

(S. B. 1000)

(No. 113-2010)

(Approved July 30, 2010)

AN ACT

To create the “Puerto Rico Central Cancer Registry Act”; repeal Act No. 28 of March 20, 1951, as amended; and for other purposes.

STATEMENT OF MOTIVES

During the past decade, significant objectives have been achieved with regards to cancer control in Puerto Rico. Such achievement is the result of combined education, prevention, early detection, and treatment efforts. Puerto Rico has been at the forefront of cancer control and research on the causes and factors of this disease since the mid 20th century, when the Cancer Control Program of the Department of Health of Puerto Rico was established. Act No. 28 of March 20, 1951, was approved to increase our knowledge about cancer epidemiology in Puerto Rico and to entrust the Program with the mission of gathering, analyzing, and publishing data on all cancer cases of Puerto Rico residents. Thus, the Puerto Rico cancer surveillance system, one of the oldest in the world, was created. The aforesaid Act made it mandatory to report all cases of cancer, carcinoma, lymphoma (including Hodgkin’s disease), sarcoma, leukemia, or any other malignant growth or neoplastic disease to the Cancer Control Program of the Department of Health of Puerto Rico. Such reporting was required from every physician, hospital administrator, or person in charge of a public or private hospital, among others. The Cancer Control Program of the Department of Health of Puerto Rico was eventually divided into two components: the Puerto Rico Central Cancer Registry and the Early Cancer Detection Program, which ceased to

exist years ago. However, the Puerto Rico Central Cancer Registry continued to be attached to the Department of Health. In July 2008, the administration of the Puerto Rico Central Cancer Registry was transferred to the Comprehensive Cancer Center of the University of Puerto Rico through a memorandum of understanding.

The National Cancer Institute was founded in 1973[sic]. The Surveillance, Epidemiology, and End Results program (SEER), which is the U.S. cancer surveillance system, was entrusted to such Institute, and the Puerto Rico Central Cancer Registry was invited to join. SEER is a model program that collects data on cancer cases from certain states and defined geographic areas that are representative of the demographics of the entire U.S. population. As part of this system, the Puerto Rico Central Cancer Registry received Federal grants from 1973 until 1989, when the Island's participation concluded. During such time, treatment for the vast majority of cancer patients was provided only in a few facilities, which had to report to the Registry. Even though the responsibility to report to the Registry always rested on the entities that provided diagnosis and treatment to patients, the Registry had to send personnel to collect case information from such facilities, as well as medical offices, in order to meet SEER program participation requirements. The loss of the SEER funds, which represented the main source of income of the Registry, resulted in a loss of personnel and of the Registry's ability to keep up with technological developments in the field of health information.

The SEER program did not gather information from each and every cancer case in the Nation, but only from certain defined regions which covered about one fourth of the population. To create a surveillance system with cancer registries in every state and territory, the 102nd Congress promulgated Public Law 102-515, known as the "Cancer Registries Amendment Act," in October of 1992. Such

Public Law sought to establish a national program of state registries to collect data for each type of in situ and invasive cancer.

Advances in modern medicine and the changes introduced by the Health Reform allowed cancer patients to receive services in almost every institution in the Island, as well as outpatient diagnostic, treatment, or follow-up service in many medical offices, centers, and others. However, these amendments are still not enough for our Registry to receive case reports in accordance with the completeness, timeliness, and quality standards set by Federal law, thus causing a significant delay.

The Comprehensive Cancer Center was created by virtue of Act No. 230 of August 26, 2004, to be the entity responsible for executing the public policy regarding prevention, education, research, and rendering of clinical services and related cancer treatments in Puerto Rico. The powers and duties of the Comprehensive Cancer Center of the University of Puerto Rico include maintaining an updated register of cancer incidence and mortality in the Island. For such reason, to streamline the Registry's operation and achieve the goal of improving the quality of data for scientific research to optimum levels, the Comprehensive Cancer Center requested the Department of Health to grant them the administration of the Puerto Rico Central Cancer Registry.

'Cancer' is a term used for diseases in which abnormal cells divide without control and are able to invade other tissues, thus spreading to other parts of the body. When these conditions are not diagnosed or treated on time, serious complications, and ultimately death, may ensue.

Currently, one third of men and one fourth of women in Puerto Rico will suffer from cancer at some point in their lives. Today, tens of thousands of people live with cancer or have suffered from the disease. The risk of developing most types of cancer may be reduced by making changes in lifestyle, such as quit

smoking, limiting sun exposure, exercising, and eating a balanced diet. The earlier cancer is diagnosed or treated, the better chances will a patient have to survive many years.

A cancer registry is an epidemiologic surveillance system designed to determine cancer incidence and distribution. Such information is essential for planning and evaluating the impact of cancer programs and treatment, as well as for studying risk factors and conducting cancer research. The information is obtained through an active search of cancer case data in facilities where research, diagnosis, or treatment of cancer patients occurs. In such cases, health information privacy regulations protect the privacy of certain individually identifiable health data, which is referred to as protected health information. Balancing the protection of individual health information with the need to protect public health, the Privacy Rule (HIPAA) expressly permits disclosure without individual authorization to public health authorities allowed by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to public health surveillance, investigation, and intervention. Cancer reporting is included in this definition. HIPAA does not impair any state law that supports or directs the reporting of disease or injury for public health purposes.

One of the main purposes of the Puerto Rico Central Cancer Registry is to describe the clinical, histological, and sociodemographic characteristics of cancer cases diagnosed in the Island, as well as its areas of incidence. Furthermore, it seeks to create an updated incidence and mortality database that allows for comparative analyses on cancer behavior at a national and international level. It also serves to determine the burden of cancer in our population and assess the impact of social policies related to cancer prevention programs on the Island.

Considering that cancer is the second cause of death in Puerto Rico and that technological and health advances have evolved dramatically during the past years,

it is meritorious to establish a new Act that addresses the needs of the Puerto Rico Central Cancer Registry and allows it to collect all the demographic, clinical, and follow-up information of every cancer case diagnosed and treated in the Island, in accordance with the regulations that govern health information management and sharing. The accuracy, precision, and reporting of such information within the established time frames shall allow to join the necessary efforts to address cancer diagnoses in a timely manner and reduce cancer mortality in Puerto Rico.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF PUERTO RICO:

Article 1. – Title

This Act shall be known and may be cited as the “Puerto Rico Central Cancer Registry Act.”

Article 2. – Purpose

The Puerto Rico Central Cancer Registry shall be attached to the Comprehensive Cancer Center of the University of Puerto Rico. It shall be in charge of handling and maintaining an optimal cancer surveillance system in order to process, analyze, and disclose information regarding cancer incidence and mortality in the Island in accordance with the highest standards of quality and compliance, as established by national and Commonwealth agencies that regulate cancer data and information. This Registry shall keep a database of all patients diagnosed with, treated for, or deceased due to cancer in Puerto Rico.

Article 3. – Powers and Duties

The Registry shall have the following powers and duties:

1. To determine the annual incidence of cancer in Puerto Rico by age group, sex, ethnicity, anatomical location, histological type, and stage of the disease. Likewise, it shall provide case distribution statistics based on the aforementioned variables.
2. To study trends over time, as well as the incidence and mortality of different types of tumors by geographic area in Puerto Rico.
3. To identify population groups with a higher risk of suffering the disease, and help plan and evaluate control activities for this pathology.
4. To advance and conduct epidemiologic research and facilitate basic and clinical cancer research.
5. To guide planning and evaluation of cancer control programs, as well as promote the disclosure of relevant epidemiologic information for cancer prevention.
6. To maintain a database of cancer incidence and mortality information.
7. To maintain the physical and electronic security, as well as the confidentiality of the information gathered and stored in accordance with the applicable confidentiality standards and laws.
8. To provide decision-making support in the development of early detection and prevention strategies for all types of cancer, and assist in setting priorities for allocating health resources.
9. To publish cancer data in such format and groupings as necessary to prevent potential identification of a particular cancer case.

10. To maintain the necessary agreements with Federal and Commonwealth agencies that regulate cancer information and data, such as the National Program of Cancer Registries created under the Federal Public Health Service Act, the National Cancer Institute, and any other national cancer surveillance regulatory agency to ensure compliance with its responsibilities.

11. To meet the appropriate national standards on completeness, timeliness, and quality of reporting established for population-based registries.

12. To issue a Certificate of Compliance to those hospital institutions, clinics, laboratories, medical offices, diagnostic centers, and radiology centers that comply with the provisions of this Act.

13. To submit an Annual Report to the Legislative Assembly on the financial status and administrative operation of the Registry, on or before June 30 of each year.

Article 4. – Requirement to Report to the Registry

Section 1. – It shall be required to report to the Puerto Rico Central Cancer Registry any case of cancer, carcinoma, lymphoma (including Hodgkin's disease), sarcoma, leukemia, benign and malignant tumor in the central nervous system, or any other malignant growth or neoplastic disease, as well as any other related information as required by Regulations to. Such report shall be filed within thirty (30) days after the entity's first contact with the patient for clinical or pathological diagnosis, advice about treatment options, or treatment of such condition. The following parties shall be required to report the cases to the Registry through the means and in the medium or format required by Regulations:

a. Administrators or persons in charge of public or private hospitals; outpatient clinics; radiation therapy facilities; cancer, oncology, and chemotherapy centers; or any other institution or organization that provides diagnostic or treatment services to cancer patients;

b. Physicians, surgeons, dentists, and any other health professionals diagnosing or providing treatment to cancer patients, or who are sought for advice regarding treatment options for such patients;

c. Administrators or persons in charge of clinics, nursing homes, rest homes, hospices, and any other similar institution with cancer patients under its care or custody.

Section 2. - It shall be required to report to the Puerto Rico Central Cancer Registry every pathology, cytology, or bone marrow report; autopsy; clinical laboratory result; pathological reviews, tumor markers, imaging studies, and any other clinical, laboratory, or pathology report that is consistent with clinical diagnosis, or that shows, confirms, or contributes to the specific diagnosis or the determination of the extent of the disease at the time of diagnosis of any case of cancer, carcinoma, lymphoma (including Hodgkin disease), sarcoma, leukemia, benign tumors in the central nervous system, or any other malignant growth or neoplastic disease, as well as any other information related to the diagnosis or extent of the condition within thirty (30) days following such diagnosis or test. The following parties shall be required to report the cases to the Registry using the selection criteria and through the means, and in medium or format established by the Registry through Regulations:

- a. Private or public pathology and clinical laboratories;
- b. Dermatopathologists;
- c. Hematologic and medical oncologists who diagnose any of the conditions described in this Section;
- d. Any other center where tests are conducted to prove or confirm that a person suffers a reportable condition pursuant to this Act.

Section 3. – In the case that a physician, surgeon, dentist, or any other health professional who provides a diagnosis, sends the tumor specimen or sample to be analyzed or studied in laboratories outside Puerto Rico, which are not subject to the law of Puerto Rico, it shall be mandatory for these persons to send a copy of the microscopic examination report to the Registry within thirty (30) days as of the date of the report, through the means and in the medium or format prescribed by the Registry through Regulations.

Section 4. – Cases of basal cell or squamous cell carcinoma, as well as carcinoma in situ of the cervix, shall not be reported to the Registry, with certain exceptions as established through Regulations.

Section 5. – In the case of administrators or persons in charge of private or public clinics, nursing homes, rest homes, hospices, or other similar institutions with cancer patients under their care or custody shall also report to the Registry about the condition of the patient, as well as the treatment administered, in the format and medium and with the frequency prescribed to such effect through Regulations, in strict confidentiality and for statistical purposes only.

Section 6. – Every entity subject to the reporting requirement under this Act shall allow the Registry to access records, admission records, disease indices, or any other physical or electronic document that the Registry deems necessary to identify or complete each and every cancer case or to establish cancer characteristics, treatment, or status of any identified cancer patient. Such

information shall be kept under strict confidentiality by the Registry. Records shall be accessed in accordance to Federal and Commonwealth patient confidentiality laws.

Section 7. – The Registry shall periodically carry out audits to ensure complete identification of cancer cases and to validate the data submitted to the Registry, as required by national and Commonwealth agencies that regulate cancer data and information, with the purpose of assessing quality and full reporting of cases.

Article 5. – Reporting

Section 1. – The Registry shall establish the data elements it deems necessary to guarantee compliance with its duties and responsibilities as set forth herein, as well as with Federal and Commonwealth regulatory agency requirements. Said elements shall also be established to conduct epidemiologic studies aimed at researching the presence and effect of risk factors related to cancer.

Section 2. – The Registry shall gather the following information from medical and other documents for each case of in situ or invasive cancer or benign or malignant tumors of the central nervous system:

1. Demographic data on the age, ethnicity, and sex of the cancer patient;
2. Data on clinical history;
3. Administrative information, including date of diagnosis and data source;
4. Diagnostic data and related studies;
5. Data on the characteristic pathology of such cancer, including its location, stage, and extent;
6. Specific data on treatment;
7. Follow-up data;

8. Any other information required by the Registry for statistical purposes only.

Section 3. – Case reports shall be sent in electronic format using programs designed for reporting cancer cases which have been supplied or approved by the Registry. Likewise, entities required to report shall send such data through the means and in the medium and format that the Registry deems more appropriate to guarantee the confidentiality, safety, and integrity thereof.

Section 4. – The Registry shall be in charge of evaluating and training the personnel designated by the entity for case reporting, and shall certify the person when he/she is qualified for reporting thereto. It shall be the responsibility of the reporting entity to designate persons with the minimum necessary qualifications, as established through Regulations, to be trained for this task.

Section 5. – The Registry shall establish the methods, criteria, and additional requirements to ensure the optimum quality of the data through training, certification, evaluation, and any other methods it deems necessary therefor.

Article 6. – Penalties

Section 1. – Every entity, person, physician, or institution that fails to comply with the provisions of this Act or the Regulations promulgated thereunder shall be sanctioned by the Registry, for the first violation, by an administrative fine of three thousand dollars (\$3,000) per unreported case and, for subsequent violations, by an administrative fine of five thousand dollars (\$5,000) per unreported case.

Section 2. – The Registry shall request the suspension of any license issued by the Department of Health, for a term of not less than six (6) months, to any physician, health professional, or institution that fails to comply with Section 1 of this Article.

Section 3. – Any entity, person, physician, or institution that fails to submit complete, accurate, and timely reports for two consecutive quarters, regardless of the reason, and has not shown progress in terms of compliance, shall allow the Registry to immediately access medical records and other documents. The Registry shall collect the data and demand the reimbursement of expenses incurred in obtaining such data, up to \$100 per collected case, in addition to the corresponding fines.

Section 4. - Any entity, person, physician, or institution that, while rendering services under Act No. 72 of September 7, 1993, which creates the Puerto Rico Health Insurance Administration, fails to comply with the provisions of this Act, shall have any payments for services rendered withheld and any future contract negotiation with the Administration shall be stayed until the data is reported to the Registry and any fines or administrative expenses imposed by the same are paid. The Registry may arrange with the Health Insurance Administration for the collection of debts on account of fines and administrative expenses set forth herein to be paid from the income that such entities, persons, physicians, or institutions would earn for services rendered.

Section 5. – Special Fund of the Registry

Sums collected on account of administrative fines and reimbursement of expenses incurred in gathering the data of unreported cases, as set forth in this Article, shall be covered into the Special Fund of the Registry, to be used

exclusively by the Registry. This Fund shall be administered by the Registry and governed by the Regulations promulgated by the Registry under Article 19 of this Act.

Section 6. – Any person who provides false information to the Registry shall be guilty of fourth-degree felony.

Article 7. – Confidentiality

Section 1. – Information provided to the Registry that can or may be used to identify a particular cancer patient shall be strictly confidential, and shall be used exclusively for statistical, public health, or scientific purposes.

Section 2. – All Registry employees and researchers shall sign a confidentiality agreement whereby they shall be liable for any breach thereof. These agreements shall continue to be effective even after the employee or researcher no longer has a relationship with the Registry.

Article 8. – Disclosure of Information for Scientific and Research Purposes

Section 1. – For cancer prevention, control, and research, the Registry is hereby authorized to provide the minimum data to researchers and scientists that is necessary to answer the research question while preserving the confidentiality of both the patient and the reporting entities pursuant to the appropriate Federal and Commonwealth laws.

Section 2. – The Registry is hereby authorized to provide Federal and Commonwealth entities that regulate cancer surveillance with the detailed information required for public policy and scientific research purposes after entering into a data sharing agreement pursuant to the appropriate Federal and Commonwealth laws.

Section 3. – The Registry is hereby authorized to conduct or commission other persons or organizations to conduct research on cancer risks and causes; perform cost, quality, efficacy, and relevance assessments on services and programs related to cancer prevention, diagnosis, therapy, and rehabilitation; and any other clinical, epidemiological, or cancer-related research using data of the Registry.

Section 4. - The Registry is hereby authorized to require any privileged information deemed necessary to complete cancer case data or conduct the aforementioned research from agencies, entities, insurers, or private or public institutions through any data sharing agreement needed.

Article 9. – Cancer Data Sharing

Section 1. – The Registry is hereby authorized to enter into data sharing agreements for cancer patient health information, insofar as the confidentiality of the data reported and the entity’s information is guaranteed. Such agreements shall be entered into with the following entities:

- (a) Entities that report to the Registry reporting entities;
- (b) Cancer Registries in other states and territories with the purpose of obtaining cancer case data on residents of Puerto Rico who have been diagnosed and treated in facilities located in those states and territories, or to provide cancer case data of residents of those states and territories who have been diagnosed or treated in Puerto Rico;
- (c) Federal and Commonwealth agencies that regulate cancer information and data for purposes of compliance with agreements to conduct data quality assessments, cancer surveillance, and scientific research.

Section 2. - The Registry is hereby authorized to share general cancer patient data with any other cancer control agency, healthcare service provider, and any other entity deemed pertinent in order to obtain the information needed to complete the required data. All the information, interviews, reports, statements, memoranda, and other data provided by virtue of this Section shall be deemed privileged and, therefore, confidential.

Article 10. – Medical Supervision or Evaluation Prohibited

None of the provisions of this Act shall be construed to coerce a patient who suffers from any of the diseases listed herein into submitting him/herself to the medical supervision or evaluation of the Registry.

Article 11. – Official Data

The official statistical data on cancer incidence in Puerto Rico shall be those published by the Registry.

Article 12. – Educational Campaign

It shall be the responsibility of the Registry to develop an educational and awareness campaign about the importance of complying with the complete, accurate, and timely cancer case reporting and the need to meet the requirements set forth in this Act and the Regulations promulgated thereunder.

Article 13. – Hold Harmless Provision

Any person or institution that provides information to the Registry in compliance with this Act and the Regulations promulgated thereunder is hereby held harmless from all civil and criminal liability.

Article 14. – Donations

The Registry is hereby authorized to solicit, accept, and receive donations or aid as money, goods, or services in accordance with applicable laws and regulations. These resources shall be covered into the Special Fund of the Registry.

Article 15. – Commonwealth Funds

The Government of Puerto Rico, through the Department of Health, shall continue guaranteeing an annual recurring appropriation of two hundred fifty thousand dollars (\$250,000) for the Registry's operation. This Act does not impair the Registry from receiving or soliciting funds or aid as money, goods, or services from any instrumentality of the Government of Puerto Rico, or appropriations from the Legislative Assembly in order to continue operating. Such funds shall be covered into the Special Fund of the Registry.

Article 16. – Federal Funds

The Registry may solicit, accept, and receive funds or aids as money, goods, or services from any Federal government agency in order to continue operating. Such funds shall be covered into the Special Fund of the Registry.

Article 17. – Rulemaking Authority

The Registry shall adopt rules and regulations as necessary to ensure full compliance with the provisions of this Act, pursuant to the provisions of Act No. 170 of August 12, 1988, as amended, known as the "Uniform Administrative Procedure Act." The Registry shall provide a copy of such regulations to all parties required to comply with this Act within one hundred and twenty (120) days after the approval of this Act.

Article 18. – Repealing Clause

Act No. 28 of March 20, 1951, as amended, as well as its corresponding amendments, are hereby repealed.

Section 19. – Supplementary Provisions

(a) The parties required to report cancer information and data under the herein repealed Act No. 28 of March 20, 1951, as amended, shall continue to report such information and data to the Registry through the means and in the medium and format set forth in Act No. 28, *supra*, until the new regulations take effect as established in this Act.

(b) All legally-binding agreements entered into by the Registry, or by the Department of Health with regards to such Registry, under the herein repealed Act No. 28 of March 20, 1951, as amended, shall continue in effect until the term expires, insofar as they are consistent with this Act.

(c) This Act shall be construed and applied supplementarily to the provisions of Act No. 230 of August 26, 2004, which creates the Comprehensive Cancer Center of the University of Puerto Rico.

(d) None of the provisions of this Act shall be construed to revoke or impair the powers and authorities granted by the laws that created the Department of Health and the Comprehensive Cancer Center of the University of Puerto Rico, respectively.

Article 20. – Effectiveness

This Act shall take effect immediately after its approval.

CERTIFICATION

I hereby certify to the Secretary of State that the following **Act No. 113-2010 (S. B. 1000)** of the **3rd Session of the 16th Legislature** of Puerto Rico:

AN ACT to create the “Puerto Rico Central Cancer Registry Act”; repeal Act No. 28 of March 20, 1951, as amended; and for other purposes.

has been translated from Spanish to English and that the English version is correct.

In San Juan, Puerto Rico, on this 31st day of January, 2014.

Juan Luis Martínez Martínez
Acting Director