JANUARY 1, 2011

REGULATORY REVIEW AND EVALUATION ACT:

EVALUATION REPORTS FOR:

Subtitle 18	**HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION AND ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS)**
Subtitle 47	**ALCOHOL AND DRUG ABUSE ADMINISTRATION**
Subtitle 48	**CHILD ABUSE AND NEGLECT MEDICAL REIMBURSEMENT PROGRAM**
Subtitle 49	**STATE ANATOMY BOARD**
Subtitle 51	**MARYLAND PRIMARY CARE**
Subtitle 52	**PREVENTIVE MEDICINE**

SUBMITTED BY:

Department of Health and Mental Hygiene
Office of Regulation and Policy Coordination
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EXEMPTION REQUESTED

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 18 HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION AND ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS)

10.18.01 Maryland AIDS Insurance Assistance Program
10.18.02 HIV and CD4+Lymphocyte Investigations and Case Reporting
10.18.03 AIDS Investigations and Case Reporting
10.18.04 Disease Control
10.18.05 Maryland AIDS Drug Assistance Program: Eligibility
10.18.06 Maryland AIDS Drug Assistance Program: Services
10.18.07 Maryland AIDS Drug Assistance Program: Health Insurance (MASAP-Plus)
10.18.08 HIV Counseling and Testing Procedures
10.18.09 HIV Counseling and Testing for Pregnant Women

Subtitle 47 ALCOHOL AND DRUG ABUSE ADMINISTRATION

10.47.01 Requirements
10.47.02 Specific Program Requirements
10.47.03 Specific Program Requirements for Correctional Levels of Care
10.47.04 Certification Requirements
10.47.05 Education Programs
10.47.06 Substance Abuse Treatment Outcomes Partnerships (S.T.O.P.) Fund

Subtitle 49 STATE ANATOMY BOARD

10.49.01 Fees

Subtitle 52 PREVENTIVE MEDICINE

10.52.04 Condom Vending Machines
10.52.05 Pertussis and Pertussis Vaccine
10.52.06 Use of Tanning Devices by Minors
10.52.11 Universal Infection Control Precautions
10.52.12 Newborn Screening
10.52.17 Maryland Asthma Control Program

CHAPTERS THAT HAVE BEEN REPEALED

Subtitle 51 MARYLAND PRIMARY CARE

10.51.01 Purpose and Definitions
10.51.02 Eligibility and Enrollment
10.51.03 Provider Application
10.51.04 Provider Conditions for Participation
10.51.05 Subcontractual Relationships
10.51.06 Reimbursement
10.51.07 Access Standards
10.51.08 Benefits
10.51.09 Complaints
10.51.10 Sanctions and Appeals
10.51.11 Availability of Funds

Subtitle 52 PREVENTIVE MEDICINE

10.52.07 Maryland AIDS Drug Assistance Program: Services
10.52.08 HIV Testing and Counseling Procedures
10.52.09 HIV/CD4+ Lymphocyte Count Reporting by Unique Patient Identifying Number
10.52.15 Maryland AIDS Drug Assistance Program Health Insurance Project (MADAP-Plus)

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Chapter Codification: 10.48.01

Chapter Name: Services (Child Abuse and Neglect Medical Reimbursement Program)

Authority: Family Law Article, §§ 5-701—5-910, Annotated Code of Maryland

Date Originally Adopted or Last Amended: October 20, 1997

Purpose: This chapter defines the emergency medical treatment and the limitations on this treatment paid for by the Department of Health and Mental Hygiene for the victims of child abuse and neglect; defines provider license requirements and conditions for participation, payment, and reimbursement provisions; and establishes appeal procedures.

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.

Representatives from the Maryland Chapter of the American Academy of Pediatrics were invited to comment on the regulations. No comments were received.

(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.

Representatives from the Family Health Administration, Center for Maternal and Child Health; the Maryland Hospital Association; the Department of Human Resources, Child Protective Services; the Maryland Medical Assistance Program; the Mental Hygiene Administration, Child and Adolescent Services; and all local health departments were invited to comment on the regulations. No comments were received.

(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.

Comments from the public were solicited by publishing a public notice in the Maryland Register as well as on the Sexual Assault Reimbursement Unit, Center for Health Promotion's Website. The comment period ended October 8, 2010. No comments were received from either posting.

(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.

N/A

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

The Victims of Crime Act of 1984 established the Office for Victims of Crime which is charged by Congress with administering the Crime Victim's Fund, a major source of funding for victim services. The Crime Victim's Fund is administered at the State level and supplements State funds that reimburse victims, including those of child abuse and neglect, for out-of-pocket expenses resulting from the crime. However, compensation is provided only when other financial resources, such as private health insurance (including Medical Assistance) or disability insurance do not cover the loss.

The Child Abuse and Neglect Medical Reimbursement Program provides for reimbursement to physicians and health care institutions directly, thus eliminating what might be an onerous financial burden to victims as they await compensation from the Maryland Criminal Injuries Compensation Board.

(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 [X] No

Has the agency promulgated all regulations required by recent legislation? [X] Yes [ ] 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)

XX no action

amendment

repeal

repeal and adopt new regulations

reorganization

Summary:

After reviewing this chapter, it has been determined that the chapter requires no amendments.

Person performing review:	Lisa Garceau, RN, MSN
Title:	Nursing Supervisor, Sexual Assault Reimbursement Unit. Center for Health Promotion and Education

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Chapter Codification: 10.52.01

Chapter Name: General Regulations for Hereditary Diseases

Authority: Health-General Article, §13-109, Annotated Code of Maryland

Date Originally Adopted or Last Amended: November 20, 1994

Purpose: COMAR 10.52.01 applies to the procurement for programs providing services in human genetics or services for person who are affected by or suspected of being affected by a hereditary disorder.

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 [ ] No [X]

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.

Representatives from the State Advisory Council on Hereditary and Congenital Disorders, local health departments, the MD Chapter of the American Academy of Pediatrics, the MD Chapter of the American College or Obstetricians and Gynecologists, Johns Hopkins Medical Institutions, the Univ. of MD Medical Center, and MHA were invited to comment on these regulations. The State Advisory Council on Hereditary and Congenital Disorders then formally convened on September 29, 2010 and October 20, 2010, respectively, to evaluate and provide comments on the regulations.

(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.

Representatives from the State Laboratories Administration, the Family Health Administration's Center for Maternal and Child Health, the MD Medical Assistance Program, the Office of Health Care Quality, the Mental Hygiene Administration, the Vital Statistics Administration, the Office of Procurement and Support Services, and the Office of the Attorney General were invited to comments on these 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.

Comments from the public were solicited by publishing a public notice in the Maryland Register requesting comments by October 8, 2010. No comments were received from the posting.

(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.

Representatives of the State Advisory Committee on Hereditary and Congenital Disorders and the State Laboratories Administration provided comments on this chapter. The Office for Genetics and Children with Special Health Care Needs accepted all of the comments proposing that COMAR 10.52.01 should be amended. A summary of the proposed amendments are set forth below at the end of this Evaluation Report.

(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.

N/A

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

The following documents were obtained and reviewed in evaluating the relevant and current status of these regulations: The Clinical Laboratories Improvement Act of 1988, 42 U.S.C. §263a The American Board of Medical Genetics standards of clinical practice and certification process for genetics laboratories/personnel

(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

Has the agency promulgated all regulations required by recent legislation? ☒ Yes ☐ 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:

Based upon the Office for Genetics and Children with Special Health Care Needs' review, stakeholder comments, and review of pertinent documents, the Office proposes that COMAR 10.52.01 should be updated to modernize references to certain subspecialties and to update a federal regulations citation. The amendments should also update the standards of clinical practice and the certification process for genetics laboratories/personnel.

Person performing review: Ms. Donna Harris

Title: Acting Director, Office for Genetics and Children with Special Health Care Needs

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Chapter Codification: 10.52.02

Chapter Name: High Blood Pressure Control Services

Authority: Health-General Article, §2-104(b) and 13-201 et seq., Annotated Code of Maryland

Date Originally Adopted or Last Amended: November 20, 1994

Purpose: These regulations provide for high blood pressure control services, subject to the availability of funds and program priorities. The regulations also encourage providers to promote a multiple risk factor approach to cardiovascular disease control.

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.

Representatives from the MD State Advisory Council on Heart Disease and Stroke; local health departments; the American Heart Association/American Stroke Association – MD Chapters; Maryland Stroke Alliance; Maryland Institute for emergency Medical Services Systems; the Preventive Health & Health Services Block Grant Advisory Committee; Maryland Healthy Eating & Active Lifestyle Coalition; Maryland State Advisory Council on Physical Fitness; and the Health Quality & Cost Council Wellness and Prevention Workgroup were invited to comment on the regulations. A comment by the MD State Advisory Council on Heart Disease and Stroke was received.

(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.

Representatives from FHA's Center for Health Promotion and Education and FHA's Center for Maternal and Child Health were invited to comment on these regulations. No comments were received.

(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.

Comments from the public were solicited by publishing a notice in the Maryland Register requesting comments by October 8, 2010. No comments were received from this posting.

(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 comment received from the MD State Advisory Council on Heart Disease and Stroke requested further characterization of a component of high blood pressure services. The adopting authority responded that further definition of the components of high blood pressure services is not required in the regulation and can be determined by the adopting authority without the promulgation of regulations.

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

Not applicable.

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

None.

(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 [X] No

Has the agency promulgated all regulations required by recent legislation? [X] Yes [ ] 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:

After reviewing this chapter, it has been determined that the chapter requires no amendments.

Person performing review: Audrey S. Regan, Ph.D.

Title: Director,
Office of Chronic Disease Prevention

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Chapter Codification: COMAR 10.52.03

Chapter Name: Health Education – General Regulations

Authority: Section II, Chapter 292, Laws of Maryland, 1984

Date Originally Adopted or Last Amended: Originally Adopted – April 8, 1985

Purpose: These regulations provide for general health education services for Maryland residents, subject to the availability of funding. The purpose of these health education services is to inform the public about various health issues, promote healthy behaviors, and organize groups to promote health enhancing activities or achieve environmental changes.

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.

In order to achieve due diligence regarding the review and evaluation of these regulations, targeted e-mails were sent to the following stakeholders inviting them to submit comments:

- Johns Hopkins Bloomberg School of Public Health, Johns Hopkins University
- Department of Health Science, Towson State University
- Department of Public and Community Health, University of Maryland College Park
- Public Health Program, Morgan State University
- Directors of Health Promotion and Education, a CDC affiliate
- Society of Public Health Education

Comments were received only from the Graduate Program Director at Towson State University who recommended the inclusion of regulatory language specifying the minimum qualifications of those delivering health education services. Included with her comments were examples from both New Jersey and Arkansas documenting the science base of health education and which make clear that a definitive credential exists through the National Commission for Health Education Credentialing, Inc. to support competency driven performance in the field.

(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.

To insure participation in the review process of other units affected by the regulations, an e-mail soliciting comments was sent to the following units within the Family Health Administration (FHA) and to the following local health department health education units:

- Office of Chronic Disease Prevention
- Center for Cancer Surveillance and Control
- Office of Oral Health
- Center for Maternal and Child Health
- Carroll County Health Department
- Garrett County Health Department
- Wicomico County Health Department
- Worcester County Health Department

No comments were received from the cited units within FHA or from the local health departments

(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.

To invite public comment, a notice was published in the Maryland Register and also posted on the Center for Health Promotion's Website requesting comments by October 8, 2010. No comments were received from either posting.

(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.

As indicated, the only comment received concerned language regarding health educator qualifications and included examples from two states that have successfully incorporated the recommended language into the policy standards of their respective states. The Center for Health Promotion and Education responded that the comment had been noted and that work has been done with DHMH Personnel to promote a hiring preference for Certified Health Educators in State service. The Center plans to consider amending the regulations to address health educator qualifications.

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

N/A

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

The following documents were obtained and reviewed in evaluating the relevancy and current status of these regulations.

- Public Health Solutions Through Changes in Policies, Systems, and the Built Environment, Specialized Competencies for the Public Health Workforce, James Emery, MPH and Carolyn Crump, PhD, UNC School of Public Health (2006)
- Core Competencies: Essentials for Injury and Violence Prevention, Society for the Advancement of Violence and Injury Research and State and Territorial Injury Prevention Directors Association Joint Committee Infrastructure Development (2004)
- A Competency – Based Framework for Health Educators (2006), the National Commission for Health Education Credentialing, Inc.

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

Health education units in the following State health departments were contacted to request copies of similar regulations in their respective states:

- California Department of Health Services
- South Carolina Department of Health and Environmental Control
- Wisconsin Division of Public Health
- Florida Department of Public Health
- Delaware Division of Public Health
- Virginia Department of Health
- Washington State Department of Health

Three of the seven health departments contacted responded, California, Delaware and Wisconsin. Wisconsin and Delaware have no such regulations; California submitted their Standards of Practice for Public Health Education in California Local Health Departments document. This document identifies the general range of functions and responsibilities included in public health education and provides guidelines and criteria for implementing and improving health education in local health departments.

(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 [X] No

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

Provide explanations of the above responses, as needed:

The Center for Health Promotion and Education is not aware of any legislation requiring the promulgation of regulations related to health education other than the underlying authority that supports the promulgation of COMAR 10.52.03.

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:

Based on the Center for Health Promotion and Education's review of the available scientific information, standards from other states, stakeholder comments and pertinent documents submitted, these regulations should be amended to include: 1) information on health educator qualifications/practice standards; 2) an expanded/revised list of health education services including those related to policy and environmental change strategies; and 3) updated language.

Person performing review: Ms. Joyce Dantzler

Title: Deputy Director,
Center for Health Promotion
and Education

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Chapter Codification: COMAR 10.52.10

Chapter Name: HIV Testing of Persons Accused or Convicted, or Both, of Certain Crimes

Authority: Authority: Criminal Procedure Article, §§11-107 – 11-117, Annotated Code of Maryland

Date Originally Adopted or Last Amended: Effective date: December 20, 1993 (20:25 Md. R. 1948)

Purpose: The purpose of the chapter is to establish the procedures for HIV testing ordered under the provisions of §§11-107 – 11-117 of the Criminal Procedure Article, Annotated Code of Maryland. This report describes the adopting unit process of review and the adopting unit's recommendations for modifications based on the review.

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 adopting unit received comments from several stakeholders including local health departments, State's Attorney's Offices, and the Department of Public Safety and Correctional Services. The comments ranged from technical in nature to recommendations for substantive process and policy modifications. An internal working group of subject matter experts was convened to assess the public health and operational implications of each comment. The internal workgroup then assessed the comments in the context of research, guidance, and the applicable law. The adopting unit developed recommendations on modifications to the regulations.

(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 Public Safety and Correctional Services
The Department of Juvenile Services

(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 adopting unit reviewed the applicable research and guidance from academic institutions, federal authorities and other State agencies. The adopting unit mailed invitations to provide comment to entities referenced in statute and regulations. The adopting unit also mailed invitations for comment to other State agencies who may be involved in the process of HIV testing of offenders or victims.

The adopting unit reviewed the comments.

(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.

Based on the comments received from the various stakeholders, the adopting unit recommends the following modifications to COMAR 10.52.10.:

Definitions

The adopting unit recommends that the definitions for the words and phrases "Exposure," "Intact skin contact of a victim with large amounts of blood or body fluids of an offender for a prolonged period," "Mucocutaneous contact of a victim with blood or body fluids of an offender," "Open wound contact of a victim with blood or body fluids of an offender for a prolonged period," and "Percutaneous contact of a victim with blood or body fluids of an offender" be stricken. The definitions are not in the statute nor are they relevant to the implementation of the regulations. The adopting unit is concerned that the additional language may add confusion regarding the process for implementing the regulations.

The definition of "Health officer" should be expanded to include the Chief Medical Officers of the Department of Public Safety and Correctional Services and the Department of Juvenile Services. The definition should be expanded because both departments have resources and authority to execute the responsibilities of the local health officers in state detention facilities. Additionally, the dispersal of the departments' facilities may make managing the process of offender HIV testing inter-jurisdictionally challenging for local health officers. The adopting unit also recommends that other language throughout the chapter be modified to ensure consistency with the inclusion of the departments.

Notice

The adopting unit recommends that the notice provision in COMAR 10.52.10.03 be expanded to include contact information for the parent or guardian of the victim, if the victim is a minor child. The adopting unit recommends this change because the health officer should coordinate HIV testing of a minor with the party responsible for his or her care not with the minor directly.

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

N/A

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

The following documents were reviewed in evaluating the relevancy and current status of these regulations.
The Centers for Disease Control and Prevention, (CDC) recommends HIV testing of adults, adolescents, and pregnant women in health-care settings. This is documented in the revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings.

Branson, Bernard M., Handsfield, Handsfield, H.Hunter, Lampe, Margaret A., Janssen, Robert S., Taylor, Allan W., Lyss, Sheryl B., Clark, Jill E., *Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings*. Morbidity and Mortality Weekly Report, 2006;55:1-17.

Liddicoat RV, Horton NJ, Urban R, Maier E, Christiansen D, Samet JH. *Assessing Missed Opportunities for HIV Testing in Medical Settings.* Journal of General Internal Medicine, 2004;19:349--56.

Marks G, Crepaz N, Senterfitt JW, Janssen RS. *Meta-analysis of High-risk Sexual Behavior in Persons Aware and Unaware They are Infected With HIV in The United States: Implications For HIV Prevention Programs.* Journal of Acquired Immune Deficiency Syndromes, 2005;39:446--53.

Klein D, Hurley LB, Merrill D, Quesenberry CP Jr. *Review of Medical Encounters in the Five Years Before a Diagnosis of HIV-1 Infection: Implications for Early Detection.* Journal of Acquired Immune Deficiency Syndromes, 2003; 32:143--52.

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

The only relevant information found is described in item 6.

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

N/A

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 [X] No

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:

See B(4) above.

Person performing review: William Honablew

Title: Chief, OPPI

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Chapter Codification: 10.52.13

Chapter Name: Screening for Sickle-Cell Disease, Thalassemia, & Related Conditions

Authority: Health-General Article, §13-109, Annotated Code of Maryland

Date Originally Adopted or Last Amended: April 24, 1995

Purpose: COMAR 10.52.13 governs screening and testing for sickle-cell disease, thalassemia, and related conditions in an individual other than a newborn.

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 [ ] No [X]

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.

Representatives from the State Advisory Council on Hereditary and Congenital Disorders, local health departments, the MD Chapter of the American Academy of Pediatrics, the MD Chapter of the American College or Obstetricians and Gynecologists, Johns Hopkins Medical Institutions, the Univ. of MD Medical Center, and MHA were invited to comment on these regulations. The State Advisory Council on Hereditary and Congenital Disorders then formally convened on September 29, 2010 and October 20, 2010, respectively, to evaluate and provide comments on the regulations.

(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.

Representatives from the State Laboratories Administration, the Family Health Administration's Center for Maternal and Child Health, the MD Medical Assistance Program, the Office of Health Care Quality, the Mental Hygiene Administration, the Vital Statistics Administration, the Office of Procurement and Support Services, and the Office of the Attorney General were invited to comments on these 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.

Comments from the public were solicited by publishing a public notice in the Maryland Register requesting comments by October 8, 2010. No comments were received from the posting.

(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.

Representatives of the State Advisory Committee on Hereditary and Congenital Disorders and the State Laboratories Administration provided comments on COMAR 10.52.13. The Office for Genetics and Children with Special Health Care Needs accepted all of the comments proposing that this chapter should be amended. A summary of the proposed amendments is set forth below at the end of this Evaluation Report.

(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.

N/A

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

N/A

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

None.

D. 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? [X] Yes [ ] 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:

Based upon the Office for Genetics and Children with Special Health Care Needs' review, stakeholder comments, and review of pertinent documents, the Office proposes that COMAR 10.52.13 should be modernized stylistically, legally, and technically.

Person performing review:

Ms. Donna Harris

Title:

Acting Director, Office for Genetics and Children with Special Health Care Needs

Regulatory Review and Evaluation Act
Evaluation Report Form
2003 – 2011

Chapter Codification: 10.52.14

Chapter Name: Screening for Neural Tube Defects in the Fetus (10.52.14)

Authority: Health-General Article, §13-109, Annotated Code of Maryland

Date Originally Adopted or Last Amended: January 2, 1995

Purpose: COMAR 10.52.14 governs screening and testing for neural tube defects.

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 [ ] No [X]

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.

Representatives from the State Advisory Council on Hereditary and Congenital Disorders, local health departments, the MD Chapter of the American Academy of Pediatrics, the MD Chapter of the American College or Obstetricians and Gynecologists, Johns Hopkins Medical Institutions, the Univ. of MD Medical Center, and MHA were invited to comment on these regulations. The State Advisory Council on Hereditary and Congenital Disorders then formally convened on September 29, 2010 and October 20, 2010, respectively, to evaluate and provide comments on the regulations.

(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.

Representatives from the State Laboratories Administration, the Family Health Administration's Center for Maternal and Child Health, the MD Medical Assistance Program, the Office of Health Care Quality, the Mental Hygiene Administration, the Vital Statistics Administration, the Office of Procurement and Support Services, and the Office of the Attorney General were invited to comments on these 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.

Comments from the public were solicited by publishing a public notice in the Maryland Register requesting comments by October 8, 2010. No comments were received from the posting.

(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.

Representatives of the State Advisory Committee on Hereditary and Congenital Disorders and the State Laboratories Administration provided comments on the three chapters under review. The Office for Genetics and Children with Special Health Care Needs accepted all of the comments proposing that COMAR 10.52.14 should be amended. A summary of the proposed amendments is set forth below at the end of this Evaluation Report.

(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.

New data were collected between 1994 and 2010 that: (1) confirm the usefulness of AFP (Alpha-Fetaprotein) screening for open neural tube defects and Down Syndrome; (2) demonstrate that the use of additional maternal serum markers in conjunction with AFP can enhance the predictive value of AFP testing for open neural tube defects and Down Syndrome; and (3) show that the use of these markers combined can identify pregnancies at risk for trisomy 18 and other chromosomal abnormalities. This data lead to broader acceptance of maternal serum screening, and the recommendations of the American College of Medical Genetics were updated to include the use of these additional tests.

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

The following documents were obtained and reviewed in evaluating the relevant and current status of these regulations:
Food and Drug Administration regulations pertaining to current standards of clinical practice for neural tube defect screening
The American College of Obstetricians and Gynecologists guidelines on neural tube defects screening

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

None.

E. 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 [X] No

Has the agency promulgated all regulations required by recent legislation? [X] Yes [ ] 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:

COMAR 10.52.14 has become obsolete and need a substantial overhaul to recognize improvements in the techniques used to screen for neural tube defects and to include the expansion of biochemical maternal serum screening to certain disorders other than neural tube defects. They also need to be amended to be consistent with changes in the federal Food and Drug Administration regulations and to reflect current standards of clinical practice. In addition, provisions relating to laboratory aspects of screening have been incorporated into the regulations of the Laboratories Administration and are now redundant.

Person performing review: Ms. Donna Harris

Title: Acting Director, Office for Genetics and Children with Special Health Care Needs