

RULES AND REGULATIONS
PERTAINING TO THE RHODE ISLAND
CANCER REGISTRY
(R23-12-CA)

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

Department of Health

September 1986

As Amended:

August 1995

December 1997

**January 2002 (re-filing in accordance with
the provisions of section 42-35-4.1 of the
Rhode Island General Laws, as amended)**

INTRODUCTION

These *Rules and Regulations Pertaining to the Rhode Island Cancer Registry (R23-12-CA)* are promulgated pursuant to the authority conferred under sections 23-1-1, 23-1-18(2), 23-8-1, 23-12-4 and 42-35 of the General Laws of Rhode Island, as amended, and are hereby adopted for the purpose of establishing a unified procedure for the reporting of malignant and related diseases to the Rhode Island Cancer Registry.

These amended rules and regulations shall supersede all previous rules and regulations pertaining to the Rhode Island Cancer Registry promulgated by the Rhode Island Department of Health and filed with the Rhode Island Secretary of State.

TABLE OF CONTENTS

	<i>Page</i>
Section R23-12-CA	
1.0 Definitions	1
2.0 Administration of the Rhode Island Cancer Registry	2
3.0 Reporting Requirements	2
4.0 Procedure For Reporting	4
5.0 Validation of Data	4
6.0 Confidentiality	4
7.0 Ownership and Publication of Data	5
8.0 Violations/Sanctions	5
9.0 Exception and Severability	5

RHODE ISLAND CANCER REGISTRY
(R23-12-CA)

Section 1.0 ***Definitions***

Wherever used in these rules and regulations the following terms shall be construed as follows:

- 1.1 ***"Acts"*** refers to Chapters 23-1, 23-8, and 23-12 of the General Laws of Rhode Island, as amended.
- 1.2 ***"Benign neoplasm of the brain or central nervous system"*** means a diagnosis of neoplasm, established by a licensed physician, whose topography is classified as C70.0-C70.9, "meninges," or C71.0-C71.9, "brain," or C72.0-C72.9, "spinal cord, cranial nerves, and other parts of central nervous system," or C75.1, "pituitary gland," or C75.2, "craniopharyngeal duct," or C75.3, "pineal gland," or other related anatomical sites, as the Director shall specify, and whose behavior is classified as "/0, benign neoplasms," or "/1, neoplasms of uncertain and unknown behavior" by the current amended "International Classification of Diseases for Oncology" (ICD-0) published by the World Health Organization.
- 1.3 ***"Director"*** means the Director of the Rhode Island Department of Health.
- 1.4 ***"Health care facility and/or health care provider"*** means hospitals, freestanding ambulatory surgical centers and radiotherapy facilities, health maintenance organizations, independent clinical laboratories providing histopathology, licensed pursuant to Chapters 23-17, 23-16.2 or 27-41 of the General Laws of Rhode Island, as amended, and furthermore includes such other health care facilities not listed above and health care providers (such as physicians, dentists) licensed in accordance with statutory provisions of this state, who may make a diagnosis of cancer or benign neoplasm of the brain or central nervous system or provide treatment for cancer or benign neoplasm of the brain or central nervous system independent of the health care facilities listed above.
- 1.5 ***"Malignant disease"*** means a diagnosis of cancer (made microscopically and/or non-microscopically) established by a licensed physician which includes cancers at all sites and all stages of the disease and which are listed in the current amended "International Classification of Diseases for Oncology" (ICD-0), published by the World Health Organization. Excluded are basal epithelial, papillary and squamous cell carcinomas of the skin but included are all carcinomas of the vulva, labia, penis and scrotum. Also excluded are all *in situ* carcinomas of the cervix uteri.
- 1.6 ***"Registrar of the Rhode Island Cancer Registry"*** hereinafter referred to as Registrar, means the person within the Department of Health designated by the Director to be responsible for the operation of the Rhode Island Cancer Registry.
- 1.7 ***"Rhode Island Cancer Registry"*** means the Central Registry established within the Department of Health by the Director pursuant to sections 23-1-1, 23-1-18(2), 23-8-1 and 23-12-4 of the Acts as the statewide Registry for the collection and recording of information on certain cases of malignant and related diseases for the purpose of understanding the extent and nature of the diseases among the citizens of the state and to apply preventive and control measures.

Section 2.0 *Administration of the Rhode Island Cancer Registry*

- 2.1 All new cases of malignant disease as defined in section 1.5 (above) diagnosed on and after 1 October 1986 in Rhode Island and all new cases of benign neoplasm of the brain or central nervous system as defined in section 1.2 (above) diagnosed on and after January 1, 1998 shall be reportable in accordance with the statutory and regulatory provision herein.
- 2.2 Pursuant to section 23-12-4 of the Acts, the Director may enter into a contract with a non-profit organization to be responsible to the Rhode Island Cancer Registry for the collection and recording of all new cases of malignant disease or benign neoplasm of the brain or central nervous system diagnosed in health care facilities and/or by health care providers in Rhode Island.
 - 2.2.1 A contract entered into with a non-profit organization shall clearly delineate the mutual responsibilities of the parties involved and shall include other terms of agreement such as reimbursement, designation of services to be rendered, confidentiality, disclosure of data, assurance of compliance with the requirements herein, and such other terms of agreement as may be mutually acceptable.

Section 3.0 *Reporting Requirements*

- 3.1 Health care facilities and/or health care providers as defined in section 1.4 herein, shall be responsible to report to the Rhode Island Cancer Registry and the organization and/or agency approved by the Director, each case of malignant disease diagnosed and/or confirmed within the health care facility and/or by the health care provider on and after 1 October 1986, and each case of benign neoplasm of the brain or central nervous system diagnosed and/or confirmed within the health care facility and/or by the health care provider on and after 1 January 1998, including all pathology specimens removed elsewhere but found to be positive for malignant disease or benign neoplasm of the brain or central nervous system upon initial reading or upon consultative reading at the health care facility and/or by the health care provider. Health care facilities and/or health care providers shall report each case of malignant disease treated within the health care facility and/or by the health care provider if that malignancy was diagnosed on and after January 1, 1995, and the treatment is part of the first course of definitive treatment for the malignancy, and each case of benign neoplasm of the brain or central nervous system treated within the health care facility and/or by the health care provider if that benign neoplasm was diagnosed on and after January 1, 1998, and the treatment is part of the first course of definitive treatment for the benign neoplasm.
- 3.2 Each health care facility and/or health care provider shall submit data in such a manner as to make uniform a system of periodic reporting and shall include no less than the following detailed statistical data and information:
 - a) patient's full name;
 - b) social security number;
 - c) street address, city or town, state and zip code;

- d) census tract;
- e) date of birth;
- f) sex and race;
- g) primary anatomical site of malignancy or benign neoplasm;
- h) date, place and method of diagnosis (place of diagnosis must be reported in coded form, using "class of case" coding developed by the American College of Surgeons);
- i) extent of disease at diagnosis (with documentation using SEER program criteria and AJCC program criteria);
- j) histology/behavior/grade;
- k) laterality;
- l) tumor sequence number;
- m) medical record number;
- n) reporting facility;
- o) usual industry of employment;
- p) usual occupation;
- q) first course of definitive treatment, including class of treatment, specific treatment, place of treatment, date of initiation of therapy;
- r) date of admission;
- s) source of information [type of medical record];
- t) primary physician;
- u) such other data as may be required by the Director.

3.2.1 Such data and information on cases of malignant disease or benign neoplasm of the brain or central nervous system shall be reported on forms approved by the Director or may be reported by such other method as electronic data processing tape or disk as approved by the Director, provided however that such other method contains all the required information in a format compatible with the data processing equipment used by the Rhode Island Cancer Registry. On and after August 1, 1995, such data and information on cases of malignant disease or benign neoplasm of the brain or central nervous system shall be reported electronically by computer modem unless reporting by

another means has been approved in writing by the Director or the health care facility and/or health care provider usually reports fewer than one hundred (100) cases annually.

- 3.2.2 Such data and information shall be abstracted from medical charts and other sources of patient information by personnel possessing, at a minimum, a basic working knowledge of medical terminology, human anatomy, and physiology.
- 3.2.3 Such data and information shall be coded in a manner specified by the Director.
- 3.2.4 Such data and information shall be submitted with sufficient narrative substantiation to allow a visual assessment of the accuracy of coded data and information.

Section 4.0 ***Procedure For Reporting***

- 4.1 Within one hundred eighty (180) days from the date of diagnosis or confirmation of a new case of malignant disease or a benign neoplasm of the brain or central nervous system as defined in sections 1.5 and 1.2, respectively, herein, a health care facility and/or health care provider shall report in the manner specified above all the information and data requested. The originating health care facility and/or provider shall retain a duplicate copy of submitted information for a two (2) year period from the date of submission. Said information and data shall be submitted in a manner acceptable to the Director.

Section 5.0 ***Validation of Data***

- 5.1 To ensure the accuracy of the data and the completeness of reporting, the Registrar is authorized to review periodically patients' medical records and all other sources of patient information, including but not limited to, pathology reports or logs, cytology reports or logs, disease indexes, operating room logs, or radiation therapy logs, as may be necessary to substantiate the accuracy of the data and the completeness of reporting.
 - 5.1.1 Nothing under the provisions of the Acts and the rules and regulations herein shall be construed to compel any individual to submit to physical examination or medical supervision.

Section 6.0 ***Confidentiality***

- 6.1 The Rhode Island Cancer Registry shall maintain comprehensive records of all reports of cases of malignant disease or benign neoplasm of the brain or central nervous system submitted pursuant to the provisions of the Acts and the rules and regulations herein. Such reports shall be confidential in accordance with Chapter 5-37.3 of the General Laws of Rhode Island, as amended, and subject to the restrictions on release incorporated therein.
 - 6.1.1 The mutual exchange of cancer related data with neighboring states pursuant to reciprocal contracts for said purpose shall also be subject to the aforementioned statutory provisions on confidentiality.

Section 7.0 *Ownership and Publication of Data*

- 7.1 All individual records and aggregate data including abstract report forms relating to the Rhode Island Cancer Registry are the property of the Rhode Island Department of Health. The use of records and aggregate data by any person shall be subject to the approval of the Director. Furthermore requests for access to data compiled pursuant to the provisions of these regulations may be granted only by the Director in accordance with applicable federal and state law, rules and regulations regarding confidentiality and public access to data.

Section 8.0 *Violations/Sanctions*

- 8.1 Failure of any health care facility and/or health care provider to comply with the provisions of the Acts and the rules and regulations herein, shall be subject to sanctions and referred to the appropriate licensing and/or disciplinary body.

Section 9.0 *Exception and Severability*

- 9.1 Modification of any individual rule and regulation herein may be granted by the Director upon motion of the Rhode Island Cancer Registry or upon request of a contracting agency and/or organization in a specific case, if the Director finds that the modification to the rule is not contrary to the purpose of the Rhode island Cancer Registry nor contrary to the public interest.

9.1.1 A request for modification of a rule shall require advance written request to the Director and written approval by the Director.

- 9.2 If any provision of the rules and regulations herein or the application thereof to any facility or provider or circumstances shall be held invalid, such invalidity shall not affect the provisions or application of the regulations which can be given effect, and to this end the provisions of the rules and regulations are declared to be severable.