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1. What’s New

- **Market research** tells us that Healthcare providers are a valued and trusted source of health information and now play an even bigger role in a patient’s decision to get vaccinated. Engage all staff in efforts to start conversations with patients about the importance of getting vaccinated, and remember: **even vaccinating one person makes it worth opening the vial!**

- CDC updated its **COVID-19 vaccination guidance** with additional information to help vaccine providers determine the optimal interval between the first and second dose of an mRNA vaccine series, based on the individual patient’s age and health condition. Regardless of the interval between the first and second dose, data show mRNA vaccines remain highly effective at reducing the risk of hospitalization or serious complications from COVID-19 infection.
  - The guidance announced that an **8-week interval** may be best for some people ages 12 years and older, and especially for males ages 12 to 39 years.
  - This updated interval guidance is **specific to the mRNA (Pfizer-BioNTech or Moderna) COVID-19 vaccine primary series** and is only for some patients who have not yet begun their COVID-19 vaccine are not yet vaccinated with their primary series. Specifically:
    - People ages 12 through 64 years who are not moderately or severely immunocompromised—particularly males ages 12 through 39 years—may benefit from getting their second mRNA COVID-19 vaccine dose 8 weeks after their first dose.
    - Patients meeting these criteria who have already received their primary mRNA series at the 3-week (Pfizer-BioNTech) or 4-week (Moderna) interval remain well-protected—especially if they have received a booster dose—and do not need to repeat any doses.
  - **Potential benefits of an 8-week interval:**
    - Stronger immune response—Data show that a longer interval between the first and second doses may give the body a chance to build a stronger immune response, increasing the effectiveness of these vaccines.
    - Further adverse effect risk—New studies have shown the small risk of myocarditis and pericarditis associated with mRNA COVID-19 vaccination—mostly among males between the ages of 12 and 39 years—might be reduced with a longer interval between 1st and 2nd doses.
  - Providers should **continue to recommend the 3-week** (Pfizer-BioNTech) or 4-week (Moderna) intervals between primary doses for those who are:
    - In need of rapid protection due to concern about high levels of community transmission
    - Moderately or severely immunocompromised
    - Ages 65 years or older
    - 5-11 years of age (There are currently no data available for children younger than age 12 years regarding any impact of intervals longer than 3 weeks
between the 1st and 2nd doses of the Pfizer-BioNTech COVID-19 vaccine)

- **SPECIAL BULLETIN COVID-19 #230:** Update on Temporary Rate Increases and HCBS Rate Implementation: Detail on continuing, end-dating and revised rates

- **Updated CDC Guidance for:**
  - Boosters for Immunocompromised Individuals
  - Persons Vaccinated Outside of the U.S.
  - Timing of COVID-19 vaccines for recipients of monoclonal antibodies or convalescent plasma
  - History of myocarditis or pericarditis after an mRNA COVID-19 vaccine as a precaution

- **Effectiveness of Maternal Vaccination with mRNA COVID-19 Vaccine During Pregnancy Against COVID-19–Associated Hospitalization in Infants Aged <6 Months**

2. Getting Started

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**Welcome to the NCDHHS COVID-19 Provider Guidance!**

The links and information below will help you find information related to COVID-19 vaccine administration and product logistics.

For patient-facing resources like the ones linked throughout this document, please see:
- **DHHS COVID-19 Communications Toolkit**
- **CDC Vaccine Recipient Information**

For the most up-to-date COVID-19 related information from NCDHHS, we invite you to attend the weekly Provider Webinar at 12:30 PM EST. [Click here to access and save the link](#) or use Meeting ID: 161 406 4331; Passcode 906994.

3. Guiding Principles

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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.
Equity
All North Carolinians have equitable access to vaccines based on risk of exposure and risk of severe illness.
NCDHHS has a specific focus on building trust with historically marginalized populations (HMP). 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.

Inclusivity
Vaccine planning and distribution is inclusive; actively engages state and local government, public and private partners; and draws upon the experience and expertise of leaders from historically marginalized populations.
Coordination is facilitated by state and local entities to ensure all priority populations can be reached. Vaccine and health care providers have a responsibility to take intentional action to reach and engage historically marginalized communities.

Transparency
Transparent, accurate, and frequent public communications is essential to building trust. All North Carolinians, including vaccine providers and the public, should understand what to expect in the vaccination campaign.
4. Overview of North Carolina’s COVID-19 Vaccine Plan

Please see the NC Vaccine Strategy page for full details and an administration timeline.

5. General Vaccine Information

Current information can always be found in the CDC Interim Clinical Considerations for Use of COVID-19 Vaccines and at the DHHS Vaccination Information for Healthcare Professionals page.

5a. Vaccine Eligibility

Please see the CDC Eligibility Page for detailed info. Important notes include:

- The vaccine is free everywhere in North Carolina.
  - See the Medicaid billing guide
- No photo or government ID or insurance is required.
Everyone can be vaccinated, regardless of their immigration status. Getting vaccinated will not affect an individual’s immigration status.

The CDC now recommends the Moderna or Pfizer COVID-19 vaccines as the preferred vaccine for both the initial series and booster dose.

People can self-attest (no proof is needed) that they are eligible for an additional dose of an mRNA COVID-19 vaccine.

5b. General Vaccine Messaging

COVID-19 primary series vaccination is recommended for everyone ages 5 years and older in the United States for the prevention of COVID-19.

- Pfizer-BioNTech or Moderna COVID-19 Vaccines are preferred over the Janssen COVID-19 Vaccine for primary and booster vaccination.
- A booster dose of COVID-19 vaccine is recommended for everyone ages 12 years and older.

Additional Resources

- NCDHHS COVID-19 Communications Toolkit
- NCDHHS Patient Fast Facts Sheet
- NCDHHS Vaccine Video Library
- CDC Vaccine FAQ for Healthcare Professionals
- CDC Training and Education for Healthcare Professionals Resources
- CDC Vaccine Recipient Education Information
- Bilingual Community Protection Poster
- CDC Resources for Health Departments
- CDC Learning Connection

5c. Vaccine Hesitancy Resources
Your conversations with patients about COVID-19 vaccines in routine care can make a difference:

**Personal Stories**
Use your credibility as a healthcare provider to help guide the conversation. Don't be afraid to tell your personal vaccination story!

**Tested & TRUE**
Build trust in the vaccine development process, without getting bogged down in overly technical details or medical jargon.

**Help Loved Ones**
Frame the conversation around how getting the vaccine helps patient's loved ones.

Vaccine Hesitancy Resources
- NCDHHS [Vaccine Discussion Guide for Healthcare Providers](#)
5d. Booster Information

For the general population, a booster dose of COVID-19 vaccine is recommended for everyone ages 12 years and older according to the schedule below. There is no need for people to go back to the location where they received their original vaccines.

Individuals 12 to 17 years of age can only receive the Pfizer booster, and adults 18 years of age and older can get any brand.

See the CDC’s [Booster Information](#) page for up-to-date guidance.

For immunocompromised persons, please see the CDC’s guidance for [COVID-19 vaccinations for people who are moderately or severely immunocompromised](#).

### COVID-19 vaccination schedule for the general population

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>0 month</th>
<th>1 month</th>
<th>2 month</th>
<th>3 month</th>
<th>4 month</th>
<th>5 month</th>
<th>6 month</th>
<th>7 month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer-BioNTech (ages 5-11 years)</td>
<td>1st dose</td>
<td>2nd dose*</td>
<td>(3-8 weeks after 1st dose)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pfizer-BioNTech (ages 12 and older)</td>
<td>1st dose</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderna (ages 12 and older)</td>
<td>1st dose</td>
<td>2nd dose*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderna (ages 18 and older)</td>
<td>1st dose</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Janssen (ages 18 and older)</td>
<td>1st dose</td>
<td></td>
<td></td>
<td>Booster dose**</td>
<td>(at least 2 months after 1st dose)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Additional Resources:**

- NCDHHS [COVID-19 Vaccine Boosters](#)
- NCDHHS “Double Your Protection” flyer
- NCDHHS Patient Booster Fact Sheet

6. Special Populations
6a. Cultural Humility

The National Institutes of Health (NIH) defines cultural humility as “a lifelong process of self-reflection and self-critique whereby the individual not only learns about another's culture, but one starts with an examination of her/his own beliefs and cultural identities.”

Cultural humility recognizes the correlation between a person’s health and their identities related to race and ethnicity, gender, sexual orientation, socioeconomic status, education, social needs, and others. These factors can influence:

- How patients perceive symptoms and health conditions
- When and how patients seek care
- Patients’ expectations of care and preferences regarding treatment
- Who patients believe should participate in making healthcare decisions

Additional Resources:
- Cultural Humility vs. Cultural Competence — and Why Providers Need Both
- Cultural Humility Is Critical to Health Equity
- How to Improve Cultural Competence in Health Care

6b. Historically Marginalized Populations (HMP)

Many individuals, groups, and communities have historically and systematically been denied access to services, resources and power relationships across economic, political, and cultural dimensions. This marginalization is a result of systemic and persistent racism, discrimination and other forms of oppression.

Historic marginalization can result in poor health outcomes and has contributed to the inequitable distribution of COVID-19 cases and fatalities within these communities.

It is important as a provider to be aware of historical implications that can be perceived as a barrier to access, acceptance, and overall vaccine confidence for these groups.

Additional Resources:
- NCDHHS Historically Marginalized Populations Engagement Toolkit

6c. 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.

See the CDC’s guidance and best practices for vaccinating homebound persons
Additional resources:
- NCDHHS Accessibility Checklist
- NCDHHS Homebound Vaccine Providers
- CDC Guidance for Vaccinating Older Adults and People with Disabilities
- PREP act and state authorizations for individuals to administer COVID-19 vaccines
- Liability protection: PREP Act and state Executive Order 193, Section 3B
- Partnering with Uber to reach homebound persons

6d. Pregnant and Lactating Individuals

COVID-19 vaccination is strongly recommended for all people who are pregnant, breastfeeding, trying to get pregnant now, or might become pregnant in the future in order to prevent serious illness, deaths, and adverse pregnancy outcomes.

Pregnant people who are 12-17 years of age can receive age-appropriate authorized Pfizer-BioNTech COVID-19 vaccine products.

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.

See the American College of Obstetricians and Gynecologists Practice Advisory for COVID-19 Vaccination Considerations for Obstetric–Gynecologic Care and the CDC recommendations for pregnant and breastfeeding individuals.

Additional Resources:
- NCDHHS COVID-19 Vaccination: Pregnancy, Fertility, and Breastfeeding
- NCDHHS Pregnant and Nursing Flyer for patients
- CDC COVID-19 Vaccines While Pregnant or Breastfeeding
- CDC Guidance for Breastfeeding in the Context of COVID-19
- CDC Statement on Pregnancy Health Advisory
- CDC Statement on Pregnancy Health Advisory
- ACOG patient videos on recommended vaccines during pregnancy

6e. Long-term Care and Congregate Facilities

Additional Resources:
- NCDHHS COVID-19 Infection Prevention Guidance for Long-Term Care Facilities
- CDC COVID-19 Risks and Vaccine Information for Older Adults
- FAQs About Medical Consent & Pfizer-BioNTech Booster Doses for Long-term Care
- Medical Management of Vaccine Reactions in Adults in a Community Setting

6f. Immunocompromised Individuals
A 3-dose primary mRNA COVID-19 vaccine series is recommended for people ages 5 years and older who are moderately or severely immunocompromised, followed by a booster dose in those ages 12 years and older.

See the CDC’s guidance for COVID-19 vaccinations for people who are moderately or severely immunocompromised.

<table>
<thead>
<tr>
<th>Primary Vaccination</th>
<th>Age Group</th>
<th>Number of Primary Vaccine Doses</th>
<th>Number of Booster Doses</th>
<th>Interval Between 1st and 2nd Dose</th>
<th>Interval Between 2nd and 3rd Dose</th>
<th>Interval Between 4th and 5th dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer-BioNTech</td>
<td>5–11 years</td>
<td>3</td>
<td>NA</td>
<td>3 weeks</td>
<td>≥4 weeks</td>
<td>N/A</td>
</tr>
<tr>
<td>Pfizer-BioNTech</td>
<td>≥12 years</td>
<td>3</td>
<td>1</td>
<td>3 weeks</td>
<td>≥4 weeks</td>
<td>≥3 months</td>
</tr>
<tr>
<td>Moderna</td>
<td>≥18 years</td>
<td>3</td>
<td>1</td>
<td>4 weeks</td>
<td>≥4 weeks</td>
<td>≥3 months</td>
</tr>
<tr>
<td>Janssen</td>
<td>≥18 years</td>
<td>1 Janssen, followed by 1 mRNA</td>
<td>1</td>
<td>4 weeks</td>
<td>≥2 months</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Additional Resources
- CDC “How to Talk with Immunocompromised Patients”
- ACIP’s general best practices for vaccination of people with altered immunocompetence
- CDC Guidance for persons vaccinated as part of a clinical trial

6g. Individuals Vaccinated Outside the United States

Please see Appendix E of the CDC Clinical Considerations for up-to-date information.

6h. Additional Special Populations Resources

- Tips for Effective Communication with Individuals Who Have Hearing Loss at a Mass Vaccination Event
- Ensuring the Rights of People with Limited English Proficiency in Health Care During COVID-19
7. Pediatric Vaccines

7a. Children 6 months – 4 years old

The FDA is delaying next steps of the authorization process for the Pfizer’s COVID-19 vaccine for children ages 6 months – 4 years old. This means that the Wave 1 orders for this product placed in February have been canceled by the CDC. Should this product become available again in the Spring, we will communicate its ordering process and next steps.

Additional Resources:
- Pediatric vaccine social media assets
- How to Talk with Parents and Caregivers about COVID-19 Vaccination
- Barriers to Equity in Childhood Vaccination
- Ingredients included in the COVID-19 Vaccines

7b. Children 5 and Older

All children over the age of 5 are eligible to receive the age-appropriate Pfizer BioNTech COVID-19 vaccine.

See the CDC’s Clinical Considerations for offering pediatric vaccines

Additional Resources:
- NCDHHS pediatric vaccine social media assets
- NCDHHS 5-11 side effects flyer
- NCDHHS 5-11 Parent/Guardian flyer
- Barriers to Equity in Childhood Vaccination
- How to Talk with Parents and Caregivers about COVID-19 Vaccination
- Translations of the Pfizer-BioNTech Fact Sheet for Recipients and Caregivers for 5 through 11 years of age
- Ingredients included in the COVID-19 Vaccines

8. North Carolina Vaccination Legal Considerations

Starting August 20, 2021, a 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."

Written consent from a parent or legal guardian is still required in order to receive Pfizer-BioNTech COVID-19 vaccine for the following children and teens because the age-appropriate Pfizer-BioNTech COVID-19 vaccine products are only available under emergency use authorization:

- Children 5 – 15 years of age as primary series
- Children and teens (5 years and older) eligible for an additional dose of a Pfizer-BioNTech COVID-19 vaccine due to being moderately or severely immunocompromised; and
- Teens (12 -17 years of age) who are eligible for a booster dose of a Pfizer-BioNTech COVID-19 vaccine.

**Additional Resources:**
- FAQs about Consent from Minors
- Legal Issues Related to Minors, School Staff, and Volunteers
- NC Immunization Law

**9. Moderna COVID-19 Vaccines**

*Moderna COVID-19 Vaccine* is FDA-approved or FDA-authorized in people ages 18 years and older as a 2-dose primary series, with an interval of 4 weeks between doses.

- Some individuals may benefit from getting their second dose 8 weeks after their first dose, rather than the typical 4-week interval. See the [CDC Guidance for Individualized Vaccination Schedules](https://www.cdc.gov/vaccines/schedules/hcp/personalized-schedule/index.html) for more.
- See the [CDC Guidance for contraindications and precautions](https://www.cdc.gov/vaccines/ppv/adverse-events/contraindications.html) and [Triage of People with a History of Allergies or Allergic Reactions](https://www.cdc.gov/vaccines/ppv/adverse-events/allergies.html) before administering vaccine.
- COVID-19 vaccines may be administered without regard to timing of other vaccines.

See the [Moderna Fact Sheet for Healthcare Providers](https://www.moderna.com/media-library/releases/2021-02-11/moderna-fact-sheet-healthcare-providers) and the [Moderna Storage and Handling Overview](https://www.moderna.com/media-library/releases/2021-02-11/moderna-storage-and-handling-overview) for the most recent product info.

**Additional Resources:**
- [Communication Resources for COVID-19 Vaccines](https://www.moderna.com/media-library/releases/2021-02-11/moderna-communication-resources)
- [Moderna Online Training Module](https://www.moderna.com/media-library/releases/2021-02-11/moderna-online-training-module)
- [Ingredients included in the COVID-19 Vaccines](https://www.moderna.com/media-library/releases/2021-02-11/moderna-ingredients)
- Interchangeability of COVID-19 Vaccine Products

**Moderna Customer Service**
- 1-866-MOD-ERNA or 1-866-663-3762

Pfizer-BioNTech COVID-19 Vaccine is FDA-approved or FDA-authorized in people ages 5 years and older as a 2-dose primary series, with an interval of 3 weeks between doses.

- Some individuals may benefit from getting their second dose 8 weeks after their first dose, rather than the typical 3-week interval. See the CDC Guidance for Individualized Vaccination Schedules for more.
- See the CDC Guidance for contraindications and precautions and Triage of People with a History of Allergies or Allergic Reactions before administering vaccine.
- COVID-19 vaccines may be administered without regard to timing of other vaccines.

Please see the Pfizer BioNTech Fact Sheet for Healthcare Providers and the Pfizer Storage and Handling Checklist for up-to-date information.

The image below demonstrates the handling and administration differences between available Pfizer products and preliminary information about the vaccine for children ages 6 months-4 years of age.

_Janssen COVID-19 Vaccine_ is FDA-authorized for use in people ages 18 years and older. The primary series is a single primary dose.

- See the [CDC Guidance for contraindications and precautions](https://www.cdc.gov/vaccines/hcp/professionals/COVID-19/contraindication-guidance.html) and [Triage of People with a History of Allergies or Allergic Reactions](https://www.cdc.gov/vaccines/hcp/professionals/COVID-19/allergy-coverage.html) before administering vaccine.
- Although mRNA vaccines are preferentially recommended in most situations over the Janssen COVID-19 Vaccine, the Janssen COVID-19 Vaccine may be considered in some situations.
- COVID-19 vaccines may be administered without regard to timing of other vaccines.

The Johnson & Johnson vaccine supply will be limited indefinitely. We understand this product serves a variety of populations with different needs, and supply will be strategically placed across the state to serve those populations.

See _Considerations for Janssen COVID-19 Vaccine_, _Janssen COVID-19 Vaccine Fact Sheet_, and the _Janssen Storage and Handling Overview_.

Additional Resources:
- [Communication Resources for COVID-19 Vaccines](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/communicate.html)
12. Safety Monitoring and Resources

The CDC and FDA are actively engaged in safety monitoring of COVID-19 vaccines with numerous vaccine safety monitoring systems, including VAERS, to watch for adverse events after vaccination.

The Center for Biologics Evaluation and Research (CBER) at the FDA is monitoring safety of authorized COVID-19 vaccines through both passive and active safety surveillance systems. CBER is doing so in collaboration with the Centers for Disease Control and Prevention (CDC), the Center for Medicare and Medicaid Services (CMS), the Department of Veterans Affairs (VA), and other academic and large non-government healthcare data systems. In addition, CBER participates actively in ongoing international pharmacovigilance efforts, including those organized by the International Coalition of Medicines Regulatory Authorities (ICMRA) and the World Health Organization (WHO). These efforts are in addition to the pharmacovigilance efforts being undertaken by the individual manufacturers for authorized vaccines. A coordinated and overlapping approach using state-of-the-art technologies has been implemented. These systems can also potentially be leveraged to assess safety in specific subpopulations and to assess vaccine effectiveness, including against emerging variants.

These monitoring systems include:

- **Vaccine Adverse Event Reporting System (VAERS)**
  
  *An early warning system that helps CDC and FDA monitor problems following vaccination. Anyone can report suspected vaccine reactions and issues to VAERS.*

  VAERS can provide vaccine safety experts with valuable information to assess possible safety concerns. VAERS is especially useful for quickly detecting unusual or unexpected patterns of adverse event reporting that might signal a possible safety problem with a vaccine. VAERS is not designed to assess cause and effect so VAERS reports alone cannot be used to determine if a vaccine caused or contributed to an adverse event or illness. Experts from CDC and FDA monitor VAERS reports to identify adverse events that need to be studied further. All serious reports are reviewed daily by vaccine safety experts. Scientists at CDC and FDA also use statistical models to
help understand whether there are any safety signals for a vaccine product and compare them with safety signals for other vaccines to determine if further investigation is needed. VAERS staff obtain follow-up medical records for reports classified as serious. A serious report describes an event that resulted in permanent disability, hospitalization, life-threatening illness, or death. VAERS staff may also obtain follow-up medical records for adverse events of interest, like anaphylaxis. Reviewing these records can help CDC and FDA medical staff better understand cases.

Anyone can submit a report to VAERS, including patients, family members, healthcare providers, vaccine manufacturers and the general public. These reports are submitted directly to VAERS and not through the state. CDC, the FDA and NC DHHS encourage anyone who experiences an adverse event after receiving a vaccine to report to VAERS.

Experts from CDC and FDA monitor VAERS reports to identify adverse events that need to be studied further. Information provided to VAERS which identifies a person who received the vaccine or vaccines will not be made available to the public. De-identified VAERS data are made available to each jurisdiction 4-6 weeks after the report is received. VAERS data available to the public include only the initial report data to VAERS. Updated data which contains data from medical records and corrections reported during follow-up are used by the federal government for analysis. However, for numerous reasons including data consistency, these amended data are not available to the public. CDC shares VAERS summary data for each jurisdiction for their awareness. Summary data is monitored weekly by North Carolina, which includes county as a variable.

- **CDC v-safe**
  A smartphone-based, after-vaccination health checker for people who receive COVID-19 vaccines.

  V-safe uses text messaging and web surveys from CDC to check in with vaccine recipients following COVID-19 vaccination. V-safe also provides second vaccine dose reminders if needed, and telephone follow-ups to anyone who reports medically-attended adverse events. Participants can enroll in v-safe after any dose of vaccine, and parents and guardians can enroll on behalf of their children.

- **V-safe COVID-19 Vaccine Pregnancy Registry**
  As part of v-safe, information about pregnancy status at the time of vaccination and at defined follow up time points after vaccination is collected.

  Given the lack of safety data from pre-EUA clinical trials of COVID-19 vaccines among pregnant persons, the v-safe pregnancy surveillance system will provide critical information to monitor the safety of COVID-19 vaccines administered under EUA and is intended to capture information about pregnant persons and their infants who have been vaccinated. This can inform clinical guidance regarding COVID-19 vaccination during pregnancy and can provide an additional method to detect adverse events that warrant further evaluation using existing safety and database systems.

- **Clinical Immunization Safety Assessment (CISA) Project**
A partnership between CDC and several medical centers that conduct clinical research on vaccine-associated health risks in certain groups of people.

- **Vaccine Safety Datalink (VSD)**
  A collaboration between CDC and several health care organizations that allows ongoing monitoring and proactive searches of vaccine-related data.

- **Emergency Preparedness for Vaccine Safety**
  *In the event of a disease outbreak in which a mass vaccination campaign is needed, CDC activates emergency preparedness activities to ensure that vaccines remain safe.*

- **The BEST**
  Part of the [Sentinel initiative](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8188420/), that comprises large-scale claims data, electronic health records (EHR), and linked claims-EHR databases with a data lag of approximately three months.

  The system makes use of multiple data sources and enables rapid queries to detect or evaluate adverse events as well as studies to answer specific safety questions for vaccines. The linked claims-EHR database makes it possible to study the safety of vaccines in sub-populations with pre-existing conditions or in pregnant women. The major partners for BEST currently are Acumen, IBM Federal HealthCare, IQVIA, and Columbia University and many affiliated partners such as MedStar Health, BlueCross BlueShield of America, the Observational Health Data Sciences and Informatics (OHDSI), OneFlorida, University of California and several others. Using BEST, CBER plans to monitor about [15 adverse events](https://www.cdc.gov/vaccines/vac-reqs/evs/cber-novel.html) that have been seen with the deployment of previous vaccines but have yet to be associated with a safety concern for an authorized COVID-19 vaccine at this time. CBER further plans to use the BEST system to conduct more in-depth analyses should a safety concern be identified from sources such as VAERS.

- **Medicare Claims Database**
  *During the current pandemic, FDA, CMS, and CDC have already used the Medicare data to publish a study showing that frailty, comorbidities, and race/ethnicity were strong risk factors of COVID-19 hospitalization and death among the U.S. elderly.*

  CBER has worked over the past several years with CMS to develop capabilities for routine and time-sensitive assessments of the safety of vaccines for people 65 years of age and older using the [Medicare Claims database](https://www.cms.gov). Because it was already in place, this system was immediately put into use for COVID-19 vaccine surveillance to monitor for adverse events.

**Additional Resources**

- [VAERS fact sheet](https://www.vaers.hhs.gov)
- [v-safe Fact Sheet](https://www.cdc.gov/vaccines/vac-reqs/evs/cber-vsafe.html)
- [How Vaccines are Tested, Licensed, and Monitored for Safety](https://www.cdc.gov/vaccines/vac-reqs/evs/cber-novel.html)
- [Reporting Adverse Events](https://www.cdc.gov/vaccines/vac-reqs/evs/cber-novel.html)
- [Understanding Side Effects and Adverse Events](https://www.cdc.gov/vaccines/vac-reqs/evs/cber-novel.html)
- [Vaccine Safety Research](https://www.cdc.gov/vaccines/vac-reqs/evs/cber-novel.html)
13. Statewide Standing Orders

Please see the latest Statewide Standing Orders:

- Statewide Standing Order for FDA Approved Pfizer/COMIRNATY COVID-19 Vaccine Administration in Patients Ages 5-11 Years (Feb. 15, 2022)
- Statewide Standing Order for FDA Approved Pfizer/COMIRNATY COVID-19 Vaccine Administration in Patients Ages 12 Years and Older (Feb. 28, 2022)
- Statewide Standing Order for FDA Authorized Moderna COVID-19 Vaccine Administration (Feb. 28, 2022)
- Statewide Standing Order for FDA Authorized Johnson and Johnson (Janssen) COVID-19 Vaccine Administration (Feb. 15, 2022)

14. Documentation, Reporting, and Transfer

14a. Ordering and Managing Vaccine

Please see the COVID-19 Ordering Guidance One-Pager for vaccine ordering details.

Providers can choose to use CVMS or NCIR to manage their COVID-19 vaccine inventory. Please see the NCIR Process Guide if you wish to make this change.

Whether a provider uses CVMS or NCIR, the COVID-19 Vaccination Program Provider Enrollment Process takes place in the CVMS Provider Enrollment Portal.

- CVMS
  - CVMS User Guide
  - CVMS Upcoming Trainings
  - CVMS Provider Portal
  - CVMS Organization Portal for Healthcare Location Managers
  - CVMS Managing Inventory Best Practices document

- NCIR
  - NCIR User Guide
  - NCIR interoperability with electronic health records
  - NCIR Managing Inventory Best Practices

Important Notes:
• 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.

• We encourage all providers to post and manage their available excess inventory that is below the Minimum Order Quantity (MOQ) they are willing to transfer on Vaccine Marketplace.

Additional Resources:
• NC Vaccines HelpDesk Portal
• Tips for Preparing for First Vaccine Allocation

14b. Transporting Vaccine

Please see the COVID-19 Vaccine Transport Guidance.

15. COVID-19 Vaccine Coding and Billing

• COVID-19 Vaccination Coding and Billing Resources
• AMA COVID-19 Vaccine CPT® Codes to find the appropriate CPT code combination for the type of vaccine and services being offered
• NC Medicaid billing guide
COVID-19 Vaccination
A Quick Guide to Coding and Billing

Did you know?
NC Medicaid has increased the reimbursement for COVID vaccine administration from $40 to $65.

The 3rd dose of a primary series vaccine (Pfizer and Moderna) given to immunocompromised kids can be billed.

NC Medicaid-enrolled providers can bill code 99401 for telephone outreach to unvaccinated Medicaid beneficiaries.

Find your COVID-19 Vaccine CPT® Codes
The American Medical Association (AMA) has created a CPT Combination Tool. Just type in the vaccine type and dose of vaccine that you are using, and pull up your CPT codes immediately!

Additional Resources:
- NC Medicaid COVID-19 Guidance & Resources for Medicaid Providers
- NC Medicaid Policy Modifications
**NC Medicaid Special Bulletins**

## 16. Additional Help

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 and Saturday 8:00 AM – 4:00 PM ET.

**Additional Resources:**
- [How to Submit a HelpDesk Case One-Pager](#)
- CDC [Learning Connection](#)

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<td>1-877-878-6247 (select Option 3)</td>
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<td>Vaccines.gov/VaccineFinder Support</td>
<td>Available M-F, 8am – 8pm ET</td>
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<td>VAMS</td>
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Tiberius: Tiberius-Help@cdc.gov |