosting extended hours (e.g., early mornings, evenings, and weekends) is recommended. This expanded access is important for those unable to get to a vaccination site during normal weekday business hours.
16.5 Consecutive Days at an Offsite Clinic

If satellite clinics are temporary administration sites, then per CDC, providers do not need to register these locations as a site. More specifically, if providers set up a clinic, take it down and take all the vaccine back to the site to which it was shipped and where it is located in inventory the same day, that site does not need to be registered. However, if storage will occur overnight at a site, providers do need to register the site via the CVMS Enrollment Portal. Important elements to ensure for off-site clinics include:

- Protecting the cold-chain storage and abiding by manufacturing transport limits
- Documenting each dose
- Reporting inventory from the hub and keeping it up to date at the end of the clinic

16.6 Make a Staffing Plan

- Refine staffing plans to allow for improved staff and patient experiences Identify roles and responsibilities for vaccination and any required trainings or certifications required for staff fulfilling these roles
- The CDC COVID-19 Vaccination Training Programs and Reference Materials has a list of immunization training and education materials for vaccine providers, including basic and COVID-19-vaccine specific information.

<table>
<thead>
<tr>
<th>Role/Responsibility</th>
<th>Requirements and Considerations</th>
</tr>
</thead>
</table>
| Vaccine coordination         | Primary and back-up vaccine coordinators, who have completed required trainings and ensure appropriate staff trained for vaccine receipt, storage, transport and handling of COVID-19 vaccine. Vaccine coordinators must complete the following trainings:  
  - Review the CDC Storage and Handling Toolkit, including the COVID-19 vaccine addendum  
  - Complete the You Call The Shots: Storage and Handling module  
  - Complete the Pfizer-BioNTech, Moderna, and Janssen/J&J COVID-19 Vaccine training(s), as appropriate for the vaccine product(s) being offered at your facility Complete the COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare Providers. |
<p>| Check-in, registration       | Must be enrolled and trained in using CVMS unless using paper forms for later data entry (must be completed within 72 hours)                                  |
| Screen patients for eligibility | See sample pre-vaccination screening form from CDC                                                                                                           |</p>
<table>
<thead>
<tr>
<th>Process</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccination</td>
<td>Vaccinators must be health care providers whose scope of practice includes vaccinations. Provides completed vaccination card to document vaccine receipt.</td>
</tr>
<tr>
<td>Monitor patient post-vaccination</td>
<td>Appropriate medical treatment used to manage immediate allergic reactions, including on site epinephrine, equipment to measure vital signs, and antihistamines, must be immediately available in the event that an acute anaphylactic reaction occurs following administration of an mRNA COVID-19 vaccine. Vaccine providers should observe patients with a history of anaphylaxis (due to any cause) for 30 minutes after vaccination. All other persons should be observed for 15 minutes after vaccination to monitor for the occurrence of immediate adverse reactions. It is very important to report all adverse reactions after the receipt of a COVID-19 vaccine. Providers should use Vaccine Adverse Event Reporting System (VAERS) and also provide v-safe information to the recipient so that recipients can self-enroll for a post-vaccination health check-in, as well as a 2nd dose reminder.</td>
</tr>
<tr>
<td>Schedule 2nd dose</td>
<td>Patients should be counseled on the importance of completing the 2-dose series in order to optimize protection. Individuals should receive an appointment for their second dose per the vaccine-specific dosing interval ideally at the time of the first dose and employ 2nd dose reminders, if possible.</td>
</tr>
<tr>
<td>Field incoming requests from individuals</td>
<td>Build upon existing call center functions, if available. See scripts in Appendix 33 for additional considerations.</td>
</tr>
<tr>
<td>Data entry</td>
<td>All vaccine doses administered in North Carolina must be documented in CVMS within 72 hours of administration. At this time, providers should fully enter administrations into CVMS within 24 hours as often as possible. Providers should plan capacity for real-time or simultaneous data entry during vaccine efforts and identify local support or request help with staffing or centralized data entry immediately if they are not certain they can get the data entered within the timeframe.</td>
</tr>
<tr>
<td>Logistics</td>
<td>Vaccine providers should consider the need for security, traffic control, cleaning, medical waste, bathrooms, running water, power/electrical, online access</td>
</tr>
</tbody>
</table>
### 16.7 Scheduling and Filling Appointments

Scheduling vaccine appointments allows individuals to safe and timely access to vaccines and allows vaccine providers to manage the supply of vaccine in response to demand. There is a need for efforts in each of four components as part of the efforts related to scheduling and filling appointments: developing partnerships with local organizations and employers prior to allocation; planning around filling appointments once allocation is confirmed; pre-event communication efforts to fill any appointments that remain 1-3 days prior to the event; and efforts to continue to fill appointments and respond to no-shows during the event. Please see Appendix 51 for more detailed information about each component summarized below.

#### Developing Partnerships
- Develop partnerships with local organizations and employers to help fill appointments. While providers are ultimately responsible for filling appointments quickly and equitably, a community organization can be an important partner in achieving these goals. See a list of organizations that have already volunteered to help support vaccine events [here](#).
- Host vaccination Q&As with community partners or employers to address questions and concerns people may have before booking appointments. Key resource: Vaccine 101.
- As you plan your vaccine event, consider how to make the site easily accessible. Choose a trusted familiar location and include weekend and evening hours. If the event is accessible through public transportation, publicize those options, use free funding for public transit, and use free rides through Ride United NC.
- Support language access to your event.

#### Planning: Filling Appointments
- Make it easy for people to find your clinic and schedule appointments
- Promote your clinic or event on social media, websites, and via local businesses and media outlets (local news channels, e-newsletters). Use communications resources from the Communications Toolkit to get you started.
- Work with Partners to schedule appointments
- Make a Standby list to fill appointments in the case of cancellations or no-shows

#### Pre-Event Communication: Filling Appointments That Are Still Open
- Push out information about the vaccine event including the link or phone number to schedule appointments again—let people know that there are available appointments.
- Contact people and organizations on the standby waiting list to notify them that there are appointments available to ensure no doses are wasted.
During the Event

- Ensure people are not turned away
- Consider promoting that you are taking walk-ups and be staffed appropriately to handle walk-up traffic.
- Schedule second dose appointments (if needed) before individual leaves the vaccine clinic.

16.8 Offering Transportation

- For vaccine providers scheduling appointments for vaccines, we recommend as a best practice informing anyone who makes an appointment, “if you need a ride, reach out to your local transportation agency” and provide them the contact info: https://www.ncdot.gov/divisions/public-transit/Documents/NC_public_transit.pdf
- Coordinate with community organizations (e.g., faith-based organizations, local agencies) that can provide transportation to help get people to vaccine appointments and events.
  - Review the Database of Organizations Interested in Hosting or Support Vaccine Events periodically for updates to see if there are community organizations in your county that are willing to contribute vehicles with drivers to help transport people to vaccination events. (You can filter column C to find organizations in your county, filter column K to find organizations interested in ‘Partnering with or supporting another organization’s vaccine event’, and check column BB to see they are offering vehicles with drivers (yes/no). Reach out directly to those organizations to see if they can help provide transportation.
- We recommend that any communications by a vaccine provider to the community include messaging: “If you need a ride, call your local transportation agency at X.”
- Inform local transportation agencies of changes to your operations
  - Vaccine providers should proactively reach out to local transit agencies to promptly flag any changes that could impact ride assistance. This includes but is not limited to addition, subtraction, or change of physical location of vaccine site.

See North Carolina Public Transit Systems map and list of contact information

16.9 Walk In Vaccinations

- Walk-in vaccinations are being offered and encouraged more frequently throughout the state. They provide greater flexibility to vaccine recipients and can help you use your vaccine allocation. Keep the below tips in mind as you consider your ability to support walk-in recipients:
  - Compare your vaccine inventory with the total scheduled appointments to know approximately how many doses are available to support walk-ins. This can be checked on a cadence that fits your schedule and appointment volume. Frequently check for “no-shows,” and add these doses to the amount of vaccine available for walk-ins. Familiarize yourself and other CVMS users at your location on how to document walk-in appointments within the CVMS Provider Portal.
  - Offer vaccine to others who may have accompanied a recipient to their appointment. They may not know they have the ability to be vaccinated on the spot.
Plan for walk-ins by considering setting a routine walk-in timeframe that works for your staffing model and the number of appointments you have scheduled. Keep in mind that administering vaccine for walk-ins may require CVMS recipient registration and could take additional time.

Advertise walk-in vaccinations are available: Share information on social media, display signs within your location(s), ask community organizations (e.g. schools, churches, local businesses) to support you in spreading the word, etc.

Make sure you’ve also communicated to your staff members that walk-ins are welcome!

16.10 Registering individuals in CVMS

As of the date of this publication, CVMS registration can be accomplished in three ways. Please see Section 7.0 for more details on CVMS.

- **Pre-registration**: Refers to uploading a group of individuals in CVMS using the bulk upload template either by a vaccine provider or an invited organization for a pre-determined group of eligible employees or community members. Note that patient pre-registration currently requires a functional email address and completion of registration steps online prior to vaccination appointment. Pre-registration is not required for vaccination since all vaccine providers have the option for point-of-care registration, but may save time at the vaccination appointment.

- **CVMS Scheduling**: If an enrolled provider opts to use the CVMS Scheduling tool, recipient registration in CVMS is completed automatically as part of scheduling the appointment.

- **Point-of-care registration**: Refers to registering an eligible individual on-site at the time vaccination in CVMS or by phone prior to vaccination encounter. Sites can also use paper registration forms and record vaccination information in CVMS within 72 hours. Accommodations for point-of-care registration for people with disabilities must be made available to enroll and register people in CVMS by phone prior to the vaccination encounter or onsite. Additional accommodations need to be available to assist people during the onsite registration process in order to complete registration forms and questionnaires in hardcopy or electronically. Examples of accommodations may include registration and appointment tools that use screen access software that people who are blind or have low vision can use to read and access information on a computer onsite.

16.11 Documenting Vaccine Administration in CVMS

All vaccine doses administered in North Carolina must be documented in CVMS. At this time, providers should fully enter administrations into CVMS **within 24 hours as often as possible**, but must enter administration data within 72 hours of administration. Providers should plan capacity for real-time or simultaneous data entry during vaccine efforts and identify local support or request help with staffing or centralized data entry immediately if they are not certain they can get the data entered within the timeframe. For current EHR integration options with CVMS, see Section 7.5.

**Documentation in CVMS Promising Practices**

- CVMS pre-registration for vaccine recipients when possible
• Review/enter into CVMS any patient information gathered during appointment scheduling prior to the vaccine appointment or event so that on-site data entry is limited to the point-of-administration vaccine screening and administration documentation.

• Online or paper registration forms should not require for people to submit ID, SSN, or insurance information to be able to register for an appointment. These fields should be made optional or should not be included on registration forms at all. The form should allow for people to proceed to register even if they do not have these documents.
  o Asking for SSN or ID information in a registration form presents a special barrier since many people will see the questions and elect to simply not register for the event, without opportunity to speak to the vaccine provider about whether the documents are actually required.

• Plan staff capacity for real-time or simultaneous data entry during vaccine efforts. For example, consider having additional administrative staff to support data entry or scribe efforts.

• Plan technology, IT, or hardware needs to support real-time or simultaneous date entry. For example, consider using electronic tablets and onsite Wi-Fi units or hotspot units.

• Train registration or screening volunteers in CVMS to allow more staff members to assist as scribes. Plan ahead to upload volunteer vaccinators into the system for ease of real time documentation.

• Complete COVID vaccine cards with vaccine administration information, then enter recipient information from that vaccination card to improve data entry accuracy.

• For large vaccination clinics, utilize rolling laptop carts to aid mobility and provide cleanable surface for documents.

• Utilize mobile hotspots for drive-through operations or large areas to aid mobility.

• Have a plan for using off-line paper forms in case of internet or system interruption.

• If using paper-based processes, legibility is critical and cannot be over-emphasized.

• Using these revised CVMS offline forms will help with speed and accuracy of data entry.

• **Recipient Registration and COVID-19 Vaccine Administration Form**
  o This form aids in collecting required vaccine administration data any time CVMS is not in use or not immediately available. It also includes fields for collecting insurance information and the CDC screening questions.
  o Providers had previously worked across multiple forms to capture necessary recipient and vaccine dose information. For convenience, the forms have been merged and simplified.
  o The front page (page 0) contains instructions for how to use the form. **Please do not print this page.**
  o The second page (page 1) mirrors the experience in CVMS and is not editable.
The third page (page 2) is customizable to include additional information that the provider may choose to collect. **Please note that this page does not have any CVMS fields on it and is not required for entering data into CVMS.**

 Consider adding Add a note to the third page of the form that says:

- **English:** Everyone 12 years and older will be vaccinated. No one will be turned away
- **Spanish:** Se vacunará a todas las personas mayores de 12 años. Nadie será rechazado.

**CVMS Inventory Levels Form**

- For the vaccine inventory levels, a team member must capture the required data elements identified in CVMS Inventory Levels Form. This form also mirrors the user experience of CVMS. Providers should enter the data captured offline into the CVMS as soon as possible when the CVMS is back online or providers have access to a connected device.

### 16.12 Vaccination Clinic or Event Flow

**16.12.1 Indoor events:**

All operations within an indoor vaccinations site should be set up using social distancing best practices to protect patients and vaccine clinic staff. Vaccination clinics should follow Governor Cooper’s most current executive orders related to the pandemic response found at: https://www.nc.gov/covid-19/covid-19-orders-directives.d.

- Experience to-date is that the process from on-site registration to vaccination takes approximately 15 minutes. Time can be reduced as vaccinators gain experience. The CDC recommends that people who have a history of anaphylaxis (due to any cause) should be observed for 30 minutes following vaccination. All other people should be observed for 15 minutes following vaccination.
Clear and frequently repeated messaging is crucial for compliance at vaccination sites. (For example, repeat instructions to stay inside vehicles or maintain 6 feet of social distancing in lines as appropriate).

16.12.2 Drive Through Clinics.
Vaccine providers should consider using the following strategies for drive-through clinics:
- Consider an “Express” lane or carpool lane for those patients waiting in group transit (such as vans or mini-buses).
- Include the transit drivers working in drive through clinics as part of the vaccination team and ensure access to vaccine for these healthcare workers.
- Educate your community about the importance of having patients who are taking group transit wear masks and be spaced 6 feet apart while they are on group transit.
- It is suggested that traffic flow in only one direction. The patient monitoring station should have designated slots for 15 minute and 30 minute observation holds so that traffic does not get held up.

17.0 Promoting Equitable Vaccine Distribution

COVID-19 has disproportionately impacted historically marginalized populations (HMP). The pandemic didn’t create these disparities, but it made them more acutely visible for all to see. Understandably, historically marginalized communities who have faced longstanding and continuing racial and ethnic injustices in our health care system may feel greater distrust towards vaccines.

One of the guiding principles for North Carolina’s COVID-19 Vaccine Plan is that transparent, accurate, and frequent public communications is essential to building trust. NCDHHS is undertaking a comprehensive effort to make sure that North Carolinians can make an informed decision about getting a COVID-19 vaccine. We have completed statewide research with a focus on historically marginalized populations that is informing our outreach and engagement efforts. Resources are available in English and Spanish at YourSpotYourShot.nc.gov and Vacunate.nc.gov.

Providers should include the following information on their websites and communications:
- **English**: People are not required to present an ID to be vaccinated. Vaccine providers may ask for an ID for insurance or HRSA reimbursement purposes. However, everyone will be vaccinated even if they don’t present an ID. No one will be turned away. See HRSA Provider Fact Sheet (English | Spanish) and Patient Fact Sheet (English | Spanish).
- **Spanish**: No se requiere que las personas presenten una identificación para ser vacunados. Los proveedores de vacunas pueden solicitar una identificación para fines de reembolso del seguro medico o de la HRSA. Sin embargo, todos serán vacunados incluso si no presentan una identificación. Nadie será rechazado. (Consulte la Hoja de información para proveedores de HRSA (inglés | español) y la Hoja de información del paciente (inglés | español).

It is the responsibility of all vaccine providers to ensure equitable access to vaccines. The percentage of vaccines administered to historically marginalized populations should meet or exceed the population estimates of these
communities in their county and region. This will mean taking intentional actions to reach and engage historically marginalized communities. In addition, providers should be aware of the potential additional barriers that individuals with behavioral health conditions and intellectual and developmental disabilities face in obtaining vaccinations and consider pro-active outreach to these populations, partnering with local Behavioral Health/Intellectual Developmental Disability (BH/IDD) organizations for vaccine events, and options for home bound individuals.

17.1 Engage Marginalized Communities

- Virtually convene faith leaders, local media personalities, health care providers, and other local influencers to serve as vaccine ambassadors. Share the Vaccine 101 presentation and provide time to answer questions. Ask the group how you can support them in being ambassadors to their communities. Share resources that they can use with their networks, including this flyer.
- Regularly communicate with this group, sharing information about upcoming vaccination clinics and information on who is currently eligible for vaccination, and ensuring they are included in vaccine event planning efforts.
- Ask trusted leaders to record and share a video about why they plan to get vaccinated when it is their turn.
- Avoid use of terms “targeting” or “strike teams” when describing initiatives in HMP communities.
- Encourage community leaders to be trained as Vaccine 101 presenters to be equipped with accurate and up-to-date information about the vaccines. People can register for these 1-hour virtual presentations here: https://www.eventbrite.com/e/vaccine-101-presenter-trainings-tickets-136015480965
- Go to the Historically Marginalized Populations Engagement Toolkit for Health Care Systems & Providers at: https://docs.google.com/document/d/1tqFvTeTyAJJU5SMClpURZkKlsKhUyVLX/edit#

17.2 Partner with Community Health Workers

NCDHHS has a network of over 400 Community Health Workers (CHWs), who are deployed in 55 counties to connect North Carolinians affected by COVID-19 with needed services and support. A roster of contacts by county is available here. We encourage you to connect directly with CHWs in your county to assist in making the most of your vaccination activities. They are available to help and may also reach out to you directly.

CHWs can help with the following vaccine areas:

- **Educate** – CHWs are trained to educate and address vaccine hesitancy. Town Halls, Q&A sessions, Facebook live events are part of their scope of work.
- **Outreach** – CHWs can leverage existing relationships and proactive outreach to HMP communities to generate interest in HMP individuals who can be pre-registered in CVMS and/or scheduled for vaccine appointments. CHWs can also provide any other supports needed (e.g., transportation)
- **Support** – CHWs provide logistical support for vaccine events (e.g., Calling registered patients/waiting list, marketing, site selection, entering data into CVMS, language support). CHWs can provide end-to-end vaccine support.
- **Register** – CHWs are CVMS users and have the statewide location manager user role, which allows them to work across all vaccine provider sites. CHWs can help register individuals in CVMS for vaccination.
- **Schedule** – CHWs can schedule real-time appointments based on individual site needs
For more information about Community Health Workers please go to: https://www.ncdhhs.gov/divisions/office-rural-health/community-health-workers

17.3 Embed Equity in Vaccine Operations

- **Offer vaccine events in settings trusted and easily or frequently accessed by historically marginalized communities, such as churches, schools, community center, food pantries, and others.** Also consider partnering with BH/IDD day programs, such as club houses, to ensure individuals with disabilities have adequate access to vaccine.

- **Provide transportation.** Transportation can be a significant barrier in many communities. Ask every individual if they need assistance with arranging transportation. Coordinate with trusted partners such as places of worship or community centers to arrange for people to safely get people to and from vaccination appointments or reach out to your local transit agency.

- **Allow people to register onsite.** Not everyone has access to email or the internet. Use point-of-care registration and provide accommodations for people with disabilities to enroll people in CVMS onsite. It does not require an email address.

17.4 Address Limited English Proficiency

To ensure meaningful access for persons with LEP under a variety of circumstances, vaccine providers should, among other things:

- Contract with entities qualified to provide language access services through multiple types of media (telephonic interpretation, video remote interpreting, etc.)

- Disseminate COVID-19 information and messaging about testing and treatment in plain language and in the non-English languages prevalent in the affected area through all forms of media, including online, television, or social media, and through specific outreach to community and faith-based organizations that can reach individuals with LEP

- Post COVID-19 documents in multiple languages in multiple locations, including at providers’ initial point of contact

- Offer services in multiple languages and provide notices of such language access services online, in advertisements, and at points of service
  - Providers should include the following information on their **websites and communications:**
    - **English:** People are not required to present an ID to be vaccinated. Vaccine providers may ask for an ID for insurance or HRSA reimbursement purposes. However, everyone will be vaccinated even if they don’t present an ID. No one will be turned away. See HRSA Provider Fact Sheet (English | Spanish) and Patient Fact Sheet (English | Spanish).
    - **Spanish:** No se requiere que las personas presenten una identificación para ser vacunados. Los proveedores de vacunas pueden solicitar una identificación para fines de reembolso del seguro medico o de la HRSA. Sin embargo, todos serán vacunados incluso si no presentan una identificación. Nadie será rechazado. (Consulte la Hoja de información para proveedores de HRSA (inglés | español) y la Hoja de información del paciente (inglés | español).)
• Designate a person on every shift to be responsible for ensuring and coordinating the delivery of language access services for patients with LEP at every stage of contact, from intake and admission to treatment and discharge
• Create and disseminate widely to staff an up to date list of in-person and remote translation and interpreter services and of bilingual staff who are qualified to respond quickly to the needs of patients with LEP
• Use “I Speak” resources or ask open-ended questions to determine an individual’s written and spoken language preference at the first point of contact
• Upon identifying a patient with LEP, make sure critical information is communicated in the patient’s preferred language by using a qualified interpreter or translated materials, remotely if necessary
• Clearly mark patient charts (or EHR records) with their LEP status and preferred written and spoken language
• Where feasible, respect patients’ wishes to use their own interpreter, such as an adult friend or family member, if they are qualified and if appropriate under the circumstances.

A service email address is available for vaccine providers requesting assistance with connections to resources to better serve individuals with communications needs, including limited English proficiency: communication.access@dhhs.nc.gov


17.5 Address Access for HMP with Disabilities

To ensure equal access for everyone, vaccine providers should plan vaccination efforts with consideration for communication and environmental barriers. All vaccine providers are covered under the American’s with Disabilities Act (ADA), which requires that facilities, activities, services, and programs be accessible to individuals with disabilities. Ensuring effective communication and provision of auxiliary aids (i.e., qualified ASL interpreters, TDD, alternate formats) is just as important as providing facilities that are accessible to individuals with disabilities under the ADA. See Section 10.5 for more information.

17.6 Prioritize scheduling historically marginalized populations at vaccine clinics

<table>
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<tr>
<th>Suggested Practices for Using Equity Doses</th>
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<td>Partnering with faith and community organizations</td>
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</table>
17.7 Engage with local partners serving historically marginalized populations

- Ensure that federally qualified health centers, rural health centers, and free and charitable clinics are at the table planning and coordinating vaccinations in your community. Note that many of these entities are enrolled vaccine providers and are eligible for vaccine transfer.
- NCDHHS has developed a Survey for Organizations Interested in Hosting or Supporting Vaccine Events for organizations that are interested in hosting a community vaccine event or supporting a vaccine event by contributing volunteers, equipment, or other resources. The survey results are collected into a Database of Organizations Interested in Hosting or Support Vaccine Events (which is a read-only Google Document that will update in real-time). **Vaccine providers are strongly encouraged to:**
  - Share the link to the survey with organizations that are offering to host or support vaccine events
  - Use the database to learn which organizations in your county want to help with either 1) hosting a vaccine event, 2) contributing volunteers, facilities, equipment, or resources to support another organization’s vaccine event. You can filter column C to see which organizations are in your county, and you can filter column K to see whether organizations are offering to host a vaccine event or contribute resources.
  - Reach out directly to organizations to form partnerships for vaccine events, using contact information from the database.

17.8 Foster learning and rapid-cycle improvement to drive equitable implementation

- Assess the equity of vaccine distribution using the community-level data on the North Carolina COVID-19 vaccination dashboard.
- Be transparent with the data to your staff and partners, share when equity success happens, and be humble in receiving feedback and support.
17.9 Social Vulnerability Index (SVI) Map of North Carolina Census Tracts

- There is a map that can help North Carolina reach its goal of vaccinating as many North Carolinians as quickly and fairly as possible. This map shows census tracts in North Carolina with the highest rates of social vulnerability and the lowest rates of COVID-19 vaccination.
- Social vulnerability is measured by Social Vulnerability Index (SVI); the higher the score, the higher the social vulnerability. The map also includes the ability to see where COVID-19 vaccine providers and community-based organizations that have offered to support vaccine events are located.
- NC DHHS encourages vaccine providers and partners to use this map to help determine where to conduct outreach efforts and where to locate vaccination sites and mobile units. Census tracts to focus on are those that have high social vulnerability (red areas) and lower vaccination rates (smallest turquoise circles). Census tracts are subdivisions of counties.
- The map is now available on YourSpotYourShot.nc.gov. An instructional video is available linked from the map and here.

18.0 Cost, Coding and Billing of COVID-19 Vaccine

**Cost**

The COVID-19 vaccine must be provided at no cost to recipient. The vaccine, along with the ancillary supplies, is provided by the federal government at no cost to enrolled COVID-19 vaccine providers. Vaccine providers should bill third party payers whenever possible, including commercial insurance, Medicare or Medicaid, for the administration fee as appropriate. HRSA will reimburse providers for COVID-19 vaccines administered to uninsured individuals (Provider Relief Fund found at https://www.hrsa.gov/CovidUninsuredClaim). As noted in the CDC COVID-19 Vaccination Program Provider Agreement signed by your organization’s leadership, providers may not seek any reimbursement, including through balance billing, sliding fee scales or co-pays from the vaccine recipient.

Source: Key Things to Know About COVID-19 Vaccines (cdc.gov)

**Coding**

The American Medical Association (AMA) published an update to the Current Procedural Terminology (CPT®) code set that includes new vaccine-specific codes to report immunizations for the novel coronavirus (SARS-CoV-2, COVID-19). This level of specificity offers the ability to track each vaccine dose, even when the vaccine product is not reported (e.g., when the vaccine may be given to the patient for free). These CPT codes report the actual work of administering the vaccine, in addition to all necessary counseling provided to patients or caregivers and updating the electronic record.”

Source: COVID-19 CPT coding and guidance | American Medical Association (ama-assn.org)
Billing

Vaccine doses are available to all in the United States at no cost. However, vaccination providers may be able to charge administration fees for giving the shot. Vaccination providers can get this fee reimbursed by the patient’s public or private insurance company or, for uninsured patients, by the Health Resources and Services Administration’s Provider Relief Fund (HRSA).

Source: CDC, Key Things to Know About COVID-19 Vaccines (cdc.gov). For more detailed information, please see the COVID-19 Vaccination Coding and Billing Resources.

19.0 Additional Support and Resources

Upcoming CVMS Training

NCDHHS invites you to attend live and recorded CVMS Orientation and Readiness Training Sessions. The Readiness Training will cover key actions you can do to prepare for CVMS and administering the COVID-19 vaccine. During the live training there will be time in the sessions for Q&A. We also provide specific training sessions for Location Manager and Healthcare Provider designated roles in CVMS. Please visit the NCDHHS webpage for recorded and live training sessions. Please note the same sessions are being offered multiple times on different days of the week. New provider orientations are also available. For more information see Appendix 59.

Additional Resources:

- If you have any questions, please use the CVMS Help Desk Portal. To submit a question, issue, or request, please follow the instructions below:
  - Go to CVMS Help Desk Portal
  - Click on ‘Vaccine Provider’
  - Login using your username and password
    - If you already registered, use your Service Now username and password (not your NCID)
    - If this is your first time registering for the CVMS Help Desk Portal, refer to this knowledge article to register
  - Open a ticket by selecting relevant Request Type drop down menu (e.g., CVMS access or login issue, Request CVMS provider enrollment assistance, Manage CVMS provider agreement).
  - Explicitly write the question, issue, or request in the description field
  - Submit case
- In addition to submitting questions or issues via the CVMS Help Desk Portal, providers can also search the CVMS Help Desk Portal for knowledge articles to help immediately address questions or issues.
- The COVID-19 Vaccine Provider Help Center is available for vaccine providers and organizations to call and receive live support for COVID-19 vaccine and CVMS-related questions, issues, or requests. To reach the Help Center, call (877) 873-6247 and select option 1 for COVID-19 questions. The COVID-19 Vaccine Provider Help Center is available:
  - Monday – Friday 7:00 AM – 7:00 PM ET
  - Saturday – Sunday 10:00 AM – 6:00 PM ET
• The NC COVID-19 Vaccine Help Center for individuals in NC is available at 1-888-675-4567 to handle COVID-19 vaccine and CVMS related questions.

• If you have general storage and handling questions, please contact our storage and handling staff at (919) 707-5574. Please leave a message if you do not reach anyone and someone will return your call as soon as possible. You may also find additional storage and handling resources on our website (Storage Resources). To report temperature excursions, please contact the manufacturer directly.

• If you have a clinical question, please call our clinical nurse on-call number at (919) 707-5575. Please leave a message if you do not reach anyone and someone will return your call as soon as possible.

• You may also contact your regional immunization nurse (RIN map) or regional immunization consultant (RIC map) if you need assistance.

• Virtual Agent:
  o Providers can connect with the Virtual Agent to resolve common questions and inquiries about COVID-19 vaccine and the COVID-19 vaccination program. Here you can receive immediate support 24 hours a day, 7 days a week. To engage with the Virtual Agent, please go to the CVMS Help Desk Portal and click on the chat icon in the bottom right of the page. CVMS Help Desk Portal and click on the chat icon in the bottom right of the page.

• Information for how individuals you have vaccinated can view their COVID-19 vaccination information can be found here.

• Pfizer is providing Customer Service for those vaccine providers that receive Pfizer vaccine for questions related to its product, please see below:

**Pfizer US Customer Service Information**

<table>
<thead>
<tr>
<th>General Product Inquiries</th>
<th>Medical Information</th>
<th>US Shipment Support / Trade</th>
</tr>
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<tbody>
<tr>
<td>(877) 629-2010</td>
<td><a href="http://www.PfizerMedInfo.com">www.PfizerMedInfo.com</a> (800) 438-1005</td>
<td>(800) 800-7240</td>
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<tr>
<td>Open: 8am – 11pm ET, 7 days/week</td>
<td>Open (Cust Vx Only): 8am – 11pm ET, 7 days/week</td>
<td>Open 8am – 8pm ET, 5 days/week (M-F)</td>
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<tr>
<td>• Basic administration FAQs (dosing schedule, what syringes should be used for diluting and/or administration)</td>
<td>• Questions related to efficacy, safety, stability, dosage and administration</td>
<td>• Where and how can I get more dry ice?</td>
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<td>• Storage &amp; Handling FAQs</td>
<td>• Questions related to mechanism of action</td>
<td>• How can I/my institute return shipment boxes?</td>
</tr>
<tr>
<td>• Diluent FAQs (what type, how do I dilute, how can I order more, how should it be stored, etc.)</td>
<td>• Information on vaccine ingredients</td>
<td>• How can I order the Pfizer-BioNTech Covid-19 Vaccine for my practice, office, or hospital?</td>
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<tr>
<td>• Dry ice / Shipping container FAQs</td>
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<td>• I have yet to receive the vaccine quantities that I ordered. What is the status? What can I do?</td>
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<tr>
<td>• How many doses will be available and when?</td>
<td></td>
<td>• I cannot locate the diluent for the vaccine. What should I do?</td>
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</table>
- Moderna is providing Customer Service for those vaccine providers that receive Moderna for questions related to its products, please see below:

**Moderna US Customer Service Information**

**General Product inquiries**
1-800-MODERNAL
(1-888-665-3782)
Open
8am – 8pm ET, 7 days/week

- Will be routed to:
  - General Moderna Questions
  - Healthcare Provider Questions (Clinical)
  - Product Quality or Technical Questions
  - Pregnancy Registry
  - Basic administration FAQs (dosing schedule, what syringes should be used for diluting and/or administration)
  - Storage & Handling FAQs
  - Shipping Container FAQs
  - How many doses will be available and when?

**Medical Information**
https://www.modernacare.com/covid19vaccine-ss
(1-800-603-3703)
Open (Covid Vx Only):
8am – 8pm ET, 7 days/week

- Questions related to efficacy, safety, stability, dosage and administration
- Questions related to mechanism of action
- Information on vaccine ingredients
- Will be able to speak with a clinical specialist

**FAQs**
FDA will also have a Frequently Asked Questions page for the Moderna COVID-19 vaccine.

• Janssen (Johnson & Johnson) is providing Customer Service for those vaccine providers that receive Janssen (J&J) for questions related to its product, please see below:

Janssen US Customer Service Information

General Product Inquiries
Janssen COVID-19 Vaccine Support Center
1-800-565-4008 (toll free)
1-908-455-9922 (toll)
24 hours a day, 7 days a week

Medical Information
https://www.janssenmd.com/janssen-covid19-vaccine
US Toll Free: 1-800-565-4008
US Toll: 1-908-455-9922

Janssen Customer Service
1-800-565-4008
JCCOVIDTEMPERCUSION@its.jnj.com
FDA will also have a Frequently Asked Questions page for the Janssen COVID-19 Vaccine

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<td>Pfizer-BioNTech COVID-19 Vaccine</td>
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<td>EUA Fact Sheet for Health Care Providers Administering Vaccine – Pfizer</td>
<td>Pfizer-BioNTech COVID-19 Vaccine</td>
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<td>EUA Fact Sheet for Health Care Providers Administering Vaccine – Moderna</td>
<td>Moderna COVID-19 Vaccine</td>
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<td>13</td>
<td>Storage and Handling Overview Moderna</td>
<td><a href="https://www.modernatx.com/covid19vaccine-eua/providers/storage-handling">https://www.modernatx.com/covid19vaccine-eua/providers/storage-handling</a></td>
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<td>Moderna COVID-19 Vaccine</td>
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<td>Appendix 28 – Medical Management of Vaccine Reactions in Adults in a Community Setting</td>
<td><a href="https://immunize.org/catg.d/p3082.pdf">https://immunize.org/catg.d/p3082.pdf</a></td>
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<tr>
<td>Appendix 30 – FACT SHEET: Moderna</td>
<td>Moderna COVID-19 Vaccine</td>
<td>FDA</td>
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<td>Appendix 38 – COVID-19 Community Based Vaccination Events: Best Practices.</td>
<td>Please see Technical Appendix</td>
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<td>Appendix 40 – Vaccine Letter to County Leaders</td>
<td>Please see Technical Appendix</td>
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<td>Appendix 44</td>
<td>NC State Health Director’s Statewide Standing Order for COVID-19 Vaccine Administration of FDA Approved and Authorized Pfizer-BioNTech and FDA Authorized Moderna</td>
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https://covid19.ncdhhs.gov/media/2567/open
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<td>Appendix 54: Pfizer COVID-19 Vaccine Approved for Teens (flyer)</td>
<td><a href="https://covid19.ncdhhs.gov/media/2761/open">https://covid19.ncdhhs.gov/media/2761/open</a></td>
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<td><a href="https://www.fda.gov/media/151710/download">https://www.fda.gov/media/151710/download</a></td>
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