

105 CMR: DEPARTMENT OF PUBLIC HEALTH

105 CMR 301.000: CANCER REGISTRY

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301.001: Purpose

The purpose of 105 CMR 301.000 is to facilitate the maintenance of the Cancer Registry established by the Massachusetts Department of Public Health pursuant to M.G.L. c. 111, § 111B, and in particular to:

- (A) Declare those cases of malignant disease and benign brain-related tumor disease which are required to be reported to the Department of Public Health for inclusion in the Cancer Registry;
- (B) Declare other necessary and appropriate information concerning reported cases which is required to be reported to the Department;
- (C) Declare those persons, facilities and agencies which are required to report cases of malignant disease and benign brain-related tumor disease and other necessary and appropriate information to the Department;
- (D) Require that the Cancer Registry of the Department of Public Health be given access to such part of patients' medical records as are necessary to verify the accuracy of reported information, and set forth procedures which will preserve the confidentiality of such records; and
- (E) Require that, consistent with M.G.L. c. 111, § 111B, the Department of Public Health maintain the confidentiality of reported information.

301.002: Authority

105 CMR 301.000 is promulgated pursuant to M.G.L. c. 111, §§ 3 and 111B.

301.003: Citation

105 CMR 301.000 shall be known and may be cited as 105 CMR 301.000: *Cancer Registry*.

301.004: Definitions

As used in CMR 301.000, the following words have the following meanings:

Benign Brain-related Tumors means a tumor (neoplasm) that grows in place with little or no potential to spread (invade) to other tissue. Tumors included in this definition occur in the following body sites, meninges, brain, spinal cord, cranial nerves, and other nerves of the central nervous system, pituitary gland, pineal gland, and craniopharyngeal duct as listed in the most recently amended "International Classification of Diseases for Oncology" (ICD-O), published by the World Health Organization.

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Cancer Registry means the Cancer Registry established by the Massachusetts Department of Public Health pursuant to M.G.L. c.111, § 111B.

Department means the Department of Public Health.

Health Care Facility means any facility or institution, whether public or private, proprietary or not for profit, including but not limited to hospitals, including general hospitals, free-standing radiation therapy and outpatient oncology centers, nursing homes, hospices, all pathology and cytology laboratories, including hospital laboratories, health maintenance organizations and other outpatient facilities such as free-standing surgical centers, which diagnose, evaluate or provide cancer treatment to cancer patients.

Health Care Provider means any licensed physician diagnosing, evaluating or providing cancer treatment to cancer patients.

Malignant Disease means any malignant (in-situ or invasive) disease which is listed in the most recently amended "International Classification of Diseases for Oncology" (ICD-O), published by the World Health Organization, excluding basal, epithelial, papillary and squamous cell carcinomas of the skin, but including carcinomas of the vermilion border of the lip, vulva, labia, penis, scrotum and anus.

Practitioner means any physician, medical examiner, dentist, podiatrist, chiropractor, or osteopath practicing in the Commonwealth of Massachusetts.

301.010: Cases Required to be Reported

Each case of malignant disease and benign brain-related tumor disease diagnosed, evaluated, treated, medically supported or palliated within the Commonwealth of Massachusetts is required to be reported to the Department of Public Health Cancer Registry together with information specified in 105 CMR 301.015 and in accordance with the current procedure manual as specified in 105 CMR 301.017.

301.015: Information Required to be Reported

Each report required by 105 CMR 301.010 shall include the following data categories:

- (A) Patient identifiers and demographics
- (B) Provider and facility identifiers
- (C) Cancer identification
- (D) Extent of disease at diagnosis
- (E) First course of treatment
- (F) Other information as necessary to ensure completeness

301.017: Data Collection Manual

The Cancer Registry maintains a data collection manual that identifies the discrete data items to be reported under 105 CMR 301.015 and the cases required to be reported under 105 CMR 301.010, which is available to all reporting facilities. The manual will be revised periodically in accordance with national cancer registration standards and Commonwealth-specific requirements.

301.020: Persons, Facilities, and Agencies Required to Report Information

Every health care facility shall report to the Cancer Registry every case of malignant disease and benign brain-related tumor disease diagnosed, evaluated, treated, medically supported or palliated at that health care facility. Every health care provider shall report to the cancer registry every case of malignant disease and benign brain-related tumor disease diagnosed, evaluated, treated, medically supported or palliated by that health care provider which has not been previously diagnosed, evaluated or treated at a health care facility.

All health care facilities and health care providers who provide diagnosis, evaluation, treatment, medical support or palliative services to patients with malignant disease or benign brain-related tumor disease shall report to the Cancer Registry any further demographic, diagnostic, or treatment information requested by the Cancer Registry concerning any person now or formerly receiving services, diagnosed as having or having had a malignant disease, or benign brain-related tumor disease. Additionally, the Cancer Registry shall have physical access to all records which would identify cases of malignant disease or benign brain-related tumor disease or would establish characteristics of the malignant disease or benign brain-related tumor disease, treatment of the malignant disease or benign brain-related tumor disease, or medical status of any identified malignant disease or benign brain-related tumor disease patient.

301.025: Report Form

Each report of a case of malignant disease and benign brain-related tumor disease required to be reported by 105 CMR 301.010 together with all accompanying information required to be reported by 105 CMR 301.015 and 105 CMR 301.017, that is reported by a hospital or laboratory shall be reported in an electronic format approved by the Department. Health care providers shall report either in an electronic format approved by the Department or on a report form approved by the Department.

301.030: Time for Reporting

All information required to be reported by 105 CMR 301.010, 105 CMR 301.015, and 105 CMR 301.017 shall be delivered to the Department of Public Health Cancer Registry within 180 days of the date of diagnosis, or date of first contact when provide diagnosis, evaluation, treatment, medical support or palliative services occurred elsewhere, of the case of malignant disease and benign brain-related tumor disease which is the subject of the reported information.

301.035: Quality Assurance

(A) For the purpose of assuring the quality of submitted data, each health care facility and health care provider shall allow the Cancer Registry to inspect and copy from time to time such parts of patients' medical records, paper and electronic, as are necessary to verify the accuracy and completeness of submitted data.

(B) Each health care facility and health care provider shall be required by 105 CMR 301.035 to provide to the Cancer Registry for inspection and/or copying only:

- (1) Reports of all tissue analyses which have been performed for the purpose of determining the presence or absence of malignant disease and benign brain-related tumor disease;
- (2) Reports (including x-rays) of radiological examinations performed for the purpose of determining the presence or absence of malignant disease and benign brain-related tumor disease;
- (3) Reports of diagnoses of malignant disease and benign brain-related tumor disease, and notations of the reasons for such diagnoses, including both primary clinician's reports and consultations reports; and
- (4) Those portions of medical records which contain the specific information required to be reported pursuant to 105 CMR 301.015.

(C) No health care facility nor health care provider shall be required by 105 CMR 301.035 to provide to the Cancer Registry any part of any patient's medical record other than those parts listed in 105 CMR 301.035(B)(1). A health care facility or health care provider may provide the Cancer Registry with copies of medical records from which parts other than those specified in 105 CMR 301.035(B)(1), have been deleted, masked, crossed out, or otherwise rendered illegible.

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(D) Each copy of a medical record or part thereof obtained by the Cancer Registry pursuant to 105 CMR 301.035:

- (1) Shall not be re-copied by the Cancer Registry;
- (2) Shall be kept in a secure area with restricted access when not being used by the Cancer Registry;
- (3) Shall be examined only by the Cancer Registry;
- (4) 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.

301.036: Case Ascertainment

(A) For the purpose of determining if all cases of malignant disease and benign brain-related tumor disease required under 105 CMR 301.010 have been reported, each health care facility shall allow the Cancer Registry to inspect and copy from time to time such parts of patients' medical records, paper and electronic, as are necessary to discover unreported cases of malignant disease and benign brain-related tumor disease.

(B) Each health care facility and health care provider shall be required by 105 CMR 301.036 to provide to the Cancer Registry for inspection and/or copying only:

- (1) Reports of all tissue analyses in order to determine the presence or absence of malignant disease or benign brain-related tumor disease;
- (2) Reports (including x-rays) of radiological examinations performed for the purpose of determining the presence or absence of malignant disease or benign brain-related tumor disease;
- (3) Reports of diagnoses of malignant disease or benign brain-related tumor disease, and notations of the reasons for such diagnoses, including both primary clinician's reports and consultations reports; and
- (4) Those portions of medical records which contain the specific information required to be reported pursuant to 105 CMR 301.015 and 105 CMR 301.017.

(C) No health care facility nor health care provider shall be required by 105 CMR 301.036 to provide to the Cancer Registry any part of any patient's medical record other than those parts listed in 105 CMR 301.036(B)(1). A health care facility or health care provider may provide the Cancer Registry with copies of medical records from which parts other than those specified in 105 CMR 301.036(B)(1), have been deleted, masked, crossed out, or otherwise rendered illegible.

(D) Each copy of a medical record or part thereof obtained by the Cancer Registry pursuant to 105 CMR 301.036:

- (1) Shall not be re-copied by the Cancer Registry;
- (2) Shall be kept in a secure area with restricted access when not being used by the Cancer Registry;
- (3) Shall be examined only by the Cancer Registry;
- (4) 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.

301.040: Confidentiality of Reports

(A) The Department shall maintain the confidentiality of reports submitted to the Cancer Registry pursuant to 105 CMR 301.010, 105 CMR 301.015 and 105 CMR 301.025, 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 105 CMR 301.040(B), (C), (D) and (E). 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 105 CMR 301.040(B), (C), (D) and (E).

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(B) A report submitted to the Cancer Registry concerning a particular individual, and any other information maintained by the Cancer Registry which, because of name, identifying number, mark or description can be readily associated with a particular individual, shall be released:

- (1) to the particular individual upon
 - (a) receipt of a written request which is signed by the particular individual and which is witnessed or notarized as required by 105 CMR 301.040(C), and
 - (b) presentation by the particular individual of suitable identification as required by 105 CMR 301.040(D);
- (2) if the particular individual is a minor, to a parent of the particular individual upon
 - (a) receipt of a written request which is signed by the parent and which is witnessed or notarized as required by 105 CMR 301.040(C), and
 - (b) receipt of a certified copy of the birth certificate of the particular individual, and
 - (c) presentation by the parent of suitable identification as required by 105 CMR 301.040(D);
- (3) 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
 - (a) 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 105 CMR 301.040(C), and
 - (b) receipt of a certified copy of the order or decree which appoints the guardian, executor, or administrator, and
 - (c) presentation by the guardian, executor, or administrator of suitable identification as required by 105 CMR 301.040(D);
- (4) to an attorney or other person designated by the particular individual upon
 - (a) receipt of a written request which is signed by the particular individual and which is witnessed or notarized as required by 105 CMR 301.040(C), and which requests release of the information to the attorney or other person, and
 - (b) presentation by the attorney or other person of suitable identification as required by 105 CMR 301.040(D);
- (5) 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
 - (a) 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 105 CMR 301.040(C), and which requests release of the information to the attorney or other person, and
 - (b) receipt of a certified copy of the order or decree which appoints the guardian, executor or administrator, and
 - (c) presentation by the attorney or other person of suitable identification as required by 105 CMR 301.040(D);
- (6) if the particular individual is a minor, to an attorney or other person designated by the parent of the particular individual upon
 - (a) receipt of a written request which is signed by the parent and which is witnessed or notarized as required by 105 CMR 301.040(C), and which requests release of the information to the attorney or other person, and
 - (b) receipt of a certified copy of the birth certificate of the particular individual, and
 - (c) presentation by the attorney or other person of suitable identification as required by 105 CMR 301.040(D).

(C) Every written request for the release of information submitted pursuant to 105 CMR 301.040(B), shall be signed by the person making the written request, and such signature shall be either:

- (1) 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 105 CMR 301.040(D); or
- (2) notarized by a notary public or magistrate.

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(D) Any person who is required by 105 CMR 301.040(B) or (C) to present suitable identification shall present an identification document such as a drivers license, liquor purchase identification card or other document which contains both a picture of the person and the signature or mark of the person.

(E) The Commissioner of the Department of Public Health may release information maintained by the Cancer Registry to the authorized representative of a study or research project authorized by the Commissioner. However, 105 CMR 301.040(E) shall not apply to, and the Department shall not release, any part of a patient's medical record obtained pursuant to 105 CMR 301.035, or 105 CMR 301.036, nor to any participant's Social Security number obtained pursuant to 105 CMR 301.015(A). No such study or research project shall publish the name of any individual who is or was the subject of a report submitted to the Cancer Registry nor shall any such study or research project release any identifying number, mark or description which can be readily associated with an individual who is or was the subject of a report submitted to the Cancer Registry.

REGULATORY AUTHORITY

105 CMR 301.000: M.G.L. c. 111, §§ 3, 111B.