

RULE IMPACT STATEMENT

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH CHAPTER 515. COMMUNICABLE DISEASE AND INJURY REPORTING

1. DESCRIPTION:

The emergency rules OAC 310:515-1-1 and OAC 310:515-1-10 update the statutory basis for reporting communicable diseases and require that every practicing physician and clinical laboratory using an FDA-approved test for the novel coronavirus submit reports to the State Department of Health in the manner, format and frequency prescribed by the Commissioner of Health. The Rules also require that hospitals and physician clinics in Oklahoma submit to the State Department of Health in the manner, format and frequency prescribed by the Commissioner of Health, the number of patients in the hospital receiving treatment for novel coronavirus, and the number of patients receiving treatment for novel coronavirus who are currently admitted to the ICU. The emergency rule OAC 310:515-1-8 requires hospitals and laboratories to send, at a minimum, 10% of their weekly positive novel coronavirus specimens to the OSDH Public Health Laboratory for variant testing. The collection, packaging, and shipping of the positive novel coronavirus specimen must be in accordance with OSDH Public Health Laboratory guidelines.

2. DESCRIPTION OF PERSONS AFFECTED AND COST IMPACT RESPONSE:

The data collection required in this emergency rule will be critical to assess the likelihood of, and to prevent, a future public health emergency related to novel coronavirus that would affect all Oklahomans. The cost impact should be a net savings of taxpayer dollars, as data collection and prevention are key to future cost savings.

Reporting entities will also be affected. The burden of reporting will be lesser than reporting during the peak of the COVID-19 pandemic, but will be greater than it was prior to the COVID-19 pandemic. The cost impact for reporting entities will be less than it was during the peak of COVID-19 pandemic and more than it was prior to the COVID-19 pandemic.

3. DESCRIPTION OF PERSONS BENEFITING, VALUE OF BENEFIT AND EXPECTED HEALTH OUTCOMES:

All Oklahoma citizens will benefit from the proposed emergency rule as it is intended to help prevent a future novel coronavirus public health emergency.

4. ECONOMIC IMPACT, COST OF COMPLIANCE AND FEE CHANGES:

Cost of compliance will be considerably less than what is currently being asked of reporting entities. The agency anticipates minimal cost and time when having to report an aggregated count of COVID-19 patients and those in ICU. This will be done through a web form and should take a nominal amount of time.

Hospitals and laboratory facilities will experience a varying degree of upfront costs based on their systems and infrastructure, as they are currently required to report a number of other diseases. Once established, the new data feed should require little, if any, ongoing support or resources.

No fees or additional revenue are expected for the state.

5. COST AND BENEFITS OF IMPLEMENTATION AND ENFORCEMENT TO THE AGENCY:

The proposed rules will be implemented and enforced by existing OSDH personnel and will have little anticipated effect on state revenues.

The primary benefit to the agency is the ability to mitigate risk of a future public health emergency related to novel coronavirus.

6. IMPACT ON POLITICAL SUBDIVISIONS:

There will be no impact on political subdivisions, and it will not require their cooperation in implementing or enforcing the proposed amendment.

7. ADVERSE EFFECT ON SMALL BUSINESS:

There is no known adverse economic effect on small business as provided by the Oklahoma Small Business Regulatory Flexibility Act.

8. EFFORTS TO MINIMIZE COSTS OF THE RULE:

Great care has been taken to require only the data necessary to prevent future outbreaks, thereby eliminating excess reporting costs.

9. EFFECT ON PUBLIC HEALTH AND SAFETY:

This emergency rule will help reduce risk for future public health emergencies related to the novel coronavirus.

10. DETRIMENTAL EFFECTS ON PUBLIC HEALTH AND SAFETY WITHOUT ADOPTION:

Without the ability to collect critical data, public health and safety would be jeopardized due to an increased likelihood of returning to a state of emergency caused by the novel coronavirus pandemic.

11. PREPARATION AND MODIFICATION DATES:

This rule impact statement was prepared on July 12, 2021.

**TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 515. COMMUNICABLE DISEASE AND INJURY REPORTING**

RULEMAKING ACTION:

EMERGENCY adoption

RULES:

Subchapter 1. Disease and Injury Reporting

310:515-1-1 [AMENDED]

310:515-1-8 [AMENDED]

310:515-1-10 [NEW]

AUTHORITY:

Commissioner of the Oklahoma State Department of Health; 63 O.S. § 1-104

ADOPTION:

July 12, 2021

EFFECTIVE:

Immediately upon Governor's approval

EXPIRATION:

Effective through September 14, 2022, unless superseded by another rule or disapproved by the Legislature

SUPERSEDED EMERGENCY ACTIONS:

Superseded rules:

Subchapter 1. Disease and Injury Reporting

310:515-1-1 [AMENDED]

310:515-1-9 [NEW]

Gubernatorial approval:

May 4, 2021

Register publication:

38 Ok Reg 755

Docket number:

21-361

INCORPORATIONS BY REFERENCE:

n/a

FINDING OF EMERGENCY:

The emergency rules OAC 310:515-1-1, OAC 310:515-1-8 and OAC 310:515-1-10 are being implemented to provide necessary data to assess the likelihood of, and to prevent, a future public health emergency related to novel coronavirus. The data collection required in this emergency rule will be critical in avoiding a future public health emergency related to novel coronavirus.

GIST/ANALYSIS:

The emergency rules OAC 310:515-1-1 and OAC 310:515-1-10 update the statutory basis for reporting communicable diseases and require that every practicing physician and clinical laboratory using an FDA-approved test for the novel coronavirus submit reports to the State Department of Health in the manner, format and frequency prescribed by the Commissioner of Health. The Rules also require that hospitals and physician clinics in Oklahoma submit to the State Department of Health in the manner, format and frequency prescribed by the Commissioner of Health, the number of patients in the hospital receiving treatment for novel coronavirus, and the number of patients receiving treatment for novel coronavirus who are currently admitted to the ICU. The emergency rule OAC 310:515-1-8 requires hospitals and laboratories to send, at a minimum, 10% of their weekly positive novel coronavirus specimens to the OSDH Public Health Laboratory for variant testing. The collection, packaging, and shipping of the positive novel coronavirus specimen must be in accordance with OSDH Public Health Laboratory guidelines.

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PURSUANT TO THE ACTIONS DESCRIBED HEREIN, THE FOLLOWING EMERGENCY RULES ARE CONSIDERED PROMULGATED AND EFFECTIVE UPON APPROVAL BY THE GOVERNOR AS SET FORTH IN 75 O.S., SECTION 253(F):

SUBCHAPTER 1. DISEASE AND INJURY REPORTING

310:515-1-1. Purpose

The rules in this Chapter implement the Communicable Diseases Reporting Regulations, 63 O.S. ~~1981~~, §§1-104, 1-106, 1-502, and 1-503.

310:515-1-8. Organisms/specimens to be sent to the Public Health Laboratory

(a) Pure bacterial isolates of the following organisms shall be sent to the OSDH Public Health Laboratory for additional characterization, typing or confirmation within two (2) working days (Monday through Friday, state holidays excepted) of final identification or diagnosis.

- (1) Bacillus anthracis.
- (2) Brucella spp.
- (3) Carbapenem-resistant Enterobacteriaceae.
- (4) Carbapenem-resistant Pseudomonas aeruginosa.
- (5) Carbapenem-resistant Acinetobacter spp.
- (6) E. coli 0157, 0157:H7, or a Shiga toxin producing E. coli.
- (7) Francisella tularensis.
- (8) Haemophilus influenza (sterile site).
- (9) Listeria monocytogenes (sterile site).
- (10) Mycobacterium tuberculosis.
- (11) Neisseria meningitidis (sterile site).
- (12) Salmonella spp.
- (13) Vibrionaceae family (Vibrio spp. Grimontia spp., Photobacterium spp. And other genera in the family).
- (14) Yersinia spp.

(b) Following consultation with an OSDH epidemiologist, clinical specimens from suspected cases of Botulism must be sent to the OSDH Public Health Laboratory for testing.

(c) When Plasmodium spp. Is suspected by a healthcare provider, a Giemsa-stained (or other suitable stain) thin and thick, peripheral blood smear prepared from the EDTA should be submitted in addition to the EDTA purple top blood tube.

(d) Laboratories unable to perform reflex culture to isolate/recover the following bacterial pathogens detected by CIDT assays shall submit positive CIDT stool samples in Cary Blair or modified Cary Blair transport media to the OSDH Public Health Laboratory within two (2) working days (Monday through Friday, state holidays excepted) of final CIDT result.

- (1) E. coli 0157, 0157:H7, or a Shiga toxin-producing E.coli.
- (2) Salmonella spp.
- (3) Vibrio spp.
- (4) Yersinia spp.

(e) Hospitals and laboratories must send, at a minimum, 10% of their weekly positive novel coronavirus specimens to the OSDH Public Health Laboratory for variant testing. The collection, packaging, and shipping of the positive novel coronavirus specimen must be in accordance with OSDH Public Health Laboratory guidelines.

310:515-1-10. Emergency reporting requirements

(a) Every practicing physician and clinical laboratory that is utilizing, or has utilized, an FDA-approved test, including an emergency use authorization test, for human diagnostic purposes of novel coronavirus, shall

submit reports to OSDH in a manner, format, and frequency prescribed by the State Commissioner of Health of all test results, both positive and negative.

(b) Hospitals and Physician Clinics operating in the State of Oklahoma shall submit the following critical data to OSDH in a manner, format, and frequency prescribed by the State Commissioner of Health:

(1) The number of patients in the hospital receiving treatment for novel coronavirus; and

(2) The number of patients receiving treatment for novel coronavirus who are currently admitted to the ICU.

(c) This rule shall be active and remain in effect when there is a federal or state declaration of emergency related to novel coronavirus or until the State Commissioner of Health determines the reporting is no longer needed.