Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Vision: To be the **Healthiest State** in the Nation

Ron DeSantis
Governor

Scott A. Rivkees, MD
State Surgeon General

Important Updates Regarding COVID-19 Vaccine Administrations and Access to Monoclonal Antibodies for the Treatment of COVID-19

December 30, 2020

Vaccines

Who can get the COVID-19 vaccine?

In accordance with Executive Order 20-315 issued on December 23, 2020, providers shall only administer COVID-19 vaccine to the following populations: long-term care facility residents and staff, persons 65 years of age and older, and health care personnel with direct patient contact. Hospital providers, however, also may vaccinate persons who they deem to be extremely vulnerable to COVID-19. As additional information becomes available, it will be posted on the Florida Department of Health's COVID-19 website: https://floridahealthcovid19.gov/COVID-19-Vaccines-in-Florida/.

Where can an individual included in Executive Order 20-315 receive a COVID-19 vaccine?

Please see the table below which contains designated general vaccine providers.

Eligible Populations Able to Receive Vaccine Under Executive Order 20-315	Primary Vaccine Providers	Additional Vaccine Providers
Long-term care facility residents and staff	CVS and Walgreens	Florida Department of Health and Florida Department of Emergency Management
Persons 65 years of age and older	County health departments	Hospitals and other community health care providers, including a federally qualified health center (FQHC)
Health care personnel with direct patient contact	Hospitals and COVID-19 vaccine providers	County health departments and other community providers, including a FQHC
Persons deemed extremely vulnerable to COVID-19 by hospital providers	Hospital providers	

How can I become a COVID-19 vaccine provider?

To become a COVID-19 vaccine provider, your practice or organization must be enrolled in the Florida State Health Online Tracking System (SHOTS) and the Vaccines for Children/Adults Program (VFC/VFA). To enroll in the Florida SHOTS program, visit FLShotsUsers.com. Fill out the application. Check the "COVID-19 Enrollment" check box to indicate your interest in the COVID-19 vaccination effort. Complete the registration process as directed.

Once you are enrolled in Florida SHOTS, log in to the application and access the COVID-19 Enrollment page. Complete the Section A agreement, including the necessary signatures, and email the signed document to CovidVaccineProgram@flhealth.gov. Then:

- If you are not enrolled in VFC/VFA you will be contacted by an enrollment specialist to complete that process.

Florida Department of Health
Office of the State Surgeon General
4052 Bald Cypress Way, Bin A-00 • Tallahassee, FL 32399-1701
FloridaHealth.gov

Accredited Health Department
Public Health Accreditation Board

- If you are already enrolled in VFC/VFA, you must then complete and submit the necessary Section B agreements **for each site that you want to enroll as a COVID-19 vaccine provider**. The Section B form is found in Florida SHOTS on the COVID-19 enrollment page.

Once you are enrolled in Florida SHOTS and VFC/VFA and have submitted the Section A and B COVID-19 agreements, the process is complete. The COVID-19 vaccine enrollment desk will contact your organization to provide further information on how to order and receive vaccines as available.

For questions or additional information, please contact the COVID-19 Vaccine Enrollment Desk at 833-701-1397, or email CovidVaccineProgram@flhealth.gov.

Click here to view the flyer with enrollment instructions: http://www.floridahealth.gov/programs-and-services/immunization/COVID-19VaccineInfo/_documents/covid-vaccine-flow-chart-info.pdf

To view the Florida Department of Health Immunization Section COVID-19 vaccine webpage, visit: http://www.floridahealth.gov/programs-and-services/immunization/COVID-19VaccineInfo/index.html

Reporting of COVID-19 Testing and Vaccine Administration

Complete and timely reporting of COVID-19 testing results and vaccine administration data is important in the state's efforts to control the spread of COVID-19. Effective on November 12, 2020, Emergency Rule 64DER20-34 (64D-3.029), Florida Administrative Code (F.A.C.), requires the immediate reporting of test results and provides the acceptable methods for reporting to the Florida Department of Health. Emergency Rule 64DER20-43, F.A.C., became effective on December 14, 2020, and requires all health care practitioners and other enrolled COVID-19 vaccine providers to report vaccination data to the Florida Department of Health.

The Centers for Disease Control and Prevention (CDC) has shipped COVID-19 vaccine directly to the State of Florida and to other organizations, facilities, and healthcare providers (vaccine providers or providers) that are enrolled in the CDC COVID-19 Vaccine Program. Vaccine providers in Florida that did not receive a direct shipment from the CDC may request approval from the Florida Department of Health to obtain vaccine by redistribution (transfer) from the Florida Department of Health or from another vaccine provider, but only if both the transferring and receiving vaccine providers meet the conditions in Emergency Rule 64DER20-44, F.A.C.

Emergency Rule 64DER20-34 (64D-3.029), F.A.C., requires immediate reporting of all COVID-19 test results (positive, negative, and inconclusive) by health care practitioners, laboratories, and hospital facilities. All point-of-care tests results (positive and negative) must be reported within 24 hours of test administration. In addition to the data fields required by Rules 64D-3.030 and 3.031, F.A.C., all test result reports must include the CLIA number of the reporting practitioner, laboratory, or facility. Registration for electronic reporting is mandatory. All test results must be submitted electronically by electronic laboratory reporting (ELR), the Florida Department of Health's web portal at www.FloridaHealth.gov/ElectronicReportingRegistration, or through the National Healthcare Safety Network (NHSN) COVID-19 module. Enrollment for ELR or the web portal is available at www.FloridaHealth.gov/ElectronicReportingRegistration.

All health care practitioners and other enrolled COVID-19 vaccine providers must report the data elements in Emergency Rule 64DER20-43, F.A.C., to Florida SHOTS within 24 hours of any administration of any COVID-19 vaccine. Reports must be provided for any and all doses of a COVID-19 vaccine the provider administers.

How can I transfer a vaccine to another facility?

There may be times when you want to transfer COVID-19 vaccines from your inventory to another site within your organization or to another VFC provider outside of your organization. The transfer of any COVID-19 vaccine is prohibited until the Florida Department of Health approves the transfer. Emergency Rule 64DER20-44, F.A.C., requires all documents and transfer requests to be submitted to FloridaVFC@flhealth.gov not less than 24 hours before the expected transfer. All COVID-19 vaccine providers must be enrolled in Florida SHOTS, the VFC/VFA Program, the CDC COVID-19 Vaccine Program, and have completed sections A and B of the "CDC COVID-19 Vaccination Program Provider Agreement" (09/14/2020) In accordance with the emergency rule, providers must access this document through the provider's Florida SHOTS account at http://www.flshotsusers.com/.

The transferring vaccine provider must submit to the Florida Department of Health the "CDC Supplemental COVID-19 Vaccine Redistribution Agreement" (09/29/20) for any distribution outside of the provider's organization. For all transfers, both the transferring and the receiving vaccine provider will submit to FloridaVFC@flhealth.gov a completed Florida SHOTS Vaccine Transfer form (09/15) (available through the provider's Florida SHOTS account at http://www.flshotsusers.com/).

This short guide will give you the step-by-step instructions on how to transfer your site's inventory: http://flshotsusers.com/sites/default/files/FLSHOTSVaccineInventoryManual_V1.2.pdf

COVID-19 Vaccine Resources

- **FDOH COVID-19 Vaccines in Florida Webpage**
  - For updates about the vaccine and distribution from Governor Ron DeSantis
  - Webpage available in English, Spanish, and Haitian Creole.
- FDOH Daily COVID-19 Vaccine Report Available at **FloridaHealthCOVID19.gov**
- **FDOH COVID-19 Vaccine Infographics**
  - Infographics are available in Spanish and Haitian Creole.
- **CDC COVID-19 Vaccination Communication Toolkit**
- **CDC COVID-19 Vaccines Webpage**
- **FDA COVID-19 Vaccines Webpage**
- **FDA Pfizer-BioNTech COVID-19 Vaccine**
  - Fact sheets available in multiple languages.
- **FDA Moderna COVID-19 Vaccine**
  - Fact sheets available in multiple languages.

Monoclonal Antibodies

The U.S. Food and Drug Administration (FDA) has authorized two monoclonal antibody treatments for COVID-19. On November 9, 2020, the FDA issued an Emergency Use Authorization (EUA) to permit the emergency use of Eli Lily's bamlanivimab for the treatment of mild to moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing and who are at high risk for progressing to severe COVID-19 and/or hospitalization. On November 21, 2020, the FDA issued an EUA to permit the emergency use of casirivimab and imdevimab from Regeneron.

Monoclonal antibodies are optimally administered within the first three days of becoming symptomatic or testing positive of COVID-19 by intravenous infusion for 60 minutes followed by a period of observation. These products are only for non-hospitalized patients who are diagnosed with COVID-19, not on oxygen, and who are at high risk for disease progression and/or hospitalization. A complete list of criteria for high risk patients can be found on the Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) of Casirivimab and Imdevimab.

For more information regarding the FDA's EUAs for both monoclonal antibodies, please use the links below:

- EUA for bamlanivimab
- EUA for casirivimab/imdevimab

How do facilities/hospitals access monoclonal antibodies?

To receive allocation of monoclonal antibodies, the COVID-19 - Hospital Monoclonal Antibody Therapeutics for COVID-19 survey must be submitted online before close of business Tuesday of each week. Current inventories must be reported with each request. For questions, concerns, or special accommodations, please email covid.therapeutics@flhealth.gov.

How do community health care providers access monoclonal antibodies?

Health care providers in the community should contact their local hospital partners or county health department to coordinate the administration of monoclonal antibodies for their patients. Please use the link here for a list of county health departments.