

PROPOSAL

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Title 10

MARYLAND DEPARTMENT OF HEALTH

Subtitle 14 CANCER CONTROL

10.14.08 Professional and Volunteer Firefighter Innovative Cancer Screening Technologies Program

Authority: Health-General Article, §§13-4001—13-4007, Annotated Code of Maryland

Notice of Proposed Action

[20-043-P]

The Secretary of Health proposes to adopt new Regulations .01—.08 under a new chapter, **COMAR 10.14.08 Professional and Volunteer Firefighter Innovative Cancer Screening Technologies Program**.

Statement of Purpose

The purpose of this action is to adopt regulations for the Professional and Volunteer Firefighter Innovative Cancer Screening Technologies Program, which was established by Ch. 219 (S.B. 727), Acts of 2019, to provide grants to fire departments to procure innovative cancer screening tests to reduce cancer mortality among professional and volunteer firefighters.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

I. Summary of Economic Impact. Ch. 219 (S.B. 727), Acts of 2019, Health—Professional and Volunteer Firefighter Innovative Cancer Screening Program, requires the Governor to include in the budget at least \$100,000 for the Professional and Volunteer Firefighter Innovative Cancer Screening Program in fiscal year (FY) 2021 and each year thereafter. In FY 2021, the Department intends to consider awarding the entire amount of \$100,000 to at least one qualified applicant.

II. Types of Economic Impact.	Revenue (R+/R-)	Magnitude
	Expenditure (E+/E-)	
A. On issuing agency:	(E+)	\$100,00
B. On other State agencies:	NONE	
C. On local governments:	NONE	
	Benefit (+)	Magnitude
	Cost (-)	
D. On regulated industries or trade groups:	(+)	\$100,000
E. On other industries or trade groups:	NONE	
F. Direct and indirect effects on public:	NONE	

III. Assumptions. (Identified by Impact Letter and Number from Section II.)

A. Ch. 219 (S.B. 727), Acts of 2019, Health—Professional and Volunteer Firefighter Innovative Cancer Screening Program, requires the Governor to include in the budget at least \$100,000 for the program in fiscal year (FY) 2021 and each year thereafter. The Department expects \$100,000 to be appropriated annually for the program.

D. The Department intends to consider awarding the entire amount of \$100,000 to at least one qualified applicant.

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 Jake Whitaker, Acting Director, Office of Regulation and Policy Coordination, Maryland Department of Health, 201 West Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499 (TTY 800-735-2258), or email to mdh.regs@maryland.gov, or fax to 800-735-2258. Comments will be accepted through March 2, 2020. A public hearing has not been scheduled.

.01 Purpose and Scope.

This chapter sets forth the:

- A. Responsibilities of the Maryland Department of Health for the Professional and Volunteer Firefighter Innovative Cancer Screening Technologies Program established by Health-General Article, §§13-4001—13-4007, Annotated Code of Maryland;*
- B. Responsibilities of a grantee that receives funds under the Professional and Volunteer Firefighter Innovative Cancer Screening Technologies Program;*
- C. Application process for a grant under the Professional and Volunteer Firefighter Innovative Cancer Screening Technologies Program; and*
- D. Reporting requirements for the Professional and Volunteer Firefighter Innovative Cancer Screening Technologies Program.*

.02 Definitions.

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

B. Terms Defined.

- (1) “Applicant” means an entity that applies to receive a grant under the Professional and Volunteer Firefighter Innovative Cancer Screening Technologies Program.*
- (2) Cancer Screening Test.
 - (a) “Cancer screening test” means a test that is designed to find cancer in an individual who does not present cancer symptoms.*
 - (b) “Cancer screening test” includes, but is not limited to:
 - (i) A laboratory test;*
 - (ii) An imaging procedure;*
 - (iii) A medical procedure; and*
 - (iv) A genetic test.***
- (3) “Cost effectiveness” means a comparison between cost and expected health outcomes of a cancer test or intervention.*
- (4) “Department” means the Maryland Department of Health.*
- (5) “Grant” means funds distributed to a grantee under the Professional and Volunteer Firefighter Innovative Cancer Screening Technologies Program.*
- (6) “Grantee” means a local fire department, volunteer fire department, or volunteer fire company approved to receive funds under the Professional and Volunteer Firefighter Innovative Cancer Screening Technologies Program.*
- (7) “Health care provider” means a doctor of medicine or osteopathy, dentist, nurse practitioner, or physician assistant who is authorized to practice medicine, surgery, or dentistry by the state in which the doctor practices.*
- (8) “Local fire department” means a county fire department or the Baltimore City Fire Department.*
- (9) “Program” means the Professional and Volunteer Firefighter Innovative Cancer Screening Technologies Program.*
- (10) “Qualifications” means the education, experience, skills, and licensing of an individual associated with a Program grant application.*
- (11) “Volunteer fire company” means a volunteer fire company operating in a county or Baltimore City.*
- (12) “Volunteer fire department” means a volunteer fire department operating in a county or Baltimore City.*

.03 Responsibilities of the Department.

The Department shall:

- A. Administer the Program;*
- B. Provide one or more grants to local fire departments, volunteer fire companies, or volunteer fire departments to procure innovative cancer screening tests according to Health-General Article, §13-4003(a), Annotated Code of Maryland;*
- C. Develop and distribute an application for Program grants at the start of each fiscal year;*
- D. Maintain a record of information submitted by a grantee to the Department; and*
- E. Monitor the activities of a grantee to ensure compliance with the requirements of the Program.*

.04 Entities Eligible for Grants.

The following entities are eligible to apply for and receive a grant from the Department under the Program:

- A. A local fire department;*
- B. A volunteer fire company;*
- C. A volunteer fire department; and*
- D. If authorized by a local fire department, volunteer fire company, or volunteer fire department, a county.*

.05 Use of Grant Funds.

A. A grantee may use awarded funds to:

(1) Procure and administer innovative cancer screening tests that are not otherwise conducted during routine physical examinations or covered by insurance to professional firefighters employed by a local fire department and volunteer firefighters who serve in a volunteer fire company or department; and

(2) Pay for activities directly associated with the grant that are approved by the Department.

B. A grantee may not use awarded funds to pay for an activity that is not included in the approved grant application.

.06 Application for Professional and Volunteer Firefighter Innovative Cancer Screening Technologies Program Grants.

A. An applicant:

(1) Shall submit a completed application to the Department by the due date listed in the request for applications;

(2) Shall include in the application all required information listed in the request for applications, including:

(a) The names and qualifications of the health care providers that will advise the applicant on the selection and administration of cancer screening tests;

(b) The number of firefighters to be screened;

(c) The criteria used to select firefighters determined to be at the highest cancer risk based on the latest scientific and medical research reports to be screened; and

(d) A description of each test to be procured by the applicant, including:

(i) The claimed accuracy and reliability of the test;

(ii) The scientific and clinical evidence supporting the claimed accuracy and reliability of the test;

(iii) Whether the test employs innovative or novel technologies, such as DNA sequencing, genomics, proteomics, metabolomics, machine learning, artificial intelligence, big data analytics, or other state-of-the-art technology;

(iv) Whether the test has the ability to simultaneously screen for two or more cancer types for which firefighters have a higher incidence or death rate;

(v) The cost of the test; and

(vi) Whether the test is developed, manufactured, or commercialized by a business entity located in the State; and

(3) May voluntarily withdraw an application at any time.

B. The county in which a volunteer fire company or department is located shall assist a volunteer fire company or a volunteer fire department in submitting an application.

.07 Application Review, Selection of Grantees, and Grant Period.

A. The Department shall:

(1) Determine the amount of money available for grants under the Program in each fiscal year;

(2) Develop a weighting formula to rate each application received by the Program;

(3) Make available the weighting formula on the Program website and include the weighting formula in the request for applications;

(4) Request additional information or changes to the application if necessary; and

(5) Reject an application that does not meet the application requirements.

B. The Department shall review and prioritize applications based on the quality of the application received and the degree to which the tests listed on the application meet the following criteria:

(1) The scientific and clinical evidence supporting the claimed accuracy and reliability of test;

(2) Whether the test employs innovative or novel technologies;

(3) The ability of the test to simultaneously screen for two or more cancers types;

(4) The cost effectiveness of the test; and

(5) Whether the test is developed, manufactured, or commercialized by a business entity located in the State.

C. The Department may review an application in consultation with one or more experts in cancer screening.

D. If the Department receives applications for grant funds totaling more than the amount of funds appropriated for the Program, the Department shall award the funds based on the rating given to each application using the weighting formula.

E. Funds shall be awarded under the Program for a maximum of 1 year.

.08 Payments, Terms and Conditions of Grant Awards, and Terminations.

A. Payments.

(1) The Department may not pay grantees more frequently than on a quarterly basis during the grant period.

(2) The Department may approve an advance payment before the first payment is scheduled for the grant based on financial need.

(3) If a financial or progress report required by §B or C of this regulation is overdue, the Department may withhold payment of funds to a grantee until the financial or progress report is submitted.

B. Financial Reports and Records.

(1) A grantee shall:

(a) Establish a separate account to track expenditures under the grant;

(b) Maintain accurate records, including documentation of each transaction associated with the grant; and

(c) Submit to the Department:

(i) Quarterly invoices for payment of grant funds; and

(ii) An annual financial expenditure report containing the signature of the financial officer of the grantee.

- (2) *The Department may audit the accounts referenced in §B(1) of this regulation at any time.*
 - (3) *Within 90 days after the date the grant period ends, a grantee shall submit to the Department:*
 - (a) *A final report listing grant expenditures; and*
 - (b) *A refund of any unexpended funds.*
 - (4) *A grantee shall retain all records pertaining to a grant for 3 years from the date the final 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. A grantee shall submit to the Program electronically:*
- (1) *An interim report describing the progress of the grant 6 months after the date of award of the grant; and*
 - (2) *A comprehensive final report that provides a summary of all activities conducted under the grant no later than 60 days after the date the grant period ends, including the:*
 - (a) *Number of individuals screened;*
 - (b) *Tests used;*
 - (c) *Cost of the tests; and*
 - (d) *Cancers detected by the tests.*
- D. Publications.*
- (1) *A grantee who publishes results from activities supported by a grant approved under this chapter shall include in the publication the following acknowledgement: "Supported in part with funds from the Professional and Volunteer Firefighter Innovative Cancer Screening Technologies Program of the Maryland Department of Health."*
 - (2) *A grantee shall provide the Department with one electronic copy of any published article associated with an activity conducted under a grant.*
- E. Ownership of Cancer Screening Tests. A grantee:*
- (1) *Shall ensure that a cancer screening test purchased under a Program grant is used for the sole purpose of the grant;*
 - (2) *Shall keep an inventory of cancer screening tests purchased; and*
 - (3) *May not transfer a cancer screening test to another entity without written permission from the Department.*
- F. Termination.*
- (1) *The Department 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 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 may not be held 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. Liability.*
- (1) *A grantee shall be solely responsible for its actions related to the:*
 - (a) *Program application process; and*
 - (b) *Activities conducted under a grant.*
 - (2) *The Department may not be held liable for any claims, losses, liabilities, expenses, or damages arising from activities related to the:*
 - (a) *Program application process; or*
 - (b) *Activities conducted under a grant.*

ROBERT R. NEALL
Secretary of Health