dhec

Healthy People. Healthy Communities.

Activated Provider Reference Guide

Phase 1

Winter 2020-21

Contents

1 VaccineFinder

2 VAMS

3 Vaccine Management Requirements

4 Vaccine Safety Programs

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Provider Onboarding Checklist

- Review **VAMS** onboarding considerations and **document** onboarding decisions via this **required survey** no later than 48 hours of activation. *Failure to do so will result in exclusion from COVID-19 Vaccination Program.*
    - Please note that vaccine supply requests are submitted in VAMS.
- Attend the new provider onboarding session on Tuesdays from 11a-12:30p (click on link to access)
- Review **VaccineFinder** inventory reporting requirements. The organization contact email address from your section A form submission will receive an automated email from vaccinefinder@auth.castlighthealth.com within 48 hours. Please follow the set-up instructions.
- Review DHEC's phase 1a 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 and/or Moderna **vaccine preparation and administration trainings** with all vaccinating staff
- Review Pfizer and/or Moderna **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 a COVID-19 Vaccine Provider Town Hall Q&A on Wednesdays and Fridays from 11a-12p

Emails

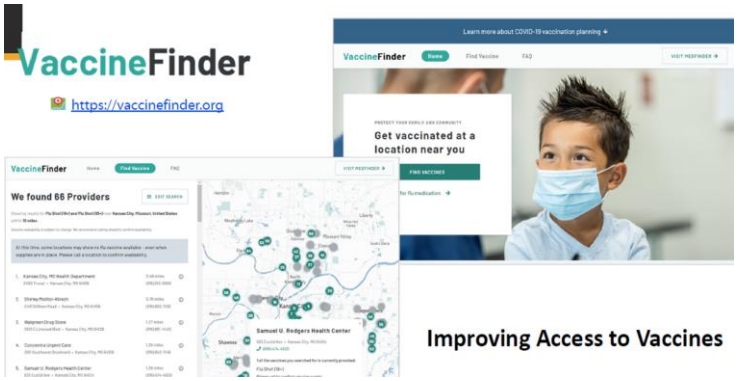
To ensure communications do not get delayed or blocked by organization servers, please work with your IT teams to whitelist/approve the following email addresses:

- vaccinefinder@auth.castlighthealth.com
- vams@cdc.gov
- No-reply@mail.vams.cdc.gov
- VAMSHelp@cdc.gov
- No-reply@envelope.mail.vams.cdc.gov
- *@salesforce.com
- CVGOVERNMENT@Pfizer.com
- Pfizer.logistics@controlant.com

South Carolina Department of Health and Environmental Control

VaccineFinder

Daily inventory reporting



Improving Access to Vaccines

Inventory Reporting

- COVID-19 vaccination providers will report on-hand inventory supply at least daily to VaccineFinder.
- Inventory quantities will not be made publicly available.
- Optional: Providers may choose to make their location(s) visible on the public-facing website to increase access to vaccine once supply is available to the public.

  Note: While the COVID-19 vaccine supply is limited, VaccineFinder will only be used for COVID-19 vaccine inventory reporting, not as a resource for the public to find vaccine at provider locations. The public-facing functionality will only be available when vaccine is more widely available.

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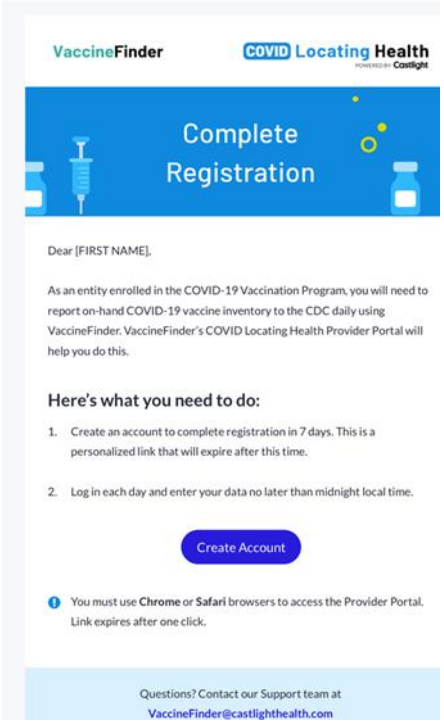
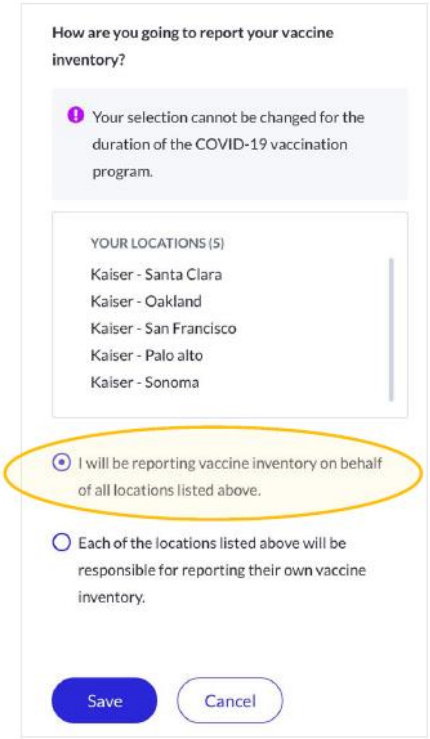
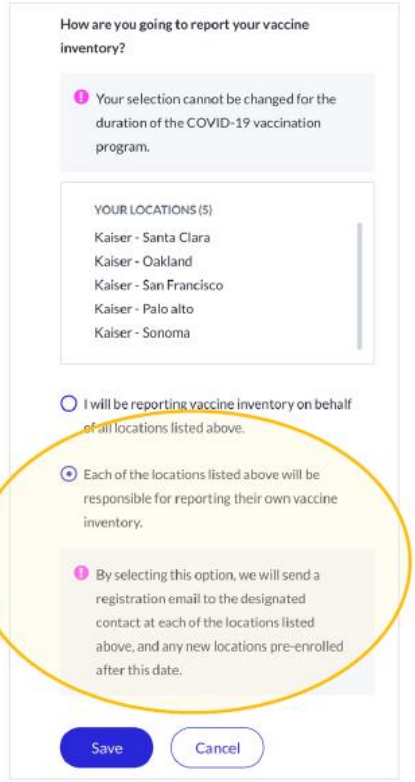
VaccineFinder Account Activation Steps

1. The organization email listed from an enrolled provider's section A form will receive an email from vaccinefinder@auth.castlighthealth.com prompting them to complete their account registration in VaccineFinder.
2. The email will look like the image to the right. Providers will click the "Create Account" link to complete VaccineFinder onboarding 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 (Safari, Chrome, or Microsoft Edge). You may need to right click, copy the link and paste it into one of the above approved browsers.
5. You will be directed to the registration page where you will enter your username and create a new password.
6. Click submit, you'll be redirected back to the VaccineFinder login page. Please bookmark this page for future use as well.



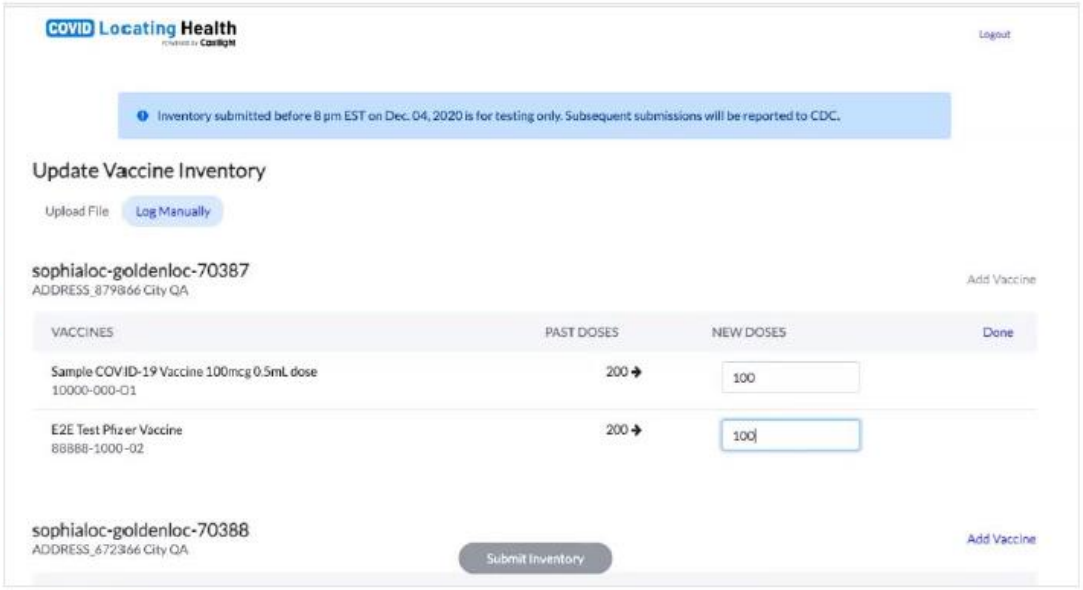
Provider Set-Up





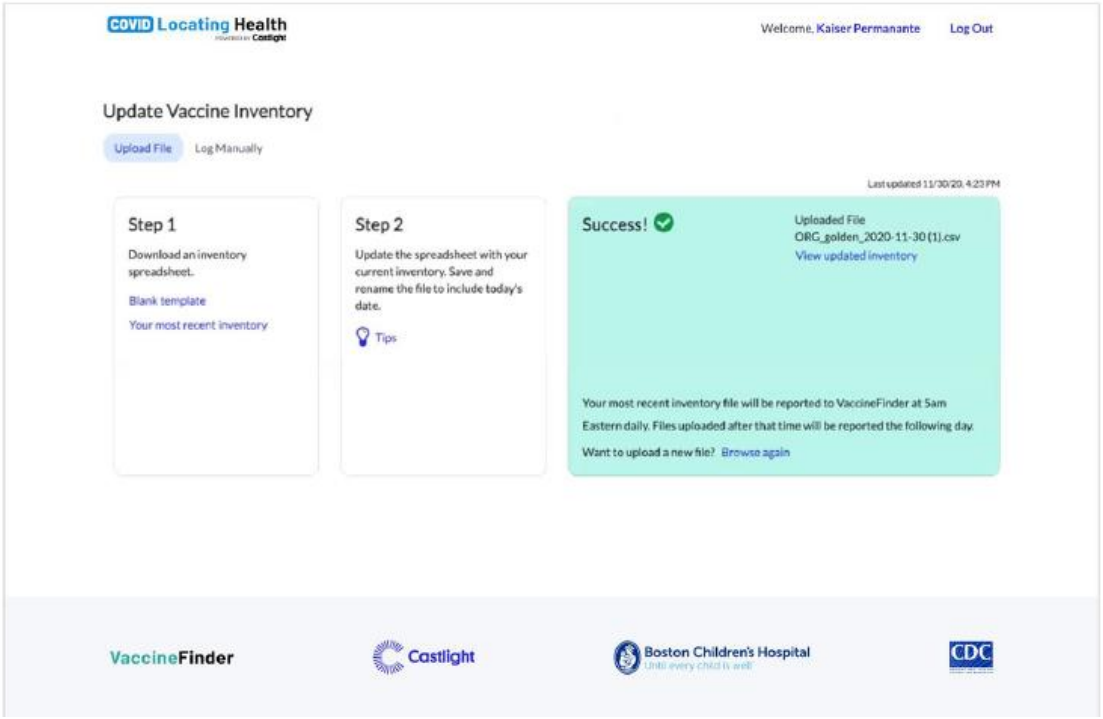
Inventory Reporting

Manual Reporting



Inventory Reporting

File Upload



VaccineFinder Resources

- Need help? Email the VaccineFinder helpdesk vaccinefinder@castlighthealth.com
- DHEC's COVID-19 Provider Webpage
  - 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
- VaccineFinder COVID 19 Vaccine Provider Information website (includes training videos): https://vaccinefinder.org/covid-provider-resources
- CDC COVID 19 Vaccination Provider Support, Data and Reporting: https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html

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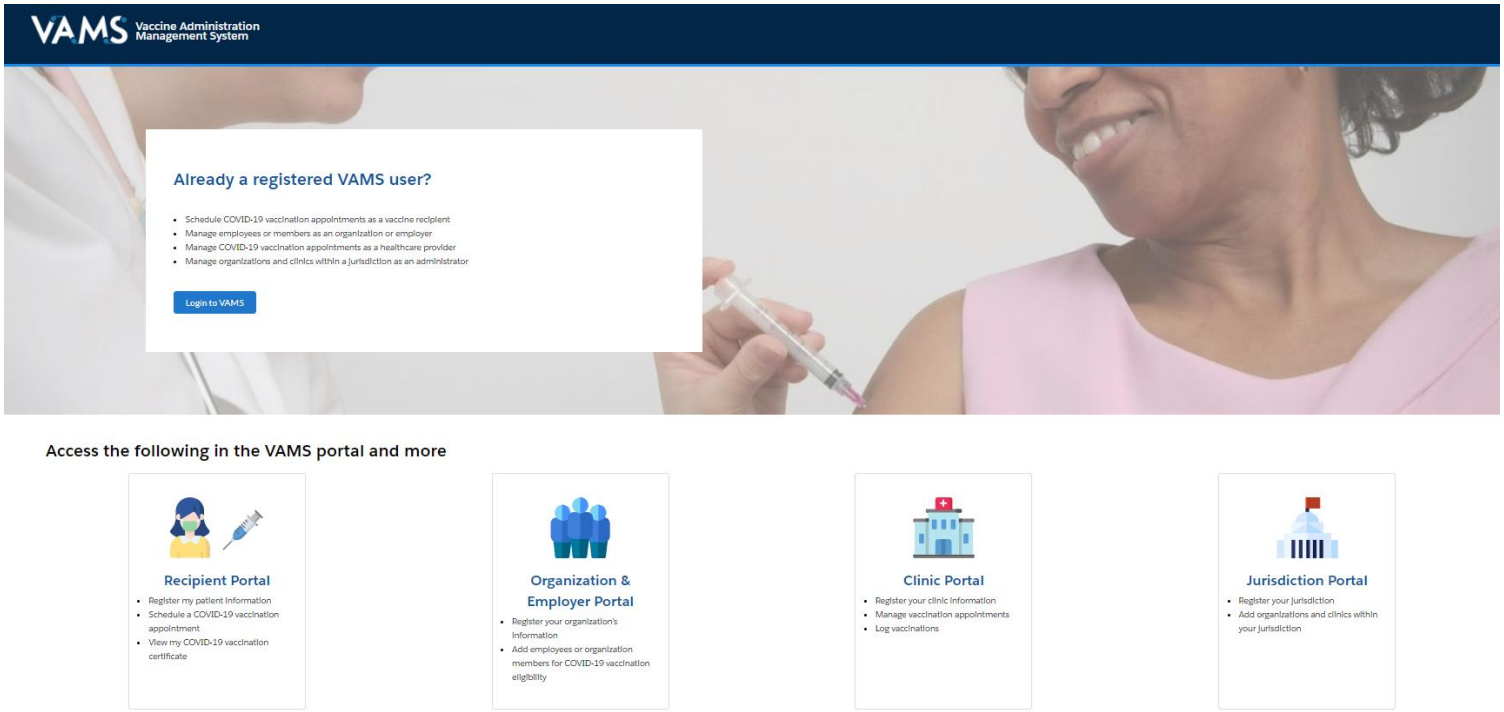


VAMS Overview

Vaccine Administration Management System (VAMS)

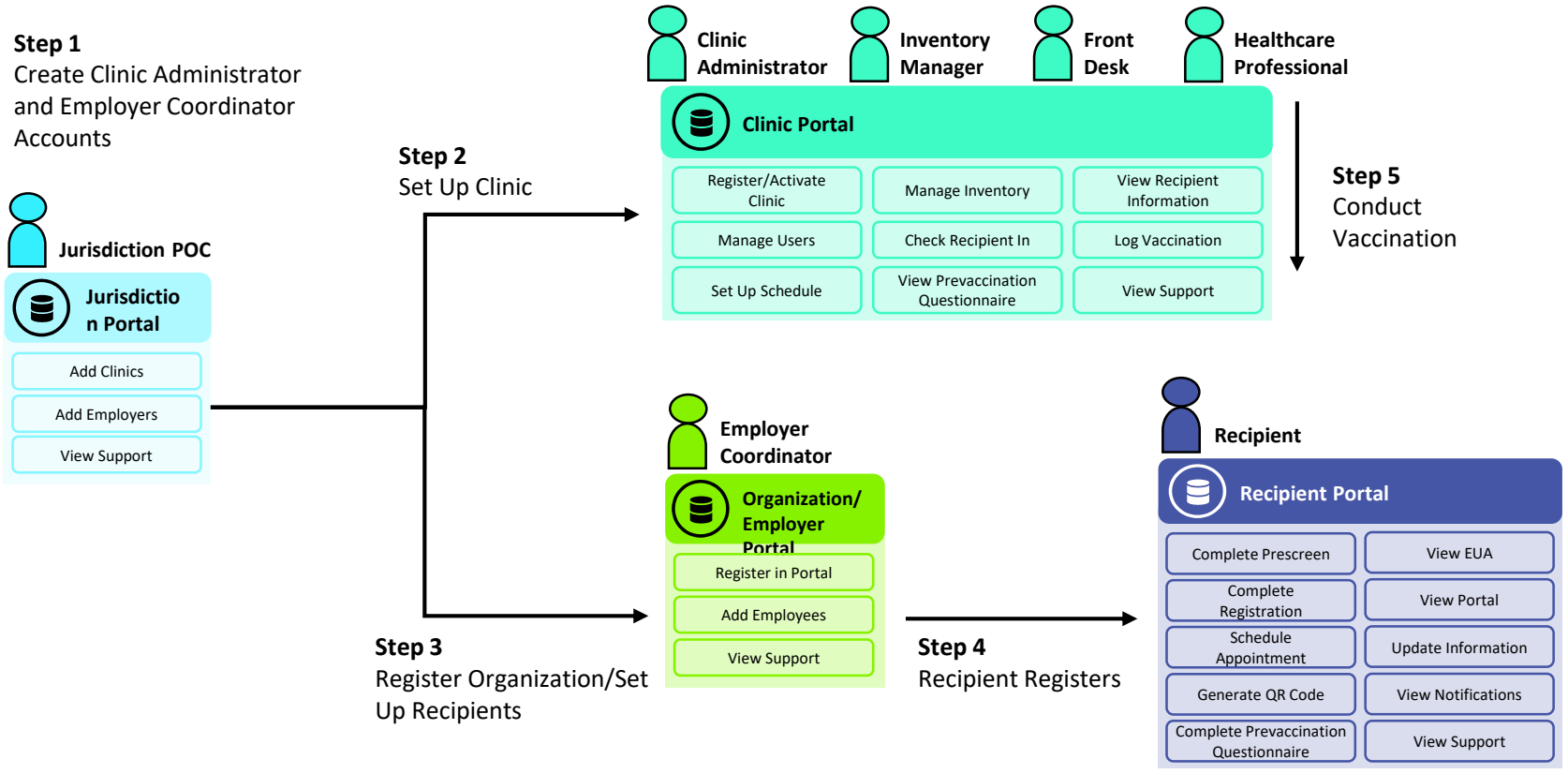
What is VAMS ?

VAMS is a web-based system that allows jurisdictions and clinics to support vaccination operations for critical populations. SC may use this system primarily for phase 1 vaccination only.

- VAMS is a clinical system that records vaccine administration events.
- VAMS sends the vaccine data to the corresponding immunization information system (IIS) and allows providers to fulfill all federal data reporting requirements**.**
  - **All documented VAMS doses will transmit to SIMON (South Carolina's statewide immunization registry)**
- VAMS is "invite only" and is not open to the public.

- ✓ 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

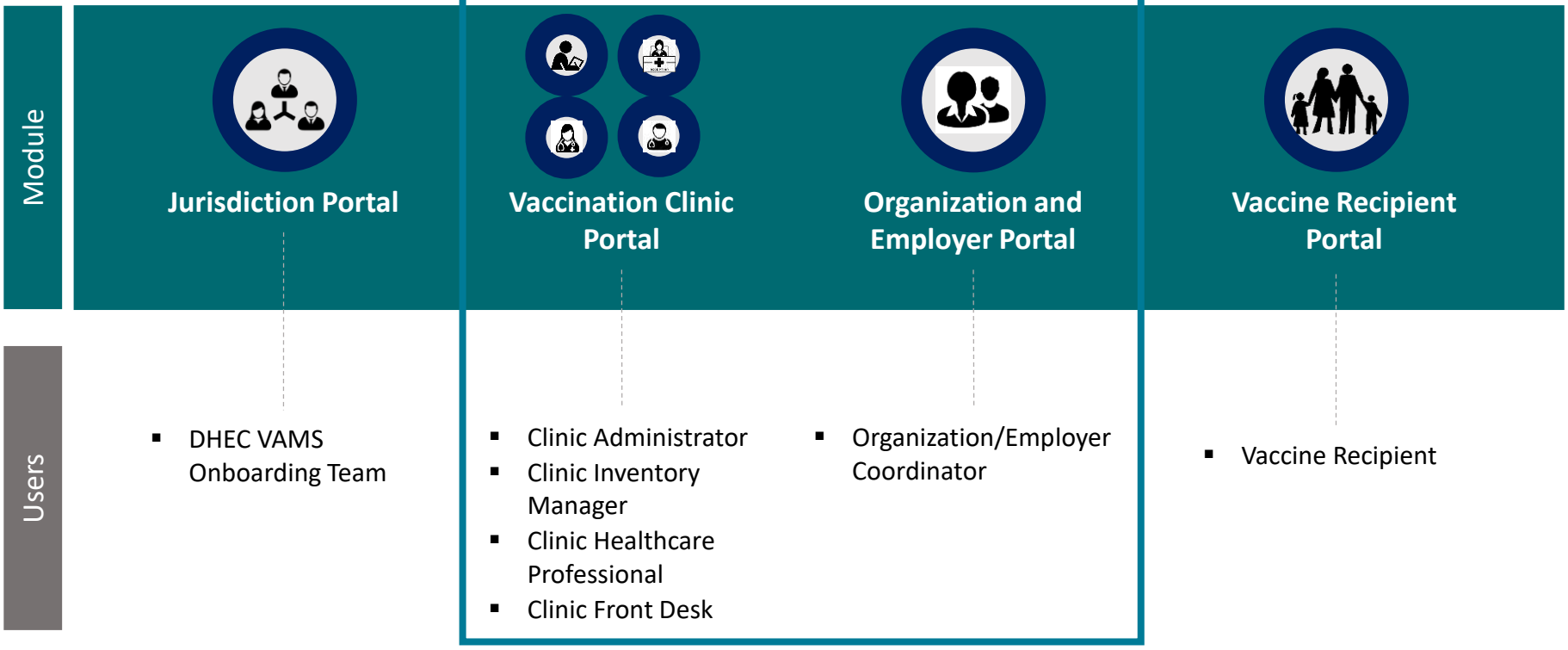
VAMS Users Interact with Each Other Following the VAMS Workflow



VAMS

- Vaccine providers must request and track all inventory in VAMS
- Vaccine providers must document all administered vaccines within 24 hours
- Vaccine providers must have a vaccination strategy in place to determine onboarding decisions

VAMS is Composed of Four Portals Spanning Multiple User Groups



South Carolina Department of Health and Environmental Control

Vaccination Clinic Portal

VAMS Overview

STEP 2
Vaccination Clinic Portal

What is the Vaccination Clinic Portal?

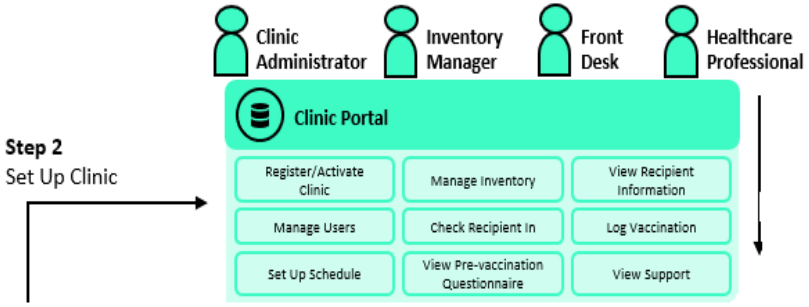
- An interface for clinics to support scheduling, immunization tracking, and inventory management

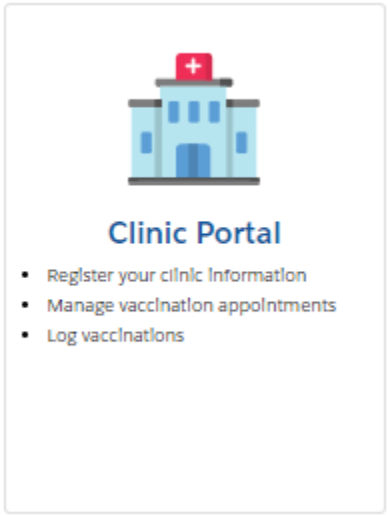
What are the Key Goals of the Vaccination Clinic Portal?

- Set up and manage clinic schedules and inventory
- Review recipient self-reported information during the healthcare encounter

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)





Clinic Types

Clinic Type	Description	Considerations
Clinic **Hospital** **Pharmacy**	Settings with one permanent location for vaccination and vaccine storage. Vaccine supply can be either direct ship or redistributed from another location but is stored on-location.	• Vaccine recipients must pre-register in VAMS and schedule vaccination appointments in VAMS • Site is considered “live” and searchable in VAMS • Requires clinic schedule set up • Allows inventory management based on scheduled appointments • VAMS provides 2nd dose reminders and notifications to recipients • VAMS digitally provides pre-vaccination questionnaire, EUA, and vaccination certificate to recipients

Mobile Clinic Type

Clinic Type	Description	Considerations
Mobile	Settings with one permanent location for vaccine storage and multiple vaccine administration locations (daily offsite, temporary clinics). Vaccine is not stored at any offsite vaccine administration sites and is delivered/returned to permanent location for storage on the same day.	• Permanent location for vaccine storage is set up in VAMS as primary location for inventory management • Clinic administrator adds multiple temporary vaccine clinic locations in VAMS • Site is considered “live” and searchable in VAMS • Vaccine recipients must pre-register in VAMS and search for your location to schedule vaccination appointments in VAMS • Requires clinic schedule set up (operating hours, etc) • Allows inventory projections based on scheduled appointments • VAMS digitally provides pre-vaccination questionnaire, EUA, and vaccination certificate to recipients • VAMS provides 2nd dose reminders and notifications to recipients • *start and end dates of vaccination events cannot be the same-see next slide*

Mobile Clinic Set-up

Mobile clinic locations cannot have the same start and end dates. Clinic schedules must be set up similar to the graphic with the green check mark

	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATUDAY	SUNDAY
Clinic #1							
Clinic #2							
Clinic #3							
Clinic #4							

	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATUDAY	SUNDAY
Clinic #1							
Clinic #2							
Clinic #3							
Clinic #4							

Hospital/Clinic/Pharmacy/ Mobile Clinic Types

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			✓	

Vaccination Clinic Portal-
User Responsibilities Overview

Clinic Administrator

Primary Role: Serve as vaccination clinic POC for jurisdiction and manage clinic

What does the **clinic administrator** need to learn in VAMS?

Processes	Related Tasks
• **Set up/manage clinic in VAMS**	. Establish yourself as clinic POC . Verify and add clinic information such as physical and shipping address
• **Set up/manage clinic schedule**	. Set up operating hours, appointment duration, and number of treatment stations
• **Add/manage VAMS clinic users**	. Add clinic users in VAMS . Set or edit user role permissions . Remove users from VAMS
• **Monitor/manage clinic vaccine inventory**	. View clinic inventory . Submit inventory requests to jurisdiction
• **Find VAMS support or additional training resources when needed**	. Search for your question in the FAQs on the Help page

How will they learn?

Training Tools

- VAMS Clinic Staff User Manuals (clinic administrator should be familiar with all clinic roles)
- VAMS Clinic Setup Quick Start Guide
- 1:1 Support with SC DHEC POC
- Attend DHEC Townhall Q&A sessions
- View training videos

Considerations: clinic administrators can fulfill this role for multiple locations

Vaccination Clinic Portal
User Responsibilities Overview

Clinic Inventory Manager

Primary Role: Monitor and manage clinic's vaccine inventory

What does the **clinic inventory manager** need to learn in VAMS?

Processes	Related Tasks
• **Manage clinic vaccine inventory**	. View clinic inventory . Submit inventory requests to jurisdiction
• **Find VAMS support or additional training resources when needed**	. Search for your question in the FAQs on the Help page

How will they learn?

Training Tools

- VAMS Clinic Inventory Manager User Manual
- Demo Presentation Videos
- VAMS FAQs

Vaccination Clinic Portal
User Responsibilities Overview

Clinic Healthcare Professional

Primary Role: Administer vaccine to recipients

What does the **clinic healthcare professional** need to learn in VAMS?

Processes	Related Tasks
• **View/manage recipient appointments**	. View scheduled appointments
• **Administer vaccine**	. Access recipient record . Review recipient record . Add note to recipient record . Review previously added notes . Record decision to administer vaccine . Log vaccination . Log waste
• **Find VAMS support or additional training resources when needed**	. Search for your question in the FAQs on the Help page

How will they learn?

Training Tools

- VAMS Clinic Healthcare Professional User Manual
- Demo Presentation Videos
- VAMS Pocket Manual
- VAMS FAQs

Vaccination Clinic Portal
User Responsibilities Overview

Clinic Front Desk

Primary Role: Welcome and check in recipients

What does the **clinic front desk** need to learn in VAMS?

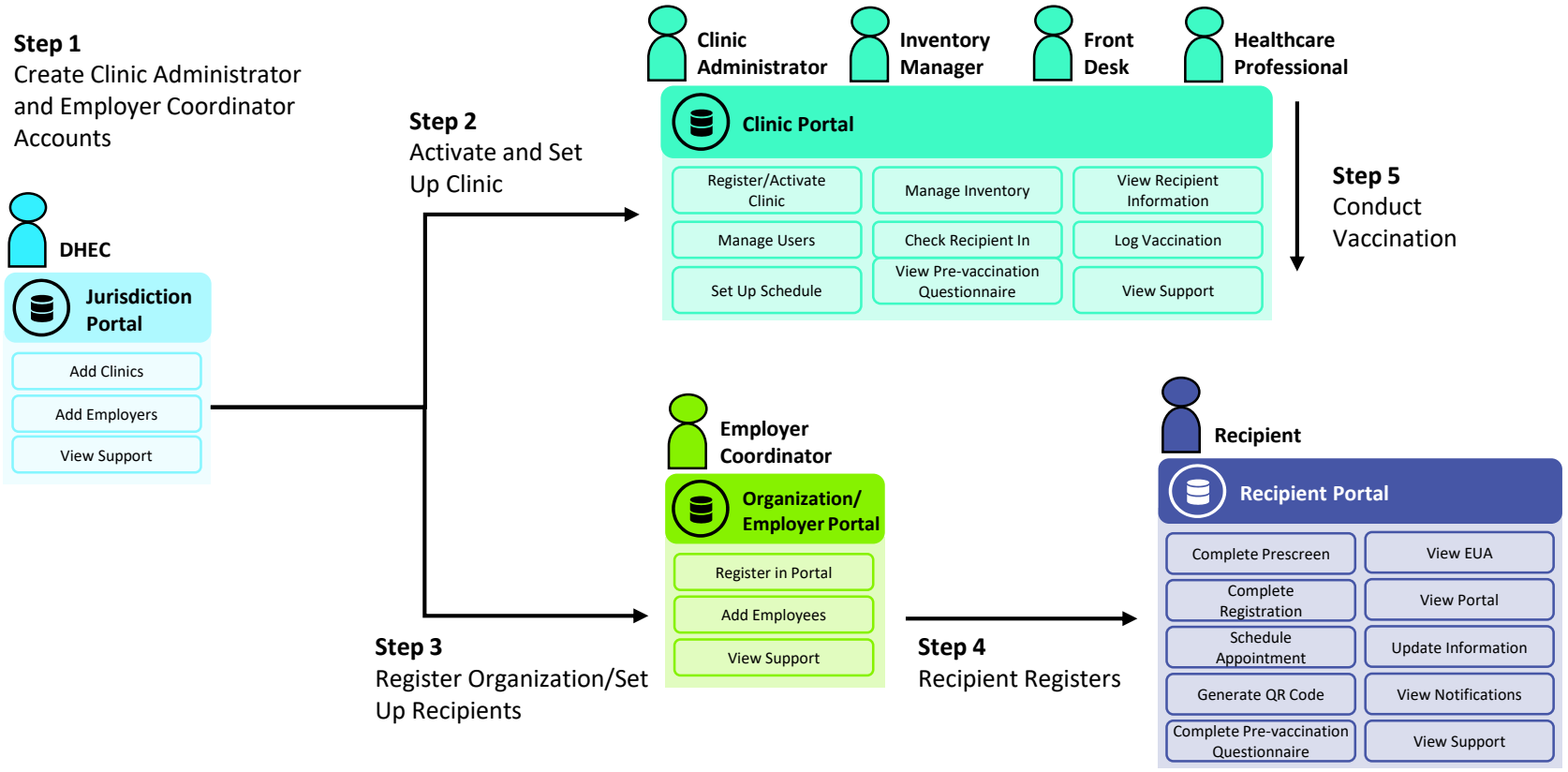
Processes	Related Tasks
• **Check in vaccine recipients**	. Use QR code to locate recipient appointment . Manually locate recipient appointment . Validate recipient identification . Validate pre-vaccination questionnaire compliance
• **Modify/cancel recipient appointments**	. View appointment status . Cancel appointments . Auto-cancellation for no-show appointments
• **Find VAMS support or additional training resources when needed**	. Search for your question in the FAQs on the Help page

How will they learn?

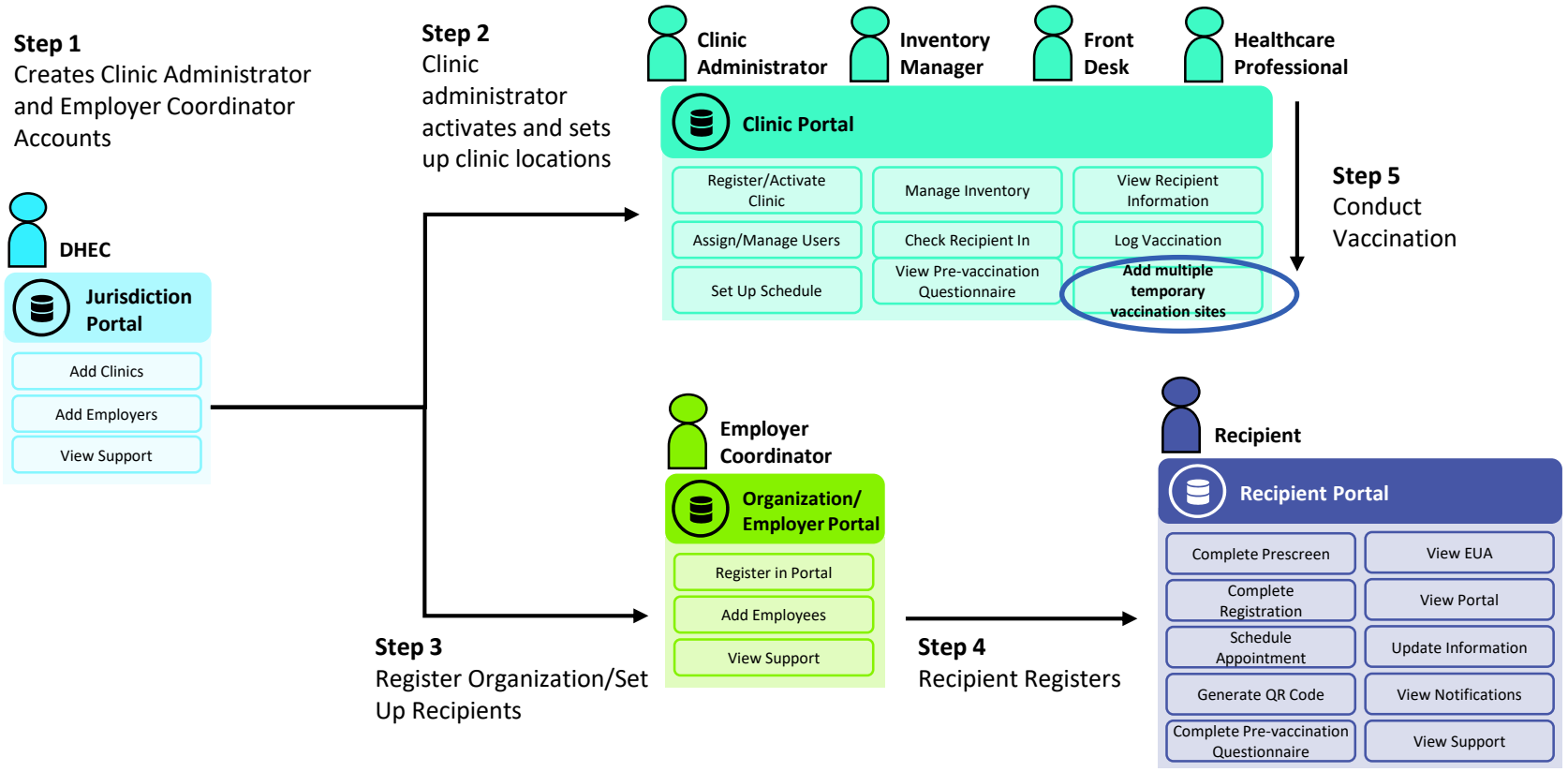
Training Tools

- VAMS Clinic Front Desk User Manual
- Demo Presentation Videos
- VAMS FAQs

VAMS Workflow-Hospital/Clinic/Pharmacy



VAMS Workflow-MOBILE CLINIC



Clinic Type: Third Party

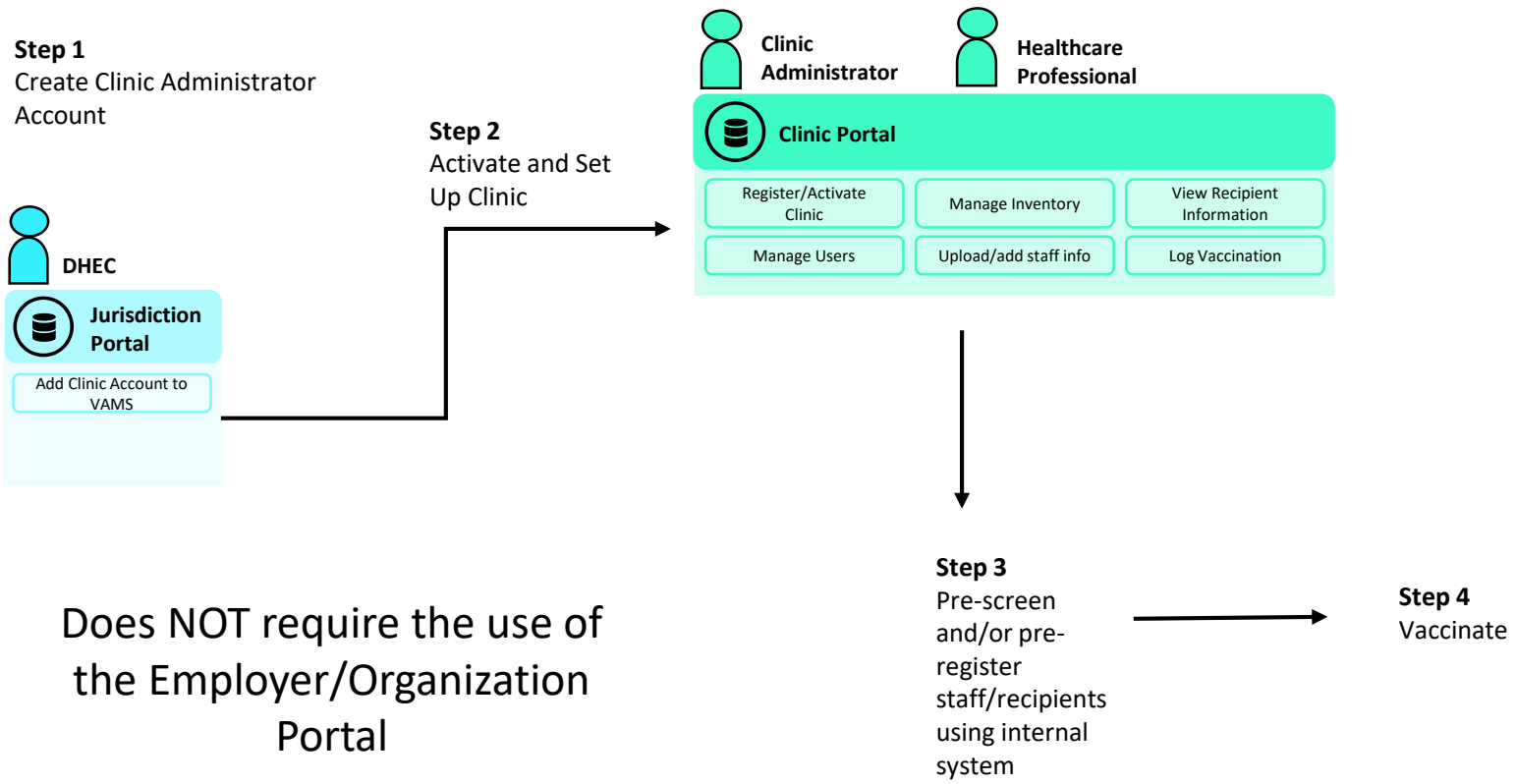
Clinic Type	Description	Considerations
Third-party	Clinics in settings for administering vaccine to recipients unable to access VAMS (i.e. nursing homes, correctional facility) OR for locations that desire to use a pre-existing notification, scheduling, and pre-screening system for vaccine recipients	• Vaccine recipients do not use VAMS to pre-register or schedule appointments • Does NOT require the use of the Employer/Organization Portal • Clinic location is not searchable by VAMS users • Requires manual inventory tracking for 2nd dose needs • Facilities must coordinate and communicate recipient vaccination events internally or through existing means • Requires collection of demographic and screening information from recipients prior to vaccination OR at the time of the vaccination • Requires manually adding each recipient, or bulk uploading a list of pre-screened recipients, prior to vaccination • Facility is responsible for distributing the EUA sheet, issuing 2nd dose reminders, and coordinating 2nd dose events

Third Party

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				✓

VAMS Workflow-THIRD PARTY



Does NOT require the use of the Employer/Organization Portal

VAMS Onboarding Decisions

- Determine the clinic location's point of contact (POC) who will serve as the clinic administrator (default is primary vaccine coordinator who can re-assign if needed)
- Determine desired location clinic type
  - Clinic
  - Mobile
  - Hospital
  - Pharmacy
  - Third-party

- Review user manuals and training videos on DHEC's COVID-19 Provider Webpage
  - Quick Start Guide for Clinic Set-up
  - Clinic administrator and employer coordinator role demo videos

South Carolina Department of Health and Environmental Control

Employer and Organization Portal

VAMS Overview

Applies to non-Third Party Clinics Only

STEP 3 Your Portal: Employer and Organization Portal

What is the Employer and Organization Portal?

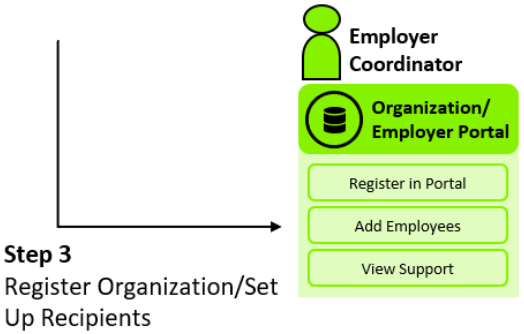
- An interface for employers/organizations to upload employee/staff information

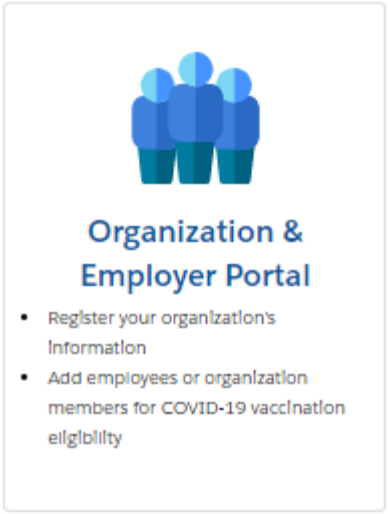
What are the Key Goals of the Employer and Organization Portal?

- Identify potential vaccine recipients to register for COVID-19 vaccination through the Recipient Portal

The Employer and Organization Portal is not:

- An interface clinics will access (they will have their own portal)
- An interface recipients will access (they will have their own portal)
- An interface jurisdictions or CDC will access (they will have their own portal)
- A downloadable app (i.e., from the App Store)





Employer/Organization Portal
User Responsibilities Overview

Employer Coordinator (EC)

Primary Role: Register employer and initiate registration for employees

What does the **Employer Coordinator** need to learn in VAMS?

Processes	Related Tasks
• **Complete employer registration**	. Have all employer contact information ready to input . Review and submit employer registration
• ***Upload employees into VAMS***	. *Add employees individually or in a bulk upload* . *View employee roster*
• **Find VAMS support or additional training resources when needed**	. Search for your question in the FAQs on the Help page

How will they learn?

Training Tools

- VAMS Model Training Plan
- Employer Coordinator User Manual
- Demo Presentation Videos
- VAMS FAQs

Employee Registration

Personalized Employee Registration Option 1	
The EC adds employees via manual addition, either one at a time or bulk upload, generating an auto email notification to identified employee/staff	
Pros	• No email address restrictions • Cannot be forwarded to others
Cons	• Cannot control messaging of generated email to staff

Employee Registration

Policy-Enabled Registration (PER) Option 2	
The EC opts to have a common registration link using up to three (3) linked email address domains (i.e. @dhec.sc.gov) 1. EC crafts email messaging and sends organization-specific registration link to targeted employees, or EC can post the link for all employees to access via intranet or other source 2. Employees access the link and enter their organization name and email 3. VAMS will validate the email entered by the employee matches one of the specific organization domains 4. VAMS will send a unique registration link to the employee email 5. Employees click the registration link and start the standard registration flow	
Pros	• Potentially reduces administrative burden on EC • EC can control messaging to employees about registration
Cons	• Third-party email domains cannot be used for PER (gmail.com; yahoo.com) • Employees cannot change their email during registration • Once PER is selected, DHEC cannot edit the organization's record in VAMS • Targeted employees can forward link to other non-targeted employees in the organization with the same email domain

VAMS Onboarding Decisions

DHEC will need to know:

- The organization's point of contact (POC) information who will serve as the EC
  - First name, last name, and email address
- Organization category
  - Inpatient healthcare providers
  - Outpatient healthcare providers
- Employee registration process option
  - Option 1: Personalized registration link
  - Option 2: Policy-Enabled Registration

Complete this VAMS onboarding survey within 48 hours of activation notice using your location ID

South Carolina Department of Health and Environmental Control

Vaccine Management Requirements

Temperature Monitoring

- 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.
  - Ultra-cold vaccine storage (Celsius)
  - Ultra-cold vaccine storage (Fahrenheit)
  - Refrigerator or Freezer vaccine storage
- COVID-19 Vaccine Primary and Back-up Coordinators must download continuous temperature monitoring device reports weekly
- Temperature logs are also required for any vaccine redistribution transport
- Submit both temp logs and DDL reports to COVIDProviderEnrollment@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
- Pfizer Shipments:
  - Pfizer: 1-877-829-2619 or cvgovernment@Pfizer.com
- Moderna 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
- Upon resolution, providers must submit a Vaccine Troubleshooting Record to COVIDProviderEnrollment@dhec.sc.gov that documents the event and any associated case number

Inventory Reporting

- Adjust (Add/Reduce) all vaccine inventory and waste in VAMS
  - Upon delivery receipt
  - Track extra Pfizer doses (estimated 1 or 2 extra vial) or Moderna doses (estimated potential for 1 extra per vial) pulled from MDVs
  - Add “vials” in VAMS to accommodate the overages
    - Every 5 Pfizer doses= 1 vial
    - Every 10 Moderna doses= 1 vial
- Report daily on-hand inventory doses to the COVID Health VaccineFinder portal (Mon-Sun)

VAMS Inventory requests

- When placing your weekly inventory requests in VAMS:
  - Select your facility's vaccine type
  - Add quantity desired
  - In the notes section:
    - Add number of your phase 1a staff to be vaccinated (initial doses)
    - Include any 2nd doses needed for that week
    - Include specific names of external partners that your facility has agreed to vaccinate
    - Add estimated number of phase 1a community members your site intends to vaccinate, or has the potential to vaccinate, within that week
    - Please refer to your submitted VAMS inventory request for confirmation and details (ensure to click FOLLOW to receive email notifications for updates)

Vaccine Ordering Cadence

Ordering Cadence for Direct ship to site: Pfizer and Moderna			
Requests submitted in VAMS	**Sites Receive Vaccine**	**Sites Receive Federal Ancillary Supply Kits**	**Sites Receive State-Supplied Ancillary Kits**
By Tuesday, 12pm	Monday	Within 24-hour window of vaccine	Tuesday

Ordering Cadence for DHEC Redistribution Sites		
New Bulk Requests submitted in VAMS	**Sites Receive Vaccine**	**Sites Receive Ancillary Kits**
By Tuesday, 12pm	Based on frequency request (see sub-order request below)	At the time of DHEC delivery

DHEC-Redistribution Orders in Process- Delivery Cadence		
Sub-order request submission to RSS@dhec.sc.gov and parksln@dhec.sc.gov by 5pm	**Prepared at DHEC**	**Delivery to Facility**
Monday	Tuesday	Wednesday
Tuesday	Wednesday	Thursday
Wednesday	Thursday	Friday
Thursday	Friday	Monday
Friday	Monday	Tuesday

South Carolina Department of Health and Environmental Control

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 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.

South Carolina Department of Health and Environmental Control

Clinical Staff Training

Interim Clinical Considerations for use of mRNA COVID-19 Vaccines Currently Authorized in the United States

Authorized age groups

- Under the EUAs, the following age groups are authorized to receive vaccination:
  - Pfizer-BioNTech: ages ≥16 years
  - Moderna: ages ≥18 years
  - Children and adolescents outside of these authorized age groups should not receive COVID-19 vaccination at this time

Administration

- mRNA vaccines are not live vaccines
- The mRNA COVID-19 vaccine series consist of two doses administered intramuscularly:
  - Pfizer-BioNTech (30 µg, 0.3 ml each): three weeks (21 days) apart
  - Moderna (100 µg, 0.5 ml): one month (28 days) apart
- Second doses administered within a grace period of ≤4 days from the recommended date for the second dose are considered valid; however, doses administered earlier do not need to be repeated.
- The second dose should be administered as close to the recommended interval as possible. However, there is no maximum interval between the first and second dose for either vaccine.

Interchangeability with other COVID-19 products

- Either of the currently authorized mRNA COVID-19 vaccines can be used when indicated; ACIP does not state a product preference.
- However, these mRNA COVID-19 vaccines are **not** interchangeable with each other or with other COVID-19 vaccine products. 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.

Coadministration with other vaccines

- Given the lack of data on the safety and efficacy of mRNA COVID-19 vaccines administered simultaneously with other vaccines, the vaccine series should be administered alone, with a minimum interval of 14 days before or after administration with any other vaccines.
- If mRNA COVID-19 vaccines are inadvertently administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine.

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

- Persons with current or prior hx of SARS CoV-2-infection
  - Vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection.
  - Vaccination of persons with known current SARS-CoV-2 infection should be deferred until the person has recovered from the acute illness (if the person had symptoms) and criteria have been met for them to discontinue isolation.
  - While there is otherwise no recommended minimum interval between infection and vaccination, current evidence suggests that reinfection is uncommon in the 90 days after initial infection. Thus, persons with documented acute SARS-CoV-2 infection in the preceding 90 days may delay vaccination until near the end of this period, if desired

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

- Persons who previously received passive antibody therapy for COVID-19
  - Currently, there are no data on the safety and efficacy of mRNA COVID-19 vaccines in persons who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment.
  - Based on the estimated half-life of such therapies as well as evidence suggesting that reinfection is uncommon in the 90 days after initial infection, vaccination should be deferred for at least 90 days, as a precautionary measure until additional information becomes available, to avoid interference of the antibody treatment with vaccine-induced immune responses.

Vaccination of persons with underlying medical conditions

- Immunocompromised persons
  - Persons with HIV infection or other immunocompromising conditions, or who take immunosuppressive medications or therapies might be at increased risk for severe COVID-19. Data are not currently available to establish vaccine safety and efficacy in these groups.
  - Persons with stable HIV infection were included in mRNA COVID-19 vaccine clinical trials, though data remain limited.
  - Immunocompromised individuals may still receive COVID-19 vaccination if they have no contraindications to vaccination. However, they should be counseled about the unknown vaccine safety profile and effectiveness in immunocompromised populations, as well as the potential for reduced immune responses and the need to continue to follow all current guidance to protect themselves against COVID-19 (i.e. mask, social distancing, hand hygiene)

Vaccination of persons with underlying medical conditions

- Persons with autoimmune conditions
  - No data are currently available on the safety and efficacy of mRNA COVID-19 vaccines in persons with autoimmune conditions, though these persons were eligible for enrollment in clinical trials.
  - No imbalances were observed in the occurrence of symptoms consistent with autoimmune conditions or inflammatory disorders in clinical trial participants who received an mRNA COVID-19 vaccine compared to placebo.
  - Persons with autoimmune conditions who have no contraindications to vaccination may receive an mRNA COVID-19 vaccine

Vaccination of persons with underlying medical conditions

- Persons with a history of Guillain-Barré syndrome (GBS)
  - To date, no cases of GBS have been reported following vaccination among participants in the Pfizer-BioNTech or Moderna COVID-19 vaccines clinical trials.
  - With few exceptions, Advisory Committee on Immunization Practices (ACIP) general best practice guidelines for immunization does not include history of GBS as a contraindication or precaution to vaccination.
  - Persons with a history of GBS may receive an mRNA COVID-19 vaccine unless they have a contraindication to vaccination.
  - Any occurrence of GBS following mRNA COVID-19 vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS).

Vaccination of persons with underlying medical conditions

- Persons with a history of Bell's palsy
  - Cases of Bell's palsy were reported following vaccination in participants in both the Pfizer-BioNTech and Moderna COVID-19 vaccines clinical trials.
  - However, the FDA does not consider these to be above the frequency expected in the general population and has not concluded that these cases were causally related to vaccination.
  - Post-authorization safety surveillance will be important to further assess any possible causal association.
  - In the absence of such evidence, persons with a history of Bell's palsy may receive an mRNA COVID-19 vaccine unless they have a contraindication to vaccination.
  - Any occurrence of Bell's palsy following mRNA COVID-19 vaccination should be reported to VAERS

Vaccination of pregnant women

- There are currently few data on the safety of COVID-19 vaccines, including mRNA vaccines, in pregnant people.
- The mRNA in the vaccine is degraded quickly by normal cellular processes and does not enter the nucleus of the cell. Based on current knowledge, experts believe that mRNA 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 (e.g., healthcare personnel), 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.

Vaccination of lactating women

- There are no data on the safety of COVID-19 vaccines in lactating people or the effects of mRNA COVID-19 vaccines on the breastfed infant or milk production/excretion.
- mRNA vaccines are not thought to be a risk to the breastfeeding infant.
- A lactating person who is part of a group recommended to receive a COVID-19 vaccine (e.g., healthcare personnel) may choose to be vaccinated

Patient Counseling: Vaccine Efficacy

- Preliminary data suggest high vaccine efficacy in preventing COVID-19 following receipt of two doses of mRNA COVID-19 vaccine (Pfizer-BioNTech: 95.0% [95% CI: 90.3%, 97.6%]; Moderna: 94.1% [95% CI: 89.3%, 96.8%]).
- Limited data are currently available regarding the efficacy of a single dose.
- Patients should be counseled on the importance of completing the two-dose series (of the same vaccine product) to optimize protection

Patient Counseling: Reactogenicity

- Before vaccination, providers should counsel mRNA COVID-19 vaccine recipients about expected local (e.g., pain, swelling, erythema at the injection site, localized axillary lymphadenopathy on the same side as the vaccinated arm) and systemic (e.g., fever, fatigue, headache, chills, myalgia, arthralgia) post-vaccination symptoms.
- Most systemic post-vaccination symptoms are mild to moderate in severity, occur within the first three days of vaccination, and resolve within 1–3 days of onset.
  - These symptoms are more frequent and severe following the second dose and among younger persons compared to older persons
- Antipyretic or analgesic medications (e.g., acetaminophen, non-steroidal anti-inflammatory drugs) may be taken for the treatment of post-vaccination local or systemic symptoms, if medically appropriate.
  - However, routine prophylactic administration of these medications for the purpose of preventing post-vaccination symptoms is not currently recommended, as information on the impact of such use on mRNA COVID-19 vaccine-induced antibody responses is not available at this time

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

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)

Moderna COVID-19 Vaccine

Click here to visit the Resource Page:

- Vaccine administration overview
  - 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°)

Clinical Guidance Resource

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.

CONTACT US

COVID-19 Vaccination Program

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