



Maryland Cancer Registry

Reporting Requirements

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Purpose

This document outlines the Maryland Cancer Registry's reporting requirements for Maryland abstractors and reporting facilities.

Introduction to the Maryland Cancer Registry

State Cancer Registries

State cancer registries are designed to:

- Monitor cancer trends over time.
- Determine cancer patterns in various populations.
- Guide planning and evaluation of cancer control programs (e.g., determine whether prevention, screening, and treatment efforts are making a difference).
- Help set priorities for allocating health resources.
- Advance clinical, epidemiologic, and health services research.
- Provide information for a national database of cancer incidence.

Maryland Cancer Registry

The MCR registers all new cases of reportable cancer and benign brain and central nervous system tumors diagnosed and/or treated in Maryland according to Maryland law (see Appendix 1).

- In 1992, the Maryland General Assembly enacted Maryland Health-General Article, §§18-203 and 18-204. These laws required hospitals, radiation therapy centers, and in-state and out-of-state cancer diagnostic laboratories (that provide services to Maryland physicians) to electronically report all cancer cases diagnosed and/or treated in Maryland, beginning on July 1, 1993.
- In 1996, the laws were amended to require freestanding ambulatory care facilities, surgical centers, and physicians to report cancer cases diagnosed and/or treated, beginning on January 1, 1999.
- In 2001, the Maryland General Assembly enacted House bill 626, which requires the reporting of benign brain and central nervous system (CNS) tumors to the MCR, effective October 2001.

Through data exchange agreements with 12 other states, including the neighboring states of Delaware, Pennsylvania, Virginia, and West Virginia, as well as the District of Columbia, the MCR received information on all Maryland residents diagnosed and/or treated for cancer in these jurisdictions. The MCR also receives information on Maryland residents from selected District of Columbia and Federal hospitals.

The MCR receives funding from the State of Maryland, the Cigarette Restitution Fund, and the Centers for Disease Control and Prevention (CDC) National Program of Cancer Registries (NPCR).

The MCR is composed of a central office and a data management contractor. The MCR central office, located in the Department of Health and Mental Hygiene, 201 West Preston Street, Baltimore, MD, 21201, is part of the Center for Cancer Surveillance and Control and has administrative, technical, analytical, and custodial oversight of MCR data. For more information, please contact the MCR at 410-767-4055

Reporting Requirements: Frequently Asked Questions

What is the “reference date” of the Maryland Cancer Registry (MCR)?

The “reference date” of the MCR is the date of diagnosis after which reports must be submitted to the MCR. Any reportable cancer with a date of diagnosis of 1/1/1992 or after must be reported to the MCR (Health-General §18-204 (b)). Non-malignant central nervous system tumors with a date of diagnosis of 10/1/2001 or after must be reported to the MCR.

Who must report to the MCR and how? (Health-General §18-204 (b))

- Each hospital which has care of a patient with cancer or a central nervous system tumor,
- Each freestanding laboratory, freestanding ambulatory care facility, or therapeutic radiological center which has care of or has diagnosed cancer or a central nervous system tumor for a nonhospitalized patient, and
- Each physician who has care of or has diagnosed cancer or a central nervous system tumor for a nonhospitalized patient not otherwise reported
 - A "nonhospitalized patient not otherwise reported" means a patient diagnosed or treated for cancer or a CNS tumor in a physician's office without admission to a hospital or referral to a freestanding ambulatory care facility or freestanding therapeutic radiological center (COMAR 10.14.01.02 B. (11))

shall:

- Submit a cancer report to the Secretary, on the form that the Secretary provides or in a computerized file;
- Make available to the Secretary, or an agent of the Secretary, at the facility the information necessary to compile a cancer report; **or**
- Enter into an agreement with a hospital or other facility or agency that agrees to report to the Maryland Cancer Registry to act as the reporting source for a cancer or central nervous system tumor patient who has been referred to or from that facility, or reported to that agency with regard to cancer or central nervous system tumor screening, diagnosis, or treatment;

and shall

- Submit a cancer report in a computerized file* on a quarterly basis to the Secretary, or an agent of the Secretary, for all patients initially diagnosed, treated, or admitted to a facility for cancer or a central nervous system tumor during that calendar quarter.

Note: the MCR will contact reporting sources to obtain additional required information if it is not initially reported to the MCR.

* If a computerized record is not possible, the MCR will work with a reporter to accommodate reporting on *hard copy* forms if the reporter reports only a small number of cases each year.

How are these entities defined? (COMAR 10.14.01.02)

A “**hospital**” means a facility which is licensed by the State pursuant to COMAR 10.07.01.

A “**freestanding laboratory**” means a facility, place, establishment, or institution which performs a laboratory examination for a person, authorized by law to request the examination, in connection with the diagnosis of a reportable human cancer or CNS tumor, and is licensed by the State pursuant to COMAR 10.10.03, and:

- (a) Not under the administrative control of a hospital; or
- (b) Under the administrative control of a hospital for a diagnosis of reportable human cancer or CNS tumor of a nonhospitalized patient.

A “**freestanding ambulatory care facility**” has the meaning stated in Health-General Article, §19-3B-01, Annotated Code of Maryland.

A “**freestanding therapeutic radiological center**” means a facility, place, establishment, or institution performing radiological treatment for a person, authorized by law to request this treatment, in connection with a reportable human cancer or a CNS tumor, and licensed or registered by the State pursuant to COMAR 10.05.03, and not under the administrative control of a hospital.

A “**physician**” means an individual who practices medicine, as stated in Health Occupations Article, §14-101, Annotated Code of Maryland,

A “**nonhospitalized patient not otherwise reported**” means a patient diagnosed or treated for cancer or a CNS tumor in a physician's office without admission to a hospital or referral to a freestanding ambulatory care facility or freestanding therapeutic radiological center.

Which cases of cancer, in situ, and benign tumors are reportable to the MCR? Which are excluded? (COMAR 10.14.01.02 and Health-General §18-204 (a)(3))

The following is a list of reportable tumors followed by ICD-9-CM codes:

- Malignant Neoplasm: 140-208.9 (excludes basal and squamous cell carcinoma of *non-genital* skin sites)
- Carcinoma in situ: 230.0-234.9 (excludes codes 233.1 and 233.4 [cervical carcinoma in situ (CIS, CINIII)], and basal and squamous cell carcinoma of *non-genital* skin sites)

- Benign and borderline tumor of the brain or central nervous system: 225.0-225.9, 227.3-227.4
- Neoplasm involving plasma cells: 238.6

This table provides specific inclusions regarding reportable diagnoses:

Reportable Diagnoses	<ul style="list-style-type: none"> ▪ Any malignant and in situ tumor (behavior code 2 or 3 in ICD-O-3). ▪ Intraepithelial neoplasia of the following sites (abbreviation and ICD-O-3 codes): <ul style="list-style-type: none"> ▪ vaginal squamous intraepithelial neoplasia (VAIN 8077/2), ▪ vulvar squamous intraepithelial neoplasia (VIN 8077/2), and ▪ anal squamous intraepithelial neoplasia (AIN III 8077/2), ▪ Any non malignant primary intracranial and central nervous system tumor including juvenile astrocytoma for primary sites including the brain, the cauda equina, a cranial nerve, the craniopharyngeal duct, the meninges, the pineal gland, the pituitary gland, or the spinal cord. ▪ Neoplasm involving plasma cells (ICD-9-CM code 238.6). ▪ Squamous or basal cell cancer of <i>genital</i> skin sites.
Exclusions (NOT reportable)	<ul style="list-style-type: none"> ▪ Squamous or basal cell cancer of <i>non-genital</i> skin sites. ▪ Cervical carcinoma in situ (CIS) ▪ Intraepithelial neoplasia of the following sites (abbreviation, ICD-O-3 code): <ul style="list-style-type: none"> ▪ cervical squamous intraepithelial neoplasm (CIN III, 8077/2), ▪ prostatic glandular intraepithelial neoplasia (PIN, 8148/2) ▪ Borderline malignancy of the ovary (ICD-9-CM code 236.2).

**What is a “cancer report” and what information must a report contain?
(Health-General §18-204 (a) (2), COMAR 10.14.01.03)**

A "cancer report" means a 1-time abstract of the medical record of a patient diagnosed or treated for cancer or a central nervous system tumor which contains:

- (i) Reasonably obtained patient demographic information, including risk factors;
- (ii) Relevant information on the:
 1. Initial histologically precise diagnosis;
 2. Initial treatment;
 3. Extent of the disease by the end of the first hospitalization using a standard nomenclature specified by the Secretary; and
 4. Extent of the disease within 2 months of diagnosis using a standard nomenclature specified by the Secretary if the information is available to the reporting facility and the reporting facility has a tumor registry; and
- (iii) Facility and other provider identification information.
- (iv) Other requirements as considered necessary by the Secretary.

See Appendix 2 for a list of the fields required for reporting by type of facility/reporter.

What about reporting tumors that are not histologically confirmed?

What to report:

If a facility or reporter is in doubt about whether a case is reportable, please consult with the MCR or report the tumor. The MCR will match the report with any other reports on the same tumor in order to update the record on the tumor.

Ambiguous Terminology: Reporters must report tumors whose diagnosis is not histologically confirmed but that are *clinically diagnosed* cancer. Cases include those where “**ambiguous terminology**” is used (NAACCR Standards for Cancer Registries, Data Standards and Data Dictionary V11.1, page 22 [COC, SEER, and NPCR agree on these terms]). **The following ambiguous terms are considered diagnostic of cancer and must be reported:**

- | | |
|-------------------|-----------------------|
| - apparent(ly) | - malignant appearing |
| - appears | - most likely |
| - comparable with | - presumed |
| - compatible with | - probable |
| - consistent with | - suspect(ed) |
| - favors | - suspicious (for) |
| | - typical of |

Example: The inpatient discharge summary documents that the patient had a chest X-ray consistent with a carcinoma of the right upper lobe. The patient refused further work-up or treatment.

**Exception: if the cytology is reported as “suspicious” and neither a positive biopsy nor a physician’s clinical impression supports the cytology findings, do not consider as a diagnosis of cancer and do NOT report.*

Are there some tumors that should NOT be reported?

What NOT To Report: Exclusions

MCR reporting facilities and physicians are **not** required to submit abstracts for cases that meet the following criteria:

- A patient seen in consultation only. This could be a slide review from another laboratory, or a radiation therapy consultation where radiation is not recommended or the patient chooses not to have treatment at the facility;
- A patient seen for continuation of treatment started elsewhere in order to avoid interruption of a course of therapy. **Example:** A patient from California visiting Maryland, who was

diagnosed and had treatment in California, is admitted to a hospital for a course of chemotherapy while on vacation;

- A patient with an active, previously diagnosed cancer who is admitted to the reporting facility for an unrelated medical condition;
- A patient with a history of malignancy who is clinically free of disease;
- A patient admitted for terminal supportive care or hospice care.
- **Ambiguous Terminology:** The following ambiguous terms are NOT considered diagnostic of cancer and should NOT be reported (NAACCR Standards for Cancer Registries, Data Standards and Data Dictionary V11.1, page 22 [COC, SEER, and NPCR agree on these terms]):

-cannot be ruled out	- questionable
-equivocal	- rule out
-possible	-suggests
-possibly malignant	-worrisome

Example: Final diagnosis states “Mammogram shows possible carcinoma of the breast”. This case is not reportable.

When in doubt, call your assigned CTR for assistance.

Are “nonanalytic” cases reportable?

No. Reporters must report “analytic” cases as follows:

- **Class of Case = 0:** Diagnosis at the reporting facility and all of the first course of treatment was performed elsewhere or the decision not to treat was made at another facility.
- **Class of Case = 1:** Diagnosis at the reporting facility, and all or part of the first course of treatment was performed at the reporting facility.
- **Class of Case = 2:** Diagnosis elsewhere, and all or part of the first course of treatment was performed at the reporting facility, and
- **Class of Case = 7:** Pathology report only.

If, however, your facility does abstract non-analytic cases, you may submit them with your submissions to the MCR.

Is an out-of-state patient reportable to the MCR?

Yes, a cancer report **must** be submitted to the MCR on an **out-of-state patient if:**

- an out-of-state patient is hospitalized in a Maryland hospital;

- a non-hospitalized out-of-state patient is treated at an ambulatory care facility in Maryland or at a therapeutic radiological center in Maryland;
- a non-hospitalized out-of-state patient's specimen is sent to a laboratory located in and licensed in Maryland; or
- a non-hospitalized out-of-state patient is not otherwise reported to the MCR and is treated by a physician licensed in Maryland and practicing in Maryland.

When is a Maryland resident diagnosed or treated out of state reportable to the MCR?

A laboratory licensed in Maryland pursuant to COMAR 10.10.03 but *located outside of Maryland* **must report** to the MCR a Maryland resident who has a reportable cancer or benign brain or CNS tumor.

A physician licensed in Maryland but *practicing outside of Maryland* **must report** non-hospitalized Maryland resident who is not otherwise reported to the MCR and who is diagnosed and treated exclusively in his/her offices

A Maryland resident admitted to an out-of-state hospital or treated at an out-of-state facility will be reported to the other state's cancer registry and the MCR will receive the report from the other state if Maryland has an interstate agreement with the state.

Must a physician who gives outpatient chemotherapy to a patient report the case of cancer to the MCR?

Yes, a physician must report any non-hospitalized case of cancer (or benign brain or CNS tumor) that is not previously reported to the MCR. A physician who gives outpatient chemotherapy to a patient who has been previously reported to the MCR by, for example, a hospital, is not required to report the case.

Note, however, that the MCR will contact a reporting source to obtain additional required information if it is not initially reported to the MCR (e.g., if chemotherapy is not reported to the MCR from the hospital or laboratory, the MCR will contact the physician to obtain additional information).

Which data fields does the MCR require to be reported?

Fields that cover the information listed above are required. Appendix 2 gives the exact list of fields the MCR requires for each type of reporting facility.

What text should be entered in the Text fields?

Text fields allow more detail to be entered about a specific tumor. Appendix 3 details the Text fields in the North American Association of Central Cancer Registries (NAACCR) record layout, their purpose, and examples of the text facilities should enter.

When are reports due to the MCR? (COMAR 10.14.01.04 C.)

A report containing abstracted information from the medical record, surgery report, pathology report, and/or radiation therapy or chemotherapy report should be submitted **not later than 6 months** of initial diagnosis or treatment of a cancer patient by all hospitals, freestanding laboratories, and ambulatory surgical centers, therapeutic radiology centers, and physicians.

Reports should be submitted electronically* via MCR's Web Plus system, not less than quarterly. (If a computerized record is not possible, the MCR will work with a reporter to accommodate reporting on *hard copy* forms if the reporter reports only a small number of cases each year.)

Quarterly submissions from each facility are due by **the last day of March, June, September, and December** as follows:

Date of Diagnosis (example uses 2007 dates of diagnosis)	Date reports due to MCR
January 1, 2007 - March 31, 2007	September 30, 2007
April 1, 2007 - June 30, 2007	December 31, 2007
July 1, 2007 - September 30, 2007	March 31, 2008
October 1, 2007 - December 31, 2007	June 30, 2008

The MCR encourages monthly reporting. If you cannot make the deadline for reporting, please contact your assigned QA Field Representative before the end of the quarter.

How does the MCR maintain confidentiality of reports? Can MCR data be released? (COMAR 10.14.01.05)

The Maryland Department of Health and Mental Hygiene regards all tumor data received, processed, and reported to the MCR as confidential, but the law states that information obtained by the MCR is not a medical record. The MCR manages and releases information in accordance with the laws and regulations established for and by the State of Maryland as set forth in the Code of

Maryland Regulations 10.14.01, Cancer Registry, and Health-General Articles, §§18-203 and 18-204, and §§4-101—4-103 Annotated Code of Maryland.

The MCR Data Use Policy defines how data from the registry are handled and released consistent with Maryland law. The MCR Data Use Policy is available for viewing or download at:

<http://www.fha.state.md.us/cancer/registry/html/data.html>

How are MCR reports categorized by the Health Insurance Portability and Accountability Act (HIPAA)?

See Appendix 4 for an information sheet explaining the MCR’s surveillance responsibilities and HIPAA. The MCR is a “public health authority,” as defined by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Federal regulations [see 45 CFR §164.512(a), (b), and (d) and §160.203(c)] authorize disclosure without patient consent in a number of circumstances, including the following:

Disclosure is permitted to a public health authority authorized by law to access information to prevent/control disease, injury, disability, e.g., disease reporting, vital statistics reporting, public health surveillance, public health investigations, public health interventions and partner notification. See 45 CFR §164.512(b).

Does the MCR assure compliance with reporting requirements? (18-204 ((b) (2) and COMAR 10.14.01.06)

Yes, the MCR reporting laws and regulations enable the MCR to inspect, upon reasonable notice, a representative sample of the medical records, pathology reports, or radiological records maintained by a reporting facility from which a cancer report should have been previously made for patients diagnosed, treated, or admitted for cancer or a CNS tumor at the facility. The MCR conducts audits of facilities consistent with these provisions.

What ICD-9 codes should be included in the annual “disease index” or case finding list? What data elements should be on the list?

Please include the ICD-9 CM codes from Appendix 5 when developing a reporting facility’s annual case finding list (“disease index”)

For each of these tumors, please include on the following data elements on the list:

- «Facility» Medical Record Number
- Patient Last Name
- Patient First Name
- Patient Middle Name/Initial
- Patient Maiden Name
- Patient Social Security Number
- Patient Date of Birth
- Date of Admission (month, day and year)
- Date of Discharge (month, day and year)
- Date of Surgery (if outpatient surgery) (month, day and year)
- ICD-9-CM Codes for Reportable Discharge Diagnoses

Whom should I contact with questions?

Appendix 6 has the current names and contact numbers of the DHMH and the data management contractor staff. Updates will be issued periodically. For questions regarding your data submissions, contact the data management contractor staff; to request site-specific data or for comments or other information, contact DHMH staff.

Appendix 1: Laws and Regulations

Annotated Code of Maryland

Article - Health – General

§ 18-203.

Notwithstanding any other provision of law, the Department may provide patient-identifying information for patients treated in this State for cancer to a cancer control agency in another state if:

- (1) The patient is a resident of the other state;
- (2) The Department determines that the agency will preserve the confidentiality of the information; and
- (3) The other state has authority to provide equivalent information on Maryland residents to this State.

§ 18-204.

- (a) (1) In this section the following words have the meanings indicated.
- (2) "Cancer report" means a 1-time abstract of the medical record of a patient diagnosed or treated for cancer or a central nervous system tumor which contains:
 - (i) Reasonably obtained patient demographic information, including risk factors;
 - (ii) Relevant information on the:
 1. Initial histologically precise diagnosis;
 2. Initial treatment;
 3. Extent of the disease by the end of the first hospitalization; and
 4. Extent of the disease within 2 months of diagnosis if the information is available to the reporting facility and the reporting facility has a tumor registry; and
 - (iii) Facility and other provider identification information.
- (3) (i) "Central nervous system tumor" means, irrespective of histologic type or behavior, a primary tumor in the following sites:
 1. The brain;
 2. The caudal equina;

3. A cranial nerve;
4. The craniopharyngeal duct;
5. The meninges;
6. The pineal gland;
7. The pituitary gland; or
8. The spinal cord.

(ii) "Central nervous system tumor" includes a primary intracranial tumor.

(4) "Freestanding ambulatory care facility" has the meaning stated in § 19-3B-01 of the article.

(b) (1) Each hospital which has care of a patient with cancer or a central nervous system tumor, each freestanding laboratory, freestanding ambulatory care facility, or therapeutic radiological center which has care of or has diagnosed cancer or a central nervous system tumor for a nonhospitalized patient, and each physician who has care of or has diagnosed cancer or a central nervous system tumor for a nonhospitalized patient not otherwise reported shall:

(i) 1. Submit a cancer report to the Secretary, on the form that the Secretary provides or in a computerized file;

2. Make available to the Secretary, or an agent of the Secretary, at the facility the information necessary to compile a cancer report; or

3. Enter into an agreement with a hospital or other facility or agency that agrees to report to the Maryland Cancer Registry to act as the reporting source for a cancer or central nervous system tumor patient who has been referred to or from that facility, or reported to that agency with regard to cancer or central nervous system tumor screening, diagnosis, or treatment; and

(ii) Effective July 1, 1993, submit a cancer report in a computerized file on a quarterly basis to the Secretary, or an agent of the Secretary, for all patients initially diagnosed, treated, or admitted to a facility for cancer or a central nervous system tumor during that calendar quarter.

(2) To assure compliance with this section, the Secretary, or an agent of the Secretary, may inspect upon reasonable notice a representative sample of the medical records of patients diagnosed, treated, or admitted for cancer or a central nervous system tumor at the facility.

(3) (i) Information obtained under this subsection shall be confidential and subject to Title 4, Subtitle 1 of this article.

(ii) This subsection does not apply to a disclosure by the Secretary to another governmental agency performing its lawful duties pursuant to State or federal law where the

Secretary determines that the agency to whom the information is disclosed will maintain the confidentiality of the disclosure.

(iii) A cancer report is not a medical record under Title 4, Subtitle 3 of this article, but is subject to the confidentiality requirements of Title 4, Subtitle 1 of this article.

(4) Each hospital, freestanding laboratory, freestanding ambulatory care facility, therapeutic radiological center, or physician who in good faith submits a cancer report to the Secretary is not liable in any cause of action arising from the submission of the report.

(5) The Secretary, after consultation with the Cancer Registry Advisory Committee, the Maryland Hospital Association, and representatives of freestanding laboratories and therapeutic radiological centers, shall adopt regulations to implement the requirements of this section.

(6) The Secretary, in accordance with § 2-1246 of the State Government Article, shall submit an annual report to the Governor and General Assembly on the activities of the cancer registry, including utilization of cancer registry data.

Code of Maryland Regulations 10.14.01

Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 14 CANCER CONTROL

Chapter 01 Cancer Registry

Authority: Health-General Article, §§18-203 and 18-204, Annotated Code of Maryland

.01 Scope.

These regulations define key terms, detail the information to be contained in a cancer report, and specify requirements of reporting facilities. In addition, these regulations identify requestors authorized to receive confidential data and allow a fee to be charged for data reports. An annual report shall be submitted by the Secretary to the Governor and the General Assembly.

.02 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Cancer registry" means a computerized system to register all cases of reportable human cancer or central nervous system (CNS) tumors of Maryland residents, or nonresidents diagnosed or treated in Maryland.

(2) "Cancer report" means a one-time abstract from one or more of the following documents maintained by a reporting facility of each new case of reportable human cancer or CNS tumor diagnosed or treated, and any other case of reportable human cancer or CNS tumor initially diagnosed or treated for time periods as designated by the Secretary:

(a) Medical record;

(b) Pathology report; and

(c) Radiological report.

(3) Case of a CNS Tumor.

(a) "Case of a CNS tumor" means an identified human tumor, irrespective of histologic type or behavior, occurring in the following sites:

(i) The brain;

(ii) The meninges;

(iii) The spinal cord;

(iv) The cauda equina;

(v) A cranial nerve;

(vi) The pituitary gland;

(vii) The pineal gland; or

(viii) The craniopharyngeal duct.

(b) "Case of a CNS tumor" includes all benign tumors of the CNS (ICD-9-CM Codes 225.0—225.9 and 227.3—227.4 and ICD-0-3 behavior code of "0") for the ICD-0-3 topography codes C70.0—C72.9 and C75.1—C75.3, which includes codes from:

(i) The International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM); and

(ii) The International Classification of Diseases for Oncology, Third Edition (ICD-0-3).

(4) "Case of reportable human cancer" means the identification of a human cancer from the following list, which includes codes from the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and the International Classification of Diseases for Oncology, Third Edition (ICD-0-3):

(a) All malignant neoplasms (ICD-9-CM Codes 140.0—208.9 and ICD-0-3 behavior code of "3") excluding the following basal and squamous cell carcinomas of the skin (the topography term "skin" is defined as ICD-0-3 topography codes C44.0 — C44.9) with a behavior code of "3" (malignant) for the ICD-0-3 morphology numbers listed, except that these lesions are reportable for skin of the genital sites of the vagina, clitoris, vulva, prepuce, penis, and scrotum (ICD-9-CM Codes 184.0—184.4, 187.1, 187.4, and 187.7 and ICD-0-3 topography codes C51.0—C51.9, C52.9, C60.0, C60.9, and C63.2):

(i) M-8000—8004 Neoplasms, malignant, NOS of skin,

(ii) M-8010—8045 Epithelial carcinomas of skin,

(iii) M-8050—8082 Papillary and squamous cell carcinomas of skin, and

(iv) M-8090—8110 Basal cell carcinomas;

(b) All cases of carcinoma in situ (ICD-9-CM Codes 230.0—234.9 and ICD-0-3 behavior code of "2"), excluding the following basal and squamous cell carcinomas in situ of the skin (the topography term "skin" is defined as ICD-0-3 topography codes C44.0—C44.9) with a behavior code of "2" (in situ) for the ICD-0-3 morphology numbers listed, except that these lesions are reportable for skin of the genital sites of the vagina, clitoris, vulva, prepuce, penis, and scrotum (ICD-9-CM Codes 233.2, 233.5, and 233.6, and ICD-0-3 topography codes C51.0—C51.9, C52.9, C60.0, C60.9, and C63.2):

(i) M-8000—8004 Neoplasms, malignant, NOS of skin,

(ii) M-8010—8045 Epithelial carcinomas of skin,

(iii) M-8050—8082 Papillary and squamous cell carcinomas of skin, and

(iv) M-8090—8110 Basal cell carcinomas;

(c) Borderline malignancies of the ovary (ICD-9-CM Codes 183.0 and 236.2);

(d) Neoplasms involving plasma cells as described in ICD-9-CM Code 238.6; or

(e) Histology report using the terminology of cervical CIS, CIN3, or any combination of them.

(5) "Computerized file" means an electronic data file using software approved for use by the Secretary, containing complete cancer report information transferable to a master electronic database system maintained by the Department.

(6) "Department" means the Department of Health and Mental Hygiene or a designee.

(7) "Freestanding ambulatory care facility" has the meaning stated in Health-General Article, §19-3B-01, Annotated Code of Maryland.

(8) "Freestanding laboratory" means a facility, place, establishment, or institution which performs a laboratory examination for a person, authorized by law to request the examination, in connection with the diagnosis of a reportable human cancer or CNS tumor, and is licensed by the State pursuant to COMAR 10.10.03, and:

(a) Not under the administrative control of a hospital; or

(b) Under the administrative control of a hospital for a diagnosis of reportable human cancer or CNS tumor of a nonhospitalized patient.

(9) "Freestanding therapeutic radiological center" means a facility, place, establishment, or institution performing radiological treatment for a person, authorized by law to request this treatment, in connection with a reportable human cancer or a CNS tumor, and licensed or registered by the State pursuant to COMAR 10.05.03, and not under the administrative control of a hospital.

(10) "Hospital" means a facility which is licensed by the State pursuant to COMAR 10.07.01.

(11) "Nonhospitalized patient not otherwise reported" means a patient diagnosed or treated for cancer or a CNS tumor in a physician's office without admission to a hospital or referral to a freestanding ambulatory care facility or freestanding therapeutic radiological center.

(12) "Physician" means an individual who practices medicine, as stated in Health Occupations Article, §14-101, Annotated Code of Maryland.

(13) "Reporting facility" means a hospital, freestanding laboratory, freestanding ambulatory care facility, or freestanding therapeutic radiological center.

(14) "Secretary" means the Secretary of Health and Mental Hygiene or a designee of the Secretary.

(15) "Tumor registry" means a data base of human cancer or CNS tumor cases diagnosed or treated at a reporting facility.

.03 Content of a Cancer Report.

A cancer report shall contain:

A. Reasonably obtained patient demographic information, including risk factors;

B. Relevant information on the:

(1) Initial diagnosis,

(2) Initial treatment,

(3) Extent of the disease by the end of the first hospitalization using a standard nomenclature specified by the Secretary, and

(4) Extent of the disease within 2 months of diagnosis using a standard nomenclature specified by the Secretary if the information is available to the reporting facility and the reporting facility has a tumor registry;

C. Facility and other provider identification information; and

D. Other requirements as considered necessary by the Secretary.

.04 Requirements of Reporting Facilities.

The reporting facility shall submit a:

A. Cancer report to the Secretary in a computerized file containing standard information required by the Secretary;

B. Computerized file not less than quarterly; and

C. Completed report of any new individual case of cancer or CNS tumor not later than 6 months after diagnosis or treatment.

.05 Confidentiality of Cancer Reports.

A. Information obtained under Regulations .03 and .06 of this chapter is not a medical record under Health-General Article, §4-301, Annotated Code of Maryland, but is subject to the confidentiality requirements of Health-General Article, §4-101 et seq., Annotated Code of Maryland.

B. Confidential data may be released by the Secretary to:

(1) An institution or individual researcher for medical, epidemiological, health care, or other cancer-related or CNS tumor-related research approved by the Secretary and the Institutional Review Board (IRB) of the Department, which will further the cancer control goals of the State;

(2) A reporting facility which:

(a) Routinely submits cancer or CNS tumor patient information to the cancer registry,

(b) Has been formally accepted as a participant in the cancer registry system, and

(c) Requests routine data relating to patients of the facility;

(3) An out-of-State cancer registry or cancer control agency which requests routine data if the:

(a) Patient is a resident of the other state, and

(b) Other state has authority to provide equivalent information on Maryland residents to this State;

(4) Each county health officer and the Baltimore City Commissioner of Health; and

(5) Another governmental agency performing its lawful duties pursuant to State or federal law.

C. The Secretary shall release confidential data to a requestor in response to a written request only, in accordance with Health-General Article, §§4-101 and 4-102, Annotated Code of Maryland.

D. The release of confidential data is subject to a determination by the Secretary that a recipient of the information disclosed will maintain the confidentiality of the disclosure.

E. The summarization or aggregation of confidential records which does not disclose the identity of any person who is the subject of the confidential record is not subject to the provisions of Health-General Article, §4-101, Annotated Code of Maryland.

.06 Authority and Requirements of the Secretary.

A. To assure compliance by a reporting facility with Regulation .03 of this chapter, the Secretary may, upon advance notice, inspect a representative sample of medical records, pathology reports, or radiological reports maintained by a reporting facility, from which a cancer report should have been previously made.

B. The Secretary may charge a reasonable fee to cover the cost of providing data reports to appropriate requestors, as allowed by COMAR 10.01.08.04. All applicable fees shall be paid in full in advance of filling the request.

C. After receiving all necessary information to support a request to release cancer registry data, the Secretary shall act in a timely manner and decide on the request with one of the following outcomes:

(1) Final approval;

(2) Interim approval, if the request has been accepted with one or more conditions which shall be met before final approval is granted; or

(3) Disapproval.

D. The Secretary, in accordance with State Government Article, §2-1246, Annotated Code of Maryland, shall submit an annual report to the Governor and General Assembly on the activities of the cancer registry, including use of cancer registry data.

E. Nothing in this chapter is intended to limit or otherwise restrict the Secretary from obtaining cancer report information on Maryland residents from sources located either inside or outside the State.

Administrative History

Effective date: September 28, 1992 (19:19 Md. R. 1707)

Regulation .01 amended effective April 21, 1997 (24:8 Md. R. 616)

Regulation .02B amended effective April 26, 1993 (20:8 Md. R. 723); April 21, 1997 (24:8 Md. R. 616); June 23, 2003 (30:12 Md. R. 788)

Regulation .04 amended effective April 21, 1997 (24:8 Md. R. 616)

Regulation .04C amended effective June 23, 2003 (30:12 Md. R. 788)

Regulation .05B amended effective June 23, 2003 (30:12 Md. R. 788)

Regulation .06B, D amended effective June 23, 2003 (30:12 Md. R. 788)

Appendix 2: Required Fields

See Separate Document

Appendix 3: Text Fields

See Separate Document

Appendix 4: HIPAA Information

The Maryland Cancer Registry’s Surveillance Responsibilities and The Health Insurance Portability and Accountability Act of 1996 (HIPAA)

This information sheet has been prepared to clarify and confirm the authority of staff of the Maryland Cancer Registry (MCR) or an agent of the Secretary of DHMH officially acting on the MCR’s behalf, to receive, access, inspect, and/or abstract patient medical records and/or patient medical listings relating to the diagnosis and treatment of cancer and benign central nervous system (CNS) tumors. Such access, inspection, and/or abstraction relates to the review and abstracting of selected patient records and/or listings as a part of the MCR’s quality control review of the completeness and accuracy of reporting of cancer and benign CNS tumors in Maryland. Periodic quality control review is a part of the MCR’s ongoing public health surveillance activities.

Disclosure of cancer and benign CNS tumors to the MCR is required under the Maryland Department of Health and Mental Hygiene (DHMH) authority pursuant to Maryland Code Annotated, Health-General (“Health-General”), §18-204.

The Maryland Cancer Registry is a “public health authority,” as defined by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Federal regulations [see 45 CFR §164.512(a), (b), and (d) and §160.203(c)] authorize disclosure without patient consent in a number of circumstances, including the following:

Disclosure is permitted to a public health authority authorized by law to access information to prevent/control disease, injury, disability, e.g., disease reporting, vital statistics reporting, public health surveillance, public health investigations, public health interventions and partner notification.
See 45 CFR §164.512(b).

Because the MCR is a public health authority, cancer reporting and surveillance are required by state law, and the MCR is not performing such functions on behalf of the covered entity, reporting entities do not need to complete a business associate’s agreement before providing reports that include the requested personally identifiable information to the MCR or to an agent of the Secretary of DHMH acting on the MCR’s behalf. The required information is needed to conduct public health surveillance. MCR information is not a medical record under Health-General §4-301, and is protected under the confidentiality requirements of Health-General §4-101 et seq.

If you have any questions with respect to the Maryland Cancer Registry’s authority to receive, access, inspect and/or abstract personally identifiable information, please contact Diane Dwyer, M.D. MCR Director, at 410-767-4055.

This information sheet has been reviewed and approved by the legal counsel to the Maryland Cancer Registry in the Attorney General’s Office, but is not a formal opinion of that office.

Appendix 5: Disease Index

See Separate Document

Appendix 6: Contact Information

**Maryland Cancer Registry (MCR)
Center for Cancer Surveillance and Control
Maryland Department of Health and Mental Hygiene (DHMH)
Room 400
201 West Preston Street
Baltimore, MD 21201**

DHMH MCR Staff List, August 2008

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Diane Dwyer, MD	Medical Director, CCSC
Kimberly Stern, MHA, CTR	Director, Maryland Cancer Registry, CCSC
Jennifer Hayes, MEd, MPH	Senior Epidemiologist, MCR, CCSC
Afaq Ahmad, MD, MPH	Epidemiologist, MCR, CCSC
Delores Rich, MLA	Coordinator Special Programs, MCR, CCSC
Carolyn Davis-Harris	Secretary, MCR, CCSC

**For questions or comments, please contact
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