

ADMINISTRATIVE AGENCY RULE REPORT
75 O.S. Supp. 2000, § 303.1
SUBMITTED TO THE GOVERNOR AND TO THE LEGISLATURE

1. Date the Notice of Intended Rulemaking was published in the Oklahoma Register:

October 3, 2016, Vol. 34 Ok Reg 2, Docket No. 16-747

2. Name and address of the Agency:

Oklahoma State Department of Health
1000 N.E. Tenth Street
Oklahoma City, Oklahoma 73117-1299

3. Title and Number of the Rule:

Title 310. Oklahoma State Department of Health
CHAPTER 515. COMMUNICABLE DISEASE AND INJURY REPORTING

4. Citation to the Statutory Authority for the Rule:

Oklahoma State Board of Health, Title 63 O.S. § 1-104 and 63 O.S. §§ 1-502 and 1-503.

5. Brief Summary of the Content of the Adopted Rule:

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. The proposal also adds conditions of public health importance that require investigation and implementation of prevention activities. 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 removes the reference to a “non-versioned/non-codified” document which could further specify requirements of reporting. This change will eliminate any possibility of requirements that are not stated in rule. The duplicative requirements at OAC 310:515-1-4(3) (relating to occupational or environmental diseases) are amended by removing the requirements listed here and adding a reference to the amended rules on reporting blood lead levels at OAC 310:512, Childhood Lead Poisoning Prevention Rules. This proposal changes the current reporting guidance for hepatitis C to include persons of all ages, and lowers the alanine aminotransferase (ALT) levels for reporting from 400 to 200. This modification is in accordance with the CSTE case definition for hepatitis C that was revised effective January 1, 2016. Lastly, the proposal will more clearly specify which syphilis tests are required for reporting to the Department.

6. Statement explaining the Need for the Adopted Rule:

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.

7. Date and Location of the Meeting at which such Rules Were Adopted:

Adopted December 13, 2016, in the offices of the Oklahoma State Department of Health.

8. Summary of the Comments and Explanation of Changes or Lack of any Change Made in the Adopted Rules as a Result of Testimony Received at Public Hearings:

None received.

9. List of Persons or Organizations Who Appeared or Registered For or Against the Adopted Rule at Any Public Hearing Held by the Agency or Those Who Have Commented in Writing Before or After the Hearing:

None

10. Rule Impact Statement: Hereto annexed as Exhibit B.

11. Incorporation by Reference Statement:

"n/a"

12. Members of the Governing Board of the Agency Adopting the Rules and the Recorded Vote of Each Member:

Dr. Jenny Alexopoulos - Aye
Mrs. Martha Burger - Aye
Dr. Terry Gerard - Aye
Dr. Charles Grim - Aye
Dr. R. Murali Krishna - Aye
Mr. Timothy Starkey - Aye
Dr. Robert Stewart - Aye
Ms. Cris Hart-Wolfe - Aye
Dr. Ronald Woodson – Aye

13. Additional information: Information regarding this rule may be obtained by contacting Kristy Bradley, State Epidemiologist, Oklahoma State Department of Health, 1000 N.E. 10th Street, Oklahoma City, OK 73117-1207; phone (405) 271-7637, e-mail KristyB@health.ok.gov

RULE IMPACT STATEMENT

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. The proposal also adds conditions of public health importance that require investigation and implementation of prevention activities. 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 removes the reference to a “non-versioned/non-codified” document which could further specify requirements of reporting. This change will eliminate any possibility of requirements that are not stated in rule. The duplicative requirements at OAC 310:515-1-4(3) (relating to occupational or environmental diseases) are amended by removing the requirements listed here and adding a reference to the amended rules on reporting blood lead levels at OAC 310:512, Childhood Lead Poisoning Prevention Rules. This proposal changes the current reporting guidance for hepatitis C to include persons of all ages, and lowers the alanine aminotransferase (ALT) levels for reporting from 400 to 200. This modification is in accordance with the CSTE case definition for hepatitis C that was revised effective January 1, 2016. Lastly, the proposal will more clearly specify which syphilis tests are required for reporting to the Department.

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 is estimated to be \$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. There will be no increased personnel costs.
6. **IMPACT ON POLITICAL SUBDIVISIONS:** There will be no impact on any political subdivision as a result of implementing or enforcing this rule.
7. **ADVERSE EFFECT ON SMALL BUSINESS:** Implementation of the proposed rule should have no adverse effect on small businesses as provided by the Oklahoma Small Business Regulatory Flexibility Act.
8. **EFFORTS TO MINIMIZE COSTS OF RULE:** No less costly methods were 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 monitor trends of diseases or conditions of public health importance and 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 surveillance 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. This rule impact statement was prepared on July 13, 2016 and revised on August 31, 2016 and November 23, 2016. No modifications made subsequent to the publication of the *Notice of Rulemaking Intent*.

(the date the rule impact statement was prepared and if modified, the date modified [75 O.S. §303.D.2(k)])

**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:

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

"**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.

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

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

"**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.

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

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

"**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 be an emerging or re-emerging disease, and/or represent diseases 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.

~~"**VISA**" means vancomycin intermediate *Staphylococcus aureus*.~~

~~"**VRSA**" means vancomycin resistant *Staphylococcus aureus*.~~

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. ~~The current "Oklahoma Disease Reporting Manual" shall serve as the standard for disease specific diagnostic test results to be reported. Ancillary laboratory test results, signs, and symptoms must be reported upon request. The current edition of the "Oklahoma Disease Reporting Manual" may be accessed from the Acute Disease Service disease reporting and alerts web page of the OSDH web site at <http://IDReportingAndAlerts.health.ok.gov>.~~ Laboratories having greater than 400 positive tests performed on-site per year for reportable 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 no later than August 30, 2010 using secure electronic data transmission meaningful use standards.

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

The following diseases must be reported by any health practitioner or laboratory personnel to the OSDH electronically via the secure web-based Public Health Investigation and Disease Detection of Oklahoma system or by telephone (405-271-4060 or 800-234-5963) immediately upon suspicion, diagnosis, or testing ~~as specified in the "Oklahoma Disease Reporting Manual".~~

- (1) Anthrax (*Bacillus anthracis*).
- (2) Bioterrorism - suspected disease.
- (3) Botulism (*Clostridium botulinum*).
- (4) Diphtheria (*Corynebacterium diphtheriae*).
- ~~(5) *Haemophilus influenzae* invasive disease.~~
- ~~(6) Hepatitis A (Anti HAV IgM+).~~
- (5) Free-living amebae infections causing primary amebic meningoencephalitis (*Naegleria fowleri*).
- ~~(7)(6) Hepatitis B during pregnancy (HBsAg+).~~
- ~~(8)(7) Measles (Rubeola).~~
- ~~(9)(8) Meningococcal invasive disease (*Neisseria meningitidis*).~~
- ~~(10)(9) Novel coronavirus.~~
- ~~(11)(10) Novel influenza A.~~
- ~~(12)(11) Outbreaks of apparent infectious disease.~~
- ~~(13)(12) Plague (*Yersinia pestis*).~~
- ~~(14)(13) Poliomyelitis.~~
- ~~(15)(14) Rabies.~~
- ~~(16)(15) Smallpox.~~
- ~~(17)(16) Tularemia (*Francisella tularensis*).~~
- ~~(18)(17) Typhoid fever (*Salmonella Typhi*).~~
- ~~(19)(18) 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 as specified in the "Oklahoma Disease Reporting Manual".

(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 (Acquired Immunodeficiency Syndrome).

(C) *Anaplasma phagocytophilum* infection.

~~(C)(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).

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

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

~~(F)(G)~~ Congenital rubella syndrome.

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

~~(H)(I)~~ Dengue Fever.

~~(I)(J)~~ *E. coli* O157, O157:H7, or a Shiga toxin producing *E. coli*.

~~(J)(K)~~ Ehrlichiosis (*Ehrlichia* or ~~*Anaplasma*~~ spp.).

(L) *Haemophilus influenzae* invasive disease.

(M) Hantavirus infection, without pulmonary syndrome.

~~(K)(N)~~ Hantavirus pulmonary syndrome.

~~(L)(O)~~ Hemolytic uremic syndrome, postdiarrheal.

(P) Hepatitis A (Anti-HAV-IgM+).

~~(M)(Q)~~ Hepatitis B. If HBsAg+, anti-HBc-IgM+, HBeAg+, or HBV DNA+ then report results of the entire hepatitis panel.

~~(N)(R)~~ Hepatitis C in persons ~~< or = 40 years or in persons~~ having jaundice or ALT > or = ~~400/200~~ regardless of age with laboratory confirmation. If hepatitis C EIA is confirmed by NAT for HCV RNA, or signal-to-cut-off (s/co) ratio or index is predictive of a true positive then report results of the entire hepatitis panel.

~~(O)(S)~~ Human Immunodeficiency Virus (HIV) infection.

~~(P)(T)~~ Influenza associated hospitalization or death.

~~(Q)(U)~~ Legionellosis (*Legionella* spp.).

~~(R)(V)~~ Leptospirosis (*Leptospira interrogans*).

~~(S)(W)~~ Listeriosis (*Listeria monocytogenes*).

~~(T)(X)~~ Lyme disease (*Borrelia burgdorferi*).

~~(U)(Y)~~ Malaria (*Plasmodium* spp.).

~~(V)(Z)~~ Mumps.

~~(W)(AA)~~ Pertussis (*Bordetella pertussis*).

~~(X)(BB)~~ Psittacosis (*Chlamydomphila psittaci*).

~~(Y)(CC)~~ Q Fever (*Coxiella burnetii*).

~~(Z)(DD)~~ Rocky Mountain Spotted Fever (*Rickettsia rickettsii*).

~~(AA)(EE)~~ Rubella.

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

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

~~(DD)~~ *Staphylococcus aureus* with reduced susceptibility to vancomycin (VISA or VRSA).

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

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

~~(FF)~~(JJ) 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 = 12 months, all syphilis tests ordered, regardless of test result, must be reported.

~~(GG)~~(KK) Tetanus (*Clostridium tetani*).

~~(HH)~~(LL) Trichinellosis (*Trichinella spiralis*).

~~(H)~~(MM) Tuberculosis (*Mycobacterium tuberculosis*).

~~(JJ)~~(NN) Unusual disease or syndrome.

~~(KK)~~(OO) Vibriosis (*Vibrionaceae* family: *Vibrio* spp. (including cholera), *Grimontia* spp., *Photobacterium* spp., and other genera in the family).

~~(LL)~~(PP) 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 as specified in the OSDH Disease Reporting Manual.

(A) CD4 cell count with corresponding CD4 cell count percentage of total (by laboratories only).

(B) Chlamydia infections (*Chlamydia trachomatis*).

(C) Creutzfeldt-Jakob disease.

(D) Gonorrhea (*Neisseria gonorrhoeae*).

(E) HIV viral load (by laboratories only).

(3) **Occupational or Environmental diseases.** ~~Laboratories must report blood lead level results greater than 105 ug/dL within one (1) week and results less than 105 ug/dL within one (1) month, and Health health care providers must report blood lead level results pursuant to the requirements established in Title 310, Chapter 512, Childhood Lead Poisoning Prevention Rules 20 ug/dL or greater within twenty four (24) hours and results 105-19 ug/dL within one (1) week.~~

(4) **Injuries (hospitalized and fatal cases only).**

(A) Burns.

(B) Drownings and Near Drownings.

(C) Traumatic Brain Injuries.

(D) Traumatic Spinal Cord Injuries.

310:515-1-6. Additional diseases may be designated

The Commissioner of Health may designate any disease or condition as reportable for a designated period of time for the purpose of enhanced public health surveillance or special investigation.

310:515-1-7. Control of Communicable Diseases Manual

The OSDH adopts the most recently published edition of the publication, "Control of Communicable Diseases Manual," published by the American Public Health Association, as a guideline for the prevention and control of communicable diseases. ~~In order to determine the most recently published edition of the "Control of Communicable Diseases Manual," access the American Public Health Association web site at <https://secure.apha.org/source/orders/index.cfm>.~~

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

(a) Isolates or appropriate specimens of the following organisms shall be sent to the OSDH Public Health Laboratory for typing.

- (1) *Bacillus anthracis*.
- (2) *Brucella* spp.
- (3) Carbapenem-resistant *Enterobacteriaceae*.
- ~~(3)~~(4) *E. coli* O157, O157:H7, or a Shiga toxin producing *E. coli*.
- ~~(4)~~(5) *Francisella tularensis*.
- ~~(5)~~(6) *Haemophilus influenzae* (sterile site).
- ~~(6)~~(7) *Listeria monocytogenes* (sterile site).
- ~~(7)~~(8) *Mycobacterium tuberculosis*.
- ~~(8)~~(9) *Neisseria meningitidis* (sterile site).
- ~~(9)~~(10) *Plasmodium* spp.
- ~~(10)~~(11) *Salmonella* spp.
- ~~(11)~~ *Staphylococcus aureus* that are VISA or VRSA
- (12) *Vibrionaceae* family (*Vibrio* spp., *Grimontia* spp., *Photobacterium* spp. and other genera in the family).
- (13) *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 referral and testing.