

**TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 567. STATE CENTRAL CANCER REGISTRY**

RULEMAKING ACTION:

Notice of proposed PERMANENT rulemaking.

PROPOSED RULES:

Chapter 567. State Central Cancer Registry [AMENDED]

SUMMARY:

The proposed updates to OAC 310:567 will clean up language to make the rule clearer, including removing unnecessary language as well as incorporating statute by reference. This proposal is in response to the Governor's Executive Order 2020-03.

AUTHORITY:

Commissioner of Health, Title 63 O.S. § 1-104, 63 O.S. § 1-551.1

COMMENT PERIOD:

November 16, 2020, through December 16, 2020, interested persons may informally discuss the proposed rules with the contact person identified below; or may, through December 16, 2020, 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 16, 2020, via WebEx accessible from the site www.publichearings.health.ok.gov, from 9AM to noon. The alternate date and time in the event of extreme inclement weather is December 18, 2020, via WebEx accessible from the site www.publichearings.health.ok.gov, from 9AM to noon. Those wishing to present oral comments should be registered to speak by 9:15 a.m. Directions for comment registration will be provided on the website. The hearing will close at the conclusion of comments from those registered to speak. Interested persons may attend for the purpose of orally submitting data, views, or concerns 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 December 16, 2020, 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, 1000 N. E. 10th Street, Oklahoma City, OK 73117-1207, phone (405) 271-9444 ext.56535, e-mail AudreyT@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 567. STATE CENTRAL CANCER REGISTRY

1. **DESCRIPTION:**

With legal authority per Oklahoma State Statute 63-1-551.1, beginning in 1997, all Oklahoma healthcare facilities that diagnose and/or treat patients for cancer are required to report to the Oklahoma Central Cancer Registry. The updates to this rule, 310:567, are a direct result of the Governor's Executive Order 2020-03. The proposed changes clean up language to ensure the rule is transparent and effective, including incorporation by reference and removing unnecessary or outdated language.

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

The proposed changes do not impact cancer reporters, as they are simply language changes. There are no potential fiscal impacts from the proposed changes.

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

The language is now more clear and concise for those cancer reporters throughout the state. Additionally, all Oklahomans may benefit from a cleaner version of the Cancer Registry rule.

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

There are no known potential fiscal or economic impacts, cost of compliance, or fee changes.

5. **COST AND BENEFITS OF IMPLEMENTATION AND ENFORCEMENT TO THE AGENCY.**

There are no costs associated with implementation.

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 RULE:

There are no less costly means currently identified.

9. EFFECT ON PUBLIC HEALTH AND SAFETY:

There is no known impact or effect on public health and safety, as the proposed amendments to the rule are simple language changes.

10. DETRIMENTAL EFFECTS ON PUBLIC HEALTH AND SAFETY WITHOUT ADOPTION:

There are no known detrimental effects on public health and safety without the adoption of this proposal to amend the language of this rule to make it more clear and concise.

11. PREPARATION AND MODIFICATION DATES:

This rule impact statement was prepared on October 2, 2020.

**TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 567. STATE CENTRAL CANCER REGISTRY**

SUBCHAPTER 1. GENERAL PROVISIONS

310:567-1-2. Definitions

The following words or terms, when used in this Chapter, shall have the following meaning, unless the context clearly indicates otherwise:

"Cancer diseases" means a general term frequently used to indicate any of various types of malignant neoplasms, most of which invade surrounding tissues, may metastasize to several sites, and are likely to recur after attempted removal and to cause death of the patient unless adequately treated; especially, any such carcinoma or sarcoma, but in ordinary usage, especially the former.

"Clinic" means any licensed facility serving persons on an out-patient basis which provides diagnostic and/or treatment of cancerous diseases and precancerous conditions.

"Commissioner" means the Oklahoma Commissioner of Health.

"Confidentiality pledge" ~~means a legal document acknowledging the confidential and sensitive nature of personal data stored in the State Central Cancer Registry which prohibits the release of registry data without the written consent of the Commissioner of Health.~~

"Department" means the Oklahoma State Department of Health.

"Dentist" means a person trained in the diagnosis, treatment and prevention of diseases of the teeth and related structures of the oral cavity who is licensed by the Board of Governors Registered Dentists State of Oklahoma and qualified to practice dentistry.

"Diagnostic services" means any service which entails the diagnosis of a cancerous disease or precancerous condition, including such services as those provided by Oncologists, Pathologists, Radiologists, and surgeons.

"Facility" means any licensed or certified medical facility or establishment which provides diagnostic and/or treatment services for cancerous diseases and precancerous conditions.

"Histology" means the microscopic description of the type of cells in the specimen examined pathologically. The components of the histology ~~shall~~ include but are not limited to: Morphology, Behavior, and Grade.

"Hospital" means any medical facility licensed by the state to provide medical care on an in-patient or out-patient basis for the diseases of cancer, for precancerous conditions, or for early detection services related to the detection and treatment of cancerous and precancerous conditions.

"Hospital identifier" means a unique code assigned to each hospital in the state which serves to uniquely identify each hospital in the State Central Cancer Registry, to assure the proper assignment of cancer data to the correct hospital.

"In situ" means local within the original place, or a growth of abnormal cells which is detected in its anatomic site of origin.

"Laboratory" means any accredited or certified laboratory which provides cytopathology services for defining the degree of abnormality of cells related to both cancerous and precancerous conditions.

"Pathologist" means any person who is licensed by the State and has board certification to perform pathology and performs the scientific study of the nature of disease, its causes, processes, development, and consequences. This includes the study of the anatomic or functional manifestations of cancerous disease and precancerous conditions.

"Pathology laboratory identifier" means a unique code assigned to an approved medical laboratory which provides cytopathology services for defining the behavior and degree of abnormality of a patient's laboratory specimen.

"Physician" means any person who has completed a course of medical training, has received a degree and is licensed by the Oklahoma State Board of Medical Licensure or the Oklahoma Osteopathic Board of Examiners to practice medicine.

"Precancerous condition" means exhibiting a likelihood of becoming cancerous.

"Registry" means a computerized system for collecting and compiling cancer data in a standard format, with the functional ability to merge data from various sources and perform correlations between a variety of data elements within the system. The Registry is also designed to produce summary reports and statistical analysis reports of the data contained in the Registry.

"Stage of disease" means terms frequently used to describe stage of disease: localized (if limited to the primary site), regional (if the disease has spread to adjacent organs or tissues and/or regional lymph nodes), and distant (if the cancer has spread to distant organs or nodes.)

"TNM" means the summary stage of a tumor, "T" meaning tumor, "N" meaning nodes and "M" meaning metastasis.

"Treatment services" means any type of treatment delivery for cancerous disease or precancerous conditions, performed in a medical facility on an out-patient or in-patient basis.

"Tumorous" means a circumscribed, non-inflammatory growth arising from existing tissue but growing independently of the normal rate or structural development of such tissue and serving no physiological function.

SUBCHAPTER 3. REPORTING

310:567-3-3. Methods of reporting

- (a) The reporting of cancer may be done through automated hospital tumor registries.
- (b) If the hospital does not have an automated cancer registry, cancer cases are to be reported manually in the form of case abstracts.
- (c) If a biopsy was performed as an out-patient procedure, the pathology laboratory shall report any cases of cancer, or conditions defined in ~~section~~ 310:567-3-2.
- (d) By January 1, 1997, all Oklahoma reporting sources shall be initiated. The Oklahoma Central Cancer Registry ~~shall have as its~~ reference date is January 1, 1997.
- (e) All hospitals, clinics, laboratories, pathologists, physicians or dentists, or all facilities providing diagnostic or treatment services in relation to cancer diseases or precancerous conditions, shall report:
 - (1) all cancer within 180 days of diagnosis or treatment
 - (2) and all cancers occurring in patients under 20 years of age within 30 days of diagnosis or treatment.
- (f) All hospitals, clinics, laboratories, pathologists, physicians or dentists, or all facilities providing diagnostic or treatment services in relation to cancer diseases or precancerous conditions, shall have capability to perform quality edits so that all cancer data reported to the Oklahoma Central Cancer Registry meets the 100% accuracy standard.

SUBCHAPTER 5. CONFIDENTIALITY AND USE OF DATA

310:567-5-1. Confidentiality of registry data

~~—The Commissioner shall protect the identity of the patient and physician involved in any report required by this act and may not release their identity without written consent, except that: The Commissioner may grant any person involved in a legitimate research activity access to confidential information obtained by the Department concerning individual patients if:~~

- ~~—(1) the research activity is determined to be in the interest of public health and welfare;~~
- ~~—(2) the person conducting the research provides written information about the purpose of the research project, the nature of the data to be collected and how the researcher intends to analyze it, the records the researcher wishes to review, and the safeguards the researcher will take to protect the identity of patients whose records the researcher will be reviewing;~~
- ~~—(3) the proposed safeguards are adequate to protect the identity of each patient whose records will be reviewed; and~~

~~— (4) an agreement is executed between the Commissioner of Health and the researcher that specifies the researcher's use of the records and prohibits the publication or release of the names of individual cancer patients or any facts tending to lead to the identification of individual cancer patients (and their physicians). [63:1-551.1(C)]~~

In accordance with 63 O.S. Section 1-551.1(D), the Commissioner has a duty to protect the identity of patients and physicians involved in any report for the State Cancer Registry. The Commissioner also has the authority to determine if a legitimate research activity allows for access to confidential patient information by satisfying 63 O.S. Section 1-551.1(D)(1).

310:567-5-3. Reciprocity agreements with other registries

(a) In accordance with 63 O.S. Section 1-551.1(D)(3), ~~The~~ the Commissioner may enter into reciprocity agreements with other governmental cancer registries for the purpose of sharing of cancer data.

(b) Shared cancer data cannot be used for any purpose other than non-confidential summary statistics of cancer, or related purposes, without a separate agreement of confidentiality, ~~as defined in section 310:567-5-2.~~