STATE OF RHODE ISLAND DEPARTMENT OF HEALTH
PUBLIC NOTICE OF PROPOSED RULE MAKING

In accordance with Rhode Island General Laws (RIGL) 42-35-2.7, notice is hereby given that the Rhode Island Department of Health (RIDOH) proposes to amend the following rule: Rhode Island Cancer Registry (216-RICR-10-10-2). This proposed regulation would supersede ERLID 6503 (Effective October 17, 2011).

REGULATION TITLE

RICR Title 216 – Rhode Island Department of Health
Chapter 10 – Public Health Administration
Subchapter 10 – Registries
Part 2 – Rhode Island Cancer Registry

TYPE OF FILING: Amendment

RULEMAKING ACTION: Public Notice of Proposed Rule Making

TIMETABLE FOR ACTION ON THE PROPOSED RULE: The public comment period ends on Tuesday, November 14, 2017. A public hearing will be held on Thursday, October 26, 2017 at 10:00AM.

SUMMARY OF PROPOSED RULE: The RIDOH is proposing rulemaking to conform with a new CDC National Program of Cancer Registry initiative, ensure complete and timely cancer data collection, increase the percentage of cancer cases reported and reviewed by the RI Cancer Registry within thirty (30) days of first encounter, and technically revise those sections which fall under the new definition “reportable case.”

COMMENTS INVITED: All interested parties are invited to submit written or oral comments concerning the proposed regulations. Oral/written comments can be submitted by the public at a public hearing to be held:

Thursday, October 26, 2017
10:00AM – 11:00AM
Rhode Island Department of Health
Auditorium
3 Capitol Hill (Lower Level)
Providence, Rhode Island

Also, written comments can be submitted by mail to Paula Pullano, Rhode Island Department of Health, 3 Capitol Hill, Providence, RI 02908-5097 or by email at paula.pullano@health.ri.gov by the close of Tuesday, November 14, 2017.
Please note that comments submitted to RIDOH by other means than the prescribed mailing and email address may not be received and addressed in RIDOH’s concise explanatory statement. To ensure that your comments are received, please send them to the prescribed mailing and email address, or submit them at the public hearing described above.

WHERE COMMENTS MAY BE INSPECTED: Rhode Island Department of Health, 3 Capitol Hill, Providence, Rhode Island 02908-5097.

PUBLIC HEARING INFORMATION: The RIDOH is accessible to the handicapped. If communication assistance (readers/interpreters/captioners) are needed, or any other accommodation to ensure equal participation, please contact Paula Pullano at 401-222-1042 or paula.pullano@health.ri.gov or Relay 711 at least three (3) business days prior to the meeting so arrangements can be made to provide such assistance at no cost to the person requesting.

FOR FURTHER INFORMATION CONTACT: Paula Pullano, Rhode Island Department of Health, Division of Policy, Information, and Communications, 3 Capitol Hill, Providence, Rhode Island 02908-5097, 401-222-1042, or paula.pullano@health.ri.gov.


REGULATORY FINDINGS: In the development of the proposed amendment, consideration was given to: 1) alternative approaches; 2) overlap or duplication with other statutory and regulatory provisions; and 3) significant economic impact on small business. No alternative approach, duplication, or overlap was identified based on available information.

THE PROPOSED AMENDMENT: The RIDOH proposes to amend Rhode Island Cancer Registry (216-RICR-10-10-2) as follows in the concise explanatory statement of proposed non-technical amendments.
### Amendement Coordinates  |  Rationale/Summary of Change
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Section 2.1 (page 1, lines 9-10): Revises reporting requirement from “malignant” to “cancer and cancer related” diseases (with malignant disease falling under the definition of “reportable case,” see new section 2.2(A)(5) below).

Section 2.2(A)(2) (page 1, lines 16-20): Creates definition for Administrator of the Cancer Registry, synonymous with the prior designation of “Registrar.”

Section 2.2(A)(3 & “old” 5) (page 1, lines 21-31, page 2, lines 12-43, page 3, lines 1-2): Revises these separate disease definitions to fall under the new definition of “reportable case” (see new section 2.2(A)(5) below)

Section 2.2(A)(4) (page 2, lines 2 and 6-10): Adds facilities providing cytology to be more inclusive and specific about providers’ scope of work.

New Section 2.2(A)(5) (formerly 2.2(A)(6) (page 2, lines 24-43, page 3, lines 1-2): Creates definition of “reportable case,” including the former definition of “benign neoplasm of the brain or central nervous system,” and adding “cancer” (including in-situ carcinoma of the cervix). This is intended to simplify the definition and make it more concise.

Section 2.2(A)(6) (page 3, lines 6-7): Replaces malignant disease with cancer and cancer related.

Section 2.3(A-B) (page 3, lines 14-17 and 21-24): Replaces malignant disease with cancer and cancer related.

Section 2.4 (A-B) (page 3, lines 35-38, page 4, lines 1-17): Replaces prior definitions with variations on “reportable case,” and implements effective timeframe related to reporting of in-situ carcinoma of the cervix.

Section 2.4(B) (page 4, lines 18-22): Removes reference to NAACCR and revises “Registrar” to “Administrator,” per new definition (see section 2.2(A)(2) above).

Section 2.4(B) (page 4, lines 23-36, page 5, lines 1-26, page 6, lines 1-14): Revised to remove list of reported data elements, as from time to time, or year by year, standards for cancer data abstraction/coding change. This section was revised to leave out specific codes/data abstraction and avoid unnecessary frequent revisions in the future.
Section 2.5 (page 6, lines 16-27): Revises submission requirement of initial case encounter from 180 to 30 days, in order to ensure complete and timely cancer data collection, and increase the percentage of cancer case reported and reviewed by the RI Cancer Registry within two weeks of initial diagnosis (associated to a goal in the RI Cancer Control Strategic Plan 2013-2018). Additionally, the term “contact” (line 17-18) has been revised to more specific term “first encounter.”

Section 2.6(A) (page 6, line 33): Revises “Registrar” to “Administrator,” per new definition (see section 2.2(A)(2) above).

Section 2.7(A) (page 7, lines 6-7): Replaces disease types with new defined “reportable” case (see new Section 2.2(A)(5) above).

Section 2.10(B) (page 7, lines 32-35): Removes Severability section.
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 malignant and cancer-related diseases to the Rhode Island Cancer Registry.

2.2 Definitions

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


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 these Regulations, this individual may also be referred to as the Registrar.

3. "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, "meningeal," 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.

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 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 produce a positive test result for, make a diagnosis of, or provide treatment for cancer and cancer-related disease 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.

5. "Malignant disease" means a diagnosis of cancer (made microscopically and/or nonmicroscopically) 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 included are such precursors of malignant disease as may be required by the Director [of Health] in conformity with initiatives and requirements of the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services. Also excluded are all in situ carcinomas of the cervix uteri.

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."Reportable case" means all incident cancer and cancer-related disease 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 vagina.
"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 reportable certain cancer and cancer-related 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.

"These Regulations" mean all parts of Rhode Island Rules and Regulations Pertaining to the Rhode Island Cancer Registry (216-RICR-10-10-2R23-12-CA).

### 2.3 Administration of the Rhode Island Cancer Registry

**A.** All cancer and cancer-related new cases of malignant disease as defined in §21.2(A)(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.

**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 cancer and cancer-related cases as defined in §2.2(A)(5), 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 as specified by the Rhode Island Cancer Registry.

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 §21.2(A)(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 reportable case of 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, and each reportable case of 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 Januaryuly-20187, including all histopathology and cytology specimens removed elsewhere but found to be positive for each reportable case 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 reportable 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 case benign neoplasm was diagnosed therein or thereby on and after 1 January 1998, or if and the treatment therein or thereby is part of the first course of definitive treatment for the case the benign neoplasm.

B. Each health care facility and/or health care provider shall electronically submit such data and information on reportable cases of malignant disease or benign neoplasm of the brain or central nervous system, in up-to-date North American Association of Central Cancer Registries (NAACCR) format, as specified annually by the AdministratorRegistrar, and shall meet data element requirements, format, completeness, quality, and timelines prescribed by the Rhode Island Cancer Registry include no less than the following detailed statistical data and information:

1. Patient’s full name;
2. Maiden name
3. Social security number;
4. Street address, city or town, state and zip code at time of diagnosis;
5. Street address, city or town and zip code—current address;
6. Census tract;
7. Date of birth and place of birth;
8. Vital status;
9. Date of last contact or death;
10. Cause of death;
11. Place of death (narrative and coded);
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<tr>
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<th>Description</th>
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<tr>
<td>12.</td>
<td>Co-morbidities and complications;</td>
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<td>13.</td>
<td>Sex, race and ethnicity;</td>
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<td>14.</td>
<td>Usual occupation and employment/industry;</td>
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<td>15.</td>
<td>Marital status;</td>
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<td>16.</td>
<td>Primary anatomical site of malignancy or benign neoplasm;</td>
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<td>17.</td>
<td>Histology, behavior and grade of malignancy or benign neoplasm;</td>
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<td>18.</td>
<td>Laterality;</td>
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<td>19.</td>
<td>Tumor size;</td>
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<td>20.</td>
<td>Lymph nodes examined and positive;</td>
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<tr>
<td>21.</td>
<td>Multiple primary;</td>
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<td>22.</td>
<td>Date of diagnosis;</td>
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<td>Method of diagnosis;</td>
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<td>24.</td>
<td>Class of case;</td>
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<td>25.</td>
<td>Extent of disease (reported in Collaborative Stage and AJCC T-N-M staging);</td>
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<td>26.</td>
<td>Cancer status;</td>
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<td>27.</td>
<td>Tumor sequence number;</td>
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<td>28.</td>
<td>Medical record number;</td>
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<td>29.</td>
<td>Reporting facility;</td>
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<td>30.</td>
<td>Diagnostic procedures, including codes, dates and descriptive narrative;</td>
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<td>31.</td>
<td>First course of definitive treatment including codes, dates and descriptive narrative;</td>
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<td>32.</td>
<td>Date of admission;</td>
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<td>33.</td>
<td>Source of information;</td>
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<td>34.</td>
<td>Primary, attending and treating physicians and physician id numbers;</td>
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<td>35.</td>
<td>Inclusion in clinical trials;</td>
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36. 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

37. Such other data as may be required by the Director.

   a. [DELETED]

   ba. 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.

   cb. Such data and information shall be coded in a manner specified by the Registrar.

   dc. Such data and information shall be submitted with sufficient narrative substantiation to allow a visual assessment of the accuracy of coded data and information.

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) 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 these Regulations, 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 first contact with a new case of malignant disease or a benign neoplasm of the brain or central nervous system as defined in §2.15 and §1.2, respectively, of these Regulations, a health care facility and/or health care provider shall report complete all required information data, 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 §2.43.1 of these Regulations.

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 these Regulations 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 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.

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 these Regulations, shall be subject to sanctions and referred to the appropriate licensing and/or disciplinary body.

2.10 Exception and Severability

A. 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.

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

B. 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.