

**REGULATORY REVIEW AND EVALUATION ACT:**

**WORKPLANS 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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In accordance with State Government Article, §10-132-1, Annotated Code of Maryland, the Secretary of Health and Mental Hygiene 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) or comprehensively amended (CA) during the preceding 8 years:

**Subtitle 10 LABORATORIES**

- 10.10.01 [General](#) (C.A.: 12-13-99)
- 10.10.02 [Medical Laboratories—General](#) (IA: 12-13-99)
- 10.10.03 [Medical Laboratories—Licenses](#) (IA: 12-13-99)
- 10.10.04 [Medical Laboratories—Fees](#) (IA: 12-13-99)
- 10.10.05 [Medical Laboratories—Proficiency Testing](#) (IA: 12-13-99)
- 10.10.06 [Medical Laboratories—Quality Assurance](#) (IA: 12-13-99)
- 10.10.07 [Medical Laboratories—Personnel](#) (IA: 12-13-99)
- 10.10.08 [Medical Laboratories—Sanctions](#) (IA: 12-13-99)
- 10.10.09 [Law Enforcement Laboratories—Personnel Certification & Approval of Laboratory Procedures](#) (IA: 12-13-99)
- 10.10.10 [Job-Related Alcohol and Controlled Dangerous Substances Testing](#) (IA: 12-13-99)
- 10.10.11 [Biological Agents Registry Program](#) (CA 7-31-06)
- 10.10.12 [Medical Laboratories—Public Health HIV Testing Programs](#) (IA: 3-14-05)

**Subtitle 11 MATERNAL AND CHILD HEALTH**

- 10.11.03 [Children's Medical Services Program](#) (Will be CA by Late Spring 2007)
- 10.11.04 [Lead Poisoning Screening Program](#) (IA: 5-12-03)

**Subtitle 12 ADULT HEALTH**

- 10.12.02 [Rape and Sexual Offenses—Physician and Hospital Charges](#) (CA: 7-5-04)
- 10.12.04 [Day Care for the Elderly and Medically Handicapped Adults](#) (CA: 11-13-06)

**Subtitle 13 DRUGS**

- 10.13.08 [Sale of Needles and Syringes or Other Paraphernalia](#) (CA: 3-6-00)
- 10.13.12 [Impoundment and Disposal of Drugs and Prescription Records](#) (IA: 6-24-02)

**Subtitle 14 CANCER CONTROL**

- 10.14.01 [Cancer Registry](#) (CA: 6-23-03)
- 10.14.02 [Reimbursement for Breast and Cervical Cancer Diagnosis and Treatment](#) (CA: 10-14-02)
- 10.14.04 [Breast Cancer Program](#) (IA: 11-10-03)
- 10.14.05 [Maryland Cancer Fund](#) (IA: 10-9-06)

**Subtitle 50 TISSUE BANKS**

- 10.50.01 [Tissue Banks](#) (CA: 3-15-04)

In addition, the following chapters have been repealed and therefore are not part of the Regulatory Review:

**Subtitle 12 ADULT HEALTH**

10.12.01 [Abortion Referral Services](#)

10.12.03 [Expanded Maternity Plan](#)

**Subtitle 13 DRUGS**

10.13.02 [Retail Sales or Use of Hydrocyanic Acid and its Salts, Compounds, and Preparations](#)

10.13.03 [Sale of Sodium Fluoride or Hydrofluoric Acid Preparations for Use as Insecticides](#)

10.13.04 [Labeling of Prescriptions for Drugs \(Other Than Narcotic Drugs\) That May be Dispensed Only on 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](#)

**DEPARTMENT OF HEALTH AND MENTAL HYGIENE  
WORK PLAN FOR EVALUATION REPORT ON  
COMAR 10.11.01 Identification of Infants**

<b>OBJECTIVES</b>	<b>ACTION STEPS</b>	<b>RESPONSIBLE PERSON</b>	<b>SCHEDULED COMPLETION DATE</b>
I. Evaluate COMAR for the purpose of satisfying the requirement of State Government Article, §10-130 - 10-139, Annotated Code of Md.	1. Inventory affected regulations.	Bonnie Birkel, Director, Office of Child and Maternal Health	January 2007
	2. Procedures and methods to be used to ensure comments from public / stakeholders / other affected units.	Bonnie Birkel	March 15, 2007
	A. To invite public comment on these regulations, the following procedures and methods will be used:  Publication of notice in the Maryland Register on Feb. 2 and Feb. 16, 2007 for comment by March 15.		
	B. To ensure the participation of stakeholders in the review process, the following procedures will be used:  An email containing COMAR 10.11.01 was sent to American Association of Pediatrics, Obstetrical & Gynecologic Society of Maryland, The American College of Obstetricians and Gynecologists, to FHA's Office of for Genetics & CSHCN, and to the local health departments on January 31, 2007, inviting their comments by March 15, 2007.		
	C. To ensure the participation in the review process of other units affected by the regulations, the following procedures will be used:  The email noted in B. above was also sent to legislative liaisons in the Labs Administration and the Maryland Hospital Association.		
	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 Office of the Attorney General will review these regulations for assistance in reviewing other state and federal laws. The stakeholders contacted in 2B above will be used to review recent scientific information.	Bonnie Birkel	May, 2007
	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;	Bonnie Birkel	November 1, 2007

- 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	Bonnie Birkel	December 3, 2007
	2. Write draft report.	Bonnie Birkel	January 7, 2008
	3. Coordinate executive reviews of draft report.	Bonnie Birkel	February 1, 2008
	4. Consolidate review comments, prepare final report, and obtain internal signoffs.	Bonnie Birkel	March 3, 2008

**DEPARTMENT OF HEALTH AND MENTAL HYGIENE  
WORK PLAN FOR EVALUATION REPORT ON  
COMAR 10.11.02 Program for Hearing-Impaired Infants**

<b>OBJECTIVES</b>	<b>ACTION STEPS</b>	<b>RESPONSIBLE PERSON</b>	<b>SCHEDULED COMPLETION DATE</b>
I. Evaluate COMAR for the purpose of satisfying the requirement of State Government Article, §10-130 - 10-139, Annotated Code of Md.	1. Inventory affected regulations.	Dr. Susan Panny, Director, Office for Genetics and CSHCN	January 2007
	2. Procedures and methods to be used to ensure comments from public / stakeholders / other affected units.	Susan Panny, MD	March 15, 2007
	<p>A. To invite public comment on these regulations, the following procedures and methods will be used:</p> <p>Publication of notice in the Maryland Register on Feb. 2 and Feb. 16, 2007 for comment by March 15.</p> <p>B. To ensure the participation of stakeholders in the review process, the following procedures will be used:</p> <p>An email containing COMAR 10.11.02 was sent to Maryland Speech and Hearing Association, Maryland Academy of Audiology, A.G. Bell Association, Maryland Academy of Pediatrics, Maryland School for the Deaf, Maryland State Department of Education, Maryland Coalition of the Deaf and Hard of Hearing, Maryland Association of the Deaf, Maryland Society of Otolaryngology, Universal Newborn Hearing Screening Advisory Council, and the local health departments on January 31, 2007, inviting their comments by March 15, 2007.</p> <p>C. To ensure the participation in the review process of other units affected by the regulations, the following procedures will be used:</p> <p>While not a unit of DHMH, certain hospitals are affected by these regulations, so the email noted in B. above was sent to the Maryland Hospital Association liaison.</p>		
	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:	Susan Panny, MD	May 2007
	The Office of the Attorney General will review these regulations for assistance in reviewing other state and federal laws. The stakeholders contacted in 2B above will be used to review recent scientific information.		
	4. Evaluate the need to retain, amend, or repeal each existing regulation based on the following criteria:	Susan Panny, MD	November 1, 2007

- 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.

II. Prepare report to the Administrative, Executive and Legislative Review (AELR) Committee	1. Consolidate information obtained from objective #1 above	Susan Panny, MD	December 3, 2007
	2. Write draft report.	Susan Panny, MD	January 7, 2008
	3. Coordinate executive reviews of draft report.	Susan Panny, MD	February 1, 2008
	4. Consolidate review comments, prepare final report, and obtain internal signoffs.	Susan Panny, MD	March 3, 2008

**DEPARTMENT OF HEALTH AND MENTAL HYGIENE  
WORK PLAN FOR EVALUATION REPORT ON  
COMAR 10.12.05 Breast Implantation**

<b>OBJECTIVES</b>	<b>ACTION STEPS</b>	<b>RESPONSIBLE PERSON</b>	<b>SCHEDULED COMPLETION DATE</b>
I. Evaluate COMAR for the purpose of satisfying the requirement of State Government Article, §10-130 - 10-139, Annotated Code of Md.	1. Inventory affected regulations.	Marsha Bienia Director, Center for Cancer Surveillance & Control	December 2006
	2. Procedures and methods to be used to ensure comments from public / stakeholders / other affected units.	Marsha Bienia	March 1, 2007
	A. To invite public comment on these regulations, the following procedures and methods will be used:  Publication of notice in the Maryland Register on Jan. 19 and Feb. 2, 2007 for comment by March 1.		
	B. To ensure the participation of stakeholders in the review process, the following procedures will be used:  An email containing COMAR 10.12.05 was sent to Breast Cancer Awareness Cumberland Valley, Maryland Hospital Association, Arm in Arm, Anne Arundel Medical Center, Cancer Information Service, Women Supporting Women, Sisters Network, The Center for Women's Health & Medicine at Mercy Hospital, and the local health departments on January 3, 2007, inviting their comments by February 15, 2007.		
	C. To ensure the participation in the review process of other units affected by the regulations, the following procedures will be used:  No other units or agencies will be affected by these 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 Office of the Attorney General will review these regulations for assistance in reviewing other state and federal laws. The stakeholders contacted in 2B above will be used to review recent scientific information.	Marsha Bienia	May, 2007
	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;	Marsha Bienia	November 1, 2007

- 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	Marsha Bienia	December 3, 2007
	2. Write draft report.	Marsha Bienia	January 7, 2008
	3. Coordinate executive reviews of draft report.	Marsha Bienia	February 1, 2008
	4. Consolidate review comments, prepare final report, and obtain internal signoffs.	Marsha Bienia	March 3, 2008

**DEPARTMENT OF HEALTH AND MENTAL HYGIENE  
WORK PLAN FOR EVALUATION REPORTS ON  
COMAR 10.13.01**

<b>OBJECTIVES</b>	<b>ACTION STEPS</b>	<b>RESPONSIBLE PERSON</b>	<b>SCHEDULED COMPLETION DATE</b>
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.	Anna Jeffers	April 16, 2007
	2. Procedures and methods to be used to ensure comments from public / stakeholders / other affected units. <ul style="list-style-type: none"> <li>A. To invite public comment on these regulations, the following procedures and methods will be used:               <ul style="list-style-type: none"> <li>1. Publication of notice in the Maryland Register;</li> <li>2. Posting of notice on the unit's website;</li> <li>3. Submission of the notice to the Board of Physicians, Board of Dental Examiners and Board of Podiatric Medical Examiners for posting on their websites and newsletters</li> </ul> </li> <li>B. To ensure the participation of stakeholders in the review process, the following procedures will be used:               <p style="margin-left: 40px;">Posting of notice on the unit's website and in the Board of Pharmacy Newsletter. The stakeholders for this chapter would also be the Board of Physicians, Board of Dental Examiners and the Board of Podiatric Medical Examiners. The notices listed in Step 2A will ensure that those Boards are involved and the public.</p> </li> <li>C. To ensure the participation in the review process of other units affected by the regulations, the following procedures will be used:               <p style="margin-left: 40px;">Email the request for comments will be sent to internal departmental units.</p> </li> </ul>	Anna Jeffers	August 1, 2007
	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: <ul style="list-style-type: none"> <li>A. Not applicable</li> <li>B. A search will be conducted on the Internet of other States, particularly those state that surround Maryland, to find out whether they have similar regulations and how their regulations are structured.</li> <li>C. A search will be conducted on the Internet of other Maryland State Department regulations to find out whether they have similar regulations and how their regulations are structured.</li> </ul>	Anna Jeffers	September 3, 2007

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|----|---|--------------|------------------|
| 4. | Evaluate the need to retain, amend, or repeal each existing regulation based on the following criteria: | Anna Jeffers | November 1, 2007 |
|    | 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.   |              |                  |

II. Prepare report to the Administrative, Executive and Legislative Review (AELR) Committee

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|----|--|--------------|-------------------|
| 1. | Consolidate information obtained from objective #1 above                         | Anna Jeffers | December 3, 2007  |
| 2. | Write draft report.  | Anna Jeffers | January 7, 2008   |
| 3. | Coordinate executive reviews of draft report.                                    | Anna Jeffers | February 1, 2008  |
| 4. | Consolidate review comments, prepare final report, and obtain internal signoffs. | Anna Jeffers | February 29, 2008 |

**DEPARTMENT OF HEALTH AND MENTAL HYGIENE  
WORK PLAN FOR EVALUATION REPORTS ON  
COMAR 10.13.05**

OBJECTIVES	ACTION STEPS	RESPONSIBLE PERSON	SCHEDULED COMPLETION DATE	
I. Evaluate COMAR for the purpose of satisfying the requirement of State Government Article, §10-130 - 10-139, Annotated Code of Md.	1. Inventory affected regulations.	Michelle Rollins	April 16, 2007	
	2. Procedures and methods to be used to ensure comments from public / stakeholders / other affected units.	Michelle Rollins	August 1, 2007	
	A. To invite public comment on these regulations, the following procedures and methods will be used:	1. Publication of notice in the Maryland Register.		
	B. To ensure the participation of stakeholders in the review process, the following procedures will be used: Affected departments and agencies will be contacted via phone and/or mail to assess the impact of the regulations on their operations and budgets. Advocacy organizations and providers will also be contacted via phone and/or mail to solicit comments on the regulations applicability to their constituencies.	C. To ensure the participation in the review process of other units affected by the regulations, the following procedures will be used: Affected departments and agencies will be contacted via phone and/or mail to assess the impact of the regulations on their operations and budgets.		
	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: Staff will review applicable scientific and government reports on the subject. Staff will also assess the state of the law to ascertain if the current program is duplicative of other State sponsored efforts. If the program is duplicative, assess which program should be retained.	Michelle Rollins	September 3, 2007	
	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.	Michelle Rollins	November 1, 2007	

II. Prepare report to the Administrative, Executive and Legislative Review (AELR) Committee

- |   |                  |                  |
|---|------------------|------------------|
| 1. Consolidate information obtained from objective #1 above                         | Michelle Rollins | December 3, 2007 |
| 2. Write draft report.  | Michelle Rollins | January 7, 2008  |
| 3. Coordinate executive reviews of draft report.                                    | Michelle Rollins | February 1, 2008 |
| 4. Consolidate review comments, prepare final report, and obtain internal signoffs. | Michelle Rollins | March 3, 2008    |

**DEPARTMENT OF HEALTH AND MENTAL HYGIENE  
WORK PLAN FOR EVALUATION REPORTS ON  
COMAR 10.13.11**

<b>OBJECTIVES</b>	<b>ACTION STEPS</b>	<b>RESPONSIBLE PERSON</b>	<b>SCHEDULED COMPLETION DATE</b>
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.	Michael Wajda	April 16, 2006
	2. Procedures and methods to be used to ensure comments from public / stakeholders / other affected units.	Michael Wajda	August 1, 2007
	A. To invite public comment on these regulations, the following procedures and methods will be used: 1. Publication of notice in the Maryland Register; 3. Posting of notice on the unit's website;		
	B. To ensure the participation of stakeholders in the review process, the following procedures will be used: Part of the task for the review of this chapter will be to identify stakeholders, which will be done as part of the research in item #3 below.		
	C. To ensure the participation in the review process of other units affected by the regulations, the following procedures will be used: The Maryland Board of pharmacy will be invited to participate in the review process.		
	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: Part of the review process for this chapter will involve a literature and legal review of other states and the federal rules.	Michael Wajda	September 3, 2007
	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.	Michael Wajda	November 1, 2007
II. Prepare report to the Administrative, Executive and Legislative Review (AELR) Committee	1. Consolidate information obtained from objective #1 above	Michael Wajda	December 3, 2007
	2. Write draft report.	Michael Wajda	January 7, 2008
	3. Coordinate executive reviews of draft report.	Michael Wajda	February 1, 2008
	4. Consolidate review comments, prepare final report, and obtain internal signoffs.	Michael Wajda	February 29, 2008

**DEPARTMENT OF HEALTH AND MENTAL HYGIENE  
WORK PLAN FOR EVALUATION REPORT ON  
COMAR 10.14.03 Alternative Methods of Breast Cancer Treatment**

<b>OBJECTIVES</b>	<b>ACTION STEPS</b>	<b>RESPONSIBLE PERSON</b>	<b>SCHEDULED COMPLETION DATE</b>
I. Evaluate COMAR for the purpose of satisfying the requirement of State Government Article, §10-130 - 10-139, Annotated Code of Md.	1. Inventory affected regulations.	Marsha Bienia Director, Center for Cancer Surveillance & Control	December 2006
	2. Procedures and methods to be used to ensure comments from public / stakeholders / other affected units.	Marsha Bienia	February 15, 2007
	A. To invite public comment on these regulations, the following procedures and methods will be used:  Publication of notice in the Maryland Register on Jan. 19 and Feb. 2, 2007 for comment by March 1.		
	B. To ensure the participation of stakeholders in the review process, the following procedures will be used:  An email containing COMAR 10.14.03 was sent to Susan G. Komen Breast Cancer Foundation, American Cancer Society, Arm in Arm, Maryland Hospital Association, Anne Arundel Medical Center, Men Against Breast Cancer, Nubian Women, Sinai Hospital, The Center for Women's Health & Medicine at Mercy Hospital, Chase Brexton Health Services, and the local health departments on January 3, 2007, inviting their comments by February 15, 2007.		
	C. To ensure the participation in the review process of other units affected by the regulations, the following procedures will be used:  No other unites or agencies are affected by these 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 Office of the Attorney General will review these regulations for assistance in reviewing other state and federal laws. The stakeholders contacted in 2B above will be used to review recent scientific information.	Marsha Bienia	May, 2007
	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;	Marsha Bienia	November 1, 2007

- 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	Marsha Bienia	December 3, 2007
	2. Write draft report.	Marsha Bienia	January 7, 2008
	3. Coordinate executive reviews of draft report.	Marsha Bienia	February 1, 2008
	4. Consolidate review comments, prepare final report, and obtain internal signoffs.	Marsha Bienia	March 3, 2008