

COVID-19 Vaccine LHD Toolkit

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1. Executive Summary

1.1 Purpose of the COVID-19 Vaccine Toolkit for Local Health Departments

The purpose of this COVID-19 vaccine toolkit for local health departments (LHDs) is to serve as a collection of key resources for LHDs who are on the front lines of implementing a safe and effective COVID-19 vaccination campaign in North Carolina. This toolkit aims to meet the specific needs of COVID-19 vaccination for the full spectrum of LHD COVID-19 vaccine providers. The intended audience for this toolkit is all personnel involved in the planning or administration of COVID-19 vaccines.

This toolkit should complement your existing medical countermeasures, mass vaccination, points of dispensing and other jurisdictional plans.

1.2 Organization of Toolkit

This document is organized to serve as a step-by-step guide for LHDs to prepare for and then administer COVID-19 vaccines to prioritized populations in North Carolina.

The first section of the toolkit describes the LHD readiness checklist with steps that must be completed to prepare for receiving the first shipment of vaccine doses at an LHD.

The next sections of the toolkit provide important information on the following immunization program components:

- COVID-19 Vaccine Management System (CVMS): The COVID-19 vaccine tracking and monitoring system used in North Carolina
- Storage and handling
- Vaccine clinical information and guidance
- Communicating with patients about the vaccine
- Training materials

Links to additional resources are included throughout the document with key documents attached in the appendices.

1.3 Updating of Toolkit

This toolkit will be distributed on a regular cadence to health directors and immunization coordinators at each LHD. We anticipate that the content of the toolkit will change frequently as federal and state health officials receive and provide additional guidance on the various vaccine products. At this time, we anticipate sending an updated toolkit on a regular cadence, with new changes highlighted in yellow.

1.4 Revision Log and Document Live Link

The most recent version of the document will be posted on the Immunization Branch website and we will provide the link once available.

Date	Updates
12/17/2020	Initial publication
12/22/2020	5.1.1 Moderna Storage and Handling 6.1.1 Moderna Administration

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	Appendices 13-24
12/31/2020	Upcoming Training Sessions 4.2 CVMS Help Desk Link 5.1.1 Moving Moderna Vaccine Between Sites 6.3 Revised Guidance 6.11 Coding and Billing

2. COVID-19 Vaccine Timeline

- **December 11, 2020:** Pfizer vaccine receives Emergency Use Authorization from the FDA.
- **December 13, 2020:** CDC releases recommendations for COVID-19 vaccination from the Advisory Committee on Immunization Practices.
- **Week of December 14:** 53 hospitals anticipate receipt of Pfizer vaccine to start vaccinating Phase 1a. These hospitals were prioritized based on ultra-cold storage, bed capacity, health care workers, and county population.
- **December 17, 2020:** FDA's advisory committee will meet to discuss the Moderna vaccine application for Emergency Use Authorization.
- **December 18, 2020:** Moderna vaccine receives Emergency Use Authorization from the FDA.
- **December 20, 2020:** CDC releases recommendations for COVID-19 vaccination from the Advisory Committee on Immunization Practices.
- **Week of December 21:** NC receives 2nd week's allocation of Pfizer vaccine and 1st week's allocation of Moderna vaccine for Phase 1a vaccinations. This is the first week of LHD Pfizer or Moderna allocations.
- **Week of December 28:** Anticipate Pharmacy Partnership for Long-Term Care Program in partnership with CVS and Walgreens will begin vaccinating in LTC settings

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3. Readiness Checklist (Abbreviated)

This checklist contains recommended action items to help organizations ensure their readiness to receive and administer COVID-19 vaccine. Please see Appendix 7: COVID-19 Vaccine Readiness Checklist for long form.

Onboarding	
◇	Identify internal single point of contact for your employees to send questions or provide feedback related to the administration of COVID-19 vaccine
◇	Identify your organization's users that need access to CVMS and confirm that these users have a valid NCID. Instruct users that do not have an NCID to create an NCID and provide it to you. Complete the HCP User Onboarding Template and send the file to COVID-Help@dhhs.nc.gov . (See Section 4 for information on CVMS).
◇	Fill out the State-provided Recipient/Individual Bulk Upload Template with the requested information for each of your eligible employees or individuals outside of the LHD that meet the Phase 1 criteria to receive the COVID-19 vaccine. When vaccines are available and you have obtained access to CVMS, you will be able to upload your completed Recipient Bulk Upload Template into CVMS so that the identified employees or individuals can complete their registration process in CVMS. A confirmed Appointment Walk-in registration option for individuals not uploaded will be available within CVMS in Release 2. Please see https://immunize.nc.gov/providers/covid-19training.htm or Appendix 12 for the template.
Training	
◇	Vaccine Coordinators: Provide orientation and training materials to your organization's designated primary and back-up vaccine coordinators. At a minimum the primary and back-up Immunization Coordinators must complete these vaccine trainings: ○ Review the CDC Storage and Handling Toolkit, including the COVID-19 vaccine addendum https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf ○ Complete the You Call The Shots: Storage and Handling module ○ Complete the Pfizer-BioNTech COVID-19 Vaccine training and other vaccine brand specific trainings as they become available ○ Complete the COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare Providers.
◇	Receipt of COVID vaccine: Train your staff that are designated to receive COVID-19 vaccines and manage inventory levels in CVMS on how to receive vaccines in CVMS, document received quantities, contact CVMS help desk, return shipping containers. Please reference section 4.1 for CVMS overview, section 4.2 for CVMS training, Appendix 10 for Pfizer Storage and Handling Checklist and Appendix 15 for Moderna Storage and Handling Summary Guidance.
◇	Storage and Handling: Train your staff that are designated to handle and store COVID-19 vaccines on how to (a) properly handle the COVID-19 vaccines, (b) monitor and document the storage temperature for COVID-19 vaccines, and (c) for Pfizer vaccine, recharge COVID-19 vaccine shipping containers if they are being used to store COVID-19 vaccines. Please see Appendix 10 and Appendix 11 for additional Storage and Handling information.
◇	Other CVMS Training: Train your staff that are designated to check-in employees prior to administration of COVID-19 vaccine on how to use CVMS to complete their responsibilities. Please reference section 4.1 for CVMS overview and section 4.2 for CVMS training.
Communication	
◇	FAQ: Consider developing internal FAQs for your organization to help employees understand the COVID-19 vaccination process.
◇	Operational Communications: Develop and distribute the communications to identified employees or individuals that were uploaded into CVMS on the process, timing, and logistics to receive the COVID-19 vaccine (two doses).

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Vaccine Administration Prep	
◇	Prioritizing and scheduling: Determine process for prioritizing and scheduling employees or individuals to receive the COVID-19 vaccine (two doses) and logistics on where employees or individuals will need to go to receive the COVID-19 vaccine. (See Section 6.3) ○ Priority populations in week 1: Long-term care facilities not covered by federal program and high-risk health care workers not vaccinated in a hospital ○ Coordinate with local hospitals also receiving vaccine in early week allocations ○ Start planning for community-wide coordination on vaccines for Phase 1b, which includes adults with 2+ chronic conditions including those in congregate settings (e.g., correctional, homeless shelters, migrant farm, etc) and frontline workers.
◇	CVMS and shipments: Understand how to view status of COVID-19 vaccine shipments to your organization in CVMS. (See Section 4.2)
◇	Pfizer vaccine storage: If storing the Pfizer vaccine in an ultra-cold freezer, ensure proper equipment and processes are being used with adequate capacity. Each tray contains 195 vials and is roughly 9"x9"x1.6". (See Appendix 10 and 11)
◇	Moderna vaccine Storage: Moderna vaccine vials may be stored in the refrigerator or freezer. Each box contains 10 multidose vials (100 doses). This vaccine does not need to be mixed with a diluent before administration. (See Appendix 15).
◇	EUA fact sheet: Obtain copy of Emergency Use Authorization Fact Sheet for each COVID-19 vaccine product your organization receives and establish process to provide a printed copy of this document to each recipient prior to administration of the vaccine (both first and second dose). (See Appendix 1)
◇	V-SAFE information sheet: Obtain copies of the V-safe Information Sheet. (See Appendix 4)

North Carolina Identification

As part of the readiness checklist, you are required to have an NCID in order to access COVID-19 Vaccine Management System (CVMS) for scheduling and entering vaccine administrative data or inventory. If you are only a vaccine recipient, then you do not need an NCID. If you do not already have an NCID, please follow the steps below to register for one (for step #2, refer to the Readiness Checklist in Appendix 7):

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

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

Upcoming Training

The Immunization Branch invites you to attend live CVMS Orientation and Readiness Training Sessions this week. The Readiness Training will cover key actions you can do right now to prepare for CVMS and administering the COVID-19 vaccine. There will be time in this training session for Q&A. We will also provide specific training sessions for Location Managers and Healthcare Providers. Please see below for the full CVMS

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training and office hours schedule for 12/18/20. Calendar invitations will be sent for these sessions below. Please note the same sessions are being offered multiple times on different days of the week.

Upcoming Training Sessions

Please see list below for training sessions the week of 01/04 and <https://immunize.nc.gov/providers/covid-19training.htm> for future sessions.

1. **Day in the Life of a Healthcare Provider:** 1/4/21 at 2:00 PM – 3:00 PM ET
Zoom link: <https://ey.zoom.us/j/98250358614?pwd=TDVMVxRdHdyOGdreU4zMdJKMIROZz09>
Passcode: 779008
2. **CVMS Provider Enrollment Training:** 1/5/21 at 10:30 AM – 12:00 PM ET
Zoom link: <https://ey.zoom.us/j/93976600784?pwd=SFBzc29Bams4azNmMnVsb3pXVU5VQT09>
Passcode: 634159
3. **Day in the Life of a Healthcare Provider:** 1/6/21 at 10:30 AM – 11:30 AM ET
Zoom link: <https://ey.zoom.us/j/98975240988?pwd=eldRTzI4NjZ0bHkwRThqbFc5UC9qUT09>
Passcode: 779667
4. **Day in the Life of a Location Manager:** 1/6/21 at 2:00 PM – 3:30 PM ET
Zoom link: <https://ey.zoom.us/j/95413404810?pwd=dEq0QlErUVBCdmtMV1FTeDdnODImUT09>
Passcode: 387398
5. **CVMS Provider Enrollment Training:** 1/7/21 at 2:00 PM – 3:30 PM ET
Zoom link: <https://ey.zoom.us/j/95174218451?pwd=RDNYs0J3WDhcllBd0VtXBPV1R6UT09>
Passcode: 737039
6. **Day in the Life of a Location Manager:** 1/8/21 at 11:00 AM – 12:30 PM ET
Zoom link: <https://ey.zoom.us/j/96720436924?pwd=enpnZUZLO2NXS2hxTEN3emdZZ0hmUT09>
Passcode: 374228
7. **Day in the Life of a Healthcare Provider:** 1/8/21 at 2:00 PM – 3:00 PM ET
Zoom link: <https://ey.zoom.us/j/94140695168?pwd=d1pmdFF1MUZtRIIXU05EYU9IVW1MUT09>
Passcode: 341008
8. **What is new in Release 3 of CVMS:** 1/11/21 at 10:30 AM – 11:30 AM ET
Zoom link: <https://ey.zoom.us/j/96176911499?pwd=T3RoSmNNN3BMUDZrTUNpcmY4aVhTZz09>
Passcode: 422668
9. **Day in the Life of a Healthcare Provider:** 1/11/21 at 2:00 PM – 3:00 PM ET
Zoom link: <https://ey.zoom.us/j/96531569478?pwd=Q090YzMvSmUrWmRjRkIFa2IFYWJmZz09>
Passcode: 799112
10. **CVMS Provider Enrollment Training:** 1/12/21 at 10:30 AM – 12:00 PM ET
Zoom link: <https://ey.zoom.us/j/95680385848?pwd=TmFWRnNqWjVkJRTJBkYzeIBGYUFZQT09>
Passcode: 420280
11. **Day in the Life of a Healthcare Provider:** 1/13/21 at 10:30 AM – 11:30 AM ET
Zoom link: <https://ey.zoom.us/j/99752978447?pwd=Z2dDNFBjOEExNaTYvMXdrRGViUkNnQT09>
Passcode: 781147
12. **Day in the Life of a Location Manager:** 1/13/21 at 2:00 PM – 3:30 PM ET
Zoom link: <https://ey.zoom.us/j/97693466240?pwd=ZzZleVJOaWZEelc0cytvZ3RrVFRnUT09>
Passcode: 341493
13. **CVMS Provider Enrollment Training:** 1/14/21 at 2:00 PM – 3:30 PM ET
Zoom link: <https://ey.zoom.us/j/99073059819?pwd=bVgyYzhYYys3Nk9nQUVJVVhrRFZxdz09>
Passcode: 397831
14. **Day in the Life of a Location Manager:** 1/15/21 at 11:00 AM – 12:30 PM ET
Zoom link: <https://ey.zoom.us/j/91601343114?pwd=YXhZSDFYWpXWnBxYWwkaHhWaFlnUT09>
Passcode: 499884
15. **Day in the Life of a Healthcare Provider:** 1/15/21 at 2:00 PM – 3:00 PM ET
Zoom link: <https://ey.zoom.us/j/97681237646?pwd=VHZaTVRvb0t0b0hoZjdVTUYxSEdFZz09>
Passcode: 121834

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For Additional Help:

- If you have any questions, please use the [ServiceNow](#) platform.
- You may also send an email to the COVID-19 Vaccine Helpdesk at cvms-help@dhhs.nc.gov
 - Current helpdesk hours of operations Monday – Friday, 8am – 5pm ET; Saturday – Sunday, 10am – 6pm ET
- Reminder, if you have storage and handling questions, please contact our storage and handling staff at (919) 707-5574. Please leave a message if you do not reach anyone and someone will return your call as soon as possible. You may also find additional storage and handling resources on our website ([Storage Resources](#)).
- If you have a clinical question, please call our clinical nurse on-call number at (919) 707-5575. Please leave a message if you do not reach anyone and someone will return your call as soon as possible.
- You may also contact your regional nurse ([RIN map](#)) or regional immunization consultant ([RIC map](#)) if you need assistance.
- For those LHDs that receive Pfizer, Pfizer is providing Customer Service for questions related to its product, please see below:

Pfizer US Customer Service Information

 General Product Inquiries (877) 829-2819 Open: 8am – 11pm ET, 7 days/week • Basic administration FAQs (dosing schedule, what syringes should be used for diluting and/or administration) • Storage & Handling FAQs • Diluent FAQs (what type, how do I dilute, how can I order more, how should it be stored, etc) • Dry ice / Shipping Container FAQs • How many doses will be available and when?	 Medical Information www.PfizerMedInfo.com (800) 438-1985 Open (Covid Vx Only): 8am – 11pm ET, 7 days/week • Questions related to efficacy, safety, stability, dosage and administration • Questions related to mechanism of action • Information on vaccine ingredients	 US Shipment Support / Trade Customer Service (800) 666-7248 Open: 8am – 8pm ET, 5 days/week (M-F) • Where and how can I get more dry ice? • How can I / my institute return shipment boxes? • How can I order the Pfizer-BioNtech Covid-19 Vaccine for my practice, office, or hospital? • I have yet to receive the vaccine quantities that I ordered. What is the status? What can I do? • I cannot locate the diluent for the vaccine. What should I do?
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- For those LHDs that receive Moderna, Moderna is providing Customer Service for questions related to its products, please see below:



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Moderna US Customer Service Information



General Product Inquiries
1-866-MODERNA
(1-866-663-3762)
Open:
8am – 8pm ET, 7 days/week

- Will be routed to:
 - General Moderna Questions
 - Healthcare Provider Questions (Clinical)
 - Product Quality or Technical Questions
 - Pregnancy Registry
- Basic administration FAQs (dosing schedule, what syringes should be used for diluting and/or administration)
- Storage & Handling FAQs
- Shipping Container FAQs
- How many doses will be available and when?



Medical Information
<https://www.modernabx.com/covid19vaccine-eua>
(1-866-663-3762)
Open (Covid Vx Only):
8am – 8pm ET, 7 days/week

- Questions related to efficacy, safety, stability, dosage and administration
- Questions related to mechanism of action
- Information on vaccine ingredients
- Will be able to speak with a clinical specialist



FAQs

FDA will also have a Frequently Asked Questions page for the Moderna COVID-19 vaccine.

<https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine>



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- See Section 9 for additional Technical Assistance opportunities

4. CVMS

4.1 Overview

What is CVMS?

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

With the first release of CVMS launched on 12/10/2020, providers are currently able to:

- Enroll in the COVID-19 Vaccination Program and upload individuals so they can register for COVID-19 vaccination
- Manage COVID-19 vaccine inventory
- Track COVID-19 vaccine administration

Scheduling, order management, Spanish language translation, accommodation of walk-in vaccination and point-of-care registration, and integration with the NCIR for one complete vaccine record are planned for subsequent CVMS releases.

Who will use CVMS?

- State of NC Administrators will enroll providers and verify provider eligibility and site readiness.
- Providers will verify patient eligibility, log dosage administration, and track frequency and timing of second doses.

Who will NOT use CVMS?

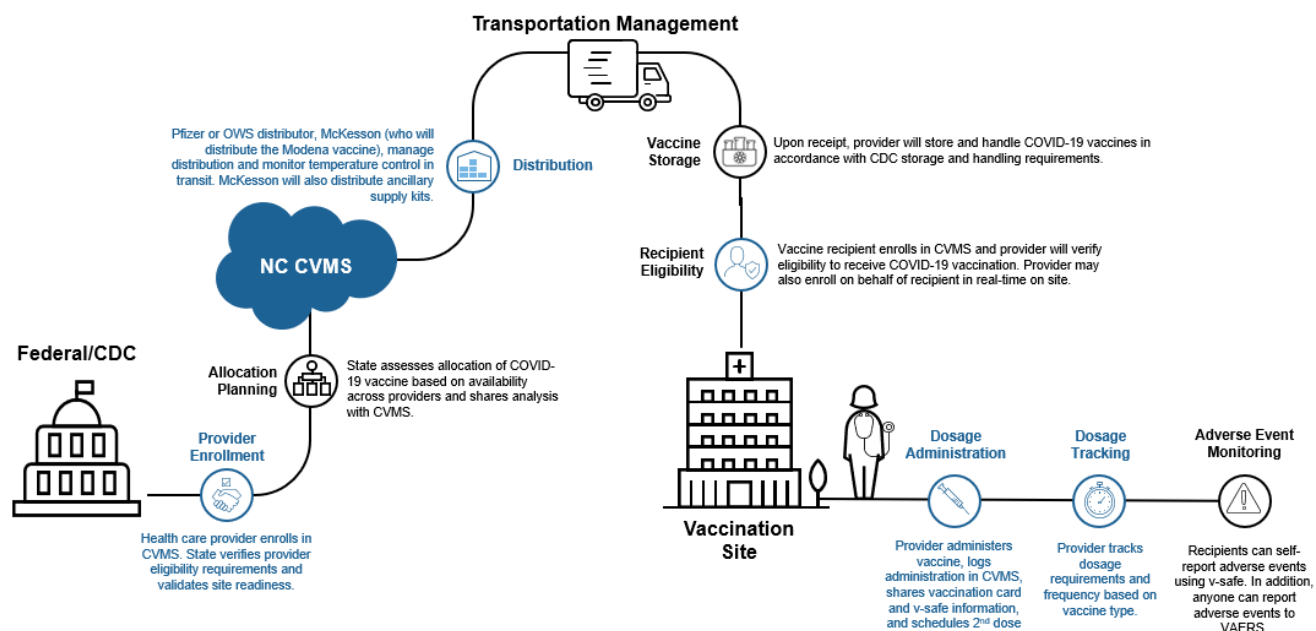
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- Pharmacies (e.g., Walgreens and CVS) and providers enrolled through the Federal Government.

Why CVMS?

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

CVMS in the COVID-19 Vaccine Journey



Below you will find the direct links and details on the username to use for each CVMS Portal.

CVMS Provider Enrollment Portal: <https://covid-enroll.ncdhhs.gov> – Use your Provider Enrollment username, which is the email address you registered with, and password you created.

CVMS Provider Portal: <https://covid-vaccine-provider-portal.ncdhhs.gov> – Use your NCID username and password you created when registering for your NCID.

CVMS Recipient Portal: <https://covid-vaccine-portal.ncdhhs.gov/> – Use your Recipient Portal username, which is the email address that was used to register you with plus.covid19vaccine (e.g., emailaddress.covid19vaccine), and password you created. For additional information, you may also reference Finding your CVMS Recipient Portal Username (Appendix 22) and CVMS Recipient Portal Reset Password Job Aid (Appendix 23).

4.2 Online Resources: CVMS

Training Program / Reference Material	Description
CVMS Introduction	Prepare for the new COVID-19 Vaccine Management System (CVMS) by learning what it is, who will be using it, and why.

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CVMS Provider Enrollment Demo	A recorded walk-through of the steps needed for Providers to complete enrollment in CVMS.
CVMS Readiness Training	This readiness training will cover key actions you can do right now to prepare for CVMS and administering the COVID-19 vaccine. We will also review important upcoming dates to keep in mind as we prepare for CVMS go-live.
CVMS Readiness Checklist	A comprehensive list of action items for Providers to complete before enrolling in CVMS. The action items are grouped by topic (Onboarding, Training, Communications and Vaccine Administration Preparation) and listed in recommended sequence to address.
CVMS Orientation Training	In this training session, we will explain what CVMS is, who will be using it, and why we are using it as our statewide platform. We will also cover functionalities of the tool, including: Provider Enrollment, Recipient Registration, Recipient Vaccine Administration, and Inventory Management.

5. Storage and Handling

5.1 Overview

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

5.1.1 Moderna

The Moderna vaccine is a cold vaccine that is to be stored frozen between -25° to -15°C (-13° to 5°F) in vaccine storage unit. Store in the original carton to protect from light. Do not store on dry ice or below -40°C. Vials can be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use. Unpunctured vials may be stored between 8° to 25°C (46° to 77°F) for up to 12 hours. Do not refreeze once thawed. After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Discard vial after 6 hours. McKesson will be handling the distribution of the Moderna Vaccine.

Moving Moderna Vaccine Between Sites

Moderna vaccine may be shipped directly to sites in volumes of 100 doses per carton. While the CDC recommends that each site administering vaccine receive a direct shipment due to the smaller shipment size, CDC recognizes that redistribution of vaccine may be required in some instances by jurisdictions, federal and pharmacy partners. Based on information to date from the manufacturer, immunization planners should consider the following general principles for redistribution of the Moderna COVID-19 vaccine:

- Once a vial of vaccine has been thawed, it may be stored refrigerated at 2-8°C (36° to 46°F) for up to 30 days
- Once thawed, the vaccine cannot be re-frozen
- When thawed, the vaccine should be handled with care and protected from shocks, drops, vibration, etc.
- Vaccine being transported at temperatures other than frozen (-15 to -25°C) should begin with the vaccine in the frozen state whenever possible

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- If you must transport vaccine that has already been thawed, follow these general principles:
 - Punctured vials should not be transported
 - Care must be taken to ensure vaccine does not re-freeze during transport
 - Vaccine must be protected as much as possible from drops, shocks, and vibration whether in the carton, vial, case or cooler
 - Vaccine should be transported in the carton whenever possible
 - If transport must be conducted at the vial level, the vial should be placed with dunnage (padding material like bubble wrap or similar padding) to minimize movement during transport
 - The vaccine should always be transported in insulated containers qualified to maintain 2-8°C for the duration of transport
 - The transport containers must be secured when being transported to prevent unnecessary movement
 - After completion of transport, vaccine should immediately be placed into a vaccine storage unit at 2-8°C
 - Vaccine should only be transported one time and should not be transported back again to the point of origin or to a new location
 - Allowable timelines for transport of thawed vaccine are shown below. Total transport time should not exceed 12 hours in total
 - Transport while walking or using hand cart: not to exceed 1 hour
 - Vehicle transport: not to exceed 12 hours
 - Airplane transport (rotary wing aircraft not allowed): not to exceed 3 hours

5.1.2 Pfizer

The Pfizer COVID-19 vaccine is an ultra-cold product (-90°C to -60°C) and is delivered in a thermal shipper. The thermal shipper can be used to store the product if appropriate equipment is not available for up to 30 days with dry ice refills every 5 days, the first of which will arrive the day after vaccine is received. The Pfizer COVID-19 vaccine can last up to 5 days at refrigerated temperatures. It is recommended that the thermal shipping container not be opened more than 2 times a day and should not be opened for more than 3 minutes at a time. Please see Appendix 11 for an overview of Pfizer vaccine storage and handling. The ancillary kits will be shipped separately from vaccine product, see Appendix 6 for more information.

Pfizer has prepared a checklist for storage and handling. Please see Appendix 10. This document is also available at <https://www.cvdvaccine-us.com>. **This document is imperative to read prior to handling the product.**

5.2 Online Resources: Storage and Handling

Training Program / Reference Material	Description
Pfizer COVID-19 Resources for HCP	This Pfizer vaccine website is intended for healthcare professionals. Resources include training videos, administration guidance, and storage and handling resources.
CDC COVID-19 Information by Product	The CDC website has detailed storage and handling documentation for each available product.

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COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare Providers	A web-based training course outlining best practices and principles for healthcare providers when preparing to administer COVID-19 vaccine. It is a high-level overview of the following topics with links to detailed information: vaccine development and safety, safety monitoring programs, Emergency Use Authorizations (EUAs), vaccine storage/handling, preparation, administration, PPE, scheduling, documentation, and reporting adverse events. Information on each vaccine product will be added as each is authorized by FDA.
You Call the Shots: Vaccine Storage and Handling	An interactive, web-based immunization training course on storage and handling best practices and principles.
“Keys to Storing and Handling Your Vaccine Supply” video	This video is designed to decrease vaccine storage and handling errors by demonstrating recommended best practices and addressing frequently asked questions.
Vaccine Storage and Handling Toolkit	Comprehensive guide that reflects best practices for vaccine storage and handling from Advisory Committee on Immunization Practices (ACIP) recommendations, product information from vaccine manufacturers, and scientific studies.
Vaccine Storage and Handling Toolkit, COVID-19 Vaccine Addendum	The <i>Vaccine Storage and Handling Toolkit, COVID-19 Vaccine Addendum</i> , provides information, recommendations, and resources on storage and handling best practices to help safeguard the COVID-19 vaccine supply and ensure patients receive safe and effective vaccines.
Epidemiology and Prevention of Vaccine-Preventable Diseases	Comprehensive information on routinely used vaccines and the diseases they prevent. Chapter 5 is dedicated to vaccine storage and handling (updated 2020).

5.3 Pfizer and Moderna Training

Pfizer Training Sessions Jan 4-11, 2021

Pfizer will be hosting a series of training sessions to review COVID-19 vaccine information and answer questions. Please click on the link below to join the sessions at the designated times. Each training below will include the same content.

Date & Time	Password
Attendee Link January 4 - 5 PM ET	u3gP7Jpt7Gj
Attendee Link January 5 - 10 AM ET	ThvtuEfs239
Attendee Link January 5 - 5 PM ET	Rp5m9Um3JEN
Attendee Link January 6 - 10 AM ET	95QqGJSFp2W
Attendee Link January 6 - 5 PM ET	Mm8eufxew25
Attendee Link January 7 - 10 AM ET	umJUvmYz232

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Attendee Link January 7 - 5 PM ET	vK6m9esWRN8
Attendee Link January 8 - 10 AM ET	79ydMmcCY2M
Attendee Link January 8 - 5 PM ET	CtEuVKmQ943
Attendee link – January 11 – 10 AM ET	nFXGZ3udX92
Attendee link – January 11 – 5 PM ET	AeC7Rx6yKv3
Attendee link – January 12 – 10 AM ET	3HJj34mdwCv
Attendee link – January 12 – 5 PM ET	YYewqnA4A44
Attendee link – January 13 – 10 AM ET	8hGM2KtJAd3
Attendee link – January 13 – 5 PM ET	SMmBaubM477
Attendee link – January 14 – 10 AM ET	j3G8xShVAJ3
Attendee link – January 14 – 5 PM ET	mS2HYxwE96Z
Attendee link – January 15 – 10 AM ET	B9mrTXK932b
Attendee link – January 15 – 5 PM ET	mZBNJsXy392

Moderna Training: [Moderna COVID-19 Vaccine: What Healthcare Professionals Need to Know](#)

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6. COVID-19 Vaccine Clinical Information and Guidance

6.1 Overview

Pfizer: On December 11, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 Vaccine for the prevention of Coronavirus Disease 2019 (COVID-19) in individuals who are 16 years of age and older.

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

Under the FDA investigational vaccine development process, clinical trial participants must give a written informed consent to participate. Now that the COVID-19 Pfizer vaccine is authorized, a written informed consent is no longer required.

Per the EUA, the vaccination provider must 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.cvdvaccine.com to obtain the Fact Sheet) prior to the individual receiving either the Pfizer-BioNTech COVID-19 Vaccine or the Moderna COVID-19 Vaccine, including:

- FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine and the Moderna COVID-19 Vaccine, which are not FDA-approved vaccines.
- The recipient or their caregiver has the option to accept or refuse Pfizer-BioNTech COVID-19 Vaccine or the Moderna COVID-19 Vaccine.
- The significant known and potential risks and benefits of Pfizer-BioNTech COVID-19 Vaccine and 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.

Consent for medical treatment must be obtained prior to being vaccinated. That consent can be verbal. COVID-19 vaccination provider must provide the necessary information for receiving the second dose to every vaccine recipient.

6.2 Requirements for Providers Who Administer COVID-19 Vaccine

NC DHHS has developed a COVID-19 Vaccine Readiness Checklist that is summarized in Section 3 and can be found in longer form in Appendix 7. This checklist encompasses a comprehensive explanation of items to be completed for providers to be ready to administer COVID-19 vaccine. Specific requirements are listed in the vaccine-specific EUAs and the COVID-19 Readiness Checklist. Please see the EUA Letter of Authorization for Pfizer-BioNTech COVID-19 Vaccine (Appendix 3) and for Moderna COVID-19 Vaccine (Appendix 17) and the COVID-19 Readiness Checklist (Appendix 7) for a full explanation of the requirements and links to the trainings. Below is the basic list of requirements to prepare you to administer COVID-19 vaccine.

1. Obtain CVMS access and complete the recommended CVMS trainings
2. At a minimum the primary and back-up Immunization Coordinators must complete these vaccine trainings:
 - a. Review the CDC Storage and Handling Toolkit, including the COVID-19 vaccine addendum

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- b. Complete the You Call The Shots: Storage and Handling module
- c. Complete the Pfizer-BioNTech COVID-19 Vaccine training, Moderna COVID-19 Vaccine training and other vaccine brand specific trainings as they become available
- d. Complete the COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare Providers
3. Complete the COVID-19 Readiness Checklist (Appendix 7)
4. Obtain copies of the EUA Fact Sheet for patients/caregivers and for healthcare providers (Appendix 4 & 5 for Pfizer and Appendix 13 & 14 for Moderna)
5. Obtain copies of the v-safe Information Sheet (Appendix 4)

6.3 Risk Based Prioritization of COVID-19 Vaccine Recipients

A tested, safe and effective vaccine will be available to all who want it, but supplies will be limited at first. To save lives and slow the spread of COVID-19, independent state and federal public health advisory committees made recommendations for who to vaccinate first based on limited supplies of vaccine being available. In North Carolina, the NC Institute of Medicine (NCIOM) convened a Vaccine Advisory Committee of more than 65 people representing diverse constituencies across the state. These committees 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.

North Carolina has prioritized vaccination in the following groups (see infographic below). This guidance document provides additional details on vaccinations for eligible individuals in Phase 1a and Phase 1b Group 1. All vaccine providers are expected to ensure that the vaccine is administered equitably within each group. North Carolina will communicate with vaccine providers about the recommended timeline for moving to additional phases and groups, while allowing local flexibility to adjust based on vaccine supply and local demand for vaccination. As North Carolina moves into future phases and groups, this guidance will be updated to add information for specific populations.

Those most at risk get it first.

YOU HAVE A
SPOT. TAKE YOUR
SHOT.



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Vaccination Prioritization Key Points for LHDs:

- **Priority populations in Phase 1a:** Long-term care facilities not covered by federal program and high-risk health care workers not vaccinated in a hospital.
 - **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.
- Please see Appendix 26 for further clarification on phase 1a: DEEPER DIVE: Phase 1a. Health care workers fighting COVID-19 & Long-Term Care
- **Coordinate with local hospitals** also receiving vaccine in early week allocations.
- ACIP released updated prioritization recommendations on 12/20/2020 which were published on 12/22/2020. Based on these recommendations, NC has adjusted the prioritization framework.
- **Priority populations in Phase 1b:** The goals are to save lives by protecting North Carolinians who are at high risk of being hospitalized or dying from COVID-19 and slow the spread by protecting those at high risk of exposure. Due to limited supply, phase 1b will not be open to everyone at first. Vaccinations will happen by group in the following order:
 - Group 1: Persons 75 years and older. All people age 75 and older will be eligible to be vaccinated first in this group. There is no requirement to have certain qualifying chronic conditions.
 - Group 2: Any patient-facing direct health care workers not vaccinated in Phase 1a and essential frontline workers who are over age 50. Patient-facing direct health care workers are those directly caring for or working directly in areas where in-person patient care occurs. Essential frontline workers are defined by the Centers for Disease Control and Prevention (CDC) as workers who are in sectors essential to the functioning of society and who are at substantially higher risk for exposure to COVID-19. There is no requirement to have certain qualifying chronic conditions.
 - Group 3: All other patient-facing direct health care workers not vaccinated in Phase 1a and frontline essential workers of any age. There is no requirement to have certain qualifying chronic conditions.
 - Please see Appendix 27 for further clarification on phase 1b: DEEPER DIVE: Phase 1b. Adults at highest risk of severe illness and those at highest risk for exposure
- The state will provide further guidance on moving from one phase to another as additional vaccine becomes available.

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NCDHHS expects that North Carolina may move to Phase 1b and begin vaccinating adults 75 years or older in Group 1 the week of January 4th, 2021. However, this timeline is subject to change based on vaccine availability.

Based on estimated vaccine allocations, NCDHHS anticipates the following timeline. These timeframes **are estimates only and subject to change** based on the supply North Carolina actually receives from the federal government and local supply on hand

- January 6th, 2021 – Open to Phase 1b, Group 1 and continue 1a
 - Some vaccine providers may begin as early as January 6th, but we expect most vaccine providers will begin on January 11th
- January 20th, 2021 – Open to Phase 1b, Group 2 and continue all previous groups and 1a
- February 8th, 2021 – Open to Phase 1b, Group 3 and continue all previous groups and 1a

As with Phase 1a, hospitals, health systems and local health departments should coordinate for Phase 1b and health systems should vaccinate people not affiliated with their system, even if they indicated a closed system in the initial NC DHHS survey.

We encourage hospitals, health systems, and local health departments to continue proactive planning and communications efforts with the communities they serve so that individuals who are eligible in Phase 1b and Phase 2 will know how and when they can get the vaccine when it is their turn.

All vaccine providers are expected to ensure that vaccine is equitably administered within each group. NCDHHS has a specific focus on building trust with historically marginalized populations. Longstanding and continuing racial and ethnic injustices in our health care system contribute to lack of trust in vaccines. We hope you will join us in partnering with trusted leaders and organizations to provide accurate information about the vaccine.

6.4 Vaccine Brands

The Product Information Guide for COVID-19 Vaccines and Associated Products (See Appendix 6) provides an overview of COVID-19 vaccine products.

Brands of COVID-19 vaccine are currently NOT interchangeable. Always use the same brand of COVID-19 vaccine to complete a series if there is more than one dose recommended. Always refer to the package insert of the product you are using for licensure information or the EUA Fact Sheet for each vaccine and the ACIP Recommendations for COVID-19 vaccines before administering a COVID-19 vaccine. See the EUA Fact Sheet section below for specific information on the vaccine currently available. Here is the link to the ACIP Homepage <https://www.cdc.gov/vaccines/hcp/acip-recs/index.html>.

Pfizer-BioNTech COVID-19 Vaccine

Please see Appendix 3 for the FDA Letter of Authorization for Pfizer-BioNTech COVID-19 Vaccine.

Moderna COVID-19 Vaccine

Please see Appendix 17 for the FDA Letter of Authorization for Moderna COVID-19 Vaccine.

On 11/30, Moderna announced further data analysis has shown that their mRNA vaccine candidate has an efficacy of 94.5% against COVID-19. This data analysis revealed the following data points:

- 15,000 trial participants received the real vaccine – 11 developed COVID-19, with no severe cases observed
- 15,000 trial participants received the placebo – 185 developed COVID-19, with 30 severe cases observed

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6.5 EUA Fact Sheet

The EUA Fact Sheet for each vaccine is required to be given to each patient before administration of COVID-19 vaccine. There is **no federal or state requirement to document** that the patient fact sheet was received or to document a publication date. The EUA also requires the *Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers): Emergency Use Authorization (EUA) of Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19)* be provided to vaccination providers

- Appendix 1: EUA Fact Sheet for Recipients and Caregivers for Pfizer-BioNTech COVID-19 Vaccine.
- Appendix 2: EUA Fact Sheet for Healthcare Providers for Pfizer-BioNTech COVID-19 Vaccine
- Appendix 3: FDA Letter of Authorization for Pfizer-BioNTech Vaccine.
- Appendix 13: EUA Fact Sheet for Recipients and Caregivers for Moderna COVID-19 Vaccine.
- Appendix 14: EUA Fact Sheet for Healthcare Providers for Moderna COVID-19 Vaccine
- Appendix 17: FDA Letter of Authorization for Moderna Vaccine.

Currently there is no VIS for COVID-19 vaccine. Federal law (under the National Childhood Vaccine Injury Act) requires a healthcare professional to provide a copy of the current VIS to an adult patient or to a child's parent/legal representative before vaccinating an adult or child with other routine vaccines (e.g., diphtheria, tetanus, pertussis, measles, mumps, rubella) that are FDA-approved vaccines. Because no COVID-19 vaccines have full FDA approval, this requirement does not include the COVID-19 vaccine.

6.6 Clinical Considerations for COVID-19 Vaccine

Currently information is only available for the Pfizer-BioNTech COVID-19 Vaccine and Moderna COVID-19 Vaccine. Please see Appendix 3 and Appendix 17 for the FDA letter of authorization for the full EUA Prescribing information regarding components of the vaccine. Once information on other vaccines become available, this document will be updated.

6.6.1 Contraindications and Precautions for mRNA COVID-19 Vaccines

Contraindications:

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

1. Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components
2. Immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components (including polyethylene glycol [PEG])*
3. Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)*
4. Note: It is very important to report all adverse reactions after the receipt of a COVID-19 vaccine. See section 6.13 for information on the Vaccine Adverse Event Reporting System (VAERS).

Precautions

1. CDC considers a history of any immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies not related to a component of mRNA COVID-19 vaccines or polysorbate) as a precaution but not a contraindication to vaccination for both the Pfizer-BioNTech and Moderna COVID-19 vaccines.

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Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of vaccine.

Vaccine providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions in the following manner:

- Persons with a history of anaphylaxis: monitor for 30 minutes
- All other persons: monitor for 15 minutes

6.6.2 Warnings for the Pfizer-BioNTech COVID-19 Vaccine and Moderna COVID-19 Vaccine

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine and Moderna COVID-19 Vaccine. [CDC provides guidance on Preparing for the Potential Management of Anaphylaxis After COVID-19 Vaccination](#)

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to both vaccines.

Pfizer-BioNTech COVID-19 Vaccine and Moderna COVID-19 Vaccine may not protect all vaccine recipients.

Additional Considerations for Pfizer-BioNTech COVID-19 Vaccine and Moderna COVID-19 Vaccine

- Vaccination should be offered to persons **regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection**
- Vaccination should be deferred until recovery from acute illness (if person had symptoms) AND criteria have been met to discontinue isolation.
- For persons with a known SARS-CoV-2 exposure in the community, defer vaccination until quarantine period has ended to avoid exposing health care personnel or other persons during vaccination visit. For residents of congregate health care settings (e.g. long-term care facilities) or other congregate settings (e.g., correctional facilities, homeless shelters), person may be vaccinated.
- No minimum interval between infection and vaccination. However, current evidence suggests reinfection uncommon in the 90 days after initial infection, and thus persons with documented acute infection in the preceding 90 days may defer vaccination until the end of this period, if desired.
- There is no current data on the safety of COVID-19 vaccines in pregnant women. If a woman is part of a group (e.g. health care personnel) who is recommended to receive a COVID-19 vaccine and is pregnant, she may choose to be vaccinated. A discussion with her health care provider can help her make an informed decision.
- Prior receipt of an mRNA COVID-19 vaccine will not affect the results of SARS-CoV-2 viral tests (nucleic acid amplification or antigen tests). To evaluate the evidence of prior infection in an individual with a history of an mRNA COVID-19 vaccine, a test specifically evaluating IgM/IgG to the nucleocapsid protein should be used.
- The need for and timing of booster doses for mRNA COVID-19 vaccines has not been established. No additional doses beyond the two-dose primary series are recommended at this time.
- Second doses administered within a grace period of ≤ 4 days from the recommended date for the second dose are considered valid; however, doses administered earlier do not need to be repeated. The second dose should be administered as close to the recommended interval as possible; however, there is no maximum interval between the first and second dose for either vaccine.
- No COVID test recommended prior to vaccination.

Adverse Reactions

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In clinical trials, hypersensitivity-related adverse events were observed in 0.63% of participants who received the Pfizer-BioNTech COVID-19 vaccine and 1.5% of participants who received the Moderna COVID-19 vaccine.

The most common adverse reactions to mRNA COVID-19 vaccines include soreness at the injection site, fatigue, headache, muscle aches, chills, joint pain, and fever. Side effects can last from 24-48 hours.

An immediate allergic reaction to any component or previous dose of an mRNA COVID-19 vaccine is a contraindication to vaccination. If an individual had a severe allergic reaction after getting the first dose of an mRNA COVID-19 vaccine, the CDC recommends the individual not get the second dose. The following is a list of ingredients for the Pfizer-BioNTech external icon and Moderna external icon COVID-19 vaccines, as reported in the prescribing information for each vaccine.

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	PEG2000-DMG: 1,2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine
	Cholesterol	Cholesterol
	(4-hydroxybutyl)azanediylbis(hexane-6,1-diyl)bis(2-hexyldecanoate)	SM-102: heptadecan-9-yl 8-((2-hydroxyethyl)(6-oxo-6-(undecyloxy) hexyl) amino) octanoate
Salts, sugars, buffers	Potassium chloride	Tromethamine
	Monobasic potassium phosphate	Tromethamine hydrochloride
	Sodium chloride	Acetic acid
	Dibasic sodium phosphate dihydrate	Sodium acetate
	Sucrose	Sucrose

* Neither vaccine contain eggs, gelatin, latex, or preservatives

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the mRNA COVID-19 Vaccines. For guidance on responding the management of vaccine reactions, see Medical Management of Vaccine Reactions in Adults in a Community Setting Appendix 28

Triage of Persons Presenting for mRNA COVID-19 Vaccination

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	MAY PROCEED WITH VACCINATION	PRECAUTION TO VACCINATION	CONTRAINDICATION TO VACCINATION
CONDITIONS	CONDITIONS - Immunocompromising conditions - Pregnancy - Lactation ACTIONS - Additional information provided* 15 minute observation period	CONDITIONS - Moderate/severe acute illness ACTIONS - Risk assessment - Potential deferral of vaccination 15-minute observation period if vaccinated	CONDITIONS - None ACTIONS - N/A
ALLERGIES	ALLERGIES History of allergies that are unrelated to components of an mRNA COVID-19 vaccine, other vaccines, injectable therapies, or polysorbate, such as: - Allergy to oral medications (including the oral equivalent of an injectable medication) - History of food, pet, insect, venom, environmental, latex, etc., allergies - Family history of allergies ACTIONS 30-minute observation period: Persons with a history of anaphylaxis (due to any cause) 15-minute observation period: All other persons	ALLERGIES - History of any immediate allergic reaction* to vaccines or injectable therapies (except those related to component of mRNA COVID-19 vaccines* or polysorbate, as these are contraindicated) ACTIONS: - Risk assessment - Consider deferral of vaccination and/or referral to allergist-immunologist 30-minute observation period if vaccinated	ALLERGIES History of the following are contraindications to receiving either of the mRNA COVID-19 vaccines*: - Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components - Immediate allergic reaction* of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components* (including polyethylene glycol)* - Immediate allergic reaction of any severity to polysorbate** ACTIONS - Do not vaccinate* - Consider referral to allergist-immunologist

6.7 Expected Reactions and How to Prepare Your Patients

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

6.8 Consent for Vaccination

North Carolina does not require written consent for vaccines with one specific exception for children.

North Carolina law allows a provider or local health department to immunize a minor who is presented for immunization by **any** adult who signs a statement that he or she has been authorized by the parent, guardian or person standing in loco parentis to receive the vaccine. Any person 18 years of age or older who signs this statement may fall under this provision. This person could be related to the minor or be unrelated, such as a

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babysitter. COVID-19 vaccine will not be treated any differently than any other vaccine in terms of written consent.

Consent for medical treatment must be obtained prior to being vaccinated. That consent can be verbal. A provider or local health department may choose to have patients provide written consent for vaccines per their facility policy. NC General Statute 90-21.5. gives minors the legal authority to consent for the prevention, diagnosis and treatment of reportable communicable disease. This may come into play for minors who are recommended to receive COVID-19 vaccine or who request it.

See Appendix 9 for the UNC School of Government Health Law Bulletin Number 91 from July 2009 *Immunizations for Children and Adolescents: Frequently Asked Questions about North Carolina's Laws*. This document provides information regarding consent for vaccines.

6.9 NC Immunization Law

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

- NC Immunization Laws link: <https://immunize.nc.gov/schools/ncruleslaws.htm> .
- NC Minor's consent link:
https://www.ncleg.net/enactedlegislation/statutes/html/bysection/chapter_90/gs_90-21.5.html

6.10 Orders to Administer COVID-19 Vaccine

- **A Standing Order template** in the North Carolina Board of Nursing format will be provided for Local Health Departments for your Medical Director or other physician that signs your vaccine standing orders to sign. Please see Appendix 16.
- See Appendix 18 for the Moderna Standing Order and Appendix 19 for the Pfizer Standing Order.

6.11 Administration of Vaccine

Pfizer-BioNTech vaccine is approved for 0.3mL in a 2-dose series administered intramuscularly 3 weeks apart. The 4-day grace period does apply to the minimum interval between dose one and two. Therefore, if the second dose is given on days 17-21, it can be counted as valid. If greater than 21 days have elapsed since the first dose, the second dose should be administered at the earliest opportunity. The series does not need to be repeated.

Moderna COVID-19 vaccine is approved for 0.5mL in a 2-dose series administered intramuscularly 28 days apart. The Moderna COVID-19 vaccine is authorized for use in individuals 18 years of age and older. There is a grace period of 4 days before and 7 days after the date for when the 2nd dose is due. If greater than 35 days, then the second dose should be administered at the earliest opportunity. The series does not need to be repeated.

Both doses are necessary for protection; efficacy of a single dose has not been systematically evaluated. Patients should be counseled on the importance of completing the 2-dose series in order to optimize protection. Vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection. Viral or serologic testing for acute or prior infection, respectively, is not recommended for the purpose of vaccine decision-making.

Co-Administration: No data on the safety and efficacy of mRNA COVID-19 vaccines administered simultaneously with other vaccines. 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

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inadvertently administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine.

6.12 Payment and Billing of COVID-19 Vaccine

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

American Medical Association (AMA) has published new COVID-19 vaccine product and administration CPT® codes for two coronavirus vaccines. The codes will become effective once each vaccine product receives an EUA or becomes licensed by the FDA. For quick reference, these codes are listed below:

- **Pfizer-BioNTech vaccine**

91300: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3mL dosage, diluent reconstituted, for intramuscular use.

NDC (11 digit format) Labeler Product ID (Vial): 59267-1000-01

- **0001A:** Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3mL dosage, diluent reconstituted; first dose.
- **0002A:** Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3mL dosage, diluent reconstituted; second dose.

- **Moderna COVID-19 vaccine**

91301: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5mL dosage, for intramuscular use.

NDC (11 digit format) Labeler Product ID (Vial): 80777-0273-10

- **0011A:** Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5mL dosage; first dose.
- **0012A:** Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5mL dosage; second dose.

Visit AMA's website for more detailed information on COVID-19 vaccine coding: <https://www.ama-assn.org/practice-management/cpt/covid-19-cpt-vaccine-and-immunization-codes>

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NC Medicaid Coding and Billing for COVID-19 Vaccine Administration

Medicaid and NC Health Choice will reimburse at the Medicare approved COVID-19 vaccination administration rate at first dose \$16.94 and second dose \$28.39.

Vaccine CPT Code	ICD-10 Code	Vaccine Code Descriptor	Vaccine Admin Code(s)	Vaccine Name	Unit of Coverage	NDC 11 Digit Product ID
91300	Z23	Severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3mL dosage, diluent reconstituted, for intramuscular use	0001A (1st dose) 0002A (2nd dose)	Pfizer-BioNTech COVID-19 Vaccine	0.3mL	59267-1000-01 59267-1000-02 59267-1000-03 NDC Units reported as "UN1"
91301	Z23	Severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5mL dosage, for intramuscular use	0011A (1st dose) 0012A (2nd dose)	Moderna COVID-19 Vaccine	0.5mL	80777-0273-10 80777-0273-99 NDC Units reported as "UN1"

- Claims must contain both administration codes and vaccine codes to pay. Vaccine codes should be reported as \$0.00.
- Claims for first vaccine dose must have been processed in NCTracks prior to processing a claim for second dose.
- Medicaid and NC Health Choice **do not** allow copays to be charged for COVID-19 immunization or administrations.
- Modifiers
 - TJ modifier should be used for NC Health Choice claims (age 6 through 18 years).
 - EP modifier should be used for all non-NC Health Choice (only Medicaid beneficiaries) younger than 21 years of age.

If you have any questions about product specific information, please contact the Immunization Branch Help Desk at 1-877-873-6247 and press option '6.' If you have any questions about billing NC Medicaid, please call the GDIT Call Center at 1-800-688-6696.

Visit Medicaid's website for these guidelines: <https://medicaid.ncdhhs.gov/providers/medicaid-bulletin>

COVID-19 Vaccine LHD Toolkit

6.13 Safety Monitoring – VAERS and V-safe

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

VAERS

Vaccine Adverse Event Reporting System (VAERS) is a national early warning system to detect possible safety problems with vaccine and continuously monitors the safety of vaccines given to children and adults in the United States. There are certain situations stated below where reporting to VAERS is required by the EUA for providers. Vaccination providers are required to report the following to VAERS:

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events (irrespective of attribution to vaccination)

Serious adverse events are defined as:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

- Cases of Multisystem Inflammatory Syndrome in children and adults
- Cases of COVID-19 that result in hospitalization or death
- Any additional select adverse events and/or any revised safety reporting requirements per FDA's conditions of authorized use of vaccine(s) throughout the duration of any COVID-19 vaccine being authorized under an Emergency Use Authorization

Complete and submit reports to VAERS online at <https://vaers.hhs.gov/reportevent.html> or by calling 1-800-822-7967. The reports should include the words "[Manufacturer Name] COVID-19 Vaccine EUA" in the description section of the report. Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

V-safe

V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins to vaccine recipients following COVID-19 vaccination. V-safe also provides second dose vaccine reminders, if needed. This program is **only for COVID-19 vaccine** and serves as an important active surveillance system for adverse events.

All providers who administer COVID-19 vaccine are asked to provide printed hard copies of the v-safe information sheet to each vaccinated individual and counsel them on the importance of enrolling in v-safe.

See Appendix 4 for the v-safe information sheets to give to patients who receive COVID-19 vaccine and Appendix 5 for a poster for your clinic.

V-Safe information from CDC: <https://www.cdc.gov/coronavirus/2019ncov/vaccines/safety/vsafe.html>

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6.14 Online Resources: Vaccine Clinical Information and Guidance

Training Program / Reference Material	Description
<u><i>You Call the Shots: Vaccine Administration</i></u>	An interactive, web-based vaccine administration course that provides training using videos, job aids, and other resources.
<u>Vaccine administration videos</u>	Short, skill-based demonstration videos of vaccine administration activities, including injection techniques based on age and medication preparation.
<u>Skills Checklist for Vaccine Administration</u>	This checklist from the Immunization Action Coalition is a self-assessment tool for healthcare professionals who administer vaccines.
<u>CDC Guidance by COVID-19 Vaccine Product</u>	The CDC website provides Clinical Information and Guidance by product.

COVID-19 Vaccine LHD Toolkit

7. Communicating with Patients about Vaccines

7.1 Overview

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

- Trust the information that they receive from local health departments and NC DHHS about COVID-19 vaccinations
- Understand the benefits and risks of COVID-19 vaccinations
- Make informed decisions about COVID-19 vaccinations
- Know how and when to get a COVID-19 vaccine

NC DHHS is developing a toolkit of communications materials on COVID-19 vaccine based on research with North Carolinians. The toolkit will include materials, such as fact sheets, talking points, messaging “palm cards” for easy distribution to providers and patients, posters and other signage, sharable and editable graphics for personalization, video testimonials, safety infographic, prioritization group infographic.

7.2 Online Resources: Communicating with Patients about Vaccines

Training Program / Reference Material	Description
NC DHHS COVID-19 Vaccine Communications Toolkit *Additional content will be added here over time	The most up-to-date materials will be posted on the NC DHHS COVID-19 vaccine landing page: YourSpotYourShot.nc.gov
How Nurses and Medical Assistants Can Foster a Culture of Immunization in the Practice video	Research shows that healthcare professionals are patients’ most trusted source of information when it comes to vaccines. By highlighting key points before, during, and after a patient’s visit, this presentation will support vaccine conversations and reinforce best practices for improving vaccination coverage.
“#HowIRecommend” vaccination video series	These videos explain the importance of vaccination, how to effectively address questions from patients about vaccine safety and effectiveness, and how clinicians routinely recommend same day vaccination for their patients.
Provider Resources for COVID-19 Vaccine Conversations with Patients	Information for healthcare providers on how to talk to patients about COVID-19 vaccines, including giving strong recommendations, setting expectations about vaccine availability, and preparing to answer likely patient questions.
Epidemiology and Prevention of Vaccine-Preventable Diseases	Comprehensive information on routinely used vaccines and the diseases they prevent. Chapter 3, discusses essential strategies healthcare professionals can use when talking to patients about vaccines (updated 2020).

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8. Training Materials

Please visit the following link for available training materials: <https://immunize.nc.gov/providers/covid-19training.htm>

8.1 Overview

This section provides important links to training programs and references materials for planning and administration of COVID-19 vaccine. Additional training materials will be added as they become available.

8.2 Online Resources: Training Materials

Training Program / Reference Material	Description
COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare Providers *Required	A web-based training course outlining best practices and principles for healthcare providers when preparing to administer COVID-19 vaccine. It is a high-level overview of the following topics with links to detailed information: vaccine development and safety, safety monitoring programs, Emergency Use Authorizations (EUAs), vaccine storage and handling, preparation, administration, PPE, scheduling, documentation, and reporting adverse events. Information on each vaccine product will be added as each is authorized by FDA.
Ongoing webinars, including posted recordings (CE available)	These webinars will address ACIP recommendations and vaccine products as they become available.
Clinical Materials	COVID-19 vaccine screening form for contraindications and precautions Expiration date tracker Reporting a temperature excursion IIS off-line vaccine administration documentation tool Guide to ancillary supplies kit (for staff helping providers order vaccine) COVID-19 vaccine frequently asked clinical questions web page
CVMS Training	Guidance on using the CVMS platform.
Pfizer Vaccine Materials	Online training module Vaccine preparation and administration summary Storage and handling summary Temperature log and beyond use date tracking tool when using the thermal shipping container for storage, including online fillable PDF version Temperature log for ultra-cold freezer units, including online fillable PDF version Beyond use date tracker labels for refrigerator storage

COVID-19 Vaccine LHD Toolkit

Moderna Vaccine Materials	Safety information Fact sheet for vaccination providers Fact sheet for vaccine recipients and caregivers Dosing and administration Storage and Handling Adverse event reporting
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9. Additional Support and Technical Assistance

NC DHHS will provide tailored technical assistance, along with a range of tools and methods for CVMS and vaccine training, including communications, user guides, live trainings, and helpdesk support. The Technical assistance support checklist can be used, along with the readiness checklist to request technical assistance. For technical assistance email lhdhealthserviceta@dhhs.nc.gov

☐ **Leadership**

- Check in with LHDs in leadership transition. DPH Local and Community Support Team will reach out to LHDs with interim or new health directors to identify support needs or gaps.
- DPH Chief Nurse/Local Technical Assistance and Training will offer same to LHDs with new or transition in clinical leadership.
- LHDs may also self-refer.

☐ **Support for community and stakeholder communications –**

- DHHS will provide facilitation supports for strategic partnerships including HMP local Community Groups and healthcare system relationships (particularly in rural counties)

☐ **Assistance with CVMS**

- In partnership with help desk - CVMS-help@dhhs.nc.gov

☐ **Support with vaccine administration planning and staffing**

- Logistics to implement Points of Dispensing plans to include closed, mobile and mass events
- Identify LHD professional staff/administrative staffing needs for vaccination clinics
- Integrating vaccine planning with billing/scheduling/electronic health records
- Coordinating with special populations – long term care, health care, congregant living, etc.

☐ **Medical Director support**

- DHHS will facilitate conversations with physician leadership with LHD request

☐ **Legal support**

- For questions about consent, privacy, release of public facing data

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Appendix

Appendix 1 – EUA Fact Sheet for Recipients and Caregivers – Pfizer

As of 12/11/2020

COVID-19 Vaccine LHD Toolkit

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

You are being offered the Pfizer-BioNTech COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the Pfizer-BioNTech COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Pfizer-BioNTech COVID-19 Vaccine is a vaccine and may prevent you from getting COVID-19. There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19.

Read this Fact Sheet for information about the Pfizer-BioNTech COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Pfizer-BioNTech COVID-19 Vaccine.

The Pfizer-BioNTech COVID-19 Vaccine is administered as a 2-dose series, 3 weeks apart, into the muscle.

The Pfizer-BioNTech COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.cvdvaccine.com.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE?

WHAT IS COVID-19?

COVID-19 disease is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

WHAT IS THE PFIZER-BIONTECH COVID-19 VACCINE?

The Pfizer-BioNTech COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19. There is no FDA-approved vaccine to prevent COVID-19.

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The FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19 in individuals 16 years of age and older under an Emergency Use Authorization (EUA).

For more information on EUA, see the “**What is an Emergency Use Authorization (EUA)?**” section at the end of this Fact Sheet.

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE PFIZER-BIONTECH COVID-19 VACCINE?

Tell the vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine

WHO SHOULD GET THE PFIZER-BIONTECH COVID-19 VACCINE?

FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine in individuals 16 years of age and older.

WHO SHOULD NOT GET THE PFIZER-BIONTECH COVID-19 VACCINE?

You should not get the Pfizer-BioNTech COVID-19 Vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine

WHAT ARE THE INGREDIENTS IN THE PFIZER-BIONTECH COVID-19 VACCINE?

The Pfizer BioNTech COVID-19 Vaccine includes the following ingredients: mRNA, lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

HOW IS THE PFIZER-BIONTECH COVID-19 VACCINE GIVEN?

The Pfizer-BioNTech COVID-19 Vaccine will be given to you as an injection into the muscle.

The Pfizer-BioNTech COVID-19 Vaccine vaccination series is 2 doses given 3 weeks apart.

If you receive one dose of the Pfizer-BioNTech COVID-19 Vaccine, you should receive a second dose of this same vaccine 3 weeks later to complete the vaccination series.

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HAS THE PFIZER-BIONTECH COVID-19 VACCINE BEEN USED BEFORE?

The Pfizer-BioNTech COVID-19 Vaccine is an unapproved vaccine. In clinical trials, approximately 20,000 individuals 16 years of age and older have received at least 1 dose of the Pfizer-BioNTech COVID-19 Vaccine.

WHAT ARE THE BENEFITS OF THE PFIZER-BIONTECH COVID-19 VACCINE?

In an ongoing clinical trial, the Pfizer-BioNTech COVID-19 Vaccine has been shown to prevent COVID-19 following 2 doses given 3 weeks apart. The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE PFIZER-BIONTECH COVID-19 VACCINE?

Side effects that have been reported with the Pfizer-BioNTech COVID-19 Vaccine include:

- injection site pain
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever
- injection site swelling
- injection site redness
- nausea
- feeling unwell
- swollen lymph nodes (lymphadenopathy)

There is a remote chance that the Pfizer-BioNTech COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Pfizer-BioNTech COVID-19 Vaccine.

Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

These may not be all the possible side effects of the Pfizer-BioNTech COVID-19 Vaccine. Serious and unexpected side effects may occur. Pfizer-BioNTech COVID-19 Vaccine is still being studied in clinical trials.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?

If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

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Report vaccine side effects to **FDA/CDC Vaccine Adverse Event Reporting System (VAERS)**. The VAERS toll-free number is 1-800-822-7967 or report online to <https://vaers.hhs.gov/reportevent.html>. Please include "Pfizer-BioNTech COVID-19 Vaccine EUA" in the first line of box #18 of the report form.

In addition, you can report side effects to Pfizer Inc. at the contact information provided below.

Website	Fax number	Telephone number
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

WHAT IF I DECIDE NOT TO GET THE PFIZER-BIONTECH COVID-19 VACCINE?

It is your choice to receive or not receive the Pfizer-BioNTech COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES PFIZER-BIONTECH COVID-19 VACCINE?

Currently, there is no approved alternative vaccine available for prevention of COVID-19. FDA may allow the emergency use of other vaccines to prevent COVID-19.

CAN I RECEIVE THE PFIZER-BIONTECH COVID-19 VACCINE WITH OTHER VACCINES?

There is no information on the use of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.

WHAT IF I AM PREGNANT OR BREASTFEEDING?

If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

WILL THE PFIZER-BIONTECH COVID-19 VACCINE GIVE ME COVID-19?

No. The Pfizer-BioNTech COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

KEEP YOUR VACCINATION CARD

When you get your first dose, you will get a vaccination card to show you when to return for your second dose of Pfizer-BioNTech COVID-19 Vaccine. Remember to bring your card when you return.

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ADDITIONAL INFORMATION

If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

Global website	Telephone number
www.cvdvaccine.com 	1-877-829-2619 (1-877-VAX-CO19)

HOW CAN I LEARN MORE?

- Ask the vaccination provider.
- Visit CDC at <https://www.cdc.gov/coronavirus/2019-ncov/index.html>.
- Visit FDA at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.
- Contact your local or state public health department.

WHERE WILL MY VACCINATION INFORMATION BE RECORDED?

The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. This will ensure that you receive the same vaccine when you return for the second dose. For more information about IISs visit: <https://www.cdc.gov/vaccines/programs/iis/about.html>.

WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?

The United States FDA has made the Pfizer-BioNTech COVID-19 Vaccine available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The Pfizer-BioNTech COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19

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pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.

The EUA for the Pfizer-BioNTech COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).



Manufactured by
Pfizer Inc., New York, NY 10017

BIONTECH

Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

LAB-1451-0.7

Revised: December 2020



Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

Barcode Date: 12/2020

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Appendix 2 – EUA Fact Sheet for Health Care Providers – Pfizer

As of 12/11/2020

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FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)

EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, **Pfizer-BioNTech COVID-19 Vaccine**, for active immunization to prevent COVID-19 in individuals 16 years of age and older.

SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS

Vaccination providers enrolled in the federal COVID-19 Vaccination Program must report all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Pfizer-BioNTech COVID-19 Vaccine. See "MANDATORY REQUIREMENTS FOR PFIZER-BIONTECH COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION" for reporting requirements.

The Pfizer-BioNTech COVID-19 Vaccine is a suspension for intramuscular injection administered as a series of two doses (0.3 mL each) 3 weeks apart.

See this Fact Sheet for instructions for preparation and administration. This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.cvdvaccine.com.

For information on clinical trials that are testing the use of the Pfizer-BioNTech COVID-19 Vaccine for active immunization against COVID-19, please see www.clinicaltrials.gov.

DESCRIPTION OF COVID-19

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by the novel coronavirus, SARS-CoV-2, that appeared in late 2019. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have reported a wide range of symptoms, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

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DOSAGE AND ADMINISTRATION

Storage and Handling

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Do not refreeze thawed vials.

Frozen Vials Prior to Use

Cartons of Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vials arrive in thermal containers with dry ice. Once received, remove the vial cartons immediately from the thermal container and store in an ultra-low temperature freezer between -80°C to -60°C (-112°F to -76°F). Vials must be kept frozen between -80°C to -60°C (-112°F to -76°F) and protected from light until ready to use.

If an ultra-low temperature freezer is not available, the thermal container in which the Pfizer-BioNTech COVID-19 Vaccine arrives may be used as temporary storage when consistently re-filled to the top of the container with dry ice. Refer to the re-icing guidelines packed in the original thermal container for instructions regarding the use of the thermal container for temporary storage. The thermal container maintains a temperature range of -90°C to -60°C (-130°F to -76°F). Storage within this temperature range is not considered an excursion from the recommended storage condition.

Thawed Vials Before Dilution

Thawed Under Refrigeration

Thaw and then store undiluted vials in the refrigerator [2°C to 8°C (35°F to 46°F)] for up to 5 days (120 hours). A carton of 25 vials or 195 vials may take up to 2 or 3 hours, respectively, to thaw in the refrigerator, whereas a fewer number of vials will thaw in less time.

Thawed at Room Temperature

For immediate use, thaw undiluted vials at room temperature [up to 25°C (77°F)] for 30 minutes. Thawed vials can be handled in room light conditions. Vials must reach room temperature before dilution.

Undiluted vials may be stored at room temperature for no more than 2 hours.

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Vials After Dilution

- After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution.
- During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.
- Any vaccine remaining in vials must be discarded after 6 hours.
- Do not refreeze.

Dosing and Schedule

The Pfizer-BioNTech COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.3 mL each) 3 weeks apart.

There are no data available on the interchangeability of the Pfizer-BioNTech COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Pfizer-BioNTech COVID-19 Vaccine should receive a second dose of Pfizer-BioNTech COVID-19 Vaccine to complete the vaccination series.

Dose Preparation

Prior to Dilution

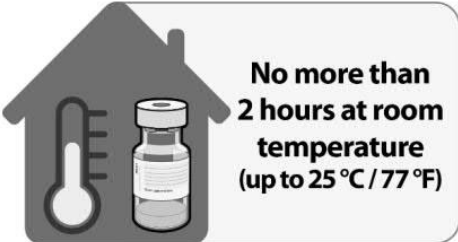
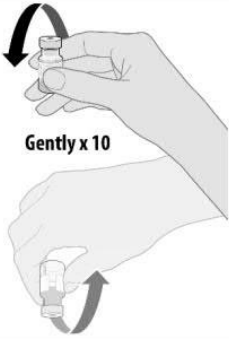
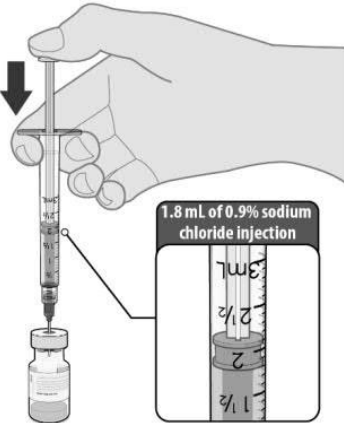
- The Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vial contains a frozen suspension that does not contain preservative and must be thawed and diluted prior to administration.
- Vials may be thawed in the refrigerator [2°C to 8°C (35°F to 46°F)] or at room temperature [up to 25°C (77°F)] (*see Storage and Handling*).
- Refer to thawing instructions in the panels below.

Dilution

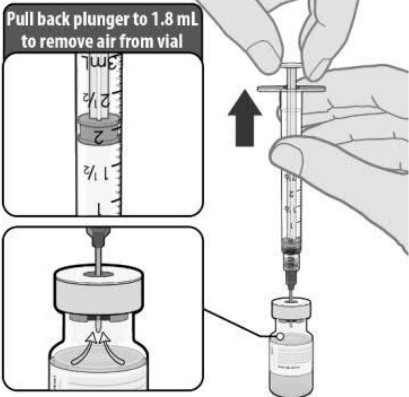
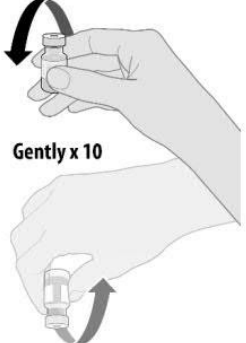
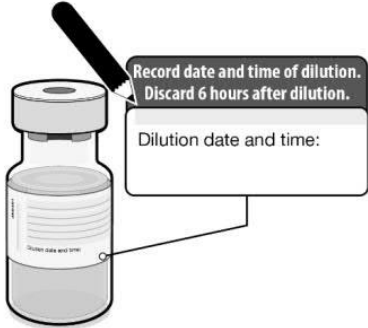
Dilute the vial contents using 1.8 mL of 0.9% Sodium Chloride Injection, USP (not provided) to form the Pfizer-BioNTech COVID-19 Vaccine. ONLY use 0.9% Sodium Chloride Injection, USP as the diluent. This diluent is not packaged with the vaccine and must be sourced separately. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.

- Refer to dilution and dose preparation instructions in the panels below.

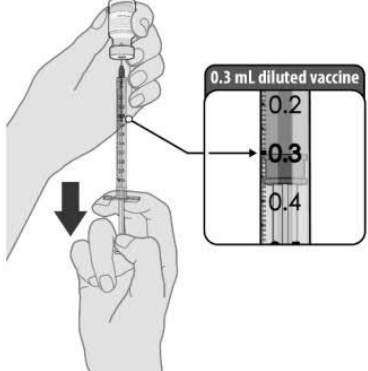
COVID-19 Vaccine LHD Toolkit

THAWING PRIOR TO DILUTION	
	- Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by: - Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]. A carton of vials may take up to 3 hours to thaw, and thawed vials can be stored in the refrigerator for up to five days (120 hours). - Allowing vial(s) to sit at room temperature [up to 25°C (77°F)] for 30 minutes. - Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours.
	- Before dilution invert vaccine vial gently 10 times. <u>Do not shake.</u> - Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles. - Do not use if liquid is discolored or if other particles are observed.
DILUTION	
	- Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent. - Using aseptic technique, withdraw 1.8 mL of diluent into a transfer syringe (21-gauge or narrower needle). - Cleanse the vaccine vial stopper with a single-use antiseptic swab. - Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.

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	Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe.
	- Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix. <u>Do not shake.</u> - Inspect the vaccine in the vial. - The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter.
	- Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label. - Store between 2°C to 25°C (35°F to 77°F). - Discard any unused vaccine 6 hours after dilution.

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PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF PFIZER-BIONTECH COVID-19 VACCINE	
	• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw <u>0.3 mL</u> of the Pfizer-BioNTech COVID-19 Vaccine. • Administer immediately.

Administration

Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be an off-white suspension. During the visual inspection,

- verify the final dosing volume of 0.3 mL.
- confirm there are no particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains particulate matter.

Administer the Pfizer-BioNTech COVID-19 Vaccine intramuscularly.

Contraindications

Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine (*see Full EUA Prescribing Information*).

Warnings

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine.

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine.

Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients.

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Adverse Reactions

Adverse reactions following the Pfizer-BioNTech COVID-19 Vaccine that have been reported in clinical trials include injection site pain, fatigue, headache, muscle pain, chills, joint pain, fever, injection site swelling, injection site redness, nausea, malaise, and lymphadenopathy (*see Full EUA Prescribing Information*).

Severe allergic reactions have been reported following the Pfizer-BioNTech COVID-19 Vaccine during mass vaccination outside of clinical trials.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Pfizer-BioNTech COVID-19 Vaccine.

Use with Other Vaccines

There is no information on the co-administration of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.

INFORMATION TO PROVIDE TO VACCINE RECIPIENTS/CAREGIVERS

As the vaccination provider, you must 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.cvdvaccine.com to obtain the Fact Sheet) prior to the individual receiving Pfizer-BioNTech COVID-19 Vaccine, including:

- FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine, which is not an FDA-approved vaccine.
- The recipient or their caregiver has the option to accept or refuse Pfizer-BioNTech COVID-19 Vaccine.
- The significant known and potential risks and benefits of Pfizer-BioNTech 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.

For information on clinical trials that are testing the use of the Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19, please see www.clinicaltrials.gov.

Provide a vaccination card to the recipient or their caregiver with the date when the recipient needs to return for the second dose of Pfizer-BioNTech COVID-19 Vaccine.

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MANDATORY REQUIREMENTS FOR PFIZER-BIONTECH COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION

In order to mitigate the risks of using this unapproved product under EUA and to optimize the potential benefit of Pfizer-BioNTech COVID-19 Vaccine, the following items are required. Use of unapproved Pfizer-BioNTech COVID-19 Vaccine for active immunization to prevent COVID-19 under this EUA is limited to the following (all requirements **must** be met):

1. Pfizer-BioNTech COVID-19 Vaccine is authorized for use in individuals 16 years of age and older.
2. The vaccination provider must communicate to the individual receiving the Pfizer-BioNTech COVID-19 Vaccine or their caregiver, information consistent with the “Fact Sheet for Recipients and Caregivers” prior to the individual receiving Pfizer-BioNTech COVID-19 Vaccine.
3. The vaccination provider must include vaccination information in the state/local jurisdiction’s Immunization Information System (IIS) or other designated system.
4. The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):
 - vaccine administration errors whether or not associated with an adverse event,
 - serious adverse events* (irrespective of attribution to vaccination),
 - cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and
 - cases of COVID-19 that result in hospitalization or death.

Complete and submit reports to VAERS online at <https://vaers.hhs.gov/reportevent.html> or by calling 1-800-822-7967. The reports should include the words “Pfizer-BioNTech COVID-19 Vaccine EUA” in the description section of the report.

5. The vaccination provider is responsible for responding to FDA requests for information about vaccine administration errors, adverse events, cases of MIS in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Pfizer-BioNTech COVID-19 Vaccine to recipients.

* Serious adverse events are defined as:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;

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- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

OTHER ADVERSE EVENT REPORTING TO VAERS AND PFIZER INC.

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to Pfizer Inc. using the contact information below or by providing a copy of the VAERS form to Pfizer Inc.

Website	Fax number	Telephone number
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

ADDITIONAL INFORMATION

For general questions, visit the website or call the telephone number provided below.

To access the most recent Pfizer-BioNTech COVID-19 Vaccine Fact Sheets, please scan the QR code provided below.

Global website	Telephone number
www.cvdvaccine.com 	1-877-829-2619 (1-877-VAX-CO19)

AVAILABLE ALTERNATIVES

There is no approved alternative vaccine to prevent COVID-19. There may be clinical trials or availability under EUA of other COVID-19 vaccines.

AUTHORITY FOR ISSUANCE OF THE EUA

The Secretary of Health and Human Services (HHS) has declared a public health emergency that justifies the emergency use of drugs and biological products during the COVID-19 pandemic. In response, FDA has issued an EUA for the unapproved product, Pfizer-BioNTech COVID-19 Vaccine, for active immunization against COVID-19 in individuals 16 years of age and older.

FDA issued this EUA, based on Pfizer-BioNTech's request and submitted data.



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Although limited scientific information is available, based on the totality of the scientific evidence available to date, it is reasonable to believe that the Pfizer-BioNTech COVID-19 Vaccine may be effective for the prevention of COVID-19 in individuals as specified in the *Full EUA Prescribing Information*.

This EUA for the Pfizer-BioNTech COVID-19 Vaccine will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.

For additional information about Emergency Use Authorization visit FDA at:
<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

The Countermeasures Injury Compensation Program

The Countermeasures Injury Compensation Program (CICP) is a federal program that has been created to help pay for related costs of medical care and other specific expenses to compensate people injured after use of certain medical countermeasures. Medical countermeasures are specific vaccines, medications, devices, or other items used to prevent, diagnose, or treat the public during a public health emergency or a security threat. For more information about CICP regarding the Pfizer-BioNTech COVID-19 Vaccine used to prevent COVID-19, visit www.hrsa.gov/cicp, email cicp@hrsa.gov, or call: 1-855-266-2427.



Manufactured by
Pfizer Inc., New York, NY 10017

BIONTECH

Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

LAB-1450-1.0

Revised: December 2020

END SHORT VERSION FACT SHEET
Long Version (Full EUA Prescribing Information) Begins On Next Page

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FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

PFIZER-BIONTECH COVID-19 VACCINE

FULL EMERGENCY USE AUTHORIZATION PRESCRIBING INFORMATION: CONTENTS*

- 1 AUTHORIZED USE
- 2 DOSAGE AND ADMINISTRATION
 - 2.1 Preparation for Administration
 - 2.2 Administration Information
 - 2.3 Vaccination Schedule for Individuals 16 Years of Age and Older
- 3 DOSAGE FORMS AND STRENGTHS
- 4 CONTRAINDICATIONS
- 5 WARNINGS AND PRECAUTIONS
 - 5.1 Management of Acute Allergic Reactions
 - 5.2 Altered Immunocompetence
 - 5.3 Limitation of Effectiveness
- 6 OVERALL SAFETY SUMMARY
 - 6.1 Clinical Trials Experience

- 8 REQUIREMENTS AND INSTRUCTIONS FOR REPORTING
ADVERSE EVENTS AND VACCINE ADMINISTRATION
ERRORS
- 10 DRUG INTERACTIONS
- 11 USE IN SPECIFIC POPULATIONS
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- 13 DESCRIPTION
- 14 CLINICAL PHARMACOLOGY
 - 14.1 Mechanism of Action
- 18 CLINICAL TRIAL RESULTS AND SUPPORTING DATA FOR
EUA
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- 19 HOW SUPPLIED/STORAGE AND HANDLING
- 20 PATIENT COUNSELING INFORMATION
- 21 CONTACT INFORMATION

* Sections or subsections omitted from the full emergency use authorization prescribing information are not listed.

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FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

1 AUTHORIZED USE

Pfizer-BioNTech COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

2 DOSAGE AND ADMINISTRATION

For intramuscular injection only.

2.1 Preparation for Administration

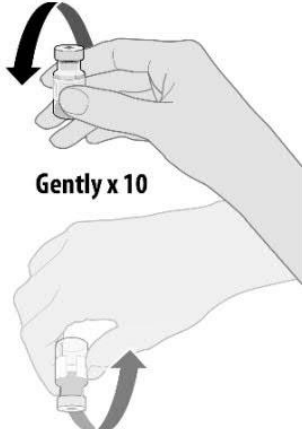
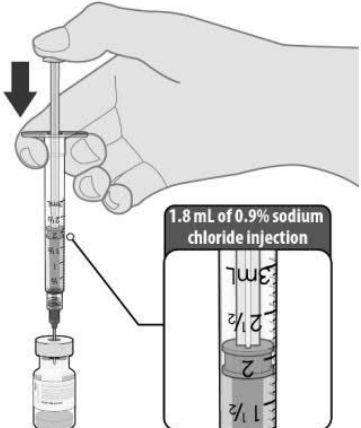
Prior to Dilution

- The Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vial contains a frozen suspension that does not contain preservative and must be thawed and diluted prior to administration.
- Vials may be thawed in the refrigerator [2°C to 8°C (35°F to 46°F)] or at room temperature [up to 25°C (77°F)] [*see How Supplied/Storage and Handling (19)*].
- Refer to thawing instructions in the panels below.

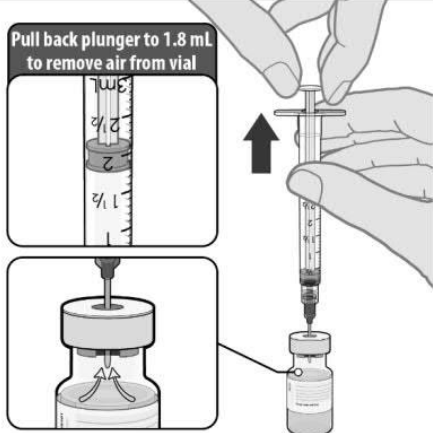
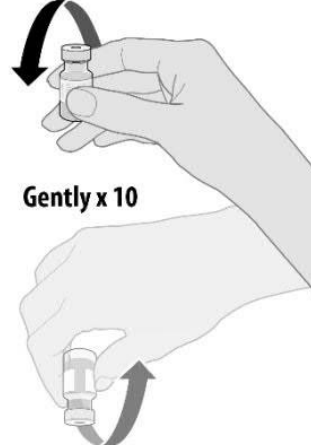
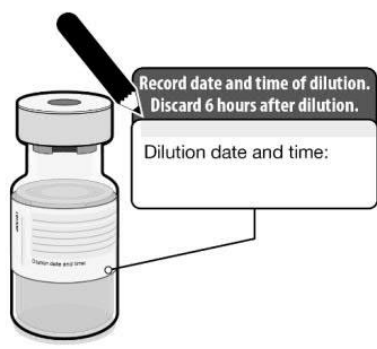
Dilution

- Dilute the vial contents using 1.8 mL of 0.9% Sodium Chloride Injection, USP (not provided) to form the Pfizer-BioNTech COVID-19 Vaccine.
- ONLY use 0.9% Sodium Chloride Injection, USP as the diluent. This diluent is not packaged with the vaccine and must be sourced separately. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.
- Refer to dilution and dose preparation instructions in the panels below.

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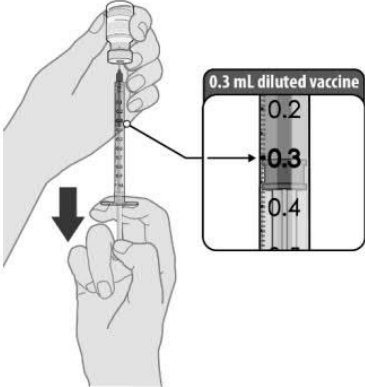
THAWING PRIOR TO DILUTION	
 No more than 2 hours at room temperature (up to 25°C / 77°F)	- Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by: - Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]. A carton of vials may take up to 3 hours to thaw, and thawed vials can be stored in the refrigerator for up to five days (120 hours). - Allowing vial(s) to sit at room temperature [up to 25°C (77°F)] for 30 minutes. - Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours.
 Gently x 10	- Before dilution invert vaccine vial gently 10 times. <u>Do not shake.</u> - Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain <u>white to off-white opaque amorphous particles.</u> - Do not use if liquid is discolored or if other particles are observed.
DILUTION	
 1.8 mL of 0.9% sodium chloride injection	- Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent. - Using aseptic technique, withdraw 1.8 mL of diluent into a transfer syringe (21-gauge or narrower needle). - Cleanse the vaccine vial stopper with a single-use antiseptic swab. - Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.

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 Pull back plunger to 1.8 mL to remove air from vial	Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe.
 Gently x 10	- Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix. <u>Do not shake.</u> - Inspect the vaccine in the vial. - The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter.
 Record date and time of dilution. Discard 6 hours after dilution. Dilution date and time:	- Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label. - Store between 2°C to 25°C (35°F to 77°F). - Discard any unused vaccine 6 hours after dilution.

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PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF PFIZER-BIONTECH COVID-19 VACCINE

	• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw <u>0.3 mL</u> of the Pfizer-BioNTech COVID-19 Vaccine. • Administer immediately.
---	---

2.2 Administration Information

Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be an off-white suspension. During the visual inspection,

- verify the final dosing volume of 0.3 mL.
- confirm there are no particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains particulate matter.

Administer the Pfizer-BioNTech COVID-19 Vaccine intramuscularly.

2.3 Vaccination Schedule for Individuals 16 Years of Age and Older

The Pfizer-BioNTech COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.3 mL each) three weeks apart.

There are no data available on the interchangeability of the Pfizer-BioNTech COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Pfizer-BioNTech COVID-19 Vaccine should receive a second dose of Pfizer-BioNTech COVID-19 Vaccine to complete the vaccination series.

3 DOSAGE FORMS AND STRENGTHS

Pfizer-BioNTech COVID-19 Vaccine is a suspension for injection. After preparation, a single dose is 0.3 mL.

4 CONTRAINDICATIONS

Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine [see *Description (13)*].

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5 WARNINGS AND PRECAUTIONS

5.1 Management of Acute Allergic Reactions

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine.

5.2 Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine.

5.3 Limitation of Effectiveness

The Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients.

6 OVERALL SAFETY SUMMARY

It is MANDATORY for vaccination providers to report to the Vaccine Adverse Event Reporting System (VAERS) all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and hospitalized or fatal cases of COVID-19 following vaccination with the Pfizer-BioNTech COVID-19 Vaccine. To the extent feasible, provide a copy of the VAERS form to Pfizer Inc. Please see the REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS section for details on reporting to VAERS and Pfizer Inc.

In clinical studies, adverse reactions in participants 16 years of age and older included pain at the injection site (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%), injection site swelling (10.5%), injection site redness (9.5%), nausea (1.1%), malaise (0.5%), and lymphadenopathy (0.3%).

Severe allergic reactions have been reported following the Pfizer-BioNTech COVID-19 Vaccine during mass vaccination outside of clinical trials.

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety of Pfizer-BioNTech COVID-19 Vaccine was evaluated in participants 16 years of age and older in two clinical studies conducted in the United States, Europe, Turkey, South Africa, and South America. Study BNT162-01 (Study 1) was a Phase 1/2, two-part, dose-escalation trial that enrolled 60 participants, 18 through 55 years of age. Study C4591001 (Study 2) is a Phase 1/2/3, multicenter, multinational, randomized, saline placebo-controlled, observer-blind, dose-finding, vaccine candidate-selection (Phase 1) and efficacy (Phase 2/3) study that has enrolled approximately 44,000 participants, 12 years of age or older. Of these, approximately 43,448 participants (21,720 Pfizer-BioNTech COVID-19 Vaccine; 21,728 placebo) in Phase 2/3 are 16 years of age or older (including 138 and 145 adolescents 16 and 17 years of age in the vaccine and placebo groups, respectively).

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At the time of the analysis of Study 2 for the EUA, 37,586 (18,801 Pfizer-BioNTech COVID-19 Vaccine and 18,785 placebo) participants 16 years of age or older have been followed for a median of 2 months after the second dose of Pfizer-BioNTech COVID-19 Vaccine.

The safety evaluation in Study 2 is ongoing. The safety population includes participants enrolled by October 9, 2020, and includes safety data accrued through November 14, 2020. Participants 18 years and older in the reactogenicity subset are monitored for solicited local and systemic reactions and use of antipyretic medication after each vaccination in an electronic diary. Participants are being monitored for unsolicited adverse events, including serious adverse events, throughout the study [from Dose 1 through 1 month (all unsolicited adverse events) or 6 months (serious adverse events) after the last vaccination].

Demographic characteristics in Study 2 were generally similar with regard to age, gender, race, and ethnicity among participants who received Pfizer-BioNTech COVID-19 Vaccine and those who received placebo. Overall, among the total participants who received either the Pfizer-BioNTech COVID-19 Vaccine or placebo, 50.6% were male and 49.4% were female, 83.1% were White, 9.1% were Black or African American, 28.0% were Hispanic/Latino, 4.3% were Asian, and 0.5% were American Indian/Alaska Native.

Local and Systemic Adverse Reactions Solicited in the Study 2

Table 1 and Table 2 present the frequency and severity of solicited local and systemic reactions, respectively, within 7 days following each dose of Pfizer-BioNTech COVID-19 Vaccine and placebo in the subset of participants 18 to 55 years of age included in the EUA safety population who were monitored for reactogenicity with an electronic diary.

Table 3 and Table 4 present the frequency and severity of reported solicited local and systemic reactions, respectively, within 7 days of each dose of Pfizer-BioNTech COVID-19 Vaccine and placebo for participants 56 years of age and older.

Across both age groups, the mean duration of pain at the injection site after Dose 2 was 2.5 days (range 1 to 36 days), for redness 2.6 days (range 1 to 34 days), and for swelling 2.3 days (range 1 to 34 days) for participants in the Pfizer-BioNTech COVID-19 Vaccine group.

Solicited reactogenicity data in 16 and 17 year-old participants are limited.

Table 1: Study 2 – Frequency and Percentages of Participants with Solicited Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 18-55 Years of Age* – Reactogenicity Subset of the Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N^a=2291 n^b (%)	Placebo Dose 1 N^a=2298 n^b (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N^a=2098 n^b (%)	Placebo Dose 2 N^a=2103 n^b (%)
Redness^c				
Any (>2 cm)	104 (4.5)	26 (1.1)	123 (5.9)	14 (0.7)
Mild	70 (3.1)	16 (0.7)	73 (3.5)	8 (0.4)
Moderate	28 (1.2)	6 (0.3)	40 (1.9)	6 (0.3)
Severe	6 (0.3)	4 (0.2)	10 (0.5)	0 (0.0)
Swelling^c				
Any (>2 cm)	132 (5.8)	11 (0.5)	132 (6.3)	5 (0.2)
Mild	88 (3.8)	3 (0.1)	80 (3.8)	3 (0.1)



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	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N^a=2291 n^b (%)	Placebo Dose 1 N^a=2298 n^b (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N^a=2098 n^b (%)	Placebo Dose 2 N^a=2103 n^b (%)
Moderate	39 (1.7)	5 (0.2)	45 (2.1)	2 (0.1)
Severe	5 (0.2)	3 (0.1)	7 (0.3)	0 (0.0)
Pain at the injection site ^d				
Any	1904 (83.1)	322 (14.0)	1632 (77.8)	245 (11.7)
Mild	1170 (51.1)	308 (13.4)	1039 (49.5)	225 (10.7)
Moderate	710 (31.0)	12 (0.5)	568 (27.1)	20 (1.0)
Severe	24 (1.0)	2 (0.1)	25 (1.2)	0 (0.0)

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.

a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.

b. n = Number of participants with the specified reaction.

c. Mild: >2.0 to ≤5.0 cm; Moderate: >5.0 to ≤10.0 cm; Severe: >10.0 cm.

d. Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.

† Eight participants were between 16 and 17 years of age.

* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

Table 2: Study 2 – Frequency and Percentages of Participants with Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 18-55 Years of Age[†] – Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N^a=2291 n^b (%)	Placebo Dose 1 N^a=2298 n^b (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N^a=2098 n^b (%)	Placebo Dose 2 N^a=2103 n^b (%)
Fever				
≥38.0°C	85 (3.7)	20 (0.9)	331 (15.8)	10 (0.5)
≥38.0°C to 38.4°C	64 (2.8)	10 (0.4)	194 (9.2)	5 (0.2)
>38.4°C to 38.9°C	15 (0.7)	5 (0.2)	110 (5.2)	3 (0.1)
>38.9°C to 40.0°C	6 (0.3)	3 (0.1)	26 (1.2)	2 (0.1)
>40.0°C	0 (0.0)	2 (0.1)	1 (0.0)	0 (0.0)
Fatigue ^c				
Any	1085 (47.4)	767 (33.4)	1247 (59.4)	479 (22.8)
Mild	597 (26.1)	467 (20.3)	442 (21.1)	248 (11.8)
Moderate	455 (19.9)	289 (12.6)	708 (33.7)	217 (10.3)
Severe	33 (1.4)	11 (0.5)	97 (4.6)	14 (0.7)
Headache ^c				
Any	959 (41.9)	775 (33.7)	1085 (51.7)	506 (24.1)
Mild	628 (27.4)	505 (22.0)	538 (25.6)	321 (15.3)
Moderate	308 (13.4)	251 (10.9)	480 (22.9)	170 (8.1)
Severe	23 (1.0)	19 (0.8)	67 (3.2)	15 (0.7)
Chills ^c				
Any	321 (14.0)	146 (6.4)	737 (35.1)	79 (3.8)
Mild	230 (10.0)	111 (4.8)	359 (17.1)	65 (3.1)
Moderate	82 (3.6)	33 (1.4)	333 (15.9)	14 (0.7)
Severe	9 (0.4)	2 (0.1)	45 (2.1)	0 (0.0)



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	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N^a=2291 n^b (%)	Placebo Dose 1 N^a=2298 n^b (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N^a=2098 n^b (%)	Placebo Dose 2 N^a=2103 n^b (%)
Vomiting^d				
Any	28 (1.2)	28 (1.2)	40 (1.9)	25 (1.2)
Mild	24 (1.0)	22 (1.0)	28 (1.3)	16 (0.8)
Moderate	4 (0.2)	5 (0.2)	8 (0.4)	9 (0.4)
Severe	0 (0.0)	1 (0.0)	4 (0.2)	0 (0.0)
Diarrhea^e				
Any	255 (11.1)	270 (11.7)	219 (10.4)	177 (8.4)
Mild	206 (9.0)	217 (9.4)	179 (8.5)	144 (6.8)
Moderate	46 (2.0)	52 (2.3)	36 (1.7)	32 (1.5)
Severe	3 (0.1)	1 (0.0)	4 (0.2)	1 (0.0)
New or worsened muscle pain^c				
Any	487 (21.3)	249 (10.8)	783 (37.3)	173 (8.2)
Mild	256 (11.2)	175 (7.6)	326 (15.5)	111 (5.3)
Moderate	218 (9.5)	72 (3.1)	410 (19.5)	59 (2.8)
Severe	13 (0.6)	2 (0.1)	47 (2.2)	3 (0.1)
New or worsened joint pain^c				
Any	251 (11.0)	138 (6.0)	459 (21.9)	109 (5.2)
Mild	147 (6.4)	95 (4.1)	205 (9.8)	54 (2.6)
Moderate	99 (4.3)	43 (1.9)	234 (11.2)	51 (2.4)
Severe	5 (0.2)	0 (0.0)	20 (1.0)	4 (0.2)
Use of antipyretic or pain medication^f	638 (27.8)	332 (14.4)	945 (45.0)	266 (12.6)

Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose.

a. N = Number of participants reporting at least 1 yes or no response for the specified event after the specified dose.

b. n = Number of participants with the specified reaction.

c. Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity.

d. Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration.

e. Mild: 2 to 3 loose stools in 24 hours; Moderate: 4 to 5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours.

f. Severity was not collected for use of antipyretic or pain medication.

‡ Eight participants were between 16 and 17 years of age.

* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.



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Table 3: Study 2 – Frequency and Percentages of Participants with Solicited Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 56 Years of Age and Older – Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N^a=1802 n^b (%)	Placebo Dose 1 N^a=1792 n^b (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N^a=1660 n^b (%)	Placebo Dose 2 N^a=1646 n^b (%)
Redness^c				
Any (>2 cm)	85 (4.7)	19 (1.1)	120 (7.2)	12 (0.7)
Mild	55 (3.1)	12 (0.7)	59 (3.6)	8 (0.5)
Moderate	27 (1.5)	5 (0.3)	53 (3.2)	3 (0.2)
Severe	3 (0.2)	2 (0.1)	8 (0.5)	1 (0.1)
Swelling^c				
Any (>2 cm)	118 (6.5)	21 (1.2)	124 (7.5)	11 (0.7)
Mild	71 (3.9)	10 (0.6)	68 (4.1)	5 (0.3)
Moderate	45 (2.5)	11 (0.6)	53 (3.2)	5 (0.3)
Severe	2 (0.1)	0 (0.0)	3 (0.2)	1 (0.1)
Pain at the injection site^d				
Any (>2 cm)	1282 (71.1)	166 (9.3)	1098 (66.1)	127 (7.7)
Mild	1008 (55.9)	160 (8.9)	792 (47.7)	125 (7.6)
Moderate	270 (15.0)	6 (0.3)	298 (18.0)	2 (0.1)
Severe	4 (0.2)	0 (0.0)	8 (0.5)	0 (0.0)

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.

a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.

b. n = Number of participants with the specified reaction.

c. Mild: >2.0 to ≤5.0 cm; Moderate: >5.0 to ≤10.0 cm; Severe: >10.0 cm.

d. Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.

* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

Table 4: Study 2 – Frequency and Percentages of Participants with Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 56 Years of Age and Older – Reactogenicity Subset of the Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N^a=1802 n^b (%)	Placebo Dose 1 N^a=1792 n^b (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N^a=1660 n^b (%)	Placebo Dose 2 N^a=1646 n^b (%)
Fever				
≥38.0°C	26 (1.4)	7 (0.4)	181 (10.9)	4 (0.2)
≥38.0°C to 38.4°C	23 (1.3)	2 (0.1)	131 (7.9)	2 (0.1)
>38.4°C to 38.9°C	1 (0.1)	3 (0.2)	45 (2.7)	1 (0.1)
>38.9°C to 40.0°C	1 (0.1)	2 (0.1)	5 (0.3)	1 (0.1)
>40.0°C	1 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)
Fatigue^c				
Any	615 (34.1)	405 (22.6)	839 (50.5)	277 (16.8)
Mild	373 (20.7)	252 (14.1)	351 (21.1)	161 (9.8)
Moderate	240 (13.3)	150 (8.4)	442 (26.6)	114 (6.9)
Severe	2 (0.1)	3 (0.2)	46 (2.8)	2 (0.1)



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	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N^a=1802 n^b (%)	Placebo Dose 1 N^a=1792 n^b (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N^a=1660 n^b (%)	Placebo Dose 2 N^a=1646 n^b (%)
Headache^c				
Any	454 (25.2)	325 (18.1)	647 (39.0)	229 (13.9)
Mild	348 (19.3)	242 (13.5)	422 (25.4)	165 (10.0)
Moderate	104 (5.8)	80 (4.5)	216 (13.0)	60 (3.6)
Severe	2 (0.1)	3 (0.2)	9 (0.5)	4 (0.2)
Chills^c				
Any	113 (6.3)	57 (3.2)	377 (22.7)	46 (2.8)
Mild	87 (4.8)	40 (2.2)	199 (12.0)	35 (2.1)
Moderate	26 (1.4)	16 (0.9)	161 (9.7)	11 (0.7)
Severe	0 (0.0)	1 (0.1)	17 (1.0)	0 (0.0)
Vomiting^d				
Any	9 (0.5)	9 (0.5)	11 (0.7)	5 (0.3)
Mild	8 (0.4)	9 (0.5)	9 (0.5)	5 (0.3)
Moderate	1 (0.1)	0 (0.0)	1 (0.1)	0 (0.0)
Severe	0 (0.0)	0 (0.0)	1 (0.1)	0 (0.0)
Diarrhea^e				
Any	147 (8.2)	118 (6.6)	137 (8.3)	99 (6.0)
Mild	118 (6.5)	100 (5.6)	114 (6.9)	73 (4.4)
Moderate	26 (1.4)	17 (0.9)	21 (1.3)	22 (1.3)
Severe	3 (0.2)	1 (0.1)	2 (0.1)	4 (0.2)
New or worsened muscle pain^c				
Any	251 (13.9)	149 (8.3)	477 (28.7)	87 (5.3)
Mild	168 (9.3)	100 (5.6)	202 (12.2)	57 (3.5)
Moderate	82 (4.6)	46 (2.6)	259 (15.6)	29 (1.8)
Severe	1 (0.1)	3 (0.2)	16 (1.0)	1 (0.1)
New or worsened joint pain^c				
Any	155 (8.6)	109 (6.1)	313 (18.9)	61 (3.7)
Mild	101 (5.6)	68 (3.8)	161 (9.7)	35 (2.1)
Moderate	52 (2.9)	40 (2.2)	145 (8.7)	25 (1.5)
Severe	2 (0.1)	1 (0.1)	7 (0.4)	1 (0.1)
Use of antipyretic or pain medication	358 (19.9)	213 (11.9)	625 (37.7)	161 (9.8)

Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose.

a. N = Number of participants reporting at least 1 yes or no response for the specified event after the specified dose.

b. n = Number of participants with the specified reaction.

c. Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity.

d. Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration.

e. Mild: 2 to 3 loose stools in 24 hours; Moderate: 4 to 5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours.

* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.



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Unsolicited Adverse Events

Serious Adverse Events

In Study 2, among participants 16 to 55 years of age who had received at least 1 dose of vaccine or placebo (Pfizer-BioNTech COVID-19 Vaccine = 10,841; placebo = 10,851), serious adverse events from Dose 1 through up to 30 days after Dose 2 in ongoing follow-up were reported by 0.4% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 0.3% of placebo recipients. In a similar analysis, in participants 56 years of age and older (Pfizer-BioNTech COVID-19 Vaccine = 7960, placebo = 7934), serious adverse events were reported by 0.8% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 0.6% of placebo recipients who received at least 1 dose of Pfizer-BioNTech COVID-19 Vaccine or placebo, respectively. In these analyses, 91.6% of study participants had at least 30 days of follow-up after Dose 2. Appendicitis was reported as a serious adverse event for 12 participants, and numerically higher in the vaccine group, 8 vaccine participants and 4 placebo participants. Currently available information is insufficient to determine a causal relationship with the vaccine. There were no other notable patterns or numerical imbalances between treatment groups for specific categories of serious adverse events (including neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine.

Non-Serious Adverse Events

Overall in Study 2 in which 10,841 participants 16 to 55 years of age received Pfizer-BioNTech COVID-19 Vaccine and 10,851 participants received placebo, non-serious adverse events from Dose 1 through up to 30 days after Dose 2 in ongoing follow-up were reported in 29.3% of participants who received Pfizer-BioNTech COVID-19 Vaccine and 13.2% of participants in the placebo group, for participants who received at least 1 dose. Overall in a similar analysis in which 7960 participants 56 years of age and older received Pfizer-BioNTech COVID-19 Vaccine, non-serious adverse events within 30 days were reported in 23.8% of participants who received Pfizer-BioNTech COVID-19 Vaccine and 11.7% of participants in the placebo group, for participants who received at least 1 dose. In these analyses, 91.6% of study participants had at least 30 days of follow-up after Dose 2. The higher frequency of reported unsolicited non-serious adverse events among Pfizer BioNTech COVID-19 Vaccine recipients compared to placebo recipients was primarily attributed to local and systemic adverse events reported during the first 7 days following vaccination that are consistent with adverse reactions solicited among participants in the reactogenicity subset and presented in Tables 3 and 4. From Dose 1 through 30 days after Dose 2, reports of lymphadenopathy were imbalanced with notably more cases in the Pfizer-BioNTech COVID-19 Vaccine group (64) vs. the placebo group (6), which is plausibly related to vaccination. Throughout the safety follow-up period to date, Bell's palsy (facial paralysis) was reported by four participants in the Pfizer-BioNTech COVID-19 Vaccine group. Onset of facial paralysis was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of Bell's palsy were reported in the placebo group. Currently available information is insufficient to determine a causal relationship with the vaccine. There were no other notable patterns or numerical imbalances between treatment groups for specific categories of non-serious adverse events (including other neurologic or neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine.

8 REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS

See Overall Safety Summary (Section 6) for additional information.

The vaccination provider enrolled in the federal COVID-19 Vaccination Program is responsible for MANDATORY reporting of the listed events following Pfizer-BioNTech COVID-19 Vaccine to the Vaccine Adverse Event Reporting System (VAERS):

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- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events* (irrespective of attribution to vaccination)
- Cases of Multisystem Inflammatory Syndrome (MIS) in children and adults
- Cases of COVID-19 that result in hospitalization or death

*Serious adverse events are defined as:

- Death
- A life-threatening adverse event
- Inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- A congenital anomaly/birth defect
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above

Instructions for Reporting to VAERS

The vaccination provider enrolled in the federal COVID-19 Vaccination Program should complete and submit a VAERS form to FDA using one of the following methods:

- Complete and submit the report online: <https://vaers.hhs.gov/reportevent.html>, or
- If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366. If you need additional help submitting a report you may call the VAERS toll-free information line at 1-800-822-7967 or send an email to info@vaers.org.

IMPORTANT: When reporting adverse events or vaccine administration errors to VAERS, please complete the entire form with detailed information. It is important that the information reported to FDA be as detailed and complete as possible. Information to include:

- Patient demographics (e.g., patient name, date of birth)
- Pertinent medical history
- Pertinent details regarding admission and course of illness
- Concomitant medications
- Timing of adverse event(s) in relationship to administration of the Pfizer-BioNTech COVID-19 Vaccine
- Pertinent laboratory and virology information
- Outcome of the event and any additional follow-up information if it is available at the time of the VAERS report. Subsequent reporting of follow-up information should be completed if additional details become available.

The following steps are highlighted to provide the necessary information for safety tracking:

1. In Box 17, provide information on Pfizer-BioNTech COVID-19 Vaccine and any other vaccines administered on the same day; and in Box 22, provide information on any other vaccines received within one month prior.
2. In Box 18, description of the event:
 - a. Write "Pfizer-BioNTech COVID-19 Vaccine EUA" as the first line.
 - b. Provide a detailed report of vaccine administration error and/or adverse event. It is important to provide detailed information regarding the patient and adverse event/medication error for ongoing safety evaluation of this unapproved vaccine. Please see information to include listed above.

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3. Contact information:

- a. In Box 13, provide the name and contact information of the prescribing healthcare provider or institutional designee who is responsible for the report.
- b. In Box 14, provide the name and contact information of the best doctor/healthcare professional to contact about the adverse event.
- c. In Box 15, provide the address of the facility where vaccine was given (NOT the healthcare provider's office address).

Other Reporting Instructions

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to Pfizer Inc. using the contact information below or by providing a copy of the VAERS form to Pfizer Inc.

Website	Fax number	Telephone number
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

10 DRUG INTERACTIONS

There are no data to assess the concomitant administration of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.

11 USE IN SPECIFIC POPULATIONS

11.1 Pregnancy

Risk Summary

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. Available data on Pfizer-BioNTech COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

11.2 Lactation

Risk Summary

Data are not available to assess the effects of Pfizer-BioNTech COVID-19 Vaccine on the breastfed infant or on milk production/excretion.

11.3 Pediatric Use

Emergency Use Authorization of Pfizer-BioNTech COVID-19 Vaccine in adolescents 16 and 17 years of age is based on extrapolation of safety and effectiveness from adults 18 years of age and older. Emergency Use Authorization of Pfizer BioNTech COVID-19 Vaccine does not include use in individuals younger than 16 years of age.



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11.4 Geriatric Use

Clinical studies of Pfizer-BioNTech COVID-19 Vaccine include participants 65 years of age and older and their data contributes to the overall assessment of safety and efficacy [see *Overall Safety Summary (6.1) and Clinical Trial Results and Supporting Data for EUA (18.1)*]. Of the total number of Pfizer-BioNTech COVID-19 Vaccine recipients in Study 2 (N=20,033), 21.4% (n=4,294) were 65 years of age and older and 4.3% (n=860) were 75 years of age and older.

13 DESCRIPTION

The Pfizer-BioNTech COVID-19 Vaccine is supplied as a frozen suspension in multiple dose vials; each vial must be diluted with 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP prior to use to form the vaccine. Each dose of the Pfizer-BioNTech COVID-19 Vaccine contains 30 mcg of a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2.

Each dose of the Pfizer-BioNTech COVID-19 Vaccine also includes the following ingredients: lipids (0.43 mg (4-hydroxybutyl)azanediylbis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.2 mg cholesterol), 0.01 mg potassium chloride, 0.01 mg monobasic potassium phosphate, 0.36 mg sodium chloride, 0.07 mg dibasic sodium phosphate dihydrate, and 6 mg sucrose. The diluent (0.9% Sodium Chloride Injection, USP) contributes an additional 2.16 mg sodium chloride per dose.

The Pfizer-BioNTech COVID-19 Vaccine does not contain preservative. The vial stoppers are not made with natural rubber latex.

14 CLINICAL PHARMACOLOGY

14.1 Mechanism of Action

The modRNA in the Pfizer-BioNTech COVID-19 Vaccine is formulated in lipid particles, which enable delivery of the RNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits an immune response to the S antigen, which protects against COVID-19.

18 CLINICAL TRIAL RESULTS AND SUPPORTING DATA FOR EUA

18.1 Efficacy in Participants 16 Years of Age and Older

Study 2 is a multicenter, multinational, Phase 1/2/3, randomized, placebo-controlled, observer-blind, dose-finding, vaccine candidate-selection, and efficacy study in participants 12 years of age and older. Randomization was stratified by age: 12 through 15 years of age, 16 through 55 years of age, or 56 years of age and older, with a minimum of 40% of participants in the ≥ 56 -year stratum. The study excluded participants who were immunocompromised and those who had previous clinical or microbiological diagnosis of COVID-19. Participants with preexisting stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrollment, were included as were participants with known stable infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV).

In the Phase 2/3 portion approximately 44,000 participants 12 years of age and older were randomized equally and received 2 doses of Pfizer-BioNTech COVID-19 Vaccine or placebo separated by 21 days. Participants are planned to be followed for up to 24 months, for assessments of safety and efficacy against COVID-19.



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The population for the analysis of the primary efficacy endpoint included, 36,621 participants 12 years of age and older (18,242 in the Pfizer-BioNTech COVID-19 Vaccine group and 18,379 in the placebo group) who did not have evidence of prior infection with SARS-CoV-2 through 7 days after the second dose. Table 5 presents the specific demographic characteristics in the studied population.

Table 5: Demographics (population for the primary efficacy endpoint)^a

	Pfizer-BioNTech COVID-19 Vaccine (N=18,242) n (%)	Placebo (N=18,379) n (%)
Sex		
Male	9318 (51.1)	9225 (50.2)
Female	8924 (48.9)	9154 (49.8)
Age (years)		
Mean (SD)	50.6 (15.70)	50.4 (15.81)
Median	52.0	52.0
Min, max	(12, 89)	(12, 91)
Age group		
≥12 through 15 years	46 (0.3)	42 (0.2)
≥16 through 17 years	66 (0.4)	68 (0.4)
≥16 through 64 years	14,216 (77.9)	14,299 (77.8)
≥65 through 74 years	3176 (17.4)	3226 (17.6)
≥75 years	804 (4.4)	812 (4.4)
Race		
White	15,110 (82.8)	15,301 (83.3)
Black or African American	1617 (8.9)	1617 (8.8)
American Indian or Alaska Native	118 (0.6)	106 (0.6)
Asian	815 (4.5)	810 (4.4)
Native Hawaiian or other Pacific Islander	48 (0.3)	29 (0.2)
Other ^b	534 (2.9)	516 (2.8)
Ethnicity		
Hispanic or Latino	4886 (26.8)	4857 (26.4)
Not Hispanic or Latino	13,253 (72.7)	13,412 (73.0)
Not reported	103 (0.6)	110 (0.6)
Comorbidities^c		
Yes	8432 (46.2)	8450 (46.0)
No	9810 (53.8)	9929 (54.0)

- All eligible randomized participants who receive all vaccination(s) as randomized within the predefined window, have no other important protocol deviations as determined by the clinician, and have no evidence of SARS-CoV-2 infection prior to 7 days after Dose 2.
- Includes multiracial and not reported.
- Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19 disease
 - Chronic lung disease (e.g., emphysema and chronic bronchitis, idiopathic pulmonary fibrosis, and cystic fibrosis) or moderate to severe asthma
 - Significant cardiac disease (e.g., heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)
 - Obesity (body mass index ≥ 30 kg/m²)
 - Diabetes (Type 1, Type 2 or gestational)
 - Liver disease
 - Human Immunodeficiency Virus (HIV) infection (not included in the efficacy evaluation)



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Efficacy Against COVID-19

The population in the primary efficacy analysis included all participants 12 years of age and older who had been enrolled from July 27, 2020, and followed for the development of COVID-19 through November 14, 2020. Participants 18 to 55 years of age and 56 years of age and older began enrollment from July 27, 2020, 16 to 17 years of age began enrollment from September 16, 2020 and 12 to 15 years of age began enrollment from October 15, 2020.

The vaccine efficacy information is presented in Table 6.

Table 6: Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Age Subgroup – Participants Without Evidence of Infection and Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

First COVID-19 occurrence from 7 days after Dose 2 in participants without evidence of prior SARS-CoV-2 infection*			
Subgroup	Pfizer-BioNTech COVID-19 Vaccine N^a=18,198 Cases n¹^b Surveillance Time^c (n²^d)	Placebo N^a=18,325 Cases n¹^b Surveillance Time^c (n²^d)	Vaccine Efficacy % (95% CI)
All subjects ^e	8 2.214 (17,411)	162 2.222 (17,511)	95.0 (90.3, 97.6) ^f
16 to 64 years	7 1.706 (13,549)	143 1.710 (13,618)	95.1 (89.6, 98.1) ^g
65 years and older	1 0.508 (3848)	19 0.511 (3880)	94.7 (66.7, 99.9) ^g
First COVID-19 occurrence from 7 days after Dose 2 in participants with or without evidence of prior SARS-CoV-2 infection			
Subgroup	Pfizer-BioNTech COVID-19 Vaccine N^a=19,965 Cases n¹^b Surveillance Time^c (n²^d)	Placebo N^a=20,172 Cases n¹^b Surveillance Time^c (n²^d)	Vaccine Efficacy % (95% CI)
All subjects ^e	9 2.332 (18,559)	169 2.345 (18,708)	94.6 (89.9, 97.3) ^f
16 to 64 years	8 1.802 (14,501)	150 1.814 (14,627)	94.6 (89.1, 97.7) ^g
65 years and older	1 0.530 (4044)	19 0.532 (4067)	94.7 (66.8, 99.9) ^g

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

a. N = number of participants in the specified group.

b. n1 = Number of participants meeting the endpoint definition.

c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.



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- d. n_2 = Number of participants at risk for the endpoint.
 - e. No confirmed cases were identified in participants 12 to 15 years of age.
 - f. Credible interval for VE was calculated using a beta-binomial model with a beta (0.700102, 1) prior for $\theta = r(1-VE)/(1+r(1-VE))$, where r is the ratio of surveillance time in the active vaccine group over that in the placebo group.
 - g. Confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted to the surveillance time.

19 HOW SUPPLIED/STORAGE AND HANDLING

Pfizer-BioNTech COVID-19 Vaccine Suspension for Intramuscular Injection, Multiple Dose Vials are supplied in a carton containing 25 multiple dose vials (NDC 59267-1000-3) or 195 multiple dose vials (NDC 59267-1000-2).

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Do not refreeze thawed vials.

Frozen Vials Prior to Use

Cartons of Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vials arrive in thermal containers with dry ice. Once received, remove the vial cartons immediately from the thermal container and store in an ultra-low temperature freezer between -80°C to -60°C (-112°F to -76°F). Vials must be kept frozen between -80°C to -60°C (-112°F to -76°F) and protected from light, in the original cartons, until ready to use.

If an ultra-low temperature freezer is not available, the thermal container in which the Pfizer-BioNTech COVID-19 Vaccine arrives may be used as temporary storage when consistently re-filled to the top of the container with dry ice. Refer to the re-icing guidelines packed in the original thermal container for instructions regarding the use of the thermal container for temporary storage. The thermal container maintains a temperature range of -90°C to -60°C (-130°F to -76°F). Storage within this temperature range is not considered an excursion from the recommended storage condition.

Thawed Vials Before Dilution

Thawed Under Refrigeration

Thaw and then store undiluted vials in the refrigerator [2°C to 8°C (35°F to 46°F)] for up to 5 days (120 hours). A carton of 25 vials or 195 vials may take up to 2 or 3 hours, respectively, to thaw in the refrigerator, whereas a fewer number of vials will thaw in less time.

Thawed at Room Temperature

For immediate use, thaw undiluted vials at room temperature [up to 25°C (77°F)] for 30 minutes. Thawed vials can be handled in room light conditions.

Vials must reach room temperature before dilution.

Undiluted vials may be stored at room temperature for no more than 2 hours.

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Vials After Dilution

After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Any vaccine remaining in vials must be discarded after 6 hours. Do not refreeze.

20 PATIENT COUNSELING INFORMATION

Advise the recipient or caregiver to read the Fact Sheet for Recipients and Caregivers.

The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system. Advise recipient or caregiver that more information about IISs can be found at: <https://www.cdc.gov/vaccines/programs/iis/about.html>.

21 CONTACT INFORMATION

For general questions, visit the website or call the telephone number provided below.

Website	Telephone number
www.cvdvaccine.com 	1-877-829-2619 (1-877-VAX-CO19)

This Full EUA Prescribing Information may have been updated. For the most recent Full EUA Prescribing Information, please see www.cvdvaccine.com.



Manufactured by
Pfizer Inc., New York, NY 10017

BIONTECH

Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

LAB-1457-1.0

Revised: December 2020

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Appendix 3 – FDA Letter of Authorization – Pfizer

As of 12/11/2020

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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

You are being offered the Pfizer-BioNTech COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the Pfizer-BioNTech COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Pfizer-BioNTech COVID-19 Vaccine is a vaccine and may prevent you from getting COVID-19. There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19.

Read this Fact Sheet for information about the Pfizer-BioNTech COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Pfizer-BioNTech COVID-19 Vaccine.

The Pfizer-BioNTech COVID-19 Vaccine is administered as a 2-dose series, 3 weeks apart, into the muscle.

The Pfizer-BioNTech COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.cvdvaccine.com.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE?

WHAT IS COVID-19?

COVID-19 disease is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

WHAT IS THE PFIZER-BIONTECH COVID-19 VACCINE?

The Pfizer-BioNTech COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19. There is no FDA-approved vaccine to prevent COVID-19.

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The FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19 in individuals 16 years of age and older under an Emergency Use Authorization (EUA).

For more information on EUA, see the “**What is an Emergency Use Authorization (EUA)?**” section at the end of this Fact Sheet.

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE PFIZER-BIONTECH COVID-19 VACCINE?

Tell the vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine

WHO SHOULD GET THE PFIZER-BIONTECH COVID-19 VACCINE?

FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine in individuals 16 years of age and older.

WHO SHOULD NOT GET THE PFIZER-BIONTECH COVID-19 VACCINE?

You should not get the Pfizer-BioNTech COVID-19 Vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine

WHAT ARE THE INGREDIENTS IN THE PFIZER-BIONTECH COVID-19 VACCINE?

The Pfizer BioNTech COVID-19 Vaccine includes the following ingredients: mRNA, lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

HOW IS THE PFIZER-BIONTECH COVID-19 VACCINE GIVEN?

The Pfizer-BioNTech COVID-19 Vaccine will be given to you as an injection into the muscle.

The Pfizer-BioNTech COVID-19 Vaccine vaccination series is 2 doses given 3 weeks apart.

If you receive one dose of the Pfizer-BioNTech COVID-19 Vaccine, you should receive a second dose of this same vaccine 3 weeks later to complete the vaccination series.

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HAS THE PFIZER-BIONTECH COVID-19 VACCINE BEEN USED BEFORE?

The Pfizer-BioNTech COVID-19 Vaccine is an unapproved vaccine. In clinical trials, approximately 20,000 individuals 16 years of age and older have received at least 1 dose of the Pfizer-BioNTech COVID-19 Vaccine.

WHAT ARE THE BENEFITS OF THE PFIZER-BIONTECH COVID-19 VACCINE?

In an ongoing clinical trial, the Pfizer-BioNTech COVID-19 Vaccine has been shown to prevent COVID-19 following 2 doses given 3 weeks apart. The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE PFIZER-BIONTECH COVID-19 VACCINE?

Side effects that have been reported with the Pfizer-BioNTech COVID-19 Vaccine include:

- injection site pain
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever
- injection site swelling
- injection site redness
- nausea
- feeling unwell
- swollen lymph nodes (lymphadenopathy)

There is a remote chance that the Pfizer-BioNTech COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Pfizer-BioNTech COVID-19 Vaccine.

Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

These may not be all the possible side effects of the Pfizer-BioNTech COVID-19 Vaccine. Serious and unexpected side effects may occur. Pfizer-BioNTech COVID-19 Vaccine is still being studied in clinical trials.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?

If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

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Report vaccine side effects to **FDA/CDC Vaccine Adverse Event Reporting System (VAERS)**. The VAERS toll-free number is 1-800-822-7967 or report online to <https://vaers.hhs.gov/reportevent.html>. Please include "Pfizer-BioNTech COVID-19 Vaccine EUA" in the first line of box #18 of the report form.

In addition, you can report side effects to Pfizer Inc. at the contact information provided below.

Website	Fax number	Telephone number
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

WHAT IF I DECIDE NOT TO GET THE PFIZER-BIONTECH COVID-19 VACCINE?

It is your choice to receive or not receive the Pfizer-BioNTech COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES PFIZER-BIONTECH COVID-19 VACCINE?

Currently, there is no approved alternative vaccine available for prevention of COVID-19. FDA may allow the emergency use of other vaccines to prevent COVID-19.

CAN I RECEIVE THE PFIZER-BIONTECH COVID-19 VACCINE WITH OTHER VACCINES?

There is no information on the use of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.

WHAT IF I AM PREGNANT OR BREASTFEEDING?

If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

WILL THE PFIZER-BIONTECH COVID-19 VACCINE GIVE ME COVID-19?

No. The Pfizer-BioNTech COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

KEEP YOUR VACCINATION CARD

When you get your first dose, you will get a vaccination card to show you when to return for your second dose of Pfizer-BioNTech COVID-19 Vaccine. Remember to bring your card when you return.

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ADDITIONAL INFORMATION

If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

Global website	Telephone number
www.cvdvaccine.com 	1-877-829-2619 (1-877-VAX-CO19)

HOW CAN I LEARN MORE?

- Ask the vaccination provider.
- Visit CDC at <https://www.cdc.gov/coronavirus/2019-ncov/index.html>.
- Visit FDA at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.
- Contact your local or state public health department.

WHERE WILL MY VACCINATION INFORMATION BE RECORDED?

The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. This will ensure that you receive the same vaccine when you return for the second dose. For more information about IISs visit: <https://www.cdc.gov/vaccines/programs/iis/about.html>.

WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?

The United States FDA has made the Pfizer-BioNTech COVID-19 Vaccine available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The Pfizer-BioNTech COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19

COVID-19 Vaccine LHD Toolkit

pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.

The EUA for the Pfizer-BioNTech COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).



Manufactured by
Pfizer Inc., New York, NY 10017

BIONTECH

Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

LAB-1451-0.7

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Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

Barcode Date: 12/2020

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Appendix 4 – V-safe Information Sheet

As of 12/01/2020



COVID-19 Vaccine LHD Toolkit



What is v-safe?

V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccination. Through **v-safe**, you can quickly tell CDC if you have any side effects after getting the COVID-19 vaccine. Depending on your answers, someone from CDC may call to check on you. And **v-safe** will remind you to get your second COVID-19 vaccine dose if you need one.

Your participation in CDC's **v-safe** makes a difference—it helps keep COVID-19 vaccines safe.

How can I participate?

Once you get a COVID-19 vaccine, you can enroll in **v-safe** using your smartphone. Participation is voluntary and you can opt out at any time. You will receive text messages from **v-safe** around 2pm local time. To opt out, simply text "STOP" when **v-safe** sends you a text message. You can also start **v-safe** again by texting "START."

How long do v-safe check-ins last?

During the first week after you get your vaccine, **v-safe** will send you a text message each day to ask how you are doing. Then you will get check-in messages once a week for up to 5 weeks. The questions **v-safe** asks should take less than 5 minutes to answer. If you need a second dose of vaccine, **v-safe** will provide a new 6-week check-in process so you can share your second-dose vaccine experience as well. You'll also receive check-ins 3, 6, and 12 months after your final dose of vaccine.

Is my health information safe?

Yes. Your personal information in **v-safe** is protected so that it stays confidential and private.*

*To the extent **v-safe** uses existing information systems managed by CDC, FDA, and other federal agencies, the systems employ strict security measures appropriate for the data's level of sensitivity. These measures comply, where applicable, with the following federal laws, including the Privacy Act of 1974; standards enacted that are consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA); the Federal Information Security Management Act, and the Freedom of Information Act.



Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second vaccine dose.



Sign up with your smartphone's browser at
vsafe.cdc.gov

OR

Aim your smartphone's camera at this code





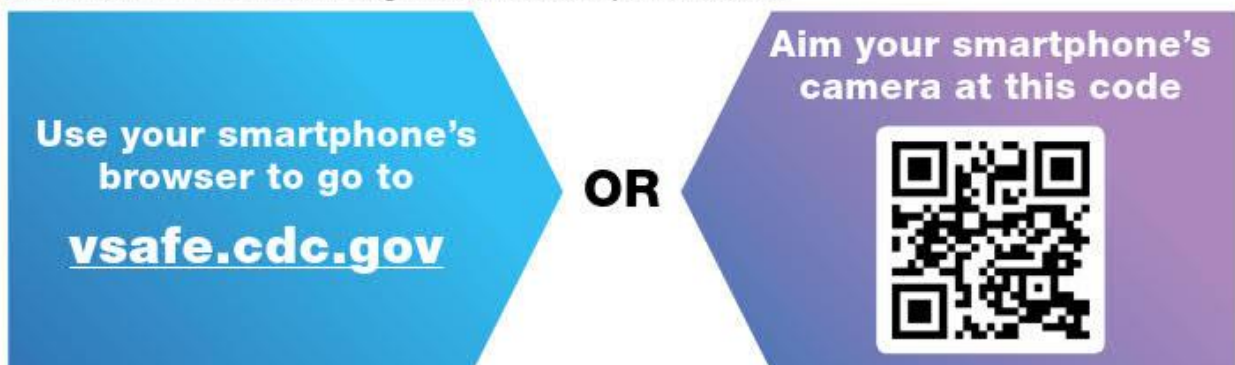
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How to register and use v-safe

You will need your smartphone and information about the COVID-19 vaccine you received. This information can be found on your vaccination record card; if you cannot find your card, please contact your healthcare provider.

Register

1. Go to the **v-safe** website using one of the two options below:



2. Read the instructions. Click **Get Started**.
3. Enter your name, mobile number, and other requested information. Click **Register**.
4. You will receive a text message with a verification code on your smartphone. Enter the code in **v-safe** and click **Verify**.
5. At the top of the screen, click **Enter your COVID-19 vaccine information**.
6. Select which COVID-19 vaccine you received (found on your vaccination record card; if you cannot find your card, please contact your healthcare provider). Then enter the date you were vaccinated. Click **Next**.
7. Review your vaccine information. If correct, click **Submit**. If not, click **Go Back**.
8. **Congrats! You're all set!** If you complete your registration before 2pm local time, **v-safe** will start your initial health check-in around 2pm that day. If you register after 2pm, **v-safe** will start your initial health check-in immediately after you register—just follow the instructions.
You will receive a reminder text message from **v-safe** when it's time for the next check-in—around 2pm local time. Just click the link in the text message to start the check-in.

Complete a v-safe health check-in

1. When you receive a **v-safe** check-in text message on your smartphone, click the link when ready.
2. Follow the instructions to complete the check-in.

Troubleshooting

How can I come back and finish a check-in later if I'm interrupted?

- Click the link in the text message reminder to restart and complete your check-in.

How do I update my vaccine information after my second COVID-19 vaccine dose?

- **V-safe** will automatically ask you to update your second dose information. Just follow the instructions.

Need help with v-safe?

Call 800-CDC-INFO (800-232-4636)

TTY 888-232-6348

Open 24 hours, 7 days a week

Visit www.cdc.gov/vsafe



COVID-19 Vaccine LHD Toolkit

Appendix 5 – V-safe poster

As of 12/01/2020

COVID-19 Vaccine LHD Toolkit



Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second vaccine dose.

When you get your COVID-19 vaccination, ask your healthcare provider about getting started with **v-safe**

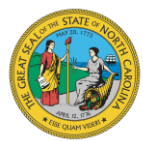
Learn more about **v-safe**

www.cdc.gov/vsafe



COVID-19 Vaccine LHD Toolkit

Appendix 6 – Product Information Guide for COVID-19 Vaccines and Associated Products



COVID-19 Vaccine LHD Toolkit



Product Information Guide for COVID-19 Vaccines and Associated Products

COVID-19 Vaccine LHD Toolkit

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Version 1—December 4, 2020

COVID-19 Vaccine LHD Toolkit

Product Information Guide Summary

»Purpose:

This guide provides specifications for COVID-19 vaccine and associated products. **This is NOT a catalog from which you can order products.** It provides key product information including product package dimensions and weight, minimum order quantities, product presentation, distribution method, storage information, and additional information. This guide will be updated as more products become available.

»How to use this guide

Jurisdictional immunization program staff—use this guide to help you:

- Learn about available COVID-19 vaccines and associated products.
- Provide answers to questions from COVID-19 vaccination providers.

COVID-19 vaccination providers—use this guide to help you:

- Learn about available COVID-19 vaccines and associated products.
- Prepare storage space to ensure ordered quantities can be stored at the proper temperature.
- Prepare staff responsible for receipt and storage of vaccine deliveries.

Refer to CDC's [Vaccine Storage and Handling Toolkit](#) for recommendations and best practices on related topics such as vaccine inventory management.

»Addendum:

The [COVID-19 Vaccine Ancillary Supply Kit Guidance](#) in the addendum (page 8) provides more specific information on the ancillary supply kits.



At this time, the products in this guide are only available for use in adults (i.e., persons aged 18 years or older). You will receive additional information, and this guide will be updated to reflect any changes COVID-19 age indications.



Additional COVID-19 vaccine may be authorized or licensed in the future. This guide will be updated as more products become available.

VTrckS: <https://www.cdc.gov/vaccines/programs/vtrcks/index.html>

Vaccine Storage and Handling Toolkit: <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html>

COVID-19 Vaccine LHD Toolkit

Centrally Distributed Vaccines and Ancillary Kits*

Vaccines (Centrally Distributed)

Manufacturer	Moderna
NDC # in VTrckS	80777-0273-99
Carton dimensions	53mm x 53mm x 137mm (approximately 2in x 2in x 5 3/8in)
Minimum order size and increment	100 doses
Presentation	10-dose multidose vial/10 MDV per carton
Items automatically added to your VTrckS order when you select this product	Ancillary supply administration kit: standard syringe
Vaccination schedule	2-dose series separated by at least 28 days
Age indications	TBD
On-site vaccine storage	• -25°C to -15°C (-13°F to 5°F) in vaccine storage unit • 2° to 8°C (36° to 46°F) in vaccine storage unit for up to 30 days if the vial is not entered. • Freezer temperature settings will require adjustment if storing this vaccine and varicella-containing vaccines in the same unit. The temperature range for this vaccine is limited compared to varicella-containing vaccines.

*Pfizer's COVID-19 vaccine is not centrally distributed; it is distributed directly from the manufacturer. Please refer to the next section for information on Pfizer COVID-19 vaccine.

Moderna: <https://www.modernatx.com/>

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Ancillary Supply Administration Kit: Standard Syringe (Centrally Distributed)

Kit description	Standard syringe kit for vaccine administration		
NDC # in VTrcks	11111-0001-01 (Adult)		
Kit dimensions/weight	14 in x 13 in x 9 in/3.5 lbs (standard ancillary adult kit)		
Minimum order size and increment	Kit to support administration of 100 doses (plus overage)		
Accompanies 0.5mL-dose vaccines	Moderna		
Order Intention	Initially only adult kits will be available, when authorized for use in younger populations, pediatric and mixed (pediatric and adult) will be available for ordering.		
Contents	Adult Kit 85 needles (22-25G x 1") 20 needles (22-25G x 1.5") 105 syringes (1mL or 3mL) 210 alcohol pads 100 vaccination record cards 1 needle gauge and length chart 2 face shields 4 surgical masks	Pediatric Kit 105 needles (25G x 1") 105 syringes (1mL or 3mL) 210 alcohol pads 100 vaccination record cards 1 needle gauge and length chart 2 face shields 4 surgical masks	Mixed Kit 95 needles (25G x 1") 10 needles (22-25G x 1.5") 105 syringes (1mL or 3mL) 210 alcohol pads 100 vaccination record cards 1 needle gauge and length chart 2 face shields 4 surgical masks
Additional information	- Products and brands for kit components may vary. - All needles for vaccine administration are safety needles. - Due to the limited supply of needles and syringes, specification of preferences for needles or syringes is not feasible. - Kit and pallet configuration 1 kit = 100 vaccinations (plus overage) 1 pallet = 36 kits (supports 3,600 vaccinations, plus overage)  For more information about ancillary kits components: COVID-19 Vaccine Ancillary Supply Kit Guidance		

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Direct-Ship Vaccine and Ancillary Kit

Pfizer Vaccine (Direct Ship)

Manufacturer	Pfizer
NDC # in VTrckS	59267-1000-02
Tray dimensions	229mm x 229mm x 40mm (approximately 9in x 9in x 1.5in)
Minimum order size and increment	975 doses
Presentation	5-dose multidose vial/195 MDV per tray
Items automatically added to your VTrckS order when you select this vaccine	Combined ancillary supply kit for administration and mixing (includes 0.9% preservative-free normal saline diluent)
Age indications	TBD
Vaccination schedule	2-dose series separated by at least 21 days
On-site vaccine storage	-80°C to -60°C (-112°F and -76°F) in ultracold storage unit -80°C to -60°C (-112°F and -76°F) in the original thermal shipping container with dry ice recharges. Please allow for forthcoming information on the maximum time for storage in these conditions. 2° C to 8°C (36° F to 46°F) in a storage unit for up to 5 days (120 hours)
Additional information	- Vaccine will be shipped in a container that includes dry ice. Thermal shipping container dimensions are 400mm x 400mm x 560 mm (approximately 15 3/4in x 15 3/4in x 22in). - A thermal shipping container holds up to 5 cartons/trays. - If using the thermal shipping container to store vaccine, add dry ice pellets (9 mm to 16 mm) within 24 hours of delivery and every 5 days or as needed to maintain temperatures. - Unless a provider opts out, dry ice will be delivered within 24 hours of vaccine delivery to refill the thermal shipping container for the first re-ice only. Additional dry ice will not be provided. Locate a dry ice source if planning to use the shipping container to store vaccine for more than 5 days. - Do not use or store dry ice or liquid nitrogen (LN₂) in confined areas, walk-in refrigerators, environmental chambers or rooms without ventilation. A leak in such an area could cause an oxygen-deficient atmosphere. - A full shipping container with vaccine and dry ice weighs approximately 80 pounds.

COVID-19 Vaccine LHD Toolkit

Combined Ancillary Supply Kit for Administration and Mixing (Direct Ship)

Kit description	Combined kit with small syringes for vaccine administration, mixing supplies, and diluent		
NDC # in VTrcks	11111-0006-02 (Adult)		
Kit dimensions/weight	24 in x 20 in x 24 in/40 lbs		
Minimum order size and increment	Kit to support administration of 975 doses (plus overage), including 0.9% preservative-free normal saline diluent		
Accompanies 0.3mL-dose vaccines	Pfizer		
Order Intention	Initially only adult kits will be available, when authorized for use in younger populations, pediatric and mixed (pediatric and adult) will be available for ordering.		
Contents	Adult Kit* 829 needles (22-25G X 1") 200 needles (22-25G X 1.5") 205 mixing needles (21-25G X 1.5") 1024 syringes (1mL) 205 syringes (3mL or 5mL) 2458 alcohol pads 1000 vaccination record cards 10 needle gauge and length charts 20 face shields 40 surgical masks 200 Diluent vials	Pediatric Kit* 1024 needles (25G X 1") 205 mixing needles (21-25G X 1.5") 1024 syringes (1mL) 205 syringes (3mL or 5mL) 2458 alcohol pads 1000 vaccination record cards 10 needle gauge and length charts 20 face shields 40 surgical masks 200 Diluent vials	Mixed Kit* 926 needles (25G X 1") 100 needles (22-25G X 1.5") 205 mixing needles (21-25G X 1.5") 1024 syringes (1mL) 205 syringes (3mL or 5mL) 2458 alcohol pads 1000 vaccination record cards 10 needle gauge and length charts 20 face shields 40 surgical masks 200 Diluent vials
Additional information	- Products and brands for kit components may vary. - All needles for vaccine administration are safety needles. - Mixing needles are conventional. - Due to the limited supply of needles and syringes, specification of preferences for needles or syringes is not feasible. - Kit and pallet configuration 1 kit = 975 vaccinations (plus overage) 1 pallet = 8 kits (supports 7,800 vaccinations, plus overage)   For more information about ancillary kit components: COVID-19 Vaccine Ancillary Supply Kit Guidance		

*The total number of needles in each adult, pediatric, and mixed combined ancillary supply kit for administration and mixing will vary (adult—1,029; pediatric—1,024; mixed—1,026). The difference in total number is related to increasing the kit build efficiency.

COVID-19 Vaccine LHD Toolkit

Dry Ice Kit (Direct Ship)

Kit description	Dry ice kit with starter materials
NDC # in VTrcks	11111-0007-03
Kit dimensions/weight	TBD
Minimum order size and increment	Kit to support initial dry ice recharge of one thermal shipping container
Accompanies ultracold vaccine	Pfizer
Contents	• Dry ice (weight and pellet size requested from the Strategic National Stockpile) • Gloves for working with dry ice(1 pair) • Face shield (1) • Ice scoop (1) • OSHA dry ice safety card (1)
Additional information	• Products and brands for kit components may vary.

COVID-19 Vaccine LHD Toolkit

Addendum: COVID-19 Vaccine Ancillary Supply Kit Guidance

COVID-19 Vaccine LHD Toolkit

COVID-19 Vaccine Ancillary Supply Kit Guidance

»Purpose:

This guidance provides an overview of the COVID-19 vaccine ancillary supply kits the U.S. Department of Health and Human Services (HHS) is providing to enrolled COVID-19 vaccination providers as part of the federal COVID-19 vaccination program. It includes a general description of seven different COVID-19 vaccine ancillary kit configurations, as well as a list of select corresponding products, product descriptions, and product quantities. For reference and to access additional product-specific information and training resources, this document also includes website hyperlinks and contact information for select product manufacturers.

»Background:

HHS is providing ancillary supply kits for the administration of COVID-19 vaccine. The Strategic National Stockpile (SNS), managed by the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR), is partnering with McKesson Corporation to produce, store and distribute these vaccine ancillary supply kits on behalf of the SNS.

»How to use this guide:

Jurisdictional immunization program staff—use this guide to help you:

- Learn about products that will arrive in ancillary kit(s).

COVID-19 vaccination providers—use this guide to help you:

- Learn about products that will arrive in ancillary kit(s).
- Prepare storage space for the ancillary kit products you will receive.

»Ancillary kit basics:

How does a provider order ancillary kits?

You do not need to order ancillary kits. When you order COVID-19 vaccine in VTrckS, ancillary supplies will automatically be ordered in amounts to match the vaccine orders.

Note: To receive COVID-19 vaccine, vaccination provider facilities and organizations must enroll in the federal COVID-19 Vaccination Program coordinated through their jurisdiction's immunization program.

How much do ancillary kits cost?

Ancillary kits will be provided at no cost to enrolled COVID-19 vaccination providers.

What products are in ancillary kits?

Refer to page 11 for possible ancillary kits.

Each ancillary kit, **except for the kits designated for use with the Pfizer vaccine**, contains supplies to administer 100 doses of vaccine (with some overage). The **Pfizer vaccination kit** will support 975 doses of vaccine (with some overage). Refer to page 12 for possible variations on kit contents.

How will needles and syringes be packaged?

Needles and syringes for vaccine administration may be packaged as integrated units (i.e. NO assembly required) or as separate items in a kit (i.e. assembly required).

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Can I order specific brand(s) of needles and/or syringes?

Due to a limited supply of needles and syringes, specification of preferences for needles or syringes is not feasible. Products included in the kits may vary over time. In order to meet the demand for supplies, the federal government has purchased single-use, sterile needles and syringes from multiple manufacturers (to include foreign sources) to ensure adequate supplies. These products are approved by the Food and Drug Administration, safety-engineered and compliant with standards established by the Occupational Safety and Health Administration.

What is considered "pediatric" and "adult"?

For the purpose of immunizations **pediatric is birth through 18 years** and **adult is 19 years and older**. Refer to each product's EUA for age indications.

» Related guidance and resources:

- [Preliminary Strategy for Distributing a COVID-19 Vaccine - PDF](#)
- [COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations - PDF](#)

» Contact for questions:

Vaccination providers should contact the manufacturer with questions related to proper product use. Concerns related to needle/syringe quality and performance or other contents of the vaccine ancillary supply kit should be directed to the state or local health department.

Becton Dickinson (BD) Worldwide	https://www.bd.com/en-us/	844-823-5433
Cardinal Health	https://www.cardinalhealth.com/en.html	1-800-964-5227
HTL Strefa	https://htl-strefa.com/home-page/	877-660-1900
Duopross Meditech Corp	https://www.duopross.com/	1-800-844-1350
Retractable Technologies Inc. (RTI)	https://retractable.com/	888-703-1010
Marathon/Smiths Medical	N/A	941-704-7864

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Possible Ancillary Kits—COVID-19 Vaccines, *Excluding Pfizer*

The following tables list the contents of each possible ancillary kit by product and quantity. All kits are configured for 100 doses with 5% surplus.

Needle and Syringe Sizes for *Adult* Ancillary Kits

Product	Quantity
Needle (22–25G x 1")	85
Needle (22–25G x 1.5")	20
Syringe (1mL or 3mL)	105
Alcohol Pad (sterile, individually sealed)	210
Vaccination Record Card	100
Needle Gauge and Length Chart	1
Face Shield	2
Surgical Mask	4



Needle and Syringe Sizes for *Pediatric* Ancillary Kits

Product	Quantity
Needle (25G x 1")	105
Syringe (1mL or 3mL)	105
Alcohol Pad (sterile, individually sealed)	210
Vaccination Record Card	100
Needle Gauge and Length Chart	1
Face Shield	2
Surgical Mask	4



Needle and Syringe Sizes for *Mixed* Ancillary Kits

Product	Quantity
Adult/Pediatric Needle (22–25G x 1")	85
Adult Needle (22–25G x 1.5")	20
Syringe (1mL or 3mL)	105
Alcohol Pad (sterile, individually sealed)	210
Vaccination Record Card	100
Needle Gauge and Length Chart	1
Face Shield	2
Surgical Mask	4



Needle and Syringe Sizes for Mixing Kits

Needle and Syringe Sizes for *Mixing* Kits

Product	Quantity
Needle (19–21G x 1.5")	11
Syringe (5mL or 6mL)	11
Alcohol Pad (sterile, individually sealed)	22



Needle Gauge and Length Chart: www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-needle-length.pdf

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Possible Ancillary Kits—COVID-19 Vaccine, *Pfizer* Only

Needle and Syringe Sizes for Pfizer Mega *Adult* Ancillary Kits

Product	Quantity
Needle (22–25G x 1")	829
Needle (22–25G x 1.5")	200
Needle, Mixing (21–25G x 1.5")	205
Syringe (1mL)	1,024
Syringe, Mixing (3mL or 5mL)	205
Alcohol Pad (sterile, individually sealed)	2,458
Vaccination Record Card	1,000
Needle Gauge and Length Chart	10
Face Shield	20
Surgical Mask	40
Diluent	200



Needle and Syringe Sizes for Pfizer Mega *Pediatric* Ancillary Kits

Product	Quantity
Needle (25G x 1")	1,024
Needle, Mixing (21–25G x 1.5")	205
Syringe (1mL)	1,204
Syringe, Mixing (3mL or 5mL)	205
Alcohol Pad (sterile, individually sealed)	2,458
Vaccination Record Card	1,000
Needle Gauge and Length Chart	10
Face Shield	20
Surgical Mask	40
Diluent	200



Needle and Syringe Sizes for Pfizer Mega *Mixed* Ancillary Kits

Product	Quantity
Needle (25G x 1")	926
Needle (22–25G x 1.5")	100
Needle, Mixing (21–25G x 1.5")	205
Syringe (1mL)	1,024
Syringe, Mixing (3mL or 5mL)	205
Alcohol Pads (sterile, individually sealed)	2,458
Vaccination Record Card	1,000
Needle Gauge and Length Chart	10
Face Shield	20
Surgical Mask	40
Diluent	200



Needle Gauge and Length Chart: www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-needle-length.pdf

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General Needle and Syringe Resources



Web Resources

- [Vaccine Administration Resource Library](#): Includes resources for preparing, administering, and documenting vaccines



PDF Resources

- [Vaccine Administration: Needle Gauge and Length–PDF](#)
- [Vaccine Administration: Intramuscular \(IM\) Injection Children 7 through 18 years of age–PDF](#)
- [Vaccine Administration: Intramuscular \(IM\) Injection Adults 19 years of age and older–PDF](#)



Video Resources

- [Assemble a Manufacturer-filled Syringe](#): This training addresses how to assemble a manufacturer-filled syringe, available for a variety of vaccines.

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Specific Ancillary Kit Products and Product Information

The following tables, organized by manufacturer or broker, list possible ancillary kit products with an example image (colors may vary) and links to more information. Resources for additional information are organized by:



Web resources



Pdf resources



Video resources

[Becton Dickinson Products](#) (Phone: 844-823-5433)

Item	Where to Find more Information
Hypodermic Needle PrecisionGlide™ Conventional* Gauge: 22-25/Length: 1.5" 	 PrecisionGlide™ Conventional Needle overview Visit Becton Dickinson catalog and search product numbers: 305127, 305156, 305194
Safety Hypodermic Needle BD Eclipse™ - Gauge: 22-25/Length: 1-1.5" - Gauge: 23/25/Length: 1-1.25" 	 BD Eclipse™ Needle overview Visit Becton Dickinson catalog and search product numbers: 22-25G, 1-1.5": 305762, 305761, 305763, 305767 23/25, 1-1.25": 305866, 305891, 305892  BD Eclipse™ directions for use  BD Eclipse™ Needle instruction video
Safety Combo, Syringe with BD Eclipse™ Needle 3mL BD Luer-Lok™ Syringe Gauge: 22-25/ Length: 1-1.5" 	 BD Eclipse™ Needle overview Visit Becton Dickinson catalog and search product numbers: 305782, 305783, 305787  BD Eclipse™ directions for use  BD Eclipse™ Needle Instruction video

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Item	Where to Find more Information
1mL/3mL BD Luer-Lok™ Syringe 	 Conventional syringe overview Visit Becton Dickinson catalog and search product numbers: 309628, 309657
Conventional Combo* Syringe (3mL/5mL) with attached needle Gauge: 22-25/Length: 1-1.5" 	 Conventional syringe Overview Visit Becton Dickinson catalog and search product numbers: 309361, 309571, 309572, 309574, 309581, 309582, 309589

*For mixing ONLY and NOT for vaccine administration

PrecisionGlide™ Conventional Needle overview: <https://www.bd.com/en-us/offering/capabilities/syringes-and-needles/conventional-syringes-and-needles/conventional-needles>

Becton Dickinson Product catalog: <http://catalog.bd.com/>

BD Eclipse™ Needle overview: <https://www.bd.com/en-us/offering/capabilities/syringes-and-needles/safety-syringes-and-needles/safety-needles/bd-eclipse-needle>

BD Eclipse™ directions for use: https://www.bd.com/documents/guides/directions-for-use/MPS_HY_Eclipse-needle-usage-guidelines_DF_EN.pdf

BD Eclipse™ Needle instruction video: <https://www.bd.com/en-us/company/video-gallery?video=618677712001>

Conventional Syringe overview: <https://www.bd.com/en-us/offering/capabilities/syringes-and-needles/conventional-syringes-and-needles/conventional-syringes>



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[Cardinal Health](#) (Phone: 1-800-964-5227)

Item	Where to find more information
Tuberculin Syringe Monoject™ • 1mL Luer Lock Tip Conventional Syringe 	 1 mL Luer Lock Syringes product page Visit Cardinal Health webpage and search product numbers: 1180100777, 1180300777
Magellan™ 3mL Syringe with Hypodermic Safety Needle • Gauge: 23/25/Length: 1" 	 Magellan™ Safety Needle and Syringe Combination product page Visit Cardinal Health webpage and search product numbers: 8881833310, 8881833510
Magellan™ Hypodermic Safety Needle • Gauge: 23/25 Length: 1" 	 Magellan™ Hypodermic Safety Needle Product page Visit Cardinal Health webpage and search product numbers: 8881850310, 8881850510

1 mL Luer Lock Syringes product page: <https://www.cardinalhealth.com/en/product-solutions/medical/patient-care/sharp-safety/needles-and-syringes/1-ml-luer-lock-syringes.html>
Cardinal Health webpage: <https://www.cardinalhealth.com/en.html>
Magellan™ Safety Needle and Syringe Combination product page: <https://www.cardinalhealth.com/en/product-solutions/medical/patient-care/sharp-safety/needles-and-syringes/safety-needles-and-syringes/magellan-safety-needle-and-syringe-combination.html>
Magellan™ Hypodermic Safety Needle product page: <https://www.cardinalhealth.com/en/product-solutions/medical/patient-care/sharp-safety/needles-and-syringes/safety-needles-and-syringes/magellan-safety-needles.html>

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Duopross Meditech Corp (Phone: 1-800-844-1350)

Item	Where to find more information
Safety Combo, 1mL Syringe with Safety Needle* Gauge: 23- 25/Length: 1-1.5" 	Website and product information currently unavailable.
Safety Combo, 3mL Syringe with Safety Needle* Gauge: 23-25/Length: 1-1.5" 	Website and product information currently unavailable.

*Image for product is a placeholder stock image only. Product image is not currently available.

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Goldbelt (Contact information currently unavailable)

Item	Where to find more information
Safety Needle* Gauge: 23-25/Length: 1-1.5" 	Website and product information currently unavailable.
Conventional Syringe 1mL* 	Website and product information currently unavailable.
Conventional Syringe 3mL* 	Website and product information currently unavailable.
Conventional Syringe 5mL* 	Website and product information currently unavailable.

*Image for product is a placeholder stock image only. Product image is not available currently.

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Gold Coast (contact information not currently available)

Item	Where to find more information		
Safety Combo, 1mL Syringe with Safety Needle • Gauge: 23/Length: 1" 	 EasyTouch-FlipLock_Syringe_Instructions	 CP_Safety_Flyer_Product	 EasyTouch-Safety_Syringe_Needle_Brochur
	Product Number: Carepoint 35-8204		
Safety Combo, 1mL Syringe with Safety Needle • Gauge: 25/ Length: 1" 	 EasyTouch-FlipLock_Syringe_Instructions	 CP_Safety_Flyer_Product	 EasyTouch-Safety_Syringe_Needle_Brochur
	Product Number: Carepoint 35-8203		
Safety Combo, FlipLock 3mL Syringe with Safety Needle • Gauge: 23/Length: 1" 	 EasyTouch-FlipLock_Syringe_Instructions	 CP_Safety_Flyer_Product	 EasyTouch-Safety_Syringe_Needle_Brochur
	Product Number: 822331		
Safety Combo, FlipLock 3mL Syringe with Safety Needle • Gauge: 25/ Length: 1" 	 EasyTouch-FlipLock_Syringe_Instructions	 CP_Safety_Flyer_Product	 EasyTouch-Safety_Syringe_Needle_Brochur
	Product Number: 825231		
Safety Needle • Gauge: 25/ Length: 1" 	 EasyTouch-FlipLock_Syringe_Instructions	 CP_Safety_Flyer_Product	 EasyTouch-Safety_Syringe_Needle_Brochur
• Gauge: 23/ Length: 1" 	Product Numbers: 25G x 1": EasyTouch 802501 23G x 1": EasyTouch 812301		



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HTL Strefa (Phone: 877-660-1900)

Item	Where to find more information
Safety Combo, 1mL Syringe with Safety Needle Gauge: 25/Length: 1" 	 HTL Strefa home page (product 6054 currently unlisted)   Appendix 1 Products picture and artwork_i
Safety Combo, 3mL Syringe with Safety Needle Gauge: 23/Length: 1" 	 HTL Strefa home page (product 6053 currently unlisted)   Appendix 1 Products picture and artwork_i
Safety Combo, 3mL Syringe with Safety Needle Gauge: 25/Length: 1" 	 HTL Strefa home page (product 6055 currently unlisted)   Appendix 1 Products picture and artwork_i

HTL Strefa home page: <https://htl-strefa.com/home-page/>

Marathon/Smiths Medical (Phone: 941-704-7864)

Item	Where to find more information
Safety Combo, 3mL Syringe with Safety Needle* Gauge: 22-25/Length: 1-1.5" 	Website and product information currently unavailable. Product numbers: 4234, 4236, 423510

*Image for product is a placeholder stock image only. Product image is not available currently.

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Medline (Contact information currently unavailable)

Item	Where to find more information
Safety Combo, 1mL Syringe with Safety Needle - Gauge: 23/Length: 1"  - Gauge: 25/Length: 1" 	Website and product information currently unavailable.
Safety Needle - Gauge: 23/Length: 1-1.5"  - Gauge: 25/Length: 1" 	Website and product information currently unavailable.
Conventional Syringe 1mL  3mL 	 Luer Lock Syringe product page Visit Medline webpage and search product numbers: SYR101010, SYR103010
Luer Lock Syringe product page: https://www.medline.com/product/Luer-Lock-Syringes/Syringes-without-Needle/Z05-PF11377?question=SYR103010&index=P1&indexCount=1#mrkOrderingInfoTable Medline webpage: https://www.medline.com	



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Quality Impact (Contact information currently unavailable)

Item	Where to find more information
Safety Combo, 1mL Syringe with Safety Needle* • Gauge: 23-25/Size: 1" 	Website and product information currently unavailable.
Safety Combo, 3mL Syringe with Safety Needle* • Gauge: 23-25/Size: 1" 	Website and product information currently unavailable.

*Image for product is a placeholder stock image only. Product image is not available currently.

[Retractable Technologies Inc.](#) (Phone: 888-703-1010)

Item	Where to find more information
Safety Combo Unit, 1mL/3mL, with attached needle • Gauge: 23/25/Length: 1" 	 Visit Retractable Technologies Inc. webpage and search product numbers: 10161, 10311, 10391  VanishPoint® Syringes brochure VanishPoint® Syringes product usage information  VanishPoint® Syringes video

Retractable Technologies Inc. webpage: <https://vanishpoint.com/>

VanishPoint® Syringes brochure: <https://d2ghdaxqb194v2.cloudfront.net/577/166728.pdf>

VanishPoint® Syringes product usage information: <https://d2ghdaxqb194v2.cloudfront.net/577/166715.pdf>

VanishPoint® Syringes video: <https://youtu.be/wC-uXq3uUdQ>

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Appendix 7 – COVID-19 Vaccine Readiness Checklist

This checklist contains recommended action items to help organizations ensure their readiness to receive and administer the COVID-19 vaccine. Providers must be approved through the Provider Enrollment portal before beginning the readiness checklist. The State will contact providers for enrollment in accordance with the State's Vaccine Distribution Prioritization framework. Additional information can be found here: <https://files.nc.gov/covid/documents/vaccines/NCDHHS-Vaccine-Infographic.pdf>

The action items below are grouped by topic (Onboarding, Training, Communications and Vaccine Administration Preparation) and listed in recommended sequence to address. Action items that are shaded blue are only applicable to Health Care Provider (HCP) organizations that are enrolled with the State of North Carolina to administer COVID-19 vaccines.

Please contact the COVID-19 Vaccine Management System (CVMS) Help Desk at CVMS-help@dhhs.nc.gov with any questions related to this Readiness Checklist.

Onboarding:

☐	Action Item	Supporting Information
☐	1. Identify internal single point of contact for your employees to send questions or provide feedback related to the administration of COVID-19 vaccine.	Identifying and providing employees a point of contact within your organization will give employees a clear channel to get answers to their questions or communicate issues related to the COVID-19 vaccination process. Any questions related to NCID or CVMS access should be directed through the designated point of contact.
☐	2. Enrolled HCP Organization Only: Identify your organization's users that need access to CVMS and confirm that these users have a valid NCID. Instruct users that do not have an NCID to create an NCID and provide it to you. Complete the HCP User Onboarding Template and send the file to COVIDHelp@dhhs.nc.gov .	Please see https://immunize.nc.gov/providers/ncip/training/HCP%20User%20Onboarding%20Template.xlsx for a summary of the two profiles in CVMS to help you determine which profile is appropriate for each of your identified CVMS user's needs. Instructions for a user to create an NCID: 1. Navigate to https://ncid.nc.gov/ 2. Click Register! (in the bottom right corner of the blue box) 3. Click Business user type option 4. Complete the required fields to create an NCID 5. Follow the steps to access your NCID account and create your security questions Please see https://immunize.nc.gov/providers/covid-19training.htm for the HCP User Onboarding Template.

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□	Action Item	Supporting Information
□	3. Fill out the State-provided Recipient Bulk Upload Template in Appendix 12 with the requested information for each of your eligible employees or individuals that meet the Phase 1 criteria to receive the COVID-19 vaccine. If there are multiple locations in your organization, create a new file for each location with employees/individuals who should be associated with each location. Complete the Recipient Bulk Upload Template and send the file to COVIDHelp@dhhs.nc.gov. When vaccines are available and you have obtained access to CVMS, you will be able to upload your completed Recipient Bulk Upload Template into CVMS so that the identified employees or individuals can complete their registration process in CVMS.	Please see Section 6.3 for the North Carolina CDC COVID-19 Vaccination Program Phase 1 Prioritization / Eligibility Matrix. Please see https://immunize.nc.gov/providers/covid-19training.htm for the State-provided Recipient Bulk Upload Template to begin to document Phase 1 eligible employees / individuals. See below for definitions of Risk column and Type column in the Recipient Bulk Upload Template. FIELD DEFINITIONS FOR RECIPIENT BULK UPLOAD TEMPLATE • RISK (column D): Enter "High" if the employee is responsible for one or more of the following: caring/cleaning in areas with COVID-19 patients, performing tasks with high risks of aerosolization (Intubation, Bronchoscopy, Suctioning, Invasive Dental Procedures, Invasive Specimen Collection, CPR), responsible for handling decedents with COVID-19, or planning to administer the COVID-19 vaccine. Otherwise enter "Low" if the employee does not meet any of the above criteria. • TYPE (column E): Enter "Employee" if person is working for the organization or enter "Individual" if the person is a resident of the organization (e.g., residents of a nursing home). Training materials to show you how to upload the Recipient Bulk Upload Template into CVMS can be located at the link below: https://immunize.nc.gov/providers/ncip/training/CVMS%20Provider%20Portal%20Recipient%20Bulk%20Upload%20User%20Guide.pptx If an Employer has more than 100 employees or individuals that meet Phase 1 criteria, they can email their completed Recipient Bulk Upload Template to COVIDHelp@dhhs.nc.gov to be uploaded into CVMS.

Training:

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☐	Action Item	Supporting Information
☐	4. Enrolled HCP Organization Only: Provide orientation and training materials to your organization's designated primary and back-up vaccine coordinators.	The designated primary and back-up vaccine coordinators must review the CDC's Vaccine Storage and Handling Toolkit, which includes the COVID-19 Vaccine Addendum and complete the COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare Providers and the CDC's You Call the Shots: Vaccine Storage and Handling module. https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html https://www2.cdc.gov/vaccines/ed/covid19/ https://www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp Please see link below for Provider Portal Log In and Getting Started User Guide: https://immunize.nc.gov/providers/ncip/training/CVMS%20Provider%20Portal%20Log%20In%20and%20Getting%20Started%20User%20Guide.pptx Additional training materials will be provided when available.



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☐	Action Item	Supporting Information
☐	5. Enrolled HCP Organization Only: Train your staff that are designated to receive COVID-19 vaccines and manage inventory levels in CVMS on how to: - Receive COVID-19 vaccine shipments in CVMS - How to document and manage discrepancies between shipped quantities and actually received quantities - Look up and document (both on packaging and in CVMS) the Beyond Use for all COVID-19 vaccines - How to receive emails from the manufacturer on shipment status and temperature excursions - How to contact the manufacturer or CVMS Help Desk if there are any issues with the vaccine shipment - Make adjustments to inventory on-hand in CVMS due to spoilage, wastage, or returns - How to request or process transfers of COVID-19 vaccine inventory - How to return COVID-19 vaccine shipping containers to the manufacturer for reuse - How to return COVID-19 vaccines to the manufacturer if directed to do so.	Training materials for Receiving and Processing Vaccine Shipments can be found at the link below: https://immunize.nc.gov/providers/ncip/training/CVMS%20Provider%20Portal%20Receiving%20and%20Processing%20Vaccine%20Shipments%20User%20Guide.pptx Training materials for Inventory Wastage and Return can be found at the link below: https://immunize.nc.gov/providers/ncip/training/CVMS%20Provider%20Portal%20Inventory%20Wastage%20Return%20and%20Transfer%20User%20Guide.pptx Links to the CDC website to look up Beyond Use Dates based on vaccine manufacturer lot numbers will be provided when available.
☐	6. Enrolled HCP Organization Only: Train your staff that are designated to handle and store COVID-19 vaccines on how to: - Properly handle the COVID-19 vaccines - Monitor and document the storage temperature for COVID-19 vaccines - Recharge COVID-19 vaccine shipping containers if they are being used to store COVID-19 vaccines (Pfizer)	Please see Appendix 11 for additional guidance on storage and recharging (Pfizer). https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html https://www.cvdvaccine-us.com/product-storage-and-dry-ice Additional training materials will be provided when available.
☐	7. Enrolled HCP Organization Only: Train your staff that are designated to check-in employees prior to administration of COVID-19 vaccine on how to use CVMS to complete their responsibilities.	Training materials for HCP User check in are provided in the link below: https://immunize.nc.gov/providers/ncip/training/CVMS%20Provider%20Portal%20Recipient%20Check-In%20User%20Guide.pptx

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☐	Action Item	Supporting Information
☐	8. Enrolled HCP Organization Only: Train your staff that are designated to administer COVID-19 vaccines to eligible employees or individuals on how to: on how to: - Prepare the vaccine - Administer the vaccine - Provide the recipient a populated COVID-19 vaccination record card (mandatory requirement) - Document in CVMS	Training materials for vaccine administration can be found at the link below: https://immunize.nc.gov/providers/ncip/training/CVMS%20Provider%20Portal%20Vaccine%20Administration%20User%20Guide%20.pptx Training materials for Proof of Vaccine can be found in the link below: https://immunize.nc.gov/providers/ncip/training/CVMS%20Provider%20Portal%20Viewing%20Proof%20of%20Vaccination%20Use%20Guide.pptx Information on COVID-19 record card: COVID-19 vaccination record cards will be provided as part of vaccine ancillary kits. Vaccination providers should provide a completed card with accurate vaccine information (i.e., vaccine manufacturer, lot number, date of first dose administration, and second dose due date), and give them to each patient who receives vaccine to ensure a basic vaccination record is provided. Vaccination providers should encourage vaccine recipients to take a picture of the vaccine card with their cell phone to remind them of the next due date for the second dose, and keep the card in case the CVMS or other system is not available when they return for their second dose.
☐	9. Enrolled HCP Organization Only: Train your designated vaccine administrators on how to report an adverse event in VAERS following a COVID-19 vaccine administration.	Per the CDC COVID-19 Vaccination Program Provider Agreement, COVID-19 vaccination providers are required to report adverse events following COVID-19 vaccination and should report clinically important adverse events even if they are not sure if the vaccination caused the event. https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html

Communications:

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☐	Action Item	Supporting Information
☐	10. Consider developing internal FAQs for your organization to help employees understand the COVID-19 vaccination process.	This document could include details on the specific process for employees to schedule and receive the COVID-19 vaccine, determining if eligible employees/individuals should pre-register in CVMS or register upon arriving to receive the vaccine, timing on when the COVID-19 vaccine is expected to be received, where to go to learn more about the COVID-19 vaccines, and your organization's policy or expectations on employees getting the COVID-19 vaccine.
☐	11. Develop and distribute communications to identified employees or individuals that were uploaded into CVMS on the process, timing, and logistics to receive the COVID-19 vaccine (two doses).	Communications could provide the identified employees or individuals the following key points: 1. They were identified by the organization as being eligible for inclusion in the first Priority Tier to receive the COVID-19 vaccine. 2. Their name and email address were uploaded into the State of North Carolina's COVID-19 Vaccine Management System (CVMS). 3. They will receive an email from CVMS with instructions on how to complete their registration to receive the COVID-19 vaccine. 4. They will receive additional details on when and where they should go to receive the two doses of the COVID-19 vaccine once the vaccines are received by the organization. 5. Where they can view any developed FAQs or other resources related to the COVID-19 vaccination program. Who they can contact within the organization with any questions related to the COVID-19 vaccination program..

Vaccine Administration Preparation:

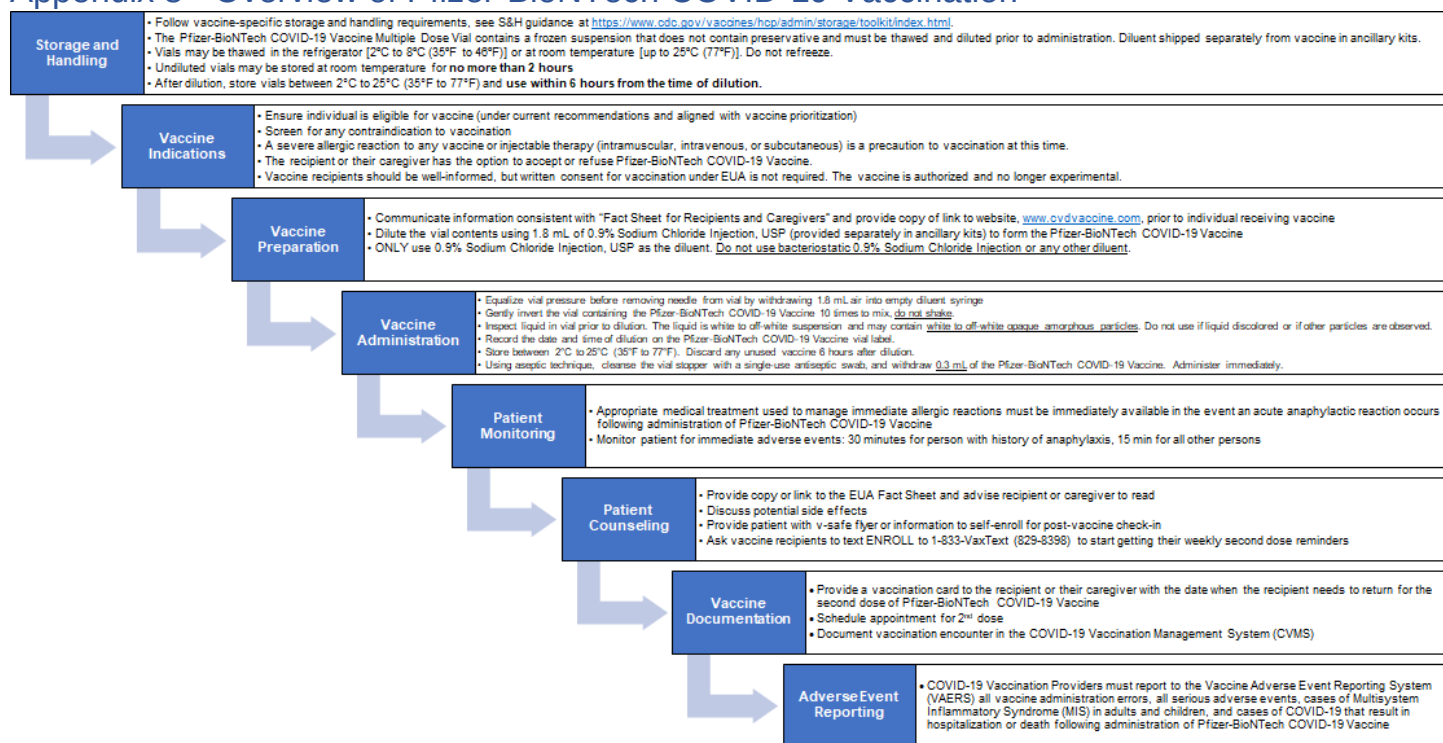
☐	Action Item	Supporting Information
☐	12. Determine process for prioritizing and scheduling employees or individuals to receive the COVID-19 vaccine (two doses) and logistics on where employees or individuals will need to go to receive the COVID-19 vaccine.	The Pfizer and Moderna COVID-19 vaccines require two doses. The minimum number of days between the first and second dose is expected to be 21 calendar days for the Pfizer vaccine and 28 calendar days for the Moderna vaccine.
☐	13. Enrolled HCP Organization Only: Understand how to view status of COVID-19 vaccine shipments to your organization in CVMS.	Training materials for shipment handling can be found at the link below: https://immunize.nc.gov/providers/ncip/training/CVMS%20Provider%20Portal%20Receiving%20and%20Processing%20Vaccine%20Shipments%20User%20Guide.pptx

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☐	Action Item	Supporting Information
☐	14. Enrolled HCP Organization Only: If storing the Pfizer vaccine in an ultra-cold freezer, ensure proper equipment and processes are being used (non-exhaustive list): - Freezer must hold vaccine at a temperature of -80°C to -60°C (-112°F to -76°F) - Use a Digital Data Logger (DDL) for temperature monitoring - For accurate ultra-cold temperature monitoring, it is essential to use an air-probe as opposed to pure propylene glycol - Ensure the DDL has an alarm for out of range temperatures, low battery alarm, and displays current/min/max temperatures - Ensure DDL has current and valid certificate of calibration	Please see Appendix 10 and Appendix 11 for information on storing the Pfizer vaccine. https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html https://www.cvdvaccine-us.com/product-storage-and-dry-ice
☐	15. Enrolled HCP Organization Only: If storing the Pfizer vaccine in an ultra-cold freezer, ensure capacity. Each tray contains 195 vials and is roughly 9"x9"x1.6" inches.	
	16. Enrolled HCP Organizations Only: If storing the Pfizer vaccine in dry-ice, ensure proper equipment and processes are being used (non-exhaustive list): - Locate a dry-ice vendor - Create an account with the identified Dry-Ice vendor - Discuss and coordinate anticipated needs with the dry-ice vendor	Please see Appendix 10 and Appendix 11 for information on storing the Pfizer vaccine. https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html https://www.cvdvaccine-us.com/product-storage-and-dry-ice
☐	17. Enrolled HCP Organization Only: Obtain copy of Emergency Use Authorization Fact Sheet for each COVID-19 vaccine product your organization receives and establish process to provide a printed copy of this document to each recipient prior to administration of the vaccine (both first and second dose).	Please see Appendix 1. Link to the Emergency Use Authorization Fact Sheet can be found in the link below: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine
☐	18. Enrolled HCP Organization Only: Establish process to provide a printed copy of the v-safe Information Sheet to each recipient after administration of the COVID-19 vaccine (both first and second dose) to support adverse effect monitoring.	Please see Appendix 4 for the v-safe Information Sheet.

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Appendix 8 - Overview of Pfizer-BioNTech COVID-19 Vaccination



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Appendix 9 – Immunizations for Children and Adolescents: FAQ about NC Law



Immunizations for Children and Adolescents: Frequently Asked Questions about North Carolina's Laws

Jill Moore

Immunization laws have existed in the United States since the 1800s. The earliest laws required vaccination against smallpox. Later laws extended the requirements to include immunization against other highly feared diseases such as polio, or widely prevalent diseases such as measles. Many of the early laws required immunization only when there was an outbreak in a community, but in the 1960s and 1970s there was a shift toward laws designed to achieve universal immunity against particular diseases by requiring children to be immunized. Today every state has laws requiring children to be immunized.¹

In North Carolina, laws requiring childhood immunizations have been in place for over fifty years. Recently, changes in immunization practices—especially the introduction of new vaccines and new immunization schedules—have raised new questions about the application of long-standing laws. Changes in how immunizations are viewed by the public have also provoked a number of legal questions.

This bulletin uses a question and answer format to provide guidance about several current issues in the application of North Carolina's childhood and adolescent immunization laws. The bulletin is organized into topic areas for quick reference.

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1. Lawrence O. Gostin, *Public Health Law: Power, Duty, Restraint*, 2d ed. (Berkeley and Los Angeles, Calif.: University of California Press, 2008), 379–80. The constitutionality of laws requiring immunization was tested early in the 20th century. In 1905 the United States Supreme Court upheld a law mandating smallpox vaccinations, concluding that the law was a legitimate exercise of a state's police power—that is, the general power of government to protect the health and safety of its citizens. *Jacobson v. Massachusetts*, 197 U.S. 11 (1905). The North Carolina Supreme Court upheld a similar law five years earlier. *State v. Hay*, 126 N.C. 999, 35 S.E. 459 (1900).



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Basic Childhood Immunization Requirements

1. Does North Carolina law require children to be immunized?

Yes. A state statute requires “[e]very child present in this state” to be immunized against certain diseases. The person responsible for ensuring a child is immunized is the child’s parent, guardian, person standing in loco parentis, or other person or agency with legal custody of the child.²

A state rule specifies which vaccines are required, how many doses of each are required, and when a child should receive each dose.³ For example, the rule requires four doses of polio vaccine: two before the child reaches the age of five months, a third before the child reaches nineteen months, and a fourth before the child enters school. Children must be immunized according to this schedule, which appears in the North Carolina Administrative Code—a multivolume document that contains rules adopted by administrative agencies.⁴ Such rules are effective statewide and have the force of law.

The rule establishing the schedule identifies some limited circumstances in which a child or adolescent is not required to have a particular vaccine. For example, the varicella (chickenpox) vaccine is not required for a child who has a documented history of having had chickenpox.⁵

The state health director has the authority to temporarily suspend an immunization requirement under certain emergency conditions, such as a shortage of the required vaccine. When the state health director takes this action, the North Carolina Department of Health and Human Services (DHHS) must give written notice of the suspension to local health departments and other health care providers who receive state-supplied vaccine. Additionally, DHHS must notify health departments and providers in writing when the suspension is lifted. When a child misses an immunization as a result of such a suspension, the required immunization schedule must be resumed within ninety days after the suspension is lifted.⁶

2. How are childhood immunizations documented?

North Carolina law requires health care providers who administer required vaccines to provide a certificate of immunization for each child the provider immunizes. The certificate must include specific information, including the child’s name, date of birth, and sex; the number of doses of vaccine given and the dates given; and the name and address of the health care provider who administered the vaccine.⁷ North Carolina vaccine providers who use the North Carolina Immunization Registry (NCIR) can produce the certificate of immunization by creating a report called “Immunization Record-Patient Copy.”⁸

2. N.C. GEN. STAT. (hereinafter G.S.) § 130A-152.

3. North Carolina Administrative Code, title 10A, subchapter 41A, section .0401 (typically cited in state government documents as 10A N.C.A.C. 41A .0401).

4. Immunization rules are adopted by the North Carolina Commission for Public Health. G.S. 130A-152(c) (authorizing the Commission to adopt rules implementing an immunization program); *see also* G.S. 130A-29 (establishing the Commission and giving it rule-making authority).

5. 10A N.C.A.C. 41A .0401(a)(8)(A).

6. 10A N.C.A.C. 41A .0401(c).

7. G.S. 130A-154.

8. NCIR User Manual, Chapter 10: Reports and Forms, at 10.3 (available at www.immunizenc.com/images/PDFs/Reports_and_Forms.pdf).



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3. Are there any exemptions or exceptions to the immunization requirements?

Yes. There are two exemptions: one for children with medical contraindications,⁹ and one for children whose parents or guardians have bona fide religious objections to immunization.¹⁰ North Carolina law does not recognize a nonreligious “philosophical” or “personal” exemption to immunizations.¹¹

Medical Exemptions

4. Who qualifies for a medical exemption?

A child with a medical contraindication to an immunization may qualify for this exemption. In most cases the contraindication must be one that is recognized in the most recent version of the general recommendations of the federal Advisory Committee on Immunization Practices (ACIP).¹² The recommendations identify both *contraindications* to vaccination and *precautions*. According to ACIP, if a child has a contraindication, the vaccine should not be administered. If a child has a precaution, the vaccine should not be administered at the time the precaution is present (most precautions are temporary and the vaccine may be administered at a later date).¹³

There is a limited exception to the general rule that a contraindication must be recognized by ACIP—upon request of a licensed physician, the state health director may grant a medical exemption for a contraindication that is not on the list.¹⁴

5. How is a medical exemption documented?

A licensed physician must certify that the immunization is medically contraindicated for the child.¹⁵ In most cases, the physician may use a form developed by the North Carolina Immunization Branch.¹⁶ The form provides boxes for a physician to check to indicate which contraindication or precaution the child has, and a space for indicating the length of time the exemption applies. The check-boxes reflect the contraindications and precautions recognized by ACIP. The

9. G.S. 130A-156.

10. G.S. 130A-157.

11. 10A N.C.A.C. 41A .0403 (“[T]here is no exception to these requirements for the case of a personal belief or philosophy of a parent or guardian not founded upon a religious belief.”).

12. G.S. 130A-156 authorizes the Commission for Public Health to develop a list of medical contraindications. Instead of creating its own list, the Commission has adopted the ACIP’s General Recommendations. See 10A N.C.A.C. 41A .0404. ACIP was established to advise and guide the U.S. Secretary of Health and Human Services and the Centers for Disease Control and Prevention on the control of vaccine-preventable diseases. See Charter, Advisory Committee on Immunization Practices (2008), available at www.cdc.gov/vaccines/recs/acip/charter.htm.

13. Andrew T. Kroger, William L. Atkinson, Edgar K. Marcuse, and Larry K. Pickering. *General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP)*. 55 Morbidity & Mortality Weekly Report 1 (December 1, 2006), available at www.cdc.gov/mmwr/preview/mmwrhtml/rr5515a1.htm.

14. G.S. 130A-156.

15. *Id.* The statute specifies that the physician must be licensed to practice medicine in North Carolina.

16. The form is available for download through the Immunization Branch’s website. Go to www.immunizenc.com/forms.htm and click on “Medical Exemption Statement” (DHHS Form 3987).



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medical exemption statement may be presented to schools, day cares, or others to document the child's exemption. Neither physicians nor parents are required to submit it to the state for approval.

However, if the physician is seeking to certify a medical exemption for a child for a contraindication that is *not* listed on the form, the form may not be used. Instead, the physician must submit a written request for the exemption to the state health director. If the medical exemption is granted, the state health director will provide a letter verifying the exemption and this letter serves as documentation of the exemption.

6. Does a physician's note that a child has not been immunized for medical reasons constitute adequate certification of a medical exemption?

The law does not require physicians to use the state's Medical Exemption Statement. A physician may provide a note instead, but to constitute a valid certification of a medical exemption, the note must meet specific criteria. It must be written by a physician licensed to practice in North Carolina and it must certify that the child has a medical contraindication to vaccination that is recognized by ACIP or has been approved by the state health director, and state all of the following: the basis for the exemption, the specific vaccine or vaccines the child should not receive, and the length of time the exemption will apply.¹⁷ The document should also include the child's name and date of birth, clearly identify the certifying physician, and be signed and dated by the physician.

Thus whether a note is adequate depends on the contents of the note. For example, a note that states only that a child was "not immunized for medical reasons" would not be adequate certification of a medical exemption.

7. May a physician certify a medical exemption for a child whose parents choose to follow an alternative (usually slower) schedule for immunizations?

A physician may certify a medical exemption only if a child has a medical contraindication or precaution that is recognized by ACIP or has been approved by the state health director. If a child has such a contraindication or precaution, and as a result an alternative immunization schedule is indicated, the physician may certify the medical exemption. However, if the child does not have a contraindication or precaution for which an alternative schedule is indicated, the child does not qualify for medical exemption.

Religious Exemptions

8. Who qualifies for a religious exemption?

A parent, guardian, or person standing in loco parentis who has bona fide religious beliefs that are contrary to the immunization requirements may obtain a religious exemption for his or her child. The objections must be based on *religious* beliefs for this exemption to apply. State law explicitly states that the religious exemption does not include personal or philosophical objections to immunization that are not founded upon a religious belief.¹⁸

17. 10A N.C.A.C. 41A .0404.

18. 10A N.C.A.C. 41A .0403.



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9. Is a person required to belong to a particular religion or denomination to qualify for this exemption?

No. North Carolina's religious exemption law does not require affiliation with any particular religion or denomination.

10. How is a religious exemption documented?

North Carolina's religious exemption law requires "a written statement of the bona fide religious beliefs and opposition to the immunization requirements."¹⁹ The state does not provide a religious exemption form, but the North Carolina Immunization Branch website offers advice on how to claim a religious exemption.²⁰ The written statement need not be prepared by an attorney or notarized, nor must it be submitted to or approved by the state.

Immunizations and School or Day Care

11. Must a child be immunized before attending school or day care?

North Carolina's childhood immunization requirements apply to all children, not just those enrolling in school or day care. "Every child present in this state" must be immunized according to the schedule in the state immunization rules.²¹

Thus North Carolina's childhood immunization requirements are not triggered by school or day care enrollment—but they are reinforced by it. When a child enrolls in school or day care, the child's parent or other responsible person must present a certificate of immunization verifying that the child has received the immunizations required by law.²² This requirement applies to public, private, and religious schools that serve children in grades pre-K through 12, and to licensed or registered child day care facilities.

12. May children who have medical or religious exemptions from the requirements attend school or day care?

Yes, if proper documentation of the exemption is provided to the school or day care in lieu of the certificate of immunization. If there is an outbreak of a vaccine-preventable disease in the school or day care, children with exemptions may be excluded from school or day care for the duration of the outbreak.²³

13. Are children who are homeschooled required to be immunized?

Yes. Again, this is because North Carolina law extends the immunization requirements to "[e]very child present in this state." Home schools in North Carolina are required by law to

19. G.S. 130A-157.

20. See www.immunizenc.com/Exemptions.htm.

21. G.S. 130A-152; 10A N.C.A.C. 41A .0401.

22. G.S. 130A-155.

23. G.S. 130A-145 (authorizing local health directors to exercise quarantine authority); 130A-2(7a) (defining "quarantine authority" to include the authority to limit the freedom of movement of unimmunized individuals during an outbreak).

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maintain immunization records for each child being homeschooled.²⁴ If a homeschooled child qualifies for an exemption from the immunization requirements, the home school must maintain documentation of the exemption.

Consent for Immunizations

14. Does a health care provider need consent to immunize a child?

Yes. Because immunizations are required by law, health care providers sometimes believe consent is not necessary. It is true that when a medical treatment is required by law, refusing the treatment can have legal consequences for the person who refuses.²⁵ However, those consequences are carried out in courts, not in health care providers' offices. Therefore, it is not appropriate for a health care provider to attempt to immunize a child without the consent of either the child's parent or another person authorized by law to give consent.

15. Who is authorized by law to give consent for a child's immunization?

Under North Carolina law, the following people can give consent for a minor child's immunization:

- A parent
- A legal guardian
- A person standing in loco parentis
- Any adult (a person age 18 or older) who signs a statement affirming that he or she has been authorized by the child's parent to obtain the immunization for the child²⁶
- The department of social services, if it has custody of the child²⁷
- In some cases—generally involving adolescents or teens—the minor child himself or herself²⁸

16. Who is a "legal guardian"?

A legal guardian is a person who has gone through formal legal proceedings and has obtained a court order granting guardianship of a child.²⁹

24. G.S. 115C-564 requires a home school to comply with either the legal requirements pertaining to church/religious schools or those pertaining to other qualified nonpublic (private) schools. The home school is permitted to choose which requirements it wishes to comply with, but in either case, the requirements specify that immunization records must be maintained. *See* G.S. 115C-548 (requiring church/religious schools to maintain the records); G.S. 115C-556 (requiring other nonpublic schools to maintain the records).

25. For more information about the potential legal consequences of refusing required immunizations, see question 23.

26. G.S. 130A-153(d).

27. G.S. 7B-903(a)(2)c.; 130A-152(a).

28. G.S. 90-21.5(a).

29. A district court may appoint a guardian for a child who is the subject of a juvenile proceeding, if the court finds that appointment of a guardian is in the child's best interest. G.S. 7B-600 (appointment of a guardian for a child who is abused, neglected, or dependent); 7B-2001 (appointment of a guardian for a child who is undisciplined or delinquent). A clerk of superior court may appoint a guardian for a child who does not have a parent. G.S. 35A-1203(a).



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17. Who is a “person standing in loco parentis”?

A “person standing in loco parentis” (PILP) is an adult who has taken on parental responsibility for a child without going through formal legal guardianship or adoption proceedings. A PILP can be hard to identify. Since there has been no formal court proceeding, there is no court order or other document stating that he or she is a PILP.

As a matter of practice, the key to identifying a PILP is to look for evidence that a person is more than just a regular babysitter—that he or she is truly acting as the child’s *parent* by taking on the duties associated with actually rearing the child, such as providing basic necessities (shelter, food) and financial support, ensuring that the child goes to school, and supervising the child or arranging for the child’s supervision.

18. When may an adult who is not a parent, guardian, or PILP give permission for a child’s immunizations?

North Carolina law allows a physician or local health department to immunize a minor who is presented for immunization by *any* adult who signs a statement that he or she has been authorized by the child’s parent, guardian, or PILP to obtain the immunization.³⁰ Any person age 18 or older who signs the statement that the parent, guardian, or PILP has authorized the immunization may fall under this provision. It could be a grandparent or other adult relative, but it could also be an unrelated adult, such as a babysitter.

19. When may a department of social services (DSS) give permission for a child’s immunizations?

A county department of social services may give permission for the immunization of a child in its custody. The immunization laws specifically state that agencies with legal custody of children are responsible for obtaining immunizations that are required by law.³¹ Furthermore, a child welfare law permits DSS to consent to routine or emergency medical care for children in its custody (unless there is a court order to the contrary).³² The North Carolina Court of Appeals has held that children in DSS custody as a result of parental neglect may be immunized with DSS’s permission, even if the parents have a religious objection to immunization.³³

20. When may a minor child (a person under age 18) give consent for his or her own immunizations?

A North Carolina law, commonly known as the minor’s consent law, allows physicians to accept the consent of an unemancipated minor in some circumstances. First, the minor must have the decisional capacity to give informed consent (in other words, the minor must be competent to make health care decisions).³⁴ Second, the law permits unemancipated minors to give con-

30. G.S. 130A-153(d). We sometimes say that an adult who presents a child for immunization under this provision has “consented” to the immunization, but strictly speaking, this is incorrect. The parent, guardian, or person standing in loco parentis has decided to permit the immunization. The nonparent is simply acting on behalf of the parent, guardian, or PILP by presenting the child to the health care provider.

31. G.S. 130A-152.

32. G.S. 7B-903(a)(2)c.

33. *In re Stratton*, 153 N.C. App. 425, 571 S.E.2d 234, *reconsideration dismissed, appeal dismissed, and discretionary review denied*, 336 N.C. 436, 573 S.E.2d 513 (2002).

34. Decisional capacity is discussed in more detail later in this document. See question 34.



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sent only for medical services that prevent, diagnose, or treat particular conditions—including venereal diseases and reportable communicable diseases.³⁵ Most of the immunizations that are required or recommended for children and adolescents prevent either venereal diseases or communicable diseases that are reportable under North Carolina law.³⁶ Therefore, a minor who has the decisional capacity to give informed consent may consent to those immunizations. For more questions and answers about a minor's consent to immunizations, see the section below titled "Special Issues with Adolescent Immunizations."

21. Does consent for immunizations need to be in writing? Should a parent (or other authorized person) sign something before a child is immunized?

With one notable exception (see the next paragraph), whether to obtain a signature is a judgment call for the health care provider to make. No law requires a provider to obtain consent for immunizations in writing. Nevertheless, health care providers' attorneys sometimes advise them to obtain consent in writing, because if the question of whether a health care provider had consent to give a particular immunization is ever disputed, a signature is evidence that consent was given.³⁷ Different attorneys may advise differently; therefore, health care providers should seek and follow their own attorneys' advice on this issue.

There is one case in which a signature is required. If the child is presented for immunization by an adult who has been authorized by the parent, guardian, or PILP to obtain the immunization, that adult *must* sign a statement affirming that he or she has been authorized by the parent, guardian, or PILP to obtain the immunization. The law specifically requires a signature in this case.³⁸

Refusal of Immunizations

22. What should a health care provider do if a parent refuses to have his or her child immunized?

No North Carolina law addresses this situation specifically, but it is advisable for the health care provider to take steps to ensure that it is an informed refusal. The provider can explain to the parent the following:

- The purpose of the immunization, its risks and benefits
- The medical consequences of refusing to immunize the child

35. G.S. 90-21.5(a). Emancipated minors may give effective consent to any medical treatment, G.S. 90-21.5(b), except an unmarried, emancipated minor may not consent to sterilization. *See* G.S. 90-272. A minor may be emancipated only by marriage or a court decree of emancipation. G.S. Ch. 7B, Art. 35. A minor who is serving in the U.S. armed forces is effectively emancipated and may consent to any medical treatment, except sterilization, if he or she is unmarried. G.S. 7B-3402; 90-272.

36. *See* 10A N.C.A.C. 41A .0101 for the complete list of communicable diseases that are reportable in North Carolina.

37. *See* G.S. 90-21.13(b) ("A consent which is evidenced in writing . . . which is signed by the patient or other authorized person, shall be presumed to be a valid consent.").

38. G.S. 130A-153(d) (authorizing physicians and local health departments to immunize "a minor who is presented for immunization by an adult who *signs a statement* that he or she is authorized by a parent, guardian, or person standing in loco parentis to obtain the immunization for the minor" (emphasis added)).



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- The North Carolina law that requires immunization
- The legal consequences of refusing to immunize the child

23. What are the legal consequences of refusing to immunize a child?

In North Carolina, if a parent refuses immunizations for a child who does not qualify for a medical or religious exemption, there are several potential legal consequences. The most likely consequence is that the child may be prohibited from enrolling in public or private school or day care.³⁹ Also, the child may be quarantined if there is an outbreak of the disease the immunization prevents.⁴⁰

Other legal consequences are possible, though perhaps less likely to be pursued. For example, any person in North Carolina who violates a state public health law or rule commits a misdemeanor and may be criminally prosecuted.⁴¹ Although this method is not often used to enforce the immunization laws, it is available as a legal remedy. Another remedy that is available to public health officials is a civil (noncriminal) action: a local health director may seek a court order compelling a person to comply with the immunization laws.⁴²

24. The American Academy of Pediatrics (AAP) has a form, "Refusal to Vaccinate" that some providers use with parents who refuse to immunize their children. What is the legal effect of this form? Should health care providers ask parents who refuse immunizations to sign it?

Whether or not to use this form is a decision for the health care provider. However, it is important for both the provider and the parent to understand what the form is, and perhaps more importantly, what it is not.

The AAP form is not a means for obtaining a legal exemption to North Carolina's immunization requirements. As explained earlier in this document, a child is legally exempt from the requirements only if the child has a medical contraindication to the immunization or the parent has a bona fide religious objection to the immunization requirements.⁴³

The AAP form is not proper documentation of an exemption for a child who qualifies for an exemption. The state provides a form for health care providers to document medical exemptions.⁴⁴ The state does not provide a form for documenting religious exemptions, but the Immunization Branch website explains the written statement a parent should prepare to request a religious exemption.⁴⁵

The AAP form is evidence that the provider has offered immunization and given the parent important information to attempt to ensure that the parent's refusal of the immunization is an informed refusal. More information on the form and the AAP's recommendations regarding its use are available on the Internet.⁴⁶

39. G.S. 130A-155.

40. G.S. 130A-2(7a); 130A-145.

41. G.S. 130A-25(a).

42. G.S. 130A-18.

43. See questions 3, 4, and 8.

44. Physicians are not required to use the form, but any alternate method for documenting a medical exemption must meet the particular criteria outlined in question 6.

45. See question 10.

46. This information is available through the AAP's Childhood Immunization Support Program (www.cispimmunize.org). The form and recommendations for its use are available at www.cispimmunize.org.



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Confidentiality of Immunization Information

25. Is immunization information confidential?

Yes. Individually identifiable health information—including information about immunizations—is confidential under both North Carolina law and the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy rule (for health care providers and others who are “covered entities” under that rule).

Information about a child’s immunizations may be disclosed only when the applicable confidentiality laws permit the disclosure. A full review of those laws is beyond the scope of this bulletin. The remainder of this section addresses some of the most frequently asked questions about disclosing immunization information, but it does not provide a comprehensive treatment of every question that may arise. Providers should seek an attorney’s advice if they have questions about disclosures not addressed by these provisions, or specific questions about the application of these provisions.

26. Must a health care provider obtain a written release (or authorization) before disclosing immunization information?

Sometimes, but not always. Written permission to disclose information is required *unless* a particular provision of law allows disclosure of the information without it.

The general rule is that health information created or obtained by health care providers may not be disclosed without the permission of either the patient or, if the patient cannot make his or her own health care decisions, the patient’s personal representative.⁴⁷ The HIPAA privacy rule uses the term “authorization” to describe the permission that is required. To comply with HIPAA, an authorization must be in writing and must include particular elements spelled out in the privacy rule.⁴⁸

Under the general rule, the starting assumption is always that information may be released with authorization—but that does not mean that authorization is always required. There are a number of exceptions to the general rule, two of which are particularly relevant to the release of immunization information.

- *The “required by law” exception.* When disclosure of information is required by law, authorization is not required.⁴⁹
- *The “public health purposes” exception.* When information is disclosed to a public health agency or official that is authorized by law to collect the information for certain public health purposes (including preventing or controlling disease and conducting public health surveillance), authorization is not required.⁵⁰

.org/pro/pdf/RefusaltoVaccinate.pdf (accessed July 20, 2009).

47. 45 C.F.R. 164.508(a)(1) (establishing the general rule that written authorization is required); 164.502(g) (defining the role of personal representatives). A full discussion of personal representatives is beyond the scope of this bulletin. In most cases, the personal representative for a minor child is the child’s parent, guardian, or person standing in loco parentis. For more information about who may authorize the disclosure of a minor’s health information, see www.sog.unc.edu/programs/ncphl/ReqsForConfMedInfo/Disclosing%20Minors.pdf.

48. 45 C.F.R. 164.508(c).

49. 45 C.F.R. 164.512(a).

50. 45 C.F.R. 164.512(b).



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In North Carolina, there are a number of circumstances in which immunization information either may or must be released *without* authorization. For example, North Carolina law requires health care providers to release immunization information to schools, public health agencies, and certain others upon request.⁵¹ Authorization is not required for those disclosures.

27. When are health care providers required to disclose immunization information upon request?

North Carolina law requires health care providers to disclose immunization certificates and certain other information upon request to the following entities:

- Local health departments in North Carolina
- The North Carolina Department of Health and Human Services
- The patient's attending physician⁵²
- K–12 schools (whether public, private, or religious)
- Licensed and registered child care facilities
- Head Start programs
- Colleges and universities (whether public, private, or religious)
- Health maintenance organizations (HMOs)
- State or local health departments in other states⁵³

The information that must be disclosed upon request is the patient's name and address; name of the parent, guardian, or person standing in loco parentis; date of birth; gender; race and ethnicity; vaccine type, date and dose number administered; the name and address of the physician or local health department that administered each dose; and the existence of a medical or religious exemption, if applicable.⁵⁴

Because these disclosures are required by law, the health care provider does not need the patient's (or patient's representative's) authorization for the disclosure.

28. Suppose the local health department requests "tracking information" or asks to see the immunization records of some or all of the children served by a private health care provider. Must the provider comply with this request?

Yes. When the local health department requests this information, the health care provider must disclose the information to the health department, because North Carolina law requires health care providers to disclose immunization information to local health departments upon the department's request.⁵⁵ Authorization is not needed because this disclosure is required by law.

29. Suppose a parent refuses to immunize a child who does not qualify for an exemption to the immunization requirements. May the health care provider report the refusal to the local health department?

No. The provider may not make such a report without the parent's authorization. This may appear to contradict the answer to question 28, but the key distinction between the two ques-

51. G.S. 130A-153(c); 10A N.C.A.C. 41A .0406.

52. G.S. 130A-153(c).

53. 10A N.C.A.C. 41A .0406.

54. *Id.* See the rule for more details on the specific information to be disclosed about exemptions.

55. G.S. 130A-153(c).



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tions lies in who initiates the disclosure. Question 28 describes a situation in which the health department initiates the disclosure by requesting the information. There is a state law that requires health care providers to disclose immunization information to health departments *upon request*; thus the provider must disclose it and authorization is not required. In contrast, this question describes a circumstance in which a provider would not be responding to the health department's request, but would be initiating a disclosure by making a report. In North Carolina there is no law that either authorizes or requires a health care provider to initiate a report of an immunization refusal to the local health department. In the absence of such a law, the provider lacks the legal authority to disclose the information.

30. Suppose a school requests a copy of a child's immunization record. Must the parent give authorization for the record to be disclosed to the school?

No. North Carolina law requires health care providers to disclose immunization information upon request to public and private schools, public and private colleges and universities, and licensed and registered child care facilities.⁵⁶ Authorization is not needed because this disclosure is required by law.

31. Do confidentiality laws allow providers to enter information into the North Carolina Immunization Registry (NCIR)?

Yes. Under HIPAA, health care providers are specifically permitted to disclose information to public health authorities who are authorized by law to collect the information for certain public health purposes, including preventing and controlling diseases, and conducting public health surveillance.⁵⁷ The NCIR is maintained by the North Carolina Department of Health and Human Services (DHHS). DHHS is a public health authority as that term is defined by HIPAA,⁵⁸ and it is authorized by law to prevent and control disease and to collect information about immunizations.⁵⁹ NCIR is one means by which it carries out those duties.

32. Must a health care provider give a copy of a child's immunization record to a parent upon request?

Yes, in most cases. Under the HIPAA privacy rule, patients or their personal representatives have a "right of access" to this information.⁶⁰ The right of access includes the right to obtain a copy of the record. There are only a few limited circumstances in which this right may be denied.

Children who are immunized according to the state schedule receive most of their immunizations when they are infants or preschoolers. The child's parent (or a parent substitute, such as a legal guardian or PILP) makes decisions about the child's health care and thus is the child's "personal representative" for HIPAA purposes. Therefore, the parent is ordinarily the person

56. 10A N.C.A.C. 41A .0406.

57. 45 C.F.R. 164.512(b).

58. 45 C.F.R. 164.501 (defining "public health authority" to include state and local public health agencies and their employees).

59. G.S. 130A-5 (general authority to provide for the control of disease); 130A-153 (specific authority to collect immunization information).

60. 45 C.F.R. 164.524.



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who may exercise HIPAA's right of access to immunization records.⁶¹ There is a limited exception to this when adolescents receive immunizations on their own consent, which is discussed in more detail below in the section, "Special Issues with Adolescent Immunizations."

33. Suppose there is an unpaid balance on a child's account. Can a health care provider refuse to give the child's parent a copy of the immunization record until the bill is paid?

No. HIPAA grants patients or their personal representatives a right of access to information which includes the right to obtain a copy of a record.⁶² Although there are a few circumstances in which the right of access may be denied, they are quite limited and this circumstance is not one of them.⁶³

Special Issues with Adolescent Immunizations

34. May adolescents consent to their own immunizations?

Under North Carolina's minor's consent law, some adolescents may consent to receive immunizations on their own. The law allows physicians to accept an unemancipated minor's consent for the prevention of venereal diseases and reportable communicable diseases.⁶⁴ Most of the immunizations that are required or recommended for children and adolescents prevent either venereal diseases or communicable diseases that are reportable under North Carolina law.⁶⁵ The minor's consent law therefore authorizes physicians to accept a minor's consent for those immunizations.

The law actually says that "any" minor may give effective consent, but "any" must not be taken literally. A health care provider must not accept a minor's consent unless the minor has both *legal capacity* to consent to the treatment, and *decisional capacity* (or competence)—that is, the ability to understand health care treatment options and make informed decisions. Ordinarily, unemancipated minors lack the legal capacity to consent to their own treatment. The minor's consent law gives unemancipated minors legal capacity to consent to immunizations for venereal disease or reportable communicable diseases, but a health care provider still must deter-

61. 45 C.F.R. 164.502(g)(3).

62. 45 C.F.R. 164.524; see also question 32.

63. See also North Carolina Medical Board, Position Statement: Access to Medical Records (August 2003), available at www.ncmedboard.org/position_statements/detail/access_to_medical_records/ ("Medical records should not be withheld because an account is overdue or a bill is owed.").

64. G.S. 90-21.5 authorizes physicians and those working under their supervision to accept an unemancipated minor's consent for the prevention, diagnosis, and treatment of (1) venereal diseases and reportable communicable diseases, (2) pregnancy (but not including sterilization or abortion), (3) abuse of controlled substances or alcohol (but not including inpatient services, except in emergencies), or (4) emotional disturbance (but not including inpatient services, except in emergencies). Emancipated minors may consent to most medical services. G.S. 90-21.51(b); see also footnote 35, *supra*.

65. See 10A N.C.A.C. 41A .0101 for the complete list of communicable diseases that are reportable in North Carolina. Varicella is the only required vaccine that prevents a disease that is neither venereal nor reportable under North Carolina law. The following diseases for which vaccines are required are all reportable: diphtheria, tetanus, pertussis (whooping cough), polio, measles, mumps, rubella, haemophilus influenzae b, and hepatitis B.

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mine that a particular minor who presents himself or herself for immunization has the capacity to make that decision on his or her own.⁶⁶

35. What is the minimum age for a minor to give consent for immunizations?

The law does not establish a minimum age. It says “any minor”—but obviously, an infant cannot give consent. On the other hand, most older adolescents can. Whether or not to accept a particular minor’s consent is a decision that must be made on a case-by-case basis. Before accepting a minor’s consent, the health care provider must determine that the particular minor in question has the ability to make this health care decision for himself or herself.

36. May a minor consent to human papillomavirus (HPV) vaccination?

HPV is not reportable under North Carolina law, but state public health officials consider it a venereal disease.⁶⁷ Since the minor’s consent law permits a minor to consent to medical services that prevent venereal diseases, a minor with capacity to give informed consent may consent to the HPV vaccine.

37. Suppose a minor has capacity to consent to immunization and the provider accepts the minor’s consent. The minor would like to keep the immunization confidential from his or her parents. Can the health care provider keep this information confidential from the parents?

Ordinarily, when a minor receives treatment under North Carolina’s minor’s consent law, information about the treatment is confidential and may not be disclosed to the minor’s parent without the minor’s consent. This general rule has two exceptions, which allow the provider to give the parent information about the minor’s treatment in two circumstances:

1. if the provider believes that notifying the parent about the treatment is essential to the minor’s life or safety (in this case the provider initiates the disclosure of information), or
2. if the parent contacts the provider and asks for information about the minor’s treatment (in this case, the parent initiates the disclosure of information).⁶⁸

The application of this rule to immunization information can be complicated. A minor’s immunization record may include information about immunizations for which the minor’s parent gave consent, immunizations for which the minor gave consent, or both. When a parent consents to a child’s treatment, the parent is the child’s personal representative with respect to information about that treatment. Among other things, this means that under HIPAA the parent has a right of access to information about the treatment, as described above.⁶⁹ However, the parent is not the minor’s personal representative with respect to information about the

66. For more information about decisional capacity, see Anne Dellinger & Arlene Davis, *Health Care for Pregnant Adolescents: A Legal Guide*, 6–9, (Chapel Hill, NC: Institute of Government, 2001), available at www.adolescentpregnancy.unc.edu/pdf/HCP91901.pdf.

67. See Memorandum from Beth Rowe-West, North Carolina Immunization Branch, to Universal Childhood Vaccine Distribution Participants, *Minors’ Consent for Human Papilloma Virus (HPV) Vaccine* (April 23, 2007), available at www.immunizenc.com/images/PDFs/4-23-07%20HPV%20Minor%20Privacy.pdf.

68. G.S. 90-21.4.

69. See question 32.

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treatment the minor received upon his or her own consent under the minor's consent law.⁷⁰ Therefore, in North Carolina, a parent does not have the HIPAA right of access to information about immunizations a minor receives upon his or her own consent. Instead, parents may receive information only in accordance with the state law described in the first paragraph of this answer.

As a result, when a parent requests an immunization record that includes information about immunizations a minor received upon his or her own consent, a health care provider must decide how to respond. State law *allows* the provider to give the parent information about the immunizations to which the minor consented in this circumstance, but it does not *require* the provider to do so. Thus, the provider could choose to release a complete immunization record to a parent who requests it, even if it includes information about immunizations a minor received upon his or her own consent. Alternatively, the provider may choose not to provide information about the immunizations the minor received upon her own consent.⁷¹

Regardless of how a provider chooses to deal with disclosing the provider's own records to parents, the provider should keep in mind that he or she is required by law to release the *entire* immunization record to schools, public health agencies, and certain others upon request.⁷² It is possible that those entities will make the complete record available to a minor's parent. Thus parents might learn about an immunization a minor has received on his own consent, even if the health care provider who gave the immunization does not notify the parent. For this reason it is advisable to tell minors who receive immunizations on their own consent that the information will become part of an immunization record that may be disclosed to others, potentially including the minor's parents.

70. 45 C.F.R. 164.502(g)(3)(i)(A).

71. Choosing not to provide the complete immunization record to the parent is a practice that may make providers uncomfortable. See Memorandum from Beth Rowe-West, North Carolina Immunization Branch, to Universal Childhood Vaccine Distribution Program Participants, *Update to Privacy Issues as Stated in April 23, 2007 Memo, Minor's Consent for Human Papillomavirus (HPV) Vaccine* (September 17, 2007), available at www.immunizenc.com/images/PDFs/09_17_2007_HPV_memo.pdf (acknowledging provider concerns with an earlier memorandum that addressed this issue). Providing a partial record is supported by G.S. 90-21.4, but it is appropriate for providers to consider other professional and practical concerns as well in deciding how to handle this situation.

72. 10A N.C.A.C. 41A .0406 (requiring disclosures to schools and others upon request); see also question 27.

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Appendix 10 – Pfizer Storage and Handling Checklist

As of 12/10/2020

CHECKLIST

for storage, handling, and preparation of the Pfizer-BioNTech COVID-19 Vaccine

Current as of December 10, 2020. For the most up-to-date
version, visit www.cvdvaccine.com.

Operation Warp Speed has requested that prior to the potential FDA authorization of the Pfizer-BioNTech Covid-19 Vaccine, Pfizer send select training materials containing information for properly storing, preparing and administering the vaccine to anticipated vaccination sites. Although there is no guarantee that the vaccine will be authorized by FDA, given the urgency of the pandemic, providing these materials in advance will enhance sites' preparation. Materials, specifications and assumptions are subject to change. For the most up-to-date materials upon authorization, please visit www.cvdvaccine.com. Pfizer will not begin shipment of the vaccine unless and until FDA has granted an Emergency Use Authorization.



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Change Log

Version	History of Changes
01	Initial version



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Storage and Handling of the Vaccine and Thermal Shipping Container

Review the following instructional materials on www.cvdvaccine.com:

- | | |
|--|---|
| ☐ Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) | ☐ Dry Ice Replenishment Requirements |
| ☐ Full EUA Prescribing Information | ☐ Returning the Thermal Shipping Container Video |
| ☐ Storage and Handling Video | ☐ Thermal Shipping Container Return Instructions |
| ☐ Preparation and Administration Video | ☐ ULT Vendor List |
| ☐ The S.T.E.P.S. to Pfizer-BioNTech COVID-19 Vaccination Infographic | ☐ Dry Ice Vendor List |

Materials checklist for storage and handling:

- | | |
|--|---|
| ☐ Safety goggles or safety glasses with side shields | If using the thermal shipping container as temporary storage: |
| ☐ Waterproof insulated gloves | ☐ Identify dry ice supply (ice pellets 10-16 mm, for re-icing) |
| ☐ Box cutter or tool to open box | ☐ Dry ice scoop |
| ☐ Hand truck or dolly to move the thermal shipping container, which can weigh up to 36.5 kg (81 lb) | ☐ Temperature-monitoring device |
| ☐ Ultra-low-temperature (ULT) freezer (if possible) | ☐ Packing tape or equivalent |

Before receiving the thermal shipping container, you must have:

- ☐ A well-ventilated room set up to safely handle the thermal shipping container and dry ice
- ☐ An appropriate area for discarding dry ice so it can sublime from a solid to a gas
- ☐ A method for tracking to ensure the re-icing protocol is being followed (if using the thermal shipping container as temporary storage)
- ☐ Proper security so only authorized personnel can access the thermal shipping container contents
- ☐ Access to an occupational health department that can be consulted to ensure appropriate safeguards

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Thawing, Dilution, and Preparation

Materials checklist for vaccine preparation:

- ☐ Refrigerator (for thawing and to maintain thawed vaccine vials at a temperature of 2°C to 8°C [35°F to 46°F])
- ☐ 3-mL or 5-mL syringe (for dilution)
- ☐ 21-gauge or narrower needle (for dilution)
- ☐ 1-mL Luer-lock syringe (for administration) and needles appropriate for intramuscular injection
- ☐ Personal protective equipment (including gloves that allow manual dexterity)
- ☐ Vials of 0.9% Sodium Chloride Injection, USP (for one-time use)
- ☐ Vaccine vials
- ☐ Antiseptic swabs
- ☐ Sharps container for disposal

Please see Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Full EUA Prescribing Information at www.cvdvaccine.com

CONNECT WITH US

For general questions about the Pfizer-BioNTech COVID-19 Vaccine, visit:

www.cvdvaccine.com



1-877-VAX-C019

(1-877-829-2619)



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Operation Warp Speed has requested that prior to the potential FDA authorization of the Pfizer-BioNTech Covid-19 Vaccine, Pfizer send select training materials containing information for properly storing, preparing and administering the vaccine to anticipated vaccination sites. Although there is no guarantee that the vaccine will be authorized by FDA, given the urgency of the pandemic, providing these materials in advance will enhance sites' preparation. Materials, specifications and assumptions are subject to change. For the most up-to-date materials upon authorization, please visit www.cvdvaccine.com. Pfizer will not begin shipment of the vaccine unless and until FDA has granted an Emergency Use Authorization.



Manufactured by
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BIONTECH

Manufactured for
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55131 Mainz, Germany

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December 2020



Appendix 11 – Pfizer Storage and Handling Overview

As of 12/06/2020

Shipping, Handling & Storage Overview

Current as of December 6, 2020

Breakthroughs that change patients' lives

Current as of December 2020, Operation Warp Speed has requested that prior to the potential FDA authorization of the Pfizer-BioNTech Covid-19 Vaccine, Pfizer send select training materials containing information for properly storing, preparing and administering the vaccine to anticipated vaccination sites. Although there is no guarantee that the vaccine will be authorized by FDA, given the urgency of the pandemic, providing these materials in advance will enhance sites' preparation. Materials, specifications and assumptions are subject to change. For the most up-to-date materials upon authorization, please visit www.cvdvaccine.com. Pfizer will not begin shipment of the vaccine unless and until FDA has granted an Emergency Use Authorization. PFIZER CONFIDENTIAL.

Change Log

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Breakthroughs that
change patients' lives

Current as of December 2020, Operation Warp Speed has requested that prior to the potential FDA authorization of the Pfizer-BioNTech Covid-19 Vaccine, Pfizer send select training materials containing information for properly storing, preparing and administering the vaccine to anticipated vaccination sites. Although there is no guarantee that the vaccine will be authorized by FDA, given the urgency of the pandemic, providing these materials in advance will enhance sites' preparation. Materials, specifications and assumptions are subject to change. For the most up-to-date materials upon authorization, please visit www.cvdvaccine.com. Pfizer will not begin shipment of the vaccine unless and until FDA has granted an Emergency Use Authorization. PFIZER CONFIDENTIAL.



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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 -90°C to -60°C (-130°F to -76°F). 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 -90°C to -60°C (-130°F to -76°F) 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)



Vials 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

Current as of December 2020, Operation Warp Speed has requested that prior to the potential FDA authorization of the Pfizer-BioNTech Covid-19 Vaccine, Pfizer send select training materials containing information for properly storing, preparing and administering the vaccine to anticipated vaccination sites. Although there is no guarantee that the vaccine will be authorized by FDA, given the urgency of the pandemic, providing these materials in advance will enhance sites' preparation. Materials, specifications and assumptions are subject to change. For the most up-to-date materials upon authorization, please visit www.covidvaccine.com. Pfizer will not begin shipment of the vaccine unless and until FDA has granted an Emergency Use Authorization. PFIZER CONFIDENTIAL.

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

Current as of December 2020, Operation Warp Speed has requested that prior to the potential FDA authorization of the Pfizer-BioNTech Covid-19 Vaccine, Pfizer send select training materials containing information for properly storing, preparing and administering the vaccine to anticipated vaccination sites. Although there is no guarantee that the vaccine will be authorized by FDA, given the urgency of the pandemic, providing these materials in advance will enhance sites' preparation. Materials, specifications and assumptions are subject to change. For the most up-to-date materials upon authorization, please visit www.covidvaccine.com. Pfizer will not begin shipment of the vaccine unless and until FDA has granted an Emergency Use Authorization. PFIZER CONFIDENTIAL.

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Product Packaging Overview

Vials



2 mL Type 1 glass
preservative-free

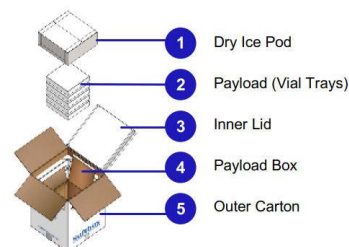
- 2 mL type 1 glass preservative free multi-dose vial (MDV)
- MDV has 0.45 mL frozen liquid drug product
- 5 doses per vial after dilution

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 -90°C to -60°C (-130°F to -76°F) 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

Current as of December 2020, Operation Warp Speed has requested that prior to the potential FDA authorization of the Pfizer-BioNTech Covid-19 Vaccine, Pfizer send select training materials containing information for properly storing, preparing and administering the vaccine to anticipated vaccination sites. Although there is no guarantee that the vaccine will be authorized by FDA, given the urgency of the pandemic, providing these materials in advance will enhance sites' preparation. Materials, specifications and assumptions are subject to change. For the most up-to-date materials upon authorization, please visit www.covidvaccine.com. Pfizer will not begin shipment of the vaccine unless and until FDA has granted an Emergency Use Authorization. PFIZER CONFIDENTIAL.

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

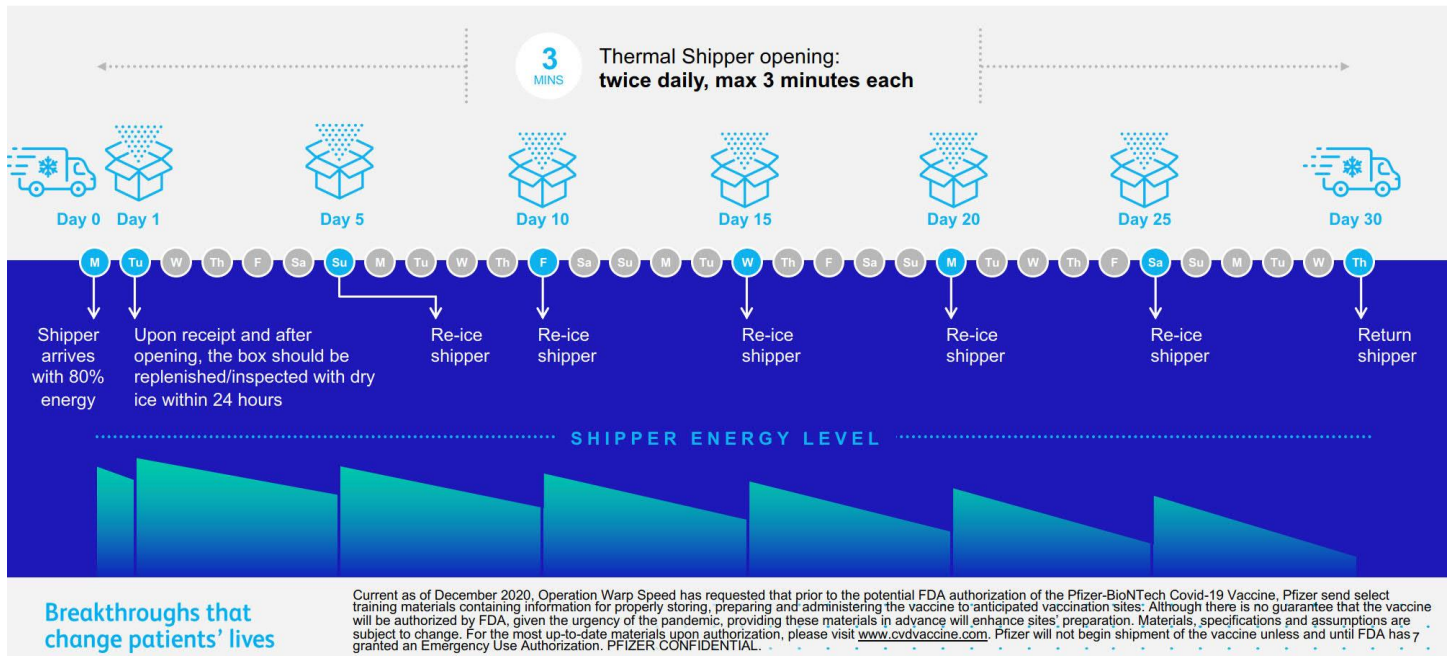
Current as of December 2020, Operation Warp Speed has requested that prior to the potential FDA authorization of the Pfizer-BioNTech Covid-19 Vaccine, Pfizer send select training materials containing information for properly storing, preparing and administering the vaccine to anticipated vaccination sites. Although there is no guarantee that the vaccine will be authorized by FDA, given the urgency of the pandemic, providing these materials in advance will enhance sites' preparation. Materials, specifications and assumptions are subject to change. For the most up-to-date materials upon authorization, please visit www.covidvaccine.com. Pfizer will not begin shipment of the vaccine unless and until FDA has granted an Emergency Use Authorization. PFIZER CONFIDENTIAL.

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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.



Appendix 12 – Bulk upload template



Recipient Bulk
Upload - ORG.xlsx

COVID-19 Vaccine LHD Toolkit

Appendix 13 – EUA Fact Sheet for Recipients and Caregivers – Moderna

COVID-19 Vaccine LHD Toolkit

FACT SHEET FOR RECIPIENTS AND CAREGIVERS EMERGENCY USE AUTHORIZATION (EUA) OF THE MODERNA COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER

You are being offered the Moderna COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the Moderna COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Moderna COVID-19 Vaccine is a vaccine and may prevent you from getting COVID-19. There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19.

Read this Fact Sheet for information about the Moderna COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Moderna COVID-19 Vaccine.

The Moderna COVID-19 Vaccine is administered as a 2-dose series, 1 month apart, into the muscle.

The Moderna COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit www.modernatx.com/covid19vaccine-eua.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?

COVID-19 is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

WHAT IS THE MODERNA COVID-19 VACCINE?

The Moderna COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19. There is no FDA-approved vaccine to prevent COVID-19.

The FDA has authorized the emergency use of the Moderna COVID-19 Vaccine to prevent COVID-19 in individuals 18 years of age and older under an Emergency Use Authorization (EUA).

For more information on EUA, see the “**What is an Emergency Use Authorization (EUA)?**” section at the end of this Fact Sheet.

COVID-19 Vaccine LHD Toolkit

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE MODERNA COVID-19 VACCINE?

Tell your vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine

WHO SHOULD GET THE MODERNA COVID-19 VACCINE?

FDA has authorized the emergency use of the Moderna COVID-19 Vaccine in individuals 18 years of age and older.

WHO SHOULD NOT GET THE MODERNA COVID-19 VACCINE?

You should not get the Moderna COVID-19 Vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine

WHAT ARE THE INGREDIENTS IN THE MODERNA COVID-19 VACCINE?

The Moderna COVID-19 Vaccine contains the following ingredients: messenger ribonucleic acid (mRNA), lipids (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate, and sucrose.

HOW IS THE MODERNA COVID-19 VACCINE GIVEN?

The Moderna COVID-19 Vaccine will be given to you as an injection into the muscle.

The Moderna COVID-19 Vaccine vaccination series is 2 doses given 1 month apart.

If you receive one dose of the Moderna COVID-19 Vaccine, you should receive a second dose of the same vaccine 1 month later to complete the vaccination series.

HAS THE MODERNA COVID-19 VACCINE BEEN USED BEFORE?

The Moderna COVID-19 Vaccine is an unapproved vaccine. In clinical trials, approximately 15,400 individuals 18 years of age and older have received at least 1 dose of the Moderna COVID-19 Vaccine.

WHAT ARE THE BENEFITS OF THE MODERNA COVID-19 VACCINE?

In an ongoing clinical trial, the Moderna COVID-19 Vaccine has been shown to prevent COVID-19 following 2 doses given 1 month apart. The duration of protection against COVID-19 is currently unknown.

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WHAT ARE THE RISKS OF THE MODERNA COVID-19 VACCINE?

Side effects that have been reported with the Moderna COVID-19 Vaccine include:

- Injection site reactions: pain, tenderness and swelling of the lymph nodes in the same arm of the injection, swelling (hardness), and redness
- General side effects: fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, and fever

There is a remote chance that the Moderna COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Moderna COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

These may not be all the possible side effects of the Moderna COVID-19 Vaccine. Serious and unexpected side effects may occur. The Moderna COVID-19 Vaccine is still being studied in clinical trials.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?

If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to **FDA/CDC Vaccine Adverse Event Reporting System (VAERS)**. The VAERS toll-free number is 1-800-822-7967 or report online to <https://vaers.hhs.gov/reportevent.html>. Please include “Moderna COVID-19 Vaccine EUA” in the first line of box #18 of the report form.

In addition, you can report side effects to ModernaTX, Inc. at 1-866-MODERNA (1-866-663-3762).

You may also be given an option to enroll in **v-safe**. **V-safe** is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. **V-safe** asks questions that help CDC monitor the safety of COVID-19 vaccines. **V-safe** also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: www.cdc.gov/vsafe.

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WHAT IF I DECIDE NOT TO GET THE MODERNA COVID-19 VACCINE?

It is your choice to receive or not receive the Moderna COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES MODERNA COVID-19 VACCINE?

Currently, there is no FDA-approved alternative vaccine available for prevention of COVID-19. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

CAN I RECEIVE THE MODERNA COVID-19 VACCINE WITH OTHER VACCINES?

There is no information on the use of the Moderna COVID-19 Vaccine with other vaccines.

WHAT IF I AM PREGNANT OR BREASTFEEDING?

If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

WILL THE MODERNA COVID-19 VACCINE GIVE ME COVID-19?

No. The Moderna COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

KEEP YOUR VACCINATION CARD

When you receive your first dose, you will get a vaccination card to show you when to return for your second dose of the Moderna COVID-19 Vaccine. Remember to bring your card when you return.

ADDITIONAL INFORMATION

If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

Moderna COVID-19 Vaccine website	Telephone number
www.modernatx.com/covid19vaccine-eua 	1-866-MODERNA (1-866-663-3762)

HOW CAN I LEARN MORE?

- Ask the vaccination provider
- Visit CDC at <https://www.cdc.gov/coronavirus/2019-ncov/index.html>
- Visit FDA at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>
- Contact your state or local public health department

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WHERE WILL MY VACCINATION INFORMATION BE RECORDED?

The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. This will ensure that you receive the same vaccine when you return for the second dose. For more information about IISs, visit: <https://www.cdc.gov/vaccines/programs/iis/about.html>.

WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?

The United States FDA has made the Moderna COVID-19 Vaccine available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The Moderna COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of the scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used during the COVID-19 pandemic.

The EUA for the Moderna COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

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Patent(s): www.modernatx.com/patents

Revised: 12/2020



Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

Barcode Date: 12/2020

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Appendix 14 – EUA Fact Sheet for Providers – Moderna

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FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS) EMERGENCY USE AUTHORIZATION (EUA) OF THE MODERNA COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, **MODERNA COVID-19 VACCINE**, for active immunization to prevent COVID-19 in individuals 18 years of age and older.

SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS

Vaccination providers enrolled in the federal COVID-19 Vaccination Program must report all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults, and cases of COVID-19 that result in hospitalization or death following administration of the Moderna COVID-19 Vaccine. See “MANDATORY REQUIREMENTS FOR THE MODERNA COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION” for reporting requirements.

The Moderna COVID-19 Vaccine is a suspension for intramuscular injection administered as a series of two doses (0.5 mL each) 1 month apart.

See this Fact Sheet for instructions for preparation and administration. This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.modernatx.com/covid19vaccine-eua.

For information on clinical trials that are testing the use of the Moderna COVID-19 Vaccine for active immunization against COVID-19, please see www.clinicaltrials.gov.

DESCRIPTION OF COVID-19

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by the novel coronavirus, SARS-CoV-2, that appeared in late 2019. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have reported a wide range of symptoms, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle and body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

DOSAGE AND ADMINISTRATION

Storage and Handling

The storage and handling information in this Fact Sheet supersedes the storage and handling information on the vial and carton labels.

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Storage Prior to Use

As Displayed on the Vial Labels and Cartons

The Moderna COVID-19 Vaccine multiple-dose vials are stored frozen between -25° to -15°C (-13° to 5°F). Store in the original carton to protect from light.

Additional Storage Information Not Displayed on the Vial Labels and Cartons

Do not store on dry ice or below -40°C (-40°F).

Vials can be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use.

Unpunctured vials may be stored between 8° to 25°C (46° to 77°F) for up to 12 hours.

Do not refreeze once thawed.

Storage After First Puncture of the Vaccine Vial

After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Discard vial after 6 hours. Do not refreeze.

Dosing and Schedule

The Moderna COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.5 mL each) 1 month apart.

There are no data available on the interchangeability of the Moderna COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of the Moderna COVID-19 Vaccine should receive a second dose of the Moderna COVID-19 Vaccine to complete the vaccination series.

Dose Preparation

- The Moderna COVID-19 Vaccine multiple-dose vial contains a frozen suspension that does not contain a preservative and must be thawed prior to administration.
- Remove the required number of vial(s) from storage and thaw each vial before use.
- Thaw in refrigerated conditions between 2° to 8°C (36° to 46°F) for 2 hours and 30 minutes. After thawing, let vial stand at room temperature for 15 minutes before administering.
- Alternatively, thaw at room temperature between 15° to 25°C (59° to 77°F) for 1 hour.
- After thawing, do not refreeze.
- Swirl vial gently after thawing and between each withdrawal. **Do not shake.** Do not dilute the vaccine.
- The Moderna COVID-19 Vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates. Visually inspect the Moderna COVID-

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19 Vaccine vials for other particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.

- Each dose is 0.5 mL.
- After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Record the date and time of first use on the Moderna COVID-19 Vaccine vial label. Discard vial after 6 hours. Do not refreeze.

Administration

Visually inspect each dose of the Moderna COVID-19 Vaccine in the dosing syringe prior to administration. The white to off-white suspension may contain white or translucent product-related particulates. During the visual inspection,

- verify the final dosing volume of 0.5 mL.
- confirm there are no other particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains other particulate matter.

Administer the Moderna COVID-19 Vaccine intramuscularly.

CONTRAINDICATION

Do not administer the Moderna COVID-19 Vaccine to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 Vaccine (*see Full EUA Prescribing Information*).

WARNINGS

Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Moderna COVID-19 Vaccine.

Monitor Moderna COVID-19 vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (<https://www.cdc.gov/vaccines/covid-19/>).

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Moderna COVID-19 Vaccine.

The Moderna COVID-19 Vaccine may not protect all vaccine recipients.

ADVERSE REACTIONS

Adverse reactions reported in a clinical trial following administration of the Moderna COVID-19 Vaccine include pain at the injection site, fatigue, headache, myalgia, arthralgia, chills, nausea/vomiting, axillary swelling/tenderness, fever, swelling at the injection site, and erythema at the injection site. (*See Full EUA Prescribing Information*)

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Moderna COVID-19 Vaccine.

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USE WITH OTHER VACCINES

There is no information on the co-administration of the Moderna COVID-19 Vaccine with other vaccines.

INFORMATION TO PROVIDE TO VACCINE RECIPIENTS/CAREGIVERS

As the vaccination provider, you must 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, including:

- 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

For information on clinical trials that are evaluating the use of the Moderna COVID-19 Vaccine to prevent COVID-19, please see www.clinicaltrials.gov.

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.

Provide the **v-safe** information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in **v-safe**. **V-safe** is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. **V-safe** asks questions that help CDC monitor the safety of COVID-19 vaccines. **V-safe** also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information, visit: www.cdc.gov/vsafe.

MANDATORY REQUIREMENTS FOR MODERNA COVID-19 VACCINE

ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION

In order to mitigate the risks of using this unapproved product under EUA and to optimize the potential benefit of the Moderna COVID-19 Vaccine, the following items are required. Use of unapproved Moderna COVID-19 Vaccine for active immunization to prevent COVID-19 under this EUA is limited to the following (all requirements **must** be met):

1. The Moderna COVID-19 Vaccine is authorized for use in individuals 18 years of age and older.
2. The vaccination provider must communicate to the individual receiving the Moderna COVID-19 Vaccine or their caregiver, information consistent with the “Fact Sheet for Recipients and Caregivers” prior to the individual receiving the Moderna COVID-19 Vaccine.

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3. The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system.
4. The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):
 - vaccine administration errors whether or not associated with an adverse event,
 - serious adverse events* (irrespective of attribution to vaccination),
 - cases of Multisystem Inflammatory Syndrome (MIS) in adults, and
 - cases of COVID-19 that result in hospitalization or death.

Complete and submit reports to VAERS online at <https://vaers.hhs.gov/reportevent.html>. For further assistance with reporting to VAERS, call 1-800-822-7967. The reports should include the words "Moderna COVID-19 Vaccine EUA" in the description section of the report.

5. The vaccination provider is responsible for responding to FDA requests for information about vaccine administration errors, adverse events, cases of MIS in adults and cases of COVID-19 that result in hospitalization or death following administration of the Moderna COVID-19 Vaccine to recipients.

* Serious adverse events are defined as:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

OTHER ADVERSE EVENT REPORTING TO VAERS AND MODERNATX, INC.

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to ModernaTX, Inc. using the contact information below or by providing a copy of the VAERS form to ModernaTX, Inc.

Email	Fax number	Telephone number
ModernaPV@modernatx.com	1-866-599-1342	1-866-MODERNA (1-866-663-3762)

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ADDITIONAL INFORMATION

For general questions, visit the website or call the telephone number provided below.

To access the most recent Moderna COVID-19 Vaccine Fact Sheets, please scan the QR code or visit the website provided below.

Website	Telephone number
www.modernatx.com/covid19vaccine-eua 	1-866-MODERNA (1-866-663-3762)

AVAILABLE ALTERNATIVES

There is no approved alternative vaccine to prevent COVID-19. There may be clinical trials or availability under EUA of other COVID-19 vaccines.

AUTHORITY FOR ISSUANCE OF THE EUA

The Secretary of the Department of Health and Human Services (HHS) has declared a public health emergency that justifies the emergency use of drugs and biological products during the COVID-19 Pandemic. In response, the FDA has issued an EUA for the unapproved product, Moderna COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 18 years of age and older.

FDA issued this EUA, based on ModernaTX, Inc.'s request and submitted data.

Although limited scientific information is available, based on the totality of the scientific evidence available to date, it is reasonable to believe that the Moderna COVID-19 Vaccine may be effective for the prevention of COVID-19 in individuals as specified in the *Full EUA Prescribing Information*.

This EUA for the Moderna COVID-19 Vaccine will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.

For additional information about Emergency Use Authorization visit FDA at:
<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

COUNTERMEASURES INJURY COMPENSATION PROGRAM

The Countermeasures Injury Compensation Program (CICP) is a federal program that has been created to help pay for related costs of medical care and other specific expenses to compensate people injured after use of certain medical countermeasures. Medical countermeasures are

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specific vaccines, medications, devices, or other items used to prevent, diagnose, or treat the public during a public health emergency or a security threat. For more information about CICP regarding the vaccines to prevent COVID-19, visit <http://www.hrsa.gov/cicp>, email cicp@hrsa.gov, or call: 1-855-266-2427.

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Patent(s): www.modernatx.com/patents

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END SHORT VERSION FACT SHEET

Long Version (Full EUA Prescribing Information) Begins On Next Page

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FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

MODERNA COVID-19 VACCINE

FULL EUA PRESCRIBING INFORMATION: CONTENTS*

- 1 AUTHORIZED USE**
- 2 DOSAGE AND ADMINISTRATION**
 - 2.1 Preparation for Administration
 - 2.2 Administration
 - 2.3 Dosing and Schedule
- 3 DOSAGE FORMS AND STRENGTHS**
- 4 CONTRAINDICATIONS**
- 5 WARNINGS AND PRECAUTIONS**
 - 5.1 Management of Acute Allergic Reactions
 - 5.2 Altered Immunocompetence
 - 5.3 Limitations of Vaccine Effectiveness
- 6 OVERALL SAFETY SUMMARY**
 - 6.1 Clinical Trials Experience
- 8 ADVERSE EVENTS AND VACCINE ADMINISTRATION
ERRORS REPORTING REQUIREMENTS AND
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- 10 DRUG INTERACTIONS**
 - 11 USE IN SPECIFIC POPULATIONS**
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 - 13 DESCRIPTION**
 - 14 CLINICAL PHARMACOLOGY**
 - 14.1 Mechanism of Action
 - 18 CLINICAL TRIAL RESULTS AND SUPPORTING DATA
FOR EUA**
 - 19 HOW SUPPLIED/STORAGE AND HANDLING**
 - 20 PATIENT COUNSELING INFORMATION**
 - 21 CONTACT INFORMATION**
- *Sections or subsections omitted from the full prescribing information are not listed

FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

1 AUTHORIZED USE

Moderna COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

2 DOSAGE AND ADMINISTRATION

For intramuscular injection only.

2.1 Preparation for Administration

- The Moderna COVID-19 Vaccine multiple-dose vial contains a frozen suspension that does not contain a preservative and must be thawed prior to administration.
- Remove the required number of vial(s) from storage and thaw each vial before use.
- Thaw in refrigerated conditions between 2° to 8°C (36° to 46°F) for 2 hours and 30 minutes. After thawing, let vial stand at room temperature for 15 minutes before administering.
- Alternatively, thaw at room temperature between 15° to 25°C (59° to 77°F) for 1 hour.
- After thawing, do not refreeze.
- Swirl vial gently after thawing and between each withdrawal. **Do not shake.** Do not dilute the vaccine.
- The Moderna COVID-19 Vaccine is a white to off-white suspension. It may contain

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white or translucent product-related particulates. Visually inspect the Moderna COVID-19 Vaccine vials for other particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.

- Each dose is 0.5mL.
- After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Record the date and time of first use on the Moderna COVID-19 Vaccine vial label. Discard vial after 6 hours. Do not refreeze.

2.2 Administration

Visually inspect each dose of the Moderna COVID-19 Vaccine in the dosing syringe prior to administration. The white to off-white suspension may contain white or translucent product-related particulates. During the visual inspection,

- verify the final dosing volume of 0.5 mL.
- confirm there are no other particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains other particulate matter.

Administer the Moderna COVID-19 Vaccine intramuscularly.

2.3 Dosing and Schedule

The Moderna COVID-19 Vaccine is administered as a series of two doses (0.5 mL each) 1 month apart.

There are no data available on the interchangeability of the Moderna COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Moderna COVID-19 Vaccine should receive a second dose of Moderna COVID-19 Vaccine to complete the vaccination series.

3 DOSAGE FORMS AND STRENGTHS

Moderna COVID-19 Vaccine is a suspension for intramuscular injection. A single dose is 0.5 mL.

4 CONTRAINDICATIONS

Do not administer the Moderna COVID-19 Vaccine to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 Vaccine [see Description (13)].

5 WARNINGS AND PRECAUTIONS

5.1 Management of Acute Allergic Reactions

Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Moderna COVID-19 Vaccine.

Monitor Moderna COVID-19 vaccine recipients for the occurrence of immediate adverse

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reactions according to the Centers for Disease Control and Prevention guidelines (<https://www.cdc.gov/vaccines/covid-19/>).

5.2 Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished response to the Moderna COVID-19 Vaccine.

5.3 Limitations of Vaccine Effectiveness

The Moderna COVID-19 Vaccine may not protect all vaccine recipients.

6 OVERALL SAFETY SUMMARY

It is MANDATORY for vaccination providers to report to the Vaccine Adverse Event Reporting System (VAERS) all vaccine administration errors, all serious adverse events, cases of Multi-inflammatory Syndrome (MIS) in adults, and hospitalized or fatal cases of COVID-19 following vaccination with the Moderna COVID-19 Vaccine. To the extent feasible, provide a copy of the VAERS form to ModernaTX, Inc. Please see the REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS section for details on reporting to VAERS and ModernaTX, Inc.

In clinical studies, the adverse reactions in participants 18 years of age and older were pain at the injection site (92.0%), fatigue (70.0%), headache (64.7%), myalgia (61.5%), arthralgia (46.4%), chills (45.4%), nausea/vomiting (23.0%), axillary swelling/tenderness (19.8%), fever (15.5%), swelling at the injection site (14.7%), and erythema at the injection site (10.0%).

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared with rates in the clinical trials of another vaccine and may not reflect the rates observed in practice.

Overall, 15,419 participants aged 18 years and older received at least one dose of Moderna COVID-19 Vaccine in three clinical trials (NCT04283461, NCT04405076, and NCT04470427).

The safety of Moderna COVID-19 Vaccine was evaluated in an ongoing Phase 3 randomized, placebo-controlled, observer-blind clinical trial conducted in the United States involving 30,351 participants 18 years of age and older who received at least one dose of Moderna COVID-19 Vaccine (n=15,185) or placebo (n=15,166) (NCT04470427). At the time of vaccination, the mean age of the population was 52 years (range 18-95); 22,831 (75.2%) of participants were 18 to 64 years of age and 7,520 (24.8%) of participants were 65 years of age and older. Overall, 52.7% were male, 47.3% were female, 20.5% were Hispanic or Latino, 79.2% were White, 10.2% were African American, 4.6% were Asian, 0.8% were American Indian or Alaska Native, 0.2% were Native Hawaiian or Pacific Islander, 2.1% were Other, and 2.1% were Multiracial. Demographic characteristics were similar among participants who received Moderna COVID-19 Vaccine and those who received placebo.

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Solicited Adverse Reactions

Data on solicited local and systemic adverse reactions and use of antipyretic medication were collected using standardized diary cards for 7 days following each injection (i.e., day of vaccination and the next 6 days) among participants receiving Moderna COVID-19 Vaccine (n=15,179) and participants receiving placebo (n=15,163) with at least 1 documented dose. Solicited adverse reactions were reported more frequently among vaccine participants than placebo participants.

The reported number and percentage of the solicited local and systemic adverse reactions by age group and dose by subject are presented in Table 1 and Table 2, respectively.

Table 1: Number and Percentage of Participants With Solicited Local and Systemic Adverse Reactions Within 7 Days* After Each Dose in Participants 18-64 Years (Solicited Safety Set, Dose 1 and Dose 2)

	Moderna COVID-19 Vaccine		Placebo ^a	
	Dose 1 (N=11,406) n (%)	Dose 2 (N=10,985) n (%)	Dose 1 (N=11,407) n (%)	Dose 2 (N=10,918) n (%)
Local Adverse Reactions				
Pain	9,908 (86.9)	9,873 (89.9)	2,177 (19.1)	2,040 (18.7)
Pain, Grade 3 ^b	366 (3.2)	506 (4.6)	23 (0.2)	22 (0.2)
Axillary swelling/tenderness	1,322 (11.6)	1,775 (16.2)	567 (5.0)	470 (4.3)
Axillary swelling/tenderness, Grade 3 ^b	37 (0.3)	46 (0.4)	13 (0.1)	11 (0.1)
Swelling (hardness) ≥25 mm	767 (6.7)	1,389 (12.6)	34 (0.3)	36 (0.3)
Swelling (hardness), Grade 3 ^c	62 (0.5)	182 (1.7)	3 (<0.1)	4 (<0.1)
Erythema (redness) ≥25 mm	344 (3.0)	982 (8.9)	47 (0.4)	43 (0.4)
Erythema (redness), Grade 3 ^c	34 (0.3)	210 (1.9)	11 (<0.1)	12 (0.1)
Systemic Adverse Reactions				
Fatigue	4,384 (38.4)	7,430 (67.6)	3,282 (28.8)	2,687 (24.6)
Fatigue, Grade 3 ^d	120 (1.1)	1,174 (10.7)	83 (0.7)	86 (0.8)
Fatigue, Grade 4 ^e	1 (<0.1)	0 (0)	0 (0)	0 (0)
Headache	4,030 (35.3)	6,898 (62.8)	3,304 (29.0)	2,760 (25.3)
Headache, Grade 3 ^f	219	553	162	129



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	Moderna COVID-19 Vaccine		Placebo ^a	
	Dose 1 (N=11,406) n (%)	Dose 2 (N=10,985) n (%)	Dose 1 (N=11,407) n (%)	Dose 2 (N=10,918) n (%)
	(1.9)	(5.0)	(1.4)	(1.2)
Myalgia	2,699 (23.7)	6,769 (61.6)	1,628 (14.3)	1,411 (12.9)
Myalgia, Grade 3 ^d	73 (0.6)	1,113 (10.1)	38 (0.3)	42 (0.4)
Arthralgia	1,893 (16.6)	4,993 (45.5)	1,327 (11.6)	1,172 (10.7)
Arthralgia, Grade 3 ^d	47 (0.4)	647 (5.9)	29 (0.3)	37 (0.3)
Arthralgia, Grade 4 ^e	1 (<0.1)	0 (0)	0 (0)	0 (0)
Chills	1,051 (9.2)	5,341 (48.6)	730 (6.4)	658 (6.0)
Chills, Grade 3 ^g	17 (0.1)	164 (1.5)	8 (<0.1)	15 (0.1)
Nausea/vomiting	1,068 (9.4)	2,348 (21.4)	908 (8.0)	801 (7.3)
Nausea/vomiting, Grade 3 ^h	6 (<0.1)	10 (<0.1)	8 (<0.1)	8 (<0.1)
Fever	105 (0.9)	1,908 (17.4)	37 (0.3)	39 (0.4)
Fever, Grade 3 ⁱ	10 (<0.1)	184 (1.7)	1 (<0.1)	2 (<0.1)
Fever, Grade 4 ^j	4 (<0.1)	12 (0.1)	4 (<0.1)	2 (<0.1)
Use of antipyretic or pain medication	2,656 (23.3)	6,292 (57.3)	1,523 (13.4)	1,248 (11.4)

* 7 days included day of vaccination and the subsequent 6 days. Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary).

^a Placebo was a saline solution.

^b Grade 3 pain and axillary swelling/tenderness: Defined as any use of prescription pain reliever; prevents daily activity.

^c Grade 3 swelling and erythema: Defined as >100 mm / >10 cm.

^d Grade 3 fatigue, myalgia, arthralgia: Defined as significant; prevents daily activity.

^e Grade 4 fatigue, arthralgia: Defined as requires emergency room visit or hospitalization.

^f Grade 3 headache: Defined as significant; any use of prescription pain reliever or prevents daily activity.

^g Grade 3 chills: Defined as prevents daily activity and requires medical intervention.

^h Grade 3 nausea/vomiting: Defined as prevents daily activity, requires outpatient intravenous hydration.

ⁱ Grade 3 fever: Defined as $\geq 39.0 - \leq 40.0^{\circ}\text{C}$ / $\geq 102.1 - \leq 104.0^{\circ}\text{F}$.

^j Grade 4 fever: Defined as $>40.0^{\circ}\text{C}$ / $>104.0^{\circ}\text{F}$.

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Table 2: Number and Percentage of Participants With Solicited Local and Systemic Adverse Reactions Within 7 Days* After Each Dose in Participants 65 Years and Older (Solicited Safety Set, Dose 1 and Dose 2)

	Moderna COVID-19 Vaccine		Placebo ^a	
	Dose 1 (N=3,762) n (%)	Dose 2 (N=3,692) n (%)	Dose 1 (N=3,748) n (%)	Dose 2 (N=3,648) n (%)
Local Adverse Reactions				
Pain	2,782 (74.0)	3,070 (83.2)	481 (12.8)	437 (12.0)
Pain, Grade 3 ^b	50 (1.3)	98 (2.7)	32 (0.9)	18 (0.5)
Axillary swelling/tenderness	231 (6.1)	315 (8.5)	155 (4.1)	97 (2.7)
Axillary swelling/tenderness, Grade 3 ^b	12 (0.3)	21 (0.6)	14 (0.4)	8 (0.2)
Swelling (hardness) ≥25 mm	165 (4.4)	400 (10.8)	18 (0.5)	13 (0.4)
Swelling (hardness), Grade 3 ^c	20 (0.5)	72 (2.0)	3 (<0.1)	7 (0.2)
Erythema (redness) ≥25 mm	86 (2.3)	275 (7.5)	20 (0.5)	13 (0.4)
Erythema (redness), Grade 3 ^c	8 (0.2)	77 (2.1)	2 (<0.1)	3 (<0.1)
Systemic Adverse Reactions				
Fatigue	1,251 (33.3)	2,152 (58.3)	851 (22.7)	716 (19.6)
Fatigue, Grade 3 ^d	30 (0.8)	254 (6.9)	22 (0.6)	20 (0.5)
Headache	921 (24.5)	1,704 (46.2)	723 (19.3)	650 (17.8)
Headache, Grade 3 ^e	52 (1.4)	106 (2.9)	34 (0.9)	33 (0.9)
Myalgia	742 (19.7)	1,739 (47.1)	443 (11.8)	398 (10.9)
Myalgia, Grade 3 ^d	17 (0.5)	205 (5.6)	9 (0.2)	10 (0.3)
Arthralgia	618 (16.4)	1,291 (35.0)	456 (12.2)	397 (10.9)
Arthralgia, Grade 3 ^d	13 (0.3)	123 (3.3)	8 (0.2)	7 (0.2)
Chills	202 (5.4)	1,141 (30.9)	148 (4.0)	151 (4.1)
Chills, Grade 3 ^f	7 (0.2)	27 (0.7)	6 (0.2)	2 (<0.1)
Nausea/vomiting	194 (5.2)	437 (11.8)	166 (4.4)	133 (3.6)
Nausea/vomiting,	4	10	4	3



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	Moderna COVID-19 Vaccine		Placebo ^a	
	Dose 1 (N=3,762) n (%)	Dose 2 (N=3,692) n (%)	Dose 1 (N=3,748) n (%)	Dose 2 (N=3,648) n (%)
Grade 3 ^g	(0.1)	(0.3)	(0.1)	(<0.1)
Nausea/vomiting, Grade 4 ^h	0 (0)	1 (<0.1)	0 (0)	0 (0)
Fever	10 (0.3)	370 (10.0)	7 (0.2)	4 (0.1)
Fever, Grade 3 ⁱ	1 (<0.1)	18 (0.5)	1 (<0.1)	0 (0)
Fever, Grade 4 ^j	0 (0)	1 (<0.1)	2 (<0.1)	1 (<0.1)
Use of antipyretic or pain medication	673 (17.9)	1,546 (41.9)	477 (12.7)	329 (9.0)

* 7 days included day of vaccination and the subsequent 6 days. Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary).

^a Placebo was a saline solution.

^b Grade 3 pain and axillary swelling/tenderness: Defined as any use of prescription pain reliever; prevents daily activity.

^c Grade 3 swelling and erythema: Defined as >100 mm / >10 cm.

^d Grade 3 fatigue, myalgia, arthralgia: Defined as significant; prevents daily activity.

^e Grade 3 headache: Defined as significant; any use of prescription pain reliever or prevents daily activity.

^f Grade 3 chills: Defined as prevents daily activity and requires medical intervention.

^g Grade 3 Nausea/vomiting: Defined as prevents daily activity, requires outpatient intravenous hydration.

^h Grade 4 Nausea/vomiting: Defined as requires emergency room visit or hospitalization for hypotensive shock.

ⁱ Grade 3 fever: Defined as $\geq 39.0 - \leq 40.0^{\circ}\text{C}$ / $\geq 102.1 - \leq 104.0^{\circ}\text{F}$.

^j Grade 4 fever: Defined as $> 40.0^{\circ}\text{C}$ / $> 104.0^{\circ}\text{F}$.

Solicited local and systemic adverse reactions reported following administration of Moderna COVID-19 Vaccine had a median duration of 2 to 3 days.

Grade 3 solicited local adverse reactions were more frequently reported after Dose 2 than Dose 1. Solicited systemic adverse reactions were more frequently reported by vaccine recipients after Dose 2 than after Dose 1.

Unsolicited Adverse Events

Participants were monitored for unsolicited adverse events for up to 28 days following each dose and follow-up is ongoing. Serious adverse events and medically attended adverse events will be recorded for the entire study duration of 2 years. As of November 25, 2020, among participants who had received at least 1 dose of vaccine or placebo (vaccine=15,185, placebo=15,166), unsolicited adverse events that occurred within 28 days following each vaccination were reported by 23.9% of participants (n=3,632) who received Moderna COVID-19 Vaccine and 21.6% of participants (n=3,277) who received placebo. In these analyses, 87.9% of study participants had at least 28 days of follow-up after Dose 2.

Lymphadenopathy-related events that were not necessarily captured in the 7-day e-Diary were reported by 1.1% of vaccine recipients and 0.6% of placebo recipients. These events included lymphadenopathy, lymphadenitis, lymph node pain, vaccination-site lymphadenopathy,

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injection-site lymphadenopathy, and axillary mass, which were plausibly related to vaccination. This imbalance is consistent with the imbalance observed for solicited axillary swelling/tenderness in the injected arm.

Hypersensitivity adverse events were reported in 1.5% of vaccine recipients and 1.1% of placebo recipients. Hypersensitivity events in the vaccine group included injection site rash and injection site urticaria, which are likely related to vaccination.

Throughout the same period, there were three reports of Bell's palsy in the Moderna COVID-19 Vaccine group (one of which was a serious adverse event), which occurred 22, 28, and 32 days after vaccination, and one in the placebo group which occurred 17 days after vaccination. Currently available information on Bell's palsy is insufficient to determine a causal relationship with the vaccine.

There were no other notable patterns or numerical imbalances between treatment groups for specific categories of adverse events (including other neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Moderna COVID-19 Vaccine.

Serious Adverse Events

As of November 25, 2020, serious adverse events were reported by 1.0% (n=147) of participants who received Moderna COVID-19 Vaccine and 1.0% (n=153) of participants who received placebo, one of which was the case of Bell's palsy which occurred 32 days following receipt of vaccine.

In these analyses, 87.9% of study participants had at least 28 days of follow-up after Dose 2, and the median follow-up time for all participants was 9 weeks after Dose 2.

There were two serious adverse events of facial swelling in vaccine recipients with a history of injection of dermatological fillers. The onset of swelling was reported 1 and 2 days, respectively, after vaccination and was likely related to vaccination.

There was one serious adverse event of intractable nausea and vomiting in a participant with prior history of severe headache and nausea requiring hospitalization. This event occurred 1 day after vaccination and was likely related to vaccination.

There were no other notable patterns or imbalances between treatment groups for specific categories of serious adverse events (including neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Moderna COVID-19 Vaccine.

8 REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS

See Overall Safety Summary (Section 6) for additional information.

The vaccination provider enrolled in the federal COVID-19 Vaccination Program is responsible for the MANDATORY reporting of the listed events following Moderna COVID-19 Vaccine to

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the Vaccine Adverse Event Reporting System (VAERS)

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events* (irrespective of attribution to vaccination)
- Cases of multisystem inflammatory syndrome (MIS) in adults
- Cases of COVID-19 that results in hospitalization or death

*Serious Adverse Events are defined as:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

Instructions for reporting to VAERS

The vaccination provider enrolled in the federal COVID-19 Vaccination Program should complete and submit a VAERS form to FDA using one of the following methods:

- Complete and submit the report online: <https://vaers.hhs.gov/reportevent.html>, or
- If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366. If you need additional help submitting a report, you may call the VAERS toll-free information line at 1-800-822-7967 or send an email to info@vaers.org.

IMPORTANT: When reporting adverse events or vaccine administration errors to VAERS, please complete the entire form with detailed information. It is important that the information reported to FDA be as detailed and complete as possible. Information to include:

- Patient demographics (e.g., patient name, date of birth)
- Pertinent medical history
- Pertinent details regarding admission and course of illness
- Concomitant medications
- Timing of adverse event(s) in relationship to administration of Moderna COVID-19 Vaccine
- Pertinent laboratory and virology information
- Outcome of the event and any additional follow-up information if it is available at the time of the VAERS report. Subsequent reporting of follow-up information should be completed if additional details become available.

The following steps are highlighted to provide the necessary information for safety tracking:

1. In Box 17, provide information on Moderna COVID-19 Vaccine and any other vaccines administered on the same day; and in Box 22, provide information on any other vaccines received within one month prior.

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2. In Box 18, description of the event:
 - a. Write "Moderna COVID-19 Vaccine EUA" as the first line
 - b. Provide a detailed report of vaccine administration error and/or adverse event. It is important to provide detailed information regarding the patient and adverse event/medication error for ongoing safety evaluation of this unapproved vaccine. Please see information to include listed above.
3. Contact information:
 - a. In Box 13, provide the name and contact information of the prescribing healthcare provider or institutional designee who is responsible for the report.
 - b. In Box 14, provide the name and contact information of the best doctor/healthcare professional to contact about the adverse event.
 - c. In Box 15, provide the address of the facility where vaccine was given (NOT the healthcare provider's office address).

Other Reporting Instructions

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to ModernaTX, Inc. using the contact information below or by providing a copy of the VAERS form to ModernaTX, Inc.

Email	Fax number	Telephone number
ModernaPV@modernatx.com	1-866-599-1342	1-866-MODERNA (1-866-663-3762)

10 DRUG INTERACTIONS

There are no data to assess the concomitant administration of the Moderna COVID-19 Vaccine with other vaccines.

11 USE IN SPECIFIC POPULATIONS

11.1 Pregnancy

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Moderna COVID-19 Vaccine during pregnancy. Women who are vaccinated with Moderna COVID-19 Vaccine during pregnancy are encouraged to enroll in the registry by calling 1-866-MODERNA (1-866-663-3762).

Risk Summary

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically

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recognized pregnancies is 2% to 4% and 15% to 20%, respectively. Available data on Moderna COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

In a developmental toxicity study, 0.2 mL of a vaccine formulation containing the same quantity of nucleoside-modified messenger ribonucleic acid (mRNA) (100 mcg) and other ingredients included in a single human dose of Moderna COVID-19 Vaccine was administered to female rats by the intramuscular route on four occasions: 28 and 14 days prior to mating, and on gestation days 1 and 13. No vaccine-related adverse effects on female fertility, fetal development or postnatal development were reported in the study.

11.2 Lactation

Risk Summary

Data are not available to assess the effects of Moderna COVID-19 Vaccine on the breastfed infant or on milk production/excretion.

11.3 Pediatric Use

Safety and effectiveness have not been assessed in persons less than 18 years of age. Emergency Use Authorization of Moderna COVID-19 Vaccine does not include use in individuals younger than 18 years of age.

11.4 Geriatric Use

Clinical studies of Moderna COVID-19 Vaccine included participants 65 years of age and older receiving vaccine or placebo, and their data contribute to the overall assessment of safety and efficacy. In an ongoing Phase 3 clinical study, 24.8% (n=7,520) of participants were 65 years of age and older and 4.6% (n=1,399) of participants were 75 years of age and older. Vaccine efficacy in participants 65 years of age and older was 86.4% (95% CI 61.4, 95.2) compared to 95.6% (95% CI 90.6, 97.9) in participants 18 to <65 years of age [see *Clinical Trial Results and Supporting Data for EUA (18)*]. Overall, there were no notable differences in the safety profiles observed in participants 65 years of age and older and younger participants [see *Clinical Trials Experience (6.1)*].

13 DESCRIPTION

Moderna COVID-19 Vaccine is provided as a white to off-white suspension for intramuscular injection. Each 0.5 mL dose of Moderna COVID-19 Vaccine contains 100 mcg of nucleoside-modified messenger RNA (mRNA) encoding the pre-fusion stabilized Spike glycoprotein (S) of SARS-CoV-2 virus.

Each dose of the Moderna COVID-19 Vaccine contains the following ingredients: a total lipid content of 1.93 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), 0.31 mg tromethamine, 1.18 mg tromethamine hydrochloride, 0.043 mg acetic acid, 0.12 mg sodium acetate, and 43.5 mg sucrose.

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Moderna COVID-19 Vaccine does not contain a preservative.

The vial stoppers are not made with natural rubber latex.

14 CLINICAL PHARMACOLOGY

14.1 Mechanism of Action

The nucleoside-modified mRNA in the Moderna COVID-19 Vaccine is formulated in lipid particles, which enable delivery of the nucleoside-modified mRNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits an immune response to the S antigen, which protects against COVID-19.

18 CLINICAL TRIAL RESULTS AND SUPPORTING DATA FOR EUA

A Phase 3 randomized, placebo-controlled, observer-blind clinical trial to evaluate the efficacy, safety, and immunogenicity of the Moderna COVID-19 Vaccine in participants 18 years of age and older is ongoing in the United States (NCT04470427). Randomization was stratified by age and health risk: 18 to <65 years of age without comorbidities (not at risk for progression to severe COVID-19), 18 to <65 years of age with comorbidities (at risk for progression to severe COVID-19), and 65 years of age and older with or without comorbidities. Participants who were immunocompromised and those with a known history of SARS-CoV-2 infection were excluded from the study. Participants with no known history of SARS-CoV-2 infection but with positive laboratory results indicative of infection at study entry were included. The study allowed for the inclusion of participants with stable pre-existing medical conditions, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 3 months before enrollment, as well as participants with stable human immunodeficiency virus (HIV) infection. A total of 30,420 participants were randomized equally to receive 2 doses of the Moderna COVID-19 Vaccine or saline placebo 1 month apart. Participants will be followed for efficacy and safety until 24 months after the second dose.

The primary efficacy analysis population (referred to as the Per-Protocol Set), included 28,207 participants who received two doses (at 0 and 1 month) of either Moderna COVID-19 Vaccine (n=14,134) or placebo (n=14,073), and had a negative baseline SARS-CoV-2 status. In the Per-Protocol Set, 47.4% were female, 19.7% were Hispanic or Latino; 79.5% were white, 9.7% were African American, 4.6% were Asian, and 2.1% other races. The median age of participants was 53 years (range 18-95) and 25.3% of participants were 65 years of age and older. Of the study participants in the Per Protocol Set, 18.5% were at increased risk of severe COVID-19 due to at least one pre-existing medical condition (chronic lung disease, significant cardiac disease, severe obesity, diabetes, liver disease, or HIV infection) regardless of age. Between participants who received Moderna COVID-19 Vaccine and those who received placebo, there were no notable differences in demographics or pre-existing medical conditions.

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Efficacy Against COVID-19

COVID-19 was defined based on the following criteria: The participant must have experienced at least two of the following systemic symptoms: fever ($\geq 38^{\circ}\text{C}$), chills, myalgia, headache, sore throat, new olfactory and taste disorder(s); or the participant must have experienced at least one of the following respiratory signs/symptoms: cough, shortness of breath or difficulty breathing, or clinical or radiographical evidence of pneumonia; and the participant must have at least one NP swab, nasal swab, or saliva sample (or respiratory sample, if hospitalized) positive for SARS-CoV-2 by RT-PCR. COVID-19 cases were adjudicated by a Clinical Adjudication Committee.

The median length of follow up for efficacy for participants in the study was 9 weeks post Dose 2. There were 11 COVID-19 cases in the Moderna COVID-19 Vaccine group and 185 cases in the placebo group, with a vaccine efficacy of 94.1% (95% confidence interval of 89.3% to 96.8%).

Table 3: Primary Efficacy Analysis: COVID-19* in Participants 18 Years of Age and Older Starting 14 Days After Dose 2 per Adjudication Committee Assessments – Per-Protocol Set

Moderna COVID-19 Vaccine			Placebo			% Vaccine Efficacy (95% CI) [†]
Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	
14,134	11	3.328	14,073	185	56.510	94.1 (89.3, 96.8)

* COVID-19: symptomatic COVID-19 requiring positive RT-PCR result and at least two systemic symptoms or one respiratory symptom. Cases starting 14 days after Dose 2.

[†] VE and 95% CI from the stratified Cox proportional hazard model

The subgroup analyses of vaccine efficacy are presented in Table 4.

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Table 4: Subgroup Analyses of Vaccine Efficacy: COVID-19* Cases Starting 14 Days After Dose 2 per Adjudication Committee Assessments – Per-Protocol Set

Age Subgroup (Years)	Moderna COVID-19 Vaccine			Placebo			% Vaccine Efficacy (95% CI)*
	Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	
18 to <65	10,551	7	2.875	10,521	156	64.625	95.6 (90.6, 97.9)
≥65	3,583	4	4.595	3,552	29	33.728	86.4 (61.4, 95.2)

* COVID-19: symptomatic COVID-19 requiring positive RT-PCR result and at least two systemic symptoms or one respiratory symptom. Cases starting 14 days after Dose 2.

† VE and 95% CI from the stratified Coxproportional hazard model

Severe COVID-19 was defined based on confirmed COVID-19 as per the primary efficacy endpoint case definition, plus any of the following: Clinical signs indicative of severe systemic illness, respiratory rate ≥ 30 per minute, heart rate ≥ 125 beats per minute, SpO₂ $\leq 93\%$ on room air at sea level or PaO₂/FIO₂ < 300 mm Hg; or respiratory failure or ARDS, (defined as needing high-flow oxygen, non-invasive or mechanical ventilation, or ECMO), evidence of shock (systolic blood pressure < 90 mmHg, diastolic BP < 60 mmHg or requiring vasopressors); or significant acute renal, hepatic, or neurologic dysfunction; or admission to an intensive care unit or death.

Among all participants in the Per-Protocol Set analysis, which included COVID-19 cases confirmed by an adjudication committee, no cases of severe COVID-19 were reported in the Moderna COVID-19 Vaccine group compared with 30 cases reported in the placebo group (incidence rate 9.138 per 1,000 person-years). One PCR-positive case of severe COVID-19 in a vaccine recipient was awaiting adjudication at the time of the analysis.

19 HOW SUPPLIED/STORAGE AND HANDLING

Moderna COVID-19 Vaccine Suspension for Intramuscular Injection, Multiple-Dose Vials are supplied as a carton of 10 multiple-dose vials (NDC 80777-273-99).

Store frozen between -25° to -15°C (-13° to 5°F). Store in the original carton to protect from light. Do not store on dry ice or below -40°C (-40°F).

Vials can be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use. Do not refreeze.

Unpunctured vials may be stored between 8° to 25°C (46° to 77°F) for up to 12 hours. Do not refreeze.

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After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Discard vial after 6 hours. Do not refreeze.

20 PATIENT COUNSELING INFORMATION

Advise the recipient or caregiver to read the Fact Sheet for Recipients and Caregivers.

The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system. Advise recipient or caregiver that more information about IISs can be found at:

<https://www.cdc.gov/vaccines/programs/iis/about.html>.

21 CONTACT INFORMATION

For general questions, send an email or call the telephone number provided below.

Email	Telephone number
medinfo@modernatx.com	1-866-MODERNA (1-866-663-3762)

This EUA Prescribing Information may have been updated. For the most recent Full EUA Prescribing Information, please visit www.modernatx.com/covid19vaccine-eua.

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Patent(s): www.modernatx.com/patents

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Appendix 15 – Storage and Handling Overview Moderna



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Moderna COVID-19 Vaccine Storage and Handling Summary



» Basics

- Store vaccine in a freezer or refrigerator. See guidance below for each storage unit.
- Each box contains 10 multidose vials (100 doses).
- Use vaccine vials stored in the refrigerator before removing vials from frozen storage.
- This vaccine does not need to be mixed with a diluent before administration.
- Check and record storage unit temperature each workday. See guidance below for each type of temperature monitoring device. Save storage records for 3 years, unless your jurisdiction requires a longer time period.

» Deliveries

Vaccine

1. The vaccine will arrive frozen between -25°C and -15°C (-13°F and 5°F).
2. Examine the shipment for signs of damage.
3. Open the box and remove TagAlert Temperature Monitor from box (placed in the inner box next to vaccine).
4. Check the TagAlert temperature monitoring device by pressing the blue "start and stop" button.
 - Left arrow points to a **green checkmark**: The vaccine is ready to use. Store the vaccine at proper temperatures immediately.
 - Right arrow points to a **red X**: The numbers 1 and/or 2 will appear in the display. Store the vaccine at proper temperatures and label **DO NOT USE!** Call the phone number indicated in the instructions or your jurisdiction's immunization program **IMMEDIATELY!**

Ancillary Supply Kit

An ancillary supply kit will be provided for administering the vaccine and includes enough supplies to administer 100 doses of vaccine.

Administration supplies include needles, syringes, sterile alcohol prep pads, vaccination record cards (shot cards), and some PPE.

The kit is delivered separately from the vaccine. Unpack the kit and check for receipt of the correct administration supplies and quantities.



» Freezer

Vaccine may be stored in a freezer between -25°C and -15°C (-13°F and 5°F).

Note: These temperatures are within the appropriate range for routinely recommended vaccines BUT the temperature range for this vaccine is tighter.

- If storing the vaccine in a freezer with routinely recommended vaccines, carefully adjust the freezer temperature to the correct temperature range for this vaccine.

Store in the original carton and protect from light. | Do not use dry ice for storage.



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Moderna COVID-19 Vaccine Storage and Handling Summary



» Refrigerator

- Vaccine vials may be stored in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to 30 days before vials are punctured. After 30 days, remove any remaining vials from the refrigerator and discard following manufacturer and jurisdiction guidance on proper disposal.
- Thawed vaccine cannot be refrozen.
- Use beyond-use date labels to track how long the vaccine has been in the refrigerator. Monitor the beyond-use date/time.
 - Remove the box from frozen storage.
 - Complete the information on the storage label and attach it to the box holding the vaccine vials.
 - Once labeled, store vaccine in the refrigerator.

Moderna COVID-19 Vaccine

Vaccine may be stored in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to 30 days.

Lot number(s): 123456A

Today's date: 4 / 01 / 2021

USE BY*

Date: 5 / 01 / 2021

*After this date/time, do NOT use. Contact the manufacturer for guidance. If directed to discard the vaccine, follow the manufacturer's and your jurisdiction's guidance on proper disposal.

Name: Amy Nurse RN

» Temperature Monitoring

Storage unit temperatures must be monitored regularly and checked and recorded at the beginning of each workday to determine if any excursions have occurred since the last temperature check. For accurate temperature monitoring, use a digital data logger (DDL) with a detachable probe that best reflects vaccine temperatures (e.g., probe buffered with glycol, glass beads, sand, or Teflon®). Check and record the temperature daily using a temperature log and one of the options below:

• Option 1: Minimum/Maximum Temperatures (preferred)

Most DDLs display minimum and maximum (min/max) temperatures. Check and record the min/max temperatures at the start of each workday.

• Option 2: Current Temperature

If the DDL does not display min/max temperatures, check and record the current temperature at the start and end of the workday. Review the continuous DDL temperature data daily.

For CDC temperatures logs, see <https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html>.

For additional information, refer to the manufacturer's product information at <https://www.modernatx.com/covid19vaccine-eua/>.

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Appendix 16 - Sample/Template LHD Standing Order for Moderna 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 <i>Fact Sheet for Recipients and Caregivers</i> (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 <i>Contraindications for Use of this Order</i> section of this standing order before administering the COVID-19 vaccine.

COVID-19 Vaccine LHD Toolkit

- 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.

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	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: • <u>Medical Record</u>: 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. • <u>CVMS</u>: 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 <i>Fact Sheet for Healthcare Providers Administering Vaccine</i>: • 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.

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	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	- 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. - 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. - 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. - 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



COVID-19 Vaccine LHD Toolkit

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. <i>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</i> 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 <i>Contraindications for Use of this Order</i> section of this standing order before administering the COVID-19 vaccine. b. Review the patient-completed <i>Pre-Vaccination Form for Pfizer- BioNTech COVID-19 Vaccine</i>. 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



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	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.
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Sample/Template Standing Order for Pfizer-BioNTech COVID-19 Vaccine – December 19, 2020

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Associated Resources and Guidelines:

- [NCDHHS COVID-19 Vaccine Plan](#)
- [Consent to Health Care for Minors Children: Overview of NC Law \(Jill Moore, 2016\)](#)
- [December 18, 2020 FDA Letter of Authorization - Food and Drug Administration \(FDA\) issued an Emergency Use Authorization \(EUA\) for Emergency Use of Moderna COVID-19 Vaccine](#)



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- [Fact Sheet for Healthcare Providers Administering Vaccine \(Vaccination Providers\) Emergency Use Authorization \(EUA\) of the Moderna Covid-19 Vaccine to Prevent Coronavirus Disease 2019 \(COVID-19\)](#)
- [Fact Sheet for Recipients and Caregivers - Emergency Use Authorization \(EUA\) of the Moderna Covid-19 Vaccine to Prevent Coronavirus Disease 2019 \(Covid-19\) In Individuals 18 Years of Age and Older](#)
- [The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Moderna COVID-19 Vaccine — United States, December 2020](#)
- [Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States](#)

COVID-19 Vaccine LHD Toolkit

Appendix 17 – FDA Letter of Authorization for Moderna

COVID-19 Vaccine LHD Toolkit



FDA **U.S. FOOD & DRUG**
ADMINISTRATION

December 18, 2020

ModernaTX, Inc.
Attention: Ms. Carlota Vinals
200 Technology Square
Cambridge, MA 02139

Dear Ms. Vinals:

This letter is in response to a request from ModernaTX, Inc. that the Food and Drug Administration (FDA) issue an 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, as described in the Scope of Authorization (Section II) of this letter, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act or the Act) (21 U.S.C. 360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19.¹ On the basis of such determination, the Secretary of HHS on March 27, 2020, declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to Section 564 of the Act, subject to terms of any authorization issued under that section.²

Moderna COVID-19 Vaccine is for use for active immunization to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older. The vaccine contains a nucleoside-modified messenger RNA encoding the viral spike (S) glycoprotein of SARS-CoV-2 formulated in lipid particles. It is an investigational vaccine not licensed for any indication.

FDA reviewed safety and efficacy data from an ongoing phase 3 trial in approximately 30,000 participants randomized 1:1 to receive Moderna COVID-19 Vaccine or saline control. The trial has enrolled participants 18 years of age and older.

¹ U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3, February 4, 2020.

² U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3, 85 FR 18250 (April 1, 2020).

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FDA's review of the available safety data from 30,351 participants 18 years of age and older, who were followed for a median of 7 weeks after receiving the second dose, did not identify specific safety concerns that would preclude issuance of an EUA. Review of additional safety data from these participants with a median of 9 weeks of follow-up after receipt of the second dose did not change FDA's assessment of safety of the vaccine.

FDA's analysis of the efficacy data from 28,207 participants 18 years of age and older without evidence of SARS-CoV-2 infection prior to dose 1 confirms the vaccine was 94.1% effective (95% confidence interval (CI) 89.3, 96.8) in preventing COVID-19 occurring at least 14 days after the second dose (with 11 COVID-19 cases in the vaccine group compared to 185 COVID-19 cases in the placebo group). In this final scheduled analysis participants had been followed for a median of 9 weeks following the second dose. This result is consistent with that obtained from an interim analysis of efficacy conducted after these participants had been followed for a median of 7 weeks after the second dose (vaccine efficacy 94.5%, 95% CI: 86.5, 97.8).

Based on the safety and effectiveness data, and review of manufacturing information regarding product quality and consistency, it is reasonable to believe that Moderna COVID-19 Vaccine may be effective. Additionally, it is reasonable to conclude, based on the totality of the scientific evidence available, that the known and potential benefits of Moderna COVID-19 Vaccine outweigh the known and potential risks of the vaccine, for the prevention of COVID-19 in individuals 18 years of age and older. Finally, on December 17, 2020, the Vaccines and Related Biological Products Advisory Committee voted in agreement with this conclusion.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of Moderna COVID-19 Vaccine for the prevention of COVID-19, as described in the Scope of Authorization section of this letter (Section II) and subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of Moderna COVID-19 Vaccine for the prevention of COVID-19 when administered as described in the Scope of Authorization (Section II) meets the criteria for issuance of an authorization under Section 564(c) of the Act, because:

1. SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;
2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that Moderna COVID-19 Vaccine may be effective in preventing COVID-19, and that, when used under the conditions described in this authorization, the known and potential benefits of Moderna COVID-19 Vaccine when used to prevent COVID-19 outweigh its known and potential risks; and

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3. There is no adequate, approved, and available alternative to the emergency use of Moderna COVID-19 Vaccine to prevent COVID-19.³

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited as follows:

- ModernaTX, Inc. will supply Moderna COVID-19 Vaccine either directly or through authorized distributor(s)⁴, to emergency response stakeholders⁵ as directed by the U.S. government, including the Centers for Disease Control and Prevention (CDC) and/or other designee, for use consistent with the terms and conditions of this EUA;
- The Moderna COVID-19 Vaccine covered by this authorization will be administered by vaccination providers⁶ and used only to prevent COVID-19 in individuals ages 18 and older; and
- The Moderna COVID-19 Vaccine may be administered by a vaccination provider without an individual prescription for each vaccine recipient.

³ No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

⁴ “Authorized Distributor(s)” are identified by ModernaTX, Inc. or, if applicable, by a U.S. government entity, such as the Centers for Disease Control and Prevention (CDC) and/or other designee, as an entity or entities allowed to distribute authorized Moderna COVID-19 Vaccine.

⁵ For purposes of this letter, “emergency response stakeholder” refers to a public health agency and its delegates that have legal responsibility and authority for responding to an incident, based on political or geographical boundary lines (e.g., city, county, tribal, territorial, State, or Federal), or functional (e.g., law enforcement or public health range) or sphere of authority to administer, deliver, or distribute vaccine in an emergency situation. In some cases (e.g., depending on a state or local jurisdiction’s COVID-19 vaccination response organization and plans), there might be overlapping roles and responsibilities among “emergency response stakeholders” and “vaccination providers” (e.g., if a local health department is administering COVID-19 vaccines; if a pharmacy is acting in an official capacity under the authority of the state health department to administer COVID-19 vaccines). In such cases, it is expected that the conditions of authorization that apply to emergency response stakeholders and vaccination providers will all be met.

⁶ For purposes of this letter, “vaccination provider” refers to the facility, organization, or healthcare provider licensed or otherwise authorized by the emergency response stakeholder (e.g., non-physician healthcare professionals, such as nurses and pharmacists pursuant to state law under a standing order issued by the state health officer) to administer or provide vaccination services in accordance with the applicable emergency response stakeholder’s official COVID-19 vaccination and emergency response plan(s) and who is enrolled in the CDC COVID-19 Vaccination Program. For purposes of this letter, “healthcare provider” also refers to a person authorized by the U.S. Department of Health and Human Services (e.g., under the PREP Act Declaration for Medical Countermeasures Against COVID-19) to administer FDA-authorized COVID-19 vaccine (e.g., qualified pharmacy technicians and State-authorized pharmacy interns acting under the supervision of a qualified pharmacist). See, e.g., HHS. *Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration*. 85 FR 79190 (December 9, 2020).

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Product Description

The Moderna COVID-19 Vaccine is supplied as a frozen suspension in multiple dose vials. The Moderna COVID-19 Vaccine does not contain a preservative.

Each 0.5 mL dose of the Moderna COVID-19 Vaccine contains 100 mcg of a nucleoside-modified messenger RNA encoding the viral spike (S) glycoprotein of SARS-CoV-2. Each dose of the Moderna COVID-19 Vaccine also includes the following ingredients: lipids (SM-102; 1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 [PEG2000-DMG]; cholesterol; and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate, and sucrose.

The dosing regimen is two doses of 0.5 mL each, one month apart.

The manufacture of the authorized Moderna COVID-19 Vaccine is limited to those facilities identified and agreed upon in the ModernaTX, Inc. request for authorization.

The Moderna COVID-19 Vaccine vial label and carton labels are clearly marked for “Emergency Use Authorization.” The Moderna COVID-19 Vaccine is authorized to be distributed, stored, further redistributed, and administered by emergency response stakeholders when packaged in the authorized manufacturer packaging (i.e., vials and cartons), despite the fact that the vial and carton labels may not contain information that otherwise would be required under the FD&C Act.

The Moderna COVID-19 Vaccine is authorized for emergency use with the following product-specific information required to be made available to vaccination providers and recipients, respectively (referred to as “authorized labeling”):

- Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers): Emergency Use Authorization (EUA) of the Moderna COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19)
- Fact Sheet for Recipients and Caregivers: Emergency Use Authorization (EUA) of the Moderna COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) in Individuals 18 Years of Age and Older

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of Moderna COVID-19 Vaccine, when used to prevent COVID-19 and used in accordance with this Scope of Authorization (Section II), outweigh its known and potential risks.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that Moderna COVID-19 Vaccine may be effective in preventing COVID-19 when used in accordance with this Scope of Authorization (Section II), pursuant to Section 564(c)(2)(A) of the Act.

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Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that Moderna COVID-19 Vaccine (as described in this Scope of Authorization (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of Moderna COVID-19 Vaccine under this EUA must be consistent with, and may not exceed, the terms of the Authorization, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section III). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), Moderna COVID-19 Vaccine is authorized to prevent COVID-19 in individuals 18 years of age and older as described in the Scope of Authorization (Section II) under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

III. Conditions of Authorization

Pursuant to Section 564 of the Act, I am establishing the following conditions on this authorization:

ModernaTX, Inc. and Authorized Distributor(s)

- A. ModernaTX, Inc. and authorized distributor(s) will ensure that the authorized Moderna COVID-19 Vaccine is distributed, as directed by the U.S. government, including CDC and/or other designee, and the authorized labeling (i.e., Fact Sheets) will be made available to vaccination providers, recipients, and caregivers consistent with the terms of this letter.
- B. ModernaTX, Inc. and authorized distributor(s) will ensure that appropriate storage and cold chain is maintained until delivered to emergency response stakeholders' receipt sites.
- C. ModernaTX, Inc. will ensure that the terms of this EUA are made available to all relevant stakeholders (e.g., emergency response stakeholders, authorized distributors, and vaccination providers) involved in distributing or receiving authorized Moderna COVID-19 Vaccine. ModernaTX, Inc. will provide to all relevant stakeholders a copy of this letter of authorization and communicate any subsequent amendments that might be made to this letter of authorization and its authorized labeling.
- D. ModernaTX, Inc. may develop and disseminate instructional and educational materials (e.g., video regarding vaccine handling, storage/cold-chain management, preparation, disposal) that are consistent with the authorized emergency use of the vaccine as described in the letter of authorization and authorized labeling, without FDA's review and concurrence, when necessary to meet public health needs during an emergency. Any instructional and educational materials that are inconsistent with the authorized labeling are prohibited.
- E. ModernaTX, Inc. may request changes to this authorization, including to the authorized Fact Sheets for Moderna COVID-19 Vaccine, that do not alter the analysis

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of benefits and risks that underlies this authorization and FDA may determine that such changes may be permitted without amendment of this EUA. That determination must be made by joint decision of the Office of Vaccines Research and Review (OVRR)/Center for Biologics Evaluation and Research (CBER), the Preparedness and Response Team (PREP)/Office of the Center Director (OD)/CBER, and the Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist/Office of the Commissioner (OCS).

- F. ModernaTX, Inc. will report to Vaccine Adverse Event Reporting System (VAERS):
- Vaccine administration errors whether or not associated with an adverse event;
 - Serious adverse events (irrespective of attribution to vaccination);
 - Cases of Multisystem Inflammatory Syndrome in adults; and
 - Cases of COVID-19 that result in hospitalization or death, that are reported to ModernaTX, Inc.

These reports should be submitted to VAERS as soon as possible but no later than 15 calendar days from initial receipt of the information by ModernaTX, Inc.

- G. ModernaTX, Inc. must submit to Investigational New Drug application (IND) number 19745 periodic safety reports at monthly intervals, within 15 days after the last day of a month, beginning after the first full calendar month after authorization. Each periodic safety report is required to contain descriptive information which includes:
- A narrative summary and analysis of adverse events submitted during the reporting interval, including interval and cumulative counts by age groups, special populations (e.g., pregnant women), and adverse events of special interest.
 - Newly identified safety concerns in the interval; and
 - Actions taken since the last report because of adverse experiences (for example, changes made to Healthcare Providers Administering Vaccine (Vaccination Providers) Fact Sheet, changes made to studies or studies initiated).
- H. No changes will be implemented to the description of the product, manufacturing process, facilities, or equipment without notification to and concurrence by the Agency.
- I. All manufacturing facilities will comply with Current Good Manufacturing Practice requirements.
- J. ModernaTX, Inc. will submit to the EUA file Certificates of Analysis (CoA) for each drug product lot at least 48 hours prior to vaccine distribution. The CoA will include the established specifications and specific results for each quality control test performed on the final drug product lot.
- K. ModernaTX, Inc. will submit to the EUA file quarterly manufacturing reports that include a listing of all Drug Substance and Drug Product lots produced after issuance of this authorization. This report must include lot number, manufacturing site, date of manufacture, and lot disposition, including those lots that were quarantined for investigation or those lots that were rejected. Information on the reasons for lot

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quarantine or rejection must be included in the report. The first report is due July 2021.

- L. ModernaTX, Inc. and authorized distributor(s) will maintain records regarding release of Moderna COVID-19 Vaccine for distribution (i.e., lot numbers, quantity, release date).
- M. ModernaTX, Inc. and authorized distributor(s) will make available to FDA upon request any records maintained in connection with this EUA.
- N. ModernaTX, Inc. will conduct post-authorization observational studies to evaluate the association between Moderna COVID-19 Vaccine and a pre-specified list of adverse events of special interest, along with deaths and hospitalizations, and severe COVID-19. The study population should include individuals administered the authorized Moderna COVID-19 Vaccine under this EUA in the general U.S. population (18 years of age and older), populations of interest such as healthcare workers, pregnant women, immunocompromised individuals, subpopulations with specific comorbidities. The studies should be conducted in large scale databases with an active comparator. ModernaTX, Inc. will provide protocols and status update reports to the IND 19745 with agreed-upon study designs and milestone dates.
- O. ModernaTX, Inc., working with its contract research organization, will continue to monitor the performance of its clinical investigators in ongoing clinical studies of its vaccine and will report to FDA promptly any significant deviations from the protocols.

Emergency Response Stakeholders

- P. Emergency response stakeholders will identify vaccination sites to receive authorized Moderna COVID-19 Vaccine and ensure its distribution and administration, consistent with the terms of this letter and CDC's COVID-19 Vaccination Program.
- Q. Emergency response stakeholders will ensure that vaccination providers within their jurisdictions are aware of this letter of authorization, and the terms herein and any subsequent amendments that might be made to the letter of authorization, instruct them about the means through which they are to obtain and administer the vaccine under the EUA, and ensure that the authorized labeling [i.e., Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Fact Sheet for Recipients and Caregivers] is made available to vaccination providers through appropriate means (e.g., e-mail, website).
- R. Emergency response stakeholders receiving authorized Moderna COVID-19 Vaccine will ensure that appropriate storage and cold chain is maintained.

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Vaccination Providers

- S. Vaccination providers will administer the vaccine in accordance with the authorization and will participate and comply with the terms and training required by CDC's COVID-19 Vaccination Program.
- T. Vaccination providers will provide the Fact Sheet for Recipients and Caregivers to each individual receiving vaccination and provide the necessary information for receiving their second dose.
- U. Vaccination providers administering Moderna COVID-19 Vaccine must report the following information associated with the administration of Moderna COVID-19 Vaccine of which they become aware to VAERS in accordance with the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers):
 - Vaccine administration errors whether or not associated with an adverse event
 - 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 VAERS online at <https://vaers.hhs.gov/reportevent.html>. The VAERS reports should include the words "Moderna COVID-19 Vaccine EUA" in the description section of the report. More information is available at vaers.hhs.gov or by calling 1-800-822-7967. To the extent feasible, report to ModernaTX, Inc., by contacting 1-866-663-3762, by providing a copy of the VAERS form to ModernaTX, Inc., Fax: 1-866-599-1342 or by email; ModernaPV@modernatx.com.

- V. Vaccination providers will conduct any follow-up requested by the U.S. government, including CDC, FDA, or other designee, regarding adverse events to the extent feasible given the emergency circumstances.
- W. Vaccination providers will monitor and comply with CDC and/or emergency response stakeholder vaccine management requirements (e.g., requirements concerning obtaining, tracking, and handling vaccine) and with requirements concerning reporting of vaccine administration data to CDC.
- X. Vaccination providers will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to CDC and FDA for inspection upon request.

Conditions Related to Printed Matter, Advertising, and Promotion

- Y. All descriptive printed matter, advertising, and promotional material relating to the use of the Moderna COVID-19 Vaccine shall be consistent with the authorized

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labeling, as well as the terms set forth in this EUA, and meet the requirements set forth in section 502(a) and (n) of the FD&C Act and FDA implementing regulations.

- Z. All descriptive printed matter, advertising, and promotional material relating to the use of the Moderna COVID-19 Vaccine clearly and conspicuously shall state that:
- This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 18 years of age and older; and
 - 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.

IV. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

--/S/--

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures

COVID-19 Vaccine LHD Toolkit

Appendix 18 – Moderna Standing Order



COVID-19 Vaccine LHD Toolkit

Moderna COVID-19 Vaccine

Standing Orders for Administering Vaccine
to Persons 18 Years of Age and Older



Note: For more information/guidance, please contact the immunization program at your state or local health department or the appropriate state body (e.g., state board of medical/nursing/pharmacy practice).

» Purpose

- To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

» Policy

- Where authorized under state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.

» Procedure

Assess persons 18 years of age and older for vaccination with Moderna COVID-19 Vaccine based on the following criteria:

- No complete 2-dose COVID-19 vaccination history, regardless of brand. If 2 doses of a same-brand or mixed-brand series have been administered, no additional doses are recommended.
 - If the recipient has received 1 previous dose of Moderna COVID-19 Vaccine, a second dose of the same brand should be administered.
 - This vaccine is administered in a 2-dose series. Separate doses by at least 28 days.*
- Moderna COVID-19 Vaccine should not be administered at the same time as other vaccines. Separate Moderna COVID-19 Vaccine from other vaccines by 14 days before or after the administration of Moderna COVID-19 vaccine.
- Moderna COVID-19 Vaccine should be deferred for at least 90 days for persons who received passive antibody therapy (monoclonal antibodies or convalescent plasma) as part of COVID-19 treatment.
- Screen for contraindications and precautions.

○ Contraindication

- » Severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine for both Pfizer-BioNTech and Moderna COVID-19 vaccines. For a list of vaccine components, see the Emergency Use Authorization (EUA).

○ Precautions

- » Severe allergic reaction (e.g., anaphylaxis) to any other vaccine or injectable therapy (e.g., intramuscular, intravenous, or subcutaneous)
- » Moderate to severe illness

- Provide all recipients with a copy of the current federal Emergency Use Authorization (EUA) Fact Sheet for Recipients and Caregivers.

- Prepare to administer the vaccine.

○ Choose the correct needle gauge, needle length, and injection site for persons:

- » 18 years of age: 1-inch needle is recommended.
- » 19 years of age and older: See table below.

- Follow the manufacturer's guidance for storing/handling punctured vaccine vials.

Sex and Weight of Patient	Needle Gauge	Needle Length	Injection Site†
Female or male fewer than 130 lbs	22–25	5/8 [§] –1"	Deltoid muscle of arm
Female or male 130–152 lbs	22–25	1"	Deltoid muscle of arm
Female 152–200 lbs	22–25	1–1½"	Deltoid muscle of arm
Male 153–260 lbs	22–25	1–1½"	Deltoid muscle of arm
Female 200+ lbs	22–25	1½"	Deltoid muscle of arm
Male 260+ lbs	22–25	1½"	Deltoid muscle of arm

* If the second dose of Moderna COVID-19 Vaccine was given as early as 24 days after the first dose, then do not repeat a second dose.

† Alternatively, the anterolateral thigh also can be used.

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



COVID-19 Vaccine LHD Toolkit

Moderna COVID-19 Vaccine

Standing Orders for Administering Vaccine
to Persons 18 Years of Age and Older



- Administer 0.5 mL Moderna COVID-19 Vaccine by intramuscular (IM) injection.
- Document vaccination.
 - COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration and use their best efforts to report administration data to the relevant system (e.g., immunization information system) for the jurisdiction as soon as practicable and no later than 72 hours after administration.
 - Document each recipient's vaccine administration information:
 - » Medical record: The vaccine and the date it was administered, manufacturer, lot number, vaccination site and route, name and title of the person administering the vaccine
 - » Vaccination record card: Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or healthcare professional. Give to the vaccine recipient.
 - » Immunization information system (IIS): Report the vaccination to the appropriate state/local IIS.
- Additional preparation and administration information is available on the manufacturer's website at <https://www.modernatx.com/>.
- Be prepared to manage medical emergencies.
 - Vaccination providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions:
 - » Persons with a history of any anaphylaxis: 30 minutes
 - » All other persons: 15 minutes
 - Have a written protocol to manage medical emergencies following vaccination, as well as equipment and medications, including at least 3 epinephrine prefilled syringes or autoinjectors, H1 antihistamine, blood pressure cuff, and stethoscope and timing device to assess pulse.
- For more information, please see:
 - » **Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites** at <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html>
 - » **CDC's General Best Practice Guidelines for Immunization, "Preventing and Managing Adverse Reactions,"** at <https://www.cdc.gov/vaccines/hcp/acip-recs/generalrecs/adverse-reactions.html>
 - » **Immunization Action Coalition's "Medical Management of Vaccine Reactions in Adults in a Community Setting"** at <https://www.immunize.org/catg.d/p3082.pdf>
- Report adverse events to the Vaccine Adverse Event Reporting System (VAERS).
 - While this vaccine is under [Emergency Use Authorization \(EUA\)](#), healthcare professionals are required to report to VAERS:
 - » Vaccine administration errors (whether associated with an adverse event [AE] or not)
 - » Serious AEs (irrespective of attribution to vaccination)
 - » Multisystem inflammatory syndrome (MIS) in [adults](#) or [children](#)
 - » Cases of COVID-19 that result in hospitalization or death
 - » Any additional AEs and revised safety requirements per the [Food and Drug Administration's](#) conditions for use of an authorized vaccine throughout the duration of the EUA
 - Healthcare professionals are encouraged to report to [VAERS](#):
 - » Clinically important adverse events that occur after vaccination, even if you are not sure whether the vaccine caused the adverse event.

» Standing Orders Authorization

This policy and procedure shall remain in effect for all patients of the _____ effective _____ until rescinded or until _____.

Medical director (or other authorized practitioner)

_____/_____/_____.

Adapted from Immunization Action Coalition Standing Orders templates. These templates for routinely recommended vaccines can be found at <https://www.immunize.org/standing-orders/>. We thank the Immunization Action Coalition for the use of their resources.



COVID-19 Vaccine LHD Toolkit

Appendix 19 - Pfizer Standing Order

Pfizer-BioNTech COVID-19 Vaccine

Standing Orders for Administering Vaccine
to Persons 16 Years of Age and Older



Note: For more information/guidance, please contact the immunization program at your state or local health department or the appropriate state body (e.g., state board of medical/nursing/pharmacy practice).

» Purpose

- To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

» Policy

- Where authorized under state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.

» Procedure

- Assess persons 16 years of age and older for vaccination with Pfizer-BioNTech COVID-19 Vaccine based on the following criteria: No complete 2-dose COVID-19 vaccination history, regardless of brand. If 2 doses of a same-brand or mixed-brand series have been administered, no additional doses are recommended.
 - If the recipient has received 1 previous dose of Pfizer-BioNTech COVID-19 Vaccine, the second dose of the same brand should be administered.
 - This vaccine is administered in a **2-dose** series. Separate doses by at least 21 days.*
 - Pfizer-BioNTech COVID-19 Vaccine should not be administered at the same time with other vaccines. Separate Pfizer-BioNTech COVID-19 Vaccine from other vaccines by 14 days before or after the administration of COVID-19 vaccine.
- Pfizer-BioNTech COVID-19 Vaccine should be deferred for at least 90 days for persons who received passive antibody therapy as part of (monoclonal antibodies or convalescent plasma) as part of COVID-19 treatment.
- Screen for contraindications and precautions.
 - Contraindications
 - » Severe allergic reaction (e.g., anaphylaxis) to a previous dose of Pfizer-BioNTech COVID-19 Vaccine or to a component of the vaccine.
 - Precautions
 - » Severe allergic reaction (e.g., anaphylaxis) to a previous dose of any vaccine (not including Pfizer-BioNTech COVID-19 Vaccine).
 - » Severe allergic reaction (e.g., anaphylaxis) to a medication that is injectable
 - » Moderate to severe acute illness
- Provide Emergency Use Authorization (EUA) patient information.
 - Provide all recipients with a copy of the current federal EUA Fact Sheet for Recipients and Caregivers.
- Prepare to administer the vaccine.
 - Choose the correct needle gauge, needle length, and injection site for persons:
 - » 16 through 18 years of age: 1-inch needle is recommended, administered in the deltoid muscle of the arm.**
 - » 19 years of age and older: See table below.

Sex and Weight of Patient	Needle Gauge	Needle Length	Injection Site**
Female or male fewer than 130 lbs	22–25	5/8*** – 1"	Deltoid muscle of arm
Female or male 130–152 lbs	22–25	1"	Deltoid muscle of arm
Female 152–200 lbs	22–25	1–1½"	Deltoid muscle of arm
Male 153–260 lbs	22–25	1–1½"	Deltoid muscle of arm
Female 200+ lbs	22–25	1½"	Deltoid muscle of arm
Male 260+ lbs	22–25	1½"	Deltoid muscle of arm

* If the 2nd dose Pfizer-BioNTech COVID-19 Vaccine was given as early as 17 days after the 1st dose, then do not repeat a 2nd dose.

** Alternatively, the anterolateral thigh also can be used.

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



COVID-19 Vaccine LHD Toolkit

Pfizer-BioNTech COVID-19 Vaccine

Standing Orders for Administering Vaccine
to Persons 16 Years of Age and Older



- Mix 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.
- Administer 0.3 mL Pfizer-BioNTech COVID-19 Vaccine by intramuscular (IM) injection. Document vaccination.
- Document vaccination.
 - COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration and use their best efforts to report administration data to the relevant system (e.g., Immunization Information System) for the jurisdiction as soon as practicable and no later than 72 hours after administration.
 - Document each recipient's vaccine administration information:
 - » Medical record: The vaccine and the date it was administered, manufacturer, lot number, vaccination site and route, name and title of the person administering the vaccine
 - » Vaccination record card: Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or healthcare professional. Give to the vaccine recipient.
 - » Immunization information system: Report the vaccination to the appropriate state/local IIS.
- Additional preparation and administration information is available on the manufacturer's website at www.cvdvaccine.com.
- Be prepared to manage medical emergencies.
 - Vaccination providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions:
 - » Persons with a history of a any anaphylaxis: 30 min
 - » All other persons: 15 minutes
 - Have a written protocol to manage medical emergencies following vaccination, as well as equipment and medications, including at least 3 epinephrine prefilled syringes or autoinjectors, H1 antihistamine, blood pressure cuff, and stethoscope and timing device to assess pulse. For more information, please see:
 - » **Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites** at <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html>.
 - » **CDC's General Best Practice Guidelines for Immunization, "Preventing and Managing Adverse Reactions,"** at <https://www.cdc.gov/vaccines/hcp/adip-recs/generalrecs/adverse-reactions.html>.
 - » **Immunization Action Coalition's "Medical Management of Vaccine Reactions in Adults in a Community Setting"** at <https://www.immunize.org/catg.d/p3082.pdf>.
- Report adverse events to the **Vaccine Adverse Event Reporting System (VAERS)**.
 - While this vaccine is under **Emergency Use Authorization (EUA)**, healthcare professionals are required to report to VAERS:
 - » Vaccine administration errors (whether associated with an adverse event [AE] or not)
 - » Serious AEs (irrespective of attribution to vaccination)
 - » Multisystem inflammatory syndrome (MIS) in [adults](#) or [children](#)
 - » Cases of COVID-19 that result in hospitalization or death
 - » Any additional AEs and revised safety requirements per the [Food and Drug Administration's](#) conditions for use of an authorized vaccine throughout the duration of the EUA
 - Healthcare professionals are encouraged to report to **VAERS**:
 - » Clinically important adverse events that occur after vaccination, even if you are not sure whether the vaccine caused the adverse event

» Standing Orders Authorization

This policy and procedure shall remain in effect for all patients of the _____ effective _____ until rescinded or until _____.

Medical director (or other authorized practitioner)

_____/_____/_____

Adapted from Immunization Action Coalition Standing Orders templates. These templates for routinely recommended vaccines can be found at <https://www.immunize.org/standing-orders/>. We thank the Immunization Action Coalition for the use of their resources.

12/17/20 CS321570H



COVID-19 Vaccine LHD Toolkit

Pre-Vaccination Checklist for COVID-19 Vaccines



For vaccine recipients:

The following questions will help us determine if there is any reason you should not get the COVID-19 vaccine today.

If you answer "yes" to any question, it does not necessarily mean you should not be vaccinated. It just means additional questions may be asked. If a question is not clear, please ask your healthcare provider to explain it.

Patient Name _____

Age _____

	Yes	No	Don't know
1. Are you feeling sick today?			
2. Have you ever received a dose of COVID-19 vaccine?			
• If yes, which vaccine product?			
☐ Pfizer			
☐ Moderna			
☐ Another product _____			
3. Have you ever had a severe allergic reaction (e.g., anaphylaxis) to something? For example, a reaction for which you were treated with epinephrine or EpiPen®, or for which you had to go to the hospital?			
• Was the severe allergic reaction after receiving a COVID-19 vaccine?			
• Was the severe allergic reaction after receiving another vaccine or another injectable medication?			
4. Have you received passive antibody therapy (monoclonal antibodies or convalescent serum) as treatment for COVID-19?			
5. Have you received another vaccine in the last 14 days?			
6. Have you had a positive test for COVID-19 or has a doctor ever told you that you had COVID-19?			
7. Do you have a weakened immune system caused by something such as HIV infection or cancer or do you take immunosuppressive drugs or therapies?			
8. Do you have a bleeding disorder or are you taking a blood thinner?			
9. Are you pregnant or breastfeeding?			

Form reviewed by _____

Date _____



COVID-19 Vaccine LHD Toolkit

Pre-Vaccination Checklist for COVID-19 Vaccines

Information for Healthcare Professionals



For additional information on COVID-19 vaccine clinical guidance, see: <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>.

For additional information on ACIP general recommendations, see: <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html>.

Two COVID-19 vaccines are currently authorized for use in the United States. These vaccines are authorized for use among different age populations.

PRODUCT	AUTHORIZED AGE GROUPS
Pfizer-BioNTech COVID-19 Vaccine	16 years of age and older
Moderna COVID-19 Vaccine	18 years of age and older

Anyone outside of the authorized age groups for a product should not receive the vaccine.

Are you feeling sick today?

There is no evidence that acute illness reduces vaccine efficacy or increases vaccine adverse events. However, as a precaution with moderate or severe acute illness, all vaccines should be delayed until the illness has improved. **Mild illnesses (e.g., upper respiratory infections, diarrhea) are NOT contraindications to vaccination.** Do not withhold vaccination if a person is taking antibiotics.

Vaccination of persons with current SARS-CoV-2 infection should be deferred until the person has recovered from acute illness and they can discontinue isolation. This recommendation applies to persons who develop SARS-CoV-2 infection before receiving any vaccine doses as well as those who develop SARS-CoV-2 infection after the first dose but before receipt of the second dose.

Have you ever received a dose of COVID-19 vaccine?

COVID-19 vaccines are **NOT** interchangeable. Currently authorized COVID-19 vaccines require two doses. Both doses of the series should be completed with the same product. Product dosing schedules vary.

Check medical records, immunization information systems, and vaccination record cards to help determine the initial product received. Those who received a trial vaccine should consult with the trial sponsors to determine if it is feasible to receive additional doses.

PRODUCT	DOSING SCHEDULE Between doses 1 and 2
Pfizer-BioNTech COVID-19 Vaccine	21 days
Moderna COVID-19 Vaccine	28 days

The second dose should be administered as close to the recommended interval as possible. The vaccine can be given up to four days in advance of the recommended interval if a patient presents early and you are concerned they will not return at the appropriate interval for vaccination. However, there is no maximum interval between the first and second dose for either vaccine. The series does not need to be restarted.



COVID-19 Vaccine LHD Toolkit

Pre-Vaccination Checklist for COVID-19 Vaccines

Information for Healthcare Professionals



COVID-19 Vaccine Components

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-diyl)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

Have you ever had a severe allergic reaction (e.g., anaphylaxis) to something? For example, a reaction for which you were treated with epinephrine or EpiPen®, or for which you had to go to the hospital?

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. HOWEVER, individuals who have had severe allergic reactions to something, regardless of cause, **should be observed for 30 minutes after vaccination**. All other persons should be observed for 15 minutes.

Was the severe allergic reaction after receiving a COVID-19 vaccine?

History of severe allergic reaction (e.g., anaphylaxis) to a previous dose or component of the COVID-19 vaccine product being offered is a contraindication to any current COVID-19 vaccine. Ask questions about previous severe reactions that might indicate an allergy to a vaccine component. For example, PEG may have been a component of medication for a colonoscopy.

Was the severe allergic reaction after receiving another vaccine or another injectable medication?

History of severe allergic reaction (e.g., anaphylaxis) to another vaccine or a component of another vaccine OR anaphylactic reaction to any other injectable medication is a **precaution to currently authorized COVID-19 vaccine**. Vaccine may be given, but counsel patients about unknown risks of developing a severe allergic reaction and balance these risks against the benefits of vaccination. These individuals should be observed for 30 minutes after vaccination. A history of mild allergic reaction to a vaccine or injectable therapy is not a precaution to vaccination.

Healthcare professionals should be familiar with identifying immediate-type allergic reactions, including anaphylaxis, and be competent in treating these events at the time of vaccine administration. Appropriate medical treatment for severe allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of a COVID-19 vaccine. See [Management of Anaphylaxis at COVID-19 Vaccination Sites](#) | CDC for additional guidance.

Have you received passive antibody therapy as treatment for COVID-19?

Based on the estimated half-life of monoclonal antibodies or convalescent plasma as part of COVID-19 treatment, as well as evidence suggesting that reinfection is uncommon in the 90 days after initial infection, **vaccination should be deferred for at least 90 days**, as a precautionary measure until additional information becomes available, to avoid interference of the antibody treatment with vaccine-induced immune responses.



COVID-19 Vaccine LHD Toolkit

Pre-Vaccination Checklist for COVID-19 Vaccines

Information for Healthcare Professionals



Clinical Consideration Questions

Responses to these questions are not (on their own) contraindications or precautions to vaccination. However, healthcare professionals should be prepared to discuss information and options with patients based on their responses to the following questions.

Have you received another vaccine in the last 14 days?

COVID-19 vaccine series should be administered alone, with a minimum interval of 14 days before or after administration with other vaccines. This recommendation is based on the lack of data on the safety and efficacy of mRNA COVID-19 vaccines administered simultaneously with other vaccines.

Have you had a positive test for COVID-19 or has a doctor ever told you that you had COVID-19?

Vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection. Vaccination of persons with known current SARS-CoV-2 infection should be deferred until the person has recovered from the acute illness (if the person had symptoms) and criteria have been met for them to discontinue isolation.

Persons with documented acute SARS-CoV-2 infection in the preceding 90 days may delay vaccination until near the end of this period, if desired, because current evidence suggests reinfection is uncommon during this time.

Viral testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection solely for the purposes of vaccine decision-making is not recommended.

Do you have a weakened immune system caused by something such as HIV infection or cancer or do you take immunosuppressive drugs or therapies?

Persons with HIV infection or other immunocompromising conditions, or who take immunosuppressive medications or therapies might be at increased risk for severe COVID-19. mRNA COVID-19 vaccines may be administered to persons with underlying medical conditions who have no contraindications to vaccination. However, they should be counseled about the unknown vaccine safety profile and effectiveness in immunocompromised populations, as well as the potential for reduced immune responses and the need to continue to follow all current guidance to protect themselves against COVID-19, including wearing a mask, social distancing, and washing hands frequently.

Do you have a bleeding disorder or are you taking a blood thinner?

COVID-19 vaccine may be given to these patients, if a physician familiar with the patient's bleeding risk determines that the vaccine can be administered intramuscularly with reasonable safety. ACIP recommends the following technique for intramuscular vaccination in patients with bleeding disorders or taking blood thinners: a fine-gauge needle (23-gauge or smaller caliber) should be used for the vaccination, followed by firm pressure on the site, without rubbing, for at least 2 minutes.

Are you pregnant or breastfeeding?

If pregnant people are part of a group that is recommended to receive a COVID-19 vaccine (e.g., healthcare personnel), they may choose to be vaccinated. For pregnant people seeking guidance in making a decision, pregnant people and their healthcare providers should consider the level of COVID-19 community transmission, the patient's personal risk of contracting COVID-19, the risks of COVID-19 to the patient and potential risks to the fetus, the efficacy of the vaccine, the side effects of the vaccine, and the lack of data about the vaccine during pregnancy.

A lactating person who is part of a group recommended to receive a COVID-19 vaccine (e.g., healthcare personnel) may choose to be vaccinated. There are no data on the safety of COVID-19 vaccines in lactating people or the effects of mRNA COVID-19 vaccines on the breastfed infant or milk production/excretion.

COVID-19 Vaccine LHD Toolkit

Appendix 21 – COVID-19 Vaccine Temperature Log Celsius



COVID-19 Vaccine LHD Toolkit

COVID-19 Vaccine

Temperature Log for Refrigerator Vaccine Storage (Celsius) Days 1-15



Store COVID-19 vaccines between 2°C and 8°C. Using a digital data logger (DDL), check and record the temperature daily using one of the options below. Save this record for 3 years, unless your state/local jurisdiction requires a longer time period. See CDC's *Vaccine Storage and Handling Toolkit, COVID-19 Addendum*, for additional information.

Option 1: Minimum/Maximum (Min/Max) Temperatures (preferred)

1. Most DDLs display minimum and maximum temperatures. Check and record the min/max temperatures at the start of each workday.
2. Document these temperatures in the min/max temperature row under the appropriate date.

Option 2: Current Temperature

1. If the DDL does not display min/max temperatures, check and record the current temperature at the start and end of the workday.
2. Document these temperatures by writing an "X" in the row that corresponds to the refrigerator temperature under the appropriate day of the month.
3. Review the continuous DDL temperature data daily.



If the temperature is out of range,
TAKE ACTION!

1. Do **NOT** discard the vaccine.
2. Label the vaccine "**Do Not Use.**"
3. Complete the Vaccine Troubleshooting Record.
4. Contact the manufacturer to determine under what conditions (refrigerated) to store the vaccine as quickly as possible.

Month _____ PIN Number _____

Facility Name _____

OPTION 1	Day of the month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
	Time															
	Staff initials															
	Min/max temperatures															
	Temperatures lower than 2°C and higher than 8°C are out of range. Complete a Vaccine Troubleshooting Record. Contact the manufacturer and your immunization program.															

OPTION 2	Time	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
	Staff initials																														
	2°C																														
	3°C																														
	4°C																														
	5°C																														
	6°C																														
	7°C																														
8°C																															

For additional information, see the vaccine manufacturer's product information.

Adapted with appreciation from the Immunization Action Coalition (IAC) temperature log

12/22/2020 CS3216294



COVID-19 Vaccine LHD Toolkit

COVID-19 Vaccine

Temperature Log for Refrigerator Vaccine Storage (Celsius) Days 16–31



Store COVID-19 vaccines between 2°C and 8°C. Using a digital data logger (DDL), check and record the temperature daily using one of the options below. Save this record for 3 years, unless your state/local jurisdiction requires a longer time period. See CDC's *Vaccine Storage and Handling Toolkit, COVID-19 Addendum*, for additional information.

Option 1: Minimum/Maximum (Min/Max) Temperatures (preferred)

1. Most DDLs display minimum and maximum temperatures. Check and record the min/max temperatures at the start of each workday.
2. Document these temperatures in the min/max temperature row under the appropriate date.

Option 2: Current Temperature

1. If the DDL does not display min/max temperatures, check and record the current temperature at the start and end of the workday.
2. Document these temperatures by writing an "X" in the row that corresponds to the refrigerator temperature under the appropriate day of the month.
3. Review the continuous DDL temperature data daily.

! If the temperature is out of range, TAKE ACTION!

1. Do **NOT** discard the vaccine.
2. Label the vaccine **"Do Not Use."**
3. Complete the Vaccine Troubleshooting Record.
4. Contact the manufacturer to determine under what conditions (refrigerated) to store the vaccine as quickly as possible.

Month _____ PIN Number _____

Facility Name _____

OPTION 1	Day of the month	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
	Time																
	Staff initials																
	Min/max temperatures																
	Temperatures lower than 2°C and higher than 8°C are out of range. Complete a Vaccine Troubleshooting Record. Contact the manufacturer and your immunization program.																

OPTION 2	Time	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
	Staff initials																														
	2°C																														
	3°C																														
	4°C																														
	5°C																														
	6°C																														
	7°C																														
8°C																															

For additional information, see the vaccine manufacturer's product information.

Adapted with appreciation from the Immunization Action Coalition (IAC) temperature log

12/22/2020 CS3216294

COVID-19 Vaccine LHD Toolkit

Appendix 22 – COVID-19 Vaccine Temperature Log Fahrenheit



COVID-19 Vaccine LHD Toolkit

COVID-19 Vaccine

Temperature Log for Refrigerator Vaccine Storage (Fahrenheit) Days 1-15



Store COVID-19 vaccines between 36°F and 46°F. Using a digital data logger (DDL), check and record the temperature daily using one of the options below. Save this record for 3 years, unless your state/local jurisdiction requires a longer time period. See CDC's *Vaccine Storage and Handling Toolkit, COVID-19 Addendum*, for additional information.

Option 1: Minimum/Maximum (Min/Max) Temperatures (preferred)

1. Most DDLs display minimum and maximum temperatures. Check and record the min/max temperatures at the start of each workday.
2. Document these temperatures in the min/max temperature row under the appropriate date.

Option 2: Current Temperature

1. If the DDL does not display min/max temperatures, check and record the current temperature at the start and end of the workday.
2. Document these temperatures by writing an "X" in the row that corresponds to the refrigerator temperature under the appropriate day of the month.
3. Review the continuous DDL temperature data daily.



If the temperature is out of range,
TAKE ACTION!

1. Do **NOT** discard the vaccine.
2. Label the vaccine **"Do Not Use."**
3. Complete the Vaccine Troubleshooting Record.
4. Contact the manufacturer to determine under what conditions (refrigerated) to store the vaccine as quickly as possible.

Month _____ PIN Number _____

Facility Name _____

OPTION 1	Day of the month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
	Time																
	Staff initials																
	Min/max temperatures																
Temperatures lower than 36°F and higher than 46°F are out of range. Complete a Vaccine Troubleshooting Record. Contact the manufacturer and your immunization program.																	
OPTION 2	Time	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
	Staff initials																
	36°F																
	37°F																
	38°F																
	39°F																
	40°F																
	41°F																
	42°F																
	43°F																
	44°F																
45°F																	
46°F																	

For additional information, see the vaccine manufacturer's product information.

Adapted with appreciation from the Immunization Action Coalition (IAC) temperature log

12/22/2020 CS3216294



COVID-19 Vaccine LHD Toolkit

COVID-19 Vaccine

Temperature Log for Refrigerator Vaccine Storage (Fahrenheit) Days 16–31



Store COVID-19 vaccines between 36°F and 46°F. Using a digital data logger (DDL), check and record the temperature daily using one of the options below. Save this record for 3 years, unless your state/local jurisdiction requires a longer time period. See CDC's *Vaccine Storage and Handling Toolkit, COVID-19 Addendum*, for additional information.

Option 1: Minimum/Maximum (Min/Max) Temperatures (preferred)

- Most DDLs display minimum and maximum temperatures. Check and record the min/max temperatures at the start of each workday.
- Document these temperatures in the min/max temperature row under the appropriate date.

Option 2: Current Temperature

- If the DDL does not display min/max temperatures, check and record the current temperature at the start and end of the workday.
- Document these temperatures by writing an "X" in the row that corresponds to the refrigerator temperature under the appropriate day of the month.
- Review the continuous DDL temperature data daily.

! If the temperature is out of range, **TAKE ACTION!**

- Do **NOT** discard the vaccine.
- Label the vaccine **"Do Not Use."**
- Complete the Vaccine Troubleshooting Record.
- Contact the manufacturer to determine under what conditions (refrigerated) to store the vaccine as quickly as possible.

Month _____ PIN Number _____
Facility Name _____

OPTION 1	Day of the month	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
	Time																
	Staff initials																
	Min/max temperatures																
	Temperatures lower than 36°F and higher than 46°F are out of range. Complete a Vaccine Troubleshooting Record. Contact the manufacturer and your immunization program.																

OPTION 2	Time	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
	Staff initials																														
	36°F																														
	37°F																														
	38°F																														
	39°F																														
	40°F																														
	41°F																														
	42°F																														
	43°F																														
	44°F																														
	45°F																														
46°F																															

For additional information, see the vaccine manufacturer's product information.
12/22/2020 CS3216294

Adapted with appreciation from the Immunization Action Coalition (IAC) temperature log



COVID-19 Vaccine LHD Toolkit

Appendix 23 – Recipient Portal Username



COVID-19 Vaccine Management System (CVMS) Recipient Portal Resetting Your Password Job Aid

Before you begin the process of resetting your password to the CVMS Recipient Portal, please have the following items ready.

- **Your CVMS Recipient Portal Username**

IMPORTANT! Your CVMS Recipient Portal Username is unique. It will have **.covid19vaccine** added to the end of the email address that was provided when your account was created. You can find your CVMS Recipient Portal Username in the CVMS Recipient Portal Welcome Email, or you can follow the example below if you do not have that email.

For example: If your email is **johndoe@gmail.com**, your CVMS Recipient Portal Username is **johndoe@gmail.com.covid19vaccine**.

If your email is **jane.doe@firefox.com**, your CVMS Recipient Portal Username is **jane.doe@firefox.com.covid19vaccine**.

- **One of the following browsers open: Chrome, Firefox, or Safari**

IMPORTANT! Internet Explorer and Edge are not compatible with the CVMS Recipient Portal.

The following instructions are for resetting your CVMS Recipient Portal Password.

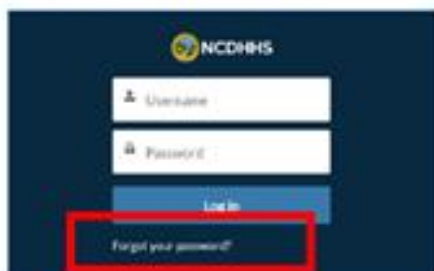
1. Within your browser, click <https://covid-vaccine-portal.ncdhhs.gov/> to go to the CVMS Recipient Portal.
2. On the homepage, click **Login as registered user OR Login**.



COVID-19 Vaccine LHD Toolkit



3. Click Forgot your password?.



4. You will see the Password Reset page. Enter your CVMS Recipient Portal Username.

5. Click Reset Password.



6. Check your Email Inbox. You will receive an email from the CVMS Recipient Portal with a link to Reset your password.

7. Open the Email. Click the Reset Password Link.



8. A new page will open.

COVID-19 Vaccine LHD Toolkit

Appendix 24 - CVMS Recipient Portal Reset Password Job Aid



Finding Your Username for the CVMS Recipient Portal

This document contains instructions on how a recipient can find their Username for the North Carolina COVID-19 Vaccine Management System (CVMS) Recipient Portal.

Step 1: Navigate to your email inbox (the email your employer used to register you in CVMS)

Step 2: Find the email that says, 'Welcome to the COVID-19 Vaccine Management System'. The email should look similar to the image below.



Step 3: See your username within the email and store it in a safe place. If you did not receive the email referenced in Step 2 or have deleted the email, **you can derive your username by taking the email address that was used by your employer to register you in CVMS and adding .COVID19vaccine to it** (e.g., emailusedatupload.covid19vaccine).

Step 4: You can now navigate to the CVMS Recipient Portal Homepage at <https://covid-vaccine-portal.ncdhhs.gov/> and click 'Login as registered user' or 'Login'



If you are still experiencing issues getting into your CVMS Recipient Portal account, please contact the CVMS Help Desk at CVMS-help@dhhs.nc.gov



COVID-19 Vaccine LHD Toolkit

Appendix 25 - CVMS Offline Appointment Scheduling User Guide

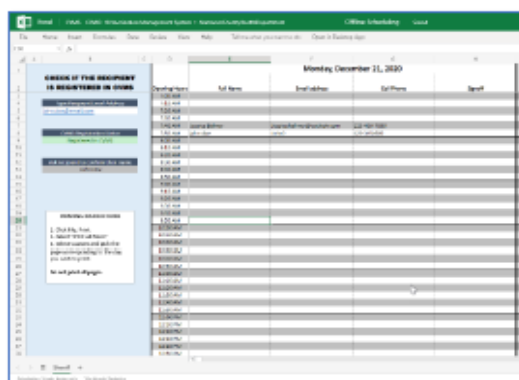


CVMS Offline Appointment Scheduling User Guide

Last Updated: 12/31/2020

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2	Search for a Recipient and Check CVMS Registration Status.....	5
3	Schedule an Appointment	6
4	Printing the Day's Appointment	7



Thank you for your continued efforts to prepare for the COVID-19 vaccine. We are excited to announce that soon recipients will be able to schedule their own COVID-19 vaccination appointments in the COVID-19 Management System (CVMS).

Also, we recognize that not all Local Health Departments (LHDs) or Hospitals may have an appointment scheduling system to leverage until the functionality is available in CVMS.

In the meantime, organizations who do not currently have appointment scheduling capabilities can do the following:

1. Access the Offline Schedule Spreadsheet on the NC DHHS SharePoint site
2. Verify if a recipient has finalized registering in CVMS
3. Schedule an appointment on a table¹
4. Repeat for all vaccination appointments occurring on one day
5. Print the appointments for the day

Note: if you need to manage multiple sites, you can duplicate the scheduling file to cover other clinics scheduling (simply click on File, Save a Copy).

¹ Note: If a recipient did not register in CVMS, you can still verify that the individual falls into priority group 1A (in accordance with the CDC and NC DHHS prioritization of COVID-19 vaccine recipients) and enter the individual as a new recipient in CVMS on the day of their appointment. However, to do this, the recipient must complete the COVID-19 Vaccination questionnaire before the appointment (on-site using a paper form that you can print for them).

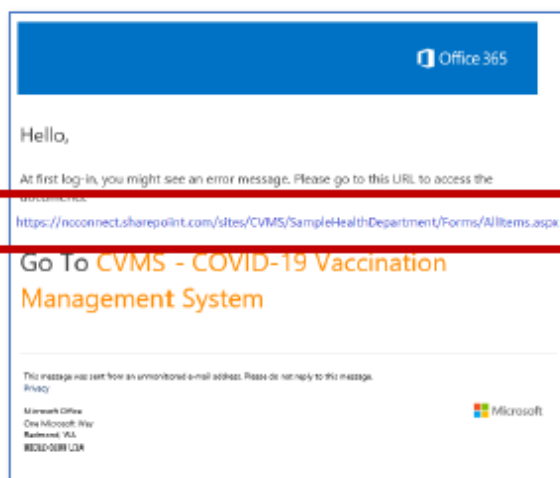


COVID-19 Vaccine LHD Toolkit

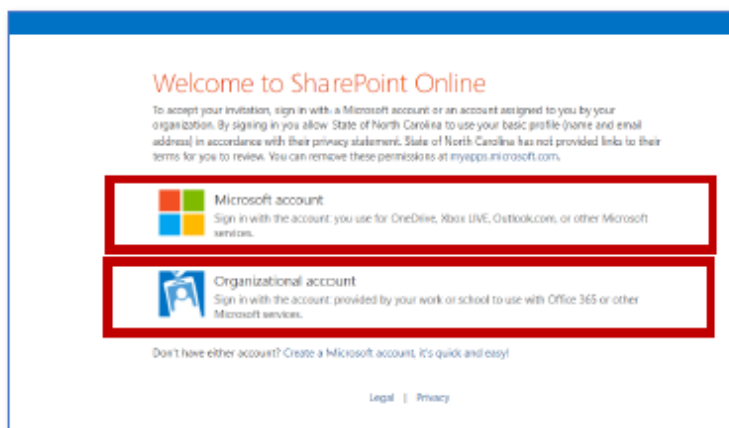


1 Access CVMS Offline Appointment Scheduling File

1. Please send the list of email addresses that would need an access to the file, with the subject: CVMS Offline Appointment Scheduling, and the name of your department
To: Rebecca.Webb@dhhs.nc.gov if you are a local health department
or tim.davis@dhhs.nc.gov if you are a hospital
2. Once your account has been set up, you will receive an email granting you access to SharePoint. You may copy and paste the link from the body of the message into your browser window to directly access the file.



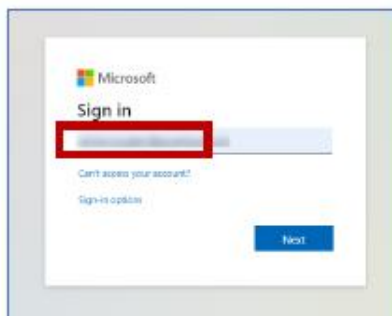
3. You will be prompted to a SharePoint Log In screen. Select **Organizational** account if your email address is linked to a Microsoft365 account provided by your organization, otherwise, select **Microsoft** account (if you do not have a Microsoft account, also click 'Microsoft Account').



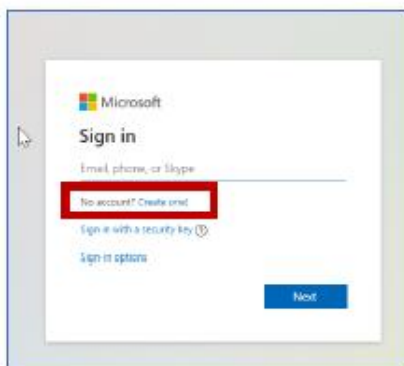
COVID-19 Vaccine LHD Toolkit



- a. If you selected **Organizational Account**
- Type your email address, then Press **Next**



- Then type your password, and press **Sign In**²
- b. If you selected **Microsoft Account**
- Type your email address, then press **Next**
 - Or, if you do not have a Microsoft account, type **Create one!**



- Type your password and click **Next** (Note: if you are creating a Microsoft account, a verification code will first be sent to your email account, type the verification code and click **Next** to login).

² The button **Sign In** might appear differently depending on the organization authentication settings.



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-
- The screenshot displays the CVMS - COVID-19 Vaccination Management System interface. On the left is a sidebar menu with options: Home, Dashboard, Documents, Reports, CVMS Links, and Settings. The main content area features two sections:
- Physicians and Healthcare Providers with Week 1 allocation of Vaccine**: Includes a link labeled "CLICK HERE TO ACCESS YOUR PAGER".
 - Local Health Departments - Access your folder under the link below**: A red-bordered box contains a grid of 20 links to various local health departments, such as Adams County Health Department, Alameda County Health Department, and Alameda County Health Services.

- [+ New](#)
[Upload](#)
[Edit in grid view](#)
[Sync](#)
[Add shortcut to OneDrive](#)
[Export to Excel](#)
[Power Apps](#)
[Automate](#)

County Health Department

Name	Modified	Modified By	+ Add columns
 Offline Scheduling.xlsx	A few seconds ago	hutchinson, Nicholas	

-
- The screenshot shows the 'Transfer' screen in the 'Financials' application. The interface is split into a left sidebar and a main table area. The sidebar contains a section titled 'CHECK IF THE RECIPIENT IS TRANSFERRED IN OVER' with a 'Transfer' button and a 'When do service ends' section with a date picker. The main table area has a header row for 'Monday, December 21, 2020' and 'Tuesday, December 22, 2020'. The table has columns for 'Activity Name', 'Est. Name', 'Est. Address', 'Est. Phone', 'Est. Email', 'Est. Website', and 'Est. Notes'. The table is currently empty.

COVID-19 Vaccine LHD Toolkit



COVID-19 Vaccine LHD Toolkit



2 Search for a Recipient and Check CVMS Registration Status

1. If a recipient call to make an appointment, ask for their email address.
2. Enter the email address in the field located under the label "Type Recipient Email Address," and press the ENTER key.

CHECK IF THE RECIPIENT IS REGISTERED IN CVMS			
Type Recipient Email Address	Opening Hours	Full Name	
archoek@gmail.com	7:00 AM		
	7:10 AM		
	7:20 AM		
	7:30 AM		
	7:40 AM		
	7:50 AM		
CVMS Registration Status	8:00 AM		
	8:10 AM		
	8:20 AM		
Ask recipient to confirm their name	8:30 AM		
	8:40 AM		

3. Once the patient's email address has been entered, wait a few seconds for the system to check the latest database of recipients³.

CHECK IF THE RECIPIENT IS REGISTERED IN CVMS			
Type Recipient Email Address	Opening Hours	Full Name	
archoek@gmail.com	7:00 AM		
	7:10 AM		
	7:20 AM		
	7:30 AM		
	7:40 AM		
	7:50 AM		
CVMS Registration Status	8:00 AM		
Invited but Not Registered in CVMS	8:10 AM		
	8:20 AM		
Ask recipient to confirm their name	8:30 AM		
	8:40 AM		

- a. In the CVMS Registration Status will appear one of the following 3 options:

Registered in CVMS: The recipient has been loaded in the CVMS online system and completed online registration.

Invited but not registered in CVMS: the recipient email address has been loaded in CVMS by an employer or a care organization but has not yet created an account in the CVMS Recipient portal. Note: you can ask still decide schedule an appointment with them, and either ask them to

³ The database will be refreshed every evening after opening hours.



COVID-19 Vaccine LHD Toolkit



finalize their registration prior their appointment for a faster vaccine appointment, or, the day of their appointment provide them with the COVID-19 Vaccination Questionnaire form⁴, ask them to write their information, and then create their recipient account on their behalf.

Not preloaded in CVMS by Employer: the recipient has not been loaded into CVMS by any eligible organization. If you believe this recipient is eligible nonetheless, the day of their appointment, provide them with the registration form, ask them to write their information, and then create their recipient account on their behalf in CVMS.

3 Schedule an Appointment

1. Once a recipient has deemed ready for a vaccine dose, you can schedule their appointment. Simply add their information in the schedule according to the data and time of the appointment.

Monday, December 21, 2020				
Opening Hours	Full Name	Email address	Cell Phone	Signoff
7:00 AM				
7:10 AM				
7:20 AM				
7:30 AM				
7:40 AM	John Doe	john.doe@email.com	123-456-7890	
7:50 AM				
8:00 AM				
8:10 AM				
8:20 AM				
8:30 AM				
8:40 AM				
8:50 AM				
9:00 AM				
9:10 AM				
9:20 AM				
9:30 AM				

John Doe is scheduled for a vaccination at 7:40AM on 12/21/2020

Feel free to use the fields as preferred. For example, the Signoff field can be used to enter comments, mention that the recipient would need more time to finalize the registration on paper, or to sign off when the recipient completed to the appointment.

⁴ If your recipient record cannot be found and needs to be created in the system, the first step in doing so is to connect to the CVMS Provider portal (<https://covid-vaccine-provider-portal.ncdhhs.gov>), go to the HELP & INFORMATION tab at the top of the screen and navigate to the COVID-19 VACCINATION QUESTIONNAIRE. This is going to download a PDF that you print and hand to recipients to fill out with pen and paper. On this form you'll have everything you need to create their recipient record, as well as all the exact same questions that you would see when filling out the questionnaire through the RECIPIENT PORTAL.

COVID-19 Vaccine LHD Toolkit

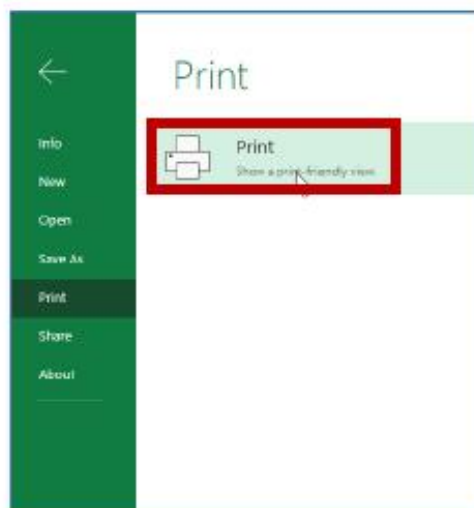
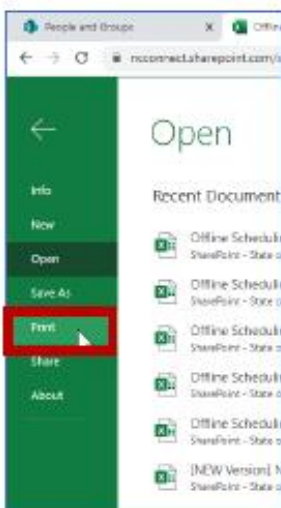


COVID-19 Vaccine LHD Toolkit

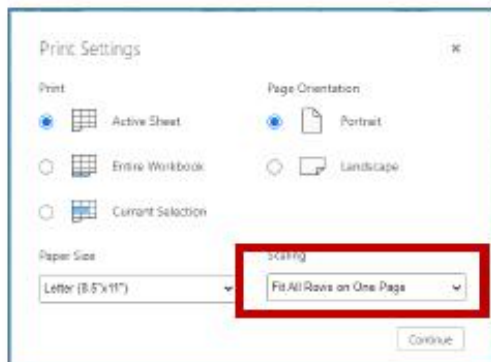


4 Printing the Day's Appointment

1. You can print on paper the Day's Appointment.
2. Click on FILE, Print, Print (Show a print-friendly view.)



3. On the pop-up window that open, modify the Scaling to FIT ALL ROWS ON ONE PAGE



IMPORTANT NOTE: Make sure the "Scaling" field is set to "Fit All Rows on One Page", otherwise your document will not print correctly.

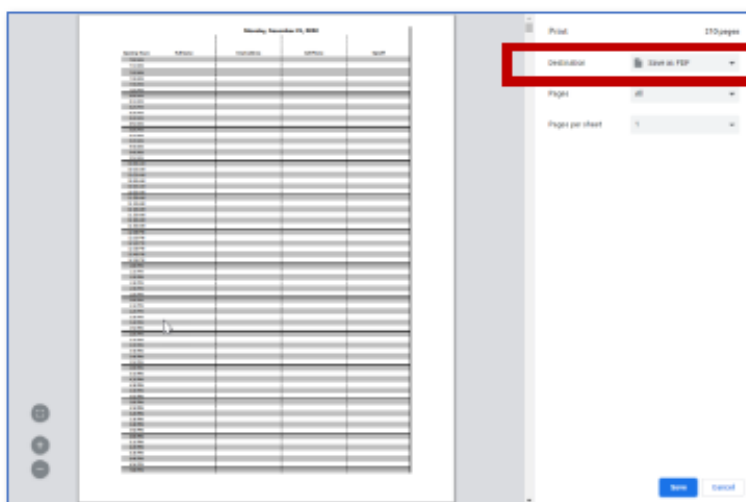
4. Click "Continue."



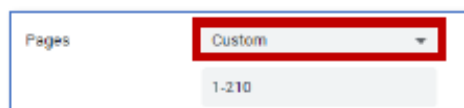
COVID-19 Vaccine LHD Toolkit



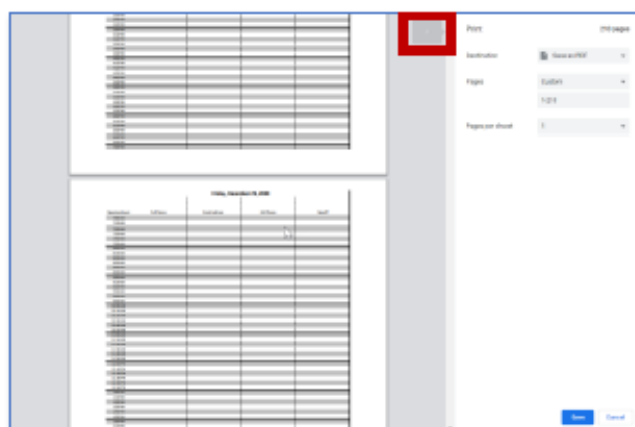
- Wait for a preview window to show up. Select the correct Printer in Destination, or Save the file as a PDF.



- In Pages, select custom.



- Scroll down until you find the day you wish to print. While you scroll-down, please pay attention to the page numbers that will show next to the scrolling bar:



- Enter the page number(s) that corresponds to the day you want to print.
- Click "Print" at the bottom of the window.



COVID-19 Vaccine LHD Toolkit

Appendix 26 DEEPER DIVE: Phase 1a. Health care workers fighting COVID-19 & Long-Term Care



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DEEPER DIVE: Phase 1a. Health care workers fighting COVID-19 & Long-Term Care

COVID-19 Vaccinations: Slow the spread and save lives.

A tested, safe and effective vaccine will be available to all who want it, but supplies will be limited at first. Independent state and federal public health advisory committees have determined that the best way to fight COVID-19 is to start first with vaccinations for those most at risk, reaching more people as the vaccine supply increases. Keep practicing the 3W's—wear a mask, wait six feet apart, wash your hands—until everyone has a chance to be vaccinated.

1a

Health care workers fighting COVID-19 & Long-Term Care



PHASE 1a: The goal is to protect the health care workers who care for patients with COVID-19, those working on the vaccination rollout, and North Carolinians who are at the highest risk of being hospitalized or dying from COVID-19.

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 on patients with COVID-19 that put them at risk, such as intubation, bronchoscopy, suctioning, invasive dental procedures, invasive specimen collection, and CPR
- handling people for who have died from COVID-19

Outpatient providers who have an increased risk of exposure beyond that of a typical general outpatient setting should be included in the Phase 1a. This could include outpatient providers who are focused on COVID-19 patient evaluation, respiratory care (e.g., respiratory diagnostic testing centers), members of a dedicated respiratory care team, or those 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.

In addition, health care workers administering vaccine in initial mass vaccination clinics are part of this first phase.

The following types of people could meet this definition:

- | | | |
|--------------------------------|--|--|
| • behavioral health providers | • health care trainees (e.g., medical students, pharmacy students, nursing students) | • personal care aides |
| • community health workers | • home health workers | • pharmacists |
| • dental hygienists | • morticians/funeral home staff | • physicians |
| • dentists | • nurses | • public health and emergency preparedness workers |
| • EMT/paramedics | • nursing assistants | • public health nurses |
| • environmental services staff | | • respiratory techs |

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How do health care workers in this first phase get their vaccine?

Due to very limited supplies, vaccines were available first through a small number of hospitals that 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.

Local Health Departments, 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 requirements 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.

HEALTH CARE EMPLOYERS (e.g., medical practices, hospice providers, EMS) should determine which of their employees are at high risk for exposure to COVID-19—those that 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 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 staff who are eligible for Phase 1a. They also can:

- Vaccinate non-employed or non-affiliated community-based health care workers who meet Phase 1a eligibility requirements.
- Work with the Local Health Department to coordinate access to vaccine for non-affiliated health care workers for those they pre-register.

LONG-TERM CARE STAFF AND RESIDENTS include people and staff in skilled nursing facilities and in adult, family and group homes:

- adult care homes
- family care homes
- group homes
- skilled nursing facilities
- group homes for people with intellectual and developmental disabilities who receive home or community-based services
- in-patient hospice facilities

How do long-term care staff and residents get their vaccine?

The federal government manages vaccinations for most staff and residents of long-term care facilities through the newly created Pharmacy Partnership for Long-Term Care Program with CVS and Walgreens. Staff and residents will be vaccinated at the same time. Other long-term care staff and residents will receive vaccinations through their Local Health Departments and other long-term care pharmacies if not participating in the federal program. North Carolina is working to enroll other vaccinating providers who may also reach this population.

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Appendix 27 DEEPER DIVE: Phase 1b. Adults at highest risk of severe illness and those at highest risk for exposure



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DEEPER DIVE: Phase 1b. Adults at highest risk of severe illness and those at highest risk for exposure

COVID-19 Vaccinations: Your best shot at stopping COVID-19

A tested, safe and effective vaccine will be available to all who want it, but supplies will be limited at first. 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. Keep practicing the 3 Ws—wear a mask, wait six feet apart, wash your hands—until everyone has a chance to get vaccinated.

Phase 1b: The goals are to save lives by protecting North Carolinians who are at high risk of being hospitalized or dying from COVID-19 and slow the spread by protecting those at high risk of exposure.

Due to limited supply, phase 1b will not be open to everyone at first. Vaccinations will happen by group in the following order:

- **Group 1: Persons 75 years and older.** All people age 75 and older will be eligible to be vaccinated first in this group. There is no requirement to have certain qualifying chronic conditions.
- **Group 2: Any patient-facing direct health care workers not vaccinated in Phase 1a and essential frontline workers who are over age 50.** Patient-facing direct health care workers are those directly caring for or working directly in areas where in-person patient care occurs. Essential frontline workers are defined by the Centers for Disease Control and Prevention (CDC) as workers who are in sectors essential to the functioning of society and who are at substantially higher risk for exposure to COVID-19. There is no requirement to have certain qualifying chronic conditions.
- **Group 3: All other patient-facing direct health care workers not vaccinated in Phase 1a and frontline essential workers of any age.** There is no requirement to have certain qualifying chronic conditions.

Patient-facing direct health care workers include any paid or unpaid health care workers with direct patient contact including, but not limited to:

- | | | |
|--------------------------------|--|--|
| • behavioral health providers | • health care trainees (e.g., medical students, pharmacy students, nursing students) | • front desk administrative staff |
| • community health workers | • home health workers | • personal care aides |
| • dental hygienists | • laboratory and phlebotomy staff | • pharmacists |
| • dentists | • nurses | • pharmacy techs |
| • EMT/paramedics | • nursing aides and assistants | • physicians |
| • environmental services staff | • nursing techs | • public health and emergency preparedness workers |
| • food services staff | | • public health nurses |
| | | • respiratory techs |

Frontline essential workers as defined by the [CDC](#) include these jobs:



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- first responders (firefighters, police)
- education (teachers, support staff, day care)
- manufacturing
- corrections workers
- public transit workers
- grocery store workers
- food and agriculture
- US postal workers

North Carolina revised the prioritization for who qualifies for vaccination in Phase 1b from its original plan submitted to the CDC in October 2020 to more closely align with [new recommendations from the CDC](#) on vaccine allocation published on December 22, 2020.

How do people who are 75 and older get their vaccine?

Because vaccine supplies are still limited, those 75 and over may have to wait, but they have one of the first spots to take their shot. If you are 75 or over—or assisting someone who is—here is how to take your shot against COVID-19:

- **Supplies are very limited.** Right now, very few vaccine doses are available.
- **You will likely need an appointment to get vaccinated.** You may have to wait to schedule your appointment to get your vaccine.
- **Your local health department or hospital can help you get your shot.** Because supplies are very limited right now, most doctors cannot provide vaccinations in their offices.
- **Find your local health department or hospital.** Visit <https://covid19.ncdhhs.gov/findingyourspot>. Because vaccine supplies are very limited, providers on this list may have very little to no vaccine doses available when you contact them.
- **You can also call the COVID-19 Line 1-877-490-6642.** It's a free call.

The COVID-19 vaccine will be available to everyone for free, whether or not you have health insurance. You will need two shots to build up your immunity. You will get a printed card and email to remind you to come back 3 to 4 weeks later for your second dose. Your personal information is private and strictly confidential.



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Appendix 28 Medical Management of Vaccine Reactions in Adults in a Community Setting

Medical Management of Vaccine Reactions in Adults in a Community Setting

The table below describes steps to take if an adverse reaction occurs following vaccination.

Administering any medication, including vaccines, has the potential to cause an adverse reaction. To minimize the likelihood of an adverse event, screen patients for vaccine contraindications and precautions prior to vaccination (see "Screening Checklist for Contraindications to Vaccines for Adults" at www.immunize.org/catg.d/p4065.pdf). When adverse reactions do occur,

they can vary from minor (e.g., soreness, itching) to the rare and serious (e.g., anaphylaxis). Be prepared.

Vaccine providers should know how to recognize allergic reactions, including anaphylaxis. Have a plan in place and supplies available to provide appropriate medical care should such an event occur.

REACTION	SIGNS AND SYMPTOMS	MANAGEMENT
Localized	Soreness, redness, itching, or swelling at the injection site	Apply a cold compress to the injection site. Consider giving an analgesic (pain reliever) or antipruritic (anti-itch) medication.
	Slight bleeding	Apply pressure and an adhesive compress over the injection site.
	Continuous bleeding	Place thick layer of gauze pads over site and maintain direct and firm pressure; raise the bleeding injection site (e.g., arm) above the level of the patient's heart.
Psychological fright, presyncope, and syncope (fainting)	Fright before injection is given	Have patient sit or lie down for the vaccination.
	Patient feels "faint" (e.g., light-headed, dizzy, weak, nauseated, or has visual disturbance)	Have patient lie flat. Loosen any tight clothing and maintain open airway. Apply cool, damp cloth to patient's face and neck. Keep them under close observation until full recovery.
	Fall, without loss of consciousness	Examine the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated.
	Loss of consciousness	Check to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated. Call 911 if patient does not recover immediately.
Anaphylaxis	Skin and mucosal symptoms such as generalized hives, itching, or flushing; swelling of lips, face, throat, or eyes. Respiratory symptoms such as nasal congestion, change in voice, sensation of throat closing, stridor, shortness of breath, wheeze, or cough. Gastrointestinal symptoms such as nausea, vomiting, diarrhea, cramping abdominal pain. Cardiovascular symptoms such as collapse, dizziness, tachycardia, hypotension.	See the emergency medical protocol on the next page for detailed steps to follow in treating anaphylaxis.

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Suggested Medications for Managing Anaphylaxis in a Community Immunization Clinic Setting

FIRST-LINE medication

- ☐ Epinephrine 1.0 mg/mL aqueous solution (1:1000 dilution) in prefilled autoinjector or prefilled syringe (0.3 mg), prepackaged syringes, vials, or ampules. At least three epinephrine doses should be available onsite.

OPTIONAL medications: H₁ antihistamines

These relieve itching and hives only; they DO NOT relieve upper or lower airway obstruction, hypotension, or shock.

- ☐ Diphenhydramine (e.g., Benadryl) oral, 12.5 mg/5 mL liquid, 25 or 50 mg tablets

Additional emergency supplies you may need

- ☐ Syringes (1 and 3 cc) and needles (22 and 25 g, 1", 1½", and 2") if needed for epinephrine
- ☐ Alcohol wipes
- ☐ Tourniquet
Applied on the extremity above the injection site to slow systemic absorption of antigen and anaphylactic mediators
- ☐ Stethoscope
- ☐ Blood pressure measuring device with adult-sized and extra-large cuffs
- ☐ Tongue depressors
- ☐ Light with extra batteries (for examination of the mouth and throat)
- ☐ A timing device, such as wristwatch, for checking pulse
- ☐ Cell phone or access to onsite phone

For remote areas without EMS support

- ☐ Adult airways (various sizes)
- ☐ Adult-sized pocket mask with one-way valve
- ☐ Oxygen (if available)

REFERENCES

± American Academy of Pediatrics. *Red Book: 2018–2021*, 31st ed (p. 66).

Campbell RL, Kelso JM. Anaphylaxis: Emergency treatment. In: UpToDate, Post TW (Ed). UpToDate, Waltham, MA. November 2018.

Kroger AT, Duchin J, Vazquez M. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP) at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html.

Emergency medical protocol for management of anaphylactic reactions in adults in a community setting

- 1 If itching and swelling are confined to the injection site where the vaccination was given, observe patient closely for the development of generalized symptoms.
- 2 If symptoms are generalized, activate the emergency medical system (EMS; e.g., call 911) and notify the patient's physician. This should be done by a second person, while the primary healthcare professional assesses the airway, breathing, circulation, and level of consciousness of the patient. Vital signs should be monitored continuously.
- 3 **DRUG DOSING INFORMATION:** The first-line and most important therapy in anaphylaxis is epinephrine. There are NO absolute contraindications to epinephrine in the setting of anaphylaxis.
 - a **First-line treatment: EPINEPHRINE is the first-line treatment for anaphylaxis, and there is no known equivalent substitute.** Use epinephrine in a 1.0 mg/mL aqueous solution (1:1000 dilution). Administer a 0.3 mg dose IM using a premeasured or prefilled syringe or an autoinjector in the mid-outer thigh. If using another epinephrine formulation, the recommended dose is 0.01 mg/kg, ranging for adults from 0.3 mg to maximum dose of 0.5 mg. Administer IM, preferably in the mid-outer thigh. Epinephrine dose may be repeated 2 additional times every 5–15 minutes (or sooner as needed) while waiting for EMS to arrive.
 - b **Optional treatment: H₁ ANTIHISTAMINES** relieve itching and urticaria (hives). These medications DO NOT relieve upper or lower airway obstruction, hypotension, or shock. Consider giving diphenhydramine (e.g., Benadryl) for relief of itching and hives. Administer orally 1–2 mg/kg every 4–6 hours, up to a maximum single dose of 100 mg.*
- 4 Monitor the patient closely until EMS arrives. Perform cardiopulmonary resuscitation (CPR), if necessary, and maintain airway. Keep patient in recumbent position (flat on back) unless he or she is having breathing difficulty. If breathing is difficult, patient's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs. Monitor blood pressure and pulse every 5 minutes.
- 5 Record the patient's reaction (e.g., hives, anaphylaxis) to the vaccine, all vital signs, medications administered to the patient, including the time, dosage, response, and the name of the medical personnel who administered the medication, and other relevant clinical information.
- 6 Notify the patient's primary care physician.
- 7 Report the incident to the Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov.

These standing orders for the medical management of vaccine reactions in adult patients shall remain in effect for patients of the

_____ until rescinded or until _____
NAME OF CLINIC DATE

MEDICAL DIRECTOR'S SIGNATURE DATE OF SIGNING

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