What do practices need to know now?

NC COVID-19 Vaccination Plan: A Four-Phased Approach
Due to a limit amount of vaccines North Carolina has determined a four phased approach to vaccine distribution, following prioritization recommendations to protect health care workers caring for patients with COVID-19, people who are at the highest risk of being hospitalized or dying, and those at high risk of exposure to COVID-19. Note: the distribution plan was revised due to updated recommendations from the CDC Prevention’s Advisory Committee on Immunization Practices.

Phase 1a: Health care workers fighting COVID-19 & Long-Term Care staff and residents
• Health care workers caring for and working directly with patients with COVID-19, including staff responsible for cleaning and maintenance in those areas
• Health care workers administering vaccine
• Long-term care staff and residents—people in skilled nursing facilities and in adult, family and group homes

Phase 1b: Adults 75 years or older and frontline essential workers (possibly week of 1/4/21)
There is not enough vaccine for everyone in this phase to be vaccinated at the same time. Vaccinations will be available to groups in the following order:
• Group 1: Anyone 75 years or older, regardless of health status or living situation
• Group 2: Health care workers and frontline essential workers 50 years or older*
• Group 3: Health care workers and frontline essential workers of any age

* The CDC defines frontline essential workers as first responders (e.g., firefighters and police officers), corrections officers, food and agricultural workers, U.S. Postal Service workers, manufacturing workers, grocery store workers, public transit workers, and those who work in the education sector (teachers and support staff members as well as child care workers).

Phase 2: Adults at high risk for exposure and at increased risk of severe illness
Vaccinations will happen by group in the following order:
• Group 1: Anyone 65-74 years old, regardless of health status or living situation
• Group 2: Anyone 16-64 years old with high-risk medical conditions that increase risk of severe disease from COVID-19 such as cancer, COPD, serious heart conditions, sickle cell disease, Type 2 diabetes, among others, regardless of living situation
• Group 3: Anyone who is incarcerated or living in other close group living settings who is not already vaccinated due to age, medical condition or job function
• Group 4: Essential workers not yet vaccinated*
* The CDC defines these as workers in transportation and logistics, water and wastewater, food service, shelter and housing (e.g., construction), finance (e.g., bank tellers), information technology and communications, energy, legal, media, and public safety (e.g., engineers), and public health workers.

Phase 3: Students

- College and university students
- K-12 students age 16 and over.
- Younger children will only be vaccinated when the vaccine is approved for them

Phase 4: Everyone who wants a safe and effective COVID-19 vaccination

A COVID-19 Vaccination Infographic is available in English and Spanish. For more detailed information, NCDHHS has also created a Deep Dive: Phase 1a (English/Spanish) and Deep Dive: Phase 1b (English/Spanish coming soon).

How do individuals get their vaccine when eligible?

**Phase 1a**

- Local Health Departments are compiling lists of health care providers who are not affiliated with a hospital or health system and who meet the criteria for Phase 1a.
- Health care employers (e.g., medical practices, hospice providers, EMS) should determine which of their employees meet the criteria of being 1a.
  - If they are not already working with their Local Health Department, health care employers should:
  - Contact their local health department to submit their list of eligible health care workers in order to pre-register employees for vaccination or determine if they will be registered around time of vaccination.
  - Understand that the ability for Local Health Departments to schedule appointments will depend on the supply of vaccine available.
- Hospitals and health systems are compiling lists of and pre-registering their employees and affiliated staff who meet the criteria for Phase 1a. They also may:
  - Vaccinate non-employed or non-affiliated community-based health care workers who meet Phase 1a eligibility criteria.
  - Work with the Local Health Department to coordinate access to vaccine for non-affiliated health care workers
- Long Term Care staff and residents
  - On-site in long-term care facilities in Federal Pharmacy Partnership for Long-Term Care Program with CVS and Walgreens
  - Those that did not enroll in the federal program can work with local health departments to get vaccinated.
  - Enrolling other long-term care pharmacies to provide vaccinations to LTC facilities
Phase 1b

- To start, only hospitals and local health departments have been allocated vaccine. At the beginning of Phase 1b, people may need to be vaccinated in those organizations.
- If your patients are eligible and you are not enrolled or do not have vaccine, you can contact the local health department or another enrolled vaccination site.
- A website with enrolled providers who have been allocated vaccine can be found here: https://covid19.ncdhhs.gov/vaccines

COVID-19 Vaccination Provider Recruitment and Enrollment

North Carolina has prioritized early outreach, recruitment and enrollment of key providers and agencies who serve populations with high risk of clinical severity and high risk of exposure. North Carolina has created a streamlined electronic process for provider enrollment applications, licensure verification, storage and handling assessments, and approval and denial letters. It is expected that Primary and Urgent Care providers will be able to enroll as vaccination provider around January 11, 2021 on the COVID 19 Training website. To enroll, a provider must attend CVMS trainings and will move through the enrollment process.

COVID-19 Vaccination Management System (CVMS)

What is CVMS?
CVMS is a secure, cloud-based vaccine management solution for COVID-19 that enables vaccine management and data sharing across providers, hospitals, agencies, and local, state, and federal governments on one common platform.

What does it help providers do?
It allows providers to enroll in the COVID-19 Vaccine Program and upload employees so they can register for COVID-19 vaccination, manage the COVID-19 vaccine inventory, and track COVID-19 vaccine administration. In future CVMS releases, providers will be able to schedule clinics. Pharmacies such as CVS and Walgreens will not be using CVMS.

Training on CVMS use is needed
NCDHHS provides a range of live and recorded CVMS trainings including:
  - Provider Enrollment
  - A Day in the Life of a Location Manager
  - A Day in the Life of a Healthcare Provider

Recorded sessions available on https://immunize.nc.gov/providers/covid-19training.htm
Also available are FAQs, User guides, and other materials to assist in the use of CVMS website.
COVID 19 Vaccinations

How is the vaccine stored and handled?
North Carolina will assess cold-storage capacity across the state and will develop, coordinate, and support an ultra-cold chain storage system if an approved vaccine candidate requires it. This effort will be informed by guidance from Operation Warp Speed (OWS), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), vaccine manufacturers, and NC state health officials. Each vaccine has their own storage requirements, which can be reviewed on the specific vaccine fact sheet and slide 7 (Pfizer) and 18 (Moderna) of the NCDHHS briefing primary care webinar.

COVID 19 Vaccine Ingredients

<table>
<thead>
<tr>
<th>Description</th>
<th>Pfizer-BioNTech COVID-19 vaccine</th>
<th>Moderna COVID-19 vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>mRNA</td>
<td>Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2</td>
<td>Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2</td>
</tr>
<tr>
<td>Lipids</td>
<td>Polyethylene glycol (PEG) 2000, N,N-ditetradecylacetamide, 1,2-dioleoyl-sn-glycero-3-phospholamine, Cholesterol, (4-hydroxybutyl)azanediylisobutane-6,1-diol/bis(2-hexyldecanoate)</td>
<td>Polyethylene glycol (PEG) 2000 dimyristoyl glycerol (DMG), 1,2-distearyloylsnglycero-3-phosphocholine, Cholesterol, SM-102 (Proprietary to Moderna)</td>
</tr>
<tr>
<td>Salts, sugars, buffers</td>
<td>Potassium chloride, Monobasic potassium phosphate, Sodium chloride, Dibasic sodium phosphate dihydrate</td>
<td>Tromethamine, Tromethamine hydrochloride, Acetic acid, Sodium acetate</td>
</tr>
</tbody>
</table>

COVID 19 Vaccine Precautions

- Per EUA Contraindications
  - Do not administer to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech or the Moderna COVID-19 Vaccine

- Per CDC ACIP Precaution
  - A history of severe allergic reaction (e.g., anaphylaxis) to any other vaccine or injectable therapy (e.g., intramuscular, intravenous, or subcutaneous) is a precaution but not a contraindication to vaccination for both the Pfizer-BioNTech and Moderna COVID-19 vaccines (as these vaccines contain ingredients in common).
  - These persons may still receive mRNA COVID-19 vaccination, but they should be counseled about the unknown risks of developing a severe allergic reaction and balance these risks against the benefits of vaccination.

-slide 11 NCDHHS Vaccination Briefing, 12.22.20
A history of mild allergic reaction to a vaccine or injectable therapy, such as localized urticaria alone without signs or symptoms of anaphylaxis, is not a contraindication or precaution to vaccination with either mRNA COVID-19 vaccine.

Allergic reactions (including severe allergic reactions) not related to vaccines or injectable therapies (e.g., food, pet, venom, or environmental allergies; allergies to oral medications [including the oral equivalents of injectable medications]) are not a contraindication or precaution to vaccination with either mRNA COVID-19 vaccine.

The vial stoppers of these mRNA vaccines are not made with natural rubber latex, and there is no contraindication or precaution to vaccination for persons with a latex allergy.

Vaccine providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions:
- Persons with a history of anaphylaxis: 30 minutes
- All other persons: 15 mins

### Special Population Considerations

- Persons with underlying medical conditions or immunocompromised persons
  - Vaccine may be administered to persons with underlying medical conditions or who are immunocompromised who have no contraindications to vaccination
  - Persons with HIV infection, other immunocompromising conditions, or who take immunosuppressive medications or therapies might be at increased risk for severe COVID-19 and may still receive COVID-19 vaccine unless otherwise contraindicated
- Persons who previously received passive antibody therapy for COVID-19
  - Currently no data on safety or efficacy of COVID-19 vaccination in persons who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment
  - Vaccination should be deferred for at least 90 days to avoid interference of the treatment with vaccine-induced immune responses

### How are adverse events managed?

COVID-19 Vaccine Safety Monitoring Clinically important, adverse events following any vaccination must be reported by healthcare providers to the [Vaccine Adverse Event Reporting System](https://vaers.hhs.gov/) as required of all COVID-19 vaccination providers. Adverse events will also be monitored through electronic health record and claims-based systems (e.g., Vaccine Safety Datalink). The patient will also have the ability to self-report any adverse events thru [V-safe](https://www.v-safe.hhs.gov/).

### What can practices do now?

**Focus on getting prepared for enrollment and CVMS onboarding**

- CVMS Provider Enrollment and other trainings listed previously
- Register and attend CVMS live or recorded trainings
- Visit [CDC COVID-19 Vaccination Training Programs and Reference Materials](https://www.cdc.gov/vaccines/) for list of immunization training and education materials for vaccine providers

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Recruit, Train, and Retain: Developing the workforce for a healthy North Carolina

NC AHEC Program | 145 N. Medical Drive, Chapel Hill, NC 27599 | ncahec.net | 919-966-5830
**Communication to Patients is Important.**
Throughout each phase of distribution, healthcare providers will have a vital role in the communication of the importance of the vaccine and helping patients to do the following:

- Trust the information that they receive form NCDHHS and local health departments about COVID-19 vaccinations
- Understand the benefits and risks of COVID-19 vaccinations
- Make informed decisions about COVID-19 vaccinations
- Know how and where to get a COVID-19 vaccination

**Have patient education materials available.**
In order to help your patients understand more about the vaccine, consider creating or having available patient material, such as brochures, posters, phone/website messages, scripts for staff, NCDHHS Vaccine Flyer ([English/Spanish](https://ncdhhs.gov)), NCDHHS’s infographic on phases of vaccine distribution ([English/Spanish](https://ncdhhs.gov)) or Pfizer’s fact sheet for recipients and caregivers ([also serves as the VIS sheet for patients receiving the vaccine](https://www.pfizer.com)). Consider creating a video with a provider explaining why patients should get the vaccine and upload the video to your website, social media pages, and send as a message through the patient portal.

When deciding what to disseminate, consider the following:

- Be proactive. Use messages through the patient portal or mail to provide information.
- Don’t frighten people into wanting to take the shot. They already fear & take COVID seriously. Acknowledge vaccine fears and hesitancy as valid.
- Give people honest information about vaccine development, testing, safety, reactions.
- Build trust in and during the prioritized vaccine rollout: Confidence to frontline workers, patience to eager early adopters, and witness to those who are waiting and seeing.
- Direct people to “their spot” for reliable information: Official sources or community/peers
- Solve for the logistics of getting people to vaccination sites that may not be connected to their everyday health experiences and health care.
- Assure everyone of equitable and inclusive access.
- Have a clear call to action that works across all campaign phases and compliments the 3W’s.

**Know who on your patient panel is eligible and willing to receive the vaccine in phases 1 & 2.**

- Run a list of your patients who will be eligible for the vaccine in phase 1b and 2. If you send a letter or message to these patients, inform them of their eligibility, be aware of contraindications to receiving the vaccine.
- Consider sending patients a survey asking if they plan on getting the COVID19 vaccine and where they would consider getting the vaccine. This could help you in choosing your communication and whether to administer the vaccine in your office.
**Coordinate how and where your eligible patients can get a vaccine**

- Remind your patients that supplies are very limited right now and very few vaccine doses are available.
- It’s helpful to utilize a script for staff communication, update your website and phone messaging with the latest updated information. Ensure this information is accurate and updated as needed.
- Consider coordinating with your local vaccine providers to make it as easy for your patients as possible.
- Go to [YourShotYourSpot.nc.gov](http://YourShotYourSpot.nc.gov) for a list of local vaccine providers.

If you are a PCP affiliated with an enrolled vaccine provider hospital or health system

1. Coordinate with your affiliated hospital or health system to share information with your patients about how to get the vaccine.
2. Contact (by phone, email and/or mailed letter) all patients who are age 75 years or older to recommend getting the COVID-19 vaccine.
   - Make a COVID vaccine conversation part of every portal, telephone, telehealth or face-to-face encounter with older adults
   - Share information with patients about where to get the vaccine in the system

If you are a PCP NOT affiliated with an enrolled vaccine provider hospital

1. Coordinate with your LHD on where your pts can get vaccinated (e.g., LHD, local hospital, or other enrolled vaccine provider) prior to reaching out to your patients.
2. Contact (by phone, email and/or mailed letter) all patients who are age 75 years or older to recommend getting the COVID-19 vaccine.
   - Make a COVID vaccine conversation part of every portal, telephone, telehealth or face-to-face encounter with older adults.
   - Share information with their patients about where to get the vaccine (i.e., local health department, local hospital, or other vaccine provider) and how to work with that organization to get vaccinated.

**Communicate to patients that there is no cost.**

There is no cost to patients to receive the vaccine, including those with and without insurance.

**Remind patients of the 3 W’s.**

It is important to remind patients that until they are eligible to receive all doses of the needed vaccine, they should practice the 3 W’s:
Communicate with Clinicians and Staff.
Patients will have many questions for staff and providers; the more you can answer, the more they can make the best informed decision for them.

Develop a training plan.
- Develop a training plan to educate the clinicians and staff on the following:
  - How and what communication is needed with the patient
  - Who is eligible for the vaccine in each phase
  - How a vaccine is developed, manufactured, and distributed
  - Possible side effects of the vaccine
  - The importance of equity and why some patients might be hesitant to get the vaccine
  - FAQs in English, FAQs-Spanish.
- Remain non-judgmental and acknowledge the patient's concerns.
- Identify a key point of contact for this information for the practice so that someone monitors any changes within the distribution plan and providers, staff and patients have someone to go to for questions. This person/group should review the resources listed below and attend or watch the recorded training webinars on CVMS.
- NCDHHS has created a readiness checklist for providers to prepare for administering the COVID 19 Vaccine. If you plan on being a vaccination provider, the checklist is a tool to help you prepare now.

Understand costs and revenue opportunities for the practice.
- While there is no cost to the recipients of the vaccine, HRSA and CMS are reimbursing administrative costs to vaccine providers. Medicare and Medicaid will be reimbursing $16.94 for the first dose and $28.39 for the second dose. An overview provided by NCDHHS can be found on slide 20 here. HCPCS codes and ICD codes for CMS can be found here.
- NCTracks Medicaid and Health Choice billing guide for Moderna COVID-19 Vaccine (N/A) HCPCS code 91301 and PFIZER-BioNTech COVID-19 Vaccine (N/A) HCPCS code 91300.

Prepare for documenting vaccine administration.
- Capturing vaccines in your Electronic Health Record will help you know if your patients have had the vaccine dosage.
- Consider other multi-dose vaccinations administered in your office and how you document them (i.e. HPV, Hepatitis B, Pneumococcal). If possible, document the COVID 19 vaccination similarly.
- Ensure you are following all ACIP documentation and administration guidelines for multi-dose vaccines. If you don’t have the capability to create documentation in the EHR, reach out to your vendor and request this be added.
- Additional documentation is required in COVID 19 Vaccination Management System (CVMS). Here, Providers will verify patient eligibility, log dosage administration, and track frequency and
timing of additional dosages. *At this time, CVMS is not integrated with any EHR, so there will be
duplicate entry.

Resources are available.

1. NCDHHS COVID 19 Vaccine Information: yoursportyourshot.nc.gov
4. Pfizer COVID19 Fact sheet for administrators: https://www.fda.gov/media/144413/download
5. Pfizer COVID19 Fact sheet for recipients and caregivers: https://www.fda.gov/media/144414/download
10. NCDHHS COVID 19 What Providers Need to Know Webinar slides, 12.15.20: https://mega.nz/file/w1Q0FBj#F9sHL_ALs-uY3cX0wf219CyDi5gakJoRG40NdtwNA0
11. NCDHHS COVID 19 briefing with Q&A updates 12.22.2020: https://mega.nz/file/Bo5WnQ7a#MQBvQ5FQgv5g4bKKMZN0pHh_SAIxw3afb8GF5jMU5bM

For further assistance, there are 3 resources.

- If you have additional questions about the COVID-19 Vaccination Program, please email COVIDhelp@dhhs.nc.gov.
- If you have CVMS related questions, email CVMS-Help@dhhs.nc.gov.
- If you need help 1:1 assistance, please contact your local AHEC practice support coach or contact us at practicesupport@ncahec.net.