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 into future groups and additional vaccine becomes available, this guidance will be updated to add information for specific populations.

The administrative guidance is organized in the following sections:

Contents
1.0 Executive Summary ................................................................................................................................. 5
  1.1 Purpose .................................................................................................................................................. 5
  1.2 Organization of Guidance .................................................................................................................... 5
  1.3 Updating of Guidance .......................................................................................................................... 5
  1.4 Revision Log and Document Live Link ................................................................................................ 5
2.0 Guiding Principles .................................................................................................................................... 8
3.0 Overview of North Carolina’s COVID-19 Vaccine Plan ............................................................................. 9
4.0 Vaccination Prioritization .......................................................................................................................... 9
  4.1 Group 1 ................................................................................................................................................ 9
    4.1.1 Who is eligible for vaccination in Group 1 ..................................................................................... 9
    4.1.2 Who is responsible for vaccinating in Group 1 .............................................................................. 11
    4.1.3 Timeline for Group 1 vaccinations ............................................................................................... 12
  4.2 Group 2 .................................................................................................................................................. 12
    4.2.1 Who is eligible for vaccination in Group 2? .................................................................................. 12
    4.2.2 How do North Carolinians who are 65 and older get vaccinated? .................................................. 12
  4.3 Group 3 ................................................................................................................................................ 13
    4.3.1 Who is eligible for vaccination in Group 3? .................................................................................. 13
    4.3.2 How do North Carolinians who are in Group 3 get vaccinated? .................................................... 14
    4.3.3 Managing Demand. ....................................................................................................................... 15
    4.3.4 Partnering with Employers. ......................................................................................................... 15
    4.3.5 Using the Organization Portal in CVMS ....................................................................................... 17
    4.3.7 Timeline for Vaccinations in Group 3 .......................................................................................... 17
4.4 Group 4

4.1 Adults at high risk for exposure and increased risk of severe illness

4.5 Group 5

4.5.1 Group 5: Everyone who wants a safe and effective COVID-19 vaccination Will open by May 1st

4.6 Self-Attestation of Verification

5.0 Special Populations to Consider

5.1 Vaccinating Homebound Persons

5.1.1. Identifying homebound persons

5.1.2 Vaccination Models to Consider for Homebound Persons

5.1.3 Planning Vaccinations for Homebound Persons with Partners

5.1.4 Best Practices for Vaccinating Homebound Persons

5.2 Vaccination of Minors

6.0 Communicating with Patients about Vaccines

6.1 Overview

6.2 Key Messaging to North Carolinians:

6.3 Key Messages About Johnson & Johnson (Janssen) COVID-19 Vaccine

6.4 Communication Resources

7.0 COVID-19 Vaccine Management System (CVMS)

7.1 Overview

7.2 Online Resources: CVMS

7.3 CVMS Organization Portal

7.4 CVMS Updates

8.0 Who Can Be A COVID-19 Vaccine Provider?

8.1 North Carolina COVID-19 Vaccine Providers

8.2 Federal COVID-19 Vaccine Providers

8.2.1 Federal Retail Pharmacy Program

8.2.2 Federally Qualified Health Centers Program

8.2.3 Federally Supported Vaccination Site in North Carolina

9.0 Readiness Checklist for Newly Enrolled Providers (Abbreviated)

10.0 Guidance for Collaboration Among Vaccine Providers

10.1 Local Health Departments

10.2 Enrolled Hospitals, Health Systems, and Other Vaccine Providers Should:
10.3 All Vaccine Providers Should: ................................................................. 38

11.0 COVID-19 Vaccination Legal Considerations .................................................... 38
11.1 NC Immunization Law .................................................................................. 38

11.2 Consent for Vaccination .................................................................................. 38
11.3 Vaccinating Outside Jurisdiction .................................................................. 39
11.4 Limited English Proficiency ........................................................................ 40

11.5 Americans with Disabilities Act (ADA) and Accessibility .................................. 40
11.6 Immigration Status ....................................................................................... 41

12.0 COVID-19 Vaccine Clinical Information and Guidance ..................................... 41
12.1 Overview ....................................................................................................... 41
12.2 Authorized Vaccines ...................................................................................... 41
  12.2.1 Pfizer-BioNTech COVID-19 Vaccine .......................................................... 41
  12.2.2 Moderna COVID-19 Vaccine .................................................................... 41
  12.2.3 Johnson & Johnson (Janssen) COVID-19 Vaccine ...................................... 41

12.2.4 Brands of COVID-19 vaccine are currently NOT interchangeable. ............... 41
  12.2.5 EUA Fact Sheets ....................................................................................... 42

12.3 Contraindications and Precautions for mRNA COVID-19 Vaccines .................... 43
12.4 Contraindications and Precautions for Johnson & Johnson/ Janssen COVID-19 vaccine ........................................................................................................... 43
12.5 Triage of Persons Presenting for COVID-19 Vaccination .................................. 44
12.6 Warnings for the Pfizer-BioNTech COVID-19 Vaccine, Moderna COVID-19 Vaccine, and Johnson & Johnson/ Janssen COVID-19 Vaccine ............................................................ 45
12.7 Expected Reactions and How to Prepare Your Patients .................................... 45
12.8 Adverse Reactions Reported During the Clinical Trails ..................................... 46

12.9 Safety Monitoring – VAERS and V-safe .......................................................... 46
  12.9.1 VAERS ..................................................................................................... 47
  12.9.2 Ancillary Kit Deficiency Reporting .......................................................... 47
  12.9.3 V-safe ..................................................................................................... 48

12.10 Online Resources: Vaccine Clinical Information and Guidance ......................... 48

13.0 Orders to Administer COVID-19 Vaccine ......................................................... 50
14.0 Vaccine Storage and Handling ........................................................................ 50
14.1 Pfizer ............................................................................................................. 50
14.2 Moderna ....................................................................................................... 52
14.3 Johnson & Johnson/ Janssen ......................................................................... 53
14.4 Satellite, Temporary, and Off-Site Clinics Guidance ................................................................. 55
14.5 Online Resources: Storage and Handling ......................................................................................... 55
15.0 Administration of Vaccine .............................................................................................................. 56
  15.1 Dosing .............................................................................................................................................. 57
    15.1.1 Pfizer-BioNTech COVID-19 Vaccine .................................................................................. 57
    15.1.2 Moderna COVID-19 Vaccine .............................................................................................. 57
    15.1.3 Johnson & Johnson/ Janssen COVID-19 Vaccine ................................................................ 57
  15.2 Intervals between the first and second doses of Pfizer-BioNTech COVID-19 and Moderna COVID-19 vaccines: 57
  15.4 Second COVID-19 Vaccination Doses for Pfizer-BioNTech and Moderna COVID-19 Vaccines ............... 58
    15.4.1 Scheduling Second Dose Appointments and Managing Second Dose Inventory ....................... 58
    15.4.2 Converting second doses to first doses: .................................................................................. 59
    15.4.3 Unused doses at the end of a second dose clinics. ...................................................................... 59
    15.4.4 Providing second doses to individuals who received first doses elsewhere ................................. 60
  15.5 Additional Vaccine Administration Considerations for COVID-19 Vaccines ........................................ 60
16.0 Vaccine Transfer Guidance ............................................................................................................. 61
  17.0 Planning and Running Vaccination Clinics and Events .................................................................... 62
    17.1 Vaccine allocation ......................................................................................................................... 62
    17.2 Identify vaccine sites ...................................................................................................................... 64
    17.3 Identify local partners. .................................................................................................................. 65
    17.4 Identify dates and times. ............................................................................................................... 65
    17.5 Consecutive days at an offsite clinic .............................................................................................. 65
    17.6 Make a Staffing Plan .................................................................................................................... 66
    17.7 Schedule Appointments ............................................................................................................... 67
    17.8 Maintain a Waitlist ......................................................................................................................... 68
    17.9 Offer Transportation ..................................................................................................................... 68
    17.10 Register individuals in CVMS. ....................................................................................................... 69
    17.11 Document vaccine administration in CVMS. ............................................................................... 69
    17.12 Vaccination Clinic or Event Flow. .............................................................................................. 70
      17.12.1 Indoor events: ...................................................................................................................... 70
      17.12.2 Drive Through Clinics. .......................................................................................................... 71
18.0 Promoting Equitable Vaccine Distribution ....................................................................................... 71
  18.1 Engage marginalized communities .................................................................................................. 71
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 directions. 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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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


A tested, safe and effective vaccine will be available to all who want it, but supplies will be limited at first. 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 recommend first protecting health care workers caring for patients with COVID-19, people who are 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 the limited supply of vaccines. North Carolina will move through vaccination groups by aligning to federal priorities and working with local vaccine providers to understand their local demand and available supply. North Carolina has prioritized vaccination in the following simplified groups to remove barriers to identifying eligible individuals (see infographic). This guidance document provides additional details on vaccinations for individuals in Groups 1, 2, 3 and 4. As NC moves into future groups, this guidance will be updated with information for specific populations.

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. The state continues to experience a limited supply of vaccines. As long as we are getting such a small amount of vaccine as a state, there will be challenges and shortages as we try to ensure equitable access to vaccine, while getting vaccinations into people quickly.

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 Prioritization

4.1 Group 1

4.1.1 Who is eligible for vaccination in Group 1

The goal of vaccinations in Group 1 is to protect health care workers who are a critical workforce during the COVID-19 pandemic and at risk for exposure to COVID-19 and North Carolinians who are at the highest risk of being hospitalized or dying from COVID-19.

Group 1: Health care workers & Long-Term Care staff and residents - OPEN

- Health care workers with in-person patient contact
• Long-term care staff and residents—people in skilled nursing facilities, adult care homes and continuing care retirement communities

Health care workers in Group 1 are those with in-person patient contact. Health care workers in this group are defined as paid and unpaid persons serving in health care settings who have the potential for direct or indirect exposure to patients, bodies, or infectious materials. This group also includes individuals who are involved in COVID-19 vaccination efforts, including health care personnel and volunteers supporting vaccination efforts.

Health care settings include, but are not limited to, settings such as:

• Hospitals
• Long-term care facilities
• Outpatient clinics
• Vaccination sites
• Home health care
• Public health clinical services
• Emergency medical services
• Mortuaries
• Pharmacies

Health care worker comprise clinical staff members, including nursing or medical assistants and support staff members (e.g., those who work in food, environmental, and administrative services) and pharmacies.

Health care workers with in-person patient contact can include, but are not limited to:

• Behavioral health providers
• Blood banks workers
• Chiropractors
• Community health workers
• Dental hygienists
• Dentists
• Dialysis centers
• Diagnostic and therapeutic technicians
• EMTs/paramedics
• Environmental services staff
• Food services staff
• Front desk administrative staff
• Health care trainees (e.g., medical students, pharmacy students, nursing students)
• Home caregivers providing regular medical care to medically fragile children and adults
• Home health aides or workers
• Hospice homes
• Laboratory staff
• Morticians/funeral home staff
• Medical Interpreters
• Nurses
• Nursing aides, techs, and assistants
• Nurse Practitioners
• Optometrists
• Personal care aides
• Pharmacists
• Pharmacy techs
• Phlebotomists
• Physicians
• Physicians Assistants
• Physical, occupational, and speech therapists
• Podiatrists
• Public health and emergency s workers
• Public health nurses
• Respiratory techs
• Syringe Exchange Providers

Long-term care staff and residents include people living or working in the following settings:

• Adult care homes/assisted living
• Family care homes
• Group homes
• Skilled nursing facilities
• Mental health group homes
• Shared housing with two or more individuals with intellectual and developmental disabilities receiving home and community-based services
• Continuing care retirements communities
• In-patient hospice facilities
• It also includes people receiving long term home care for more than 30 days including Home and Community Based Services for persons with intellectual and developmental disability, private duty nursing, personal care services, and home health and hospice.

For more information, read Deeper Dive Group 1.

4.1.2 Who is responsible for vaccinating in Group 1

All vaccine providers enrolled in CVMS and who is administering vaccines may vaccinate Group 1 since eligible individuals can continue to be vaccinated as North Carolina moves to additional vaccination groups.

All enrolled vaccine providers also play an important role in vaccinating healthcare workers who are not affiliated with a hospital or health system that is an enrolled provider. Local health departments and hospitals should continue to do outreach to health care employers who may have staff eligible for vaccination in Group 1. Hospitals, health systems, and other enrolled vaccinating providers should provide access to vaccine for health care workers regardless of hospital affiliation.

The federal government manages vaccinations for most staff and residents of long-term care facilities through the Pharmacy Partnership for Long-Term Care Program with CVS and Walgreens. Staff and residents will be vaccinated at the same time. Other long-term care staff and residents will receive vaccinations through their Local Health
Departments or other vaccination providers and other long-term care pharmacies if not participating in the federal program. If a resident is discharged from a facility before their second dose is administered through the federal long-term care partnership (CVS/Walgreens), they can coordinate with the facility to return at the next scheduled clinic date or may schedule with another community provider.

4.1.3 Timeline for Group 1 vaccinations
Vaccination for Group 1 began on December 14, 2020, and expanded to all health care workers with in-person patient contact regardless of risk of exposure to COVID-19 on January 14, 2021. Individuals who meet criteria for Group 1 have continued to be eligible to get the COVID-19 vaccine at any time, even as we have moved into other groups.

4.2 Group 2

4.2.1 Who is eligible for vaccination in Group 2?
The goal of vaccination in Group 2 is to save lives by protecting North Carolinians who are at high risk of being hospitalized or dying from COVID-19. NCDHHS recognizes that flexibility as vaccine roll-out continues is necessary to ensure the demand meets supply efficiently and effectively.

**Group 2: Older adults - OPEN**
- Anyone 65 years or older, regardless of health status or living situation

We strongly recommend that vaccine providers prioritize people 75 years or older if local demand for vaccination is greater than vaccine supply. Vaccinating vulnerable populations, including those age 75 years and older, should remain at the forefront.

Additional details on Group 2 can be found in the Deeper Dive Group 2.

4.2.2 How do North Carolinians who are 65 and older get vaccinated?
Any enrolled vaccine provider may vaccinate individuals in Group 2, and individuals 65 years and older can schedule an appointment with their local provider. NCDHHS has launched Find My Spot ([https://myspot.nc.gov/mapview](https://myspot.nc.gov/mapview)), a vaccination location search tool where individual can enter their zip code or current location to find a nearby vaccine provider. Individuals may also call the COVID-19 Vaccine Help Center at 1-888-675-4567 for assistance.

- **Health care providers can leverage electronic health records’ demographic data** to generate exportable lists of patients within hospitals, health systems, and clinics that are age 65 or older. Lists should include name, date of birth, and contact information (phone and email if available); health care providers may choose to include additional information, such as patient identifier (e.g., medical record number) or address, if applicable. Any transmittal of lists containing PHI/PII must be sent via secure, HIPAA-compliant means.
• **Vaccine providers are encouraged to partner with PCPs** for identification and vaccine coordination among eligible patients, while some PCPs are awaiting to be onboarded as vaccine providers. As noted above, PCPs can leverage their electronic health record systems for identification of all patients 65 years and older. When working with vaccination partners (e.g., local health department, FQHC or local hospital), the vaccination partners may request that patient lists be provided on a specific template to facilitate patient contact, scheduling, and/or registration in CVMS. Any transmittal of lists containing PHI/PII must be sent via secure, HIPAA-compliant means. Keep in mind that recipients do not need to be pre-registered in CVMS to receive a vaccine and this can be done at the time of an appointment.

### Outreach Strategies

• For patient groups identified through their health care provider, the provider can use multiple methods of patient outreach, including messaging through the EHR (e.g., MyChart message), email, text, and phone calls. See [Technical Appendix](#) for sample content to use for patient outreach.

• Assure inclusive and accessible outreach to those patients who may be blind or have low vision when using digital methods (i.e., web sites and social media). [Resources](#) and best practices are available from the National Federation of the Blind.

• There are many opportunities for outreach specifically to North Carolinians age 65 years and older, particularly since approximately 20% of adults 60 years and older receive [community-based supports and services](#).

• NCDHHS is working to help reach the 65+ population by recognizing the need to use best practices with non-web-based forms of communication including television, radio, and newspapers. Include translations into other languages (including Spanish) whenever possible. Local media outlets where this population recognizes the speaker’s face or voice can promote trust in the messaging.

• Identify trusted resources for seniors and help them find their vaccination site.

• The [Area Agencies on Aging](#) can help identify community-based supports and services as well as existing partnerships with senior-serving organizations.

• In-home caregivers are an important resource to consider for connecting to the 65+ population.

• Consider partnering with the area’s Meals on Wheels program to distribute vaccine information as thousands of seniors are served each year with congregate and home-delivered meals.

• Establish points of contact with faith leaders, parish nurses, and faith community nurses to provide vaccine registration instructions to church members, particularly those serving historically marginalized populations as well as Spanish-speaking congregations.

### 4.3 Group 3

#### 4.3.1 Who is eligible for vaccination in Group 3?

![Frontline Essential Workers](#)

The goal of vaccination in Group 3 is to protect those at high risk of exposure.

**Frontline essential workers** Opened February 24th to childcare and PreK – 12 school staff and March 3 to all Frontline Essential Workers
Because supply is still very limited and the population of frontline essential workers is so large, Group 3 will begin with anyone working in childcare or in PreK – 12 schools, with the plan to then move to additional frontline essential workers. NCDHHS opened Group 3 to all frontline essential workers starting March 3 due to the authorization of Johnson & Johnson (Janssen) vaccine and additional vaccine supply coming to North Carolina. Previously eligible groups - health care workers, long-term care staff and residents, and people 65 and older – continue to be prioritized. Not all vaccine providers are ready to open to frontline essential workers on these dates if they are still experiencing high demand for vaccines in Groups 1 and 2.

The CDC defines frontline essential workers as workers who are in sectors essential to the functioning of society and who are at substantially higher risk for exposure to COVID-19. The frontline essential sectors and workers, as categorized by Cybersecurity and Infrastructure Security Agency (CISA) align with federal prioritization guidance from the Centers for Disease Control and Prevention’s Advisory Committee on Immunization Practices (ACIP) recommendations.

- **Frontline essential workers** are individuals who:
  - Must be in-person at their place of work **AND**
  - Work in one of the eight essential sectors: critical manufacturing, education, essential goods, food and agriculture, government and community services, health care and public health, public safety, and transportation

### Critical Manufacturing
- Workers manufacturing medical supplies, medical equipment or PPE
- Workers manufacturing products needed for food and agricultural supply chains

### Education
- Including for example:
  - Child care staff
  - K-12 teachers and support staff
- College and university instructors and support staff

### Essential Goods
- Including for example:
  - Workers in stores that sell groceries and medicine

### Food & Agriculture
- Including for example:
  - Meat packing workers
  - Food processing workers
  - Farm workers
  - Migrant farm/foodworkers
  - Food distribution and supply chain workers
  - Restaurant workers

### Government and Community Services
- Including for example:
  - U.S. Postal Service Workers and other shipping workers
  - Court workers
  - Elected officials
  - Clergy
  - Homeless shelter staff

### Health Care and Public Health
- Including for example:
  - Public health workers
  - Social workers

### Public Safety
- Including for example:
  - Firefighters and EMS
  - Law enforcement
  - Corrections workers
  - Security officer
  - Public agency workers responding to abuse and neglect

### Transportation
- Including for example:
  - Public transit workers
  - Division of Motor Vehicles workers
  - Transportation maintenance and repair technicians
  - Workers supporting highway infrastructure

Additional details for Schools and Childcare can be found in the Deeper Dive: Group 3 – Frontline Essential Workers (School and Childcare)

Additional details on Group 3 and all frontline essential workers can be found in the Deeper Dive Group 3.

### 4.3.2 How do North Carolinians who are in Group 3 get vaccinated?
Any enrolled vaccine provider may vaccinate individuals in Group 3 as individuals become eligible. Frontline essential workers can schedule an appointment with any enrolled provider, and vaccine providers are encouraged to establish local partnerships with employers of frontline essential workers. All vaccine providers should participate in vaccinating frontline essential workers as supply allows.
4.3.3 Managing Demand. Because Group 3 frontline essential workers is a very large group, vaccine providers are encouraged to prioritize appointments for eligible individuals at highest risk of severe illness or exposure to COVID-19. Criteria that could be considered include age (i.e., older age is associated with more severe illness), equity (i.e., worker groups with higher proportions of historically marginalized populations; see Section 18 for additional suggestions on promoting equitable vaccine distribution), work environments where social distancing is most challenging (e.g., food processing, migrant farm camps). Prioritizing frontline essential workers with underlying medical conditions that puts an individual at higher risk of severe illness (i.e., see a list of conditions maintained by the CDC) can be considered. However, any personal health information (e.g., underlying medical conditions) should be handled in a HIPAA-compliant manner, not require divulging of an employee’s health history to their employer, and not require documentation of medical condition.

Providers should also continue to prioritize Group 1 and 2 if there is still demand in their community and may move to Group 3 at different times. For example, vaccine providers may choose to continue vaccinating only individuals in Groups 1 and 2 if still experiencing high demand, or vaccine providers may choose to use a portion of their vaccine for Groups 1 and 2 and another portion for Group 3. Vaccine providers may choose to consider the CDC recommendations for moving between phases or groups:

- When most people in the current phase are vaccinated (e.g., when approximately 60-70% of the target population in a phase has been vaccinated)
- When demand in the current phase appears to have been met (e.g., appointments for vaccination are <80% filled for several days)
- When vaccine supply within a certain location is in danger of going unused unless vaccination is expanded to persons in the next phase.
- When supply of authorized vaccine increases substantially (e.g., more vaccine doses are available than are necessary to complete vaccination of persons in the current phase)

4.3.4 Partnering with Employers. Vaccine providers are encouraged to coordinate with employers to help frontline essential workers get vaccinated.

Guidance for employers of frontline essential workers suggest that they take the following steps:

1. Encourage their frontline employees to get vaccinated when vaccine is available for them.
2. Share information and resources with their employees on how they can find their spot to take their shot
3. Offer to work with their local vaccination providers
4. Consider what type of vaccination model would work best for the organization and their employees.

Guidance specifically for schools, child care, and homeless shelter employers are also available on the NCDHHS website.

Vaccine providers may choose to partner or vaccinate frontline essential workers in a way that matches their existing infrastructure. Vaccine providers may choose to use one of following vaccination models for frontline essential workers, though the list is not exhaustive of potential approaches.
<table>
<thead>
<tr>
<th>Model</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Occupational health</td>
<td>• 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).</td>
</tr>
<tr>
<td></td>
<td>• Initially, while vaccine supplies are so limited, this will not be the main way employees will be vaccinated.</td>
</tr>
<tr>
<td></td>
<td>• When vaccine supply is more available, enrolled and onboarded occupational health providers may be directly allocated vaccines. Occupational health providers will be held to the same expectations as all other vaccine providers.</td>
</tr>
<tr>
<td>Onsite vaccination event</td>
<td>• Local vaccine provider partners with employer who have a large workforce and are committed to supporting efforts to vaccinate their employees.</td>
</tr>
<tr>
<td></td>
<td>• 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)</td>
</tr>
<tr>
<td></td>
<td>The employer role for these onsite events can include the following:</td>
</tr>
<tr>
<td></td>
<td>o Providing and arranging the onsite vaccination clinic space, including space for patient registration, vaccination, and post-vaccine monitoring</td>
</tr>
<tr>
<td></td>
<td>o Identifying eligible employees and assisting with employee registration in the COVID-19 Vaccine Management System (CVMS)</td>
</tr>
<tr>
<td></td>
<td>o Scheduling employees into pre-specified appointment slots</td>
</tr>
<tr>
<td></td>
<td>o Notifying employees of their assigned appointment slot</td>
</tr>
<tr>
<td></td>
<td>o Staffing to assist with registration or traffic control</td>
</tr>
<tr>
<td></td>
<td>o 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</td>
</tr>
<tr>
<td>Vaccination event with local vaccine provider</td>
<td>• 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.</td>
</tr>
<tr>
<td></td>
<td>• 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)</td>
</tr>
<tr>
<td></td>
<td>• The employer role for these events held at a clinic or other community-based site can include the following:</td>
</tr>
<tr>
<td></td>
<td>o Identifying eligible employees and assisting with employee registration in the COVID-19 Vaccine Management System (CVMS)</td>
</tr>
<tr>
<td></td>
<td>o Scheduling employees into pre-specified appointment slots</td>
</tr>
<tr>
<td></td>
<td>o Notifying employees of their assigned appointment slot</td>
</tr>
<tr>
<td></td>
<td>o Staffing to assist with registration or traffic control</td>
</tr>
<tr>
<td></td>
<td>o Supporting vaccination clinic needs, such as basic beverage and food provision</td>
</tr>
<tr>
<td></td>
<td>o Providing transportation to the vaccination sites for employees</td>
</tr>
<tr>
<td></td>
<td>o Providing paid time off for the employee to be vaccinated</td>
</tr>
<tr>
<td>Employee independently seeks vaccination</td>
<td>• 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.</td>
</tr>
<tr>
<td></td>
<td>• Employees can self-attest to the qualifying criteria for Frontline Essential Workers.</td>
</tr>
</tbody>
</table>
4.3.5 Using the Organization Portal in CVMS

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 but is not a requirement for vaccinating frontline or other essential workers. Please see Section 7.3 for more information.

4.3.7 Timeline for Vaccinations in Group 3

Since supply is still very limited and the population of frontline essential workers is so large, Group 3 began with anyone working in childcare or in PreK – 12 schools on February 24th, and then opened to additional frontline essential workers on March 3rd. Please note that providers should continue to prioritize Group 1 and 2 if there is still demand in their community and may move to Group 3 at different times.

4.4 Group 4

4.1 Adults at high risk for exposure and increased risk of severe illness

- North Carolina moved to Group 4 on March 17, beginning with people with high-risk medical conditions, people experiencing homelessness, and incarcerated people who have not been vaccinated. North Carolina plans to move to other essential workers and other people in close group living settings on April 7. Some vaccine providers may not be ready to open to Group 4 on this date if they are still experiencing high demand for vaccines in Groups 1 through 3.
- Group 4 Adults at High Risk for Exposure and Increased Risk of Severe Illness (High-risk conditions and additional congregate settings) includes:
  - Anyone 16-64 years old with high-risk medical conditions identified by the CDC that increase risk or may increase risk of severe disease from COVID-19 such as cancer, COPD, serious heart conditions, sickle cell disease, Type 2 diabetes, among others, regardless of living situation. The list of conditions can be found in the Deeper Dive Group 4.
  - This population includes anyone who is living in congregate or close group living settings who is not already vaccinated due to age, medical condition or job function, including:
    - People experiencing homelessness or living in a homeless shelter. See Vaccine Operational Guidance for Homeless Provider Staff and People Experiencing Homelessness.
    - Correctional facility, such as jail or prison
  - Group 4 Adults at High Risk for Exposure and Increased Risk of Severe Illness (Essential workers not yet vaccinated and other group living settings):
    - Essential workers not yet vaccinated. The CDC defines these as workers in transportation and logistics, water and wastewater, food service, shelter and housing (e.g., construction), finance (e.g., bank tellers), information technology and communications, energy, legal, media, public safety (e.g., engineers) and public health workers.
• This population includes students living in dormitories or other group living settings (e.g., fraternity or sorority houses), who are not already vaccinated due to age, medical condition or job function.

Beginning March 31, the rest of Group 4 including additional essential workers and people living in other congregate settings (such as dormitories) will be eligible for the vaccine. More information on all of Group 4 can be found here.

4.5 Group 5

4.5.1 Group 5: Everyone who wants a safe and effective COVID-19 vaccination - Will open April 7

4.6 Self-Attestation of Verification

Individuals can self-attest to their eligibility status. This self-attestation may occur at the time of scheduling, registration, and/or on-site at a vaccination event, and it can be done verbally, in print, in an electronic medical record (EMR), and/or via electronic form. Providers found to be vaccinating outside of the state’s prioritization groups will be referred to the NCDHHS General Counsel’s office for enforcement action.

Vaccine providers should have a process for self-attestation of vaccine eligibility and significant time spent in North Carolina. This self-attestation may occur at the time of scheduling, registration, and/or on-site at a vaccination event. 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. In addition, people who do not reside in North Carolina may still spend significant time in North Carolina (e.g., for work) and can contribute to the spread of virus in North Carolina. 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. Sample language is provided below:

Attestation of Eligibility for COVID-19 Vaccination

I understand that vaccine supply is limited and, therefore, subject to strict prioritization in accordance with Centers for Disease Control and North Carolina Department of Health and Human Services guidelines.

With that understanding, I hereby attest that I meet the eligibility for the following group (https://findmygroup.nc.gov) below that is currently eligible for vaccination:

• Group 1: Health Care Workers and Long-term Care Staff and Residents
• Group 2: Older Adults (65+)
• Group 3: Frontline Essential Workers
• Group 4: High-risk conditions and additional congregate settings
5.0 Special Populations to Consider

5.1 Vaccinating 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. There have been 223 agencies that have said they can help identify homebound persons for vaccination. **NCDHHS will distribute this list by county to vaccine providers to facilitate partnerships.**

5.1.2 Vaccination Models to Consider for Homebound Persons

1. 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

2. 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.

3. 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

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
- **Vaccinating workforce**
  - Licensed health professionals or other individuals authorized by the federal [PREP act](#) or the [state](#) to administer COVID-19 vaccines
o Trained in vaccine administration of COVID-19 vaccine product they have available
o Trained and able to provide emergency management of severe allergic reactions and anaphylaxis
o **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

### 5.1.4 Best Practices for Vaccinating Homebound Persons

1. **Best Practice #1: Plan to maximize efficiency and ensure that no vaccine is wasted**
   - Estimate the number of doses needed as accurately as possible
   - Map out travel plans to ensure that all vaccine is used within 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
   - To prevent wasted doses, may administer vaccine to eligible caretakers and family members
     - **Group 1**: Home caregivers providing regular medical care to medically fragile children & adults
     - **Group 2**: Older adults 65+
     - **Group 3**: Frontline essential workers including “Workers providing dependent care services, including childcare, eldercare, and other service providers necessary to maintain a comprehensive, supportive environment for individuals and caregivers needing these services”
     - **Group 4**: Individuals with high-risk medical conditions that increase risk of severe disease

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 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 includes guidance for transporting pre-drawn vaccine in syringes
   - **Product Specific 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).

- **Assemble the necessary materials**
  - Temperature monitoring device

<table>
<thead>
<tr>
<th></th>
<th>Moderna</th>
<th>Johnson &amp; Johnson (Janssen)</th>
<th>Pfizer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Refrigerated unpunctured vials before dilution</strong></td>
<td>Refrigerated: 2-8°C x 30 days before 1st use, Room temp: 8-25°C x 12 hrs</td>
<td>Refrigerated: 2-8°C x 3 months, Room temp: 9-25°C x 12 hrs</td>
<td>Refrigerated (at clinic site): 2-8°C x 120 hrs (5 days), Refrigerated (during transport): 2-8°C x 12 hrs, Room temp: Up to 25°C x 2 hrs</td>
</tr>
<tr>
<td><strong>Vials after puncture</strong></td>
<td>Refrigerated to room temp: 2-25°C x 6 hrs</td>
<td>Refrigerated: 2-8°C x 6 hrs, Room temp: Up to 25°C x 2 hrs</td>
<td>Refrigerated to room temp: 2-25°C x 6 hrs</td>
</tr>
<tr>
<td><em><em>Pre-drawn syringe</em> (not recommended)</em>*</td>
<td>Refrigerated to room temp: 2-25°C x 6 hrs</td>
<td>Refrigerated: 2-8°C x 6 hrs, Room temp: Up to 25°C x 2 hrs</td>
<td>Refrigerated to room temp: 2-25°C x 6 hrs</td>
</tr>
</tbody>
</table>

- Bubble wrap or corrugated cardboard cushioning
- Zip-lock bags for syringes or vials
- Ice pack or other cooling agent
- Expanded foam container to maintain temperature
- Hard surface container to protect during transport

- **Prepare pack-out for transportation**
- **Record date, time, and temperature every time container is opened at a destination**
- Additional details can be found at [https://www.usp.org/covid-19/vaccine-handling-toolkit](https://www.usp.org/covid-19/vaccine-handling-toolkit)

### 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](https://www.usp.org/covid-19/vaccine-handling-toolkit) / [Spanish](https://www.usp.org/covid-19/vaccine-handling-toolkit))
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:
     - Working with people who are blind or have limited vision
     - Those who are deaf or hard of hearing
     - Those who work with service animals
     - 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](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 get 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](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/homebound-persons.html).

### 5.2 Vaccination of Minors

Of the currently FDA authorized COVID-19 vaccines, Pfizer’s vaccine can be used in people as young as 16 years, while Moderna and Janssen (J&J) are authorized only for adults (18 years and older) at this time. As North Carolina moves through the eligible vaccination groups, more 16 and 17-year-old individuals may qualify for Pfizer vaccination. NCDHHS recommends that vaccine providers put practices in place to ensure only appropriately authorized vaccine is given to 16 and 17 year-olds. 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

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

NC General Statute 90-21.5 allows minors with decisional capacity to consent for COVID-19 vaccination. For additional information around minor’s consent, see Section 11.2.

### 6.0 Communicating 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.

Key messages and talking points across these categories are available in Appendix 32.

#### 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 lives 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.
- **You have a spot to take your shot.** Supplies are currently limited so you may have to wait, but rest assured that you a spot to get your shot.
The vaccines will be available to all—for free. You will be 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.

Supplies are very limited. Right now, very few vaccine doses are available.

Because vaccine supplies are still limited, eligible individuals may have to wait. If you are in one of the eligible categories, here is how to take your shot against COVID-19:

- Are you eligible? Go to Find My Group at https://findmygroup.nc.gov/ to help individuals know when they will be eligible to receive their vaccine.
- Find your local vaccine provider. NCDHHS has launched Find My Spot (https://myspot.nc.gov/map-view), a vaccination location search tool where individuals can enter their zip code or current location to find nearby vaccine providers.
- Individuals can also call the NC COVID-19 Vaccine Help Center at 1-888-675-4567. It’s a free call.

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.

Available Pfizer-BioNTech and Moderna COVID-19 vaccines require 2 shots to provide the best protection against COVID-19 given several weeks apart. Remember to schedule your second dose when you receive your first dose. To the best of your ability, do not miss your appointment.

6.3 Key Messages About Johnson & Johnson (Janssen) COVID-19 Vaccine

The Johnson & Johnson COVID-19 vaccine, authorized as the Janssen vaccine on February 27th, is the 3rd COVID-19 vaccine to be authorized by the FDA. These talking points can be used when discussing this vaccine:

- There is good news in the fight against COVID-19: we now have another tested, safe and effective vaccine to increase the supply and help us get more people vaccinated quickly.
- A vaccine from Johnson & Johnson (Janssen), a one-shot vaccine, has received FDA emergency use authorization and will arrive as early as the first week of March in our state.
- Like the Pfizer and Moderna vaccines, scientists built on decades of previous work on similar vaccines to create the Johnson & Johnson (Janssen) one-shot vaccine.
- Like the other COVID-19 vaccines currently in use, it will help prevent COVID-19 and is extremely effective in preventing hospitalization and death with no serious safety concerns.
- There are possible temporary reactions like a sore arm, fever, headache or feeling tired and achy for a day or two.
- The Johnson & Johnson vaccine is given in one shot and does not require extreme cold storage, so it can be more easily shipped, stored and administered, providing opportunities to increase the number of vaccination sites and make them more convenient.
- Having a third safe and effective vaccine will help North Carolina vaccinate as many people as quickly as possible and meet its goals to provide equitable access to COVID-19 vaccinations in every community in the state.
- Getting as many people as possible vaccinated quickly will also help stop the spread of COVID-19 variants—and get us back in control of our lives and back to the people and places we love.
### 6.4 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>
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</table>
| NC DHHS 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:  
  - Frequently Asked Questions ![](English / Spanish)  
  - Presentation COVID-Vaccination 101 ![](English / Spanish)  
  - Flyer on Vaccines, English and Spanish ![Simple / Detailed](English / Spanish)  
  - NCDHHS Vaccine Communications Toolkit ![](English / Spanish)  
  - Videos on COVID-19 Vaccine ![YouTube](https://youtube.com)  
  - Infographic of Vaccine Groups ![English / Spanish](https://www.covid19 nc.gov)  
  - Deeper Dive: Group 1 ![English / Spanish](https://www.covid19 nc.gov)  
  - Deeper Dive: Group 2 ![English / Spanish](https://www.covid19 nc.gov)  
  - Deeper Dive: Group 3 ![English / Spanish](https://www.covid19 nc.gov)  
  - Deeper Dive: Group 4 ![English / Spanish](https://www.covid19 nc.gov) |
| Vaccine eligibility screener ![](https://findmygroup nc.gov) | Easy to use online tool to help individuals find their spot in the NC priority vaccination groups and receive notification when NC moves to the next group. |
| Vaccine site locator ![](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. |
| NC COVID-19 Vaccine Help Center 1-888-675-4567 | Call center to increase capacity to respond to constituent questions. |
| How Nurses and Medical Assistants Can Foster a Culture of Immunization in the Practice video ![](https://youtube.com) | 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. |
| “#HowIReadyRecommend” 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. |
| Provider Resources for COVID-19 Vaccine Conversations with Patients | Information for healthcare providers on how to talk to patients about COVID-19 vaccines, including giving strong recommendations, setting expectations about vaccine availability, and preparing to answer likely patient questions. |
| Epidemiology and Prevention of Vaccine-Preventable Diseases | 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). |
| NC DHHS COVID-19 Vaccine site | COVID-19 vaccine guidance, resources, tools, data dashboard, etc. |

**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.

Scheduling, order management, Spanish language translation, and integration with the North Carolina Immunization Registry (NCIR) for one complete vaccine record are planned for subsequent CVMS releases. CVMS is developing EHR integration through the Health Information Exchange (HIE) and pilot activities will begin on February 15, 2021. In the meantime, 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.

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 when making allocations. 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.

**CVMS Help Desk Portal:** [https://ncgov.servicenowservices.com/csm_vaccine](https://ncgov.servicenowservices.com/csm_vaccine) – 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](https://covid-vaccine-employer-portal.ncdhhs.gov) - Please see Section 7.3.
7.2 Online Resources: CVMS

<table>
<thead>
<tr>
<th>Training Program / Reference Material</th>
<th>Description</th>
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<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></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 201</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 202</td>
<td></td>
</tr>
<tr>
<td>CVMS Provider Enrollment Demo</td>
<td>A recorded walk-through of the steps needed for Providers to complete enrollment in CVMS.</td>
</tr>
<tr>
<td>CVMS Readiness Training</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>CVMS Visual Roadmaps:</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</td>
<td></td>
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<tr>
<td>and Upcoming Trainings</td>
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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 but is **not a requirement for vaccinating frontline or other essential workers**.

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.

**At this time, NCDHHS recommends that vaccine providers only use the Organization Portal for coordinated and established events for frontline essential workers.** For example, if a local health department collaboratively set up a vaccination event at a local school to vaccinate school staff, the school could identify individuals with scheduled...
appointments to be pre-registered in CVMS. 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 based on equity (i.e., worker groups with higher proportions of historically marginalized populations; see Section 18.0 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.

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 Updates

CVMS has added functionality (Release 5.0) to support the administration of and required CVMS data entry for the one-shot Johnson & Johnson (Janssen) COVID-19 Vaccine. CVMS also includes the ability to identify federal vaccine allocations, used by some Federally Qualified Health Centers (FQHCs) and the Federal Emergency Management Agency (FEMA).

The Spanish translation of the COVID-19 Vaccine Portal for recipients is now available, as well as a streamlined registration process, which removed the CVMS priority tiering for recipients and instead directs to the online ‘Find My Group’ tool.

On March 14, additional enhancements were implemented as part of Release 5.2. With CVMS Version 5.2, Healthcare Location Managers now have the ability to manage location data within the CVMS Provider Portal that can be displayed on MySpot.nc.gov, the site 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

Also as part of this latest release, CVMS scheduling capability went live and 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
- 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.

CVMS Direct is a new integration solution offering for Providers to seamlessly connect COVID vaccination records with CVMS. Providers submit a standardized flat file from their Electronic Health Records (EHRs) that pass through the HIE (Health Information Exchange) 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. Providers are onboarding in groups in rolling 2-3 week sprints over the next few weeks. Please reach out to hiea@nc.gov if you are interested in using CVMS Direct.

7.5 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. If you are a provider calling from a number with a North Carolina area code, please call (877) 873-6247 and select option 8 for COVID-19 questions. If you are a provider calling from a number with an area code outside of North Carolina, dial (919) 707-5588 and select option 8. 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.

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-19 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.
Walgreens is the retail pharmacy that working with North Carolina with incremental expansion planned for additional pharmacy partners, including CVS and others. Their allocations come from the federal government allocations and will not impact NC weekly jurisdictional allocations. Their priority groups match NC Vaccination Groups.

**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) have launched a program to directly allocate a limited supply of COVID-19 vaccine to select HRSA-funded health centers starting the week of February 15. 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 will be staffed by federal personnel, mostly from the Department of Defense. It will be 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 will include logistics, information technology, data entry, emergency medical services and security.

The first site launched on March 10, 2021. Appointments are required for vaccination at the site and are available through a central system and through community partners to ensure access among marginalized populations. People can go to gsomassvax.org to schedule their appointment indoors or in the drive-thru, or call the COVID-19 Vaccine Help Center at 1-888-675-4567. People can also go to: https://www.guilfordcountync.gov/how-do-i/gso-mass-vax-online-registration to change or cancel their appointment.

**9.0 Readiness Checklist for Newly Enrolled Providers (Abbreviated)**
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:

- 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](https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf)
- Complete the You Call The Shots: Storage and Handling module
- Complete the Pfizer-BioNTech COVID-19 Vaccine training and other vaccine brand specific trainings as they become available

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 for CVMS, Appendix 8 for Pfizer Storage and Handling Checklist](https://www.pfizer.com) and [Appendix 13 for Moderna Storage and Handling Summary Guidance](https://www.mrn.org).

Storage and Handling: Train your staff that are designated to handle and store COVID-19 vaccines on how to (a) properly handle COVID-19 vaccines, (b) monitor and document the storage temperature for COVID-19 vaccines, and (c) for Pfizer vaccine, recharge COVID-19 vaccine shipping containers if they are being used to store COVID-19 vaccines. Please see [Section 14.1 for information about the Dry Ice Opt Out process](https://www.cdc.gov) available when dry ice refills are no longer needed for storage in thermal shippers. Please see [Appendix 9 for additional Storage and Handling information and the updated EUA Fact Sheet for Health Care Providers – Pfizer](https://www.pfizer.com) which added an alternative option for frozen storage and transportation.

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](https://www.cdc.gov).
**Vaccine Administration Prep**

◊ **Prioritizing and scheduling:** Determine process for prioritizing and scheduling employees or individuals to receive the COVID-19 vaccine (two doses) 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.

◊ **Moderna vaccine Storage:** Moderna vaccine vials may be stored in the refrigerator or freezer. Each box contains 10 multidose vials (100 doses). This vaccine does not need to be mixed with a diluent before administration. (See Appendix 13).

  • **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).

◊ **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 cartoons 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)

◊ **EUA fact sheet:** Obtain copy of Emergency Use Authorization Fact Sheet for each COVID-19 vaccine product your organization receives and establish a process to provide a printed copy of this document to each recipient prior to administration of the vaccine (both first and second dose). (See Appendix 1, 2, 11, 12, 43)

◊ **V-SAFE information sheet:** Obtain copies of the V-safe Information Sheet to also provide to vaccine recipients. (See Appendix 4) There are now V-safe print resources from CDC available in Spanish, Vietnamese, Korean, and simple Chinese at: [https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe/printresources.html](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 Guidance for Collaboration Among Vaccine Providers
All vaccine providers will need to partner locally to effectively, efficiently, and equitably vaccinate North Carolinians. All vaccine providers have a role to play, and they will need to work together to determine the best approach based on resources and strengths.

10.1 Local Health Departments
Local health departments have a responsibility for assuring a COVID Vaccine plan. Several LHDs have lifted up best practices to support this work. This will allow more vaccinating providers to prepare and better understand the vaccine challenges and opportunities, with local perspective leading the way.

- **Coordinate with local hospitals, health systems, and other health care providers that are enrolled vaccine providers:** The local health department will serve as the coordinating entity across local enrolled vaccine providers in the county. Therefore, LHDs and enrolled providers need a shared plan on:
  - Ensuring equity in vaccine program implementation.
  - Managing vaccine supplies, including the number of doses able to offer each week, feasibility of vaccine transfer from LHDs to other enrolled local providers (e.g., community health center, primary care practice), or other providers to LHDs (e.g., health system), and how that transfer will occur within vaccine-specific storage and handling requirements.
  - Hosting vaccination clinics and events, including planned sites, schedules, and staffing.
  - Communicating regularly to assess vaccine demand, including readiness to move through groups depending on uptake and vaccine supply, vaccine hesitancy levels and approaches to mitigate.
  - Engaging other partners to address vaccine hesitancy (e.g., community-based organizations, local public officials).

- We strongly encourage local health departments to establish standing meetings with hospitals, health systems, and clinics to ensure effective coordination and immediately address challenges with all partners.

- DHHS sends out to LHDs each week a list that includes all providers in their jurisdiction who have enrolled in CVMS. Each LHD should review the list and consider reaching out and/or convening certain providers for a coordinated strategy that may include:
  - Expectations and provider capacity
  - Short/long term goals, i.e. vaccine community reach, number of doses they could administer in 7 days
Consider transferring a small number of doses – 50 or no more than 100 – for providers to ease in to COVID-19 vaccination.

Consider forming partnerships to share shipments of Pfizer, as Pfizer vaccine continues to be more than half of the NC vaccine supply each week with a minimum ship quantity of 1170 doses.

Consider partnering with event requests and pull partners into working with CVMS to learn the system.

Consider HMP goals for the jurisdiction – how strong is the current provider reach and where are gaps that need to be filled.

**Coordinate with local primary care providers (PCPs)** LHDs should build upon existing and new relationships with PCP practices in their county. LHDs should coordinate with PCPs on vaccinating the PCP’s staff as well as their patients who fall into eligible groups while practices do not yet have vaccine. See Appendix 34 for sample letter templates that LHDs can use for this coordination. Potential areas of partnership and coordination include:

- Determining which local enrolled vaccine provider is available to help vaccinate patients in a primary care practice. For example, local health departments may assign some PCP practices for vaccination at the local health department and others at a local enrolled hospital also providing vaccines. If a PCP is assigned to local vaccine provider, the assignment should be communicated in writing locally to assure connection and visibility across the local vaccine providers. An email with key points of contact copied is sufficient.

- Sharing information about how a PCP’s patients can get vaccinated, such as when and where to get vaccinated, and how to schedule a vaccine appointment (e.g., who is going to reach out to patients about an appointment or provide a phone number).

- Here are some example scenarios of how LHDs and PCPs could partner on vaccinating patients in eligible groups while PCPs are awaiting enrollment as vaccine providers and vaccine allocations:
  - **Scenario 1:** PCP is the main point of contact with patients for identification, outreach, scheduling, and communication. The PCP completes a spreadsheet provided by the vaccine provider that includes information for all eligible patients. The assigned vaccine provider will provide a scheduling spreadsheet with available dates/times for vaccine appointments, along with other patient logistics. PCP then fills available appointment slots and sends patient reminders and other needed patient communication. The PCP and vaccine provider may share vaccine clinic staffing responsibilities.
  - **Scenario 2:** Vaccine provider is the primary point of contact with patients. PCP supports patient identification and outreach and provides any necessary patient contact information in a spreadsheet provided by the vaccine provider. The assigned vaccine provider communicates directly with eligible patients, manages scheduling, and provides necessary logistics for vaccination.
  - **Scenario 3:** Assigned vaccine provider groups PCP practices to offer vaccination clinic opportunities for groups of smaller practices or a single large practice. PCP and vaccine provider may share vaccine clinic staffing responsibilities.

**NOTE:** Any PHI being transmitted must be done in a HIPAA-compliant manner.

10.2 Enrolled Hospitals, Health Systems, and Other Vaccine Providers Should:

- **Coordinate with local health department(s):** The local health department will serve as the coordinating entity across local enrolled vaccine providers. In addition to the topics for coordination that are detailed above (i.e., vaccine supply management, vaccination clinic and event plans, vaccine demand updates, partners engaged, and approaches to ensure equity in the vaccine program implementation), coordination is also required for vaccinating patients that are not part of the health system, such as patients of non-affiliated primary care providers.

- LHDs may assign non-affiliated practices to hospitals and health systems for vaccination depending on available vaccine supply. Frequent communication will allow the most timely access to vaccines for eligible individuals.
- Refer patients to another local enrolled vaccine provider with available vaccine and earlier vaccine appointment availability (e.g., if the local hospital has greater vaccine availability than a local health department and can accommodate earlier appointments).
- Coordinate with local primary care providers (PCPs): Enrolled hospitals, health systems, and other enrolled vaccinating providers receiving vaccine are encouraged to work directly with local PCPs who have been partnered with them for vaccination of eligible patients. To facilitate vaccination, PCPs may assist in patient outreach and provide specific instructions to their patients, including when and where to get vaccinated and how to schedule a vaccine appointment (e.g., who is going to reach out to them about an appointment or provide a phone number) (see Appendix 33 for sample language PCPs can use to conduct outreach to patients). PCPs can also remind patients to wear a sleeveless or short sleeve shirt to their appointments to make it easier to receive a vaccination.

10.3 All Vaccine Providers Should:
Ensure that the vaccine provider’s contact information (i.e., phone number, website, email address) is up to date on the NCDHHS Find a Vaccine Location website listing of enrolled vaccine providers who are currently vaccinating. If you need to update your organization’s contact information on the NCDHHS Find Your Spot website, please open a "Find A Vaccine Location” ticket at [https://ncgov.servicenowservices.com/csm_vaccine](https://ncgov.servicenowservices.com/csm_vaccine).

11.0 COVID-19 Vaccination Legal Considerations

11.1 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: [https://immunize.nc.gov/schools/ncruleslaws.htm](https://immunize.nc.gov/schools/ncruleslaws.htm).
- NC Minor’s consent link: [https://www.ncleg.net/enactedlegislation/statutes/html/bysection/chapter_90/gs_90-21.5.html](https://www.ncleg.net/enactedlegislation/statutes/html/bysection/chapter_90/gs_90-21.5.html)

11.2 Consent for Vaccination

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), the Food and Drug Administration (FDA) requires that vaccine recipients or their caregivers are provided with vaccine-specific information consistent with the EUA to help make an informed decision about vaccination.

Individuals under 18 years of age

NC General Statute 90-21.5 gives minors the legal authority to consent for the prevention, diagnosis and treatment of reportable communicable disease and COVID-19 is a reportable disease under NCGS 130A-135 pursuant to rules of the Public Health Commission (10A NCAC 41A.0107). Therefore, minors with decisional capacity may consent for COVID-19 vaccination under G.S. 90-21.5. Please note that under HIPAA, if the minor alone consents, the minor also controls access to their health information.
11.3 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.

However, to promote the public health goals for North Carolina, it is permissible to not offer vaccine to temporary travelers who do not reside, work, or spend significant time in the North Carolina. This could include persons briefly passing or traveling through North Carolina or coming to North Carolina for the main purpose of receiving a COVID-19 vaccine and then returning to another state.

Operational considerations

Vaccination eligibility documentation - Vaccine providers should have a process for self-attestation of vaccine eligibility and significant time spent in North Carolina. However, 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. In addition, people who do not reside in North Carolina may still spend significant time in North Carolina (e.g., for work) and can contribute to the spread of virus in North Carolina. 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.
11.4 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 18 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.


11.5 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 new 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
11.6 Immigration Status
The COVID-19 vaccine will be 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.

12.0 COVID-19 Vaccine Clinical Information and Guidance

12.1 Overview
Currently information is only available for 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.

12.2 Authorized Vaccines
12.2.1 Pfizer-BioNTech COVID-19 Vaccine
On December 11, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 Vaccine for the prevention of Coronavirus Disease 2019 (COVID-19) in individuals who are 16 years of age and older.

12.2.2 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.

12.2.3 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.

12.2.4 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. 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.

### 12.2.5 EUA Fact Sheets

EUA Fact Sheets for each authorized vaccine is available [here](#). The 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 / Johnston & 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 were recently updated with additional important information. 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 authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine, 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 authorized COVID-19 vaccines. The significant known and potential risks and benefits of each of the authorized COVID-19 vaccines and the extent to which such risks and benefits are unknown.
- Information about available alternative 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.
- 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 2: EUA Fact Sheet for Healthcare Providers for Pfizer-BioNTech COVID-19 Vaccine](#).
- [Appendix 3: FDA Letter of Authorization for Pfizer-BioNTech Vaccine](#).
- [Appendix 11: EUA Fact Sheet for Recipients and Caregivers for Moderna COVID-19 Vaccine](#).
- [Appendix 12: EUA Fact Sheet for Healthcare Providers for Moderna COVID-19 Vaccine](#).
- [Appendix 15: FDA Letter of Authorization for Moderna Vaccine](#).
- [Appendix 42: EUA Fact Sheet for Recipients and Caregivers for Janssen (Johnson & Johnson) COVID-19 Vaccine](#).
- [Appendix 43: EUA Fact Sheet for Health Care Providers Administering Vaccine for Janssen (Johnson & Johnson) COVID-19 Vaccine](#).
12.3 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])*
3. Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)*
4. Note: It is very important to report all adverse reactions after the receipt of a COVID-19 vaccine. See Section 12.9 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.

12.4 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, it is 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.

### 12.5 Triage of Persons Presenting for COVID-19 Vaccination

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

12.6 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 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

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.

12.7 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
12.8 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.

An immediate 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><strong>Active ingredient</strong></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>
<tr>
<td><strong>Inactive ingredients</strong></td>
<td>2[(polyethylene glycol (PEG))-2000]-N,N-ditetradecylacetamide</td>
<td>PEG2000-DMG: 1,2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol</td>
<td>Polysorbate-80</td>
</tr>
<tr>
<td>1,2-distearoyl-sn-glycero-3-phosphocholine</td>
<td>1,2-distearoyl-sn-glycero-3-phosphocholine</td>
<td>2-hydroxypropyl-β-cyclodextrin</td>
<td></td>
</tr>
<tr>
<td>Cholesterol</td>
<td>Cholesterol</td>
<td>Citric acid monohydrate</td>
<td></td>
</tr>
<tr>
<td>(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)</td>
<td>SM-102: heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate</td>
<td>Trisodium citrate dihydrate</td>
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<tr>
<td>Sodium chloride</td>
<td>Tromethamine</td>
<td>Sodium chloride</td>
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<tr>
<td>Monobasic potassium phosphate</td>
<td>Tromethamine hydrochloride</td>
<td>Sodium hydroxide</td>
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<tr>
<td>Potassium chloride</td>
<td>Acetic acid</td>
<td>Hydrochloric acid</td>
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<tr>
<td>Dibasic sodium phosphate dihydrate</td>
<td>Sodium acetate</td>
<td>Ethanol</td>
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<tr>
<td>Sucrose</td>
<td>Sucrose</td>
<td>Water for injection</td>
<td></td>
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</tbody>
</table>

12.9 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 2\textsuperscript{nd} dose reminder. These two systems are described below:

12.9.1 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. 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
- 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

12.9.2 Ancillary Kit Deficiency Reporting

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.

1. **Report deficiencies to McKesson** the customer service desk is charged with responding to problems and identifying trends.

2. **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.

3. **Report adverse events to VAERS**. Adverse events involving vaccines should be reported to the Vaccine Adverse Event Reporting System (VAERS).

4. **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/

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

12.9.3 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.

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 now available in English, Spanish, simple Chinese, Korean, and Vietnamese.

V-Safe information from CDC: https://www.cdc.gov/coronavirus/2019ncov/vaccines/safety/vsafe.html

12.9.4 Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to COVID-19 Vaccine during pregnancy. Women who receive COVID-19 vaccine during pregnancy are encouraged to enroll in the registry by visiting https://c-viper.pregistry.com.

12.10 Online Resources: Vaccine Clinical Information and Guidance

<table>
<thead>
<tr>
<th>Training Program / Reference Material</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>COVID-19 Vaccine Training:</strong> General Overview of Immunization Best Practices for Healthcare Providers</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,</td>
</tr>
</tbody>
</table>
**Required**
administration, PPE, scheduling, documentation, and reporting adverse events. Information on each vaccine product will be added as each is authorized by FDA.

<table>
<thead>
<tr>
<th>You Call the Shots: Vaccine Administration</th>
<th>An interactive, web-based vaccine administration course that provides training using videos, job aids, and other resources.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine administration videos</td>
<td>Short, skill-based demonstration videos of vaccine administration activities, including injection techniques based on age and medication preparation.</td>
</tr>
<tr>
<td>Skills Checklist for Vaccine Administration</td>
<td>This checklist from the Immunization Action Coalition is a self-assessment tool for healthcare professionals who administer vaccines.</td>
</tr>
<tr>
<td>CDC Guidance by COVID-19 Vaccine Product</td>
<td>The CDC website provides Clinical Information and Guidance by product.</td>
</tr>
</tbody>
</table>

**Moderna Trainings**
- Moderna Online training Module
- Moderna EUA Fact Sheet for HCP
- Fact sheet for vaccination providers
- Fact sheet for vaccine recipients and caregivers
- Dosing and administration
- Storage and Handling
- Adverse event reporting

**Pfizer Trainings**
- Pfizer Online Training Module
- Pfizer EUA Fact Sheet for HCP
- Fact sheet for vaccine recipients and caregivers
- Vaccine preparation and administration summary
- Storage and handling summary
- Temperature log for ultra-cold freezer units, including online fillable PDF version
- Beyond use date tracker labels for refrigerator storage

**Clinical Materials**
- COVID-19 vaccine screening form for contraindications and precautions
- Expiration date tracker
- Reporting a temperature excursion
- IIS off-line vaccine administration documentation tool
- Guide to ancillary supplies kit (for staff helping providers order vaccine)
- COVID-19 vaccine frequently asked clinical questions web page
13.0 Orders to Administer COVID-19 Vaccine

- A Standing Order template in the North Carolina Board of Nursing format has been provided to Local Health Departments for signature by the Medical Director or other physician that signs the LHD’s vaccine standing orders. See Appendix 14 for the Sample/Template LHD Standing Order for Moderna COVID-19 Vaccine & Pfizer-BioNTech COVID-19 Vaccine. A statewide Standing Order for Pharmacists was issued December 28th, 2020.
- 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 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 (Appendix 50)
- Co-Administration: No data on the safety and efficacy of COVID-19 vaccines administered simultaneously with other vaccines. The vaccine series should be administered alone, with a minimum interval of 14 days before or after administration with any other vaccines. A shorter interval may be used in situations where the benefits of vaccination are deemed to outweigh the potential unknown risks (e.g., tetanus toxoid vaccine for wound management, etc.) or to avoid barriers or delays to vaccination. If COVID-19 vaccines are inadvertently administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine.
- See Appendix 16 for the CDC Moderna Standing Order, Appendix 17 for the CDC Pfizer Standing Order template and Appendix 50 for the CDC Janssen (Johnson & Johnson) Standing Order.

14.0 Vaccine Storage and Handling

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

14.1 Pfizer

The Pfizer COVID-19 vaccine is an ultra-cold product (-90°C to -60°C) and is delivered in a thermal shipper. 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. Please see Appendix 9 for an overview of Pfizer vaccine storage and handling. The ancillary kits will be shipped separately from vaccine product, see Appendix 6 for more information.

On February 25, the U.S. Food and Drug Administration (FDA) announced that it is allowing undiluted frozen vials of the Pfizer-BioNTech COVID-19 Vaccine to be transported and stored at conventional temperatures commonly found in pharmaceutical freezers for a period of up to two weeks. This reflects an alternative to the preferred storage of the undiluted vials in an ultra-low temperature freezer between -80ºC to -60ºC (-112ºF to -76ºF). The change is being reflected in updates to the Fact Sheet for Health Care Providers Administering Vaccine (See Appendix 2), and Fact Sheet for Vaccine Recipients and Caregivers (See Appendix 1) which are intended to help frontline workers understand the new alternative transportation and storage temperatures and are available on the FDA website.

The alternative temperature for storage of frozen vials is not applicable to the storage of thawed vials before dilution (which can be held in the refrigerator for up to 5 days), or on the storage of thawed vials after dilution (which can be held at refrigerator temperature or room temperature for use within 6 hours).

**Dry Ice Kit Opt-Out - Pfizer**

A dry ice kit is automatically added to all orders for Pfizer-BioNTech to assist with safe storage and transport of the vaccine. Pfizer-BioNTech will continue to provide dry ice with every order, but you may find that the dry ice orders are no longer needed in your program. In this case, you may opt out of receiving dry ice in order to prevent shipment of unnecessary dry ice and supplies. This will help to ensure there are sufficient dry ice kits for those who need them.

**How Do I Opt Out?**

There are two ways to opt out of dry ice delivery:

1. **On the order itself**
   
   You can select the opt out option when you create a new order through the awardee portal, in VTrckS, or through the ExS order file upload.

2. **On the provider master data record (jurisdictions only)**
   
   Jurisdictions may opt out on the master data record which allows a provider to always opt out of the dry ice kit. Whenever the provider orders vaccine that has a dry ice kit as an optional item, VTrckS will not add the dry ice kit to any of the provider’s orders. This option is not available to commercial or federal partners.

Information about how to opt out of dry ice is available in the VTrckS training library at [https://vtrckslibrary.cdc.gov/gm/folder-1.11.16412 (jurisdictions)] and [https://transfer1.cdc.gov/w/y1toPpiH2Z5rdGYSz (federal agencies, commercial partners)]. In addition, if you have questions about how to opt out of dry ice, please reach out to the Vaccine Order Management Contact Center to request assistance at 1-877-878-6247 (select Option 3), or email vaccineordrmgmt@cdc.gov.
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. McKesson has increased the individual Pfizer ancillary kit contents from a kit that supported 975 doses to a kit supporting 1,170 doses. The shipping of modified kits will begin the week of January 25, 2021.

**Supplies**

Ancillary supplies will contain supplies necessary to deliver the additional dose. These supplies have been added to the boxes. 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.

### 14.2 Moderna

The Moderna vaccine is a cold vaccine that is to be stored frozen between -25°C to -15°C (-13°F to 5°F) in vaccine storage unit. Store in the original carton to protect from light. Do not store on dry ice or below -40°C. Vials can be stored refrigerated between 2°C to 8°C (36°F to 46°F) for up to 30 days prior to first use. Unpunctured vials may be stored between 8°C to 25°C (46°F to 77°F) for up to 12 hours. Do not refreeze once thawed. After the first dose has been withdrawn, the vial should be held between 2°C to 25°C (36°F to 77°F). Discard vial after 6 hours. McKesson will be handling the distribution of the Moderna Vaccine.

- **Potential new 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).

**Moving Moderna Vaccine Between Sites**

Moderna vaccine may be shipped directly to sites in volumes of 100 doses per carton. While the CDC recommends that each site administering vaccine receive a direct shipment due to the smaller shipment size, CDC recognizes that redistribution of vaccine may be required in some instances by jurisdictions, federal and pharmacy partners. Based on
information to date from the manufacturer, immunization planners should consider the following general principles for redistribution of the Moderna COVID-19 vaccine:

- Once a vial of vaccine has been thawed, it may be stored refrigerated at 2-8°C (36° to 46°F) for up to 30 days
- Once thawed, the vaccine cannot be re-frozen
- When thawed, the vaccine should be handled with care and protected from shocks, drops, vibration, etc.
- Vaccine should be stored and transported in the frozen state at -25°C to -15°C (-13°F to 5°F) and should not be transported or stored below -40°C (-40°F) however when frozen transportation is not feasible, the vaccine can be transported in the liquid state at 2°C -8°C, for up to 12 hours, under routine road and air transport conditions with shaking and vibration minimized.

- If you must transport vaccine that has already been thawed, follow these general principles:
  - Care must be taken to ensure vaccine does not re-freeze during transport
  - Vaccine must be protected as much as possible from drops, shocks, and vibration whether in the carton, vial, case or cooler
  - Vaccine should be transported in the carton whenever possible
  - The vial should be placed with dunnage (padding material like bubble wrap or similar padding) to minimize movement during transport
  - The vaccine should always be transported in insulated containers qualified to maintain 2-8°C for the duration of transport
  - The transport containers must be secured when being transported to prevent unnecessary movement
  - Allowable timelines for transport of thawed vaccine are shown below. Total transport time should not exceed 12 hours in total
    - Transport while walking or using hand cart: not to exceed 1 hour
    - Vehicle transport: not to exceed 12 hours
    - Airplane transport (rotary wing aircraft not allowed): not to exceed 3 hours

14.3 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 for 3 months. 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.

Expiration Date

• The expiration date is NOT printed on the Janssen vaccine vial or carton.
• To determine the expiration date:
  o Scan the QR code located on the outer carton, or
  o Call 1-800-565-4008 or go to www.vaxcheck.jnj

Moving Janssen COVID-19 Vaccine Between Sites

• Transport Janssen COVID-19 Vaccine in a portable refrigerator unit or a container/ packout qualified to maintain temperature between 2°C and 8°C (36°F and 46°F). DO NOT use dry ice when transporting vaccine.
• To monitor vaccine temperatures, use a digital data logger with a buffered temperature probe that displays current, minimum, and maximum temperatures. A DDL with an external temperature display is preferred to minimize opening the transport container.
• Upon arrival at clinic, place vaccine in an on-site storage unit that maintains recommended temperatures, if available. If there is no storage unit available, keep the vaccine in the transport container, maintaining recommended temperatures.
• Temperature monitoring: Record time and min/max temperatures:
  o At the start of transport
  o Whenever the transport container is opened
  o When transport concludes
• Vaccine vials may be transported more than once.
• Both punctured and unpunctured vials may be transported.
  o Unpunctured vials of vaccine may be transported at refrigerated temperatures until the expiration date.
    ▪ CDC recommends the total time for transport alone or transport plus clinic workday should be a maximum of 8 hours (e.g., if transport to an off-site clinic is 1 hour each way, the clinic may run for up to 6 hours).
    ▪ CDC recommends transporting vaccine in vials. However, there may be instances when the only option is to transport predrawn vaccine in a syringe.
  o Punctured vials may be transported at refrigerated temperatures.
    ▪ Once punctured, store the vaccine at refrigerated temperatures.
    ▪ Vaccine must be used within 6 hours.
    ▪ Time used for transport counts as part of the 6-hour time limit.

For more information please see Janssen (Johnson & Johnson) COVID-19 Vaccine Transporting Vaccine for Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations (Appendix 48) See also the Transport Temperature Log When Transporting Vaccine Refrigerated Temperatures (Appendix 49)
14.4 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.
- 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.

14.5 Online Resources: Storage and Handling

<table>
<thead>
<tr>
<th>Training Program / Reference Material</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer COVID-19 Resources for HCP</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>Moderna COVID-19 Resources for HCP</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>Moderna COVID-19 Training</td>
<td></td>
</tr>
<tr>
<td>Resource</td>
<td>Description</td>
</tr>
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<td>----------</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 authorized by FDA.</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>
</tbody>
</table>

**15.0 Administration of Vaccine**
15.1 Dosing

15.1.1 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 vaccine is authorized for use in individuals 16 years of age and older.

15.1.2 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.

15.1.3 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>Doses/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>10</td>
<td>0.5 mL</td>
<td>10 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

1. Administer only full doses
2. Never try to pool vials to make a full dose
3. 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.

15.2 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.

15.3 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 of 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.

15.4 Second COVID-19 Vaccination Doses for Pfizer-BioNTech and Moderna COVID-19 Vaccines

15.4.1 Scheduling Second Dose Appointments and Managing Second Dose Inventory

The federal allocation system is designed such that providers will always automatically receive second doses to match the first dose allocation they received 2 or 3 weeks prior, depending on vaccine manufacturer, and in enough time to ensure availability for administration. Sites will be notified of the 2nd dose shipments at the appropriate time. It is important to remember that second doses do not arrive on the same day as first doses. For example, if you receive the allocation notice via email on Thursday night, the second doses outlined in that email will arrive at your site on that same day or the next day, Friday.

- Because second doses that match first dose allocations are sent to the same provider, the expectation is that individuals receive their second dose at the same site as their first dose. Providers should be ensuring plans are made to conduct second dose clinics when planning a first dose clinic and instructing and doing outreach to people to come back to the same provider for the second dose.

- While some providers may be able to accommodate a small number of people presenting to them for a second dose when they received the first dose from another provider due to no shows and overages, it is expected that second dose appointments are prioritized for people who had the first dose with that same provider while vaccines are in such limited supply.
• Note that if first doses were transferred to another provider, the corresponding second doses will need to be transferred 2 or 3 weeks later when they ship automatically. These transfers should be reflected in CVMS inventory for accurate tracking.

**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. |
| • Hold second-dose appointments on Saturday, Sunday, Monday, Tuesday, or Wednesday. Monday, Tuesday, or Wednesday second-dose appointments may smooth out vaccine administrations if they complement the days you hold first-dose clinics. |
| • 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. |

15.4.2 Converting second doses to first doses: The second dose should be administered as close to the recommended interval as possible.

• If it is not feasible to get the 2nd dose in that period (21 and 28 days for Pfizer and Moderna, respectively), a second dose appointment may be scheduled up to 6 weeks (42 days) after the first shot.

• If the provider has had 2 failed attempts to schedule an individual to come in for a 2nd shot and at least 49 days have passed since the first vaccination, a vaccinating provider may choose to proceed with using that designated 2nd dose as a 1st dose.

• Providers would need to plan accordingly when turning a second dose to a first knowing that a matching second dose will not be shipped to them.

• Providers should not convert more than 50% of their unused second doses as first doses to ensure sufficient supply for second doses and should ensure proper storage of the doses to be used at a later date as a second dose.

15.4.3 Unused doses at the end of a second dose clinics.

Every attempt should be made to limit the number of unused doses at the end of a second dose vaccination clinic using strategies described above.

• If you only need a small number of doses to finish a second dose clinic, for example 1-2 extra doses, you could take the extra doses from a thawed first dose vial if available, instead of thawing an entire new vial meant for second doses.

• If, even with employing these strategies, you still end a second dose clinic with unused doses in a vial, you can convert second doses to first doses and assume the overages (for example getting 6 doses from a Pfizer vial or 11 doses from a Moderna vial) or no-shows will even out the supply over time.

• As we only have supply promised for second doses to match first doses, you will need to use first doses that arrive in the week the 2nd doses are due to match those 2nd doses used as first doses.
15.4.4 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.). In such instances, individuals should be encouraged to return to the provider or location where they received their first dose. If that is not possible, providers should offer second doses to these individuals using unused second doses as outlined above.

15.5 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
- Any authorized COVID-19 vaccine can be used when indicated, no product preference
- 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.
- There are currently limited data on the safety of COVID-19 vaccines in pregnant people. All currently authorized COVID-19 vaccines are inactivated vaccines. There were no concerns demonstrated in animal developmental and reproductive toxicity (DART) studies. The Johnson & Johnson (Janssen) adenovirus vector platform was previously used for other clinical development programs that included pregnant people vaccinated during any trimester, including a large-scale Ebola vaccine trial. No adverse pregnancy-related outcomes – including infant outcomes – were determined to be related to the vaccine in these trials. There is increased risk in pregnant people of severe illness with COVID-19 (ICU admission, mechanical ventilation and death) and possible increased risk of adverse pregnancy outcomes such as preterm birth. Therefore, pregnant people may choose to receive COVID-19 vaccine when eligible. A conversation between the patient and clinical team may assist with decision but not required. That conversation should consider level of COVID-19 community transmission, personal risk of contracting COVID-19, risks of COVID-19 to patient and fetus, efficacy and side effects of vaccine, and limited data about vaccine during pregnancy.
- Prior receipt of an mRNA COVID-19 vaccine will not affect the results of SARS-CoV-2 viral tests (nucleic acid amplification or antigen tests). To evaluate the evidence of prior infection in an individual with a history of an mRNA COVID-19 vaccine, a test specifically evaluating IgM/IgG to the nucleocapsid protein should be used.
- The need for and timing of booster doses for mRNA COVID-19 vaccines has not been established. No additional doses beyond the one-dose Janssen (J&J) COVID-19 vaccine or two-dose mRNA COVID-10 vaccine primary series are recommended at this time.
- Any currently authorized COVID-19 vaccine can be administered to persons with underlying medical conditions who have no contraindication to vaccination, including:
  - Immunocompromised persons
People with autoimmune conditions
People with history of Guillain-Barre syndrome, Bell’s palsy, dermal filler use

- Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to both vaccines.
- Clinical trials demonstrate similar safety and efficacy profiles in persons with underlying medical conditions including those that place them at increased risk for severe COVID-19, compared to person without comorbidities.
- Because data are lacking on the safety and efficacy of COVID-19 vaccines administered simultaneously with other vaccines, the COVID-19 vaccine should routinely be administered alone, with a minimum interval of 14 days before or after administration of any other vaccine.
  - However, COVID-19 and other vaccines may be administered within a shorter period in situations where the benefits of vaccination are deemed to outweigh the potential unknown risks of vaccine coadministration (e.g., tetanus-toxoid-containing vaccination as part of wound management, rabies vaccination for post-exposure prophylaxis, measles or hepatitis A vaccination during an outbreak) or to avoid barriers to or delays in to COVID-19 vaccination (e.g., in long-term care facility residents or healthcare personnel who received influenza or other vaccinations before or upon admission or onboarding).
  - If COVID-19 vaccines are administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine.
- COVID-19 vaccine may not protect all vaccine recipients.

16.0 Vaccine Transfer Guidance

- CDC recommends that each site administering vaccine receive a direct shipment. However, CDC and NCDHHS recognize 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)
- Given the limited availability of vaccine, local health departments and hospitals should coordinate with each other and other COVID-19 vaccine enrolled community providers to determine if transfer of vaccine is necessary to reach priority population and to minimize waste of vaccine.
- Please note that the sending provider is also responsible for transferring the second dose corresponding to the first dose transfers.
- 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.
- Vaccine should only be transported and redistributed /transferred one time and should not be transported back again to the point of origin or to a new location.
- A current list of enrolled providers will be updated and shared regularly with all enrolled vaccine providers based on new enrollees in CVMS. The list should be used to assist with coordination of local efforts.
  - 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 below overview of the transfer process for COVID-19 vaccine only:
  - To initiate an OUTBOUND REDISTRIBUTION/TRANSFER to another location, the Healthcare Location Manager will have to submit a request through the CVMS Provider Portal by selecting the Vaccine Inventory tab from the Home Page. Then select the inventory record of the lot number you wish to transfer. Click the Related tab and select New beside Orders. Complete the required information.
  - The transferring provider will be asked to confirm the following:
    - Receiving Provider has a fully completed and submitted CDC COVID-19 Vaccine Program Provider Agreement and Profile in CVMS Provider Enrollment Portal
    - Sending Provider has confirmed with Receiving Provider that they have the appropriate capability and capacity to store the transferred COVID-19 Vaccines.
    - Sending Provider is not requesting transfer of open or partial vials.
    - Sending Provider is responsible for also transferring the corresponding 2nd doses for Pfizer and Moderna vaccine.
  - If the transfer is approved, you will receive an approval email, the status of the transfer will change to “transfer in transit” and your inventory will automatically reduce by the amount transferred.

### 17.0 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. These will initially be restricted to those currently eligible to receive vaccine and will expand as North Carolina moves through vaccination groups. 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.

#### 17.1 Vaccine allocation

Due to the hard work of vaccine providers in NC, we are now in a new phase of slowly improving vaccine supply and increasing percentages of county populations now vaccinated. However, demand still exceeds supply. NCDHHS is evolving the vaccine allocation strategy for the current stage, which continues to maintain a focus on speed and ensuring equitable vaccine distribution to historically marginalized populations. The updated methodology provides vaccine across the state in areas where it is most needed and helps ensure access to those that are not yet vaccinated.

The state continues to be allocated vaccines on a weekly basis from the federal government. Starting with vaccine allocations the week of March 22, NCDHHS will provide three-week baseline allocations based on the percentage of
residents in a county not yet vaccinated. This is a shift from previous baseline allocations that were based on the number of residents in a county.

**Allocation Strategy**

As outlined in the **Vaccine Allocation and Strategy letter** from January 26, we will continue reserving doses of the federal government allocation to North Carolina for enrolled providers to guarantee a minimum baseline allocation for the weeks of March 22, March 29, and April 5. For the next three-week period, we are continuing our two-part allocation process, composed of a “baseline allocation with equity increases” and a “set-aside allocation.”

Baseline first doses from the federal allocation are divided among all 100 counties based on the percentage of people unvaccinated in the county. Within each county, vaccine is then divided among providers depending on their reported capacity relative to other providers in the county. An additional amount of doses will be placed into the baseline and divided among certain providers who applied for “equity doses.” These equity doses were awarded based on criteria such as: a specific plan and partners to drive success for these doses, historical performance in the equity space, and readiness.

The remaining doses of the state’s allocation will be set aside to support various initiatives that are more likely to fluctuate. Set aside doses will go to long-term care settings, state facilities and community vaccination events based on applications and geographically spread throughout the state. Current supply levels do not allow for week-after-week support of any large events or efforts. As such, the State is currently rotating geographically around the state to support these efforts, to ensure geographic access. Events will be considered based on:

- **Equity**: Will the vaccine provider increase access in underserved communities and among historically marginalized populations (HMP)? This includes intentional outreach and engagement of HMP and geographic location across the state, including in places with relatively low amount of vaccine per population.
- **Operational readiness and speed**: Will the vaccine provider be able to start vaccination when doses arrive and exhaust all vaccine in a week? This includes full staffing needs, data entry lag in CVMS, and demonstrated ability to exhaust first dose supply within 7 days
- **Community partnerships**: Will the vaccine provider coordinate with multiple community partners, who may include local government, health department, health system, hospital, private organizations, and others.

New providers, including many pharmacies and primary care providers, are receiving allocation to help expand vaccine reach throughout North Carolina. We will continue to strategically add new providers in an effort to increase the State’s total vaccine administration capacity and ability to reach more of the population. However, we have far more providers that wish to receive vaccine than supply allows. Therefore, not all enrolled and activated providers will be included for a baseline allocation at this time.

Pfizer vaccine continues to be more than half of the NC vaccine supply each week with a minimum ship quantity of 1170 doses. This means that as we bring more providers onboard, we may also have to partner providers to share shipments of Pfizer. Sites that will need to share trays of Pfizer will be contacted directly and connected with partnering sites.

**Allocation weekly timing as of March 17, 2021**

- NCDHHS typically receives the state’s weekly allocation on Tuesday afternoon, and we aim to provide weekly allocations to our vaccine providers on Thursday. Baseline allocations will generally remain the same for a given three-week period.
• Providers must accept or decline their allocation in whole or in part no later than 12:00pm ET on Friday each week. Failure to accept doses each week by the deadline will result in doses being forfeited and reallocated to other providers.

• First doses of vaccine outlined in that allocation will arrive at the provider’s location on Tuesday or Wednesday of the following week, approximately 5 days after receiving notice of the allocation.

• Providers will ONLY receive notification of allocation on Thursdays if they are receiving vaccines for the following week. Even if a provider received vaccine allocation in a previous week, they are not guaranteed a first dose allocation in subsequent weeks.

• Please note that allocations of the Johnson & Johnson (Janssen) vaccine continue to be irregular and off-cycle and are not included in this baseline allocations. This will be reassessed in the next baseline.

• As long as vaccine supply remains very low, all first-doses of vaccine that arrive on Tuesday or Wednesday must be administered and entered into the CVMS platform by Monday evening of the following week.

• Attempt to complete your first-dose administrations on Thursday, Friday, Saturday, and Sunday. Reserve Monday for using up vaccine that is left from no-shows or cancellations and to confirm that all administration data is entered into CVMS. You can call individuals from your waitlist Sunday night to finish up the small clinic on Monday.

Providers must be ready to follow these expectations when accepting the allocation:

• All first doses of vaccines must be administered and entered into the COVID-19 Vaccine Management System (CVMS) by the Monday evening after their arrival.

• Providers should fully enter vaccine administrations into CVMS within 24 hours, but no later than 72 hours.
  o 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.

• Vaccine cannot be restricted based on county of residency. Individuals should not be required to present identification to verify age or residency.

• High-volume vaccination events should create access for individuals in the community in addition to serving the provider’s patients.

• 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, targeted outreach and vaccine events to vaccinate historically marginalized populations and meet this goal.

• Providers agree to vaccinate in accordance with the State’s prioritized groups.

Enrolled providers receiving vaccine may transfer vaccine in accordance with vaccine-specific storage/handling requirements to other enrolled, onboarded providers who are ready to administer vaccines. Further details on vaccine transfer can be found in Section 16. The list of enrolled providers will be sent out via email weekly to enrolled providers receiving vaccine allocations to assist with coordination of local efforts.

17.2 Identify vaccine sites. 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 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, 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

17.3 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

17.4 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.

17.5 Consecutive days at an offsite clinic. If satellite clinics/PODS 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. 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

17.6 Make a Staffing Plan

• Refine staffing plans to allow for improved staff and patient experiences as increasing numbers of North Carolinians are eligible for COVID-19 vaccination
• 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](https://www.cdc.gov/vaccines/COVID-19/training/index.html) has a list of immunization training and education materials for vaccine providers, including basic and COVID-19-vaccine specific information.

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<th>Role/ Responsibility</th>
<th>Requirements and Considerations</th>
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| 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](https://www.cdc.gov/vaccines/COVID-19/storage-handling/index.html), including the COVID-19 vaccine addendum  
   • Complete the [You Call The Shots: Storage and Handling module](https://www.cdc.gov/vaccines/COVID-19/storage-handling/index.html)  
   • Complete the Pfizer-BioNTech and [Moderna] COVID-19 Vaccine training and other specific trainings as they become available  
   • Complete the [COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare Providers](https://www.cdc.gov/vaccines/COVID-19/training/index.html)  |
| 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](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/screening/cancing-pre-vaccination-screening-form.pdf)                                                                                                                   |
| Vaccinate                        | Vaccinators must be health care providers whose scope of practice includes vaccinations. Provides completed vaccination card to document vaccine receipt.                                                                                                                                 |
| Monitor patient post-vaccination | 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)](https://www.vaers.hhs.gov) and also provide [v-safe](https://www.cdc.gov/vaccines/COVID-19/v-safe.html) information to the recipient so that recipients can self-enroll for a post-vaccination health check-in, as well as a 2nd dose reminder. |
| Schedule 2nd dose                 | 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. |
Field incoming requests from individuals

Build upon existing call center functions, if available. See scripts in Appendix 33 for additional considerations.

Data entry

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.

Logistics

Vaccine providers should consider the need for security, traffic control, cleaning, medical waste, bathrooms, running water, power/electrical, online access

17.7 Schedule Appointments.

Scheduling vaccine appointments allows individuals to safely socially distance and allows vaccine providers to manage limited supply of vaccine and variable demand across the vaccine groups.

Scheduling Promising Practices

- You should indicate at the top of your website and on your phone system messaging whether you are currently scheduling appointments or if all are full.
- Wait to schedule appointments for the coming vaccine week until you have received the allocation. Use a waitlist to allow individuals to know they are “in line” and pull appointments from that waitlist for the following week as soon as you receive the allocation. (See Section 17.8)
- Reserve appointment slots to promote equitable vaccine distribution (see Section 18 for more details)
- Avoid scheduling first-dose administration or planning first-dose events on Tuesday and Wednesday, because of the variability in shipping from the federal government.
- Have an on-call list of people in the current priority groups who can be called to come to a vaccination event if doses remain at the end of the event due to no-shows, last-minute cancellations, or unforeseen additional doses from available vials (e.g., consistently getting 6 doses per vial of Pfizer).
- Create Vaccine Interest portals/forms where people can input information, and the vaccine provider can contact individuals when vaccine availability allows.
- Vaccine providers can use their own existing software solutions for scheduling or look into no-cost, online scheduling solutions (e.g., Calendly, Setmore, Picktime).
- Use emergency alert systems that email, text, or call to reach out to the public to indicate current vaccine group and instructions on securing a vaccine appointment.
- Schedule individual or groupings of appointments. If not using EHR for scheduling, consider an application that can be embedded in your website.

Second Dose Scheduling Promising 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.
- Hold second-dose appointments on Saturday, Sunday, Monday, Tuesday, or Wednesday. Monday, Tuesday, or Wednesday second-dose appointments may smooth out vaccine administrations if they complement the days you hold first-dose clinics.
• 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

17.8 Maintain a Waitlist
With current vaccine demand far exceeding supply, waitlists can be a useful tool to help people find their spot. They should be developed and managed with care in order to maintain and create a positive patient experience. Additional considerations are outlined below:

• Provide clear communication to people about your waitlist, including when (and how) they might expect to hear from you, if (and how) they can inquire about their place in line, and realistic expectations about current vaccine supply.
• An effective waitlist or short-notice call-in list can be as simple as a call-back sheet maintained within the office, or as robust as an on-line software application with reporting capability for provider office staff to manage.
• Early experience shows that unlimited waitlists or interest portals can create challenges for vaccine providers to manage. Placing individuals on a waitlist based on their vaccine group, risk of severe illness or death, and/or risk of COVID-19 exposure can mitigate this challenge.
• Consider ongoing capacity for COVID vaccination, first and second doses, to determine the number of people that could be placed on a waitlist.
• Develop a process so that people who receive a vaccine elsewhere can easily notify your office to be removed from the waitlist.

17.9 Offer 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](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
  o 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
  o See North Carolina Public Transit Systems map and list of contact information
17.10 Register individuals in CVMS.

As of the date of this publication, CVMS registration can be accomplished in two ways. Please see Section 7 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 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.

17.11 Document 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. Future releases of CVMS will be designed to support EHR integration and minimize the need for dual documentation.

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<th>Documentation in CVMS Promising Practices</th>
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<tbody>
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<td>• CVMS pre-registration for vaccine recipients when possible</td>
</tr>
<tr>
<td>• 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.</td>
</tr>
<tr>
<td>• 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.</td>
</tr>
<tr>
<td>• Plan technology, IT, or hardware needs to support real-time or simultaneous data entry. For example, consider using electronic tablets and onsite Wi-Fi units or hotspot units.</td>
</tr>
<tr>
<td>• 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.</td>
</tr>
<tr>
<td>• Complete COVID vaccine cards with vaccine administration information, then enter recipient information from that vaccination card to improve data entry accuracy.</td>
</tr>
<tr>
<td>• For large vaccination clinics, utilize rolling laptop carts to aid mobility and provide cleanable surface for documents.</td>
</tr>
<tr>
<td>• Utilize mobile hotspots for drive-through operations or large areas to aid mobility.</td>
</tr>
</tbody>
</table>
• 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.
  o 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.**
• **CVMS Inventory Levels Form**
  o 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.

17.12 Vaccination Clinic or Event Flow.

17.12.1 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 adhere to the mask requirements as issued in Governor Cooper’s executive orders, which includes wearing a mask in any public indoor space even when maintaining 6 feet of distance or whenever a person is with someone who is not from the same household.

• 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).
17.12.2 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.

18.0 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.

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 BH/IDD organizations for vaccine events, and options for home bound individuals.

18.1 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.
Partner with community health workers to provide accurate information about vaccines and how to get vaccinated
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](https://www.eventbrite.com/e/vaccine-101-presenter-trainings-tickets-136015480965)

18.2 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 behavioral health/IDD day programs, such as club houses, to ensure individuals with disabilities have adequate access to vaccine. Vaccine providers can request allocations of NCDHHS’ set-aside COVID-19 vaccine doses for events. To do this, providers submit requests via a ReadyOp online survey form. Requests can be for one-time events or recurring. Submitting a request for a recurring event does not guarantee an allocation. Due to limited supply, the State is only able to support a limited number of events or efforts per week. Each week, there will likely be more requests than what can be supported with current supply as of March 2021.
  - Current supply levels do not allow for week-after-week support of any large events or efforts. There are always more top-scoring proposals than available doses, so we must sometimes reduce the requested amount. As such, the State is currently rotating geographically around the state to support these efforts for one week at a time, to ensure geographic access.
  - NCDHHS assesses requests for event allocations and scores them on a scale of 0 to 2 across the following criteria:
    - **Equity** - Will the vaccine provider increase access in underserved communities and among historically marginalized populations (HMP)? This includes intentional outreach and engagement of HMP and geographic location across the state, including in places with relatively low amount of vaccine per population.
    - **Operational readiness** - Will the vaccine provider be able to start vaccination when doses arrive and exhaust all vaccine in a week? This includes full staffing needs, data entry lag in CVMS, and demonstrated ability to exhaust first dose supply within 7 days
    - **Community partnerships** - Will the vaccine provider coordinate with multiple community partners, who may include local government, health department, health system, hospital, private organizations, and others?
  - Doses allocated for events are included with a provider’s regular vaccine shipment if using Pfizer or Moderna or may come off-cycle for Johnson and Johnson. It is up the provider to carry out the proposed event. DHHS vaccine case managers check in with providers about vaccine operations and help troubleshoot issues that providers may be facing, such as inventory management or CVMS data entry.
  - In some cases, North Carolina Emergency Management and/or National Guard work with providers to help coordinate event logistics.

- **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.

### 18.3 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
- 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.

This is an excerpt from the HHS Office for Civil Rights in Action released a Bulletin: Ensuring the Rights of Persons with Limited English Proficiency in Health Care During COVID-19 at:


### 18.4 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.

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 new 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

18.5 Prioritize scheduling historically marginalized populations at vaccine clinics

<table>
<thead>
<tr>
<th>Suggested Practices for Using Equity Doses</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Event Tickets</strong></td>
</tr>
<tr>
<td>• Print and pre-populate tickets with time/date of vaccine slot</td>
</tr>
<tr>
<td>• Distribute in person to groups who meet the priority criteria; allow them to share their ticket to someone else who meets criteria in their place</td>
</tr>
<tr>
<td>• Hold event in accessible location to the community</td>
</tr>
<tr>
<td><strong>Partnering with senior subsidized housing organizations</strong></td>
</tr>
<tr>
<td>• Offering events “on location” with appointments planned and scheduled with housing partner</td>
</tr>
<tr>
<td><strong>Partnering with faith and community organizations</strong></td>
</tr>
<tr>
<td>• Offering events “on location” in large locations or offering “special events” for members of the same congregation</td>
</tr>
<tr>
<td>• Partner organization assists with scheduling appointments in advance</td>
</tr>
<tr>
<td>o Partner with Hispanic/LatinX community-based organizations to offer interpretation services and culturally appropriate strategies on the outreach.</td>
</tr>
<tr>
<td>o Partner with black churches, fraternity and sororities to adopt a vaccination day</td>
</tr>
<tr>
<td>o Coordinate clinics and appointment registration with agencies that serve low-income individuals in eligible groups</td>
</tr>
<tr>
<td><strong>Holding slots for HMPs</strong></td>
</tr>
<tr>
<td>• Reserve slots proportionate to your county’s HMP population. For example, out of 100 daily slots, reserve 40 to ensure they are filled with individuals from HMP first. Notate this on waitlists or create different waitlists to allow for this prioritization</td>
</tr>
<tr>
<td>• Preferentially reach out to and schedule slots before opening to general population based on EMR demographic data</td>
</tr>
<tr>
<td>• The number of these reserved appointments should match the demographics of your local community.</td>
</tr>
<tr>
<td>• Open a set-aside block of appointments first to community health workers, care managers, churches or other community partners that will educate and recruit underserved community members</td>
</tr>
</tbody>
</table>

18.6 Engage with local partners serving historically marginalized populations
• First call health care providers serving historically marginalized communities to coordinate outreach to their patients who are 65 years and older or front-line essential workers
• 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

**18.7 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](#) and vaccine provider reports that are distributed weekly
- Be transparent with the data to your staff and partners, share when equity success happens, and be humble in receiving feedback and support

**19.0 Payment and Billing of COVID-19 Vaccine**

**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](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.

American Medical Association (AMA) has published new COVID-19 vaccine product and administration CPT® codes for two coronavirus vaccines. The codes will become effective once each vaccine product receives an EUA or becomes licensed by the FDA. For quick reference, these codes are listed below:

- **Pfizer-BioNTech vaccine**
  
  **91300:** Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3mL dosage, diluent reconstituted, for intramuscular use.
  
  **NDC (11 digit format) Labeler Product ID (Vial):** 59267-1000-01

  **0001A:** Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3mL dosage, diluent reconstituted; first dose.

  **0002A:** Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3mL dosage, diluent reconstituted; second dose.
• Moderna COVID-19 vaccine
  91301: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5mL dosage, for intramuscular use.
  NDC (11 digit format) Labeler Product ID (Vial): 80777-0273-10

  0011A: Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5mL dosage; first dose.

  0012A: Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5mL dosage; second dose.

• Janssen COVID-19 vaccine (Johnson & Johnson)
  91303: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, adenovirus type 26 (Ad26) vector, preservative free, 5x10^10 viral particles/0.5mL dosage, for intramuscular use.
  NDC (11 digit format) Labeler Product ID (Vial): 59676-0580-15

  0031A: Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, adenovirus type 26 (Ad26) vector, preservative free, 5x10^10 viral particles/0.5mL dosage, single dose.


NC Medicaid Coding and Billing for COVID-19 Vaccine Administration

<table>
<thead>
<tr>
<th>Vaccine CPT Code</th>
<th>ICD-10 Code</th>
<th>Vaccine Code Descriptor</th>
<th>Vaccine Admin Code(s)</th>
<th>Vaccine Name</th>
<th>Unit of Coverage</th>
<th>NDC 11 Digit Product ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>91300</td>
<td>223</td>
<td>Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike</td>
<td>0001A (1st dose) 0002A (2nd dose)</td>
<td>Pfizer-BioNTech COVID-19 Vaccine</td>
<td>0.3mL</td>
<td>59267-1000-01 59267-1000-02 59267-1000-03</td>
</tr>
<tr>
<td>NDC Units reported as “UN1”</td>
<td>NDC Units reported as “UN1”</td>
<td>NDC Units reported as “UN1”</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>protein, preservative free, 30 mcg/0.3mL dosage, diluent reconstituted, for intramuscular use</td>
<td>0011A (1st dose) 0012A (2nd dose)</td>
<td>Moderna COVID-19 Vaccine 0.5mL 80777-0273-10 80777-0273-99</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>91301 Z23 Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5mL dosage, for intramuscular use</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>91303 Z23 Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, adenovirus type 26 (Ad26) vector, preservative free, 5x10¹⁰ viral particles/0.5mL dosage, for intramuscular use</td>
<td>0031A (single dose)</td>
<td>Janssen COVID-19 Vaccine 0.5mL 59676-0580-05 59676-0580-15</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Claims must contain both administration codes and vaccine codes to pay. Vaccine codes should be reported as $0.00.
- The NDC units should be reported as “UN1”
  - Pfizer BioNTech COVID-19 Vaccine 0.3mL = 1 unit
  - Moderna COVID-19 Vaccine 0.5mL = 1 unit
  - Janssen COVID-19 Vaccine 0.5mL = 1 unit
- Claims for first vaccine dose must have been processed in NCTracks prior to processing a claim for second dose.
- Medicaid and NC Health Choice do not allow copays to be charged for COVID-19 immunization or administrations.
- Modifiers
  - TJ modifier should be used for NC Health Choice claims (age 6 through 18 years).
EP modifier should be used for all non-NC Health Choice (only Medicaid beneficiaries) younger than 21 years of age.
SL modifier should be used for reporting state supplied vaccines.

If you have any questions about product specific information, please contact the Immunization Branch Help Desk at 1-877-873-6247 and press option ‘6.’ If you have any questions about billing NC Medicaid, please call the GDIT Call Center at 1-800-688-6696.

Visit Medicaid’s website for these guidelines: https://medicaid.ncdhhs.gov/providers/medicaid-bulletin

Health Resources and Services Administration (HRSA) COVID-19 Uninsured Program Coding and Billing for COVID-19 Vaccine Administration

The HRSA COVID-19 Uninsured Program’s reimbursement will be based on current year Medicare fee schedule rates. The Medicare approved COVID-19 vaccination administration rate at first dose $16.94 and second dose $28.39. The Medicare approved COVID-19 vaccination administration for single-dose vaccines is $28.39.

Claims submitted for the administration of a FDA-licensed or authorized vaccine must be submitted as single line item claims, and must include one of the following codes to be eligible for reimbursement:

- Pfizer: 0001A, 0002A
- Moderna: 0011A, 0012A
- Janssen: 0031A

Please note that only the administration of the vaccine is eligible for reimbursement through the HRSA COVID-19 Uninsured Program.

Visit HRSA’s Uninsured Program website for these guidelines: https://coviduninsuredclaim.linkhealth.com/

20.0 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.

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. If you are a provider calling from a number with a North Carolina area code, please call (877) 873-6247 and select option 8 for COVID-19 questions. If you are a provider calling from a number with an area code outside of North Carolina, dial (919) 707-5588 and select option 8. 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:
  - 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.

- Pfizer is providing Customer Service for those vaccine providers that receive Pfizer vaccine for questions related to its product, please see below:
• 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**
1-855-MODERNAC (1-855-663-7082)
Open: 8am – 8pm ET, 7 days/week

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

**Medical Information**
https://www.modernac.com/covid19vaccine-
edusa
(1-855-663-3702)
Open (Covid Vaccine 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

FDA will also have a Frequently Asked Questions page for the Janssen COVID-19 Vaccine
### Appendix / Reference Material

| Appendix 1 – EUA Fact Sheet for Recipients and Caregivers – Pfizer | Pfizer-BioNTech COVID-19 Vaccine | FDA |
| Appendix 2 – EUA Fact Sheet for Health Care Providers Administering Vaccine – Pfizer | Pfizer-BioNTech COVID-19 Vaccine | FDA |
| Appendix 4 – V-safe Information Sheet | V-safe Print Resources | CDC |
| Appendix 5 – V-safe poster | V-safe Print Resources | CDC |
| Appendix 7 – COVID-19 Vaccine Readiness Checklist | https://files.nc.gov/covid/organization_readiness_checklist_vfinal.docx |
| Appendix 8 – Pfizer Storage and Handling Checklist | Product Storage and Dry Ice | CVDvaccine-US.com (cvdvaccine-us.com) |
| Appendix 9 – Pfizer Storage and Handling Overview | Please see Technical Appendix |
| Appendix 10 – Bulk upload template | https://files.nc.gov/covid/recipient_bulk_upload_file.csv |
| Appendix 11 – EUA Fact Sheet for Recipients and Caregivers – Moderna | Moderna COVID-19 Vaccine | FDA |
| Appendix 12 – EUA Fact Sheet for Health Care Providers Administering Vaccine – Moderna | Moderna COVID-19 Vaccine | FDA |
| Appendix 13 – Storage and Handling Overview Moderna | https://www.modernatx.com/covid19vaccine-eua/providers/storage-handling.pdf |
| Appendix 14 - Sample/Template LHD Standing Order for Moderna COVID-19 Vaccine & Pfizer-BioNTech COVID-19 Vaccine | Please see Technical Appendix |
| Appendix 15 – FDA Letter of Authorization for Moderna | Moderna COVID-19 Vaccine | FDA |
| Appendix 18 – CDC Pre-Vaccination Checklist English and Spanish Version for COVID-19 Vaccines | English: Vaccine Administration: Intramuscular (IM) injections: Adults 19 years of age and older (cdc.gov)  
<p>| Appendix 25 – CVMS Offline Appointment Scheduling User Guide | CVMS Offline Operations (Bottom of Page) |</p>
<table>
<thead>
<tr>
<th>Appendix</th>
<th>DEEPER DIVE: Group 1. Health Care Workers &amp; Long-Term Care Staff and Residents</th>
<th><a href="https://files.nc.gov/covid/documents/vaccines/Deeper-Dive-Group-1.pdf">Link</a></th>
</tr>
</thead>
<tbody>
<tr>
<td>Appendix 26.2</td>
<td>DEEPER DIVE: Group 2 – Older Adults</td>
<td><a href="https://files.nc.gov/covid/documents/vaccines/Deeper-Dive-Group-2.pdf">Link</a></td>
</tr>
<tr>
<td>Appendix 28</td>
<td>Medical Management of Vaccine Reactions in Adults in a Community Setting</td>
<td><a href="https://immunize.org/catg.d/p3082.pdf">Link</a></td>
</tr>
<tr>
<td>Appendix 29</td>
<td>FACT SHEET: Pfizer-BioNTech</td>
<td>[Link](Pfizer-BioNTech COVID-19 Vaccine</td>
</tr>
<tr>
<td>Appendix 30</td>
<td>FACT SHEET: Moderna</td>
<td>[Link](Moderna COVID-19 Vaccine</td>
</tr>
<tr>
<td>Appendix 31</td>
<td>DEEPER DIVE: Group 4 - Adults at High Risk for Exposure and Increased Risk of Severe Illness</td>
<td><a href="https://files.nc.gov/covid/documents/vaccines/Deeper-Dive-Group-4-Essential-Workers-Not-Yet-Vaccinated.pdf">Link</a></td>
</tr>
<tr>
<td>Appendix 36</td>
<td>Tip Sheet for Selfie Video on COVID-19 Vaccination.</td>
<td><a href="https://files.nc.gov/covid/documents/vaccines/NC-Vaccine-Selfie-Video-Tip-Sheet.pdf">Link</a></td>
</tr>
<tr>
<td>Appendix 38</td>
<td>COVID-19 Community Based Vaccination Events: Best Practices.</td>
<td>Please see Technical Appendix</td>
</tr>
<tr>
<td>Appendix 39</td>
<td>CDC COVID-19 Vaccination Program Provider Agreement</td>
<td>Please see Technical Appendix</td>
</tr>
<tr>
<td>Appendix 40</td>
<td>Vaccine Letter to County Leaders</td>
<td>Please see Technical Appendix</td>
</tr>
<tr>
<td>Appendix 45</td>
<td>CVMS Organization Portal email template for vaccine providers to use to invite organizations</td>
<td>Please see Technical Appendix</td>
</tr>
<tr>
<td>Appendix 46</td>
<td>CVMS Organization Portal email templates for organizations to use to inform employees</td>
<td>Please see Technical Appendix</td>
</tr>
<tr>
<td>Appendix 47</td>
<td>Janssen (Johnson &amp;Johnson) Storage and Handling Summary</td>
<td><a href="https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/downloads/janssen-storage-handling-summary.pdf">Link</a></td>
</tr>
<tr>
<td>Appendix 48</td>
<td>Janssen (Johnson &amp; Johnson) COVID-19 Vaccine Transporting Vaccine for Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations</td>
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<tr>
<td>Appendix 49</td>
<td>Transport Temperature Log When Transporting Vaccine Refrigerated Temperatures</td>
<td></td>
</tr>
<tr>
<td>Appendix 50</td>
<td>– NC State Health Director’s Statewide Standing Order for FDA Authorized COVID-19 Vaccine Administration of Janssen (Johnson &amp; Johnson)</td>
<td></td>
</tr>
</tbody>
</table>