216-RICR-10-10-2

TITLE 216 - DEPARTMENT OF HEALTH

CHAPTER 10 - PUBLIC HEALTH ADMINISTRATION

SUBCHAPTER 10 - REGISTRIES

PART 2 - RHODE ISLAND CANCER REGISTRY

2.1 Authority

These rules and regulations are promulgated pursuant to the authority conferred under R.I. Gen. Laws §§ 23-1-18(2), 23-8-1, and 23-12-4 for the purpose of establishing a unified procedure for the reporting of cancer to the Rhode Island Cancer Registry.

2.2 Definitions

A. Whenever used in these Regulations, the following terms shall be construed as follows:

1. "Acts" refers to R.I. Gen. Laws Chapters 23-1, 23-8, and 23-12.

2. "Administrator 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 this Part, this individual may also be referred to as the Registrar.

3. "Director" means the Director of the Rhode Island Department of Health.

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 and/or cytology, licensed pursuant to R.I. Gen. Laws Chapters 23-17, 23-16.2 or 27-41 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 produce a positive test result for, make a diagnosis of, or provide treatment for cancer as defined in § 2.2(A)(5) of this Part, independent of the health care facilities listed above.

5. "Reportable case" means all incident cancer, benign neoplasm (tumor), or premalignant (precancerous) case specified by the Rhode Island Cancer Registry as follows:

a. “Benign neoplasm of the brain or central nervous system”, a diagnosis of benign or borderline neoplasm, established by a licensed physician, occurring in the brain, meninges, spinal cord, cauda equine, a cranial nerve or nerves, other part of the central nervous system, pituitary gland, pineal gland, craniopharyngeal duct,” or other related anatomical sites, by the current amended “International Classification of Diseases for Oncology” (ICD-O) published by the World Health Organization.

b. "Cancer", a diagnosis of *in situ* or invasive malignant disease (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-O), published by the World Health Organization. Excluded are squamous cell and basal cell carcinomas of the skin, but included are all carcinomas (including *in situ*) of the breast (including lobular carcinoma in situ: LCIS), cervix (also known as squamous intraepithelial neoplasia 3: CIN-3), vagina (including intraepithelial neoplasia 3: VAIN-3), prepuce, clitoris, vulva (including intraepithelial neoplasia 3: VIN-3), labia, penis and scrotum.

6. "Rhode Island Cancer Registry" means the Central Registry established within the Department of Health by the Director pursuant to R.I. Gen. Laws §§23-1-1, 23-1-18(2), 23-8-1 and 23-12-4 as the statewide Registry for the collection and recording of information on reportable cases as defined in §2.2(A)(5) of this Part 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.

7. “This Part” mean all parts of the rules and regulations pertaining to the Rhode Island Cancer Registry (216-RICR-10-10-2).

2.3 Administration of the Rhode Island Cancer Registry

A. All cases as defined in § 2.2(A)(5) of this Part shall be reportable in accordance with the statutory and regulatory provision herein.

B. Pursuant to R.I. Gen. Laws § 23-12-4, 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 reportable cases as defined in § 2.2(A)(5) of this Part.

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.

2.4 Reporting Requirements

A. Health care facilities and/or health care providers as defined in § 2.2(A)(4) of this Part, shall be responsible to report to the Rhode Island Cancer Registry and the organization and/or agency approved by the Director, each reportable malignant disease indicated by test results, diagnosed and/or confirmed within the health care facility and/or by the health care provider on and after 1 October 1986, each reportable benign neoplasm of the brain or central nervous system indicated by test results, diagnosed and/or confirmed within the health care facility and/or by the health care provider on and after 1 January 1998, and each reportable *in-situ* carcinomas of the cervix (also known as squamous intraepithelial neoplasia 3: CIN-3) indicated by test results, diagnosed and/or confirmed within the health care facility and/or by the health care provider on and after 1 January 2018, including all histopathology and cytology specimens removed elsewhere but found to be positive for each reportable case 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 reportable case treated within the health care facility and/or by the health care provider if that case was diagnosed therein or thereby, or if the treatment therein or thereby is part of the first course of definitive treatment for the case.

B. Each health care facility and/or health care provider shall electronically submit such data and information on reportable cases and shall meet data element requirements, format, completeness, quality, and timelines prescribed by:.

1. Chapter VII “Record Layout Table” of the “Standards Volume II” of the “Central Cancer Registry Standards” (Version 18, Revised December 18, 2017) published by the North American Association of Central Cancer Registries, incorporated herein by reference, not including any later editions or amendments thereof; and

2. “Facility Oncology Registry Data Standards” (Revised January 1, 2016) published by the Commission on Cancer, incorporated herein by reference, not including any later editions or amendments thereof.

2.5 Procedure for Reporting

A. Each health care facility and/or health care provider shall submit a set of available information on reportable cases within thirty (30) to forty-five (45) days from the date of a case first seen by provider (including but not limited to: patient demographic information, date of diagnosis, primary site, histology, behavior, tumor identifier, tumor sequence number, and facility/provider information), as defined in § 2.2 of this Part, and specified by the Rhode Island Cancer Registry.

B. Within one hundred eighty (180) days from the date of a reportable case first seen by provider as defined in § 2.2 of this Part, a health care facility and/or health care provider shall report complete all required information, as specified by the Rhode Island Cancer Registry. 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 § 2.4 of this Part.

2.6 Validation of Data

A. To ensure the accuracy of the data and the completeness of reporting, the Administrator 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.

1. Nothing under the provisions of the Acts and this Part shall be construed to compel any individual to submit to physical examination or medical supervision.

2.7 Confidentiality

A. The Rhode Island Cancer Registry shall maintain comprehensive records of all reports of reportable cases submitted pursuant to the provisions of the Acts and the rules and regulations herein. Such reports shall be confidential in accordance with R.I. Gen. Laws Chapter 5-37.3 and subject to the restrictions on release incorporated therein.

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.

2.8 Ownership and Publication of Data

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.

2.9 Violations/Sanctions

Failure of any health care facility and/or health care provider to comply with the provisions of the Acts and this Part, shall be subject to sanctions and referred to the appropriate licensing and/or disciplinary body.

2.10 Exception

A. Modification of any individual requirement of this Part 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.

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