dhec

Healthy People. Healthy Communities.

Activated COVID-19 Vaccine Provider Reference Guide

version 5

Phase 1

Spring 2021











Contents

New Provider Checklist

- ❑ Submit new provider activation **survey** no later than **24 hours following activation**
  Failure to do so will result in exclusion from COVID-19 Vaccination Program.
- ❑ Set up **VaccineFinder** account and review inventory reporting requirements.
- ❑ Review DHEC's phase 1a guidance and phase 1b guidance to ensure your facility understands the target groups for vaccination
- ❑ Review **v-safe** and **VAERS** vaccine safety program considerations with all applicable vaccinating staff
- ❑ Review Pfizer/Moderna/Janssen **Emergency Use Authorizations (EUA) fact sheets**
- ❑ Review Pfizer/Moderna/Janssen **vaccine preparation and administration trainings** with all vaccinating staff
- ❑ Review Pfizer/Moderna/Janssen **storage and handling trainings** with all appropriate staff
- ❑ Ensure your **storage unit is prepared** to receive your first vaccine supply, including the placement of any approved continuous monitoring device, and utilization of temperature monitoring logs for twice-daily monitoring
- ❑ Review DHEC's COVID-19 Vaccine Provider Webpage for training and resource documents for programs and systems listed above
- ❑ Attend COVID-19 Vaccine Provider Town Hall Q&A forums on Wednesdays and Fridays from 11a-12p

COVID-19 Vaccine Provider: DHEC Contacts

- **DHEC VaxLocator Map**
  - Red/green color updates, information updates
  - VaxStatus@dhec.sc.gov
- **COVID-19 Vaccine Management Branch**
  - Vaccine inventory requests, vaccine orders, direct ship vaccine shipments/deliveries, temperature monitoring, transport logs
  - COVIDVaccines@dhec.sc.gov
- **COVID-19 Provider Enrollment Branch**
  - New enrollment form submissions, vaccine coordinator contact information changes, enrollment form updates, redistribution agreements
  - COVIDProviderEnrollment@dhec.sc.gov
- **New Provider Onboarding and Support/VAMS**
  - VAMS@dhec.sc.gov
- **COVID-19 Provider Portal Reporting**
  - vaxreporting@dhec.sc.gov
- **Schools and COVID-19 vaccine planning**
  - ACC-schools@dhec.sc.gov
- **DHEC Redistribution Warehouse**
  - State-supplied ancillary kits, vaccine redistribution orders
  - RSS@dhec.sc.gov

South Carolina Department of Health and Environmental Control

COVID-19 Vaccination Program Overview

SC COVID-19 Vaccine Program

COVID-19 Program Requirements Refresher

- Cannot bill for the vaccine provided via the program
- Must waive any out-of-pocket fees for vaccine administration due to inability to pay
- Retain all COVID-19 Vaccination Program-related documentation for three (3) years
- Provide current EUA fact sheets, updated/completed vaccination record card, and v-safe information to vaccine recipients each time a vaccine is administered

COVID-19 Program Requirements Refresher

- Report administered doses within 24 hours of administration to VAMS and/or SIMON
- Report COVID-19 vaccine inventory daily to VaccineFinder
- Report temperature excursions to DHEC after consulting with vaccine manufacturers and documenting outcomes on required form
- Report all spoiled, expired, and wasted vaccine to VAMS
- Report all suspected vaccine adverse events and administration errors to the Vaccine Adverse Event Reporting System (VAERS)

COVID-19 Vaccine Landscape

- Review DHEC phase 1a and phase 1b guidance to understand priority groups listed that should be targeted for vaccination
- DHEC currently receives limited federal allocations for three vaccine types
  - Pfizer 1st and 2nd doses
  - Moderna 1st and 2nd doses
  - Janssen 1st doses
- Orders are placed once a week for delivery the following week
- Only one vaccine type is assigned to providers at activation
- Currently ~500 activated vaccine providers participating in statewide program

Vaccine Comparison

	Pfizer	*Moderna*	*Janssen*
Vaccine Type	mRNA vaccine	mRNA vaccine	Adenovirus vaccine
Vial Presentation	Multi-dose vial: 6 doses per vial	Multi-dose vial: 10 doses per vial	Multi-dose vial: 5 doses per vial
Minimum dose vaccine order	1170 doses	100 doses	100 doses
Administration/Route	2-dose series/Intramuscular	2-dose series/Intramuscular	Single dose/Intramuscular
Interval between Doses	21 days	28 days	n/a
Storage	• Ultra-cold storage at -80°C to -60°C for up to 6 months • Frozen storage at -25°C to -15°C for up to 2 weeks • Refrigerated storage at 2°C to 8°C for up to 120 hours/5 days	• Frozen storage at -25°C to -15°C for up to six (6) months, or • Refrigerated storage at 2°C to 8°C for up to 30 days	Refrigerated storage at 2°C to 8°C for up to three (3) months
Fact Sheet Link	Pfizer EUA Fact Sheet	Moderna EUA Fact Sheet	Janssen EUA fact sheet

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DHEC and CDC Systems

Provider Reporting and Documentation Requirements

Provider Participation Requirements Overview: **Inventory**

- Inventory requests submitted via VAMS **by 11:59pm on Mondays**
- Inventory shipments documented in VAMS **same day** as shipment receipt
- All inventory waste and transfers documented in VAMS **within 24 hours** of occurrence
  - All transfers documented on COVID-19 Transport Log
- Report on-hand COVID-19 vaccine supply **daily** through the VaccineFinder COVID Locating Health Portal

Provider Participation Requirements Overview: Vaccine Administration Documentation

- COVID-19 providers must document all administered vaccines **within 24 hours** of administration via one of the following methods:
  - VAMS Standard/Mobile Clinic or Third-Party Clinic Type
  - Organization Electronic Health Record (EHR) with existing interface with SIMON
  - Direct data entry into SIMON

Provider Participation: **DHEC Provider Portal**

- H3707 signed into law February 19, 2021
- Mandated reporting effective Wednesday, March 10, 2021
- Law requires daily provider reporting into a DHEC reporting mechanism that includes metrics such as inventory and scheduled appointments
- Access and next steps guidance notices will be automatically sent to primary and back-up vaccine coordinators via provider portal
- The portal will issue daily reporting reminders by 4pm if no data has been reported
- Provider participation is mandatory and required by law

VaccineFinder Overview

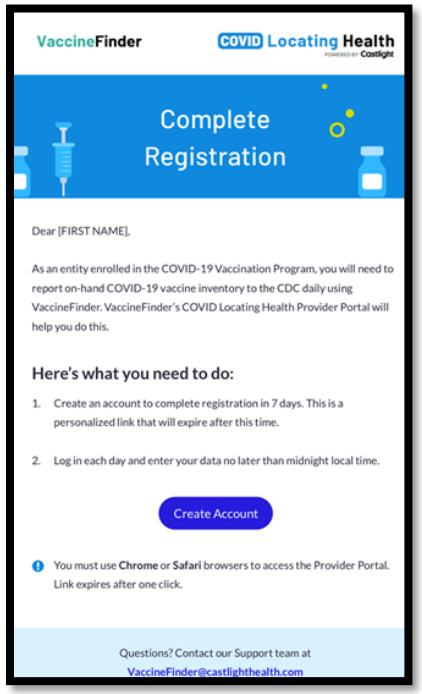
- VaccineFinder is a web-based tool for the public that has been traditionally used to locate routine immunizations
- Serves as the inventory reporting tool for COVID-19 providers (not public facing)
- Providers can elect to make their locations visible in VaccineFinder to facilitate better access to vaccines among eligible groups

VaccineFinder: Registration

- The monitored organization contact email address listed in the DHEC Enrollment Form Section A receives an account registration email from vaccinefinder@auth.castlighthealth.com
- The contact must complete account registration steps to
  - Confirm contact information
  - Determine reporting method (facility level or organization level)

VaccineFinder Account Activation Steps

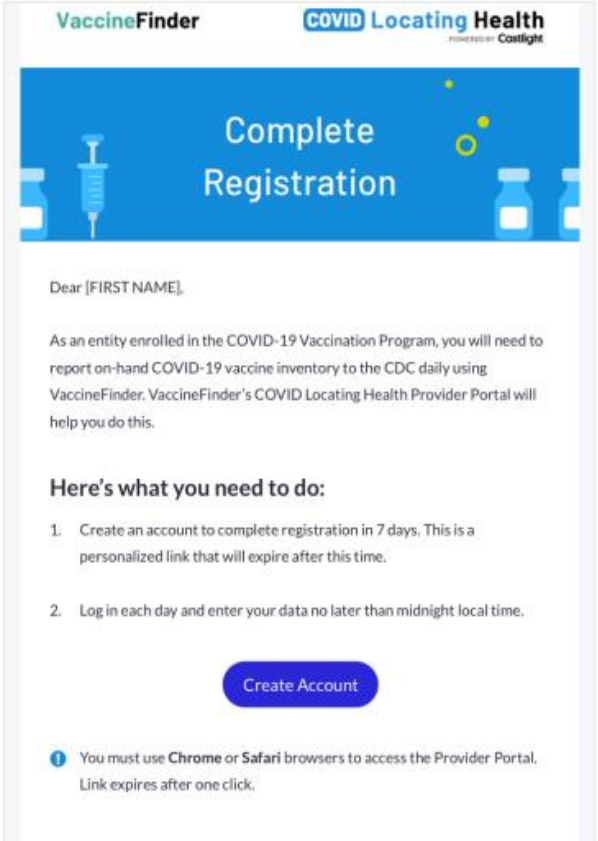
1. The organization email listed from an enrolled provider's section A form will receive an email from vaccinefinder@auth.castlighthealth.com to complete account registration in VaccineFinder.
2. The email will look like the image to the **right**. Click the "Create Account" button to complete VaccineFinder registration via the COVID Locating Health Provider Portal.
3. Open the registration email and click on the "Create Account" button. **Please note, the link is a one-time use only and will expire after the first click.**
4. Please ensure the link opens in one of the approved browsers (Chrome or Safari).
   a) Troubleshooting: use mouse to right-click the link and select copy link; paste link directly into one of the above approved browsers.
5. Registration page will refresh to prompt username and new password creation
6. Click submit, the page will redirect to the VaccineFinder login page.
   a) Please bookmark this page for future use



Create Account

Email Outreach

vaccinefinder@auth.castlighthealth.com



VaccineFinder COVID Locating Health

Complete Registration

Dear [FIRST NAME],

As an entity enrolled in the COVID-19 Vaccination Program, you will need to report on-hand COVID-19 vaccine inventory to the CDC daily using VaccineFinder. VaccineFinder's COVID Locating Health Provider Portal will help you do this.

Here's what you need to do:

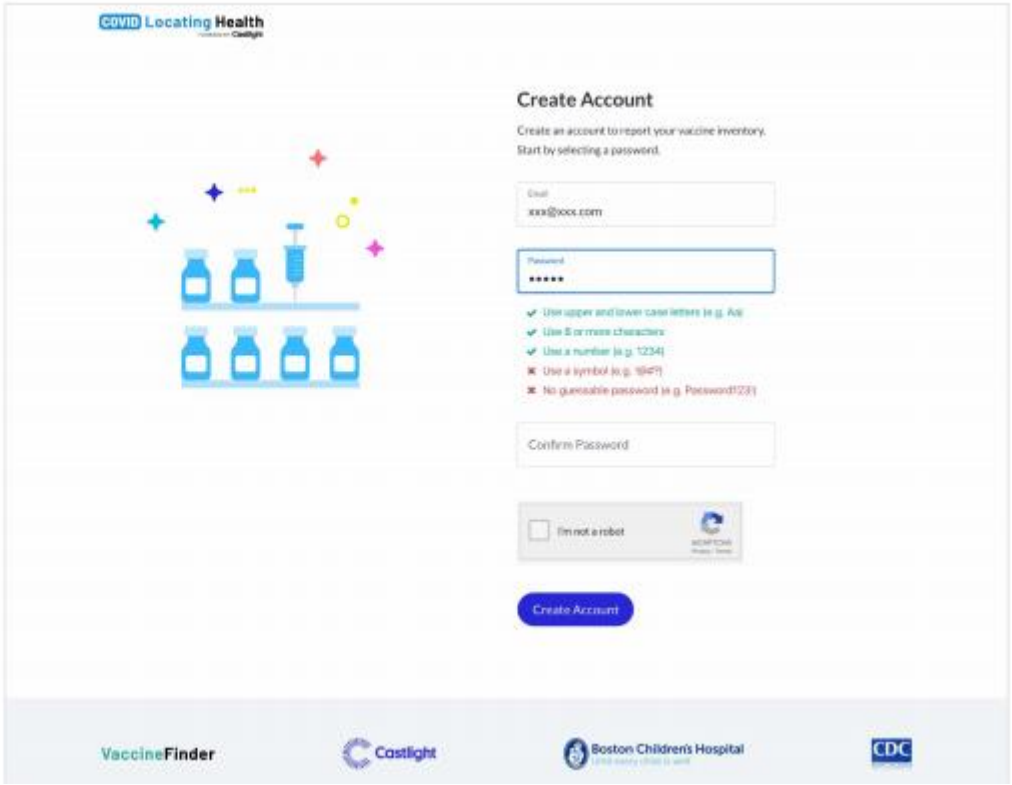
1. Create an account to complete registration in 7 days. This is a personalized link that will expire after this time.
2. Log in each day and enter your data no later than midnight local time.

Create Account

You must use **Chrome** or **Safari** browsers to access the Provider Portal. Link expires after one click.

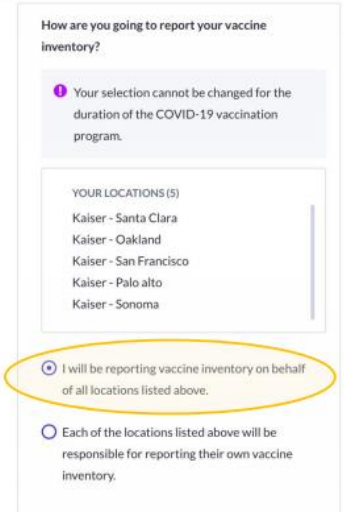
Create New Password

Provider Registration

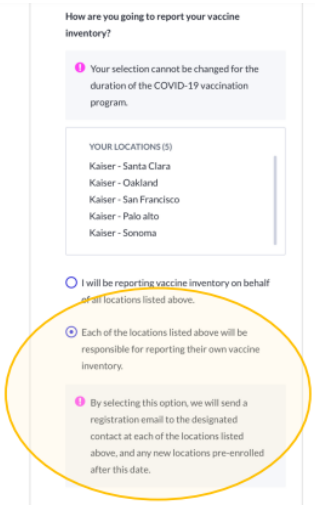


Choose Reporting Method

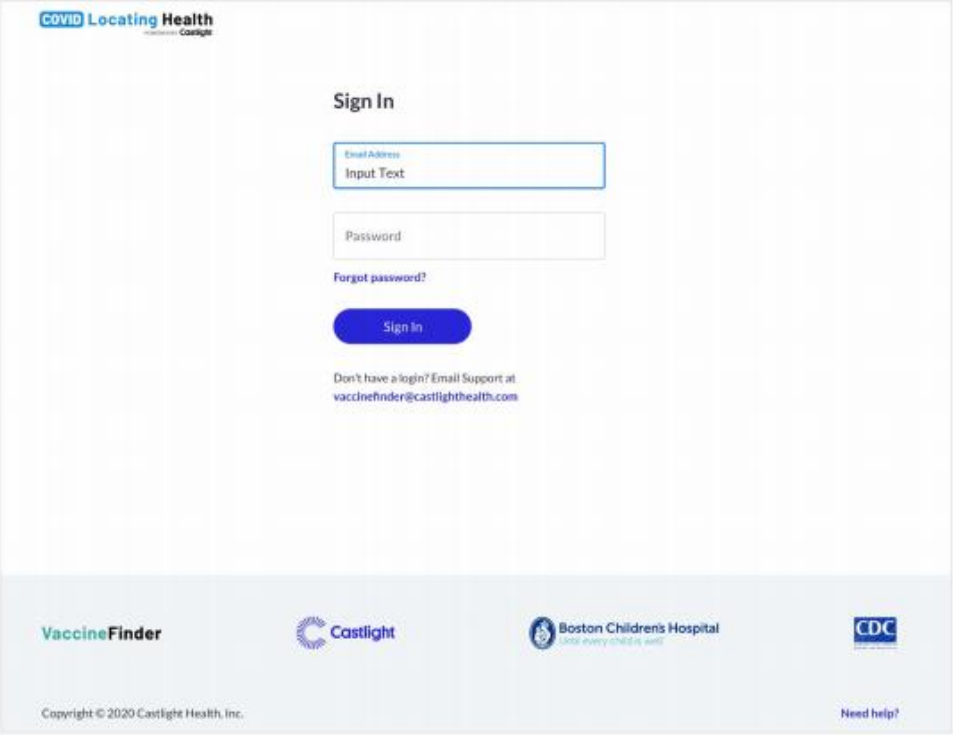
Provider Setup (Org-level reporting)



Provider Setup (Location-level reporting)

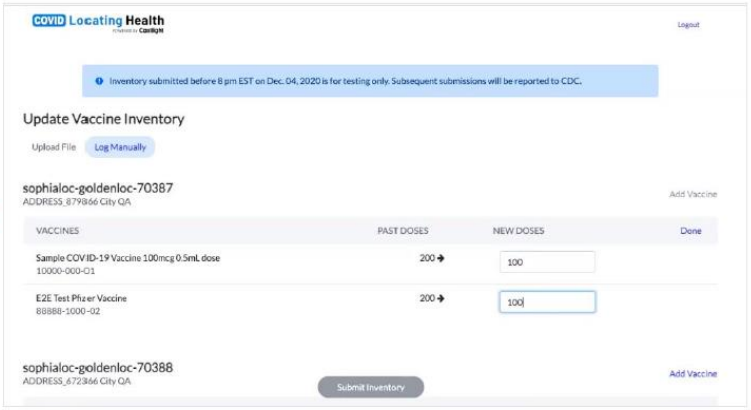


Bookmark website and login



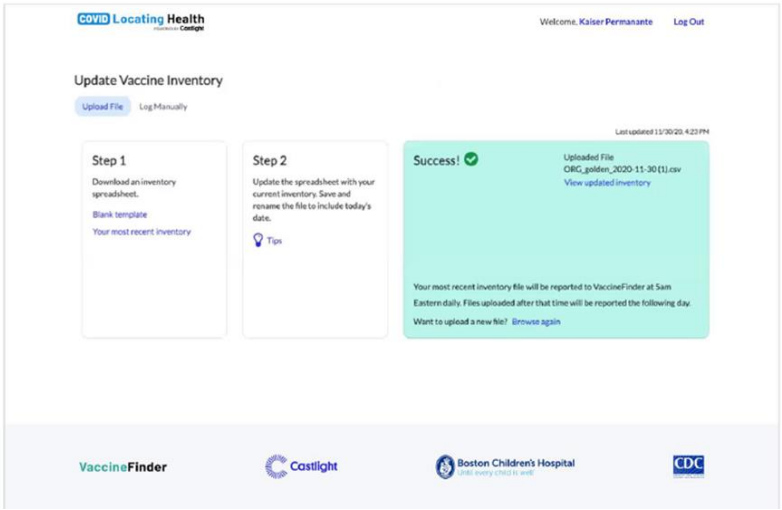
Report Inventory

Manual Reporting



OR

File Upload



VaccineFinder Contact and Training Resources

- **VaccineFinder IT Support Helpdesk**
  - vaccinefinder@castlighthealth.com
  - password resets, file uploads

- **VaccineFinder HelpDesk for Providers**
  - eocevent522@cdc.gov
  - Request registration email resends
  - Request updates to facility or contact information

- **VaccineFinder COVID 19 Vaccine Provider Information website (includes training videos): https://vaccinefinder.org/covid-provider-resources**
  - Quick Start Guide for VaccineFinder Provider Setup
  - COVID Locating Health Provider Portal Training for Providers
  - Quick Start Guide VaccineFinder Inventory Reporting- Log Manually
  - Quick Start Guide VaccineFinder Inventory Reporting- File Upload

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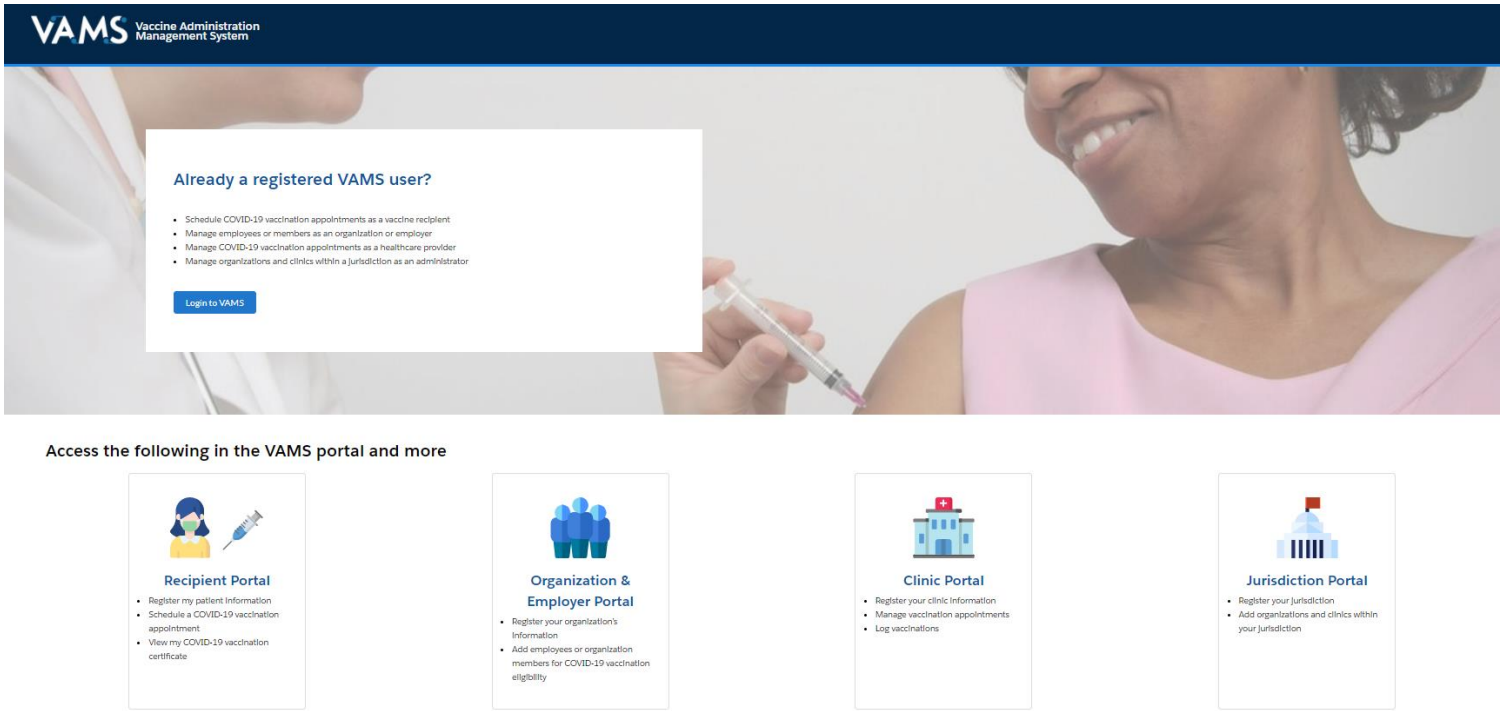


VAMS Overview

Vaccine Administration Management System (VAMS)

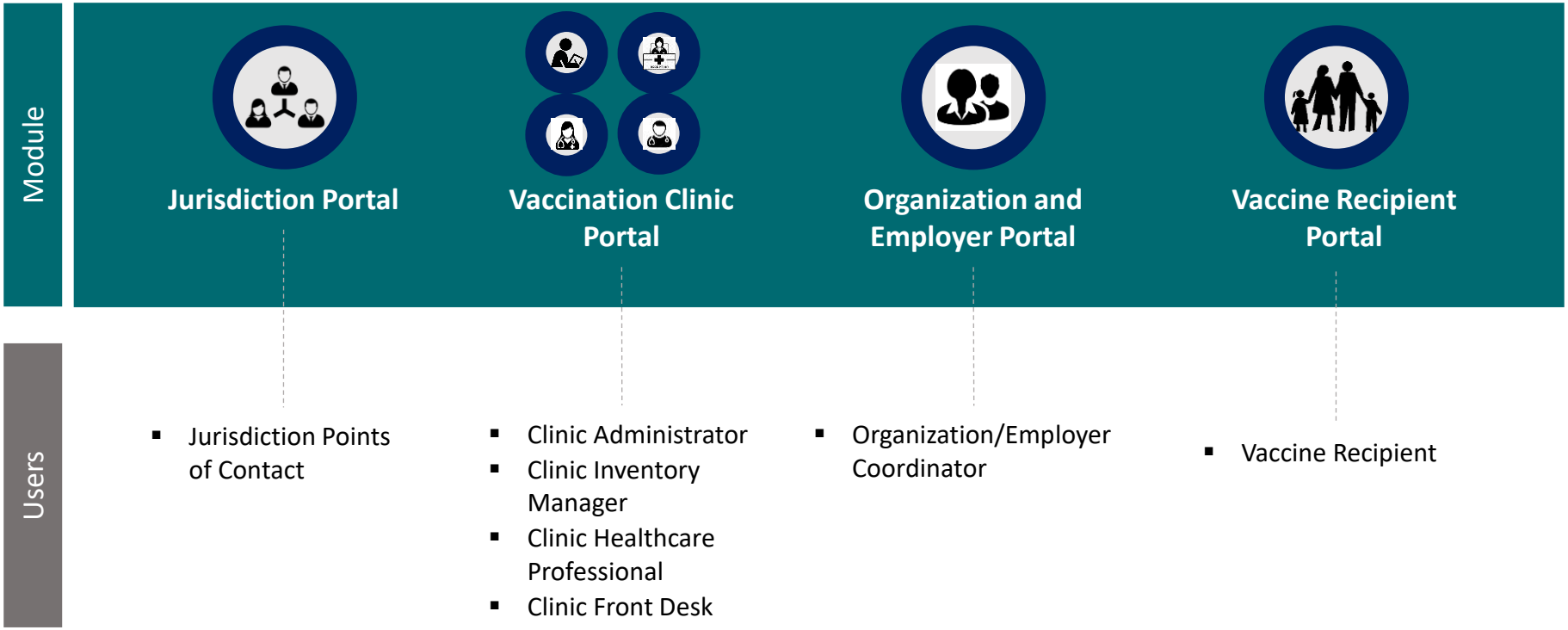
What is VAMS ?

VAMS is a web-based system that allows jurisdictions and clinics to support vaccination operations for critical populations.

- VAMS:
  - Provides appointment scheduling services
  - Houses inventory request and management tools
  - Documents vaccine administration events
  - Sends vaccine data to the corresponding immunization information system (IIS) and allows providers to fulfill all federal data reporting requirements.

- ✓ Can provide real-time reporting metrics
- ✓ Can request and track vaccine inventory
- ✓ Has dose-level accountability
- ✓ Meets data security requirements
- ✓ Can send reminders to vaccine recipients for follow-up doses and appointments
- ✓ Can provide a certificate of completion to the recipient

VAMS is Composed of Four Portals Spanning Multiple User Groups



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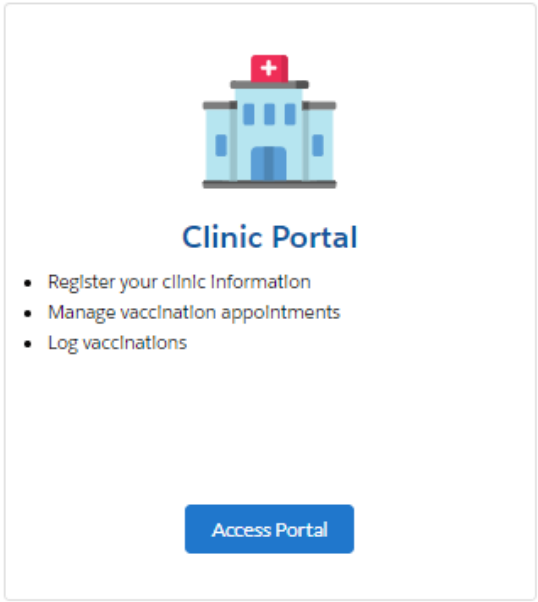
Vaccination Clinic Portal

Clinic Portal Overview and User Types

VAMS: Vaccination Clinic Portal

What is the Vaccination Clinic Portal?

- An interface for clinics to support scheduling, immunization tracking, and inventory management
- Vaccination Clinic Types include:
  - Standard
    - Hospital
    - Pharmacy
    - Clinic
  - Mobile
  - Third-Party



What are the Key Goals of the Vaccination Clinic Portal?

- Set up and manage clinic schedules, if applicable
- Document administered doses
- Manage and request inventory

The Vaccination Clinic Portal is not:

- An interface DHEC can access
- An interface recipients will access (they will have their own portal)
- An interface employers will access (they will have their own portal)
- A downloadable app (i.e., from App Store)

Key Differences Between Clinic Types in VAMS

Standard and Mobile

Clinic Roles (4)
- Clinic administrator
- Healthcare professional
- Inventory manager
- Front desk

Scheduling
Set up clinic schedule in VAMS for appointments.

Accessibility
Recipients use VAMS to:
- Record medical history
- Search for vaccination clinics
- Schedule appointments
- View vaccination certificates

Next-Dose Eligibility
Recipients receive reminders from VAMS on when they should schedule follow-up appointments.

Third-Party

Clinic Roles (3)
- Clinic administrator
- Healthcare professional
- Inventory manager *(optional)*

Scheduling
No clinic schedule set up because no appointments are scheduled by recipients.

Accessibility
Recipients do NOT use VAMS
- Third-party clinics do not appear in vaccination clinic search results

Next-Dose Eligibility
Clinic staff tracks vaccine recipients' next-dose eligibility and communicates it to recipients.

Benefits and Considerations of Clinic Types

Standard Clinics	
Benefits	Appointments can be scheduled by recipients and/or VAMS clinic users on behalf of recipients. Registration and appointment scheduling does not require recipient email address or phone number.
	VAMS manages all recipient notifications, if contact information provided (e.g. appointment reminders, confirmations, cancellations)
	Clinic schedule is easily adjustable
	Can provide vaccination events for specific groups
Considerations	Clinic schedules must be set up in VAMS
	Site is visible to the general recipient population in VAMS
	May be challenging for vaccination events in low internet connectivity areas

Benefits and Considerations of Clinic Types

Mobile Clinics	
Benefits	Appointments can be scheduled by recipients and/or front desk users on behalf of recipients. Registration and appointment scheduling does not require recipient email address or phone number.
	VAMS manages all recipient notifications if contact information provided (e.g. appointment reminders, confirmations, cancellations)
	Clinic schedule is easily adjustable
	Can provide vaccination events for specific groups
	Can add multiple temporary vaccination locations via one portal

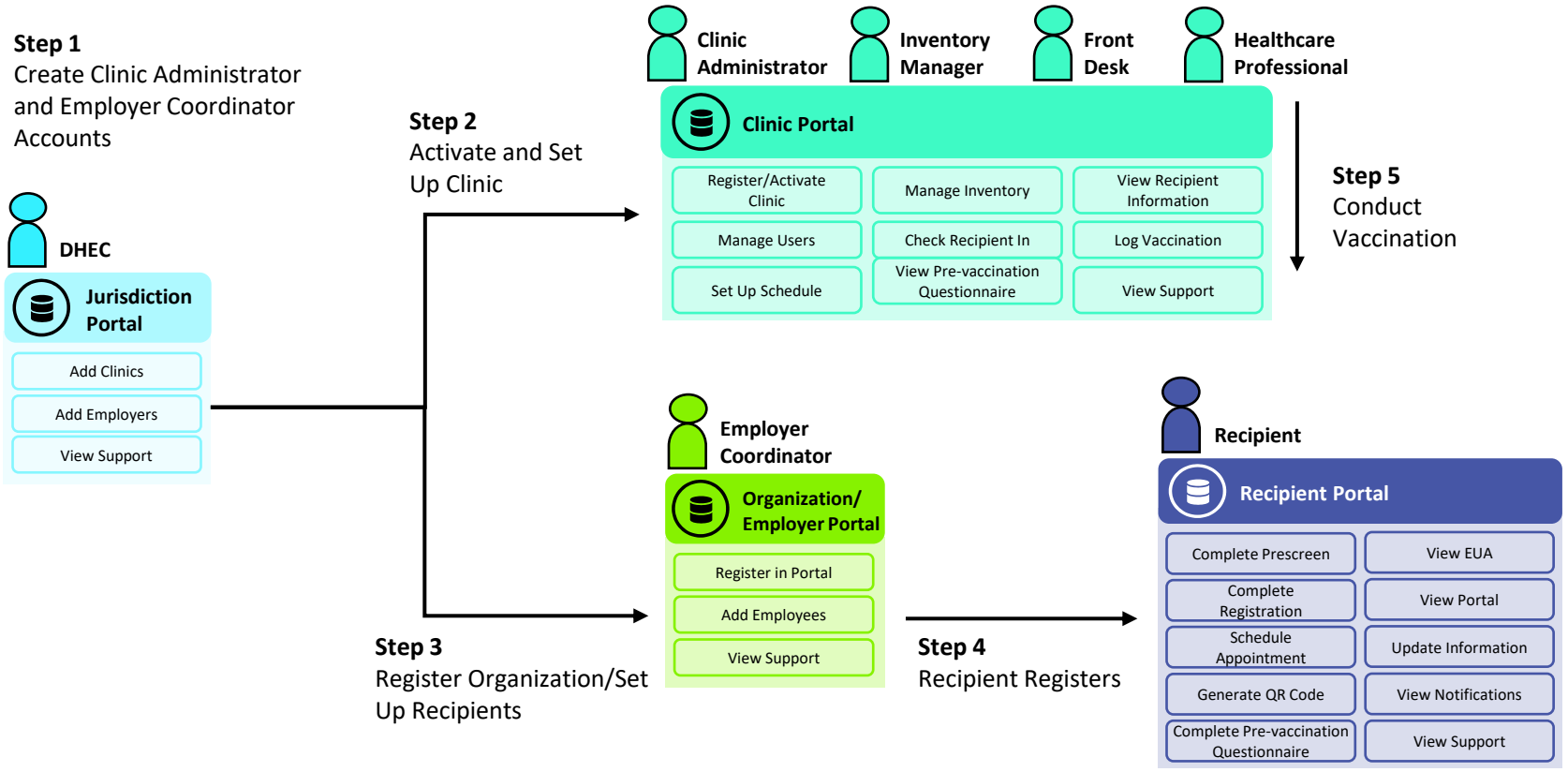
Considerations	Clinic schedules must be set up in VAMS
	Site is visible to the general recipient population in VAMS
	May be challenging for vaccination events in low internet connectivity areas

Benefits and Considerations of Clinic Types

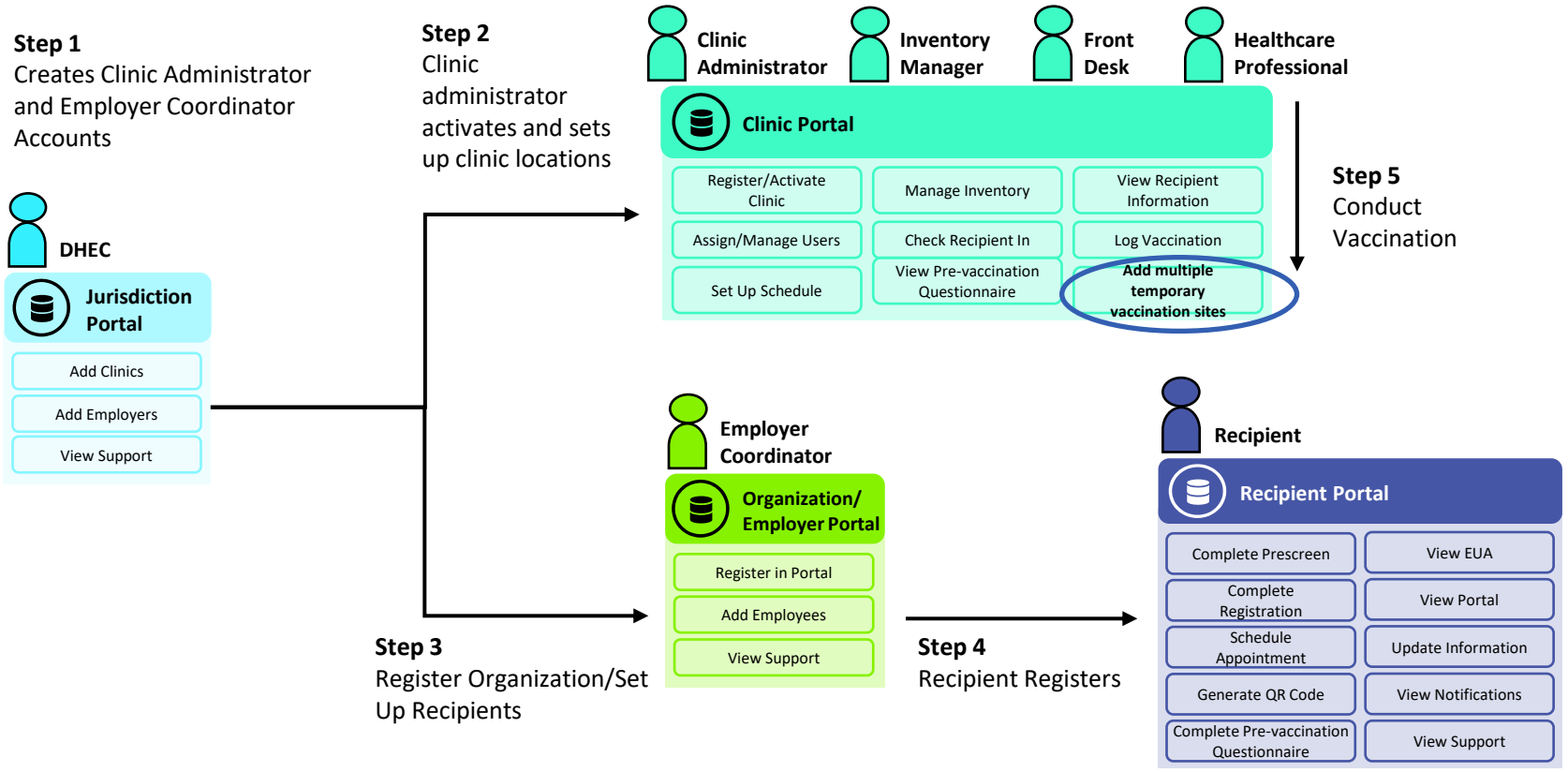
Third-Party Clinics	
Benefits	No clinic schedule set-up needed
	Not publicly searchable in VAMS
	Serves as administered vaccine documentation and/or inventory management tool only

Considerations	Facilities must establish processes for the following activities:
	• Managing clinic and recipient schedule at the clinic-level • Conducting pre-vaccination actions, such as the pre-vaccination questionnaire and EUA fact sheet distribution • Notifying recipients when they are able to receive their next vaccine dose, if applicable

VAMS Workflow-Standard Clinic



VAMS Workflow-MOBILE CLINIC



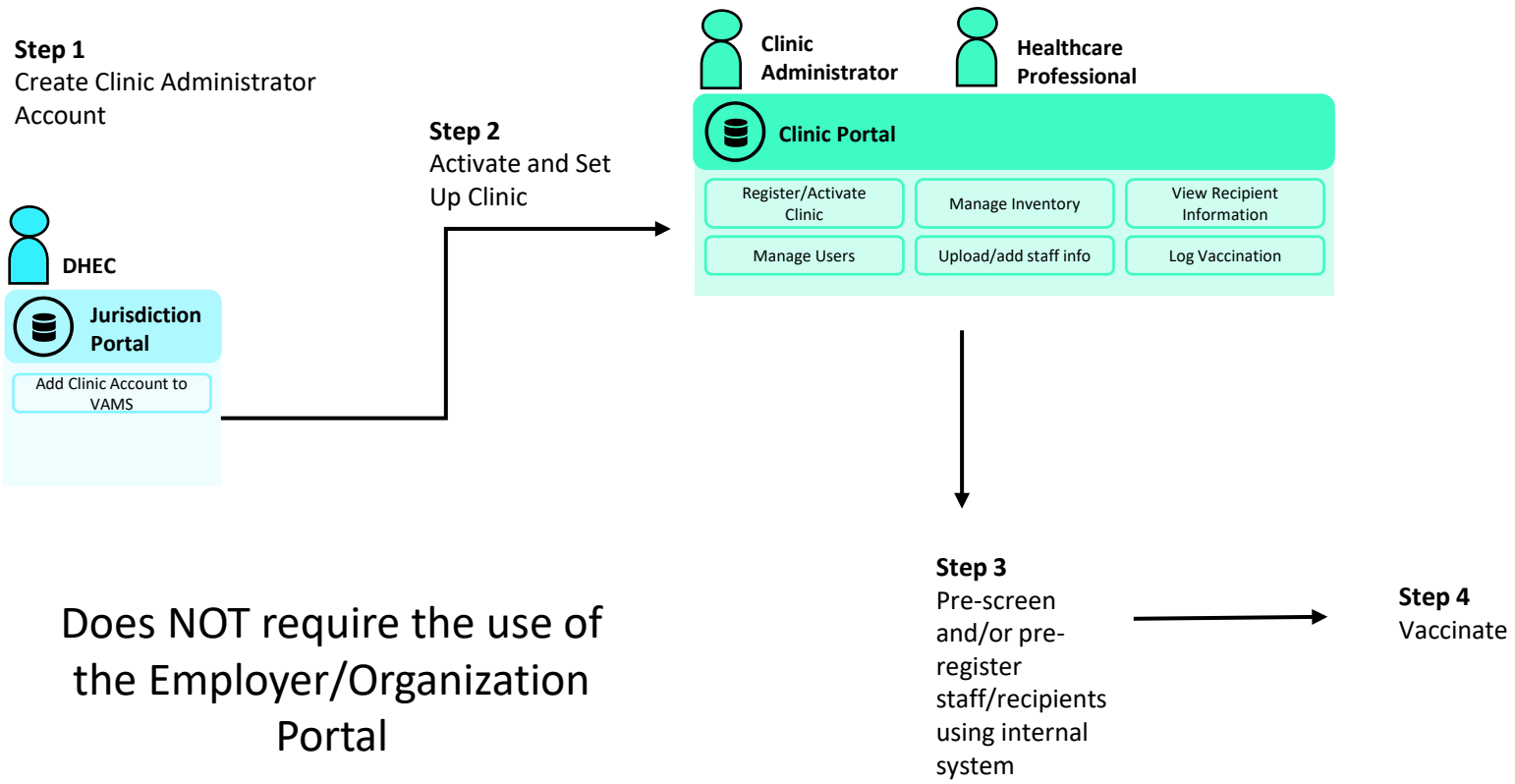
Standard/Mobile Clinic User Matrix

VAMS Roles and Activity Matrix				
Activity in VAMS	**Clinic User Role**			
	Clinic Administrator	**Inventory Manager**	**Healthcare Professional**	**Front Desk**
Serve as a clinic point of contact for your jurisdiction	✓			
Manage clinic information (e.g., physical address, operating hours)	✓			
Set and manage clinic schedule	✓			
Manage (add, edit, remove) VAMS users	✓			
Submit inventory requests	✓	✓		
Log vaccine inventory when received	✓	✓		
Log vaccine waste	✓	✓		
Monitor clinic vaccine inventory levels to match appointments scheduled	✓	✓		
Check in vaccine recipients				✓
Create recipient appointments				✓
Cancel recipient appointments			✓	✓
Confirm recipient Identity			✓	✓
View recipient medical history and personal information; add notes to record			✓	
Log vaccine administration			✓	
Administer vaccine to recipients			✓	
Log vaccine waste that occurred during administration (if applicable)			✓	
View next-dose eligibility dates			✓	

VAMS Clinic Portal Users

- VAMS users can have access to multiple portals in VAMS as an organization coordinator, clinic user, and/or recipient
- VAMS users can use the same VAMS login to access the landing page to access the appropriate portal
- Any clinic type can have up to five (5) clinic administrators assigned
  - Clinics must have the clinic administrator, front desk, healthcare professional roles filled to maintain clinic operations. At minimum, one clinic administrator can be assigned all user access roles.
- All other clinic user roles are unlimited

VAMS Workflow-THIRD PARTY



Does NOT require the use of the Employer/Organization Portal

Third Party Clinic User Types Matrix

VAMS Roles and Activity Matrix

Activity in VAMS	Standard Clinic Administrator	Third-Party Clinic Administrator	Standard Clinic Healthcare Professional	Third-Party Clinic Healthcare Professional
Serve as the clinic's point of contact for your jurisdiction	✓	✓		
Manage clinic information (e.g., physical address)	✓	✓		
Set and manage clinic schedule	✓			
Manage (add, edit, remove) VAMS users	✓	✓		
Submit inventory requests	✓	✓		
Log vaccine inventory when received	✓	✓		
Log vaccine waste	✓	✓		
Add recipient information and insurance (if applicable), and record vaccine consent in VAMS		✓		✓
View recipient medical history and personal information; add notes to record			✓	✓
Log vaccine administration			✓	✓
Administer vaccine to recipients			✓	✓
Log vaccine waste that occurred during administration (if applicable)			✓	✓
View next dose eligibility dates			✓	✓
Track recipients' next dose eligibility				✓

Provider Onboarding Survey: Clinic Decisions

- Determine the clinic location's point of contact (POC) who will serve as the **Clinic Administrator**
  - First name, last name, phone number, and email address must be documented
- **Determine desired location clinic type based on appointment scheduling and vaccine documentation needs**
  - Standard/Mobile Clinic
    - Clinic
    - Mobile
    - Hospital
    - Pharmacy
  - Third-party

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Organization Portal

VAMS Overview

Applies to non-Third Party Clinics Only

STEP 3 Your Portal: Organization Portal

Organization Portal

Organization* Portal users can use VAMS to:

- Add priority group members to VAMS to be considered for COVID-19 vaccination.
- Automatically send email notifications to those individuals to register in VAMS and schedule their vaccination appointment(s).

As an **organization coordinator**, you will use VAMS to identify priority group workers and other at-risk groups who need to receive COVID-19 vaccine when it first becomes available and add these individuals in VAMS so they can schedule vaccination appointments. You will also serve as a liaison between your jurisdiction point of contact (POC) and the members of your organization.

Recipient Registration

Registration Option	
The Organization Coordinator adds organization members via manual addition, either one at a time or bulk upload, generating an auto email notification to register a VAMS account and schedule an appointment	
Pros	• No email address restrictions • Cannot be forwarded to others
Cons	• Cannot control messaging of autogenerated email to recipients

VAMS Onboarding Decisions: Organization Portal

Please note the organization portal is optional

If desired, please document on the onboarding survey:

- The organization's point of contact (POC) information who will serve as the Organization Coordinator
  - First name, last name, and email address

Complete the new provider activation survey (click link) within 24 hours of activation notice using your location ID.

Your location ID is contained within your activation email.

VAMS Training Materials

VAMS Standard and Mobile Clinics
- Clinic Administrator User Manual
- Healthcare Professional User Manual
- Documenting Vaccines Quick Reference Guide
- Front Desk User Manual
- Standard and Mobile Set-Up and Training Video

VAMS Third-Party Clinics
- Clinic Administrator User Manual
- Healthcare Professional User Manual
- Third-Party Clinic Set-Up and Training Video

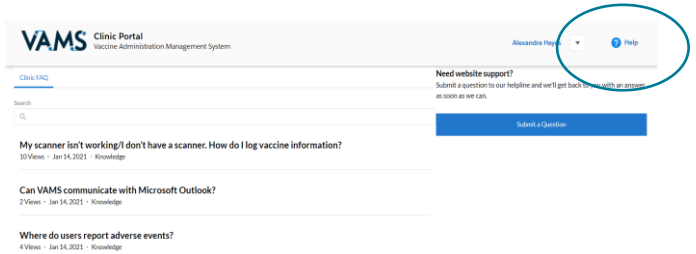
Inventory Manager
- Inventory Manager User Manual
- VAMS Inventory Management Training Video
- Pfizer and Moderna product guide

Organization Coordinator
- Organization Coordinator User Manual

Recipient
- Recipient User Manual

VAMS Help Desks

- **CDC VAMS Help Desk**
  - Clinic Users submit a help desk ticket
    - submit questions, technical assistance, other issues via the Help function to submit a ticket, or
  - Call 1-833-957-1100, M-F, 8a-8p
- **DHEC Help Desk**
  - Serves SC VAMS Clinic Users, Organization Coordinators and Recipients
  - Email vams@dhec.sc.gov
    - **Clinic Users**: technical assistance, VAMS onboarding, new clinic set-up, additional clinic set-up requests
    - **Organizations**: VAMS onboarding, registration
    - **Recipient:** registration issues



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Vaccine Management Requirements

Key Storage and Handling Resources

- **CDC Product Information Guide for COVID-19 Vaccines and Associated Products**
  - https://scdhec.gov/sites/default/files/media/document/Vaccine-Product-Information-Guide_v7_03_02_21.pdf
  - Includes ancillary kit, vaccine shipment, storage, and handling information for all three COVID-19 vaccines
- **CDC Storage and Handling Toolkit**
  - https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf
  - Review the COVID-19 Vaccine Addendum
  - Review the transport recommendations for any COVID-19 vaccines
- **US Pharmacopeia COVID-19 Vaccine Handling Toolkit**
  - https://www.usp.org/covid-19/vaccine-handling-toolkit
  - Additional preparation and labeling, storage, handling, and transport, and waste and disposal guidance

Temperature Monitoring Requirements

- COVID-19 Vaccine Primary and Back-up Coordinators must monitor and document temperatures of storage units containing COVID-19 vaccines twice daily using approved temperature logs. Daily minimum and maximum temperatures must also be documented daily, ideally at the start of the day.
- COVID-19 Vaccine Primary and Back-up Coordinators must download continuous temperature monitoring device reports weekly
- COVID-19 vaccine transport logs are also required for any vaccine redistribution/transfer/transport
- Submit both completed weekly temperature logs and summary continuous temperature monitoring device reports to COVIDVaccines@dhec.sc.gov every Friday by COB.
    - Include Facility Name + Temp Logs in subject line

Temperature Excursions: during shipment

- Providers must immediately report any temperature excursions during shipment to the manufacturer
- Pfizer Shipments:
  - Pfizer: 1-877-829-2619 or cvgovernment@Pfizer.com
- Moderna and Janssen Shipments:
  - McKesson: 1-833-272-6635 (M-F, 8a-8p/ET)
    - After-hours email COVIDVaccineSupport@McKesson.com

Temperature Excursions: post-shipment

- Providers must immediately report any temperature excursions to the manufacturer for guidance
  - Pfizer: 1-877-829-2619
  - Moderna: 1-866-663-3762
  - Janssen: 1-800-565-4008
- Upon resolution, providers must submit a Vaccine Troubleshooting Record to COVIDVaccines@dhec.sc.gov that documents the event and any associated case number

Pfizer- BioNTech COVID-19 Vaccine

Click here to visit the Resource Page:

- **Vaccine administration overview**
  - Pre-vaccination screening form
  - Standing orders
  - Preparation and Administration Summary
  - Mixing Diluent and Vaccine Poster
- **Storage and Handling**
  - Storage and handling summary
  - Delivery checklist
  - Storage and handling labels
  - Ultra-cold vaccine storage temperature monitoring logs
  - Pfizer Beyond Use Date (BUD) Guidance and Labels (refrigerated storage)

Pfizer Contacts (Direct Ship only)

Pfizer Customer Service; for communications from Pfizer to primary and back-up vaccine coordinators regarding Pfizer vaccine order shipments	cvgovernment@pfizer.com
For confirmation of the ancillary kit shipment to primary and back-up vaccine coordinators	donotreply@pfizer.com
For communication from Controlant, including: • Notice at time of vaccine shipment with tracking information • Exceptions for either shipment delay or cancellation	Pfizer.logistics@controlant.com
24/7 support inbox and line. Contact this address for issues or call 1-701-540-4039 or 1-855-442-668765 to reach the Controlant 24/7 hotline.	support@controlant.com
All temperature notifications and alerts will come from this email address. This address must be unblocked to receive temperature notifications.	onsitemonitoring@controlant.com
Pfizer vaccine shipment has a problem	**Questions/concerns about vaccine viability issues during shipment must be reported on the same day as delivery.** Pfizer Customer Service Phone # (800) 666-7248 Email: cvgovernment@pfizer.com
Pfizer ancillary kit has a problem	McKesson Customer Service Phone #: 833-272-6634 Email: SNSSupport@McKesson.com

It is critical that providers ensure these email addresses are approved/whitelisted with their organization's IT program so correspondences are received in a timely manner

Moderna COVID-19 Vaccine

Click here to visit the Resource Page:

- **Vaccine administration overview**
  - Pre-vaccination screening form
  - Standing Orders
  - Preparation and Administration Summary
- **Storage and Handling**
  - Vaccine Expiration Date Tracking Tool
  - Storage and Handling labels
  - Beyond-Use-Date Guidance and Labels
  - Freezer temperature logs (C° and F°)

Moderna Contacts (Direct Ship only)

For communications from McKesson to primary and back-up coordinators regarding MODERNA vaccine order shipments	CDCCustomerService@McKesson.com CDCnotifications@mckesson.com
For communication from McKesson to primary and back-up coordinators about ancillary kits	SNSSupport@McKesson.com
Moderna vaccine shipment has a problem	**Questions/concerns about vaccine viability issues during shipment must be reported on the same day as delivery.** **Phone:** (833) 272-6635 Monday – Friday, 8 a.m. - 8 p.m. ET **Email:** COVIDVaccineSupport@McKesson.com (only send email if after hours)
Moderna ancillary kit has a problem	McKesson Customer Service Phone #: 833-272-6634 Email: SNSSupport@McKesson.com

It is critical that providers ensure these email addresses are approved/whitelisted with their organization's IT program so emails are received in a timely manner

Janssen COVID-19 Vaccine

Click here to visit the Resource Page:

- **Vaccine administration overview**
  - Pre-vaccination screening form
  - Standing Orders
  - Preparation and Administration Summary
- **Storage and Handling**
  - Storage and Handling Summary
  - Storage and Handling labels
  - Vaccine Expiration Date Tracking Tool
  - Refrigerator storage temperature logs (C° and F°)

Janssen Contacts (Direct Ship only)

For communications from McKesson to primary and back-up coordinators regarding **Janssen** vaccine order shipments	CDCCustomerService@McKesson.com CDCnotifications@mckesson.com
For communication from McKesson to primary and back-up coordinators about ancillary kits	SNSSupport@McKesson.com
Janssen vaccine shipment has a problem	**Questions/concerns about vaccine viability issues during shipment must be reported on the same day as delivery.** **Phone:** (800) 565-4008 or (908) 455-9922 Email address: JSCCOVIDTEMPEXCURSION@its.jnj.com
Janssen ancillary kit has a problem	McKesson Customer Service Phone #: 833-272-6634 Email: SNSSupport@McKesson.com

It is critical that providers ensure these email addresses are approved/whitelisted with their organization's IT program so emails are received in a timely manner

Provider Participation Requirements Overview: **Inventory**

- Refer to DHEC's Inventory Management, Inventory Request Submission and Delivery Cadence document for detailed guidance
- Inventory requests submitted via VAMS **on Mondays no later than 11:59pm**
- Inventory shipments documented in VAMS **same day** as shipment receipt
- All inventory waste and transfers documented in VAMS **within 24 hours** of occurrence
  - All transfers documented on COVID-19 Transport Log
- Report on-hand COVID-19 vaccine supply **daily** through the VaccineFinder COVID Locating Health Portal

COVID-19 Vaccine Expiration Dates

Pfizer Vaccine	Moderna Vaccine	Janssen Vaccine
This vaccine product has an expiration date located on the vaccine vial. CDC	The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date: • Scan the QR code located on the outer carton, or • Go to www.modernatx.com/covid19vaccine-eua/.	The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date: • Scan the QR code located on the outer carton • Call 1-800-565-4008, or • Go to www.vaxcheck.jnj/

CDC's COVID-19 Vaccine Expiration Date Tracking Tool can help providers keep track of the expiration date by lot number.

VAMS Inventory Requests

- Inventory requests must be submitted in VAMS on Mondays by 11:59pm to be considered for the next ordering/shipping cycle
- Please refer to DHEC's Inventory Management, Inventory Request Submission and Delivery Cadence document for detailed guidance

VAMS Inventory Request Submission

- DHEC processes CDC vaccine orders once a week; DHEC receives separate federal allocations for 1st and 2nd doses and must order these separately

- Please see the VAMS Inventory Manager User Manual to step-by-step guidance
- All providers must submit inventory requests in VAMS on **Mondays by 11:59pm** for consideration for new deliveries
  - Moderna, Janssen and Pfizer Direct Ship
    - Only one (1) new inventory request should be submitted per week
    - Organizations ordering on behalf of multiple sites should only submit a request via the ordering organization's VAMS account
    - DHEC only processes inventory requests based on "date requested". The "date required by" is not considered for processing for direct shipments as final vaccine order delivery arrivals are contingent on the manufacturer and transportation/delivery companies processing timelines
  - Include Total Amount of 1st and 2nd doses in the requested amount
  - Specify the amount of 1st and 2nd doses in the notes section; if 0 for either, please specify

- Please note:
  - Inventory requests are NOT guaranteed and are not considered orders
  - 2nd dose requests based on 1st dose shipments are guaranteed by DHEC
  - DHEC will post updates concerning final allocation amounts to inventory requests once determinations have been made
  - The requesting user should select the + Follow button of the inventory request to receive email updates when information is posted from DHEC. The requesting VAMS user will need to make a comment on the inventory request in order to enable the automatic email notification system.
  - DHEC staff will update pending inventory requests with a status update

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Inventory Request, Vaccine Order, and Vaccine Delivery Cadence Visual
all anticipated delivery dates are subject to change and are tentative

Monday	Tuesday	Wednesday	Thursday	Friday
Provider submits inventory requests for 1st and 2nd doses in VAMS by end of day			DHEC orders Moderna 1st and 2nd doses from CDC DHEC orders Janssen single doses	DHEC orders Pfizer 1st doses from CDC
Provider submits inventory requests for 1st and 2nd doses in VAMS by end of day DHEC orders Pfizer 2nd doses from CDC Pfizer providers receive 1st dose shipments Moderna providers receive both 1st and 2nd dose shipments Janssen providers receive vaccine deliveries		Pfizer providers receive 2nd dose shipments		

Federal Ancillary supply kits: Pfizer

DHEC will deliver additional ancillary supply kits to support **Pfizer** vaccine administration

- Adhesive bandages
- Gloves
- Cotton balls
- Surgical face masks

- needles (22-25G X 1”)
- needles (22-25G X 1.5”)
- mixing needles (21-25G X1.5”)
- syringes (1mL)
- syringes (3mL or 5mL)
- alcohol pads
- vaccination record cards
- needle gauge and length charts
- face shields
- surgical masks
- diluent vials

Federal ancillary supply kits: **Moderna and Janssen**

Sites receiving Moderna and Janssen direct shipments will automatically receive federal ancillary supply kits that will contain the supplies contained in the image to the right. Please consult the Product Information Guide for more information.

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, Janssen		
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 order.		
Contents: Each kit contains a label on the outside of the box with a complete inventory list.	**Adult Kit** • 85 needles (22-25G x 1") • 20 needles (22-25G x 1.5") • 105 syringes (1 mL 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 (1 mL 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 (1 mL or 3 mL) • 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.		

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Vaccine Order and Ancillary Supply Delivery Cadence

all anticipated delivery dates are subject to change and are tentative

Ordering Cadence for Pfizer 1st Doses: Direct Ship				
Requests submitted in VAMS	**Orders Placed by DHEC**	**Sites Receive Vaccine**	**Sites Receive Federal Ancillary Supply Kits**	**Sites Receive State-Supplied Ancillary Kits**
By Monday, 11:59pm	By Friday, 9am	Monday	Within 24-hour window of vaccine	Wednesday

Ordering Cadence for Pfizer 2nd doses: Direct Ship				
Requests submitted in VAMS	**Orders Placed by DHEC**	**Sites Receive Vaccine**	**Sites Receive Federal Ancillary Supply Kits**	**Sites Receive State-Supplied Ancillary Kits**
By Monday, 11:59pm	By Monday, 9am	Wednesday	Within 24-hour window of vaccine	Wednesday

Ordering Cadence for Direct ship to site: Moderna 1st and 2nd doses			
Requests submitted in VAMS	**Orders Placed by DHEC**	**Sites Receive Vaccine**	**Sites Receive Federal Ancillary Supply Kits**
By Monday, 11:59pm	By Thursday, 9am	Monday	Within 24-hour window of vaccine

Ordering Cadence for Direct ship to site: Janssen			
Requests submitted in VAMS	**Orders Placed by DHEC**	**Sites Receive Vaccine**	**Sites Receive Federal Ancillary Supply Kits**
By Monday, 11:59pm	By Thursday, 9am	Monday	Within 24-hour window of vaccine

Ancillary Supplies

- Important to keep ancillary supplies for the vaccine shipments separate from existing ancillary supplies at the facility
- Refer to the Product Information Guide for COVID-19 Vaccines and Associated Products for more information about federally-supplied ancillary kits

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Vaccine Safety Programs

Vaccine Adverse Event Reporting System (VAERS)

All COVID-19 vaccine providers must report any suspected moderate or severe reactions post COVID-19 vaccine administration and/or vaccine administration errors to VAERS.

- Smartphone-based text messaging program designed for vaccine recipients
- Recipients can opt-in and quickly tell CDC if they have any side effects
- Providers must post v-safe poster during vaccination events and share information
- See DHEC's COVID-19 provider website to download v-safe poster and information sheets.

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Clinical Staff Training and Resources

Key resources

- **CDC's Interim Clinical Considerations for use of COVID-19 Vaccines Currently Authorized in the United States**
  - https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html
  - Sign up for email updates when content changes
- **All COVID-19 Vaccination Clinician Resources**
  - https://www.cdc.gov/vaccines/covid-19/index.html

CDC Clinician On-Call Center

If a healthcare professional at your facility has clinical guidance needs, please contact:

- **Clinician On-Call Center:**
  - **Call 800-CDC-INFO (800-232-4636) and ask for the Clinician On-Call Center.**
  - **Email:** eocevent168@cdc.gov
- The Clinician On-Call Center is a 24-hour hotline with trained CDC clinicians standing by to answer COVID-19 questions from healthcare personnel on a wide range of topics, such as diagnostic challenges, clinical management, and infection prevention and control.

Vaccine Administration

Administration of COVID-19 vaccines: At-a-Glance

- COVID-19 vaccines are administered intramuscularly as either a two-dose series or single dose
- One valid vaccination series should be completed

Vaccine	Authorized age group	Dose	Dose volume	Number doses/series	Interval between doses
Pfizer-BioNTech	≥16 years	30 µg	0.3 ml	2	3 weeks (21 days)
Moderna	≥18 years	100 µg	0.5 ml	2	1 month (28 days)
Janssen	≥18 years	5×10^{10} virus particles	0.5 ml	1	N/A

Administration: **Second Dose Strategies**

- Provide a COVID-19 vaccination record card to all vaccine recipients, asking recipients to bring their card to their appointment for the second dose, and encouraging recipients to make a backup copy (e.g., by taking a picture of the card of their phone).
- Encourage all vaccine recipients to enroll in VaxText, a free text message-based platform to receive COVID-19 vaccination second-dose reminders.
- DHEC requires that providers make an appointment for the second dose before the vaccine recipient leaves to increase the likelihood that patients will present at the same vaccination site for the second dose.

Administration: **Second Dose Considerations**

- Persons should not be routinely scheduled to receive the second dose earlier than recommended.
  - However, second doses administered within a grace period of 4 days earlier than the recommended date for the second dose are still considered valid. Doses inadvertently administered earlier than the grace period should not be repeated.
- The second dose should be administered as close to the recommended interval as possible.
  - However, if it is not feasible to adhere to the recommended interval and a delay in vaccination is unavoidable, the second dose may be administered up to 6 weeks (42 days) after the first dose.
  - There are currently limited data on efficacy of COVID-19 vaccines administered beyond this window.
  - If the second dose is administered beyond these intervals, there is no need to restart the series

Interchangeability with other COVID-19 products

- Currently authorized COVID-19 vaccines can be used when indicated; ACIP does not state a product preference.
- However, COVID-19 vaccines are not interchangeable.
  - The safety and efficacy of a mixed-product series have not been evaluated.
- Both doses of the series should be completed with the same product.
  - However, if two doses of different mRNA COVID-19 vaccine products are inadvertently administered, no additional doses of either product are recommended at this time.

Interchangeability with other COVID-19 products: **Exceptional Situations**

- In exceptional situations in which the first-dose vaccine product cannot be determined or is no longer available, any available COVID-19 vaccine may be administered at a minimum interval of 28 days between doses to complete the mRNA COVID-19 vaccination series.
- If two doses of different mRNA COVID-19 vaccine products are administered in these situations (or inadvertently), **no additional doses of either product are recommended at this time.**

Coadministration with other vaccines

- COVID-19 vaccines should be administered alone, with a minimum interval of 14 days before or after administration with any other vaccines.
- If COVID-19 vaccines are inadvertently administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine.

COVID-19 Vaccination and SARS-CoV-2 infection

Vaccination of persons with SARS-CoV-2 infection or exposure

- **Persons with prior history of SARS CoV-2-infection**
  - Vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection.
  - Viral testing for current infection, or serologic testing for prior infection, is not recommended for the purpose of vaccine decision-making

Vaccination of persons with SARS-CoV-2 infection or exposure

- **Persons with current 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
  - No minimal interval between infection and vaccination
  - Current evidence suggests that reinfection is uncommon in the months after initial infection, thus while vaccine supply remains limited, persons with recent documented infection may choose to temporarily delay vaccination

Vaccination of persons who previously received passive antibody therapy for COVID-19

- Currently no data on safety and efficacy of COVID-19 vaccination in persons who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment
- Vaccination should be deferred for at least 90 days to avoid interference of the passive antibody therapy with vaccine-induced immune responses
- Recommendation does not apply to persons receiving antibody therapies not specific to COVID-19 treatment

COVID-19 Vaccination of Special Populations

Vaccination of persons with underlying medical conditions

- Any currently authorized COVID-19 vaccine can be administered to persons with underlying medical conditions who have no contraindications to vaccination, including
  - Immunocompromised persons
  - Persons with autoimmune conditions
  - People with history of Guillain-Barre syndrome, Bell's palsy, dermal filler use
- Clinical trials demonstrate similar safety and efficacy profiles in persons with underlying medical conditions, including those that place them at increased risk for severe COVID-19, compared to persons without comorbidities

COVID-19 vaccination of immunocompromised persons

- Persons with HIV infection, other immunocompromising conditions, or who take immunosuppressive medications or therapies might be at increased risk for severe COVID-19
- Immunocompromised persons may receive COVID-19 vaccine unless otherwise contraindicated
  - All currently authorized vaccines are inactivated vaccines
- Individuals should be counseled about
  - Unknown vaccine safety and efficacy profiles in immunocompromised persons
  - Potential for reduced immune responses
  - Need to continue to follow current guidance to protect themselves against COVID-19

Vaccination of pregnant women

- There are limited data on safety of COVID-19 vaccines in pregnant people
- Currently authorized COVID-19 vaccines are all inactivated vaccines. **Based on current knowledge, experts believe that COVID-19 vaccines are unlikely to pose a risk to the pregnant person or the fetus.**
- If pregnant people are part of a group that is recommended to receive a COVID-19 vaccine, **they may choose to be vaccinated.**
  - A conversation between the patient and their clinical team may assist with decisions regarding the use of a mRNA COVID-19 vaccine, though a conversation with a healthcare provider is not required prior to vaccination.
- There is **no recommendation for routine pregnancy testing** before receipt of a COVID-19 vaccine. Those who are trying to become pregnant do not need to avoid pregnancy after mRNA COVID-19 vaccination.

Management of allergic reactions

- Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of an mRNA COVID-19 vaccine.
- Vaccine providers should observe patients with a history of anaphylaxis (due to any cause) for 30 minutes after vaccination.
- All other persons should be observed for 15 minutes after vaccination to monitor for the occurrence of immediate adverse reactions.
- Review CDC's Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites

Contraindications and precautions for COVID-19 vaccines

CONTRAINDICATION TO VACCINATION	PRECAUTION TO VACCINATION	MAY PROCEED WITH VACCINATION
History of the following: • Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the vaccine† • Immediate allergic reaction* of any severity after a previous dose or known (diagnosed) allergy to a component of the vaccine† Actions: • Do not vaccinate. • Consider referral to allergist-immunologist. • Consider other vaccine alternative.†	Among persons without a contraindication, a history of: • Any immediate allergic reaction* to other vaccines or injectable therapies‡ Note: persons with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 vaccine, and vice versa# Actions: • Risk assessment • Consider referral to allergist-immunologist • 30-minute observation period if vaccinated	Among persons without a contraindication or precaution, a history of: • 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 history of anaphylaxis (due to any cause) • 15-minute observation period: all other persons

† See Appendix C for a list of ingredients. Persons with a contraindication to one of the mRNA COVID-19 vaccines should not receive doses of either of the mRNA vaccines (Pfizer-BioNTech or Moderna).

* Immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms consistent with urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.

‡ Includes persons with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is a vaccine component, but in whom it is unknown which component elicited the immediate allergic reaction.

Polyethylene glycol (PEG) is an ingredient in both mRNA COVID-19 vaccines, and polysorbate 80 is an ingredient in Janssen COVID-19 vaccine. PEG and polysorbate are structurally related, and cross-reactive hypersensitivity between these compounds may occur. Persons with a contraindication to mRNA COVID-19 vaccines (including due to a known [diagnosed] allergy to PEG) have a precaution to Janssen COVID-19 vaccine. Among persons who received one mRNA COVID-19 dose but for whom the second dose is contraindicated, consideration may be given to vaccination with Janssen COVID-19 vaccine (administered at least 28 days after the mRNA COVID-19 dose). Persons with a contraindication to Janssen COVID-19 vaccine (including due to a known [diagnosed] allergy to polysorbate) have a precaution to mRNA COVID-19 vaccines. In patients with these precautions, vaccination should be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions. Consider referral to allergist-immunologist.

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CONTACT US

DHEC VaxLocator Map: VaxStatus@dhec.sc.gov

COVID-19 Vaccine Management Branch: COVIDVaccines@dhec.sc.gov

COVID-19 Provider Enrollment Branch: COVIDProviderEnrollment@dhec.sc.gov

DHEC Redistribution Warehouse: RSS@dhec.sc.gov

New Provider Onboarding/VAMS: VAMS@dhec.sc.gov

Provider Portal Reporting: VaxReporting@dhec.sc.gov

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