



FLORIDA DEPARTMENT *of* STATE

RON DESANTIS
Governor

LAUREL M. LEE
Secretary of State

December 14, 2020

Amanda Bush
Office of the General Counsel
Florida Department of Health
4052 Bald Cypress Way, Bin A-02
Tallahassee, FL 32399-1703

Attention: Deann Peltz

Dear Ms. Bush:

Your adoption package for Emergency Rule 64DER20-43, F.A.C. was received, electronically, by the Florida Department of State, Administrative Code and Register at 9:29 a.m. on December 14, 2020. After review, it appears that the package meets statutory requirements and those of Rule 1-1.010, F.A.C. and is deemed filed for adoption at the time received, as indicated above. The effective date is December 14, 2020.

Sincerely,

Ernest L. Reddick
Program Administrator

ELR/ag

Grosenbaugh, Anya C.

From: Peltz, Deann <Deann.Peltz@flhealth.gov>
Sent: Monday, December 14, 2020 9:29 AM
To: Reddick, Ernest L.; Grosenbaugh, Anya C.; Administrative Code
Cc: Bush, Amanda; Young, Wanda
Subject: 64DER20-43 > Emergency Rule Adoption
Attachments: 64DER20-43 Coded Rule_v2, w'o auto #s.docx; 64DER20-43 Ltr to DOS (emerg rule) =PANDEMIC.PDF

Importance: High

EMAIL RECEIVED FROM EXTERNAL SOURCE

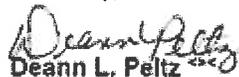
The attachments/links in this message have been scanned by Proofpoint.

Ernie and Anya:

Attached is the adoption package for the above-referenced **emergency** rule(s) which has been fully-executed by the State Surgeon General. Pursuant to Emergency Rule 1ER20-3 which became effective on 4/17/20, this package is hereby being submitted electronically for adoption today and the documents bearing original signatures will be mailed thereafter. Also attached is an MS Word version of the proposed emergency rule adoption text.

Thank you for your attention to this matter, and we look forward to receipt of your approval of this adoption package.

Sincerely,



Deann L. Peltz
Senior Legal Assistant
Office of the General Counsel
Florida Department of Health
4052 Bald Cypress Way, Bin A-02
Tallahassee, FL 32399-1703
850-617-1422 | 850-245-4790 Fax
Deann.Peltz@flhealth.gov
www.floridahealth.gov



Values: (ICARE)

Innovation: We search for creative solutions and manage resources wisely.
Collaboration: We use teamwork to achieve common goals & solve problems.
Accountability: We perform with integrity & respect.
Responsiveness: We achieve our mission by serving our customers & engaging our partners.
Excellence: We promote quality outcomes through learning & continuous performance improvement.

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

PLEASE NOTE: Florida has a very broad public records law. Most written communications to or from state officials regarding state business are public available to the public and media upon request. Your email may, therefore, be subject to public disclosure.

 Please consider the environment before printing this email. 

Mission:

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



Ron DeSantis
Governor

Scott A. Rivkees, MD
State Surgeon General

Vision: To be the Healthiest State in the Nation

December 11, 2020

VIA U.S. MAIL & EMAIL: Ernest.Reddick@DOS.MyFlorida.com; anya.grosenbaugh@DOS.MyFlorida.com

Mr. Ernest L. Reddick, Program Administrator
BUREAU OF ADMINISTRATIVE CODE
Florida Department of State – The Capitol
500 S. Bronough Street, Room 701
Tallahassee, FL 32399

**Re: Dept. of Health: Division of Disease Control
64DER20-43, F.A.C. – (Emergency) Rule Adoption Package**

Dear Mr. Reddick:

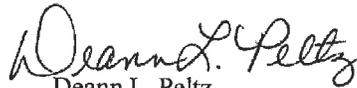
Enclosed are the **original and one (1) copy** of the rule adoption package in anticipation of adoption of the above-referenced EMERGENCY rule(s). Each package includes the following documents:

1. Certification of the Department of Health Emergency Rule Filed with the Department of State;
2. Designation of Rule the Violation of Which is a Minor Violation Certification;
3. Statement of Facts, etc.;
4. Proposed rule text (double-spaced).

The proposed rule text was provided in Microsoft Word format via email. Should you have any questions regarding the enclosures, Amanda Bush is the attorney handling this rule promulgation and can be contacted directly at 245-4027, Amanda.Bush@flhealth.gov, or the mailing address below; also, my direct line is 617-1422.

If you deem this rule adoption package to be in order, please send your approval email to the handling attorney and me at Deann.Peltz@flhealth.gov. Thank you for your attention to this matter.

Sincerely,


Deann L. Peltz
Senior Legal Assistant

/dlp
Enclosures

cc: Amanda G. Bush, Chief Legal Counsel (w/o encs.)

CERTIFICATION OF THE DEPARTMENT OF HEALTH

EMERGENCY RULE FILED WITH THE DEPARTMENT OF STATE

I hereby certify that an immediate danger to the public health, safety or welfare requires emergency action and that the attached rule is necessitated by the immediate danger. I further certify that the procedures used in the promulgation of this emergency rule were fair under the circumstances and that the rule otherwise complies with Section 120.54(4), F.S. The adoption of this rule was authorized by the head of the agency and this rule is hereby adopted upon its filing with the Department of State.

Rule No. 64DER20-43

Under the provision of Section 120.54(4)(d), F.S., this rule takes effect upon filing unless a later time and date less than 20 days from filing, is set out below:

Effective Date: _____
(month) (day) (year)



Scott A. Rivkees, MD

State Surgeon General, Department of Health
Title

2
Number of Pages Certified

DESIGNATION OF RULE THE VIOLATION OF WHICH IS A MINOR VIOLATION

CERTIFICATION

Pursuant to Section 120.695(2)(c)3, Florida Statutes, I certify as agency head, as defined by section 20.05(1)(b), Florida Statutes, that:

All rules covered by this certification are not rules the violation of which would be a minor violation pursuant to Section 120.695, F.S.

The following parts of the rules covered by this certification have been designated as rules the violation of which would be a minor violation pursuant to Section 120.695, F.S.:

Rule No(s).

Rules covered by this certification:

Rule No.: 64DER20-43



Scott A. Rivkees, MD

State Surgeon General, Department of Health
Title

Department of Health, Emergency Rule 64DER20-43

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 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 reporting of vaccine administration in the effort to control this communicable disease in the State of Florida.

64DER20-43 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 12-14-2020