RULEMAKING ACTION:
PERMANENT final adoption

RULES:
310:567-1-2. [AMENDED]
Subchapter 3. Reporting
310:567-3-3. [AMENDED]
Subchapter 5. Confidentiality and Use of Data
310:567-5-1. [AMENDED]

AUTHORITY:
Commissioner of the Oklahoma State Department of Health; 63 O.S. § 1-104

SUBMISSION OF PROPOSED RULES TO GOVERNOR AND CABINET SECRETARY:
October 20, 2020

COMMENT PERIOD:
November 16, 2020 through December 16, 2020

PUBLIC HEARING:
December 18, 2020

ADOPTION:
January 25, 2021

SUBMISSION OF ADOPTED RULES TO GOVERNOR AND LEGISLATURE:
January 25, 2021

LEGISLATIVE APPROVAL:
Approved June 11, 2021 by HJR 1046

FINAL ADOPTION:
June 11, 2021

EFFECTIVE:
September 11, 2021

SUPERSEDED EMERGENCY ACTIONS:
n/a

INCORPORATIONS BY REFERENCE:
n/a

GIST/ANALYSIS:
The amendments edit and revise 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. The proposed changes do not impact cancer reporters, as they are simply language changes. The language is now clearer and more concise for cancer reporters throughout the state.

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PURSUANT TO THE ACTIONS DESCRIBED HEREIN, THE FOLLOWING RULES ARE CONSIDERED FINALLY ADOPTED AS SET FORTH IN 75 O.S., SECTIONS 250.3 (5) AND 308 (E), WITH AN EFFECTIVE DATE OF SEPTEMBER 11, 2021
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 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.