

North Carolina COVID-19 Vaccination Guide for Medical Practices

What do practices need to know now?

NC COVID-19 Vaccination Plan: A Four-Phased Approach

It is important to note when a vaccine is approved by the FDA for distribution, there will be limited quantities due to manufacturing. Therefore, North Carolina will have a four-phased approach to risk-based prioritization to distribute the vaccine. **Please note, Phase 1b and following are in revision as of December 22, 2020.** Phase 1a will continue until further notice from NCDHHS.

PHASE 1A: Health care workers critical to caring for patients with COVID-19 at high risk for COVID-19 exposure based on work duties or vital to the initial COVID-19 vaccine response are included in Phase 1a.

Health care workers at high risk for exposure to COVID-19 are defined as those:

- caring for patients with COVID-19
- working directly in areas where patients with COVID-19 are cared for, including staff responsible for cleaning, providing food service, and maintenance in those areas
- performing procedures at high risk of aerosolization on patients with COVID-19 (e.g., intubation, bronchoscopy, suctioning, invasive dental procedures, invasive specimen collection, CPR)
- handling decedents with COVID-19

Outpatient providers who have an increased risk of exposure beyond that of a typical general outpatient setting should be included in the first phase (1A). This could include outpatient providers who are focused on COVID-19 patient evaluation, respiratory care such as respiratory diagnostic testing centers, members of a dedicated respiratory care team, or frequently involved in COVID-19 testing sites. Outpatient dentists or dental hygienists are included in Phase 1a if they meet the above criteria for outpatient providers.

Health care workers administering vaccine in initial mass vaccination clinics are part of this first phase.

How do healthcare workers in Phase 1a get their vaccine?

Due to very limited supplies, vaccines were available first through a small number of hospitals. These hospitals were chosen based on bed capacity, health care workers, and county population. Additional hospitals and Local Health Departments have begun to receive vaccine in Week 2.

LHDs, health care employers, hospitals and health systems all play a role in vaccinating health care workers in 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. Local Health Departments will pre-register eligible health care workers in the state's COVID-19 Vaccination Management System (CVMS) or can register eligible individuals at the time of vaccination.

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Health care employers (e.g., medical practices, hospice providers, EMS) should determine which of their employees meet the criteria of being at high risk for exposure to COVID-19 as defined above, meaning that they interact with or care for patients with COVID-19 or work in designated COVID-19 areas (e.g., cleaning). **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.
- Understand that the ability for Local Health Departments to schedule appointments will depend on the supply of vaccine available.
- Know that Local Health Departments will prioritize responding to and scheduling vaccinations first for those with workers eligible for Phase 1a and based upon vaccine availability.

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 for those they pre-register.

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. NCDHHS provides a range of tools and methods for CVMS and vaccine training including communications, user guides, live trainings, a readiness checklist and helpdesk support [here](#).

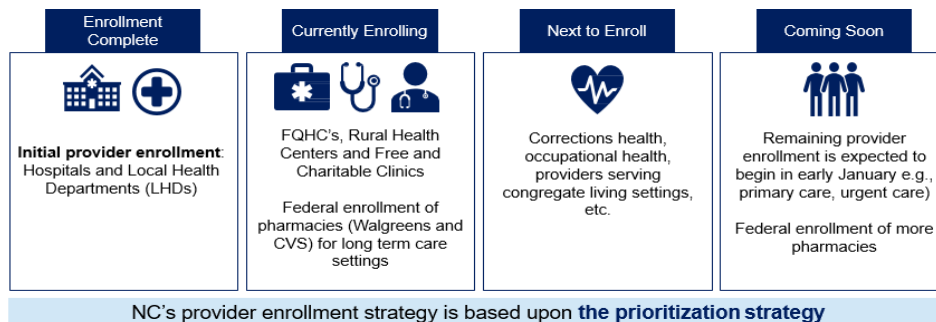
COVID-19 Vaccination Provider Recruitment and Enrollment

How is recruitment and enrollment prioritized?

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. Enrollment of hospitals and health departments is 100%.

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If you are interested in enrolling to be a COVID 19 vaccination provider, NC DHHS will announce when CVMS will be available for you to apply to become a provider of the vaccine, based on the prioritized strategy here:



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.² 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

Description	Pfizer-BioNTech COVID-19 vaccine	Moderna COVID-19 vaccine
mRNA	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2
Lipids	2[[polyethylene glycol]-2000]-N,N-ditetradecylacetamide	Polyethylene glycol (PEG) 2000 dimyristoyl glycerol (DMG)
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine
	Cholesterol	Cholesterol
	(4-hydroxybutyl)azanediylbis(hexane-6,1-diy)bis(2-hexyldecanoate)	SM-102 (Proprietary to Moderna)
Salts, sugars, buffers	Potassium chloride	Tromethamine
	Monobasic potassium phosphate	Tromethamine hydrochloride
	Sodium chloride	Acetic acid
	Dibasic sodium phosphate dihydrate	Sodium acetate
	Sucrose	Sucrose

[-slide 11 NCDHHS Vaccination Briefing, 12.22.20](#)

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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.
 - 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

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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](#) 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](#).

What can practices do now?

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 from 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's infographic on phases of vaccine distribution](#) or [Pfizer's fact sheet for recipients and caregivers](#) (also serves as the VIS sheet for patients receiving the vaccine).

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.

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

- Run a list of your high-risk 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.

**Patients with 2 or more chronic conditions will be eligible in earlier phases, but this is in revision as of 12/22/2020.

Be able to 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.
- 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

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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 released a [Medicaid and Health Choice billing guide](#) for the Moderna Covid-19 vaccine on December 22.

Prepare for document 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 19 101 with information on 1) how a vaccine works to fight the virus 2) Vaccine testing and FDA approval phases 3) NC's plan, and 4) four phases of vaccine distribution:** <https://files.nc.gov/covid/documents/COVID19-Vaccine-101-Deck-Final.pdf>
2. **NC DHHS COVID Vaccination Plan:** <https://files.nc.gov/covid/documents/NC-COVID-19-Vaccine-Plan-with-Executive-Summary.pdf>
3. **CDC COVID 19 Vaccination Page:** <https://www.cdc.gov/vaccines/covid-19/hcp/index.html>
4. **NCDHHS Covid-19 Vaccination Update:** <https://files.nc.gov/covid/documents/COVID-19-Vaccine-Update.pdf>
5. **NCDHHS COVID 19 What Providers Need to Know Webinar slides, 12.15.20:** https://mega.nz/file/w1Q0FBjI#F9sHL_ALs-uY3cX0wf219CyDiSgakJoRG40NDntwNA0
6. **CMS billing and coding for COVID-19 vaccines:** <https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-mono-clonal-antibodies>
7. **NCTRACKS Medicaid and Health Choice Billing guide:** <https://www.nctracks.nc.gov/content/public/providers/provider-communications/Provider-Announcements-2020-/2020-Announcements/Moderna-COVID-19-Vaccine--N-A--HCPCS-code-91301--Billing-Guidelines.html>
8. **Pfizer COVID19 Fact sheet for administrators:** <https://www.fda.gov/media/144413/download>
9. **Pfizer COVID19 Fact sheet for recipients and caregivers:** <https://www.fda.gov/media/144414/download>
10. **CDC guidelines for Special Population Considerations:** <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>
11. **NCDHHS COVID 19 briefing with Q&A updates 12.22.2020:** https://mega.nz/file/Bo5WnQ7a#MQBvO5FQgv5g4bKKMZn0pHh_SAlxw3afb8GFSjIMU5bM
12. **NCDHHS COVID 19 Vaccine Information:** <https://covid19.ncdhhs.gov/vaccines#resources>

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.

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Note that the information provided is taken directly from publicly available information provided by NC DHHS. The information provided is not legal advice and is solely educational information to assist healthcare practices during the COVID-19 pandemic.

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