

# Draft

## Significant Legislative Rule Analysis (SA)

WAC 246-102-001, Purpose

WAC 246-102-010, Definitions

WAC 246-102-020, Who must report

WAC 246-102-030, Cancer case identification

WAC 246-102-040, Data reporting requirements

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

WAC 246-102-060, Data quality assurance, and

WAC 246-102-070, Access and release of information

## Rules Concerning the Washington State Cancer Registry

### **Section 1. What is the scope of the rule?**

The Washington State Cancer Registry (WSCR) monitors the incidence of cancer in the state. The registry works with health care facilities and health care providers that have information regarding the diagnosis of cancer and information on the first course of treatment for diagnosed cancer. 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.

These proposed rules amend existing rules to clarify the criteria and the process for health care facilities and health care providers when they identify and report new cancer cases and first course of treatment. The proposed rules also identify the standards for accessing and releasing cancer case information. The rules have been updated to accurately reflect currently collected data elements, timeframes for reporting and report format options. WSCR's roles and responsibilities are also outlined.

### **Section 2. What are the general goals and specific objectives of the proposed rule's authorizing statute?**

The general goal of RCW 70.54.230 is to establish a statewide cancer registry program and to obtain cancer reports from all relevant reporting entities, ensure data conforms to national standards of quality, and to make available data for use in cancer research and for purposes of improving the public health.

RCW 70.54.240 directs the Department of Health to adopt rules to identify what is defined as cancer, which types of cancer shall be reported, who shall report and the form and timing of the reports. It also requires every health care facility, clinical laboratories, physicians and others

who provide health care that diagnose or treat any patient with cancer, who has not been hospitalized within one month of diagnosis, to provide information to the cancer registry.

**Section 3. What is the justification for the proposed rule package?**

The Centers for Disease Control and Prevention’s National Program of Cancer Registries (CDC/NPCR) has revised and expanded the scope and requirements of cancer surveillance and registration activities. The Cancer Registries Amendment Act in 42 USC 280(e) requires that states receiving federal funds establish regulations to meet reporting requirements. In order to stay in compliance with the current federal regulations and standards and to maintain funding, it is necessary for the department to update the existing rules.

**Section 4. What are the costs and benefits of each rule included in the rules package? What is the total probable cost and total probable benefit of the rule package?**

1. Identification of total number of rules in package 8

2. Non-Significant Rule Identification Table

**Table: Non-Significant Rule Identification**

#	WAC Section	Section Title	Section Subject	Reason
1	246-102-001	Purpose	WSCR Purpose	Clarifies purpose
2	246-102-010	Definitions	Definitions	Definitions were updated to reflect current federal reporting standards. Definitions are not enforceable standards. New proposed standards are analyzed below.
3	246-102-020	Who must report	Defines who must report to WSCR	Clarifies the intent of RCW 70.54.240
4	246-102-030	Cancer case identification	Defines WSCR’s role	Reflects current practices of WSCR. The proposed rules only relate to internal Department of Health/WSCR operations.
5	246-102-060	Data quality assurance	Defines quality assurance practices	Meets NPCR’s program standards and expected best practices. The proposed rules only relate to internal Department of Health/WSCR operations.

6	246-102-070	Access and release of information	Defines the acceptable use of data	Clarifies definitions and NPCR standards. The proposed rules only relate to internal Department of Health/WSCR operations.
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### 3. Significant Rule Analysis

#### A. WAC 246-102-040-Data collection requirements

##### **Rule Overview**

The proposed rule establishes the timeline for data reporting. Health care facilities and health care providers shall submit case reports to the registry within 6 months of the date of diagnosis or if the diagnosis is made elsewhere within 6 months of the date the patient is first seen for the first course of treatment. The existing rule requires practitioners to send in a notification report within 60 days of the initial diagnosis. The proposed rule identifies the data that must be submitted as part of the case report. The table below identifies the new data that must be submitted.

##### New data elements

#	Data Element	Description
1	Primary Payer	Insurance information
2	Text	Text that describes the extent of the disease at diagnosis (i.e. TNM Staging)
3	Treatment information	Any surgery, radiation or chemotherapy patient may have had as first course treatment
4	Date of last contact	Date the facility/physician was last in contact with patient
5	Vital status at time of last contact	Patient's vital status

Prior to this rule update health care facilities and health care providers were only required to notify the department within 60 days of initial diagnosis. Department staff was then responsible for collecting the required data and creating case reports. Since then the standard of practice has shifted and now health care facilities and health care providers are expected to compile complete case reports and send the data to the department. The 6 month timeframe allows enough time for reporters to compile a complete case report and send it to the registry.

The department estimates that, collectively, it will take approximately 10-15 minutes, depending on the specifics of the case, to provide the additional data elements when reporting using either hard copies or when reporting electronically.

##### **Rule Cost/Benefit Analysis**

There are no probable costs of the proposed rule. All health care facilities and health care providers submit case reports to the registry. This is the standard of practice. Although new data elements are proposed, the department's assumption is that the new data is already being collected and submitted. Therefore, the rule will not have an actual impact on those that are required to report. The benefit of the rule is that the reporting entity clearly understands the timeline and the data reporting requirements.

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

### **Rule Overview**

The proposed rule establishes that the WSCR will provide the template for reporting data, the frequency of reporting, and the required reporting requirements for laboratories. Laboratories will be required to provide files or reports, including patient demographic information, within ten days of the close of each month, or an alternate schedule determined by the volume of cases the laboratory processes.

### **Rule Cost/Benefit Analysis**

The proposed rule will not have an actual impact on health care facilities and health care providers and therefore there are no probable costs of the proposed rule. Reporting entities are already submitting data using the proposed timelines, some using advanced technology, specifically submitting data electronically, making this an increasingly standard practice. The probable benefit of the proposed rule is that the reporting entities clearly understand the timeline for reporting cancer diagnosis and first course of treatment information. There are expected to be cost savings if an entity chooses to submit data electronically from decreasing printing, handling and mailing costs.

### **Cost Benefit Summary**

The majority of the proposed changes clarify existing requirements of the cancer registry program. In the two sections above that are significant, the department's assumption is that the proposed rule will not impose additional costs to health care facilities and health care providers, because they are already complying with the proposed rule. The overall benefit of the proposed rule is that it clearly identifies everyone's role, which will make the entire program more effective and efficient. Therefore, the probable benefits of the proposed rule exceed the probable costs.

### **Section 5. What alternative versions of the rule did we consider? Is the proposed rule the least burdensome approach?**

When working with stakeholders a common complaint was that the rules were too convoluted and unintelligible. Stakeholders requested that the department update and clarify the rules to make them more useful to reporting entities. One example of an alternative version that the stakeholders discussed and elected not to propose is to have all physicians' offices and facilities report non-analytical cases. It was determined that it's easier and more appropriate for the

department to do follow up on cases. Ultimately, the department determined that the proposed language was less burdensome than the alternatives and still achieved the rule's objective.

**Section 6. Did you determine that the rule does not require anyone to take an action that violates another federal or state law?**

The rule does not require those to whom it applies to take an action that violates requirements of federal or state law.

**Section 7. Did you determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless the difference is required in federal or state law?**

The Department of Health determined that the rule does not impose more stringent performance requirements on private entities than on public entities.

**Section 8. Did you determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, did you determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary?**

The rule does not differ from any applicable federal regulation or statute.

**Section 9. Did you demonstrate that the rule has been coordinated, to the maximum extent possible, with other federal, state, and local laws applicable to the same activity or subject matter?**

Yes, the rule is coordinated to the maximum extent practicable with other applicable laws.