COVID-19 Vaccine Provider Guidance
Published January 5, 2021 | Updated December 1, 2021

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

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1.0 Executive Summary

1.1 Purpose

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

1.2 Organization of Guidance

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

1.3 Updating of Guidance

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

1.4 Revision Log and Document Live Link

The most recent version of the document will be posted on the NCDHHS website. The link will be provided once available.
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|               |                 | **Section 3**: Group 1 [updated]                                       |
|               |                 | **Section 4**: Group 2 [updated]                                       |
|               |                 | **Section 5**: Planning and Running Vaccination Clinics and Events [updated]; Vaccinating Outside Jurisdiction [new section], Modifications to the Pfizer/Moderna Standing Order template [new section] |
|               |                 | **Section 7**: Vaccine Transfer Guidance [updated]                     |
|               |                 | **Appendix 1** [updated to reference Group 1]                         |
|               |                 | **Appendix 2** [updated to include new talking points]                |
|               |                 | **Appendix 3** [updated to reference Group 2]                        |
|               |                 | **Appendix 4** [updated to reference Group 2]                        |
|               |                 | **Appendix 5** [updated to include new content]                      |
| Version 3.0   | January 27, 2021| Changed the title of the document  
|               |                 | **Section 2**: Overview of NC’s COVID-19 Vaccination Plan [updated]  
|               |                 | **Section 3**: Group 1 [minor updates]                                |
|               |                 | **Section 4**: Group 2 [minor updates]                                |
|               |                 | **Section 5**: Group 3 [New section]                                  |
|               |                 | **Section 6**: Guidance for Vaccine Providers [updated]               |
|               |                 | **Section 7**: Scenario Planning [updated]                            |
|               |                 | **Appendix 2** [minor updates]                                         |
|               |                 | **Appendix 4** [minor updates]                                         |
|               |                 | **Appendix 5** [minor updates]                                         |
|               |                 | **Appendix 7** [minor updates]                                         |
|               |                 | **Appendix 8 COVID-19 Community Based Vaccination Events: Best Practices [New] |
| Version 4.0   | February 16, 2021| Combined with LHD Vaccine Toolkit with several new sections noted below  
<p>|               |                 | <strong>Section 3</strong>: Group 1 [minor updates]                                |
|               |                 | <strong>Section 4</strong>: Group 2 [Updated]                                       |
|               |                 | <strong>Section 5</strong>: Group 3 [Updated]                                       |
|               |                 | <strong>Section 9</strong>: Communicating with Patients about Vaccines [Updated]    |
|               |                 | <strong>Section 10</strong>: Who Can Be A COVID Vaccine Provider? [New]             |
|               |                 | <strong>Section 11</strong>: Readiness Checklist for Newly Enrolled Providers (Abbreviated) [Updated] |
|               |                 | <strong>Section 12</strong>: Guidance for Collaboration Among Vaccine Providers [Updated and renamed] |</p>
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| Section 5.0: Special Populations to Consider [Updated Subsections 5.2, 5.3 and 5.4] |
| Section 6.0: Communicating with Patients About Vaccines [Updates to 6.2 and New Subsections 6.3 Key Messages Related to Adolescents and 6.4.3 Vaccinating North Carolinians Ages 12 and Older] |
| Section 7.0: COVID-19 Vaccine Management System [Subsection 7.6 Added Information about CVMS Version 7.0] |
| Section 9.0: Newly Enrolled Providers [Added More Information about Increasing Access to and Use of Vaccine] |
| Section 11: COVID-19 Vaccination Legal Considerations [Updates to Include Language About Authorization to 12 years] |
| Section 12: COVID-19 Vaccine Clinical Information and Guidance [Updates related to Pfizer, Moderna and Janssen (Johnson &amp; Johnson)] |
| Section 13: Orders to Administer COVID-19 Vaccine [Updated with Information About Amended Pfizer/Moderna Combined Standing Order] |
| Section 14: Vaccine Storage and Handling [Updates to Pfizer Storage and Transportation Guidance] |
| Section 15: Administration of Vaccine [Updated &amp; Renamed Section 15.5 Vaccine Wastage and Unused Doses, New Subsection 15.6 Coadministration with Other Vaccines, Updates to Additional Vaccine Administration Considerations] |
| Section 17: Planning and Running Vaccination Clinics and Events [Updates to Subsection 17.1 Vaccine Allocation] |
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Section 5.0: Special Populations to Consider [Renumbering of Subsections, Added to 5.1.2 Information About Vaccine at Home Program, Added to Section 5.2 Vaccination of Minors About FDA Approved and Authorized Pfizer COVID-19 Vaccine and Changes Related to Minor’s Consent, Section 5.3 Added New CDC Recommendation About Pregnant and Lactating Women, and Added New Subsection 5.4 Vaccination of People Who Are Moderately to Severely Immunocompromised]

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

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

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

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

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

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

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

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

Section 16.0: Planning and Running Vaccination Clinics and Events [Added to Subsection 16.2 About the Vaccine at Home Program]
<table>
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**Appendix/Reference Material [Added Appendices 59 and 60]**

| Section 4.0: Vaccine Eligibility [Added Information Related to the Booster Dose of Pfizer COVID-19 Vaccine] |
| Section 5.0: Special Populations to Consider [Added Information to Subsection 5.2 Vaccination of Minors and Subsection 5.5 Vaccination of Employees] |
| Section 6.0: Communication and Outreach with Patients About Vaccines [Updates to Several Subsections with Some Renumbering and New Subsection on Key Messages Related to the Booster Dose] |
| Section 7.0: COVID-19 Vaccine Management System (CVMS): [Updated and Renumbered from Subsections 7.8 - 7.12 with New Subsection on Entering Information in CVMS If a Person Has More Than One Name] |
| Section 9.0: Newly Enrolled Providers [Minor Updates on Process] |
| Section 11.0: COVID-19 Clinical Information and Guidance [Added Information About Booster Dose of Pfizer COVID-19 Vaccine, Information about People Who Received COVID-19 Vaccine as Part of a Clinical Trial and Renumbered Several Subsections] |
| Section 12.0: Orders to Administer COVID-19 Vaccine [Updated Information About Revised and Now Separate Statewide Standing Orders for Pfizer and Moderna] |
| Section 13.0: Vaccine Storage and Handling [Added Information in Subsection 13.1 About Pfizer Ultra-Cold Storage, First Re-Icing, and 450 Dose Configuration, Updates to Section 13.5 Vaccine Expiration] |
| Section 14.0: Vaccine Administration [Updated, Added and Renumbered Several Subsections to Include Information About Additional and Booster Doses, Use of Monoclonal Antibodies, and Proof of Vaccination] |
| Section 15.0: Vaccine Transfer Guidance [Updated Throughout] |
| Section 16.0: Planning and Running Vaccination Clinics and Events [Significant Updates to Subsection 16.1 Vaccine Allocation and Expectations] |
| Section 17.0: Promoting Equitable Vaccine Distribution [Revised and Renumbered All Subsections and Added New Graphic Equity Tips at a Glance] |

**Appendix and Reference Material** [Appendix 44 Changed to Separate Statewide Standing Order for Pfizer and Added Appendix 61 for Separate Statewide Standing Order for Moderna]
Version 14.0  October 29, 2021

**Section 4.0**: Vaccine Eligibility [Added New Information Related to Booster Doses of Pfizer, Moderna and Johnson & Johnson (Janssen) vaccines]

**Section 6.0**: Communication and Outreach with Patients About Vaccines [Updated Several Sections and Added New Information Related to Booster Doses and Related to Anticipated Pediatric Vaccines for ages 5-11]

**Section 7.0**: COVID-19 Vaccine Management System [Shortened, Renumbered, and Updated in Several Subsections Including Information Related to Integration with NCIR]

**Section 9.0**: Newly Enrolling Providers [Revised and Updated]

**Section 11**: COVID-19 Clinical Information and Guidance [Updates Including New Information Related to Booster Doses for Pfizer, Moderna, and Johnson & Johnson (Janssen)]

**Section 12.0**: Orders to Administer COVID-19 Vaccine [Updated with Information About Revised Statewide Standing Orders for All COVID-19 Vaccines]

**Section 13**: Vaccine Storage and Handling [Updates Especially Related to Moderna Booster Dose and Moderna Expirations Dates]

**Section 14**: Administration of Vaccines [Updates Related to Dosing, Intervals, and Interchangeability for Pfizer, Moderna and Johnson & Johnson (Janssen) Vaccines]

**Section 16**: Planning and Running Vaccination Clinics and Events [Updated, Reorganized, and Reinforced Need to Follow Weekly Emails and How to Order Minimum Vaccine Allocations]

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Version 15.0  November 12, 2021

**Section 3.0**: Overview of North Carolina’s COVID-19 Plan [Updated about EUA for 5-11 Years of Age Pfizer Vaccine]

**Section 4.0**: Vaccine Eligibility [Updated About EUA for 5-11 Years of Age Pfizer Vaccine]

**Section 5.0**: Special Populations to Consider [Updated About 5-11 Years of Age Pfizer Vaccine and Different Pfizer Formulations, and Vaccinating Pregnant and Lactating Women]

**Section 6.0**: Communication and Outreach With Patients About Vaccines [Updated Several Sections About Key Messages Revised Section on Vaccinating All North Carolinians 5 Years and Older and Additional Communication Resources]

**Section 7.0**: COVID-19 Vaccine Documentation and Reporting [Renamed Section to Reflect Ability to Use NCIR Due to More NCIR/CVMS Integration]
Section 8.0: Who Can Be A COVID-19 Vaccine Provider [Added Information About Use of CVMS Provider Enrollment Portal]

Section 9.0: Newly Enrolling Providers [Added Information About Use of CVMS Provider Enrollment Portal and NCIR COVID-19 Vaccine Provider Enrollment Process]

Section 10: COVID-19 Vaccination Legal Considerations [Added Information About Use and Written Consent for 5-11 Years of Age Pfizer Vaccine]

Section 11: COVID-19 Vaccine Clinical Information and Guidance [Added More Information About Use of COMIRNATY, New Information Related to 5 Through 11 Years of Age Pfizer Vaccine and New Formulation of Pfizer for 12 Years and Older, Revised EUA Fact Sheets for Health Care Providers, Recipients and Caregivers For the Pfizer Formulations, Other Updated Pfizer Documents, and Updated CDC Ingredients Summary Table With Different Authorized Pfizer Formulations]

Section 12: Orders to Administer COVID-19 Vaccine [Two Statewide Standing Orders Now Exist for 5-11 Years of Age and 12 Years and Older, Revisions to Moderna and Johnson & Johnson (Janssen) Statewide Standing Orders to Clarify for Boosters]

Section 13: Vaccine Storage and Handling [Multiple Updates Related to Pfizer Vaccine Formulations Especially 5-11 Years of Age Pfizer and Moderna]

Section 14: Administration of Vaccines [Multiple Updates Related to 5-11 Years of Age Pfizer]

Section 16: Planning and Running Vaccination Clinics and Events [IMPORTANT UPDATES to 16.1 Vaccine Allocation]

Appendix and Reference Materials: Updated Several Links for Appendices Related to Pfizer and Now Two Statewide Standing Orders Related to Pfizer Vaccine Products:

REVISED Appendix 44: NC State Health Director’s Statewide Standing Order for COMIRNATY/Pfizer-BioNTech mRNA COVID-19 Vaccine Administration in Patients Ages 12 Years and Older

NEW Appendix 62: NC State Health Director’s Statewide Standing Order for Pfizer-BioNTech mRNA COVID-19 Vaccine Administration in Patients Ages 5-11 Years

Section 4.0: Vaccination Eligibility: Individuals Ages 5 Years and Older [Updates About CDC Emergency Use Instructions (EUI) for Booster Dose]
and Additional Dose with Pfizer-BioNTech COVID-19 Vaccine and CDC Recommends All Individuals 18 Years and Older Should Receive A Booster Dose]

**Section 5.0:** Special Populations to Consider [Updated and Revised Subsection 5.6 to Updates to People Vaccinated Outside of the United States]

**Section 6.0:** Communication and Outreach with Patients About Vaccines [Small Updates to Subsection 6.2 Key Messaging to North Carolinians, Major Updates to Subsection 6.5 Key Messages Related to Booster Doses]

**Section 7.0:** COVID-19 Vaccine Documentation and Reporting [Updates About NCIR Integration with EHR and HIE]

**Section 11:** COVID-19 Vaccine Clinical Information and Guidance [Updates to Subsection 11.2 Approved and Authorized Vaccines Related to CDC EUI for People Vaccinated Outside of the US for Pfizer and/or in Clinical Trials, FDA and CDC Stronger Guidance About Use of All COVID-19 Vaccines as Booster Dose After Primary Vaccination; Updates Subsections on Triage of Persons, Warnings, Contraindications and Precautions, Adverse Reactions, and Guidance for Individuals in Clinical Trials]

**Section 12:** Orders to Administer COVID-19 Vaccine [Updated Statewide Standing Orders for Pfizer, Moderna and Johnson&Johnson (Janssen) to Include EUI Special Circumstances and Revised Booster Doses Guidance]

**Section 14:** Administration of Vaccine [Updates Throughout Subsections on Dosing and Intervals to Include Information about EUI for Pfizer and CDC Booster Dose Guidance on all COVID-19 Vaccines]

**Appendix/Reference Material:** New Appendices 63, 64, and 65 on CDC Emergency Use Instructions (EUI) Fact Sheet for Health Care Providers, EUI Fact Sheet for Recipients/Caregivers, and FAQ Related to EUI

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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.
  o *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.
  o *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.
  o *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.
  o *Vaccinations will be administered in a way that protects the safety of all North Carolinians. All North Carolinians are able to receive their vaccine in as timely a manner as possible, recognizing the limited vaccine supply and that limited vaccine supply does not go unused.*

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

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

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

Since April 7, 2021, all North Carolinians ages 16 and over have been eligible to be vaccinated. In May 2021, the US Food and Drug Association (FDA) authorized and the Advisory Committee on Immunization Practices (ACIP) recommended the use of Pfizer-BioNTech COVID-19 vaccine in individuals from 12-15 years of age. Since November 2, 2021, an FDA authorization and CDC recommendations allow the use of a specific Pfizer-BioNTech COVID-19 vaccine formulation for children ages 5-11 years. As a result, all North Carolinians ages 5 years and older are now eligible to be vaccinated with an age-appropriate COVID-19 vaccine.

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

4.0 Vaccination Eligibility: Individuals Ages 5 Years and Older

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

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

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

Starting October 21, 2021, the FDA Emergency Use Authorization and CDC recommendations allow use of a single booster dose of any of the currently authorized or approved COVID-19 vaccines with eligible populations who have completed primary vaccination with an mRNA COVID-19 vaccine (Pfizer-BioNTech or Moderna) at last 6 months ago or completed primary vaccination with Johnson & Johnson (Janssen) COVID-19 vaccine at least two months ago. (See Sections 11.2.5-11.2.7 for more information about eligible populations and clinical information)

Starting November 2, 2021, the FDA Emergency Use Authorization and CDC recommendations allow use of a specific Pfizer-BioNTech COVID-19 vaccine formulation for a 2-dose primary vaccination series in children ages 5-11 years. (See Section 11.2.1 for more information)

On November 17, 2021, CDC issued Emergency Use Instructions (EUI) to provide information about use of the COVID-19 vaccine by Pfizer-BioNTech for an additional dose in certain immunocompromised persons aged ≥12 years and/or a single booster dose in certain adults aged ≥18 years who completed primary vaccination with non-FDA authorized or approved COVID-19 vaccines. The CDC EUI also cover use of the COVID-19 vaccine by Pfizer-BioNTech in individuals who were vaccinated outside of the United States or in clinical trials with the AstraZeneca COVID-19 vaccine, the Novavax COVID-19 vaccine, or the Sinopharm COVID-19 vaccine, among others. (See Sections 5.6.2 and 11.11 for more information)
Starting November 19, 2021, revised FDA guidance and CDC recommendations for Pfizer-BioNTech COVID-19 vaccine formulations allowed all individuals 18 years or older to be eligible to request a single booster dose of any approved or authorized COVID-19 vaccine in certain situations.

On November 29, 2021, CDC strengthened its recommendation on booster doses for individuals who are 18 years and older. CDC currently recommends that everyone ages 18 and older should get a single booster shot of any approved or authorized COVID-19 vaccine if:

- they are 6 months after their two dose primary vaccination series (or after their additional dose if immunocompromised) with Pfizer-BioNTech COVID-19 vaccine or Moderna COVID-19 vaccine OR
- they are 2 months after their primary vaccination with Johnson & Johnson (Janssen) COVID-19 vaccine

(See Sections 11.2.5 and 13 and 14 for more information)

What you should know:

- The vaccine is free everywhere in North Carolina.
- There is ample supply of vaccines across the state at this time.
- No photo or government ID or insurance is needed.
- Only Pfizer vaccine is currently approved or authorized for use in people 5 years and older.
- Only people who are moderately to severely immunocompromised are eligible to receive an additional dose of mRNA COVID-19 vaccine.
- Any of the COVID-19 vaccines can be used for a single booster dose for individuals 18 years and older who have completed their primary vaccination, regardless of the vaccine product used for primary vaccination.
- People can self-attest (no proof is needed) that they are eligible for an additional dose of an mRNA COVID-19 vaccine.
- Depending on where you get your vaccine, you may need to make an appointment.
- Everyone can be vaccinated, regardless of their immigration status. Getting vaccinated will not affect an individual’s immigration status.
- Find out the answers to additional frequently asked questions about who can get a COVID-19 vaccine.

In response to concerns of access barriers some people are facing regarding documentation requests prior to receiving COVID-19 vaccine, the Health Resources and Services Administration (HRSA) developed and posted two fact sheets to help both patients and providers better understand their rights and responsibilities regarding access to COVID-19 vaccines.

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

5.0 Special Populations to Consider
5.1 Vaccination of Homebound Persons

5.1.1 Identifying homebound persons
Homebound persons are those that need the help of another person or medical equipment such as crutches, a walker, or a wheelchair to leave their home, or their medical provider believes that their health or illness could get worse if they leave their home. In North Carolina, there are estimated to be as many as over 97,000 homebound persons. Vaccine providers should coordinate with other health care providers, community-based organizations, and community healthcare workers to identify homebound persons in your community. Examples include:

- Medicaid/Medicare-Sponsored Organizations
- Home Health Agencies
- Veterans Associations
- Area Aging Agencies
- Community-Based Organizations
- Agencies Serving People with Disabilities
- Health Insurance Companies

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

5.1.2 Vaccination Models to Consider for Homebound Persons

- **Onboard New Providers to Vaccinate Homebound Persons:** Examples of providers include but are not limited to hospice and home care agencies, palliative care organizations, Long Term Care or independent pharmacies, and EMS. These providers are allocated vaccine to deliver to homebound persons in their communities.

- **Events Allocation to Vaccinate Homebound Persons:** Partner existing vaccine providers with community-based organizations that can identify and reach homebound persons. Apply to host a vaccination event, one time or recurring, until demand is met.

- **Existing Vaccine Providers Vaccinate Homebound Persons on an Ongoing Basis:** Existing providers set aside a portion of allocated vaccines or use left-over doses from missed appointments to vaccinate homebound persons.

- **Vaccine Providers Can Participate in the Vaccines at Home Program:** The North Carolina Department of Health and Human Services is partnering with Piedmont Triad Regional Council Area Agency on Aging (PTRC AAA) to provide free COVID-19 vaccinations to people with limited mobility who cannot leave their home. This new initiative expands PTRC AAA’s successful local at-home vaccination program to communities across the state. There is also an At-Home Vaccination Hotline at 1-866-303-0026 which allows caregivers, providers and individuals across North Carolina to schedule an at-home vaccination. An online registration form is also available at www.ptrc.org/covid. A PTRC Vaccination Specialist will follow up to schedule an at-home vaccination. For more information about how the Vaccine at Home Program, please see Section 7.6 and Section 16.2.

5.1.3 Planning Vaccinations for Homebound Persons with Partners
Requirements for local medical providers to administer the vaccine to homebound individuals:
• Enrolled and onboarded to CVMS to be a COVID-19 vaccine provider and meet all storage and handling requirements (See Section 13)

• **Vaccinating workforce**
  - Licensed health professionals or other individuals authorized by the federal [PREP act](#) or the state to administer COVID-19 vaccines
  - Trained in vaccine administration of COVID-19 vaccine product they have available
  - Trained and able to provide emergency management of severe allergic reactions and anaphylaxis
  - **Vaccinator workforce options include, but are not limited to:**
    - Paramedics
    - Home Health and Hospice Staff
    - Individual Pharmacists
    - Home health nurses
    - Dentists
    - Respiratory therapists
    - Optometrists
    - Midwives
    - Emergency Medical Technicians
    - Paramedics
    - Students (e.g., nurses)

• Have a medical provider order vaccine or use the appropriate statewide standing order

• Liability protection is available at federal level through PREP Act and through state [Executive Order 193](#), Section 3B

A list of vaccine providers who are providing or interested in providing vaccinations to homebound individuals can be found on [NCDHHS’s website](#).

### 5.1.4 Best Practices for Vaccinating Homebound Persons

• **Best Practice #1: Plan to maximize efficiency of vaccinations**
  - Estimate the number of doses needed as accurately as possible.
  - Map out travel plans to increase efficiency within the approved time frame specified for the vaccine product, factoring in pre-vaccination preparation time and post-vaccine observation.
  - Ensure readiness to maintain, monitor, & report temperature of vaccine from the time vaccine is taken out of a clinic facility, during transportation & up to the time that vaccine is administered.
  - Providers may also administer vaccine to caretakers and family members.

• **Best Practice #2: Follow transport guidance for the specific vaccine product**
  - **Temperature:** A digital data logger should be used to monitor the temperature of the vaccine. Place the probe near the vaccine. Document the min/max temperatures and time when transport begins, every time the container is opened, and upon return to the facility using the transport temperature log (retain for a minimum of three years).
  - **Vials vs Pre-Drawn Syringe:**
- **Vials:** Recommended by CDC. Punctured vial may be transported from one home to another by the same health care professional if the cold chain is properly maintained. A partially used vial cannot be transferred from one provider to another or across state lines.
- **Pre-Drawn Syringe:** If only option, *U.S. Pharmacopeia* includes guidance for transporting pre-drawn vaccine in syringes.

  - **General Information:**
    - If using a company or personal vehicle, only transport vaccines inside the passenger compartment (not in the trunk or bed of a truck, which may be too hot or too cold).
    - Move transport containers directly to a vehicle that is already at a comfortable temperature—neither too hot nor too cold.
    - Keep containers out of direct sunlight.
    - Pack loose vials carefully to prevent them from breaking.
    - Never leave the container unattended in the vehicle.
    - The total time for transport plus vaccine administration should not exceed 8 hours (unless stated otherwise by the vaccine manufacturer).

See *Section 13.0* for more information on storage, handling, and transporting COVID-19 vaccine.

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

- **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
• 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. Transportations options to consider:
  o 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. Local transit agencies serve all 100 North Carolina counties.
  o 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.
  o Consider partnering with Uber to provide homebound persons with discounted or free ride vouchers to and from vaccination events.
  o Partner with local EMS to provide transportation for medically fragile homebound persons.
  o 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.

5.2 Vaccination of Minors

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

On August 23, 2021, FDA-approved the Pfizer-BioNTech COVID-19 vaccine, which is being marketed as COMIRNATY, as a 2-dose series for the prevention of COVID-19 in individuals 16 years of age and older.

In addition to the approved Pfizer vaccine for 16 years and older, Pfizer-BioNTech COVID-19 vaccine is available under Emergency Use Authorization and recommended for children and adolescents ages 5-15 years of age. Starting November 2, 2021, Pfizer-BioNTech COVID-19 vaccine is available under EUA for the prevention of COVID-19 in individuals 5 through 11 years of age and continues to be available for individuals 12 years through 15 years of age. Moderna and Janssen (J&J) are authorized only for adults (18 years and older) at this time.

NCDHHS recommends that vaccine providers put practices in place to ensure that age-appropriate Pfizer-BioNTech COVID-19 vaccine formulations are given to eligible individuals under 18 years of age. This could include practices, such as:

• Sharing which brands of COVID-19 vaccines and formulations 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 age-appropriate Pfizer vaccine formulations are offered to children or adolescents younger than 18 years of age. It is also important to ensure that children under 12 years of age are scheduled to receive the Pfizer-BioNTech COVID vaccine formulation for individuals 5-11 years of age.
• Review scheduled appointments ahead of time to identify individuals that are younger than 18 years of age. Ensure the age-appropriate Pfizer vaccine formulation (5-11 years or 12 years and older) is available or refer the individual to another community provider with the age-appropriate Pfizer formulation.
• Review age as part of pre-screening for COVID-19 vaccine to ensure only the age-appropriate Pfizer vaccine formulation is given to those 5-11 years of age and those older than 12 years but under 18 years of age.
• Leverage EHR Order Sets (i.e., SmartSets) to incorporate decision logic for Pfizer COVID-19 vaccine for those individuals 5-11 years and 12 years and older but less than 18 years of age.

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

On August 23, 2021, when Pfizer-BioNTech COVID-19 vaccine (marketed as COMIRNATY) received full FDA approval for use in individuals 16 years and older, according to SL 2021-110, individuals who are 16 and 17 years old have the legal authority to consent to receive the Pfizer-BioNTech COVID-19 Vaccine (COMIRNATY) for the 2-dose primary vaccinations series if they demonstrate the decisional capacity to do so (See Section 10.2.2). Since Pfizer-BioNTech COVID-19 vaccine is only available under emergency use authorization for individuals 5 through 15 years of age, health care providers are required to obtain written consent from a parent or legal guardian prior to administration of the age-appropriate Pfizer-BioNTech COVID-19 vaccine formulation as a 2-dose primary series. The additional dose of Pfizer-BioNTech COVID-19 for those who are moderately or severely immunocompromised is also allowed under emergency use authorization for individuals 12 years and older, therefore administration of an additional dose also requires written consent from a parent or legal guardian prior to administration in those eligible in this age group. For more information around minor’s consent, see Section 10.2.2.

A booster dose of COVID-19 vaccine after completion of a COVID-19 primary series is not authorized by FDA or recommended by CDC for anyone under 18 years of age at this time.

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

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

5.3 Vaccination of Pregnant and Lactating Women

COVID-19 vaccination is strongly recommended for all people 5 years of age and older, including people who are pregnant, breastfeeding, trying to get pregnant now, or might become pregnant in the future. On Sept. 29, CDC issued an urgent health advisory to increase COVID-19 vaccination among those who are pregnant, recently pregnant (including those who are breastfeeding), who are trying to become pregnant, or who might become pregnant in the future in order to prevent serious illness, deaths, and adverse pregnancy outcomes. Growing evidence shows that COVID-19 vaccination during pregnancy is safe and effective and the benefits of getting a vaccine far outweigh the risks. The risks of COVID-19 virus are greater for pregnant women compared to people who are not pregnant. Pregnant women with COVID-19 have a higher risk of being hospitalized and needing care in the ICU. Pregnant women with COVID-19 are at
increased risk for preterm birth (delivering the baby earlier than 37 weeks) and might be at increased risk for other poor outcomes related to pregnancy compared to pregnant people without COVID-19, such as a pregnancy loss. There is currently no evidence that any vaccines, including COVID-19 vaccines, cause fertility problems in women or men.

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

Pregnant people can receive any of the currently FDA-approved or FDA-authorized COVID-19 vaccines as a booster dose.

- Please see more information from ACOG on COVID-19 Vaccination Considerations for Obstetric-Gynecologic Care.
- More information can also be found at the NC DHHS Frequently Asked Questions About COVID-19 Vaccinations.
- NC DHHS has also created a flyer related to addressing fertility: COVID-19 Vaccines – Pregnancy, Breastfeeding, and Fertility: What You Need to Know (See Appendix 52)

### 5.4 Vaccination of People Who Are Moderately to Severely Immunocompromised

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

### 5.5 Vaccination of All Employees

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

- Encourage all of their employees to get vaccinated
- Share information and resources with all of their employees on how they can find their spot to take their shot
- Offer to work with their local vaccination providers
- Consider what type of vaccination model would work best for the organization and their employees
Vaccine providers may choose to partner or vaccinate frontline essential workers and all other employees in a way that matches their existing infrastructure. Vaccine providers may choose to use one of following vaccination models for employees, though the list is not exhaustive of potential approaches.

<table>
<thead>
<tr>
<th>Model</th>
<th>Description</th>
</tr>
</thead>
</table>
| Occupational health                | • Company or contracted clinics for employers and facilities with their own occupational health providers who are enrolled and onboarded onto the COVID-19 Vaccine Management System (CVMS).  
  • Now that vaccine supply is more available, enrolled and onboarded occupational health providers can be directly allocated vaccines. Occupational health providers are held to the same expectations as all other vaccine providers. |
| Onsite vaccination event           | • Local vaccine provider partners with employer who have a large workforce and are committed to supporting efforts to vaccinate their employees.  
  • Vaccine providers may choose to invite an employer to assist with employee registration and bulk upload employees using the Organizational Portal in the COVID-19 Vaccine Management System (CVMS) (See Section 7.1 for more information).  
  The employer role for these onsite events can include the following:  
  • Providing and arranging the onsite vaccination clinic space, including space for patient registration, vaccination, and post-vaccine monitoring  
  • Identifying eligible employees and assisting with employee registration in the COVID-19 Vaccine Management System (CVMS)  
  • Scheduling employees into pre-specified appointment slots  
  • Notifying employees of their assigned appointment slot  
  • Staffing to assist with registration or traffic control  
  • Supporting vaccination clinic needs, such as Wi-Fi, toilet and handwashing facilities, basic beverage and food provision, eating location away from vaccination locations, clear identification for vaccination site staff |
| Vaccination event with local vaccine provider | • Local vaccine provider partners with employer who have a large workforce and are committed to supporting efforts to vaccinate their employees. For example, the vaccine provider can host a vaccine clinic with appointments made available first to a certain employer group, such as meat processing or childcare workers.  
  • Vaccine providers may choose to invite an employer to assist with employee registration and bulk upload employees using the Organizational Portal in the COVID-19 Vaccine Management System (CVMS). |
<table>
<thead>
<tr>
<th>Employee independently seeks vaccination</th>
<th>School-Located Vaccination Clinics Web Resources</th>
</tr>
</thead>
<tbody>
<tr>
<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>
<td>Webpage for planning and implementing school-located vaccination (SLV) clinics for any routinely recommended vaccine as well as COVID-19 vaccine. The target audiences for this guidance are public and private entities interested in planning and implementing SLV clinics, including staff from state and local public health departments, community health care clinics, pharmacies, pediatric practices, and health systems.</td>
</tr>
</tbody>
</table>

**5.6 People Vaccinated with COVID-19 Vaccines Outside of the United States**

There are clinical considerations, guidance, and Emergency Use Instructions (EUI) from CDC related to different situations when people have received one or more COVID-19 vaccines outside of the United States. These situations can include receiving a vaccine or combination of vaccines that are and are not FDA-approved or FDA-authorized or World Health Organization Emergency Use Listing Procedure (WHO-EUL) vaccines to fight or prevent infection with COVID-19:

- People who were vaccinated outside the United States with a currently FDA-approved or FDA-authorized COVID-19 vaccine
- People who completed all of the recommended doses of a World Health Organization- Emergency Use Listing Procedure (WHO-EUL)* COVID-19 vaccine not approved or authorized by FDA, or people who completed a heterologous (mix and match) series composed of any combination of FDA-approved, FDA-authorized, or WHO-EUL* COVID-19 vaccines
- People who received only the first dose of a multidose WHO-EUL* COVID-19 primary series that is not FDA-approved or FDA-authorized, or who received all or some of the recommended doses of a COVID-19 vaccine primary series that is not listed for emergency use by WHO*:

Please go to the following resources for detailed clinical considerations, guidance and EUI from CDC:
• CDC’s Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States under the heading, “People who received COVID-19 vaccine outside of the United States.”
• EUI Healthcare Provider Fact Sheet
• EUI Recipient/Caregiver Fact Sheet
• EUI FAQs

*WHO has a list of the which will be updated as additional COVID-19 vaccines receive an EUL from WHO. A list of COVID-19 vaccines and their approval or authorization status by WHO and FDA can also be found [here](#).

(See also Sections 11.2.5, 11.2.6, and 11.11)

### 6.0 Communication and Outreach with Patients about Vaccines

#### 6.1 Overview

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

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

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

#### 6.2 Key Messaging to North Carolinians

- **The COVID-19 vaccines approved and authorized** in the United States are working well to prevent severe illness, hospitalization, and death, even against the widely circulating Delta variant.
- **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.
- **The vaccines are available to all—for free.** You are able to get a vaccine for free, even if you don’t have health insurance.
• Your privacy and personal information are protected at all times. We do not send any personal information to the CDC or ICE.

• The recent emergence of the Omicron variant (B.1.1.529) further emphasizes the importance of vaccination, boosters, and prevention efforts needed to protect against COVID-19.

• You are considered fully vaccinated if you have completed a primary vaccine series (i.e. 2-dose mRNA vaccine series or a single dose of the Janssen/Johnson & Johnson vaccine), and it has been 2 or more weeks since you have completed the primary series. This also includes some people who participated in a clinical trial in the United States. (For more information related to clinical trials see Section 11.11)
  o The above definition of fully vaccinated applies to everyone which includes if you receive an additional dose because you are moderate to severely immunocompromised or if you receive a booster dose.

• Fully vaccinated people can participate in many of the activities that they did before the pandemic; for some of these activities, they should wear a mask. Although infections happen in only a small proportion of people who are fully vaccinated, even with the Delta variant, preliminary evidence suggests that fully vaccinated people who do become infected with the Delta variant can spread the virus to others. People who are fully vaccinated should:
  o Wear a mask in all indoor public spaces if you live in area of high or substantial levels transmission as defined by the CDC until more people are vaccinated and viral transmission decreases.
  o Wear a face covering in all K-12 schools, child care, indoor settings with a large number of children or child-focused activities (e.g, children’s museums), public transportation, healthcare settings, high density congregate settings (e.g., correction and detention facilities, homeless shelters, migrant farm camps), and large crowded indoor venues (e.g., arenas, stadiums).
  o Get tested if you have any symptoms of COVID-19. After an exposure to COVID-19, you should get tested 3-5 days after exposure and wear a mask around others until you get a negative test result.
  o More information can be found from the CDC here.

6.3 Key Messages Related to Adolescents

• Pfizer-BioNTech COVID-19 vaccine (marketed as COMIRNATY) now has full approval by the FDA for use as a 2-dose series to prevent COVID-19 in individuals 16 years and older.

• Pfizer-BioNTech COVID-19 vaccine is available under Emergency Use Authorization by the FDA for use as a 2-dose series to prevent COVID-19 in all individuals 5 years of age and older.
  o At this time according to current state statute, written consent from a parent or a legal guardian is required for any vaccine under EUA for individuals under 18 years of age. This applies to youth under 16 years of age who are eligible under EUA to receive an age-appropriate Pfizer-BioNTech COVID-19 vaccine for the 2-dose primary series. The requirement for written consent also applies to individuals 12-15 years of age eligible under EUA for an additional dose of Pfizer-BioNTech COVID-19 vaccine with certain immunocompromised conditions.

• Adolescents ages 12-15 represent approximately 17 million people in the United States.

• At least 2.5 million 12-17-year-olds have gotten COVID-19 during the pandemic.
School age children saw a significant increase in case rates of COVID-19 and there is no way to tell in advance if your adolescent will get a severe or mild case. Without vaccination, your adolescent may be at risk for getting seriously ill and suffering pain, disability, and even death from COVID-19.

**COVID-19 vaccines are safe and effective in adolescents.**

- Millions of adolescents and tens of millions of adults in the United States have received COVID-19 vaccines under the most intense safety monitoring in U.S. history.
- This vaccine can help protect your adolescent from getting infected or sick from COVID-19.
- Adolescents, like adults, may have some side effects, which are usually normal signs that their body is building protection. These side effects may affect your adolescent’s ability to do daily activities, but they should go away in a few days.
- Parents/caregivers can enroll their adolescent in v-safe, a free, smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins. Through v-safe, you can report any side effects your adolescent may have after vaccination. (See Section 11.10.3 for more information on v-safe).

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

### 6.4 Key Messages Related to Children 5-11 Years of Age

- The Pfizer-BioNTech COVID-19 vaccine is available for children 5-11 years of age
- There are over 500,000 children who are 5-11 years of age living in North Carolina.
- Vaccinating children ages 5 years and older can help keep them in school and help them safely participate in sports, playdates, and other group activities.
- The Pfizer-BioNTech COVID-19 vaccine product for children is different dose and formulation than for adolescents and adults. Individuals should make sure that the vaccination location has the appropriate pediatric product.
  - Kids 5 to 11 years of age will get two doses of the Pfizer-BioNTech COVID-19 product 21 days apart.
  - Temporary side effects for the COVID-19 vaccine for kids 5 to 11 were similar to side effects seen in adults. A child may temporarily experience a sore arm, headache and being tired or achy for a day or so.
- The arm muscle is preferred for COVID-19 vaccines for children 5-11 years of age. However, the leg can be used as well, if needed. A child can receive the shot however works best for that child.
- Children between the ages of 2 and 4 years old, other unvaccinated children 5 years or older and adults should continue to wear a mask in public spaces and around people they don’t live with.

### 6.5 Key Messages Related to People Who Are Immunocompromised
• People who are moderately to severely immunocompromised are especially vulnerable to COVID-19 because they are more at risk of serious, prolonged illness.
• People who have compromised immune systems may benefit from an additional dose to make sure they have enough protection against COVID-19.
• CDC recommends that people with moderately to severely compromised immune systems receive an additional age-appropriate dose of mRNA COVID-19 vaccine at least 28 days after a second dose of Pfizer-BioNTech COVID-19 vaccine (12 years of age or older) or Moderna COVID-19 vaccine (18 years of age or older).
• The definition of fully vaccinated is not different for people who are moderately to severely immunocompromised.
  o People who are immunocompromised are considered fully vaccinated if they have completed a primary vaccine series (i.e. 2-dose mRNA vaccine series or a single dose of the Janssen vaccine), and it has been 2 or more weeks since they have completed the primary series.
• Immunocompromised people (including those who receive an additional mRNA dose) should be counseled about the potential for reduced immune response to COVID-19 vaccination and need to follow prevention measures.
  o Wear a mask
  o Stay 6 feet apart from others they don’t live with
  o Avoid crowds and poorly ventilated indoor spaces until advised otherwise by their healthcare provider
• Close contacts of immunocompromised people should be strongly encouraged to be vaccinated against COVID-19.
• Moderately and severely immunocompromised people aged ≥18 years who completed an mRNA COVID-19 vaccine primary series and received an additional mRNA vaccine dose may receive a single COVID-19 booster dose (Pfizer-BioNTech, Moderna, or Janssen) at least 6 months after completing their third mRNA vaccine dose.

6.6 Key Messages Related to Booster Doses
• To strengthen and extend protections against COVID-19, boosters are recommended for North Carolinians 18 years and older.
• A booster dose is an additional dose of vaccine when the initial immune response was sufficient after the first vaccine series, but is likely to have waned over time.
• You should receive a single booster dose if you are 18 years of age and older AND:
  o You received your second/final dose of the Pfizer or Moderna vaccines more than 6 months ago, OR
  o You received your Johnson & Johnson vaccine more than 2 months ago.
• Individuals 18 years and older are able to request any brand of COVID-19 vaccine for their booster shot.
  o Some people may have a preference for the vaccine type that they originally received and others may prefer to get a different booster.
  o Limited preliminary evidence suggests that booster doses of one of the two mRNA vaccines – Moderna or Pfizer-BioNTech – more effectively raise antibody levels than a booster dose of the Johnson & Johnson vaccine.
• Individuals can receive booster shots at their healthcare provider, pharmacies and other locations where COVID-19 vaccines are available. There is no need for people to go back to the location where they received their original vaccines—the site does not need to have the same vaccine that a person first received.

• People who have received a booster dose should continue to follow guidance for fully vaccinated persons to minimize spread of SARS-CoV-2 to others at this time.

6.7 Outreach Campaigns

6.7.1 Healthier Together

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

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

• Building and earning trust on the ground with BIPOC and other historically marginalized communities and the organizations that are led by and support them

• Co-creating strategies in collaboration with nonprofit, grassroots, and community partners rooted in BIPOC and other historically marginalized communities

• Using data on vaccination efforts to inform planning and investment of resources

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

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

As part of this initiative, Healthier Together is providing grants to community-based organizations to do this work and hire regional health equity teams to support community-based organizations in their outreach and education efforts, help match vaccine providers with community-based organizations, and work with NCDHHS to ensure that communities have the vaccine supply, outreach, and transportation resources they need to get people vaccinated. As we move from COVID-19 response to recovery, we will extend this program’s infrastructure as a foundation for a longer-term framework for health equity. The program is funded by federal COVID-19 dollars. For more information about Healthier Together please click on this link.
6.7.2 Incentives for Vaccination
NCDHHS has offered various incentive programs to encourage COVID-19 vaccination. These have included the Summer Card Program and the Summer Cash Drawings. Providers will be notified if additional incentive programs are developed.

6.7.3 Vaccinating All North Carolinians 5 Years of Age And Older
NCDHHS has developed materials to help you spread the word and stay informed about the availability of vaccine for children and adolescents. Please visit the communications toolkit for “Kids Have A Spot To Take Their Shot” resources and https://covid19.ncdhhs.gov/vaccines/kids for a vaccine locator and more resources. For adolescents, see “Vaccine for Teens” and teens and their families can also visit TeenVaxFacts for more information in English and Spanish. Please also see this FAQ related to minors and parental consent.

CDC has also developed and compiled several COVID-19 vaccine resources for health care providers, pharmacists, schools, parents, adolescents and community partners.

Information for Health Care Providers
- How to Talk with Parents and Caregivers about COVID-19 Vaccination: This toolkit provides materials to help healthcare providers give parents clear and accurate information about COVID-19 vaccines. The toolkit includes answers to common questions, an explanation of how mRNA vaccines work, and printable materials to give to parents.
- COVID-19 Vaccines for Children and Teens
- FAQs about consent for minors: FAQs have been posted on the Pfizer-BioNTech product page for providers with information about consent, prescreening questions, and other issues related to the vaccination of minors.

Information for Parents and Adolescents:
- Web page: COVID-19 Vaccines for Children and Teens provides information about the benefits of COVID-19 vaccines for children and adolescents, how to find a vaccination provider for adolescents, and what to expect during and after vaccination.
- Fact sheet: COVID-19 Vaccines for Preteens and Teens is a printable fact sheet for parents that explains the benefits of a COVID-19 vaccine for their children, safety information, and what to expect during and after vaccination. is a printable fact sheet for parents that explains the benefits of a COVID-19 vaccine for their children, safety information, and what to expect during and after vaccination.
- Myth-buster about menstrual cycles: Your menstrual cycle cannot be affected by being near someone who received a COVID-19 vaccine. This question and answer explains why.
- Myth-buster about infertility: It is safe for people who would like to have a baby one day to get a COVID-19 vaccine. This question and answer explains why.
- Key things to know: Key Things to Know about COVID-19 Vaccines and About COVID-19 Vaccines
- Vaccine information for specific groups: COVID-19 Vaccine Information for Specific Groups
- Recipient education page: The Vaccine Recipient Education page has been updated to include resources about COVID-19 vaccination for adolescents.

Information for Community Groups and Health Departments
- Toolkit for community-based organizations: The Community-Based Organizations COVID-19 Vaccine Toolkit has been updated to include information and resources on COVID-19 vaccination for adolescents ages 12 and older.
### 6.8 Examples of Additional Communication Resources

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

<table>
<thead>
<tr>
<th>Training Program / Reference Material</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NC DHHS COVID-19 Vaccine Communications Toolkit</strong></td>
<td>The most up-to-date materials will be posted on the NC DHHS COVID-19 vaccine website</td>
</tr>
<tr>
<td><strong>NC DHHS Vaccination Sites for Teens and Their Friends and Families</strong></td>
<td>Information, Tools and Resources in English and Spanish to help educate about the benefits of COVID-19 vaccines which include:</td>
</tr>
<tr>
<td><strong>English</strong></td>
<td>• Get the Facts Flyer: Don’t Wait to Vaccinate</td>
</tr>
<tr>
<td><strong>Spanish</strong></td>
<td>• Discussion Guide: Vax Facts for Teens</td>
</tr>
<tr>
<td><strong>NC DHHS COVID-19 Vaccines for Children Ages 5-11</strong></td>
<td>Information and resources for parents and caregivers about COVID-19 vaccines for children ages 5-11 years</td>
</tr>
<tr>
<td><strong>Vaccine Site Locator</strong></td>
<td>Easy to use online tool to help individuals find their spot to get a vaccination in NC, including vaccine provider locations and contact information.</td>
</tr>
<tr>
<td><strong>Vaccine Site Locator (Vaccines.gov)</strong></td>
<td><strong>Vaccines.gov</strong> helps people find the latest information on COVID-19 vaccine availability at certain providers and pharmacies.</td>
</tr>
<tr>
<td><strong>NC COVID-19 Vaccine Help Center</strong></td>
<td>Call center to respond to constituent questions.</td>
</tr>
<tr>
<td><em>1-888-675-4567</em></td>
<td></td>
</tr>
<tr>
<td><strong>How Nurses and Medical Assistants Can Foster a Culture of Immunization in the Practice video</strong></td>
<td>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</td>
</tr>
</tbody>
</table>
conversations and reinforce best practices for improving vaccination coverage.

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>“#HowIRecommend” vaccination video series</td>
<td>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.</td>
</tr>
<tr>
<td>Provider Resources for COVID-19 Vaccine Conversations with Patients</td>
<td>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.</td>
</tr>
<tr>
<td>Epidemiology and Prevention of Vaccine-Preventable Diseases</td>
<td>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 November 2021).</td>
</tr>
<tr>
<td>NC DHHS COVID-19 Vaccine site</td>
<td>COVID-19 vaccine guidance, resources, tools, data dashboard, etc.</td>
</tr>
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### 7.0 COVID-19 Vaccine Documentation and Reporting

#### 7.1 Overview

**What is CVMS?**

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

CVMS includes scheduling, inventory management, the opportunity for EHR integration through the Health Information Exchange (HIE) and a Vaccine Marketplace to facilitate vaccine transfers. CVMS is now integrated with the North Carolina Immunization Registry (NCIR) for expanded provider access for patient query and a consolidated vaccine record for an individual that includes COVID-19. NCIR may also now be used for COVID-19 vaccination documentation (see below). Providers wishing to capture vaccination records for the purposes of clinical documentation, billing, or other
data capture, must do so separately in the EHR. Of note, there should be no out-of-pocket cost to vaccination for any patient, regardless of insurance coverage.

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

Why CVMS?
CVMS provides a flexible approach for managing, delivering, and administering COVID-19 vaccine programs. It is a scalable, integrated platform with configurable modules. This will allow for quicker updates to the system in order to meet certain needs. In addition, built-in automation features mean less time spent on routine tasks and more time for high-value activities.

Documentation of COVID-19 vaccination
CVMS is the state’s module for COVID-19 vaccine tracking as well as the federal government’s reference point for North Carolina COVID-19 vaccination progress. 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.

NC DHHS is now offering providers the ability to use the NC Immunization Registry (NCIR) for COVID-19 vaccine management to help streamline the experience for those providers currently using NCIR for other vaccines. Your organization will be able to use your chosen system for documenting COVID-19 vaccine administrations, managing inventory, and querying COVID-19 immunization status, among other system-dependent functionalities. Organizations should review the considerations detailed in the System Selection Information one-pager, which provides an overview of the implications of choosing either system. Organizations may also use NCIR integration with their EHR (through HIE or directly) for COVID-19 vaccine administration reporting and querying. If your organization is currently utilizing, or would like to utilize HL7 data exchange, please contact the NC Vaccines Help Desk by submitting a web ticket via the Immunization Inquiry webform or call (877) 873-6247 to get connected.

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 – 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 – 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/ – 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.

- NC Vaccines Help Desk Portal: [https://ncgov.servicenowservices.com/csm_vaccine](https://ncgov.servicenowservices.com/csm_vaccine) – Use your NC Vaccines Help Desk username, which is a custom ID sent via email upon registration. Registration Link: [https://covid19.ncdhhs.gov/media/3055/download?attachment](https://covid19.ncdhhs.gov/media/3055/download?attachment). The virtual agent can answer common questions on demand 24/7. The NC Vaccines Help Desk Portal is located on the bottom right corner of the NC Vaccines Help Desk Portal homepage.

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

- For information about CVMS, please go [here](#).
- For information on NCIR, please go [here](#).
- For information about NCIR interoperability with electronic health records, please go [here](#).

### 7.2 Provider Enrollment Process Overview

Whether a provider uses CVMS or NCIR, the COVID-19 Vaccination Program Provider Enrollment Process takes place in the CVMS PROVIDER ENROLLMENT PORTAL in five steps:

- **Start:** Create your user account.
- **The Organization Administrator completes Section A**
  - Enter organization details
  - Add Vaccine Location(s) contact information.
  - Add your CEO and CMO contact information.
- **The Vaccine Coordinator completes Section B**
  - Enter location details
  - Enter practicing providers details.
  - Enter vaccine shipping/storage details.
- **CEO & CMO submit E-sign the agreement(s)**
- **NCDHHS Reviews and approves or declines enrollment**

The Provider Enrollment Roadmap guide provides an overview on how to enroll as a North Carolina vaccine provider in the state’s COVID-19 Vaccine Management System (CVMS). Please reference the User Guides in the Links section, for detailed instructions on how to complete each numbered step referenced in the Provider Enrollment Roadmap. Job Aids are also available for detailed instructions on how to complete tasks within the CVMS system.
7.3 CVMS Direct

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

7.4 CVMS Data Entry Tool

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

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

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

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

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

- Recipient Registration and COVID-19 Vaccine Administration Form (English)
- Recipient Registration and COVID-19 Vaccine Administration Form (Spanish)

7.5 Vaccinating During the CVMS Outage

If you plan to administer vaccines during scheduled maintenance outages, you must collect the CVMS required information offline and add it to the system when it is available again, within 72 hours from vaccine administration. Offline operations forms can be found on the NC DHHS COVID-19 CVMS website (under the section “CVMS Offline Operations – How to Proceed”). Direct links to the forms can also be found in the instructions below.
Recipient Registration & Vaccine Administration in CVMS
Providers need to follow proper procedures when checking in COVID-19 vaccine recipients. Please use the CVMS Recipient Registration Form and COVID-19 Vaccine Administration Form (English) or the Spanish version and follow these instructions:

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

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

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

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

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

- CVMS Provider Portal Offer Vaccine Through Vaccine Marketplace Job Aid
- CVMS Provider Portal Request Vaccine Through Vaccine Marketplace Job Aid
This COVID-19 Transport Guidance document details how to safely transport vaccines being transferred between provider locations.

### 7.8 COVID-19 Vaccine Support

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

- Go to NC Vaccines 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 NC Vaccines 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 NC Vaccines Help Desk Portal, providers can also search the NC Vaccines Help Desk Portal for knowledge articles to help immediately address questions or issues.

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

- Monday – Friday 7:00 AM – 7:00 PM ET
- Saturday 8:00 AM – 4:00 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 NC Vaccines 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) Provider Enrollment Portal. While some providers may use NCIR going forward for COVID-19 documentation, the provider agreement is
completed through 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 Provider Toolkit
- 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.

8.2.2 Federally Qualified Health Centers Program
To ensure our nation’s underserved communities and those disproportionately affected by COVID-19 are equitably vaccinated against COVID-19, the Health Resources and Services Administration (HRSA) and the Centers for Disease Control and Prevention (CDC) launched a program in mid-February to directly allocate a limited supply of COVID-19 vaccine to select HRSA-funded health centers. Additional details on the program can be found here.

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

9.0 Newly Enrolling Providers
For providers not yet enrolled, go to the CVMS Provider Enrollment Portal to get started. Information about new provider orientation is available here: CVMS User Guides, Recorded Trainings and Upcoming Trainings. There is also a COVID-19 Vaccine Provider Toolkit available (you can also find it, along with other materials, at the NC DHHS site under Reference Materials for Serving as a Vaccine Provider). The COVID-19 Vaccine Provider Toolkit provides a step by step walk through of becoming a vaccine provider, all the way from considerations to think about at the outset through onboarding, training, receiving vaccines and administration, and reaching out to your population to encourage vaccination.

Detailed steps about how to enroll as a new provider in CVMS can be found here on the NCDHHS website. The NC COVID-19 RESPONSE: Provider Enrollment Process guide provides an overview on how to enroll as a North Carolina vaccine provider in the state’s COVID-19 Vaccine Management System (CVMS). For providers who plan to use NCIR for COVID-19 vaccine documentation, please see this process guide.

The process to become enrolled and activated can take up to two weeks depending on the completeness of the application, so now is a great time to encourage new providers to get started.
Once a new practice is enrolled and activated in CVMS or NCIR, the location will be able to request COVID-19 doses via the NC DHHS Vaccination Allocation Request Form. See Section 16.1 for more information on vaccine allocations.

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 individuals 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 NC Vaccines Help Desk Portal at [https://ncgov.servicenowservices.com/csm_vaccine](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 vaccine brand specific training(s) from CDC for each vaccine product being offered at your location.

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

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

**Vaccine Administration Prep**

- **Prioritizing and scheduling**: Determine process for prioritizing and scheduling individuals to receive the COVID-19 vaccine and logistics on where 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.

- **Storing Vaccine**: Ensure staff is appropriately trained on storage and handling of COVID-19 vaccines. Please see Section 13 for more information on Storage and Handling.

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

- **V-SAFE information sheet**: Obtain copies of the V-safe Information Sheet to also provide to vaccine recipients (See Appendix 4). Resources from CDC are available in multiple languages. Please see Section 11.10.3 for information about the v-safe COVID-19 Vaccine Pregnancy Registry

**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):

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

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

10.0 COVID-19 Vaccination Legal Considerations

10.1 NC Immunization Law

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

- NC Immunization Laws [link]

10.2 Consent for Vaccination

10.2.1 Informed Consent

Informed consent for medical treatment must be obtained prior to anyone being vaccinated with any of the COVID-19 vaccines. That consent can be verbal if no special consent considerations (see below for consent for individuals under 18 years of age), but a provider may choose to have patients provide written consent for vaccines per their facility policy. For each COVID-19 vaccine authorized under an Emergency Use Authorization (EUA) or approved by the Food and Drug Administration (FDA), the FDA requires that vaccine recipients or their caregivers are provided with vaccine-specific information consistent with the approval or EUA to help make an informed decision about vaccination.

10.2.2 Consent for Individuals Under 18 Years of Age

On August 23, 2021, the FDA approved the Pfizer-BioNTech COVID-19 mRNA vaccine (marketed as COMIRNATY) for the prevention of COVID-19 in individuals 16 years of age and older. Starting November 2, 2021, the FDA Emergency Use Authorization and CDC recommendations allow use of an age-appropriate Pfizer-BioNTech COVID-19 vaccine for a 2-dose primary vaccination series in children and adolescents ages 5-15 years.

For individuals under 18 years who present to local health department clinics, practices and other locations for a COVID-19 vaccine without a parent or legal guardian, there are changes related to minor’s consent law (N.C.G.S. 90-21.5) per SL 2021-110 to keep in mind:
- N.C.G.S. 90-21.5 gives minors the legal authority to consent for the prevention, diagnosis, and treatment of reportable communicable diseases. As COVID-19 is a reportable communicable disease, under N.C.G.S. 130A-135 and 10A NCAC 41A .0101, .0107, it has been permissible for minors to consent to receive the COVID-19 vaccine for themselves, if they have decisional capacity, meaning that they are able to understand and make decisions about their health.
• However, on August 20, 2021, SL 2021-110, S.9, made a change to the minor’s consent law. Pursuant to a new paragraph added to N.C.G.S. 90-21.5(a1), health care providers are now required to “obtain written consent from a parent or legal guardian prior to administering any vaccine that has been granted emergency use authorization and is not yet fully approved by the United States Food and Drug Administration to an individual under 18 years of age.”

• Starting August 23, 2021, when Pfizer-BioNTech COVID-19 vaccine received full FDA approval for individuals 16 years and above, these individuals once again have the legal authority to consent to receive the Pfizer-BioNTech vaccine in accordance with the minor’s consent law. Adolescents 16 and 17 years of age have the ability to make certain health decisions, including the choice to get an approved COVID-19 vaccine, if they show the decisional capacity to do so. Decisional capacity is a person’s ability to understand their health and health care needs and options, and to make decisions about them. However, it is expected that for most teens, information about vaccination with parents and guardians and parental/guardian consent will be obtained for COVID-19 vaccination.

• Pfizer COVID-19 vaccine is available under emergency use authorization for use for a 2-dose primary vaccination series in children and adolescents who are 5-15 years of age and for use as an additional dose in those adolescents 12-17 years of age who may be eligible after completion of a primary 2-dose series due to being moderately or severely immunocompromised. Therefore, written consent from parent or a legal guardian is required for children and adolescents 5-15 years of age for the primary 2-dose series of Pfizer or youth 12-17 years of age receiving an additional dose if immunocompromised at this time.

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

10.2.3 Students presenting for COVID-19 Vaccine in School Settings
Many North Carolina Schools have been excellent partners in efforts to provide COVID-19 vaccines to school staff, often on school grounds, in a manner similar to past influenza clinics. CDC has developed considerations for planning school-located vaccination clinics available at for interested public and private agencies. Current FDA approval of Pfizer-BioNTech COVID vaccine for 16 years and above, and the amended FDA emergency use authorization of the Pfizer vaccine for people 5–15 years of age, are good reasons to work with your local school districts on school located opportunities for qualifying elementary, middle school, and high school students, their families, and school staff. Please see Sections 10.2.1 and 10.2.2 for more details about informed consent for vaccination for minors. The provision of COVID-19 vaccine on school grounds will present a need to partner with the school district about language and procedures related to student/parent consent.

10.3 Vaccinating Outside Jurisdiction

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

Therefore, to protect the health of North Carolinians and promote equity in vaccine distribution, people who are able to spread the virus in North Carolina should be vaccinated when and where they have access to vaccine.

**Operational Considerations**

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

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

### 10.4 Limited English Proficiency

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

Please see [Section 17.4](#) for important examples of strategies of reasonable steps for providers to ensure meaningful access for persons with LEP to COVID-19 vaccine information which includes assistance with phone, onsite and online registration and enrollment. A service email address is available for vaccine providers requesting assistance with connections to resources to better serve individuals with communications needs, including for those with limited English proficiency: [communication.access@dhhs.nc.gov](mailto:communication.access@dhhs.nc.gov)

Additional HHS resources include information on [Limited English Proficiency](#) and a Limited English Proficiency [Bulletin](#).
10.5 Americans with Disabilities Act (ADA) and Accessibility

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

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

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

10.6 Immigration Status

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

11.0 COVID-19 Vaccine Clinical Information and Guidance

11.1 Overview

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

11.2 Approved and Authorized Vaccines

11.2.1 Pfizer-BioNTech COVID-19 Vaccine

Pfizer COVID-19 Vaccine Products (Formulations)

COMIRNATY is the only FDA approved Pfizer-BioNTech COVID-19 vaccine product and is approved for use in individuals 16 years and older for the primary 2 dose series, for an additional dose and for a single booster dose in eligible individuals. There are now two authorized Pfizer-BioNTech COVID-19 product formulations for use in individuals 12 years and older for the primary 2-dose vaccine series, for an additional dose and for a booster dose in eligible individuals. There is also a newly authorized Pfizer-BioNTech COVID-19 vaccine product for use in individuals 5-11 years of age but only for use as the 2-dose primary vaccination series at least 3 weeks apart. (For more clinical information see Sections 11.2.4-11.2.6, 11.3, 11.6-11.13 and 14)

Recent Authorizations, Approvals, Recommendations, and Instructions

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

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

On September 22, 2021, the US FDA amended the Emergency Use Authorization for the Pfizer-BioNTech/COMIRNATY vaccine to allow for use of a single booster dose of Pfizer-BioNTech COVID-19/COMIRNATY vaccine at least six months after completion of the primary Pfizer/COMIRNATY vaccine series in eligible populations. On September 24, 2021, CDC provided more detailed recommendations based on the Advisory Committee on Immunizations Practices (ACIP) interim recommendations. On October 20, 2021, the FDA authorized the use of a heterologous (or “mix and match”) booster doses in eligible populations with currently available (i.e., FDA-authorized or approved) COVID-19 vaccines. Eligible Pfizer-BioNTech COVID-19 vaccine recipients can receive a single booster dose of the Moderna COVID-19 vaccine (at 0.25ml dose) or Janssen COVID-19 vaccine at least six months after completing their primary vaccination. In addition, a single dose of Pfizer COVID-19 vaccine can be used as a booster dose at least six months after completion of the primary COVID-19 vaccination series with Moderna and at least two months after completion of primary COVID-19 vaccination with Johnson & Johnson (Janssen). See Sections 14.4 and 11.2.5-11.2.7 for more information.
On October 29, 2021, the US FDA amended the EUA for the Pfizer-BioNTech vaccine to allow for use of a pediatric product for a 2-dose primary series (0.2ml) at least 3 weeks apart in individuals 5-11 years of age. The EUA authorized a manufacturing change to include an additional formulation of the Pfizer-BioNTech COVID-19 Vaccine that uses tromethamine (Tris) buffer instead of phosphate buffered saline (PBS) used in the originally authorized Pfizer-BioNTech COVID-19 Vaccine. On November 2, 2021, CDC provided detailed and updated recommendations for use of Pfizer products. See Sections 11.2.4, 11.8, 11.9, and 14 for more information.

On November 17, 2021, CDC released Emergency Use Instructions (EUI) to provide information and allow use of the COVID-19 vaccine by Pfizer-BioNTech for an additional dose in certain immunocompromised persons aged ≥12 years and/or a single booster dose in certain adults aged ≥18 years who completed primary vaccination with non-FDA authorized or approved COVID-19 vaccines. For example, these EUI cover use of the COVID-19 vaccine by Pfizer-BioNTech in individuals who were vaccinated outside of the United States or in clinical trials with non-FDA approved or authorized COVID-19 vaccines (i.e., COVID-19 vaccine, the Novavax COVID-19 vaccine, or the Sinopharm COVID-19 vaccine, among others). (See Sections 11.2.5 and 11.2.6)

Emergency Use Instructions fact sheets were created for health care providers, recipients/caregivers and FAQs and are available here and referenced in CDC’s Interim Clinical Considerations:
- EUI Healthcare Provider Fact Sheet
- EUI Recipient/Caregiver Fact Sheet
- EUI FAQs
- CDC’s Interim Clinical Considerations

Starting November 19, 2021, revised FDA guidance and CDC recommendations for Pfizer-BioNTech COVID-19 vaccine formulations allowed all individuals 18 years or older to be eligible to request a single booster dose of any approved or authorized COVID-19 vaccine in certain situations.

On November 29, 2021, CDC strengthened its recommendation on booster doses for individuals who are 18 years and older. CDC currently recommends that everyone ages 18 and older should get a single booster shot of any approved or authorized COVID-19 vaccine if:

- they are 6 months after completion of their two dose primary series (or after their additional dose if immunocompromised) with Pfizer-BioNTech COVID-19 vaccine or Moderna COVID-19 vaccine
  
  OR

- they are 2 months after completion of their primary vaccination with Johnson & Johnson (Janssen) COVID-19 vaccine

(See Sections 11.2.5 and 13 and 14 for more information)

11.2.2 Moderna COVID-19 Vaccine

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

On August 12, 2021, a third dose of the Moderna COVID-19 Vaccine (0.5 mL) administered at least 28 days following the first two doses of this vaccine was authorized by FDA for administration to individuals at least 18 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise. See Section 11.2 for more information.

On October 20, 2021, the FDA authorized Moderna COVID-19 vaccine for use as single booster dose to be administered at 0.25ml, which is half of the dose administered for the primary series dose (0.5ml) of Moderna COVID-19 vaccine. The FDA also authorized the use of a heterologous (or “mix and match”) booster dose for currently available (i.e., FDA-authorized or approved) COVID-19 vaccines. As a result, eligible Moderna COVID-19 Vaccine recipients can receive a booster dose of Moderna COVID-19 vaccine (0.25ml), COMIRNATY COVID-19 vaccine, an age-appropriate Pfizer-BioNTech COVID-19 vaccine, or Janssen COVID-19 vaccine at least six months after completing their primary vaccination with Moderna. Moderna can also be used as a single booster dose at least six months after completion of the primary vaccination series with Pfizer and at least two months after completion of primary vaccination with Johnson & Johnson (Janssen). See Sections 14 for information on administration and Sections 11.2.4, 11.2.5, 11.3-11.6, 11.8-11.13 for more clinical information.

Starting November 19, 2021, revised FDA guidance and CDC recommendations for Moderna COVID-19 vaccine allowed all individuals 18 years or older to be eligible to request a single booster dose of any approved or authorized COVID-19 vaccine in certain situations.

On November 29, 2021, CDC strengthened its recommendation on booster doses for individuals who are 18 years and older. CDC currently recommends that everyone ages 18 and older **should** get a single booster shot of any approved or authorized COVID-19 vaccine if:

- they are 6 months after completion of their two dose primary series (or after their additional dose if immunocompromised) with Pfizer-BioNTech COVID-19 vaccine or Moderna COVID-19 vaccine

  OR

- they 2 months after completion of their primary vaccination with Johnson & Johnson (Janssen) COVID-19 vaccine

(See Sections 11.2.5, 13 and 14 for more information)

### 11.2.3 Johnson & Johnson (Janssen) COVID-19 Vaccine

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

On October 20, 2021, the FDA amended the EUA for the Johnson & Johnson (Janssen) COVID-19 vaccine to allow people who are 18 years of age and older to be eligible to receive a single booster dose of any authorized COVID-19 vaccine - Johnson & Johnson (Janssen) COVID-19 vaccine, Moderna COVID-19 vaccine (0.25ml for booster) or Pfizer-BioNTech
COVID-19 vaccine - at least two months after completion of their single dose primary COVID-19 vaccination with Johnson & Johnson (Janssen). In addition, the FDA authorized the emergency use of the Johnson & Johnson (Janssen) COVID-19 vaccine for a single booster dose in people 18 years and older at least six months after completion of the primary vaccination series with an mRNA COVID-19 vaccine (Pfizer-BioNTech/COMIRNATY and Moderna).

On November 29, 2021, CDC strengthened its recommendation on booster doses for individuals who are 18 years and older. CDC currently recommends that everyone ages 18 and older should get a single booster shot of any approved or authorized COVID-19 vaccine if:

- they are 6 months after completion of their two dose primary series (or after their additional dose if immunocompromised) with Pfizer-BioNTech COVID-19 vaccine or Moderna COVID-19 vaccine

  OR

- they are 2 months after completion of their primary vaccination with Johnson & Johnson (Janssen) COVID-19 vaccine

See Sections 11.2.7, 11.2.8, 11.3, 11.4, 11.7,11.8-11.13 for more clinical information and 14 for more administration information.

11.2.4 EUA Fact Sheets

The Vaccine Information/EUA Fact Sheet for Recipients and Caregivers for the appropriate vaccine product and age of the recipient 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 appropriate Fact Sheet for Healthcare Providers Administering Vaccine (Pfizer / Moderna / Johnson & Johnson (Janssen)) be provided to vaccination providers. Please note that there are now two different Pfizer-BioNTech COVID-19 EUA Fact Sheets for Recipients and Caregivers based on the age of the recipient (5-11 years of age AND 12 years and above with moderate to severe immunocompromise) and different Pfizer-BioNTech COVID-19 Vaccine Fact Sheets for Healthcare Providers Administering Vaccine based on the age of the recipient and product/formulation. The most current fact sheets should be used and accessed at the each of the FDA links for Pfizer, Moderna and Johnson & Johnson (Janssen).

Per the EUA, the vaccination provider must communicate to the recipient or their caregiver, information consistent with the appropriate “Fact Sheet for Recipients and Caregivers” (and provide a copy or direct the individual to the website CDC Centers for Disease Control and Prevention Website to obtain the appropriate Fact Sheet) prior to the individual receiving either the Pfizer-BioNTech/COMIRNATY COVID-19 Vaccine, the Moderna COVID-19 Vaccine or the Johnson & Johnson (Janssen) COVID-19 vaccine, including:

- FDA has approved COMIRNATY COVID-19 mRNA vaccine made by Pfizer for BioNTech as a 2-dose series to prevent COVID-19 for use in individuals 16 years and older.
- FDA has authorized the emergency use of a Pfizer-BioNTech COVID-19 vaccine formulation (10mcg) for use in individuals 5-11 years of age and two formulations of a Pfizer-BioNTech COVID-19 Vaccine (30mcg) for use in individuals 12 years and older for a 2-dose series to prevent COVID-19.
- FDA has also authorized emergency use of COMIRNATY and the two formulations of Pfizer-COVID-19 vaccine for an additional dose in eligible individuals 12 years and above with moderate to severe immunocompromise at least 28 days after completion of the primary vaccination series with an age-appropriate Pfizer-BioNTech vaccine product.
• FDA has authorized the emergency use of the Moderna COVID-19 vaccine for the primary vaccination series in individuals 18 years and above and use as an additional dose after completion of the primary vaccination series with Moderna in individuals 18 years and above who are moderately to severely immunocompromised.
• FDA has authorized the emergency use of the Johnson & Johnson (Janssen) vaccine as a single dose primary COVID-19 vaccination.
• FDA has authorized the emergency use of the age-appropriate Pfizer-BioNTech COVID-19 vaccines, COMIRNATY COVID-19 vaccine and Moderna COVID-19 vaccine at 0.25 ml (half the dose used for the primary vaccination series for Moderna) for a single booster dose at least six months after completion of the primary series of mRNA COVID-19 vaccine (appropriate Pfizer-BioNTech COVID-19 vaccine, COMIRNATY vaccine, and Moderna vaccine) to eligible populations or to individuals 18 years and older at least 2 months following primary Johnson & Johnson (Janssen) COVID-19 vaccine dose.
• FDA has authorized the emergency use of the Johnson & Johnson (Janssen) COVID-19 vaccine for a single booster dose in people 18 years and older at least two months after completion of the primary vaccination for COVID-19 with Johnson & Johnson (Janssen) and at least six months after completion of the primary vaccination series with an age-appropriate mRNA COVID-19 vaccine (Pfizer-BioNTech COVID-19 vaccines, COMIRNATY vaccine and Moderna vaccine).
• The recipient or their caregiver has the option to accept or refuse any of the approved or authorized COVID-19 vaccines. The significant known and potential risks and benefits of each of the approved or authorized COVID-19 vaccines and the extent to which such risks and benefits are unknown.
• Information about available alternative approved or authorized vaccines and the risks and benefits of those alternatives.
• Consent for medical treatment must be obtained prior to being vaccinated. That consent can be verbal. Please see Section 10.2.2 for more information about consent for minors.
• COVID-19 vaccination providers must provide the necessary information for receiving the primary, additional and booster doses to every vaccine recipient or their caregiver when receiving Pfizer-BioNTech/COMIRNATY, Moderna, or Johnson & Johnson (Janssen) 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. It is important to note again that although CDC’s VIS Code Set files are used to convey the codes for EUA Fact Sheets for Recipients and Caregivers, these Fact Sheets are distinct from VISs. VISs will become available when there are licensed COVID-19 vaccines. At this time there is no VIS available for COMIRNATY COVID-19 vaccine.

Resources in Technical Appendix:
• Appendix 1: EUA Fact Sheet for Recipients and Caregivers for Pfizer-BioNTech COVID-19 Vaccine.
• EUA Fact Sheet for Health Care Providers for Pfizer-BioNTech COVID-19 Vaccine
• FDA Letter of Authorization For Pfizer-BioNTech Vaccine (Reissued)
• Appendix 60: FDA Letter of Approval for COMIRNATY (COVID mRNA vaccine made by Pfizer for BioNTech) FDA Letter of Approval for COMIRNATY (COVID mRNA Vaccine Made By Pfizer for BioNTech)
• Appendix 11: EUA Fact Sheet for Recipients and Caregivers for Moderna COVID-19 Vaccine.
11.2.5 Clinical Guidance About Use of Single Booster Doses of Pfizer-BioNTech COVID-19 Vaccine and Moderna COVID-19 Vaccine

- On September 22, 2021, the FDA amended the Emergency Use Authorization (EUA) for the Pfizer-BioNTech/COMIRNATY COVID-19 vaccine to allow for the administration of a single booster dose at least six months after completion of the primary series of the COMIRNATY/Pfizer-BioNTech COVID-19 vaccine in certain groups of people.
- On September 22 and 23, the ACIP met to review data and provided more detailed interim recommendations. On September 24, 2021, the CDC Director endorsed the CDC Advisory Committee on Immunization Practices’ (ACIP) recommendation for a booster shot of the COMIRNATY/Pfizer-BioNTechCOVID-19 vaccine in certain populations and also recommended a booster dose for those in high risk occupational and institutional settings.
- On October 20, 2021, the FDA authorized Moderna COVID-19 vaccine for use as single booster dose to be administered at 0.25ml intramuscularly. It is important to note that the only authorized Moderna booster dose is half of the dose administered for the primary series dose (0.5ml) of Moderna COVID-19 vaccine.
- On November 29, 2021, CDC strengthened its recommendation on booster doses for individuals who are 18 years and older:
  - All individuals who are 18 years and older should receive a single COVID-19 vaccine booster dose (Pfizer-BioNTech, Moderna, or Janssen) ≥6 months after completion of their primary mRNA vaccine series (or after completion of their additional dose of mRNA vaccine if immunocompromised).
  - These booster dose recommendations also apply to people who received two doses of different mRNA COVID-19 vaccine products for their primary series.
  - All individuals who are 18 years and older should receive a single COVID-19 vaccine booster dose (Pfizer-BioNTech, Moderna, or Janssen) ≥2 months after their Janssen primary dose.
  - Currently, a booster dose is not recommended in people aged <18 years.
  - Pregnant people can receive any of the currently FDA-approved or FDA-authorized COVID-19 vaccines as a booster dose.
- On November 17, 2021, CDC released Emergency Use Instructions (EUI) to provide information allow use of the COVID-19 vaccine by Pfizer-BioNTech for a single booster dose in certain adults aged ≥18 years who completed primary vaccination with non-FDA authorized or approved COVID-19 vaccines. The CDC EUI address use of the COVID-19 vaccine by Pfizer-BioNTech in individuals who were vaccinated outside of the United States or in clinical trials with non-FDA approved or authorized vaccines (i.e., the AstraZeneca COVID-19 vaccine, the Novavax COVID-19 vaccine, or the Sinopharm COVID-19 vaccine, among others. (See Section 11.2.6)
For more information, go to the following resources:
  - EUI Healthcare Provider Fact Sheet
  - EUI Recipient/Caregiver Fact Sheet
  - EUI FAQs
  - CDC’s Interim Clinical Considerations has detailed recommendations on use of Pfizer-BioNTech COVID-19 vaccine products under the EUI with relevant information under the heading, “People who received COVID-19 vaccine outside of the United States” and “People who received COVID-19 as part of a clinical trial”.

The frequency and type of transient local and systemic symptoms after a booster dose are generally similar to those experienced after a primary series. Anaphylaxis is a rare risk, but the rate of anaphylaxis after a booster dose is not yet known.

There are several resources from the CDC that have been updated to reflect the Pfizer, Moderna, and Johnson & Johnson (Janssen) COVID-19 vaccine booster recommendations, and these resources will continue to be revised and available:
  - CDC Booster Page
  - CDC Interim Clinical Considerations
  - Interchangeability of COVID-19 vaccine products

NC DHHS also has created a COVID-19 Vaccine Booster Page with a booster calendar calculator on line at: https://covid19.ncdhhs.gov/vaccines/boosters

11.2.6 Clinical Guidance About Additional Doses of Pfizer-BioNTech COVID-19 Vaccine Formulations and Moderna Vaccine in People Who Are Moderately to Severely Immunocompromised

- On August 12, 2021, FDA modified the Emergency Use Authorizations (EUAs) for Pfizer-BioNTech COVID-19 vaccine and Moderna COVID-19 vaccine to allow for administration of an additional dose (i.e., a third dose) of an mRNA COVID-19 vaccine after an initial 2-dose primary mRNA COVID-19 vaccine series for certain people who are immunocompromised.

- On August 13, 2021, ACIP met and reviewed the data for use of an additional dose of mRNA COVID-19 vaccine for immunocompromised people within the Evidence to Recommendation Framework. ACIP made an interim recommendation for emergency use of an additional dose of Pfizer-BioNTech COVID-19 vaccine (for persons aged ≥12 years) or Moderna COVID-19 vaccine (for persons aged ≥18 years) after an initial 2-dose primary mRNA COVID-19 vaccine series for moderately to severely immunocompromised people.

- Only COMIRNATY COVID-19 vaccine and the Pfizer-BioNTech COVID-19 vaccine for eligible individuals 12 years and older can be used as an additional dose in people who are moderately or severely immunocompromised. COMIRNATY COVID-19 vaccine and the Pfizer-BioNTech COVID-19 vaccine can be used for the additional dose interchangeably for the eligible individuals.

- While not specifically an additional dose for immunocompromised individuals who received a single-dose J&J (Janssen) COVID-19 vaccine, all individuals who received J&J (Janssen) COVID-19 vaccine at least 2 months prior are eligible for a booster COVID-19 vaccine dose (either mRNA vaccine (Pfizer or Moderna) or J&J (Janssen)) booster.
Moderately and severely immunocompromised people aged ≥18 years who completed an mRNA COVID-19 vaccine primary series and received an additional mRNA vaccine dose may receive a single COVID-19 booster dose (Pfizer-BioNTech, Moderna, or Janssen) at least 6 months after completing their third mRNA vaccine dose.

On November 17, 2021, CDC released Emergency Use Instructions (EUI) to provide information to allow use of the COVID-19 vaccine by Pfizer-BioNTech as a single additional primary series dose in certain moderately or severely immunocompromised persons aged ≥12 years who completed primary vaccination with non-FDA authorized or approved COVID-19 vaccines. The EUI address and CDC Clinical Considerations address use of the COVID-19 vaccine by Pfizer-BioNTech in individuals who were vaccinated outside of the United States or in clinical trials with the AstraZeneca COVID-19 vaccine, the Novavax COVID-19 vaccine, or the Sinopharm COVID-19 vaccine, among others.

For more information, go to the following resources:
- [EUI Healthcare Provider Fact Sheet](#)
- [EUI Recipient/Caregiver Fact Sheet](#)
- [EUI FAQs](#)
- [CDC’s Interim Clinical Considerations](#) has detailed recommendations on use of Pfizer-BioNTech COVID-19 vaccine products under the EUI with relevant information under the heading, “People who received COVID-19 vaccine outside of the United States.”

Conditions and treatments associated with moderate and severe immune compromise include but are not limited to:
- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids (i.e., ≥20mg prednisone or equivalent per day), alkylation agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory.

Healthcare professionals and public health officials should consider the following for use of an additional mRNA COVID-19 vaccine dose after an initial 2-dose primary mRNA COVID-19 vaccine series for people who are moderately to severely immunocompromised people:
- The currently FDA-approved or authorized COVID-19 vaccines are not live vaccines and therefore can be safely administered to immunocompromised people.
- Studies indicate some immunocompromised people don’t always build the same level of immunity after vaccination the way non-immunocompromised people do, and may benefit from an additional dose to ensure adequate protection against COVID-19. In small studies, fully vaccinated immunocompromised people have accounted for a large proportion of hospitalized post-vaccination cases.
Studies have further demonstrated that including an additional mRNA COVID-19 vaccine dose after an initial 2-dose primary mRNA COVID-19 vaccine series in some immunocompromised populations may enhance immune response.

The clinical benefit of an additional mRNA vaccine dose after an initial 2-dose primary mRNA COVID-19 vaccine series for immunocompromised people is not precisely known. However, for people with moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments, the potential to increase immune response coupled with an acceptable safety profile, support the recommendation for an additional mRNA vaccine dose after an initial 2-dose primary mRNA COVID-19 vaccine series.

Reactions reported after the third mRNA dose were similar to that of the two-dose series: fatigue and pain at injection site were the most commonly reported side effects, and overall, most symptoms were mild to moderate. However, as with the two-dose series, serious side effects are rare, but may occur.

Whenever possible, mRNA COVID-19 vaccination primary series and additional dose should be given at least two weeks before initiation or resumption of immunosuppressive therapies, but timing of COVID-19 vaccination should take into consideration immunosuppressive therapies and optimization of both the patient’s medical condition and response to vaccine

- Patient’s clinical team is best situated to determine the degree of immune compromise and appropriate timing of vaccination
- Factors to consider in assessing the general level of immune competence of patients include disease severity, duration, clinical stability, complications, comorbidities, and any potentially immune-suppressing treatment

Utility of serologic testing or cellular immune testing to assess immune response to vaccination and guide clinical care (e.g., need for an additional dose) has not been established and is not recommended at this time.

Please go to CDC Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United for more information.

**11.2.7 Clinical Guidance About Use of a Single Booster Dose of Johnson & Johnson (Janssen) COVID-19 Vaccine**

- On October 20, 2021, the FDA amended the EUA for the Johnson & Johnson (Janssen) COVID-19 vaccine to allow people who are 18 years of age and older and had completed their single dose primary series of Johnson & Johnson (Janssen) COVID-19 vaccine at least two months prior to be eligible to receive a single booster dose of any authorized COVID-19 vaccine [Janssen (Johnson & Johnson) COVID-19 vaccine, Moderna COVID-19 vaccine (0.25ml for booster) or Pfizer-BioNTech COVID-19 vaccine].
- In addition, the FDA authorized the emergency use of the Johnson & Johnson (Janssen) COVID-19 vaccine for a single booster dose in people 18 years and older at least six months after completion of the primary vaccination series with an mRNA COVID-19 vaccine (Pfizer-BioNTech/COMIRNATY and Moderna).
- During the October 21, 2021 ACIP meeting there was data about the safety and immunogenicity of the Johnson & Johnson (Janssen) booster dose and supported the need for and benefits of use.
- **On November 19, 2021, FDA amended guidance and CDC revised recommendations to allow use of a single COVID-19 vaccine booster dose after completion of a primary vaccination series with any COVID-19 vaccine.**
• On November 29, 2021, CDC strengthened its recommendation on booster doses for individuals who are 18 years and older:
  o All individuals who are 18 years and older should receive a single COVID-19 vaccine booster dose (Pfizer-BioNTech, Moderna, or Janssen) ≥6 months after completion of their primary mRNA vaccine series (or after completion of their additional dose of mRNA vaccine if immunocompromised)
    ▪ These booster dose recommendations also apply to people who received two doses of different mRNA COVID-19 vaccine products for their primary series.
  o All individuals who are 18 years and older should receive a single COVID-19 vaccine booster dose (Pfizer-BioNTech, Moderna, or Janssen) ≥2 months after their Janssen primary dose.
• Currently, a booster dose is not recommended in people aged <18 years.
• Pregnant people can receive any of the currently FDA-approved or FDA-authorized COVID-19 vaccines as a booster dose.
• There are several resources from the CDC that have been updated to reflect the Johnson & Johnson (Janssen), Pfizer and Moderna booster recommendations, and these resources will continue to be revised and available:
  o CDC Booster Page
  o CDC Interim Clinical Considerations
  o Interchangeability of COVID-19 vaccine products
• NC DHHS has created a COVID-19 Vaccine Booster Page with a booster calendar calculator on line at: https://covid19.ncdhhs.gov/vaccines/boosters

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

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

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

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

For Healthcare Providers

- Review the revised Janssen COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers), which has been revised to include a warning about the risk TTS.
- Read the official CDC health alert, Cases of Cerebral Venous Sinus Thrombosis with Thrombocytopenia after Receipt of the Johnson & Johnson COVID-19 Vaccine, which includes details about how to assess and care for a patient that presents with thrombosis or thrombocytopenia.
- Report adverse events to the Vaccine Adverse Event Reporting System. (See Section 11.10.1)

For Vaccine Providers

- Vaccine providers may resume use of the Janssen COVID-19 Vaccine.
- Review the Janssen COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers), external icon which has been revised to include a warning about the risk of TTS that has occurred in a small number of people who have received the Janssen COVID-19 Vaccine.
- CDC encourages vaccine providers to promote the use of v-safe among vaccine recipients using CDC’s free print resources. See information on CDC’s webpage: CDC Recommends Use of Johnson & Johnson’s Janssen COVID-19 Vaccine Resume

11.3 Contraindications and Precautions for mRNA COVID-19 Vaccines

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

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose of a COVID-19 vaccine or any of its components
- Known diagnosed allergy to a component of the COVID-19 vaccine
- Note: It is very important to report all adverse reactions after the receipt of a COVID-19 vaccine. See Section 11.10.1 for information on the Vaccine Adverse Event Reporting System (VAERS).

Precautions:

- 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.
- Persons with a contraindication to Johnson & Johnson (Janssen) COVID-19 vaccine have a precaution for mRNA COVID-19 vaccine.

For the most updated information please go to: CDC Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States
11.4 Contraindications and Precautions for Johnson & Johnson/Janssen COVID-19 vaccine

Contraindications:
Do not administer the Janssen COVID-19 Vaccine to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Janssen COVID-19 Vaccine

Precautions:
Persons with a contraindication to mRNA COVID-19 vaccines have a precaution to Johnson & Johnson/ Janssen vaccine.

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

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

11.5 Triage of Persons Presenting for COVID-19 Vaccination

<table>
<thead>
<tr>
<th>CONTRAINDICATION TO COVID-19 VACCINATION</th>
<th>PRECAUTION TO COVID-19 VACCINATION</th>
<th>MAY PROCEED WITH COVID-19 VACCINATION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>History of the following:</strong></td>
<td><strong>Among people without a contraindication, a history of:</strong></td>
<td><strong>Among people without a contraindication or precaution, a history of:</strong></td>
</tr>
<tr>
<td>Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of a COVID-19 vaccine</td>
<td>Any immediate allergic reaction(^1) to other vaccines (non-COVID-19) or injectable therapies(^2)</td>
<td>Allergy (including anaphylaxis) to oral medications (including the oral equivalent of an injectable medication)</td>
</tr>
<tr>
<td></td>
<td>Non-severe, immediate (onset &lt;4 hours)</td>
<td></td>
</tr>
<tr>
<td>CONTRAINDICATION TO COVID-19 VACCINATION</td>
<td>PRECAUTION TO COVID-19 VACCINATION</td>
<td>MAY PROCEED WITH COVID-19 VACCINATION</td>
</tr>
<tr>
<td>-----------------------------------------</td>
<td>------------------------------------</td>
<td>--------------------------------------</td>
</tr>
<tr>
<td>• Known (diagnosed) allergy to a component of a COVID-19 vaccine</td>
<td>allergic reaction(^2) after a previous dose of COVID-19 vaccine</td>
<td>• History of food, pet, insect, venom, environmental, latex, etc., allergies, including anaphylaxis</td>
</tr>
<tr>
<td></td>
<td>Note: people with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 Vaccine, and vice versa(^5)</td>
<td>• Family history of allergies</td>
</tr>
</tbody>
</table>

**Actions:**
- Do not vaccinate
- Consider referral to allergist-immunologist
- Consider other vaccine alternative if age appropriate\(^1,5\)

**Actions:**
- **Risk assessment**
- 30-minute observation period if vaccinated (see footnotes 5 and 6 for information on vaccination setting)
- Consider referral to allergist-immunologist

**Actions:**
- 30-minute observation period: people with history of anaphylaxis (due to any cause)
- 15-minute observation period: all other people

---

\(^1\) See Appendix C for a list of ingredients. People with a contraindication to one of the mRNA COVID-19 vaccines should not receive doses of either of the mRNA vaccines (Pfizer-BioNTech or Moderna). However, some of these individuals may be able to receive Janssen COVID-19 Vaccine after a detailed risk assessment and possibly allergy testing (see footnote 5 below).

\(^2\) Severe allergic reactions include:
- Possible anaphylaxis, a progressive life-threatening reaction that typically includes urticaria but also with other symptoms such as wheezing, difficulty breathing, or low blood pressure (see Appendix D)
- Any angioedema affecting the airway (i.e., tongue, uvula, or larynx)
- Diffuse rash which also involves mucosal surfaces (e.g., Stevens-Johnson Syndrome)

Non-severe allergic reactions may include:
- Urticaria (hives) beyond the injection site
- Angioedema (visible swelling) involving lips, facial skin, or skin in other locations. NOTE: Any angioedema affecting the airway (i.e., tongue, uvula, or larynx) would NOT be in this category and is considered a severe allergic reaction.

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

4 People with a history of an immediate allergic reaction to a non-COVID-19 vaccine or injectable therapy that contains multiple components, one or more of which is a component of a COVID-19 vaccine, but it is unknown which component elicited the allergic reaction, have a precaution to vaccination with that COVID-19 vaccine. These individuals may benefit from consultation with an allergist-immunologist who can perform a more detailed risk assessment for COVID-19 vaccine receipt and possibly allergy testing.

5 Polyethylene glycol (PEG) is an ingredient in both mRNA COVID-19 vaccines, and polysorbate 80 is an ingredient in Janssen COVID-19 Vaccine. PEG and polysorbate are structurally related, and cross-reactive hypersensitivity between these compounds may occur. People with a contraindication to mRNA COVID-19 vaccines (including due to a known allergy to PEG) have a precaution to Janssen COVID-19 Vaccine. Among people who received a first 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 professionals 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 healthcare professional experienced in the management of severe allergic reactions.

6 For people with a history of an immediate, non-severe allergic reaction after an mRNA COVID-19 vaccine, vaccination with a subsequent dose of either of the mRNA COVID-19 vaccines should only be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions. Similarly, for people with a history of an immediate, non-severe allergic reaction after Janssen COVID-19 Vaccine, vaccination with a subsequent dose of Janssen vaccine should only be undertaken under the supervision of a health care provider experienced in the management of severe allergic reactions. Administering the other vaccine type is another option; this can be done with a 30-minute observation period in a usual COVID-19 vaccination setting.

Additional updated information from the CDC included is in the Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States.
**11.6 Warnings for the Pfizer-BioNTech COVID-19 Vaccine, Moderna COVID-19 Vaccine, and Johnson & Johnson/Janssen COVID-19 Vaccine**

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

- **30 minutes:**
  - 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 non-severe, immediate (onset less than 4 hours) allergic reaction after a previous dose of COVID-19 vaccine
  - History of an immediate allergic reaction of any severity to non-COVID-19 vaccines or injectable therapies
  - People with a contraindication to a different type of COVID-19 vaccine (for example, people with a contraindication to mRNA COVID-19 vaccines who receive Janssen viral vector vaccine should be observed for 30 minutes following Janssen vaccination)
  - History of anaphylaxis due to any cause

- **15 minutes:** All other people

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

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine, Moderna COVID-19 Vaccine, and Johnson & Johnson/ Janssen COVID-19 Vaccine. Further information on anaphylaxis management can be found in the interim considerations for the management of anaphylaxis following COVID-19 vaccination and laboratory evaluation of people who experience anaphylaxis after vaccination.

**People with a history of thrombosis or risk factors for thrombosis**

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

There are no data on the safety of administering a booster dose of either the Janssen COVID-19 Vaccine or an mRNA COVID-19 vaccine to people who had TTS following the first dose. **Given the clinical severity of TTS, experts do not recommend administering a second dose of the Janssen Vaccine to people who had TTS after their first dose.** These people may receive a dose of an mRNA COVID-19 vaccine as a booster at least 2 months (8 weeks) following their dose of the Janssen Vaccine and after their clinical condition has stabilized. Prior to booster vaccination, a conversation between the patient and their clinical team, including a hematologist or other specialists, may assist with decisions about using an mRNA COVID-19 vaccine as a booster and the timing of the booster vaccination. **Considerations for Janssen COVID-19 Vaccine** can be consulted for additional information.
People with a history of multisystem inflammatory syndrome in children (MIS-C) or adults (MIS-A)

Currently, there are no data on the safety and efficacy of COVID-19 vaccines in people with a history of multisystem inflammatory syndrome in children (MIS-C) or in adults (MIS-A). The mechanisms of MIS-C and MIS-A are not well understood but include a dysregulated immune response to SARS-CoV-2 infection. It is unclear if people with a history of MIS-C or MIS-A are at risk of recurrence of the same dysregulated immune response following reinfection with SARS-CoV-2 or in response to vaccination. These theoretical concerns should be weighed against the known risks of COVID-19 from reinfection and the benefits of protection from a COVID-19 vaccine. Children with MIS-C have high antibody titers to SARS-CoV-2; however, it is unknown if this correlates with protection against reinfection and for how long protective antibody levels persist. People with a history of MIS-C or MIS-A may choose to be vaccinated. Considerations for vaccination may include:

- Clinical recovery from MIS-C or MIS-A, including return to normal cardiac function
- Personal risk of severe acute COVID-19 (e.g., age, underlying conditions)
- Level of COVID-19 community transmission and personal risk of reinfection
- Lack of safety data of COVID-19 vaccines following these illnesses
- Timing of any immunomodulatory therapies (ACIP’s general best practice guidelines for immunization can be consulted for more information)

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

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

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

mRNA COVID-19 Vaccines and Risk of Myocarditis and Pericarditis

On June 23, 2021, ACIP met to review reported cases of myocarditis or pericarditis in mRNA COVID-19 vaccine (Pfizer-BioNTech and Moderna) recipients. Cases of myocarditis or pericarditis have occurred predominantly in males aged 12-29 years, with symptoms typically developing within a few days after receipt of the second dose of vaccine. ACIP reviewed the benefits and risks of mRNA COVID-19 vaccines in the United States and determined that the benefits of using mRNA COVID-19 vaccines under the Food and Drug Administration’s (FDA) Emergency Use Authorization (EUA) clearly outweigh the risks of myocarditis and pericarditis in all people aged 5 years or older. The FDA updated the EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and the Fact Sheet for Recipients and Caregivers for Pfizer-BioNTech COVID-19 vaccine and Moderna COVID-19 vaccine to include information about the occurrence of myocarditis or pericarditis in some people following use of the vaccine. Based on the benefit-risk assessment, COVID-19 vaccination continues to be recommended for everyone aged 5 years and older under the FDA’s EUAs.
Based on data after mRNA COVID-19 primary series, the group at highest risk for myocarditis and pericarditis are males aged < 30 years. **No cases of myocarditis or pericarditis were seen with the clinical trial with 5-11 years of age individuals but it was also not sufficient numbers for this rare event and there will be ongoing adverse event monitoring.** Patient and vaccination provider education about the risk of myocarditis or pericarditis occurring after receipt of COVID-19 mRNA vaccines, especially among males aged 12–29 years, is important to ensure timely diagnosis and treatment. A vaccine-specific EUA fact sheet should be provided to all vaccine recipients, parents or guardians, and caregivers (when relevant) before vaccination with any FDA-approved or authorized COVID-19 vaccine.

Clinicians should consult [current clinical guidance](#) for information on the evaluation and management of myocarditis or pericarditis. Healthcare professionals should [report all cases of myocarditis or pericarditis after COVID-19 vaccination to VAERS](#).

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

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

Additional resources include:

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

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

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

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

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

**There are no data on the safety of administering a booster dose of either Janssen Vaccine or an mRNA vaccine to people who had GBS following the first dose of Janssen Vaccine. People who had GBS after receiving Janssen Vaccine should be made aware of the option to receive an mRNA COVID-19 vaccine booster dose at least 2 months after the Janssen dose. However, Janssen Vaccine may be used as a booster, particularly if GBS occurred more than 42 days after vaccination or was related to a non-vaccine factor. Prior to booster vaccination, a conversation between the patient and their clinical**
team, including a neurologist or other specialists, may assist with decisions about use of a COVID-19 booster dose, including the timing of administration.

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

11.7 Expected Reactions and How to Prepare Your Patients

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

11.8 Adverse Reactions Reported During the Clinical Trials

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

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

Clinical trials in children ages 5-11 years found the vaccine to be 90.7% effective in preventing symptomatic COVID-19. The vaccine also met immunobridging success criteria for geometric mean neutralizing antibody titers and seroresponse rates. Safety data from the trials, which included more than 3,000 children who received the vaccine, found the most common reactions were pain at the injection site, fatigue and headache. Reactions were mostly mild or moderate. There were no serious adverse events related to the vaccine, including anaphylaxis or myocarditis, although the latter likely was too rare for detection in a trial of that size.
The frequency and type of transient local and systemic symptoms after a booster dose are generally similar to those experienced after a primary series. Anaphylaxis is a rare risk, but the rate of anaphylaxis after a booster dose is not yet known.

An immediate or severe allergic reaction to any component or previous dose of a COVID-19 vaccine is a contraindication to vaccination. If an individual had a severe allergic reaction after getting the first dose of an mRNA COVID-19 vaccine, the CDC recommends the individual not get the second dose. Please check [here](#) for a list of ingredients included in COVID-19 vaccines. 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](#).

More information: [CDC Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States](#)

### 11.9 Interim Recommendations for COVID-19 Vaccine Administration Errors and Deviations

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

**For all vaccine administration errors:**
- Inform the recipient of the vaccine administration error.
- Contact the NC Vaccines Help Desk at 877-873-6247 to receive support for COVID-19 vaccine management and CVMS questions. For clinical questions, contact the North Carolina Immunization Branch On-Call Nurse Line at 919-707-5575.
- Providers are required to report all COVID-19 vaccine administration errors-even those not associated with an adverse event to VAERS.
- Determine how the error occurred and implement strategies to prevent it from happening again.
- All vaccine administration errors secondary to a medical device malfunction must follow the steps for ancillary kit deficiency reporting.
- If an additional dose is intentionally (or inadvertently) administered, appropriate documentation in CVMS of the administration is still required, regardless of the reason.

The CDC provides a table listing resources for preventing and reporting COVID-19 vaccine administration errors, as well as actions to take after an error has occurred. Please see [COVID-19 Vaccine Administration Errors and Deviations](#). Please also see Appendix A Vaccine Administration Errors and Deviations in the Interim Clinical Considerations for Use of COVID-19 Vaccines [Currently Approved or Authorized in the United States](#).
11.10 Safety Monitoring – VAERS and V-safe

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

11.10.1 VAERS

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

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

Health care providers are encouraged to report any adverse event they think is medically important or clinically significant, even if they think the event might not be related to the vaccine. Please go to the VAERS home page at: https://vaers.hhs.gov/reportevent.html

If a person who has SARS-CoV-2 RNA or antigen detected on a respiratory specimen collected ≥14 days after they complete all recommended doses of an FDA-approved or authorized COVID-19 vaccine (defined as a COVID-19 vaccine breakthrough case), CDC encourages local health departments, healthcare professionals, and clinical laboratories to:

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

V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins to vaccine recipients following COVID-19 vaccination. V-safe also provides second dose vaccine reminders, if needed. This program is only for COVID-19 vaccine and serves as an important active surveillance system for adverse events. All providers who administer COVID-19 vaccine are asked to provide printed hard copies of the v-safe information sheet to each vaccinated individual and counsel them on the importance of enrolling in v-safe. Please take advantage of the post-vaccination observation period to encourage V-safe participation.

See Appendix 4 for the v-safe information sheets to give to patients who receive COVID-19 vaccine and Appendix 5 for a poster for your clinic. V-safe information sheets are available in multiple languages from CDC.

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

11.10.3 Pregnancy Exposure Registry

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

11.11 Information on People Who Received COVID-19 Vaccine As Part of a Clinical Trial

CDC continues to update the Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States to include information on people vaccinated for COVID-19 as part of a clinical trial within or outside of the United States.
Participants in clinical trials within or outside the United States who received all of the recommended “active” (not placebo) primary series doses of a WHO-EUL COVID-19 vaccine* that is not FDA-approved or FDA-authorized or a vaccine that is not listed for emergency use by WHO* but for which a U.S. data and safety monitoring board or equivalent has independently confirmed efficacy (i.e., Novavax COVID-19 vaccine, Moderna COVID-19 vaccine in children aged 6-17 years):

• Are considered fully vaccinated.

• Unless they have received or plan to receive an additional dose through a clinical trial, under the recent CDC EUI, moderately or severely immunocompromised clinical trial participants aged ≥12 years should receive an additional primary dose of Pfizer-BioNTech COVID-19 vaccine (30 µg formulation [purple cap]) at least 28 days after receiving the second vaccine dose of their primary series as described in the CDC Interim Clinical Considerations.

• Unless they have received or plan to receive a booster dose through a clinical trial, under the recent CDC EUI, clinical trial participants aged ≥18 years (including moderately or severely immunocompromised people who received an additional primary dose) are eligible to receive a single booster dose of Pfizer-BioNTech COVID-19 vaccine (30 µg formulation [purple cap]) at least 6 months after completing their primary series, as detailed in CDC Interim Clinical Considerations.

• If clinical trial participants have questions about whether they should receive an additional and/or booster dose outside of the clinical trial, they should consult with their healthcare provider.

Clinical trial participants who did not receive all of the recommended doses, or who received other vaccines not listed above, should consult with their healthcare provider to determine if they should receive an FDA-approved or FDA-authorized COVID-19 vaccine series.

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

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

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

For more information please go to the statement from FDA.
## 11.13 Online Resources: Vaccine Clinical Information and Guidance

<table>
<thead>
<tr>
<th>Training Program / Reference Material</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare Providers</strong></td>
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<tr>
<td><em>Required</em></td>
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<tr>
<td>A web-based training course outlining best practices and principles for healthcare providers when preparing to administer COVID-19 vaccine. It is a high-level overview of the following topics with links to detailed information: vaccine development and safety, safety monitoring programs, Emergency Use Authorizations (EUAs), vaccine storage and handling, preparation, administration, PPE, scheduling, documentation, and reporting adverse events. Information on each vaccine product will be added as each is approved or authorized by FDA.</td>
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<tr>
<td><strong>You Call the Shots: Vaccine Administration</strong></td>
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<tr>
<td>An interactive, web-based vaccine administration course that provides training using videos, job aids, and other resources.</td>
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<tr>
<td><strong>Vaccine administration videos</strong></td>
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<tr>
<td>Short, skill-based demonstration videos of vaccine administration activities, including injection techniques based on age and medication preparation.</td>
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<tr>
<td><strong>COVID-19 Vaccine Administration Competencies Assessment Form</strong></td>
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<tr>
<td>This checklist from CDC is an assessment tool for healthcare professionals who administer vaccines as well as medical and administrative support staff who assist with cold chain management, date reporting, etc.</td>
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<tr>
<td><strong>CDC Guidance by COVID-19 Vaccine Product</strong></td>
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<tr>
<td>The CDC website provides Clinical Information and Guidance by product.</td>
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<td><strong>Moderna Trainings</strong></td>
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<td>Moderna Online training Module</td>
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<td>Moderna EUA Fact Sheet for HCP</td>
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<td>Fact sheet for vaccination providers</td>
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<td>Fact sheet for vaccine recipients and caregivers</td>
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<tr>
<td>Dosing and administration</td>
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<td>Storage and Handling</td>
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<td>Pfizer Trainings</td>
<td>Pfizer Online Training Module</td>
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<td>Pfizer Facts Sheets for Health Care Providers</td>
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<td>Pfizer Fact Sheets for Vaccine Recipients and Caregivers</td>
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<tr>
<td></td>
<td>Vaccine preparation and administration summary (12 Years and Older)</td>
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<td></td>
<td>Storage and handling summary</td>
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<tr>
<td></td>
<td>Temperature log for ultra-cold freezer units, including online fillable PDF version</td>
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<tr>
<td></td>
<td>Beyond use date tracker labels for refrigerator storage</td>
</tr>
<tr>
<td></td>
<td>The Pfizer-BioNTech COVID-19 Vaccine Storage and Handling Summary (5 through 11 years of age) pdf icon[2 pages]</td>
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<tr>
<td></td>
<td>The Pfizer-BioNTech COVID-19 Vaccine Transporting Vaccine for Vaccination Clinics Held at Satellite, Temporary or Off-Site Locations (5 through 11 years of age) pdf icon[2 pages]</td>
</tr>
<tr>
<td></td>
<td>Pfizer-BioNTech COVID-19 Vaccine Dosage Chart pdf icon[1 page]</td>
</tr>
<tr>
<td>Clinical Materials</td>
<td>COVID-19 vaccine screening form for contraindications and precautions</td>
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<td>CDC Expiration Date Tracker Tool</td>
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<td>Reporting a temperature excursion</td>
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<td></td>
<td>Vaccine Storage Troubleshooting Record</td>
</tr>
<tr>
<td></td>
<td>Guide to ancillary supplies kit (for staff helping providers order vaccine)</td>
</tr>
<tr>
<td></td>
<td>COVID-19 vaccine frequently asked clinical questions webpage</td>
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<td>Adverse event reporting</td>
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<tr>
<td></td>
<td>Quick Reference Guide for Healthcare Professionals: provides basic information on proper storage, preparation, and administration of all three vaccines</td>
</tr>
<tr>
<td>Janssen (J&amp;J) Trainings</td>
<td>Janssen Online Training</td>
</tr>
<tr>
<td></td>
<td>Janssen COVID-19 Webinar: Information for Healthcare Providers</td>
</tr>
<tr>
<td></td>
<td>Janssen EUA Fact Sheet for HCP</td>
</tr>
</tbody>
</table>
12.0 Orders to Administer COVID-19 Vaccine

- Originally a combined statewide Standing Order for COVID-19 vaccines was authorized under Executive Order 193 and was effective February 25, 2021 for Pfizer-BioNTech COVID-19 vaccine and Moderna COVID-19 vaccine. This combined standing order was revised last on August 31, 2021.
- On September 24, 2021, separate standing orders were created for Pfizer-BioNTech COVID-19 vaccine and for Moderna COVID-19 vaccine in order to account for CDC recommendations related to the eligibility of certain populations to receive a booster dose of COMIRNATY/Pfizer at least 6 months after completion of their primary series with COMIRNATY/Pfizer.
- The Statewide COVID-19 Vaccine Standing Order for COMIRNATY/Pfizer continues to be revised to include new CDC recommendations. In December 2021, the Statewide Standing Order for COMIRNATY/Pfizer mRNA COVID-19 Vaccine Administration in Patients 12 Years and Older (Appendix 44) was revised to include new FDA and CDC recommendations related to booster doses and the CDC COVID-19 Vaccine Emergency Use Instructions (EUI) for use of Pfizer-BioNTech COVID-19 vaccine in people who were vaccinated outside of the United States and/or who participated in clinical trials.
- A Statewide Standing Order for Pfizer-BioNTech mRNA COVID-19 Vaccine Administration in Patients Ages 5-11 Years (Appendix 62) was created on November 3, 2021 and revised on November 19, 2021.
- The Statewide COVID-19 Vaccine Standing Order for Moderna (Appendix 61) was revised in December 2021, to clarify the new FDA authorizations and CDC recommendations related to when individuals 18 years and older should receive the Moderna COVID-19 vaccine as a single booster dose and the CDC EUI addressing use of Pfizer-BioNTech COVID-19 vaccine in people who were vaccinated outside of the United States and/or who participated in clinical trials.
- A separate statewide Standing Order for Johnson & Johnson (Janssen) COVID-19 vaccine was effective March 4, 2021 revised last in December 2021, to clarify information about the new FDA authorization and CDC recommendations related to when individuals 18 years and older should receive a COVID-19 vaccine as a booster dose and the COVID-19 EUI addressing the use of Pfizer-BioNTech COVID-19 vaccine in people who were vaccinated outside of the United States and/or who participated in clinical trials. (Appendix 50)
- For all of the current statewide standing orders, please visit https://covid19.ncdhhs.gov/guidance#vaccination-info-for-providers
- Please note: Prior to February 25, 2021 when Dr. Betsey Tilson, State Health Director/Chief Medical Officer received the authority to write a statewide standing order via North Carolina Executive Order 193, standing order templates for COVID-19 vaccines were encouraged. Local health departments could then adopt the state-approved standing order templates for use by their medical director and nursing staff. A statewide Standing Order for Pharmacists was issued December 28th, 2020. Upon Dr. Tilson receiving the authority to write the North Carolina statewide standing order, the previous standing order and templates have not been maintained and should be retired.
13.0 Vaccine Storage and Handling

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

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

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

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

Ancillary Kits

Ancillary kits will be shipped separately from each vaccine product (see Appendix 6 which is not updated at the time of the release of this document). The kits contain a 5% overage of supplies from CDC. If vaccine needs to be transported to another enrolled provider location, be sure to pack equal amounts of vaccine administration supplies from the ancillary kits (e.g., diluents (Pfizer only), needles, syringes, vaccination record cards, alcohol prep pads) to ensure the receiving site has sufficient quantities to vaccinate their patients.

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

- **Report 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.
Report to NCDHHS: 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.

Report 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.

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

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

13.1 Pfizer

COMIRNATY is the FDA approved Pfizer-BioNTech COVID-19 vaccine product. FDA recently authorized a Pfizer-BioNTech COVID-19 vaccine product/formulation for use in individuals 5-11 years of age (vials with orange caps and labels). There are also now two authorized Pfizer-BioNTech COVID-19 product formulations (vials with purple caps and labels and vials with gray caps and labels) for use in individuals 12 years and older. All of the Pfizer COVID-19 vaccine products are usually shipped from the manufacturer in a thermal shipper as an ultra-cold product (-90ºC to -60ºC). However, cartons of Pfizer-BioNTech COVID-19 Vaccine multiple dose vials with gray caps and labels with gray borders may arrive frozen at ultra-cold conditions in thermal containers with dry ice or at -25°C to -15°C (-13°F to 5°F).

13.1.1 Vial Storage and Handling of Pfizer COVID-19 Formulation for Age Group 5 through 11:
Cartons of Pfizer-BioNTech COVID-19 Vaccine multiple dose vials with orange caps and labels with orange borders may arrive frozen at ultra-cold conditions in thermal containers with dry ice or at -25°C to -15°C (-13°F to 5°F). Once received, frozen vials may be immediately transferred to the refrigerator [2ºC to 8ºC (35ºF to 46ºF)], thawed and stored for up to 10 weeks. The 10-week refrigerated expiry date should be recorded on the carton at the time of transfer. A carton of 10 vials may take up to 4 hours to thaw at this temperature. Alternatively, frozen vials may be stored in an ultra-low temperature freezer at -90ºC to -60ºC (-130ºF to -76ºF). Do not store vials at -25°C to -15°C (-13°F to 5°F). Once vials are thawed they should not be refrozen. Cartons of Pfizer-BioNTech COVID-19 Vaccine multiple dose vials with orange caps and labels with orange borders may also arrive at 2°C to 8°C. If received at 2°C to 8°C, they should be stored at 2°C to 8°C. Check that the carton has been updated to reflect the 10-week refrigerated expiry date. Regardless of storage condition, vaccines should not be used after 6 months from the date of manufacture printed on the vial and cartons.
13.1.2 Vial Storage and Handling of Pfizer COVID-19 Formulations for 12 Years and Older:
Cartons of Pfizer-BioNTech COVID-19 Vaccine multiple dose vials with purple caps arrive in thermal containers with dry ice. Once received, remove the vial cartons immediately from the thermal container and preferably store in an ultra-low temperature freezer between -90ºC to -60ºC (-130ºF to -76ºF) until the expiry date printed on the label. This information in the package insert supersedes the storage conditions printed on the vial cartons.
When mixing the vaccine with diluent, gently invert the vial 10 times. DO NOT shake. If the vial is shaken, contact the manufacturer prior to use.

Cartons of Pfizer-BioNTech COVID-19 Vaccine multiple dose vials with gray caps and labels with gray borders may also arrive at 2°C to 8°C. If received at 2°C to 8°C, they should be stored at 2°C to 8°C. Check that the carton has been updated to reflect the 10-week refrigerated expiry date.

The vaccine should be stored in the original tray or box in one of the storage unit options listed below and protected from light at all times. The vaccine must be thawed prior to use (either in the refrigerator or at room temperature if needed for immediate use). Please see Appendix 9 for an overview of Pfizer vaccine storage and handling. Refer to the S.T.E.P.S document for your guide to proper storage, handling, administration and disposal/wastage of the Pfizer-BioNTech COVID-19 Vaccination.

See the table below for a visual of the information about the different Pfizer-BioNTech COVID-19 products with different preparation and storage guidelines. For the latest information go to: https://www.cvdvaccine-us.com/

### Three Pfizer-BioNTech COVID-19 Vaccine Presentations

<table>
<thead>
<tr>
<th>Description</th>
<th>Dilute Before Use</th>
<th>Do Not Dilute</th>
<th>Dilute Before Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age Group</td>
<td>12 years and older</td>
<td>12 years and older</td>
<td>5 through 11 years</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(&quot;Age 5y to &lt;12y&quot; on vial label)</td>
</tr>
<tr>
<td>Vial Cap Color</td>
<td>Purple</td>
<td>Gray</td>
<td>Orange</td>
</tr>
<tr>
<td>Dose</td>
<td>30 mcg</td>
<td>30 mcg</td>
<td>10 mcg</td>
</tr>
<tr>
<td>Dose Volume</td>
<td>0.3 mL</td>
<td>0.3 mL</td>
<td>0.2 mL</td>
</tr>
<tr>
<td>Amount of Diluent Needed per Vial*</td>
<td>1.8 mL</td>
<td>NO DILUTION</td>
<td>1.3 mL</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>--------</td>
<td>-------------</td>
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</tr>
<tr>
<td>Doses per Vial</td>
<td>6 doses per vial</td>
<td>6 doses per vial</td>
<td>10 doses per vial</td>
</tr>
<tr>
<td></td>
<td>(after dilution)</td>
<td></td>
<td>(after dilution)</td>
</tr>
<tr>
<td>Emergency Use Authorization (EUA) Fact Sheet</td>
<td>[Click here]</td>
<td>[Click here]</td>
<td>[Click here]</td>
</tr>
</tbody>
</table>

### Storage Conditions

<table>
<thead>
<tr>
<th>Storage Condition</th>
<th>9 months†</th>
<th>6 months‡</th>
<th>6 months‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ultra-Low-Temperature (ULT) Freezer [-90°C to -60°C (-130°F to -76°F)]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Freezer [-25°C to -15°C (-13°F to 5°F)]</td>
<td>2 weeks</td>
<td>DO NOT STORE</td>
<td>DO NOT STORE</td>
</tr>
<tr>
<td>Refrigerator [2°C to 8°C (35°F to 46°F)]</td>
<td>1 month</td>
<td>10 weeks</td>
<td>10 weeks</td>
</tr>
<tr>
<td>Room Temperature [8°C to 25°C (46°F to 77°F)]</td>
<td>2 hours prior to dilution (including any thaw time)</td>
<td>12 hours prior to first puncture</td>
<td>12 hours prior to dilution</td>
</tr>
<tr>
<td>After First Puncture [2°C to 25°C (35°F to 77°F)]</td>
<td>Discard after 6 hours</td>
<td>Discard after 12 hours</td>
<td>Discard after 12 hours</td>
</tr>
</tbody>
</table>

* Diluent: sterile 0.9% Sodium Chloride Injection, USP. Bacterostatic saline or other diluents must NOT be used.
† Regardless of storage condition, vaccine should not be used past the 9-month expiry (6 months printed on the vial plus additional 3 months).
‡ Regardless of storage condition, vaccines should not be used after 6 months from the date of manufacture printed on the vial and cartons.

### 13.1.3 Use of the Thermal Shipper with Pfizer-BioNTech Formulations/Products

The thermal shipper can be used to store the 12 Years and older Pfizer-BioNTech COVID-19 vaccine formulation/product for up to 30 days if appropriate equipment is not available. 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, then every five days thereafter. CDC no longer provides the first re-icing. The provider is responsible for procuring all dry ice refills. Close the container using packing tape. The Pfizer COVID-19 vaccine can last up to 31 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.
The thermal shipping container SHOULD NOT BE USED to store the 5 through 11 Years of Age Pfizer-BioNTech vaccine formulation/product. Follow the manufacturer’s guidance for unpacking the vaccine. Remove the temperature monitoring device from the shipping container and return using the included prelabeled foldable return box. Dispose of the single-use thermal shipping container.

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

13.2.1 Moderna Formulations/Products
The Moderna COVID-19 Vaccine is currently being supplied in two multiple-dose vial presentations:

- A multiple-dose vial containing 5.5 mL
- A multiple-dose vial containing 7.5 mL
- Primary series doses of 0.5 mL and booster doses of 0.25 mL may be extracted from either vial presentation, preferentially using low dead-volume syringes and/or needles.
- When extracting only primary series doses, depending on the syringes and needles used, a maximum of 11 doses (range: 10-11 doses) may be extracted from the vial containing 5.5 mL or a maximum of 15 doses (range: 13-15 doses) may be extracted from the vial containing 7.5 mL. When extracting only booster doses or a combination of primary series and booster doses, the maximum number of doses that may be extracted from either vial presentation should not exceed 20 doses. Do not puncture the vial stopper more than 20 times.
- The Moderna COVID-19 Vaccine multiple-dose vials contain a frozen suspension that does not contain a preservative and must be thawed prior to administration.
- Remove the required number of vial(s) from storage and thaw each vial before use following the instructions below.

<table>
<thead>
<tr>
<th>Vial</th>
<th>Thaw in Refrigerator</th>
<th>Thaw at Room Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Multiple-Dose vial containing 5.5 mL</strong>&lt;br&gt;(range: 10-11 primary series doses or combination of primary series and booster doses, not to exceed 20 doses. Do not puncture the vial stopper more than 20 times)</td>
<td>Thaw in refrigerated conditions between 2º to 8ºC for 2 hours and 30 minutes. Let each vial stand at room temperature for 15 minutes before administering</td>
<td>Alternatively, thaw at room temperature between 15º to 25ºC for 1 hour.</td>
</tr>
</tbody>
</table>
| **Multiple-Dose vial containing 7.5 mL**  
(range: 13-15 primary series doses or combination of primary series and booster doses, not to exceed 20 doses. **Do not puncture the vial stopper more than 20 times**) | **Thaw in refrigerated conditions between 2° to 8°C for 3 hours. Let each vial stand at room temperature for 15 minutes before administering.** | **Alternatively, thaw at room temperature between 15° to 25°C for 1 hour and 30 minutes.** |

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### 13.2.2 Potential tinting with Moderna vaccine vials

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

### 13.2.3 Ancillary Kits and Moderna

**Ancillary kits and Moderna vaccine currently on provider shelves:**

- The U.S. Government will not provide additional 1 ml syringes
- When possible, please use 3 mL syringes for extraction of primary series doses to ensure you have an adequate supply of 1 mL syringes to support extraction of booster doses from a Moderna vial
- For awareness of vaccine and supplies in the field, continue with inventory reconciliation. Try to use existing vaccine and supplies prior to ordering additional doses of vaccine
- Unused ancillary supplies from Pfizer and J&J/Janssen kits also may be used to administer Moderna boosters as long as [CDC Clinical Considerations](https://www.cdc.gov/vaccines/shields-clinical-considerations.html) are maintained.

**Ancillary kits and new Moderna vaccine orders:**

- Ancillary kits will include only 1 ml syringes to ensure accurate extraction of 0.25 mL of booster doses
- New orders of Moderna will include extra ancillary supplies to support the 20-extract dose maximum limit per vial.

### 13.2.4 Different Dosage Amounts and Handling for Moderna Boosters

**Moderna boosters have been authorized at a 0.25 mL dosage amount.** The same vial will be able to be used for both primary series doses (0.5 mL) as well as for booster doses (0.25 mL) with a maximum limit of 20 doses to be extracted per vial. Do not puncture the vial stopper more than 20 times. If the vial stopper has been punctured 20 times, discard the vial and contents. Please refrain from using dispensing pins or vial adapters as COVID-19 vaccines are preservative free and such practices increase the risk of contamination. According to [CDC Injection Safety FAQs](https): “A needle should not
be left inserted into a medication vial septum for multiple uses. This provides a direct route for microorganisms to enter the vial and contaminate the fluid.” For more information, please see USP’s FAQ for Optimizing COVID-19 Vaccine Preparation and Safety.

13.3 Johnson & Johnson/Janssen

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

13.3.1. 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.

13.3.2 Storage After First Puncture of the Vaccine Vial

- After the first dose has been withdrawn, hold the vial between 2° to 8°C (36° to 46°F) for up to 6 hours or at room temperature (maximally 25°C/77°F) for up to 2 hours. Discard the vial if vaccine is not used within these times. (See Section 13.4)

13.4 Transport Guidance

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

**Items required for transporting COVID-19 vaccine:**
1) Portable vaccine refrigerator and/or freezer

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

2) Digital Data Logger (DDL) Thermometer

- Must be placed with the vaccine in the transport container.

3) Sufficient coolant (phase change materials or conditioned water bottles) and insulating materials (bubble wrap and corrugated cardboard)

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

4) Adequate ancillary supplies for preparation and administration

- Include all ancillary supplies (and diluent, if applicable) to correspond with the number of doses being transported.

Start of transport  ➔  Upon opening the storage container  ➔  When transport is completed
**Items required for transporting COVID-19 vaccine:**

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

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

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

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

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

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

**Important Reminders:**

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

Pfizer-BioNTech COVID-19 Vaccine: Transporting Vaccine
Pfizer-BioNTech COVID-19 Vaccine Formulation: 5 through 11 Years of Age Transport Guidance
Moderna COVID-19 Vaccine: Transporting Vaccine
  • Johnson & Johnson (Janssen) COVID-19 Vaccine: Transporting Vaccine

Additional Resources:
• CDC Storage and Handling Toolkit
• CDC Refrigerator Transport Temperature Log
• USP COVID-19 Vaccine Handling Toolkit
• CDC Emergency Transport Guidance
### Pfizer-BioNTech COVID-19 Vaccine (12+ formulation ONLY – purple cap)

**Vaccine Temperature Ranges:**
- **Ultra-cold (ULT):** -90°C to -60°C (-130°F to -76°F)
- **Frozen:** -25°C to -15°C (-13°F to 5°F) for up to 2 weeks
- **Refrigerated:** 2°C to 8°C (36°F to 46°F) for up to one month (31 days)

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

**Vaccine Transport:**

**Ultra-cold transport** (-90°C to -60°C, -130°F to -76°F): Only full trays/cartons of vaccine may be transported at ultra-cold temperatures.
- ULT vaccine may be transported using a medium ULT thermal shipping containers with dry ice or in a portable ultra-cold freezer.

**Frozen transport** (-25°C to -15°C, -13°F to 5°F): If local redistribution is needed and full cartons containing vials cannot be transported at ULT temperatures, vials may be transported at -25°C to -15°C (-13°F to 5°F).
- Any hours used for storage or transport at -25°C to -15°C count against the 2-week limit for storage at -25°C to -15°C.
- **Frozen vials transported at -25°C to -15°C may be returned one time** to the recommended storage condition of -90°C to -60°C (-130°F to -76°F).

**Refrigerated transport** (2°C to 8°C, 36°F to 46°F): Individual vials or partially filled trays must be transported at refrigerated temperatures.
- Once vaccine vials are removed from the tray, the thawing process has begun, and the vaccines require refrigerated transport. **Once vials have been thawed, they cannot be refrozen.**
- **Unpunctured** vials can be transported for up to 12 hours.
- **Punctured** vials can be transported at refrigerated temperatures. Once punctured, the refrigerated vials must be used within 6 hours. Transport time counts as part of the 6-hour time limit.
- Vaccines may be stored at refrigerated temperatures for up to 31 days.
  - Any time used for transport counts against the 31-day limit.

### Pfizer-BioNTech Pediatric COVID-19 Vaccine (5 through 11 years of age – orange cap)

**Vaccine Temperature Ranges:**
- **Ultra-cold (ULT):** -90°C to -60°C (-130°F to -76°F)
- **Refrigerated:** 2°C to 8°C (36°F to 46°F) for up to 10 weeks

**Vaccine Storage Unit(s):**
- Ultra-cold freezer until the expiration date (6 months after manufactured date)
- Refrigerator (for up to 10 weeks)

**Vaccine Transport:**

**Ultra-cold transport** (-90°C to -60°C, -130°F to -76°F): Only full trays/cartons may be transported at ultra-cold temperatures.
- ULT vaccine may be transported in a portable ultra-cold freezer OR container/packout qualified to maintain the recommended temperatures.
- Only unpunctured vials can be transported.

**Refrigerated transport** (2°C to 8°C, 36°F to 46°F): Individual vials or full cartons may be transported at refrigerated temperatures.
- Once vaccine vials are removed from the tray, the thawing process has begun, and the vaccines require refrigerated transport. **Once vials have been thawed, they cannot be refrozen.**
- Only unpunctured vials can be transported.
- Vaccines may be stored at refrigerated temperatures for up to 10 weeks.
Over the next several months, several lots of Pfizer, Moderna, and Johnson & Johnson (Janssen) vaccines are set to expire. It is recommended to check for expiration dates at least weekly for each COVID-19 vaccine in the following ways:

- For Pfizer COVID-19 vaccine for 12 years and older, the vaccine product has an expiration date located on the vaccine vial.
  - On August 23, 2021, the FDA amended the Pfizer-BioNTech Fact Sheet for Health Care Providers with the following information, “cartons and vials of Pfizer-BioNTech COVID-19 Vaccine with an expiry date of August 2021 through February 2022 printed on the label may remain in use for 3 months beyond the printed date as long as approved storage conditions between -90°C to -60°C (-130°F to -76°F) have

Source: https://covid19.ncdhhs.gov/media/3070/download?attachment
been maintained.” Please see page 3 of the Fact Sheet for Health Care Providers for Updated Expiry Dates at: https://www.fda.gov/media/144413/download (Appendix 2)

- As a reminder, location managers are responsible for monitoring inventory records in the CVMS Provider Portal. In response to the August 23 expiration extension, NCDHHS has updated expiration dates for each provider location’s on-hand Pfizer COVID-19 vaccines that were impacted by the change. Please ensure all expiration dates for your on-hand COVID-19 doses in CVMS reflect the respective manufacturer’s most current expiration dates. Please reference the COVID-19 Vaccine Expiration Date Job Aid (See Appendix 59 for a Listing of Job Aids) for steps on how to change expiration dates in CVMS.

- Continue to follow the beyond-use date guidance for doses being stored at frozen (-25°C to -15°C) or refrigerated (2°C to 8°C) temperatures.

- For Pfizer Vaccine for 5-11 years of age patients, there is no expiration date printed on the box or vial. The date on these pediatric vials and boxes is the manufacturer date. Providers need to use the Pfizer Ages 5-11 Years EUA Fact Sheet for Health Care Providers or the Pfizer website and the manufacturer date printed on the box in order to determine the expiration date. Pfizer does not have a look-up tool, the QR code is linked only to the EUA factsheet.

  - Please note that Pfizer Ped (5-11) has a 6-month expiration if stored in an ultra-low temperature freezer at -90°C to -60°C, thus the manufactured date + six months is the expiration date, using the manufacturer date as month one.
  - For example, a carton or vials that state 8/2021 will have an expiration date of Jan 31, 2022.

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

  - Several lots of Moderna vaccine have received shelf-life extensions from FDA. Extensions of Moderna expirations are ongoing.
  - Please continue to check your on-hand vials expiration dates using Moderna’s Vial Expiration Date Lookup Tool before disposing of presumably expired Moderna vaccine to see if it is included in the ongoing set of approved lots. You can also confirm all expiration dates using the QR code on the Moderna vial.
  - The provider locations impacted by “expired” Moderna vials received a separate email with instructions to follow the “Mark and Hold” policy until NC DHHS gets an update on the complete Moderna vaccine shelf-life extension expected in the coming days and/or weeks.

  - Please continue to use best practices by safely quarantining vials or properly disposing of expired vials. We encourage all providers to check your inventory, dispose of expired vaccine, update vaccine inventory records, and submit vaccine wastage reports.

- For Johnson & Johnson COVID-19 vaccine, the expiration date can be obtained by entering the lot number from the carton or vial using the website www.vaxcheck.jnj or by phone using an automated response system at 1-800-565-4008.

  - On July 28, 2021, the Food & Drug Administration authorized an extension of the shelf life for the Johnson & Johnson’s Janssen COVID-19 vaccine from 4.5 months to 6 months (an additional 45 days). Please visit the Official Johnson & Johnson Statement for more information.

  - NC DHHS has updated expiration dates of the Janssen COVID-19 vaccine for provider locations. All dates have been updated based on information provided to the State via the CDC.
Location Managers are responsible for monitoring inventory records in the CVMS Provider Portal and should double check all updated expiration dates. If a Location Manager finds an incorrect expiration date, they should manually edit the vaccine inventory.

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

- Designate a Point of Contact (POC)s responsible for managing inventory
- Providers should view inventory data in CVMS to identify expiration dates of lots in inventory. Sort data by expiration date to identify lots with earliest expiration date(s).
- Inventory Point of Contact (POC) and/or POC responsible for pulling and thawing doses in preparation for upcoming appointments should coordinate the lots that need to be prioritized based on earliest expiration date.
- Rotate vaccine stock and check for expired doses expiration weekly as well as whenever a shipment is received. Follow a “first in, first out” strategy to manage inventory.
- Conduct weekly analysis of available inventory and expiration date compared with forecasted demand (appointments plus estimated walk-ins) to assess whether vaccines can be used before reaching expiration date(s)
- If analysis indicates that doses expiring within 30-60 days cannot be used, reach out to enrolled providers in your local area or utilize the Vaccine Marketplace in CVMS to coordinate a transfer. Escalate to NC DHHS if the number of doses forecasted to expire exceeds 1000 doses.
- If nearing expiration, check posted manufacturer information for the most up to date expiration/extension information for vaccine lots.
- Arrange stock so doses with earliest expiration dates are physically in front of those with later expiration dates or use visible marking for easy identification
- Based on the latest expiration information, REMOVE expired vaccine from the storage unit IMMEDIATELY. Do not give staff opportunity to administer expired vaccine.
  - If expired vaccine is inadvertently administered, it is considered a vaccine administration error and requires remediation including a VAERS report, contacting the recipient to inform them of the error, and may or may not require revaccination based on the manufacturers’ guidance. Guidance on vaccine administration errors can be found in Appendix A of the CDC document (which was not updated at the time of this release to include information about the FDA approved Pfizer–BioNTech COVID vaccine) Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States.
  - Log expired vaccine under wastage in CVMS. Use these user guide instructions (also see Appendix 59) to help you accurately log doses in CVMS. There are no negative consequences for reporting waste and it will not negatively affect future allocations. This helps NCDHHS and CDC accurately monitor the amount of vaccine in the field. CDC recognizes that unused expired vaccine is a normal part of any vaccination program, especially one of this scope and size. Expired vaccine is a normal part of any vaccination program, especially one of this scope and size.
13.6 Unused Doses, Wastage, and Disposal of Vaccine and Related Materials

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

- Vaccine wastage is increasing as the vaccine rollout continues because:
  - More providers, including smaller provider sites, are now receiving vaccine
  - Vial sizes for some vaccines have increased
  - Vaccine vials may be opened without every dose being used
  - To ensure providers do not miss an opportunity to vaccinate every eligible person, CDC recommends:
    - Providers follow clinical best practice for vaccination as well as best practices when managing inventory to maximize vaccination and minimize dose wastage.
    - Providers should not miss any opportunities to vaccinate every eligible person who presents at a vaccination site, even if it means puncturing a multidose vial to administer vaccine without having enough people available to receive each dose
    - Consider establishing and promoting standing vaccination days or half-days to increase likelihood of larger numbers of people presenting for vaccination on the same day.
    - Vaccinate family members or friends who accompany patients to medical visits even if they are not established patients at the vaccinating practice
    - Continue outreach to employers or other community partners that have a large membership or network to arrange vaccination events.
    - As contingency plan, vaccine providers should attempt to contact additional persons (i.e., from a waitlist or through personal contacts of persons being vaccinated) to use as many vaccine doses as possible.
  - Please see Section 16.9 for more strategies about walk-in clinics
  - Dispose of any expired vaccine vials and packaging following your agency’s policies.
    - Empty vaccine vials are usually not considered hazardous or pharmaceutical waste and do not require disposal in a biomedical waste container, **however**, to reduce the risk of fake or counterfeit COVID-19 vaccines, the CDC recommends providers “dispose of vials and packaging as medical waste by placing vials in a sharps container and packaging in a red medical waste bag. If medical waste containers are in short supply, deface or safely crush packaging materials so they cannot be reintroduced or reproduced. After the products are sufficiently defaced or destroyed, dispose with regular waste”.
    - There are currently no vaccine return programs. **Do NOT return vaccine in the thermal shipping container.**
    - **Do not dispose of the ancillary kit supplies received to administer the vaccine(s) that has since expired.**
    - Please also refer to the CDC document about the Identification, Disposal, and Reporting of COVID-19 Vaccine Wastage **here**.
13.7 Satellite, Temporary, and Off-Site Clinics Guidance

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

- Before making any vaccine movements / transports, please refer to the product-specific transport guidelines and limitations from the manufacturer. See Section 13.4 for more information on vaccine transport.
- The quantity of COVID-19 vaccines transported to a satellite, temporary, or off-site clinic should be based on the anticipated number of COVID-19 vaccine recipients and the ability of the vaccination provider to store, handle, and transport the vaccine appropriately in order to minimize vaccine wastage and spoilage.
- COVID-19 vaccines may be transported—**not shipped**—to a satellite, temporary, or off-site COVID-19 vaccination clinic using vaccine transportation procedures outlined in the COVID-19 addendum to CDC’s Vaccine Storage and Handling Toolkit.
- Upon arrival at the COVID-19 vaccination clinic site, vaccines must be stored correctly to maintain appropriate temperature throughout the clinic day.
- Temperature data must be reviewed and documented according to guidance in the COVID-19 addendum to CDC’s Vaccine Storage and Handling Toolkit.
- As with all vaccines, if COVID-19 vaccines are exposed to temperature excursions at any time, the temperature excursion is required to be documented and reported immediately to the vaccine manufacturer for further guidance. Exposed vaccines must be labeled “do not use” and stored at the required temperature range until further information on usability can be obtained by the manufacturer. Providers must document all actions taken.
- Temperature records, including daily temperature logs and information for each temperature excursion event must be kept for a minimum of three years.

13.8 Online Resources: Storage and Handling

<table>
<thead>
<tr>
<th>Training Program / Reference Material</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>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>This Moderna vaccine website is intended for healthcare professionals. Resources include training videos, administration guidance, and storage and handling resources.</td>
</tr>
<tr>
<td>Janssen (J&amp;J) COVID-19 Resources for HCP</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 handing documentation for each available product.</td>
</tr>
<tr>
<td><strong>COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare Providers</strong></td>
<td>A web-based training course outlining best practices and principles for healthcare providers when preparing to administer COVID-19 vaccine. It is a high-level overview of the following topics with links to detailed information: vaccine development and safety, safety monitoring programs, Emergency Use Authorizations (EUAs), vaccine storage/handling, preparation, administration, PPE, scheduling, documentation, and reporting adverse events. Information on each vaccine product will be added as each is approved and authorized by FDA.</td>
</tr>
<tr>
<td><strong>You Call the Shots: Vaccine Storage and Handling</strong></td>
<td>An interactive, web-based immunization training course on storage and handling best practices and principles.</td>
</tr>
<tr>
<td><strong>“Keys to Storing and Handling Your Vaccine Supply” video</strong></td>
<td>This video is designed to decrease vaccine storage and handling errors by demonstrating recommended best practices and addressing frequently asked questions.</td>
</tr>
<tr>
<td><strong>Vaccine Storage and Handling Toolkit</strong></td>
<td>Comprehensive guide that reflects best practices for vaccine storage and handling from Advisory Committee on Immunization Practices (ACIP) recommendations, product information from vaccine manufacturers, and scientific studies.</td>
</tr>
<tr>
<td><strong>Vaccine Storage and Handling Toolkit, COVID-19 Vaccine Addendum</strong></td>
<td>The Vaccine Storage and Handling Toolkit, COVID-19 Vaccine Addendum, provides information, recommendations, and resources on storage and handling best practices to help safeguard the COVID-19 vaccine supply and ensure patients receive safe and effective vaccines.</td>
</tr>
<tr>
<td><strong>Epidemiology and Prevention of Vaccine-Preventable Diseases</strong></td>
<td>Comprehensive information on routinely used vaccines and the diseases they prevent. Chapter 5 is dedicated to vaccine storage and handling (updated 2020).</td>
</tr>
<tr>
<td><strong>Pfizer Storage and Handling Label</strong></td>
<td>Pfizer-BioNTech COVID-19 Beyond Use Date/Time (BUD) Tracking Label (cdc.gov) The Pfizer-BioNTech COVID-19 Vaccine Storage and Handling labels (5 through 11 years of age) pdf icon[1 page]</td>
</tr>
<tr>
<td><strong>Pfizer (5-11 years of age) Storage and Handling Labels</strong></td>
<td></td>
</tr>
</tbody>
</table>
### Administration of Vaccine

#### 14.0 Administration of Vaccine

#### 14.1 Dosing

14.1.1 Pfizer-BioNTech COVID-19 Vaccines

**COMIRNATY COVID-19 Vaccine for Individuals Over Than 16 Years of Age**

- COMIRNATY/Pfizer-BioNTech COVID-19 vaccine has full approval by the FDA individuals 16 years and above for 0.3ml (30mcg) in a 2-dose primary vaccination series at least 21 days apart administered intramuscularly.
- COMIRNATY is also authorized for emergency use for 0.3ml (30 mcg) administered intramuscularly in the following ways:
  - a 2-dose primary series to individuals 12 through 15 years
  - a third additional dose to eligible individuals 12 years of age and older who have moderate to severe immunocompromise at least 28 days after they have completed their primary series with COMIRNATY or another age-appropriate Pfizer COVID-19 vaccine formulation (See Section 11.2.6)
  - a single booster dose to the eligible individuals who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY (See Section 11.2.5)
  - a single booster dose to eligible individuals who have completed primary vaccination with a different authorized COVID-19 vaccine. (See Section 11.2.5)
There are now two FDA authorized formulations of Pfizer-BioNTech COVID-19 COVID-19 vaccine for use in individuals 12 years and older

- A formulation of Pfizer-BioNTech COVID-19 vaccine that is supplied in a multiple dose vial with a gray cap and a label with a gray border (this product is NOT diluted prior to use)
- A formulation of Pfizer-BioNTech COVID-19 vaccine that is supplied in a multiple dose vial with a purple cap and a label with a purple border (this product must be diluted prior to use)
- Both formulations of the Pfizer-BioNTech COVID-19 vaccine are authorized for use in the following ways:
  - 2-dose primary series to individuals 12 years of age and older
  - A third additional dose of 0.3ml to be administered to individuals 12 years of age and older who have moderate to severe immunocompromise at least 28 days after they have completed their primary series with an age-appropriate Pfizer COVID-19 vaccine formulation. (See Section 11.2.6)
  - A single booster dose of 0.3ml should be administered to individuals 18 years and older who request a booster and who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY ≥ 6 months ago (See Section 11.2.5)
  - A single booster dose of 0.3 ml should be administered to individuals 18 years and older who request a booster and have completed primary vaccination with Moderna COVID-19 vaccine ≥ 6 months ago. (See Section 11.2.5)
  - In addition, Pfizer-BioNTech COVID-19 vaccine should be given when requested as a single booster dose to individuals 18 years and older if it has been at least two months since they have completed their primary single dose COVID-19 vaccination with Johnson & Johnson (Janssen). (See Section 11.2.7 for more information)
  - The eligible population(s) and dosing interval for the heterologous booster dose are the same as those authorized for a booster dose of the vaccine used for primary vaccination.
  - See the table below for more specific dosing and dose preparation information related to the formulations.

CDC issued Emergency Use Instructions which allow use of the COVID-19 vaccine by Pfizer-BioNTech for an additional dose in certain immunocompromised persons aged ≥12 years and/or a single booster dose in certain adults aged ≥18 years who completed primary vaccination with non-FDA authorized or approved COVID-19 vaccines. (For more details see Sections 11.2.5 and 11.2.6)

**Pfizer-BioNTech COVID-19 Vaccine for Individuals 5-11 Years of Age (Pediatric)**

- There is an Emergency Use Authorization by FDA for a Pfizer-BioNTech COVID-19 vaccine for use as a 2-dose primary vaccination series (0.2ml) at least 21 days apart to prevent COVID in individuals 5-11 years of age.
  - The pediatric formulation of Pfizer vaccine for individuals 5-11 years of age is supplied in a multiple dose vial with an orange cap and a label with an orange border.
  - The dose in pediatric formulation (orange cap) for 5-11 years old individuals is 10mcg which is one-third of the dose of COMIRNATY and the other formulations of the Pfizer-BioNTech COVID-19 vaccine for children 12 years and older
    - **Children should receive the age-appropriate vaccine formulation regardless of their size or weight.** In contrast to many medications, vaccine dosages (for COVID-19 vaccines and for other
routinely recommended vaccines) are based on age and not size or weight. Different dosages are evaluated during vaccine development to determine the lowest effective dose for the target age group. Clinical trials evaluate various dosing regimens to determine the best dosage and schedule that produces an adequate immune response which is both safe and effective.

- Children should receive the vaccine dosage and formulation based on their age on the day of vaccination with each dose. If a child turns 12 years old between their first and second dose, they should receive the age-appropriate 30 µg Pfizer-BioNTech COVID-19 Vaccine (purple cap) formulation or COMIRNATY for their second dose to complete their series. However, the FDA authorization allows children who will turn from 11 years to 12 years of age between their first and second dose in the primary regimen to receive, for either dose, either: (1) the Pfizer-BioNTech COVID-19 Vaccine formulation for children aged 5–11 years (each 0.2 ml dose containing 10 µg in an orange cap vial); or (2) COMIRNATY or the Pfizer-BioNTech COVID-19 Vaccine formulation authorized for use in individuals 12 years of age and older (each 0.3 mL dose containing 30 mcg in a purple cap vial). If such dosing occurred, the child is considered fully vaccinated. This is not considered an error and VAERS reporting is not indicated.
  - Pfizer-BioNTech COVID-19 Vaccine for 5-11 years of age individuals should not be used in individuals 12 years of age and older. Children ages 5 through 11 years old should only be vaccinated with the Pfizer ages 5 through 11 years formulation. It is important that no other vaccine products/formulations should be used for children 5 through 11 years old because of the potential for vaccine administration errors, including dosing errors.
  - See the table below for more information about the 5-11 years of age Pfizer-BioNTech COVID-19 vaccine formulation.

<table>
<thead>
<tr>
<th>Description</th>
<th>Dilute Before Use</th>
<th>Do Not Dilute</th>
<th>Dilute Before Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age Group</td>
<td>12 years and older</td>
<td>12 years and older</td>
<td>5 through 11 years (“Age 5y to &lt;12y” on vial label)</td>
</tr>
<tr>
<td>Vial Cap Color</td>
<td>PURPLE</td>
<td>GRAY</td>
<td>ORANGE</td>
</tr>
<tr>
<td>Dose</td>
<td>30 mcg</td>
<td>30 mcg</td>
<td>10 mcg</td>
</tr>
<tr>
<td>Dose Volume</td>
<td>0.3 mL</td>
<td>0.3 mL</td>
<td>0.2 mL</td>
</tr>
<tr>
<td>Amount of Diluent Needed per Vial*</td>
<td>1.8 mL</td>
<td>NO DILUTION</td>
<td>1.3 mL</td>
</tr>
<tr>
<td>Doses per Vial</td>
<td>6 doses per vial  (after dilution)</td>
<td>6 doses per vial</td>
<td>10 doses per vial (after dilution)</td>
</tr>
</tbody>
</table>

Source: Pfizer-BioNTech COVID-19 Vaccine Dosage Chart at: https://www.cvdvaccine-us.com/
See section 13.1 and 13.4 for details about storage, handling and transport.
14.1.2 Moderna COVID-19 Vaccine

- Moderna COVID-19 vaccine is approved for 0.5mL in a 2-dose series administered intramuscularly 28 days apart. The Moderna COVID-19 vaccine is authorized for use in individuals 18 years of age and older.
- FDA amended the Emergency Use Authorization (EUA) and CDC has provided recommendations for the use of an additional dose of 0.5mL to be administered intramuscularly at least 28 days after completion of the primary of the primary Moderna COVID-19 vaccine series in people who are moderately to severely immunocompromised. (See Section 11.2.6 for more information)
- CDC has provided stronger recommendations that all individuals 18 years and older should receive a single booster dose of 0.25mL (half the authorized dose for the primary series and additional dose) of Moderna COVID-19 vaccine administered intramuscularly when requested at least six months after completing the primary vaccination series with Pfizer-BioNTech COVID-19 vaccine or Moderna COVID-19 vaccine. In addition, Moderna COVID-19 vaccine should be given when requested as a single booster dose to individuals 18 years and older if it has been at least two months since they have completed their primary single dose COVID-19 vaccination with Johnson & Johnson (Janssen). (See Section 11.2.5 for more information)

14.1.3 Johnson & Johnson/Janssen COVID-19 Vaccine

- Johnson & Johnson (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.
- CDC has provided stronger recommendations for the Johnson & Johnson (Janssen) COVID-19 vaccine that all people who are 18 years of age and older and have completed their single dose primary series of Johnson & Johnson (Janssen) COVID-19 vaccine at least two months prior should receive a single booster dose of any authorized COVID-19 vaccine [Janssen (Johnson & Johnson) COVID-19 vaccine, Moderna COVID-19 vaccine (0.25mL for booster) or Pfizer-BioNTech COVID-19 vaccine]. (See Section 11.2.5 and 11.2.7)
- In addition, CDC recommends the emergency use of the Johnson & Johnson (Janssen) COVID-19 vaccine should be given as single booster dose in people 18 years and older if it has been at least six months after completion of the primary vaccination series with an mRNA COVID-19 vaccine (Pfizer-BioNTech/COMIRNATY and Moderna). (See Section 11.2.5 and 11.2.7)

14.1.4 Vaccine Dosing Reminders

- Administer only full doses
- Never combine or “pool” partial doses from two or more vials to obtain a full dose of vaccine.
- Never combine or “pool” any COVID-19 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:
  - 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.
• Do not refreeze any doses of COVID vaccine. 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.

14.1.5 Needle Gauge and Length

**Needle Sizing Chart from NC State Health Director’s Statewide Standing Orders**

<table>
<thead>
<tr>
<th>Sex and Weight of Patient</th>
<th>Needle Gauge Needle Length</th>
<th>Injection Site*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female or male fewer than 130 lbs.</td>
<td>22–25</td>
<td>5/8 **–1&quot;</td>
</tr>
<tr>
<td>Female or male 130–152 lbs.</td>
<td>22–25</td>
<td>1&quot;</td>
</tr>
<tr>
<td>Female 152–200 lbs.</td>
<td>22–25</td>
<td>1-1/2&quot;</td>
</tr>
<tr>
<td>Male 153–260 lbs.</td>
<td>22–25</td>
<td>1-1/2&quot;</td>
</tr>
<tr>
<td>Female 200+ lbs.</td>
<td>22–25</td>
<td>11/2&quot;</td>
</tr>
<tr>
<td>Male 260+ lbs.</td>
<td>22–25</td>
<td>11/2&quot;</td>
</tr>
</tbody>
</table>

* Alternatively, the anterolateral thigh also can be used.
** Some experts recommend a 5/8-inch needle for men and women who weigh less 130 pounds. If used, skin must be stretched tightly (do not bunch subcutaneous tissue).

• Vaccines must reach the desired tissue to provide an optimal immune response and reduce the likelihood of injection-site reactions.
• Needle selection should be based on the route, age, gender and weight for adults (19 years and older) and injection site (see chart above).
• The document from CDC “You call the shots vaccine administration: Needle Gauge and Length” outlines recommended needle gauges and lengths.
• In addition, clinical judgment should be used when selecting needles to administer injectable vaccines.
• For more information, please see USP’s FAQ for Optimizing COVID-19 Vaccine Preparation and Safety

14.2 Intervals

14.2.1 Intervals between the first and second doses of the Pfizer-BioNTech COVID-19 vaccines and Moderna COVID-19 vaccine primary 2-dose series

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

14.2.2 Intervals between use of an additional dose after completion of the primary 2-dose series of an mRNA vaccine (COMIRNATY COVID-19 vaccine, age-appropriate Pfizer-COVID-19 vaccine, and Moderna COVID-19 vaccine)

- An additional (third) dose should be administered no earlier than 28 days after the completion of the primary 2-dose age-appropriate Pfizer-BioNTech COVID-19 vaccine series (for those individuals 12 years and older) or the primary 2-dose Moderna COVID-19 vaccine series (for those individuals 18 years of older) in individuals who are moderately or severely immunocompromised.

14.2.3 Intervals between the single booster dose and completion of the primary 2-dose series of Pfizer-BioNTech/COMIRNATY COVID-19 vaccine and Moderna COVID-19 vaccine

- A booster dose of COMIRNATY, an age-appropriate Pfizer-BioNTech COVID-19 vaccine or Moderna COVID-19 vaccine should be given to individuals 18 years and older no earlier than 6 months after completion of the 2-dose primary vaccine series of an mRNA COVID vaccine. Since immunity wanes gradually over time, the booster dose of COMIRNATY, an age-appropriate Pfizer-BioNTech COVID-19 vaccine or Moderna COVID-19 vaccine may be given at an interval greater than 6 months after completion of the primary vaccine series of mRNA COVID-19 vaccine
- A booster dose of COMIRNATY, an age-appropriate Pfizer-BioNTech COVID-19 vaccine or Moderna COVID-19 vaccine should be given to individuals 18 years and older no earlier than 2 months after their completion of the single dose primary series of Johnson & Johnson (Janssen) COVID-19 vaccine.

14.2.4 Intervals between a single booster dose of COVID-19 vaccine and completion of the single dose primary series of Johnson & Johnson (Janssen) COVID-19 vaccine

- The Johnson & Johnson (Janssen) COVID-19 vaccine should be given as a single booster dose to people 18 years of age and older at least two months after completion of their primary series of a single Janssen COVID-19 vaccine.
- The Johnson & Johnson (Janssen) COVID-19 vaccine should be given as a single booster dose to people 18 years and older at least six months after completion of the primary vaccination series with an mRNA COVID-19 vaccine (COMIRNATY, Pfizer-BioNTech COVID-19 vaccine and Moderna COVID-19 vaccine)
14.3 Proof of COVID-19 Vaccination for Individuals and Special Situation

14.3.1 Acceptable Forms of Proof of Administration of COVID-19 Vaccination

Individuals who have been vaccinated for COVID-19 may demonstrate proof of vaccination in several ways. Employers that are requesting employees provide proof of vaccination are encouraged to accept any of the following forms of proof of vaccination:

- An original or copy of a COVID-19 Vaccination Record Card issued on the form provided by the U.S. Centers for Disease Control and Prevention (CDC). Individuals may contact their vaccine provider with questions about this record.
- A note or receipt signed by an individual’s health care provider, including a licensed nurse, physician, pharmacist, or physician’s assistant, or another healthcare provider or a representative of a health care provider. This note or receipt must show at least:
  - The employee’s name
  - The name of the health care provider administering the vaccine
  - Date(s) of vaccination
  - Place of vaccination
  - Vaccine product name (i.e., Moderna, Pfizer or Johnson & Johnson)
- A print-out of the employee’s vaccination record from the provider who administered the vaccine – for example, a pharmacy participating in the Federal Retail Pharmacy Program like Walgreens, CVS, Walmart, and grocery store pharmacies.
- Immunization record from the NC Immunization Registry (NCIR)
- A printout of the employee’s record from North Carolina’s COVID-19 Vaccine Management System (CVMS) Portal. People can visit covid-vaccine-portal.ncdhhs.gov to access their vaccine record if they got their shot from a North Carolina provider (such as a local health department, primary care provider or at a local community event) and gave an email address. Note that people who received their vaccine through the Federal Retail Pharmacy Program as noted above or from another federal vaccine provider such as the U.S. Department of Defense will not have their information available in CVMS. For information about accessing CVMS and to register, people may visit covid-vaccine-portal.ncdhhs.gov (Spanish page: Vacunate.nc.gov/registro)

14.3.2 Inappropriate Use of Vaccine Record Cards

- There have been instances in which the CDC Vaccination Record Cards provided to vaccine recipients have been reproduced and fraudulently sold or forged to reflect full vaccination for someone who has not received a COVID-19 vaccine. We remind you to please make sure your vaccination cards are kept in a secure location or locked in your desk to protect them from inappropriate distribution. If you encounter someone using cards inappropriately or under suspicious circumstances, we encourage you to report the incident to the HHS Office of Inspector General or the FBI at the number provided below. Please contact the HHS Office of Inspector General with any concerns at:
  - 1-800-hhs-TIPS
  - www.oig.hhs.govwww.oig.hhs.gov
14.4 Recommendations on interchangeability of COVID-19 vaccine products

Any currently FDA-approved or FDA-authorized COVID-19 vaccine can be used when indicated. ACIP and CDC do not state a product preference. However, in general, primary series and additional doses should be with the same vaccine product. In addition, use of heterologous booster doses is authorized.

mRNA COVID-19 vaccines (Pfizer-BioNTech products and Moderna): primary series and additional doses

- All doses of the primary series and the additional dose for moderately and severely immunocompromised people, if indicated, should be completed with the same product. Various strategies can help ensure that people receive the appropriate product and interval between doses.
- In exceptional situations in which the mRNA vaccine product given for the first dose of the primary series cannot be determined or is not available, any available mRNA COVID-19 vaccine may be administered at a minimum interval of 28 days between doses to complete the mRNA COVID-19 vaccination series.
- In situations where the same mRNA vaccine product is temporarily unavailable, it is preferable to delay the second dose to receive the same product than to receive a mixed primary series using a different product. If two doses of different mRNA COVID-19 vaccine products are administered in these situations (or administered inadvertently), the primary series is considered complete, and no subsequent doses of either product are recommended to complete the primary series. Such persons are considered fully vaccinated against COVID-19 ≥2 weeks after receipt of the second dose of an mRNA vaccine and may be offered an additional dose or booster dose.

Johnson & Johnson (Janssen) vaccine: primary series

- In limited, exceptional situations where an individual received the first dose of an mRNA COVID-19 vaccine but is unable to complete the series with either the same or different mRNA COVID-19 vaccine (e.g., due to contraindication), a single dose of Janssen COVID-19 vaccine may be considered at a minimum interval of 28 days from the mRNA COVID-19 vaccine dose. See the CDC Contraindications and Precautions section for additional information on use of Janssen COVID-19 vaccine and additional precautions in people with a contraindication to mRNA COVID-19 vaccines. People who receive Janssen COVID-19 vaccine after a dose of an mRNA COVID-19 vaccine should be considered to have received a valid, single-dose Janssen vaccination—not a mixed primary vaccination series—and are considered fully vaccinated against COVID-19 ≥2 weeks after receipt of the single dose of the Janssen vaccine.

Interchangeability of booster doses

- Heterologous (mix and match) booster doses can be used (see Considerations for use of a COVID-19 vaccine booster dose for more details).

The complete document with all of the above information about the interchangeability of COVID-19 vaccine products is the CDC Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States.

14.5.1 Scheduling Second Dose Appointments and Managing Second Dose Inventory

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

<table>
<thead>
<tr>
<th>Second Dose Scheduling Suggested Practices</th>
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<tbody>
<tr>
<td>• 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.</td>
</tr>
<tr>
<td>• Create a priority phone number for second-dose scheduling or appointment changes to reduce confusion and increase likelihood of vaccine series completion.</td>
</tr>
<tr>
<td>• 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.</td>
</tr>
<tr>
<td>• Use auto-dialers, text messages, email, staff outreach, or other means to remind individuals of appointments</td>
</tr>
</tbody>
</table>

14.5.2 Providing second doses to individuals who received first doses elsewhere

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

For Long Term Care residents and staff that received first doses from Walgreens or CVS through the Federal Long Term Care Pharmacy program and are not able to get a second dose, a list of Long-Term Care Pharmacies is available to provide second doses. Long Term Care facilities needing second dose supports should contact their long-term care pharmacy partners, or can contact Patrick Brown atpatrick.brown@dhhs.nc.gov to receive the full list.
14.6 Providing an Additional Dose (COMIRNATY, Pfizer or Moderna COVID-19 Vaccine) or Booster Dose [COMIRNATY, Pfizer COVID-19 Vaccine, Moderna, or Johnson & Johnson (Janssen)]

14.6.1 Scheduling an Additional Dose or Booster Dose
- Providers with CVMS Scheduling enabled can modify a vaccine supply record for additional dose/booster appointments
- Recipients can schedule their initial doses, an additional or booster dose on vaccines.gov
- Providers can receive recipient-booked appointments for additional or booster doses
- Location settings must be updated to include the amount of appointments for additional doses or booster doses

14.6.2 Verification of Completion and Timing of Primary mRNA COVID-19 Vaccines Series
- Many individuals who are eligible for an additional dose or booster dose may present for a third dose to a different provider than they received their first and/or second doses of the primary COVID-19 vaccine series.
- Most but not all individuals will have information about the primary vaccination series in CVMS.
- Providers should request an individual’s CDC card or attempt to retrieve records to assess vaccination status. However, if dose details are not available, a provider may use the individual’s reported information to inform vaccine eligibility.

14.6.3 Self-Attestation
- Individuals may self-attest to having one or more medical conditions or treatments associated with moderate or severe immune compromise in order to receive an additional dose.
- People may self-attest that they are eligible for a booster dose.
- Providers can utilize the free-form “Notes” field on the Vaccine Administration page in CVMS for capturing the recipient's self-attestation. Slide 56 of the CVMS vaccine documentation user guide overviews the process.

14.7 Coadministration with Other Vaccines

COVID-19 vaccines were previously recommended to be administered alone, with a minimum interval of 14 days before or after administration of any other vaccines. This was out of an abundance of caution and not due to any known safety or immunogenicity concerns. However, substantial data have now been collected regarding the safety of COVID-19 vaccines currently approved by FDA or authorized by FDA for use under EUA. Although data are not available for COVID-19 vaccines administered simultaneously with other vaccines, extensive experience with non-COVID-19 vaccines has demonstrated that immunogenicity and adverse event profiles are generally similar when vaccines are administered simultaneously as when they are administered alone.

COVID-19 vaccines and other vaccines may be administered without regard to timing. This includes simultaneous administration of COVID-19 vaccines and other vaccines on the same day, as well as coadministration within 14 days. It is unknown whether reactogenicity of COVID-19 vaccine is increased with coadministration, including with other vaccines known to be more reactogenic, such as adjuvanted vaccines or live vaccines. When deciding whether to
coadminister another vaccine(s) with COVID-19 vaccines, providers should consider whether the patient is behind or at risk of becoming behind on recommended vaccines, their risk of vaccine-preventable disease (e.g., during an outbreak or occupational exposures), and the reactogenicity profile of the vaccines.

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

Best practices for coadministration include:
- Label each syringe with the name and the dosage (amount) of the vaccine, lot number, the initials of the preparer, and the exact beyond-use time, if applicable.
- Separate injection sites by 1 inch or more, if possible.
- Administer the COVID-19 vaccines and vaccines that may be more likely to cause a local reaction (e.g., tetanus-toxoid-containing and adjuvanted vaccines) in different limbs, if possible.
- The deltoid muscle can be used for older children (≥11 years).
- For younger children (5–10 years), if more than 2 vaccines are injected in a single limb, the vastus lateralis muscle of the anterolateral thigh is the preferred site because of greater muscle mass.

For the more information on coadministration, please see CDC considerations on coadministration.

A summary document created by NC DHHS on coadministration of COVID-19 vaccine with flu vaccine is also available.

14.8 Additional Vaccine Administration Considerations for COVID-19 Vaccines

- Vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection. Viral testing for current infection, or serologic testing for prior infection, is NOT recommended for vaccine decision-making purposes.
- Vaccination should be deferred until recovery from acute illness (if person had symptoms) AND criteria have been met to discontinue isolation.
- For persons with a known SARS-CoV-2 exposure in the community, defer vaccination until quarantine period has ended to avoid exposing health care personnel or other persons during vaccination visit. For residents of congregate health care settings (e.g. long-term care facilities) or other congregate settings (e.g., correctional facilities, homeless shelters), person may be vaccinated.
- COVID-19 vaccines should not be delayed because of testing for TB infection. Testing for TB infection with one of the immune-based methods, either the tuberculin skin test (TST) or an interferon release assay (IGRA) can be done before or during the same encounter as COVID-19 vaccination. When testing with TST or IGRA cannot be done at the same time as COVID-19 vaccination, these tests should be delayed ≥4 weeks after the completion of COVID-19 vaccination but generally should not be cancelled. See Laboratory Testing Section under Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States from the CDC at: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#laboratory-testing

Vaccinated People Who Subsequently Develop COVID-19
For people who have received one or more doses of COVID-19 vaccine and subsequently experience COVID-19, prior receipt of a COVID-19 vaccine should not affect treatment decisions (including use of monoclonal antibodies, convalescent plasma, antiviral treatment, or corticosteroid administration) or timing of such treatments.

The FDA has authorized emergency use (EUA) of SARS-CoV-monoclonal antibodies (mAb) in high-risk individuals in outpatient settings for (1) the treatment of mild to moderate acute COVID-19 and (2) COVID-19 post-exposure prophylaxis.

Adults considered at high-risk for severe COVID-19 and high-risk youth ages 12-17 who weigh at least 88 pounds (40kg) may be eligible for mAb treatment. These high-risk individuals who have recently tested positive for COVID-19 and have had symptoms for 10 days or less, should be evaluated to see if monoclonal antibody treatment is appropriate for them. For more information from NC DHHS please go to: https://covid19.ncdhhs.gov/treatment

Additionally, the FDA has authorized the REGEN-COV (Casirivimab + Imdevimab) mAb product for use in some patients who are exposed to COVID-19 even if they are not showing symptoms. People who are not fully vaccinated or who have immunocompromising conditions, including those taking immunosuppressive medications, and have either been exposed to COVID-19 or are at high risk of exposure due to where they live or work may qualify for preventative treatment. This treatment is not a substitute for vaccination against COVID-19.

Providers can find more information about mAb treatment and treatment centers at 877-332-6585 or at www.covid.infusioncenter.org

15.0 Vaccine Transfer Guidance

NCDHHS recognizes that redistribution or transfer of vaccine may be necessary in some instances.

- **Redistribution** is the planned and scheduled movement of inventory between two enrolled sites within the same organization with an approved redistribution agreement.
- **Transfer** is the unplanned and unscheduled movement of inventory between two enrolled sites (move inventory between those who have vaccine to the those who do not)

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

**Providers who cannot store the minimum order quantity or follow the minimum ordering guidelines:**

- We recommend you look at posts on the Vaccine Marketplace in the CVMS Provider Portal to facilitate transfers from a nearby provider or hub before requesting doses from the state. The Vaccine Marketplace streamlines the transfer process by enabling providers to check all on-hand inventory and transfer opportunities in a centralized database.

**Providers in need of transfer doses should:**

- Locate the closest provider in the Vaccine Marketplace with excess available vaccine inventory that may be used for your patient population. **Next, contact that provider via email or phone to coordinate a transfer.** Please visit the Vaccine Marketplace in CVMS to find local providers with excess on-hand inventory. See Section 7.8 for additional information on the Vaccine Marketplace. **If you are unable to identify a transfer**, please utilize the
always-open Allocation Request Form to request vaccine doses (inclusive of first and second doses), **NC DHHS Vaccination Allocation Request Form**.

- All requests to the State will be confirmed via direct phone call to identify the best course of action. Following that conversation, providers will be notified of their final allocation and the necessary details. Given the new process, final allocation confirmations may be delayed as we solution the best course of action to fulfill requests. We appreciate your patience and understanding.
  - When transporting vaccine between providers, proper storage and handling must be maintained to ensure potency is not compromised. See Section 13.0 for information on safe transport of COVID-19 vaccine for each available product.
  - Please be sure to include the diluent vials supplied with your order when redistributing or transporting Pfizer COVID-19 vaccine. Diluent is critical to the administration of Pfizer vaccine and must be included to ensure proper administration.
  - If the diluent vials have been lost, misplaced, or are no longer useable, CDC recommends the following actions:
    - Determine how the diluent was lost and develop strategies to prevent this from happening again. Replacing diluent must be done at the expense of the provider or jurisdiction. Replacement diluent increases the risk of vaccine administration errors and may impact the safety of the vaccine if managed incorrectly.
    - All COVID-19 vaccines are preservative free. When replacing diluent for Pfizer vaccine, **only 0.9% preservative-free sodium chloride** can be used. **Do not use** bacteriostatic 0.9% Sodium Chloride Injection or any other diluent as they contain preservatives. This information is included in the **manufacturer’s fact sheet for healthcare providers**.
    - Diluent vials can only be used once and cannot be repeatedly punctured for multiple vials. Once diluent has been withdrawn from a vial it **MUST be discarded**, even if excessive saline is still available in the vial. Do not be tempted to re-puncture a diluent vial and withdraw additional diluent, even if mixing multiple vials for a mass vaccination clinic. Use only 1 vial of diluent with 1 vial of Pfizer vaccine. Failure to follow this practice may impact the safety of the vaccine. Additional information may be found at: **Questions about Single-dose/Single-use Vials | Injection Safety | CDC**
    - A full list of approved Pfizer distributors can be found at: **Pfizer Distributors | pfpfizeruscom**

- 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.**

2. Transfer requests require NCDHHS IMMUNIZATION BRANCH APPROVAL to ensure proper storage capabilities and tracking of COVID-19 Vaccine Inventory movements. There are three scenarios that transfer requests will fall under.
   - If a provider requests a redistribution between two CVMS Provider locations **within the same organization**, who have an existing redistribution agreement, **THE TRANSFER IS AUTOMATICALLY APPROVED BY NCDHHS IMMUNIZATION BRANCH**
   - If a provider requests a redistribution between two locations **within the same organization**, but there is no existing redistribution agreement, the **TRANSFER MUST BE MANUALLY APPROVED BY NCDHHS IMMUNIZATION BRANCH**
   - If a provider requests a transfer to a location that is **outside their location’s organization**, the **TRANSFER MUST BE MANUALLY APPROVED BY NCDHHS IMMUNIZATION BRANCH**
Please see pages 74-94 in the Step 6 – Receive and Manage Vaccine Inventories Job Aid for an overview of the transfer process for COVID-19 vaccines. There are also specific notification processes that must be followed by health centers that transfer HRSA-allocated vaccine doses to other health centers or external partners. Any interested health centers should reach out to Health Center Program Support or call 877-464-4772, option 2, 7:00 a.m. to 8:00 p.m. ET, Monday-Friday (except federal holidays).

16.0 Planning and Running Vaccination Clinics and Events

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

16.1 Vaccine Allocation

North Carolina’s allocation guidance has changed given ample supply and to give more flexibility to providers. The NC allocation strategy was initially an allocation method based on percentage of people unvaccinated in the county to provider requests. Providers can now request doses using the always-open Allocation Request Form.* Requested doses should include all doses your provider location intends to administer for the coming week(s), including scheduled appointments, walk-ins, and community events. Please continue to look at the emails from vaccineinfo@dhhs.nc.gov and weekly provider webinars.

Special note on minimum allocation requests: Practices wanting to place a minimum allowable order of vaccine are instructed to order through the state using the vaccination Allocation Request Form. Locations requesting less than the minimum allowable order are instructed to follow up with their assigned hub or request vaccine through the marketplace. If providers are using NCIR for COVID-19 vaccine management, vaccine transfers will have to be done with another NCIR provider so please reach out to your Immunization consultant if you need assistance identifying available COVID-19 vaccine in NCIR.

Weekly Ordering Cadence from the State:
Please watch out for emails from vaccineinfo@dhhs.nc.gov to ensure that you submit your COVID-19 vaccine request via the NC DHHS Vaccination Allocation Request Form in a timely manner to receive shipments for your location administration needs next week. For the latest vaccine ordering process and guidelines, please review the COVID-19 Adult and Pediatric Provider Ordering Guidance One-Pager. The State may be reviewing and placing pediatric vaccine orders outside of the regular ordering cadence to support the high demand of pediatric vaccine at the beginning of the roll-out. Requests for additional pediatric vaccine will not be considered at the time of this update until 70% of your Pfizer pediatric inventory has been used. That may change along with shifts in ordering limits in the future. If ordering for second doses, please indicate amount needed. For more on the latest vaccine ordering process and guidelines, please review the COVID-19 Vaccine Ordering Guidance One-Pager.
If you cannot store the minimum order quantity or follow the minimum ordering guidelines in the COVID-19 Vaccine Ordering Guidance One-Pager, we recommend CVMS providers look at posts on the Vaccine Marketplace in the CVMS Provider Portal to facilitate transfers from a nearby provider before requesting doses from the state. The Vaccine Marketplace streamlines the transfer process by enabling providers to check all on-hand inventory and transfer opportunities in a centralized database. Best practice is to:

- Locate the closest provider in the Vaccine Marketplace with excess available vaccine inventory that may be used for your patient population.
- Contact that provider via email or phone to coordinate a transfer. Please see Section 15 Vaccine Transfer Guidance.
- See 7 for additional information on the Vaccine Marketplace. Further details on vaccine transfer can be found in Section 15.0.
- Please see the job aids for instructions on how to post available vaccine doses to the Marketplace.
- CVMS Provider Portal Offer Vaccine Through Vaccine Marketplace Job Aid

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

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

- Providers are encouraged to accommodate walk-in vaccination requests and to offer vaccines as part of regular patient visits to provide the greatest flexibility and access to people wanting the vaccine.
- Because of how COVID-19 vaccines are packaged and their storage and use requirements, using every dose in a vial before it expires can be challenging in some settings.
- In these circumstances, getting vaccine to people who want the vaccine easily should be prioritized over ensuring that every dose is used in an open vial.
- Providers should fully enter vaccine administrations into the appropriate system as selected by the organization for COVID-19 vaccine management (CVMS or NCIR) within 24 hours, but no later than 72 hours.
- COVID-19 vaccine can only be transferred to other enrolled COVID-19 vaccination providers. Physical transfer of vaccine in accordance with vaccine-specific storage and handling requirements must not be initiated until the transfer has been approved by DHHS.
- The percentage of vaccine administered to historically marginalized and minority populations should meet or exceed the population estimates of these communities in their county and region. Providers should engage in partnerships and targeted outreach to vaccinate historically marginalized populations and meet this goal.
- People should not be required to present identification to verify age or residency.

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

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

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

Below is the general process:

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

16.3 Identify Local Partners

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

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

Vaccine providers are strongly encouraged to:

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

- Reach out directly to organizations to form partnerships for vaccine events, using contact information from the database

### 16.4 Identify Dates and Times

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

### 16.5 Consecutive Days at an Offsite Clinic

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

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

### 16.6 Make a Staffing Plan

- Refine staffing plans to allow for improved staff and patient experiences
- Identify roles and responsibilities for vaccination and any required trainings or certifications required for staff fulfilling these roles
- The [CDC COVID-19 Vaccination Training Programs and Reference Materials](https://www.cdc.gov/vaccines/trainings/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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<thead>
<tr>
<th>Role/Responsibility</th>
<th>Requirements and Considerations</th>
</tr>
</thead>
</table>
| Vaccine coordination | Primary and back-up vaccine coordinators, who have completed required trainings and ensure appropriate staff trained for vaccine receipt, storage, transport and handling of COVID-19 vaccine. Vaccine coordinators must complete the following trainings:  
  - Review the [CDC Storage and Handling Toolkit](https://www.cdc.gov/vaccines/technical-guidance/storage-and-handling-toolkit.html), including the COVID-19 vaccine addendum  
  - Complete the You Call the Shots: [Storage and Handling module](https://www.cdc.gov/vaccines/technical-guidance/storage-and-handling.html) |
- Complete the Pfizer-BioNTech, Moderna, and Janssen/J&J COVID-19 Vaccine training(s), as appropriate for the vaccine product(s) being offered at your facility. Complete the COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare Providers.

<table>
<thead>
<tr>
<th>Task</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Check-in, registration</td>
<td>Must be enrolled and trained in using CVMS unless using paper forms for later data entry (must be completed within 72 hours)</td>
</tr>
<tr>
<td>Screen patients for eligibility</td>
<td>See sample pre-vaccination screening form from CDC</td>
</tr>
<tr>
<td>Vaccinate</td>
<td>Vaccinators must be health care providers whose scope of practice includes vaccinations. Provides completed vaccination card to document vaccine receipt.</td>
</tr>
<tr>
<td>Monitor patient post-vaccination</td>
<td>Appropriate medical treatment used to manage immediate allergic reactions, including on site epinephrine, equipment to measure vital signs, and antihistamines, must be immediately available in the event that an acute anaphylactic reaction occurs following administration of an mRNA COVID-19 vaccine. Vaccine providers should observe patients with a history of anaphylaxis (due to any cause) for 30 minutes after vaccination. All other persons should be observed for 15 minutes after vaccination to monitor for the occurrence of immediate adverse reactions. It is very important to report all adverse reactions after the receipt of a COVID-19 vaccine. Providers should use Vaccine Adverse Event Reporting System (VAERS) and also provide v-safe information to the recipient so that recipients can self-enroll for a post-vaccination health check-in, as well as a 2nd dose reminder.</td>
</tr>
<tr>
<td>Schedule 2nd dose</td>
<td>Patients should be counseled on the importance of completing the 2-dose series in order to optimize protection. Individuals should receive an appointment for their second dose per the vaccine-specific dosing interval ideally at the time of the first dose and employ 2nd dose reminders, if possible.</td>
</tr>
<tr>
<td>Field incoming requests from individuals</td>
<td>Build upon existing call center functions, if available. See scripts in Appendix 33 for additional considerations.</td>
</tr>
<tr>
<td>Data entry</td>
<td>All vaccine doses administered in North Carolina must be documented in the organization’s selected system for COVID-19 vaccine management (CVMS or NCIR) within 72 hours of administration. At this time, providers should fully enter</td>
</tr>
</tbody>
</table>
administrations 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 |

### 16.7 Scheduling and Filling Appointments

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

### Developing Partnerships

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

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

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

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

16.8 Offering Transportation

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

See North Carolina Public Transit Systems map and list of contact information
16.9 Walk-In Vaccinations

- Walk-in vaccinations are being offered and encouraged more frequently throughout the state. They provide greater flexibility to vaccine recipients and can help you use your vaccine allocation. Keep the below tips in mind as you consider your ability to support walk-in recipients:
  - Compare your vaccine inventory with the total scheduled appointments to know approximately how many doses are available to support walk-ins. This can be checked on a cadence that fits your schedule and appointment volume. Frequently check for “no-shows,” and add these doses to the amount of vaccine available for walk-ins. Familiarize yourself and other CVMS users at your location on how to document walk-in appointments within the CVMS Provider Portal.
  - Offer vaccine to others who may have accompanied a recipient to their appointment. They may not know they have the ability to be vaccinated on the spot.
  - Plan for walk-ins by considering setting a routine walk-in timeframe that works for your staffing model and the number of appointments you have scheduled. Keep in mind that administering vaccine for walk-ins may require CVMS recipient registration and could take additional time.
  - Advertise walk-in vaccinations are available: Share information on social media, display signs within your location(s), ask community organizations (e.g. schools, churches, local businesses) to support you in spreading the word, etc.
  - Make sure you’ve also communicated to your staff members that walk-ins are welcome!

16.10 Registering individuals in CVMS

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

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

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

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

All vaccine doses administered in North Carolina must be documented in CVMS at this time. In the future, some providers may be able to use the NC Immunization Registry (NCIR). At this time, providers should fully enter administrations into CVMS **within 24 hours as often as possible**, but must enter administration data within 72 hours of administration. Providers should plan capacity for real-time or simultaneous data entry during vaccine efforts and identify local support or request help with staffing or centralized data entry immediately if they are not certain they can get the data entered within the timeframe. For current EHR integration options with CVMS, see Section 7.3.

### Documentation in CVMS Promising Practices

- CVMS pre-registration for vaccine recipients when possible
- Review/enter into CVMS any patient information gathered during appointment scheduling prior to the vaccine appointment or event so that on-site data entry is limited to the point-of-administration vaccine screening and administration documentation.
- Online or paper registration forms should not require for people to submit ID, SSN, or insurance information to be able to register for an appointment. These fields should be made optional or should not be included on registration forms at all. The form should allow for people to proceed to register even if they do not have these documents.
  - Asking for SSN or ID information in a registration form presents a special barrier since many people will see the questions and elect to simply not register for the event, without opportunity to speak to the vaccine provider about whether the documents are actually required.
- Plan staff capacity for real-time or simultaneous data entry during vaccine efforts. For example, consider having additional administrative staff to support data entry or scribe efforts.
- Plan technology, IT, or hardware needs to support real-time or simultaneous date entry. For example, consider using electronic tablets and onsite Wi-Fi units or hotspot units.
- Train registration or screening volunteers in CVMS to allow more staff members to assist as scribes. Plan ahead to upload volunteer vaccinators into the system for ease of real time documentation.
- Complete COVID vaccine cards with vaccine administration information, then enter recipient information from that vaccination card to improve data entry accuracy.
- For large vaccination clinics, utilize rolling laptop carts to aid mobility and provide cleanable surface for documents.
Utilize mobile hotspots for drive-through operations or large areas to aid mobility.

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

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

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

• 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.

16.12 Vaccination Clinic or Event Flow

16.12.1 Indoor Events
All operations within an indoor vaccinations site should be set up using social distancing best practices to protect patients and vaccine clinic staff. Vaccination clinics should follow Governor Cooper’s most current executive orders related to the pandemic response found at: https://www.nc.gov/covid-19/covid-19-orders-directives.d.
  o Experience to-date is that the process from on-site registration to vaccination takes approximately 15 minutes. Time can be reduced as vaccinators gain experience. The CDC recommends that people who
have a history of anaphylaxis (due to any cause) should be observed for 30 minutes following vaccination. All other people should be observed for 15 minutes following vaccination.

- Clear and frequently repeated messaging is crucial for compliance at vaccination sites. (For example, repeat instructions to stay inside vehicles or maintain 6 feet of social distancing in lines as appropriate).

**16.12.2 Drive Through Clinics**

Vaccine providers should consider using the following strategies for drive-through clinics:

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

**17.0 Promoting Equitable Vaccine Distribution**

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

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

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

17.1 Key Equity Data Resources

Foster learning and rapid-cycle improvement to drive equitable implementation. NCDHHS encourages providers to frequently reference the following data sources to assess equity performance and planning:

- Assess the equity of vaccine distribution using the community-level data on the North Carolina COVID-19 vaccination dashboard.
- Use the census tract map to prioritize locations for vaccination clinics. An instructional video is available here.
- Review the Historically Marginalized Population toolkit for providers.

**TIP:** Be transparent with the data to your staff and partners, share when equity success happens, and be humble in receiving feedback and support.
17.2 Equity Tips At-a-Glance

- **Be clear: no ID, no insurance required.** If you are requesting ID or insurance, train staff to remind patients that it is not required. Consider displaying Know Your COVID-19 Vaccine Rights.

- **Address access for people with disabilities.** Reminder: All vaccine providers are covered under the Americans with Disabilities Act (ADA), which requires that facilities, activities, services, and programs be accessible to individuals with disabilities.

- **Address language access.** Offer services in multiple languages and provide notices of such language access services online, in advertisements, and at points of service. If ASL or language interpretation is needed, ensure all elements of vaccine education and vaccination process are provided using preferred communication method.

- **Re-visit trusted and easily or frequently accessed sites by historically marginalized communities that you may have visited for primary series cases.

17.3 Strategies to Promote Vaccine Equity

**Be clear: no ID, no insurance required.** If you are requesting ID or insurance, train staff to remind patients that it is not required. Consider displaying Know Your COVID-19 Vaccine Rights.

Providers should include the following information on their websites and communications:

- **English:** People are not required to present an ID to be vaccinated. Vaccine providers may ask for an ID for insurance or HRSA reimbursement purposes. However, everyone will be vaccinated even if they don’t present an ID. No one will be turned away. See HRSA Provider Fact Sheet (English | Spanish) and Patient Fact Sheet (English | Spanish).

- **Spanish:** No se requiere que las personas presenten una identificación para ser vacunados. Los proveedores de vacunas pueden solicitar una identificación para fines de reembolso del seguro medico o de la HRSA. Sin embargo, todos serán vacunados incluso si no presentan una identificación. Nadie será rechazado. (Consulte la Hoja de información para proveedores de HRSA (inglés | español) y la Hoja de información del paciente (inglés | español).

**Engage Community Partners.** Connect with Community Health Workers, Healthier Together, and Database of Organizations Interested in Hosting or Supporting Vaccine Events for advice, onsite support, transportation connections, and outreach/scheduling support.
NCDHHS has a network of over 600 Community Health Workers (CHWs), who are deployed in statewide in all 100 counties to connect North Carolinians affected by COVID-19 with needed services and support. A roster of contacts by county is available here. We encourage you to connect directly with CHWs in your county to assist in making the most of your vaccination activities. They are available to help and may also reach out to you directly.

CHWs can help with the following vaccine areas:

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

For more information about Community Health Workers please go to: [https://www.ncdhhs.gov/divisions/office-rural-health/community-health-workers](https://www.ncdhhs.gov/divisions/office-rural-health/community-health-workers)


**Plan for walk-ins for people receiving their primary series**, others who may have trouble accessing vaccination. Consider blocking off time for walk-ins or in lieu of overscheduling in anticipation of no-shows.

**Prioritize scheduling historically marginalized populations at vaccine clinics.** Set-aside appointments with a special link that CHWs and other community partners can use to schedule or provide partners with “tickets” that don’t require an appointment. Reserve appointments for people who call the clinic to schedule (rather than only online).

**Address transportation access.** 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.

**Address language access.** Offer services in multiple languages and provide notices of such language access services online, in advertisements, and at points of service. If ASL or language interpretation is needed, ensure all elements of vaccine education and vaccination process are provided using preferred communication method.

- Contract with entities qualified to provide language access services through multiple types of media (telephonic interpretation, video remote interpreting, etc.)
- Post COVID-19 documents in multiple languages in multiple locations, including at providers’ initial point of contact.
• 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.


Address access for people with disabilities. Reminder: All vaccine providers are covered under the Americans with Disabilities Act (ADA), which requires that facilities, activities, services, and programs be accessible to individuals with disabilities.

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

Offer extended hours (nights/weekends) outside of the workday.

18.0 Cost, Coding and Billing of COVID-19 Vaccine

Cost

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

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

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

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

Billing

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

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

For more detailed information, please see the COVID-19 Vaccination Coding and Billing Resources. The AMA has updated the COVID-19 CPT vaccine and immunization codes regularly at: https://www.ama-assn.org/practice-management/cpt/covid-19-cpt-vaccine-and-immunization-codes

19.0 Additional Support and Resources

Upcoming CVMS Training

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

Additional Resources:

- **If you have any questions, please use the NC Vaccines Help Desk Portal.** To submit a question, issue, or request, please follow the instructions below:
  - Go to NC Vaccines 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 NC Vaccines Help Desk Portal, refer to this knowledge article to register
o 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).
 o Explicitly write the question, issue, or request in the description field
 o Submit case

• In addition to submitting questions or issues via the NC Vaccines Help Desk Portal, providers can also search the NC Vaccines Help Desk Portal for knowledge articles to help immediately address questions or issues.
• The NC Vaccines Help Center is available for vaccine providers and organizations to call and receive live support for COVID-19 vaccine and CVMS-related questions, issues, or requests. To reach the Help Center, call (877) 873-6247 and select option 1 for COVID-19 questions. The COVID-19 Vaccine Provider Help Center is available:
  o Monday – Friday 7:00 AM – 7:00 PM ET
  o Saturday 8:00 AM – 4:00 PM ET
• The NC COVID-19 Vaccine Help Center for individuals in NC is available at 1-888-675-4567 to handle COVID-19 vaccine and CVMS related questions.
• If you have general storage and handling questions, please contact our storage and handling staff at (919) 707-5574. Please leave a message if you do not reach anyone and someone will return your call as soon as possible. You may also find additional storage and handling resources on our website (Storage Resources). To report temperature excursions, please contact the manufacturer directly.
• If you have a clinical question, please call our clinical nurse on-call number at (919) 707-5575. Please leave a message if you do not reach anyone and someone will return your call as soon as possible.
• You may also contact your regional immunization nurse (RIN map) or regional immunization consultant (RIC map) if you need assistance.
• Virtual Agent:
  o Providers can connect with the Virtual Agent to resolve common questions and inquiries about COVID-19 vaccine and the COVID-19 vaccination program. Here you can receive immediate support 24 hours a day, 7 days a week. To engage with the Virtual Agent, please go to the NC Vaccines Help Desk Portal and click on the chat icon in the bottom right of the page. NC Vaccines Help Desk Portal and click on the chat icon in the bottom right of the page.
• Information for how individuals you have vaccinated can view their COVID-19 vaccination information can be found here.

• Pfizer is providing Customer Service for those vaccine providers that receive Pfizer vaccine for questions related to its product, please see below:
• Moderna is providing Customer Service for those vaccine providers that receive Moderna for questions related to its products, please see below:
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:
**Appendix / Reference Material**

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<tr>
<th>Appendix 1: Two EUA Fact Sheets for Recipients and Caregivers Based on Age of Recipients – Pfizer</th>
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<td>- 12 Years of Age and Older Products</td>
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<td>- 5-11 Years of Age Product</td>
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<td><strong>EUA Fact Sheets for Recipients and Caregivers – Pfizer Products</strong></td>
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<tr>
<td>- 12 Years of Age and Older (dilute Purple Cap)</td>
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<tr>
<td>- 12 Years of Age and Older (no dilution Gray Cap)</td>
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<tr>
<td>- 5-11 Years of Age Product</td>
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<tr>
<td><strong>EUA Fact Sheets for Health Care Providers Administering Vaccine– Pfizer Products</strong></td>
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<td>Appendix 7: COVID-19 Vaccine Readiness Checklist</td>
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Pfizer Storage and Handling Summary (5 Through 11 Years not available at time of the release of this document) |
| Appendix 10: Bulk Upload Template   | Bulk Upload Template    |
| Appendix 11: EUA Fact Sheet for Recipients and Caregivers – Moderna | EUA Fact Sheet for Recipients and Caregivers – Moderna |
| Appendix 12: EUA Fact Sheet for Providers – Moderna | EUA Fact Sheet for Providers – Moderna |
| Appendix 13: Storage and Handling Overview Moderna | Moderna Storage and Handling Overview |
| Appendix 16: CDC Moderna Standing Order | CDC Moderna Standing Order |
| Appendix 17: CDC Pfizer Standing Order | CDC Pfizer Standing Order |
| Appendix 18: CDC Pre-Vaccination Checklist English and Spanish | English: CDC Pre-Vaccination Checklist for COVID-19 Vaccines  
Spanish: CDC Pre-Vaccination Checklist for COVID-19 Vaccines |
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<th>Appendix</th>
<th>Description</th>
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<td><a href="#">COVID-19 Vaccine Temperature Log Celsius</a></td>
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<td>COVID-19 Vaccine Temperature Log Fahrenheit</td>
<td><a href="#">COVID-19 Vaccine Temperature Log Fahrenheit</a></td>
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<td>23</td>
<td>CVMS Recipient Portal Reset Username Job Aid</td>
<td><a href="#">CVMS Recipient Portal Reset Username Job Aid</a></td>
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