

DEPARTMENT OF COMMUNITY HEALTH

OFFICE OF THE STATE REGISTRAR

CANCER REPORTING

(By authority conferred on the department of community health by section 2619 of 1978 PA 368, MCL 333.2619)

R 325.9050 Registry.

Rule 9050.(1) The department shall establish a registry to record cases of cancer and other specified tumorous and precancerous diseases that occur in the state. The registry shall include information concerning these cases as the department considers necessary and appropriate to conduct epidemiologic surveys of cancer and cancer-related diseases in the state.

(2) Each diagnosed case of cancer and other specified tumorous and precancerous diseases shall be reported to the department pursuant to subrule (4) of this rule, or reported to a cancer reporting registry if the cancer reporting registry meets standards established pursuant to subrule (4) of this rule to ensure the accuracy and completeness of the reported information. A person or facility required to report a diagnosis pursuant to subrule (4) of this rule may elect to report the diagnosis to the state through an existing cancer registry only if the registry meets minimum reporting standards established by the department.

(3) The department shall maintain comprehensive records of all reports submitted pursuant to this rule. These reports shall be subject to the same requirements of confidentiality as provided in section 2631 of 1978 PA 368, MCL 333.2619 for data or records concerning medical research projects.

(4) The director shall provide for all of the following:

(a) A list of tumorous and precancerous disease other than cancer to be reported pursuant to subrule (2) of this rule.

(b) The quality and manner in which the cases and other information described in subrule (1) of this rule are reported to the department.

(c) The terms and conditions under which records disclosing the name and medical condition of a specific individual and kept pursuant to this rule are released by the department.

(5) This rule does not require an individual to submit to medical or department examination or supervision.

(6) The department may contract for the collection and analysis of, and research related to, the epidemiologic data required by this rule.

(7) Within 2 years after the effective date of these rules, the department shall begin evaluating the reports collected pursuant to subrule (2) of this rule. The department shall publish and make available to the public reports summarizing the information collected. The first summary report shall be published not later than 180 days after the end of the first 2 full calendar years after the effective date of this rule. Subsequent annual summary reports shall be made on a full calendar year basis and published not later than 180 days after the end of each calendar year.

(8) Reporting pursuant to subrule (2) of this rule shall begin the next calendar year after the effective date of this rule.

History: 2004 AACCS.

R 325.9051 Definitions.

Rule 9051. (1) As used in these rules:

(a) "Primary brain-related tumor" means a primary tumor, whether malignant or benign, of the brain, meninges, spinal cord, cauda equina, a cranial nerve or nerves, or any part of the central nervous system or of the pituitary gland, pineal gland, or craniopharyngeal gland.

(b) "Cancer" means all diagnosis with a behavior code of 2 (carcinoma in situ) or 3 (malignant primary site) as listed in the publication entitled "International Classification of Diseases for Oncology," 1976,

excluding basal, epithelial, papillary, and squamous cell carcinomas of the skin, but including carcinomas of skin of the vagina, prepuce, clitoris, vulva, labia, penis, and scrotum.

(c) "Department" means the department of community health.

(2) The terms "clinical laboratory" and "hospital," as defined in sections 20104 and 20106, respectively, of 1978 PA 368 and MCL 333.20106 have the same meanings when used in these rules.

History: 1985 AACCS; 2004 AACCS.

R 325.9052 Reportable diagnoses.

Rule 9052. (1) Cancer diagnoses, diagnoses of benign brain-related tumors and any tumorous and precancerous diseases otherwise required to be reported by state or federal law shall be reported to the department in a manner consistent with these rules and procedures issued by the department.

(2) Diagnoses shall be reported by all hospitals and clinical laboratories.

(3) A hospital or clinical laboratory may elect to report cases through a hospital or regional cancer registry that meets the rules set by the department.

(4) Reports shall be submitted within 180 days of a diagnosis on a form prescribed or approved by the department, except for reports forwarded on electronic media.

(5) Reports submitted on electronic media shall meet data quality, format, and timeliness standards prescribed by the department.

History: 1985 AACCS; 2004 AACCS.

R 325.9053 Quality assurance.

Rule 3. (1) For the purpose of assuring the quality of submitted data, each reporting entity shall allow the department to inspect such parts of a patient's medical records as are necessary to verify the accuracy of submitted data.

(2) A reporting entity which meets the standards of quality and completeness set by the department shall be subject to inspection not more than once every 2 years for the purpose of assessing the quality and completeness of reporting from the entity.

(3) A reporting entity shall, upon request of the department, supply missing information, if known, or clarify information submitted to the department.

(4) Upon mutual agreement between a reporting entity and the department, the reporting entity may elect to submit copies of medical records instead of inspection. Each copy of a medical record or part thereof submitted to the department pursuant to this rule shall be used only for verification of corresponding reported data, shall not be recopied by the department, and shall be kept in a locked file cabinet when not being used. Such copies shall be destroyed promptly following verification of the corresponding reported data or, if the reported data appears to be inaccurate, following clarification or correction of the reported data.

(5) Both of the following provisions shall be complied with to preserve the confidentiality of each patient's medical records:

(a) Each reporting entity shall provide to the department, for inspection only, all of the following records and reports:

(i) Reports of tissue analyses which have been performed for the purpose of determining the presence or absence of malignant disease.

(ii) Reports of radiological examinations performed for the purpose of determining the presence or absence of malignant disease.

(iii) Reports of diagnoses of malignant disease and notations of the reasons for such diagnoses, including both the primary clinician's reports and consultation reports.

(iv) Those parts of medical records which contain the specific information required to be reported.

(b) A reporting entity shall not be required by this rule to allow inspection of any part of any patient's medical record other than those parts listed in subrule (3) of this rule. A reporting entity may allow the inspection of medical records from which parts, other than those specified, have been deleted, masked, crossed out, or otherwise rendered illegible.

History: 1985 AACs.

R 325.9054 Confidentiality of reports.

Rule 4. (1) The department shall maintain the confidentiality of all reports of cancer submitted to the department and shall not release such reports, or any information which, because of name, identifying number, mark, or description, can be readily associated with a particular individual, except in accordance with subrules (2), (3), (4), and (5) of this rule. The department shall not release any information that would indicate whether or not the name of a particular person is listed in the cancer registry, except in accordance with subrules (2), (3), (4), and (5) of this rule.

(2) A report of cancer submitted to the department concerning a particular individual, and any other information maintained in the cancer reporting system which, because of name, identifying number, mark, or description, can be readily associated with a particular individual, shall be released as follows:

(a) To the particular individual upon compliance with both of the following provisions:

(i) Receipt of a written request which is signed by the particular individual and which is witnessed or notarized as required by subrule (3) of this rule.

(ii) Presentation by the particular individual of suitable identification as required by subrule (4) of this rule.

(b) If the particular individual is a minor, to a parent of the particular individual upon compliance with all of the following provisions:

(i) Receipt of a written request which is signed by the parent and which is witnessed or notarized as required by subrule (3) of this rule.

(ii) Receipt of a certified copy of the birth certificate of the particular individual.

(iii) Presentation by the parent of suitable identification as required by subrule (4) of this rule.

(c) If the particular individual has a court-appointed guardian or if the particular individual is deceased, to the court-appointed guardian or to the executor or administrator of the particular individual's estate upon compliance with all of the following provisions:

(i) Receipt of a written request which is signed by the court-appointed guardian, executor, or administrator and which is witnessed or notarized as required by subrule (3) of this rule.

(ii) Receipt of a certified copy of the order or decree which appoints the guardian, executor, or administrator.

(iii) Presentation by the guardian, executor, or administrator of suitable identification as required by subrule (4) of this rule.

(d) To an attorney or other person designated by the particular individual upon compliance with both of the following provisions:

(i) Receipt of a written request which is signed by the particular individual, which is witnessed or notarized as required by subrule (3) of this rule, and which requests release of the information to the attorney or other person.

(ii) Presentation by the attorney or other person of suitable identification as required by subrule (4) of this rule.

(e) To an attorney or other person designated by the court-appointed guardian of the particular individual or designated by the executor or administrator of the estate of the particular individual upon compliance with all of the following provisions:

(i) Receipt of a written request which is signed by the court-appointed guardian, executor, or administrator, which is witnessed or notarized as required by subrule (3) of this rule, and which requests release of the information to the attorney or other person.

(ii) Receipt of a certified copy of the order or decree which appoints the guardian, executor, or administrator.

(iii) Presentation by the attorney or other person of suitable identification as required by subrule (4) of this rule.

(f) If the particular individual is a minor, to an attorney or other person designated by the parent of the particular individual upon compliance with all of the following provisions:

(i) Receipt of a written request which is signed by the parent, which is witnessed or notarized as required by subrule (3) of this rule, and which requests release of the information to the attorney or other person.

(ii) Receipt of a certified copy of the birth certificate of the particular individual.

(iii) Presentation by the attorney or other person of suitable identification as required by subrule (4) of this rule.

(3) Every written request for the release of information submitted pursuant to subrule (2) of this rule shall be signed by the person making the written request. Such signature shall comply with either of the following provisions:

(a) Be witnessed by an employee of the department who has been designated to witness such requests and to whom the person making the request presents suitable identification as required by subrule (4) of this rule.

(b) Be notarized by a notary public or magistrate.

(4) Any person who is required by subrule (2) or (3) of this rule to present suitable identification shall present an identification document, such as a driver's license, or other document which contains both a picture of the person and the signature or mark of the person.

(5) The director of the department may, pursuant to R 325.9055, release information from the cancer reporting system to an authorized representative of a study or research project reviewed by the scientific advisory panel and approved by the director. The department shall not release any part of a patient's medical record obtained pursuant to R 325.9053.

History: 1985 AACS.

R 325.9055 Scientific advisory panel; release of information for research.

Rule 5. (1) The director of the department shall appoint a scientific advisory panel of not less than 3 scientists to review research proposals whereby a release of information maintained by the department which identifies an individual reported to have a diagnosis of cancer is required.

(2) All research proposals which require the release of information that identifies individuals with reported diagnoses of cancer shall be reviewed by the scientific advisory panel.

(3) The panel shall, in writing, advise the director concerning the merits of the study.

(4) The release of information for research which identifies individuals with reported diagnoses of cancer shall be subject to the terms and conditions set by the department. Such study or research project shall not publish the name of any individual who is or was the subject of a report of cancer submitted to the department, and such study or research project shall not release any identifying number, mark, or description which can be readily associated with an individual who is or was the subject of a report of cancer submitted to the department.

(5) A reporting entity shall, upon notification that the director has approved a research project, provide to the department or a researcher named by the director the name of the primary physician responsible for the medical care of persons selected for the research study as indicated in the reporting entity's records.

History: 1985 AACS.

R 325.9056 Exchange of records.

Rule 6. The department, by agreement, may transmit transcripts or copies of reports of cancer diagnoses to state or national cancer registries when the reports relate to residents of other states or countries. The agreement shall require that the transcripts or records be used for statistical purposes only as specified in the agreement and that the identity of a person subject to the report shall not be released.

History: 1985 AACS.

R 325.9057 Adoption by reference.

Rule 7. The publication entitled "International Classifications of Diseases for Oncology," 1976, specified in R 325.9051 is adopted by reference in these rules. Copies of the adopted matter may be obtained from the World Health Organization Publications Center, U.S.A., 49 Sheridan Avenue, Albany, NY 12210, or from the Department of Public Health, Box 30035, 3500 N. Martin Luther King, Jr. Blvd., Lansing, Michigan 48909. At the time of adoption of these rules the cost per copy is \$10.00.

History: 1985 AACCS.