NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

COVID-19 Vaccine Provider Guidance Appendix

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Appendix 9 – Pfizer Storage and Handling Overview

As of 12/6/2020

Shipping, Handling & Storage Overview

Current as of December 16, 2020

Breakthroughs that change patients' lives

The Pfizer-BioNTech COVID-19 Vaccine has not been approved or licensed by FDA, but has been authorized for emergency use by FDA under an Emergency Use Authorization to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 16 years of age and older. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

Please see Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) including Full EUA Prescribing Information available at www.cvdvaccine.com.

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Change Log

Version	History of Changes
01	Initial version
02	• New content includes Overview of Shipping, Storage & Handling, Key Timing Considerations, and Re-icing Thermal Shipper • Modified temperature of Thermal shipper from -75+15°C (-103° to 5°F) to -90ºC to -60ºC (-130ºF to -76ºF)
03	Disclaimer language updated to reflect post-EUA mandatory language
04	Updated vial tray image

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Overview of Shipping, Storage & Handling

1 Thermal Shipper Arrival

The thermal shipper that the vaccine arrives in can be used as temporary storage, so long as dry ice is replenished upon receipt and every 5 days (up to 30 days).

The thermal shipper maintains a temperature range of -90ºC to -60ºC (-130ºF to -76ºF). Storage within this temperature range is not considered an excursion from the recommended storage condition.

2 Storage & Handling

Storage options for vials/trays include:

1. **Ultra Low Temperature Freezer at** -80° and -60°C (-112 to -76°F) for up to 6 months
2. **Thermal Shipper at** -90ºC to -60ºC (-130ºF to -76ºF) for up to 30 days from delivery, if replenished with dry ice upon receipt and every 5 days
3. **Refrigerator** at 2 to 8 °C (35.6° to 46.4°F) for up to 120 hours (5 days)

Vial are glass and should be handled with care. Visual inspection prior to use should be carried out.

Vials should be protected from light and kept in the original packaging.

Vials should always remain upright in trays during storage.

3 Returning Thermal Shipper

The thermal shipping container may be used as temporary storage for up to 30 days from delivery, including temperature data logger.

Breakthroughs that change patients' lives

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Direct Shipment to Points of Vaccination

Direct Shipments* to Vaccination Center by Transport Courier

Pfizer has designed a distribution model which is built on a flexible just in time system to ship the vaccine from manufacturing site and/or storage facility directly to the points of vaccination.

Temperature & Location Tracking During Transportation

Controlant Reusable RTM Logger

- Each thermal shipper has reusable GPS enabled temperature monitoring device which will be enabled when the shipper is packed.
- All shipments will be tracked via the onboard GPS monitoring device to ensure end-to-end distribution within required temperatures.
- Shipments will be executed under the management of Pfizer Quality processes and controls to ensure that upon ownership transfer, product has arrived under acceptable conditions.
- Temperature records of the shipments can be shared with upon request.

*COVID Vaccine supply chain model is a drop ship direct from Pfizer manufacturing sites to the designated locations by the government.
Markets with no Pfizer commercial legal entity: Product ownership transfer at port of entry for governmental customer importation and in-market distribution

Breakthroughs that change patients' lives

The Pfizer-BioNTech COVID-19 Vaccine has not been approved or licensed by FDA, but has been authorized for emergency use by FDA under an Emergency Use Authorization to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 16 years of age and older. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

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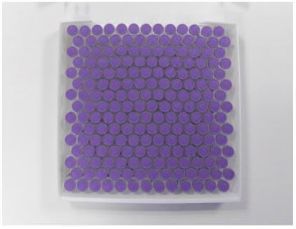
Product Packaging Overview

Vials

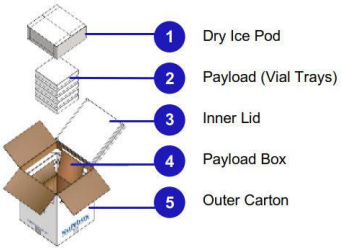
- 2 mL type 1 glass preservative free multi-dose vial (MDV)
- MDV has 0.45 mL frozen liquid drug product
- 5 doses per vial after dilution

Trays



- Single tray holds 195 vials
- 975 doses per tray
- A smaller tray, containing 25 vials (125 doses) is in development with estimated availability in early 2021

Thermal Shipper



- Minimum 1 tray (975 doses) or up to 5 trays (4875 doses) stacked in a payload area of the shipper
- Payload carton submerged in dry ice pellets
- Thermal shipper keeps ULT -90ºC to -60ºC (-130ºF to -76ºF) up to 10 days if stored at 15°C to 25°C (5° to 77°F) temperatures without opening
- Thermal shippers are reusable and designed to be a temporary storage containers by replenishing dry ice.

Breakthroughs that change patients' lives

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Key Timing Considerations

TRAYS

3 MINS

Open-lid vial trays, or vials trays containing less than 195 vials removed from frozen storage (< -60°C) may be at room temperature (< 25°C) for up to **3 minutes** for transfer between ultra low temperature environments or to remove vials for thawing or use.

5 MINS

Closed-lid vial trays containing 195 vials removed from frozen storage (< -60°C) may be at room temperature (< 25°C) for up to **5 minutes** for transfer between ultra low temperature environments.

2 HRS

After vial trays are returned to frozen storage following room temperature exposure, they must remain in frozen storage for at least **2 hours** before they can be removed again.

VIALS

Once an individual vial is removed from a vial tray at room temperature, it should not be returned to frozen storage and should be thawed for use.

Breakthroughs that change patients' lives

The Pfizer-BioNTech COVID-19 Vaccine has not been approved or licensed by FDA, but has been authorized for emergency use by FDA under an Emergency Use Authorization to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 16 years of age and older. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

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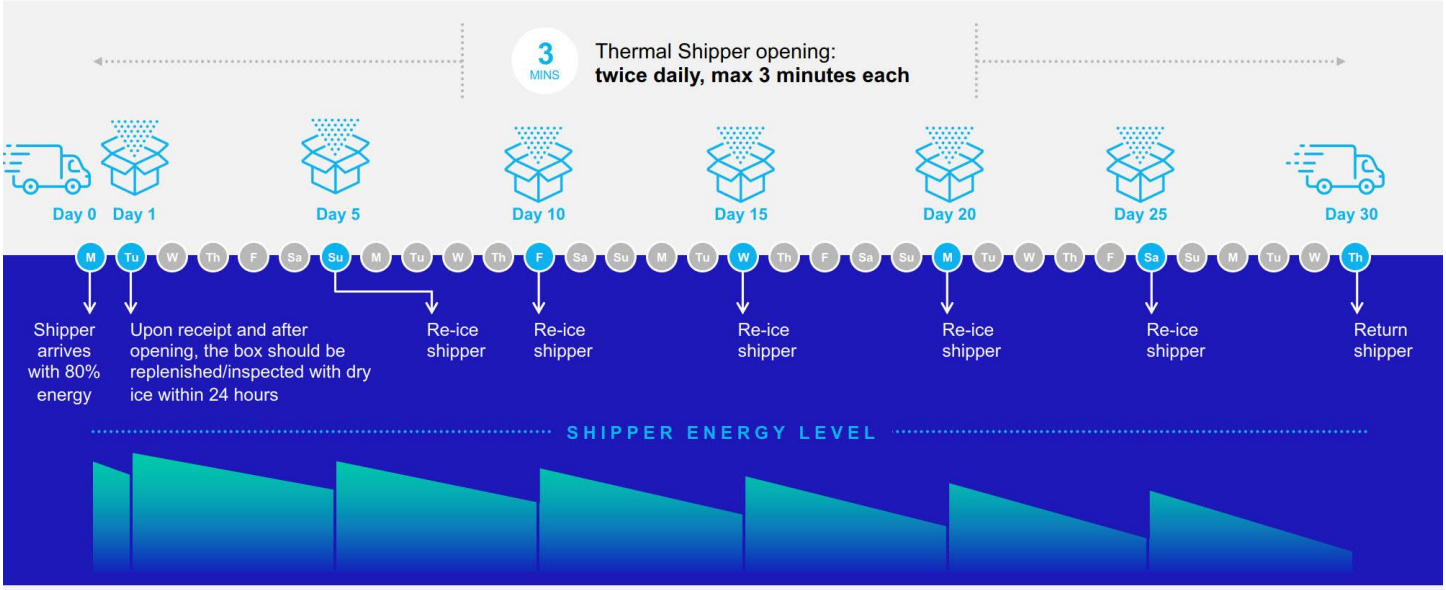
Re-icing Thermal Shipper

Handling instructions

- Re-ice at a minimum of every 5 days (based on normal use). No restriction to number of re-icing. If box is left open for longer than 3 minutes, recommendation is to re-ice more frequently, as needed.
- If re-icing occurs and a holiday or weekend, plan ahead to re-ice the thermal shipping container.
- Thermal shipping container may be used as temporary storage for up to 30 days from delivery.
- Sites are required to maintain temperature monitoring.



Breakthroughs that change patients' lives

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Please see Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) including Full EUA Prescribing Information available at www.cvdvaccine.com.

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Appendix 14 - Sample/Template LHD Standing Order for Moderna COVID-19 Vaccine & Pfizer-BioN Tech COVID-19 Vaccine

Sample/Template LHD Standing Order for Moderna COVID-19 Vaccine

This Standing Order (SO) is for Registered Nurses (RN's) and Licensed Practical Nurses (LPN's) functioning as vaccination providers and practicing in local health departments in North Carolina to administer Moderna COVID-19 Vaccine authorized by the FDA through an Emergency Use Authorization (EUA) in accordance with the current Phase of Vaccination and conditions of this order.

COVID-19 Testing	
Condition or Situation	Patients (recipients of vaccine), 18 years of age and older, who present requesting and consent to Moderna COVID-19 Vaccine and who meet the vaccination criteria in the current Phase of Vaccination or any of the previous phases and have legal and decisional capacity to consent to the vaccine.
Assessment Criteria	

Assessment Criteria

Patients shall be vaccinated with Moderna COVID-19 Vaccine based on:

1. the conditions of this order
2. no history of complete 2-dose COVID-19 vaccination, regardless of brand.
3. meeting at least **one** of the criteria listed in the vaccination priority criteria defined by the current Phase of Vaccination or any previous phases indicated at https://covid19.ncdhhs.gov/vaccines.

Plan of Care

Actions

1. **Patient Education and Data Collection**
   a. Prior to patients receiving the Moderna COVID-19 Vaccine, the nurse shall
      i. Communicate to the recipient or their caregiver information consistent with the *Fact Sheet for Recipients and Caregivers* (and provide a copy or direct the individual to the website www.modernatx.com/covid19vaccine-eua to obtain the Fact Sheet) prior to the individual receiving the Moderna COVID-19 Vaccine. Note: Providers need to ensure the most current version of this document by visiting https://www.modernatx.com/covid19vaccine-eua/. Information communicated must include:
         - FDA has authorized the emergency use of the Moderna COVID-19 Vaccine, which is not an FDA-approved vaccine.
         - The recipient or their caregiver has the option to accept or refuse the Moderna COVID-19 Vaccine.
         - The significant known and potential risks and benefits of the Moderna COVID-19 Vaccine, and the extent to which such risks and benefits are unknown.
         - Information about available alternative vaccines and the risks and benefits of those alternatives
      ii. Providers should counsel Moderna COVID-19 vaccine recipients about expected local and systemic reactions.
      iii. Provide anticipatory guidance regarding vaccination to the patient, which at a minimum shall include where, how, and when to obtain the second COVID-19 vaccination.
2. **COVID-19 Pre-Vaccination Procedures**
   a. Review *Contraindications for Use of this Order* section of this standing order **before** administering the COVID-19 vaccine.
   b. Instruct patients with bleeding disorders or who take blood thinners to consult with their medical provider who is familiar with their bleeding risk to determine if the patient can receive an intramuscular injection with reasonable safety. Once the patient presents written documentation that the patient's medical provider advises that the patient can receive the vaccine, administer the vaccine using a 23 gauge or smaller caliber needle, followed by firm pressure on the site, without rubbing, for at least 2 minutes.
   c. Instruct patients who have received passive antibody therapy as treatment for COVID-19 that as a precautionary measure to avoid interference of the

antibody treatment with vaccine-induced immune responses, COVID-19 vaccination will be deferred for at least 90 days.

d. Instruct patients who are immunocompromised that the vaccine might be less effective than in someone who is immunocompetent.
e. Instruct patients who are pregnant or lactating that these conditions are not contraindications to the current COVID-19 vaccine and may choose to get vaccinated. Available data on Moderna COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy. Encourage women who are pregnant and receive the vaccine to Women who are vaccinated with Moderna COVID-19 Vaccine during pregnancy to enroll in the Pregnancy Exposure Registry by calling 1-866-MODERNA (1-866-663-3762). Data are not available to assess the effects of Moderna COVID-19 Vaccine on the breastfed infant or on milk production/excretion.
f. Consent must be obtained from the patient or the patient's legally authorized representative. North Carolina, G.S. 90-21.5 authorizes a physician to accept the consent of a minor for medical health services for the prevention, diagnosis, or treatment of reportable communicable diseases. The statute states that any minor may give effective consent for the services described in the law. However, any given minor must still have the decisional capacity to consent.
g. Don appropriate personal protective equipment (PPE) per Universal Precautions and to protect against the transmission of COVID-19.

3. COVID-19 Vaccination Administration Procedures

a. See the Dosage and Administration sections of the current *Fact Sheet for Healthcare Providers Administering Vaccine* for instructions for preparation and administration. This Fact Sheet may be updated as needed. For the most recent Fact Sheet, please see www.modernatx.com/covid19vaccineeua .
b. Provide a vaccination card to the recipient or their caregiver with the date when the recipient needs to return for the second dose of Moderna COVID-19 Vaccine.
c. Ensure that all Mandatory Requirements for Moderna COVID-19 Vaccine Administration Under Emergency Use Authorization as indicated in the *Fact Sheet for Healthcare Providers Administering Vaccine* are met.
d. Provide the v-safe information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in v-safe.
e. The Moderna COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.5mL each) 1 month apart.
f. If the recipient has received one (1) previous Moderna COVID-19 Vaccine dose, the second dose of the same brand shall be administered.
g. There is no information on the use of the Moderna COVID-19 Vaccine with other vaccines. Consult the medical provider for further orders. The vaccine series should be administered alone, with a minimum interval of 14 days before or after administration with any other vaccines. If mRNA

COVID-19 vaccines are inadvertently administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine.

h. Patients with allergic reactions, including severe allergic reactions, NOT related to vaccines or injectable therapies (e.g., food, pet, venom, environmental, or latex allergies; oral medications) are NOT a contraindication or precaution to vaccination with currently authorized COVID-19 vaccine. CDC considers a history of severe allergic reaction (e.g., anaphylaxis) to any other vaccine or injectable therapy (e.g., intramuscular, intravenous, or subcutaneous) as a precaution but not a contraindication to vaccination. Individuals who have had severe allergic reactions to something, regardless of cause, shall be monitored for 30 minutes post COVID-19 vaccination. All other patients shall be monitored for 15 minutes post COVID-19 vaccination. See **Contraindications for Use of this Order** section below for contraindications regarding severe allergic reaction (e.g., anaphylaxis) to a previous dose of Moderna COVID-19 Vaccine or to any component of the vaccine.

i. Document each patient's vaccine administration information in the patient's medical record and the COVID-19 Vaccine Management System (CVMS) following systems:
   - Medical Record: Within 24 hours of administering the vaccine, document pertinent patient history (including the Pre-Vaccination Form and consent), the date of administration, manufacturer, lot number, vaccination site and route, name, and title of the person administering the vaccine. Provide patient with a copy of their vaccination information: date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or healthcare professional.
   - CVMS: Document within 24 hours after vaccine administration per system guidelines found at https://immunize.nc.gov/providers/covid-19training.htm .

j. Follow vaccine storage and handling, dosing, and administration required by the manufacturer.

Follow-up

Follow up

1. Nurses administering Moderna COVID-19 Vaccine must report the following information associated with the administration of the vaccine in accordance with the *Fact Sheet for Healthcare Providers Administering Vaccine*:
   - Vaccine administration errors, whether associated with an adverse event or not
   - Serious adverse events (irrespective of attribution to vaccination)
   - Cases of Multisystem inflammatory syndrome in adults
   - Cases of COVID-19 that result in hospitalization or death

   Complete and submit reports to Vaccine Adverse Event Reporting System (VAERS) online at https://vaers.hhs.gov/reportevent.html or by calling 1-800-822-7967. The VAERS reports must include the words "Moderna COVID-19 Vaccine EUA" in the description section of the report.

2. Nurses are required to follow the instructions in the letter issued by the Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for emergency use of Moderna COVID-19 Vaccine for the prevention of Coronavirus Disease 2019 (COVID-19) for individuals 18 years of age and older.

Contraindications for Use of this Order

Do not give this vaccine if the following contraindication is present:

- Severe allergic reaction (e.g., anaphylaxis) to a previous dose of Moderna COVID-19 Vaccine or to any component of the vaccine.

Criteria or Circumstances for Notifying Medical Provider

1. Allergic reaction: Call 911, implement medical emergency protocols and immediately notify the medical provider from the organization providing clinical supervision of the vaccination site/service.
2. Notify the medical provider if a patient has a moderate or severe acute illness, has a current COVID-19 infection, or is unaware of the COVID vaccine that they previously received.
3. Notify the medical provider if patient findings and/or conditions do not align with the instructions defined under, Plan of Care/Actions/2b.iii above.
4. Notify the Medical Provider from the organization providing clinical supervision of the vaccination site/service at any time there are questions or problems with carrying out this SO.

Approved by: _____ **Date Approved:** _____

Effective Date: _____

Expiration Date: This standing order shall remain in force and effect for the duration of the state of emergency declared under Executive Order 116 unless otherwise modified, rescinded, or replaced.

Legal Authority:

- Nursing Practice Act, N.C. General Statutes 90-171.20 (7)(f)(h)(i) & (8)(c)(c1.)(e.)(f.)

Sample Standing order for Pfizer-BioNTech COVID-19 Vaccine

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency logo

Sample/Template LHD Standing Order for Pfizer-BioNTech COVID-19 Vaccine

This Standing Order (SO) is for Registered Nurses (RN's) and Licensed Practical Nurses (LPN's) functioning as vaccination providers and practicing in local health departments in North Carolina to administer Pfizer-BioNTech COVID-19 Vaccine authorized by the FDA through an Emergency Use Authorization (EUA) in accordance with the current Phase of Vaccination and conditions of this order.

COVID-19 Testing	
Condition or Situation	Patients (recipients of vaccine), 16 years of age and older, who present requesting and consent to Pfizer-BioNTech COVID-19 Vaccine and who meet the vaccination criteria in the current Phase of Vaccination or any of the previous phases and have legal and decisional capacity to consent to the vaccine.
Assessment Criteria	
Assessment Criteria	Patients shall be vaccinated with Pfizer-BioNTech COVID-19 Vaccine based on: 1. the conditions of this order 2. no history of complete 2-dose COVID-19 vaccination, regardless of brand. 3. meeting at least **one** of the criteria listed in the vaccination priority criteria defined by the current Phase of Vaccination or any of the previous phases indicated at https://covid19.ncdhhs.gov/vaccines .
Plan of Care	
Actions	**1. Patient Education and Data Collection** a. Prior to patients receiving the Pfizer-BioNTech COVID-19 Vaccine, the nurse shall provide anticipatory guidance regarding vaccination to the patient, which at a minimum shall include: i. Where, how, and when to obtain the second COVID-19 vaccination. ii. Pre-Vaccination Form for Pfizer-BioNTech COVID-19 Vaccine *iii. Fact Sheet for Recipients and Caregivers – Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) in Individuals 16 Years of Age and Older* https://www.cvdvaccine-us.com/images/pdf/fact-sheet-for-recipients-and-caregivers.pdf Note: Providers need to assure the most current version of this document by visiting http://www.cvdvaccine.com/ **2. COVID-19 Vaccination Administration Procedures** a. Review *Contraindications for Use of this Order* section of this standing order **before** administering the COVID-19 vaccine. b. Review the patient-completed *Pre-Vaccination Form for Pfizer- BioNTech COVID-19 Vaccine.* i. For questions 1-3 and 5-9, if all responses are "no," then administer the vaccine per the SO. ii. For questions 1-3, if there is a "yes" or "don't know" response, consult a medical provider (physician or advanced practice provider [nurse practitioner, certified nurse-midwife, or physician assistant]) for further orders. iii. For question 4, if the patient has received a trial vaccine as a part of a COVID vaccine clinical trial, confirm that the trial sponsor determined it is feasible for the patient to receive additional doses. Consult the medical provider for further orders. iv. If there is a "yes" for questions 5-9, follow the instructions below: 1. Instruct patients with bleeding disorders or who are taking blood thinners to consult with their medical provider who is

	familiar with their bleeding risk to determine if the patient can receive an intramuscular injection with reasonable safety. Once the patient presents written documentation that the patient's medical provider advises that the patient can receive the vaccine, administer the vaccine using a 23 gauge or smaller caliber needle, followed by firm pressure on the site, without rubbing, for at least 2 minutes. 2. Instruct patients who have received passive antibody therapy as treatment for COVID-19 that as a precautionary measure to avoid interference of the antibody treatment with vaccine-induced immune responses, COVID-19 vaccination will be deferred for at least 90 days. 3. Instruct patients who are immunocompromised that the vaccine might be less effective than in someone who is immunocompetent. 4. Instruct patients who are pregnant or lactating that these conditions are not contraindications to current COVID-19 vaccine and may choose to get vaccinated. Educate the patient that there are currently no data available on the safety of COVID-19 vaccines in pregnant women, but studies and results are expected soon. Data demonstrate that while the absolute risk is low, pregnant women with COVID-19 have increased risk of severe illness. Also educate patients that there is no data available for lactating women on the effects of mRNA vaccines. c. Consent must be obtained from the patient or the patient's legally authorized representative. North Carolina, G.S. 90-21.5 authorizes a physician to accept the consent of a minor for medical health services for the prevention, diagnosis, or treatment of reportable communicable diseases. The statute states that any minor may give effective consent for the services described in the law. However, any given minor must still have the decisional capacity to consent. d. Before administering the COVID-19 vaccination, don appropriate personal protective equipment (PPE) per Universal Precautions and to protect against the transmission of COVID-19. e. Choose the correct needle gauge, needle length, and injection site for persons: i. 16 through 18 years of age: 1-inch needle, administered in the deltoid muscle of the arm. ii. 19 years of age and older: See table in Appendix 1 below. f. Mix, observing sterile technique, Pfizer-BioNTech COVID-19 Vaccine with 0.9% sodium chloride (normal saline, preservative-free) diluent according to the manufacturer's instructions. Follow manufacturer's guidance for storing/handling mixed vaccine. g. Administer 0.3 mL Pfizer-BioNTech COVID-19 Vaccine by intramuscular (IM) injection in the deltoid muscle of the arm. If contraindications exist to using the deltoid, the anterolateral thigh also can be used. h. This vaccine is administered in a 2-dose series. Separate doses by at least 21 days. If the 2nd dose Pfizer vaccine was given 17 or more days after the 1st dose, then do not repeat a 2nd dose.

Template

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Appendix 32 - Sample talking points and scripts for fielding incoming requests to local health departments, hospitals, and health systems.

(1) General information about the vaccine

- Tested, safe and effective vaccines will be available to all who want to get vaccinated, but supplies are currently limited and will continue to be for the next few months.
  - To save lives and slow the spread of COVID-19, independent state and federal public health advisory committees recommend first protecting health care workers caring for patients with COVID-19, people who are at the highest risk of being hospitalized or dying, and those at high risk of exposure to COVID-19
  - The following regularly updated resources should be used to respond to general information inquiries about the vaccine:
    - NCDHHS COVID-19 Vaccine Frequently Asked Questions (English / Spanish)
    - NCDHHS Presentation COVID-Vaccination 101 (English / Spanish)
    - NCDHHS Flyer on COVID-19 Vaccines (English / Spanish)

(2) Information about how to get vaccinated

- North Carolina's updated groups are as follows:
  - Group 1: Health care workers and Long-Term Care staff and residents
  - Group 2: Older Adults
  - Group 3: Front-line essential workers
  - Group 4: Adults at high risk for exposure and at increased risk of severe illness
  - Group 5: Everyone who wants a safe and effective COVID-19 vaccination

- The following resources should be used to respond to inquiries about NCDHHS vaccination phases
  - Infographic of Vaccine Phases (English / Spanish)
  - Deeper Dive: Group 1 (English / Spanish)
  - Deeper Dive: Group 2 (English / Spanish)
  - Deeper Dive: Group 3 (English/ Spanish)

- Key vaccine messages for 65+ population
  - Anyone 65 years or older may now get their first COVID-19 shot.
  - Vaccine supplies are limited, and you may have to wait, but you have one of the first spots to take your shot.
  - Most doctors can't provide COVID-19 shots in their offices, so work with local health department or hospital to get your shot.
  - Take your shot to get life back to when we could be with family and friends and come together at events and celebrations.
  - Take your shot to gain the peace of mind that you're protected and you're protecting others from getting sick from COVID-19

(3) Customer relations.

The following talking points can be used when fielding questions or concerns from the public on various topics related to the vaccine.

- *Talking points to set expectations about vaccine availability*
  - A vaccine will be available to all who want it, but right now vaccine supply is very limited. There is not enough vaccine supply for everyone to get vaccinated right away.
  - The federal government decides how many COVID-19 vaccine doses each state gets based on the state's population of people ages 18 and up and notifies our state each week of how much vaccine we will receive.

- *Talking points to respond to dissatisfaction about the phases of vaccine prioritization*
  - Independent state and federal public health advisory groups have determined that the best way to fight COVID-19 is to start first with vaccinations for those most at risk, and then reach more people as vaccine supply increases throughout 2021.
  - North Carolina, like many other states, aligned its vaccine prioritization with federal recommendations and had input from an external Advisory Committee.

- *Talking points to respond to mistrust and vaccine hesitancy*
  - The vaccines are tested, safe, and effective.
    - More than 70,000 people volunteered in clinical trials for two vaccines (Pfizer and Moderna) to see if they are safe and work to prevent COVID illness. Volunteers included Black/African Americans, Hispanic LatinX, Asians and others.
    - Vaccines were found to help prevent COVID-19 and are effective in preventing hospitalization and death, with no serious safety concerns noted in the clinical trials.
    - The U.S. Food and Drug Administration (FDA) makes sure the vaccines are safe and can prevent people from getting COVID-19. Like all drugs, vaccine safety continues to be monitored after they are authorized for use.
  - You cannot get COVID-19 from the vaccine.
    - You may have temporary reactions like a sore arm, headache or feeling tired and achy for a day or two after receiving the vaccine.

(4) Example auto-response message:

Thank you for your inquiry about COVID-19 vaccination. For up-to-date information about vaccination in North Carolina, please visit yourspotyourshot.nc.gov.

As of **<insert date>**, we are currently vaccinating the following groups:

- Health care workers with in-person patient contact
- Health care workers administering vaccine in initial vaccine groups
- Long-term care staff and residents—people in skilled nursing facilities and in adult, family and group homes
- Anyone 65 years or older, regardless of health status or living situation
- Essential workers

If you fall into one of these categories, please contact **<insert local vaccine number>** to schedule an appointment for your spot in line -OR- **<insert local vaccination schedule details here>**.

Remember: you have a spot, take your shot!

(5) Example automated phone messages*:

Automated Message, part 1:

Thank you for calling **<insert organization name>**. *Para español, oprima* **<insert number for Spanish-version of message>**. For questions related to the COVID-19 vaccine, please press **<insert number>. <Insert remainder of typical outgoing automated message here>**.

Automated Message, part 2:

For **<insert date/the week of _____>**, we are actively vaccinating for COVID-19 according to the North Carolina Department of Health and Human Services guidelines, which are available at YourSpotYourShot.nc.gov.

Anyone who is 65 years or older and essential workers may now get vaccinated. Supplies are very limited, so people may have to wait. If you are 65 or older or an essential worker, **<insert instructions here>**.

We are also still vaccinating all health care workers with in-person patient contact. If you are a member of this group, **<insert instructions here>**. We are also still vaccinating residents and staff in nursing homes and other long term are facilities.

*Local health departments would need to use part 1 in their opening outgoing message and then have an extension for part 2. The message in Part 2 would need to be updated weekly.

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Appendix 33 - Vaccine patient outreach template for providers.

Health care providers can use the following email/letter template to share important information about COVID-19 vaccines with patients, especially patients 65 years or older who are eligible to receive the vaccine as part of Group 2. The template is intended to inform patients about vaccines and how they can get a vaccine. It can be customized to fit your community and can be used in multiple formats, such as electronic health record messages, your website, patient e-newsletters, etc.

Template For Health Care Provider Outreach to Patients:

Dear patients,

Vaccines are your best protection against COVID-19. Beginning on **<insert date on or after January XXth>,** anyone age 65 years or older and essential workers can receive a safe vaccine to protect you from getting COVID-19.

Vaccine supplies are limited, and you may have to wait, but you have one of the first spots to take your shot.

We strongly recommend you get the vaccine. The COVID-19 vaccine is our best shot to help us all get back control of our lives and back to the people and places we love. Vaccines were found to help prevent COVID-19 and are effective in preventing hospitalization and death, with no serious safety concerns noted in the clinical trials. You cannot get COVID-19 from the vaccine. You may have temporary reactions like a sore arm, headache or feeling tired and achy for a day or two after receiving the vaccine. You will need a second shot, at least 3 tor 4 weeks after the first shot, to build up your immunity. You can get your shot at no cost.

Vaccines are being offered at <insert name of hospital/health system that is an enrolled vaccine provider>. Here are your next steps for getting vaccinated:

[Insert all options that are available to your patients]:

- Go to <insert website> and call one of the local vaccine providers on the list; OR
- Respond to this message indicating your interest in being vaccinated against COVID-19. The COVID-19 vaccination team will contact you about when and where you can get vaccinated; OR
- Schedule a vaccination appointment by calling <insert phone number>; OR
- Schedule a vaccination appointment by taking the following steps in your electronic chart <insert instructions>; OR
- Let us know if you will need assistance with arranging for transportation to this appointment
- Attend walk-in hours at the following times and locations: <insert information>
    - *Note: Exercise caution when using this option due to the potential for crowded vaccination events or prolonged wait time for elderly patients*
- Get your vaccine through drive-through or curbside events at the following times and locations: <insert information>; OR
- Visit our website for upcoming vaccine events we will be hosting in the community at <insert link>; OR
- **<Insert any other ways people can get the vaccine>**

If you have questions about the vaccine, you can take the following steps:

- Visit the NCDHHS website for more information about the vaccine: **YourSpotYourShot.nc.gov**
- Call our office at **<insert phone number>** during **<insert hours>**
- Send us a message in your electronic chart
- **<Insert any other ways your patients can learn about the vaccine or ask questions>**

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Appendix 34 - Letter template to conduct outreach to primary care providers for vaccinations for Older Adults in Group 2 (for Local Health Departments).

Local Health Departments can use this email/letter template below for outreach to primary care providers who may have patients 65 years or older. Local Health Departments should focus their outreach efforts with primary care providers who serve historically marginalized populations and who are not affiliated with a hospital or health system that is an enrolled vaccine provider. The letter template can be customized to fit your community.

Dear providers,

Beginning on <*insert date on or after January 14th*>, your patients in Groups 1, 2 and 3 will be eligible to take a safe vaccine to protect them from getting COVID-19.

Vaccines are currently being offered for the following populations:

- Group 1: Health care workers and Long-Term Care staff and residents.
- Group 2: Older Adults
- Group 3: Frontline Essential Workers

If your practice is not yet an enrolled vaccine provider that has received a vaccine allocation, our agency is prepared to help support vaccinations for your staff and your patients who fall into these groups. One strategy for this partnership is for you to identify your eligible staff and your patients who are eligible for the COVID-19 vaccine in Group 1, 2 and 3. We can then work with you to provide your staff and patients with instructions to get vaccinated in as timely a manner as possible.

Some potential scenarios for how primary care providers are working with vaccine providers to get their staff and patients vaccinated are described below:

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

<Insert local details as needed>

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Appendix 35 - Sample content for communicating with patients about COVID-19 vaccines (for LHDs, hospitals/health systems, or PCPs).

A COVID-19 Vaccination Communications Toolkit is available and regularly updated at yourspotyourshot.nc.gov. The page is also available in Spanish: covid19.ncdhhs.gov/vacuna.

We encourage vaccine and health care providers to use and share the following vaccine resources with your patients and networks:

- Infographic of COVID-19 Vaccine Phases (English / Spanish)
- Deeper Dive: Group 1 (English / Spanish)
- Deeper Dive: Group 2 (English / Spanish)
- Deeper Dive: Group 3 (English/ Spanish)
- Flyer on COVID-19 Vaccines (English / Spanish)
- Flyer on COVID-19 Vaccines – 65 years or older (English / Spanish)
- Postcard (4x6, two sided) (English / Spanish Coming)
- Handout (8x11) (English / Spanish Coming)
- Presentation COVID-Vaccination 101 (English / Spanish)
- COVID-19 Vaccine Frequently Asked Questions (English / Spanish)
- Videos on COVID-19 Vaccine Rollout
    - NCDHHS Secretary Mandy Cohen shares information on the COVID-19 vaccine rollout plan (30-second)
    - NCDHHS Deputy Secretary Ben Money shares information on the COVID-19 vaccine rollout plan (link)
- Videos for Long-Term Care
    - North Carolina long-term care workers share their reason for taking the newly developed COVID-19 vaccine (90-second, 60-second, 30-second)
    - NCDHHS Secretary Mandy Cohen shares information on the COVID-19 vaccine rollout plan long-term care facility workers (60-second)
    - NCDHHS Secretary Mandy Cohen shares information on the COVID-19 vaccine rollout plan for families of long-term care residents (link)
    - NCDHHS Deputy Secretary Ben Money shares information on the COVID-19 vaccine rollout plan for long-term care facilities (60-second, 30-second)
- NC Vaccine Selfie Video Tip Sheet (English / Spanish Coming)

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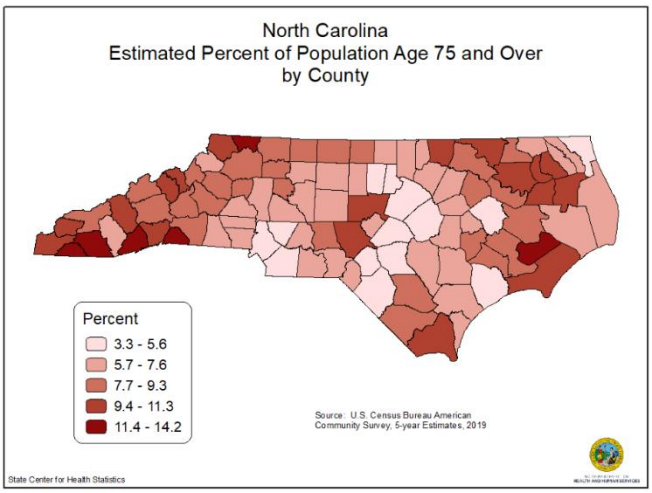
Appendix 38 - COVID-19 Community Based Vaccination Events: Best Practices.

Why Vaccinate in the Community?



Example of a hot spot map to guide testing site location

For North Carolina to successfully meet its goal of vaccinating as many people as quickly as possible given the limited supply of vaccines, we must mobilize community based vaccination events. To meet North Carolina's equally important goal of ensuring equity to access to the vaccine, intentional actions should be taken in the planning of those mass vaccination events.

Best Practice: Hold vaccination events in settings that will enable prioritized and historically marginalized populations to access vaccination. Well established patterns of COVID-19 infection continue to demonstrate that Black/African American and LatinX/Hispanic populations are disparately impacted by the pandemic.

While there is probably not a wrong place to do community mass vaccinations, there are certainly some locations with more potential to support and protect historically marginalized populations who have disproportionately borne the burden of the COVID-19 pandemic. Use existing data sources to identify specific locations with a high concentration of low-income earners, subsidized housing, concentrations of multiple chronic illness, etc. You can also use the NCDHHS Social Determinants of Health Interactive Map to identify locations where they reside.

Transportation Assistance - Ensuring access to transportation in an important element for equity. Local transit agencies serve all 100 North Carolina counties and funding has been given to local transit agencies to help provide this support. People who need transportation assistance to a COVID-19 vaccine should reach out to their local transit agency which are listed here NC_Public_Transit.pdfOpen PDF (ncdot.gov). As you are planning an vaccination event, publicizing this resources can increase access to those with limited transportation.

No charge to patients/vaccine recipients - To receive free supplies of the COVID-19 vaccine(s), vaccine providers must sign the provider agreement with the U.S. Government. Under the agreement, all providers must vaccinate individuals regardless of whether they have health insurance coverage or what type of coverage they have, and all providers are prohibited from balance billing or otherwise charging vaccine recipients.

Residency requirements - The Centers for Disease Control and Prevention has instructed states that this is a federal vaccine bought with federal funding. Hence, jurisdictions should not put restrictions on administering vaccinations to non-residents, as long as those persons meet the current eligibility criteria. This applies to both county and state residency.

Proof of identification is not required to schedule an appointment or to receive a vaccine. Individuals can self-attest to the criteria (e.g., age, job role, health status, living situation) that they qualify for in eligible priority groups.

Creating the Community Based Vaccination Team

Community based vaccination clinics will be successful if championed by a leadership team that includes the local health department (LHD), health care providers such as community health centers (also known as federally qualified health centers or FQHCs), hospitals, private and hospital-based providers and community partners. The CDC link for full planning information can be found at https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/index.html.

It is important to note that, for many people, their first experience with the public health system may be the vaccine event and creating an environment that instills confidence and inspires trust is crucial. It is essential that partners who are trusted within their communities are part of the leadership team, such as faith, community service organizations and other non-profit leaders.

There are other strategies that can ensure we are vaccinating equitably – partner with local organizations with trusted relationships and help them facilitate sign-up for your events or compile waiting lists for your next clinic or event. Think about how an online-only sign-up method impacts access and consider instead filling first appointments by calling individuals compiled on a waiting list created by a key community partner. Hold vaccine clinics in historically marginalized communities, partnering with the community to organize and bring-on volunteers.

Staffing

A large-scale immunization administration event requires three main types of personnel:

- Healthcare professionals authorized to provide vaccinations and who can respond to medical emergencies, including severe allergic reactions and anaphylaxis.
- Healthcare staff with knowledge about vaccines and experience handling vaccines and preparing vaccine doses.
- Nonmedical personnel to fill a variety of support roles, including check-in and registration, data entry, logistics, traffic flow, safety personnel.

These events can be staffed by your employees or community volunteers.

Training

Train your staff and volunteers with as much lead time as possible by using the online training modules. Trainings can be recorded and then reviewed online as new members are brought onboard:

- CDC COVID-19 Vaccine Training Modules: https://www2.cdc.gov/vaccines/ed/covid19/
    - This is a series of 3 online trainings that your medical professionals need to complete prior to assisting during an event. They will receive continuing education credit for completing the modules.
- Z-Track IM Injection Method: https://www.youtube.com/watch?v=DBHnd3N-5Ns
- Example of a training/welcoming video for volunteers from Orange County.
- https://www.youtube.com/watch?v=kenVwQGeDUg&feature=youtu.be
- Many counties are using online portals to coordinate their volunteers. Some portal examples are Calendy, Sign-Up Genius, chat lines on websites and MyChart. Here is an example of the Orange County Volunteer Portal. https://www.signupgenius.com/go/10c0d49aaad2aabfac07-covid

Vaccine Guidance

In order for all staff to give consistent answers to any questions related to the vaccines, use the following guidance:

https://files.nc.gov/covid/documents/COVID-19-Vaccine-Update.pdf and

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

Personal Protective Equipment (PPE)

Personal Protective Equipment (PPE) is needed for the staff vaccinating and in close contact with persons being vaccinated. It is a Best Practice to provide masks to everyone attending an event where individuals are to be vaccinated and emphasize how to correctly use them (i.e., cover the nose and mouth). Gloves and hand sanitizer are other common items that you will need to provide. Organizations should order PPE through their regular supply chains, if possible. Organizations can also request and access PPE through the state-maintained PPE supply site.

Community Mass Vaccination ABCs

Advance Planning

Perhaps the most important part of a successful mass vaccination is the coordination and clear identification of all partners early in the process. A site visit in advance of the vaccination event provides the ability to plan for missing requirements, such as water, Wi-Fi, shelter and to layout the traffic patterns. The CDC has a checklist to take you

through each step of the process and can be found here:
https://www.izsummitpartners.org/content/uploads/2019/02/off-site-vaccination-clinic-checklist.pdf

Access to the Internet

Accessing Wi-Fi can be crucial for the medical partner to register patients, whether through expanded network near the testing spot or adequately powered hotspot. It is a Best Practice for patients and administered vaccine doses to be entered into CVMS at the time of vaccination to optimize data collection for ongoing follow up and to show real time vaccination data. Using tablets onsite allows you to enter the data in real-time. Allow for extra tablets so that charging can occur on a rotational basis and provide heavy-duty outdoor extension cords for this equipment.

Basic Needs

Staff at vaccination sites may be exposed to the elements for long periods depending on the length of time the event is scheduled. There are certain basic needs that should be attended to thoughtfully, to include at a minimum:

- Toilet facilities (portable rentals if indoor facility is not close)
- Handwashing facilities (portable station if indoor facility is not close)
- Eating location with seats and cover away from vaccination or patient locations
- Shelter in the form of several secure, heavy-duty tents to endure heavy wind, rain and sun; cover the medical team, health department educators, vaccinators, etc., and their electronics; and provide adequate space to social distance. You should plan on at least one tent for each workstation including the traffic monitors and patient monitoring stations.
- Basic beverage and food provision (consider coffee/pastries at start up, bottled water all day, lunch delivered to site)

Clear Identification of Vaccination Site Staff

Team members need to be easily and clearly identified. Without a standardized identification (could be as simple as a colored sticky name tag on the chest), it is difficult to tell who is there to be vaccinated and who is a volunteer since everyone has different face coverings. Clear identification keeps the environment safe for privacy (if not well identified, others can access areas intended only for staff) and makes it easy for people presenting for vaccination to know who can answer their questions. One thing to consider is that depending on the community you are vaccinating; fear of authorities may deter people from coming to a testing event. Avoiding highly uniformed staff and instead wearing more casual street clothes creates a safer-feeling environment at times.

Orange County team working with a rural faith-based community partner.

Clear Incident Command on the Ground

Identify the Incident Commander of the operation before the event begins. This individual should be empowered to make critical decisions in the moment, such as those related to vaccination parameters, complications in logistics, conflicts and environmental threats. This person should have the contact information of the executive leaders from each organization participating in the vaccination event and feel comfortable reaching out immediately for support if needed. Finally, this person needs to make themselves known and available for the entire testing event.

Community Engagement and Promotion

Advanced planning also allows the team to provide promotional material and communication to alert the community about the event. Local media outlets are often willing to assist in promoting an event; additionally, bringing in non-medical partners to volunteer at the event can lead to great attendance and engagement. It is important to provide in advance clearly defined roles for volunteers, schedules, written instructions for safety and a designated point of contact (such as the Incident Commander) to address questions.

- **Anticipatory guidance and health education** should be provided by the patient monitors during the observation period. This allows the individual to ask any questions they may have. The appointment for the second dose should be done at the time of the first vaccination appointment and can be done while you are reviewing the patient information sheet with the individual. https://files.nc.gov/covid/documents/COVID-19-Vaccine-Update.pdf
- **Media liaisons** on site can be helpful as often the local media becomes interested in the vaccination event, especially if publicity was effective in advance. Identifying one person at the site to monitor for and manage media requests is important. If media can be scheduled in advance to arrive and complete interviews before the event there is less concern of patient privacy compromise or creating discomfort for community members who would like to be vaccinated.

Thoughts from the Field

- Use appointments with block shifts to spread out the volume and shorten wait times. For example, based on your staffing, you could anticipate 20 patients an hour.
- Use carpooling or personal transportation to bring elderly to the mobile site
- Use individuals from your community partner to work the initial greeting station so that individuals see a familiar face
- Flexibility on the ground is key so that you can respond to issues as they arise
- Schedule 2nd appointment while they are in the patient monitoring phase
- Have extra staff or runners available
- Virtual translators
- Allow onsite registration
- EMS on call
- Embrace technology; use apps or online portals to schedule appointments both for patients or your volunteer team
- Paper forms for back-up
- If you have both types of vaccines available on a given day, use the Pfizer types first.
- One way in, one way out traffic pattern
-

If a community is having difficulty executing a community vaccination event, NCDHHS is willing to help connect and direct a vaccination strategy, as well as making connections to forge partnership at the local level. For answers to questions about COVID-19 resources, visit the North Carolina COVID-19 Information Hub.

Appendix 39 - CDC COVID-19 Vaccination Program Provider Agreement

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

SAMPLE

CDC COVID-19 Vaccination Program Provider Agreement

Please complete Sections A and B of this form as follows:

The Centers for Disease Control and Prevention (CDC) greatly appreciates your organization's (Organization) participation in the CDC COVID-19 Vaccination Program. Your Organization's chief medical officer (or equivalent) and chief executive officer (or chief fiduciary)—collectively, Responsible Officers—must complete and sign the *CDC COVID-19 Vaccination Program Provider Requirements and Legal Agreement* (Section A). *CDC COVID-19 Vaccination Program Provider Profile Information* (Section B) must be completed for each vaccination Location covered under the Organization listed in Section A.

Section A. COVID-19 Vaccination Program Provider Requirements and Legal Agreement

ORGANIZATION IDENTIFICATION	
Organization's legal name: Complete in CVMS	
Number of affiliated vaccination locations covered by this agreement: _____	
Organization telephone number:	Email *(must be monitored and will serve as dedicated contact method for the COVID-19 Vaccination Program)*:
Organization address:	

RESPONSIBLE OFFICERS		
For the purposes of this agreement, in addition to Organization, Responsible Officers named below will also be accountable for compliance with the conditions specified in this agreement. The individuals listed below must provide their signature after reviewing the agreement requirements.		
Chief Medical Officer (or Equivalent) Information		
Last name Complete in CVMS	First name	Middle initial
Title	Licensure (state and number)	
Telephone number:	Email:	
Address:		
Chief Executive Officer (or Chief Fiduciary) Information		
Last name Complete in CVMS	First name	Middle initial
Telephone number:	Email:	
Address:		

Sample

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

SAMPLE

CDC COVID-19 Vaccination Program Provider Agreement

AGREEMENT REQUIREMENTS	
I understand this is an agreement between Organization and CDC. This program is a part of collaboration under the relevant state, local, or territorial immunization's cooperative agreement with CDC. To receive one or more of the publicly funded COVID-19 vaccines (COVID-19 Vaccine), constituent products, and ancillary supplies at no cost, Organization agrees that it will adhere to the following requirements**:**	
1.	Organization must administer COVID-19 Vaccine in accordance with all requirements and recommendations of CDC and CDC's Advisory Committee on Immunization Practices (ACIP).[1]
2.	Within 24 hours of administering a dose of COVID-19 Vaccine and adjuvant (if applicable), Organization must record in the vaccine recipient's record and report required information to the relevant state, local, or territorial public health authority. Details of required information (collectively, Vaccine-Administration Data) for reporting can be found on CDC's website.[2] Organization must submit Vaccine-Administration Data through either (1) the immunization information system (IIS) of the state and local or territorial jurisdiction or (2) another system designated by CDC according to CDC documentation and data requirements.[2] Organization must preserve the record for at least 3 years following vaccination, or longer if required by state, local, or territorial law. Such records must be made available to any federal, state, local, or territorial public health department to the extent authorized by law.
3.	Organization must not sell or seek reimbursement for COVID-19 Vaccine and any adjuvant, syringes, needles, or other constituent products and ancillary supplies that the federal government provides without cost to Organization.
4.	Organization must administer COVID-19 Vaccine regardless of the vaccine recipient's ability to pay COVID-19 Vaccine administration fees.
5.	Before administering COVID-19 Vaccine, Organization must provide an approved Emergency Use Authorization (EUA) fact sheet or vaccine information statement (VIS), as required, to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative.
6.	Organization's COVID-19 vaccination services must be conducted in compliance with CDC's Guidance for Immunization Services During the COVID-19 Pandemic for safe delivery of vaccines.[3]
7.	Organization must comply with CDC requirements for COVID-19 Vaccine management. Those requirements include the following: a) Organization must store and handle COVID-19 Vaccine under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with the manufacturer's package insert and CDC guidance in CDC's Vaccine Storage and Handling Toolkit[4], which will be updated to include specific information related to COVID-19 Vaccine; b) Organization must monitor vaccine-storage-unit temperatures at all times using equipment and practices that comply with guidance located in CDC's Vaccine Storage and Handling Toolkit[4]; c) Organization must comply with each relevant jurisdiction's immunization program guidance for dealing with temperature excursions;

This agreement expressly incorporates all recommendations, requirements, and other guidance that this agreement specifically identifies through footnoted weblinks. Organization must monitor such identified guidance for updates. Organization must comply with such updates.

[1] https://www.cdc.gov/vaccines/hcp/acip-recs/index.html
[2] https://www.cdc.gov/vaccines/programs/iis/index.html
[3] https://www.cdc.gov/vaccines/pandemic-guidance/index.html
[4] https://www.cdc.gov/vaccines/hcp/admin/storage-handling.html

Sample

SAMPLE

CDC COVID-19 Vaccination Program Provider Agreement

	d) Organization must monitor and comply with COVID-19 Vaccine expiration dates; and e) Organization must preserve all records related to COVID-19 Vaccine management for a minimum of 3 years, or longer if required by state, local, or territorial law.
8.	Organization must report the number of doses of COVID-19 Vaccine and adjuvants that were unused, spoiled, expired, or wasted as required by the relevant jurisdiction.
9.	Organization must comply with all federal instructions and timelines for disposing COVID-19 vaccine and adjuvant, including unused doses.[5]
10.	Organization must report moderate and severe adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS).[6]
11.	Organization must provide a completed COVID-19 vaccination record card to every COVID-19 Vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative. Each COVID-19 Vaccine shipment will include COVID-19 vaccination record cards.
12.	a) Organization must comply with all applicable requirements as set forth by the U.S. Food and Drug Administration, including but not limited to requirements in any EUA that covers COVID-19 Vaccine. b) Organization must administer COVID-19 Vaccine in compliance with all applicable state and territorial vaccination laws.

By signing this form, I certify that all relevant officers, directors, employees, and agents of Organization involved in handling COVID-19 Vaccine understand and will comply with the agreement requirements listed above and that the information provided in sections A and B is true.

The above requirements are material conditions of payment for COVID-19 Vaccine-administration claims submitted by Organization to any federal healthcare benefit program, including but not limited to Medicare and Medicaid, or submitted to any HHS-sponsored COVID-19 relief program, including the Health Resources & Services Administration COVID-19 Uninsured Program. Reimbursement for administering COVID-19 Vaccine is not available under any federal healthcare program if Organization fails to comply with these requirements with respect to the administered COVID-19 Vaccine dose. Each time Organization submits a reimbursement claim for COVID-19 Vaccine administration to any federal healthcare program, Organization expressly certifies that it has complied with these requirements with respect to that administered dose.

Non-compliance with the terms of Agreement may result in suspension or termination from the CDC COVID-19 Vaccination Program and criminal and civil penalties under federal law, including but not limited to the False Claims Act, 31 U.S.C. § 3729 *et seq.*, and other related federal laws, 18 U.S.C. §§ 1001, 1035, 1347, 1349.

By entering Agreement, Organization does not become a government contractor under the Federal Acquisition Regulation.

Coverage under the Public Readiness and Emergency Preparedness (PREP) Act extends to Organization if it complies with the PREP Act and the PREP Act Declaration of the Secretary of Health and Human Services.[7]

Sample

[5] The disposal process for remaining unused COVID-19 Vaccine and adjuvant may be different from the process for other vaccines; unused vaccines must remain under storage and handling conditions noted in Item 7 until CDC provides disposal instructions; website URL will be made available.

[6] https://vaers.hhs.gov/reportevent.html

[7] *See* Pub. L. No. 109-148, Public Health Service Act §§ 319F-3 and 319F-4, 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e; 85 Fed. Reg. 15,198, 15,202 (March 17, 2020).

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

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CDC COVID-19 Vaccination Program Provider Agreement

Chief Medical Officer (or Equivalent)		
Last name	First name	Middle initial
Signature: Complete in CVMS		Date:
Chief Executive Officer (or Chief Fiduciary)		
Last name	First name	Middle initial
Signature: Complete in CVMS		Date:

For official use only:

VTrckS ID for this Organization, if applicable: _____

Vaccines for Children (VFC) PIN, if applicable: _____ *Other PIN (e.g., state, 317):* _____

IIS ID, if applicable: _____

Unique COVID-19 Organization ID (Section A):* _____

**The jurisdiction's immunization program is required to create a unique COVID-19 ID for the organization named in Section A that includes the awardee jurisdiction abbreviation (e.g., an organization located in Georgia could be assigned "GA123456A"). This ID is needed for CDC to match Organizations (Section A) with one or more Locations (Section B). These unique identifiers are required even if there is only one location associated with an organization.*

Sample

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

SAMPLE

Section B. CDC COVID-19 Vaccination Program Provider Profile Information

Please complete and sign this form for your Organization location. If you are enrolling on behalf of one or more other affiliated Organization vaccination locations, complete and sign this form for each location. Each individual Organization vaccination location must adhere to the requirements listed in Section A.

ORGANIZATION IDENTIFICATION FOR INDIVIDUAL LOCATIONS	
Organization location name: Complete in CVMS	Will another Organization location order COVID-19 vaccine for this site? ☐ Yes; provide Organization name: _____ ☐ No

CONTACT INFORMATION FOR LOCATION'S PRIMARY COVID-19 VACCINE COORDINATOR		
Last name:	First name:	Middle initial:
Telephone:	Email:	

CONTACT INFORMATION FOR LOCATION'S BACK-UP COVID-19 VACCINE COORDINATOR		
Last name:	First name:	Middle initial:
Telephone:	Email:	

ORGANIZATION LOCATION ADDRESS FOR RECEIPT OF COVID-19 VACCINE SHIPMENTS			
Street address 1:	Street address 2:		
City:	County:	State:	ZIP:
Telephone:		Fax:	

ORGANIZATION ADDRESS OF LOCATION WHERE COVID-19 VACCINE WILL BE ADMINISTERED (IF DIFFERENT FROM RECEIVING LOCATION)			
Street address 1:	Street address 2:		
City:	County:	State:	ZIP:
Telephone:		Fax:	

DAYS AND TIMES VACCINE COORDINATORS ARE AVAILABLE FOR RECEIPT OF COVID-19 VACCINE SHIPMENTS				
Monday	Tuesday	Wednesday	Thursday	Friday
AM:	AM:	AM:	AM:	AM:
PM:	PM:	PM:	PM:	PM:

For official use only:

VTrckS ID for this location, if applicable: _____ *Vaccines for Children (VFC) PIN, if applicable:* _____

IIS ID, if applicable: _____ *Unique COVID-19 Organization ID (from Section A):* _____ *Unique Location ID**:* _____

***The jurisdiction's immunization program is required to create an additional unique Location ID for each location completing Section B. The number will include the awardee jurisdiction abbreviation. For example, if an organization (Section A) in Georgia (e.g., GA123456A), has three locations (main location plus two additional) completing section B, they could be numbered as GA123456B1, GA123456B2, and GA123456B3.*

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NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

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CDC COVID-19 Vaccination Program Provider Profile Information

COVID-19 VACCINATION PROVIDER TYPE FOR THIS LOCATION (SELECT ONE)

- ☐ Commercial vaccination service provider
- ☐ Corrections/detention health services
- ☐ Health center – community (non-Federally Qualified Health Center/non-Rural Health Clinic)
- ☐ Health center – migrant or refugee
- ☐ Health center – occupational
- ☐ Health center – STD/HIV clinic
- ☐ Health center – student
- ☐ Home health care provider
- ☐ Hospital
- ☐ Indian Health Service
- ☐ Tribal health
- ☐ Medical practice – family medicine
- ☐ Medical practice – pediatrics
- ☐ Medical practice – internal medicine
- ☐ Medical practice – OB/GYN
- ☐ Medical practice – other specialty
- ☐ Pharmacy – chain
- ☐ Pharmacy – independent
- ☐ Public health provider – public health clinic
- ☐ Public health provider – Federally Qualified Health Center
- ☐ Public health provider – Rural Health Clinic
- ☐ Long-term care – nursing home, skilled nursing facility, federally certified
- ☐ Long-term care – nursing home, skilled nursing facility, non-federally certified
- ☐ Long-term care – assisted living
- ☐ Long-term care – intellectual or developmental disability
- ☐ Long-term care – combination (e.g., assisted living and nursing home in same facility)
- ☐ Urgent care
- ☐ Other (Specify: _____)

SETTING(S) WHERE THIS LOCATION WILL ADMINISTER COVID-19 VACCINE (SELECT ALL THAT APPLY)

- ☐ Childcare or daycare facility
- ☐ College, technical school, or university
- ☐ Community center
- ☐ Correctional/detention facility
- ☐ Health care provider office, health center, medical practice, or outpatient clinic
- ☐ Hospital (i.e., inpatient facility)
- ☐ In-home
- ☐ Long-term care facility (e.g., nursing home, assisted living, independent living, skilled nursing)
- ☐ Pharmacy
- ☐ Public health clinic (e.g., local health department)
- ☐ School (K – grade 12)
- ☐ Shelter
- ☐ Temporary or off-site vaccination clinic – point of dispensing (POD)
- ☐ Temporary location – mobile clinic
- ☐ Urgent care facility
- ☐ Workplace
- ☐ Other (Specify: _____)

APPROXIMATE NUMBER OF PATIENTS/CLIENTS ROUTINELY SERVED BY THIS LOCATION

Number of children 18 years of age and younger: _____ *(Enter "0" if the location does not serve this age group.)*
☐ Unknown

Number of adults 19 – 64 years of age: _____ *(Enter "0" if the location does not serve this age group.)*
☐ Unknown

Number of adults 65 years of age and older: _____ *(Enter "0" if the location does not serve this age group.)*
☐ Unknown

Number of unique patients/clients seen per week, on average: _____
☐ Unknown
☐ Not applicable (e.g., for commercial vaccination service providers)

INFLUENZA VACCINATION CAPACITY FOR THIS LOCATION

Number of influenza vaccine doses administered during the peak week of the 2019–20 influenza season:
_____ *(Enter "0" if no influenza vaccine doses were administered by this location in 2019-20)*
☐ Unknown

Sample

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

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CDC COVID-19 Vaccination Program Provider Profile Information

POPULATION(S) SERVED BY THIS LOCATION (SELECT ALL THAT APPLY)

- ☐ General pediatric population
- ☐ General adult population
- ☐ Adults 65 years of age and older
- ☐ Long term care facility residents (nursing home, assisted living, or independent living facility)
- ☐ Health care workers
- ☐ Critical infrastructure/essential workers (e.g., education, law enforcement, food/agricultural workers, fire services)
- ☐ Military – active duty/reserves
- ☐ Military – veteran
- ☐ People experiencing homelessness
- ☐ Pregnant women
- ☐ Racial and ethnic minority groups
- ☐ Tribal communities
- ☐ People who are incarcerated/detained
- ☐ People living in rural communities
- ☐ People who are under-insured or uninsured
- ☐ People with disabilities
- ☐ People with underlying medical conditions* that are risk factors for severe COVID-19 illness
- ☐ Other people at higher-risk for COVID-19 (Specify: _____)

DOES YOUR ORGANIZATION CURRENTLY REPORT VACCINE ADMINISTRATION DATA TO THE STATE, LOCAL, OR TERRITORIAL IMMUNIZATION INFORMATION SYSTEM (IIS)?

- ☐ Yes [List IIS Identifier: _____]
- ☐ No
- ☐ Not applicable

If "No," please explain planned method for reporting vaccine administration data to the jurisdiction's IIS or other designated system as required:

If "Not applicable," please explain:

ESTIMATED NUMBER OF 10-DOSE MULTIDOSE VIALS (MDVs) YOUR LOCATION IS ABLE TO STORE DURING PEAK VACCINATION PERIODS (E.G., DURING BACK-TO-SCHOOL OR INFLUENZA VACCINE SEASON) AT THE FOLLOWING TEMPERATURES:

Refrigerated (2°C to 8°C):	☐ No capacity	☐ Approximately _____ additional 10-dose MDVs
Frozen (-15° to -25°C):	☐ No capacity	☐ Approximately _____ additional 10-dose MDVs
Ultra-frozen (-60° to -80°C):	☐ No capacity	☐ Approximately _____ additional 10-dose MDVs

STORAGE UNIT DETAILS FOR THIS LOCATION

List brand/model/type of storage units to be used for storing COVID-19 vaccine at this location:

1. *Example: CDC & Co/Red series two-door/refrigerator*
2.
3.
4.
5.

I attest that each unit listed will maintain the appropriate temperature range indicated above: (*please sign and date*)

Complete in CVMS

Medical/pharmacy director or location's vaccine coordinator signature

Complete in CVMS

Date

* https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-at-increased-risk.html

Sample

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CDC COVID-19 Vaccination Program Provider Profile Information

PROVIDERS PRACTICING AT THIS FACILITY *(additional spaces for providers at end of form)*

Instructions: *List below all licensed healthcare providers at this location who have prescribing authority (i.e., MD, DO, NP, PA, RPh).*

Provider Name	Title	License No.
Complete in CVMS		

Sample

Appendix 40 – Vaccine Letter to County Leaders

NC DEPARTMENT OF
HEALTH AND
HUMAN SERVICES

STATE OF NORTH CAROLINA
DEPARTMENT OF HEALTH AND HUMAN SERVICES

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

February 12, 2021

Dear County Leaders:

On Wednesday, Governor Cooper and I announced plans for how the state will move to Group 3 for COVID-19 vaccines. Because vaccine supply is still limited and the Group 3 population of frontline essential workers is so large, the state will move to the next group gradually. Therefore, we will begin with anyone working in child care or in PreK – 12 schools starting on February 24th and plan to move to additional frontline essential workers on March 10th. **Some vaccine providers may not be ready to open to frontline essential workers on these dates if they are still experiencing high demand for vaccines in Groups 1 and 2.**

Beginning on February 24th, those working in child care and schools, such as teachers, bus and van drivers, custodial and maintenance staff, and food service workers, will be eligible for vaccines. This includes staff in child care centers and homes, Head Start Programs, Preschool and PreK programs, traditional public schools, charter schools and private schools. (See Deeper Dive for additional detail.)

While staff in child care settings and PreK-12 schools will be eligible starting February 24th that **does not guarantee** they will get an appointment or get vaccinated between February 24th and March 10th because of very limited supply. However, the two-week period between February 24th and March 10th will allow for a more measured opening of the frontline essential workforce group.

NCDHHS is developing operational guidance to support child care and school staff in accessing vaccines. However, current prevention measures will not change. Schools can and should be providing in-person instruction. Under robust safety measures, all students can be in classrooms, with middle and high school students also following six-feet social distancing protocols.

North Carolina is currently vaccinating people in Groups 1 and 2, which include health care workers, long-term care staff and residents, and people 65 and older. Many local vaccine providers do not have enough vaccines to meet the needs of the currently eligible Groups. In the coming weeks, some providers will continue to vaccinate only these groups, whereas others may be ready to start vaccinating school and child care staff on February 24th. Whether vaccine providers can vaccinate school and child care staff will depend on vaccine supply and whether they are still experiencing high levels of demand from Groups 1 and 2.

We look forward to working with you to develop operational guidance to support vaccine distribution to child care and school staff. Thank you for your ongoing partnership.

Sincerely,

Mandy K Cohen

Mandy K. Cohen, MD, MPH
Secretary

WWW.NCDHHS.GOV
TEL 919-855-4800 • FAX 919-715-4645
LOCATION: 101 BLAIR DRIVE • ADAMS BUILDING • RALEIGH, NC 27603
MAILING ADDRESS: 2001 MAIL SERVICE CENTER • RALEIGH, NC 27699-2000
AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

Appendix 45 – CVMS Organization Portal email template for vaccine providers to use to invite organizations

Organization Portal Template Email (Vaccine Providers to Send to Organization Point of Contact).
Details about Template Email:

Sender: Vaccine providers partnering with an Organization/Employer to use the CVMS Organization Portal

Recipient: Organization points of contact (e.g., superintendents and/or their designee, CCR&R point of contact) who are invited by vaccine provider to use the Organization Portal and will be responsible for bulk upload of employee information

Purpose: Explains what to expect in CVMS, common issues/questions that might arise from a user who has not used CVMS before

Instructions before sending: Customize the highlighted information below.

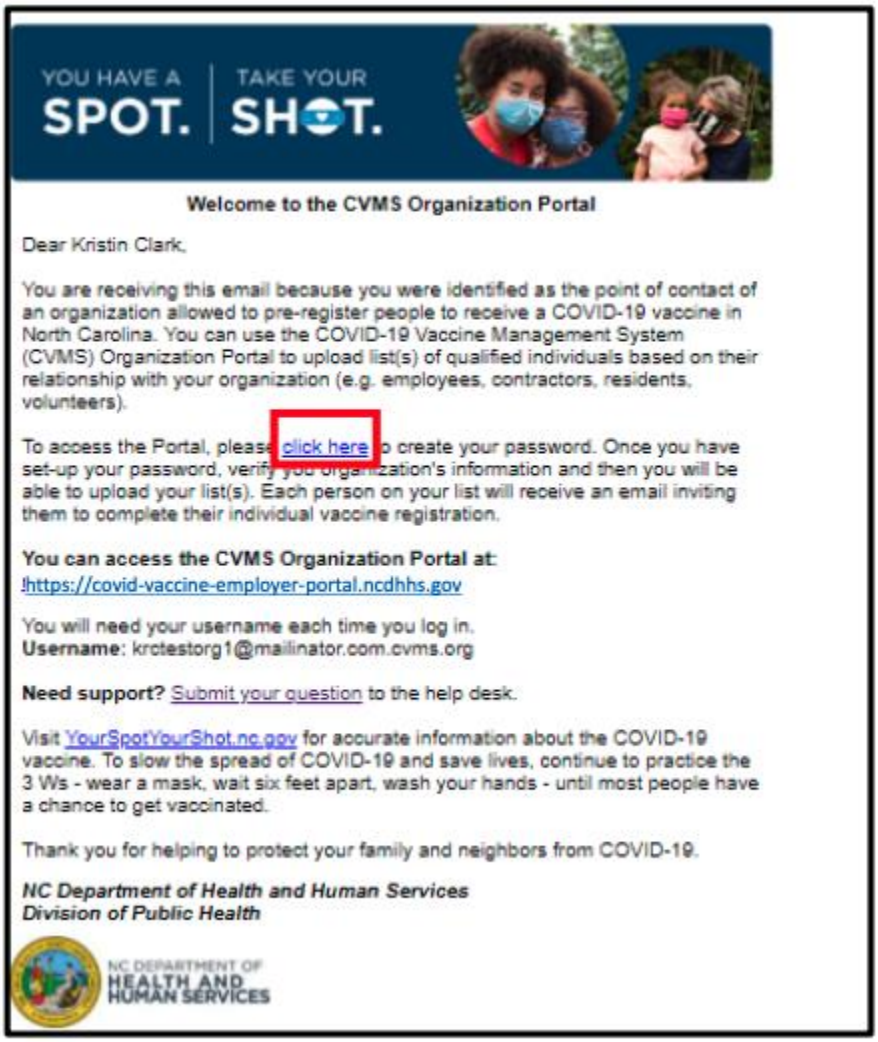
Email Subject: Please use Organization Portal to upload employees to register for vaccination

Hello,

Thank you for your support and patience as we partner to use the COVID-19 Vaccine Management System (CVMS) Organization Portal.

North Carolina has created an Organization Portal so employers and organizations can register employees or members to receive the COVID-19 vaccine at the appropriate time. Employers/organizations can upload an Excel (CSV) file to facilitate registration of eligible employees. Once uploaded, employees will receive a private and secure email to complete the registration process ahead of getting their vaccine – saving time and paperwork. **Registration does not guarantee an appointment or that vaccine is available.**

[Insert vaccine provider name] will add your organization into CVMS, so you can use the CVMS Organization Portal. We will also add you as the point of contact for your organization. You will receive an email shortly from nccvms@dhhs.nc.gov that provides your login information for the Organization Portal and specific instructions on next steps (see sample email in screenshot below).



YOU HAVE A SPOT. | TAKE YOUR SHOT.

Welcome to the CVMS Organization Portal

Dear Kristin Clark,

You are receiving this email because you were identified as the point of contact of an organization allowed to pre-register people to receive a COVID-19 vaccine in North Carolina. You can use the COVID-19 Vaccine Management System (CVMS) Organization Portal to upload list(s) of qualified individuals based on their relationship with your organization (e.g. employees, contractors, residents, volunteers).

To access the Portal, please click here to create your password. Once you have set-up your password, verify your organization's information and then you will be able to upload your list(s). Each person on your list will receive an email inviting them to complete their individual vaccine registration.

You can access the CVMS Organization Portal at:
https://covid-vaccine-employer-portal.ncdhhs.gov

You will need your username each time you log in.
Username: krctestorg1@mailinator.com.cvms.org

Need support? Submit your question to the help desk.

Visit YourSpotYourShot.nc.gov for accurate information about the COVID-19 vaccine. To slow the spread of COVID-19 and save lives, continue to practice the 3 Ws - wear a mask, wait six feet apart, wash your hands - until most people have a chance to get vaccinated.

Thank you for helping to protect your family and neighbors from COVID-19.

NC Department of Health and Human Services
Division of Public Health

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

What You Should Expect as the Organization Point of Contact

1. [Insert name of vaccine provider] will develop a plan with your organization to vaccinate employees.
2. [Insert name of vaccine provider] will add your organization to CVMS and will add you as the Organization Point of Contact in CVMS.
3. **Please check your email and confirm you have received an invitation from nccvms@dhhs.nc.gov to access the CVMS Organization Portal.** If you experience a delay in receiving the email, please check your spam folder. If the issue seems to be occurring for other people in your organization as well, your organization's IT department may be able to help. A link to the NCDHHS Help Desk Portal and a phone number for support can also be found at the bottom of this letter.
4. We strongly recommend you use the email template, Organization Portal Email Template_Organization POC to Employees, in Vaccine Provider Guidance Appendix 46) to communicate with your employees/members **prior** to completing the bulk upload process in CVMS. The email template covers what employees/members should expect about registration, how to schedule a vaccination appointment, and actions they will need to take. You can customize the template to include information that is specific to your employees, such as details and logistics on the day of the vaccination appointment or event.

5. **After you have communicated with your employees/members using the email template above, you can upload your list of employees/members in the CVMS Organization Portal.** The bulk upload template can be downloaded directly from the CVMS Organization Portal and is also posted on the NCDHHS website. Step-by-step instructions and tips are outlined in the CVMS Organization Portal User Guide. Please note that you will need the first names, last names, and email addresses (enter in the order shown in the bulk upload template) of all employees/members you wish to upload into the CVMS Organization Portal. We strongly recommend reading the user guide and attending a training before you complete the bulk upload process. Please check the NCDHHS website for a listing of all upcoming trainings, with information on how to join.
6. Once you finish the bulk upload process, all uploaded employees will receive an email notifying them that they can complete COVID-19 vaccine registration in the COVID-19 Vaccine Portal.
7. After completing registration, employees will be able to schedule their vaccine appointments through the method that you have jointly agreed upon. Registration in the COVID-19 Vaccine Portal is not required for vaccination. If an individual does not have an email address, that person can be registered in the COVID-19 Vaccine Portal by the vaccine provider at the time of vaccination.

Please be on the lookout for emails from nccvms@dhhs.nc.gov, which are from the NCDHHS team. These messages contain important guidance and announcements related to NC's fight against COVID-19 and the use of CVMS.

If you experience any issues using the CVMS Organization Portal to bulk upload employees, please submit a ticket in the CVMS Help Desk Portal. Select "Organization/Employer" and complete all required fields in the Vaccine Organization web form. The Provider and Organization Contact Center is also available Monday-Friday 7:00AM to 7:00PM ET and Saturday-Sunday 10:00AM-6:00PM ET. Call (877) 873-6247 and select option 8.

Thank you for your continued support,
[Vaccine Provider]

Appendix 46 - CVMS Organization Portal email templates for organizations to use to inform employees

Organization Portal Template Email (Organization Point of Contact to Send to Employees).
Details about Template Email:

Sender: Organization Point of Contact (POC) who will be responsible for completing bulk upload of employee names and emails into CVMS Organization Portal
Recipient: Employees/members of an employer/organization whose name and email address will be bulk uploaded in the CVMS Organization Portal and will be invited by email to complete their registration in the COVID-19 Vaccine Portal.
Purpose: What employees should expect in CVMS, completing registration, steps to get a vaccination appointment.
Instructions before sending: Customize the highlighted information below.

Email Subject: Please complete your COVID-19 vaccine registration
Dear employees:
You'll soon be able to take a tested, safe and effective COVID-19 vaccine. The vaccines help prevent COVID-19 and are effective in preventing hospitalization and death, with no serious safety concerns noted in the clinical trials. They are free of charge to all North Carolina residents.

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Insert organization/employer name] is working with [Insert vaccine provider name] to get employees pre-registered for the COVID-19 vaccine. As part of registration, a representative from [Insert organization/employer name] will upload employees' first names, last names, and email addresses to North Carolina's COVID-19 Vaccine Management System (CVMS). If you haven't already, you will receive an email that will allow you to register for the vaccine before coming in for your vaccination appointment, so that the process is faster when you show up for your vaccination.
Please follow the steps below to complete your COVID-19 vaccine registration in the COVID-19 Vaccine Portal.

COVID-19 Vaccine Portal & COVID-19 Vaccine Registration Instructions

1. You will receive an email from nccvms@dhhs.nc.gov inviting you to pre-register on the COVID-19 Vaccine Portal. Click the link in the email and follow the instructions to reset your password. You may need to check your spam folder.
2. Follow the instructions to change your COVID-19 Vaccine Portal Password
3. Complete the COVID-19 Vaccination Registration before your appointment to get your first vaccine dose.
    a. Enter your contact and demographic details
    b. Answer a few questions related to vaccine eligibility

To see more detailed registration instructions with screenshots, please visit the COVID-19 Vaccine Portal User Guide.

If you experience a delay in receiving an email invitation to pre-register, check your spam folder. If you still do not see an email, contact *[Sender should customize this message based on who uploaded employees/members].*

Important things to know about registration:

- Your privacy and personal information will be protected at all times.
- If you do not have an email address or did not complete the registration steps, you can still complete registration in-person when you arrive for a vaccine appointment – you do not need to pre-register in order to be able to get a vaccination.
- If you do not wish to get the vaccine at this time, you do not need to take any additional steps.

Follow instructions below to sign up for a vaccination appointment.
[Sender should customize this message to include steps for how employees can get vaccinated, based on your plan with your vaccine provider to vaccinate employees.] You will still need to take the additional action of getting an appointment by taking the following steps: [insert steps employee should take to get an appointment or when/where employees should arrive for a scheduled vaccine event] Please note, as vaccine is still limited in supply, registering in the COVID-19 Vaccine Portal does not guarantee immediate vaccination for everyone and you may have to wait.
For other COVID-19 related questions, you may contact the COVID-19 Vaccine Help Center at 888-675-4567 Monday through Friday from 7:00 AM until 7:00 PM ET, and on Saturday and Sunday from 8:00 AM until 4:00 PM ET. The CVMS Help Desk Portal is also available for submitting questions and requests for support (select Vaccine Recipient).

[Sender's choice of close]
[Name]