REGULATORY REVIEW AND EVALUATION ACT:

EVALUATION REPORTS — APRIL 1, 2016

Subtitle 10 LABORATORIES
Subtitle 11 MATERNAL AND CHILD HEALTH
Subtitle 12 ADULT HEALTH
Subtitle 13 DRUGS
Subtitle 14 CANCER CONTROL
Subtitle 50 TISSUE BANKS

SUBMITTED BY:

Department of Health and Mental Hygiene
Office of Regulation and Policy Coordination
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EVALUATION REPORTS

CHAPTERS AFFECTED	ACTIONS NEEDED
Subtitle 10 LABORATORIES	
COMAR 10.10.10 Job-Related Alcohol and Controlled Dangerous Substances Testing	No Action
Subtitle 12 ADULT HEALTH	
10.12.05 Breast Implantation	No Action
Subtitle 13 DRUGS	
10.13.05 AIDS Education Program for Persons Convicted of Drug/Sex-Related Crimes	Amendments
10.13.08 Sale of Needles and Syringes or Other Paraphernalia	No Action
10.13.11 Exemption to Allow Sale of Drugs by Vending Machines	No Action
10.13.12 Impoundment and Disposal of Drugs and Prescription Records	Amendment
Subtitle 14 CANCER CONTROL	
10.14.03 Breast Cancer Treatment Methods	No Action
10.14.04 Breast Cancer Program	No Action
10.14.06 Cigarette Restitution Fund Program	Amendment
Subtitle 50 TISSUE BANKS	
10.50.01 Tissue Banks	Amendment

EXEMPTIONS REQUESTED

In accordance with State Government Article, §10-132-1, Annotated Code of Maryland, the Secretary of DHMH has certified to the Governor and the AELR Committee that a review of the following chapters would not be effective or cost-effective and therefore are exempt from the review process based on the fact that they were either initially adopted (IA), comprehensively amended (CA) during the preceding 8 years, or Federally mandated (FM):

Subtitle 10 LABORATORIES	
10.10.01 General	CA 6-1-09
10.10.02 Medical Laboratories—General	CA 6-1-09
10.10.03 Medical Laboratories—Licenses	CA 6-1-09
10.10.04 Medical Laboratories—Fees	CA 6-1-09
10.10.05 Medical Laboratories—Proficiency Testing	CA 6-1-09
10.10.06 Medical Laboratories—Quality Assurance	CA 6-1-09
10.10.07 Medical Laboratories—Personnel	CA 6-1-09
10.10.08 Medical Laboratories—Sanctions	CA 6-1-09
10.10.09 Law Enforcement Laboratories—Personnel Cert. and Approval of Lab. Procedures	CA 11-11-13
10.10.11 Biological Agents Registry Program	CA 1-23-12
10.10.12 Medical Laboratories—Public Health HIV Testing Programs	CA 4-1-13
10.10.13 Medical Laboratories—Testing for Hereditary & Congenital Disorders in Newborn Infants	CA 3-23-09

Subtitle 11 MATERNAL AND CHILD HEALTH

10.11.01 Identification of Infants		CA 3-6-09
10.11.02 Program for Hearing-Impaired Infants		CA 6-22-15
10.11.03 Children's Medical Services Program		CA 1-14-08
10.11.04 Lead Poisoning Screening Program	(Amendments printed 1-8-16 Md.R.)	Anticipated CA: 3-28-16
10.11.05 Child Death Review Case Reporting System		IA 4-6-09
10.11.06 Morbidity, Mortality, and Quality Review Committee—Pregnancy and Childhood		IA 9-21-09
10.11.07 Prohibition of Sale of Baby Bumper Pads		IA 11-26-12

Subtitle 12 ADULT HEALTH

10.12.01 Surgical Abortion Facilities	IA 7-23-12
10.12.02 Rape and Sexual Offenses—Physician and Hospital Charges	CA 12-29-08
10.12.04 Day Care for the Elderly and Adults with a Medical Disability	CA 12-13-14

Subtitle 13 DRUGS

10.13.01 Dispensing of Prescription Drugs by a Licensee	CA 6-22-15
10.13.02 Purchase— and Distribution of Prescription Drugs and Devices	IA 8-22-11

Subtitle 14 CANCER CONTROL

10.14.01 Cancer Registry	CA 1-13-11
10.14.02 Reimbursement for Breast and Cervical Cancer Diagnosis and Treatment	CA 5-12-14
10.14.05 Maryland Cancer Fund	CA 5-12-14
10.14.07 Cord Blood Transplant Center Support Fund	IA 4-28-14

CHAPTERS THAT HAVE BEEN REPEALED

Subtitle 12 ADULT HEALTH

10.12.03 Expanded Maternity Plan -

Subtitle 13 DRUGS

10.13.03 Sale of Sodium Fluoride or Hydrofluoric Acid Preparations for Use as Insecticides -
10.13.04 Labeling of Prescriptions for Drugs (Other Than Narcotic Drugs)... Prescription –
10.13.06 Acceptance of Oral Prescriptions for Certain Narcotic Drugs -
10.13.07 Sale of Dihydrocodeinone or any of its Salts
10.13.09 Sale of Nitrous Oxide -
10.13.10 Prescribing, Administering, and Dispensing of Amphetamines and Methamphetamines -

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Chapter Codification: COMAR 10.10.10

Chapter Name: Job-Related Alcohol and Controlled Dangerous Substances Testing

Authority: Health – General Article § 17-214, Annotated Code of Maryland

Date Originally Adopted or Last Amended: Last Amended: Effective July 22, 2002 (29:14 Md.R. 1074)

Purpose: COMAR 10.10.10 provides standards and procedures for applicants and employees who are required to undergo job-related alcohol and controlled dangerous substances testing. As provided in COMAR 10.10.10.01, this regulation is intended to "provide for the protection of employers, employees, and the public by setting fair and effective job-related alcohol and controlled dangerous substances testing standards to ensure accurate and reliable test results and to promote drug-free workplaces."

A. Review Criteria. (State Government Article, §10-132(1)(i), Annotated Code of Maryland; COMAR 01.01.3002.20E)

(1) Do the regulations continue to be necessary for the public interest? Yes [X] No [ ]

(2) Do the regulations continue to be supported by statutory authority and judicial opinion? Yes [X] No [ ]

(3) Are the regulations obsolete or otherwise appropriate for amendment or repeal? Yes [ ] No [X]

(4) Are the regulations effective in accomplishing their intended purpose? Yes [X] No [ ]

B. Outreach and Research. (State Government Article, §10-135(a)(2)(i)–(viii), Annotated Code of Maryland)

(1) List any stakeholders invited to review the regulations and provide a summary of their participation in and input into the review process.

In an effort to provide stakeholders with an opportunity to participate in the review and evaluation of COMAR 10.10.10, a Notice of Opportunity for Public Inspection and Comment was posted on the websites for the Department of Health and Mental Hygiene and the DHMH Laboratories Administration. No comments were provided.

(2) List any other affected agencies that were invited to review the regulations and provide a summary of their participation in and input into the review process.

The Department of Health and Mental Hygiene Health Professionals Boards and Commissions including the Maryland Board of Pharmacy, Board of Physicians, Board of Dental Practitioners, Board of Nursing, Board of Dental Practitioners, Maryland Association of Counties, and the DHMH Office of Health Care Quality were invited to participate in the review of COMAR 10.10.10. No comments were provided.

(3) Describe the process used to solicit public comment, including:
(a) any notice published in the Maryland Register;
(b) any notice published in newspapers of general circulation;

(c) any notice posted on the unit's website or on a Statewide website created for units to post notices of regulation review;
(d) any mailing by the adopting authority; and
(e) any public hearing held.

Notice of Opportunity for Public Inspection and Comment was posted on the websites for the Department of Health and Mental Hygiene and the DHMH Laboratories Administration.

(4) Provide summaries of:
(a) all comments received from stakeholders, affected units, or the public; and
(b) the adopting authority's responses to those comments.

No comments were received.

(5) Describe any interunit conflict reviewed and the resolution or proposed resolution of that conflict.

None.

(6) Provide a summary of any relevant scientific data gathered.

Not applicable.

(7) Provide a summary of any relevant information gathered related to the regulations of other states or the federal government.

Federal regulatory provisions for job-related alcohol and controlled dangerous substances testing are codified under 49 CFR Part 382. This part regulates controlled substances and alcohol use testing for the Federal Motor Carrier Safety Administration. The regulations are designed to prevent accidents and injuries resulting from the misuse of alcohol or use of controlled substances by drivers of commercial motor vehicles. Similarly, Maryland and the surrounding states of Delaware, Virginia, West Virginia, North Carolina, Connecticut, New Jersey and Pennsylvania either require or provide public and/or private employers with the option of conducting some form of employee drug testing (if required and/or deemed necessary by the employer). The impetus of these state regulations is to provide parameters for pre-employment testing or protocols if there are reasonable indications that a prospective employee has a drug abuse problem.

(8) Provide a summary of any other relevant information gathered.

The specific regulatory provisions of COMAR 10.10.10 provides that employers may require applicants, contractors or employees to undergo job-related alcohol or controlled dangerous substances testing. However, such testing may only be conducted by a state certified laboratory. Moreover, any positive test result will afford employees an opportunity (at their own expense) to have an independent test performed to verify the results.

COMAR 10.10.10 does not pertain to the authorized use of medical marijuana and all tests received or produced as a result of job-related alcohol or controlled dangerous substances testing are confidential. Tests results may only be released by subpoena, court order or upon a signed authorization of the person tested or by his or her parent or legal guardian.

C. Under COMAR 01.01.2003.20E(3), does the agency have any existing policy statements, guidelines, or standards being applied or enforced which should be promulgated as regulations, in accordance with the Administrative Procedure Act?

Yes [ ] No [X]

Has the agency promulgated all regulations required by recent legislati Yes [X] No [ ]

Provide explanations of the above responses, as needed:

Not applicable.

D. Actions Needed. (State Government Article, §10-135(a)(2)(ix) – (xi), Annotated Code of Maryland)
(check all that apply)

- [X] no action
- [ ] amendment
- [ ] repeal
- [ ] repeal and adopt new regulations
- [ ] reorganization

Summary:

COMAR 10.10.10 continues to be an essential and effective regulation for the protection of employers, employees and the public in the State of Maryland. By setting standards, protocols and procedures for job-related alcohol and controlled dangerous substances testing, accurate and reliable test results are achieved and promotes drug-free workplaces.

Person performing review: Renee E. Scurry

Title: Administrator for Regulatory and Administrative Programs

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Chapter Codification: COMAR 10.12.05

Chapter Name: Breast Implantation

Authority: Health-General Article, §20-114, Annotated Code of Maryland

Date Originally Adopted or Last Amended: September 3, 1990

Purpose:

To require:
1) The Department of Health and Mental Hygiene (the Department) to:
   a) provide and distribute a standardized written summary of information about breast implantation including the side effects, warnings, and cautions;
   b) provide a statement acknowledging receipt of information for signature by patients; and
   c) provide a waiver form for the time requirements for the summary distribution.
2) Physicians to:
   a) provide the standardized written summary to patients within a certain timeframe;
   b) obtain patient signature on the acknowledgement form provided by the Department; and
   c) retain any waiver and the signed acknowledgement form in the patient's medical record.

A. Review Criteria. (State Government Article, §10-132(1)(i), Annotated Code of Maryland; COMAR 01.01.3002.20E)

(1) Do the regulations continue to be necessary for the public interest? Yes [X] No [ ]

(2) Do the regulations continue to be supported by statutory authority and judicial opinion? Yes [X] No [ ]

(3) Are the regulations obsolete or otherwise appropriate for amendment or repeal? Yes [ ] No [X]

(4) Are the regulations effective in accomplishing their intended purpose? Yes [X] No [ ]

B. Outreach and Research. (State Government Article, §10-135(a)(2)(i)–(viii), Annotated Code of Maryland)

(1) List any stakeholders invited to review the regulations and provide a summary of their participation in and input into the review process.

The Department invited comments from: the general public (via notice posted to the Department's website), local Breast and Cervical Cancer Program coordinators and other key contacts at the 24 local health departments, clinical providers participating in the Breast and Cervical Cancer Diagnosis and Treatment Program, members of the Maryland State Council on Cancer Control, members of the Breast Cancer Medical Advisory Committee, members of the Maryland Cancer Collaborative, and other key stakeholders and groups that represent patients and health care providers.

(2) List any other affected agencies that were invited to review the regulations and provide a summary of their participation in and input into the review process.

No other agencies are affected by these regulations; therefore no other agencies were invited to review the regulations.

(3) Describe the process used to solicit public comment, including:
(a) any notice published in the Maryland Register;
(b) any notice published in newspapers of general circulation;
(c) any notice posted on the unit's website or on a Statewide website created for units to post notices of regulation review;
(d) any mailing by the adopting authority; and
(e) any public hearing held.

The Department solicited comments by:
- posting a notice to the Department's website;
- sending email messages to Breast and Cervical Cancer Program coordinators and other key contacts at the local health departments;
- mailing letters to the providers participating in the Breast and Cervical Cancer Diagnosis and Treatment Program;
- emailing members of the Maryland State Council on Cancer Control and announcement at the May 15, 2015 meeting;
- emailing members of the Breast Cancer Medical Advisory Committee; and
- emailing members of the Maryland Cancer Collaborative, which includes key stakeholders and groups that represent patients and health care providers.

(4) Provide summaries of:
(a) all comments received from stakeholders, affected units, or the public; and
(b) the adopting authority's responses to those comments.

No comments were received.

(5) Describe any interunit conflict reviewed and the resolution or proposed resolution of that conflict.

No inter-unit conflicts identified.

(6) Provide a summary of any relevant scientific data gathered.

An internet search of scientific data related to breast implantation summary information was conducted. No scientific information was available.

(7) Provide a summary of any relevant information gathered related to the regulations of other states or the federal government.

A national scan of existing state statutes and regulations pertaining to breast implantation summary information was conducted using internet searches and historical CDC documents as points of reference. In general, statutes and regulations relating to breast implantation summary information are similar from state to state and were enacted generally starting in the early 1990's through the early 2000's with minimal revisions since enactment. There is evidence that some states had similar statutes that were repealed, but information about the justification for any such repeal was not available. In general, no evidence was found to substantiate revisions to Maryland COMAR or statute for breast implantation summary information.

(8) Provide a summary of any other relevant information gathered.

No other relevant information was gathered.

C. Under COMAR 01.01.2003.20E(3), does the agency have any existing policy statements, guidelines, or standards being applied or enforced which should be promulgated as regulations, in accordance with the Administrative Procedure Act?

Yes [ ] No [X]

Has the agency promulgated all regulations required by recent legislation? Yes [X] No [ ]

Provide explanations of the above responses, as needed:

No recent legislation has required promulgation of regulations.

D. Actions Needed. (State Government Article, §10-135(a)(2)(ix) – (xi), Annotated Code of Maryland) (check all that apply)

X no action

amendment

repeal

repeal and adopt new regulations

reorganization

Summary:

Comments were solicited from stakeholders regarding COMAR 10.12.05; no comments were received. A national scan of similar statutes and regulations revealed no evidence to suggest a need for revision or repeal of the existing regulations. It is recommended that no action be taken at this time.

Person performing review:	Sarah Conolly Hokenmaier
Title:	Deputy Director, Center for Cancer Prevention and Control

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Evaluation Report Form
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Chapter Codification: COMAR 10.13.05

Chapter Name: AIDS Education Program for Persons Convicted of Drug/Sex-Related Crimes

Authority: Health-General Article, §18-339; Criminal Law Article , §5-906; Annotated Code of Maryland

Date Originally Adopted or Last Amended: Adopted October 12, 1992; last amended January 12, 2001

Purpose: COMAR 10.13.05 AIDS Education Program for Persons Convicted of Drug/Sex-Related Crimes provides the requirements for the delivery of services by a Substance Abuse and Sexual Offender AIDS Education Program, and outlines the responsibilities of participating agencies, as well as program participants.

A. Review Criteria. (State Government Article, §10-132(1)(i), Annotated Code of Maryland; COMAR 01.01.3002.20E)

(1) Do the regulations continue to be necessary for the public int Yes [x] No [ ]

(2) Do the regulations continue to be supported by statutory authority and judicial opinion? Yes [x] No [ ]

(3) Are the regulations obsolete or otherwise appropriate for amendment or repeal? Yes [x] No [ ]

(4) Are the regulations effective in accomplishing their intended purpose? Yes [x] No [ ]

B. Outreach and Research. (State Government Article, §10-135(a)(2)(i)–(viii), Annotated Code of Maryland)

(1) List any stakeholders invited to review the regulations and provide a summary of their participation in and input into the review process.

In April 2015, representatives from the Charles, Anne Arundel, Frederick, and Baltimore County health departments were asked to review the current regulations. Each representative was asked during an in-person meeting to make recommendations regarding additions or deletions to update the regulations. In December 2015, the Department of Health and Mental Hygiene (the Department) invited the Department of Public Safety and Correctional Services (DPSCS) and staff from the 22 local health departments (LHDs) to participate in a survey to assess the utility of the regulations. Feedback was received from the DPSCS, and written comments were received via email from Harford, Worcester, and Somerset County health department staff.

In January 2016, the Department posted a notice for public comment on COMAR 10.13.05 on it's website for two weeks. No comments were received as a result of the notice.

(2) List any other affected agencies that were invited to review the regulations and provide a summary of their participation in and input into the review process.

Input was not solicited from any other agencies.

(3) Describe the process used to solicit public comment, including:
(a) any notice published in the Maryland Register;
(b) any notice published in newspapers of general circulation;
(c) any notice posted on the unit's website or on a Statewide website created for units to post notices of regulation review;

(d) any mailing by the adopting authority; and
(e) any public hearing held.

The Department posted a notice for public comment on it's website for two weeks. No comments were received as a result of the notice.

(4) Provide summaries of:
(a) all comments received from stakeholders, affected units, or the public; and
(b) the adopting authority's responses to those comments.

LHD staff from Charles, Anne Arundel, Frederick, Baltimore, Harford, Worcester, and Somerset Counties participated in the stakeholder review of COMAR 10.13.05. The general consensus was to amend the regulations due to the lack of available funding to support administrative duties of the program. The Department agreed with LHDs that language could be added to the regulations to specify that program implementation is dependent on available funding. The DPSCS also participated in the review of these regulations and expressed no objections to amending the regulations to reflect that program implementation is contingent upon available funding.

(5) Describe any inter-unit conflict reviewed and the resolution or proposed resolution of that conflict.

None identified.

(6) Provide a summary of any relevant scientific data gathered.

The last available data for similar programs offered in other States is from the CDC in 1992. There is no current scientific data that would speak to the efficacy of this type of intervention.

(7) Provide a summary of any relevant information gathered related to the regulations of other states or the federal government.

This program is a state-specific program; therefore, information is not available from other states or the federal government.

(8) Provide a summary of any other relevant information gathered.

Over the past decade, the Centers for Disease Control and Prevention have gradually eliminated the funding needed to support the administrative duties of the AIDS Education Program for Persons Convicted of Drug/Sex-Related Crimes. There is no current scientific data that would speak to the efficacy of this type of intervention. CDC funds were critical to maintaining operations of this program. While enabling statute permits the Department to charge a fee for this program, the nominal fees that would be affordable to those required to attend could not cover the substantial administrative and financial burden (e.g. tracking, paperwork, scheduling, and presentation of course material) of implementing this program. As a result the Department will add language to the regulations that specifies that program implementation is dependent on available funding.

C. Under COMAR 01.01.2003.20E(3), does the agency have any existing policy statements, guidelines, or standards being applied or enforced which should be promulgated as regulations, in accordance with the Administrative Procedure Act?

Yes [ ] No [x]

Has the agency promulgated all regulations required by recent legislation? Yes [x] No [ ]

Provide explanations of the above responses, as needed:

N/A

D. Actions Needed. (State Government Article, §10-135(a)(2)(ix) – (xi), Annotated Code of Maryland)
(check all that apply)

	no action
X	amendment
	repeal
	repeal and adopt new regulations
	reorganization

Summary:

The Department recommends that language be added to COMAR 10.13.05 - AIDS Education Program for Persons Convicted of Drug/Sex-Related Crimes to indicate that this program will be implemented if funding is available. Therefore the following regulations should be amended to include:

1. 10.13.05.03 – As funding allows, the Department shall:
2. 10.13.05.04 – As funding allows, the local health department shall:
3. 10.13.05.05 – As funding allows, the contractor shall:
4. 10.13.05.06 – An individual attending an SASOE educational session, when funding is made available, shall:

Person performing review: Jenna McCall, MPH

Title: Deputy Center Chief

Regulatory Review and Evaluation Act
Evaluation Report Form
2012 – 2020

Chapter Codification:	10.13.08
Chapter Name:	Sale of Needles and Syringes or Other Paraphernalia
Authority:	Health-General Article, §2-104(b), Annotated Code of Maryland
Date Originally Adopted or Last Amended:	March 6, 2000
Purpose:	The purpose of this chapter is to allow the sale of needles and syringes or other paraphernalia by a pharmacist only in good faith to patients showing proper identification and indication of need.

A. Review Criteria. (State Government Article, §10-132(1)(i), Annotated Code of Maryland; COMAR 01.01.3002.20E)

(1) Do the regulations continue to be necessary for the public interest? Yes [x] No [ ]

(2) Do the regulations continue to be supported by statutory authority and judicial opinion? Ye s [x] No [ ]

(3) Are the regulations obsolete or otherwise appropriate for amendment or repeal? Yes [ ] No [x]

(4) Are the regulations effective in accomplishing their intended purpose? Yes [x] No [ ]

B. Outreach and Research. (State Government Article, §10-135(a)(2)(i)–(viii), Annotated Code of Maryland)

(1) List any stakeholders invited to review the regulations and provide a summary of their participation in and input into the review process.

On September 8, 2015 the following stakeholders were emailed regarding the review of COMAR 10.13.08.01:

sherry.adams@maryland.gov; Paul Ballard -DHMH-
; elizabeth.barnard@maryland.gov; alice.bauman@maryland.gov; irma.bevans@maryland.gov; Rianna P. Brown -DHMH-; brownt@ocmemd.org; lbucher@dhmh.state.md.us;erin.butler@maryland.gov; hannah.byron@maryland.gov; Shawn Cain -DHMH-; Sara Cherico -DHMH-; Michael Cimmino -DHMH-; Audrey Clark -DHMH-
; michael.conti@maryland.gov; Cheryl B. Cooper -DHMH-; Leon Carlton -DHMH-; Anthony DeFranco -DHMH-
; peter.defries@maryland.gov; ari.elbaum@maryland.gov; Kathleen Ellis -DHMH-; Lisa Ellis -DHMH-; Barbara Fagan -DHMH-; lisa.fassett1@maryland.gov; Rachael Faulkner -DHMH-;david.fowler@maryland.gov; Mary Kay Goetter -DHMH-; harry.goodman@maryland.gov; Donna Gugel -DHMH-; howard.haft@maryland.gov; Margie Heald -DHMH-
; robin.henderson@maryland.gov; brian.hepburn@maryland.gov;mark.hoffman@maryland.gov; isabelle.horon@maryland.gov; alice.ike@maryland.gov; blair.inniss@maryland.gov; yolanda.jiggetts@maryland.gov; nicholas.johansson@maryland.gov; greg.jones@maryland.gov; Katie Jones -DHMH-; gayle.jordan-randolph@maryland.gov; gwendolyn.joyner@maryland.gov; david.lapp@maryland.gov; mark.leeds@maryland.gov; michelle.lehner@maryland.gov; Carlita Lindsey -DHMH-
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(2) List any other affected agencies that were invited to review the regulations and provide a summary of their participation in and input into the review process.

No comments from the following agencies:
OHCQ, Board of Physicians, Board of Nursing, Division of Drug Control, DHMH, OAG, University of Maryland.

(3) Describe the process used to solicit public comment, including:
(a) any notice published in the Maryland Register;
(b) any notice published in newspapers of general circulation;
(c) any notice posted on the unit's website or on a Statewide website created for units to post notices of regulation review;
(d) any mailing by the adopting authority; and
(e) any public hearing held.

(a) A notice was published in the Md R. on June 12, 2015 and July 10, 2015.
(b) An article was published in the Spring/Summer 2015 Maryland Board of Pharmacy News.
(c) A notice was posted on the Board's website from June 1 – August 1, 2015.

(4) Provide summaries of:
(a) all comments received from stakeholders, affected units, or the public; and
(b) the adopting authority's responses to those comments.

One comment received. The Board's response is below.

Laurie G. Kuiper
Sr. Director, Government Relations
Kaiser Foundation Health Plan of Mid-Atlantic States, Inc.
2010 East Jefferson Street
Rockville, MD 20852

Dear Ms. Kuiper:

Thank you for submitting comments to the Maryland Board of Pharmacy (the "Board") regarding COMAR 10.13.08 Sale of Needles and Syringes or Other Paraphernalia. The Board is currently reviewing and evaluating COMAR 10.13.08 in accordance with the Regulatory Review and Evaluation Act, State Government Article, §§10-130—10-139, Annotated Code of Maryland.

In your comment you noted that the law in California allows pharmacists to sell an unlimited number of syringes to adults without a prescription. The California law also requires participating pharmacists to meet uniform requirements for the provision of informational materials about safe syringe disposal, drug treatment access and options for testing and treating HIV and Hepatitis. You suggested that the Board perform a study to determine if a law similar to California would increase access to syringes and decrease the sharing of syringes by intravenous drug users, which would decrease the overall risks to public health.

The Board agrees with your comments and concern for the public health of Marylanders. The Board does not see the necessity to perform a study of existing data with respect to syringe access and public health outcomes because existing Maryland law allows the same access to syringes as the California law. The Board has long held that selling syringes to the public in good faith and a showing of indication of need includes the prevention of transmission of disease.

Additionally, the selling or providing of syringes in Maryland is not limited to pharmacists. Other persons may provide syringes to the public such as the Baltimore City Needle Exchange Program.

The Board would like to thank you again for submitting comments regarding COMAR 10.13.08 Sale of Needles and Syringes or Other Paraphernalia, pursuant to the Regulatory Review and Evaluation Act. Should you have questions or additional concerns, please feel free to contact Anna D. Jeffers, Legislation and Regulations Manager at (410) 764-4794.

(5) Describe any interunit conflict reviewed and the resolution or proposed resolution of that conflict.

None

(6) Provide a summary of any relevant scientific data gathered.

NA

(7) Provide a summary of any relevant information gathered related to the regulations of other states or the federal government. Below is a synopsis of a memorandum on the law of syringes in other states researched and prepared by Jason Lau, Board of Pharmacy Leg/Reg Intern:

ISSUE

In comparison to Maryland state laws and statutes, how do other state laws regulate the transactions of syringes, needles, and other paraphernalia (collectively "syringes")?

SALE

The Maryland state laws regarding the sale of syringes mandates that the pharmacist ask for proper identification from the patient, inquire into the patient's need, and conduct *bona fides* sales transaction. Other states have imposed higher levels of

restrictions.
California requires purchasers be "18 years of age." Cal. Bus. & Prof. Code § 4145.5 (West). Purchasers must also show that the needle is "solely" for personal use and not just a need. *Id*.
Similarly, Kentucky requires a record of sales of all syringes and such records must include the purchaser's name, address, quantity purchased, date of sale, and the "planned use of such syringes." Ky. Rev. Stat. Ann. § 217.177 (West).
Connecticut imposes a quantity limit, allowing up a maximum of ten syringes to be sold without a prescription. Conn. Gen. Stat. Ann. § 21a65 (West).
Then, there are states where additional materials must be provided or made known upon sale of syringes. This must be done in either written or verbal consultation, which imposes another duty upon the pharmacists to ensure that nonprescription customers must be, under certain circumstances, be counseled.
Hawaii, for example, says that a pharmacist "shall provide written educational material" about how to safely dispose of hazardous waste, like syringes. Haw. Rev. Stat. § 32521 (West).
New Jersey, too, mandates that pharmacists, upon sales of syringes, "shall also be required" make available proper disposal methods for syringes or make known such disposal method programs with extra educational material. N.J. Stat. Ann. § 2C:366.2 (West).
Further, states with relatively simple guidelines for the sale and disposal of syringes, similar to Maryland, offer some guidelines on disposal. New Hampshire, as an example, states clearly how hazardous waste must be stored. Otherwise, they allow for very broad interpretations on all other issues. N.H. Rev. Stat. Ann. § 318:52b.
Thus far, Maryland is one of the few states where there is no mention of disposal within the same statute that covers the sales of syringes.

DISPOSAL

Most states often require pharmacists to provide disposal services to purchasers, offer or make known such disposal services through consultation or notice, or both. New York law expressly states that syringes which are no longer "useable" shall be "crushed, broken, or otherwise rendered inoperable," and while no specific method is outlined,
power is reserved to the state department of health to determine how best to destroy syringes. N.Y. Pub. Health Law § 3381a (McKinney).
North Dakota is similar to New York insofar that it remains simple to allow for broad interpretation but still incorporates a clear destruction clause requiring used syringes to be destroyed. N.D. Cent. Code Ann. § 1903.126
(West).
California pharmacists have discretion in choosing whether to establish a syringe disposal program or "make available...sharps [containers]" to purchasers in addition to providing "written or verbal" consultation to purchasers regarding safe disposal of syringes. Cal. Bus. & Prof. Code § 4145.5 (West).
Hawaii and New Jersey both require extra materials to be made available to purchasers upon sale of syringes. Both states hold their respective health departments responsible for producing extra written educational materials, but in both states, the pharmacist is held responsible for making those materials known to the customer. Haw. Rev. Stat. § 32521 (West); *see also* N.J. Stat. Ann. § 2C:366.2 (West). In both pamphlets by both states, emphasize placing used syringes into a puncture proof, sealable container, and the New Jersey pamphlet goes further by listing several known locations where there is a syringe disposal program. State of Hawaii Department of Health, *Proper Disposal of Home Health Care Waste* (July 2000), *available at*
http://health.hawaii.gov/shwb/files/2013/06/medwaste1.pdf; *see also* State of New Jersey Department of Health, *Safe Syringe Disposal Guide for Home Generated Medical Waste* (2008), *available at* http://www.nj.gov/health/eoh/phss/syringe.pdf.
Therefore, there are many states where the purchaser of syringes is made aware of either the proper disposal procedure or of where to acquire and learn of such a procedure.

(8) Provide a summary of any other relevant information gathered.

The Maryland Pharmacy Act does not address disposal of needles and syringes. Other regulations promulgated by the Department of Health and Mental Hygiene (DHMH) indicate that a person shall handle special medical waste in accordance with the requirements of:

A. 29 CFR §1910.1030(d)(4)(iii)(A) and (B), which is incorporated by reference at COMAR 09.12.31; and
B. COMAR 26.13.12.05 and 26.13.13.
C. COMAR 10.06.06.03.

Additionally, at the April 18, 2007 Public Board Meeting the Board advised that prevention of transmission of disease is an

acceptable indication of need for the sale of needles and syringes.

C. Under COMAR 01.01.2003.20E(3), does the agency have any existing policy statements, guidelines, or standards being applied or enforced which should be promulgated as regulations, in accordance with the Administrative Procedure Act?

Yes [ ] No [x]

Has the agency promulgated all regulations required by recent legislation? Yes [x] No [ ]

Provide explanations of the above responses, as needed:

NA

D. Actions Needed. (State Government Article, §10-135(a)(2)(ix) – (xi), Annotated Code of Maryland)
(check all that apply)

√ no action

amendment

repeal

repeal and adopt new regulations

reorganization

Summary:

The Board recommended no changes to COMAR 10.13.08 at the October 21, 2015 Public Board Meeting.

Person performing review: Anna D. Jeffers

Title: Legislation Regulations Manager,
Maryland Board of Pharmacy

Regulatory Review and Evaluation Act
Evaluation Report Form
2012 – 2020

Chapter Codification: COMAR 10.13.11

Chapter Name: Exemption to Allow Sale of Drugs by Vending Machines

Authority: Health – General Article §21-1111(c), Annotated Code of Maryland

Date Originally Adopted or Last Amended:

Originally adopted on September 15, 1994; Effective Date: October 10, 1994 (21:20 Md.R. 1732)

Purpose: COMAR 10.13.11 allows the vending machine sale of non-prescription pain relievers by providing an exemption to the State's prohibition on the sale of any drug by use of a vending machine under Health – General Article §21-1111(b). The authority for the exemption is Health – General Article §21-1111(c), which allows the Secretary of Health and Mental Hygiene by regulation to exempt from the prohibition any commodity if the Secretary finds that the commodity may be dispensed by vending machine without danger to the public health.

A. Review Criteria. (State Government Article, §10-132(1)(i), Annotated Code of Maryland; COMAR 01.01.3002.20E)

(1) Do the regulations continue to be necessary for the public interest? Yes [X] No [ ]

(2) Do the regulations continue to be supported by statutory authority and judicial opinion? Yes [X] No [ ]

(3) Are the regulations obsolete or otherwise appropriate for amendment or repeal? Yes [ ] No [X]

(4) Are the regulations effective in accomplishing their intended purpose? Yes [X] No [ ]

B. Outreach and Research. (State Government Article, §10-135(a)(2)(i)–(viii), Annotated Code of Maryland)

(1) List any stakeholders invited to review the regulations and provide a summary of their participation in and input into the review process.

East Coast Vending Supply, Deltona, FL 32725: Anita Przybysz, Owner, 866-544-1976
Protocol, Inc., St. Paul, MN: Doug Lang, Owner, 800-227-5336
Relief Services, Inc., Maryland: Don Reckerman, Owner, 410-398-7800

Manager of Arundel Mills Mall, 7000 Arundel Mills Circle, Hanover, MD 21076, 410-540-5110:
Gene Condon, General Manager, 410-540-5101

(2) List any other affected agencies that were invited to review the regulations and provide a summary of their participation in and input into the review process.

The Maryland Board of Pharmacy ("Board") was invited to participate in the review of COMAR 10.13.11. The Board reviewed this chapter and recommended that the Secretary provide a definition for "vending machines." This definition should be provided to distinguish "vending machines" from "automated pharmacy kiosks" which are used to accept refill requests and provide after-hours prescription pick-up.

(3) ~~Describe the process used to solicit public comment, including:~~

(a) any notice published in the Maryland Register;
(b) any notice published in newspapers of general circulation;
(c) any notice posted on the unit's website or on a Statewide website created for units to post notices of regulation review;
(d) any mailing by the adopting authority; and
(e) any public hearing held.

In an effort to provide interested parties with an opportunity to participate in the review and evaluation of COMAR 10.13.11, a Notice of Opportunity for Public Inspection and Comment was posted on the websites for the Department of Health and Mental Hygiene and DHMH Laboratories Administration. In addition, the names and contact information for the businesses involved with the sale of non-prescription pain medication by vending machine (as noted in #2 above) were obtained from the 2008 regulatory review of 10.13.11 and were also researched and obtained from the internet.

(4) Provide summaries of:
(a) all comments received from stakeholders, affected units, or the public; and
(b) the adopting authority's responses to those comments.

There was universal agreement from all stakeholders that the exemption provided by COMAR 10.13.11 regulation should be maintained. This exemption which allows the sale of non-prescription pain relievers by vending machines in single dose quantities (oral form) is useful for both the businesses that operate the vending machines and Maryland consumers.
Direct contact was made with three national companies: Protocol Inc. in Minnesota, East Coast Vending Supply in Florida, and Relief Services in Maryland. These vendors supply vending equipment to many states, including Maryland. A few of the vending machines provided by national distributors have been identified as Medic Aid Vendor, Protocol Medicine Cabinet and Medical Medicine Box. Direct contact was also made with Arundel Mills Mall in Hanover, Maryland where several vending machines containing non-prescription pain relievers are located. The General Manager of Arundel Mills Mall disclosed that medical vending machines throughout the facility sold traditional over-the-counter pain relievers, such as aspirin, Acetaminophen and Ibuprofen.

Overall, over-the-counter drug vending machines provide consumers and businesses alike, with convenient and affordable access to a variety of non-prescription pain medications.

(5) Describe any interunit conflict reviewed and the resolution or proposed resolution of that conflict.

None

(6) Provide a summary of any relevant scientific data gathered.

Not applicable.

(7) Provide a summary of any relevant information gathered related to the regulations of other states or the federal government.

The U.S. Food and Drug Administration, Compliance Policy Guide, Section 450.400 provides that there is no provision under the Federal Food, Drug and Cosmetic Act that prohibits the sale of over-the-counter drug preparations in vending machines or in places other than pharmacies. However, labeling information must be

(8) Provide a summary of any other relevant information gathered.

The sale of non-prescription pain medications by vending machine provides a variety of over-the-counter pain medications that are widely used by consumers, particularly non-steroidal anti-inflammatory drugs (Advil, Motrin, etc.), Aspirin and Acetaminophen.

National distributors provide vending machines and equipment to local business owners in Maryland, which include shopping malls, grocery stores, hotels, convenience stores, gas stations and airports. The vending machines are both free-standing and/or wall mounted.

As a result, local owners have been successful since vending machines are a convenient and readily available method for obtaining over-the-counter pain medications.

C. Under COMAR 01.01.2003.20E(3), does the agency have any existing policy statements, guidelines, or standards being applied or enforced which should be promulgated as regulations, in accordance with the Administrative Procedure Act?

Yes [ ] No [X]

Has the agency promulgated all regulations required by recent legislation? Yes [X] No [ ]

Provide explanations of the above responses, as needed:

Not applicable.

D. Actions Needed. (State Government Article, §10-135(a)(2)(ix) – (xi), Annotated Code of Maryland)
(check all that apply)

- [X] no action
- [ ] amendment
- [ ] repeal
- [ ] repeal and adopt new regulations

☐ reorganization

Summary:

COMAR 10.13.11 continues to be essential for the public interest by providing a regulatory exemption that will authorize the sale of over-the-counter pain medications through vending machines. Chapter .11 provides a convenient method for consumers to obtain over-the-counter pain medications while benefiting both the businesses that operate the vending machines and the businesses where vending machines are located.

As for the proposed amendment provided by the Board of Pharmacy to define the term "vending machines" to distinguish the sale of over-the-counter pain medications from "automated pharmacy kiosks," the Department has considered the comment and does not believe that there is any likelihood of confusing the two types of machines.

Person performing review: Renee E. Scurry

Title: Administrator for Regulatory and Administrative Programs

Regulatory Review and Evaluation Act
Evaluation Report Form
2012 – 2020

Chapter Codification: 10.13.12

Chapter Name: Impoundment and Disposal of Drugs and Prescription Records

Authority: Health-General Article, §21-1113, Annotated Code of Maryland

Date Originally Adopted or Last Amended: Effective Date: June 24, 2002 (29:12 Md. R. 927)

Purpose: Allows the Department (DHMH) to impound drugs and prescription records from authorized prescribers and Board permit holders in accordance with Health-General Article, §21:1113, Annotated Code of Maryland.

A. Review Criteria. (State Government Article, §10-132(1)(i), Annotated Code of Maryland; COMAR 01.01.3002.20E)

(1) Do the regulations continue to be necessary for the public intere Yes [X] No [ ]

(2) Do the regulations continue to be supported by statutory authority and judicial opinion? Yes [X] No [ ]

(3) Are the regulations obsolete or otherwise appropriate for amendment or repeal? Yes [ ] No [X]

(4) Are the regulations effective in accomplishing their intended purpose? Yes [X] No [ ]

B. Outreach and Research. (State Government Article, §10-135(a)(2)(i)–(viii), Annotated Code of Maryland)

(1) List any stakeholders invited to review the regulations and provide a summary of their participation in and input into the review process.

Maryland Board of Physicians
Maryland Board of Pharmacy
Maryland Board of Podiatric Medical Examiners
Maryland Board of Nursing
Maryland Board of Veterinary Medical Examiners
Maryland Board of Dentistry

(2) List any other affected agencies that were invited to review the regulations and provide a summary of their participation in and input into the review process.

None.

(3) Describe the process used to solicit public comment, including:
(a) any notice published in the Maryland Register;
(b) any notice published in newspapers of general circulation;
(c) any notice posted on the unit's website or on a Statewide website created for units to post notices of regulation review;
(d) any mailing by the adopting authority; and
(e) any public hearing held.

Notice posted in the Maryland Register, the Division of Drug Control's website, the Department of Health and Mental Hygiene's website and notice submitted to the Board of Physicians, Board of Dentistry, Board of Pharmacy, Board of Podiatric Medical Examiners, Board of Nursing and Board of Veterinary Medical Examiners for posting on their websites.

(4) Provide summaries of:

(a) all comments received from stakeholders, affected units, or the public; and
(b) the adopting authority's responses to those comments.

(a) The Board of Pharmacy requested the deleting of "manufacturer's permit" from 10.13.12.01B(6), as they no longer issue manufacturer's permits. (b) There is no objection to Board of Pharmacy's comment.

(5) Describe any interunit conflict reviewed and the resolution or proposed resolution of that conflict.

None.

(6) Provide a summary of any relevant scientific data gathered.

Not applicable.

(7) Provide a summary of any relevant information gathered related to the regulations of other states or the federal government.

None.

(8) Provide a summary of any other relevant information gathered.

None.

C. Under COMAR 01.01.2003.20E(3), does the agency have any existing policy statements, guidelines, or standards being applied or enforced which should be promulgated as regulations, in accordance with the Administrative Procedure Act?

Yes [ ] No [X]

Has the agency promulgated all regulations required by recent legislation? Yes [X] No [ ]

Provide explanations of the above responses, as needed:

N/A

D. Actions Needed. (State Government Article, §10-135(a)(2)(ix) – (xi), Annotated Code of Maryland)
(check all that apply)

- [ ] no action
- [☒] amendment
- [ ] repeal
- [ ] repeal and adopt new regulations
- [ ] reorganization

Summary:

The only amendment would be the removal of "manufacturer's permit" from the definition of permit holder as stated in 10.13.12.01B(6)(a).

Person performing review:

Audrey P. Clark, Chief James W. Polek, Deputy Chief

Title: Chief and Deputy Chief

Regulatory Review and Evaluation Act
Evaluation Report Form
2012 – 2020

Chapter Codification: COMAR 10.14.03

Chapter Name: Breast Cancer Treatment Methods

Authority: Health-General Article, §20-113, Annotated Code of Maryland

Date Originally Adopted or Last Amended: January 20, 1992

Purpose:

To require:
1) The Department of Health and Mental Hygiene (the Department) to:
   d) provide and distribute a standardized written summary of information about breast cancer treatment methods including the advantages, disadvantages, risks, and procedures associated with each method; and
   e) provide a statement acknowledging receipt of information for signature by patients.
2) Physicians to:
   a) provide the standardized written summary of information about breast cancer treatment methods to patients within a certain timeframe; and
   b) obtain patient signature on the acknowledgement form provided by the Department to be kept in the patient's medical record.
   c) retain any waiver and the signed acknowledgement form in the patient's medical record.

A. Review Criteria. (State Government Article, §10-132(1)(i), Annotated Code of Maryland; COMAR 01.01.3002.20E)

(1) Do the regulations continue to be necessary for the public interest? Yes [X] No [ ]

(2) Do the regulations continue to be supported by statutory authority and judicial opinion? Yes [X] No [ ]

(3) Are the regulations obsolete or otherwise appropriate for amendment or repeal? Yes [ ] No [X]

(4) Are the regulations effective in accomplishing their intended purpose? Yes [X] No [ ]

B. Outreach and Research. (State Government Article, §10-135(a)(2)(i)–(viii), Annotated Code of Maryland)

(1) List any stakeholders invited to review the regulations and provide a summary of their participation in and input into the review process.

The Department invited comments from: the general public (via notice posted to the Department's website), local Breast and Cervical Cancer Program coordinators and other key contacts at the 24 local health departments, clinical providers participating in the Breast and Cervical Cancer Diagnosis and Treatment Program, members of the Maryland State Council on Cancer Control, members of the Breast Cancer Medical Advisory Committee, members of the Maryland Cancer Collaborative, and other key stakeholders and groups that represent patients and health care providers.

(2) List any other affected agencies that were invited to review the regulations and provide a summary of their participation in and input into the review process.

No other agencies are affected by these regulations, therefore no other agencies were invited to review the regulations.

(3) Describe the process used to solicit public comment, including:
(a) any notice published in the Maryland Register;
(b) any notice published in newspapers of general circulation;
(c) any notice posted on the unit's website or on a Statewide website created for units to post notices of regulation review;
(d) any mailing by the adopting authority; and
(e) any public hearing held.

The Department solicited comments by:
- posting a notice to the Department's website;
- sending email messages to Breast and Cervical Cancer Program coordinators and other key contacts at the local health departments;
- mailing letters to the providers participating in the Breast and Cervical Cancer Diagnosis and Treatment Program;
- emailing members of the Maryland State Council on Cancer Control and announcement at the May 15, 2015 meeting;
- emailing members of the Breast Cancer Medical Advisory Committee; and
- emailing members of the Maryland Cancer Collaborative, which includes key stakeholders and groups that represent patients and health care providers.

(4) Provide summaries of:
(a) all comments received from stakeholders, affected units, or the public; and
(b) the adopting authority's responses to those comments.

No comments were received.

(5) Describe any interunit conflict reviewed and the resolution or proposed resolution of that conflict.

No inter-unit conflicts identified.

(6) Provide a summary of any relevant scientific data gathered.

The breast cancer treatment methods summary information provided by the Department includes a booklet created by the National Cancer Institute (NCI) titled "What You Need To Know About Breast Cancer" (http://www.cancer.gov/publications/patient-education/WYNTK_breast.pdf). The booklet covers: basics about breast anatomy and breast cancer; treatments for breast cancer, including taking part in cancer treatment research studies; and reconstruction after mastectomy. The booklet refers to the NCI website for additional information (http://www.cancer.gov/types/breast). NCI is the U.S. government's principal agency for cancer research, and is mandated by U.S. law to disseminate information about cancer and cancer research.

(7) Provide a summary of any relevant information gathered related to the regulations of other states or the federal government.

A national scan of existing state statutes and regulations pertaining to breast cancer treatment methods summary information was conducted using internet searches and historical CDC documents as points of

(8) Provide a summary of any other relevant information gathered.

No other relevant information was gathered.

C. Under COMAR 01.01.2003.20E(3), does the agency have any existing policy statements, guidelines, or standards being applied or enforced which should be promulgated as regulations, in accordance with the Administrative Procedure Act?

Yes [ ] No [X]

Has the agency promulgated all regulations required by recent legislation? Yes [X] No [ ]

Provide explanations of the above responses, as needed:

No recent legislation has required promulgation of regulations.

D. Actions Needed. (State Government Article, §10-135(a)(2)(ix) – (xi), Annotated Code of Maryland) (check all that apply)

X no action

amendment

repeal

repeal and adopt new regulations

reorganization

Summary:

Comments were solicited from stakeholders regarding COMAR 10.14.03; no comments were received. A national scan of similar statutes and regulations revealed no evidence to suggest a need for revision or repeal of the existing regulations. It is recommended that no action be taken at this time.

Person performing review: Sarah Conolly Hokenmaier

Title: Deputy Director, Center for Cancer Prevention and Control

Regulatory Review and Evaluation Act
Evaluation Report Form
2012 – 2020

Chapter Codification: COMAR 10.14.04

Chapter Name: Breast Cancer Program

Authority: Health-General Article, §20-116, Annotated Code of Maryland

Date Originally Adopted or Last Amended: November 10, 2003

Purpose: To establish the requirements for participating medical providers; set criteria for applicant eligibility; outline services covered; and delineate the responsibilities of the Department and local health departments for breast cancer screening, diagnosis, and treatment services under the Breast Cancer Program.

A. Review Criteria. (State Government Article, §10-132(1)(i), Annotated Code of Maryland; COMAR 01.01.3002.20E)

(1) Do the regulations continue to be necessary for the public interest? Yes [X] No [ ]

(2) Do the regulations continue to be supported by statutory authority and judicial opinion? Yes [X] No [ ]

(3) Are the regulations obsolete or otherwise appropriate for amendment or repeal? Yes [ ] No [X]

(4) Are the regulations effective in accomplishing their intended purpose? Yes [X] No [ ]

B. Outreach and Research. (State Government Article, §10-135(a)(2)(i)–(viii), Annotated Code of Maryland)

(1) List any stakeholders invited to review the regulations and provide a summary of their participation in and input into the review process.

The Department invited comments from: the general public (via notice posted to the Department's website), local Breast and Cervical Cancer Program coordinators and other key contacts at the 24 local health departments, clinical providers participating in the Breast and Cervical Cancer Diagnosis and Treatment Program, members of the Maryland State Council on Cancer Control, members of the Breast Cancer Medical Advisory Committee, members of the Maryland Cancer Collaborative, and other key stakeholders and groups that represent patients and health care providers.

(2) List any other affected agencies that were invited to review the regulations and provide a summary of their participation in and input into the review process.

No other agencies are affected by these regulations; therefore no other agencies were invited to review the regulations.

(3) Describe the process used to solicit public comment, including:
(a) any notice published in the Maryland Register;
(b) any notice published in newspapers of general circulation;

(c) any notice posted on the unit's website or on a Statewide website created for units to post notices of regulation review;
(d) any mailing by the adopting authority; and
(e) any public hearing held.

The Department solicited comments by:
- posting a notice to the Department's website;
- sending email messages to Breast and Cervical Cancer Program coordinators and other key contacts at the local health departments;
- mailing letters to the providers participating in the Breast and Cervical Cancer Diagnosis and Treatment Program;
- emailing members of the Maryland State Council on Cancer Control and announcement at the May 15, 2015 meeting;
- emailing members of the Breast Cancer Medical Advisory Committee; and
- emailing members of the Maryland Cancer Collaborative, which includes key stakeholders and groups that represent patients and health care providers.

(4) Provide summaries of:
(a) all comments received from stakeholders, affected units, or the public; and
(b) the adopting authority's responses to those comments.

No comments were received.

(5) Describe any interunit conflict reviewed and the resolution or proposed resolution of that conflict.

No inter-unit conflicts identified.

(6) Provide a summary of any relevant scientific data gathered.

An internet scan of relevant scientific data related to statewide breast cancer programs was conducted. Many recent scientific articles have been published regarding the benefits and successes of the National Breast and Cervical Cancer Early Detection Program, the federal Centers for Disease Control and Prevention Program which provides funding to the Maryland Breast Cancer Program defined in COMAR 10.14.04. One recent article (available at: file:///P:/Regulations%208%20Year%20Review/National%20Breast%20and%20Cervical%20Cancer%20Early%20Detection%20Program%20in%20the%20Era%20of%20Health%20Reform.html) specifically outlines the continued need for the Program in the era of health care reform. In general, no evidence was found to substantiate revisions to Maryland COMAR or statute for breast cancer programs.

(7) Provide a summary of any relevant information gathered related to the regulations of other states or the federal government.

A national scan of existing state statutes and regulations pertaining to breast cancer programs was conducted using internet searches and historical CDC documents as points of reference. In general, statutes and regulations relating to breast cancer programs are similar from state to state and were enacted starting in the early 1990's through the early 2000's with minimal revisions since enactment. In general, no evidence was found to substantiate revisions to Maryland COMAR or statute for breast cancer programs.

(8) Provide a summary of any other relevant information gathered.

No other relevant information was gathered.

C. Under COMAR 01.01.2003.20E(3), does the agency have any existing policy statements, guidelines, or standards being applied or enforced which should be promulgated as regulations, in accordance with the Administrative Procedure Act?

Yes [ ] No [X]

Has the agency promulgated all regulations required by recent legislation? Yes [X] No [ ]

Provide explanations of the above responses, as needed:

No recent legislation has required promulgation of regulations.

D. Actions Needed. (State Government Article, §10-135(a)(2)(ix) – (xi), Annotated Code of Maryland) (check all that apply)

X no action

amendment

repeal

repeal and adopt new regulations

reorganization

Summary:

Comments were solicited from stakeholders regarding COMAR 10.14.04; no comments were received. A national scan of scientific data and similar statutes and regulations revealed no evidence to suggest a need for revision or repeal of the existing regulations. It is recommended that no action be taken at this time.

Person performing review: Sarah Conolly Hokenmaier

Title: Deputy Director, Center for Cancer Prevention and Control

Regulatory Review and Evaluation Act
Evaluation Report Form
2012 – 2020

Chapter Codification: COMAR 10.14.06

Chapter Name: Cigarette Restitution Fund Program

Authority: State Government Article, §10-130—10-139, Annotated Code of Maryland

Date Originally Adopted or Last Amended: January 15, 2007

Purpose: To establish the financial eligibility for individuals to receive cancer treatment services and tobacco treatment products under the Cigarette Restitution Fund Program.

A. Review Criteria. (State Government Article, §10-132(1)(i), Annotated Code of Maryland; COMAR 01.01.3002.20E)

(1) Do the regulations continue to be necessary for the public interest? Yes [X] No [ ]

(2) Do the regulations continue to be supported by statutory authority and judicial opinion? Yes [X] No [ ]

(3) Are the regulations obsolete or otherwise appropriate for amendment or repeal? Yes [X] No [ ]

(4) Are the regulations effective in accomplishing their intended purpose? Yes [X] No [ ]

B. Outreach and Research. (State Government Article, §10-135(a)(2)(i)–(viii), Annotated Code of Maryland)

(1) List any stakeholders invited to review the regulations and provide a summary of their participation in and input into the review process.

The Department invited comments from: the general public (the Department posted a notice to the Department's website), Health Officers, Local Health Department and Baltimore City Academic Local Public Health Cigarette Restitution Fund Programs.

(2) List any other affected agencies that were invited to review the regulations and provide a summary of their participation in and input into the review process.

No other agencies were invited to review the regulations since the regulations impact the implementation of the Cigarette Restitution Fund Program by the Local Health Departments and Baltimore City Academic Local Public Health.

(3) Describe the process used to solicit public comment, including:
(a) any notice published in the Maryland Register;
(b) any notice published in newspapers of general circulation;
(c) any notice posted on the unit's website or on a Statewide website created for units to post notices of regulation review;
(d) any mailing by the adopting authority; and
(e) any public hearing held.

The Department solicited comments by:

- posting a notice to the Department website;
- publishing in the Maryland Register;
- sending an email message to Local Health Officers on July 15, 2015;
- sending an email message (on July 15, 2015) to Local Health Department and Baltimore City Academic Local Public Health Cigarette Restitution Fund Program coordinators and contractors; and
- making an announcement on the June 18, 2015 Local Health Department Cigarette Restitution Fund Program teleconference.

(4) Provide summaries of:
(a) all comments received from stakeholders, affected units, or the public; and
(b) the adopting authority's responses to those comments.

Comments received were not substantive and were supportive of the use of funds to pay for cancer treatment. It was also recommended that DHMH clarify in program implementation guidance that local health departments can use net income for eligibility as 10.14.06.05 regulation allows the choice. The Department responded that because the Department of Legislative Services audit requires consistent criteria for eligibility for all local health departments, only gross income will be used and the regulation will be amended accordingly.

(5) Describe any inter-unit conflict reviewed and the resolution or proposed resolution of that conflict.

No inter-unit conflicts identified.

(6) Provide a summary of any relevant scientific data gathered.

No relevant scientific data was identified or gathered.

(7) Provide a summary of any relevant information gathered related to the regulations of other states or the federal government.

No relevant information from other states or the federal government was gathered due to the Cigarette Restitution Fund Program being unique to Maryland.

(8) Provide a summary of any other relevant information gathered.

The Department gathered Department of Legislative Services audit findings/reports specifically related to financial eligibility for the Cigarette Restitution Fund Program. Additionally, the Department gathered all Health Officer communications (Health Officer Memos) relating to the Cigarette Restitution Fund Program financial eligibility for cancer treatment. Health Officer Memos are communications developed by the Department to provide guidance, clarification, and other information about specific aspects of the Cigarette Restitution Fund to Health Officers, Local Health Department Cigarette Restitution Fund Programs, and contractors. The Department also reviewed the 2015 Non-Chargeable List.

C. Under COMAR 01.01.2003.20E(3), does the agency have any existing policy statements, guidelines, or standards being applied or enforced which should be promulgated as regulations, in accordance with the Administrative Procedure Act?

X

Yes ☐ No

Has the agency promulgated all regulations required by recent legislation? Yes [X] No ☐

Provide explanations of the above responses, as needed:

No recent legislation has required promulgation of regulations.

D. Actions Needed. (State Government Article, §10-135(a)(2)(ix) – (xi), Annotated Code of Maryland)
(check all that apply)

- no action
- X amendment
- repeal
- repeal and adopt new regulations
- reorganization

Summary:

COMAR 10.14.06 are relevant as they provide guidance regarding financial eligibility for cancer treatment services and tobacco cessation services to local Cigarette Restitution Fund Programs implemented through the Local Health Departments. The Department will be amending the existing regulations to align them with current practice, which was provided to the local Cigarette Restitution Fund Programs by the Department following Department of Legislative Services' audits of the Program.

Person performing review: Donna Gugel, MHS

Title: Deputy Director, Prevention and Health Promotion Administration/Director, Cigarette Restitution Fund Program

Regulatory Review and Evaluation Act
Evaluation Report Form
2012 – 2020

Chapter Codification: 10.50.01

Chapter Name: Tissue Banks

Authority: Health-General Article, 17-304, Annotated Code of Maryland

Date Originally Adopted or Last Amended: January 9, 2012

Purpose: The purpose of this proposal is to amend and update the edition of the incorporated by reference documents:
1) Standards for Tissue Banking; and
2) Standards for Blood Banks and Transfusion Services

A. Review Criteria. (State Government Article, §10-132(1)(i), Annotated Code of Maryland; COMAR 01.01.3002.20E)

(1) Do the regulations continue to be necessary for the public interest? Yes [X] No [ ]

(2) Do the regulations continue to be supported by statutory authority and judicial opinion? Yes [X] No [ ]

(3) Are the regulations obsolete or otherwise appropriate for amendment or repeal? Yes [X] No [ ]

(4) Are the regulations effective in accomplishing their intended purpose? Yes [X] No [ ]

B. Outreach and Research. (State Government Article, §10-135(a)(2)(i)–(viii), Annotated Code of Maryland)

(1) List any stakeholders invited to review the regulations and provide a summary of their participation in and input into the review process.

OHCQ requested comments on the proposed regulations from OHCQ surveyors, the Laboratories Administration, and the Laboratory Advisory Committee LAC) to assist in the development and review of this proposed changed. The LAC included representatives from various specialties: Pathology, Pharmacy, Pediatrics, Clinical Pathology, Industry, Consumer, Internal Medicine, and Family Practices.

(2) List any other affected agencies that were invited to review the regulations and provide a summary of their participation in and input into the review process.

The Laboratories Administration and Laboratories Administration Committee (LAC) provided comments on the proposed regulation. Additionally, the proposed regulations were discussed at the quarterly LAC meetings.

(3) Describe the process used to solicit public comment, including:
(a) any notice published in the Maryland Register;
(b) any notice published in newspapers of general circulation;
(c) any notice posted on the unit's website or on a Statewide website created for units to post notices of regulation review;
(d) any mailing by the adopting authority; and
(e) any public hearing held.

(a) N/A; (b) N/A; (c) N/A; (d) N/A; (e) N/A
The LAC's quarterly meeting facilitated by the Labs Administration was used as an informal means to solicit

(4) Provide summaries of:
(a) all comments received from stakeholders, affected units, or the public; and
(b) the adopting authority's responses to those comments.

(a) Updating the incorporation by reference documents was a consensus reached decision of the LAC. In addition to comments supporting the updating of the two reference documents, a commenter suggested amending the list of required tests to minimize disease transmission. Upon further review, the updated American Association of Blood Banks (AABB) approved reference documents matches the list referenced in COMAR 10.50.01.11A. The LAC members agreed that as the AABB updates the reference materials and standards, they will update the regulations accordingly.

(b) OHCQ agreed with the submitted comment to update the reference documents and intends to amend COMAR 10.50.01.04.
Dr Newby wanted 10.50.01.11 (A) to read "AATB Section D Required Infectious Disease Tests, current edition." Since we cannot amend the regs to "current" edition but are using specific editions in this case 13th edition. I reviewed the section and it is the same disease testing listed as our current regs. I think he was worried some new requirement would be added in the future and it would be missed. I think we can monitor for those changes if they occur and then amend the regulation accordingly.

(5) ~~Describe any interunit conflict reviewed and the resolution or proposed resolution of that conflict.~~

There were no inter-unit conflicts for the proposed regulation change. All parties were in agreement.

(6) Provide a summary of any relevant scientific data gathered.

No scientific data was gathered as the suggested change is to the incorporation by reference materials. All members agreed that the standards in the updated version were the standards that needed to be updated in the regulations.

(7) Provide a summary of any relevant information gathered related to the regulations of other states or the federal government.

The Tissue and Blood Bank regulations of New York and California were reviewed and discussed among the LAC. State standards, tissue types tested, and personnel qualifications were compared among the states. New York and California's regulations were comparable to Maryland and referenced the same standards.

(8) Provide a summary of any other relevant information gathered.

The expertise of the members of the LAC was utilized in addition to researching the regulations of other states.

C. Under COMAR 01.01.2003.20E(3), does the agency have any existing policy statements, guidelines, or standards being applied or enforced which should be promulgated as regulations, in accordance with the Administrative Procedure Act?

Yes [ ] No [X]

Has the agency promulgated all regulations required by recent legislation? Yes [X] No [ ]

Provide explanations of the above responses, as needed:

N/A

D. Actions Needed. (State Government Article, §10-135(a)(2)(ix) – (xi), Annotated Code of Maryland)
(check all that apply)

	no action
X	amendment
	repeal
	repeal and adopt new regulations
	reorganization

Summary:

OHCQ agreed with the submitted comment to update the reference documents and intends to amend COMAR 10.50.01.04 as follows:

.04 Incorporation by Reference.

A. (text unchanged)

B. Documents Incorporated.

(1) Standards for Tissue Banking (American Association of Tissue Banks, **[**2002**]** *13th* Edition), Sections C, D, E, F, G, H, J, K, L, and M1-8 only;

(2) Standards for Blood Banks and Transfusion Services (American Association of Blood Banks, **[**2003**]** *29th* Edition);

(3)—(5) (text unchanged)

Person performing review:	Paul Celli
Title:	Coordinator