I. Introduction

In response to the unprecedented COVID-19 pandemic, <u>Operation Warp Speed (OWS)</u> was established to develop, manufacture, and distribute three hundred million doses of COVID-19 vaccine, with the initial doses available before the end of 2020. Each State is charged with ensuring the ethical and equitable distribution of the federally owned vaccine within its boundaries once vaccines become available. This plan addresses responsibilities for state-level agencies to effectively receive, store, distribute and administer COVID-19 vaccines. The COVID-19 Vaccine Plan is Appendix A to the SC COVID-19 Response Plan, Annex 3 to <u>SC Infectious Disease Plan</u>, Appendix 14 to <u>SC Emergency Operations Plan</u>.

II. Purpose

The purpose of this plan is to outline the responsibilities of key state partners in ensuring the ethical and equitable distribution and administration of COVID-19 vaccines to the people of South Carolina. This document describes the three phases of COVID-19 vaccine distribution and administration. Critical support functions described in this Appendix include outreach and provider enrollment, vaccine program management, allocation, distribution and reporting. This document is supported by the State's Medical Countermeasures Plan, Appendix 17 to SC Emergency Operations Plan.

III. Scope and Applicability

- A. This plan's operational scope pertains to statewide actions to vaccinate against COVID-19. The plan activates in the case of the Food and Drug Administration (FDA) issuing an Emergency Use Authorization (EUA) for one of the seven COVID-19 vaccines whose production is being facilitated by Operation Warp Speed. This plan is specific to the distribution and administration of COVID-19 vaccines that have been acquired by Operation Warp Speed and allocated to the state by federal government.
- B. This plan applies federal guidance regarding the rollout of COVID-19 vaccine distribution. **See Figure 1 on page 2.**
 - Phase 1 Potentially limited supply of COVID-19 vaccine doses is available. Efforts will focus on rapidly reaching targeted populations (e.g., healthcare personnel, people at high risk, workers who are in sectors essential to the functioning of society and are at substantially higher risk of exposure to SARS-CoV-2), high throughput, and stringent storage and handling requirements for the vaccine. Inventory, distribution, and any vaccine repositioning will be closely monitored through reporting to ensure end-to-end visibility of vaccine doses.

- Phases 2 A large number of vaccine doses is available. The focus is on ensuring access to vaccines for Phase 1, equitable distribution to targeted groups who were not yet vaccinated and expanding efforts to the general population, utilizing an expanded provider network.
- Phase 3 Sufficient supply of vaccine doses for the entire population and a surplus of doses are available. Efforts will focus on ensuring equitable vaccination access in the whole population, monitoring vaccine uptake and coverage, and reassessing strategy to increase population uptake in communities with low coverage.

Administration of COVID-19 vaccine will require a phased approach

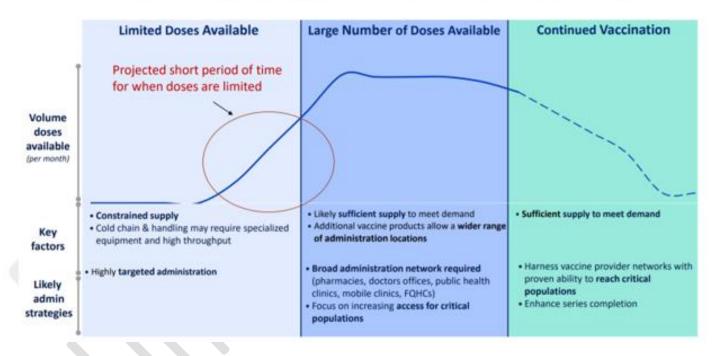


Figure 1: COVID-19 Vaccine Rollout

C. The CDC has issued guidance stating that populations of focus for initial COVID-19 vaccination (Phase 1) will likely be critical infrastructure workforce consisting of healthcare personnel and frontline essential workers, i.e., workers who are in sectors essential to the functioning of society and are at substantially higher risk of exposure to SARS-CoV-2, as well as staff and residents in long-term care and assisted living facilities.

IV. Facts and Assumptions

- A. During Phase 1, the initial COVID-19 vaccine supply will be limited.
- B. Significantly more COVID-19 vaccine will become available for distribution during Phases 2 and 3 and plans will need to evolve to address additional vaccine availability and indications for use.
- C. Given the challenging storage, handling, and administration requirements, early vaccination should focus on administration sites that can reach prioritized populations with as much throughput as possible.
- D. Pfizer and Moderna will be the vaccine candidates to be distributed to jurisdictions in Phase 1.
- E. One or more of the anticipated vaccines will require that each recipient receive two doses of the same vaccine, requiring that individuals be tracked in some manner for the second dose.
- F. The federal government will hold a second dose reserve.
- G. South Carolina's vaccine allocation is determined weekly by the federal government.
- H. There likely will be initial age restrictions for vaccine products.
- I. Initial data collection and sharing will be on the Vaccine Administration Management System (VAMS) platform. Data collection and sharing will transition to the Statewide Immunization System Online Network (SIMON) in Phase 2.
- J. In order to be authorized for use, the FDA guidance indicates that a COVID-19 vaccine will need to be at least 50 percent efficacious in placebo-controlled human clinic trials.

V. Goals and Objectives

- A. Identify, quantify, and locate critical populations, vulnerable populations and potentially underserved populations.
- B. Recruit and enroll vaccine providers to administer vaccines in a variety of settings.
- C. Educate providers about vaccine safety, indications for product use, vaccine administration and compliance with storage and handling requirements.
- D. Monitor vaccine delivery as the number of individuals vaccinated and summarize and report this information to the public.
- E. Provide accurate and timely vaccine coverage reports to state officials and state and federal partners.
- F. Educate the public about the safe development, testing and authorization of COVID-19 vaccines, plans for their distribution, and evolving information about vaccines.
- G. Educate the public about key differences in FDA emergency use authorization and FDA approval (i.e., licensure).
- H. Engage in dialogue with internal and external partners to understand their key considerations and needs related to COVID-19 vaccine program implementation.
- I. Engage critical, vulnerable and potentially underserved populations to achieve high vaccine acceptance through strategic communications campaign delivered by trusted influencers.

J. Ensure COVID-19 vaccine providers have been trained appropriately and have the appropriate supplies and equipment at their locations to manage any serious adverse events.

VI. Organizational Structure

- A. As outlined in the SC COVID-19 Response Plan, the State has established a Unified Command Group (UCG) to coordinate and unify response functions (Planning, Operations, Logistics and Finance). The Unified Command Group consists of the following:
 - Director, SC Department of Health and Environmental Control (DHEC)
 - Director, SC Emergency Management Division (SCEMD)
 - The Adjutant General, SC National Guard (SCNG)
 - The SC State Epidemiologist, DHEC
- B. The COVID-19 Vaccine Task Force was established to define agency and partner roles and responsibilities, and to determine action items and coordination efforts specific to COVID-19 vaccination. Members of Unified Command Group oversee the Vaccine Task Force. The Task Force meets weekly and obtains reports from established working groups as well as input from the COVID-19 Vaccine Advisory Committee to coordinate and synchronize planning in the following areas: Logistics, Planning, Finance, and Communications.

Working groups consist of the following:

- Logistics: DHEC (Lead), SCEMD (Support), SC National Guard (SCNG) (Support)
- Planning: DHEC (Lead), SCEMD (Support), SCNG (Support), SC Hospital Association (SCHA) (Support), Department of Commerce (Support), SC Law Enforcement Division (SLED) (Support)
- Finance: DHEC (Lead), SCEMD (Support), SCNG (Support)
- Communications: DHEC (Lead), SCEMD (Support), SCNG (Support)

VII. Concept of Operations

- A. The plan will be implemented in conjunction with the <u>State Emergency Operations Plan</u> (<u>SCEOP</u>), the <u>DHEC Emergency Operations Plan</u> (<u>DHEC EOP</u>), the SC Infectious Disease Plan, SC COVID-19 Response Plan, and the SC Medical Countermeasures Plan (MCM).
- B. South Carolina is planning for limited COVID-19 doses of Pfizer (recommended for individuals 16 years of age and older) and Moderna (recommended for individuals 18 years of age and older) vaccines to be available as early as December 2020, recognizing

that these vaccines may be approved as licensed vaccines or authorized for use under an EUA issued by the FDA.

- C. After a short period of limited vaccine supply, this plan assumes supplies will increase quickly, allowing vaccination efforts to be expanded to include additional critical populations as well as the general public. South Carolina will develop plans to ensure equitable access to vaccination for each of the critical populations as outlined in *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations*.
- D. In anticipation of receiving vaccines in sufficient quantities and transitioning to Phase 3, DHEC in conjunction with healthcare provider organizations and healthcare professionals will ensure that distribution channels are engaged and prepared to provide the vaccine to anyone desiring it. This will include, but not limited to, practitioners, retail and wholesale pharmacies, healthcare facilities, residential care facilities, schools, and other avenues of vaccine distribution including non-traditional sites like businesses and community locations.

E. Early Shipment of Pfizer Vaccine

- 1. The federal government asked jurisdictions to identify locations to receive early shipments of vaccines once the FDA issues an EUA but before Advisory Committee on Immunization Practices (ACIP) meets and makes recommendations for use and the recommendations are approved. The goal is having vaccines available at the jurisdiction level and jurisdiction are ready to support vaccine administration after ACIP recommendations are issued and approved.
- 2. Fifteen sites (based on ability to administer and store Vaccine A) have been identified.
- 3. After ACIP recommendations have been approved, additional sites (enrolled providers) will be able to place orders against the State's allocation.

F. Transitioning between Phases

- 1. ACIP presented consideration for transitioning between vaccination program phases. Phases may overlap, and it is not necessary to vaccinate every single individual in one phase before moving onto the next phase.
- 2. Suggested indicators for when it may be appropriate to transition phases include:
 - a. Vaccine demand in the current phase is less than vaccination capacity
 - b. Significant increases in vaccine supply

- c. Most people within the current phase are vaccinated (e.g. greater than 60-70%)
- G. The State's COVID-19 vaccine program consists of several components (e.g., identification of critical population, provider enrollment, recruitment, allocation, ordering, distribution, and tracking of doses) necessary for complete vaccine rollout.

Phase 1: Limited Doses Available

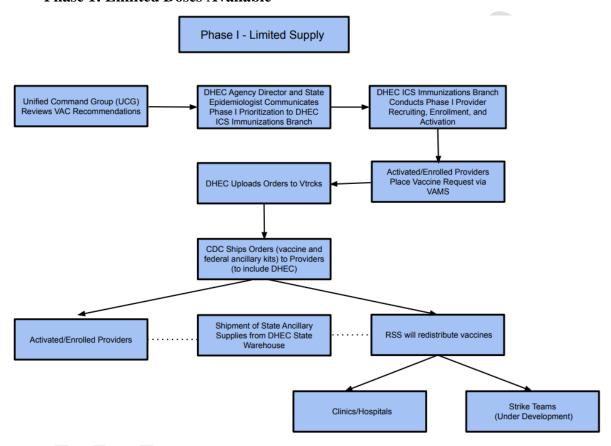


Figure 2: Phase 1 Flowchart

- a. Identification of Phase 1 Critical Populations
 - (1) Populations of focus for initial COVID-19 vaccine doses are expected to include healthcare personnel, people at high risk, and critical infrastructure workers, other essential workers, and people at higher risk for severe COVID-19 illness.
 - (2) Per federal guidance, DHEC has convened a COVID-19 Vaccine Advisory Committee engaging representatives from state agencies and professional and community organizations representing critical partners and populations to

assist in the formulation of recommendations for the equitable access to COVID-19 vaccines.

- (3) The COVID-19 Vaccine Advisory Committee's recommendation will help inform decisions regarding critical population prioritization and public messaging. These recommendations will be reviewed by the Unified Command Group (UCG).
- (4) Phase 1 will be divided into three sub-phases: Phases 1a, 1b and 1c.
 - The overarching principle in Phase 1a is averting deaths. DHEC's Phase 1a guidance can be found here.
 - In Phase 1a, vaccine allocation will be prioritized to subsets outlined by the Centers for Disease Control and Prevention (CDC) to include staff and residents of nursing homes and long-term care facilities and people serving in healthcare settings. The purpose is to maximize vaccinations for those serving in roles that reduce COVID-19 morbidity and mortality and to reduce the burden on strained healthcare capacity and facilities. Phase 1a will likely continue for many weeks, if not months.
 - Phase 1a include:
 - 70+ year old, regardless of health status or preexisting conditions
 - Anesthesiology assistants, registered cardiovascular invasive specialists, and operating room staff
 - Athletic Trainers
 - American Sign Language (ASL) and other interpreters in healthcare facilities
 - Autopsy room staff, coroners, embalmers, and funeral home staff at risk of exposure to bodily fluids
 - Chiropractors
 - Dentists and dental hygienists and technicians
 - Dietary and food services staff in healthcare facilities
 - Environmental services staff in healthcare facilities
 - Harbor pilots
 - Home health and hospice workers
 - Hospital transport personnel
 - Hospital inpatients 65 and older
 - Laboratory personnel and phlebotomists
 - Licensed dietitians

- Long-Term Care Facility (LTCF) residents and staff
- Medical assistants
- Medical first responders (paid and volunteer): EMS; fire department and law enforcement personnel who provide emergency medical care
- Nurses, nurse practitioners, and nurse's aides/ assistants
- Opticians and optometrists and assistants/ technicians
- Persons providing medical care in correctional facilities and correctional officers
- Pharmacists and pharmacy technicians
- Physical and occupational therapists and assistants
- Physicians, including medical house staff (i.e., interns, residents, fellows), and physician assistants
- Podiatrists
- Public health healthcare workers who are frequently interacting with persons with potential COVID-19 infection
- Radiology technicians
- Respiratory care practitioners, such as respiratory therapists
- Speech language pathologists and assistants and audiologists
- State/local government employees and their contractors who are mission-critical for maintaining operations of COVID-19 vaccinations and testing in SC
- Students and interns of the above categories

• Phase 1b include:

- All people aged 75 years and older
- Frontline essential workers
 - Sectors included by ACIP: firefighters, law enforcement officers, corrections officers, food and agricultural workers, USPS workers, manufacturing workers, grocery store workers, public transit workers, and those who work in the educational sector teachers, support staff, and daycare workers

• Phase 1c include:

- All people aged 65 and older
- People aged 16 and older with certain underlying health conditions that puts them at high risk for severe disease (<u>list</u> <u>by CDC</u>)
- Other essential workers.

 Examples included by ACIP: people who work in transportation and logistics, food service, housing construction and finance, information technology, communications, energy, law, media, public safety, and public health staff who are non-frontline healthcare workers

b. Vaccine Allocation

- (1) The federal government will determine the amount of COVID-19 vaccine designated for each state. The Tiberius Platform is a planning tool provided by U.S. Department of Health and Human Services (HHS) Operation Warp Speed that allows the State to view allocations to Federal entities (i.e. Indian Health Services (IHS)) and to the State in real-time.
- (2) SC Phase 1 allocation method will be based on:
 - SC COVID-19 Vaccine Advisory Committee recommendations
 - Actual number of doses allocated to the state and timing of availability
 - Populations served by vaccination providers and geographic locations to ensure distribution throughout the jurisdiction
 - Vaccination provider site capacity for vaccine storage and handling capacity
- (3) The State Epidemiologist and DHEC Public Health Director or designees will review the COVID-19 Vaccine Advisory Committee's recommendations and provide directions to the DHEC Immunization Branch to implement the recommendations that are in keeping with the algorithm for the allocation process and are determined to maximize benefit and minimize harm to the population as a whole.
- (4) Select Federal entities in South Carolina will enroll directly with CDC to order, receive and administer COVID-19 vaccine. CDC will notify the state of any entities receiving direct allocations. **Figure 3** outlines federal entities in SC to receive direct allocation.

Federal Entity	Population Served
Bureau of Prisons (BoP) - Bennettsville FCI - Edgefield FCI - Estill FCI - Williamsburg FCI	 All BoP-managed facilities: facility staff and inmates. Private contracted facilities and contracted residential reentry centers (RRCs) not included.
Department of Defense (DoD) - Fort Jackson US Army Training Center - McEntire Joint National Guard Base - Shaw Air Force Base - Joint Base Charleston - Paris Island Marine Recruit Depot - Beaufort Marine Air Station	 Active duty personnel and their dependents Retirees (does not include their dependents) U.S. Coast Guard (does not include their dependents) DoD civilian and contractor employees (those who regularly receive care through DoD as well as those who don't) To be determined: Reserves and National Guard (including those not activated)
Department of State (DoS)	 All personnel under Chief of Mission eligible to receive care through DoS Stateside civil service employees
Indian Health Service (IHS) - Catawba Nation	 Tribal nations selecting IHS for vaccine allocation. Potentially includes IHS/Tribal/Urban facility staff and individuals served
Veterans' Health Administration (VHA)	- VA staff (including volunteers and trainees) and veterans regularly receiving care at VHA facilities (State Veterans Homes not included)

Figure 3: Federal entities receiving direct allocation

- (5) Federal entities not receiving direct allocation from CDC directly will be incorporated in State's vaccination plans.
- (6) Select Pharmacy partners will receive direct allocation from OWS to expand vaccine provider network. Pharmacy partners will be required to report doses administered to DHEC and CDC.

- c. Vaccine Provider Outreach, Recruitment and Enrollment
 - (1) COVID-19 vaccine providers must be enrolled and activated in order to receive and administer COVID-19 vaccines. Enrollment does not guarantee immediate access to vaccine supply.
 - (2) South Carolina will utilize an <u>online enrollment process</u> to streamline the collection of information from interested providers.
 - Enrollment is based on completion of the CDC's *COVID-19 Vaccination Program Provider Agreement* (the Agreement).
 - The parent organization, and its responsible officers, such as the Chief Medical Officer and Chief Executive Officer will sign Section A of the Agreement.
 - Once the provider completes the enrollment, DHEC Immunization Enrollment staff will review the enrollment information to ensure each interested provider can meet the minimum requirements outlined in the Section B of the CDC's COVID-19 Vaccination Program Provider Agreement, specifically the vaccine management requirements (i.e., vaccine storage unit, temperature).
 - The parent organization will ensure that all locations under Section A of the Agreement are identified and that a Provider Profile (Section B of the Agreement) is completed. Although a parent organization may be headquartered out of state, all locations that will receive vaccines, and for which an organization will complete a Provider Profile (Section B), must be located in South Carolina.
 - (3) Providers will be responsible for overall vaccine management and accountability as outlined in CDC's *COVID-19 Vaccination Program Provider Agreement*.
 - (4) DHEC will activate enrolled providers for Phase 1 based on:
 - Capacity to a) store Moderna an Pfizer vaccines at required temperatures (See Attachments 2 and 3 of this plan) and;
 - Ability to administer at least 975 doses of Pfizer vaccine or 100 doses of Moderna vaccine to priority populations (persons employed by or served by the facility, or from the surrounding community, and/or any combination of such);

- Ability to facilitate distribution and administration of vaccine to smaller sites that will reach priority populations and;
- Capacity to ensure proper vaccine storage, handling, and administration practices
- (5) Recruit and enroll non-federal pharmacy partners and Federal Qualified Health Centers (FQHC), especially in rural areas to ensure that rural populations can access vaccines.
- (6) Closed Points of Dispensing (POD) partners may be considered upon enrollment and completion of CDC's *COVID-19 Vaccination Program Provider Agreement*.
- (7) DHEC will disseminate recruitment materials to pharmacies and hospitals not served directly by CDC.
- (8) Vaccine providers will complete training to ensure awareness of relevant processes and ensure quality control prior to receipt of vaccines.

d. Data Sharing

- (1) Three systems support vaccine logistics and administration: Vaccine Tracking System (VTrcks), Immunization Information System (IIS), and VaccineFinder.
- (2) The Vaccine Tracking System (VTrckS) is CDC's vaccine order management system, which supports routine vaccination with almost 80 million doses of vaccine annually.
 - CDC will use VTrckS as its platform for ordering all COVID-19 vaccines.
 - VTrckS users—the 64 state, local, and territorial public health jurisdictions and enrolled national provider organizations will use VTrckS to:
 - View vaccine allocations for each program
 - Place and manage vaccine orders for their providers
 - Generate reports throughout the vaccine distribution process, from vaccine order placement through distribution
 - Track vaccine shipments
- (3) Immunization Information Systems were formerly known as "immunization registries." The IISs vary by jurisdiction in their capacity to automate

processes, handle large volumes of data, and capture high-quality data. SC's IIS is called the <u>Statewide Immunization Online Network (SIMON)</u>.

- Vaccine recipients and enrolled providers use IISs to access people's vaccination records.
- In addition, IISs collect data from public and private healthcare provider organizations (e.g., electronic health records), health information systems (e.g., vital statistics, state Medicaid agencies), and pharmacies. IISs share these data with the IZ Gateway, CDC, and other jurisdictions if an agreement is in place. IISs also share vaccination records with healthcare providers and individuals.
- As part of the overall IT infrastructure to support COVID-19 vaccination IISs connect with VTrckS, VAMS (see below for details), and federal data and reporting systems.
- (4) New COVID-19 Vaccination Data Collection and Reporting Systems:
 - CDC's <u>Vaccine Administration Management System</u> (VAMS) will be the primary tool (for Phase 1) to support data collection for the COVID-19 vaccine when it first becomes available. VAMS is a secure, online tool to manage vaccine administration end-to-end, from the time COVID-19 vaccine arrives at a clinic to when it is administered to a recipient. VAMS connects with IISs via federal and data reporting systems and sends data to IISs through the IZ Gateway or IZ Data Clearinghouse.
 - IZ Gateway facilitates electronic messaging of vaccination records in a secure infrastructure allowing IIS systems across the nation to share vaccine administration data.
 - IZ Data Lake is a cloud-hosted data repository to receive, store, manage, and analyze deidentified COVID-19 vaccination data. CDC, jurisdictions, federal agencies, and pharmacy partners will use the IZ Data Lake to store and process administration, coverage, logistics, inventory, ordering, distribution, and provider data. VAMS, IISs, pharmacies, VTrckS, and VaccineFinder will provide data for the IZ Data Lake.
- (5) Per CDC guidance, administration data entered into VAMS will have the capability to be shared in near real-time with Immunization Information Systems (IIS) via the Immunization (IZ) Gateway. **See Figure 4 on page 14.**

- (6) Enrolled COVID-19 Vaccine Providers (including DHEC) will report certain data elements in VAMS for each dose administered within 24 72 hours.
- (7) Data Use Agreements (DUAs) will be required for data sharing via the IZ Gateway and other methods of vaccine administration data sharing with CDC and will be coordinated by DHEC's Immunization program.
- (8) The majority of healthcare providers in SC already submit information on administered immunizations to <u>SIMON</u>. SIMON will be integrated into Phase 2 data reporting.

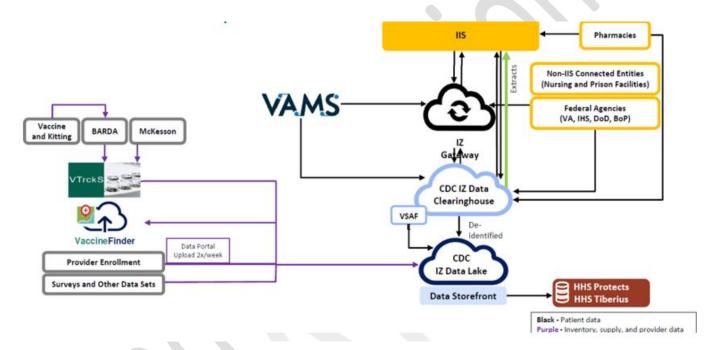


Figure 4: Primary Data Path (VAMS and SIMON (IIS))

e. Vaccine Ordering

- (1) Once South Carolina has received notification that a limited supply of COVID-19 vaccine is available for ordering: the number of doses will be reviewed by DHEC to determine how many doses can be sent to enrolled sites.
- (2) Vaccine providers will request COVID-19 doses in VAMS. The population served by the provider will be reviewed by DHEC before a vaccine order is approved. If modifications to the request are required, vaccine request changes will be made in VAMS by DHEC's Immunization Branch.

- (3) The minimum order volume for Pfizer (Vaccine A) is 975 doses. The maximum order is 4,875 doses.
- (4) The minimum order volume for Moderna (Vaccine B) is 100 doses. The maximum order is 1,200 doses.
- (5) Each provider will have to document and verify vaccine inventory levels in VAMS before placing new orders.
- (6) Each jurisdiction, federal agency, and commercial partner will receive allocations (order caps) weekly in VTrckS.
- (7) Vaccine orders will be approved and transmitted through VTrckS by DHEC's Immunizations Branch for the vaccination providers that have enrolled.
- (8) Vaccine will be delivered within 24-48 hours of order placement into VTrckS. Federal ancillary kits will be automatically added to vaccine orders and do not require additional action or separate orders from jurisdictions.
- (9) COVID-19 vaccination providers will be required to report COVID-19 vaccine inventory daily using Vaccine Finder. Once providers are enrolled in VTrckS, they will be preregistered for a Vaccine Finder account and provided instructions via email on how to submit daily vaccine supply information.

f. Vaccine Distribution

- (1) OWS will ship COVID-19 vaccines to:
 - Enrolled providers; and
 - State's Receipt, Staging and Storage (RSS) site.
- (2) The primary method of distribution will be direct shipment from the federal government to enrolled providers. Refer to **Attachment 1 (OWS Distribution Process).**
- (3) RSS site will not be receiving a bulk order of vaccines for the State.
- (4) Along with vaccine, each enrolled provider site will receive ancillary kits and an initial dry ice resupply:
 - Federal ancillary supply kits will include diluent and administration materials (including appropriate needles, syringes, alcohol swabs, and

limited personal protective equipment (PPE). CDC will provide details on dimensions of ancillary supply kits.

- OWS will provide an initial dry ice resupply to facilitate storage in coordination with each vaccine shipment. States can opt-out of initial dry ice resupply if desired. Enrolled provider sites will receive initial dry ice resupply in coordination with receipt of vaccine, as they will need to replenish the dry ice upon product receipt.
- (5) The State will supplement with additional ancillary supplies and additional PPE. State-provided supplemental kits will be shipped to enrolled provider sites from the RSS.
- (6) Vaccines (and diluent) will be shipped to enrolled provider sites (to include RSS site) enrolled by DHEC's Immunization Branch within 48 hours of order approval. Due to cold chain requirements, federal ancillary kits (and diluent) will be shipped separately from vaccines but will arrive before or on the same day as vaccines.
- (7) Once vaccine product has been shipped to COVID-19 enrolled provider site, the federal government will neither redistribute the product nor take financial responsibility for its redistribution.
- (8) The State will take responsibility for redistributing vaccines (i.e. for orders smaller than the minimum order).
- (9) Redistribution is based on State's allocation amount.
- (10) Redistribution of COVID-19 vaccines:
 - RSS site will redistribute and transport COVID-19 vaccines to enrolled providers unable to vaccinate > 975 doses within 10 days or > 100 doses of Moderna. Sites will receive federal and state ancillary kits.
 - COVID-19 Vaccine Provider can redistribute vaccines, if needed.
 Provider will obtain approval from DHEC and sign CDC's COVID-19
 Vaccine Redistribution Agreement.
- (11) RSS personnel will pull vaccine orders via VAMS. Vaccines will be redistributed and repackaged for next-day shipment to clinics.
- (12) The State contracted transportation team will distribute the vaccine and ancillary supplies to provider sites as directed. The contract transportation manager will develop delivery routes based on the RSS Manager's guidance.

Driver teams will ensure receiving provider sites sign for vaccines receive and will provide updates to the RSS of shipments.

- (13) Vaccine providers will be responsible for returning federally supplied vaccine shipping containers in accordance with federal instructions provided with the container.
- (14) The RSS Transportation Team will recover shipping containers provided by the State.
- g. Vaccine Storage, Handling and Administration
 - (1) Active Phase 1 providers will be able to administer COVID-19 vaccines to Phase 1 populations.
 - (2) DHEC will provide cold chain management guidance to include the <u>CDC's Vaccine Storage and Handling Toolkit COVID-19 Addendum.</u>
 - (3) Providers must submit completed temperature logs and digital data logger reports weekly for each unit the provider uses to store the COVID-19 vaccine. Temperature reports can be emailed to covidvaccines@dhec.sc.gov for review by DHEC's Immunization Branch.
 - (4) Transfer of COVID-19 vaccine requires pre-authorization by emailing DHEC's Immunization Branch at covidvaccines@dhec.sc.gov.
 - (5) Phase 1 populations will be able to locate vaccine providers via scdhec.gov/vaxlocator.
 - (6) Phase 1 populations and eventually the general public will able to use <u>Vaccine Finder</u> to search and find available clinics. Vaccine Finder will be closed to the public in Phase 1.
 - (7) CDC currently recommends that persons without contraindications to vaccination who receive an mRNA COVID-19 vaccine be observed after vaccination for the following time periods:
 - 30 minutes: Persons with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy and persons with a history of anaphylaxis due to any cause.
 - 15 minutes: All other persons

- (8) Two doses of COVID-19 vaccine, separated by 21 or 28 days, will be needed by some vaccine candidates; both doses will need to be with the same product. Providers will use the COVID-19 vaccination record cards provided in the federal ancillary kits accompanying each shipment of vaccine. DHEC will leverage the second dose reminder function in VAMS to recall vaccine recipients. Providers and will be encouraged to use their own mechanisms for second dose reminders, including employee listserv email blasts and electronic health record (EHR) automated reminder functionalities.
- (9) Consent forms are built into VAMS.
- (10) DHEC Immunization Branch will assess administration capacity via PanVax tool.
- (11) Pfizer vaccine EUA fact sheet with prescribing information can be found here.
- (12) The CDC will provide guidance on COVID-19 vaccine recovery.
- h. Early activation of Federal Pharmacy Program
 - (1) The federal government will engage select pharmacy partners to vaccinate a broader population group.
 - (2) State will synchronize and coordinate vaccination efforts with federal pharmacy partners to improve vaccination coverage. Federal pharmacy partners include:
 - Walgreens Servicing LTCFs in Phase 1
 - **CVS** Servicing LTCFs in Phase 1
 - Walmart Stores, Inc. (including Sam's)
 - The Kroger Store (i.e. Kroger, Harris Teeter, Fred Meyer, Frys, Ralphs, King Soopers, Smiths, City Market, Dillons, Marianos, Pick-n-Save, Copps, Metro Market)
 - Publix
 - Costco
 - Top-Co (i.e. Ingles)
- i. Pharmacy Partnership for Long Term Care Facilities (LTCFs)
 - (1) LTCFs in South Carolina will have the opportunity to receive vaccination services from CVS and Walgreens. The program provides end-to-end management of the COVID-19 vaccination process, including cold-chain

management, on-site vaccination (i.e. provides ancillary supplies), and fulfillment of reporting requirements. **See Figure 5 on page 19.**

(2) LTCF staff may be prioritized in Phase 1A or 1B prior to LTCF Pharmacy rollout. LTCF staff not already vaccinated may be vaccinated through on-site clinics offered by pharmacy partners.

Leveraging Pharmacy Partnerships to Increase Access

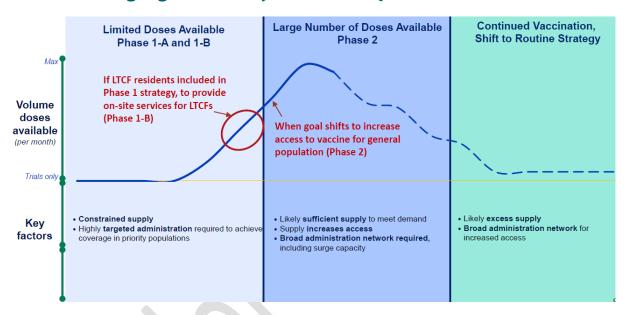


Figure 5: LTCF Pharmacy Partnership

- (3) The program includes two components: on-site vaccination support for skilled nursing facilities (SNFs) and on-site vaccination support for assisted living facilities (ALFs) and other eligible facilities.
- (4) DHEC has activated the program to begin end of December 2020.
- (5) DHEC has opted to provide Moderna for LTCF vaccination efforts.
- (6) Vaccine doses that CVS/Walgreens will use for LTCF pharmacy partnership for Phase 1a will be transferred from SC's state allocation.
- (7) Once the activation request has been received, participating pharmacy partners will have <u>two weeks</u> to prepare to administer vaccine at the skilled nursing facilities assigned to them. <u>One week prior to the program start date</u>, DHEC must transfer (via Tiberius) enough vaccine allocation to cover 50% of the first doses needed for the skilled nursing facilities enrolled in the

program into the federal vaccine allocation reserve. CDC will send DHEC a calculation of the estimated number of doses needed to cover the skilled enrolled in the program. DHEC must transfer 25% of the additional needed doses to the federal allocation reserve within the <u>first week after the program start date</u> and the remaining 25% of needed doses <u>within the second week</u> after the start date.

- (8) DHEC will disseminate LTCF pharmacy partnership materials to LTCFs in the state.
- (9) Pharmacy partners who are administering COVID-19 vaccine at long-term care facilities as part of the Federal Pharmacy Partnership for Long-term Care Program may require written consent from recipients before vaccination. This is at the discretion of the pharmacy; written consent is not required by federal law for COVID-19 vaccination in the United States.
- (10) DHEC will develop plans to vaccinate residents of State veterans' nursing homes and LTCF residents and staff outside of CVS/Walgreens service area.

j. Regional/Local Coordination

- (1) Develop and share public messaging that is consistent with the State's Joint Information Center (JIC), to include messaging regarding why some are getting the vaccine and others are not
- (2) Be prepared to provide vaccination services to LTCF when gaps are identified.
- (3) Local EMS entities may have the opportunity to enroll as COVID-19 vaccine providers to ensure accessibility to EMS and county personnel.
- (4) Coordinate with local partners to disseminate vaccination information to SC Tribal communities (state and federally recognized tribes).
- (5) DHEC regions and local partners will identify Open Points of Dispensing (POD) sites to be used as COVID-19 vaccination sites, if applicable.

Phase 2: Large Number of Doses Available, Supply Likely to Meet Demand

- b. Vaccine Provider Recruitment and Enrollment
 - (1) Recruit and enroll providers to vaccinate additional critical populations and eventually general populations when sufficient vaccine supply becomes available.
 - (2) Recruit and enroll non-traditional COVID-19 vaccine providers and settings (i.e. colleges/universities, homeless shelters, and independent living communities)
 - (3) Potential COVID-19 vaccine providers will continue to enroll via <u>State's Immunization program</u>.
 - (4) Activation of Phase 2 providers will increase due to the need to vaccinate the general public and complete remaining Phase 1 critical populations.
- c. Vaccine Allocation and Ordering
 - (1) DHEC's Immunization Branch will continue to process orders via VAMS and upload orders to VTrckS.
 - (2) Allocations to Phase 1 providers will continue to be prioritized to ensure vaccination of Phase 1 critical populations.
 - (3) Begin transitioning vaccination services to general population.
 - (4) Federal entities not receiving direct allocation from CDC directly will be incorporated in State's vaccination plans.
 - (5) Select Pharmacy partners will receive direct allocation from OWS to expand vaccine provider network. Pharmacy partners will be required to report doses administered to DHEC and CDC.

d. Vaccine Distribution

- (1) Begin demobilization of State RSS site. End goal is to have all vaccines directly shipped to enrolled providers.
- (2) COVID-19 vaccines will be directly shipped to enrolled providers (to include DHEC regional health departments).
- (3) The state will continue to supplement federal ancillary kits until providers are capable of ordering and receiving adequate supplies.

- e. Vaccine Storage, Handling and Administration
 - (1) Vaccine supply for DHEC coordinated off-site clinics will be directly shipped to regional health departments. Off-site clinic locations may be at pre-identified Points of Dispensing (POD) sites.
 - (2) Off-site clinics will have to be associated with an enrolled provider per CDC COVID provider agreement.
 - (3) DHEC will leverage its reminder/recall function of its immunization registry, SIMON, to conduct a centralized reminder/recall for vaccine recipients, as an additional notification conduit.
 - (4) Federal Pharmacy partners will receive direct federal allocation in Phase 2.
 - (5) Provider will upload temperature logs weekly into SIMON.
 - (6) Vaccine temperature excursion events will have to be reported to DHEC ICS Immunizations Branch.

f. Data Sharing

- (1) For phases 2 and 3, DHEC will require documentation and reporting through a combination of VAMS and the state's immunization information system (SIMON) depending on administration setting type (mobile clinic setting versus fixed clinic setting), and readiness of SIMON to comply with data reporting elements.
- (2) SIMON will be able to communicate with Vaccine Finder. Clinic site locations will be visible to the public.

g. Tribal Communities

- (1) The Catawba Indian Nation is the only federally recognized Indian Tribe in South Carolina and has sovereignty over tribal reservation lands located in York County.
- (2) Indian Health Services will receive a direct allocation from CDC and will provide vaccination services to Catawba Indian Nation.
- (3) State recognized tribes and special groups will be accounted for in the State's vaccine allocation.

State recognized tribes:

- Beaver Creek Indians
- Edisto Natchez-Kusso
- Pee Dee Indian Nation of Upper South Carolina
- Pee Dee Indian Tribe
- Piedmont American Indian Association
- Santee Indian Organization
- Sumter Tribe of Cheraw Indians
- The Waccamaw Indian People
- The Wassamasaw Tribe of Varnertown Indians

State Recognized Groups and Special Interest Organizations:

- American Indian Chamber of Commerce South Carolina
- Chaloklowa Chickasaw Indian People
- Eastern Cherokee, Southern Iroquois and United Tribes of South Carolina
- Little Horse Creek American Indian Cultural Center
- Natchez Tribe of South Carolina
- Pee Dee Indian Nation of Beaver Creek
- Pine Hill Indian Community Development Initiative

h. Regional / Local Coordination

- (1) Coordinate public messaging that is consistent with the State's JIC
- (2) DHEC regional office will support school located clinics (if pediatric vaccine available)
- (3) DHEC regions and community partners open and operate Regional Distribution Site (RDS) locations per the Medical Countermeasures plan, if required.
- (4) Local EMS entities may have the opportunity to enroll as COVID-19 vaccine providers to ensure accessibility to EMS and county personnel.
- (5) Support to COVID-19 vaccination sites
 - Site identification and coordination for use
 - Traffic control
 - Site equipment (if outdoors) / general support

Phase 3: Likely Sufficient Supply

a. Vaccine Allocation

- (1) Continue to focus on equitable access to vaccination services
- (2) Monitor COVID-19 vaccine uptake and coverage in critical populations and enhancing strategies to reach populations

b. Vaccine Distribution

- (1) RSS Operations have been demobilized. All active and enrolled providers will be able to receive vaccines directly from CDC.
- (2) State ancillary kits will be provided to DHEC coordinated clinics.

c. Vaccine Administration

- (1) COVID-19 Vaccine will be widely available and integrated into routine vaccination program, run by both public and private partners.
- (2) COVID-19 vaccine will be available at DHEC Health Departments. Clients will utilize the Careline to schedule COVID-19 vaccine appointment.
- (3) As federal guidance becomes available about the safety and efficacy of COVID-19 vaccines for children (under 18 y/o), it would be included into the routine Vaccine for Children (VFC) program.

d. Data Sharing

(1) Complete shift from VAMS to SIMON. All data will be reported to SIMON.

VIII. Roles and Responsibilities

- A. Department of Health and Environmental Control
 - a. Facilitate Vaccine Advisory Committee Meetings
 - b. Provide representation SC Joint Pharmacist Administered Vaccine Committee
 - c. Maintain situational awareness of enrolled partner vaccination clinics.
 - d. Coordinate provider recruitment, enrollment and outreach.
 - e. Manage and approve vaccine orders from enrolled providers.
 - f. Provide support or technical assistance for smaller vaccination providers or rural clinic settings.
 - g. Facilitate and monitor VAMS and SIMON reporting.

- h. Regional IZ team coordinate DHEC operated clinic sites and data entry into VAMS (All Phases).
- i. Develop allocation methods for critical populations of focus in early-and limitedsupply phases.
- j. Approve and conduct COVID-19 vaccines redistribution as needed.
- k. Coordinate Vaccine Adverse Event Reporting System (VAERS) and vaccine safety activities.
- 1. Coordinate RSS site and Regional Distribution Sites (RDS) operations, if required.
- m. Disseminate LTCF pharmacy partnership materials to LTCFs in the state.
- n. Provide vaccination support services to LTCF Pharmacy program, as needed.
- o. Coordinate vaccine public information messages with the state's Joint Information Center (JIC).

B. SC Emergency Management Division

- a. Coordinate partner briefings with relevant Emergency Support Functions (ESFs) and the Vaccine Task Force to include providing conference lines and meeting space.
- b. Activate/ utilize the JIC to assist with COVID-19 vaccine messaging regarding safety, administration tiers, and priority populations.
- c. Coordinate with the Governor's Office to ensure the state's emergency declaration is sustained.
- d. Provide support to the RSS Manager including oversight of the supporting transportation contract.
- e. Coordinate with DHEC and other agencies to implement the Federal Emergency Management Agency's (FEMA) reimbursement process, if necessary.
- f. Support storage of additional ancillary supplies, if needed.

C. SC Law Enforcement Division

- a. In coordination with Department of Transportation and Department of Public Safety, assist with determining potential delivery routes to vaccine distribution sites.
- b. Provide security as needed during delivery and at vaccine distribution sites.

D. SC National Guard

- a. Provide building space and infrastructure to receive, stage, and store vaccines and ancillary supplies.
- b. Provide manpower to support vaccine distribution sites, as needed.
- c. Provide transportation support for state ancillary supplies.
- d. Provide medical personnel with appropriate qualifications to assist with immunizations across the state to support the execution of immunization efforts as requested and approved.

E. SC Department of Commerce

- a. In coordination with ESF-24 members, leverage partnerships in the private sector to encourage eligible businesses to become a COVID-19 Vaccine Provider.
- b. Communicate situational awareness of the COVID-19 vaccine, to include distribution processes and vaccine efficacy, to the business community.
- c. Assist DHEC and SCEMD with the prioritization of critical infrastructure and their employees utilizing CISA and other guidelines as requested.

F. SC Hospital Association

a. Disseminate COVID-19 provider enrollment documents and outreach materials.

IX. Risk Communications

- A. Incident communications are conducted through the established JIC as outlined in SCEOP ESF-15 (Public Information) Annex.
- B. Leverage DHEC's Vulnerable Populations team to promote information sharing and communications with SC's tribal partner.
- C. Communications efforts are currently targeted at reaching the general population, state and local leaders, and key stakeholders and partners, and will be further tailored to address specific needs of the initial populations identified to be impacted by each phase of the program roll out.
- D. Once a vaccine becomes available, communications strategies will align with the COVID-19 Vaccination Program's identified phases:
 - Phase 1 Communications strategies will focus on critical populations being impacted by the vaccine rollout, including facilities, partners and providers who are providing the vaccines. Communications may vary based on supply and identified needs, but will include traditional media, direct messaging to those impacted, education to community leaders and partners, and social media as needed. Partners will be leveraged, as needed, to support messaging efforts. The state's JIC is already activated and partnering with the agency on this messaging and efforts to engage new partners, as appropriate.
 - Phase 2 As a larger number of vaccine doses become available the communications team will work with our partners to identify needs and determine our priority audience. This is an ongoing, fluid event and communications strategies will remain flexible to meet new and/or growing needs. Communications will again predominantly include traditional media, direct messaging to those impacted, and social media.

- Phase 3— Communication strategies and tactics will be focused on reaching the
 general population, including priority focus on those considered to be part of our
 vulnerable populations. To support this effort communications will expand to
 include traditional and paid media, direct messaging to those impacted, social media,
 and updates to community leaders and partners.
- E. The JIC strives to meet the goal of assuring that every person in a community has and understands the information needed to prepare for, cope with, and recover from public health emergencies and disasters. As part of this effort DHEC, will work with partners to identify and prepare messaging to respond to potential risks and keep the public updated on all emergent information. In addition, DHEC will send messages to clients and partners who are members of or serve the identified vulnerable populations. Simplified messaging, including important updates from the Governor's briefings, will be delivered from DHEC Public Information Officers who operate out of the state's JIC. All messages will be provided in multiple formats to account for any access or functional needs of individuals who are deaf or hard of hearing, have limited English proficiency, are from diverse cultural backgrounds, have cognitive limitations, and/or do not use or have access to traditional media. The team will also monitor media and online outlets to address the need to correct inaccurate information.

X. Plan Development and Maintenance

- A. The development of this plan is the responsibility of the Vaccine Task Force in coordination with the Unified Command Group.
- B. The Vaccine Taskforce will update this plan as needed. Updates may occur frequently due to evolving federal guidance.
- C. The Vaccine Task Force will distribute copies of the COVID-19 Vaccine Plan to State Emergency Response Team (SERT).

XI. Authorities and References

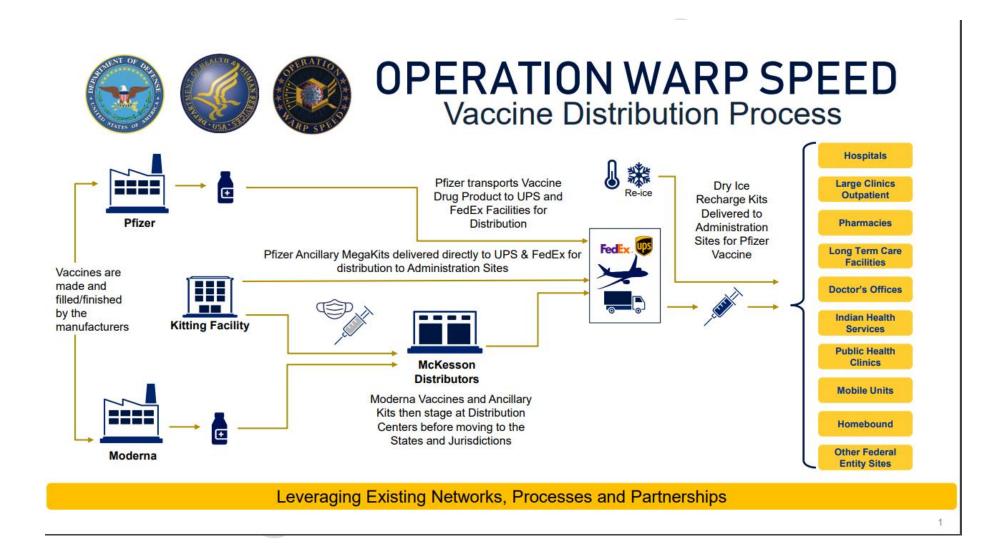
- Executive Order 2020-08 and successive executive orders related to COVID-19
- S.C. Code Ann. § 25-1-420
- S.C. Code Ann. § 25-1-440
- S.C. Code Ann. § 44-1-80
- S.C. Code Ann. § 44-1-100
- S.C. Code Ann. § 44-1-110
- S.C. Code Ann. § 44-1-140
- S.C. Code of Laws §§ 44-4-100 to 570, Emergency Health Powers Act

- S.C. Code Ann. § 44-29-40
- S.C. Code Ann. § 44-29-210
- S.C. Code Ann. Regs. 58-101, State Government Preparedness Standards
- S.C. Code Ann. Regs. 61-112, Implementation of the Emergency Health Powers Act
- S.C. Code Ann. Regs. 61-120, South Carolina Immunization Registry
- S.C. Infectious Disease Plan
- Centers of Disease Control and Prevention (CDC) Immunization and Vaccines for Children Cooperative Agreement
- South Carolina Emergency Operations Plan (SCEOP)
- Developing and Maintaining Emergency Operations Plans, Comprehensive Preparedness Guide (CPG) 101, Version 2.0, Federal Emergency Management Agency, November 2010

XII. Attachments

- 1. Operation Warp Speed Distribution Process
- 2. Pfizer-BioNTech COVID-19 Storage and Handling
- 3. Moderna Storage and Handling
- 4. COVID-19 Vaccine Outreach Plan

Attachment 1 (COVID-19 OWS Vaccine Distribution Process) to South Carolina COVID-19 Vaccine Plan



Attachment 2 (Pfizer-BioNTech COVID-19 Vaccine Storage and Handling) to South Carolina COVID-19 Vaccine Plan



Pfizer-BioNTech COVID-19 Vaccine

Storage and Handling Summary



>> Basics

- Store vaccine in an ultra-cold freezer, thermal shipping container, or refrigerator. See guidance below for each storage unit.
- Follow the manufacturer's instructions for returning the thermal shipping container.
- Each thermal shipping container holds up to 5 trays of vaccine.
 - » Each tray contains 195 multidose vials (975 doses).
- Use vaccine vials stored in the refrigerator before removing vials from frozen storage.
- Check and record storage unit temperature each workday.
 See guidance below for each type of storage unit. Save storage records for 3 years, unless your jurisdiction requires a longer time period.

» Deliveries

Vaccine

When vaccine is delivered:

- Open the thermal shipping container. Press on the stop shipment button on the temperature monitor device for 5 seconds.
- The LED indicator light will change to a solid color and a temperature status report will be e-mailed to the person who ordered the vaccine.
- Proceed based on the color of the LED indicator light. No color or red: Wait for the status report. Green: Unpack the vaccine.
- Follow the manufacturer's guidance for unpacking the vaccine. Inspect the trays.
 - Do not open the vial trays or remove vials until ready to thaw/use the vaccine.
 - If storing the vaccine at ultra-cold temperatures, return vaccine to frozen storage within 5 minutes.

Dry Ice Safety

- Dry ice is needed to maintain proper temperatures in the thermal shipping container.
- Dry ice requires special handling.
- Ensure staff is trained to handle dry ice safely and have proper PPE.
- Do not use or store dry ice in confined areas, walk-in refrigerators, environmental chambers, or rooms without ventilation. A leak in such an area could cause an oxygen-deficient atmosphere.

Ancillary Supply Kit

Ancillary supply kit will be delivered separately from the vaccine and includes

- Mixing supplies: Diluent, needles, syringes, and sterile alcohol prep pads.
- Do NOT use mixing supplies to administer vaccine.
- Administration supplies: Needles, syringes, sterile alcohol prep pads, vaccination record cards, and some PPE supplies

Each ancillary supply kits contains enough supplies to mix and administer 1 tray of vaccine.

» Ultra-Cold Freezer

Vaccine may be stored in an ultra-cold freezer between -80°C and -60°C (-112°F and -76°F).

Use a digital data logger (DDL) with a probe designed specifically to measure ultra-cold temperatures. Check and record the temperature daily using a temperature log for ultra-cold storage units. Use one of the options below:

 Option 1: Minimum/Maximum (Min/Max) Temperature (Preferred) Most DDLs display minimum and maximum temperatures. Check and record the min/max temperatures at the start of each workday. Option 2: 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.

Vaccine may be stored until the expiration date. The expiration date could be extended as more stability data become available. Store vaccine vials upright in the tray and protect from light.

» Thermal Shipping Container

CDC recommends providers consider using the thermal shipping container for temporary storage only. The container requires significant support to store vaccine at proper temperatures, including, trained staff, a regular supply of dry ice and standard operating procedures on regular maintenance.

Use the Controlant Temperature Monitoring Device (TMD), included with the thermal shipping container, to monitor

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Attachment 2 (Pfizer-BioNTech COVID-19 Vaccine Storage and Handling) to South Carolina COVID-19 Vaccine Plan



Pfizer-BioNTech COVID-19 Vaccine

Storage and Handling Summary



the temperature.

- Up to 4 contacts can be identified to receive e-mails and text alerts on the temperature status of the container.
- · Review daily e-mails on the status of the container.
- · Save the final e-mail (full summary of status reports).

Replenish dry ice pellets (10 mm to 16 mm) within 24 hours of delivery and every 5 days after. Follow manufacturer's quidance for adding dry ice.

· Dry ice will be sent for the first re-icing.

 Additional dry ice shipments will NOT be provided. Arrange for dry ice to maintain the temperature of the container after the first re-ice.

Removing vaccine vials/doses for use:

- Determine the number of vials needed before opening the thermal shipping container.
- Open the thermal shipping container no more than 2 times per day for up to 3 minutes each time. Use packaging tape to reseal the outer carton after each entry.

Store vaccine vials upright in the tray and protect from light.

» Refrigerator

Before mixing, the vaccine may be stored in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to 120 hours (5 days). After 120 hours (5 days), remove any remaining vials from the refrigerator and discard following the manufacturer's and your jurisdiction's guidance on proper disposal.

Use a 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 for ultra-cold storage units. Use one of the options below:

- Option 1: Minimum/Maximum (Min/Max) Temperature (Preferred) Most DDLs display minimum and maximum temperatures. Check and record the min/max temperatures at the start of each workday.
- Option 2: 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.

Use beyond use date labels to track how long the vaccine has been in the refrigerator. Monitor the beyond-use-date/time.

- Place vaccine vials removed from frozen storage at the same time together in a resealable plastic bag or similar container.
- Complete the information on the storage label and attach it to the container holding the unmixed vaccine vials.
- Thawed vaccine cannot be refrozen.

 Once labeled, store unmixed vaccine vials upright in the refrigerator.

>> Diluent

0.9% sodium chloride (normal saline, preservative-free) diluent is included in the ancillary supply kits. Follow the manufacturer's guidance for storing the diluent.

» Mixed Vaccine

- Once mixed, vaccine can be left at room temperature (2°C to 25°C [35°F to 77°F]) for up to 6 hours.
- · Mixed vaccine does not need to be protected from light.

- · Discard any remaining vaccine after 6 hours.
- Mixed vaccine should NOT be returned to freezer storage.

12/22/20 CS3215704 For additional information, refer to the manufacturer at www.cvdvaccine.com

Attachment 2 (Moderna COVID-19 Vaccine Storage and Handling) to South Carolina COVID-19 Vaccine Plan



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

- The vaccine will arrive frozen between -25°C and -15°C (-13°F and 5°F).
- 2. Examine the shipment for signs of damage.
- Open the box and remove TagAlert Temperature Monitor from box (placed in the inner box next to vaccine).
- 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.

ALERT: Do not Place on Dry Ice INSTRUCTIONS INSTRUCTIONS Remove TagAlert Temperature Monitor from Box (placed in inner box next to vaccine) inner box next to vaccine) Pellow Receiver Instructions on the card: Press and hold the Start & Step bullon urfall the Stop bullon

>> 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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Attachment 2 (Moderna COVID-19 Vaccine Storage and Handling) to South Carolina COVID-19 Vaccine Plan



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*	
Pate: 5 / O1 / 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.	3
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/.

12/20/20 CS321571-F 2

Phase 0: No Vaccine Available

- Key messaging:
 - vaccine availability is unknown
 - when available, will be limited to specific groups
 - vaccine is safe

Website

- General public webpage
 - Make routine updates
- Vaccine provider webpage
 - Make routine updates
- Publication of the state's vaccine plan

General messaging

- Press conference with the Governor and state agencies
- Statewide media telebriefing about the vaccine
- General public FAQS
- Provider FAQs
- Development of FAQs into one-page fact sheet
 - Once complete, the fact sheet can be made downloadable online
 - Translate to Spanish
 - Disseminate hardcopy fact sheet to regions/public health departments/community partners, state agencies
- PSA: Dr. Linda Bell soundbites of key vaccine messaging

Targeted messaging

- Keep Minority Outreach group updated
- Review federal guidance and recommendations
- Update contact information for community partner lists
- Interviews with Latino radio stations

Social media/video

- Regular promotion of DHEC vaccine webpage and FAQs
- Regular promotion of Dr. Bell soundbites/key messaging
- Social media graphics in rotation promoting current vaccine key messages
- Stakeholders for additional PSAs
 - Elected officials
 - Sports figures
 - Social influencers
 - Faith-based leaders
 - Healthcare professionals

- Monitoring misinformation/rumor control
 - Compiling common misinformation trends and working within ICS to address and respond to these
- Share federal partner information and resources

Traditional media

- News release about webpage, plan
- Statewide telebriefing about webpage, plan

• Community engagement/public outreach

- Provide downloadable/hard copy FAQs
- Build familiarity around COVID-19 vaccine webpage
- Hold virtual meetings with community partners, faith-based groups, EJ leaders to message out key points and respond to questions
 - Dr. Linda Bell (State Epidemiologist), Dr. Brannon Traxler (Interim Public Health Director), regional figures, medical experts
 - Evaluate concerns/hesitations for adapting messaging

Phase 1: Potentially Limited Doses Available

Key messaging:

- o vaccine currently available for specific groups
- o vaccine is safe
- vaccine cost
- o vaccine will be more widely available for public at an unknown time

Website

- Update general public webpage and FAQs
- Update vaccine provider webpage and FAQs

General messaging

- Press conference with the Governor and state agencies
- Update and redistribute general public FAQs
- Update and redistribute provider FAQs
- Posters/fliers for healthcare facilities

Targeted messaging

- Continued virtual meetings community groups and partners to provide information and answer questions
 - Evaluate concerns/hesitations for adapting messaging

Social media/video

- Launch new PSAs in advance of vaccine availability
 - Targeted messaging on who can receive it, who cannot
 - Address safety, hesitancy

• Traditional media

- News releases
- Weekly statewide media telebriefings to include community partners to help message vaccine information
- Individual interviews with select outlets
- Editorial/op-ed
- Share federal partner information and resources

• Community engagement/public outreach

- Small virtual meetings and townhalls with community groups
 - See COVID-19 Community Partners List
- Weekly telebriefings
- Latino radio interviews

Phase 2: Large Number of Doses Available, Supply Available Likely Meeting Demand

- Key messaging:
 - vaccine is safe
 - o requires two doses, same brand
 - vaccine cost
 - o continuing COVID-19 precautions after receiving vaccine
 - o school vaccination requirements
 - o where can the public get the vaccine

Webpages

- Update general public webpage and FAQs
- Update vaccine provider webpage and FAQs
 - List of vaccine providers, address, times

• FAQs/fact sheets

- Update and redistribute general public FAQs
- Update and redistribute provider FAQs
- Posters, fliers

PSAs

• Expand influencer PSAs in advance of vaccine availability

- Two doses, 21- 28-day follow-up
- Address safety, hesitancy
- How it works

Traditional media

- News releases
- Weekly statewide media telebriefings to include community partners to help message vaccine information
- Individual interviews with select outlets and editorial boards
- Regional media blitzes

• Social media

- Promote vaccine webpage
- Promote vaccine FAQs
- Share PSAs
- Monitor for rumor control
- Share federal partner information and resources

Community engagement/public outreach

- Expansive, statewide messaging
 - Billboards
 - Gas station and essential business signage
 - Informational fliers in utility bills
 - Updated PSAs TV, radio, social media
 - Print advertisements

Phase 3: Likely Sufficient Supply

Webpages

- Update general public webpage and FAQs
- Update vaccine provider webpage and FAQs
 - List of vaccine providers, address, times

• FAQs/fact sheets

- Update and redistribute general public FAQs
- Update and redistribute provider FAQs
- Posters, fliers

PSAs

- Expand influencer PSAs in advance of vaccine availability
 - Two doses, 21- 28-day follow-up
 - Address safety, hesitancy

How it works

• Traditional media

- News releases
- Weekly statewide media telebriefings to include community partners to help message vaccine information
- Individual interviews with select outlets and editorial boards

• Social media

- Promote vaccine webpage
- Promote vaccine FAQs
- Share PSAs
- Monitor for rumor control
- Share federal partner information and resources

• Community engagement/public outreach

- Expansive, statewide messaging
 - Billboards
 - Gas station and essential business signage
 - Informational fliers in utility bills
 - Updated PSAs TV, radio, social media
 - Print advertisement