

# **Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE**

## **Subtitle 14 CANCER CONTROL**

### **Chapter 05 Maryland Cancer Fund**

**Authority: Health-General Article, §20-117; Tax-General Article, §2-112; Annotated Code of Maryland**

#### **.01 Purpose and Scope.**

This chapter:

- A. Defines the Maryland Cancer Fund;
- B. Describes how contributions may be made to the Maryland Cancer Fund;
- C. Sets forth the responsibilities of the Department of Health and Mental Hygiene and the Comptroller with respect to the Maryland Cancer Fund;
- D. Identifies eligible applicants; and
- E. Outlines the grant application process for the Maryland Cancer Fund.

10.14.05.02

#### **.02 Definitions.**

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

B. Terms Defined.

(1) "Annual family income" means the total amount received per year from all sources before taxes are withheld.

(2) "Applicant" means a person who has applied to receive a grant under the Maryland Cancer Fund.

(3) "Applied research" means research that is undertaken to determine:

(a) Possible uses for the findings of basic research; or

(b) New ways of achieving some specific objective.

(4) "Authorized representative" means an individual or organization that has received permission from an individual diagnosed with cancer to perform certain tasks on the individual's behalf.

(5) "Basic research" means experimental or theoretical work undertaken to acquire new knowledge or understanding of cancer.

(6) "Case management" means the coordination of services by a health care professional for an individual for cancer:

(a) Screening;

(b) Diagnosis; or

(c) Treatment.

(7) "Capital expenditures" means money spent to add or expand property, equipment, and assets that will benefit an organization in the long term.

(8) "Center for Cancer Prevention and Control (CCPC)" means a unit of the Department of Health and Mental Hygiene within the Prevention and Health Promotion Administration.

(9) "Clinical research" means research:

(a) Conducted primarily on patients; and

(b) Designed to answer questions about the etiology, prevention, early detection, diagnosis, or treatment of cancer.

(10) "Community-based participatory research" means a collaborative, partnership approach to research that equitably involves community members, organizational representatives, and researchers in all aspects of the research process.

(11) "Comptroller" means the Comptroller of the Treasury.

(12) "Coinsurance" means the percent of allowable charges for a medical service that an individual with health insurance is responsible for paying.

(13) "Copayment (copay)" means the set amount of money that an individual with health insurance is responsible for paying each time the individual receives a medical service.

(14) "County" means a county of this State or Baltimore City.

(15) "Current Procedure Terminology (CPT)" means the uniform descriptive terms and identifying codes for reporting medical services and procedures performed by physicians.

(16) "Deductible" means the amount of money that an individual with health insurance is required to pay before the individual's health insurance starts coverage.

(17) "Department" means the Department of Health and Mental Hygiene.

(18) "Diagnosis" means a histopathologic finding of cancer in a:

(a) Biopsy; or

(b) Surgical specimen.

(19) Educational Institution.

(a) "Educational institution" means an organization whose primary mission is to educate individuals.

(b) "Educational institution" includes:

(i) Private and public elementary schools;

(ii) Middle schools;

(iii) High schools;

(iv) Colleges;

(v) Universities;

(vi) Graduate schools; and

(vii) Research institutions.

(20) "Family" means the unit comprised of all of the following that apply:

(a) For a financially independent adult 18 years old or older diagnosed with cancer, the adult diagnosed with cancer or the adult diagnosed with cancer and one or more of the following:

(i) Spouse;

(ii) Financially dependent child; or

(iii) Financially dependent relative; or

(b) For a financially dependent child, the child and one or more of the following:

(i) Parent, foster parent, or guardian;

(ii) Sibling living in the household; or

(iii) Half brother or half sister living in the household.

(21) "Federal poverty level" means the poverty guidelines, as amended, which are updated periodically in the Federal Register by the U.S. Department of Health and Human Services and which are incorporated by reference by COMAR 10.11.03.01-1.

(22) "Fund" means the Maryland Cancer Fund.

(23) Grant.

(a) "Grant" means financial assistance from the State to support an applicant's activities related to cancer:

(i) Research;

(ii) Primary prevention;

(iii) Secondary prevention; and

(iv) Treatment.

(b) "Grant" does not mean a contract.

(24) "Governmental entity" means a federal, State, or local governmental organization.

(25) "Health Services Cost Review Commission (HSCRC)" means the independent organization within the Department that is responsible for reviewing and approving rates for hospitals pursuant to Health-General Article, Title 19, Subtitle 2, Annotated Code of Maryland.

(26) "Hospital" means an institution that:

(a) Operates within the jurisdiction of Health-General Article, Title 19, Subtitle 3, Annotated Code of Maryland; and

(b) Is licensed pursuant to COMAR 10.07.01 or other applicable standards established by the jurisdiction in which the service is provided.

(27) "Laboratory" means a licensed or certified facility operated for the examination of material derived from the human body for the purpose of obtaining information for the diagnosis, treatment, and management of a disease.

(28) "Local health department" means a governmental entity in a county in Maryland that provides public health services.

(29) "Major medical equipment" means equipment that:

(a) Costs in excess of \$500; and

(b) Is used for the provision of medical or health services.

(30) "Maryland Comprehensive Cancer Control Plan" means the most recent edition of the cancer plan developed by the Department.

(31) "Maryland Health Insurance Plan (MHIP)" means a State-administered program that:

(a) Is operated by a unit within the Maryland Insurance Administration under Insurance Article, Title 14, Subtitle 5, Annotated Code of Maryland; and

(b) Provides health insurance coverage to medically uninsurable Maryland residents.

(32) "Medical Assistance" means the program administered by the State under Title XIX of the Social Security Act, 42 U.S.C. §§1396—1396v, which provides comprehensive medical and other health-related care for eligible categorically and medically needy persons.

(33) "Medicare" means the medical insurance program administered by the federal government under Title XVIII of the Social Security Act, 42 U.S.C. §§1395—1395hhh.

(34) "Patient contribution amount" means the amount of money required by an individual's health insurance policy to be paid by the individual for a given medical procedure or service received, excluding the deductible.

(35) "Physician" means an individual who is licensed to practice medicine in the jurisdiction in which the service is provided.

(36) "Premium" means the amount of money than an individual pays in regular installments to a health insurer for a health insurance policy.

(37) Primary Prevention.

(a) "Primary prevention" means activities to prevent or reduce the development of cancer.

(b) "Primary prevention" includes interventions such as:

(i) Tobacco use prevention and cessation;

(ii) Protection from ultraviolet light;

(iii) Proper nutrition and physical activity; and

(iv) Reduction of exposure to environmental and occupational carcinogens.

(38) Research.

(a) "Research" means activities to develop or advance the understanding of cancer or the techniques or modalities effective in the prevention, cure, screening, diagnosis, or treatment of cancer.

(b) "Research" includes basic, clinical, applied, translational, and community-based participatory research.

(39) "Secondary prevention" means activities to detect and diagnose cancer in its early stages, when the chances of treatment and control are the greatest.

(40) "Secretary" means the Secretary of Health and Mental Hygiene.

(41) "Translational research" means using or applying new discoveries to benefit patient care.

(42) "Treatment" means the medical management and care of a patient that is provided for:

(a) Obtaining a cancer diagnosis, determining the full extent of the cancer spread, or treating the cancer, including:

(i) Surgery;

(ii) Chemotherapy;

(iii) Radiation therapy;

(iv) Hormonal therapy;

(v) Biopsy;

(vi) Imaging procedures;

(vii) Laboratory testing;

(viii) Home health services; and

(ix) Medical supplies or medical equipment;

(b) Treating medical complications resulting from cancer screening or treatment;

(c) Treating other co-morbid conditions in order to treat cancer; or

(d) Providing palliative or end-of-life care.

(43) "Uninsured" means that an individual:

(a) Does not have any health insurance; or

(b) Has health insurance that does not cover the cancer prevention, screening, diagnosis, or treatment services provided under the Fund.

### **.03 Maryland Cancer Fund.**

A. The Maryland Cancer Fund is a nonlapsing, special fund created by Health-General Article, §20-117, Annotated Code of Maryland, for cancer research, prevention, and treatment, which is generated from:

(1) Contributions from the income tax checkoff system under Tax-General Article, §2-112, Annotated Code of Maryland; and

(2) Any other donations to the Fund.

B. The Department may only expend funds:

(1) In accordance with an appropriation approved by the General Assembly in the annual State budget; or

(2) Through an approved budget amendment under State Finance and Procurement Article, §§7-209 and 7-210, Annotated Code of Maryland.

C. The Department may only make grant awards under the Fund for cancer:

(1) Research;

(2) Primary prevention;

(3) Secondary prevention; or

(4) Treatment.

D. Any unspent portions of the Fund shall remain in the Fund and may not revert to the General Fund of the State.

E. Money expended from the Fund is supplemental to, and is not intended to take the place of, funding that would otherwise be appropriated to the Department for cancer:

(1) Research;

(2) Primary prevention;

(3) Secondary prevention; or

(4) Treatment.

#### **.04 Contributions to the Maryland Cancer Fund.**

An individual or each spouse in the case of a joint income tax return may contribute an amount to the Fund by:

- A. Deducting the amount of the contribution from any refund due under a tax return; or
- B. Adding the amount of the contribution to the income tax to be paid with a tax return.

#### **.05 Responsibilities of the Department.**

The Department:

- A. Shall administer the Fund;
- B. May not spend more than 5 percent of the proceeds received from the Comptroller for the Fund to promote further donations to the Fund; and
- C. Shall provide a grant in each fiscal year to persons to conduct one or more of the following cancer-related activities:
  - (1) Research;
  - (2) Primary prevention;
  - (3) Secondary prevention; or
  - (4) Treatment.

#### **.06 Responsibilities of the Comptroller.**

The Comptroller shall:

- A. Include in the individual income tax return form:
  - (1) A checkoff designated as the Maryland Cancer Fund contribution; and
  - (2) A description that the Fund may only be used for cancer:
    - (a) Research;
    - (b) Primary prevention;
    - (c) Secondary prevention; or



(d) Treatment;

B. Collect the checkoff contributions and other donations and account to the Treasurer for the money collected;

C. Distribute the amount necessary to administer the checkoff system to an administrative cost account;

D. After the distribution under §C of this regulation, distribute the remainder of the money to the Fund; and

E. Notify the Department annually of:

(1) The gross amount of donations to the Fund through the income tax checkoff system;

(2) The gross amount of other donations to the Fund; and

(3) The costs of administration of the income tax checkoff system by the Comptroller.

### **.07 Persons Eligible For Grants.**

A. Subject to any limitations imposed under §B of this regulation, the following persons are eligible to receive a grant from the Department for cancer research, primary prevention, secondary prevention, or treatment:

(1) Physicians;

(2) Hospitals;

(3) Laboratories;

(4) Educational institutions;

(5) Local health departments;

(6) Governmental entities; and

(7) Another person or organization with expertise in cancer research, primary prevention, secondary prevention, or treatment.

B. The Department may limit the persons eligible to receive a grant in §A of this regulation based on:

(1) Availability of funds; and

(2) The Department's ability to account for and monitor the grant funding.

C. In order to be eligible to receive a grant, an applicant:

- (1) May be a nonprofit or for-profit entity;
- (2) Shall have an office located in Maryland; and
- (3) May only propose work that will serve or benefit one or more Maryland residents.

**.08 Allowable Uses of the Funds.**

A. A grantee that is funded to conduct cancer research by the Fund may use the grant funds:

- (1) For basic, clinical, translational, applied, or community-based participatory research;
- (2) To support:
  - (a) The individuals engaged in the research; and
  - (b) The individual's support staff; and
- (3) To purchase office supplies.

B. A grantee that is funded to conduct cancer primary prevention or secondary prevention by the Fund may use the grant funds for:

- (1) Education;
- (2) Outreach;
- (3) Policy changes;
- (4) Provider interventions;
- (5) Clinical services;
- (6) Case management;
- (7) Quality assurance;
- (8) Data collection; or
- (9) Partnership development.

C. If a grantee is funded to conduct cancer secondary prevention services, the Fund shall provide to the grantee reimbursement for a clinical service at a rate not higher than the rate that:

(1) Medicare pays for the clinical service in the region; or

(2) The HSCRC has approved for the clinical service, if the clinical service is provided by a HSCRC-regulated facility.

D. If a grantee is funded to conduct cancer secondary prevention or treatment, the grantee shall only provide clinical services to individuals who:

(1) Are Maryland residents; and

(2) Have an annual family income that is not more than 250 percent of the federal poverty guidelines.

E. If a grantee is funded to conduct cancer treatment, a grantee may use the grant funds:

(1) For grants awarded before January 1, 2014 to provide MHIP reimbursement, to pay up to a maximum of \$15,000 for direct costs per individual per year for the premium, deductible, coinsurance, and copay of the MHIP costs and for services not covered under MHIP; or

(2) To pay up to a specified amount, as determined by the Department, for direct costs per individual per year for the:

(a) Deductible and patient contribution amount for the reimbursed medical procedure or service for insured individuals; and

(b) Medical procedure or service not covered under their health insurance policy for individuals who meet the eligibility criteria of §D of this regulation; or

(3) To pay up to a maximum of \$20,000 for direct costs per individual per year for the cancer treatment costs under the individual's treatment plan:

(a) Who meet the eligibility criteria in §D of this regulation; and

(b) At a rate not to exceed the rate that Medical Assistance pays for clinical services or the rate that the HSCRC has approved for the clinical services, if treatment is provided by a HSCRC-regulated facility.

F. If a grantee is funded to pay for cancer treatment:

(1) Under §E(1) of this regulation, the grantee shall only pay or direct the Department to pay MHIP the following for services directly related to the treatment of cancer for the individual diagnosed with cancer:

(a) Premiums;

(b) Deductibles;

(c) Coinsurance; and

(d) Copays;

(2) Under §E(2) of this regulation, the grantee shall only pay or direct the Department to pay the deductible and patient contribution amount for the reimbursed medical procedure or service that the individual is required to pay for the services directly related to the diagnosis and treatment of cancer; and

(3) May not pay any amount for the individual's spouse, children, or other family members' health insurance costs.

G. For the purpose of §F(1) and (2) of this regulation, the Department shall pay the health insurance costs out of the funds that are set aside for the grantee.

H. In addition to the direct costs allowed under §E of this regulation, the Fund shall also pay a maximum of 7 percent of the indirect costs to local health department grantees or non-local health department grantees.

### **.09 Unallowable Uses of Grant Funds.**

A grantee may not use grant funds from the Fund to pay for:

A. Major medical equipment purchases;

B. Renovations;

C. Capital expenditures; or

D. Cancer prevention or cancer treatment that would be provided by an individual's existing health insurance, including:

(1) Medical Assistance;

(2) Medicare; or

(3) Private health insurance.

### **.10 Grant Application.**

A. A person may obtain an application packet from the CCPC for a cancer:

(1) Research grant;

(2) Primary prevention grant;

(3) Secondary prevention grant; or

(4) Treatment grant.

B. An applicant may:

(1) Apply for one or more grants in any fiscal year; and

(2) Combine multiple requests for cancer research, primary prevention, or secondary prevention grants within a single application, provided that the information required for separate grant applications is included in the combined application.

### **.11 Application Process for Cancer Research Grants.**

An applicant for a cancer research grant shall:

A. Submit a completed application to the CCPC by the due date listed in the application packet; and

B. Include in the application packet the following information as specified in the Department's application packet:

(1) An executive summary stating:

(a) How the grant funds will be used;

(b) What institutions and other persons will be involved in the research;

(c) Whether basic, clinical, applied, translational, or community-based research is being proposed;

(d) Whether the proposed research is included in a recommendation of the Maryland Comprehensive Cancer Control Plan; and

(e) How the grant money is expected to further the knowledge of cancer;

(2) A statement of the need for the cancer research, including:

(a) Previous literature in the area; and

(b) Any work that the applicant has done in the research area;

(3) A proposed cancer research plan describing:

(a) How the grant funds will be used;

- (b) Who will be involved in the research;
- (c) What the anticipated results of the research with the grant funds will be; and
- (d) What goals, objectives, and activities will be pursued with the grant funds;
- (4) A brief professional resume or curriculum vitae of:
  - (a) The principal investigator; and
  - (b) Other key staff;
- (5) A description of how the proposed research will help to eliminate disparities between racial and ethnic minorities and the white population;
- (6) A list of the institutional review boards to which the research will be submitted for review and approval before the research is initiated, including the:
  - (a) Department's Institutional Review Board; and
  - (b) Applicant's relevant institutional review board;
- (7) A timeline showing the expected start date and completion date for each activity to be conducted under the grant, including application to and approval from the:
  - (a) Department's Institutional Review Board; and
  - (b) Applicant's relevant institutional review board;
- (8) An organizational chart showing where the work under the research grant is located within the applicant's organization;
- (9) A statement that the grant funds will not be used to supplant any existing funding for this cancer research and, if an applicant receives funding for a similar cancer research activity, a listing of the funding:
  - (a) Source;
  - (b) Amount; and
  - (c) Period for the activity;
- (10) A line item budget for the cancer research grant; and
- (11) A written budget justification for each line item request.

## **.12 Application Process for Cancer Primary Prevention Grants.**

An applicant for a cancer primary prevention grant shall:

A. Submit a completed application to the CCPC by the due date listed in the application packet; and

B. Include in the application packet the following information, as specified in the Department's application packet:

(1) An executive summary describing:

(a) How the grant funds will be used;

(b) What persons will be involved in the grant activities;

(c) What cancer primary prevention activities will be conducted;

(d) Whether the primary prevention activities are included in a recommendation in the Maryland Comprehensive Cancer Control Plan;

(e) What population groups will be served and in what jurisdiction groups will be served;

(f) What types of services will be offered, including education and policy initiatives;

(g) What the eligibility for services will be; and

(h) What outcome is expected as a result of the funding;

(2) A statement of the need for the cancer primary prevention intervention;

(3) A description of previous literature in the area documenting the effectiveness of the cancer primary prevention intervention;

(4) A proposed cancer primary prevention plan describing the:

(a) Estimated number of persons to be served;

(b) Goals, objectives, and activities to be conducted with the grant funds;

(c) Evaluation measures for each activity;

(d) How the grant funds will be used;

(e) Who will be involved in the plan; and

- (f) What the expected results of the activity with the grant funds are;
- (5) A description of how the primary prevention plan will address the goal of eliminating disparities between racial and ethnic minorities and the white population;
- (6) A list of key staff to be involved in the project, including:
  - (a) If existing staff will be used in the project, a description of the experience of the key staff in carrying out similar cancer primary prevention activities; or
  - (b) If new staff will be hired for the grant, a job description of the staff that will be responsible for carrying out the project;
- (7) A description of the previous experience of the applicant's organization in implementing similar cancer primary prevention activities;
- (8) A timeline showing the expected start date and completion date for each activity to be conducted under the grant;
- (9) An organizational chart showing:
  - (a) Where the activities under the cancer primary prevention grant falls within the applicant's organizational structure; and
  - (b) The relationship of the applicant with other organizations involved in the project;
- (10) A statement that the grant funds will not be used to supplant any existing funding for this cancer primary prevention activity and, if an applicant receives funding for a similar cancer primary prevention activity a list of the funding:
  - (a) Source;
  - (b) Amount; and
  - (c) Period for the activity;
- (11) A line item budget for the cancer primary prevention grant; and
- (12) A written budget justification for each line item requested.

### **.13 Application Process for Cancer Secondary Prevention Grants.**

An applicant for a cancer secondary prevention grant shall:

- A. Submit a completed application to the CCPC by the due date stated in the application packet; and



B. Include in the application packet the following information, as specified in the Department's application packet:

(1) An executive summary describing:

(a) How the grant funds will be used;

(b) What persons will be involved in the application;

(c) What cancer secondary prevention activities will be conducted;

(d) Whether the proposed activities are included in a recommendation in the Maryland Comprehensive Cancer Control Plan;

(e) What population groups will be served and in what jurisdiction groups will be served;

(f) What services will be offered, such as:

(i) Outreach;

(ii) Screening;

(iii) Case management;

(iv) Quality assurance;

(v) Data collection; and

(vi) Partnership building;

(g) What the eligibility for services will be; and

(h) What outcome is expected as a result of the grant funds;

(2) A description of previous literature in the area documenting the effectiveness of the cancer secondary prevention activity;

(3) A description and justification of the need for the cancer secondary prevention activity in the population group to be served;

(4) A description of the population to be served including, at a minimum, a description of the following for the individuals to be served:

(a) Age;

(b) Race;

- (c) Gender;
  - (d) Residency;
  - (e) Educational level;
  - (f) Income level; and
  - (g) Health insurance requirements of persons to be served;
- (5) A description of the screening guidelines to be used for clinical services and the eligibility guidelines for these services, including age, symptoms, and, if appropriate, risk factors;
- (6) A description of the reimbursement levels to be used for clinical services provided with grant funds;
- (7) A proposed cancer secondary prevention plan describing:
- (a) The estimated number of individuals to be served;
  - (b) The goals, objectives, and activities to be conducted with the grant funds;
  - (c) Evaluation measures for each activity;
  - (d) Who will be involved in the plan; and
  - (e) What the expected results of the funded activity are;
- (8) A description of how the proposed cancer secondary prevention activities will address the goal of eliminating disparities between racial and ethnic minorities and the white population;
- (9) A list of key staff to be involved in the project, including:
- (a) If existing staff will be used in the project, a description of the experience of the key staff in carrying out similar cancer secondary prevention activities; or
  - (b) If new staff will be hired for this activity, a job description of the staff responsible for carrying out the project;
- (10) A description of the previous experience of the applicant's organization in implementing similar cancer secondary prevention activities;
- (11) A timeline showing the expected start date and completion date for each activity to be conducted with the grant funds;
- (12) An organizational chart showing:

(a) Where the cancer secondary prevention grant activities fall within the applicant's organizational structure; and

(b) The relationship of the applicant with other organizations involved in the project;

(13) A statement that the grant funds will not be used to supplant any existing funding for this cancer secondary prevention activity and, if an applicant receives funding for a similar cancer secondary prevention activity, a list of the funding:

(a) Source;

(b) Amount; and

(c) Period for the activity;

(14) A line item budget for the cancer secondary prevention grant; and

(15) A written budget justification for each line item requested.

#### **.14 Application Process for Cancer Treatment Grants.**

A. An applicant for a cancer treatment grant shall submit a completed application to the CCPC.

B. Cancer treatment grants are open and continuous throughout the year to the extent that funding is available.

C. An applicant seeking a cancer treatment grant to pay for cancer treatment costs shall include in the Department's application packet:

(1) A completed cancer treatment grant application for each individual for whom grant funds are being requested, including the:

(a) Name;

(b) Phone number;

(c) Mailing address;

(d) County; and

(e) Signature of the:

(i) Individual diagnosed with cancer if the individual is an adult; or

(ii) Parent or guardian if the individual diagnosed with cancer is younger than 18 years old;

(2) A letter written by the individual's physician on the physician's letterhead:

(a) Confirming:

(i) That the individual has been diagnosed with or treated for cancer or the individual has a finding suggestive of cancer and needs to obtain a cancer diagnosis; and

(ii) The dates of diagnosis or treatment; and

(b) Containing the physician's:

(i) Full name;

(ii) Address;

(iii) Specialty; and

(iv) Medical license number;

(3) Proof of current Maryland residency for at least 6 months before the application date for each individual for whom grant funds are being requested in one of the following forms:

(a) Maryland driver's license or State identification card;

(b) Lease or rental agreement;

(c) Property tax bill;

(d) Motor vehicle registration;

(e) Pay check or stub with name and home address;

(f) Utility bill;

(g) Voter registration card; or

(h) W-2 statement issued not more than 12 months ago;

(4) Proof of annual family income for each individual for whom grant funds are being requested, including a copy of at least one of the following:

(a) Most recent:

(i) Income tax return; or

(ii) W-2 form;

- (b) Pay stubs for two:
    - (i) Consecutive pays; or
    - (ii) Pays in the same month;
  - (c) Social security entitlement letter; or
  - (d) Notarized letter from the individual stating that the individual is not working and does not have any income;
  - (5) Documentation of the eligibility of the individual for grant funds, including:
    - (a) The family size of the individual for whom the applicant is applying; and
    - (b) The family's annual household income;
  - (6) Certification that the applicant will:
    - (a) Keep financial records, as described in Regulation .16B of this chapter;
    - (b) Send demographic and fiscal information on each individual covered to the CCPC at the end of the grant period; and
    - (c) Act as the authorized representative of the individual.
  - (7) Attestation that grant funds will not be used to supplant any existing funding for this cancer treatment activity; and
  - (8) If the applicant currently receives funding for a similar cancer treatment activity, a list of the funding:
    - (a) Source;
    - (b) Amount; and
    - (c) Period for the activity.
- D. An applicant seeking a cancer treatment grant to pay for deductibles and patient contribution costs through their health insurance policy under Regulation .08E(2) of this chapter shall include in the Department's application packet:
- (1) A completed and signed Maryland Cancer Fund — Cancer Treatment Grant application that;
    - (a) Certifies that the applicant shall pay:

- (i) The deductible and patient contribution amount; and
  - (ii) Costs for services not covered under the individual's health insurance policy for a time period not to exceed 1 year; and
- (b) Includes a treatment plan for a total request not to exceed a specified amount, as determined by the Department, per individual per year, including the:
- (i) Deductible and patient contribution amount; and
  - (ii) Costs for services not covered under the individual's health insurance policy.
- (2) Documentation of the individual's health insurance policy.

E. An applicant seeking a cancer treatment grant to pay directly for cancer treatment costs under Regulation .08E(3) of this chapter shall include in the Department's application packet:

- (1) A completed Maryland Cancer Fund — Cancer Treatment Grant application; and
- (2) A signed document that certifies that the applicant shall pay directly for cancer treatment costs for the individual for a time period not to exceed 1 year; and certifies that the applicant shall:
  - (a) Reimburse the provider in an amount not greater than the Medical Assistance rate for the medical procedure or the HSCRC-regulated rate for the medical procedure performed, if the medical procedure is performed in a HSCRC-regulated facility; or
  - (b) Accept the Medical Assistance rate as payment in full for the cancer treatment procedures performed, if the applicant is a medical provider; and
- (3) Includes a treatment plan for a total request not to exceed \$20,000 per individual, including:
  - (a) The planned cancer treatment procedures; and
  - (b) The Medical Assistance or HSCRC-regulated rate for each procedure.

### **.15 Grant Application Review and Approval and Grant Extensions.**

A. Each fiscal year the CCPC shall determine:

- (1) The amount of money available for grants under the Maryland Cancer Fund;
- (2) The allocation of funding for cancer:
  - (i) Research;

(ii) Primary prevention;

(iii) Secondary prevention; and

(iv) Treatment; and

(3) The maximum grant award amount for each type of grant.

B. Each year the Department shall consider for award, funding for one or more of the following types of grant applications for cancer:

(1) Research;

(2) Primary prevention;

(3) Secondary prevention; and

(4) Treatment.

C. The CCPC shall develop one or more evaluation committees or shall contract with one or more external consultants with expertise in cancer research and prevention to review the cancer research and primary prevention and secondary prevention grant applications that are submitted for funding under the Maryland Cancer Fund.

D. Due to the need for timeliness in the cancer treatment grants, the CCPC shall review each application for cancer treatment.

E. The evaluation committee or external consultants shall review:

(1) Cancer research grant applications based on:

(a) Scientific need;

(b) The degree to which the cancer research plan will achieve the goals and objectives set forth in the plan;

(c) The inclusion of a plan for Institutional Review Board approval;

(d) The feasibility of the timeline in delivering goals and objectives of the plan;

(e) The experience and expertise of the principal investigator;

(f) The degree to which a grant application addresses eliminating disparities between racial and ethnic minorities and the white population;

(g) Whether the research is recommended in the Maryland Comprehensive Cancer Plan;

- (h) The lack of other resources or funding for the proposed research; and
- (i) The amount of the funding requested;
- (2) Cancer primary prevention grant applications based on:
  - (a) The need for the cancer primary prevention activity;
  - (b) The previously documented effectiveness of the primary prevention intervention;
  - (c) The degree to which the cancer primary prevention plan will achieve the goals and objectives set forth in the plan;
  - (d) The degree to which a grant application addresses eliminating disparities between racial and ethnic minorities and the white population;
  - (e) The experience of the applicant in cancer primary prevention;
  - (f) Whether the primary prevention intervention is recommended in the Maryland Comprehensive Cancer Control Plan;
  - (g) The lack of other resources or funding for the proposal; and
  - (h) The amount of funding requested; and
- (3) Cancer secondary prevention grant applications based on:
  - (a) The previously documented effectiveness of the secondary prevention intervention;
  - (b) The need for the cancer secondary prevention intervention in the population group to be served;
  - (c) The degree to which the cancer secondary prevention plan will achieve the goals and objectives of the plan;
  - (d) The feasibility of the timeline in delivering the goals and objectives of the plan;
  - (e) The extent to which medical guidelines for screening and diagnosis are being followed;
  - (f) The percent of the budget allocated to clinical services;
  - (g) The degree to which the grant application addresses eliminating disparities between racial and ethnic minorities and the white population;
  - (h) The experience of the applicant in cancer secondary prevention;



(i) Whether the secondary prevention intervention is recommended in the Maryland Comprehensive Cancer Control Plan;

(j) The lack of other resources or funding for the proposal; and

(k) The amount requested.

F. After reviewing each cancer research, primary prevention, and secondary prevention grant application, the evaluation committee or external consultant shall make a recommendation to the CCPC about whether to award grant funds to each applicant.

G. The CCPC shall review each cancer treatment application based on:

(1) Completeness;

(2) Availability of funds; and

(3) Whether the application meets the relevant application process requirements set forth in this chapter.

H. The Director of the CCPC shall recommend an application to the Secretary for approval based upon:

(1) The evaluation committee's or external consultant's recommendations for awarding the cancer research, primary prevention, secondary prevention, and treatment grants for each application; and

(2) The availability of funds.

I. The Secretary shall:

(1) Consider the grant recommendations of the CCPC for the cancer:

(a) Research;

(b) Primary prevention;

(c) Secondary prevention; and

(d) Treatment; and

(2) Make the final determination on which grant applications to approve.

J. A grant period expires 1 year from the date of award of the grant, unless extended as set forth in Regulation .16 of this chapter.

K. A person awarded a grant under this chapter may apply for a no-cost extension of the grant period for the award before the expiration of the grant period, as set forth in §J of this regulation, by submitting a written request for an extension to the CCPC.

L. In evaluating whether to grant an extension of the grant period, the CCPC:

- (1) Shall assess whether progress has been made on the grant; and
- (2) If progress has been made based on the reports submitted pursuant to Regulation .16C of this chapter, may recommend to the Secretary that an extension be granted.

M. The Secretary may approve an extension for up to 1 year based on:

- (1) The recommendation of the CCPC; and
- (2) Whether progress has been shown on the grant pursuant to Regulation .16C of this chapter.

## **.16 Payments, Terms and Conditions of Grant Awards, and Terminations.**

A. Payments Under the Grant.

- (1) The Department may not make more than monthly payments during the grant period to a person awarded a grant under this chapter.
- (2) Before the first payment under the grant, at the request of the person awarded the grant under this chapter, the Department may approve an advanced payment for the grant based on financial need, if a request for advanced payment was specified in the grant application.
- (3) If a financial or progress report required in §B or C of this regulation is overdue, the Department may withhold payment until the report is submitted.

B. Financial Reports and Records.

- (1) A person awarded a grant shall:
  - (a) Establish a separate account to track expenditures under the grant;
  - (b) Maintain accurate records, including documentation of each transaction pertaining to the grant; and
  - (c) Submit to the Department monthly invoices for payment and an annual financial expenditure report containing the signature of the financial officer of the entity affiliated with the grant award.
- (2) The Department may audit the accounts referenced in §B(1) of this regulation at any time.

(3) A person awarded a grant under this chapter shall submit to the Department within 90 days after the date the grant period ends:

(a) A final financial expenditure report; and

(b) A refund of any unexpended funds.

(4) A person awarded a grant under this chapter shall retain all records pertaining to a grant award for 3 years from the date the final financial expenditure report is submitted under §B(3) of this regulation.

(5) In the case of an audit or litigation, the Department may extend the time period under §B(3) or (4) of this regulation until the completion of the audit or litigation.

### C. Progress Reports.

(1) A grantee shall submit to the CCPC three copies of:

(a) An interim report describing the progress of the grant:

(i) 6 months after the date of award of the grant; and

(ii) Every 6 months until the end of the grant; and

(b) A comprehensive final report, not later than 60 days after the date the grant period ends, that provides a summary of all of the activity conducted under the grant.

(2) A grantee receiving a cancer research grant shall include the following information in the comprehensive final report:

(a) Hypothesis;

(b) Methods;

(c) Results;

(d) Discussion of results and limitations of the research; and

(e) Conclusion.

(3) A grantee receiving a cancer primary prevention or secondary prevention grant shall include the following information in the comprehensive final report:

(a) Number of individuals served, by:

(i) Type of service;

- (ii) Age;
- (iii) Race; and
- (iv) Gender;
- (b) Number of individuals with abnormal screening results, by type of cancer;
- (c) Number of cancers diagnosed; and
- (d) Other outcome measures.

(4) A grantee receiving a cancer treatment grant shall include the following information in the comprehensive final report for each individual receiving funds for cancer treatment:

- (a) Type of cancer;
- (b) Stage of cancer at diagnosis;
- (c) Age;
- (d) Race;
- (e) Gender;
- (f) County; and
- (g) Amount of funds expended.

(5) The Department shall keep research results confidential as required by Health-General Article, §§4-101—4-103, Annotated Code of Maryland.

#### D. Publications.

(1) A person who publishes results from activities supported by a grant approved by the Secretary under this chapter shall include in the publication the following acknowledgement: "Supported in part with funds from the Maryland Cancer Fund of the Maryland Department of Health and Mental Hygiene."

(2) A person awarded a grant under this chapter shall provide the Department with three copies of any published article pertaining to the activities conducted under the grant.

#### E. Ownership of Equipment. A person awarded a grant under this chapter:

(1) Shall ensure that equipment purchased under a grant under this chapter is used for the sole purpose of the grant;

(2) Shall keep an inventory of all equipment purchased; and

(3) May not transfer the equipment to another entity without the written permission of the Department.

#### F. Termination.

(1) The Secretary may terminate a grant:

(a) If a grantee fails to comply with:

(i) The requirements of this chapter; or

(ii) State, federal, and municipal laws applicable to the performance of research under the grant;

(b) If a grantee fails to carry out the purposes for which the grant was awarded;

(c) In compliance with a court order; or

(d) At the request of the grantee.

(2) The Department and the State are not responsible for any expenses incurred by a grantee after cancellation of a grant.

(3) The grantee shall return all unexpended funds to the Department within 60 days of termination of a grant.

G. Compliance with Existing Laws. A person awarded a grant under this chapter shall ensure that an activity conducted in the performance of the grant is in compliance with all State, federal, and local laws.

#### H. Liability.

(1) A person awarded a grant under this chapter is solely responsible for the person's actions pertaining to research conducted under a grant award.

(2) The State and the Department are not liable for any claims, losses, liabilities, expenses, or damages arising from research conducted under a grant awarded under this chapter.

I. Grant Agreements. A person awarded a grant under this chapter shall enter into a grant agreement with the Department.

## Administrative History

### Effective date:

Regulations .01—.16 adopted as an emergency provision effective June 1, 2006 (33:15 Md. R. 1274); adopted permanently effective October 9, 2006 (33:20 Md. R. 1616)

Regulation .02B amended as an emergency provision effective June 12, 2008 (35:14 Md. R. 1243); amended permanently effective October 20, 2008 (35:21 Md. R. 1824)

Regulation .02B amended as an emergency provision effective December 22, 2008 (36:2 Md. R. 97); amended permanently effective April 6, 2009 (36:7 Md. R. 524)

Regulation .02B amended effective March 18, 2013 (40:5 Md. R. 411)

Regulation .02B amended as an emergency provision effective January 1, 2014 (41:2 Md. R. 88)

Regulation .03A amended effective March 18, 2013 (40:5 Md. R. 411)

Regulation .05C amended as an emergency provision effective June 12, 2008 (35:14 Md. R. 1243); amended permanently effective October 20, 2008 (35:21 Md. R. 1824)

Regulation .07 amended as an emergency provision effective June 12, 2008 (35:14 Md. R. 1243); amended permanently effective October 20, 2008 (35:21 Md. R. 1824)

Regulation .08 amended effective October 4, 2010 (37:20 Md. R. 1393); March 18, 2013 (40:5 Md. R. 411)

Regulation .08 amended as an emergency provision effective January 1, 2014 (41:2 Md. R. 88)

Regulation .08D, E amended as an emergency provision effective June 12, 2008 (35:14 Md. R. 1243); amended permanently effective October 20, 2008 (35:21 Md. R. 1824)

Regulation .09 amended effective March 18, 2013 (40:5 Md. R. 411)

Regulation .10A amended effective March 18, 2013 (40:5 Md. R. 411)

Regulation .11 amended effective March 18, 2013 (40:5 Md. R. 411)

Regulation .12 amended effective March 18, 2013 (40:5 Md. R. 411)

Regulation .13 amended effective March 18, 2013 (40:5 Md. R. 411)

Regulation .14 amended effective March 18, 2013 (40:5 Md. R. 411)

Regulation .14C, D amended as an emergency provision effective June 12, 2008 (35:14 Md. R. 1243); amended permanently effective October 20, 2008 (35:21 Md. R. 1824)

Regulation .14D, E amended as an emergency provision effective January 1, 2014 (41:2 Md. R. 88)

Regulation .15 amended effective March 18, 2013 (40:5 Md. R. 411)

Regulation .15B amended as an emergency provision effective June 12, 2008 (35:14 Md. R. 1243); amended permanently effective October 20, 2008 (35:21 Md. R. 1824)

Regulation .16C amended effective March 18, 2013 (40:5 Md. R. 411)

Regulation .16C amended as an emergency provision effective January 1, 2014 (41:2 Md. R. 88)

Regulation .16D amended effective October 4, 2010 (37:20 Md. R. 1393)