REGULATORY REVIEW AND EVALUATION ACT:

EVALUATION REPORTS DUE JANUARY 1, 2019 FOR:

Subtitle 18 HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION AND ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS)
Subtitle 48 CHILD ABUSE AND NEGLECT MEDICAL REIMBURSEMENT PROGRAM
Subtitle 49 STATE ANATOMY BOARD
Subtitle 51 FORENSIC LABORATORIES
Subtitle 52 PREVENTIVE MEDICINE

SUBMITTED BY:

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EVALUATION REPORTS

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

10.18.02 HIV and CD4+ Investigations and Case Reporting	Amendment
10.18.03 AIDS Investigations and Case Reporting	Repeal

Subtitle 48 CHILD ABUSE AND NEGLECT MEDICAL REIMBURSEMENT PROGRAM

10.48.01 Services	Repeal

Subtitle 52 PREVENTIVE MEDICINE

10.52.02 High Blood Pressure Control Services	Repeal
10.52.04 Condom Vending Machines	No Action
10.52.05 Pertussis and Pertussis Vaccine	Repeal
10.52.06 Use of Tanning Devices by Minors	No Action
10.52.10 HIV Testing of Persons Accused or Convicted, or Both, of Certain Crimes	No Action
10.52.11 Universal Infection Control Precautions	Amendment
10.52.17 Maryland Asthma Control Program	No Action

EXEMPTIONS REQUESTED

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

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

10.18.01 Maryland AIDS Drug Assistance Program: Temporary Assistance Program	IA 3-28-16
10.18.05 Maryland AIDS Drug Assistance Program: Eligibility	CA 3-28-16
10.18.06 Maryland AIDS Drug Assistance Program: Services	CA 3-28-16
10.18.07 Maryland AIDS Drug Assistance Program: Health Insurance (MADAP-Plus)	CA 3-28-16
10.18.08 HIV Testing Procedures	CA 3-28-16
10.18.09 HIV Testing for Pregnant Women Receiving Prenatal Care	CA 3-27-17
10.18.10 Urgent Maryland AIDS Drug Assistance Program	CA 3-28-16

Subtitle 49 STATE ANATOMY BOARD

10.49.01 Fees	CA 4-5-10

Subtitle 51 FORENSIC LABORATORIES

10.51.01 General	IA 5-28-12
10.51.02 Responsibilities, Accreditations, and Audits	IA 5-28-12
10.51.03 Licenses	CA 8-29-16 and 3-13-17
10.51.04 Proficiency Testing	IA 5-28-12
10.51.05 Quality Assurance	CA 7-20-15
10.51.06 Employees	IA 5-28-12
10.51.07 Sanctions	IA 5-28-12

Subtitle 52 PREVENTIVE MEDICINE

10.52.01 Opioid-Associated Disease Prevention and Outreach Programs	IA 4-24-17
10.52.03 Health Education—General Regulations	CA June 25, 2012
10.52.12 Newborn Screening	CA 4-24-17
10.52.15 Screening for Critical Congenital Heart Disease (CCHD) in Newborns	CA 4-15-13

CHAPTERS THAT HAVE BEEN REPEALED

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

10.18.04 Disease Control

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
10.52.13 Screening for Sickle-Cell Disease, Thalassemia, and Related Conditions -
10.52.14 Screening for Neural Tube Defects in the Fetus -
10.52.16 Insect Sting Emergency Treatment Program -

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Chapter Codification: COMAR 10.18.02

Chapter Name: HIV and CD4+ Investigations and Case Reporting

Authority: Health-General Article, §§2-104(b), 4-101, 4-102, 18-102, 18-103, 18-201.1, 18-202.1, 18-205, 18-207, and 18-215; State Government Article, §10-617; Annotated Code of Maryland

Date Originally Adopted or Last Amended: Regulations .02, .03. and .08 were amended effective March 14, 2016. The full chapter was revised September 8, 2008.

Purpose: This chapter establishes the requirements for:
(1) Physician reporting of a:
(a) Case of human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS); and
(b) Birth of an infant whose mother has tested positive for HIV;
(2) Institution reporting of a case of HIV or AIDS;
(3) Laboratory reporting of a test result for HIV infection or CD4+ count; and
(4) Follow-up of:
(a) A physician's report of HIV or AIDS;
(b) A physician's report of an infant whose mother has tested positive for HIV;
(c) An institution's report of HIV or AIDS; and
(d) A laboratory's report of HIV infection or CD4+ count.

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? [X] Yes [ ] No

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

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

(4) Are the regulations effective in accomplishing their intended purpose? [X] Yes [ ] 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.

A notice for opportunity to comment on this chapter was sent to MedChi, The Maryland Hospital Association, the Statewide HIV Planning Group, and the Maryland AIDS Prevention List Email Group. 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.

Local health officers were asked to comment on these regulations on July 11, 2018. No other agencies are affected by 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.

The notice for public comment was posted in the Maryland Register on May 25, 2018.
The notice for public comment was posted on the MDH website on May 8, 2018.

(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.

The Department received two comments on these regulations:
(1) Kaiser Permanente submitted a comment requesting that the Department extend the requirement for timely reporting of cases from 48 hours to 5 business days. The unit responded saying that 48-hour requirement is in line with US Centers for Disease Control and Prevention (CDC) recommendations. The unit further responded that reporting within 48 hours is essential to ensure rapid follow-up with individuals with HIV infection and to link the individual with care within 30 days of diagnosis. The unit also noted that follow up for HIV-exposed infants is especially important as they require postpartum antiretroviral medication and additional HIV testing. Additionally, the regulations state that physicians may designate other staff to complete the required report.
(2) Debra Stevens from the Worcester County Health Department commented that CRNPs should be added to the regulations as providers that are required to report and are subject to the same provisions as physicians. The unit agreed with the suggested change and responded that the change would be incorporated into a future proposal for this chapter. However, upon further review, making this change to the regulations may not be possible without a change to Health-General Article §18-201.1, which specifies that reports shall be made by physicians.

(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.

In reviewing the chapter, the unit looked at internal analysis of false-positive HIV test reports. The analysis indicated many of the false-positive test results were due to changes in the testing algorithm. Many laboratories now use complex algorithms with multiple tests. If a lab uses a method with multiple tests, there may be mixed results (for example, four positive tests and one negative test). In those cases, the Department would receive reports of the four positive results, but not the negative result, and would therefore treat that case as HIV-positive. In order to have the most complete information possible, the unit would need to receive negative test results in addition to positive test results. Reporting negative results will also improve the unit's ability to track individuals who receive care in neighboring jurisdictions as well as identify new cases in Maryland residents.

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

CDC requires that all jurisdictions participating in the National HIV Surveillance System collect the last negative diagnostic test result, the first positive diagnostic test result, including all intermediate tests in the testing algorithm, all CD4 test results, all HIV viral load test results, and all HIV genotype test results on HIV cases.

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

No other relevant information was gathered.

C. Under COMAR 01.01.2003.20E(3), does the agency have any existing policy statements, guidelines, or standards being applied or enforced which should be promulgated as regulations, in accordance with the Administrative Procedure Act? ☐ Yes ☒ No

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:

After reviewing the chapter, the unit plans to amend the regulations to a) clarify which laboratory tests and test results are reportable and b) expand the reporting of HIV diagnostic tests to include all test results. The first part (a) will simplify reporting for laboratory directors, increase compliance with reporting, and improve the Department's ability to perform data-to-care activities (using data to help find individuals who need to be linked to care). The second part (b) is in response to changes in the HIV testing algorithms over the last ten years. The changes are necessary to: ensure complete reporting; reduce reporting of false positives; increase efficiency in identifying pediatric seroreverters (children born to an HIV-infected mother who do not show evidence of HIV infection); and properly identify cases that receive part of their care in neighboring jurisdictions. The changes will also improve the unit's ability to identify recent HIV infections, which will allow better identification and response to transmission clusters; provide additional information on time from infection to diagnosis; and improve ability to measure incidence (time of infection). COMAR 10.18.02.06 - Responsibilities of Laboratory Directors should be amended to clarify which laboratory tests and test results are reportable, and to expand the reporting of HIV diagnostic tests to include all test results, including negative results. The unit will also update an outdated reference in COMAR 10.18.02.08 as part of the planned proposal.

Person performing review: Colin Flynn

Title: Chief, Center for HIV Surveillance, Epidemiology and Evaluation, MDH

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Chapter Codification: COMAR 10.18.03

Chapter Name: AIDS Investigations and Case Reporting

Authority: Health-General Article, §§2-104(b), 4-101, 4-102, 18-102, 18-103, 18-201.1, 18-205, and 18-207, Annotated Code of Maryland

Date Originally Adopted or Last Amended: Chapter originally adopted February 18, 2002. Regulations .03B and .04C were amended March 14, 2016.

Purpose:

This chapter establishes requirements for:
A. Reporting a case of acquired immunodeficiency syndrome (AIDS); and
B. Follow-up of a physician report of AIDS.

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 ☒ No

(2) Do the regulations continue to be supported by statutory authority and judicial opinion? ☒ Yes ☐ No

(3) Are the regulations obsolete or otherwise appropriate for amendment or repeal? ☒ Yes ☐ No

(4) Are the regulations effective in accomplishing their intended purpose? ☒ Yes ☐ 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.

A notice for opportunity to comment on this chapter was sent to MedChi, The Maryland Hospital Association, the Statewide HIV Planning Group, and the Maryland AIDS Prevention List Email Group. 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.

Local health officers were invited to review and comment on the regulations. A notice for opportunity for comment was emailed on July 11, 2018. 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.

A notice of opportunity for public comment was posted in the Maryland Register on May 25, 2018, and on the MDH website on May 8, 2018.

(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.

There was no interunit conflict.

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

N/A; see item 8 below.

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

Other states and the federal government have similar regulations.

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

The content of this section was incorporated with that of Chapter 10.18.02 in 2008. At that time this Chapter should have been repealed in its entirety. Completion of this report has revealed that oversight.

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)

	no action
	amendment
X	repeal
	repeal and adopt new regulations
	reorganization

Summary:

The content of this section was incorporated with that of Chapter 10.18.02 in 2008. At that time this Chapter should have been repealed in its entirety. Completion of this report has revealed that oversight. The unit recommends complete repeal of this Chapter as Chapter 10.18.02 continues to provide appropriate treatment of this subject.

Person performing review:	Colin Flynn
Title:	Chief, Center for HIV Surveillance, Epidemiology and Evaluation, MDH

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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: (1) defines the emergency medical treatment and the limitations on this treatment paid for by the Maryland Department of Health for the victims of child abuse and neglect; (2) defines provider license requirements and conditions for participation, payment, and reimbursement provisions; and (3) 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? [X] Yes [ ] No

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

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

(4) Are the regulations effective in accomplishing their intended purpose? [X] Yes [ ] 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 (AAP), the Maryland Hospital Association (MHA), the Department of Human Resources, Child Protective Services, the Partnership for a Safer Maryland, and the Maryland Child Abuse Medical Providers Network were invited to comment on the regulations. Three comments were received and are summarized under B(4).

(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 Prevention and Health Promotion Administration's Maternal and Child Health Bureau; the Behavioral Health Administration's Child and Adolescent Services Unit; the Maryland Medical Assistance Program; 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 through a public notice in the Maryland Register which was published January 5, 2018. In addition, a notice was placed on the "open for comments" section of the Maryland Department of Health's website.

(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.

Three comments were received.

One comment was received from a pediatrician and member of the Maryland Academy of Pediatrics who recommended a change in the hourly rate paid by the Department for child sexual abuse cases. The Department informed the commenter that cases of child sexual abuse often fall under a different chapter of regulations (COMAR 10.12.02) which do specify an hourly limit on the physician's fee. COMAR 10.48.01 reimburses physicians according to the Medical Assistance Provider Fee Manual rather that a set fee. Further, the respondent was notified of the intended transfer of COMAR 10.12.02 to the Governor's Office of Crime Control and Prevention and the opportunity to comment on those regulations at that time.

A second comment was received from the attorney for the Maryland Chapter of AAP requesting updates to how provider fees are determined. This comment was based on an outdated version of the regulations; in 2017 the 1982 Medical Assistance Provider Fee Manual (Manual) referenced by the commenter in the regulations was updated to the current version and incorporated by reference. The Center for Injury Prevention sent the commenter the current version of the regulations and explained the recent change.

A third comment was received from a Maryland Hospital Association member who recommended an addition under COMAR 10.48.01.04(A)(5) providing for consultation with a specialist such as a forensic nurse examiner. In addition, the respondent recommended the Department provide reimbursement for other types of forensic programs such as domestic violence, non-fatal strangulation, and human trafficking. The Center for Injury Prevention acknowledged the recommendation for an addition to COMAR 10.48.01 and informed the respondent that comments regarding other forensic programs were not being solicited at this time.

(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.

None

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

The federal 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 without medical insurance and those awaiting compensation from the Maryland Criminal Injuries Compensation Board.

All states within the region have statutes similar to Family Law Article, §§5-701—910, Annotated Code of Maryland which include definitions, mandatory reports, reporting procedures, and penalties and investigative processes. Each state also has corresponding regulations. States commonly screen uninsured children for medical assistance eligibility. Those not qualifying are covered through a variety of funding streams including the Children's Health Insurance Program (e.g. Pennsylvania) and state funds (e.g. West Virginia Forensic Medical Fund managed by the WV Prosecuting Attorney's Institute). However, Maryland is unique in that the Department of Health has a specific program aside from medical assistance which has been established as the payer of last resort for child abuse and neglect medical reimbursement.

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

Up until July 1, 2018, the Child Abuse and Neglect Medical Reimbursement Program was administered by the Sexual Assault Reimbursement Unit (SARU) at the Department. As a result of Chapter 442 of the Acts of 2018, SARU was transferred on July 1, 2018 from the Department to the Governor's Office of Crime Control and Prevention (GOCCP). While a limited number of claims were paid each year by SARU under the Child Abuse and Neglect Medical Reimbursement Program, the Department no longer has the staff, infrastructure, or funds to administer the Child Abuse and Neglect Medical Reimbursement Program.

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)

	no action
	amendment
X	repeal
	repeal and adopt new regulations
	reorganization

Summary:

On July 1, 2018 the Department's Sexual Assault Reimbursement Unit (SARU) was transferred to the Governor's Office of Crime Control and Prevention (GOCCP) Victim Services Unit per Chapter 422 of the Acts of 2018 (HB 247). SARU processes and reimburses claims for services provided to victims of sexual assault. In addition to these claims, each year SARU processes and reimburses a limited number of claims under the Child Abuse and Neglect Medical Reimbursement Program. The number of claims processed by SARU in past years has been consistently small, under a dozen per year. These claims are paid out of the same funds as sexual assault forensic examinations.

With the transfer of SARU to GOCCP, the Department no longer has the funds or infrastructure to process claims for emergency medical treatment in cases of child abuse and neglect. Because Family Law Article §5-712 specifically names the Department as the payer for these claims, the Department is pursuing a statutory change to transfer responsibility for these claims from the Department to GOCCP. Following this statutory change, it is recommended to repeal COMAR 10.48.01 in its entirety.

Person performing review:	Joyce Dantzler
Title:	Chief, Center for Injury and Sexual Assault Prevention

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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: 1994

Purpose: These regulations provide for high blood pressure control services, subject to the availability of funds and according to program priorities. The regulations also encourage medical 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 ☒ No

(2) Do the regulations continue to be supported by statutory authority and judicial opinion? ☐ Yes ☒ No

(3) Are the regulations obsolete or otherwise appropriate for amendment or repeal? ☒ Yes ☐ No

(4) Are the regulations effective in accomplishing their intended purpose? ☐ Yes ☒ No

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

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

The Department discussed the regulation review process with the members of the Maryland State Advisory Council on Heart Disease and Stroke (the Council) on April 20, 2017. The Council members supported the Department's plan to publish the regulations for public comment in the Maryland Register. The publication of the regulations was also shared via email with the Maryland chapter of the American Heart Association, the Maryland Institute for Emergency Medical Services Systems, and the Maryland Association of County Health Officers.

(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.

There are no other units or agencies affected by the regulations.

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

On July 7, 2017, the Department published a notice in the Maryland Register to solicit public comment on this regulation by August 10, 2017. 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.

No comments were received from stakeholders or the public.

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

There are no other affected units, so there was no interunit conflict.

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

In November 2017, the American College of Cardiology in conjunction with the American Heart Association issued new clinical guidelines for the classification of high blood pressure. The Department reviewed the summaries of these guidelines and the implications for lifestyle changes and medications to improve population level control of high blood pressure.

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

The Department reviewed the High Blood Pressure Control Act (410 ILCS 425/3) from the State of Illinois and regulations, which were repealed in 2014. The Department also reviewed California regulations (HSC Division 103 104100-104140) for high blood pressure control, which is still in force.

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

The Department does not directly provide the services listed in the chapter under review, nor does the State provide specific funds to carry out these services. In addition, the statutory authority for these regulations has been repealed (effective 10/1/17), and current statute does not address high blood pressure control services.

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:

COMAR 10.52.07 State Advisory Council on Health and Wellness has been promulgated as required by HG §13-206, effective January 29, 2018. The enabling statute for the Council has replaced the enabling statute for COMAR 10.52.02.

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

no action

amendment

✓ repeal

repeal and adopt new regulations

reorganization

Summary:

The chapter under review requires high blood pressure control services to be conducted in the manner outlined in COMAR 10.52.02, but there is no State funding designated for providers or organizations to provide these services. Additionally, the statutory authority for the chapter has been repealed. Although high blood pressure control remains an important public health issue and the Department endorses clinical practice guidelines for high blood pressure control services, the Department recommends repealing this chapter.

Person performing review: Sadie Peters, MD, MHS

Title: Medical Director, Center for Chronic Disease Prevention and Control, PHPA

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Chapter Codification: COMAR 10.52.04

Chapter Name: Condom Vending Machines

Authority: Health-General Article, §§2-104 and 18-335; Criminal Law Article, §10-104; Annotated Code of Maryland

Date Originally Adopted or Last Amended: This chapter was revised effective January 7, 2002.

Purpose:

This chapter establishes requirements for condoms offered for sale by means of a vending machine or other automatic device, and for the vending machines or other automatic devices that sell condoms.

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? [X] Yes [ ] No

(2) Do the regulations continue to be supported by statutory authority and judicial opinion? [X] Yes [ ] 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? [X] Yes [ ] 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.

A notice for opportunity to comment on this chapter was sent to MedChi, The Maryland Hospital Association, the Statewide HIV Planning Group, and the Maryland AIDS Prevention List Email Group. 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.

Local health officers were invited to review and comment on the regulations. A notice of opportunity for comment was emailed on July 11, 2018.

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

A notice of opportunity for public comment was posted in the Maryland Register on May 25, 2018, and on the MDH website on May 8, 2018.

(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.

Several stakeholders and members of the public submitted comments in response to the public comment notice requesting that the Department allow emergency contraception to be sold in vending machines in Maryland. The unit replied that while availability of emergency contraception is an important public health issue, it is beyond the scope of this chapter. The authority for this chapter pertains specifically to condoms sold in vending machines. Further, statute does not currently include emergency contraception as exempt from the prohibition against selling over-the-counter drugs in vending machines.

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

There was no interunit conflict.

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

The US Centers for Disease Control and Prevention (CDC) recognize condom distribution programs as structural interventions that, when implemented correctly, will decrease rates of HIV and other sexually transmitted infections. Components of an effective condom distribution program include no or low-cost condoms and wide-spread availability. Allowing condoms to be sold in vending machines helps increase availability.

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

California has implemented low-cost condom vending machines on college campuses, which include also emergency contraception and Plan B. California also has regulations allowing for no-cost condom vending machines in prisons.

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

No other information was gathered.

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

X no action

amendment

repeal

repeal and adopt new regulations

reorganization

Summary:

Allowing condoms to be sold in vending machines increases availability and is in line with CDC recommendations regarding widespread condom use as a public health intervention. Although availability of emergency contraception is an important public health issue, no changes to the regulations are recommended as adding emergency contraception is outside the scope of this chapter.

Person performing review:	Elisabeth Liebow
Title:	Policy and Program Associate, CSTIP

Regulatory Review and Evaluation Act
Evaluation Report Form
2012 – 2020

Chapter Codification: COMAR 10.52.05

Chapter Name: Pertussis and Pertussis Vaccine

Authority: Health-General Article, §§2-104(b)(1) and 18-332, Annotated Code of Maryland

Date Originally Adopted or Last Amended: Regulation .04 was amended August 10, 2009. The chapter was originally adopted May 19, 1986.

Purpose: The purpose of COMAR 10.52.05 is to require healthcare providers to educate patients about possible adverse reactions to the pertussis vaccine and to report any known adverse events to the Department. The chapter outlines protocols for healthcare providers, local health departments, and the Department to respond to adverse events related to the pertussis vaccine.

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 ☒ No

(2) Do the regulations continue to be supported by statutory authority and judicial opinion? ☒ Yes ☐ No

(3) Are the regulations obsolete or otherwise appropriate for amendment or repeal? ☒ Yes ☐ No

(4) Are the regulations effective in accomplishing their intended purpose? ☐ Yes ☒ 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.

Local health departments, the MDH Office of Population Health Improvement (OPHI), and MedChi were provided copies of the regulations and were given an opportunity to review and respond.

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

None.

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

The Department solicited comments by:
(1) Posting on the unit's website and in the Maryland Register (11/13/17); and
(2) Emailing a notice of opportunity to comment to local health departments, OPHI, and MedChi.

(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.

OPHI submitted comments suggesting clarification of the definition for "reasonable" and the use of "major" when describing adverse reactions. OPHI further questioned whether these regulations should be expanded to cover all vaccines, since the medical standards are the same for all vaccines. OPHI also commented regarding the use of "parent" vs "parent or guardian" throughout the chapter.

The unit responded to OPHI noting that the unit is planning to repeal the chapter because it is no longer needed. The chapter was developed in response to adverse reactions associated with the whole cell pertussis vaccine (whole cell DTP). This vaccine is no longer in use and there is currently a more comprehensive national program to monitor vaccine safety and all vaccine adverse events.

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

No interunit conflict occurred.

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

Whole cell DTP vaccines were commonly associated with several local adverse reactions, high fever, and other systemic events including drowsiness, fretfulness, anorexia, fainting, and febrile seizures. Local adverse reactions occurred in up to 50 percent of whole cell DTP recipients. Concerns about the safety of whole cell DTP led to the development of acellular vaccines (DTaP/Tdap) that are less likely to produce adverse events because they contain purified components of the pertussis bacteria. DTaP/Tdap has considerably improved the safety profile of the vaccine. Adverse reactions are much less common with DTaP/Tdap, and include local reactions (pain, redness, swelling) occurring in 20-40 percent of recipients. More severe adverse reactions are uncommon with DTaP/Tdap.

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

State and territory immunization program managers were queried to determine what similar regulations there are in other states. Eleven states and territories responded. None have pertussis-specific adverse event reporting requirements. Two had mandatory reporting requirements for any vaccine adverse reaction (which would include pertussis). All other states and territories recommended reporting to the federal Vaccine Adverse Event Reporting System (VAERS) as required by the National Childhood Vaccine Injury Act (NCVIA).

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

Since these regulations were adopted, a number of national vaccine safety measures have been established. In 1986, Congress passed NCVIA. NCVIA required healthcare providers who administer vaccines to provide vaccine information statements (VIS) with each dose of vaccine given. VIS contain a brief description of the disease as well as the risks and benefits of the vaccine.

In addition, VAERS was established nationally to monitor and detect possible safety issues with vaccines by collecting information about adverse events that occur after vaccination. Finally the National Vaccine Injury Compensation Program was established to compensate those injured by vaccines on a "no fault" basis.

Because there are federal requirements for education through VIS and adverse event reporting though VAERS, this chapter is no longer needed. Therefore, this chapter can be repealed.

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)

no action

amendment

X **repeal**

repeal and adopt new regulations

reorganization

Summary:

This chapter was developed in response to adverse reactions associated with the whole cell DTP. Since the chapter was adopted, whole cell DTP has been discontinued and replaced with DTaP/Tdap. Adverse events associated with DTaP/Tdap are much less common than with DTP. In addition, NCVIA created a network of surveillance and compensation programs related to vaccine safety and vaccine adverse events.

Due to the changes discussed above, this chapter is unnecessary. A query of other states revealed that none have pertussis-specific reporting requirements. Most recommend reporting of adverse events to VAERS. Two jurisdictions had adverse event reporting requirements for all vaccines, including but not limited to pertussis.

Person performing review:	Kurt Seetoo
Title:	Immunization Program Manager

Regulatory Review and Evaluation Act
Evaluation Report Form
2012 – 2020

Chapter Codification: COMAR 10.52.06

Chapter Name: Use of Tanning Devices by Minors

Authority: Health-General Article, §20-106
Annotated Code of Maryland

Date Originally Adopted or Last Amended: Effective date: June 29, 2009; Regulation. 12 B amended effective March 14 2016.

Purpose: This chapter codifies in regulations the restrictions placed on the use of tanning devices by minors established in Health-General §20-106. These regulations specify the implementation, enforcement, and other administrative requirements related to this law.

The purpose of this law is to reduce the exposure of minors (individuals under the age of 18) from the potentially harmful effects of tanning devices. Tanning devices are a common source of ultraviolet radiation that can significantly increase the risk of skin cancer.

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? [X] Yes [ ] No

(2) Do the regulations continue to be supported by statutory authority and judicial opinion? [X] Yes [ ] 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? [X] Yes [ ] 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 Maryland Dermatologic Society (MDS)
The MDS supported the legislation passed in 2008 that restricted use of tanning devices by minors. While MDS supports the Department's current regulations, MDS advocates for the strengthening of the law to remove the exception with parental permission. This would prohibit all children under 18 years of age from using tanning devices.

General Public, Industry
General public and industry had an opportunity to comment through publication of a notice in the Maryland Register.

(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.

Local Health Officers and the Department's Maternal and Child Health Bureau and Center for Cancer Prevention and Control were invited to review and comment 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 through a public notice in the Maryland Register which was published January 5, 2018. In addition, a notice was placed on the "open for comments" section of the Maryland Department of Health's website.

(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.

The Maryland Dermatologic Society (MDS) recommends a complete prohibition on tanning device use based on research showing that tanning beds have serious health implications for children. The Department noted these concerns, but at this time does not have statutory authority for such an action.

No other comments were received.

(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.

Magnitude of the Problem:
Skin cancer is the most common cancer in the United States, with 5.4 million new diagnoses estimated in the year 2012.[1] The incidence rate of melanoma has steadily increased from an age-adjusted rate of 15.1 new cases per 100,000 people in 1999 to 22.1 per 100,000 in 2015; this is despite the incidence rate of all types of cancer decreasing over the same period of time.[2] Melanoma is increasing in younger populations. Surveillance data showed an increase of 3.7% in males and 4.2% in females aged 15-29 years from 1992 to 2004.[3] Non-melanoma skin cancer incidence was estimated to be 5,434,193 nationwide, a 300% increase from a 1994 estimate of 1.2 million.

Evidence of Skin Cancer Attributable to Tanning Devices:
Tanning devices significantly increase the risk of melanoma cancers and deaths (1.8% increase per tanning session per year).[4] For non-melanoma cancers, a meta-analysis of studies found 8.2% of cases for squamous cell carcinoma and 3.7% of basal cell carcinoma attributable to indoor tanning, which corresponds to 170,000 cases of nonmelanoma skin cancer each year.[5]

A study found melanoma patients were twice as likely as controls to have used a tanning bed prior to their cancer, and 90% of both control group and melanoma patients answered they knew about the risks of skin cancer from bed tanning, suggesting just public education may not be sufficient to avert the risk of cancer from tanning beds.[6]

Costs of Skin Cancer:
National costs of caring for skin cancer have increased by 126% from 2002 to $8.1 billion in 2011.[7]

Maryland:
A total of 1,452 cases of melanoma were reported in 2014 in Maryland, for an incidence rate of 21.9 per 100,000 (national average 22 per 100,000) and similar mortality rate of 2.1 per 100,000.[8]

On November 15, 2013, the Department issued a revised parental consent form to be used by indoor tanning facilities for individuals under 18 years of age. The form's download website has been visited 126 times, suggesting low uptake of the form.

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

Federal Drug Administration (FDA):
The FDA recognizes the risks of tanning devices, such as tanning beds and tanning lamps, as causes of skin cancer, skin burns, premature skin aging, and short and long-term eye damage. In 2014 the FDA introduced a new requirement for a label stating tanning lamps should not be used by anyone under the age of 18. The FDA proposed the banning of tanning beds for those under age 18. In 2016, the FDA promoted regulation of tanning devices to those over age 18 requiring consent prior to use and every six months thereafter for continued use, stating they have been informed of the health risks.[9]

Centers for Disease Control and Prevention (CDC):
According to the CDC Youth Risk Behavior Study in 2013, one in every three girls under the age of 18 has used a tanning bed within the last year.[10] In 2016 the CDC recommended restrictions for indoor tanning for minors, as well as enforcement practices and education.[11]

State legislation trends:
In 2011, California became the first state to ban tanning beds for minors. Currently, there are 44 states with some form of regulation on indoor tanning for minors, with 16 states and the District of Columbia having an underage ban. Other states combine various restrictions, including requiring parental consent or requiring operators to limit exposure.[12]

Medical Organizations:
A 2003 World Health Organization report highlights substantial evidence of increased risk of skin cancers, eye damage, and skin aging from the use of tanning beds and recommends governments regulate tanning bed operations, improve information about health risks of use to the public, and restrict use of tanning devices for those under the age of 18.[14] The American Academy of Pediatrics,[15] American Academy of Dermatology,[16] and American Medical Association[17] have all expressed support for a total ban of indoor tanning devices for minors.

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

Scientific Literature of Effect of Tanning Bed Regulations on Underage Use of Tanning Beds: Fewer adolescent girls engage in indoor tanning in states with age restrictions on the use of indoor tanning than in states with no regulation.[18] However, legislation restricting the use of indoor tanning devices by minors may only be effective with proper oversight of tanning facilities to ensure compliance.[19] Compliance with tanning bed legislation for the state of Maryland was 70% according to a study done from 2015 to 2016. The study looked at all states that regulate the use of tanning beds for minors (42 states and the District of Columbia) and found states with a total ban for minors had better compliance than states with parental/adult permission or different restrictions based on different minor age groups (78% vs. 55% compliance, respectively). The simpler the law is to follow, the greater the compliance.[20]

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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)

X no action

amendment

repeal

repeal and adopt new regulations

reorganization

Summary:

The regulations on Use of Tanning Devices by Minors (COMAR 10.52.06) continue to be supported by the weight of medical evidence and public health research. If anything, the evidence of a need to have parental consent for minors to use tanning devices has become stronger since the legislation was enacted. Because the current regulations are based on statutory law, no changes are required until or unless legislative changes are made to Health-General §20-106.

Person performing review:	Clifford S. Mitchell
Title:	Director, Environmental Health Bureau

Regulatory Review and Evaluation Act
Evaluation Report Form
2012 – 2020

Chapter Codification: COMAR 10.52.10

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

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

Date Originally Adopted or Last Amended: This chapter was substantially amended effective May 7, 2018 per Chapters 485 and 486 of the Acts of 2017.

Purpose: This chapter establishes procedures for HIV and hepatitis C testing ordered under the provisions of Criminal Procedure Article, §§11-107—11-117, Annotated Code of Maryland.

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

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

(2) Do the regulations continue to be supported by statutory authority and judicial opinion? [X] Yes [ ] 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? [X] Yes [ ] 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.

As part of the proposal required by Chapters 485 and 486 of the Acts of 2017, this chapter was shared with the Maryland Association of County Health Officers (MACHO). 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.

As part of the proposal required by Chapters 485 and 486 of the Acts of 2017, this chapter was shared with local health departments and the Department of Public Safety and Correctional Services. 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.

As part of the proposal required per Chapters 485 and 486 of the Acts of 2017, these regulations were posted in the Maryland Register on January 19, 2018.

(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.

None. The Department did not receive any comments from stakeholders when these regulations were sent out for review as part of the proposal promulgated in 2018.

(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.

None. This chapter was substantially updated due to changes in statute that passed in 2017. When the recent legislation was proposed (HB 1375/SB 781 (2017)), the Department commented that testing methods and sample collection required by the bill were not practical and would not produce valid results. However, those comments were not addressed in the final version of the bill that passed.

(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:

This chapter was substantially updated as required by Chapters 485 and 486 of the Acts of 2017. Updates included adding hepatitis C as a disease for which a person charged with causing a prohibited exposure may be tested, and amending the regulations to fulfill the testing requirements for prohibited exposures for HIV and hepatitis C.

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:

No action is required at this time. This chapter was substantially updated per a recent proposal required by Chapters 485 and 486 of the Acts of 2017. Changes to the regulations were affective May 7, 2018. In developing that proposal, the unit reviewed the chapter and made all updates required by legislation, as well as any additional clarifying changes needed.

Person performing review: Annie Olle

Title: Analyst, PHPA

Regulatory Review and Evaluation Act
Evaluation Report Form
2012 – 2020

Chapter Codification: COMAR 10.52.11

Chapter Name: Universal Infection Control Precautions

Authority: Health-General Article, §§18-102, 19-319(h), 19-3A-02(9) and (10), 19-705.3; Health Occupations Article, §§1-207, 4-313(d), 4-315, 6-205, 6-312, 6-505, 7-205, 7-316, 8-205, 8-316, 8-506, 14-205, 14-404, 14-415, 14-506, 15-205, 15-314, 16-205, 16-312, and 16-404; Annotated Code of Maryland

Date Originally Adopted or Last Amended: Regulations .02—.04 were amended effective October 27, 2003. The chapter was originally adopted on February 14, 1994.

Purpose: The purpose of these regulations is to ensure that Maryland health care providers employ "universal precautions" (now referred to as "standard precautions" by the US Centers for Disease Control and Prevention (CDC)) in all health care encounters except for rare emergencies where time does not permit the full application of the precautions. In addition, these regulations require health care facilities and certain medical practices to display an MDH-designated sign entitled "We Take Precautions for You" at the entrance to all facilities and offices.

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? [X] Yes [ ] No

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

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

(4) Are the regulations effective in accomplishing their intended purpose? [X] Yes [ ] 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.

Notices asking for comments on this chapter were sent to MedChi, the Maryland Hospital Association, and the Health Facilities Association of Maryland. No comments or recommendations 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.

Notices asking for comments on the regulations were sent to the MDH Office of Health Care Quality (OHCQ) and to local health officers and local health departments. No comments or recommendations were received. The unit subsequently discussed the requirement that a notice explaining the CDC universal precautions be placed in various health care facilities and health care providers' offices with OHCQ.

(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 notice for public comment was posted in the Maryland Register on November 13, 2017.
The notice for public comment was posted on the MDH website on August 29, 2017.

(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 from stakeholders, affected units, or the public. The unit asked OHCQ whether facilities are complying with the requirement to post a notice on the CDC guidelines for universal precautions and whether the signs are useful. OHCQ commented that they were not aware of the history of the requirement but that if a new sign was developed, it should be downloadable from the website so providers and facilities can access it if they want to post it.

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

No interunit conflicts occurred.

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

Scientific data continue to support the use of the prevention measures specified in these regulations by health care providers. CDC has changed the terminology for these precautions from "universal precautions" to "standard precautions". However, the requirement that a notice explaining the precautions be posted in facilities is antiquated and does not affect patient safety or health outcomes.

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

The unit reviewed the CDC guidelines on "standard precautions" (formerly universal precautions) –see above.

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

No other relevant information was identified.

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)

no action

X amendment

repeal

repeal and adopt new regulations

reorganization

Summary:

Based on a review of the chapter and discussions with OHCQ, the unit believes that there are statutory changes needed in order to make necessary updates to COMAR 10.52.11. The unit plans to address the following two changes in a future departmental proposal:

(1) In order to update "universal precautions" to "standard precautions" in the regulations, there will need to be a proposal to update the terminology in statute first. This would be a comprehensive clean-up bill as there are many instances of "universal precautions" throughout MD code.

(2) The unit believes that the requirement for posting a notice explaining the CDC precautions should be either repealed or modified. The requirement was put in place in the early 1990's, and is not currently enforced. Additionally, there is no evidence documenting that the notice improves patient safety or health outcomes. The notice is required by statute (Health-General Article, §19-319(h) and Health Occupations Article, §1-207), so a departmental proposal is necessary to repeal the requirement. As part of the proposal, the unit will contact the organizations listed in Health Occupations Article §1-207 for feedback on whether the notice is helpful and whether the requirement can be repealed. If, after receiving feedback from stakeholders, the unit decides not to repeal the requirement, the unit will develop new language that can be downloaded from the MDH website that providers and facilities can post.

The unit will also consult with OHCQ in consideration of the above proposal.

Additionally there are several minor updates needed in COMAR 10.52.11 that do not require statutory changes. These include removing two references that no longer exist from the authority line, removing "electrologists" from the list of providers in the definition of "health care professional" because electrologists are now under Title 8 of the Health Occupations Article (Nursing), updating the reference in the "universal precautions definition", and correcting a missing word in the title of Regulation .05.

Person performing review: David Blythe

Title: Director, IDEORB

Regulatory Review and Evaluation Act
Evaluation Report Form
2012 – 2020

Chapter Codification: COMAR 10.52.17

Chapter Name: Maryland Asthma Control Program

Authority: Health-General Article, §§13-1701—13-1706

Date Originally Adopted or Last Amended: July 31, 2006

Purpose: This Chapter facilitates the implementation of the Maryland Asthma Control Program, to the extent allowed by available funding, by providing guidelines for the administration of the Asthma Coalition in its advisory capacity to the Program, and authorizes the Maryland Asthma Control Program to obtain asthma-related data through an asthma data surveillance system.

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? [X] Yes [ ] No

(2) Do the regulations continue to be supported by statutory authority and judicial opinion? [X] Yes [ ] 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? [X] Yes [ ] 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 publication of the regulations for public comment was shared via email with the Children's Environmental Health Protection and Advisory Council, the Green and Healthy Homes Initiative, and the Maryland Environmental Health Network. The Maryland Statewide Asthma Coalition ceased to operate in 2014-15 and was not part of the review process.

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

None

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

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

Comments from the public were solicited through a public notice in the Maryland Register which was published January 5, 2018. In addition, a notice was placed on the "open for comments" section of the Maryland Department of Health's website. No comments were received over the 30 day comment period.

(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. In a meeting with the Office of Minority Health and Health Disparities, the two units (EHB and OMHHD) agreed that asthma was a Departmental priority, and agreed that they would work together to address health disparities related to asthma. The publication of the regulations for public comments was also shared within the Prevention and Health Promotion Administration with the Maternal and Child Health Bureau and the Cancer and Chronic Disease Bureau. No comments were received.

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

Data from the Health Services Cost Review Commission (HSCRC) continue to show significant disparities between blacks and whites regarding emergency department visits and hospitalizations due to asthma.

(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.

In June, 2017, the Department received approval for a Health Services Initiative (HSI) under the Children's Health Insurance Program (CHIP) in the form of a State Plan Amendment (SPA), for a program to support asthma and lead interventions in nine local health departments. The SPA permits Medicaid to reimburse the LHDs for home visits (3 – 6 visits) for children with moderate to severe persistent asthma.

This initiative will be evaluated by the Department and Centers for Medicare & Medicaid Services and is expected to significantly improve health outcomes and reduce cumulative costs related to the care of children with more severe asthma. The Department expects that it will make a significant contribution to asthma care in the State.

Health care delivery continues to focus on reducing costs associated with asthma. This intervention supports home-based environmental interventions that complement clinical management to decrease emergency department visits and high health care utilization rates related to asthma.

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)

X no action

amendment

repeal

repeal and adopt new regulations

reorganization

Summary:

Although the Department lost Federal funding for an asthma control program in 2014, the new Health Services Initiative developed by the Department offers the prospect of a sustainable model to improve asthma outcomes and reduce health disparities across the State. No changes are required to the current regulations.

Person performing review:	Clifford S. Mitchell
Title:	Director, Environmental Health Bureau