

**Department of Health, Emergency Rule 64DER21-4**

**COVID-19 Vaccine Reporting Requirements**

**STATEMENT OF FACTS AND REASONS FOR FINDING IMMEDIATE DANGER**

Novel Coronavirus Disease 2019 (COVID-19) is a severe acute respiratory illness that can spread among humans through respiratory transmission and presents with symptoms similar to those of influenza. COVID-19 is a communicable disease with significant morbidity and mortality and presents a severe danger to public health. Access to immunization and vaccine administration data is critical to the whole of government response to the COVID-19 public health emergency. In furtherance of state and federal government response efforts, the Florida Department of Health, the U.S. Department of Health and Human Services (HHS), and the Centers for Disease Control and Prevention (CDC) seek to obtain and utilize data from COVID-19 vaccine data sources, including the Florida Department of Health's immunization information system (IIS), in order to rapidly assess patterns of vaccination among the population; identify pockets of undervaccination; assist in determining vaccine resource allocation to address the needs of jurisdictions; monitor vaccine effectiveness and safety; assess spectrum of illness, disease burden, risk factors for severe disease and outcomes; and help to understand the impact of COVID-19 on the healthcare system and communities. Reporting the administration of COVID-19 vaccines to individuals in Florida is paramount to controlling this communicable disease and for reporting to the Centers for Disease Control and Prevention. Therefore, there is an immediate need to adopt rules setting forth the procedures for the continued reporting of vaccine administration in order to control the spread of COVID-19 to protect the health, safety and welfare of Florida's citizens.

**STATEMENT OF AGENCY REASONS THAT PROCEDURE IS FAIR UNDER THE CIRCUMSTANCES**

COVID-19 presents a public health threat to the state of Florida. The Surgeon General has declared a statewide Public Health Emergency due to the spread of COVID-19. There is an immediate need to set forth procedures for the continued reporting of vaccine administration in the effort to control this communicable disease in the State of Florida.

## **64DER21-4 COVID-19 Vaccine Reporting Requirements**

All health care practitioners licensed under Chapters 458, 459 or 464, F.S., and all other enrolled COVID-19 vaccine providers, must report the following vaccination data elements in Florida SHOTS within 24 hours of administration to an individual of any dose of a COVID-19 vaccine that has Emergency Use Authorization from the Food and Drug Administration.

- (1) Administered at location: facility name/ID
- (2) Administered at location: type
- (3) Administration address (including county)
- (4) Administration date
- (5) CVX (Product)
- (6) Dose number
- (7) IIS recipient ID
- (8) Recipient race
- (9) Recipient ethnicity
- (10) IIS vaccination event ID
- (11) Lot number: unit of use and/or unit of sale
- (12) MVX (manufacturer)
- (13) Recipient address
- (14) Recipient date of birth
- (15) Recipient name
- (16) Recipient sex
- (17) Sending organization
- (18) Vaccine administering provider suffix
- (19) Vaccine administering site (on the body)
- (20) Vaccine expiration date
- (21) Vaccine route of administration
- (22) Vaccination series complete

Rulemaking Authority 381.003(2), 381.0031(8), 381.005(3) FS. Law Implemented 381.0011(3), (4), 381.003(1), 381.0031,

381.005(1) FS. History—New \_\_\_\_\_.