INITIAL RULE IMPACT STATEMENT

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 517. NOVEL CORONAVIRUS REGULATIONS

1. DESCRIPTION:

The rules OAC 310:517-1-1, OAC 310:517-2-1 and OAC 310:517-2-2 update the basis for reporting novel coronavirus cases and require that every practicing physician and clinical laboratory using an FDA-approved test for the novel coronavirus 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. The Rules also require that hospitals and physician clinics in Oklahoma submit to the State Department of Health in the manner, format and frequency prescribed by the Commissioner of Health, the number of patients in the hospital receiving treatment for novel coronavirus, the number of patients receiving treatment for novel coronavirus who are currently admitted to the ICU and the vaccination status of patients receiving treatment for the novel coronavirus. The rule OAC 310:517-2-1 requires hospitals and laboratories to send, at a minimum, 10% of their weekly positive novel coronavirus specimens to the OSDH Public Health Laboratory for variant testing. The collection, packaging, and shipping of the positive novel coronavirus specimen must be in accordance with OSDH Public Health Laboratory guidelines. OAC 310:517-3-1 will allow hospitals licensed by the Commissioner of Health to expand or modify bed capacity if certain conditions are met. It also requires hospitals participating in the CMS Hospital Without Walls program to attest to certain requirements being met.

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 related to novel coronavirus that would affect all Oklahomans. 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. The burden of reporting will be less than the reporting during the peak of the COVID-19 pandemic, but will be greater than it was prior to the COVID-19 pandemic. The cost impact for reporting entities will be less than it was during the peak of COVID-19 pandemic and more than it was prior to the COVID-19 pandemic.

This emergency rule has the potential to affect all Oklahomans who may need hospital care while the rule is in effect as it allows for expanded bed capacity as needs arise.

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

All Oklahoma citizens will benefit from the proposed rule as it is intended to help prevent a future novel coronavirus public health emergency.

All Oklahomans will benefit from this rule because hospitals will have increased ability to care for patients when high volumes of patients are hospitalized.

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

Cost of compliance will be considerably less than what is currently being asked of reporting entities. The agency anticipates minimal cost and time when having to report an aggregated count of COVID-19 patients and those in ICU and the vaccination status of COVID-19 patients. This 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.

There is no expected cost impact associated with allowing conditional hospital be expansion. 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 mitigate risk of a future public health emergency related to novel coronavirus.

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 prevent future outbreaks, thereby eliminating excess reporting costs. There are no less costly means currently identified.

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

The rules will help reduce risk for future public health emergencies related to the novel coronavirus. This emergency rule will potentially improve health care access for patients needing to be hospitalized while there is an unusually high volume of patients.

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 returning to a state of emergency caused by the novel coronavirus pandemic. Without adoption of this rule, hospitals licensed by the Commissioner of Health will not have the ability to expand or modify bed capacity.

11. PREPARATION AND MODIFICATION DATES:

This rule impact statement was prepared on October 5, 2021.

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 517. NOVEL CORONAVIRUS REGULATIONS

RULEMAKING ACTION:

Notice of proposed PERMANENT rulemaking.

PROPOSED RULES:

Chapter 517. Novel Coronavirus Regulations [NEW]

SUMMARY:

The rules OAC 310:517-1-1, OAC 310:517-2-1 and OAC 310:517-2-2 update the basis for reporting novel coronavirus cases and require that every practicing physician and clinical laboratory using an FDA-approved test for the novel coronavirus 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. The Rules also require that hospitals and physician clinics in Oklahoma submit to the State Department of Health in the manner, format and frequency prescribed by the Commissioner of Health, the number of patients in the hospital receiving treatment for novel coronavirus, the number of patients receiving treatment for novel coronavirus who are currently admitted to the ICU and the vaccination status of patients receiving treatment for the novel coronavirus. The rule OAC 310:517-2-1 requires hospitals and laboratories to send, at a minimum, 10% of their weekly positive novel coronavirus specimens to the OSDH Public Health Laboratory for variant testing. The collection, packaging, and shipping of the positive novel coronavirus specimen must be in accordance with OSDH Public Health Laboratory guidelines.

OAC 310:517-3-1 will allow hospitals licensed by the Commissioner of Health to expand or modify bed capacity if certain conditions are met. It also requires hospitals participating in the CMS Hospital Without Walls program to attest to certain requirements being met.

AUTHORITY:

Commissioner of Health, Title 63 O.S. §§ 1-104, 1-106; Prevention and Control of Disease, Title 63 O.S. § 1-502; and Reports of Disease, Title 63 O.S. § 1-503; Title 63 O.S. §§ 1-701 et seq.

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 517. NOVEL CORONAVIRUS REGULATIONS

SUBCHAPTER 1. GENERAL PROVISIONS

310:517-1-1. Purpose

The purpose of this chapter is to collect data determined to be critical to assess the likelihood of, and to prevent, a future public health emergency related to novel coronavirus and to establish the specific data reporting requirements and the procedures for submission of the data to the Oklahoma State Department of Health. The rules in this Chapter implement in part, the communicable disease reporting laws in Title 63 O.S. §§ 1-104 and 1-106, Commissioner of Health, Title 63 O.S. § 1-502, Prevention and Control of Disease and Title 63 O.S. § 1-503, Reports of Disease. The rules set forth the conditions under which hospitals are allowed to expand or modify bed capacity.

SUBCHAPTER 2. NOVEL CORONAVIRUS REPORTS

310:517-2-1. Specimens to be sent to the Public Health Laboratory

Hospitals and laboratories must send, at a minimum, 10% of their weekly positive novel coronavirus specimens to the OSDH Public Health Laboratory for variant testing. The collection, packaging, and shipping of the positive novel coronavirus specimen must be in accordance with OSDH Public Health Laboratory guidelines.

310:517-2-2. Emergency reporting requirements

(a) Every practicing physician and clinical laboratory that is utilizing, or has utilized, an FDA-approved test,including an emergency use authorization test, for human diagnostic purposes of novel coronavirus, shall submit reports to OSDH in a manner, format, and frequency prescribed by the State Commissioner of Health of all test results, both positive and negative.

(b) Hospitals and Physician Clinics operating in the State of Oklahoma shall submit the following critical datato OSDH in a manner, format, and frequency prescribed by the State Commissioner of Health:

(1) The number of patients in the hospital receiving treatment for novel coronavirus;

(2) The number of patients receiving treatment for novel coronavirus who are currently admitted to the ICU; and

(3) The novel coronavirus vaccination status of patients in the hospital receiving treatment for novel coronavirus.

(c) All reports required by this section 310:5-1-10 must be submitted electronically to OSDH in digital form that is created, distributed and retrievable by a computer system. Electronic records generated according to these requirements shall be in the manner and format prescribed by the State Commissioner of Health.

(d) This rule shall be active and remain in effect when there is a federal or state declaration of emergency related to novel coronavirus or until the State Commissioner of Health determines the reporting is no longer needed.

SUBCHAPTER 3. HOSPITAL LICENSED BED CAPACITY

310:667-3-1. Procedures to expand or modify licensed bed capacity

(a) A hospital's licensed bed capacity can be expanded and/or modified, if it submits a letter to the Department that is signed by an authorized hospital authority, notarized and includes the following statements:

(1) the hospital attests that its emergency preparedness plan includes the expanded and/ or modified bed plan and is approved by its governing body;

(2) the hospital attests the location of the modified and/or expanded beds. The location must include:

(A) the building name and floor number if the modified and/or expanded beds are on the hospital's campus; or

(B) the physical address if the modified and/or expanded beds are not on the hospital's campus.

(3) if the hospital is also participating in Centers for Medicare & Medicaid Services' (CMS) Hospital Without Walls program (program), then the hospital attests:

(A) that its governing body has approved of its participation in the program;

(B) that it is participating in accordance with CMS requirements; and

(C) that the portions of the program that it is participating in is not in conflict with state statute.

(b) Licensed capacity refers to the total number and type of beds a hospital stated in the Hospital Designation of Licensed Beds Form (Form 929) filed with the Department.

(c) This rule is limited to hospitals licensed by the Commissioner of Health.

(d) This rule does not affect a hospital's obligation to comply with requirements of other regulatory bodies.

(e) This rule is effective until the Commissioner of Health determines that the need for hospitals to exceed and/or modify their licensed bed capacity is no longer needed.