**INITIAL RULE IMPACT STATEMENT**

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

**1. DESCRIPTION:**

OAC 515-1-2, OAC 515-1-3 and OAC 515-1-4 update the basis for reporting communicable diseases and require that every practicing physician and clinical laboratory 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. OAC 310:515-1-2, OAC 310:515-1-3 and OAC 310:515-1-4 clarify the requirements for submitting reports electronically. OAC 515-1-4 requires reporting of positive HIV test results, including HIV nucleotide sequences. All negative HIV test results, negative HCV RNA test results, and HIV nucleotide sequences are only reportable by laboratories. Reporting requirements for LGV were clarified to state that LGV is reported as chlamydia and designated as LGV.

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

The data collection required in this rule will be critical to assess the likelihood of, and to prevent, a future public health emergency that would affect all Oklahomans. Partner services and antiretroviral therapy will be available quicker due to reduction in incomplete and delayed laboratory reporting. The availability of HIV nucleotide sequence results supports HIV cluster detection and response efforts. The rules will give more insight into places with increased rate of high risk HCV negatives to focus prevention and intervention efforts. Information that specifies LGV infection will directly benefit clients diagnosed with this condition since timely treatment can prevent long-term complications as well as transmission. 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 by any burden from producing electronic reports.

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

People newly diagnosed with HIV may be linked to partner services and antiretroviral therapy quicker due to reduction in incomplete and delayed laboratory reporting. The proposed change is intended to improve the accuracy of HIV-related epidemiologic estimates in Oklahoma to guide policy and funding distribution. HCV test results will provide insight to places with a higher prevalence of hepatitis and enable the Department to focus on prevention and intervention efforts. Having an increased understanding of the burden of LGV can help the Department target health education and prevention efforts as well as differentiate between LGV and non-LGV infections of chlamydia. All Oklahoma citizens will benefit from the proposed rules as they are intended to help prevent a future public health emergency.

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

Cost of compliance is not expected to increase because the proposed rules clarify what is being asked of reporting entities. Electronic reporting 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 expedite public health services and to mitigate risk of a future public health emergency.

**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 mitigate and prevent future outbreaks, thereby eliminating excess reporting costs.

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

The rule proposals will help reduce risk for future public health emergencies related to communicable diseases.

**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 infectious diseases spreading.

**11. PREPARATION AND MODIFICATION DATES:**

This rule impact statement was prepared on October 6, 2021.

**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[AMENDED]
310:515-1-2 [AMENDED]
310:515-1-3 [AMENDED]
310:515-1-4 [AMENDED]

**SUMMARY:**

OAC 515-1-1 states the statutory authority for the rules. OAC 515-1-2, OAC 515-1-3 and OAC 515-1-4 update the basis for reporting communicable diseases and require that every practicing physician and clinical laboratory 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. OAC 310:515-1-2, OAC 310:515-1-3 and OAC 310:515-1-4 clarify the requirements for submitting reports electronically. OAC 515-1-4 requires reporting of positive HIV test results, including HIV nucleotide sequences. All negative HIV test results, negative HCV RNA test results, and HIV nucleotide sequences are only reportable by laboratories. Reporting requirements for LGV were clarified to state that LGV is reported as chlamydia and designated as LGV.

**AUTHORITY:**

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

**COMMENT PERIOD:**

November 15, 2021 through the close of the Department's normal business hours, 5 PM, on December 15, 2021. Interested persons may informally discuss the proposed rules with the contact person identified below; or may, through the close of the Department's normal business hours, 5 PM, on December 15, 2021, 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 December 15, 2021 at the Oklahoma State Department of Health Auditorium, 123 Robert S. Kerr Avenue, Oklahoma City, Oklahoma 73102 from 9:30 AM to 12:30 PM. The meeting may adjourn earlier if all attendees who signed up to comment have completed giving their comments. The alternate date and time in the event of an office closure due to inclement weather is January 7, 2022 in the Auditorium, from 9:30 AM to 12:30 PM. 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. Validated parking will be provided for the parking lot located at the east corner of Broadway and Robert S. Kerr Avenue, subject to availability.

**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 the close of the Department's normal business hours, 5 PM, on December 15, 2021, 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., § 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 PERSON:**

Audrey C. Talley, Agency Rule Liaison, Oklahoma State Department of Health, 123 Robert S. Kerr Avenue, Oklahoma City, OK 73102, phone (405) 426-8563, e-mail AudreyT@health.ok.gov.

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

## 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 via secure electronic data transmission and by telephone (405 426-8710) ~~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. Positive HCV RNA are reportable by both laboratories and providers. Negative test results for HCV RNA tests are reportable by laboratories only.
(T) HIV.
(i) All tests indicative of HIV infection are reportable by laboratories and providers. If any HIV test is positive, then all HIV test results on the panel must be reported by laboratories. For infants < or = 18 months, all HIV tests ordered, regardless of test result must be reported by laboratories.
(ii) All HIV nucleotide sequences and negative HIV test results are only reportable by laboratories.
(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 via secure electronic data submission 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. *Lymphogranuloma Venereum* is reportable as Chlamydia and designated as 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.