

RULES AND REGULATIONS PERTAINING TO THE RHODE ISLAND CANCER REGISTRY

[R23-12-CA]



STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

DEPARTMENT OF HEALTH

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AS AMENDED:

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

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accordance with the provisions of
§42-35-4.1 of the Rhode Island
General Laws, as amended)

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INTRODUCTION

These amended *Rules and Regulations Pertaining to the Rhode Island Cancer Registry (R23-12-CA)* are promulgated pursuant to the authority conferred under §§ 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.

Pursuant to the provisions of §§42-35-3(a)(3) and (a)(4) of the General Laws of Rhode Island, as amended, the following were given consideration in arriving at the amended regulations:

- (1) Alternative approaches to the regulations;
- (2) Duplication or overlap with other state regulations and
- (3) Significant economic impact on small business.

Based on the available information, no known alternative approach, duplication or overlap was identified.

These amended 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 Secretary of State.

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Section 1.0 *Definitions*

Wherever used in these 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"* means the individual within the Department of Health designated by the Director to be responsible for the operation of the Rhode Island Cancer Registry. For the purpose of these Regulations, this individual may also be referred to as the Registrar.
- 1.7 *"Rhode Island Cancer Registry"* means the Central Registry established within the Department of Health by the Director pursuant to §§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.

- 1.8 ***“These Regulations”*** mean all parts of Rhode Island *Rules and Regulations Pertaining to the Rhode Island Cancer Registry (R23-12-CA)*.

Section 2.0 ***Administration of the Rhode Island Cancer Registry***

- 2.1 All new cases of malignant disease as defined in §1.5 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 §1.2 of these Regulations diagnosed on and after 1 January 1998 shall be reportable in accordance with the statutory and regulatory provision herein.
- 2.2 Pursuant to §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 §1.4 of these Regulations, 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 1 January 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 1 January 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 electronically submit such data and information on cases of malignant disease or benign neoplasm of the brain or central nervous system, in up-to-date NAACCR format, as specified annually by the Registrar, and shall include no less than the following detailed statistical data and information:

- (a) Patient's full name;
- (b) Maiden name
- (c) Social security number;
- (d) Street address, city or town, state and zip code at time of diagnosis;
- (e) Street address, city or town and zip code – current address;
- (f) Census tract;
- (g) Date of birth and place of birth;
- (h) Vital status;
- (i) Date of last contact or death;
- (j) Cause of death;
- (k) Place of death (narrative and coded);
- (l) Co-morbidities and complications;
- (m) Sex, race and ethnicity;
- (n) Usual occupation and employment/industry;
- (o) Marital status;
- (p) Primary anatomical site of malignancy or benign neoplasm;
- (q) Histology, behavior and grade of malignancy or benign neoplasm;
- (r) Laterality;
- (s) Tumor size;
- (t) Lymph nodes examined and positive;
- (u) Multiple primary;
- (v) Date of diagnosis;
- (w) Method of diagnosis;
- (x) class of case;
- (y) Extent of disease (reported in Collaborative Stage and AJCC T-N-M staging);
- (z) Cancer status;
- (aa) Tumor sequence number;
- (bb) Medical record number;
- (cc) Reporting facility;
- (dd) Diagnostic procedures including codes, dates and descriptive narrative;
- (ee) First course of definitive treatment including codes, dates and descriptive narrative;
- (ff) Date of admission;

- (gg) Source of information;
- (hh) Primary, attending and treating physicians and physician id numbers;
- (ii) Inclusion in clinical trials;
- (jj) Such other data as may be required by the Centers for Disease Control and Prevention to assure uniformity among state-level central cancer registries in the United States; and
- (kk) Such other data as may be required by the Director.

3.2.1 **[DELETED]**

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 Registrar.

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 first contact with a new case of malignant disease or a benign neoplasm of the brain or central nervous system as defined in §1.5 and §1.2, respectively, of these Regulations, 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 consistent with §3.1 of these Regulations.

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 these Regulations 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 relating to the Rhode Island Cancer Registry are the property of the Rhode Island Department of Health. The use of confidential records by any person shall be subject to the approval of 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 these Regulations, 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 requirement of these Regulations 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 requirement 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 requirement shall require advance written request to the Director and written approval by the Director.

9.2 If any provision of these Regulations 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 these Regulations are declared to be severable.