

OFFICE OF THE SECRETARY OF STATE  
DENNIS RICHARDSON  
SECRETARY OF STATE  
  
LESLIE CUMMINGS  
DEPUTY SECRETARY OF STATE



ARCHIVES DIVISION  
MARY BETH HERKERT  
DIRECTOR  
  
800 SUMMER STREET NE  
SALEM, OR 97310  
503-373-0701

**NOTICE OF PROPOSED RULEMAKING**  
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 333  
OREGON HEALTH AUTHORITY  
PUBLIC HEALTH DIVISION

**FILED**  
10/18/2017 11:19 AM  
ARCHIVES DIVISION  
SECRETARY OF STATE

FILING CAPTION: Implementing changes to the state cancer registry reporting regulations

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 11/30/2017 5:00 PM

*The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.*

*A public rulemaking hearing may be requested in writing by 10 or more people, or by a group with 10 or more members, within 21 days following the publication of the Notice of Proposed Rulemaking in the Oregon Bulletin or 28 days from the date the Notice was sent to people on the agency mailing list, whichever is later. If sufficient hearing requests are received, the notice of the date and time of the rulemaking hearing must be published in the Oregon Bulletin at least 14 days before the hearing.*

CONTACT: Brittany Hall  
503-449-9808  
brittany.a.hall@state.or.us

800 NE Oregon St. Suite 930  
Portland, OR 97232

Filed By:  
Brittany Hall  
Rules Coordinator

NEED FOR THE RULE(S):

In 2017 the Oregon Legislative Assembly passed House Bill 2301 (Oregon Laws 2017, chapter 101) which will go into effect January 1, 2018, and amends the statute that guides establishment and implementation of the Oregon Cancer and Tumor Registry system (OSCaR). HB 2301 broadened the definition of health care facilities that are required to report information about cancer cases to the statewide registry to include any facilities in Oregon in which patients are diagnosed or provided treatment for cancer or benign or borderline tumors of the brain and central nervous systems. Prior to this change, health care facilities required to report were limited to hospitals or ambulatory surgical centers as defined in ORS 442.015.

HB 2301 also added "borderline" tumors to "cancer" and "benign" tumors as a reportable condition. This change helps to bring OSCaR in alignment with national standards for cancer registries. HB 2301 reduced the allowable extension for a health care facility to comply with cancer reporting requirements from two years to one year, and clarifies the ability of Oregon Health Authority (Authority) to provide reporting services to health care facilities at cost. HB 2301 shifts the option for the Authority to provide reporting services from the health care facility to the Authority. This allows the Authority to choose to provide cancer reporting services, at cost to the health care facility, to facilities that are not in compliance with the cancer registry reporting requirements.

The cancer reporting regulations in OAR 333-010-0000 through 333-010-0090 are being updated to align with the changes made in HB 2301. This includes updating health care facility and borderline tumor definitions throughout the rules, and clarifying how costs are calculated when the Authority provides reporting services to health care facilities (333-010-0090)

In addition to the changes made by HB 2301, the proposed rulemaking:

1. Aligns rule language with current statute (changes "cancer reporting facility" to "health care facility" and "health care provider" to "practitioner").
2. Removes references to outdated data standards manuals.
3. Aligns definitions of reportable cancers, non-malignant conditions, and pre-malignant conditions with national standards.
4. Clarifies quality standards procedures for communications between the Authority and cases where a patient has received care or a diagnosis at multiple reporting facilities.
5. Further clarifies when confidential and privileged information collected and maintained by OSCaR may be shared and the process for obtaining aggregate non-confidential information that is not publically available.
6. Clarifies the requirements for researchers using OSCaR data to comply with federal regulations.

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DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

1. Oregon Revised Statutes 432.500 through 432.570 and 432.900

[https://www.oregonlegislature.gov/bills\\_laws/ors/ors432.html](https://www.oregonlegislature.gov/bills_laws/ors/ors432.html)

2. 2017 Regular Session House Bill 2301 Enrolled

<https://olis.leg.state.or.us/liz/2017R1/Downloads/MeasureDocument/HB2301>

3. Oregon Administrative Rules 333-010-0000 through 333-010-0900

[http://arcweb.sos.state.or.us/pages/rules/oars\\_300/oar\\_333/333\\_010.html](http://arcweb.sos.state.or.us/pages/rules/oars_300/oar_333/333_010.html)

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FISCAL AND ECONOMIC IMPACT:

Health care facilities that currently diagnose or treat cancer in the state of Oregon that are not currently reporting cancer information to OSCaR will be required to start reporting information to OSCaR. The facilities most likely to be impacted are outpatient cancer treatment facilities not associated with a health care system. Health care facilities that diagnose or provide treatment for cancer and are not currently reporting information to OSCaR will be impacted and will likely require an increase in staff time needed to report cases. Currently, most of these types of facilities report on paper with minimal information. To report electronically with full treatment and diagnosing methods would require a Certified Tumor Registrar (CTR) to remain in compliance with current national reporting standards and quality expectations. The increase in reporting is difficult to estimate as it is not known at this time how many required reporting facilities will choose to hire a Certified Tumor Registrar to complete the reporting, or if they will choose to have OSCaR charge them for the services. This may vary based on the average number of cases a facility reports annually. It is possible rural and smaller facilities would choose to pay OSCaR to report data, rather than hire a Certified Tumor Registrar.

The proposed rule amendments also clarify how OHA charges for costs associated with reporting on behalf of health care facilities. This will allow the OSCaR program to recuperate costs incurred from providing services to health care

facilities. However, this will not generate additional revenue for OSCaR, as staff are currently providing these services to health care facilities not in compliance.

Changes in the definitions of reportable cancers, and the clarification of rules relating to quality standards, confidentiality and federal research regulations will have no fiscal or economic impact on OSCaR or other parties.

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**COST OF COMPLIANCE:**

*(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).*

(1) The proposed rules revisions are expected to clarify OSCAR processes and procedures to make them more efficient and aligned with national standards and requirements. Updates to quality standards, confidentiality requirements and research regulations will strengthen the protection of cancer patients' confidential health information. As noted above, OHA will be able to recuperate the costs incurred for providing reporting services to health care facilities. There is no anticipated cost of compliance impact to other state agencies, units of local government, or the public.

(2)(a) There are small independent health care practices that diagnose or provide treatment for cancer that are required to report data to the Authority that will be impacted by these rules changes. Small independent health care practices currently have the option to report directly to OSCaR, or to report through a health care facility that is providing treatment to the same patient. It is unknown how many small independent health care facilities are currently not reporting cancer data versus reporting through health care facilities, so the Authority is not able to estimate how many of these small independent health care practices would be impacted by the proposed rules changes.

(b) Small independent health care practices that diagnose or provide treatment for cancer that are currently not reporting to OSCaR will have to begin reporting cancer cases to OSCaR as a result of these changes in rule (and associated statute). It is unknown how many cancer patients are seen at these small independent health care facilities, so it is unknown what the increased cost of reporting or recordkeeping might be. If small independent health care practices are unable to report cases, the Authority will provide reporting services at cost to the practices.

(c) Small independent health care practices that diagnose or provide treatment for cancer that are currently not reporting to OSCaR will have to begin reporting cancer cases to OSCaR as a result of these changes in rule (and associated statute). It is unknown how many cancer patients are seen at these small independent health care facilities, so it is unknown what the increased cost of equipment, supplies labor or administration might be. If small independent health care practices are unable to report cases, the Authority will provide reporting services at cost to the practices.

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**DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):**

OHA contacted several cancer treatment facilities, small practices, and member associations that represent these stakeholders to invite participation in the RAC. The president of the Oregon Society of Medical Oncology, which represents many of these small practices, participated on the RAC.

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**WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES**

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RULES PROPOSED:

333-010-0000, 333-010-0010, 333-010-0020, 333-010-0030, 333-010-0032, 333-010-0040, 333-010-0050, 333-010-0055, 333-010-0060, 333-010-0080, 333-010-0090

AMEND: 333-010-0000

RULE SUMMARY: Changes are made to align with statute. "Cancer reporting facility" is changed to "Health Care Facility"; "Heath Care Provider" is changed to "Practitioner". The definition of "Health Care Facility" is expanded to align with statute, and include "any other facility in which patients are diagnosed or provided treatment for cancer or benign or borderline tumors of the brain and central nervous system. "Central Registry Cancer Notification Form" is changed to "Central Cancer Registry Notification Form". Clarification is added on the certification for Cancer Registrars. Clarifies that the data standards manual used is for the current year of diagnosis, and adds a website link to the most current data standards and data dictionary.

CHANGES TO RULE:

333-010-0000

Cancer Reporting Regulations: Definitions ¶¶

- (1) "Active follow-up program" means a program for ~~contacting a caregiver or cancer patient~~ a health care facility to determine, at least annually, information including but not limited to the vital status of each case.¶¶
- (2) "Admitted" means a rendering of any service by the ~~reporting health care~~ health care facility to a patient under the authority or auspices of the facility's license under ORS 441.015, including but not limited to routine admission to the hospital, admission to the emergency room, or receiving services in an out-patient clinic.¶¶
- (3) "~~Authority-~~" means the Oregon Health Authority.¶¶
- (4) "~~Cancer reporting facility" means a hospital or other health care facility in which cancer is diagnosed or treated and is also one of the following:~~"
- (a) ~~A facility currently licensed as a hospital as defined under the provisions of ORS 442.015(13); or~~¶¶
- (b) ~~A facility currently licensed as an ambulatory surgical center as defined under ORS 442.015(3)(a).~~¶¶
- (5) "Central cancer registry" means the Oregon Health Authority, Public Health Division program authorized to collect, receive, and maintain cancer data for the entire state and which maintains the system by which the collected information is reported to the Division.¶¶
- (65) "~~Central Cancer Registry Cancer Notification Form-~~" means the form required for ~~health care provid~~ practitioners to report a case of reportable cancer or reportable non-malignant condition.¶¶
- (76) "Certified tumor registrar" means an individual who passes the certification examination and is currently certified by the Council on Certification of the National Cancer Registrars Association which provides the education and skills needed to fully abstract a cancer case.¶¶
- (87) "~~Clinical laboratory-~~" means a facility where microbiological, serological, chemical, hematological, immunohematological, immunological, toxicological, cytogenetical, exfoliative cytological, histological, pathological or other examinations are performed on material derived from the human body, for the purpose of diagnosis, prevention of disease or treatment of patients by physicians, dentists and other persons who are authorized by license to diagnose or treat humans.¶¶
- (98) "~~Date of diagnosis" means the date of initial diagnosis by a health care provid~~ practitioner for the cancer being reported.¶¶
- (109) "Division" means the Public Health Division of the Oregon Health Authority.¶¶
- (140) "First course of treatment" means all methods of treatment recorded in the treatment plan and administered to a person with a case of reportable cancer or reportable non-malignant condition before disease progression or recurrence, as defined in the American College of Surgeons Commission on Cancer ~~Facility~~ Oncology Registry Data Standards Manual, 2014 that is for the current year of diagnosis.¶¶
- (121) "~~Health care provider means any person whose professional license allows him/her to~~ facility" means a hospital, as defined in ORS 442.015, or an ambulatory surgical center, as defined in ORS 442.015 or any other¶¶

facility in which patients are diagnosed or treat cancer patients provided treatment for cancer or benign or borderline tumors of the brain and central nervous system.¶

(132) "Health system cancer registry" means a cancer registry maintained by a health system that includes all reportable cancer cases occurring in the population served by at the health system, whether or not the cases are diagnosed or treated in the cancer-reporting health systems health care facilities.¶

(143) "OSCaR" means the Oregon State Cancer Registry, Oregon' and has the same meaning as "central cancer registry".¶

(14) "Practitioner" means any person whose professional license allows the person to diagnose or treat cancer patients.¶

(15) "Quality control system" means operational procedures by which the accuracy, completeness, and timeliness of the information reported to OSCaR can be determined and improved.¶

(16) "Reportable cancer" means all malignant neoplasms including carcinoma in situ, except basal and squamous cell carcinoma of the skin, carcinoma in situ of the cervix uteri, ~~and~~ CIN III (diagnosed on or after January 1, 1996), and PIN III (diagnosed on or after January 1, 2001).¶

(17) "Reportable Cancer Data Items List-" means the list of variables for reportable cancers and reportable non-malignant conditions reported by cancer-reporting health care facilities following the recommendations of the Centers for Disease Control and Prevention National Program of Cancer Registries ("CDC-NPCR-") and further defined by the North American Association of Central Cancer Registries ("NAACCR-") Data Standards and Data Dictionary, ~~2011~~available on the Oregon State Cancer Registry website: [www.healthoregon.org/oscar](http://www.healthoregon.org/oscar).¶

(18) "Reportable non-malignant condition-" means benign or borderline tumors of the brain (including the meninges and intracranial endocrine structures) and central nervous system, diagnosed on or after January 1, 2004.¶

(19) "Reportable pre-malignant condition-" means all high-grade squamous intraepithelial lesion (CIN 2,3) and adenocarcinoma in situ (AIS) of the uterine cervix, high-grade squamous intraepithelial lesion of the vagina and vulva (VAIN 2,3/VIN 2,3), and high-grade squamous intraepithelial lesion (AIN 2,3) and carcinoma in situ of the anus.¶

(20) "Special study" means a Division-sponsored project that explores a particular facet of cancer incidence, morbidity, or mortality including, but not limited to, exploring hypotheses of disease risk, treatment options or cancer control authorized under ORS 432.520.

Statutory/Other Authority: ORS 432.500, 432.510, 432.540

Statutes/Other Implemented: ORS 432.510, 432.520, 432.540

REPEAL: 333-010-0010

RULE SUMMARY: The General Authority rule is repealed because it is duplicative of the statute.

CHANGES TO RULE:

~~333-010-0010~~

~~Cancer Reporting Regulations: General Authority~~

~~ORS 432.510 directs the Oregon Health Authority to establish a uniform, statewide, population-based registry system for the collection of information determining the incidence of cancer and benign tumors of the brain and central nervous system and related data. The purpose of the registry shall be to provide information to design, target, monitor, facilitate, and evaluate efforts to reduce the burden of cancer and benign tumors among the residents of Oregon. ORS 432.510, subsections (a) through (e) further specify that such efforts may include but are not limited to:~~

- ~~(1) Targeting populations in need of screening or other cancer control services;~~
- ~~(2) Supporting the operation of hospital registries and upgrading the care of cancer and benign tumors;~~
- ~~(3) Investigating suspected clusters;~~
- ~~(4) Conducting studies to identify cancer hazards; and~~
- ~~(5) Projecting the benefits or costs of alternative policies regarding the prevention or treatment of benign tumors or cancer.~~

~~Statutory/Other Authority: ORS 432.510~~

~~Statutes/Other Implemented: ORS 432.510~~

AMEND: 333-010-0020

RULE SUMMARY: Updates language to reflect changes made in Definitions rule (333-010-0000). Shortens the reporting period for health care facilities to report cancer data to Oregon Health Authority from two years to one year.

CHANGES TO RULE:

333-010-0020

Cancer Reporting Regulations: Reporting Requirements for ~~Cancer Reporting~~Health Care Facilities ¶

This rule describes the specific requirements for ~~cancer reporting~~health care facilities. Such facilities include inpatient facilities, outpatient facilities acting under the license of a hospital, ambulatory surgical centers, ~~and~~ privately owned treatment or diagnostic centers contracted to and acting as a department of a ~~cancer reporting facility.~~¶

~~(1) Cancer reporting health care facility or any other facility in which patients are diagnosed or provided treatment for cancer or benign or borderline tumors of the brain and central nervous system.~~¶

(1) Health care facilities must report to OSCaR each case of reportable cancer or reportable non-malignant condition, as defined in OAR 333-010-0000(16) and 333-010-0000(18) respectively, in patients admitted for diagnosis ~~and/or~~ any part of the first course of treatment for that cancer. OSCaR will make lists of reportable cancers and reportable non-malignant conditions available on the Oregon State Cancer Registry website: [www.healthoregon.org/oscar](http://www.healthoregon.org/oscar).¶

(2) ~~Cancer reporting~~Health care facilities must report cases of reportable cancer or reportable non-malignant conditions to OSCaR as stipulated in OAR 333-010-0020(1) within 180 days of the date the case first receives cancer diagnostic or treatment services at the facility.¶

(3) ~~Cancer reporting~~Health care facilities with an active follow-up program must annually report vital status, date of last patient contact, and, if available, cancer or tumor status of reportable cancers and reportable non-malignant conditions to OSCaR.¶

(4) ~~Cancer reporting~~Health care facilities must report their cases of reportable cancer or reportable non-malignant conditions and any follow-up information to OSCaR in the electronic data exchange format and codes, Record Type A: Case Abstract, as specified by NAACCR, including the variables specified in the Reportable Cancer Data Items List. The OSCaR Reportable Data Items List will be available on the Oregon State Cancer Registry website: [www.healthoregon.org/oscar](http://www.healthoregon.org/oscar).¶

(5) OSCaR shall establish a system of confirmation of receipt of cases submitted by each ~~cancer reporting facility.~~¶

~~(6) Cancer reporting health care facility.~~¶

(6) Health care facilities reporting cases of reportable cancer or reportable non-malignant conditions to a health system cancer registry have discharged their reporting responsibilities provided that the health system registry reports those cases to OSCaR according to the requirements for ~~cancer reporting~~health care facilities.¶

(7) ~~Cancer reporting~~Health care facilities may also elect to contract with a private vendor or contractor to report cases of reportable cancer and reportable non-malignant conditions to OSCaR as outlined above in OAR 333-010-0020(1) through (4).¶

(8) Any ~~cancer reporting~~health care facility designated as a Type A or Type B rural hospital by the Oregon Office of Rural Health, may elect to meet the cancer reporting requirements by conducting their own identification of cases of reportable cancer and reportable non-malignant conditions and mailing a copy of the relevant portions of the medical record for each case to the central cancer registry. The central cancer registry staff will abstract and report such cases and bill the hospital for this service at its cost. Type A or Type B rural hospitals which authorize the central cancer registry to abstract and report cases have fulfilled their abstracting and reporting requirements under these rules.¶

(9) Upon application to OSCaR by a ~~cancer reporting~~health care facility, OSCaR may grant to the facility an extension of time, not to exceed ~~two~~one years, in which to meet the reporting requirements. Such requests must be in writing and directed to the ~~Medical Director of OSCaR~~state central cancer registry manager, with a copy to the State Health Officer at the Division. On request, the central cancer registry staff shall provide technical

assistance to facilities to meet the reporting requirements.¶¶

(10)(a) If cancer reports from a ~~reporting~~health care facility do not meet reporting requirements, OSCaR shall inform the facility in writing of the disparity between the facility's reports and the reporting standards. OSCaR will then consult with the facility regarding its options for meeting the reporting standards, as defined in OAR 333-010-0020(1) through (4). Options shall include, but are not limited to:¶¶

(A) Further consultation and training;¶¶

(B) Referral to contractors for reporting services;¶¶

(C) Provision, at cost, of reporting services by OSCaR. By selecting this option, ~~cancer reporting~~health care facilities will fulfill all reporting requirements as defined in OAR 333-010-0090.¶¶

(b) If, after a minimum of 30 days from the receipt of the written notification, the facility cannot meet the reporting requirements, OSCaR may activate its reporting service for the facility. When activated, OSCaR may enter the facility, obtain the information and report it in conformance with the appropriate format and standards. In these instances, the facility shall reimburse OSCaR or its authorized representative for the cost of obtaining and reporting the information.

Statutory/Other Authority: ORS 432.510, 432.520, 432.570

Statutes/Other Implemented: ORS 432.510, 432.520

AMEND: 333-010-0030

RULE SUMMARY: Updates language to reflect changes made in Definitions rule (333-010-0000).

CHANGES TO RULE:

333-010-0030

Cancer Reporting Regulations: Reporting Requirements for ~~Health Care Provider~~Practitioners ¶

(1) Any ~~health care provider~~practitioner diagnosing a case of reportable cancer or a reportable non-malignant condition, as defined in OAR 333-001-0000(16) and 333-010-0000(18) respectively, must notify OSCaR of each such case within 180 days of the diagnosis of the case. OSCaR will make lists of reportable cancers and reportable non-malignant conditions available on the Oregon State Cancer Registry website: [www.healthoregon.org/oscar](http://www.healthoregon.org/oscar).¶

(2) Data items required for reporting a case of reportable cancer or reportable non-malignant condition shall include, but not be limited to, cancer diagnosis and treatment information, patient demographics, and ~~health care provider~~practitioner contact information, as specified on the Central Cancer Registry ~~Cancer~~-Notification Form. Copies of the Central Cancer Registry ~~Cancer~~-Notification Form will be available on the Oregon State Cancer Registry website: [www.healthoregon.org/oscar](http://www.healthoregon.org/oscar).¶

(3) ~~Health care provider~~Practitioners must comply with one of the following optional notification methods as may be directed by OSCaR:¶

- (a) Completion and submission (by mail or facsimile) of the Central Cancer Registry ~~Cancer~~-Notification Form; or¶
- (b) An encrypted electronic communication directed to OSCaR containing the information required by the Central Cancer Registry ~~Cancer~~-Notification Form.¶

(4) ~~Health care providers~~Practitioners do not need ~~to~~ report any case admitted to an Oregon ~~reporting facility~~health care facility within 180 days of diagnosis for:¶

- (a) A diagnosis of a reportable cancer or reportable non-malignant condition; or¶
- (b) All or any part of the first course of treatment for that case, providing that admission to the facility occurs within 180 days of diagnosis.¶

(5) ~~Health care provider~~Practitioners reporting cases of reportable cancer and reportable non-malignant conditions to a health system cancer registry have ~~discharge~~executed their reporting responsibilities provided that the health system cancer registry reports those cases to OSCaR according to the requirements for ~~cancer reporting~~health care facilities.¶

(6) If a ~~health care provider~~practitioner fails to notify OSCaR of cases of reportable cancer and reportable non-malignant conditions according to the standards and format prescribed for ~~health care provider~~practitioners, OSCaR may inform the ~~health care provider~~practitioner in writing of the disparity between the ~~health care provider~~practitioner's reporting performance and the reporting standards and consult with the ~~health care provider~~practitioner regarding methods for bringing the ~~health care provider~~practitioner's reporting performance into compliance with the reporting standards.¶

(7) If OSCaR does not receive information from another source completing the information required for a case of reportable cancer or reportable non-malignant condition submitted by a ~~health care provider~~practitioner, or if OSCaR learns of an unreported case for which the ~~health care provider~~practitioner has reporting responsibility but of which the central cancer registry has not been notified by the ~~health care provider~~practitioner, OSCaR may notify the ~~health care provider~~practitioner of the missing information or case and the ~~health care provider~~practitioner must, within 30 days, submit requested additional information to OSCaR. In the alternative, OSCaR may contact the ~~health care provider~~practitioner and schedule a time to abstract the necessary data from the ~~health care provider's~~records. ~~The health care provider's records.~~ The practitioner must provide access to those portions of a patient's medical record which provide data for the items specified in the Reportable Cancer Data Items List. In these instances, the ~~health care provider~~practitioner must reimburse OSCaR or its authorized representative for the cost of obtaining and reporting the information.¶

(8) OSCaR shall establish a system of confirmation of receipt of cases submitted by ~~health care provider~~practitioners.

Statutory/Other Authority: ORS 432.510, 432.520

Statutes/Other Implemented: ORS 432.510, 432.520

AMEND: 333-010-0032

RULE SUMMARY: Clarifies that the reporting format for data provided by clinical laboratories is directed by the Oregon Health Authority.

CHANGES TO RULE:

333-010-0032

Cancer Reporting Regulations: Reporting Requirements for Clinical Laboratories ¶¶

(1) Clinical laboratories must report to OSCaR all cases with test results indicative of and specific for a reportable cancer or reportable non-malignant condition, as defined in OAR 333-010-0000(16) and 333-010-0000(18) respectively, ("Cancer Pathology Reports") in accordance with the following provisions. Clinical laboratories must submit all Cancer Pathology Reports to OSCaR using the electronic data exchange format and codes set forth in the guidelines for Pathology Laboratory Electronic Reporting issued by the North American Association of Central Cancer Registries ("NAACCR"), unless reported to a health system cancer registry. The NAACCR Guidelines for Pathology Laboratory Electronic Reporting are available from OSCaR.¶¶

(2) Clinical laboratories must also report to OSCaR all cases with biopsies (excluding cytologic tests) indicative of and specific for a reportable pre-malignant condition, as defined in OAR 333-010-0000(16), in an electronic format ~~mutually agreed to by OSCaR and the clinical laboratory~~ directed by OSCaR. These reports must include (if available to the clinical laboratory):¶¶

(a) Name, address, and telephone number of the physician listed on the lab order;¶¶

(b) Name, address, and telephone number of the reporting laboratory;¶¶

(c) Patient name, gender, address (if available), birth date, race/ethnicity;¶¶

(d) Primary site and type of cancer-related condition; and¶¶

(e) Date of diagnosis.¶¶

(3) OSCaR will make lists of reportable cancers, reportable non-malignant conditions, and reportable pre-malignant conditions available on the Oregon State Cancer Registry website: [www.healthoregon.org/oscar](http://www.healthoregon.org/oscar). If a clinical laboratory fails to submit the required cancer pathology reports or reports of pre-malignant conditions to OSCaR according to the standards and format prescribed, OSCaR may inform the laboratory in writing of the disparity between the laboratory's reporting performance and the reporting standards and consult with the laboratory regarding methods for bringing the clinical laboratory's reporting performance into compliance with the reporting standards.¶¶

(4) If a clinical laboratory is not able to submit cancer pathology reports or reports of pre-malignant conditions electronically, OSCaR may authorize the clinical laboratory to report by mail or facsimile for a limited period of time to be specified by OSCaR.¶¶

(5) OSCaR shall establish a system of confirmation of receipt of cancer pathology reports and reports of pre-malignant conditions submitted by clinical laboratories.

Statutory/Other Authority: ORS 432.510, 432.520

Statutes/Other Implemented: ORS 432.510, 432.520

AMEND: 333-010-0040

RULE SUMMARY: Adds provision stating that the state cancer registry may provide training and corrective measures to improve data accuracy, validity and reliability. Adds provision to allow the state cancer registry to communicate with multiple reporting facilities to evaluate the accuracy of data reported. Updates language to reflect changes made in Definitions rule (333-010-0000).

CHANGES TO RULE:

333-010-0040

Cancer Reporting Regulations: Quality Standards ¶¶

The usefulness of OSCaR data is directly dependent upon the accuracy, completeness, and timeliness of the data available in its database. ORS 432.510(5) directs the Oregon Health Authority to establish a quality control ~~program~~ system for the data reported to the state registry. In order to assess these aspects of quality for cancer reporting, the central cancer registry will institute a program of continuous quality improvement.¶¶

(1) The continuous quality ~~improvement~~control system must include, but is not limited to, assessing coding edits, completeness audits or checks, reabstracting audits, and data analysis techniques to estimate data accuracy, validity, and reliability. OSCaR may provide training and corrective measures to improve data accuracy, validity, and reliability.¶¶

(2) For the purpose of assuring the accuracy and completeness of reported data;¶¶

(a) OSCaR shall have the right to periodically review all records that would identify cases of reportable cancer and reportable non-malignant conditions or would establish characteristics of the cancer, treatment of the cancer or the medical status of any identified cancer patient. OSCaR will provide advance notification of a minimum of 30 days, to allow time for the reporting sources to prepare records for review.¶¶

(3b) ~~When the collection on a patient has been seen for care or diagnosis by multiple reporting facilities, practitioners, or for cancer data from cancer reporting~~ clinical laboratories, OSCaR may communicate with the reporting facilities, providers and laboratories to evaluate the accuracy of data reported. OSCaR may disclose confidential cancer data to a health care facility, practitioner, or laboratory to correct, complete, or improve the accuracy of the reported data.¶¶

(3) The collection of cancer data from health care facilities, including data collection performed by OSCaR staff, must be performed either by certified tumor registrars or by staff knowledgeable about the following, as recommended by the American College of Surgeons, Commission on Cancer:¶¶

(a) Cancer as a disease process;¶¶

(b) General anatomy and physiology;¶¶

(c) Cancer epidemiology and statistics;¶¶

(d) Casefinding procedures; and¶¶

(e) Basic coding and staging schemes.¶¶

(4) A ~~cancer reporting~~ health care facility must report a minimum of 98 percent of the cases reportable by that facility for any calendar year in order to meet the requirement of these rules.¶¶

(5) The item-specific agreement rate of reported data from a ~~cancer reporting~~ health care facility with the information in the facility's medical record must not be less than 95 percent for those data items identified in the OSCaR Reportable Data Items list as quality control items.¶¶

(6) A ~~cancer reporting~~ health care facility must submit 98 percent of reportable cases to the central cancer registry within 180 days of either:¶¶

(a) The date of diagnosis; or¶¶

(b) The date of admission for receipt of any part of the first course of treatment provided in that facility, whichever is later.¶¶

(7) A ~~health care provider~~ practitioner must submit a minimum of 95 percent of reportable cases to the central cancer registry within 180 days of the date of diagnosis.

Statutory/Other Authority: ORS 432.510, 432.520

Statutes/Other Implemented: ORS 432.510, 432.520

AMEND: 333-010-0050

RULE SUMMARY: Adds language to clarify the purpose of the rule. Further clarifies when confidential and privileged information collected and maintained by OSCaR may be shared and the process for obtaining aggregate non-confidential information that is not publically available.

CHANGES TO RULE:

333-010-0050

Cancer Reporting Regulations: Confidentiality and Access to Data ¶¶

This rule describes when confidential and privileged information collected and maintained by OSCaR may be shared and the process for obtaining aggregate non-confidential OSCaR information that is not publically available.¶¶

(1) All identifying information regarding individual patients, ~~cancer reporting~~health care facilities, clinical laboratories, and ~~health care provid~~practitioners reported pursuant to ORS 432.510 and 432.520, OAR 333-010-0020, 333-010-0030 and 333-010-0032 shall be confidential and privileged. Except as required in connection with the administration or enforcement of public health laws or rules, no public health official, employee, or agent shall be examined in an administrative or judicial proceeding as to the existence or contents of data collected under the cancer registry system.¶¶

(2) The information collected and maintained by OSCaR must be stored in secure locations, must be used solely for the purposes stated in ORS 432.510 and 432.520 and must not be further disclosed unless required by law, with the following exceptions:¶¶

(a) When OSCaR has entered into reciprocal cooperative agreements with other states to exchange information on resident cases, as provided for in ORS 432.540. Such agreements must provide for obtaining data on Oregon resident cases diagnosed or treated out of state, and for reciprocal rights of other states to receive information on residents of those states diagnosed or treated in Oregon. Before entering into an agreement with any other state, OSCaR must determine that the other state has comparable confidentiality protections;¶¶

(b) When disclosure to officers or employees of federal, state, or local government public health agencies is necessary to investigate or avoid a clear and immediate danger to other individuals or to the public generally;¶¶

(c) When the Authority elects to contract with another agency for performance of a registry function the Authority will require the contractor to agree to use the information only for the purposes of the central cancer registry, to maintain the information securely, and to protect the information from unauthorized disclosure as referred to in OAR 333-010-0050(1). Before entering into any contract with another agency the Authority must determine the agency has comparable confidentiality protections; and¶¶

(d) When the Authority deems that the information is necessary for others to conduct research in conformance with the purposes for which the data are collected.¶¶

(3) ~~Cancer reporting~~Health care facilities shall have access to confidential and privileged data on any case submitted by that facility. When a patient has been seen for care ~~of a case of cancer by multiple cancer reporting facilities, OSCaR may share information on treatment and follow-up by multiple health care facilities, OSCaR may share corrected or amended information among the facilities, provided that all participating facilities have signed agreements with OSCaR to do so.~~¶¶

~~(4) Health care provid~~reporting facilities due to the data standards and accuracy needed for each cancer case.¶¶

~~(4) Practitioner~~s shall have access to confidential and privileged data on any case submitted by that ~~health care provid~~practitioner. When a patient has been seen for care of a case of cancer by multiple ~~health care provid~~practitioners, OSCaR may share information on treatment and follow-up among the ~~health care provid~~practitioners, provided that all participating ~~health care provider~~practitioners have signed agreements with OSCaR to do so.¶¶

~~(5) Access to non-confidential OSCaR data combined from multiple cancer cases and summarized as counts and rates thave signed agreements with OSCaR to do so~~ is not publically available is limited as follows:¶¶

~~(a) Requestor shall make a formal request to OSCaR;~~¶¶

(b) Requestor agrees to acknowledge OSCaR as the data source in any report or publication where the data is used;

(c) County is the smallest unit of geography for which data will be released; and

(d) Data will be suppressed based upon OSCaR's current confidentiality standard.

Statutory/Other Authority: ORS 432.510, 432.520

Statutes/Other Implemented: ORS 432.530, 432.540

AMEND: 333-010-0055

RULE SUMMARY: Clarifies the requirements for researchers using OSCaR data to comply with federal regulations.

CHANGES TO RULE:

333-010-0055

Cancer Reporting Regulations: Research Studies ¶

(1) Requirements for Research Studies. Before any confidential data may be disclosed to a researcher, OSCaR must:¶

(a) Approve a submitted protocol for the proposed research, which describes how the research will be used to determine the sources of cancer among the residents of Oregon or to reduce the burden of cancer in Oregon, in accordance with ORS 432.510 and OAR 333-010-0010;¶

(b) Agree that the data requested are necessary for the effective and efficient conduct of the study;¶

(c) Approve the researcher's submitted protocol and procedures for:¶

(A) Identifying patients to be contacted;¶

(B) Protecting against inadvertent disclosure of confidential and privileged data;¶

(C) Providing secure conditions to use and store the data;¶

(D) Assuring that the data will only be used for the purposes of the study; and¶

(E) Assuring that confidential and privileged data will be destroyed upon conclusion of the research;¶

(d) Determine that the researcher has access to sufficient resources to carry out the proposed research before releasing any confidential data;¶

(e) ~~Facilitate~~Confirm appropriate review of the research, including peer review for scientific merit, and review by the body used by the Authority as the Committee for the Protection of Human Research Subjects and established in accordance with 45 C.F.R. 46; ~~and~~;¶

(A) A researchers proposed study must comply with the requirements of the Federal Policy for the Protection of Human Subjects codified at 45 C.F.R. 46 as a condition of receiving confidential information from OSCaR.¶

(B) The Committee must evaluate studies under 45 C.F.R. Part 46s requirements for disclosure and must approve the study prior to OSCaR releasing any data.¶

(f) Determine the need for and require the researcher to implement other safeguards which, in the judgment of OSCaR, may be necessary for protecting confidential and privileged data from inadvertent disclosure due to unique or special characteristics of the proposed research.¶

(2) Contacting Patients for Research. As outlined in OAR 333-010-0035(2)(e) ~~&and~~ (f), participation in research is voluntary and patients may choose whether or not they want to participate in research studies.¶

(a) Before disclosing confidential patient information to a researcher, OSCaR must determine whether any of the patients meeting the criteria for the research study have previously informed OSCaR that they do not wish to participate in research. Such patients will be excluded from the list of patients provided to the researcher or contacted by OSCaR regarding research.¶

(b) Patients may be contacted a maximum of one time per year. Patients who meet the criteria for the research study and have been contacted for any OSCaR-related research study within a year preceding the initiation of the patient contact process for the research study will be excluded from the list of patients provided to the researcher or contacted by OSCaR regarding research.¶

(c) Unless OSCaR determines it to be impracticable, OSCaR ~~and~~/or the researcher must contact the patient's current treating physician to inform them of the study prior to any contact with a patient. In situations where the treating physician of record is no longer the patient's physician, OSCaR ~~and~~/or the researcher must make a good faith effort to find the patient's current physician.¶

(ed) When contacted, the patients physician must be informed of the study and the identity of the eligible patient. Within three weeks the physician must:¶

(A) Agree that direct contact by the researcher would be appropriate; or¶

(B) Indicate the presence of a medical, psychological or social situation in the patient's life that would make

contact inappropriate at that time. The physician is under no obligation to disclose the specifics of the medical, psychological or social situation.¶

(~~d~~e) If a researcher does not receive a response from the physician within one month, the researcher may contact the patient directly.¶

(ef) When a researcher contacts a patient directly, the researcher must include information explaining the registry, why the patients contact information was disclosed, and the purpose of the disclosure.¶

(g) Researchers are strictly prohibited from redisclosing patient names or other confidential information to other researchers, individuals, or institutions not specifically identified in the approved study protocol as outlined above.

Statutory/Other Authority: ORS 432.510, 432.530, 432.540

Statutes/Other Implemented: ORS 432.510, 432.530, 432.540

AMEND: 333-010-0060

RULE SUMMARY: Updates language to reflect changes made in Definitions rule (333-010-0000).

CHANGES TO RULE:

333-010-0060

Cancer Reporting Regulations: Special Studies ¶

(1) From time to time, OSCaR may elect to conduct special studies of cancer mortality, morbidity, treatment options and cancer control. OSCaR is specifically authorized to obtain any information which may apply to a patient's reportable cancer or reportable non-malignant condition, and which may be found in the medical record of the patient under ORS 432.510 and 432.520. Upon request, the ~~health care provider~~practitioner or health care facility must provide the requested information to OSCaR or provide OSCaR personnel access to the relevant portions of the medical records. Neither OSCaR nor the record holder shall bill the other for the cost of providing or obtaining this information.¶

(2) If, in the conduct of a special study, OSCaR identifies a need for access to pathological specimens that have been collected in connection with a case, OSCaR must make a written request to the clinical laboratory or the ~~cancer reporting~~health care facility with which the clinical laboratory is affiliated for the purpose of making arrangements for the procurement of such pathological specimens upon mutually agreeable terms.

Statutory/Other Authority: ORS 432.510, 432.520

Statutes/Other Implemented: ORS 432.510, 432.520

AMEND: 333-010-0080

RULE SUMMARY: Updates language to reflect changes made in Definitions rule (333-010-0000).

CHANGES TO RULE:

333-010-0080

Cancer Reporting Regulations: Training and Consultation ¶

The Authority shall provide annual continuing education for interested persons involved in cancer registry reporting. Continuing education content must include, but is not limited to, cancer diagnosis and management, epidemiology and statistics, and hardware and software registry applications. The central cancer registry staff must supplement the continuing education with one-on-one consultations to assist ~~cancer reporting facilities and health care providers~~ health care facilities and practitioners as needed in meeting the reporting requirements.

Statutory/Other Authority: ORS 432.510

Statutes/Other Implemented: ORS 432.510

AMEND: 333-010-0090

RULE SUMMARY: Adds detail to describe the process by which the Authority will calculate the cost of providing cancer reporting services to health care facilities, practitioners or clinical laboratories.

CHANGES TO RULE:

333-010-0090

Cancer Reporting Regulations: Fees ¶

OSCaR may establish fees, reasonably calculated, to reimburse for its actual cost in making OSCaR records and data available to researchers. Such costs include, but are not limited to, costs for computer programming; consultation; and for summarizing, compiling, analyzing, or tailoring records and data to a researchers need. This rule describes the process by which the Authority will calculate the cost of providing cancer reporting services to health care facilities, practitioners or clinical laboratories. For health care facilities, practitioners and clinical laboratories that are not in compliance with cancer reporting requirements, the Authority may elect to provide reporting services at cost. The Authority may also provide reporting services at the option of a health care facility, practitioner or clinical laboratory. ¶

(1) The Authority may charge a fee reasonably calculated to reimburse the Authority for the cost of providing cancer reporting services to health care facilities: ¶

(a) Costs include but are not limited to the services, supplies and time spent in: ¶

(A) Entering the health care facility, including transportation costs: ¶

(B) Obtaining the information, including costs associated with the electronic retrieval of records: ¶

(C) Reporting in conformance with the appropriate format and standards, including costs associated with the retrieval of paper or electronic records: ¶

(D) Computer programming necessary for reporting services: ¶

(E) Consultation with the health care facility on reporting in conformance with the appropriate format and standards: ¶

(b) Staff time will be calculated based on but not limited to hourly rate of pay, fringe benefits, office costs, insurance and information technology support for the position of the person performing the work. ¶

(2) The Authority shall notify the health care facility of the estimated costs for providing cancer case reporting services.

Statutory/Other Authority: ORS 432.5620

Statutes/Other Implemented: ORS 432.500 - 432.990