APPENDIX B

Texas Cancer Incidence Reporting Act and Texas Cancer Incidence Reporting Rules

The Law
Chapter 82, Health and Safety Code
(amended September 1, 2001)

Section 82.001. Short Title

This Chapter may be cited as the Texas Cancer Incidence Reporting Act.

Section 82.002. Definition

In this chapter:

(1) Cancer includes:
  (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, including malignant and benign tumors of the central nervous system; and
  (D) malignant neoplasm, other than nonmelanoma skin cancers such as basal and squamous cell carcinomas.
(2) Clinical laboratory means an accrediated facility in which:
  (A) tests are performed identifying findings of anatomical changes; and
  (B) specimens are interpreted and pathological diagnoses are made.
(3) Health care facility means:
  (A) a general or special hospital as defined by Chapter 241 (Texas Hospital Licensing Law);
  (B) an ambulatory surgical center licensed under Chapter 243;
  (C) an institution licensed under Chapter 242; or
  (D) any other facility, including an outpatient clinic, that provides diagnosis or treatment services to patients with cancer.
(4) Health care practitioner means:
  (A) a physician as defined by Section 151.002, Occupations Code; or
  (B) a person who practices dentistry as described by Section 251.003, Occupations Code.

Section 82.003. Applicability of Chapter

This chapter applies to records of cases of cancer, diagnosed on or after January 1, 1979, and to records of all ongoing cancer cases diagnosed before January 1, 1979.

Section 82.004. Registry Required

The board shall maintain a cancer registry for the state.

Section 82.005. Content of Registry

(a) The cancer registry must be a central data bank of accurate, precise, and current information that medical authorities agree serves as an invaluable tool in the early recognition, prevention, cure, and control of cancer.
(b) The cancer registry must include:
    (1) a record of the cases of cancer that occur in the state; and
    (2) information concerning cancer cases as the board considers necessary and appropriate for the recognition, prevention, cure, or control of cancer.

Section 82.006. Board Powers

To implement this chapter, the board may:

(1) adopt rules that the board considers necessary;
(2) execute contracts that the board considers necessary;
(3) receive the data from medical records of cases of cancer that are in the custody or under the control of clinical laboratories, health care facilities, and health care practitioners to record and analyze the data directly related to those diseases;
(4) compile and publish statistical and other studies derived from the patient data obtained under this chapter to provide, in an accessible form, information that is useful to physicians, other medical personnel, and the general public;
(5) comply with requirements as necessary to obtain federal funds in the maximum amounts and most advantageous proportions possible;
(6) receive and use gifts made for the purpose of this chapter; and
(7) limit cancer reporting activities under this chapter to specified geographic areas of the state to ensure optimal use of funds available for obtaining the data.

Section 82.007. Annual Report

(a) The department shall publish an annual report to the legislature of the information obtained under this chapter.
    (b) The department, in cooperation with other cancer reporting organizations and research institutions may publish reports the department determines are necessary or desirable to carry out the purpose of this chapter.

Section 82.008. Data From Medical Records

(a) To ensure an accurate and continuing source of data concerning cancer, each health care facility, clinical laboratory, and health care practitioner shall furnish to the board or its representative, on request, data the board considers necessary and appropriate that is derived from each medical record pertaining to a case of cancer that is in the custody or under the control of the health care facility, clinical laboratory, or health care practitioner. The department may not request data that is more than three years old unless the department is investigating a possible cancer cluster.

(b) A health care facility, clinical laboratory, or health care practitioner shall furnish the data requested under Subsection (a) in a reasonable format prescribed by the department and within six months of the patient's admission, diagnosis, or treatment for cancer unless a different period is prescribed by the United States Department of Health and Human Services.

(c) The data required to be furnished under this section must include patient identification and diagnosis.

(d) The department may access medical records that would identify cases of cancer, establish characteristics or treatment of cancer, or determine the medical status of any identified patient from the following sources:
   (1) a health care facility or clinical laboratory providing screening, diagnostic, or therapeutic services to a patient with respect to cancer; or
   (2) a health care practitioner diagnosing or providing treatment to a patient with cancer, except as described by Subsection (g).

(e) The board shall adopt procedures that ensure adequate notice is given to the healthcare facility, clinical laboratory, or health care practitioner before the department accesses data under Subsection (d).

(f) A health care facility, clinical laboratory, or health care practitioner that knowingly or in bad faith fails to furnish data as required by this chapter shall reimburse the department or its authorized representative for the costs of accessing and reporting the data. The costs reimbursed under this subsection must be reasonable, based on the actual costs incurred by the department or by its authorized representative in the collection of data under Subsection (d), and may include salary and travel expenses. The department may assess a late fee on an account that is 60 days or more overdue. The late fee may not exceed one and one-half percent of the total amount due on the late account for each month or portion of a month the account is not paid in full. A health care facility, clinical laboratory, or health care practitioner may request that the department conduct a hearing to determine whether reimbursement to the department under this subsection is appropriate.

(g) The department may not require a health care practitioner to furnish data or provide access to records if:
   (1) the data or records pertain to cases reported by a health care facility providing screening, diagnostic, or therapeutic services to cancer patients that involve patients referred directly to or previously admitted to the facility; and
   (2) the facility reported the same data the practitioner would be required to report.

(h) The data required to be furnished under this section may be shared with cancer registries of health care facilities subject to the confidentiality provisions in Section 82.009.

Section 82.009. Confidentiality

(a) Reports, records, and information obtained under this chapter are confidential and are not subject to disclosure under Chapter 552, Government Code, are not subject to subpoena, and may not otherwise be released or made public except as provided by this section or Section 82.008(h). The reports, records, and information obtained under this chapter are for the confidential use of the department and the persons or public or private entities that the department determines are necessary to carry out the intent of this chapter.

(b) Medical or epidemiological information may be released:
  (1) for statistical purposes in a manner that prevents identification of individuals, health care facilities, clinical laboratories, or health care practitioners;
  (2) with the consent of each person identified in the information; or
  (3) to promote cancer research, including release of information to other cancer registries and appropriate state and federal agencies, under rules adopted by the board to ensure confidentiality as required by state and federal laws.

(c) A state employee may not testify in a civil, criminal, special, or other proceeding as to the existence or contents of records, reports, or information concerning an individual whose medical records have been used in submitting data required under this chapter unless the individual consents in advance.

(d) Data furnished to a cancer registry or a cancer researcher under Subsection (b) or Section 82.008 (h) is for the confidential use of the cancer registry or the cancer researcher, as applicable, and is subject to Subsection (a).

Section 82.010. Immunity From Liability

The following persons subject to this chapter that act in compliance with this chapter are not civilly or criminally liable for furnishing the information required under this chapter:

(1) a health care facility or clinical laboratory;
(2) an administrator, officer, or employee of a health care facility or clinical laboratory
(3) a health care practitioner or employee of a health care practitioner; and
(4) an employee of the department.

Section 82.011. Examination and Supervision Not Required

This chapter does not require an individual to submit to any medical examination or supervision or to examination or supervision by the board or its representatives.

This Act takes effect September 1, 2001.

The Rules
Title 25, Health Services
Part I. Texas Department of Health
Chapter 91. Cancer
Subchapter A. Cancer Registry

§91.1. Purpose.

These sections implement the Texas Cancer Incidence Reporting Act, Health and Safety Code, Chapter 82, that authorizes the Texas Board of Health to adopt rules concerning the reporting of cases of cancer for the recognition, prevention, cure or control of those diseases, and to facilitate participation in the national program of cancer registries established by 42 United States Code §§280e to 280e-4. Nothing in these sections shall preempt the authority of facilities or individuals providing diagnostic or treatment services to patients with cancer to maintain their own cancer registries.

§91.2. Definitions.

The following words and terms, when used in these sections, 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) **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 malignant and benign tumors of the central nervous system; and malignant neoplasm, other than non-melanoma skin cancers such as basal and squamous cell carcinomas.
(3) **Cancer reporting handbook** - The division's manual for cancer reporters that documents reporting procedures and format.
(4) **Clinical laboratory** - An accredited facility in which tests are performed identifying findings of anatomical changes; specimens are interpreted and pathological diagnoses are made.
(5) **Department** - Texas Department of Health.
(6) **Division** - Cancer Registry Division of the department.
(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.

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

(11) **Regional cancer registry** - The organization authorized by the department to receive and collect cancer data for a designated area of the state and which maintains the system by which the collected information is reported to the department.

(12) **Regional director** - The physician who is the chief administrative officer of a public health region and is designated by the department under the Local Public Health Reorganization Act, Health and Safety Code, §121.007.

(13) **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.

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

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

(16) **Texas Cancer Registry** - The cancer incidence reporting system administered by the Cancer Registry Division.

§91.3. Who Reports, Access to Records.

(a) Each health care facility, clinical laboratory or health care practitioner shall report to the department, by methods specified in §§91.4-91.7 of this title (relating to Cancer Registry), required data from each medical record pertaining to a case of cancer in its custody or under its control except for cases to which subsection (d) of this section would apply.

(b) A health care facility or clinical laboratory providing screening, diagnostic or therapeutic services to patients with cancer shall grant the department or its authorized representative access to but not removal of all medical records which would identify cases of cancer, establish characteristics or treatment of cancer, or determine the medical status of any identified cancer patient.

(c) A health care practitioner providing diagnostic or treatment services to patients with cancer shall grant the department or its authorized representative access to but not removal of all medical records which would identify cases of cancer, establish characteristics or treatment of cancer, or determine the medical status of any identified cancer patient except for cases to which subsection (d) of this section would apply.

(d) The department may not require a health care practitioner to furnish data or provide access to records if:

(1) the data or records pertain to cases reported by a health care facility providing screening, diagnostic, or therapeutic services to cancer patients that involve patients referred directly to or previously admitted to the facility; and

(2) the facility reported the same data the practitioner would be required to report.

(e) Health care facilities, clinical laboratories, and health care practitioners are subject to federal law

known as the Health Insurance Portability and Accountability Act of 1996 found at Title 42 United States Code §1320d et seq.; the federal privacy rules adopted in Title 45 Code of Federal Regulations (C.F.R.) Parts 160 and 164; and state law found in the Health and Safety Code, Chapter 181, Medical Records Privacy, §181.101. Because state law requires reporting of cancer data, persons subject to this chapter are permitted to provide the data to the department without patient consent or authorization under 45 C.F.R. §164.512(a) relating to uses and disclosures required by law and §164.512(b)(1) relating to disclosures for public health activities. Both of these exceptions to patient consent or authorization are recognized in the state law in Health and Safety Code, §181.101.

§91.4. What to Report.

(a) Reportable conditions.
  (1) The cases of cancer to be reported to the division 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 division as non-reportable in the cancer reporting handbook; and
    (B) all benign and borderline neoplasms of the central nervous system.
  (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 division's reportable list are specified in the cancer reporting handbook.

(b) Reportable information.
  (1) The 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, and birthplace, to the extent such information is available from the medical record;
    (C) information on industrial or occupational history, to the extent such information is available from the medical record;
    (D) diagnostic information including the cancer site and laterality, cell type, tumor behavior, 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 treatment codes, unless another method acceptable to the division is used to confirm these codes;

(G) health care facility or practitioner related information including reporting institution number, 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, institution referred from, institution referred to, date abstracted, abstractor, and electronic record version; and

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

(2) Each report shall:

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

(B) be in a format prescribed by the division;

(C) meet all quality assurance standards utilized by the division;

(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 division electronically, or manually if electronic means are unavailable; and the annual cancer caseload of the health care facility, clinical laboratory or health care practitioner is 50 or fewer cases; and

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

§91.5. When to Report.

(a) All reports shall be submitted to the department within six months of the patient's admission, initial diagnosis or treatment for cancer.

(b) Data shall be submitted no less than quarterly by health care facilities with annual caseloads of 400 or less. Monthly submissions are required for all other health care facilities.

(c) Data shall be submitted no less than quarterly by health care practitioners initially diagnosing a patient with cancer and performing the in-house pathological tests for that patient. Otherwise, data shall be submitted within 4 months of the request to a health care practitioner by the department or its authorized representative for a report or subset of a report on a patient diagnosed or treated elsewhere and for whom the same cancer data has not been reported.

(d) Data shall be submitted no less than bi-annually by clinical laboratories.

§91.6. How to Report.

A report of cancer can be made to the department by any of the following methods:

(1) submission of an original of a completed Confidential Cancer Reporting Form (TCR No.1) if

electronic means are unavailable and the annual cancer caseload of the health care facility, clinical laboratory or health care practitioner is 50 or fewer cases; or

(2) submission electronically of a TCR No. 1 or a subset of data items acceptable to the division using one of the following methods:

(A) three and one half inch disk;
(B) compact disc;
(C) computer modem transmission; or
(D) the Internet.

§91.7. Where to Report.

(a) Forms. All counties shall be assigned by the division to a regional cancer registry. Completed forms shall be submitted to the regional director or his designee at the regional cancer registry designated to receive data from the county where the person with cancer is admitted, diagnosed or treated.

(b) All electronic data reports should be submitted to the division as specified in the cancer reporting handbook.

§91.8. Compliance.

(a) Each health care facility, clinical laboratory or health care practitioner that reports to the department, by methods specified in §§91.4-91.7 of this title (relating to Cancer Registry), is considered compliant.

(b) A person will be notified in writing if the person has not reported in compliance with this chapter within 30 days following the end of the calendar year quarter and will be given an opportunity to take corrective action within 60 days from the date of the notification letter. A second notification letter will be sent 30 days after the date of the original notification letter if no corrective action has been taken.

(c) If a person is non-compliant and takes no corrective action within 60 days of the original notification letter, the department or its authorized representative may access the information from the health care facility, clinical laboratory or health care practitioner as provided in §91.3 of this title (relating to Who Reports, Access to Records) and report it in the appropriate format.

(1) The health care facility, clinical laboratory or health care practitioner shall be notified at least two weeks in advance before a scheduled arrival for collection of the information.

(2) A health care facility, clinical laboratory or health care practitioner that knowingly or in bad faith fails to furnish data as required by this chapter shall reimburse the department or its authorized representative for its cost to access and report the information. The costs must be reasonable, based on the actual costs incurred by the department or by its authorized representative in the collection of the data and may include salary and travel expenses. It is presumed that a health facility, clinical laboratory or health care practitioner acted knowingly or in bad faith if it failed to take corrective action within 60 days of the date of the original

notification letter.

(3) A health care facility, clinical laboratory or health care practitioner may request the department to conduct a hearing under the department's fair hearing rules to determine whether reimbursement to the department is appropriate.

(d) Any health care facility, clinical laboratory or health care practitioner which is required to reimburse the department or its authorized representative for the cost to access and report the information pursuant to subsection (c)(2) of this section shall provide payment to the department or its authorized representative within 60 days of the day this payment is demanded. In the event any health care facility, clinical laboratory or health care practitioner fails to make payment to the department or its authorized representative within 60 days of the day the payment is demanded, the department or its authorized representative may, at its discretion, assess a late fee not to exceed 1-1/2 % per month of the outstanding balance.

§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 public or private entities 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 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 the Health and Safety Code, Chapter 181, Medical Records Privacy, §181.101 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.

§91.10. Quality Assurance.

The department shall cooperate and consult with persons required to comply with this chapter so that such persons may provide timely, complete and accurate data. The department will provide:

(1) reporting training, on-site case-finding studies, and reabstracting studies;

(2) quality assessment reports to ascertain that the computerized data utilized for statistical information and data compilation is accurate; and

(3) educational information on cancer morbidity and mortality statistics available from the Texas Cancer Registry and the department**.**

§91.11. Requests for Statistical Cancer Data.

(a) Statistical cancer data previously analyzed and printed are available upon written or oral request to the division. All other requests for statistical data shall be in writing and directed to: Cancer Registry Division, Texas Department of Health, 1100 West 49th Street, Austin Texas 78756-3199.

(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, 1992-1995); and

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

§91.12. Requests and Release of Personal Cancer Data.

(a) Data requests for research.

(1) Requests for personal cancer data shall be in writing and directed to: Texas Department of Health, Institutional Review Board (IRB), 1100 West 49th Street, Austin, Texas 78756-3199.

(2) Written requests for personal data shall meet the submission requirements of the department's IRB before release.

(3) The division may release personal cancer data to state, federal, local, and other public agencies and organizations if approved by the IRB.

(4) The division may release personal cancer data to private agencies, organizations, and associations if approved by the IRB.

(5) The division may release 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 division may provide reports containing personal data back to the respective reporting entity from records previously submitted to the division 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 division may release personal data to other bureaus 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 division may release personal data to the department's Cancer Registry Program personnel headquartered in public health regions or public health departments to facilitate the collection, editing, and analysis of cancer registry data for the respective geographic area.
All communications of this nature shall be clearly labeled "Confidential" and will follow established departmental internal protocols and procedures.

(4) The division may release personal cancer data to state, federal, local, and other public agencies and organizations in accordance with subsection (a) of this section.
(5) The division may release personal cancer data to any other individual or entities for reasons deemed necessary by the board to carry out the intent of the Act and in accordance with subsection (a) of this section.
(6) A person 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.

Effective Date: April 24, 2003