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 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 require the submission of electronic records. 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, the number of patients receiving treatment for novel coronavirus who are currently admitted to the ICU and the vaccination status of patients receiving treatment for the novel coronavirus. 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. OAC 310:515-1-2, OAC 310:515-1-3 and OAC 310:515-1-4 clarify the requirements for submitting reports electronically.

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 less than the 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 August 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]
310:515-1-2 [AMENDED]
310:515-1-3 [AMENDED]
310:515-1-4 [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:
August 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]
310:515-1-8 [AMENDED]
310:515-1-10 [NEW]
Gubernatorial approval:
July 19, 2021
Register publication:
38 Ok Reg
Docket number:
21-713
INCORPORATIONS BY REFERENCE:
n/a
FINDING OF EMERGENCY:
The emergency rules OAC 310:515-1-1, OAC 310:515-1-2, OAC 310:515-1-3, OAC 310:515-1-4, 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 require the submission of electronic records. 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, the number of patients receiving treatment for novel coronavirus who are currently admitted to the ICU and the number of patients who received the novel coronavirus vaccination and are being treated for the novel coronavirus. 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. OAC 310:515-1-2, OAC 310:515-1-3 and OAC 310:515-1-4 clarify the requirement for electronic reporting.

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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.

310:515-1-2. Diseases to be reported

The diseases listed in this Chapter must be reported, along with patient identifiers, demographics, and contact information, to the Department upon discovery as dictated in sections OAC 310:515-1-3 and OAC 310:515-1-4. Laboratories ~~having greater than 400 positive tests performed on-site per year for reportable~~ reporting diseases described in 310:515-1-3, 310:515-1-4(1) and 310:515-1-4(2), or as may be otherwise required to be reported by OSDH, shall ~~begin electronic laboratory reporting~~ be reported electronically using ~~meaningful use standards~~ the manner and format prescribed by the State Commissioner of Health.

310:515-1-3. Diseases and conditions to be reported immediately

The following diseases/conditions associated with humans must be reported by any health practitioner or laboratory personnel to the OSDH electronically and by telephone (405 436-8710) ~~via the secure, web-based PHIDDO system or by telephone (405-271-4060 or 800-234-5963)~~ immediately upon suspicion, diagnosis, or testing.

(1) Anthrax (Bacillus anthracis).
(2) Bioterrorism - suspected disease.
(3) Botulism (Clostridium botulinum).
(4) Diphtheria (Corynebacterium diphtheriae).
(5) Free-living amebae infections causing primary amebic meningoencephalitis (Naegleria fowleri).
(6) Hepatitis B during pregnancy (HBsAg+).
(7) Measles (Rubeola).
(8) Meningococcal invasive disease (Neisseria meningitidis).
(9) Novel coronavirus.
(10) Novel influenza A.
(11) Outbreaks of apparent infectious disease.
(12) Plague (Yersinia pestis).
(13) Poliomyelitis.
(14) Rabies.
(15) Smallpox.
(16) Typhoid fever (Salmonella Typhi).
(17) Viral hemorrhagic fever.

310:515-1-4. Additional diseases, conditions, and injuries to be reported

The following diseases, conditions and injuries must be reported by physicians, laboratories, and hospitals (by infection control practitioners, medical records personnel, and other designees) to the OSDH as dictated in the following subsections:

(1) **Infectious diseases.** Reports of infectious diseases and conditions listed in this subsection must be submitted electronically ~~via the PHIDDO system, telephoned or submitted~~ via secure electronic data transmission to the OSDH within one (1) working day (Monday through Friday, state holidays excepted) of diagnosis or positive test.

(A) Acid Fast Bacillus (AFB) positive smear. Report only if no additional testing is performed or subsequent testing is indicative of *Mycobacterium tuberculosis* Complex.

(B) AIDS.

(C) *Anaplasma phagocytophilum* infection.

(D) Arboviral infections (West Nile virus, St. Louis encephalitis virus, Eastern equine encephalitis virus, Western equine encephalitis virus, Powassan virus, California serogroup virus, chikungunya virus, Zika virus).

(E) Brucellosis (*Brucella* spp.).

(F) Campylobacteriosis (*Campylobacter* spp.).

(G) Congenital rubella syndrome.

(H) Cryptosporidiosis (*Cryptosporidium* spp.).

(I) Cyclosporiasis (*Cyclospora cayetanensis*).

(J) Dengue Fever.

(K) *E. coli O157, O157:H7,* or a Shiga toxin producing *E. coli*. (STEC)

(L) Ehrlichiosis (*Ehrlichia* spp.).

(M) *Haemophilus influenzae* invasive disease.

(N) Hantavirus infection, without pulmonary syndrome.

(O) Hantavirus pulmonary syndrome.

(P) Hemolytic uremic syndrome, postdiarrheal.

(Q) Hepatitis A infection (Anti-HAV-IgM+).

(R) Hepatitis B infection. If any of the following are positive, then all test results on the hepatitis panel must be reported: HBsAg+, anti-HBc-IgM+, HBeAg+, or HBV DNA+.

(S) Hepatitis C infection in persons having jaundice or ALT > or = 200 with laboratory confirmation. If hepatitis C EIA is confirmed by NAT for HCV RNA, or s/co ratio or index is predictive of a true positive then report results of the entire hepatitis panel.

(T) HIV.

(U) Influenza-associated hospitalization or death.

(V) Legionellosis (*Legionella* spp.)

(W) Leptospirosis (*Leptospira interrogans*).

(X) Listeriosis (*Listeria monocytogenes*).

(Y) Lyme disease (*Borrelia burgdorferi*).

(Z) Malaria (*Plasmodium* spp.).

(AA) Mumps.

(BB) Pertussis (*Bordetella pertussis*).

(CC) Psittacosis (*Chlamydophila psittaci*).

(DD) Q fever (*Coxiella burnetii*).

(EE) Rubella.

(FF) Salmonellosis (*Salmonella* spp.).

(GG) Shigellosis (*Shigella* spp.).

(HH) Spotted Fever Rickettsiosis (*Rickettsia* spp.) hospitalization or death.

(II) Streptococcal disease, invasive, Group A (GAS) (*Streptococcus pyogenes*).

(JJ) *Streptococcus pneumoniae* invasive disease, in persons less than 5 years of age.

(KK) Syphilis (*Treponema pallidum*). Nontreponemal and treponemal tests are reportable. If any syphilis test is positive, then all syphilis test results on the panel must be reported. For infants < or = 18 months, all syphilis tests ordered, regardless of test result, must be reported.

(LL) Tetanus (*Clostridium tetani*).

(MM) Trichinellosis (*Trichinella spiralis*).
(NN) Tuberculosis (*Mycobacterium tuberculosis*).
(OO) Tularemia (*Francisella tularensis*).
(PP) Unusual disease or syndrome.
(QQ) Vibriosis (*Vibrionaceae* family: *Vibrio* spp. (including cholera), *Grimontia* spp., *Photobacterium* spp., and other genera in the family).
(RR) Yellow Fever.

(2) **Infectious diseases.** Reports of infectious diseases and conditions listed in this subsection must be reported to the OSDH within one (1) month of diagnosis or test result.
(A) CD4 cell count with corresponding CD4 cell count percentage of total (by laboratories only).
(B) Chlamydia (*Chlamydia trachomatis*).
(C) Creutzfeldt-Jakob disease.
(D) Gonorrhea (*Neisseria gonorrhoeae*).
(E) HIV viral load (by laboratories only).
(F) LGV.

(3) **Occupational or environmental diseases.** Laboratories and healthcare provides must report blood lead level results pursuant to the requirements established in Title 310, Chapter 512, childhood Lead Poisoning Prevention Rules.

(4) **Injuries.**
(A) Burns.
(B) Drownings and near drownings.
(C) Traumatic brain injuries.
(D) Traumatic spinal cord injuries.
(E) Poisonings, including toxic and adverse effects.

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) Capbapenem-resistant Pseudomonas aeruginosa.
(5) Carbapenum-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 meningitides (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) Labratories 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;

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

(3) The novel coronavirus vaccination status of patients in the hospital receiving treatment for novel coronavirus.

(c) All reports required by this section 310:5-1-10 must be submitted electronically to OSDH in digital form that is created, distributed and retrievable by a computer system. Electronic records generated according to these requirements shall be in the manner and format prescribed by the State Commissioner of Health.

(d) 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.