1. Date the Notice of Intended Rulemaking was published in the Oklahoma Register:
   October 1, 2013, Vol. 31, No. 2 Ok Reg 5, Docket No. 13-1188

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:
   Title 63 O.S. Section 1-104; and Title 63 O.S., §§ 1-502 and 1-503

5. Brief Summary of the Content of 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.  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.

6. Statement explaining the Need for the Adopted Rule:
   The proposed rule is designed to reduce the risk to the public health of communicable
diseases through requiring rapid disease reporting, especially of suspected cases of novel
   coronavirus and novel influenza A.  The proposed rule will enable the responsible Services
   of the OSDH to rapidly investigate and intervene in transmission. The proposed rule allows
   the OSDH to monitor the epidemiology of the severe end of the clinical spectrum for
   influenza and thus forecast the possible impact on the health services and the State of
   Oklahoma during influenza season and during an influenza pandemic.

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

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:
   No comments were received during the comment period or during the public hearing.
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 A.

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:

   Murali Krishna, President, M.D. – aye
   Ronald Woodson, Vice-President, M.D. – aye
   Martha Burger, M.B.A, Secretary-Treasurer – absent
   Jenny Alexopulos, D.O. – aye
   Charles W. Grim, D.D.S., M.H.S.A. – aye
   Terry Gerard, D.O. – aye
   Robert S. Stewart, M.D. – aye
   Tim Starkey, M.B.A. – aye
   Cris Hart-Wolfe – aye

13. Additional information: Information regarding this rule may be obtained by contacting Lauri Smithee, PhD, Service Director, Acute Disease Service, phone (405) 271-4060, e-mail LauriS@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. 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 adds novel coronavirus and novel influenza A to the list of infectious diseases, reportable to the Department. The proposal expands reporting of influenza associated hospitalizations and deaths. The proposal is needed prepared for the reporting of suspected cases (especially those due to international travel to endemic areas and areas that such viruses are more likely to be initially spread) and the possibility of pandemic influenza or coronavirus, which have significant public health concern and risk. The proposal also refines requirements for CD4 cell count reporting. With these changes, the Department will receive information that is more rapid and precise, and the Department thereby will be better equipped to respond quickly and effectively to disease outbreaks or unusual or uncommon adverse health conditions.

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 will use the following Performance and Outcome measures.

Change in novel coronavirus reporting:
Performance measure: Number of novel coronavirus reports.
Outcome measure: Change in number of novel coronavirus reports.

Change in novel Influenza A reporting:
Performance measure: Number of novel Influenza A reports.
Outcome measure: Change in number of novel Influenza A reports.

Change in Influenza associated hospitalization or death reporting:
Performance measure: Number of Influenza associated hospitalization or death reports.
Outcome measure: Change in number of Influenza associated hospitalization or death reports.

Change in CD4 cell count reporting:
Performance measure: Number of CD4 cell count reports.
Outcome measure: Change in number of CD4 cell count reports.

Exhibit A – Page 1
5. **COST AND BENEFITS OF IMPLEMENTATION AND ENFORCEMENT TO THE AGENCY:** The cost to the Department to implement the amendments will be approximately $3,500.00 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 any political subdivision as a result of implementing or enforcing this rule except for OU Medical Center which would be required to adhere to the reporting of suspected novel cases of coronavirus or influenza A. With regard to the changes in reporting novel cases of coronavirus or influenza A, Influenza associated hospitalization or death, CD4 cell count, the reporting burden will not significantly impact laboratories or clinicians.

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. With regard to the changes, the reporting burden will not significantly impact laboratories or clinicians.

8. **EFFORTS TO MINIMIZE COSTS OF RULE:** No less costly methods were identified.

9. **EFFECT ON PUBLIC HEALTH AND SAFETY:** The proposed rule is designed to reduce the risk to the public health of communicable diseases through requiring rapid disease reporting, especially of suspected cases of novel coronavirus and novel influenza A. The proposed rule will enable the responsible Services of the OSDH to rapidly investigate and intervene in transmission. The proposed rule will have minimal impact on the disease reporting and investigation workload for OSDH program staff and healthcare reporting partners. Although the cost savings is unknown, this person time can be redirected to other critical public health and healthcare activities. The proposal requires the reporting of suspected cases of novel coronavirus and novel influenza A, and expands the requirement of reporting cases of pediatric influenza death to reporting influenza associated hospitalization and death. The proposed rule will allow the ADS of the OSDH to monitor the epidemiology of the severe end of the clinical spectrum for influenza and thus forecast the possible impact on the health services and the State of Oklahoma during influenza season and during an influenza pandemic. These changes increase the alignment of the Department with national public health partners in efforts to conduct surveillance for novel coronaviruses and influenza A viruses with pandemic potential. It reflects diseases of concern in Oklahoma as listed CSTE List of Nationally Notifiable Conditions at [http://c.ymcdn.com/sites/www.cste.org/resource/resmgr/PDFs/CSTENotifiableConditionListA.pdf](http://c.ymcdn.com/sites/www.cste.org/resource/resmgr/PDFs/CSTENotifiableConditionListA.pdf).

The proposal refines requirements for reporting CD4 cell count and percentage results based on the federal requirement that states receiving Ryan White Part B funding must calculate the Unmet Need for Health Services, defined as the need for HIV-related health services by individuals with HIV who are aware of their HIV status, but are not receiving regular primary health care. Health Resources and Services Administration (HRSA) provides an Unmet Need Framework for this calculation and determines that an individual with HIV or AIDS is considered to have an unmet need for care (or to be out of care) when there is no evidence that s/he received any of the following three components of HIV primary medical care during a defined 12-month time frame: (1) viral load (VL) testing, (2) CD4 count, or (3) provision of anti-retroviral therapy (ART). Therefore, in order to accurately calculate unmet need in Oklahoma, all CD4 cell count and percentage test results must be reported. See [http://hab.hrsa.gov/tools2/title2/t2SecVIIIChap1.htm#SecVIIIChap1d](http://hab.hrsa.gov/tools2/title2/t2SecVIIIChap1.htm#SecVIIIChap1d) and [http://www.qualityforum.org/News_And_Resources/Press_Releases/2013/NQF_Endorses_Infectious_Disease_Measures.aspx](http://www.qualityforum.org/News_And_Resources/Press_Releases/2013/NQF_Endorses_Infectious_Disease_Measures.aspx).
10. **DETRIMENTAL EFFECTS ON PUBLIC HEALTH AND SAFETY WITHOUT ADOPTION:**
   If the proposed rule is not implemented, specific diseases of public health importance as well as clusters of disease which may occur, may not be reported and thus investigation and intervention may not begin in a timely manner. Prompt investigation of such cases and clusters can prevent additional cases of disease.

11. This rule impact statement was prepared on 29 July 2013.
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+).
(7) Hepatitis B during pregnancy (HBsAg+).
(8) Measles (Rubella).
(9) Meningococcal invasive disease (*Neisseria meningitidis*).
(10) Novel coronavirus.
(11) Novel influenza A.
(12) Outbreaks of apparent infectious disease.
(13) Plague (*Yersinia pestis*).
(14) Poliomyelitis.
(15) Rabies.
(16) Smallpox.
(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) Arboviral infections (West Nile virus, St. Louis encephalitis virus, Eastern equine encephalitis virus, Western equine encephalitis virus, Powassan virus, California serogroup virus).
(D) Brucellosis (Brucella spp.).
(E) Campylobacteriosis (Campylobacter spp.).
(F) Congenital rubella syndrome.
(G) Cryptosporidiosis (Cryptosporidium spp.).
(H) Dengue Fever.
(I) E. coli O157, O157:H7, or a Shiga toxin producing E. coli.
(J) Ehrlichiosis (Ehrlichia or Anaplasma spp.).
(K) Hantavirus pulmonary syndrome.
(L) Hemolytic uremic syndrome, postdiarrheal.
(M) Hepatitis B. If HBsAg+, anti-HBc-IgM+, HBeAg+, or HBV DNA+ then report results of the entire hepatitis panel.
(N) Hepatitis C in persons < or = 40 years or in persons having jaundice or ALT > or = 400 regardless of age with laboratory confirmation. If hepatitis C EIA is confirmed by RIBA or 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) Human Immunodeficiency Virus (HIV) infection.
(P) Influenza associated pediatric mortality/hospitalization or death.
(Q) Legionellosis (Legionella spp.).
(R) Leptospirosis (Leptospira interrogans).
(S) Listeriosis (Listeria monocytogenes).
(T) Lyme disease (Borrelia burgdorferi).
(U) Malaria (Plasmodium spp.).
(V) Mumps.
(W) Pertussis (Bordetella pertussis).
(X) Psittacosis (Chlamydophila psittaci).
(Y) Q Fever (Coxiella burnetii).
(Z) Rocky Mountain Spotted Fever (Rickettsia rickettsii).
(AA) Rubella.
(BB) Salmonellosis (Salmonella spp.).
(CC) Shigellosis (Shigella spp.).
(DD) Staphylococcus aureus with reduced susceptibility to vancomycin (VISA or VRSA).
(EE) Streptococcus pneumoniae invasive disease, in persons less than 5 years of age.
(FF) Syphilis (Treponema pallidum).
(GG) Tetanus (Clostridium tetani).
(HH) Trichinellosis (Trichinella spiralis).
(II) Tuberculosis (Mycobacterium tuberculosis).
(JJ) Unusual disease or syndrome.
(KK) Vibriosis (Vibrionaceae family: Vibrio spp. (including
cholera), Gramontia spp., Photobacterium spp., and other genera in the family).

(LL) 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 < 500 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 10 ug/dL within one (1) week and results less than 10 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 10-19 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.

310:515-1-8. **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) *E. coli* O157, O157:H7, or a Shiga toxin producing *E. coli*.
- (4) *Francisella tularensis*.
- (5) *Haemophilus influenzae* (sterile site).
- (6) *Listeria monocytogenes* (sterile site).
- (7) *Mycobacterium tuberculosis*.
- (8) *Neisseria meningitidis* (sterile site).
- (9) *Plasmodium* spp.
- (10) *Salmonella* spp.
- (11) *Staphylococcus aureus* that are VISA or VRSA.
- (12) *Vibrionaceae* family (*Vibrio* spp., *Gramontia* 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 testing.