

OREGON ADMINISTRATIVE RULES
OREGON HEALTH AUTHORITY, PUBLIC HEALTH DIVISION
CHAPTER 333

DIVISION 10

HEALTH PROMOTION AND CHRONIC DISEASE PREVENTION

Cancer Reporting Regulations

333-010-0000

Definitions

- (1) "Active follow-up program" means a program for contacting a caregiver or cancer patient 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 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.
- (6) "Central Registry Cancer Notification Form" means the form required for health care providers to report a case of reportable cancer or reportable non-malignant condition.
- (7) "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.
- (8) "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.
- (9) "Date of diagnosis" means the date of initial diagnosis by a health care provider for the cancer being reported.
- (10) "Division" means the Public Health Division of the Oregon Health Authority.
- (11) "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, 2011.

(12) "Health care provider" means any person whose professional license allows him/her to diagnose or treat cancer patients.

(13) "Health system cancer registry" means a cancer registry that includes all reportable cancer cases occurring in the population served by a health system, whether or not the cases are diagnosed or treated in the cancer reporting facility.

(14) "OSCaR" means the Oregon State Cancer Registry, Oregon's central cancer registry.

(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 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.

(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.

Stat. Auth.: ORS 432.500, 432.510, 432.540

Stats. Implemented: ORS 432.510, 432.520, 432.540

333-010-0010

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.

Stat. Auth.: ORS 432.510

Stats. Implemented: ORS 432.510

333-010-0020

Reporting Requirements for Cancer Reporting Facilities

This rule describes the specific requirements for cancer reporting 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 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.
- (2) Cancer reporting 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 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 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.
- (5) OSCaR shall establish a system of confirmation of receipt of cases submitted by each cancer reporting facility.
- (6) Cancer reporting 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 facilities.
- (7) Cancer reporting 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 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 registry. The central 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 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 facility, OSCaR may grant to the facility an extension of time, not to exceed two years, in which to meet the reporting requirements. Such requests must be in writing and directed to the Medical Director of OSCaR. On request, the central registry staff shall provide technical assistance to facilities to meet the reporting requirements.

(10)(a) If cancer reports from a reporting 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 facilities will fulfill all reporting requirements.

(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.

Stat. Auth.: ORS 432.510, 432.520

Stats. Implemented: ORS 432.510, 432.520

333-010-0030

Reporting Requirements for Health Care Providers

(1) Any health care provider 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.

(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 contact information, as specified on the Central Registry Cancer Notification Form. Copies of the Central Registry Cancer Notification Form will be available on the Oregon State Cancer Registry website: www.healthoregon.org/oscar.

(3) Health care providers 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 Registry Cancer Notification Form; or

(b) An encrypted electronic communication directed to OSCaR containing the information required by the Central Registry Cancer Notification Form.

(4) Health care providers need not report any case admitted to an Oregon reporting facility 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 providers reporting cases of reportable cancer and reportable non-malignant conditions to a health system cancer registry have discharged their reporting responsibilities provided that the health system cancer registry reports those cases to OSCaR according to the requirements for cancer reporting facilities.
- (6) If a health care provider fails to notify OSCaR of cases of reportable cancer and reportable non-malignant conditions according to the standards and format prescribed for health care providers, OSCaR may inform the health care provider in writing of the disparity between the health care provider's reporting performance and the reporting standards and consult with the health care provider regarding methods for bringing the health care provider'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, or if OSCaR learns of an unreported case for which the health care provider has reporting responsibility but of which the central registry has not been notified by the health care provider, OSCaR may notify the health care provider of the missing information or case and the health care provider must, within 30 days, submit requested additional information to OSCaR. In the alternative, OSCaR may contact the health care provider and schedule a time to abstract the necessary data from the health care provider's records. The health care provider 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 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 providers.

Stat. Auth.: ORS 432.510, 432.520

Stats. Implemented: ORS 432.510, 432.520

333-010-0032

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. 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. 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.
- Stat. Auth.: ORS 432.510, 432.520
Stats. Implemented: ORS 432.510, 432.520

333-010-0035

Patient Notification Process

This rule describes the process for notifying patients that information about a reportable cancer has been reported to OSCaR.

- (1) OSCaR may, but is not required to notify patients that information about a diagnosis of reportable cancer has been included in the registry. OSCaR may make a determination, based on budgeting constraints or otherwise, to curtail patient notification activities.
- (2) Information to be provided to patients. The notification to the patient shall include the following information about the purposes of the registry and the protection of confidentiality:
 - (a) That Oregon statute requires that every cancer newly diagnosed in Oregon, or in an Oregon resident, be reported to the Oregon State Cancer Registry maintained by the Oregon Health Authority;
 - (b) That information reported to the Authority includes the type and characteristics of the cancer, details of the diagnosis and treatment given, and patient demographic information;
 - (c) That the information is used to understand how cancer affects the population in Oregon, to design and implement prevention and control programs, and for research;
 - (d) That the information is confidential and no identifiable information about the patient can be released to anyone unless very strict requirements, as provided by law, are met;
 - (e) If those specific requirements, as provided by law, are met, researchers may be allowed to contact patients to offer them the opportunity to participate in research projects. Any invitation to participate in research is always voluntary and may be freely declined; and
 - (f) That the researcher shall first notify the patient's physician regarding the patient's participation in a research project, unless the patient specifies to OSCaR that their name never be released for any research purpose.

Stat. Auth.: ORS 432.500
Stats. Implemented: ORS 432.500 - 432.900

333-010-0040

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 for the data reported to the state registry. In order to assess these aspects of quality for cancer reporting, the central registry will institute a program of continuous quality improvement.

(1) The continuous quality improvement system must include, but is not limited to, coding edits, completeness audits or checks, reabstracting audits, and data analysis techniques to estimate data accuracy, validity, and reliability.

(2) For the purpose of assuring the accuracy and completeness of reported data, 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.

(3) The collection of cancer data from cancer reporting 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 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 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 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 must submit a minimum of 95 percent of reportable cases to the central cancer registry within 180 days of the date of diagnosis.

Stat. Auth.: ORS 432.510
Stats. Implemented: ORS 432.510

333-010-0050

Confidentiality and Access to Data

(1) All identifying information regarding individual patients, cancer reporting facilities, clinical laboratories, and health care providers 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 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 among the facilities, provided that all participating facilities have signed agreements with OSCaR to do so.

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

Stat. Auth.: ORS 432.510, 432.520

Stats. Implemented: ORS 432.530, 432.540

333-010-0055

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 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
 - (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) & (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) 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.
 - (c) When contacted, the patient's 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) If a researcher does not receive a response from the physician within one month, the researcher may contact the patient directly.
 - (e) 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.
- Stat. Auth.: ORS 432.510, 432.530, 432.540
 Stats. Implemented: ORS 432.510, 432.530, 432.540

333-010-0060
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 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 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.

Stat. Auth.: ORS 432.510, 432.520

Stats. Implemented: ORS 432.510, 432.520

333-010-0070

Advisory Committee

The Authority shall appoint an advisory committee to review the operations of the central registry and to make recommendations regarding registry policy, and to review research protocols for which confidential and privileged data are requested. The composition of the advisory committee must generally represent those with a professional or personal interest in cancer.

Stat. Auth.: ORS 432.510, 432.520

Stats. Implemented: ORS 432.510

333-010-0080

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 registry staff must supplement the continuing education with one-on-one consultations to assist cancer reporting facilities and health care providers as needed in meeting the reporting requirements.

Stat. Auth.: ORS 432.510

Stats. Implemented: ORS 432.510