Agency: Department of Health

Preproposal Statement of Inquiry was filed as WSR 09-15-186; or
Expedited Rule Making--Proposed notice was filed as WSR ; or
Proposal is exempt under RCW 34.05.310(4).

Title of rule and other identifying information: (Describe Subject)
Chapter 246-102 WAC - Cancer Registry

Submit written comments to:
Name: Riley Peters, Unit Manager, Washington State Cancer Registry
Address: Washington State Department of Health
P O Box 47855
Tumwater, WA 98504-7855
Website: http://www3.doh.wa.gov/policyreview/
fax 360-586-2714 by (date) 08/24/2011

Date of intended adoption: 08/29/2011
(Note: This is NOT the effective date)

Purpose of the proposal and its anticipated effects, including any changes in existing rules:
The purpose of the proposed rule is to update and clarify existing rules to meet the expanded and revised scope and requirements of cancer surveillance and registration activities according to the Centers for Disease Control and Prevention’s National Program of Cancer Registries. The proposed rule also requires the reporting of a patient's usually occupation or the primary occupation of the patient before retirement.

Reasons supporting proposal:
The Cancer Registries Amendment Act in 42 USC 280(e) requires that states receiving federal funds establish regulations to meet reporting requirements. The department must update the current rules in order to stay in compliance with the current federal regulations and to maintain funding. In addition, Senate Bill 5149 passed during the 2011 legislative session revising RCW 70.54.240 requiring a patient's usually occupation or, the primary occupation of the patient before retirement be reported. The best way to collect this information is through the existing cancer registry.

Statutory authority for adoption:
RCW 70.54.270

Is rule necessary because of a:
Federal Law? Yes ☑ No ☑
Federal Court Decision? Yes ☑ No ☑
State Court Decision? Yes ☑ No ☑
If yes, CITATION:

DATE 07/08/11

NAME (type or print) Mary C. Selecky

SIGNATURE

TITLE Secretary

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED
DATE: July 08, 2011
TIME: 12:06 PM
WSR 11-15-022

(COMPLETE REVERSE SIDE)
Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:
No agency comments or recommendations.

Name of proponent: (person or organization)  Department of Health

<table>
<thead>
<tr>
<th>Name of agency personnel responsible for:</th>
<th>Office Location</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drafting.......................... Pama Joyner</td>
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<td>Enforcement............Riley Peters</td>
<td>111 Israel Road SE, Tumwater WA 98501</td>
<td>360-236-3581</td>
</tr>
</tbody>
</table>

Has a small business economic impact statement been prepared under chapter 19.85 RCW?

- Yes. Attach copy of small business economic impact statement.

  A copy of the statement may be obtained by contacting:
  
  Name: 
  Address: 

  phone
  fax
  e-mail

- No. Explain why no statement was prepared.

  A small business economic impact statement was not prepared. The proposed rule would not impose more than minor cost on businesses in an industry.

Is a cost-benefit analysis required under RCW 34.05.328?

- Yes  A preliminary cost-benefit analysis may be obtained by contacting:

  Name: Riley Peters, Unit Manager
  Address: 111 Israel Road SE
  Tumwater, WA 98501

  phone 360-236-3581
  fax 360-586-2714
  e-mail Riley.Peters@DOH.WA.GOV

- No: Please explain:
**WAC 246-102-001 Purpose.** The purpose of the Washington state cancer registry is to monitor the incidence of cancer in the state and report applicable limited data according to federal requirements. Information collected through the cancer registry system is used by research and public health professionals to understand, control and reduce occurrences of cancer in residents of Washington. This chapter establishes the criteria for identifying and reporting cancer cases. It also defines the standards for access and release of cancer information.

**WAC 246-102-010 Definitions.** (For the purposes of RCW 70.54.230, 70.54.240, 70.54.250, 70.54.260, 70.54.270, and this chapter, the following words and phrases shall have the following meaning unless the context clearly indicates otherwise:

1. "Cancer case" means:
   a. Any malignant neoplasm with the exception of basal and squamous cell carcinoma of the skin;
   b. All brain tumors;
   c. Basal and squamous cell carcinoma of the external genital organ sites (vulva, labia, clitoris, prepuce, penis, scrotum);
   d. Cancer in situ, except carcinoma in situ of the uterine cervix; or
   e. Other diagnoses necessary to meet the reporting requirements of the Center for Disease Control's National Program of Cancer Registries, the National Cancer Institute's Surveillance Epidemiology and End Results Program, the Commission on Cancer, and the North American Association of Central Cancer Registries (a copy is available for review at the department).

2. "Cancer diagnosis or treatment facilities" means hospitals, surgical centers, outpatient radiation therapy centers, doctors' offices, independent clinical laboratories and any other facilities where cancer cases are diagnosed or treated.

3. "Confidential information" means any information which could lead to the identification of cancer patients, cancer diagnosis or treatment facilities, independent clinical laboratories, or attending health care providers.
(4) "Contractors" means agencies designated by contract with the department of health to perform activities related to identification, collection, and processing of cancer data.

(5) "Department" means the Washington state department of health.

(6) "Designees" means hospital-based cancer registries and other persons or entities designated by the department to perform data collection activities.

(7) "Hospital-based cancer registry" means a cancer registry which is maintained by a hospital or other health care facility.

(8) "In situ" means tumors described as "in situ" by the pathologist reading the diagnostic report(s).

(9) "Institutional review board" means any board, committee, or other group formally designated by an institution, or authorized under federal or state law, to review, approve the initiation of, or conduct periodic review of research programs to assure the protection of the rights and welfare of human research subjects as defined in RCW 70.02.010.

(10) "Patient" means a case, suspected case or contact.

(11) "Principal health care provider" means the attending health care provider recognized as primarily responsible for diagnosis and treatment of a patient, or in the absence of such, the health care provider initiating diagnostic testing or treatment for the patient.

(12) "Reportable cancer case" means any cancer case diagnosed in a Washington state resident after the effective date of these rules.

(13) "Resident" means an individual residing in Washington state at the time of cancer diagnosis.

(14) "$\text{Stage of disease}$" means a cancer classification system encompassing attributes of a tumor as determined and described by:

(a) Summary Staging Guide, Surveillance Epidemiology and End Results (SEER), Program, April 1977; except when superseded by more up-to-date measures (a copy is available for review at the department); and

(b) Manual for Staging of Cancer, 5th Edition, American Joint Committee on Cancer, (AJCC), 1998, except when superseded by more up-to-date measures (a copy is available for review at the department).

(15) "State cancer registry" means the statewide cancer data base maintained by the department of health.

(16) "State cancer registry contract" means the legal agreement by which contractors are authorized to obtain information on reportable cancer cases. It also means the document specifying the contractors' obligations to the state cancer registry with respect to how and when information is collected, processed, and provided and how quality assurance standards are met.) The definitions in this section apply throughout this chapter unless the context clearly indicates otherwise.

(1) "Cancer case" means:

(a) Any malignant or cancerous neoplasm except basal and squamous cell carcinoma of the skin;
(b) Carcinoma of the external genital organ sites, including those with histology identified as basal or squamous cell type. External genital organ sites include the vulva, labia, clitoris, prepuce, penis and scrotum;
(c) Neoplasms noted as carcinoma in situ or noninvasive carcinomas, except carcinoma in situ of the cervix uteri;
(d) All benign, uncertain, borderline or malignant solid intracranial and central nervous system tumors, including the meninges and intracranial endocrine structures;
(e) All hematopoietic and lymphoid neoplasms including certain potentially malignant hematopoietic conditions;
(f) Other diagnoses that meet the reporting requirements of:
(i) The Center for Disease Control's National Program of Cancer Registries;
(ii) The National Cancer Institute's Surveillance Epidemiology and End Results Program;
(iii) The North American Association of Central Cancer Registries as described by the International Classification of Disease for Oncology, Third Edition (ICD-O-3);
(2) "Case report" means a complete report, including all items in WAC 246-102-040(3), documenting a cancer case.
(3) "Certified tumor registrar (CTR)" means an individual certified by the National Cancer Registrars Association.
(4) "Department" means the Washington state department of health.
(5) "First course treatment" means all methods of treatment documented in the treatment plan after the original diagnosis and administered to the patient before disease progression or recurrence.
(6) "Health care facility" means any facility or institution which diagnoses, evaluates, provides treatment to patients or provides biomarker or other required prognostic or predictive information to physicians on patients with reportable or potentially reportable cancer cases. Health care facilities include:
(a) Hospitals providing either inpatient or outpatient services;
(b) Free-standing surgical, radiation therapy, imaging, and oncology centers;
(c) Health maintenance organizations;
(d) Multispecialty clinics;
(e) Hospices;
(f) Ambulatory surgical facilities; and
(g) Other outpatient facilities.
(7) "Health care provider" means a person licensed, certified, or registered under RCW 18.130.040 and who diagnoses, evaluates, or provides treatment to patients with reportable or potentially reportable cancer cases.
(8) "Laboratory" means pathology, cytology, biomarker, molecular, genetic and other clinical or reference laboratories, including both hospital laboratories and free-standing laboratories.

(9) "Potentially reportable cancer case" means the reporting of a cancer case based on ambiguous terminology.

(10) "Reporting entity" means any health care facility, laboratory, treatment center, or health care provider.

(11) "Stage of disease" means how far the cancer has spread from the organ or site of origin at the time of diagnosis and treatment planning.

(12) "State cancer registry" means the Washington state cancer registry.

AMENDATORY SECTION (Amending WSR 01-04-086, filed 2/7/01, effective 3/10/01)

WAC 246-102-020 Who must report. (By statute (RCW 70.54.240), the responsibility for identifying and reporting cases of cancer rests with health care facilities, independent clinical laboratories, and other principal health care providers. The department may, at its discretion, delegate some or all of these responsibilities to contractors or other designees. A list of the contractors and designees responsible for identifying and reporting cases of cancer diagnosed at specific sites in Washington is available for review at the department.) (1) Reporting entities that diagnose, or provide first course treatment to a patient with a cancer case or potentially reportable cancer case shall report the cancer case to the state cancer registry.

(2) If a health care provider refers patients to a health care facility with cancer registry staffing for diagnostic or first course treatment services, then the health care facility is responsible for reporting the case to the state cancer registry.

(3) For purposes of this section "health care facility with cancer registry staffing" means those health care facilities with in-house cancer registries or contracted registry staff services.

AMENDATORY SECTION (Amending WSR 01-04-086, filed 2/7/01, effective 3/10/01)

WAC 246-102-030 Cancer case identification. (Contractors or designees shall identify reportable cancer cases diagnosed and treated at cancer diagnosis and treatment facilities.

(2) Cancer diagnosis or treatment facilities shall:
(a) Organize case finding documents by procedure or service date to permit identification of cancer cases; and
(b) Submit or make available, case finding documents including the following if maintained:
(i) Disease and operation indices for cancer cases;
(ii) Pathology and cytology reports;
(iii) New patient radiation logs;
(iv) New patient chemotherapy logs; and
(v) Other alternative case finding documents that are necessary to identify or verify reportable cancer cases;
(c) Cancer diagnosis or treatment facilities shall submit case finding documents by paper form, computer disk, or electronic file or make batched hard copy documents available for on-site review, within forty-five days of the date of service.
(3) On request, principal health care providers shall identify to contractors, designees, or the department reportable cancer cases diagnosed at facilities other than hospitals, surgical centers, and outpatient radiation therapy centers (as specified under WAC 246-102-030 and 246-102-040) unless the patient was hospitalized for additional cancer diagnosis or treatment services within one month of diagnosis.) The state cancer registry shall:
(1) Publish a reportable list annually.
(2) Publish a recommended case finding list annually.
(3) Publish a list of required data items annually.
(4) Publish recommended reporting guidelines as needed.

AMENDATORY SECTION (Amending WSR 01-04-086, filed 2/7/01, effective 3/10/01)

WAC 246-102-040 Data collection and submission requirements.
(1) Contractors or designees shall complete cancer abstracts for patients identified through cancer diagnosis and treatment facilities.
(2) Cancer diagnosis or treatment facilities shall provide contractors or their designees with access to pathology and cytology reports and all medical records pertaining to identified cancer cases.
(3) On request by the contractor, designee or the department, principal health care providers or their staff shall be responsible for completing cancer abstracts for patients diagnosed at facilities other than hospitals, surgical centers, and outpatient radiation therapy centers, unless the patient was hospitalized for additional cancer diagnosis or treatment services within one month of diagnosis.
(4) The following information items shall be included in cancer abstracts, providing)) Reporting entities shall prepare and submit case reports in a format provided by the state cancer registry.
(2) Reporting entities shall submit completed case reports to
the state cancer registry within six months of the date of diagnosis or date patient is first seen for first course treatment, if the diagnosis was made at another health care facility or by another health care provider.

(3) Case reports shall include the following information ((is available)) from the patient's medical records:

(a) Patient information:
   (i) Name (last, first, middle);
   (ii) Address at time of diagnosis;
   (iii) Sex;
   (iv) Race(s);
   (v) Spanish/hispanic origin;
   (vi) Birthdate;
   (vii) Age at time of diagnosis;
   (viii) Social Security number;
   (ix) State or country of birth;
   (x) Usual occupation, or if retired, primary occupation before retirement;
   (xi) Primary payor;

(b) Diagnostic information:
   (i) Date ((first seen for this cancer)) of patient's first contact with the reporting entity for the diagnosis or treatment of the cancer;
   (ii) (Primary site or sites;
   (iii) Histologic type or types, behavior and grade;
   (iv) Date of each diagnosis;
   (v) Method or methods of diagnostic confirmation;
   (vi) Stage of disease at diagnosis using:
      (A) Summary stage; and
      (B) AJCC system if maintained by the cancer diagnostic or treatment facility;
   (vii) Sequence;
   (viii) Laterality;

(c) First course of treatment information:
   (i) Date of initial treatment;
   (ii) All treatment modalities given as part of first course of therapy;

(d) Other information:
   (i) Name and address of cancer diagnosis or treatment facility providing information;
   (ii) Medical record number;
   (iii) Name and address of principal health care provider; and
   (iv) Other items necessary to meet the reporting requirements of the Center for Disease Control's National Program of Cancer Registries, the National Cancer Institute's Surveillance Epidemiology and End Results Program, the Commission on Cancer, and the North American Association of Central Cancer Registries (a copy is available at the department).

(5) The department may require submission of additional information from contractors or designees as needed to assess data reliability and validity.

(6) Contractors shall prepare detailed data collection protocols for inclusion in the state cancer registry contract.)
Date diagnosis made;
  (iii) Primary site of originating tumor;
  (iv) Laterality (if applicable);
  (v) Histology type or types, behavior and grade of tumor;
  (vi) Documentation, including dates, of pertinent diagnostic
      or evaluation studies, and biopsies;
  (vii) Written documentation that describes the stage of
disease at diagnosis, including Collaborative Staging coding used;
  (viii) Sequence number;
  (c) First course of treatment information:
         (i) Date initial treatment began or the date the decision for
             no treatment was made;
         (ii) Description of all treatment given as part of the first
             course treatment including, but not limited to, surgery, radiation,
             chemotherapy, BRM/immunotherapy, hormone or other therapies, or a
             statement as to why no treatment was given;
  (d) Other information:
         (i) Date of last contact;
         (ii) Vital status at time of last contact;
         (iii) Identification of reporting entity providing
             information:
             (A) Name and address; or
             (B) National Provider Identification number; and
         (iv) Other items necessary to meet the reporting requirements
             of the state cancer registry as provided annually.
  (4) For the purpose of assuring high quality data, the state
cancer registry will publish reporting guidelines for assistance in
completing the requirements in subsections (2) and (3) of this
section, which will be available on the registry's web site.
  (5) All laboratories shall provide:
         (a) Report files within ten days of the close of each month or
             on a schedule determined by the volume of reports acquired daily
             and approved by the state cancer registry;
         (b) Updated information made to reports resulting in addendums
             and amendments; and
         (c) Patient demographic information.

AMENDATORY SECTION  (Amending WSR 01-04-086, filed 2/7/01, effective
3/10/01)

WAC 246-102-060  Data quality assurance.  ((1) Contractors or
designees shall:
  (a) Assess the completeness and accuracy of case
      identification and data collection through computerized edit
      programs and on-site audits, or make available information and
      documentation for this purpose; and
  (b) Maintain a system for retrieval of completed cancer
      abstracts for a period up to ten years.
  (2) Cancer diagnosis or treatment facilities shall:
(a) Make available to the contractor, designee or the department, all case finding source documents and medical records for data quality assurance activities.

(b) Maintain a system for retrieval of case finding source documents and medical records for a period up to ten years.

(3) The department may require contractors or designees to make available all findings from data quality assurance activities for review and verification.}) (1) To assure accurate monitoring of the incidence of cancer in Washington, the state cancer registry shall review the overall quality of all cases received using national guidelines.

(2) The state cancer registry shall follow up with reporting entities for additional case information as needed to ensure the completeness and quality of a case report.

(3) The state cancer registry shall provide education and training related to identifying and reporting cases. The state cancer registry shall:

(a) Offer education and training opportunities to certified tumor registrars on staff at health care facilities.

(b) Offer education and training opportunities to individuals not certified as a certified tumor registrar, but who report cancer cases to the state.

(4) The state cancer registry shall provide technical assistance to reporting entities.

(5) The state cancer registry shall perform audits of reporting entities to ensure accurate and complete reporting.

(6) The state cancer registry will provide thirty days notice of an audit.

(7) The state cancer registry shall request the following documents, as appropriate from the reporting entity, as part of the audit process:

(a) Disease and operations indices files;

(b) Pathology, cytology, and autopsy reports or files;

(c) Report files providing results of specialized testing, such as biomarker results or results of any other tests providing prognostic or predictive information;

(d) Report files providing imaging results;

(e) Radiation therapy new patient or summary treatment files;

(f) Medical oncology new patient or summary treatment files;

(g) Office visit logs; and

(h) Other alternative reports or electronic files necessary to identify and provide information on reportable or potentially reportable cancer cases.

AMENDATORY SECTION (Amending WSR 01-04-086, filed 2/7/01, effective 3/10/01)

WAC 246-102-070 Access and release of information. (1) Information collected by the state cancer registry ((information))
shall be used only for statistical, scientific, medical research and public health purposes. (Contractors and designees must comply with chapter 70.02 RCW regarding the disclosure of patient health care information.)

(2) The department may release state cancer registry information for research purposes:
   ((Research purposes)) (a) After the research project has been reviewed and approved by ((an institutional review board and a confidentiality agreement is negotiated (a copy of the institutional review board procedures and application are available from the department).

(3) The department may release confidential registry information for projects to assess threats to public health or improve public health practice after the project has been reviewed and approved by the department and a data-sharing agreement is negotiated (a copy of the procedures for data-sharing agreements is available from the department).

(4) Cancer diagnosis or treatment facilities may require contractors or designees to sign an agreement of confidentiality regarding access and release of cancer data and prepare, administer, and maintain confidentiality oaths as needed.

(5) Cancer diagnosis or treatment facilities shall adhere to recommendations in RCW 70.54.260 regarding content of confidentiality agreement if confidentiality agreements are used.

(6) Cancer diagnosis and treatment centers shall make available to cancer patients printed information which describes the purpose of the state cancer registry, the statutory requirements which apply to health care facilities, independent clinical laboratories, and other principal health care providers to identify and report cases of cancer to the state cancer registry, and to protect the confidential information that is reported, the public health and research uses of information in the state cancer registry, the circumstances under which cancer registry information is disclosed for these purposes and the relevant RCW and WAC pertaining to the state cancer registry.) the Washington state institutional review board; and

(b) After a written agreement between the department and the researcher is in place regarding state cancer registry information accessed, used or disclosed. Written agreements shall incorporate:
   (i) The confidentiality requirements in RCW 42.48.020; and
   (ii) The department's data security requirements.

(3) The department may release state cancer registry information for projects to assess threats to public health or improve public health practice after the project has been reviewed and approved by the department and a data-sharing agreement is in place.

(4) The state cancer registry shall publish an annual report that includes:
   (a) Age-adjusted incidence rates;
   (b) Age-adjusted mortality rates; and
   (c) Age-adjusted incidence and mortality rates by sex, race, ethnicity, and county at diagnosis subject to confidentiality requirements.
(5) The state cancer registry shall make available to health care facilities and health care providers:

(a) Information for patients and their families that describes the purpose of the state cancer registry;

(b) The statutory requirements;

(c) The intended use of case information;

(d) The circumstances under which cancer registry information is disclosed.

(6) The state cancer registry shall exchange data with states that have a data exchange agreement in place. The data provided to other states shall only include cancer cases with an address at the time of diagnosis outside the borders of Washington state.

REPEALER

The following section of the Washington Administrative Code is repealed:

WAC 246-102-050 Form, frequency, and format for reporting.