MARYLAND REGISTER

Proposed Action on Regulations

| | Date Filed with AELR Committee | TO BE COMPLETED BY DSD |
|---------------------------|-----------------------------------|--|
| Transmittal Sheet | 10/24/2016 | Date Filed with Division of State Documents |
| PROPOSED OR REPROPOSED | | Document Number |
| Actions on Regulations | | Date of Publication in MD Register |

1. Desired date of publication in Maryland Register: 12/9/2016

2. COMAR Codification

Title Subtitle Chapter Regulation

10 14 06 02-.06

3. Name of Promulgating Authority

Department of Health and Mental Hygiene

| 4. Name of Regulations Coordinator | Telephone Number |
|------------------------------------|------------------|
| Michele Phinney | 410-767-5623 |

Mailing Address

201 W. Preston Street

| City | State | Zip Code |
|-----------|-------|----------|
| Baltimore | MD | 21201 |

Email michele.phinney@maryland.gov

| 5. Name of Person to Call About this Document | Telephone No. |
|---|---------------|
| Anne Carlin | 410-767-1935 |

Email Address anne.carlin@maryland.gov

6. Check applicable items:

- X- New Regulations
- X- Amendments to Existing Regulations
 - Date when existing text was downloaded from COMAR online: May 28, 2015.
- X- Repeal of Existing Regulations
- _ Recodification
- _ Incorporation by Reference of Documents Requiring DSD Approval
- _ Reproposal of Substantively Different Text:
- : Md. R
- (vol.) (issue) (page nos) (date)

Under Maryland Register docket no.: --P.

7. Is there emergency text which is identical to this proposal:

_ Yes X- No

8. Incorporation by Reference

_ Check if applicable: Incorporation by Reference (IBR) approval form(s) attached and 18 copies of documents proposed for incorporation submitted to DSD. (Submit 18 paper copies of IBR document to DSD and one copy to AELR.)

9. Public Body - Open Meeting

_ OPTIONAL - If promulgating authority is a public body, check to include a sentence in the Notice of Proposed Action that proposed action was considered at an open meeting held pursuant to General Provisions Article, §3-302(c), Annotated Code of Maryland.

_ OPTIONAL - If promulgating authority is a public body, check to include a paragraph that final action will be considered at an open meeting.

10. Children's Environmental Health and Protection

_ Check if the system should send a copy of the proposal to the Children's Environmental Health and Protection Advisory Council.

11. Certificate of Authorized Officer

I certify that the attached document is in compliance with the Administrative Procedure Act. I also certify that the attached text has been approved for legality by Claire Pierson, Assistant Attorney General, (telephone #410-767-6526) on October 24, 2016. A written copy of the approval is on file at this agency.

Name of Authorized Officer

| Van T. Mitchell |
|------------------|
| Title |
| Secretary |
| Date |
| October 24, 2016 |

Telephone No. 410-767-6500

Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE Subtitle 14 CANCER CONTROL

10.14.06 Cigarette Restitution Fund Program

Authority: Health-General Article, §§13-1001—13-1002, 13-1005—13-1012, 13-1014, 13-1101—13-1102, 13-1106—13-1116, and 13-1119, Annotated Code of Maryland

Notice of Proposed Action

[]

The Secretary of Health and Mental Hygiene proposes to amend Regulations .02—.04, repeal in their entirety Regulations .05 and .06, and to adopt new Regulations .05 and .06 under COMAR 10.14.06 Cigarette Restitution Fund Program.

Statement of Purpose

The purpose of this action is to :

(1) Create a clear set of financial guidelines for local health departments and Statewide academic health centers to follow when determining an applicant's eligibility for cancer treatment services;

(2) Remove a provision that local health departments or Statewide academic health centers may establish additional financial requirements for eligibility of cancer treatment services;

(3) Simplify the description of individuals who may receive tobacco treatment products; and

(4) Update the definition of "Statewide Academic Health Centers" to include

organizations that meet the requirements of Health-General Article, §13-1115, Annotated Code of Maryland.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

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 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: TTY:800-735-2258, or email to dhmh.regs@maryland.gov, or fax to 410-767-6483. Comments will be accepted through January 9, 2017. A public hearing has not been scheduled.

Economic Impact Statement Part C

A. Fiscal Year in which regulations will become effective: FY 2017

B. Does the budget for the fiscal year in which regulations become effective contain funds to implement the regulations?

C. If 'yes', state whether general, special (exact name), or federal funds will be used:

D. If 'no', identify the source(s) of funds necessary for implementation of these regulations:

E. If these regulations have no economic impact under Part A, indicate reason briefly: The proposed amendments to these regulations do not affect the amount of money allocated to the local health departments or Statewide academic centers or how the money is distributed for services. Therefore, this proposal has no economic impact.F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason and attach small business worksheet.

These regulations apply to the Cigarette Restitution Fund Program, which is administered by local health departments and Statewide academic health centers. Therefore, there is no economic impact on small businesses.

G. Small Business Worksheet:

Attached Document:

Title 10

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 14 CANCER CONTROL

10.14.06 Cigarette Restitution Fund Program

Authority: Health-General Article, §§13-1001—13-1002, 13-1005—13-1012, 13-1014, 13-1101—13-1102, 13-1106—13-1116, and 13-1119, Annotated Code of Maryland

10.14.06.02 (May 28, 2015)

.02 Definitions.

A. (text unchanged)

B. Terms Defined.

[(1) "Annual gross income" means the total amount of income received each year from all sources before taxes are withheld or deductions are taken.

(2) "Annual net income" means the total amount of income received each year from all sources after taxes are withheld and deductions are taken.]

[(3)](1)—[(8)](6) (text unchanged)

(7) "Gross annual household income" means the total income of the applicant and any member of the applicant's household received each year from all sources before taxes are withheld or deductions are taken.

[(9)] (8)-[(11)] (10) (text unchanged)

[(12)] (11) "Statewide academic health center" means [the]:

(a) The University of Maryland Medical Group [or the];

(b) The Johns Hopkins Institutions;

(c) The organization designated by the Department as stipulated by Health-General Article, §13-1115, Annotated Code of Maryland; or

(d) One or more of the organizations in B(11)(a)—(c) of this regulation.

[(13)] (12) (text unchanged)

[(14)] (13) "Tobacco treatment product" means [a medication, including, but not limited to, nicotine patch, Zyban, nicotine gum and lozenge, and any other similar product to] *all Food and Drug Administration-approved tobacco cessation medications, including both prescription and over-the-counter medications, that* assist individuals to stop using tobacco products.

[(15)] (14)—[(17)] (16) (text unchanged)

10.14.06.03

.03 Responsibilities of the Department.

The Department shall:

A. Establish guidelines for defining financial eligibility of an uninsured individual for the purpose of receiving: (1) (text unchanged)

(2) Tobacco treatment products under the Tobacco Use Prevention and Cessation Program; and

[B. Require each local health department and Statewide academic health center to develop written financial eligibility criteria for an uninsured individual in accordance with the requirements of Regulations .04—.06 of this chapter for:

(1) Cancer treatment services; and

(2) Tobacco treatment products;

C. Require each local health department and Statewide academic health center to submit the written financial eligibility criteria for cancer treatment services and tobacco treatment products to the Department when:

(1) The financial eligibility criteria is initially developed; and

(2) Any changes are made to the financial eligibility criteria; and]

[D.] *B*. Review the written [financial eligibility criteria] *documentation* submitted by a local health department or Statewide academic health center to assure that the [factors] *criteria* listed in Regulations .05 and .06 of this chapter [are included in the financial eligibility criteria] *are followed*.

10.14.06.04

.04 Responsibilities of Local Health Departments and Statewide Academic Health Centers.

A. (text unchanged)

B. If a local health department or a Statewide academic health center decides that grant funds under the Cigarette Restitution Fund Program will be used to pay for cancer treatment services or tobacco treatment products:

(1) (text unchanged)

(2) A local health department or a Statewide academic health center shall[:

(a) Develop written financial eligibility criteria for:

(i) Cancer treatment services in accordance with Regulation .05 of this chapter; and

(ii) Tobacco treatment products in accordance with Regulation .06 of this chapter;

(b) Update the written financial eligibility criteria when any changes are made; and

(c) Send the written financial eligibility criteria to the Department:

(i) When the written financial eligibility criteria are first developed; and

(ii) At any time the written financial eligibility criteria changes] adhere to the financial guidelines

established by the Department as set forth in Regulations .05 and .06 of this chapter.

10.14.06.05

.05 Criteria for Eligibility for Cancer Treatment Services.

A. A local health department or a Statewide academic health center shall use the following financial eligibility criteria for cancer treatment services under the Cancer Prevention, Education, Screening and Treatment Program:

(1) The basis for determining financial eligibility shall be the gross annual household income;

(2) An applicant with a gross annual household income above 250 percent of the federal poverty level is not eligible to receive cancer treatment services;

(3) Written documentation required for determination of the gross annual household income shall include:

(a) The household's most recent federal income tax return; or

(b) If a household income tax return was not filed, the following:

(i) The most recent W-2 statement;

(ii) Pay stubs from two consecutive pays;

(iii) A Social Security entitlement letter; or

(*iv*) A notarized letter from the applicant stating that the applicant is not working and does not have any income;

(4) The household income level for determining financial eligibility shall be based on the size of the family unit including the applicant and may include the following individuals as verified by the most recent tax return:

(a) The applicant's spouse;

(b) Any financially dependent children; or

(c) Any financially dependent relative; and

(5) The type of written documentation that an applicant shall provide in order to document the size of the family unit includes the following:

(a) The most recent income tax return;

(b) A divorce decree, if applicable; or

(c) If a household income tax return was not filed, written documentation shall include the names, ages, and relationship to the applicant of individuals supported by the gross annual household income.

B. A local health department or a Statewide academic health center may establish requirements for eligibility of cancer treatment services in addition to those cited in §A of this regulation.

10.14.06.06

.06 Criteria for Eligibility for Tobacco Treatment Products.

A local health department shall make tobacco treatment products available free of charge to an individual participating in the Cigarette Restitution Fund Program.

VAN T. MITCHELL

Secretary of Health and Mental Hygiene