# 105 CMR 301.000: CANCER REGISTRY

Section



## 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

(E) Require that, consistent with M.G.L. c. 111, § 111B, the Department of Public Health maintain the confidentiality of reported information and restrict releases to only specifically approved purposes.

## 301.005: Definitions

As used in 105 CMR 301.000, the following words have the following meanings:

Benign Brain-related Tumors. 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) or *Classification of Tumours* series, published by the World Health Organization.

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

Department. The Department of Public Health.

Health Care Facility. 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.

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Health Care Provider. Any physician, nurse practitioner, physician assistant, dentist, podiatrist, chiropractor, or osteopath who is licensed to practice in the Commonwealth of Massachusetts and who diagnoses a case of malignant disease or benign brain-related tumor, evaluates a previously diagnosed case of malignant disease or benign brain-related tumor, or provides cancer treatment to a cancer patient.

Malignant Disease. Any malignant (*in situ* or invasive) disease which is listed in the most recently amended *International Classification of Diseases for Oncology (ICD-O) or Classification of Tumours* series, published by the World Health Organization, excluding *in-situ* carcinomas of the uterine cervix and 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.

301.010: Required Reporting

(A) A health care facility shall report all cases of malignant disease and benign brain-related tumor disease that are diagnosed, evaluated, treated, medically supported or palliated at their facility. Each case of malignant disease and benign brain-related tumor disease within the Commonwealth of Massachusetts shall be reported to the Cancer Registry with information specified in 105 CMR 301.015 and in accordance with the current Cancer Registry Data Collection Manual as specified in 105 CMR 301.020.

(B) A health care provider who diagnoses, evaluates, treats, medically supports or palliates a case of malignant disease or benign brain-related tumor disease shall report such case to the Cancer Registry as specified in 105 CMR 301.010(A), except when the health care provider knows that a health care facility has reported or will report the case to the Cancer Registry.

301.015: Information Required to Be Reported

Each report required by 105 CMR 301.010 shall include all the data elements specified in the Cancer Registry Data Collection Manual, as described in 105 CMR 301.020, in the following data categories:

(A) Patient information and demographics

(B) Provider and facility information

(C) Cancer information

(D) Extent of disease at diagnosis;

(E) First course of treatment; and

(F) 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.

301.020: Data Collection Manual

The Cancer Registry maintains the Cancer Registry Data Collection Manual, which 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. The Cancer Registry Data Collection Manual is available to all reporting facilities.

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 301.020, that is reported by a health care facility 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, 301.015 and 301.020 shall be sent to the Cancer Registry within 180 days of the date of diagnosis, or date of first contact when diagnosis, evaluation, treatment, medical support or palliative services occurred elsewhere. Any missing information or changes to previously reported information shall be sent to the Cancer Registry as soon as the new information becomes available.

301.035: Quality Assurance and Case Ascertainment

(A) For the purpose of assuring the accuracy and completeness of submitted data and to ensure that all cases of malignant disease and benign brain-related tumor disease are reported, each health care facility and health care provider shall allow authorized Cancer Registry staff or agents to inspect and copy such parts of patients' medical records, paper and electronic, as are necessary to assure accurate and complete reporting and to identify any missing required reports.

(B) Each health care facility, health care provider, and pharmacist licensed in accordance with M.G.L. c. 112, § 24, shall provide copies of the following records to the Cancer Registry upon request:

(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 clinicians' reports and consultation reports;

(4) Pharmacy records for prescriptions relating to cancer treatment; and

(5) Those portions of medical records which contain the specific information required to be reported pursuant to 105 CMR 301.015.

301.040: Confidentiality of Cancer Registry Records

(A) The Department shall maintain the confidentiality of reports submitted to the Cancer Registry as well as other information collected pursuant to 105 CMR 301.035. 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 and shall not release such reports, or any other information which because of name, identifying number, mark or description can be readily associated with a particular individual, except the Department may release information contained in the Cancer Registry regarding a particular individual:

(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(B), and

(b) presentation by the particular individual of suitable identification as required by 105 CMR 301.040(C);

(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(B), and

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(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(C);

(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(B), 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(C);

(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(B), 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(C);

(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(B), 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(C);

(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(B), and which requests release of the information to the attorney or other person, and

(b) proof of age of the particular individual, and

(c) presentation by the attorney or other person of suitable identification as required by 105 CMR 301.040(C);

(7) to the authorized representative of a state or federal agency or a nonprofit organization for cancer surveillance or statistics pursuant to a data exchange agreement and subject to any conditions deemed appropriate by the Department;

(8) to authorized representatives of the National Cancer Institute and its authorized vendors for purposes of hosting and maintaining the Surveillance, Epidemiology, and End Results (SEER) data management system on behalf of the Department;

(9) to a cancer registry custodian in another state or jurisdiction for cancer diagnoses of residents of that other state or jurisdiction pursuant to a data exchange agreement and subject to any conditions deemed appropriate by the Department; and

(10) to the authorized representative of a study or research project approved by the Commissioner pursuant to M.G.L. c. 111, § 24A. However, the Department shall not release to the authorized representative of a study or research project any part of a patient's Social Security number. The authorized representative of a study or research project who receives Cancer Registry data shall not publish the name of any individual whose information is contained in the Cancer Registry or any other information which because of identifying number, mark or description could be readily associated with an individual whose information is contained in the Cancer Registry. The Department may impose other conditions for receipt of Cancer Registry data.

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(B) Every written request for the release of information submitted pursuant to 105 CMR 301.040(A), 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(C); or

(2) notarized by a notary public or magistrate.

(C) Any person who is required by 105 CMR 301.040(A) or (B) to present suitable identification shall present an identification document that contains both a picture of the person and the signature or mark of the person, such as a driver's license or non-driver identification card issued by a state motor vehicle licensing department, passport, state-issued liquor purchase identification card, or other government-issued identification which contains both a picture of the person and the signature or mark of the person.

REGULATORY AUTHORITY

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