

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

RULEMAKING ACTION:

Notice of proposed PERMANENT rulemaking.

PROPOSED RULES:

- Subchapter 1. Disease and Injury Reporting
- 310:515-1-1.1. Definitions [AMENDED]
- 310:515-1-4. Additional diseases, conditions, and injuries to be reported [AMENDED]

SUMMARY:

The proposal updates the existing rules in accordance with recommendations from the Council of State and Territorial Epidemiologists (CSTE), the Centers for Disease Control and Prevention, and local health care partners pertaining to reportable diseases and injuries. The proposal amends the lists of reportable diseases and injuries, in order to clarify those conditions and diseases that are required to be reported to the Department. The proposal revises the list of conditions of public health importance that require investigation and implementation of prevention activities and time frames for required reporting and requiring all laboratories and providers to report lymphogranuloma venereum (LGV) which is a type of chlamydia' bacteria that attacks the lymphatic system. The additional specification of LGV will ensure that Oklahoma can better describe the type of infections or outbreaks that are occurring within the state and monitor the trends.

These changes minimally increase the reporting burden placed upon clinicians and laboratories, and do not adversely affect the public health disease control and prevention activities. Not only do these reports allow us to identify cases which have not previously been reported, but it allows subject matter experts to provide information to providers and/or parents regarding appropriate retesting, referral, and treatment options.

AUTHORITY:

Commissioner of Health, Title 63 O.S. § 1-104

COMMENT PERIOD:

February 3, 2020, through March 7, 2020. Interested persons may informally discuss the proposed rules with the contact person identified below; or may, through March 7, 2020, submit written comment to the contact person identified below, or may, at the hearing, ask to present written or oral views.

PUBLIC HEARING:

Pursuant to 75 O.S. § 303(A), the public hearing for the proposed rulemaking in this chapter shall be on March 6, 2020, at the Oklahoma State Department of Health, 1000 Northeast Tenth Street, Oklahoma City, OK 73117-1207, in room 1102 from 9AM to noon. The alternate date and time in the event of an office closure due to inclement weather is March 10, 2020, in room 1102, beginning at 9AM. Those wishing to present oral comments should be present at that time to register to speak. The hearing will close at the conclusion of those registering to speak. Interested persons may attend for the purpose of submitting data, views or concerns, orally or in writing, about the rule proposal described and summarized in this Notice.

REQUESTS FOR COMMENTS FROM BUSINESS ENTITIES:

Business entities affected by these proposed rules are requested to provide the agency with information, in dollar amounts if possible, on the increase in the level of direct costs such as fees, and indirect costs such as reporting, recordkeeping, equipment, construction, labor, professional services, revenue loss, or other costs expected to be incurred by a particular entity due to compliance with the proposed rule. Business entities may submit this information in writing through March 7, 2020, to the contact person identified below.

COPIES OF PROPOSED RULES:

The proposed rules may be obtained for review from the contact person identified below or via the agency website at www.ok.gov/health.

RULE IMPACT STATEMENT:

Pursuant to 75 O.S., Section 303(D), a rule impact statement is available through the contact person identified below or via the agency website at www.ok.gov/health.

CONTACT PERSONS:

Kim Bailey, General Counsel, Oklahoma State Department of Health, 1000 N. E. 10th Street, Oklahoma City, OK 73117-1207; phone (405) 271-6017, e-mail KimB@health.ok.gov or Audrey C. Talley, Rule Liaison, Oklahoma State Department of Health, 1000 N. E. 10th Street, Oklahoma City, OK 73117-1207, phone (405) 271-9444 ext.56535, e-mail AudreyT@health.ok.gov.

INITIAL RULE IMPACT STATEMENT

(This document may be revised based on comment received during the public comment period.)

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

1. **DESCRIPTION:**

The proposal updates the existing rules in accordance with recommendations from the Council of State and Territorial Epidemiologists (CSTE), the Centers for Disease Control and Prevention, and local health care partners pertaining to reportable diseases. The proposal amends the lists of reportable diseases, in order to clarify those conditions and diseases that are required to be reported to the Department. These changes minimally increase the reporting burden placed upon clinicians, have no impact on the reporting burden placed upon laboratories, and do not adversely affect the public health disease control and prevention activities.

The proposal will add the reporting of lymphogranuloma venereum (LGV) which is caused by a long term infection from Chlamydia trachomatis and attacks the body's lymphatic system which is needed to defend the body against infections. The additional specification of LGV will ensure that we are better able to describe the type of infections or outbreaks that are occurring in Oklahoma and monitor the trends.

2. **DESCRIPTION OF PERSONS AFFECTED AND COST IMPACT RESPONSE:**

Affected persons will be health care providers that report diagnoses of listed diseases and laboratories that perform specific testing that identifies listed diseases.

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

The citizens of Oklahoma will benefit due to the increased ability of the Oklahoma State Department of Health to identify disease and epidemics and prevent additional cases.

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

There will be no significant economic impact to Oklahoma health care providers and laboratories. The Department does not charge or collect any fees associated with this rule.

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

The cost to the Department to implement the amendments will be at most \$1,500.00 to publish, distribute, and educate health care provider and laboratory personnel on the amended lists of reportable diseases/organisms and the time frames for reporting. This cost will be borne by federal grants. There will be no increased personnel costs.

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 RULE:**

There are no less costly means currently identified.

9. **EFFECT ON PUBLIC HEALTH AND SAFETY:**

Reports of infectious disease will be submitted to the Oklahoma State Department of Health. These reports will be investigated and will be used to reduce the risk of disease transmission to the public.

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

It is critical that newly identified diseases that pose a risk to the public health be placed into the reportable disease rule, or that newly adopted national policies regarding these diseases be reflected in rule. The Department will assist the medical system in obtaining newly developed tests for certain diseases that are not available to clinicians in the private sector. The identification of cases will enable the Department to reduce the risk of transmission of these diseases to the public.

11. **PREPARATION AND MODIFICATION DATES:**

This rule impact statement was prepared on December 2, 2019.

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

SUBCHAPTER 1. DISEASE AND INJURY REPORTING

310:515-1-1.1. Definitions

When used in this Chapter, the following words or terms shall have the following meaning ~~unless the context of the sentence requires another meaning:~~

"**AFB**" means Acid Fast Bacillus.

"**AIDS**" means Acquired Immunodeficiency Syndrome.

"**ALT**" means alanine aminotransferase.

"**Anti-HAV-IgM+**" means a positive test result for the hepatitis A virus immunoglobulin M antibody.

"**Anti-HBc-IgM+**" means a positive test result for the hepatitis B core immunoglobulin M antibody.

"**CD4**" means cluster of differentiation 4 glycoprotein that serves as a receptor for HIV on T helper cells.

"**CIDT**" means culture independent diagnostic test system/panel used to detect multiple pathogens.

"**Department**" or "**OSDH**" means the Oklahoma State Department of Health.

"**E. coli**" means *Escherichia coli*.

"**EDTA**" means Ethylenediaminetetraacetic acid.

"**EIA**" means enzyme immunoassay.

"**HBeAg+**" means a positive test result for the hepatitis B "e" antigen.

"**HBsAg+**" means a positive test result for the hepatitis B surface antigen.

"**HBV DNA+**" means a positive test result for deoxyribonucleic acid of the hepatitis B virus.

"**HIV**" means Human Immunodeficiency Virus.

"**LGV**" means lymphogranuloma venereum.

"**PHIDDO**" or "**PHIDDO system**" means Public Health Investigation and Disease Detection of Oklahoma system.

"**NAT for HCV RNA+**" means a positive nucleic acid amplification test result for hepatitis C virus ribonucleic acid.

"**Novel Influenza A**" means an influenza A virus not endemic, not routinely circulating, or for which there is little to no pre-existing immunity, e.g., influenza A H3N2 variant, H5N1, H5N2, H7N3, or H7N9.

"**Outbreak of disease**" means two or more cases residing in different households that have a similar clinical syndrome of a potentially infectious disease, toxin, or agent of known or unknown etiology.

"**RIBA**" means recombinant immunoblot assay.

"**S/co**" means the signal-to-cut-off-ratio.

"**Spp.**" is an abbreviation referring to the term "species," and is used to broaden the antecedent term in order to include all organisms that may be found or described within a given genus.

"**Unusual disease or syndrome**" means a case of an uncommon, possibly infectious disease of known or unknown etiology, even if laboratory testing may be pending or inconclusive, or if testing for common etiologies is negative. Such cases of disease may not normally be endemic to Oklahoma, may represent emerging or re-emerging disease, and/or disease for which a public health intervention may be needed. Examples of such unusual diseases or syndromes include but are not limited to, unexplained adult respiratory distress syndrome, rash illness with atypical presentation, or an illness occurring along with an unusual pattern of illness or death among animals.

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 providers 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.