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 Requirements
310:515-1-1.1. Definitions [AMENDED]
310:515-1-2. Diseases to be reported [AMENDED]
310:515-1-3. Diseases to be reported immediately [AMENDED]
310:515-1-4. Additional diseases, conditions, and injuries to be reported [AMENDED]
310:515-1-6. Additional diseases may be designated [AMENDED]
310:515-1-8. Organisms/specimens to be sent to the Public Health Laboratory [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. 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, including the addition of carbapenem-resistant Enterobacteriaceae as isolates required to be submitted to the Public Health Laboratory for additional characterization. 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.

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 proposal will also change the current level of blood lead that must be reported within one week from greater than 10 μg/dL to greater than 5 μg/dL. The proposed rules also change the blood lead level to be reported within 1 month from less than 10 μg/dL to less than 5 μg/dL. This is in accordance with CDC guidelines and the newly established reference level for elevated blood lead. 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.

With these changes, the Department will receive timely reporting of information on suspected cases of infection and thus be better equipped to respond quickly and effectively to disease outbreaks or unusual or uncommon adverse health conditions.

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

COMMENT PERIOD:
October 3, 2016, through November 3, 2016. Interested persons may informally discuss the proposed rules with the contact person identified below; or may, through November 3, 2016, 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 November 3, 2016, at the Oklahoma State Department of Health, 1000 Northeast Tenth Street, Oklahoma City, OK 73117-1207, in room 1102 beginning at 10:00 a.m. 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 November 3, 2016, 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.health.ok.gov.

RULE IMPACT STATEMENT:
Pursuant to 75 O.S., §303(D), a rule impact statement is available through the contact person identified.

CONTACT PERSONS:
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
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. 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 proposal will also change the current level of blood lead that must be reported within one week from greater than 10 µg/dL to greater than 5 µg/dL. The proposed rules also change the blood lead level to be reported within 1 month from less than 10 µg/dL to less than 5 µg/dL. This is in accordance with CDC guidelines and the newly established reference level for elevated blood lead. 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. Modifications made subsequent to the publication of the *Notice of Rulemaking Intent* were made on: August 31, 2016. (the date the rule impact statement was prepared and if modified, the date modified [75 O.S. §303.D.2(k)])
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 anteceding 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. *Hemophilus influenzae* invasive disease.
7. Free-living amebae infections causing primary amebic meningoencephalitis (*Naegleria fowleri*).
8. Hepatitis B during pregnancy (HBsAg+).
9. Measles (Rubeola).
10. Meningococcal invasive disease (*Neisseria meningitidis*).
12. Novel influenza A.
13. Outbreaks of apparent infectious disease.
14. Plague (*Yersinia pestis*).
15. Poliomyelitis.
17. Tularemia (*Francisella tularensis*).
18. Typhoid fever (*Salmonella Typhi*).
19. 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.

(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) Dengue Fever.

(J) *E. coli* 0157, 0157:H7, or a Shiga toxin producing *E. coli*.

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

(L) *Haemophilus influenzae* invasive disease.

(M) Hantavirus infection, without pulmonary syndrome.

(N) Hantavirus pulmonary syndrome.

(O) Hemolytic uremic syndrome, postdiarrheal.

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

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

(R) Hepatitis C in persons < or = 40 years or in persons having jaundice or ALT > or = 400200 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.

(S) Human Immunodeficiency Virus (HIV) infection.

(T) Influenza associated hospitalization or death.

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

(V) Leptospirosis (*Leptospira interrogans*).

(W) Listeriosis (*Listeria monocytogenes*).

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

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

(Z) Mumps.

(AA) Pertussis (*Bordetella pertussis*).

(BB) Psittacosis (*Chlamydophila psittaci*).

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

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

(EE) Rubella.

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

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

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

(I) Streptococcal disease, invasive, Group A (GAS) (*Streptococcus pyogenes*).
(II) *Streptococcus pneumoniae* invasive disease, in persons less than 5 years of age.

(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.

(KK) Tetanus (*Clostridium tetani*).

(MM) Trichinosis (*Trichinella spiralis*).

(NN) Unusual disease or syndrome.


(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 405 ug/dL within one (1) week and results less than 405 ug/dL within one (1) month. Health care providers must report blood lead level results 20 ug/dL or greater within twenty-four (24) hours and results 405-19 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.


310:515-1-8. 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.
(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.