

**RULES
OF
TENNESSEE DEPARTMENT OF HEALTH
BUREAU OF HEALTH INFORMATICS
TENNESSEE CANCER REGISTRY**

**CHAPTER 1200-07-02
CANCER REPORTING SYSTEM**

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1200-07-02-.01 PURPOSE

- (1) The purpose of these regulations is to provide for the implementation of the Tennessee Cancer Reporting System Act of 1983 and its amendments requiring all hospitals, laboratories, facilities, and health care practitioners, as defined in the Act, to report certain cancer data to the Department of Health, as well as to provide for the confidentiality of certain data, and for the data to be made available to the public.

Authority: T.C.A. §§4-5-202 and 68-1-1001 et seq. **Administrative History:** Original rule filed October 6, 1986; effective November 20, 1986. Amendment filed September 5, 1990; effective October 20, 1990. Repeal and new rule filed February 1, 2002; effective April 17, 2002.

1200-07-02-.02 AUTHORITY

- (1) The regulations are issued under the authority granted the Commissioner of the Tennessee Department of Health under the Cancer Reporting System Act of 1983 and its amendments, hereinafter referred to as the Act.

Authority: T.C.A. §§4-5-202 and 68-1-1001 et seq. **Administrative History:** Original rule filed October 6, 1986; effective November 20, 1986. Repeal and new rule filed February 1, 2002; effective April 17, 2002.

1200-07-02-.03 DEFINITIONS

- (1) "Cancer" means and includes, but is not limited to:
 - (a) a large group of diseases characterized by uncontrolled growth and spread of abnormal cells;
 - (b) any condition of tumors having the properties of anaplasia, invasion, and metastasis;
 - (c) a cellular tumor, the natural course of which is fatal;
 - (d) malignant neoplasm; and
 - (e) in-situ cancer.
 - (f) brain-related tumor.

(Rule 1200-07-02-.03, continued)

- (2) Brain-related tumor means a listed primary tumor (whether malignant or benign) occurring in any of the following sites:
 - (a) The brain, meninges, spinal cord, cauda equina, a cranial nerve or nerves, or any other part of the central nervous system.
 - (b) The pituitary gland, pineal gland or craniopharyngeal duct.
- (3) "Commissioner" means the Commissioner of the Department of Health.
- (4) "Data" shall mean the original information contained on the report required by the regulations, including, but not limited to, both identifying and non-identifying information.
- (5) "Department" shall mean the Tennessee Department of Health, or "department," as used in the Act.
- (6) "Facility" means a health care facility in which diagnosis or treatment services are provided to patients with cancer, including, but not limited to, an ambulatory surgical treatment center, a freestanding cancer treatment center, a radiation therapy center, a chemotherapy treatment center, a nursing home, an oncology or dermatology clinic, a laboratory, or any other facility which provides screening, detection, diagnostic or therapeutic services to patients with cancer.
- (7) "Health care practitioner" means a physician, surgeon, or other health care professional licensed under T.C.A. Title 63 who is engaged in diagnosing and/or treating patients who have cancer.
- (8) "Hospital" means an institution as defined by T.C.A. 68-11-201.
- (9) "Identifying information" means any information that could lead to the identification of a patient who has been diagnosed or treated for cancer.
- (10) "In situ cancer" means an abnormality of the development and organization of cells without the invasion of neighboring tissue. Examples of in situ cancers include, but are not limited to:
 - (a) Cervical Intraepithelial Neoplasia (CIN) II lesions; and
 - (b) Cervical Intraepithelial Neoplasia (CIN) III lesions.
- (11) "Laboratory" means a facility where tests are performed identifying anatomical and cytological changes, and where specimens are interpreted and pathological diagnoses are made.
- (12) "Medical records" shall include, but not be limited to, pathology reports, cytology reports, radiology reports, and disease index for both inpatients and outpatients.
- (13) "Person" means any member of the "medical, scientific, and academic research community."
- (14) "Policies and Procedures Manual" means the document(s) maintained in the offices of the Tennessee Cancer Registry giving specific written instructions for the implementation of policies and procedures utilized by the Registry and which may be updated from time to time.
- (15) "Tennessee Cancer Registry" or "Registry" or "TCR" shall mean the program in the Tennessee Department of Health that administers a population-based statewide cancer registry.

(Rule 1200-07-02-.03, continued)

Authority: T.C.A. §§4-5-202, 4-5-209, 68-1-1001 et seq., 68-1-1002, 68-1-1003(a) and 68-1-1004.

Administrative History: Original rule filed October 6, 1986; effective November 20, 1986. Amendment filed September 5, 1990; effective October 20, 1990. Repeal and new rule filed February 1, 2002; effective April 17, 2002. Public necessity rule filed August 3, 2007; effective through January 15, 2008. Amendment filed August 28, 2007; effective December 28, 2007. Amendment filed August 25, 2009; effective November 23, 2009.

1200-07-02-.04 PARTICIPATION IN THE PROGRAM

- (1) All hospitals, laboratories, facilities and health care practitioners shall report data concerning Tennessee patients who are diagnosed and/or treated for cancer.
- (2) Health care practitioners are not required to report data on cancer patients who are directly referred to or have been previously admitted to a hospital or a facility for cancer diagnosis or treatment.
- (3) All hospitals, laboratories, facilities and health care practitioners shall designate one (1) staff member to be responsible for reporting the cancer data and shall notify the department of the name, title, work address, work telephone number, and e-mail address (if available) of the designated staff member.

Authority: T.C.A. §§4-5-202 and 68-1-1001 et seq. **Administrative History:** Original rule filed October 6, 1986; effective November 20, 1986. Amendment filed September 5, 1990; effective October 20, 1990. Repeal and new rule filed February 1, 2002; effective April 17, 2002.

1200-07-02-.05 CANCER CASE REPORTING

- (1) Reportable Cancer Cases
 - (a) Any newly diagnosed in-situ or invasive cancer as defined by the TCR Policies and Procedures Manual is considered a reportable diagnosis. If a patient subsequently develops a new primary cancer, it shall be reported separately.
- (2) Format for Reporting
 - (a) The format for reporting, the required codes, and the standards for completeness and quality are defined by the department in the TCR Policies and Procedures Manual.
- (3) Data Items to be Reported
 - (a) The standardized report of cancer shall include as a minimum those data items required by the Tennessee Cancer Registry, a list of which is maintained in the TCR Policies and Procedures Manual. The report of cancer shall include the listed demographic, diagnostic, and treatment data as defined by the department.
- (4) Deadline for Reporting
 - (a) Reporting shall occur no later than six months after the date of diagnosis of cancer in a patient. Reports shall be submitted to the department according to a time frame communicated by the department to each hospital, facility, laboratory, and health care practitioner.
- (5) Failure to Report

(Rule 1200-07-02-.05, continued)

- (a) A hospital, laboratory, facility, or health care practitioner that fails to report data or allow access to records, as required by T.C.A. 68-1-1003, shall be informed in writing by the department that compliance is mandatory.
 - (b) If a hospital, laboratory, facility, or health care practitioner fails to provide the required data in the format specified by the department or if the data are of unacceptable quality, the Commissioner or the Commissioner's authorized representative may enter the facility to casefind and abstract the information. In these cases, the facility shall reimburse the department for the actual cost of casefinding, abstracting, coding and editing, a maximum of which is fifty dollars (\$50) per case. A hospital, laboratory, facility or health care practitioner from whom reimbursement is sought may appeal the assessment of expenses under the Tennessee Uniform Administrative Procedures Act. The appeal shall be to the Commissioner in writing and within thirty (30) days of receipt of the assessment.
- (6) Quality Assurance
- (a) Staff members from the Tennessee Cancer Registry or their agents shall perform periodic quality assurance studies at all reporting facilities. These studies shall include:
 - 1. casefinding to ensure that all cancer cases have been accessioned; and
 - 2. reabstracting the records of cancer patients to ensure that all data have been transcribed and coded correctly.
 - (b) Reporting facilities shall assist TCR staff by providing the necessary medical records and the office space for conducting quality assurance activities.
 - (c) In order to improve the quality of the data, the TCR or their agents shall offer training for reporting facility personnel.

Authority: T.C.A. §§4-5-202 and 68-1-1001 et seq. **Administrative History:** Original rule filed October 6, 1986; effective November 20, 1986. Amendment filed September 5, 1990; effective October 20, 1990. Repeal and new rule filed February 1, 2002; effective April 17, 2002.

1200-07-02-.06 CONFIDENTIALITY

- (1) T.C.A. 68-1-1006 provides for the confidentiality of data obtained from the reports of cancer patients.
- (2) TCR Responsibilities
 - (a) The commissioner shall take strict measures to ensure that all patient identifying information is treated as confidential and privileged. All employees or consultants, including auditors of the TCR, shall sign a Tennessee Cancer Registry Employee Confidentiality Pledge and these signed pledges shall be kept on file. An employee or consultant who discloses confidential identifying information willfully or through negligence is subject to penalty, including, but not limited to, the penalty in T.C.A. 68-1-1009.
- (3) Protection of Report Sources
 - (a) Hospitals, laboratories, facilities, or health care practitioners who disclose cancer data to the Tennessee Cancer Registry or its employees in conformity with the Cancer Reporting System Act of 1983 and its amendments shall not be held liable for the release of such data to the department.

(Rule 1200-07-02-.06, continued)

- (4) Protection of Patient Identifying Information Obtained by Special Studies and Other Research Studies
 - (a) All identifying information such as records of interviews, questionnaires, reports, statements, notes, and memoranda that are procured or prepared by employees or agents of the Tennessee Cancer Registry shall be used solely for statistical, scientific and medical research purposes and shall be held strictly confidential by the TCR. This applies also to identifying information procured by any other person, agency, or organization, including public or private colleges and universities acting jointly with the TCR in connection with special cancer studies and health research investigations.

Authority: T.C.A. §§4-5-202 and 68-1-1001 et seq. **Administrative History:** Original rule filed October 6, 1986; effective November 20, 1986. Amendment filed July 14, 1989; effective August 28, 1989. Amendment filed September 5, 1990; effective October 20, 1990. Repeal and new rule filed February 1, 2002; effective April 17, 2002.

1200-07-02-.07 RELEASE OF DATA

- (1) Release of non-identifying information
 - (a) To federal agencies:
 1. The TCR is authorized to collaborate with the National Program of Cancer Registries (NPCR), the Centers for Disease Control and Prevention (CDC), and the National Cancer Institute (NCI) to provide cancer incidence statistics and participate in cancer studies.
 - (b) To the Tennessee Department of Health
 1. The Tennessee Cancer Registry shall work closely with the Tennessee Department of Health in investigating cancer-related issues and in evaluating programs. Because the TCR data are an integral part of the Tennessee Department of Health cancer prevention and control programs, the use of Registry data by public health officials shall be considered an in-house activity. Data required by the Tennessee Department of Health for responding to concerns expressed about threats to the public health shall receive priority in determining the order of processing requests.
 - (c) To the general public:
 1. Public reports published by the Tennessee Cancer Registry shall include aggregate, not patient identifying information or facility identifying information. Information that would potentially identify a cancer patient shall not be published. Non-identifying information may be made available to the general public upon request to the department. The availability of any data shall depend upon the department's financial or other ability to comply with such requests. The Registry shall respond to public requests as quickly as possible, subject to staffing constraints.
 - (d) To Others:
 1. The TCR is authorized to collaborate with the North American Association of Central Cancer Registries (NAACCR) to provide cancer incidence statistics and participate in cancer studies.

(Rule 1200-07-02-.07, continued)

- (2) Release of identifying information
 - (a) Identifying information collected from any hospital, laboratory, facility, or health care practitioner may be released to qualified persons for the purposes of cancer prevention, control, and research, provided that each request for identifying information follows the established procedure outlined in the TCR Policies and Procedures Manual and receives prior approval by the department. Identifying information that is collected solely by the Tennessee Cancer Registry for its own special studies shall not be released.
- (3) Annual Report
 - (a) A statistical report shall be prepared at the completion of each year's data collection cycle and will be distributed as requested.
- (4) Interstate Exchange of Data
 - (a) Because cancer patients may be diagnosed or receive treatment in another state, the Commissioner or the Commissioner's authorized representative is authorized to sign agreements with other states to acquire cancer data concerning Tennessee residents and, in return, to provide those states with data relating to their residents. Each signatory state shall agree in writing to keep all patient data confidential and privileged as defined in the contract for data exchange, a copy of which is included in the TCR Policies and Procedures Manual.

Authority: T.C.A. §§4-5-202 and 68-1-1001 et seq. **Administrative History:** Original rule filed October 6, 1986; effective November 20, 1986. Amendment filed September 5, 1990; effective October 20, 1990. Repeal and new rule filed February 1, 2002; effective April 17, 2002.

1200-07-02-.08 REQUEST PROCEDURE FOR PATIENT IDENTIFYING INFORMATION

- (1) Requests for identifying information shall be reviewed and approved by the department according to the policies of the Tennessee Department of Health and the Tennessee Cancer Registry.
- (2) The Tennessee Cancer Registry shall review requests for identifying information and shall recommend to the Commissioner whether to approve or deny any identifying information request. The Commissioner shall approve or deny any identifying information request after considering the reason for such request and the planned use of the identifying information.
- (3) A detailed description of the procedures for requesting identifying information can be obtained from the Tennessee Cancer Registry.

Authority: T.C.A. §§4-5-202 and 68-1-1001 et seq. **Administrative History:** Original rule filed February 1, 2002; effective April 17, 2002.