

**Department of State Health Services**  
**Council Agenda Memo for State Health Services Council**  
**August 17-18, 2016**

**Agenda Item Title:** Amendments to rules concerning the operation of the Cancer Registry.

**Agenda Number:** 4.b.

**Recommended Council Action:**

For Discussion Only

For Discussion and Action by the Council

**Background:**

The Texas Cancer Registry (TCR) is the cancer incidence reporting system administered by the Cancer Epidemiology and Surveillance Branch, located in the Epidemiology and Disease Registries Section of the Division for Disease Control and Prevention Services.

The TCR is a population-based registry that serves as the foundation for measuring the burden of cancer in Texas. The TCR collects, maintains, and disseminates complete, accurate, and quality cancer data. The information collected by the TCR includes the type and site of diagnosed cancers, cancer stage, the kinds of treatment patients receive, survival of patients following cancer diagnosis, and patient characteristics. This information is used to measure comprehensive cancer control efforts, health disparities, and progress in prevention, diagnosis, treatment, survival, and quality of life for cancer patients. The registry also supports a wide variety of cancer-related research. The TCR has achieved and maintained the Centers for Disease Control and Prevention (CDC) National Program of Central Cancer Registries (NPCR) high quality data standards since 2003, and national certification from the North American Association of Central Cancer Registries (NAACCR) since 2006.

The program receives approximately \$1.8 million in federal funding through CDC, \$3 million from the Cancer Prevention and Research Institute of Texas (CPRIT), and \$500,000 in State general revenue funds.

**Summary:**

The purpose of the rule amendment is to implement House Bill (HB) 2641, 84<sup>th</sup> Legislature, Regular Session, 2015, which amended Health and Safety Code §82.008, authorizing the submission of data through a health information exchange, and provide updated language to enhance the understanding of the program rules for the cancer registry. The rules implement Health and Safety Code, Chapter 82, Cancer Registry, and outline the purpose of the cancer registry, including who, what, where, when, and how to report cancer data to the cancer registry, as well as compliance, confidentiality, quality assurance, and requests for data.

TCR rules do not currently provide for the receipt of individual patient cancer data from health care providers who choose to submit cases via a health information exchange. The rule revision will provide the additional option for health care providers to report using health information exchanges. Persons, entities, or other organizations that may be impacted by this rule, if they choose to submit cases via a health information exchange, include: health care practitioners, health care facilities, Veteran's Administration and Department of Defense health care facilities, health information exchanges, and Texas cancer reporters. The rule amendment has no negative impact to these individuals and facilities.

The review of the rules also implement the four year review of agency rules required by Government Code, §2001.039.

**Key Health Measures:**

The impact of the rule change will be measured by tracking the number of health care providers submitting data to the TCR through a health information exchange and the number of cancer reports submitted through health information exchange to the TCR.

**Summary of Input from Stakeholder Groups:**

TCR shared the proposed rule amendment with many diverse stakeholders and received minimal feedback. Stakeholders asked to comment included: Advisory Committee to the Texas Cancer Registry, Cancer Alliance of Texas, Texas Health Services Authority, Texas eHealth Alliance, health information exchanges, Texas Tumor Registrars Association, health care providers, Texas cancer reporters, veterans hospitals and health care facilities in Texas.

One stakeholder commented regarding the proposed rules allowing providers to utilize a health information exchange to receive reports back from the registry, specifically regarding §91.12(b)(1), and to meet the “long-term goal of bi-directional exchange” with health information exchanges. In consideration of this stakeholder feedback, the proposed rule amendment includes health information exchanges in the definition of a “reporting entity,” and as such could potentially receive records previously submitted to the registry.

**Proposed Motion:**

Motion to recommend HHSC approval for publication of rules contained in agenda item # 4.b.

**Approved by Assistant Commissioner/Director:** Janna Zumbrun **Date:** 7-21-16

**Presenter:** Heidi Bojes, Ph.D. **Program:** Environmental Epidemiology and Disease Registries Section **Phone No.:** 512-776-6351

**Approved by CPEA:** Carolyn Bivens **Date:** 7/25/16

Title 25. HEALTH SERVICES  
Part 1. DEPARTMENT OF STATE HEALTH SERVICES  
Chapter 91. Cancer  
Subchapter A. Cancer Registry  
Amendments §91.2, §91.4, §91.6, §91.7, §91.9, §91.11, §91.12

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission, on behalf of the Department of State Health Services (department), proposes amendments to §91.2, §91.4, §91.6, §91.7, §91.9, §91.11 and §91.12, concerning the operation of the Texas Cancer Registry.

BACKGROUND AND PURPOSE

The purpose of the amendments is to implement House Bill (HB) 2641, 84th Legislature, Regular Session, 2015, which amended Health and Safety Code, §82.008, authorizing the submission of data through a health information exchange, and provide updated language of adopted rules to enhance the understanding of the program rules for the Texas Cancer Registry. The amendments will provide the additional option for health care providers to report data through a health information exchange.

The rules implement Health and Safety Code, Chapter 82, Cancer Registry, and outlines the purpose of the Texas Cancer Registry, including who, what, where, when, and how to report cancer data to the cancer registry, as well as compliance, confidentiality, quality assurance, and requests for data.

Government Code, §2001.039, requires that each state agency review and consider for re-adoption each rule adopted by that agency pursuant to the Government Code, Chapter 2001 (Administrative Procedure Act). Sections 91.1 - 91.12 have been reviewed and the department has determined that reasons for adopting the sections continue to exist because rules on this subject are needed.

SECTION-BY-SECTION SUMMARY

The amendments to §91.2 include deleting the definition of "branch" and replacing references to the "branch" with "Texas Cancer Registry" or "Department of State Health Services;" this change was preemptive as the Health and Human Services Transformation may affect future organizational structure. Additionally, the definition of "personal cancer data" was deleted and replaced with a new definition of "confidential cancer data" to better clarify distinctions in the types of data. In addition, a new definition for "reporting entity" was added to provide context for amendments related to health information exchange as a result of the passage of HB 2641, as well as subsequent reordering and renumbering of section.

The amendments to §91.4 include replacing references to "branch" with "Texas Cancer Registry."

The amendments to §91.6 include adding language to subsection (a) to allow for the submission of data to the Texas Cancer Registry through a health information exchange.

The amendments to §91.7 include replacing the reference to "branch" with "Texas Cancer Registry."

The amendments to §91.9 include inserting "cancer" in subsection (c) to clarify the requests for confidential or statistical cancer data.

The amendments to §91.11 include replacing references to "branch" with "Texas Cancer Registry," removing the phrase "and printed," and adding an email address contact in subsection (a) as another method of requesting information or cancer data. In subsection (b)(3), the word "sent" was replaced with "submitted" to be consistent with rule text.

The amendments to §91.12 include adding an email address contact, replacing a reference to "Institutional Review Board" with the "Texas Cancer Registry" in the mailing address in subsection (a)(1). The references to "branch" are being replaced with "Texas Cancer Registry." The name of §91.12 is revised to "Requests and Release of Confidential Cancer Data" and throughout the rule, "confidential cancer data" is replacing the references to "personal cancer data."

#### FISCAL NOTE

Heidi Bojes, PhD, MPH, Section Director, Environmental Epidemiology and Disease Registries Section has determined that for each year of the first five years that the sections will be in effect, there will be no fiscal implications to state or local governments as a result of enforcing and administering the sections as proposed.

#### SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Dr. Bojes has also determined that there would be no adverse impact on small businesses or micro-businesses required to comply with the sections as proposed. This was determined by interpretation of the rules that small businesses and micro-businesses will not be required to alter their business practices in order to comply with the sections as proposed. Therefore, an economic impact statement and regulatory flexibility analysis for small and micro-businesses are not required.

#### ECONOMIC COSTS TO PERSONS AND IMPACT ON LOCAL EMPLOYMENT

There are no anticipated economic costs to persons who are required to comply with the sections as proposed. There is no anticipated negative impact on local employment.

#### PUBLIC BENEFIT

In addition, Dr. Bojes has also determined that for each year of the first five years the sections are in effect, the public will benefit from adoption of the sections. The public benefit anticipated as a result of enforcing or administering the sections is that it encourages health information exchange connectivity and interoperability.

#### REGULATORY ANALYSIS

The department has determined that this proposal is not a "major environmental rule" as defined by Government Code, §2001.0225. "Major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

#### TAKINGS IMPACT ASSESSMENT

The department has determined that the proposed amendments do not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking under Government Code, §2007.043.

#### PUBLIC COMMENT

Comments on the proposal may be submitted to Ashley Dixon, MPH, Cancer Epidemiology and Surveillance Branch, Mail Code 1928, Department of State Health Services, P.O. Box 149347, Austin, Texas 78714-9347, (512) 776-3629, or by email to ashley.dixon@dshs.state.tx.us. Comments will be accepted for 30 days following publication of the proposal in the *Texas Register*.

#### LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Lisa Hernandez, certifies that the proposed rules have been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

#### STATUTORY AUTHORITY

The amendments are authorized Health and Safety Code, §82.008 which provides the department with the authority to accept submissions of data through a health information exchange; and Government Code, §531.0055, and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001. Review of the rules implements Government Code, §2001.039.

The amendments affect Government Code, Chapter 531; and Health and Safety Code, Chapters 82 and 1001.

Title 25. Health Services  
Part 1. Department of State Health Services  
Chapter 91. Cancer  
Subchapter A. Cancer Registry

Legend: (Proposed Amendments)

Single Underline = Proposed new language

**[Bold, Print, and Brackets]** = Current language proposed for deletion

Regular Print = Current language

(No change.) = No changes are being considered for the designated subdivision.

§91.2. Definitions.

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Act--The Texas Cancer Incidence Reporting Act, Texas Health and Safety Code, Chapter 82.

**[(2) Branch--Cancer Epidemiology and Surveillance Branch of the department.]**

(2) **[(3)]** Cancer--Includes a large group of diseases characterized by uncontrolled growth and spread of abnormal cells; any condition of tumors having the properties of anaplasia, invasion, and metastasis; a cellular tumor the natural course of which is fatal, including intracranial and central nervous system malignant, borderline, and benign tumors as required by the national program of cancer registries; and malignant neoplasm, other than non-melanoma skin cancers such as basal and squamous cell carcinomas.

(3) **[(4)]** Cancer Reporting Handbook--The Texas Cancer Registry's [branch's] manual for cancer reporters that documents reporting procedures and format.

(4) **[(5)]** Clinical laboratory--An accredited facility in which tests are performed identifying findings of anatomical changes; specimens are interpreted and pathological diagnoses are made.

(5) Confidential cancer data--Information that includes items that may identify an individual, and is subject to Health and Safety Code, §82.009.

(6) Department--Department of State Health Services.

(7) Health care facility--A general or special hospital as defined by the Health and Safety Code, Chapter 241; an ambulatory surgical center licensed under the Health and Safety Code, Chapter 243; an institution licensed under the Health and Safety Code, Chapter 242; or any other facility, including an outpatient clinic, that provides diagnostic or treatment services to patients with cancer.

(8) Health care practitioner--A physician as defined by Occupations Code, §151.002 or a person who practices dentistry as described by the Occupations Code, §251.003.

**[(9) Personal cancer data--Information that includes items that may identify an individual.]**

(9) [(10)] Quality assurance--Operational procedures by which the accuracy, completeness, and timeliness of the information reported to the department can be determined and verified.

(10) [(11)] Report--Information provided to the department that notifies the appropriate authority of the occupancy of a specific cancer in a person, including all information required to be provided to the department.

(11) Reporting Entity--A reporting entity may include a health care facility, clinical laboratory, health care practitioner, or a health information exchange as defined by Health and Safety Code, §182.151.

(12) Research--A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

(13) Statistical cancer data--Aggregate presentation of individual records on cancer cases excluding patient identifying information.

(14) Texas Cancer Registry--The cancer incidence reporting system administered by the Department of State Health Services [Cancer Epidemiology and Surveillance Branch].

#### §91.4. What to Report.

##### (a) Reportable conditions.

(1) The cases of cancer to be reported to the Texas Cancer Registry [branch] are as follows:

(A) all neoplasms with a behavior code of two or three in the most current edition of the International Classification on Diseases for Oncology (ICD-O) of the World Health Organization with the exception of those designated by the Texas Cancer Registry [branch] as non-reportable in the Cancer Reporting Handbook; and

(B) all benign and borderline intracranial and central nervous system neoplasms as required by the national program of cancer registries.

(2) Codes and taxa of the most current edition of the International Classification of Diseases, Clinical Modification of the World Health Organization which correspond to the Texas Cancer Registry's [branch's] reportable list are specified in the Cancer Reporting Handbook.

##### (b) Reportable information.

(1) Except as provided in paragraph (2) of this subsection and health care practitioners in §91.5(c) of this title (relating to When to Report), those data required to be reported for each cancer case shall include:

(A) name, address, zip code, and county of residence;

(B) social security number, date of birth, gender, race and ethnicity, marital status, birthplace, and primary payer at time of diagnosis, to the extent such information is available from the medical record;

(C) information on industrial and occupational history, smoking status, height and weight to the extent such information is available from the medical record;

(D) diagnostic information including the cancer site and laterality, cell type, tumor behavior, markers, grade and size, stage of disease, date of diagnosis, diagnostic confirmation method, sequence number, and other primary tumors;

(E) first course of cancer-related treatment, including dates and types of procedures;

(F) text information to support cancer diagnosis, stage and treatment codes;

(G) health care facility or practitioner related information including reporting institution number, casefinding source, type of reporting source, medical record number, registry number, tumor record number, class of case, date of first contact, date of last contact, vital status, facility referred from, facility referred to, managing physician, follow-up physician, date abstracted, abstractor, and electronic record version; and

(H) clinical laboratory related information including laboratory name and address, pathology case number, pathology report date, pathologist, and referring physician name and address.

(2) The department or its authorized representative may exempt a cancer reporter from providing specific reportable data items delineated in paragraph (1) of this subsection to the extent that those data to be exempted are not collected by the cancer reporter.

(3) Except as provided in §91.6(b) of this title (relating to How to Report), each report shall:

(A) be electronically readable and contain all data items required in paragraph (1) of this subsection;

(B) be fully coded and in a format prescribed by the Texas Cancer Registry **[branch]**;

(C) meet all quality assurance standards utilized by the Texas Cancer Registry **[branch]**;

(D) in the case of individuals who have more than one form of cancer, be submitted separately for each primary cancer diagnosed;

(E) be submitted to the Texas Cancer Registry **[branch]** electronically; and

(F) be transmitted by secure means at all times to protect the confidentiality of the data.

#### §91.6. How to Report.

(a) Reports of cancer from health care facilities, clinical laboratories and health care practitioners shall be submitted to the Texas Cancer Registry [branch] electronically using a secure electronic process as defined by the department. At the request and with the authorization of the applicable health care facility, clinical laboratory, or health care practitioner, data may be furnished to the Texas Cancer Registry through a health information exchange.

(b) The Texas Cancer Registry may accept the submission of paper copies of medical records from a health care facility, pathology reports from a clinical laboratory and reports or subsets of reports from a health care practitioner under the following conditions.

(1) The department, or its authorized representative, shall determine that such paper submissions are more expedient than electronic reporting.

(2) The acceptance of paper submissions from a health care facility, clinical laboratory or health care practitioner shall be approved by the department or its authorized representative.

(3) The department, or its authorized representative, may approve acceptance of paper submissions from defined groups or types of health care facilities, clinical laboratories or health care practitioners.

(4) All records and reports provided to the Texas Cancer Registry pursuant to this subsection must be transmitted by secure means at all times to protect the confidentiality of the data.

#### §91.7. Where to Report.

Data reports should be submitted to the Texas Cancer Registry [branch] as specified in the Cancer Reporting Handbook.

#### §91.9. Confidentiality and Disclosure.

(a) Pursuant to the Act, Chapter 82, §82.009, all data obtained is for the confidential use of the department and the persons or entities, public or private, that the department determines are necessary to carry out the intent of the Act.

(b) Limited release of the data is allowed by the Act, §82.008(h) and §82.009(b).

(c) Any requests for confidential or statistical cancer data shall be made in accordance with §§91.11 or 91.12 of this title (relating to Cancer Registry).

(d) The Texas Cancer Registry is subject to state law that requires compliance with portions of the federal law and regulations cited in §91.3(e) of this title (relating to Who Reports, Access to Records). The department is authorized to use and disclose, for purposes described in the Act, cancer data without patient consent or authorization under 45 C.F.R §164.512(a) relating to uses and disclosures required by law, §164.512(b)(1) and (2) relating to uses and disclosures for public health activities, and §164.512(i) relating to uses and disclosures for research purposes.

#### §91.11. Requests for Statistical Cancer Data.

(a) Statistical cancer data previously analyzed [**and printed**] are available upon written or oral request to the Texas Cancer Registry [branch]. All other requests for statistical cancer data shall be in writing and directed to: Texas Cancer Registry [Cancer Epidemiology and Surveillance Branch], Mail Code 1928, Department of State Health Services, P.O. Box 149347, Austin, Texas 78714-9347 or CancerData@dshs.state.tx.us.

(b) To ensure that the proper data are provided, the request shall include, but not be limited to, the following information:

(1) name, address, and telephone number of the person requesting the information;

(2) type of data needed and for what years (e.g. lung cancer incidence rates, Brewster County, 1998 - 2002); and

(3) name and address of person(s) to whom data and billings are to be submitted [sent] (if applicable).

#### §91.12. Requests and Release of Confidential [Personal] Cancer Data.

(a) Data requests for research.

(1) Requests for confidential [personal] cancer data shall be in writing and directed to: Texas Cancer Registry, Mail Code 1928, Department of State Health Services, [Institutional Review Board (IRB),] P.O. Box 149347, Austin, Texas 78714-9347 or CancerData@dshs.state.tx.us.

(2) Written requests for confidential cancer [personal] data shall meet the submission requirements of the department's Institutional Review Board (IRB) [IRB] before release.

(3) The Texas Cancer Registry [branch] may release confidential [personal] cancer data to state, federal, local, and other public agencies and organizations if approved by the IRB.

(4) The Texas Cancer Registry [branch] may release confidential [personal] cancer data to private agencies, organizations, and associations if approved by the IRB.

(5) The Texas Cancer Registry [branch] may release confidential [personal] cancer data to any other individual or entities for reasons deemed necessary by the department to carry out the intent of the Act if approved by the IRB.

(b) Data requests for non-research purposes.

(1) The Texas Cancer Registry [branch] may provide reports containing confidential cancer [personal] data back to the respective reporting entity from records previously submitted to the Texas Cancer Registry [branch] from each respective reporting entity for the purposes of case management and administrative studies. These reports will not be released to any other entity.

(2) The Texas Cancer Registry [branch] may release confidential cancer [personal] data to other areas of the department, provided that the disclosure is required or authorized by law. All communications of this nature shall be clearly labeled "Confidential" and will follow established departmental internal protocols and procedures.

(3) The Texas Cancer Registry **[branch]** may release confidential **[personal]** cancer data to state, federal, local, and other public agencies and organizations in accordance with subsection (a) of this section.

(4) The Texas Cancer Registry **[branch]** may release confidential **[personal]** cancer data to any other individual or entities for reasons deemed necessary to carry out the intent of the Act and in accordance with subsection (a) of this section.

(5) An individual who submits a valid authorization for release of an individual cancer record shall have access to review or obtain copies of the information described in the authorization for release.