

Subtitle 14 CANCER CONTROL

10.14.01 Cancer Registry

Authority: Health-General Article, §§2-104, 18-104, 18-203, and 18-204, Annotated Code of Maryland; 42 U.S.C. §280e

Notice of Proposed Action

[09-408-P]

The Secretary of Health and Mental Hygiene proposes to amend Regulations .01 and .02, adopt new Regulations .03 and .04, and amend and recodify existing Regulations .03 —.06 to be Regulations .05—.08 under **COMAR 10.14.01 Cancer Registry**.

Statement of Purpose

The purpose of this action is to update the regulations of the Maryland Cancer Registry to be consistent with national reporting standards and with the requirements of the federal Cancer Registries Amendment Act. This proposal will eliminate the requirement of reporting facilities to report cases of cervical carcinoma in situ (CIS), squamous intraepithelial neoplasia of the cervix (CIN III), glandular intraepithelial neoplasia of the prostate (PIN), and borderline malignancies of the ovary to the Maryland Cancer Registry, consistent with the reporting standards of national organizations such as the National Program of Cancer Registries; the Surveillance, Epidemiology and End Results (SEER) Program; and the Commission on Cancer. This proposal also updates the codes of reportable cancers included in the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and the International Classification of Diseases for Oncology (ICD-O-3), Third Edition; clarifies the definition of key terms; and addresses the release of data to researchers. This proposal will also require nursing facilities and assisted living programs to report information about reportable cancers and central nervous system (CNS) tumors pertaining to certain patients, if requested by the Secretary of Health and Mental Hygiene and if the information is under the control of that facility. This proposal specifies that a cancer report shall contain information on industrial or occupational history when such information is available.

Comparison to Federal Standards

There is a corresponding federal standard to this proposed action, but the proposed action is not more restrictive or stringent.

Estimate of Economic Impact

The proposed action has no economic impact.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Michele A. Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 West Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499, or email to regs@dhhm.state.md.us, or fax to 410-333-7687. Comments will be accepted through January 19, 2010. A public hearing has not been scheduled.

.01 Scope.

[These regulations define] *This chapter establishes a cancer registry within the Department, defines key terms, [detail] details the information to be contained in a cancer report, and [specify] specifies requirements of reporting facilities, nursing facilities, and assisted living programs.* In addition, [these regulations identify] *this chapter identifies* requestors authorized to receive confidential data and [allow] *allows* 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. (text unchanged)

B. Terms Defined.

(1) *“Assisted living program” has the meaning stated in COMAR 10.07.14.02B.*

[(1)] (2) *“Cancer registry” means a computerized system to register all cases of reportable human cancer or reportable human central nervous system (CNS) tumors of Maryland residents [, or] and nonresidents diagnosed or treated in Maryland.*

[(2)] (3) *“Cancer report” means a one-time abstract from one or more of the following documents maintained by a reporting facility, nursing facility, or assisted living program 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)—(c) (text unchanged)

[(3)] (4) *Case of a Reportable Human CNS Tumor.*

(a) *“Case of a reportable human CNS tumor” means an identified human tumor, irrespective of histologic type or behavior, occurring as a primary tumor in any of the following sites or subsites with International Classification of Diseases for Oncology, Third Edition (ICD-O-3) topography codes C70.0—C72.9 and C75.1—C75.3:*

(i)—(viii) (text unchanged)

(b) *“Case of a reportable human CNS tumor” includes all benign and uncertain behavior 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], 228.02, 237.0— 237.1, 237.5—237.9, and 239.6, and all tumors of the CNS of benign and uncertain behavior with ICD-O-3 codes of “0” or “1”), which includes codes from:*

(i) (text unchanged)

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

[(4)] (5) *“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] ICD-O-3):*

(a) All malignant neoplasms (ICD-9-CM Codes [140.0—208.9] *140—195.8 and 199—209.37* [and ICD-0-3] or ICD-O-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] *including genital [sites] skin cancer 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] and excluding other sites of skin cancer with ICD-O-3 topography codes [C51.0—C51.9, C52.9, C60.0, C60.9, and C63.2)] C44.0—C44.9 and one of the following ICD-O-3 histologies:*

(i) M-8000—[8004] *8005* Neoplasms, malignant, [NOS] *not otherwise specified* of skin[.];

(ii) M-8010—[8045] *8046* Epithelial carcinomas of skin[.];

(iii) M-8050—[8082] *8084* Papillary and squamous cell carcinomas of skin[.]; [and] or

(iv) (text unchanged)

(b) All malignant neoplasms with the following ICD-9-CM codes where ICD-O-3 behavior is “3” and ICD-O-3 histologies are:

(i) 236.0—Endometrial stroma, low grade (M-8931);

(ii) 238.3—Phylloides tumor (M-9020);

(iii) 238.4—Polycythema (M-9960);

(iv) 238.6—Plasmacytoma (M-9731, M-9734);

(v) 238.71—238.79—Essential thrombocythemia (M-9962), myelodysplastic syndromes (M-9980, M-9982, M-9983, M-9985, M-9986), myelofibrosis with myeloid metaplasia (M-9961), post transplant lymphoproliferative disorder (M-9987) or lympho and myeloproliferative disease (M-9931, M-9960, M-9961);

(vi) 273.2—Alpha and gamma heavy chain disease (M-9762) or Franklin disease (M-9763);

(vii) 273.3—Waldenstrom macroglobulinemia (M-9761);

(viii) 284.9—Refractory anemia (M-9980); or

(ix) 285.0—Refractory anemia with ringed sideroblasts (M-9982), refractory anemia with excess blasts (M9983), or refractory anemia with excess blasts in transformation (M-9984);

[(b)] *(c) All cases of carcinoma in situ (ICD-9-CM Codes 230.0—234.9 and [ICD-0-3] ICD-O-3 behavior code of “2”), including genital skin cancers of the vagina, clitoris, vulva, prepuce, penis, and scrotum and 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):] other skin cancers with ICD-O-3 topography codes C44.0—C44.9 and one of the following ICD-O-3 histologies:*

(i) M-8000—[8004] *8005* Neoplasms, malignant, [NOS] *not otherwise specified* of skin[.];

(ii) M-8010—[8045] 8046 Epithelial carcinomas of skin[,];

(iii) M-8050—[8082] 8084 Papillary and squamous cell carcinomas of skin[,]; and

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

[(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.]

(d) All cases of intraepithelial neoplasia (ICD-O-3 histology code of M-8077/2):

(i) Including squamous intraepithelial neoplasia of vagina (VAIN), vulva (VIN), and anus (AIN) (ICD-9-CM codes 233.3 and 230.6; and ICD-O-3 topography codes C52, C51, and C21.1); and

(ii) Excluding squamous intraepithelial neoplasia of the cervix (CIN III) and glandular intraepithelial neoplasia of the prostate (PIN) (ICD-9-CM codes 233.1 and 233.4; and ICD-O-3 topography codes C53 and C61.9).

[(5)] (6)—[(8)] (9) (text unchanged)

[(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) (text unchanged)

(11) “Nonhospitalized patient not otherwise reported” means a patient *with a case of reportable human cancer or a reportable human CNS tumor* 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 *and not reported by a hospital, a freestanding ambulatory care facility, or therapeutic radiological center.*

(12) “Nursing facility” has the meaning stated in COMAR 10.07.02.01B.

[(12)] (13) “Physician” means an individual who [practices]:

(a) Practices medicine, as [stated] defined in Health Occupations Article, §14-101, Annotated Code of Maryland; and

(b) Diagnoses or treats a case of reportable human cancer or a reportable human CNS tumor at a practice located in Maryland.

[(13)] (14) “Reporting facility” means [a] *any of the following:*

(a) A hospital, freestanding laboratory, freestanding ambulatory care facility, or [freestanding] therapeutic radiological center; or

(b) A physician who has care of or has diagnosed a case of reportable human cancer or reportable human CNS tumor for a nonhospitalized patient not otherwise reported.

[(14)] (15) (text unchanged)

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

(16) “Therapeutic radiological center” means a facility or institution:

(a) Performing radiological treatment for a person authorized by law to request the treatment in connection with a reportable human cancer or a reportable human CNS tumor; and

(b) Licensed or registered by the State pursuant to COMAR 10.05.03 and not under the administrative control of a hospital.

.03 Establishment of a Cancer Registry.

There is a cancer registry established within the Department, whose purpose is to collect reportable human cancer data and reportable human CNS tumor data to further the cancer control goals of the State.

.04 Cancer Control Goals of the State.

A. The cancer control goals of the State are to reduce the incidence and mortality of reportable human cancer and reportable human CNS tumors and racial, ethnic, gender, age, and geographic disparities in reportable human cancer and CNS tumor incidence and mortality in Maryland, by:

(1) Advancing the understanding of reportable human cancer and reportable human CNS tumor demographics;

(2) Describing reportable human cancer and reportable human CNS tumor sources, causes, risk factors, preventive measures, diagnostic tests, screening tests, treatment, and survival; and

(3) Evaluating the cost, quality, efficacy, and appropriateness of diagnostic, therapeutic, rehabilitative, and preventive services and programs related to reportable human cancer and reportable human CNS tumors.

B. Research that will further the cancer control goals of the State is research whose protocols have been reviewed by Department staff who have found that the research will:

(1) Advance scientific knowledge or advance knowledge of clinical practice related to cancer;

(2) Have approaches, aims, and methods that will allow the researcher to perform descriptive analyses or test hypotheses;

(3) Have one or more investigators who have training and experience with the approaches and methods; and

(4) Be conducted in a scientific environment likely to contribute to the success of the research.

[.03] .05 Content of a Cancer Report.

A cancer report shall contain the following information, using the standard nomenclature contained in the North American Association of Central Cancer Registries' Standards for Cancer Registries, Volume II, Data Standards and Data Dictionary:

A. (text unchanged)

B. Information on the industrial or occupational history of an individual with cancer, to the extent such information is available;

[B.] C. Relevant information on the:

(1) Initial diagnosis, *including the date of the 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], *nursing facility, or assisted living program;*

[C.] D.—[D.] E. (text unchanged)

[.04] .06 Reporting Requirements [of Reporting Facilities].

[The] A. A reporting facility shall submit a:

[A.] (1)—[B.] (2) (text unchanged)

[C.] (3) Completed report of any new individual case of a *reportable human cancer or reportable human CNS tumor* not later than 6 months after diagnosis or treatment.

B. A nursing facility or an assisted living program shall submit a cancer report containing information that is under the control of the facility to the Secretary if the Secretary requests a cancer report on a patient who has been a resident of the nursing facility or assisted living program.

[.05] .07 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.] §§4-101—4-103, Annotated Code of Maryland.

B. [Confidential data may be released by the Secretary to] *The Secretary may release confidential data 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 *Department's* Institutional Review Board (IRB) [of the Department, which will further the cancer control goals of the State] *in order to further the cancer control goals of the State set forth in Regulation .04 of this chapter;*

(2) A reporting facility which:

(a) Routinely submits *information on cases of reportable human cancer or reportable human CNS* [tumor patient information] *tumors* 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] *reported* by the facility;

(3)—(5) (text unchanged)

C. The Secretary may release confidential information, subject to:

(1) A determination by the Secretary that a recipient of the information disclosed will maintain the confidentiality of the disclosed information; and

(2) An agreement signed by the Secretary and by the recipient of the confidential information that the recipient of the information will maintain the confidentiality of the disclosed information.

[C.] *D.* (text unchanged)

[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. A reporting facility that in good faith submits a cancer report to the Secretary is not liable in any cause of action arising from the submission of the cancer report to the Secretary.

[E.] *F.* [The summarization or aggregation of confidential records which does not disclose] *The use or publication of any statistics, information, or other material that summarizes or refers to confidential records in the aggregate, without disclosing 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] §4-102, Annotated Code of Maryland.*

[.06] .08 Authority and Requirements of the Secretary.

A. To assure compliance by a reporting facility, *nursing facility, or assisted living program* with Regulation [.03] .05 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] *the facility*], from which a cancer report should have been previously made] *of cases of reportable human cancer and reportable human CNS tumors.*

B.—E. (text unchanged)

JOHN M. COLMERS
Secretary of Health and Mental Hygiene
