REGULATORY REVIEW AND EVALUATION ACT:

WORKPLANS DUE APRIL 1, 2015 FOR:

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:

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EXEMPTION 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 Certification and Approval of Laboratory 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 and 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	*2015
10.11.03 Children's Medical Services Program	CA	1-14-08
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		
10.12.02 Rape and Sexual Offenses—Physician and Hospital Charges	CA	12-29-08
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
Subtitle 12 ADULT HEALTH		
10.12.01 Surgical Abortion Facilities	IA	7-23-12
10.12.04 Day Care for the Elderly and Adults with a Medical Disability	CA	12-13-14
Subtitle 13 DRUGS		
10.13.02 Purchase— and Distribution of Prescription Drugs and Devices	IA	8-22-11

*Repeal of Existing Regulations and Proposed New Regulations printed in 41:22 Md.R. 1325—1328 (October 31, 2014) Adoption expected this calendar year.

CHAPTERS THAT HAVE BEEN REPEALED

Subtitle 12 ADULT HEALTH

10.12.03 Expanded Maternity Plan -	Repealed

Subtitle 13 DRUGS

10.13.03 Sale of Sodium Fluoride or Hydrofluoric Acid Preparations for Use as Insecticides -	Repealed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 Prescription –	Repealed
10.13.06 Acceptance of Oral Prescriptions for Certain Narcotic Drugs -	Repealed
10.13.07 Sale of Dihydrocodeinone or any of its Salts	Repealed
10.13.09 Sale of Nitrous Oxide -	Repealed
10.13.10 Prescribing, Administering, and Dispensing of Amphetamines and Methamphetamines -	Repealed

DEPARTMENT OF HEALTH AND MENTAL HYGIENE
2011 – 2018 WORK PLAN FOR EVALUATION REPORT ON
COMAR 10.10.10 – Job-Related Alcohol and Controlled Dangerous Substances Testing

OBJECTIVES	ACTION STEPS	RESPONSIBLE PERSON	SCHEDULED COMPLETION DATE
I. Evaluate COMAR 10.10.10 For the purpose of Satisfying the requirement of State Government Article, §10-130—10-139, Annotated Code of Md.	1. Inventory affected regulations	Michele Phinney	12/11/14
	2. Procedures and methods to be used to ensure comments from public / stakeholders / other affected units .	Renee Scurry	05/01/15
	A. To invite public comment on these regulations, the following procedures and methods will be used**:** 1. Post notice on the Department of Health and Mental Hygiene's website; 2. Post notice in the Maryland Register; and 3. Submit notice to the Department of Budget and Management (State agency governing personnel resources) for posting on their website.		
	B. To ensure the participation of stakeholders in the review process, the following procedures will be used: Posting a notice on the DHMH website, the Maryland Register and the Maryland Department of Budget and Management to invite public comment will ensure that relevant State agencies and the public is involved in the review process.		
	C. To ensure the participation in the review process of other units affected by the regulations, the following procedures will be used: Requests for comments will be forwarded via email to the DHMH Human Resources, Employment Services Unit and other respective DHMH internal departmental units (as determined) to invite their participation in the review process.		
	3. Procedures for gathering and reviewing of:	Renee Scurry	07/01/15
	A. Any recent scientific information related to the regulations reviewed, If applicable; Not applicable.		
	B. Similar regulations adopted or repealed by other states or the federal government; and Research will be performed to determine whether similar regulations have been adopted and/or repealed by the federal government and other states bordering the State of Maryland. This research may also assist with identifying the Departmental unit responsible for job-related alcohol and controlled dangerous		

		substances testing. *(See information provided in section "C" below)*.		
		C. Other appropriate information, are as follows: COMAR 10.10.10 provides standards and procedures for job-related alcohol and controlled dangerous substances testing. The DHMH Laboratories Administration is currently responsible for oversight of this regulation. However, since COMAR 10.10.10 pertains to employee drug testing, it is not within the scope of duties provided by the State Lab. Consequently, participation by Department of Health and Mental Hygiene, Department of Budget and Management, community stakeholders and the public will be required to determine the appropriate unit most suited to oversee implementation of this regulation.		
	4.	Evaluate the need to retain, amend, or repeal each existing regulation based on the following criteria: A. Continue to be necessary for public interest; B. Continue to be supported by statutory authority and judicial opinions; C. Are obsolete or otherwise appropriate for amendment or repeal; D. Continue to be effective in accomplishing the intended purpose of the regulations; E. The information gathered under Action Steps 1 - 3.	Renee Scurry	08/01/15
II. Prepare report to the Administrative, Executive and Legislative Review (AELR) Committee	1.	Consolidate information obtained from objective #1 above	Renee Scurry	09/01/15
	2.	Write draft report.	Renee Scurry	10/01/15
	3.	Coordinate executive reviews of draft report.	Renee Scurry	11/01/15
	4.	Consolidate review comments and prepare final report.	Renee Scurry	02/01/16

DEPARTMENT OF HEALTH AND MENTAL HYGIENE
2011 – 2018 WORK PLAN FOR EVALUATION REPORT ON
10.11.04 Lead Poisoning Screening Program

OBJECTIVES	ACTION STEPS	RESPONSIBLE PERSON	SCHEDULED COMPLETION DATE
I. Evaluate COMAR 10.11.04 for the purpose of satisfying the requirement of State Government Article, §10-130—10-139, Annotated Code of Md.	1. Inventory affected regulations.	**Michele Phinney**	**12/11/14**
	2. Procedures and methods to be used to ensure comments from public / stakeholders / other affected units.	**Cliff Mitchell**	**10/31/15**

A. To invite public comment on these regulations, the following procedures and methods will be used (to be completed between before 9/30/15)**:**
   1. Posting of notice on the unit's website – March 2015;
   2. Governor's Commission on Childhood Lead Poisoning Joint Public Meeting with Children's Environmental Health and Protection Advisory Council (CEHPAC) Public Meeting – May 2015;
   3. Publication of proposed changes notice in the Maryland Register – September 2015

B. To ensure the participation of stakeholders in the review process, the following procedures will be used (to be completed between before 10/31/15):

   1. Work with Governor's Commission on Childhood Lead Poisoning to host one public meeting;
   2. Work with Maryland Department of the Environment Childhood Lead Poisoning Prevention Program;
   3. Work with major non-governmental organizations, including the Coalition to End Childhood Lead Poisoning, the Children's Environmental Health Network, Health Care Provider groups (Maryland Chapter of American Academy of Pediatrics, MedChi, Nurse Practitioners, Family Practitioners, Migrant Clinicians Network, and MCO Medical Directors) via electronic communications and CEHPAC public meeting;
   4. Announce regulation evaluation at meetings with local health departments (local environmental health directors and Health Officers Roundtable) to encourage participation in comment period described in 2A and 2B;
   5. Distribute announcement electronically to Housing Community;
   6. Distribute announcement electronically to Legal Community

- Stakeholders will have the opportunity to review any proposed revisions before formal submission to the AELR.

C. To ensure the participation in the review process of other units affected by the regulations, the following procedures will be used (to be completed before 10/31/15):

   1. Work with Laboratories Administration:
   2. Work with PHPA/Maternal and Child Health;
   3. Work with Medicaid;
   4. Work with PHPA/Women, Infants, and Children program;

	5. Work Maryland State Department of Education; • Units will have the opportunity to review any proposed revisions before formal submission to the AELR		
	3. Procedures for gathering and reviewing of: A. Any recent scientific information related to the regulations being reviewed, if applicable; B. Similar regulations adopted or repealed by other states or the federal government; and C. Other appropriate information, are as follows: • The Environmental Health Bureau (Bureau) has been researching lead epidemiology for 2.5 years, looking at the changing picture of lead exposure and developing a revised targeting strategy based on new epidemiology. The Bureau has also worked with the U.S. Centers for Disease Control and Prevention through the Environmental Public Health Tracking project, developing data and tools to present these data through the Maryland Environmental Public Health Tracking portal. Any additional literature and research identified from section 2 will be reviewed.	Nancy Servatius	06/30/15
	4. Evaluate the need to retain, amend, or repeal each existing regulation based on the following criteria: A. Continue to be necessary for public interest; B. Continue to be supported by statutory authority and judicial opinions; C. Are obsolete or otherwise appropriate for amendment or repeal; D. Continue to be effective in accomplishing the intended purpose of the regulations; E. The information gathered under Action Steps 1 - 3. • For the past two years the Bureau has been conducting a review of the State's lead testing targeting strategy. In addition, the Bureau also staffed and supported the legislative Task Force on Point of Care Testing for Lead Poisoning, which issued its report to the General Assembly on 01/16/14. The revised Lead Testing Targeting Strategy and revisions by the Laboratories Administration based on the recommendations in the Point of Care Testing report are will be incorporated into the evaluation and revision of these regulations.	Cliff Mitchell	07/15/15
II. Prepare report to the Administrative, Executive and Legislative Review (AELR) Committee	1. Consolidate information obtained from objective #1 above	Cliff Mitchell	07/31/15
	2. Write draft report.	Cliff Mitchell	10/31/15
	3. Coordinate executive reviews of draft report.	Katie Jones/Subha Chandar	11/15/15
	4. Consolidate review comments and prepare final report.	Katie Jones/Cliff Mitchell	2/1/16

DEPARTMENT OF HEALTH AND MENTAL HYGIENE
2011 – 2018 WORK PLAN FOR EVALUATION REPORT ON
COMAR 10.12.05, COMAR 10.14.03, and COMAR 10.14.04

OBJECTIVES	ACTION STEPS	RESPONSIBLE PERSON	SCHEDULED COMPLETION DATE
I. Evaluate COMAR 10.12.05, COMAR 10.14.03, and COMAR 10.14.04 for the purpose of satisfying the requirement of State Government Article, §10-130—10-139, Annotated Code of Md.	1. Inventory affected regulations.	Michele Phinney	12/11/14
	2. Procedures and methods to be used to ensure comments from public / stakeholders / other affected units.	Sarah Conolly Hokenmaier	6/30/15
	A. To invite public comment on these regulations, the following procedures and methods will be used: 1. Posting of notice on the unit's website (http://phpa.dhmh.maryland.gov/cancer/SitePages/Home.aspx and http://dhmh.maryland.gov/SitePages/Open%20Requests%20for%20Comments.aspx) 2. Email the local Breast and Cervical Cancer Program coordinators and other key contacts at the 24 local health departments 3. Mail letters to the providers participating in the Breast and Cervical Cancer Diagnosis and Treatment Program 4. Email the members of the Maryland State Council on Cancer Control 5. Email other key stakeholders and groups that represent patients and health care providers, including members of the Breast Cancer Medical Advisory Committee and the Maryland Cancer Collaborative. 6. Announce at the Maryland State Council on Cancer Control meeting		
	B. To ensure the participation of stakeholders in the review process, the following procedures will be used: Comments from stakeholders will be solicited by emails and through the DHMH website. All stakeholders will have the opportunity to review any proposed regulation changes prior to submission to AELR.		
	C. To ensure the participation in the review process of other units affected by the regulations, the following procedures will be used: Comments from stakeholders will be solicited by emails and through the DHMH website. All stakeholders will have the opportunity to review any proposed regulation changes prior to submission to AELR.		
	3. Procedures for gathering and reviewing of: A. Any recent scientific information related to the regulations being reviewed, if applicable; B. Similar regulations adopted or repealed by other states or the federal government; and C. Other appropriate information, are as follows: A thorough review of Centers for Disease Control and Prevention guidance to state Breast and Cervical Cancer Programs will be conducted as well as reviews of recommendations from the National Institute of Health, the National	Sarah Conolly Hokenmaier	6/1/15

		Comprehensive Cancer Network, and the Food & Drug Administration, published best practices employed by other states, similar regulations across the nation, and guidance provided by national advocacy groups.		
		4. Evaluate the need to retain, amend, or repeal each existing regulation based on the following criteria: A. Continue to be necessary for public interest; B. Continue to be supported by statutory authority and judicial opinions; C. Are obsolete or otherwise appropriate for amendment or repeal; D. Continue to be effective in accomplishing the intended purpose of the regulations; E. The information gathered under Action Steps 1 - 3.	Sarah Conolly Hokenmaier	6/30/15
II.	Prepare report to the Administrative, Executive and Legislative Review (AELR) Committee	1. Consolidate information obtained from objective #1 above	Sarah Conolly Hokenmaier	7/15/15
		2. Write draft report.	Sarah Conolly Hokenmaier	8/15/15
		3. Coordinate executive reviews of draft report.	Sarah Conolly Hokenmaier	9/15/15
		4. Consolidate review comments and prepare final report.	Sarah Conolly Hokenmaier	11/30/15

DEPARTMENT OF HEALTH AND MENTAL HYGIENE
2011 – 2018 WORK PLAN FOR EVALUATION REPORT ON
COMAR 10.13.01 Dispensing of Prescription Drugs by a Licensee

OBJECTIVES	ACTION STEPS	RESPONSIBLE PERSON	SCHEDULED COMPLETION DATE
I. Evaluate COMAR 10.13.01 for the purpose of satisfying the requirement of State Government Article, §10-130—10-139, Annotated Code of Md.	1. Inventory affected regulations.	Michele Phinney	12/11/14
	2. Procedures and methods to be used to ensure comments from public / stakeholders / other affected units. A. To invite public comment on these regulations, the following procedures and methods will be used**:** 1. Publication of notice in the Maryland Register; 2. Posting of notice on the unit's website; 3. Posting notice on Division of State Document's website; B. To ensure the participation of stakeholders in the review process, the following procedures will be used: Posting notice on the unit's website and in the Board of Pharmacy Newsletter. C. To ensure the participation in the review process of other units affected by the regulations, the following procedures will be used: Email internal units within DHMH and other State agencies to solicit comments	Anna Jeffers	06/1/15
	3. Procedures for gathering and reviewing of: A. Any recent scientific information related to the regulations being reviewed, if applicable; B. Similar regulations adopted or repealed by other states or the federal government; and C. Other appropriate information, are as follows: A. Not Applicable; B. Conduct internet search of other states and federal government, with particular attention to states contiguous to Maryland, to find out whether they have similar regulations and how they are structured; and C. Conduct internet search of other State agency regulations to find out whether they have similar regulations and how they are structured	Anna Jeffers	09/1/15
	4. Evaluate the need to retain, amend, or repeal each existing regulation based on the following criteria: A. Continue to be necessary for public interest; B. Continue to be supported by statutory authority and judicial opinions;	Anna Jeffers	10/1/15

		C. Are obsolete or otherwise appropriate for amendment or repeal; D. Continue to be effective in accomplishing the intended purpose of the regulations; E. The information gathered under Action Steps 1 - 3.		
II.	Prepare report to the Administrative, Executive and Legislative Review (AELR) Committee	1. Consolidate information obtained from objective #1 above	Anna Jeffers	11/1/15
		2. Write draft report.	Anna Jeffers	12/1/15
		3. Coordinate executive reviews of draft report.	Anna Jeffers	1/1/16
		4. Consolidate review comments and prepare final report.	Anna Jeffers	2/1/16

DEPARTMENT OF HEALTH AND MENTAL HYGIENE
2011 – 2018 WORK PLAN FOR EVALUATION REPORT ON
COMAR 10.13.05 AIDS Education Program for Persons Convicted of Drug/Sex-Related Crimes

OBJECTIVES	ACTION STEPS	RESPONSIBLE PERSON	SCHEDULED COMPLETION DATE
I. Evaluate COMAR 10.13.05 for the purpose of satisfying the requirement of State Government Article, §10-130—10-139, Annotated Code of Md.	1. Inventory affected regulations.	Michele Phinney	12/11/14
	2. Procedures and methods to be used to ensure comments from public / stakeholders / other affected units.	Jenna McCall	04/01/15
	A. To invite public comment on these regulations, the following procedures and methods will be used: 1. Post notice on the unit's and Department's websites (by 03/2/15); http://dhmh.maryland.gov/SitePages/Open%20Requests%20for%20Comments.aspx) 2. Announce and solicit input at regularly scheduled meetings of existing planning bodies (e.g. HIV Planning Group) and grantees (e.g. HIV Prevention Coordinators Meetings) (by 04/30/15); 3. Email to Local Health Department staff who have conducted this work in the past (by 03/02/15); and 4. Invite the Department of Public Safety and Correctional Services (DPSCS) to a meeting (by 03/15/15).		
	B. To ensure the participation of stakeholders in the review process, the following procedures will be used: As described in 2A, program staff will utilize members of our existing planning bodies, grantee meetings and other forums to ensure appropriate stakeholder review. Attention will be given to ensuring that both providers and clients are represented in the stakeholder groups.		
	C. To ensure the participation in the review process of other units affected by the regulations, the following procedures will be used: Staff from DPSCS will be invited to attend grantee meetings and will be able to provide feedback related to the anticipated impact of the regulation on inmates.		
	3. Procedures for gathering and reviewing of: A. Any recent scientific information related to the regulations being reviewed, if applicable; B. Similar regulations adopted or repealed by other states or the federal government; and C. Other appropriate information, are as follows: Program staff will consult with the Centers for Disease Control and Prevention to obtain the latest relevant scientific information. Additionally, we will utilize the National Association of State and Territorial AIDS Directors to obtain information about if other states are continuing to utilize this intervention.	Jenna McCall	05/01/15

	4.	Evaluate the need to retain, amend, or repeal each existing regulation based on the following criteria: A. Continue to be necessary for public interest; B. Continue to be supported by statutory authority and judicial opinions; C. Are obsolete or otherwise appropriate for amendment or repeal; D. Continue to be effective in accomplishing the intended purpose of the regulations; E. The information gathered under Action Steps 1 - 3.	Jenna McCall	06/01/15
II. Prepare report to the Administrative, Executive and Legislative Review (AELR) Committee	1.	Consolidate information obtained from objective #1 above	Jenna McCall	07/01/15
	2.	Write draft report.	Jenna McCall	07/01/15
	3.	Coordinate executive reviews of draft report.	Katie Jones	11/1/2015
	4.	Consolidate review comments and prepare final report.	Katie Jones	12/1/15

DEPARTMENT OF HEALTH AND MENTAL HYGIENE
2011 – 2018 WORK PLAN FOR EVALUATION REPORT ON
COMAR 10.13.08 Sale of Needles and Syringes or Other Paraphernalia)

OBJECTIVES	ACTION STEPS	RESPONSIBLE PERSON	SCHEDULED COMPLETION DATE
I. Evaluate COMAR 10.13.08 for the purpose of satisfying the requirement of State Government Article, §10-130—10-139, Annotated Code of Md.	1. Inventory affected regulations.	Michele Phinney	12/11/14
	2. Procedures and methods to be used to ensure comments from public / stakeholders / other affected units.	Anna Jeffers	06/01/15
	A. To invite public comment on these regulations, the following procedures and methods will be used**:** 1. Publication of notice in the Maryland Register; 2. Posting of notice on the unit's website; 3. Posting notice on Division of State Document's website; B. To ensure the participation of stakeholders in the review process, the following procedures will be used: Posting notice on the unit's website and in the Board of Pharmacy Newsletter. C. To ensure the participation in the review process of other units affected by the regulations, the following procedures will be used: Email internal units within DHMH and other State agencies to solicit comments		
	3. Procedures for gathering and reviewing of: A. Any recent scientific information related to the regulations being reviewed, if applicable; B. Similar regulations adopted or repealed by other states or the federal government; and C. Other appropriate information, are as follows: A. Not Applicable; B. Conduct internet search of other states and federal government, with particular attention to states contiguous to Maryland, to find out whether they have similar regulations and how they are structured; and C. Conduct internet search of other State agency regulations to find out whether they have similar regulations and how they are structured	Anna Jeffers	09/01/15
	4. Evaluate the need to retain, amend, or repeal each existing regulation based on the following criteria: A. Continue to be necessary for public interest;	Anna Jeffers	10/01/15

		B. Continue to be supported by statutory authority and judicial opinions; C. Are obsolete or otherwise appropriate for amendment or repeal; D. Continue to be effective in accomplishing the intended purpose of the regulations; E. The information gathered under Action Steps 1 - 3.		
II.	Prepare report to the Administrative, Executive and Legislative Review (AELR) Committee	1. Consolidate information obtained from objective #1 above	Anna Jeffers	11/1/15
		2. Write draft report.		12/1/15
		3. Coordinate executive reviews of draft report.		1/1/16
		4. Consolidate review comments and prepare final report.		2/1/16

DEPARTMENT OF HEALTH AND MENTAL HYGIENE
2011 – 2018 WORK PLAN FOR EVALUATION REPORT ON
COMAR 10.13.11- Sale of Drugs by Vending Machine

OBJECTIVES	ACTION STEPS	RESPONSIBLE PERSON	SCHEDULED COMPLETION DATE
I. Evaluate COMAR 10.13.11 for the purpose of satisfying the requirement of State Government Article, §10-130—10-139, Annotated Code of Md.	1. Inventory affected regulations	Michele Phinney	12/11/14
	2. Procedures and methods to be used to ensure comments from public / stakeholders / other affected units.	Renee Scurry	05/01/15
	A. To invite public comment on these regulations, the following procedures and methods will be used**:** 1. Post notice on the Department of Health and Mental Hygiene's (DHMH) Website; 2. Post notice in the Maryland Register.		
	B. To ensure the participation of stakeholders in the review process, the following procedures will be used: Posting a notice on the DHMH website and in the Maryland Register to invite public comment will ensure that the public is involved in the review process. Notices will also be submitted to State Health Boards and relevant licensing entities (as determined) for review, feedback and comments.		
	C. To ensure the participation in the review process of other units affected by the regulations, the following procedures will be used: Requests for comments will be forwarded via email to respective DHMH internal departmental units (as determined) to invite their participation in the review process.		
	3. Procedures for gathering and reviewing of:	Renee Scurry	07/01/15
	A. Any recent scientific information related to the regulations reviewed, If applicable; Not Applicable.		
	B. Similar regulations adopted or repealed by other states or the federal government: Research will be performed to assess whether similar regulations have been adopted and/or repealed by the federal government and/or other states surrounding the State of Maryland. This research may also assist with identifying the applicable Departmental unit or State Agency responsible for licensing and regulating vendors that engage in the sale of nonprescription drugs (*See information provided in section "C" below*).		

		C. Other appropriate information, are as follows: The DHMH Laboratories Administration is currently responsible for the regulatory oversight of COMAR 10.13.11 – Sale of Drugs by Vending Machines. This regulation permits the sale of nonprescription drugs (that alleviate pain) by vending machine or other similar device. The drugs must be sold in oral form and in single dose quantities. However, since COMAR 10.13.11 pertains to the sale of drugs, it is not within the scope of oversight provided by the State Lab. Consequently, participation by the Department, community stakeholders and the public will be required to determine the most appropriate and suitable unit to oversee implementation of this regulation.		
		4. Evaluate the need to retain, amend, or repeal each existing regulation based on the following criteria: A. Continue to be necessary for public interest; B. Continue to be supported by statutory authority and judicial opinions; C. Are obsolete or otherwise appropriate for amendment or repeal; D. Continue to be effective in accomplishing the intended purpose of the regulations; E. The information gathered under Action Steps 1 - 3.	Renee Scurry	08/01/15
II.	Prepare report to the Administrative, Executive and Legislative Review (AELR) Committee	1. Consolidate information obtained from objective #1 above	Renee Scurry	09/01/15
		2. Write draft report.	Renee Scurry	10/01/15
		3. Coordinate executive reviews of draft report.	Renee Scurry	11/01/15
		4. Consolidate review comments and prepare final report.	Renee Scurry	02/1/16

DEPARTMENT OF HEALTH AND MENTAL HYGIENE
2011 – 2018 WORK PLAN FOR EVALUATION REPORT ON
COMAR 10.13.12 – Impoundment and Disposal of Drugs and Prescription Records

OBJECTIVES	ACTION STEPS	RESPONSIBLE PERSON	SCHEDULED COMPLETION DATE
I. Evaluate COMAR 10.13.12 for the purpose of satisfying the requirement of State Government Article, §10-130—10-139, Annotated Code of Md.	1. Inventory affected regulations **(**	Michele Phinney	12/11/14
	2. Procedures and methods to be used to ensure comments from public / stakeholders / other affected units.	Renee Scurry	05/01/15
	A. To invite public comment on these regulations, the following procedures and methods will be used**:**		
	1. Post notice on the Department of Health and Mental Hygiene's website; 2. Post notice on the Division of Drug Control's website; 3. Post notice in the Maryland Register; 4. Submit notice to the Board of Physicians, Board of Pharmacy, Board of Podiatric Medical Examiners, Board of Dental Examiners; Board of Nursing and Board of Veterinary Medical Examiners for posting on their websites; and 5. Submit notice to other health and medical organizations and associations (as determined).		
	B. To ensure the participation of stakeholders in the review process, the following procedures will be used:		
	Posting a notice to invite public comment on each unit's website (as listed in Step 2A) will ensure that the Boards and public are involved in the review process.		
	C. To ensure the participation in the review process of other units affected by the regulations, the following procedures will be used:		
	Requests for comments will be forwarded via email to respective DHMH internal departmental units to invite their participation in the review process.		
	3. Procedures for gathering and reviewing of:	Renee Scurry	07/01/15
	A. Any recent scientific information related to the regulations reviewed, If applicable; Not applicable.		
	B. Similar regulations adopted or repealed by other states or the federal Government:		
	Legal research will be performed to ascertain whether similar regulations have been adopted and/or repealed by the federal government and states contiguous to the State of Maryland.		

C. Other appropriate information, are as follows:

COMAR 10.13.12 allows the Department (DHMH or authorized agents) to impound prescription drugs and devises, non-prescription drugs and patient records of permit holders or authorized prescribers. It also allows the Department to dispose of impounded drugs and patient records, if arrangements to legally transfer the drugs and records are not made by the permit holder or authorized prescriber. The Department may dispose of the drugs and records by destruction or legal transfer.

The Division of Drug Control, as authorized agents of the Department, has used COMAR 10.13.12 to impound prescriptions drugs from at least three pharmacies and one dispensing practitioner in the past ten years. However, there were two areas of concern that arose during these impoundments. The first area of concern was COMAR 10.13.12.03A(1) - *arrange for the drugs or prescription records to be kept in a secure location*, which has been addressed by DDC having an area in the new Laboratories Administration building for secure storage of impounded drugs. The second area of concern was COMAR 10.13.12.03A(3) - *provide the permit holder or authorized prescriber with a list of all drugs and prescription records impounded*. The regulation does not define what the list of drugs must contain. In two of the past cases, the DDC made a complete and accurate count of every tablet, capsule, liquid and powder impounded, which was a tedious and labor intensive effort. In the other case, the DDC only listed the drug name, strength, dosage form and the number of containers. An overview of this regulation should therefore include a thorough assessment of the information that must be included in the list of all drugs that have been impounded.

	4.	Evaluate the need to retain, amend, or repeal each existing regulation based on the following criteria: A. Continue to be necessary for public interest; B. Continue to be supported by statutory authority and judicial opinions; C. Are obsolete or otherwise appropriate for amendment or repeal; D. Continue to be effective in accomplishing the intended purpose of the regulations; E. The information gathered under Action Steps 1 - 3.	Renee Scurry	08/01/15
II.	Prepare report to the Administrative, Executive and Legislative Review (AELR) Committee	1. Consolidate information obtained from objective #1 above	Renee Scurry	09/01/15
		2. Write draft report.	Renee Scurry	10/01/15
		3. Coordinate executive reviews of draft report.	Renee Scurry	11/01/15
		4. Consolidate review comments and prepare final report.	Renee Scurry	02/1/16

DEPARTMENT OF HEALTH AND MENTAL HYGIENE
2011 – 2018 WORK PLAN FOR EVALUATION REPORT ON
10.14.06 Cigarette Restitution Fund Program

OBJECTIVES	ACTION STEPS	RESPONSIBLE PERSON	SCHEDULED COMPLETION DATE
I. Evaluate COMAR 10.14.06 for the purpose of satisfying the requirement of State Government Article, §10-130—10-139, Annotated Code of Md.	1. Inventory affected regulations.	Michele Phinney	12/11/14
	2. Procedures and methods to be used to ensure comments from public / stakeholders / other affected units.	Blair Inniss	2/6/15
	A. To invite public comment on these regulations, the following procedures and methods will be used: 1. Publication of notice in the Maryland Register; 2. Posting of notice on the unit's website at http://crf.maryland.gov/ 3. Email notice to Local Health Departments.		
	B. To ensure the participation of stakeholders in the review process, the following procedures will be used: Comments from stakeholders will be solicited as above in 2A. Stakeholders will have the opportunity to review proposed revisions before formal submission to AELR.		
	C. To ensure the participation in the review process of other units affected by the regulations, the following procedures will be used: Comments from other units will be solicited as above in 2A. Other units will have the opportunity to review proposed revisions before formal submission to AELR.		
	3. Procedures for gathering and reviewing of: A. Any recent scientific information related to the regulations being reviewed, if applicable; B. Similar regulations adopted or repealed by other states or the federal government; and C. Other appropriate information, are as follows: 1. Current policies in the Cancer Prevention and Control program and the Tobacco Prevention and Control Program. 2. Regarding financial eligibility criteria for treatment services. 3. Results of previous audits regarding financial eligibility for treatment services.	Kelly Sage	4/1/15
	4. Evaluate the need to retain, amend, or repeal each existing regulation based on the following criteria: A. Continue to be necessary for public interest; B. Continue to be supported by statutory authority and judicial opinions; C. Are obsolete or otherwise appropriate for amendment or repeal; D. Continue to be effective in accomplishing the intended purpose of the regulations; E. The information gathered under Action Steps 1 - 3.	Donna Gugel	4/30/15

II.	Prepare report to the Administrative, Executive and Legislative Review (AELR) Committee	1. Consolidate information obtained from objective #1 above	Kelly Sage	5/29/15
		2. Write draft report.	Kelly Sage	7/15/15
		3. Coordinate executive reviews of draft report.	Blair Inniss	9/6/15
		4. Consolidate review comments and prepare final report.	Blair Inniss	11/1/15

DEPARTMENT OF HEALTH AND MENTAL HYGIENE
2011 – 2018 WORK PLAN FOR EVALUATION REPORT ON
COMAR 10.50.01 Tissue Bank

OBJECTIVES	ACTION STEPS	RESPONSIBLE PERSON	SCHEDULED COMPLETION DATE
I. Evaluate COMAR 10.50.01 for the purpose of satisfying the requirement of State Government Article, §10-130—10-139, Annotated Code of Md.	1. Inventory affected regulations.	Michele Phinney	12/11/14
	2. Procedures and methods to be used to ensure comments from public / stakeholders / other affected units.	Paul Celli	9/30/15
	A. To invite public comment on these regulations, the following procedures and methods will be used**:** 1. Publication of notice in the Maryland Register; 2. Posting of notice on the unit's website; 3. Posting notice on Division of State Document's website. B. To ensure the participation of stakeholders in the review process, the following procedures will be used: 1. Invite stakeholders for comments on regulation: i) Maryland Hospital Association ii) Maryland State Medical Society (MedChi) iii) American Association of Blood Banks iv) American Association of Tissue Bank 2. Invite public comments on websites and through emails i) Division of State Documents ii) OHCQ website C. To ensure the participation in the review process of other units affected by the regulations, the following procedures will be used: Invite OHCQ (Lab) surveyors to review regulations.		
	3. Procedures for gathering and reviewing of: A. Any recent scientific information related to the regulations being reviewed, if applicable; B. Similar regulations adopted or repealed by other states or the federal government; and C. Other appropriate information, are as follows: The 10.50 COMAR regulations will undergo an in-house regulatory review by OHCQ laboratory staff, members of the Laboratory Advisory Committee, and an opportunity for a public response from stakeholders. Scientific information related to the review will include applicable chapters of current editions of AATB and AABB standards. This regulatory review is a tool we will use to anticipate and evaluate the likely consequences of 10.50	Paul Celli	9/30/15

		amendments. It provides a formal means of organizing the evidence on the key effects, both good and bad, of the various alternatives that should be considered in developing the regulations. Among the purposes are; to learn if the quantitative and qualitative benefits of a change are likely to justify the continuation of the 10.50 chapter, also to promote accountability to the public, and to discover which of various possible alternatives would produce the highest benefits. Sometimes careful analysis can show that a less stringent alternative is best, sometimes more stringency will be shown to be justified.		
	4.	Evaluate the need to retain, amend, or repeal each existing regulation based on the following criteria: A. Continue to be necessary for public interest; B. Continue to be supported by statutory authority and judicial opinions; C. Are obsolete or otherwise appropriate for amendment or repeal; D. Continue to be effective in accomplishing the intended purpose of the regulations; E. The information gathered under Action Steps 1 - 3.	Paul Celli	9/30/15
II. Prepare report to the Administrative, Executive and Legislative Review (AELR) Committee	1.	Consolidate information obtained from objective #1 above	Amanda Thomas	11/30/15
	2.	Write draft report.	Amanda Thomas	11/30/15
	3.	Coordinate executive reviews of draft report.	Amanda Thomas	11/30/15
	4.	Consolidate review comments and prepare final report.	Amanda Thomas	11/30/15