

Mission:

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



Ron DeSantis
Governor

Scott A. Rivkees, M.D.
State Surgeon General

Vision: To be the Healthiest State in the Nation

**STATE OF FLORIDA
DEPARTMENT OF HEALTH**

In Re:

SUSPENSION OF STATUTES,
RULES AND ORDERS MADE
NECESSARY BY COVID-19.

DOH No. 20-013

2020 SEP 11 PM 4:55

EMERGENCY ORDER

WHEREAS, 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; and

WHEREAS, on March 1, 2020, I declared a Public Health Emergency exists in the State of Florida as a result of COVID-19 pursuant to Executive Order number 20-51; and

WHEREAS, on March 9, 2020, Governor Ron DeSantis issued Executive Order 20-52 declaring a state of emergency for the entire State of Florida as a result of COVID-19, and allowing for the waiver of certain statutes and rules that prevent, hinder, or delay any necessary action in coping with the state of emergency caused by COVID-19; and

WHEREAS, the Florida Department of Health continues to monitor evidence of COVID-19 in Florida, the state's response efforts, and conduct epidemiological investigations on individuals that have been reported to the Florida Department of Health as positive for COVID-19; and

WHEREAS, in order for the Florida Department of Health to successfully conduct epidemiological investigations, contact tracing, and instruct those known to have COVID-19 or to be exposed to COVID-19 to quarantine or isolate, it is necessary for laboratories conducting COVID-19 testing to report the results of all COVID-19 tests immediately to the Florida Department of Health pursuant to rules 64D-3.029 and 64D-3.031, Florida Administrative Code; and

WHEREAS, the Centers for Medicare & Medicaid Services regulates Clinical Laboratory Improvement Amendments (CLIA) certified laboratories and CLIA certificates of waiver pursuant to 42 C.F.R. § 493, and the Agency for Health Care Administration is responsible for obtaining applications for and routing complaints against CLIA-certified laboratories; and

WHEREAS, the Florida Department of Health regulates clinical laboratory personnel for laboratories operating within the State of Florida pursuant to part II of chapter 483, Florida Statutes; and

WHEREAS, the U.S. Department of Health and Human Services issued instructions pursuant to the Coronavirus Aid, Relief, and Economic Security (CARES) Act on June 4, 2020, requiring all laboratories to report data for all COVID-19 testing completed by Health Level 7 (HL7) Lab Results Interface, for each individual tested, within 24 hours of results being known or determined, on a daily basis to the Florida Department of Health for all individuals residing in Florida; and

WHEREAS, on August 25, 2020, the Centers for Medicare & Medicaid Services issued an Interim Final Rule implementing the CARES Act requirement for daily laboratory reporting of COVID-19 test results to the Secretary of Health and Human

Services, with a penalty of \$1,000 for the first day of noncompliance and an additional \$500 penalty for each subsequent day of noncompliance; and

WHEREAS, some CLIA-certified laboratories are failing to immediately report COVID-19 test results pursuant to the laws of Florida and requirements of the CARES Act, contributing to the inability of the Florida Department of Health to conduct meaningful epidemiological investigations to slow the spread of COVID-19 in Florida and drastically reducing the accuracy and meaningfulness of COVID-19 data reported daily based on the number of test results received by the Florida Department of Health; and

WHEREAS, it is necessary to waive certain statutes and rules of the Florida Department of Health in order to effectively respond to the emergency caused by COVID-19.

NOW, THEREFORE, I, SCOTT A. RIVKEES, M.D., pursuant to the authority granted by Executive Order No. 20-52, as extended by Executive Order Nos. 20-114 and 20-166, find that strict compliance with the provisions of certain regulatory statutes and rules prescribing the procedures for conduct of state business by the Florida Department of Health will prevent, hinder, or delay necessary action in coping with the emergency caused by COVID-19. In order to effectively respond to the threat posed by COVID-19 it is necessary to promulgate the following:

Section 1:

A laboratory that has not reported results of COVID-19 testing performed by the laboratory within 7 days of the completion of the COVID-19 test may not electronically report the untimely test results through the Health Level Seven (HL7) Electronic Laboratory Reporting System (ELR) unless and until the Florida Department of Health authorizes such entry.

Section 2:

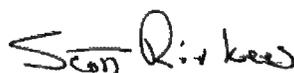
Upon discovering delinquency in COVID-19 electronic reporting described in Section 1, the laboratory must immediately comply with Florida Administrative Code Rule 64D-3.031(6) by reporting, without delay, all information required under Florida Administrative Code Rule 64D-3.031(3) for the untimely COVID-19 test results in a form specified by and acceptable to the Department of Health. The laboratory must send this data not only to the State Surgeon General but also to the county health department having jurisdiction over the area containing the office of the submitting practitioner or the patient's residence. Such notice must occur for each positive test result.

Section 3:

The limited exception to Florida Administrative Code Rule 64D-3.031(5) outlined in this order applies until the expiration of Executive Order No. 20-52, including any extensions thereof.

Because section 252.36(5)(a), Florida Statutes, allows the Governor to suspend the provisions of "any regulatory statute prescribing the procedures for [the] conduct of state business," and because Section 4. B. of Executive Order No. 20-52 provides the State Surgeon General with the authority to issue this Emergency Order, the requirements of sections 252.46 and 120.54(4), Florida Statutes, do not apply to this Order. This order shall remain in effect as specified above unless otherwise modified by order of the State Surgeon General.

Executed this 11th day of September 2020, in Department of Health offices,
Tallahassee, Leon County, Florida.



Scott A. Rivkees, M.D.
State Surgeon General