

IN THIS ISSUE

Regulatory Review and Evaluation Regulations Special Documents General Notices

Pursuant to State Government Article, §7-206, Annotated Code of Maryland, this issue contains all previously unpublished documents required to be published, and filed on or before June 8, 2015, 5 p.m.

Pursuant to State Government Article, §7-206, Annotated Code of Maryland, I hereby certify that this issue contains all documents required to be codified as of June 8, 2015.

Brian Morris Administrator, Division of State Documents Office of the Secretary of State



Information About the Maryland Register and COMAR

MARYLAND REGISTER

The Maryland Register is an official State publication published every other week throughout the year. A cumulative index is published quarterly.

The Maryland Register is the temporary supplement to the Code of Maryland Regulations. Any change to the text of regulations published in COMAR, whether by adoption, amendment, repeal, or emergency action, must first be published in the Register.

The following information is also published regularly in the Register:

- Governor's Executive Orders
- Attorney General's Opinions in full text
- Open Meetings Compliance Board Opinions in full text
- State Ethics Commission Opinions in full text
- Court Rules
- · District Court Administrative Memoranda
- Courts of Appeal Hearing Calendars
- Agency Hearing and Meeting Notices
- Synopses of Bills Introduced and Enacted by the General Assembly
- Other documents considered to be in the public interest

CITATION TO THE MARYLAND REGISTER

The Maryland Register is cited by volume, issue, page number, and date. Example:

• 19:8 Md. R. 815—817 (April 17, 1992) refers to Volume 19, Issue 8, pages 815—817 of the Maryland Register issued on April 17, 1992.

CODE OF MARYLAND REGULATIONS (COMAR)

COMAR is the official compilation of all regulations issued by agencies of the State of Maryland. The Maryland Register is COMAR's temporary supplement, printing all changes to regulations as soon as they occur. At least once annually, the changes to regulations printed in the Maryland Register are incorporated into COMAR by means of permanent supplements.

CITATION TO COMAR REGULATIONS

COMAR regulations are cited by title number, subtitle number, chapter number, and regulation number. Example: COMAR 10.08.01.03 refers to Title 10, Subtitle 08, Chapter 01, Regulation 03.

DOCUMENTS INCORPORATED BY REFERENCE

Incorporation by reference is a legal device by which a document is made part of COMAR simply by referring to it. While the text of an incorporated document does not appear in COMAR, the provisions of the incorporated document are as fully enforceable as any other COMAR regulation. Each regulation that proposes to incorporate a document is identified in the Maryland Register by an Editor's Note. The Cumulative Table of COMAR Regulations Adopted, Amended or Repealed, found online, also identifies each regulation incorporating a document. Documents incorporated by reference are available for inspection in various depository libraries located throughout the State and at the Division of State Documents. These depositories are listed in the first issue of the Maryland Register published each year. For further information, call 410-974-2486.

HOW TO RESEARCH REGULATIONS

An Administrative History at the end of every COMAR chapter gives information about past changes to regulations. To determine if there have been any subsequent changes, check the "Cumulative Table of COMAR Regulations Adopted, Amended, or Repealed" which is found online at http://www.dsd.state.md.us/PDF/CumulativeTable.pdf. This table lists the regulations in numerical order, by their COMAR number, followed by the citation to the Maryland Register in which the change occurred. The Maryland Register serves as a temporary supplement to COMAR, and the two publications must always be used together. A Research Guide for Maryland Regulations is available. For further information, call 410-260-3876.

SUBSCRIPTION INFORMATION

For subscription forms for the Maryland Register and COMAR, see the back pages of the Maryland Register. Single issues of the Maryland Register are \$15.00 per issue.

CITIZEN PARTICIPATION IN THE REGULATION-MAKING PROCESS

Maryland citizens and other interested persons may participate in the process by which administrative regulations are adopted, amended, or repealed, and may also initiate the process by which the validity and applicability of regulations is determined. Listed below are some of the ways in which citizens may participate (references are to State Government Article (SG),

Annotated Code of Maryland):

- By submitting data or views on proposed regulations either orally or in writing, to the proposing agency (see "Opportunity for Public Comment" at the beginning of all regulations appearing in the Proposed Action on Regulations section of the Maryland Register). (See SG, §10-112)
- By petitioning an agency to adopt, amend, or repeal regulations. The agency must respond to the petition. (See SG §10-123)
- By petitioning an agency to issue a declaratory ruling with respect to how any regulation, order, or statute enforced by the agency applies. (SG, Title 10, Subtitle 3)
- By petitioning the circuit court for a declaratory judgment on the validity of a regulation when it appears that the regulation interferes with or impairs the legal rights or privileges of the petitioner. (SG, §10-125)
- By inspecting a certified copy of any document filed with the Division of State Documents for publication in the Maryland Register. (See SG, §7-213)

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COMAR Online

The Code of Maryland Regulations is available at www.dsd.state.md.us as a free service of the Office of the Secretary of State, Division of State Documents. The full text of regulations is available and searchable. Note, however, that the printed COMAR continues to be the only official and enforceable version of COMAR.

The Maryland Register is also available a www.dsd.state.md.us.

For additional information, visit www.sos.state.md.us, Division of State Documents, or call us at (410) 974-2486 or 1 (800) 633-9657.

Availability of Monthly List of Maryland Documents

The Maryland Department of Legislative Services receives copies of all publications issued by State officers and agencies. The Department prepares and distributes, for a fee, a list of these publications under the title "Maryland Documents". This list is published monthly, and contains bibliographic information concerning regular and special reports, bulletins, serials, periodicals, catalogues, and a variety of other State publications. "Maryland Documents" also includes local publications.

Anyone wishing to receive "Maryland Documents" should write to: Legislative Sales, Maryland Department of Legislative Services, 90 State Circle, Annapolis, MD 21401.

CLOSING DATES AND ISSUE DATES through JANUARY 22, 2016

Issue Date	Emergency and Proposed Regulations 5 p.m.*	Final Regulations 10:30 a.m.	Notices, etc. 10:30 a.m.
July 10	June 22	July 1	June 29
July 24	July 6	July 15	July 13
August 7	July 20	July 29	July 27
August 21	August 3	August 12	August 10
September 4	August 17	August 26	August 24
September 18**	August 31	September 9	September 4
October 2	September 14	September 23	September 21
October 16	September 28	October 7	October 5
October 30**	October 9	October 21	October 19
November 13	October 26	November 4	November 2
November 30***	November 9	November 18	November 16
December 11**	November 20	December 2	November 30
December 28***	December 7	December 16	December 14
January 8**	December 18	December 30	December 28
January 22	January 4	January 13	January 11

^{*} Due date for documents containing 8 to 18 pages — 48 hours before date shown; due date for documents exceeding 18 pages — 1 week before date shown

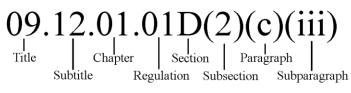
NOTE: ALL DOCUMENTS MUST BE SUBMITTED IN TIMES NEW ROMAN, 9-POINT, SINGLE-SPACED FORMAT. THE REVISED PAGE COUNT REFLECTS THIS FORMATTING.

- ** Note closing date changes
- *** Note issue date and closing date changes

The regular closing date for Proposals and Emergencies is Monday.

REGULATIONS CODIFICATION SYSTEM

Under the COMAR codification system, every regulation is assigned a unique four-part codification number by which it may be identified. All regulations found in COMAR are arranged by title. Each title is divided into numbered subtitles, each subtitle is divided into numbered chapters, and each chapter into numbered regulations.



A regulation may be divided into lettered sections, a section divided into numbered subsections, a subsection divided into lettered paragraphs, and a paragraph divided into numbered subparagraphs.

Cumulative Table of COMAR Regulations Adopted, Amended, or Repealed

This table, previously printed in the Maryland Register lists the regulations, by COMAR title, that have been adopted, amended, or repealed in the Maryland Register since the regulations were originally published or last supplemented in the Code of Maryland Regulations (COMAR). The table is no longer printed here but may be found on the Division of State Documents website at www.dsd.state.md.us.

Table of Pending Proposals

The table below lists proposed changes to COMAR regulations. The proposed changes are listed by their COMAR number, followed by a citation to that issue of the Maryland Register in which the proposal appeared. Errata pertaining to proposed regulations are listed, followed by "(err)". Regulations referencing a document incorporated by reference are followed by "(ibr)". None of the proposals listed in this table have been adopted. A list of adopted proposals appears in the Cumulative Table of COMAR Regulations Adopted, Amended, or Repealed.

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10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE

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Regulatory Review and Evaluation

Regulations promulgated under the Administrative Procedure Act will undergo a review by the promulgating agency in accordance with the Regulatory Review and Evaluation Act (State Government Article, §§10-130 — 10-139; **COMAR 01.01.2003.20**). This review will be documented in an evaluation report which will be submitted to the General Assembly's Joint Committee on Administrative, Executive, and Legislative Review. The evaluation reports have been spread over an 8-year period (see **COMAR 01.01.2003.20** for the schedule). Notice that an evaluation report is available for public inspection and comment will be published in this section of the Maryland Register.

TITLE 31 MARYLAND INSURANCE ADMINISTRATION

Subtitle 01 GENERAL PROVISIONS

Notice of Availability of Evaluation Report

Pursuant to State Government Article, §10-135(b)(1), Annotated Code of Maryland, Regulatory Review and Evaluation Act, and Executive Order 01.01.2003.20, notice is hereby given that the Evaluation Report regarding COMAR 31.01.01 is available for public inspection and comment for a period of 60 days following the date of this notice.

This report may be reviewed online at http://www.mdinsurance.state.md.us/sa/news-center/proposed-regulations.html or by appointment at the Maryland Insurance Administration, 200 St. Paul Place, Suite 2700, Baltimore, MD 21202. Information and appointments may be obtained by contacting Catherine Grason, Director of Regulatory Affairs, at 410-468-2201 or by email at insuranceregreview.mia@maryland.gov.

[15-13-32]

Subtitle 02 POWERS AND DUTIES — HEARINGS

Notice of Availability of Evaluation Report

Pursuant to State Government Article, \$10-135(b)(1), Annotated Code of Maryland, Regulatory Review and Evaluation Act, and Executive Order 01.01.2003.20, notice is hereby given that the Evaluation Report regarding COMAR 31.02.01, 31.02.03, 31.02.04, 31.02.05, and 31.02.06 is available for public inspection and comment for a period of 60 days following the date of this notice.

This report may be reviewed online at http://www.mdinsurance.state.md.us/sa/news-center/proposed-regulations.html or by appointment at the Maryland Insurance Administration, 200 St. Paul Place, Suite 2700, Baltimore, MD 21202. Information and appointments may be obtained by contacting Catherine Grason, Director of Regulatory Affairs, at 410-468-2201 or by email at insuranceregreview.mia@maryland.gov.

[15-13-38]

Subtitle 03 INSURANCE PRODUCERS AND OTHER INSURANCE PROFESSIONALS

Notice of Availability of Evaluation Report

Pursuant to State Government Article, §10-135(b)(1), Annotated Code of Maryland, Regulatory Review and Evaluation Act, and Executive Order 01.01.2003.20, notice is hereby given that the Evaluation Report regarding COMAR 31.03.01, 31.03.02, 31.03.03, 31.03.04, 31.03.05, 31.03.07, 31.03.09, 31.03.10. 31.03.11 and 31.03.13 is available for public inspection and comment for a period of 60 days following the date of this notice.

This report may be reviewed online at http://www.mdinsurance.state.md.us/sa/news-center/proposed-regulations.html or by appointment at the Maryland Insurance Administration, 200 St. Paul Place, Suite 2700, Baltimore, MD 21202. Information and appointments may be obtained by contacting Catherine Grason, Director of Regulatory Affairs, at 410-468-2201 or by email at insuranceregreview.mia@maryland.gov.

[15-13-33]

Final Action on Regulations

Symbol Kev

- Roman type indicates text already existing at the time of the proposed action.
- Italic type indicates new text added at the time of proposed action.
- <u>Single underline, italic</u> indicates new text added at the time of final action.
- Single underline, roman indicates existing text added at the time of final action.
- [[Double brackets]] indicate text deleted at the time of final action.

Title 08 DEPARTMENT OF NATURAL RESOURCES

Subtitle 02 FISHERIES SERVICE

08.02.15 Striped Bass

Authority: Natural Resources Article, §4-215, Annotated Code of Maryland

Notice of Final Action

[15-120-F]

On June 17, 2015, the Secretary of Natural Resources adopted amendments to Regulations .08—.10 under COMAR 08.02.15 Striped Bass. This action, which was proposed for adoption in 42:9 Md. R. 649—650 (May 1, 2015), has been adopted as proposed. Effective Date: July 6, 2015.

MARK J. BELTON Secretary of Natural Resources

Title 14 INDEPENDENT AGENCIES

Subtitle 36 MARYLAND LONGITUDINAL DATA SYSTEM CENTER

Notice of Final Action

[15-099-F]

On May 6, 2015, the Governing Board of the Maryland Longitudinal Data System Center adopted:

- (1) New Regulations .01 .05 under a new chapter, COMAR 14.36.05 Data Collection; and
- (2) New Regulations .01 .03 under a new chapter, COMAR 14.36.06 Center Staff.

This action, which was proposed for adoption in 42:6 Md. R. 541—543 (March 20, 2015), has been adopted as proposed.

Effective Date: July 6, 2015.

ROSS GOLDSTEIN Executive Director

Withdrawal of Regulations

Title 12 DEPARTMENT OF PUBLIC SAFETY AND CORRECTIONAL SERVICES

Subtitle 01 CRIMINAL INJURIES COMPENSATION BOARD

12.01.01 General Regulations

Authority: Criminal Procedure Article, §11-805, Annotated Code of Maryland

Notice of Withdrawal

[14-086-W]

Pursuant to State Government Article, §10-116(b), Annotated Code of Maryland, notice is given that the proposal to amend Regulations .04—.12 under COMAR 12.01.01 General Regulations, which was published in 41:7 Md. R. 426—429 (April 4, 2014), has been withdrawn by operation of law.

BRIAN MORRIS Administrator Division of State Documents

Proposed Action on Regulations

For information concerning citizen participation in the regulation-making process, see inside front cover.

Symbol Key

- Roman type indicates existing text of regulation.
- *Italic type* indicates proposed new text.
- · [Single brackets] indicate text proposed for deletion.

Promulgation of Regulations

An agency wishing to adopt, amend, or repeal regulations must first publish in the Maryland Register a notice of proposed action, a statement of purpose, a comparison to federal standards, an estimate of economic impact, an economic impact on small businesses, a notice giving the public an opportunity to comment on the proposal, and the text of the proposed regulations. The opportunity for public comment must be held open for at least 30 days after the proposal is published in the Maryland Register.

Following publication of the proposal in the Maryland Register, 45 days must pass before the agency may take final action on the proposal. When final action is taken, the agency must publish a notice in the Maryland Register. Final action takes effect 10 days after the notice is published, unless the agency specifies a later date. An agency may make changes in the text of a proposal. If the changes are not substantive, these changes are included in the notice of final action and published in the Maryland Register. If the changes are substantive, the agency must repropose the regulations, showing the changes that were made to the originally proposed text.

Proposed action on regulations may be withdrawn by the proposing agency any time before final action is taken. When an agency proposes action on regulations, but does not take final action within 1 year, the proposal is automatically withdrawn by operation of law, and a notice of withdrawal is published in the Maryland Register.

Title 02 OFFICE OF THE ATTORNEY GENERAL

Subtitle 06 GENERAL REGULATIONS

02.06.03 "Instructions on Current Life-Sustaining Treatment Options" Form

Authority: Health-General Article, §5-608.1, Annotated Code of Maryland

Notice of Proposed Action

[15-154-P]

The Office of the Attorney General proposes to repeal in their entirety Regulations .01—.10 under COMAR 02.06.03 "Instructions on Current Life-Sustaining Treatment Options" Form.

Statement of Purpose

The purpose of this action is to implement that portion of Ch. 434, Acts of 2011, which repealed the provisions regarding an "Instructions on Current Life-Sustaining Treatment Options" form. In accordance with this statute, this form has been replaced with the "Medical Orders for Life-Sustaining Treatment" form contained in COMAR 10.01.21.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

The proposed action has no economic impact.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Paul J. Ballard, Counsel for Health Decisions Policy and the Office of Health Care Quality, Department of Health and Mental Hygiene, 300 West Preston Street, Suite 302, Baltimore, MD 21201, or call 410-767-6518 (TTY 800-735-2258), or email to Paul.ballard@maryland.gov, or fax to 410-333-7894. Comments will be accepted through July 27, 2015. A public hearing has not been scheduled.

BRIAN E. FROSH Maryland Attorney General

Title 08 DEPARTMENT OF NATURAL RESOURCES

Subtitle 02 FISHERIES SERVICE

08.02.15 Striped Bass

Authority: Natural Resources Article, §4-215, Annotated Code of Maryland

Notice of Proposed Action

[15-167-P]

The Secretary of Natural Resources proposes to amend Regulation .07 under COMAR 08.02.15 Striped Bass.

Statement of Purpose

The purpose of this action is to modify the season and tolerance limits of the Atlantic striped bass commercial fishery. The Atlantic striped bass commercial permit holders requested a review of their current tolerance limit of 50 pounds per individual. Tolerance limits in this fishery changed when the Atlantic permits were converted to an Individual Transferable Quota (ITQ) fishery in 2015. The proposed action changes the tolerance from 50 pounds to a tolerance of 4% with a 50 pound minimum. Since the Atlantic operates as an ITQ fishery (no daily creel limit), the tolerance would come into play

when the individual's allocation has been reached. The tolerance is not a 4% tolerance on the initial allocation. It is an allowance to prevent a harvester from receiving a citation for incorrectly estimating how many pounds of fish are on the vessel on the final harvest day. If the harvester exceeds their allocation by more than the tolerance, they may receive a citation. The proposed action makes it clear that anyone in an ITQ fishery (Chesapeake Bay and Atlantic) who exceeds their allocation may have the overage deducted the following quota year. The 'shall be deducted' was changed to 'may be deducted' to allow the Department and the industry some flexibility in determining how the overage is deducted.

The industry also asked the Department to consider a permanent expansion of the Atlantic season to allow striped bass harvest in May and October. Currently, the Atlantic fishery is open from January—April and November—December. Adding 2 months to the season would provide permit holders more opportunity to harvest their quota. Over the past 6 years, the Atlantic fishery has harvested an average of 64% of their available quota. The proposed action expands the season to allow striped bass harvest in May and October.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

I. Summary of Economic Impact. The proposed action may impact the commercial fishing industry.

II. Types of Economic Impact.	Revenue (R+/F Expenditure (E+/E-)	R-) Magnitude
A. On issuing agency:	NONE	
B. On other State agencies:	NONE	
C. On local governments:	NONE	
	Benefit (+) Cost (-)	Magnitude

D. On regulated industries or trade groups:

(1) Season

Extension—Commercial

Harvesters (+)

(2) Season

Extension—Commercial

Industry (+) Indeterminable

\$96,453

(3) Tolerance NONE

E. On other industries or

trade groups: NONE

F. Direct and indirect

effects on public: NONE

III. Assumptions. (Identified by Impact Letter and Number from Section II.)

D(1). Harvest of striped bass from state waters of the Atlantic Ocean have averaged 71,652 pounds from 2010-2014. The quota allocated to the Maryland Atlantic coast fishery through the Atlantic States Marine Fisheries Commission is currently 98,670 pounds. The average ex-vessel price (the price received by the fisherman at point of landing) per pound of striped bass in 2014 was \$3.57. Therefore, opening two additional months, May and October, may allow permitted harvesters to land the average unharvested quota (27,018).

pounds), which is roughly equivalent to a value of \$96,453.

D(2). The value to the commercial industry increases from the exvessel price, calculated for the harvesters, when you factor in the added value to the fish dealers, packers, store fronts, and restaurants that buy and sell striped bass, but that total value is indeterminable.

D(3). The tolerance is not additional allocation. It is an allowance to prevent a harvester from receiving a citation for incorrectly estimating how many pounds of fish are on the vessel at one time. If the harvester exceeds their allocation by more than the tolerance, they may receive a citation. If a harvester exceeds their allocation, by any amount, they may have the overage deducted from the next quota allocation.

Economic Impact on Small Businesses

The proposed action has a meaningful economic impact on small business. An analysis of this economic impact follows.

The extension of the commercial season may benefit commercial fishermen, fish dealers, packers, store fronts, and restaurants. Please see assumptions for details.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Atlantic Striped Bass Regulations, Regulatory Staff, DNR, Fisheries Service, B-2, 580 Taylor Avenue, Annapolis, MD 21401, or call 410-260-8300, or email to fisheriespubliccomment.dnr@maryland.gov, or fax to 410-260-8310. Comments will be accepted through July 27, 2015. A public hearing has not been scheduled.

.07 Commercial Fishery.

- A. (text unchanged)
- B. Atlantic Ocean, its Coastal Bays and Their Tributaries.
 - (1)—(2) (text unchanged)
- (3) Season. The commercial season for the taking of striped bass for all gears is [November 1 through April 30] October 1 through May 31.
 - (4)—(7) (text unchanged)
 - C.—E. (text unchanged)
 - F. General.
 - (1) (text unchanged)
- [(2) A commercial tidal fish licensee in the Atlantic Ocean fishery may not catch more than the licensee's catch limit assigned to the striped bass permit except as provided by the tolerance allowance in pounds as follows:
- (a) For a daily catch limit, there is a 50-pound tolerance allowance:
- (b) For a weekly catch limit, there is a 50-pound tolerance allowance; and
- (c) For a seasonal catch limit, there is a 50-pound tolerance allowance.]
 - (2) Atlantic Tolerance.
- (a) A commercial tidal fish licensee registered in the Atlantic fishery is not in violation of this chapter if their landings do not exceed their allocation by more than the tolerance described in F(2)(b) of this regulation.
- (b) The tolerance for the Atlantic fishery is the greater of either 50 pounds or 4 percent of the remaining allocation available to the permit holder on the final trip when the allocation is fully harvested.
 - (3) (text unchanged)
 - (4) Overage Deductions.
- (a) If a commercial tidal fish licensee registered in the Chesapeake Bay individual transferable quota *or Atlantic* fishery exceeds the licensee's allocation, that overage [shall] *may* be

deducted from the allocation the licensee receives in the next practicable quota year.

(b) (text unchanged)

(5)—(6) (text unchanged)

MARK J. BELTON Secretary of Natural Resources

Subtitle 03 WILDLIFE

08.03.03 Open Seasons, Bag Limits for Game Birds and Game Animals

Authority: Natural Resources Article, §10-410, Annotated Code of Maryland

Notice of Proposed Action

[15-161-P]

The Secretary of Natural Resources proposes to amend Regulation .01 under COMAR 08.03.03 Open Seasons, Bag Limits for Game Birds and Game Animals.

Statement of Purpose

The purpose of this action is to add additional Sunday hunting dates to the bow deer season in Allegany, Carroll, Frederick, Garrett and Washington counties. This action will also add the State forests in Allegany and Garrett counties to the list of designated public lands open to Sunday hunting in those counties. Language in Natural Resources Article, §10-410, Annotated Code of Maryland gives the Department the ability to select which Sundays and designated public lands are open for Sunday hunting in these five counties.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

The proposed action has no economic impact.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Peter Jayne, Associate Director, Wildlife and Heritage Service, Department of Natural Resources, P.O. Box 68, Wye Mills, MD 21679, or call 410-827-8612, or email to peter.jayne@maryland.gov, or fax to 410-827-5186. Comments will be accepted through July 27, 2015. A public hearing has not been scheduled.

.01 Bag Limits and Possession Limits.

A.—C. (text unchanged)

- D. Hunting on Sunday.
 - (1) (text unchanged)
 - (2) An individual may hunt on Sunday, if the individual is:
 - (a)—(c) (text unchanged)
- (d) Hunting white-tailed or sika deer on private property as described in Regulations .07 and .08 of this chapter:
 - (i)—(iii) (text unchanged)
- (iv) On [the last three] *all* Sundays in October and [the first two Sundays in] November during the deer bow season, all Sundays in December and January during the deer muzzleloader season, and all Sundays in the deer firearms season in Carroll County; and

- (v) (text unchanged)
- (e) 16 years of age or younger when participating in the Junior Deer Hunt on private property in Allegany, Frederick, Garrett and Washington counties or a designated Wildlife Management Area or State Forest listed in §G of this regulation;
- (f) Hunting deer on private property or a designated Wildlife Management Area or State Forest listed in §G of this regulation on [the last three] all Sundays in October and [the first two Sundays in] November during the deer bow season, all Sundays in December and January during the deer muzzleloader season, and all Sundays in the deer firearms season in Allegany, Frederick, Garrett and Washington counties:
 - (g)—(h) (text unchanged)
- (i) Hunting any game mammal or any game bird, except deer, migratory game birds or wetland game birds, in Allegany, Garrett and Washington counties on private property or a designated Wildlife Management Area *or State Forest* listed in §G of this regulation during the open seasons for those game animals.
 - E.—F. (text unchanged)
- G. The Wildlife Management Areas *and State Forests* designated for Sunday hunting in accordance with §D of this regulation are as follows:
 - (1)—(3) (text unchanged)
 - (4) Garrett State Forest;
 - (5) Green Ridge State Forest;
 - [(4)](6)—[(5)](7) (text unchanged)
 - (8) Potomac State Forest;
 - [(6)](9) (text unchanged)
 - (10) Savage River State Forest;
 - [(7)] (11)—[(8)] (12) (text unchanged)

MARK J. BELTON Secretary of Natural Resources

Subtitle 03 WILDLIFE

08.03.03 Open Seasons, Bag Limits for Game Birds and Game Animals

Authority: Natural Resources Article, §§10-205, 10-405, and 10-406, Annotated Code of Maryland

Notice of Proposed Action

[15-162-P]

The Secretary of Natural Resources proposes to amend Regulation .07 under COMAR 08.03.03 Open Seasons, Bag Limits for Game Birds and Game Animals.

Statement of Purpose

The purpose of this action is to clarify that junior hunters are exempt from the provisions of the antler point restrictions established in COMAR 08.03.03.07. Any person that possesses, or is eligible to possess a Resident or Nonresident Junior Hunting License will be exempt from the antler point restrictions.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

The proposed action has no economic impact.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Peter Jayne, Associate Director, Wildlife and Heritage Service, Department of Natural Resources, P.O. Box 68, Wye Mills, MD 21679, or call 410-827-8612, or email to peter.jayne@maryland.gov, or fax to 410-827-5186. Comments will be accepted through July 27, 2015. A public hearing has not been scheduled.

.07 White-Tailed Deer.

A. (text unchanged)

71. (text unen		1
	Season Dates, subject to	Season Bag Limits
	COMAR 08.03.03.01D	
B. Antlered.		
(1)—(3) (tex	t unchanged)	
(4) All season	ns combined.	
		(a) No more than two antlered deer having less than three antler points one inch or longer on each antler present may be taken per license year. Hunters that possess, or are eligible to possess, a Resident or Nonresident Junior Hunting License are exempt from this requirement. (b) (text unchanged)
C.—D. (text und	changed)	
		II May the second

E. A hunter may only harvest two antlered deer per license year, including the Bonus antlered deer, that have antlers with less than three antler points one inch or longer on each antler. Hunters that possess, or are eligible to possess, a Resident or Nonresident Junior Hunting License are exempt from this requirement.

F. (text unchanged)

MARK J. BELTON Secretary of Natural Resources

Subtitle 03 WILDLIFE

08.03.04 Forest Wildlife

Authority: Natural Resources Article, §10-408, Annotated Code of Maryland

Notice of Proposed Action

[15-163-P]

The Secretary of Natural Resources proposes to amend Regulation .05 under COMAR 08.03.04 Forest Wildlife.

Statement of Purpose

The purpose of this action is to comply with legislation passed during the 2014 General Assembly. This legislation establishes who may carry a handgun while archery hunting for deer in Management Region A, which includes Allegany and Garrett counties and the western portion of Washington County. The legislation further described what handguns may be carried by these bow hunters and the purposes for which the handguns may be used.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

The proposed action has no economic impact.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Peter Jayne, Associate Director, Wildlife and Heritage Service, Department of Natural Resources, P.O. Box 68, Wye Mills, MD 21679, or call 410-827-8612, or email to peter.jayne@maryland.gov, or fax to 410-827-5186. Comments will be accepted through July 27, 2015. A public hearing has not been scheduled.

.05 Devices for Hunting Deer and Black Bear.

A. Bow.

- (1)—(2) (text unchanged)
- (3) An individual may not:
- (a) Possess firearms while hunting with a bow during the deer bow hunting season[;], except in Deer Management Region A as described in COMAR 08.03.03.06A(2)(a), a person 21 years old or older may carry a handgun for personal protection while hunting deer in the bow season if that handgun:
 - (i) Has a barrel length not exceeding 6 inches;
- (ii) Does not have a telescopic sight or electronic aiming device attached; and
- (iii) Is not used to kill wildlife wounded by a vertical bow or crossbow.
 - (b)—(d) (text unchanged)
 - (4)—(6) (text unchanged)
 - B.—F. (text unchanged)

MARK J. BELTON Secretary of Natural Resources

Subtitle 03 WILDLIFE

08.03.05 Upland Game Birds and Mammals

Authority: Resources Article, §10-205, Annotated Code of Maryland

Notice of Proposed Action

[15-164-P]

The Secretary of Natural Resources proposes to amend Regulation .04 under COMAR 08.03.05 Upland Game Birds and Mammals.

Statement of Purpose

The purpose of this action is to allow a DNRid number to be substituted for a hunting license number when a hunter is tagging migratory game birds left in the possession of another person. The DNRid is issued once by the Department to each person that purchases any type of license or to landowners so that they can check in deer or turkeys harvested on their private property during legal hunting seasons. The DNRid is the same number throughout the life of the person.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

The proposed action has no economic impact.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Peter Jayne, Associate Director, Wildlife and Heritage Service, Department of Natural Resources, P.O. Box 68, Wye Mills, MD 21679, or call 410-827-8612, or email to peter.jayne@maryland.gov, or fax to 410-827-5186. Comments will be accepted through July 27, 2015. A public hearing has not been scheduled.

.04 Migratory Bird Tagging Requirement.

- A. (text unchanged)
- B. Tagging.
- (1) It shall be the responsibility of the hunter to furnish and tag his migratory game birds. The tag shall include the:
 - (a)—(b) (text unchanged)
- (c) Hunting license number *or DNRid* and state where issued, when applicable;
 - (d)—(e) (text unchanged)
 - (2) (text unchanged)
 - C. (text unchanged)

MARK J. BELTON

Secretary of Natural Resources

Subtitle 03 WILDLIFE

08.03.09 Wildlife Possession

Authority: Natural Resources Article, §10-408, Annotated Code of Maryland

Notice of Proposed Action

[15-165-P]

The Secretary of Natural Resources proposes to amend Regulation .11 under COMAR 08.03.09 Wildlife Possession.

Statement of Purpose

The purpose of this action is to comply with emergency legislation passed during the 2015 General Assembly session that repealed language in Natural Resources Article, §10-408.2, Annotated Code of Maryland requiring the Department to offer training sessions on the appropriate use of rifles for the purpose of controlling the deer population in Charles and St. Mary's counties.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

The proposed action has no economic impact.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Peter Jayne, Associate Director, Wildlife and Heritage Service, Department of Natural Resources, P. O. Box 68, Wye Mills, MD 21679, or call 410-827-8612, or email to Peter.jayne@maryland.gov, or fax to 410-827-5186. Comments will be accepted through July 27, 2015. A public hearing has not been scheduled.

.11 Deer Cooperator Permit.

A.—B. (text unchanged)

- C. Qualifications for a Deer Cooperator Permit.
 - (1)—(3) (text unchanged)
 - (4) [Shooting Proficiency.]
- [(a)] Except as provided in \$C(5) of this regulation, an individual applying for a deer cooperator permit is required to successfully complete a shooting proficiency test administered by the Service, or provide proof of successful completion of an approved comparable shooting proficiency test.
- [(b) The Service shall offer training sessions on the safe and appropriate use of rifles for the purpose of controlling the deer population.
- (c) The Service will schedule this training as needed with priority given to persons holding a deer management permit in accordance with COMAR 08.03.04.02.]
 - (5) (text unchanged)
 - D.—P. (text unchanged)

MARK J. BELTON Secretary of Natural Resources

Subtitle 03 WILDLIFE

08.03.14 Waterfowl Outfitting and Guiding

Authority: Natural Resources Article, §10-309, Annotated Code of Maryland

Notice of Proposed Action

[15-166-P]

The Secretary of Natural Resources proposes to amend Regulation .06 under COMAR 08.03.14 Waterfowl Outfitting and Guiding.

Statement of Purpose

The purpose of this action is to allow a DNRid number to be substituted for a hunting license number when a waterfowl hunting guide is maintaining the field records required by this regulation. The DNRid is issued once by the Department to each person that purchases any type of license or to landowners so that they can check in deer or turkeys harvested on their private property during legal hunting seasons. The DNRid is the same number throughout the life of the person.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

The proposed action has no economic impact.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Peter Jayne, Associate Director, Wildlife and Heritage Service, Department of Natural Resources, P.O. Box 68, Wye Mills, MD 21679, or call 410-827-8612, or email to peter.jayne@maryland.gov, or fax to 410-827-5186. Comments will be accepted through July 27, 2015. A public hearing has not been scheduled.

.06 Record-Keeping Requirements.

A.—B. (text unchanged)

- C. The waterfowl hunting guide shall maintain a field record updated within 24 hours following the completion of a hunting day that contains the following information for each hunter:
 - (1)—(2) (text unchanged)

(3) Valid hunting license or DNRid number;

(4)—(6) (text unchanged)

D.—G. (text unchanged)

MARK J. BELTON Secretary of Natural Resources

Subtitle 07 FORESTS AND PARKS

08.07.07 Licensed Tree Experts

Authority: Natural Resources Article, §§1-104 and 5-415—5-423; State Government Article, §10-206; Annotated Code of Maryland

Notice of Proposed Action

[15-149-P]

The Department of Natural Resources proposes to amend Regulations .07 and .08 under COMAR 08.07.07 Licensed Tree Experts.

Statement of Purpose

The purpose of this action is to include language stating the continuing education requirements in the regulations as required by statute and to clarify the intent of imposition of a suspension and revocation.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

I. Summary of Economic Impact. This amendment will require those renewing their tree expert license to complete continuing education instruction prior to the renewal of their license. Instruction will be offered by various entities at varying costs depending on the entity and instruction length. Attendance will result in a loss of billable hours.

II. Types of Economic Impact.	Revenue (R+/R-) Expenditure (E+/E-)	Magnitude
A. On issuing agency:B. On other State agencies:	NONE NONE	16
C. On local governments:	NONE	
	Benefit (+) Cost (-)	Magnitude
D. On regulated industries or trade groups:	(-)	Potentially significant
E. On other industries or trade groups:	(+)	Potentially significant
F. Direct and indirect effects on public:	NONE	
or trade groups: E. On other industries or trade groups: F. Direct and indirect	(+) NONE	significant Potentially significant

- III. Assumptions. (Identified by Impact Letter and Number from Section II.)
- D. Small companies may have to pay a registration fee and lose billable hours to attend the instruction.
- E. Those companies conducting the instruction will have an increase in attendees and registration fees.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Marian Honeczy, Supervisor, Urban and Community Forestry, MD Forest Service, 580 Taylor Avenue, E-1, Annapolis, MD 21401, or call 410-260-8511, or email to marian.honeczy@maryland.gov. Comments will be accepted through July 27, 2015. A public hearing has not been scheduled.

.07 License Application and Renewal Fees.

- A. An applicant shall pay to the Department, as part of the examination application, a \$30 fee. If the applicant fails an examination, an additional \$20 fee must be paid for each subsequent examination application.
 - B. A tree expert license shall be renewed every 2 years.

[License Renewal Schedule.

- (1) All licensees shall renew their licenses by December 31, 2011, for the 2012 calendar year.
- (2) Commencing with 2011 renewals for the 2012 calendar year:
- (a) Odd-numbered licenses will be renewed for a 2-year period and every subsequent odd-numbered year; and
- (b) Even-numbered licenses will be renewed for a 1-year period and will be renewed for a 2-year period every subsequent even-numbered year.]
 - C. [Renewal Fees.
- (1)] A licensed tree expert shall pay a \$25 fee every 2 years for license renewal [in accordance with the schedule in §C of this regulation].
- [(2) Licensees renewing in accordance with §C(2)(b) of this regulation shall pay a \$10 renewal fee for the 2012 license year.]
- D. Professional Development. Commencing with the 2017 renewals, a licensed tree expert shall complete at least 8 hours of Department-approved continuing education instruction during the preceding 2-year term.
- E. The Department shall review and approve the curriculum for continuing education instruction provided that the curriculum includes information on:
 - (1) New State and federal laws, regulations, and policies; or
 - (2) Technologies affecting the work of a licensed tree expert.
- F. Before a course may be approved and advertised as meeting the continuing education instruction requirement of this section, the course holder shall:
- (1) Submit the course curriculum to the Department for approval at least 4 weeks before the date of the scheduled course; and
- (2) Submit documentation that includes the number of classroom hours, the curriculum, and the entity conducting the
- G. Documentation of completion of a course approved by the Department may be submitted to the Department by:
- (1) A licensed tree expert providing a Certificate of Completion; or
- (2) The approved course holder providing names and license numbers of those who completed the course.
- H. The Department may consider whether a licensee may receive credit for continuing education instruction for a course that was not pre-approved based on a licensee's submission of the documentation required under §§E, F, and G of this regulation.

- I. The Department shall maintain continuing education records for each licensed tree expert to reflect the completion of approved course hours.
- J. If a licensed tree expert does not complete the required continuing education instruction within the 2-year license renewal deadline, the licensee shall only be able to renew a license by taking and passing the tree expert examination given by the Department.

.08 Violation of Regulations.

A.—B. (text unchanged)

C. During the suspension or revocation of a tree expert license, the tree expert shall not engage in performing tree care work, whether or not under the supervision of a licensed tree expert, for the period of the suspension or revocation.

MARK BELTON Secretary of Natural Resources

Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 09 MEDICAL CARE PROGRAMS

10.09.75 Maryland Medicaid Managed Care Program—Corrective Managed Care

Authority: Health-General Article, §15-102.1(b)(9) and 15-103, Annotated Code of Maryland

Notice of Proposed Action

[15-159-P]

The Secretary of Health and Mental Hygiene proposes to repeal existing Regulations .01—.04 and adopt new Regulations .01—.05 under COMAR 10.09.75 Maryland Managed Care Program—Corrective Managed Care.

Statement of Purpose

The purpose of this action is to clarify the criteria and processes for the MCO's corrective managed care (CMC) programs and to require MCOs to implement a CMC program.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

The proposed action has no economic impact.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Michele Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 West Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499; TTY:800-735-2258, or email to dhmh.regs@maryland.gov, or fax to 410-767-6483. Comments will be accepted through July 27, 2015. A public hearing has not been scheduled.

.01 General.

- A. An MCO shall establish a corrective managed care plan that, at minimum, provides for:
- (1) The identification of an enrollee that has abused MCO pharmacy benefits; and
- (2) The enrollment of an enrollee that has been determined to have abused MCO pharmacy benefits in the MCO's corrective managed care plan.
 - B. Enrollee abuse exists when an enrollee:
- (1) Has engaged in behaviors identified in COMAR 10.09.24.14-1; or
- (2) Engages in Medicaid fraud as defined under COMAR 10.09,24.14.

.02 Corrective Managed Care Plan.

- A. An MCO's corrective managed care plan:
- (1) Shall cover enrollee abuse of medical assistance pharmacy benefits; and
- (2) May cover enrollee abuse of nonpharmacy medical assistance benefits.
- B. For all benefit abuse covered by an MCO's corrective managed care plan, the plan shall:
- (1) Use the criteria as described in Regulation .01B of this regulation to determine if enrollees have abused benefits;
- (2) Provide for a medical review of the alleged abuse consistent with \$C of this regulation;
- (3) Provide that an enrollee found to have abused benefits will be enrolled in the program for 24 months;
- (4) Provide that an enrollee who has been enrolled in a 24 month plan and is subsequently found to have abused MCO benefits shall be enrolled in the plan for an additional 36 months;
- (5) Provide for the MCO to select any participating provider in the MCO that meets the requirements of COMAR 10.09.66.05A to serve as the enrollee's primary care, specialty care, and pharmacy providers for enrollees in corrective managed care, as appropriate to the type of benefit the enrollee has been found to have abused;
- (6) Except for an emergency or pursuant to hospital inpatient treatment, require an enrollee to obtain prescribed drugs only from a single designated pharmacy provider, which may be any pharmacy or any single branch of a pharmacy chain that participates in the MCO and meets the requirements of COMAR 10.09.66.06B and .07C(2);
- (7) Provide enrollees determined to have abused benefits the ability to suggest primary care, specialty care, or pharmacy providers:
- (8) Require the MCO to accept the enrollee's suggestion referenced in \$B(7) of this regulation unless the MCO determines that the recipient's choice of provider would not serve the enrollee's best interest in achieving appropriate use of the health care systems and benefits available through the MCO;
- (9) Provide an enrollee determined to have abused benefits 20 days to present additional documentation to explain the facts that serve as the basis for the MCO's determination of benefit abuse, consistent with \$D of this regulation;
- (10) Provide for the designation of a new primary care, specialty care, or pharmacy provider if the enrollee moves out of the service area of the current primary care or pharmacy provider;
- (11) Provide for prompt reporting to the Department the name of any enrollee enrolled in the MCO's program, the duration of enrollment, or any change in the duration of enrollment; and
 - (12) Be submitted to the Department for review and approval:
- (a) Within 60 days of the effective date of this regulation; and
 - (b) Before the implementation of any modification.

- C. The medical review required in $\S B(2)$ of this regulation shall:
- (1) Be performed by a medical reviewer who is a licensed health care professional;
- (2) Consider all information that is relevant and available to the MCO, including but not limited to MCO payment records and information secured from any interviews conducted; and
- (3) Where appropriate, consider records obtained from other sources, including:
 - (a) Providers of medical services;
 - (b) Statistical reports;
 - (c) Outside complaints;
 - (d) Referrals from other agencies; or
 - (e) Any other appropriate sources.
- D. If an enrollee provides additional information pursuant to $\S B(9)$ of this regulation within 20 days:
- (1) The effective date of the enrollment provided in the notice shall be tolled pending the MCO's review of the additional information;
- (2) The MCO shall consider whether the additional information changes the MCO's determination regarding the appropriateness of the enrollee's enrollment in corrective managed care;
- (3) The MCO shall notify the enrollee of its decision whether the MCO is affirming or reversing its determination to enroll the enrollee in corrective managed care; and
- (4) If the MCO confirms its determination to enroll the enrollee in corrective managed care, the notice shall:
- (a) Identify the effective date and duration of that enrollment; and
- (b) Include an explanation of the enrollee's right to appeal the determination as described in Regulation .05 of this chapter.
- E. An MCO's corrective managed care plan may include a process for re-considering, at any interval of time, a decision to enroll an enrollee in the MCO's corrective managed care plan, if the process entitles the enrollee to appeal the decision pursuant to Regulation .05 of this chapter at the same interval of time.

.03 Enrollee Notice.

The MCO shall provide an enrollee determined to have abused MCO benefits a written notice that includes the following:

- A. An explanation of the reason or reasons for the determination that the enrollee abused benefits;
 - B. A statement that the enrollee has 20 days to provide:
- (1) Additional information for the MCO to consider before enrollment will become effective; and
 - (2) The address where the additional information shall be sent;
- C. If the enrollee does not provide additional information referenced in §B of this regulation, a statement that the enrollee will be enrolled in corrective managed care and the effective date and duration of that enrollment;
- D. A statement that the enrollee may identify a preference for an assigned primary medical care provider, specialty care provider, or pharmacy; and
- E. An explanation of the enrollee's right to appeal the MCO's determination as described in Regulation .05 of this chapter.

.04 Effective Date of Enrollment.

- A. Except as provided in §B of this regulation, the effective date of enrollment shall be 20 days from the date of the notice described in Regulation .03A and B of this chapter, whichever is later.
- B. If an enrollee determined to have abused benefits appeals the determination, the effective date of the enrollment shall be tolled pending the outcome of the appeal.
- C. The duration of an enrollee's enrollment in a plan may not be altered because of changes in how the individual receives medical assistance, including but not limited to a change in the enrollee's MCO enrollment.

.05 Enrollee Appeal.

- A. An enrollee shall have 20 days to appeal an MCO's determination of benefit abuse.
- B. Except for the timeframe specified in §A of this regulation, an appeal shall be handled as specified in:
 - (1) COMAR 10.09.71.05; and
 - (2) COMAR 10.09.72.05.
 - C. If the appeal results in a hearing, an MCO shall
 - (1) Attend the hearing; and
 - (2) Provide justification for enrollment in the program.

VAN T. MITCHELL Secretary of Health and Mental Hygiene

Subtitle 25 MARYLAND HEALTH CARE COMMISSION

10.25.17 Benchmarks for Preauthorization of Health Care Services

Authority: Health-General Article, §§19-101 and 19-108.2, Annotated Code of Maryland

Notice of Proposed Action

[15-168-P]

The Maryland Health Care Commission proposes to amend Regulations .02—.05 under COMAR 10.25.17 Benchmarks for Preauthorization of Health Care Services. This action was considered by the Commission at an open meeting on May 21, 2015, notice of which was given through publication in the Maryland Register, pursuant to State Government Article, §10-506, Annotated Code of Maryland.

Statement of Purpose

The purpose of this action is to amend the regulations to reflect changes made to Health-General Article, §19-108.2, Annotated Code of Maryland, effective July 1, 2015, and make other appropriate changes. The law added a fourth benchmark requiring certain Stateregulated insurers, nonprofit health service plans, health maintenance organizations and pharmacy benefit managers (collectively, "payors") to establish an electronic process to allow a prescriber to override the step therapy or fail-first protocol (protocol) for pharmaceutical preauthorization requests by July 1, 2015. The proposed amendments include language that payors must notify providers about the online process available to override the protocol and must inform their members about the protocol. A reporting requirement related to the fourth benchmark was added. The amendments remove expired payor reporting requirement dates pertaining to their attainment of the first three benchmarks. A provision was added stating that payors must maintain their electronic preauthorization processes and demonstrate continued compliance with all four benchmarks upon request from the Commission. The proposed amendments change the length of time a waiver is valid from 1 to 2 years and require payors to submit a renewal of their waiver request 30 days prior to its expiration; the current regulations require that renewal waiver requests be submitted 45 days prior to expiration.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

The proposed action has no economic impact.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to David Sharp, Director, Center for Health Information Technology and Innovative Care Delivery, Maryland Health Care Commission, 4160 Patterson Avenue, Baltimore, MD 21215, or call 410-764-3578, or email to dsharp@maryland.gov, or fax to 410-358-1236. Comments will be accepted through 4:30 p.m. July 27, 2015. A public hearing has not been scheduled.

Open Meeting

Final action on the proposal will be considered by the Commission during a public meeting to be held on September 17, 2015 at 1:00 p.m., at 4160 Patterson Avenue, Baltimore, MD 21215.

.02 Definitions.

- A. (text unchanged).
- B. Terms Defined.
 - (1)—(5) (text unchanged)
- (6) "Prescriber" means a health care practitioner who has the required license and, if necessary, scope of practice or delegation agreement that permits the health care practitioner to prescribe drugs to treat medical conditions or diseases.
- (7) "Step therapy or fail-first protocol" is a protocol established by an insurer, a nonprofit health service plan, a health maintenance organization, or a pharmacy benefits manager that requires a certain prescription drug or sequence of prescription drugs to be used by an insured individual or an enrollee before another specific prescription drug ordered by a prescriber is covered.
 - (8) "Supporting medical information" means:
- (a) A paid claim from a payor that requires a step therapy or fail-first protocol for an insured or an enrollee;
- (b) A pharmacy record that documents that a prescription has been filled and delivered to an insured or enrollee, or to a representative of an insured or enrollee; or
- (c) Other information mutually agreed to that constitutes sufficient supporting medical information by an insured's or enrollee's prescriber and a payor that requires a step therapy or fail-first protocol.

.03 Benchmarks.

- A. [On or before October 1, 2012, each] *Each* payor shall establish *and maintain* online access for a provider to the following:
 - (1)—(2) (text unchanged)
- B. [On or before March 1, 2013, or another date established by the Commission, in consultation with its multistakeholder workgroup and published in the Maryland Register, each] *Each* payor shall establish *and maintain* an online process for:
 - (1)—(2) (text unchanged)
- C. [On or before July 1, 2013, or another date established by the Commission, in consultation with its multistakeholder workgroup and published in the Maryland Register, each] *Each* payor shall establish *and maintain* an online preauthorization system that meets the requirements of [Insurance Article,] *Health-General Article*, §19-108.2(e), Annotated Code of Maryland, to [approve]:
- (1) [In] $Approve\ in\ real\ time,\ electronic\ preauthorization\ requests\ for\ pharmaceutical\ services:$
 - (a)—(b) (text unchanged)
- (2) [Within] Render a determination within 1 business day after receiving all pertinent information on requests not approved in real

time, electronic preauthorization requests for pharmaceutical services that:

- (a)—(b) (text unchanged)
- (3) [Within] *Render a determination within* 2 business days after receiving all pertinent information, electronic preauthorization requests for health care services, except pharmaceutical services, that are not urgent.
- D. On or before July 1, 2015, a payor that requires a step therapy or fail-first protocol shall:
- (1) Establish and shall thereafter maintain an online process to allow a prescriber to override the step therapy or fail-first protocol if:
- (a) The step therapy drug has not been approved by the U.S. Food and Drug Administration for the medical condition being treated; or
- (b) A prescriber provides supporting medical information to the payor that a prescription drug covered by the payor:
- (i) Was ordered by the prescriber for the insured or enrollee within the past 180 days; and
- (ii) Based on the professional judgment of the prescriber, was effective in treating the insured's or enrollee's disease or medical condition;
- (2) Provide notice to prescribers regarding the availability of its online process; and
- (3) Provide information to insureds or enrollees on the availability of the step therapy or fail-first protocol within its network.
- E. A payor that becomes authorized to provide benefits or services within the State of Maryland after October 1, 2012, shall meet each benchmark within [Regulation .03B of] this chapter within 3 months of the payor's offering of services or benefits within the State and shall thereafter maintain the processes or actions required by each benchmark.

.04 Reporting.

- A. On or before [March 1, 2013] August 1, 2015, a payor that requires a step therapy or fail-first protocol shall report to the Commission in a form and manner specified by the Commission on its attainment of the benchmark in Regulation .03D of this chapter.
- [(1) The status of the payor's attainment of the benchmarks in Regulation .03A and B of this chapter; and
- (2) An outline of the payor's plans for attaining the benchmark in Regulation .03C of this chapter.]
- B. [On or before December 1, 2013, a payor shall report to the Commission in a form and manner specified by the Commission on the payor's attainment of the benchmarks in Regulation .03C.] A payor that becomes authorized to provide benefits or services within the State of Maryland after October 1, 2012, shall report to the Commission in a form and manner specified by the Commission on its attainments of each benchmark in Regulation .03 of this chapter within 3 months of the payor's offering of services or benefits within the State.
- C. If requested by the Commission, a payor shall demonstrate continued compliance with the benchmarks in Regulation .03 of this chapter.

.05 Waiver from Benchmark Requirement.

- A. A payor may request that the Commission issue or renew a waiver from the requirement to meet a benchmark in Regulation [.03B] .03 of this chapter by the demonstration of extenuating circumstances, including:
 - (1)—(3) (text unchanged)
 - B. Submission of Request for Waiver or Renewal of Waiver.
- (1) A request for a waiver or renewal of waiver shall be in writing and shall include:
- (a) [A description] *An identification* of each preauthorization benchmark for which a waiver is requested; and
 - (b) (text unchanged)

- (2) A request for a waiver shall be filed with the Commission in accordance with the following:
- (a) For [the benchmark in Regulation .03A of] *benchmarks in* this chapter, [no later than 30 days after the effective date of this chapter;
- (b) For benchmarks in Regulation .03B and C of this chapter,] no later than 60 days prior to the compliance date; or]
- [(c)] (b) For renewal of a waiver, no later than [45] 30 days prior to its expiration.
 - (3) (text unchanged)
 - C. Issuance of [Waivers] Waiver.
 - (1)—(2) (text unchanged)
- (3) A waiver or renewal of a waiver shall be valid for [1 year] *two years*, unless withdrawn by the Executive Director[,] after notice to the payor.
 - D. Review of Denial of Waiver.
 - (1)—(2) (text unchanged)
- (3) The payor may address the Commission before [the Commission determines] *a determination is made by the Commission as to* whether or not to issue a waiver after a request for review of denial of waiver by the Executive Director.
 - E. (text unchanged)

CRAIG P. TANIO, M.D. Chairman

Subtitle 46 BOARD OF OCCUPATIONAL THERAPY PRACTICE

Notice of Proposed Action

[15-151-P]

The Secretary of Health and Mental Hygiene proposes to:

- (1) Amend Regulations .01, .02, and .04 under COMAR 10.46.01 General Regulations; and
- (2) Amend Regulation .04, adopt new Regulation .05, amend and recodify existing Regulation .05 to be Regulation .06, and recodify existing Regulations .06—.08 to be Regulations .07—.09 under COMAR 10.46.06 Competency Requirements for Physical Agent Modalities.

This action was considered at public meetings on November 21, 2014 and March 20, 2015, notice of which was given by publication on the Board's website at http://dhmh.maryland.gov/botp/SitePages/board-meetings.aspx, pursuant to State Government Article, § 10-506(c)(1), Annotated Code of Maryland.

Statement of Purpose

The purpose of this action is to:

- (1) Update the regulations to reflect the more prevalent use of computers and electronic means of communication and to reflect the Board's paperless licensure system;
- (2) Require that a licensee applying for license renewal who has completed the continuing competency requirement shall attest to maintenance of Current Certification with the National Board of Certification in Occupational Therapy or to completion of continuing competency activities as specified in COMAR 10.46.04;
- (3) Provide that, when applying for initial licensure or reactivation or reinstatement of a license, an applicant may submit documentation certifying maintenance of current certification with the National Board of Certification in Occupational Therapy as part of the application;
- (4) Authorize the Board to send a license renewal notice by electronic means or by first-class mail to the last known electronic mail address or physical address of a licensee;

- (5) Authorize an individual to verify a license via the Board's website or by calling the Board office;
- (6) Clarify that before applying physical agent modalities to a client, a licensee shall, after completing all required 15 contact hours of education, apply a minimum of 5 client treatments within the context of a therapeutic treatment program for each specific modality;
- (7) Provide that an occupational therapist may have met the competency requirements as required in regulations to develop a treatment plan that includes recommendations for use of physical agent modalities;
- (8) Require that the therapeutic parameters for electrical modalities shall be established by the occupational therapist or occupational therapist assistant administering the modality; and
- (9) Repeal a requirement that licenses shall be renewed annually.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

I. Summary of Economic Impact. These regulations will save licensees money by allowing the carryover of continuing education units (CEUs) from one cycle to another under certain circumstances. Thus, licensees would not have to complete and pay for as many CEU courses.

II. Types of Economic Impact.	Revenue (R+/R-) Expenditure (E+/E-)	Magnitude
A. On issuing agency:	NONE	
B. On other State agencies: C. On local governments:	NONE NONE	
	Benefit (+) Cost (-)	Magnitude
D. On regulated industries or trade groups:	(+)	Indeterminate
E. On other industries or trade groups:	NONE	
F. Direct and indirect effects on public:	NONE	

- **III. Assumptions.** (Identified by Impact Letter and Number from Section II.)
- D. These regulations will save licensees money by allowing the carryover of continuing education units (CEUs) from one cycle to another under certain circumstances. Thus, licensees would not have to complete and pay for as many CEU courses. The Board cannot estimate the exact amount of money that will be saved by licensees.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Michele Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 West Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499 (TTY 800-735-2258), or email to dhmh.regs@maryland.gov, or fax to 410-767-6483. Comments will be accepted through July 27, 2015. A public hearing has not been scheduled.

10.46.01 General Regulations

Authority: Health Occupations Article, §§10–101, 10–205, 10–311, Annotated Code of Maryland

.01 Definitions.

- A. (text unchanged)
- B. Terms Defined.
 - (1) (text unchanged)
- (2) "AOTA" means the American Occupational Therapy Association, formerly the American Occupational Therapy Certification Board (AOTCB).
- (3) "Board" means the *State* Board of Occupational Therapy Practice.
- (4) "Case resolution conference (CRC)" means a voluntary, informal, and confidential proceeding to explore the possibility of a consent order resolution of [the] *a disciplinary* matter [with the administrative prosecutor].
 - (5)—(10) (text unchanged)
- (11) "Expired license" means an [invalid license] *individual's* authority to practice occupational therapy or limited occupational therapy which has not been renewed [for an additional term] through the process of renewal or elective nonrenewal and is invalid.
- (12) "Licensed" means formally authorized by the Board to practice occupational therapy or limited occupational therapy.
- [(12)] (13) "Licensee" means an individual who is a licensed occupational therapist or a licensed occupational therapy assistant.
- [(13)] (14) "NBCOT" means the National Board for Certification in Occupational Therapy, formerly the American Occupational Therapy Certification Board (AOTCB).
 - [(14)] (15) —[(28)] (29) (text unchanged)

.02 Licensure.

- A. (text unchanged)
- B. Term and Renewal of License.
 - (1) (text unchanged)
- [(2) All licenses expire annually on June 30, regardless of the original date of licensure.]
- [(3) The] (2) At least 30 days before the expiration date of the license, the Board shall send a notice of renewal [to the last known address] by electronic means or first-class mail to the last known electronic or physical address of each active licensee, and each licensee who is inactive by elective nonrenewal, who is eligible for renewal [at least 30 days before the expiration date of the license].
- [(4)] (3) In order to renew a license, the licensee shall [return] *submit* to the Board a completed renewal application by the deadline for renewal.
- [(5)] (4) The licensee shall submit [a] *an electronic payment*, money order, *or* check[, or electronic payment] in the amount of the renewal fee established by the Board in COMAR 10.46.05.01.
 - [(6)] (5)—[(7)] (6) (text unchanged)
- [(8)] (7) A completed renewal application received with [a postmark or] *an* on-line licensure confirmation *or postmark* dated after the expiration date of June 30 will not be accepted.
- [(9)] (8) At the time of licensure renewal, a licensee who has completed the continuing competency requirement shall attest to the [completion of the required contact hours as specified in COMAR 10.46.04]:
- (a) Maintenance of Current Certification with the National Board of Certification in Occupational Therapy (NBCOT); or

- (b) Completion of continuing competency activities, as specified in COMAR 10.46.04.
- (9) At the time of licensure renewal, a licensee shall indicate a desire to:
- (a) Carry over contact hours from one continuing competency time frame to another; or
- (b) Utilize contact hours carried over from the previous renewal period.
 - (10) (text unchanged)
 - C. (text unchanged)
- D. Application Procedures for Licensure. To apply for a license, an applicant shall submit the following [original] *primary source* documentation to the Board within the time frame specified on the application:
 - (1)—(3) (text unchanged)
- (4) [A money order, check, or electronic] *An approved form of* payment in the amount of the application fee established by the Board in COMAR 10.46.05.01;
 - (5)—(6) (text unchanged)
- (7) Documentation certifying [a minimum of 12 hours of education or]:
- (a) Maintenance of Current Certification with the National Board of Certification in Occupational Therapy (NBCOT); or
- (b) Completion of continuing competency activities, as specified in COMAR 10.46.04[, obtained within the 1-year period immediately preceding the application for licensure].
 - E. Application Procedures for Temporary Licensure.
 - (1) (text unchanged)
- (2) To apply for a temporary license, an applicant shall submit the following [original] *primary source* documentation to the Board within the time frame specified on the application:
 - (a) (text unchanged)
- (b) An application confirmation [letter] from the NBCOT certifying the applicant's eligibility and registration to take the examination within the eligibility activation period;
 - (c) (text unchanged)
- (d) [A money order, check, or electronic] An approved form of payment in the amount of the application fee established by the Board in COMAR 10.46.05.01;
- (e) If currently, or previously, authorized to practice in any other state or country, or both, *primary source* documentation from the appropriate authority of that state or country verifying:
 - (i)—(iii) (text unchanged)
 - (f) (text unchanged)
- (g) Documentation certifying [a minimum of 12 hours of education or] *completion of* continuing competency activities, as specified in COMAR 10.46.04[, obtained within the 1-year period immediately preceding the application for temporary licensure].
 - F. Application Procedures for a Second Temporary License.
 - (1) (text unchanged)
- (2) To apply for a second temporary license, an applicant shall submit the following [original] *primary source* documentation to the Board within the time frame specified on the application:
- (a) An application confirmation [letter] from the NBCOT certifying the applicant's eligibility and registration to take the examination within the eligibility activation period;
- (b) [A money order, check, or electronic] *An approved form of* payment in the amount of the second temporary license fee established by the Board in COMAR 10.46.05.01; and
 - (c) (text unchanged)
 - G. Application Procedures for Nonrenewal of License.
 - (1) Elective Nonrenewal.
 - (a) (text unchanged)

- (b) For each specific [1-year] *renewal* term for which inactive status is requested, the licensee shall apply for elective nonrenewal
- (c) The Board shall send a notice of renewal [to the last known address] by electronic means or first-class mail to the last known electronic or physical address of each inactive licensee who is eligible for renewal or elective nonrenewal.
- (d) In order to electively nonrenew a license, the licensee shall [return] *submit* to the Board a completed application, by the expiration date of June 30.
- (e) A completed application for elective nonrenewal received with [a] *an online application confirmation or* postmark [or on-line licensure confirmation] dated after the expiration date will not be accepted.
 - (f) (text unchanged)
- (2) Expiration. A license that has not been renewed [for an additional] term through the process of renewal or elective nonrenewal is expired and invalid.
- H. Application Procedures for Reactivation or Reinstatement of License. To apply for reactivation after elective nonrenewal or reinstatement after expiration, an applicant shall submit the following [original] *primary source* documentation to the Board within the timeframe specified on the application:
 - (1)—(3) (text unchanged)
- (4) [A money order, check, or electronic] *An approved form of* payment in the amount of the applicable fee established by the Board in COMAR 10.46.05.01;
- (5) If currently, or previously, authorized to practice in any other state or country, or both, *primary source* documentation from the appropriate authority of that state or country verifying:
 - (a)—(c) (text unchanged)
 - (6) (text unchanged)
 - (7) Documentation certifying [a minimum of 12 contact hours]:
- (a) Maintenance of current certification with the National Board of Certification in Occupational Therapy (NBCOT); or
- (b) Completion of continuing competency activities as specified in COMAR 10.46.04 [obtained within the 1-year period immediately preceding the application for reinstatement or reactivation].
 - I. Address Change.
- (1) An applicant or licensee shall report a change of *electronic mail address or postal* address, in writing, within 30 days of the change.
 - (2) (text unchanged)
 - J. Name Change.
 - (1) (text unchanged)
 - (2) The report of a change in name shall include[:
- (a) A copy of a legal document] documentation substantiating the name change.[, such as a marriage certificate or court order, signed and certified as a true copy by the officer to whose custody the original is entrusted;
- (b) The return of official license bearing the applicant's or licensee's former name; and
- (c) The return of the pocket license bearing the applicant's or licensee's former name.
 - K. Duplicate License.
- (1) If the original license is lost, stolen, or damaged, a licensee shall make a request in writing to the Board for a duplicate license.
 - (2) The request shall include:
 - (a) The damaged official license, if available:
 - (b) The damaged pocket license, if available; and
 - (c) A letter of explanation].

- [L.] K. Verification of Maryland License.
- (1) Electronic Verification. An individual may independently obtain information on the licensure status of licensees in the following ways:
- (a) Upon accessing the Board's website, an individual may view and print a licensee's status; or
- (b) Upon phoning the Board office, an individual may receive verbal verification of a licensee's status.
 - [(1)] (2) Board-Provided Verification.
- (a) Upon request, the Board shall provide written documentation certifying licensure status and disciplinary history in Maryland.
 - [(2)] (b) The request for Board verification shall include:
 - [(a)] (i)—[(b)] (ii) (text unchanged)
- [(c) A money order, check, or electronic] (iii) An approved form of payment in the amount of the verification of licensure fee established by the Board in COMAR 10.46.05.01.
- [(3) Self-Obtained Verification. An individual may independently obtain information on the licensure status of licensees in the following ways:
- (a) Upon accessing the Board's website, an individual may view and print a licensee's status; or
- (b) Upon phoning the Board's office, an individual may receive verbal verification of a licensee's status.]

.04 Supervision Requirements.

- A. (text unchanged)
- B. Occupational Therapy Assistant.
- (1) Subject to the requirements of this section, an occupational therapy assistant may practice limited occupational therapy under the supervision of an occupational therapist *provided* [if] it is at [a minimum] *least* periodic supervision.
 - (2)—(6) (text unchanged)
 - C.—F. (text unchanged)

10.46.06 Competency Requirements for Physical Agent Modalities

Authority: Health Occupations Article, §§ 10–101, Annotated Code of Maryland

.04 Standards of Competence for Electrical Modalities.

- A.—B. (text unchanged)
- C. Clinical Requirements. Before applying physical agent modalities to a client under this chapter, a licensee shall:
 - (1) (text unchanged)
- (2) [Apply] After completing all 15 contact hours of education, a licensee shall apply a minimum of five client treatments within the context of a therapeutic treatment program for each specific modality under the direct clinical education of an educator as defined in this chapter.

.05 Treatment Plan Guidelines for Physical Agent Modalities.

- A. The occupational therapist does not need to meet the competency requirements as set forth in this chapter in order to develop a treatment plan which includes recommendations for use of physical agent modalities.
- B. The therapeutic parameters for electrical modalities shall be established by the occupational therapist or occupational therapy assistant administering the modality.

[.05] .06 Documentation of Education in Electrical Physical Agent Modalities.

A. (text unchanged)

- B. Verification shall include:
 - (1) (text unchanged)
- (2) Proof of 15 contact hours of didactic education by virtue of a certificate of completion or proof of education, *if applicable*;
 - (3)—(5) (text unchanged)

VAN T. MITCHELL

Secretary of Health and Mental Hygiene

Subtitle 58 BOARD OF PROFESSIONAL COUNSELORS AND THERAPISTS

10.58.04 Hearing Procedures

Authority: Health Occupations Article, [§17-314] §\$17-205, 17-509, and 17-511; State Government Article, §\$10-205, 10-206, 10-216, and 10-226(c)(2), Annotated Code of Maryland

Notice of Proposed Action

[15-155-P]

The Secretary of Health and Mental Hygiene proposes to adopt new Regulation .10 under COMAR 10.58.04 Hearing Procedures. This action was considered at a public meeting on November 21, 2014, notice of which was given on the Board's website at http://dhmh.maryland.gov/bopc/SitePages/Home.aspx, pursuant to State Government Article, §10-506(c)(1), Annotated Code of Maryland.

Statement of Purpose

The purpose of this action is to:

- (1) Authorize the Board to order the summary suspension of a license or certificate if the Board determines that there is a substantial likelihood that a licensee or certificate holder poses a risk of harm to the public health, safety, or welfare;
- (2) Require the Board to give the respondent proper notice of the Board's intent to summarily suspend the respondent's license or certificate and require that the notice include certain information;
- (3) Establish a process by which the Board shall serve a respondent with the notice of intent to summarily suspend;
- (4) Authorize the respondent to request a predeprivation hearing before the Board if the respondent is notified of the Board's intent to summarily suspend the respondent's license or certificate;
- (5) Establish procedures for the predeprivation hearing before the Board;
- (6) Authorize the Board to summarily suspend a license or certificate without prior notice to the licensee or certificate holder under certain circumstances;
- (7) Establish timelines for serving the order of summary suspension without prior notice and for the respondent to request a post-deprivation hearing before the Board;
- (8) Establish procedures for the post-deprivation hearing, including the burdens of production and proof;
- (9) Provide that after a predeprivation hearing or after a postdeprivation hearing, the Board may take certain actions;
- (10) Provide that, if the Board orders a summary suspension without prior notice to the licensee or certificate holder, the licensee or certificate holder is entitled to an evidentiary hearing before the Board or an administrative law judge within a certain period of time;
- (11) Require an administrative law judge to issue a recommended decision to the Board including certain information;
- (12) Authorize both parties to a decision to file exceptions to the recommended decision in accordance with State law; and
- (13) Provide that a summary suspension or final order of the Board issued after a predeprivation hearing or a post-deprivation

hearing is a final order of the Board and a public record under State law

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

I. Summary of Economic Impact. To the extent that a licensee or certificate holder hires a lawyer to defend against Board charges, there would be a financial impact to the licensee or certificate holder. Also, to the extent that the Board refers a case to the Office of Administrative hearings or to an administrative prosecutor, there would be a cost to the Board.

(D + /D)

II. Types of Economic Impact.	Expenditure (E+/E-)	Magnitude
A. On issuing agency: B. On other State	(E+)	Indeterminable
agencies:	NONE	
C. On local governments:	NONE	
15 717	Benefit (+) Cost (-)	Magnitude
D. On regulated industries		Indotorminable
or trade groups:	(-)	Indeterminable
E. On other industries or trade groups:	NONE	
F. Direct and indirect effects on public:	NONE	

III. Assumptions. (Identified by Impact Letter and Number from Section II.)

A. and D. The Board cannot estimate either of these amounts as it does not know how many cases may be referred to the OAH or how many licensees or certificate holders will hire an attorney.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Michele Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 West Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499 (TTY 800-735-2258), or email to dhmh.regs@maryland.gov, or fax to 410-767-6483. Comments will be accepted through July 27, 2015. A public hearing has not been scheduled.

.10 Summary Suspension of a License or Certificate.

- A. Pursuant to State Government Article, §10- 226(c)(2), Annotated Code of Maryland, the Board may order the summary suspension of a license holder if the Board determines that there is substantial likelihood that a licensee or certificate holder poses a risk of harm to the public health, safety, or welfare.
 - B. Notice of Intent to Summarily Suspend.
- (1) Based on information gathered in an investigation or otherwise provided to the Board, the Board may vote to issue:
- (a) A notice of intent to summarily suspend a license or certificate; or

- (b) An order of summary suspension.
- (2) If the Board votes to issue a notice of intent to summarily suspend a license or certificate or an order of summary suspension, the Board shall refer the matter to an administrative prosecutor for prosecution.
- (3) A notice of intent to summarily suspend a license or certificate shall include:
- (a) A proposed order of summary suspension which is unexecuted by the Board and includes:
- (i) The statutory authority on which the action has been taken;
- (ii) Allegations of fact that the Board believes demonstrate a substantial likelihood that the licensee or certificate holder poses a risk of harm to the public health, safety, or welfare; and
- (iii) Notice to the respondent of the right to request a full hearing on the merits of the summary suspension if the Board executes the proposed order of summary suspension; and
- (b) An order or summons to appear before the Board to show cause why the Board should not execute the order of summary suspension and which notifies the respondent of the consequences of failing to appear.

(4) Service.

- (a) The Board shall serve a respondent with a notice of intent to summarily suspend a license or certificate not later than 5 days before a predeprivation show cause hearing is scheduled before the Board.
- (b) Service of the notice of intent to summarily suspend shall be made:
 - (i) Personally upon the respondent;
- (ii) By certified mail to the address the respondent is required to maintain with the Board; or
 - (iii) By other reasonable means to effect service.
- (c) If the Board is unable to serve the notice of intent to summarily suspend a license or certificate upon the respondent as described in §B(4)(b) of this regulation, the Board may nevertheless proceed to prosecute the case.

C. Predeprivation Opportunity to Be Heard.

- (1) If the Board issues a notice of intent to summarily suspend a license or certificate, the respondent may request an opportunity to appear before the Board to show cause why the respondent's license or certificate should not be suspended before the Board executes the order of summary suspension.
 - (2) Predeprivation Show Cause Hearing Before Board.
- (a) The hearing shall be a nonevidentiary hearing to provide the parties with an opportunity for oral argument on the proposed summary suspension.
- (b) The Board member presiding at the hearing shall determine all procedural issues and may impose reasonable time limits on each party's oral argument.
- (c) The presiding Board member shall make rulings reasonably necessary to facilitate the effective and efficient operation of the hearing.
- (d) The respondent and the administrative prosecutor may not exceed 30 minutes each to present oral argument.
- (e) The respondent shall proceed first and may reserve part of the allotted time for rebuttal.
 - (3) The Board member who presides over the hearing:
- (a) May allow either the respondent or the administrative prosecutor to present documents or exhibits which are relevant and material to the proceedings and which are not duly repetitious, if the presiding Board member believes that such documents or exhibits are necessary for a fair hearing; and
- (b) May not allow testimony by any witness unless agreed to by the parties and approved by the Board in advance of the hearing.

- (4) A Board member may be recognized by the presiding member to ask questions of either party appearing before the Board.
- D. Summary Suspension Without Prior Notice or Hearing Opportunity.
- (1) Extraordinary Circumstances. The Board may, after consultation with Board counsel, order the summary suspension of a license or certificate without first issuing a notice of intent to summarily suspend a license or certificate or providing a respondent with an opportunity for a predeprivation hearing if the Board determines that:
- (a) The public health, safety, and welfare require the immediate suspension of the license; and
- (b) Prior notice and an opportunity to be heard are not feasible.
 - (2) Time—Service and Hearing.
- (a) An order of summary suspension under section \$D(1) of this regulation shall be served upon the respondent within 48 hours after its execution.
- (b) The respondent may request a show cause hearing before the Board within 30 days after the effective date of the summary suspension. The request shall be made within 10 days of the date of the notice of sumary suspension.
- (3) If the respondent requests a hearing under §B(3)(a)(iii) of this regulation, that hearing shall:
- (a) Be conducted before the Board as provided in D(2)(b) of this regulation; and
- (b) Provide the respondent with an opportunity to show cause why the Board should lift the summary suspension and reinstate the license or certificate.

E. Burdens of Production and Persuasion.

- (1) In a show cause proceeding under §C of this regulation, the respondent may present argument in opposition to the allegations presented in the order for summary suspension or which otherwise demonstrate that the public health, safety, or welfare is not at risk.
- (2) The administrative prosecutor bears the burden of demonstrating by a preponderance of the evidence that the health, safety, or welfare of the public imperatively requires the Board to summarily suspend the respondent's license or certificate.

F. Disposition.

- (1) If the Board issues a notice of intent to summarily suspend a license or certificate before summarily suspending a license or certificate, the Board may, after the show cause hearing, vote to:
 - (a) Order a summary suspension;
 - (b) Deny the summary suspension;
 - (c) Issue an order agreed upon by the parties; or
- (d) Issue an interim order warranted by the circumstances of the case, including an order providing for a stay of the summary suspension subject to certain conditions.
- (2) If the Board orders a summary suspension before a show cause hearing, the Board may, at the conclusion of the hearing, vote to:
 - (a) Affirm its order of summary suspension;
 - (b) Rescind its order of summary suspension;
 - (c) Issue an order agreed upon by the parties; or
- (d) Issue an interim order warranted by the circumstances of the case, including an order providing for a stay of the summary suspension subject to certain conditions.
- (3) An order for summary suspension or other order issued by the Board after the initiation of summary suspension proceedings are final orders of the Board and public records under State Government Article, §10–611, Annotated Code of Maryland.
 - G. Postdeprivation Opportunity for Evidentiary Hearing.
- (1) If the Board orders the summary suspension of a license or certificate under §C or D of this regulation, the respondent may request an evidentiary hearing before the Board, or if the Board

delegates the matter to the Office of Administrative hearings, before an administrative law judge.

- (2) The respondent may request an evidentiary hearing within 10 days after the Board issues the order of summary suspension.
- (3) Unless otherwise agreed by the parties, a hearing shall be provided within 45 days after the respondent's request.
- (4) An evidentiary hearing may be consolidated with a hearing on charges issued by the Board that include the facts that form the basis for the summary suspension.
- (5) An evidentiary hearing shall be conducted under the contested case provisions of State Government Article, Title 10, Subtitle 2, Annotated Code of Maryland.
- (6) If the Board delegates the matter to the Office of Administrative Hearings, the administrative law judge shall issue a recommended decision to the Board with:
 - (a) Proposed or final findings of fact;
 - (b) Proposed or final conclusions of law;
 - (c) A proposed disposition; or
- (d) Any combination of G(6)(a), (b), or (c) of this regulation, pursuant to the Board's delegation of the matter to the Office of Administrative Hearings.
- (7) If the hearing is one combined with charges, the administrative law judge's determination of the merits of the summary suspension shall be based only on the parts of the record available to the Board when the Board voted for summary suspension.
- (8) The parties may file exemptions to the recommended decision, as provided in State Government Article, §10–216, Annotated Code of Maryland.
- (9) An order issued by the Board after a post-deprivation evidentiary hearing is a final order of the Board and is a public record under State Government Article, §10–611, Annotated Code of Maryland.

VAN T. MITCHELL Secretary of Health and Mental Hygiene

Subtitle 62 NATALIE M. LAPRADE MEDICAL CANNABIS COMMISSION

Notice of Proposed Action

[15-156-P]

The Secretary of Health and Mental Hygiene proposes to:

- (1) Adopt new Regulation .01 under a new chapter, COMAR 10.62.01 Definitions;
- (2) Adopt new Regulations .01—.04 under a new chapter, COMAR 10.62.02 General Regulations;
- (3) Adopt new Regulations .01—.03 under a new chapter, COMAR 10.62.03 Certifying Physicians;
- (4) Adopt new Regulations .01—.06 under a new chapter, COMAR 10.62.04 Patient and Caregiver Registry;
- (5) Adopt new Regulations .01 and .02 under a new chapter, COMAR 10.62.05 Written Certifications:
- (6) Adopt new Regulations .01—.07 under a new chapter, COMAR 10.62.06 Patient and Caregiver Identification Cards;
- (7) Adopt new Regulations .01—.06 under a new chapter, COMAR 10.62.07 New Condition Approval Process;
- (8) Adopt new Regulations .01—.11 under a new chapter, COMAR 10.62.08 Medical Cannabis Grower License;
- (9) Adopt new Regulations .01—.09 under a new chapter, COMAR 10.62.09 Medical Cannabis Grower Agent;
- (10) Adopt new Regulations .01—.08 under a new chapter, COMAR 10.62.10 Medical Cannabis Grower Premises;

- (11) Adopt new Regulations .01—.04 under a new chapter, COMAR 10.62.11 Medical Cannabis Growing Controls;
- (12) Adopt new Regulations .01—.08 under a new chapter, COMAR 10.62.12 Inventory Control by Grower;
- (13) Adopt new Regulations .01 and .02 under a new chapter, COMAR 10.62.13 Medical Cannabis Shipment Packaging;
- (14) Adopt new Regulations .01 and .02 under a new chapter, COMAR 10.62.14 Licensed Grower Dispensary Facility;
- (15) Adopt new Regulations .01—.08 under a new chapter, COMAR 10.62.15 Medical Cannabis Grower Quality Control;
- (16) Adopt new Regulations .01—.05 under a new chapter, COMAR 10.62.16 Independent Testing Laboratory Registration;
- (17) Adopt new Regulations .01—.04 under a new chapter, COMAR 10.62.17 Complaints, Adverse Events, and Recall;
- (18) Adopt new Regulations .01—.06 under a new chapter, COMAR 10.62.18 Shipment of Products Between Licensees;
- (19) Adopt new Regulations .01—.09 under a new chapter, COMAR 10.62.19 Medical Cannabis Processor License;
- (20) Adopt new Regulations .01—.09 under a new chapter, COMAR 10.62.20 Medical Cannabis Processor Agent;
- (21) Adopt new Regulations .01—.07 under a new chapter, COMAR 10.62.21 Medical Cannabis Processor Premises:
- (22) Adopt new Regulations .01—.06 under a new chapter, COMAR 10.62.22 Medical Cannabis Processor Operations;
- (23) Adopt new Regulations .01—.07 under a new chapter, COMAR 10.62.23 Medical Cannabis Concentrates and Medical Cannabis-Infused Products;
- (24) Adopt new Regulation .01 under a new chapter, COMAR 10.62.24 Medical Cannabis Finished Products Packaging;
- (25) Adopt new Regulations .01—.10 under a new chapter, COMAR 10.62.25 Medical Cannabis Dispensary License;
- (26) Adopt new Regulations .01—.09 under a new chapter, COMAR 10.62.26 Registered Dispensary Agent;
- (27) Adopt new Regulations .01—.09 under a new chapter, COMAR 10.62.27 Licensed Dispensary Premises;
- (28) Adopt new Regulations .01—.05 under a new chapter, COMAR 10.62.28 Licensed Dispensary Operations;
- (29) Adopt new Regulations .01 and .02 under a new chapter, COMAR 10.62.29 Licensed Dispensary Packaging and Labeling for Distribution;
- (30) Adopt new Regulations .01—.09 under a new chapter, COMAR 10.62.30 Dispensing Medical Cannabis;
- (31) Adopt new Regulation .01 under a new chapter, COMAR 10.62.31 Licensed Dispensary Clinical Director;
- (32) Adopt new Regulations .01—.03 under a new chapter, COMAR 10.62.32 Records;
- (33) Adopt new Regulations .01—.08 under a new chapter, COMAR 10.62.33 Inspection;
- (34) Adopt new Regulations .01—.04 under a new chapter, COMAR 10.62.34 Discipline and Enforcement; and
- (35) Adopt new Regulation .01 under a new chapter, COMAR 10.62.35 Fee Schedule.

At this time, the Secretary of Health and Mental Hygiene is withdrawing:

- (1) New Regulations .01 and .02 under a new chapter, COMAR 10.62.01 Definitions;
- (2) New Regulations .01 .03 under a new chapter, COMAR 10.62.02 General Regulations:
- (3) New Regulations .01 .07 under a new chapter, COMAR 10.62.03 Certifying Physicians;
- (4) New Regulations .01 .06 under a new chapter, COMAR 10.62.04 New Condition Approval Process;

- (5) New Regulations .01 .04 under a new chapter, COMAR 10.62.05 Patient and Caregiver Registry and Identification Cards:
- (6) New Regulations .01 —.10 under a new chapter, COMAR 10.62.06 Medical Marijuana Grower License;
- (7) New Regulations .01 —.09 under a new chapter, COMAR 10.62.07 Medical Marijuana Grower Agents;
- (8) New Regulations .01 —.08 under a new chapter, COMAR 10.62.08 Medical Marijuana Grower Premises;
- (9) New Regulations .01 —.05 under a new chapter, COMAR 10.62.09 Medical Marijuana Growing Controls;
- (10) New Regulations .01 —.08 under a new chapter, COMAR 10.62.10 Quality Control by a Licensed Medical Marijuana Grower;
- (11) New Regulations .01 —.05 under a new chapter, COMAR 10.62.11 Complaints, Adverse Events, and Recall;
- (12) New Regulations .01 —.08 under a new chapter, COMAR 10.62.12 Inventory Control by Grower;
- (13) New Regulations .01 —.03 under a new chapter, COMAR 10.62.13 Dispensing of Medical Marijuana by a Licensed Grower;
- (14) New Regulations .01 —.08 under a new chapter, COMAR 10.62.14 Shipment of Products Containing Marijuana Between Licensees:
- (15) New Regulations .01 —.11 under a new chapter, COMAR 10.62.15 Licensed Dispensary and Licensed Processing Dispensary;
- (16) New Regulations .01 —.08 under a new chapter, COMAR 10.62.16 Medical Marijuana Concentrates and Medical Marijuana-Infused Products;
- (17) New Regulation .01 under a new chapter, COMAR 10.62.17 Licensed Dispensary Clinical Director;
- (18) New Regulations .01 —.08 under a new chapter, COMAR 10.62.18 Registered Dispensary Agents;
- (19) New Regulations .01 —.09 under a new chapter, COMAR 10.62.19 Licensed Dispensary and Licensed Processing Dispensary Premises;
- (20) New Regulations .01 —.05 under a new chapter, COMAR 10.62.20 Licensed Dispensary and Licensed Processing Dispensary Operations;
- (21) New Regulations .01 and .02 under a new chapter, COMAR 10.62.21 Licensed Dispensary Packaging and Labeling for Distribution;
- (22) New Regulations .01 —.08 under a new chapter, COMAR 10.62.22 Dispensing Medical Marijuana;
- (23) New Regulations .01 —.03 under a new chapter, COMAR 10.62.23 Records;
- (24) New Regulations .01 —.08 under a new chapter, COMAR 10.62.24 Inspection;
- (25) New Regulations .01 —.03 under a new chapter, COMAR 10.62.25 Discipline and Enforcement;
- (26) New Regulations .01 —.13 under a new chapter, COMAR 10.62.26 Academic Medical Center Program Application Contents:
- (27) New Regulations .01 —.06 under a new chapter, COMAR 10.62.27 Academic Medical Center Program Application Procedure; and
- (28) New Regulation .01 under a new chapter, COMAR 10.62.28 Fee Schedule, as proposed in the 42:2 Md.R.214—244 (January 23, 2015).

This action was considered at a public meeting on April 22, 2015, notice of which was given by publication on the Commission's website at http://mmc.maryland.gov/ pursuant to State Government Article, §10-506(c)(1), Annotated Code of Maryland.

Statement of Purpose

The purpose of this action is to:

- (1) Define certain terms;
- (2) Establish standards for individuals to register as a qualifying patient to obtain medical cannabis;
- (3) Establish requirements for licensed physicians in the State to be registered to recommend medical cannabis;
- (4) Establish requirements for grower operations, dispensaries, and processors to be licensed by the Commission;
- (5) Establish requirements for grower agents, dispensary agents, and processor agents to be registered with the Commission;
- (6) Establish requirements for individuals to become caregivers to qualifying patients;
- (7) Establish application processes for applicants to be certifying physicians, qualifying patients or caregivers, licensed growers, licensed dispensaries, licensed processors, registered grower agents, registered, processor agents, or registered dispensary agents;
- (8) Establish structural, security, procedural, and staffing requirements for the premises of licensed dispensaries, licensed growers, and licensed processors;
- (9) Establish growing controls and quality controls for licensed growers;
- (10) Provide that a licensed grower dispensary, where medical cannabis shall be dispensed, shall be constructed and operated in accordance with regulations that apply to licensed dispensary premises:
- (11) Establish a process for approving qualifying patients who suffer from new conditions not specified in the statute;
- (12) Establish a procedure for transporting medical marijuana products between licensees;
 - (13) Establish inventory control standards for licensed growers;
- (14) Authorize the Commission to inspect licensed growers, licensed dispensaries, licensed processors, and registered independent testing laboratories;
- (15) Establish controls for processing and labeling medical cannabis concentrates and medical cannabis-infused products;
- (16) Require that an independent testing laboratory shall register with the Commission and meet certain standards of care;
- (17) Set standards for licensed dispensary packaging and labeling;
- (18) Authorize the Commission to take certain disciplinary actions against certain licensees for certain offenses;
- (19) Establish a procedure to receive, organize, store, and respond to all complaints regarding medical cannabis and adverse events;
- (20) Authorize a licensed dispensary to have a clinical director on staff who is a licensed physician, nurse practitioner, or pharmacist;
- (21) Establish certain renewal procedures for certifying physicians, qualifying patients, licensed growers, licensed dispensaries, licensed processors, independent testing laboratories; and
- (22) Establish certain fees to fund the operations of the Commission.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

I. Summary of Economic Impact. Because these regulations are implementing a new program and bringing a new industry to the State, the Commission cannot estimate the economic impact to the State, except to say that demand for certain services will increase, such as construction, security, architectural, legal, laboratory testing, and secure transport. The new industry will also increase jobs in the areas in which medical marijuana facilities choose to locate.

II. Types of Economic Impact.	Revenue (R+/R-) Expenditure (E+/E-)	Magnitude	
A. On issuing agency: B. On other State agencies: C. On local	(E-)	\$2,500,000— \$3,000,000 Indeterminate	
governments:	NONE		
	Benefit (+) Cost (-)	Magnitude	
D. On regulated industries or trade groups: E. On other industries	(+)	Indeterminate	
or trade groups:	NONE		
F. Direct and indirect effects on public:	(+)	Indeterminate	
III Assumptions (Identified by Impact Letter and Number from			

- **III. Assumptions.** (Identified by Impact Letter and Number from Section II.)
- A. The Commission estimates that \$2,000,000—\$3,000,000 is needed to fund the operations of the Commission. The Commission based these figures on a number of items including indirect costs, salaries, IT costs, rent for office space, office supplies, shared services employees, telephone, postage, mileage reimbursement for Commissioners, investigators, and inspectors, the cost of inspections and investigations, laboratory costs for testing, consultants for vetting applications, costs for an Assistant Attorney General, Office of Administrative Hearings, travel and hotel stays for investigators and inspectors, printing costs, office equipment and maintenance, software maintenance, and training programs.
- B. The Commission cannot estimate the costs to any other agencies at this time.
- D. The Commission cannot estimate the cost to regulated industries because this a new program and industry in the State.
- F. The Commission cannot estimate the impact to the public because it cannot predict the number of qualifying patients or caregivers who will apply for medical marijuana or the impact of the program generally on the public.

Economic Impact on Small Businesses

The proposed action has a meaningful economic impact on small business. An analysis of this economic impact follows.

As this will be a new and growing industry in the State, it is expected that there to be a positive impact for small businesses through the creation of jobs in the industry. As the program starts, there will be a cost to small businesses for licensing, security, construction, and other startup costs. The Commission cannot estimate the exact impact at this time.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Michele Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 West Preston Street, Room 512, Baltimore, Maryland 21201, or call 410-767-6499 (TTY 800-735-2258), or email to dhmh.regs@maryland.gov, or fax to 410-767-6483. Comments will be accepted through July 27, 2015. A public hearing has not been scheduled.

10.62.01 Definitions

Authority: Health General Article, §§13-3301—13-3303, Annotated Code of Maryland

.01 Definitions.

- A. In this subtitle, the following terms have the meanings indicated.
 - B. Terms Defined.
- (1) "Association" means employment or volunteer status at a licensed grower, licensed processor, or licensed dispensary.
 - (2) Batch
- (a) "Batch" means all of the plants of the same variety of medical cannabis that have been:
 - (i) Grown, harvested, and processed together; and
- (ii) Exposed to substantially similar conditions throughout cultivation and processing.
- (b) "Batch" includes all of the processed materials produced from those plants.
- (3) "Bona fide physician-patient relationship" means a treatment or counseling relationship between a physician and a patient in which the physician has:
- (a) Reviewed the patient's relevant medical records and completed an in person assessment of the patient's medical history and current medical condition;
- (b) Created and maintained records of the patient's condition in accord with medically accepted standards; and
- (c) A reasonable expectation that the physician will monitor the progress of the patient while using medical cannabis and take any medically indicated action:
 - (i) To provide follow-up care to the patient;
- (ii) Regarding the efficacy of the use of medical cannabis as a treatment of the patient's severe or debilitating medical condition; and
- (iii) Regarding any adverse event associated with the use of medical cannabis.
 - (4) Caregiver.
- (a) "Caregiver" means an individual 21 years old or older designated by a patient who has agreed to assist with a qualifying patient's medical use of medical cannabis.
- (b) "Caregiver" means, for a qualifying patient younger than 18 years old, a parent, or legal guardian.
- (5) "Central Repository" means the Criminal Justice Information System Central Repository of the Department of Public Safety and Correctional Services.
- (6) "Certifying physician" means a physician, as defined in Health Occupations Article, \$14-101(i), Annotated Code of Maryland, who is registered by the Commission.
- (7) "Commission" means the Natalie M. LaPrade Medical Cannabis Commission.
- (8) "Criminal history record information" has the meaning provided by Criminal Procedure Article, §10-201(d)(3), Annotated Code of Maryland.
- (9) "Dispensary agent" means an owner, a member, an employee, a volunteer, an officer or a director of a licensed dispensary.
- (10) "Fund" means the Natalie M. LaPrade Medical Cannabis Commission Fund.

- (11) "Independent testing laboratory" means a facility, entity, or site that offers or performs tests of medical cannabis and products containing medical cannabis:
- (a) Accredited as operating to ISO standard 17025 by an accreditation body:
- (i) Operating in accordance with the International Organization for Standardization (ISO) standard ISO/IEC 17011; and
- (ii) That is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA); and
- (iii) That is independent from all other persons involved in the Maryland cannabis industry; and
 - (b) Registered with the Commission.
- (12) "Law enforcement agency" means a governmental police force, sheriff's office, security force, or law enforcement organization of the State, a county, or a municipal corporation that by statute, ordinance, or common law is authorized to enforce the general criminal laws of the State.
- (13) "Licensed dispensary" means an entity licensed by the Commission that acquires, possesses, repackages, processes, transfers, transports, sells, distributes, or dispenses, products containing medical cannabis, related supplies, related products including tinctures, aerosols, oils, or ointments, or educational materials for use by a qualifying patient or caregiver.
- (14) "Licensed grower" means an entity that cultivates, manufactures, packages or distributes medical cannabis to licensed processors, licensed dispensaries or registered independent testing laboratories.
- (15) "Licensed premises" means the locations at which a licensed grower, licensed processor, or licensed dispensary operates.
- (16) "Licensed processor" means an entity licensed by the Commission that:
- (a) Transforms the medical cannabis into another product or extract; and
 - (b) Packages and labels medical cannabis.
- (17) "Lot" means all of a medical cannabis finished product that is uniform, that is intended to meet specifications, and that is manufactured, packaged, or labeled together during a specified time period according to a single lot record.
- (18) "Medical cannabis" means any product containing usable cannabis or medical cannabis finished product.
- (19) "Medical cannabis concentrate" means a product derived from medical cannabis that is kief, hashish, bubble hash, oil, wax, or other product, produced by extracting cannabinoids from the plant through the use of:
 - (a) Solvents;
 - (b) Carbon dioxide; or
 - (c) Heat, screens, presses or steam distillation.
- (20) "Medical cannabis finished product" means any product containing a medical cannabis concentrate or a medical cannabisinfused product packaged and labeled for release to a qualifing patient.
 - (21) Medical Cannabis-Infused Product.
- (a) "Medical cannabis-infused product" means oil, wax, ointment, salve, tincture, capsule, suppository, dermal patch, cartridge or other product containing medical cannabis concentrate or usable cannabis that has been processed so that the dried leaves and flowers are integrated into other material.
- (b) "Medical cannabis-infused product" does not include a food as that term is defined in Health-General Article, §21-101, Annotated Code of Maryland.
- (22) "Medical cannabis grower agent" means an owner, an employee, a volunteer, an officer, or a director of a licensed grower.

- (23) "Medical cannabis transport vehicle" means a vehicle owned, or leased by a licensee, for the purpose of transporting products containing cannabis that meets the criteria specified in Regulation .06 of this chapter.
- (24) "Processing" means the manufacture of usable medical cannabis into a medical cannabis concentrate, or manufacture of a medical cannabis-infused product.
 - (25) "Qualifying patient" means an individual who:
- (a) Lives in the State or, during that time an individual is present in the State, is physically present in the State for the purpose of receiving medical care from a medical facility in the State;
- (b) Has been provided with a written certification by a certifying physician in accordance with a bona fide physician-patient relationship; and
 - (c) If younger than 18 years old, has a caregiver.
- (26) "Registered dispensary agent" means a dispensary agent who is registered by the Commission in accordance with COMAR 10.62.26.
- (27) "Registered grower agent" means a medical cannabis grower agent who is registered by the Commission in accordance with COMAR 10.62.09.
- (28) "Registered processor agent" means a medical cannabis processor agent who is registered by the Commission in accordance with COMAR 10.62.20.
- (29) "Serious adverse event" means an undesirable experience associated with the use of medical cannabis where the outcome was death, life-threatening, hospitalization, disability or permanent damage, congenital anomaly/birth defect; required intervention to prevent permanent impairment or damage, or any other important medical event.
- (30) "Shipment identification number" means a unique identification number created by the shipping licensee to track a shipment of products containing cannabis.
 - (31) "Transportation agent" means:
- (a) A registered grower agent, registered processor agent or a registered dispensary agent, authorized by the licensee to transport products containing medical cannabis, who meets the criteria specified in COMAR 10.62.18; or
- (b) A licensed and bonded courier of a secure transportation company.
- (32) "Variety" means the name of a cultivar or varietal of medical cannabis used by a licensed grower to consistently identify and control medical cannabis from batch to batch.
 - (33) Usable Cannabis.
- (a) "Usable cannabis" means the dried leaves and flowers of the cannabis plant.
- (b) "Usable cannabis" does not include seedlings, seeds, stems, stalks or roots of the plant or the weight of any non-cannabis ingredients combined with cannabis, such as ingredients added to prepare a topical administration.
- (34) "Written certification" means a certification that is issued by a certifying physician for a qualifying patient with whom the physician has a bona fide physician-patient relationship.
 - (35) "30-day supply" means:
- (a) 120 grams of usable cannabis unless the physician determines this amount would be inadequate to meet the medical needs of the qualifying patient; or
- (b) In the case of a medical cannabis-infused product, 36 grams of $\Delta 9$ -Tetrahydrocannabinol (THC) unless the physician determines this amount would be inadequate to meet the medical needs of the qualifying patient.

10.62.02 General Regulations

Authority: Health General Article, §§13-3301—13-3316, Annotated Code of Maryland

.01 Scope.

This subtitle governs operations of the Natalie M. LaPrade Medical Cannabis Commission.

.02 Donations.

- A. The Commission may accept private donations to the Fund subject to the conditions established by the Commission.
- B. Donations to the Fund may not be accepted from an individual or entity that:
 - (1) Is licensed or approved by the Commission;
 - (2) Is seeking licensure or approval by the Commission;
 - (3) Has sought licensure or approval within the past 2 years, or
- (4) Is affiliated with an individual or entity described in \$B(1)—(3) of this regulation.
- C. An individual or entity that has made a donation to the Fund may not apply for licensure or approval by the Commission for a period of 2 years from the date of donation.

.03 HIPAA Compliance.

All Commission activities shall be conducted in compliance with HIPAA regulations.

.04 Encouragement of Applications.

- A. The Commission shall broadly publicize that the Commission will be seeking:
- (1) The submission of applications for licenses to grow, process, and dispense medical cannabis; and
- (2) The submission of applications to register patients, physicians, and independent testing laboratories from all interested persons throughout the State.
- B. The Commission shall encourage applications from applicants who qualify as minority business enterprises, as defined in State Finance and Procurement Article, §14-301, Annotated Code of Maryland.
- C. The Commission shall work with a wide variety of public and private agencies, organizations and groups to publicize the application and registration processes and encourage all interested persons to contact the Commission for additional information or assistance.

10.62.03 Certifying Physicians

Authority: Health General Article, §§ 13-3301, 13-3302, and 13-3307, Annotated Code of Maryland

.01 Physician Application for Registration.

A. A physician seeking registration as a certifying physician shall submit an application provided by the Commission that includes:

- (1) The physician's:
 - (a) Full name;
 - (b) Social Security Number;
 - (c) Office addresses and phone numbers;
 - (d) Current email address;
 - (e) Maryland Board of Physicians license number; and
- (f) Plan to assess patient outcomes, provide follow-up care, and to collect and analyze data;
 - (2) An attestation that the:
- (a) Physician's Maryland license to practice medicine is active, unrestricted, and in good standing;
- (b) Physician is registered to prescribe controlled substances by the State; and

- (c) A standard patient evaluation will be completed and include:
 - (i) A history;
 - (ii) A physical examination;
 - (iii) A review of symptoms; and
 - (iv) Any other pertinent medical information;
- (3) The medical conditions for which the physician may issue written certifications for medical cannabis;
 - (4) The physician's other inclusion criteria; and
- (5) The reasons the physician may deny issuing a written certification of medical cannabis.
- B. The Commission encourages physicians to apply to register as a certifying physician to treat patients who:
- (1) Have a chronic or debilitating disease or medical condition that results in the patient being admitted into hospice or receiving palliative care;
- (2) Have a chronic or debilitating disease or medical condition or are receiving treatment for a chronic or debilitating disease or medical condition that causes:
 - (a) Cachexia;
 - (b) Anorexia;
 - (c) Wasting syndrome;
 - (d) Severe or chronic pain;
 - (e) Severe nausea;
 - (f) Seizures; or
 - (g) Severe or persistent muscle spasms;
 - (3) Have the following diseases and conditions:
 - (a) Glaucoma; or
 - (b) Post traumatic stress disorder (PTSD).
- C. A physician may be registered as a certifying physician to treat a patient who has a condition that is:
 - (1) Severe;
- (2) For which other medical treatments have been ineffective; and
- (3) If the symptoms reasonably can be expected to be relieved by the medical use of cannabis.
- D. A certifying physician may apply to amend the approval at any time.
- E. The application shall be deemed approved unless the Commission notifies the applicant that the application has been denied

.02 Compensation from a Licensed Grower, Licensed Processor or Licensed Dispensary.

- A. A certifying physician may not receive compensation, including promotion, recommendation, advertising, subsidized rent, or anything of value, from a licensed grower, licensed processor, or a licensed dispensary unless the certifying physician submits an application to the Commission for approval for the compensation.
 - B. The application shall disclose:
- (1) The specific type of compensation and specific amount or value of compensation and the services for which the compensation will be paid; and
 - (2) An attestation that the compensation does not violate the:
- (a) Maryland Medical Practice Act, codified at Health Occupations Article, §14-101 et. seq., Annotated Code of Maryland;
- (b) Patient referral laws codified at Health Occupations Article, §1-301 et. seq., Annotated Code of Maryland.
 - C. The Commission shall deny an application for compensation if:
- (1) The compensation is based on any agreement or arrangement for the certifying physician to refer, direct, or recommend qualifying patients to the licensed grower, licensed processor, or licensed dispensary to obtain medical cannabis;

- (2) The physician refuses to attest that the compensation would not violate the Maryland Medical Practice Act, codified at Health Occupations Article, §14-101 et. seq., Annotated Code of Maryland or the patient referral laws codified at Health Occupations Article, §1-301 et. seq., Annotated Code of Maryland; or
 - (3) The compensation would violate the:
- (a) Maryland Medical Practice Act, codified at Health Occupations Article, §14-101 et. seq., Annotated Code of Maryland; or
- (b) Patient referral laws codified at Health Occupations Article, §1-301 et. seq., Annotated Code of Maryland.
- D. The Commission may deny an application for compensation if the compensation agreement may create an appearance that the compensation compromises the independent judgment of the certifying physician in the treatment of a patient.
- E. If the Commission denies an application for compensation, the Commission shall provide the physician with written notice pursuant to State Government Article, §§10-201-10-226, Annotated Code of Maryland. The physician shall be entitled to a hearing to review the denial pursuant to State Government Article, §§10-201-10-226, Annotated Code of Maryland.

.03 Renewal of Certifying Physician Registration to Certify.

- A. An approval is valid for 2 years.
- B. A certifying physician shall apply to renew a registration to certify at the time of renewal of the physician's license to practice medicine by the Maryland Board of Physicians.
- C. The Commission shall provide a certifying physician with notice of renewal 90 business days before expiration of the registration.
- D. The Commission shall grant the application for renewal of registration if:
 - (1) The certifying physician attests that:
- (a) The certifying physician's license to practice medicine in Maryland is active, unrestricted and in good standing; and
- (b) The certifying physician's registration by the State to prescribe controlled dangerous substances is valid; and
- (2) The certifying physician has otherwise complied with this chapter.
- E. If a certifying physician fails to obtain a renewal of a registration to issue written certifications, the certifying physician may not issue written certifications.

10.62.04 Patient and Caregiver Registry

Authority: Health General Article. §§13-3301, 13-3302(d), 13-3303(g) and 13-3307(f)(3), Annotated Code of Maryland

.01 Registry.

The Commission shall establish a registry of qualifying patients and caregivers.

.02 Registration of Patients.

An individual seeking to become a qualifying patient shall register with the Commission by:

- A. Logging onto the Commission website;
- B. Providing name, address, date of birth, address; and
- C. Uploading an image of a government identification document to establish identity.

.03 Patient Unique Identifier.

The Commission shall issue a unique patient identifier to each person who registers with the Commission.

.04 Registration of a Caregiver.

A. A qualifying patient may designate an individual 21 years old or older to serve as a caregiver by logging onto the Commission website.

- B. Upon being designated a caregiver by a qualifying patient, a caregiver shall register with the Commission by logging onto the Commission website for caregiver registration and submitting:
- (1) The name and other details of the qualifying patient for whom the caregiver is:
 - (a) Providing assistance; or
 - (b) A parent or legal guardian;
- (2) Proof that the caregiver is authorized to act as a caregiver by the qualifying patient;
 - (3) Details to identify the caregiver;
- (4) A current, clear photograph of the caregiver's face taken within 6 months of application;
- (5) An attestation that the caregiver is not the caregiver for more than five qualifying patients;
- (6) A copy of the caregiver's government identification card or other proof of identity;
 - (7) The required fee as specified in COMAR 10.62.35; and
- (8) An attestation that the caregiver understands the restrictions on the use or redistribution of medical cannabis set forth in COMAR 10.62.30.05.
- C. If designated to serve as a caregiver by another qualifying patient, a registered caregiver may update his or her registration by logging onto the Commission website and submitting the name and other details of the additional qualifying patient for whom the caregiver is providing assistance or for whom the caregiver is a parent or legal guardian.

.05 Addition or Termination of a Caregiver.

- A. A qualifying patient may terminate a caregiver by logging onto the Commission website and making the change.
- B. Provided the qualifying patient does not have more than two caregivers, a qualifying patient may add a caregiver by logging onto the Commission website and making the change.

.06 Law Enforcement Access to Registry.

The Commission shall provide access to the Commission's register to a Maryland law enforcement agency on a real-time basis only for just cause to verify that a patient or caregiver is registered with the Commission.

10.62.05 Written Certifications

Authority: Health General Article, §§ 13-3301, 13-3302, and 13-3307, Annotated Code of Maryland

.01 Issuing a Written Certification.

- A. A certifying physician may determine that a patient qualifies for a written certification only:
- (1) If the qualifying patient has registered with the Commission;
- (2) For whom the certifying physician has a bona fide physician-patient relationship;
- (3) If the qualifying patient meets the certifying physician's inclusion criteria;
- (4) If the qualifying patient does not meet the certifying physician's exclusion criteria; and
- (5) If the certifying physician has determined that the potential benefits of the medical use of cannabis likely outweigh the health risks for the patient.
 - B. The certifying physician shall:
- (1) Log onto the website of the Commission to transmit the written certification to the Commission; and
- (2) If requested, provide a copy of the written certification to the qualifying patient.

- C. A written certification shall include the:
- (1) Physician's name, Maryland Board of Physicians license number, and office telephone number;
- (2) Qualifying patient's name, date of birth, address, and county of residence;
 - (3) Medical condition requiring medical cannabis; and
 - (4) The date of qualification as a qualifying patient.
- D. A written certification may contain, if applicable, a written statement certifying that, in the physician's professional opinion, a 30-day supply of medical cannabis would be inadequate to meet the medical needs of the qualifying patient.
- E. A certifying physician may discuss the use of medical cannabis with a qualifying patient.
 - F. A certifying physician shall terminate a written certification if:
- (1) The qualifying patient meets the physician's exclusion criteria:
- (2) Treatment with medical cannabis is no longer necessary for the qualifying patient;
- (3) Adverse effects of medical cannabis outweigh the benefits to the qualifying patient's health; or
- (4) There is evidence that the qualifying patient engaged in diversion of medical cannabis.
- G. A certifying physician may terminate a written certification if the qualifying patient demonstrates abuse of any substance of abuse.
- H. A certifying physician shall notify the Commission within 1 business day of the termination of a written certification.
- I. A qualifying patient shall have only one certifying physician at any time.

.02 Written Certification Renewal.

- A. A qualifying patient may seek renewal of a written certification not less than 30 calendar days after it was issued by notifying the patient's certifying physician.
- B. A certifying physician may renew the written certification for a qualifying patient if the certifying physician determines the patient still meets the criteria set forth in Regulation .01A of this chapter.
- C. Upon renewing a written certification for a qualifying patient, a certifying physician shall notify the Commission.
- D. A certifying physician may not renew a written certification unless the physician has made a full, in-person assessment of the qualifying patient within the 365 days before the reissuance.

10.62.06 Patient and Caregiver Identification Cards

Authority: Health General Article, §\$13-3301, 13-3302(d), 13-3303(g) and 13-3307(f)(3), Annotated Code of Maryland

.01 Patient Identification Cards.

- A. A qualifying patient may apply to the Commission for an identification card as part of the qualifying process by logging onto the Commission website and submitting:
- (1) The completed application form as provided by the Commission:
- (2) A current, clear photograph of the applicant's face taken within 6 months of application;
- (3) A copy of the qualifying patient's government identification card or other proof of identity; and
 - (4) The required fee as specified in COMAR 10.62.35.
 - B. An identification card shall contain:
 - (1) The name and date of birth of the cardholder;
 - (2) An expiration date 2 years from the date of issue;
- (3) A current, clear photograph of the applicant's face taken within the previous 6 months; and

- (4) The qualifying patient registry number assigned by the ommission.
- C. A qualifying patient in hospice care is exempt from obtaining an identification card.

.02 Caregiver Identification Cards.

- A. Upon being designated a caregiver by a qualifying patient, a caregiver shall:
 - (1) Apply to the Commission for an identification card; and
 - (2) Submit to the Commission:
- (a) The name of the qualifying patient for whom the caregiver is providing assistance or for whom the caregiver is a parent or legal guardian;
- (b) Proof that the caregiver is authorized to act as a caregiver by the qualifying patient;
- (c) A current, clear photograph of the applicant's face taken within 6 months of application;
- (d) The completed application in a format determined by the Commission:
- (e) An attestation that the caregiver is not the caregiver for more than five qualifying patients;
- (f) A copy of the caregiver's government identification card or other proof of identity;
 - (g) The required fee as specified in COMAR 10.62.35; and
- (h) An attestation that the caregiver understands the restrictions:
- (i) That it is illegal to transfer medical cannabis to any person, other than the transfer by a caregiver to a qualifying patient;
- (ii) On the use or redistribution of medical cannabis set forth in COMAR 10.62,30.05.
 - B. An identification card shall contain:
 - (1) The name and date of birth of the cardholder;
 - (2) An expiration date 2 years from the date of issue;
- (3) A current, clear photograph of the applicant's face taken within the previous 6 months; and
- (4) The caregiver registration number assigned by the Commission.

.03 Loss, Destruction or Theft of Identification Card.

- If an identification card is lost, destroyed or stolen, within 72 hours of becoming aware of the loss, destruction or theft, the cardholder shall:
 - A. Report the loss, destruction, or theft to the Commission; and
 - B. Apply for a replacement card; and
 - C. Pay the replacement card fee specified in COMAR 10.62.35.

.04 Change of Name or Address.

If there is any change in the qualifying patient or the caregiver name or address, the qualifying patient or caregiver shall:

- A. Notify the Commission within 30 days; and
- B. If seeking a replacement identification card, pay the identification card replacement fee to obtain a new identification card.

.05 Circumstances Requiring Return of Identification Card to Commission.

- A. If a certifying physician fails to renew a qualifying patient certification, a qualifying patient shall return an identification card to the Commission within 5 business days.
- B. A caregiver shall return his or her identification card with respect to a qualifying patient to the Commission within 5 business days if:
- (1) A certifying physician terminates or fails to renew a written certification of a qualifying patient; or
 - (2) A caregiver is no longer assisting a qualifying patient.

.06 Renewal of Identification Card.

- A. A qualifying patient shall renew their identification card before it expires.
- B. A caregiver shall renew their identification card before it expires.

.07 Misuse of Identification Card.

- A. If an individual attempts to use a qualifying patient or caregiver identification card to whom it has not been issued, any registered dispensary agent to whom it is offered shall confiscate it and initiate the return of the card to the Commission within 5 business days.
- B. If a person presents to a law enforcement officer an identification card of a qualifying patient or caregiver to whom it has not been issued, the law enforcement officer shall confiscate the identification card and initiate the return of the card to the Commission as soon as possible.
- C. The Commission may notify the certifying physician and revoke the identification card of a qualifying patient or caregiver who allows another person to use an identification card which has been issued to the qualifying patient or caregiver.

10.62.07 New Condition Approval Process

Authority: Health General Article, §13-3304(d) and (e), Annotated Code of Maryland

.01 Requirement of a Petition.

A person who wishes to suggest a medical condition, medical treatment, or disease for Commission consideration shall submit a petition to the Commission in a format determined by the Commission.

.02 Hearing.

At least once per year if needed, the Commission shall conduct a public hearing to evaluate any petition to consider other medical conditions, medical treatments, or diseases that may be treated by using medical cannabis and included in certifying physician applications.

.03 Petition Contents.

The Commission shall consider a petition that may include:

- A. The severity of a condition or the treatments thereof;
- B. The degree to which other medical treatments have been ineffective to alleviate pain, suffering, disability or the symptoms of the condition or the treatment thereof;
- C. Evidence that supports a finding that the use of medical cannabis alleviates pain, suffering, disability or symptoms of the condition or the treatment thereof;
- D. Any information or studies regarding any beneficial or adverse effects from the use of medical cannabis in patients with the medical condition, medical treatment, or disease that is the subject of the petition: and
- E. Letters of support from physicians or other licensed health care professionals knowledgeable about the condition, treatment, or disease.

.04 Summary Denial.

The Commission may deny a petition, without submitting it for public comment if the petition:

- A. Is facially insubstantial; or
- B. Pertains to a medical condition, medical treatment, or disease that has been previously considered and rejected by the Commission, unless scientific research not previously considered in a prior Commission review is included in the petition.

.05 Additional Evidence.

In addition to information provided in a petition, the Commission may:

- A. Examine scientific, medical, or other evidence and research pertaining to the petition; and
- B. Gather information in-person or in writing, from other persons knowledgeable about the medical conditions, medical treatments, or diseases being considered.

.06 Commission Determination.

- A. Following the public hearing, the Commission shall consider the public comments and any additional information or expertise available to the Commission for each proposed severe medical condition, medical treatment or disease considered at the hearing.
- B. The Commission may conclude that physicians will be encouraged to apply to register with the Commission to treat the medical condition, medical treatment, or disease upon a determination that:
- (1) The medical condition, medical treatment, or disease is debilitating;
- (2) The pain, suffering and disability of the medical condition, disease or medical treatment thereof can reasonably be expected to be relieved by medical cannabis; and
- (3) Other medical treatments have been ineffective in providing relief.

10.62.08 Medical Cannabis Grower License

Authority: Health General Article, §§13-3301, 13-3302, 13-3306, and 13-3312, Annotated Code of Maryland

.01 Definitions.

- A. In this chapter, the following terms have the meaning indicated. B. Terms Defined.
- (1) "Audited financial statement" means an audited financial statement that is:
- (a) Performed by a certified public accountant licensed or with practice privileges in Maryland pursuant to Business Occupations and Professions Article, Title 2, Annotated Code of Maryland;
- (b) Prepared in accordance with the Professional Standards of the American Institute of Certified Public Accountants; and
- (c) In the case of a publicly owned corporation, in conformity with the standards of the Public Company Oversight Board.
- (2) "License" means a license issued by the Commission to operate as a grower.
 - (3) "Licensee" means a licensed grower.

.02 Application for a Medical Cannabis Grower License.

- A. An applicant shall submit an application for a license.
- B. An application shall be:
 - (1) Completed on a form developed by the Commission; and
 - (2) Submitted to the Commission for consideration.
- C. In addition to the application form, the applicant shall submit the following documents to be included as addenda to the application form:
- (1) A list identifying the applicant's potential medical cannabis grower agents;
- (2) A list identifying each individual investor with 5 percent or more of investment known at the time of application;
 - (3) A detailed business plan including an organizational chart;
 - (4) Documentation and source of adequate capitalization;
- (5) If the applicant is a corporation or business entity, a copy of the articles of incorporation and authorization to do business in Maryland;

- (6) A record of tax payments in all jurisdictions in which an applicant has operated as a business for the 5 years before the filing of the application;
- (7) A description of the proposed premises, including a preliminary site plan;
 - (8) A security plan;
- (9) Details of the applicant's experience, knowledge, and training in commercial horticultural or agronomic production;
- (10) The medical cannabis varieties proposed to be grown with proposed cannabinoid profiles;
 - (11) A plan for quality control;
 - (12) A plan for inventorying, safekeeping and tracking:
 - (a) Medical cannabis from "seed to sale," and
 - (b) Waste plant material prior to destruction; and
 - (13) A disposal plan for medical cannabis waste.
- D. A grower planning to operate as a dispensary of medical cannabis shall submit a dispensary application.
- E. The application shall be accompanied by the stage 1 application fee specified in COMAR 10.62.35.
- F. A party applying for a license shall have an interest in only one grower license application.
- G. An applicant shall amend an application within 3 business days to include the name and documentation of a request to forward the criminal history record information to the Commission of:
- (1) A new individual investor of an interest of 5 percent or more; or
- (2) Another manager or director of the entity, even after a license is issued.

.03 Criminal History Record Check.

For each individual identified in the application specified in Regulation .02B(1) of this chapter, an applicant shall provide to the Director of the Central Repository:

- A. Two sets of legible fingerprints taken in a format approved by the Director of CJIS and the Director of the FBI and the fee authorized under Criminal Procedure Article, §10-221(B)(7), Annotated Code of Maryland for access to State criminal history and records for each medical cannabis grower agent and investor identified in the application; and
- B. A request that the individual's state and national criminal history record information be forwarded to the Commission.

.04 Consent for Investigation.

- A. An individual who is required to provide personal and background information under this chapter shall provide a statement that irrevocably gives consent to the Commission and persons authorized by the Commission to:
- (1) Verify all information provided in the application documents; and
 - (2) Conduct a background investigation of the individual.
- B. An applicant shall waive any contractual, statutory, or common law obligation of confidentiality and authorize any government agency in any jurisiction to release to and provide access to the Commission of any and all information the applicant has provided to any other jurisdiction while seeking a cannabis-related license in that other jurisdiction, as well as the information obtained by that other jurisdiction during the course of any investigation it may have conducted regarding the applicant.
- C. An applicant shall release all financial institutions, fiduciaries, and other parties from any contractual, statutory or common law obligation of confidentiality to provide financial, personal and background information to the Commission relevant to the applicant's capacity to manage a licensed growing facility and the applicant's good moral character.

.05 Application Review.

- A. The burden of proving an applicant's qualifications rests on the applicant.
- B. The Commission may deny an application that contains a misstatement, omission, misrepresentation, or untruth.
 - C. An application shall be complete in every material detail.
- D. The Commission may request any additional information the Commission determines is necessary to process and fully investigate an application.
- E. The applicant shall provide requested additional information by the close of business of the 14th business day after the request has been received by the applicant.
- F. If the applicant does not provide the requested information within 14 business days, the Commission may consider the application to be suspended.
- G. The Commission intends to award the licenses to the best applications that most efficiently and effectively ensure public safety and safe access to medical cannabis.
- H. The Commission shall provide guidelines and detailed instructions for submitting the application form for the Commission's consideration.
- I. The Commission, or a Commission independent contractor, shall review for a pre-approval for a license the submitted applications as described in Regulations .02B and .05E of this chapter. The applications shall be ranked based on the following weighted criteria:
- (1) Operational factors will be afforded 20 percent weight, including:
- (a) A detailed operational plan for the cultivation of medical cannabis; and
 - (b) Summaries of policies and procedures for:
 - (i) Cultivation;
 - (ii) Growth;
 - (iii) Processing; and
 - (iv) Packaging;
- (2) Safety and Security factors will be afforded 20 percent weight, including:
- (a) Detailed plan or information describing the security features and procedures;
- (b) Detailed plan describing how the grower will prevent diversion; and
 - (c) Detailed plan describing safety procedures;
- (3) Commercial horticultural or agricultural factors will be afforded 15 percent weight, including, experience, knowledge and training in:
 - (a) Horticultural production; or
 - (b) Agricultural production;
- (4) Production control factors will be afforded 15 percent weight, including:
 - (a) A detailed quality control plan;
 - (b) A detailed inventory control plan; and
 - (c) A detailed medical cannabis waste disposal plan;
- (5) Business and economic factors will be afforded 15 percent weight, including:
- (a) A business plan demonstrating a likelihood of success, a sufficient business ability and experience on the part of the applicant, and providing for appropriate employee working conditions, benefits and training;
 - (b) Demonstration of adequate capitalization;
- (c) A detailed plan evidencing how the grower will enforce the alcohol and drug free workplace policy
- (6) Additional factors that will be afforded 15 percent weight, including:
- (a) Demonstrated Maryland residency among the owners and investors;

- (b) Evidence that applicant is not in arrears regarding any tax obligation in Maryland and other jurisdictions;
- (c) A detailed plan evidencing how the grower will distribute to dispensaries and processors; and,
- (d) A list of proposed medical cannabis varieties proposed to be grown with proposed cannabinoid profiles, including:
 - (i) Varieties with high cannabidiol content; and
- (ii) Whether the strain has any demonstrated success in alleviating symptoms of specific diseases or conditions.
- J. For scoring purposes, the Commission may take into account the geographic location of the growing operation to ensure there is geographic diversity in the award of licenses.

.06 Pre-Approval of Application.

- A. Limitation on Number of Licenses.
 - (1) The Commission may issue pre-approval of up to 15 licenses:
- (a) Until May 31, 2018, in accordance with Health General Article, §13-3306(a)(2), Annotated Code of Maryland; and
- (b) In consideration of the ranking of the applications in accordance with Regulation .05 of this chapter.
- (2) Beginning June 1, 2018, the Commission may issue the number of pre-approvals of a license necessary to meet the demand for medical cannabis by qualifying patients in an affordable, accessible, secure and efficient manner.
- B. If there are more qualified applications than the number of licenses available and there is a numerical tie for the last license to be issued, the license shall be determined by public lottery.
- C. The Commission may deny issuing a pre-approval of a license if, for any individual identified in the application specified in Regulation .02B(1) of this chapter:
- (1) The criminal history record information or any other evidence that demonstrates an absence of good moral character; or
 - (2) The payment of taxes due in any jurisdiction is in arrears.
- D. Within 10 business days of the Commission's decision, the Commission shall notify an applicant who has been pre-approved for a license.
- E. The Commission may rescind pre-approval of a grower license if the grower is not operational within 1 year of pre-approval.

.07 Issuance of License.

- A. After an applicant has been issued a pre-approval for a license under this chapter the applicant shall submit to the Commission, as part of its application:
- (1) An audited financial statement for the applicant and any proposed grower agents; and
- (2) Payment of the stage 2 application fee specified in COMAR 10.62.35
- B. The Commission may issue a license either to grow medical cannabis or to grow medical cannabis and distribute it to qualifying patients and caregivers on a determination that:
- (1) All inspections are passed and all of the applicant's operations conform to the specifications of the application as preapproved pursuant to Regulation .06 of this chapter;
 - (2) The proposed premises:
 - (a) Are under the legal control of the applicant;
 - (b) Comply with all zoning and planning requirements; and
- (c) Conform to the specifications of the application as preapproved pursuant to Regulation .06 of this chapter; and
- (3) The first year's license fee specified in COMAR 10.62.35 has been paid.

.08 Change of Ownership of License.

- A. No interest of 5 percent or more of a license issued pursuant to this chapter shall be assignable or transferable unless:
- (1) The Commission has received notice of the intent of the owner of the interest, or of the estate of the owner of the interest, to transfer or assign an interest in a license to another party;

- (2) The transferee has had forwarded the criminal history record information and audited financial statement to the Commission of the transferee;
- (3) The Commission does not object to the transfer or assignment within 45 days of its receipt of notice; and
- (4) The transferee has paid the required fee specified in COMAR 10.62,35.
- B. The Commission may deny transfer of an interest in a license for any proposed transferee if the:
- (1) Criminal history record information or the background investigation demonstrate an absence of good moral character; or
 - (2) Payment of taxes due in any jurisdiction is in arrears..

.09 Change of Location.

- A. A licensee may apply to change the location of the licensee's operation.
- B. The licensee shall submit an application to the Commission along with the fee specified in COMAR 10.62.35.
- C. A licensee may not begin cultivation or dispensing of medical cannabis at a new location until all inspections have been passed.

.10 Renewal of License.

- A. A licensee is eligible to apply to renew a license every 2 years.
- B. Ninety days before the expiration of a license, the Commission shall notify the licensee of the:
 - (1) Date on which the license expires;
 - (2) Process and the fee required to renew the license; and
 - (3) Consequences of a failure to renew the license.
- C. At least 30 business days before a license expires a licensee shall submit:
 - (1) The renewal application as provided by the Commission;
- (2) Proof that fingerprints have been submitted to CJIS and the FBI for every grower agent and investor of an interest of 5 percent or more:
- (3) To full inspection of the operation, unless a full inspection was satisfactorily completed within 3 months before the date of the license expiration; and
 - (4) Payment of the fee specified in COMAR 10.62.35.
- D. The Commission shall renew a license that meets the requirements for renewal as stated in §C of this regulation.
- E. If the Commission does not renew a license due to a failed inspection or an inadequate application for renewal, the licensee may apply for reinstatement by:
- (1) Submitting a plan to correct the deficiencies noted during an inspection; and
 - (2) Amending the application for renewal.
 - F. The Commission may decline to renew a license if:
- (1) The plan to correct deficiencies identified in an inspection is deficient;
 - (2) The amended application for renewal is deficient; or
 - (3) The licensee has repeatedly failed inspections.
- G. A licensee who fails to apply for renewal of a license by the date specified by the Commission, or whose license was not renewed by the Commission:
 - (1) Shall cease operations at all premises; and
 - (2) May not provide medical cannabis to any entity or person.
 - H. A license may be reinstated upon:
- (1) Payment of the reinstatement fee specified in COMAR 10.62.35; and
- (2) Submission of a reinstatement application approved by the Commission.

.11 Annual Report on Minority Owners and Employees.

On June 1 of each year, each licensee shall submit a report in a manner determined by the Commission regarding the licensee's minority owners and employees.

10.62.09 Medical Cannabis Grower Agent

Authority: Health General Article, §§13-3301, 13-3302, 13-3306, and 13-3312, Annotated Code of Maryland

.01 Definitions.

- A. In this chapter, the following terms have the meaning indicated. B. Terms Defined.
- (1) "License" means a license issued by the Commission to operate as a licensed grower.
 - (2) "Licensee" means a licensed grower.

.02 Grower Agent Generally.

A grower agent shall be 21 years old or older.

.03 Grower Agent Registration and Criminal History Record.

- A. Each medical cannabis grower agent shall be registered with the Commission before the agent may volunteer or work for a licensed grower.
- B. A licensed grower shall apply to register a grower agent by submitting to the Commission:
- (1) The name, address, date of birth, and Social Security Number of a grower agent;
- (2) Documentation of the submission of fingerprints of the grower agent to the Central Registry; and
- (3) The request for the criminal history record information of the grower agent to be forwarded to the Commission.
- C. A prospective grower agent may not be registered if the prospective grower agent has ever been convicted of a felony drug offense.
- D. The Commission, after review of the criminal history record information, may disqualify any prospective grower agent from registration for an absence of good moral character.

.04 Registered Grower Agent Identification Cards.

- A. The Commission shall issue to each registered grower agent a identification card which includes a photograph of the face of the registered grower agent taken no more than 6 months before the date of the application.
- B. At all times every registered grower agent at a licensed premises shall visibly wear the identification card issued to the registered grower agent by the Commission.
 - C. The identification card shall be renewed every 2 years.
- D. If a registered grower agent's identification card is lost, destroyed or stolen, within 24 hours of becoming aware of the loss, destruction or theft, the licensee shall:
 - (1) Report the loss, destruction or theft to the Commission;
 - (2) Apply for a replacement card; and
 - (3) Pay a replacement card fee specified in COMAR 10.62.35.
- E. An identification card remains the property of the Commission and the Commission may order the return or seizure of an identification card if the registration is revoked or expires.
- F. If a registered grower agent's identification card is lost, destroyed or stolen, a copy of notification to the Commission shall be evidence of registration until a new card is obtained from the Commission.

.05 Termination.

- A. As soon as possible upon termination of a registered grower agent's association with a licensed grower, the licensed grower shall:
- (1) Take custody of a terminated registered grower agent's identification card;
- (2) Obtain any keys or other entry devices from a terminated registered grower agent; and
- (3) Ensure a terminated registered grower agent can no longer gain access to the licensed premises.

- B. Within 1 business day of a termination of a registered grower agent's association with a licensed grower, a licensed grower shall:
 - (1) Notify the Commission:
- (a) Of a termination and the circumstances of a termination; and
- (b) Whether a terminated registered grower agent has returned the agent's identification card; and
- (2) Initiate delivery of a terminated registered grower agent's identification card to the Commission.
- C. The Commission shall revoke a registration of a grower agent upon receiving notification that a grower agent is no longer associated with a licensed grower.
- D. If a registered grower agent did not return the agent's identification card within 30 days of the termination, the Commission shall notify the Maryland State Police and place a notice in the register of that fact.

.06 Prospective Grower Agent Drug Screen.

- A. The licensee shall require a prospective grower agent to submit to a drug screen before commencement of association.
- B. The drug screen shall be carried out following the procedures set forth in COMAR 17.04.09.04—.08.
- C. In addition to the drugs to be screened in accordance with COMAR 17.04.09.06, the screen shall include any other drugs as required by the Commission.
- D. Unless medically justified, a prospective grower agent who has a positive response to any tested substance on a drug screen that meets the requirements of COMAR 17.04.09.07 may not be registered by the Commission.

.07 Grower Agent Training.

- A. The licensee shall train all registered grower agents on:
- Federal and State medical cannabis laws and regulations and other laws and regulations pertinent to the grower agent's responsibilities;
 - (2) Standard operating procedures;
 - (3) Detection and prevention of diversion of medical cannabis;
 - (4) Security procedures; and
 - (5) Safety procedures, including responding to;
 - (a) A medical emergency;
 - (b) A fire;
 - (c) A chemical spill; and
 - (d) A threatening event such as:
 - (i) An armed robbery;
 - (ii) An invasion;
 - (iii) A burglary; or
 - (iv) Any other criminal incident.
- B. The licensee shall retain training materials and attendance records and make the training materials available for inspection by the Commission.

.08 Alcohol and Drug Free Workplace Policy.

- A. Each registered grower agent shall declare in writing that the registered grower agent will adhere to the State alcohol and drug free workplace policy, as identified in COMAR 21.11.08.03.
- B. The licensee shall retain the declaration in a registered grower agent's personnel record.

.09 Annual Verification of Registered Grower Agents.

Every year, on a date determined by the Commission, the licensee shall notify the Commission that the licensee has verified that no registered grower agent has been convicted of a felony drug offense.

10.62.10 Medical Cannabis Grower Premises

Authority: Health General Article, §§13-3306(a)(3), (d), and (e), Annotated Code of Maryland

.01 Definitions.

- A. In this chapter, the following terms have the meaning indicated. B. Terms Defined.
- (1) "License" means a license issued by the Commission to operate as a grower.
 - (2) "Licensee" means a licensed grower.

.02 Premises Generally.

- A. A licensed premises shall be located within Maryland,
- B. The premises and operations of a licensee shall conform to local zoning and planning requirements.
- C. The grower license shall be conspicuously displayed at each licensed premises.
 - D. Modification of Premises.
- (1) A licensee shall notify the Commission of proposed major renovations or modifications to a licensed premises.
- (2) No major renovation or modification shall be undertaken without notification to the Commission.

.03 Additional Provisions for Field or Greenhouse Cultivation Premises.

- A. Licensed premises for field cultivation of medical cannabis shall be situated to maintain the greatest achievable level of privacy and security.
- B. Physical Security. An area of cultivation shall be securely surrounded by fencing and gates constructed to prevent unauthorized entry.
- C. Fencing and gates shall be equipped with a security alarm system that:
 - (1) Covers the entire perimeter;
 - (2) Is continuously monitored; and
 - (3) Is capable of detecting power loss.
- D. The premises shall be protected by a video surveillance recording system to ensure:
- (1) Surveillance of the entire perimeter of the area of cultivation;
- (2) Surveillance over all portions of the security fence and all gates; and
- (3) Adherence to the video surveillance requirements of this chapter.
- E. A video surveillance system shall be supported by adequate security lighting which may be modified as necessary to include motion control sensors to protect light-dark cycles for proper cultivation.

.04 Security of Premises.

A licensed premises shall be constructed to prevent unauthorized entry.

.05 Security Lighting.

- A. Lighting fixtures of the licensed grower shall be designed and installed to ensure proper surveillance.
- B. This regulation does not apply to lighting in areas of the premises used to cultivate medical cannabis.

.06 Security Alarm Systems.

- A. A licensee shall maintain a security alarm system that covers all perimeter entry points and portals at all premises.
 - B. A security system shall be:
 - (1) Continuously monitored;
 - (2) Capable of detecting smoke and fire; and
 - (3) Capable of detecting power loss.

- C. A security alarm system shall include panic alarm devices mounted at convenient, readily-accessible locations throughout the licensed premises.
- D. A second, independent security alarm system shall be used to protect:
 - (1) A location where records are stored on-site;
 - (2) A location where records are stored off-site; and
 - (3) A cabinet or room that holds medical cannabis.
- E. A security alarm system shall remain operational until a licensed premises no longer has any medical cannabis, seeds, or cuttings on the premises.
- F. A security alarm system shall be equipped with auxiliary power sufficient to maintain operation for at least 48 hours.

.07 Video Surveillance Requirements.

- A. A licensee shall maintain a motion-activated video surveillance recording system at all premises that:
- (1) Records all activity in images of high quality and high resolution capable of clearly revealing facial detail;
- (2) Operates 24-hours a day, 365 days a year without interruption; and
 - (3) Provides a date and time stamp for every recorded frame.
- B. A licensee shall post appropriate notices advising visitors of the video surveillance.
- C. A surveillance camera shall be located and operated to capture each exit from the premises.
- D. A surveillance camera shall capture activity at each entrance to an area where medical cannabis is grown, tested, cured, manufactured, processed or stored.
- E. A recording of all images captured by each surveillance camera shall be kept:
 - (1) At the licensed premises; and
 - (2) At an off-site location.
- F. The storage of all recordings of security video surveillance shall be:
 - (1) Access-limited;
- (2) Secured by a security alarm system that is independent of the main premises security alarm system;
- (3) In a format that can be easily accessed for investigational purposes; and
 - (4) Retained for a minimum of 30 calendar days.
- G. Any recording of security video surveillance shall be made available to the Commission or law enforcement agency for just cause as requested.

.08 Visitor to a Non-Public Area of the Premises.

- A. When a visitor is admitted to a non-public area of the premises of a licensee, a registered grower agent shall:
 - (1) Log the visitor in and out;
- (2) Retain with the log a photocopy of the visitor's governmentissued identification;
- (3) Continuously visually supervise the visitor while on the premises; and
- (4) Ensure that the visitor does not touch any plant or medical cannabis.
- B. The licensee shall maintain a log of all visitors to non-public areas for 2 years.

10.62.11 Medical Cannabis Growing Controls

Authority: Health General Article, §§13-3301, 13-3302, and 13-3306, Annotated Code of Maryland

.01 Definitions.

A. In this chapter, the following terms have the meanings indicated

- B. Terms Defined.
- (1) "Green waste" means unused, surplus, returned, or out of date medical cannabis, recalled medical cannabis, and any plant debris, including dead plants, all unused plant parts, and roots.
- (2) "Growing media" means commercially produced potting mix or hydroponic solution or any other substrate used for growing.
- (3) "License" means a license issued by the Commission to operate as a grower.
 - (4) "Licensee" means a licensed grower.
- (5) "Unique identifier" means any symbol or mark that enables tracking of final product to the grower, seed, or plant from which the medical cannabis originated.

.02 Standard Operating Procedures.

A licensee shall establish written standard operating procedures to promote good growing and handling practices including:

- A. All aspects of the:
 - (1) Irrigation, propagation, cultivation, fertilization;
 - (2) Harvesting, drying, curing;
 - (3) Rework or reprocessing;
- (4) Packaging, labeling and handling of medical cannabis products, byproduct; and
- (5) Waste products, and the control thereof, to promote good growing and handling practices;
- B. Requiring that each individual engaged in the cultivation, manufacturing, handling, packaging, and testing of medical cannabis has the training, education, or experience necessary to perform assigned functions; and
- C. Requiring that all registered grower agents practice good hygiene and wear protective clothing as necessary to protect the product as well as themselves from exposure to potential contaminants.
 - D. Requirements for Receipt of Material.
- (1) A licensee shall quarantine material that is received to be used to produce medical cannabis.
- (2) A licensee shall inspect material for defects, contamination, and compliance with a licensee's specifications.
- (3) Material may not be released from quarantine by a licensee until the material:
 - (a) Passes inspection; and
 - (b) Is determined to be acceptable for use as intended.

.03 Horticultural Controls.

- A. Water. The licensee shall keep a record of water quality testing on site and make it available for inspection.
- B. Fertilizer. As part of the standard operating procedure, a licensee shall:
- (1) Adopt a nutrient management plan prepared by a certified nutrient management consultant;
- (2) Use fertilizer or hydroponic solution of a type, formulation, and at a rate, to support healthy growth of medical cannabis; and
- (3) Maintain records of the type and amounts of fertilizer and any growth additives used.
- C. A licensee shall specify in the standard operating procedure the use of growing media or hydroponic solution.
- D. Unless the medical cannabis is field grown, a licensee shall install, as part of the standard operating procedure, a system to monitor, record, and regulate:
 - (1) Temperature;
 - (2) Humidity;
 - (3) Ventilation; and
 - (4) Lighting, if used.
- E. Unless the medical cannabis is field grown, a licensee shall seal or screen the premises ventilation system with a mesh or filtering system fine enough to exclude most plant pests.

- F. Pest Monitoring. A licensee shall use, as part of the standard operating procedure, integrated pest management practices and techniques to identify and manage plant pathogen and pest problems, including:
 - (1) A door control system sufficient to prevent pest entry;
- (2) Regular visual inspection of plants and growing areas for the presence of pests;
 - (3) The use of sticky cards in growing areas; and
- (4) Identification and recording of all pests or pathogens detected and the measures taken for control.
- G. Pest Control. Pesticide applicators and applications shall follow State and federal pesticide requirements for any pesticide applied.
- H. Sanitation. Sanitation shall be in compliance with the licensee's standard operating procedures.
- I. Green Waste. A licensee shall weigh, document, and destroy all green waste in accordance with the standard operating procedures.

.04 Equipment.

- A. A licensee shall maintain equipment that comes in contact with medical cannabis to prevent contamination.
- B. A licensee shall maintain cleaning and equipment maintenance loss
- C. A licensee shall have any scale, balance, or other measurement device, and any automatic, mechanical, or electronic equipment routinely calibrated by a calibration laboratory accredited to International Organization for Standardization (ISO) standard ISO/IEC 17025 by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement.

10.62.12 Inventory Control by Grower

Authority: Health General Article, §§13-3301, 13-3302, and 13-3306(e),
Annotated Code of Maryland

.01 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

- (1) "Inventory control" means the record of the inventory in the perpetual inventory control system used by the licensee in accordance with this chapter;
 - (2) "Licensee" means a licensed grower.
- (3) "Unique identifier" means any symbol or mark which will enable tracking of medical cannabis from plant to final product by means of the inventory control.

.02 Inventory Control System.

- A. A licensee shall use a perpetual inventory control system that identifies and tracks the licensee's stock of medical cannabis from the time the medical cannabis is propagated from seed or cutting to the time it is delivered to a licensed dispensary, licensed processor or a qualifying patient or caregiver.
- B. In the event of a serious adverse event, an inventory control system shall be capable of tracking medical cannabis from a qualifying patient back to the source of medical cannabis.
- C. The inventory control system shall be designed to promptly identify a discrepancy in the stocks.

.03 Materials Received for Cultivation.

Upon receipt of raw material for cultivation, a licensee shall record in the inventory control:

- A. The date delivered; and
- B. The number of cuttings or seeds delivered or the weight of the seeds for each variety in the shipment.

.04 Plant Tagging and Entry into Inventory Control.

- A. For each plant, as soon as practical, a licensee shall:
 - (1) Create a unique identifier for each plant;
 - (2) Assign each plant to a batch;
- (3) Enter information regarding the plant into the inventory control system;
- (4) Create a tag with the unique identifier and batch number; and
 - (5) Securely attach the tag to a plant container or plant.
 - B. Tags shall be indelible and tamper-evident.
- C. Tags shall be made of a material that resists variation in temperature and moisture.

.05 Control of Harvested Medical Cannabis.

A licensee shall:

- A. Upon completion of curing or drying of each batch, weigh medical cannabis to update inventory control for the batch; and
- B. At least monthly, conduct a physical inventory of the stock and compare the physical inventory of stock with inventory control.

.06 Discrepancy Reporting.

- A. If a licensee discerns a discrepancy between the inventory of stock and inventory control outside of normal weight loss due to moisture loss and handling, the licensee shall commence an investigation of the discrepancy within 1 business day.
- B. If the licensee finds evidence of a theft or diversion within 1 business day, the licensee shall report the theft or diversion to the:
 - (1) Commission; and
 - (2) Maryland State Police.
- C. Within 30 business days of discovering a discrepancy, the licensee shall:
 - (1) Complete the investigation;
- (2) Amend the licensee's standard operating procedures, if necessary; and
 - (3) Send a report of the audit to the Commission.

.07 Product Returned for Destruction.

A licensee shall accept the return of any medical cannabis from a qualifying patient or a caregiver to destroy.

.08 Bar on Distribution of Non-Complying Medical Cannabis.

- A. A licensee or registered grower agent may not distribute any medical cannabis to any person if the licensee or registered grower agent knows, or may have reason to know, that the distribution does not comply with any provision of the Health -General Article, Title 13, Subtitle 33, Annotated Code of Maryland or this subtitle.
- B. A licensee or registered grower agent may not distribute any medical cannabis to any person if the licensee or registered grower agent knows, or may have reason to know, that the medical cannabis does not comply with any provision of the Health General Article, Title 13, Subtitle 33, Annotated Code of Maryland or this subtitle.

10.62.13 Medical Cannabis Shipment Packaging

Authority: Health General Article, §§13-3301, 13-3302, 13-3306(b) and (e), 13-3307(f), 13-3309(f) and 13-3311(c), Annotated Code of Maryland

.01 Packaging Products Containing Medical Cannabis for Shipment.

- A. Before shipping an order of products containing medical cannabis, a licensee shall, if necessary, repackage the shipment into a container:
 - (1) Constructed of tamper-evident opaque material; and
 - (2) Sealed with tamper-evident tape.
- B. Multiple packages that are being shipped to the same recipient may be sealed within one large opaque tamper-evident container.

.02 Labeling of Packages for Shipment.

- A. Each package in a shipment of products containing cannabis shall be labeled with:
- (1) The date and time of the sealing of the package for shipment;
- (2) The name and signature of the registered grower agent, registered processor agent, or registered dispensary agent who prepared the package and sealed the package;
 - (3) The name and address of the shipping licensee;
 - (4) The shipment identification number;
- (5) A description, including the weight, of each item, contained in the package; and
- (6) The name and address of the licensee, or other party if applicable, to receive the shipment.
- B. A label shall be made of weather-resistant and tamper-evident materials.
 - C. A label shall be conspicuously placed on a package.

10.62.14 Licensed Grower Dispensary Facility

Authority: Health General Article, §§13–3301, 13-3302 13-3306(c), and 13–3307, Annotated Code of Maryland

.01 Definitions.

- A. The following terms have the meanings indicated.
- B. Terms Defined.
- (1) "Dispensary license" means a license issued by the Commission to operate as a dispensary.
- (2) "Licensed grower dispensary facility" means a facility where a licensed grower may dispense medical cannabis.
 - (3) "Licensee" means a licensed grower.

.02 Licensed Grower Dispensary Facility.

- A. A licensee may dispense medical cannabis to qualifying patients and caregivers in conformity with COMAR 10.62.25 10.62.31 at a facility for which the licensee has obtained a license to dispense medical cannabis.
- B. A licensed grower dispensary facility shall be constructed and operated in conformity to COMAR 10.62.27, relating to medical cannabis dispensary premises.
- C. A licensee may hire employees or use volunteers at a licensed grower dispensary facility in conformity to COMAR 10.62.26.

10.62.15 Medical Cannabis Grower Quality Control

Authority: Health General Article, §§13-3301, 13-3302, 13-3306, and 13-3311, Annotated Code of Maryland

.01 Production and Process Controls.

- A. A licensee shall cultivate each plant and produce each batch of medical cannabis in conformity with the standard operating procedures.
- B. A licensee shall record the cultivation process in accordance to standard operating procedures to ensure:
 - (1) Consistency of the batch with the variety; and
 - (2) Accuracy of the day-to-day production.
- C. A licensee shall record any deviation defined as a material change from the standard operating procedure which would impact the quality of the batch in the log.
- D. A licensee may not release any batch of medical cannabis if there was any deviation in production of the batch from the standard operating procedure unless:
- (1) After independent testing of the batch in accordance with the criteria set forth in Regulation .04 of this chapter the batch is tested by an independent testing laboratory and the licensee

determines, as a result of such testing, that the batch meets the specification for the variety; and

(2) The determination is recorded.

.02 In-Process Inspection by Grower.

During the process of cultivation, a licensee shall regularly inspect each plant to ensure proper growth and absence of pests and disease.

.03 Holding Procedure.

A licensee shall hold medical cannabis in secure, segregated storage until released for distribution.

.04 Independent Testing Laboratory Selection.

The licensee shall use an independent testing laboratory:

- A. That has adopted a standard operating procedure to test medical cannabis and medical cannabis concentrate that is approved by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement;
- B. To obtain samples of each batch according to a statistically valid sampling method by an agent of an independent testing laboratory;
 - C. To analyze the samples according to:
- (1) The most current version of the cannabis inflorescence monograph published by the American Herbal Pharmacopeia (AHP); or
- (2) A scientifically valid methodology that is equal or superior to that of the AHP monograph;
- D. In the event of a test result which falls out of specification, the laboratory shall follow their standard operating procedure to confirm or refute the original result;
 - E. To issue a certificate of analysis; and
- F. To destroy the remains of the sample of medical cannabis after analysis is completed.

.05 Contents of Certificate of Analysis.

An independent testing laboratory shall issue a certificate of analysis for each batch, with supporting data, to report:

- A. Whether the chemical profile of the batch conforms to the variety for the following compounds:
 - (1) Δ9-Tetrahydrocannabinol (THC);
 - (2) Tetrahydrocannabinolic Acid (THCA);
 - (3) Cannabidiol (CBD);
 - (4) Cannabidiolic Acid (CBDA); and
- (5) The terpenes described in the most current version of the cannabis inflorescence monograph published by the American Herbal Pharmacopeia (AHP);
 - (6) Cannabigerol (CBG); and
 - (7) Cannabinol (CBN); and
- B. That the presence of the following contaminants does not exceed the levels as required by the AHP monograph:
 - (1) Heavy metals, mercury, lead, cadmium, or arsenic;
- (2) Foreign material such as hair, insects, or any similar or related adulterant;
 - (3) Any microbiological impurity, including:
 - (a) Total aerobic microbial count (TAMC);
 - (b) Total yeast mold count (TYMC);
 - (c) P. aeruginosa;
 - (d) Aspergillus spp.;
 - (e) S. aureus;
 - (f) Aflatoxin B1, B2, G1, and G2; and
 - (g) Ochratoxin A.; and
 - (h) Pesticide residue; and
- (4) Whether the batch is within specification for the characteristics of:
 - (a) Odor;

- (b) Appearance;
- (c) Fineness; and
- (d) Moisture content.

.06 Grower Determination That a Batch May be Released.

- A. If a licensed grower, upon review of the certificate of analysis, determines that a batch meets the specification for the variety, the grower may:
 - (1) Assign an expiration date to the batch;
 - (2) Release the batch for distribution; and
 - (3) Revise the status of the batch in the inventory control.
- B. If a licensed grower receives test results that do not meet specifications, the licensed grower may rework or reprocess the batch according to their standard operating procedure. The reworked or reprocessed batch shall be resampled and retested by the independent testing laboratory to ensure that all required specifications are met.
 - C. A licensee shall retain every certificate of analysis.

.07 Stability Testing and Retention Sampling.

- A. A licensee shall provide a sample from each released batch to an independent testing laboratory sufficient to perform stability testing at 6-month intervals to:
 - (1) Ensure product potency and purity; and
 - (2) Provide support for expiration dating.
 - B. A licensee shall retain a sample from each released batch:
 - (1) Sufficient to provide for follow-up testing if necessary; and
- (2) Properly store the sample for one year past the date of expiration of the batch.

.08 Report of Products Offered for Distribution.

A licensee shall submit to the Commission quarterly a list of the products and their specifications that the licensee offered for distribution in the previous quarter.

10.62.16 Independent Testing Laboratory Registration

Authority: Health General Article, §§13-3301, 13-3302, and 13-3311, Annotated Code of Maryland

.01 Definition.

- A. In this chapter, the following term have the meaning indicated.
- B. Terms Defined.
- (1) "Accreditation body" means a nonprofit, impartial organization that requires conformance to ISO/IEC 17025 requirements and is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement for Testing.
- (2) "Certification of accreditation" means a certificate issued by an accrediting body for the independent testing laboratory facility, entity or site to be registered in Maryland.
- (3) "Independent testing laboratory" means any facility, entity, or site in Maryland that offers or performs tests of medical cannabis or products containing medical cannabis and is independent of any entity that grows, processes or dispenses cannabis.
- (4) "Scope of accreditation" means a document issued by the accreditation body which describes the methodologies, range, and parameters for testing medical cannabis or products containing medical cannabis for which the accreditation has been granted.

.02 Registration.

- A. An independent testing laboratory shall register with the Commission.
 - B. To register, an independent laboratory shall:
- (1) Submit a completed independent laboratory registration form;
 - (2) Pay the registration fee specified in COMAR 10.62.35.01.

- (3) Submit a copy of the certification of accreditation accompanied by the scope of accreditation; and
- (4) Submit the name, address, date of birth and Social Security Number of each independent testing laboratory employee and a copy of the application form completed by each independent testing laboratory employee.
- C. The Commission may issue a provisional registration to an independent testing laboratory that has not yet been issued a certification of accreditation in Maryland if the independent testing laboratory:
- Submits a completed independent laboratory registration form;
 - (2) Pays the registration fee specified in COMAR 10.62.35.01;
- (3) Submits a copy of the contract with the accreditation body applying to become accredited accompanied by a copy of the proposed scope of the accreditation;
- (4) Submits evidence the independent testing laboratory has been accredited by the accreditation body in another jurisdiction; and
- (5) Submits the name, address, and date of birth and Social Security Number of each independent testing laboratory employee and a copy of the application form completed by each independent testing laboratory employee.
- D. Once it has obtained a certification of accreditation, a provisionally registered independent testing laboratory shall apply to be registered, but:
- (1) The term of the registration may not exceed the term of the provisional registration; and
 - (2) No additional registration fee need be paid for that term.

.03 Standards of Care.

- A. The independent testing laboratory shall follow the methodologies, ranges, and parameters which are contained in the scope of the accreditation for testing medical cannabis or products containing medical cannabis.
- B. The independent testing laboratory shall require each independent testing laboratory employee to complete and execute an application for employment on a form provided by the Commission.
- C. The independent testing laboratory shall establish and follow written procedures for verifying the experience and education of laboratory employees.
- D. The independent testing laboratory shall submit the registration information for each independent testing laboratory employee within 15 days after the date the independent testing laboratory employee was hired.
- E. Upon termination of the association of the registered independent testing laboratory employee with the independent testing laboratory, the independent testing laboratory shall:
- (1) Obtain any keys or other entry devices from the terminated independent testing laboratory employee;
- (2) Ensure the terminated independent laboratory employee can no longer gain access to the laboratory premises; and
- (3) Within 1 business day of the termination of independent laboratory employee, the independent testing laboratory shall notify the Commission of the termination.
- F. The independent testing laboratory shall notify the Commission within 1 business day after the independent testing laboratory obtains notice of any kind that its accreditation has been denied, suspended or revoked.

.04 Term and Renewal.

- A. The registration is valid for 2 years.
- B. The registration may be renewed by submitting to the Commission:
- (1) A copy of the independent testing laboratory registration form;

- (2) Payment of the registration fee specified in COMAR 10.62.35; and
 - (3) Submission of copies of the most recent:
 - (a) Assessment from the accreditation body; and
- (b) Periodic review of the proficiency testing of the results obtained by the independent testing laboratory.

.05 Independent Testing Laboratory Responsibilities.

No independent testing laboratory may handle, test, or analyze cannabis or cannabis products unless the independent testing laboratory:

- A. Has been registered by the Commission;
- B. Is independent from all other persons and entities involved in the medical cannabis industry;
- C. Is accredited by an accreditation body or has a provisional registration from the Commission; and
- D. Has established standard operating procedures that provide for adequate chain of custody controls for samples transferred to the independent testing laboratory for testing.

10.62.17 Complaints, Adverse Events, and Recall

Authority: Health General Article, §§13-3301, 13-3302, 13-3304, 13-3305, 13-3306, 13-3307 13-3309, 13-3311, Annotated Code of Maryland

.01 Receipt and Documentation of Complaints and Adverse Events.

A licensed grower, licensed processor, licensed dispensary, certifying physician, and the Commission shall establish a procedure to receive, organize, store and respond to all oral, written, electronic or other complaints regarding medical cannabis and adverse events.

.02 Report of Serious Adverse Event to Commission and Interested Parties.

In the event a complaint associated with a serious adverse event is received, a licensee, or certifying physician, shall promptly report the complaint to:

- A. The Commission;
- B. Either the licensed grower from which the medical cannabis originated, or the licensed processor from which the medical cannabis concentrate originated; and
 - C. The certifying physician caring for the qualifying patient.

.03 Complaint Investigation by Grower or Dispensary.

- A. Whenever a complaint regarding the quality or safety of medical cannabis is received by a licensed grower, licensed processor or licensed dispensary, a licensee shall, within 24 hours, review the complaint to determine if it is substantive or reports a serious adverse event.
- B. If a licensee determines that the complaint is substantive or reports a serious adverse event, a licensee shall:
- (1) Promptly determine the batch number or lot number of the medical cannabis, the medical cannabis finished product, and medical cannabis concentrate that is the subject of the complaint; and
- (2) Investigate the record and circumstances of the production of the batch and lot to determine:
- (a) If there was a deviation from the standard operating procedure in the production of the medical cannabis by reviewing production logs; and
- (b) If the sample meets specification by submitting parts of the retention samples of the batch and lot to an independent testing laboratory.
- C. If sample analysis of the batch or lot reveals that the batch or lot fails to meet specification, the licensee shall:
- (1) Order a recall of all products derived from or included in the batch or lot;

- (2) Notify all patients, caregivers, and dispensaries who may have obtained medical cannabis products from such a batch or lot of the recall; and
- (3) Offer and pay reimbursement for any returned medical cannabis.
- D. In a case of a report of a serious adverse event or a substantive complaint, if the investigation reveals a deviation from the standard operating procedure in the production of the batch or lot, the licensee may:
- (1) Order a recall of all products derived from or included in the batch or lot;
- (2) Notify all patients, caregivers, and dispensaries who may have obtained medical cannabis products from such a batch or lot of the recall; and
- (3) Offer and pay reimbursement for any returned medical cannabis.

.04 Custody of Returned Recalled Material.

- A. The licensee shall develop a procedure to ensure medical cannabis that is recalled is stored and segregated until disposal of recalled material is authorized by the Commission.
- B. Within 24 hours of the receipt of notice from the Commission that the disposal of recalled medical cannabis is authorized, the licensee shall dispose of the recalled medical cannabis according to the standard operating procedure.

10.62.18 Shipment of Products Between Licensees

Authority: Health General Article, §§13-3301, 13-3302, 13-3306(b) and (e), 13-3307(f), 13-3309(f) and 13-3311(c), Annotated Code of Maryland

.01 Definitions.

- A. The following terms have the meanings indicated.
- B. Terms Defined.
- (1) "Receiving licensee" means the licensee that receives the shipment.
- (2) "Secure transportation company" means a business that is licensed, whose employees are bonded, and that provides highly secure vehicles for the transportation of valuables, and can assure that medical cannabis is secured at all times during transport.
- (3) "Shipping licensee" means the licensee that initiates the shipment.

.02 Electronic Manifest System.

- A. A licensee shall install an electronic manifest system to record the chain of custody for the shipment of products containing medical cannabis.
- B. An electronic manifest system shall include a chain of custody that records:
 - (1) The name and address of the shipping licensee;
 - (2) The shipping licensee's shipment identification number;
- (3) The weight and description of each individual package that is part of the shipment, and the total number of individual packages;
- (4) The name of the registered grower agent or registered dispensary agent that prepared the shipment;
- (5) The name and address of the receiving licensee or other receiving party if applicable; and
 - (6) Any handling or storage instructions.

.03 Creation of Manifest.

- A. An electronic manifest shall be created by the shipping licensee for each shipment of products containing cannabis.
- B. The electronic manifest shall contain, at a minimum, the following entries as a chain of custody, in the order listed:
- (1) An entry by the registered grower agent or registered dispensary agent who has prepared the shipment, including the date and time of preparation;

- (2) An entry by a shipping licensee's transportation agent, of the date and time of the placement of the shipment into the medical cannabis transport vehicle;
- (3) An entry by licensee's agent receiving the shipment including the date and time of the acceptance; and
- (4) If any other person had custody or control of the shipment, that person's identity, the circumstances, duration, and disposition.

.04 Transportation Agents.

- A. A transportation agent driving a medical cannabis transport vehicle shall have a current driver's license.
- B. While on duty, a transportation agent may not wear any clothing or symbols that may indicate ownership or possession of cannabis.

.05 Transportation of Products Containing Medical Cannabis.

- A. Either a secure transportation company or a shipping licensee shall transport products containing medical cannabis.
- B. A shipping licensee shall use one transportation agent, who shall carry identification approved by the Commission, to:
- (1) Accompany shipment of products containing medical cannabis; and
- (2) Ensure that the product is secured at all times during transport.

.06 Medical Cannabis Transport Vehicle.

A medical cannabis transport vehicle:

- A. Shall have and display current registration from the State;
- B. Shall be insured as required by law; and
- C. May not display any sign or illustration related to medical cannabis or a licensee.

10.62.19 Medical Cannabis Processor License

Authority: Health General Article, §§13–3301, 13-3302, 13-3309 and 13–3310, Annotated Code of Maryland

.01 Definitions.

- A. In this chapter the following terms have the meanings indicated.
 - B. Terms Defined.
- (1) "Audited financial statement" means an audited financial statement that is performed by a certified public accountant licensed or with practice privileges in Maryland, pursuant to Business Occupations and Professions Article, Title 2, Annotated Code of Maryland, that:
- (a) Is prepared in accordance with the Professional Standards of the American Institute of Certified Public Accountants; and
- (b) In the case of a publicly owned corporation in conformity with the standards of the Public Company Oversight Board;
- (2) "License" means a license issued by the Commission to operate as a licensed processor; and
 - (3) "Licensee" means a licensed processor.

.02 Application.

- A. An applicant shall submit to the Commission an application for a license.
- B. An application on a form developed by the Commission shall be completed and submitted to the Commission for consideration. In addition to the application form, the applicant shall submit the following documents to be included as addenda to the application form:
 - (1) A list identifying the applicant's potential processor agents;
- (2) A list identifying each individual investor with 5 percent or more of investment known at the time of application;

- (3) A detailed business plan including an organizational chart;
- (4) Documentation and source of adequate capitalization;
- (5) If the applicant is a corporation, a copy of the articles of incorporation and authorization to do business in Maryland;
- (6) Evidence that no tax obligation is in arrears in any jurisdiction on the part of the applicant and any investor with 5 percent or more of investment known at the time of application;
- (7) A description of the proposed premises, including a preliminary site plan;
 - (8) A security plan;
 - (9) A plan for quality control;
- (10) A plan for inventorying, safekeeping and tracking medical cannabis from entry into inventory to sale or disposal of medical cannabis waste;
 - (11) A plan for the disposal of medical cannabis waste;
 - (12) A plan for training employees and volunteers;
- (13) Details of the applicant's experience, knowledge, and training in:
 - (a) the operation of a laboratory;
- (b) the operation or management of a pharmaceutical manufacturing business; or
- (c) the operation or management of a consumer products business; and
- (14) A plan of the medical cannabis concentrates and medical cannabis-infused products proposed to be manufactured and the processes to be used.
- C. The application shall be accompanied by the stage 1 application fee specified in COMAR 10.62.35.
- D. Any party applying for a license shall have an interest in only one processor license.
- E. An applicant shall amend an application within 3 business days to include the name and documentation of a request to forward the criminal history record information and audited financial statement to the Commission of a new individual investor of an interest of 5 percent or more, or another manager or director of the entity, even after a license is issued.
- F. For each individual identified in the application specified in COMAR 10.62.19.02B(1) and (2) of this chapter, an applicant shall provide to the Director of the Central Repository:
- (1) Two sets of legible fingerprints taken in a format approved by the Director of CJIS and the Director of the FBI and the fee authorized under Criminal Procedure Article, §10-221(B)(7), Annotated Code of Maryland, for access to State criminal history and records for each processor agent and investor identified in the application; and
- (2) A request that the individual's state and national criminal history record information be forwarded to the Commission.

.03 Consent for Investigation.

- A. An individual who is required to provide personal and background information under this chapter shall provide a statement that irrevocably gives consent to the Commission and persons authorized by the Commission to:
- (1) Verify all information provided in the application documents; and
 - (2) Conduct a background investigation of the individual.
- B. An applicant shall waive any contractual, statutory, or common law obligation of confidentiality and authorize any government agency in any jurisiction to release to and provide access to the Commission of any and all information the applicant has provided to any other jurisdiction while seeking a cannabis-related license in that other jurisdiction, as well as the information obtained by that other jurisdiction during the course of any investigation it may have conducted regarding the applicant.

C. An applicant shall release all financial institutions, fiduciaries and other parties from any contractual, statutory or common law obligation of confidentiality to provide financial, personal and background information to the Commission relevant to the applicant's capacity to manage a licensed processor and the applicant's good moral character.

.04 Application Review.

- A. The burden of proving an applicant's qualifications rests on the applicant.
- B. The Commission may deny an application that contains a misstatement, omission, misrepresentation, or untruth.
 - C. An application shall be complete in every material detail.
- D. The Commission may request any additional information the Commission determines is necessary to process and fully investigate an application.
- E. The applicant shall provide requested additional information by the close of business of the 14th business day after the request has been received by the applicant.
- F. If the applicant does not provide the requested information within 14 business days, the Commission may consider the application to be suspended.
- G. The Commission intends to award the licenses to the best applications that most efficiently and effectively ensure public safety and safe access to medical cannabis and medical cannabis-infused products.
- H. The Commission shall provide guidelines and detailed instructions for submitting the application form for the Commission's consideration.
- I. The Commission, or a Commission independent contractor, shall review for a pre-approval for a license the submitted applications as described in Regulations .02B and .04E of this chapter. The applications shall be ranked based on the following weighted criteria:
- (1) Operational Factors will be afforded 20 percent weight, including:
- (a) A detailed operational plan for the production of medical cannabis extracts and medical cannabis-infused products; and
 - (b) Summaries of policies and procedures for:
 - (i) Laboratory operations;
 - (ii) Processing; and
 - (iii) Packaging;
- (2) Safety and Security factors will be afforded 20 percent weight, including:
- (a) Detailed plan or information describing the security features and procedures;
- (b) Detailed plan describing how the processor will prevent diversion; and
 - (c) Detailed plan describing safety procedures;
- (3) Commercial laboratory, pharmaceutical manufacturing and consumer products production factors will be afforded 15 percent weight, including, experience, knowledge and training in:
 - (a) Chemical plant management;
 - (b) Pharmaceutical manufacturing; and
 - (c) Consumer product production;
- (4) Production control factors will be afforded 15 percent weight, including:
 - (a) A detailed quality control plan;
 - (b) A detailed inventory control plan; and
 - (c) A detailed medical cannabis waste disposal plan;
- (5) Business and economic factors will be afforded 15 percent weight, including:
 - (a) A business plan:
 - (i) Demonstrating a likelihood of success;

- (ii) Demonstrating a sufficient business ability and experience on the part of the applicant; and
- (iii) Providing for appropiate employee working conditions, benefits, and training;
 - (b) Demonstration of adequate capitalization; and
- (c) A detailed plan evidencing how the processor will enforce the alcohol and drug free workplace policy;
- (6) Additional factors that will be afforded 15 percent weight, including:
- (a) Demonstrated Maryland residency among the owners and investors;
- (b) Evidence that applicant is not in arrears regarding any tax obligation in Maryland and other jurisdictions;
- (c) A detailed plan evidencing how the processor will distribute to dispensaries; and,
- (d) A list of proposed medical cannabis extracts and medical cannabis-infused products proposed to be produced with proposed cannabinoid profiles, including:
 - (i) Varieties with high cannabidiol content; and
- (ii) Whether the product has any demonstrated success in alleviating symptoms of specific diseases or conditions.

.05 Pre-Approval of License Application.

- A. The Commission shall pre-approve a number of licenses for licensed processors sufficient to supply the demand for medical cannabis concentrates and medical cannabis-infused products in a range of routes of administration desired by qualifying patients.
- B. If there are more qualified applications than the number of licenses available and there is a numerical tie for the last license to be issued, the last pre-approved license shall be determined by public lottery.
- C. The Commission may deny issuing a pre-approval of a license if, for any individual identified in the application specified in COMAR 10.62.19.02B(1) and (2) of this chapter:
- (1) The criminal history record information or background information demonstrates an absence of good moral character; or
 - (2) The payment of taxes due in any jurisdiction is in arrears.
- D. Within 10 business days of the Commission's decision, the Commission shall notify applicants who have been pre-approved for a license
- E. The Commission may rescind pre-approval of a processor license if the processor is not operational within 1 year of pre-approval.

.06 Issuance of License.

- A. After an applicant has been issued a pre-approval for a license under this chapter, the applicant shall submit to the Commission, as part of its application:
- (1) An audited financial statement for the applicant and for each individual, partnership, corporation, or other entity review that has invested, or is proposed to invest, 5 percent or more of the capital of the applicant; and
- (2) Payment of the stage 2 application fee specified in COMAR 10.62.35.
- B. The Commission may issue a license to be a licensed processor on a determination that:
- (1) The criminal history background check and background investigation reveal no evidence that demonstrates the absence of good moral character;
- (2) All inspections are passed and all of the applicant's operations conform to the specifications of the application as preapproved pursuant to Regulation .05 of this chapter;
 - (3) The proposed premises:
 - (a) Are under the legal control of the applicant;
 - (b) Comply with all zoning and planning requirements; and
- (c) Conform to the specifications of the application as preapproved pursuant to Regulation .07 of this chapter; and

(4) The first year's license fee specified in COMAR 10.62.35 has been paid.

.07 Change of Ownership of License.

- A. No interest of 5 percent or more of a license issued pursuant to this chapter shall be assignable or transferable unless:
- (1) The Commission has received notice in a manner determined by the Commission of the intent of the owner of the interest, or of the estate of the owner of the interest, to transfer or assign an interest in a license to another party;
- (2) The transferee has had forwarded the criminal history record information and audited financial statement to the Commission of the transferee;
- (3) The Commission does not object to the transfer or assignment within 45 days of its receipt of notice; and
- (4) The transferee has paid the required fee specified in COMAR 10.62,35.
- B. The Commission may deny transfer of an interest in a license if, for any proposed transferee:
- (1) The criminal history record information or the background investigation demonstrate an absence of good moral character; or
 - (2) The payment of taxes due in any jurisdiction is in arrears.

.08 Change of Location.

- A. A licensee may apply to change the location of the licensee's operation.
- B. The licensee shall submit an application to the Commission along with the fee specified in COMAR 10.62.35.
- C. A licensee may not begin dispensing or processing medical cannabis at a new location until all inspections have been passed.

.09 Renewal of License.

- A. A licensee is eligible to apply to renew a license every 2 years.
- B. Ninety days before the expiration of a license, the Commission shall notify the licensee of the:
 - (1) Date on which the license expires;
 - (2) Process and the fee required to renew the license; and
 - (3) Consequences of a failure to renew the license.
- C. At least 30 business days before a license expires a licensee shall submit:
 - (1) The renewal application as provided by the Commission;
- (2) Proof that fingerprints have been submitted to CJIS and the FBI for every processor agent and investor of an interest of 5 percent or more:
- (3) To full inspection of the operation, unless a full inspection was satisfactorily completed within 3 months before the date of the license expiration; and
 - (4) Payment of the fee specified in COMAR 10.62.35.
- D. The Commission shall renew a license that meets the requirements for renewal as stated in §C of this regulation.
- E. If the Commission does not renew a license due to a failed inspection or an inadequate application for renewal, the licensee may apply for reinstatement by:
- (1) Submitting a plan to correct the deficiencies noted during an inspection; and
 - (2) Amending the application for renewal.
 - F. The Commission may decline to renew a license if:
- (1) The plan to correct deficiencies identified in an inspection is deficient;
 - (2) The amended application for renewal is deficient; or
 - (3) The licensee has repeatedly failed inspections.
- G. A licensee who fails to apply for renewal of a license by the date specified by the Commission, or whose license was not renewed by the Commission:
 - (1) Shall cease operations at all premises; and
 - (2) May not provide medical cannabis to any entity or person.

- H. A license may be reinstated upon:
- (1) Payment of the reinstatement fee specified in COMAR 10.62.35; and
- (2) Submission of a reinstatement application approved by the Commission.

10.62.20 Medical Cannabis Processor Agent

Authority: Health General Article, §§13–3301, 13-3302, 13-3309 and 13–3310, Annotated Code of Maryland

.01 Definitions.

- A. In this chapter, the following terms have the meaning indicated. B. Terms Defined.
- (1) "License" means a license issued by the Commission to operate as a licensed processor.
 - (2) "Licensee" means a licensed processor.

.02 Processor Agent Generally.

A processor agent shall be 21 years old or older.

.03 Processor Agent Registration and Criminal History Record.

- A. A processor agent shall be registered with the Commission before the agent may volunteer or work for a licensee.
- B. A licensee shall apply to register a processor agent by submitting to the Commission:
- (1) The name, address, date of birth and Social Security Number of a processor agent;
- (2) Documentation of the submission of fingerprints of the processor agent to the Central Registry; and
- (3) The request for the criminal history record information of the processor agent to be forwarded to the Commission.
- C. A prospective registered processor agent may not be registered by the Commission if the prospective registered processor agent has ever been convicted of a felony drug offense.
- D. The Commission, after review of the criminal history record information, may disqualify any prospective registered processor agent from registration for an absence of good moral character.

.04 Registered Processor Agent Identification Cards.

- A. The Commission shall issue to each registered processor agent a identification card that shall include a photograph of the face of the registered processor agent taken no more than 6 months before the date of the application.
- B. At all times at the premises of a licensee every registered processor agent shall visibly wear the identification card issued to the registered processor agent by the Commission.
 - C. The identification card shall be renewed every 2 years.
- D. If a registered processor agent's identification card is lost, destroyed or stolen, within 24 hours of becoming aware of the loss, destruction or theft, the licensee shall:
 - (1) Report the loss, destruction or theft to the Commission;
 - (2) Apply for a replacement card; and
 - (3) Pay a replacement card fee specified in COMAR 10.62.35.
- E. An identification card remains the property of the Commission and the Commission may order the return or seizure of an identification card if the registration is revoked or expires.
- F. If a registered processor agent's identification card is lost, destroyed, or stolen, a copy of notification to the Commission shall be evidence of registration until a new card is obtained from the Commission.

.05 Termination.

- A. As soon as possible upon termination of a registered processor agent's association with a licensee, the licensee shall:
- (1) Take custody of the terminated registered processor agent's identification card;

- (2) Obtain any keys or other entry devices from the terminated registered processor agent; and
- (3) Ensure the terminated registered processor agent can no longer gain access to the premises of the licensee.
- B. Within 1 business day of the termination of a registered processor agent's association with a licensee, the licensee shall:
- (1) Notify the commission in a manner to be determined by the Commission:
- (a) Of the termination and the circumstances of a termination; and
- (b) Whether the terminated registered processor agent has returned the agent's identification card; and
- (2) Initiate delivery of the terminated registered processor agent's identification card to the Commission.
- C. The Commission shall revoke a registration of a processor agent upon receiving notification that a processor agent is no longer associated with a licensee.
- D. If a registered processor agent did not return the agent's identification card within 30 days, the Commission shall notify the Maryland State Police and place a notice in the register of that fact.

.06 Prospective Processor Agent Drug Screen.

- A. The licensee shall require a prospective processor agent to submit to a drug screen before commencement of association.
- B. The drug screen shall be carried out following the procedures set forth in COMAR 17.04.09.04—.08.
- C. In addition to the drugs to be screened in accordance with COMAR 17.04.09.06, the screen shall include any other drugs as required by the Commission.
- D. Unless medically justified, a prospective processor agent who has a positive response to any tested substance on a drug screen that meets the requirements of COMAR 17.04.09.07 may not be registered by the Commission.

.07 Processor Agent Training.

- A. The licensee shall train all registered processor agents on:
- (1) Federal and State medical cannabis laws and regulations and other laws and regulations pertinent to the processor agent's responsibilities;
 - (2) Standard operating procedures;
 - (3) Detection and prevention of diversion of medical cannabis;
 - (4) Security procedures; and
 - (5) Safety procedures, including responding to;
 - (a) A medical emergency;
 - (b) *A fire*;
 - (c) A chemical spill; and
 - (d) A threatening event such as:
 - (i) An armed robbery;
 - (ii) An invasion;
 - (iii) A burglary; or
 - (iv) Any other criminal incident.
- B. The licensee shall retain training materials and attendance records and make the training materials available for inspection by the Commission.

.08 Alcohol and Drug Free Workplace Policy.

- A. A registered processor agent shall declare in writing that the registered processor agent shall adhere to the State alcohol and drug free workplace policy as identified in COMAR 21.11.08.03.
- B. The licensee shall retain the declaration in the registered processor agent's personnel record.

.09 Annual Verification of Registered Processor Agents.

Every year, on a date determined by the Commission, the licensee shall notify the Commission that the licensee has verified that no registered processor agent has been convicted of a felony drug offense.

10.62.21 Medical Cannabis Processor Premises

Authority: Health General Article, §§13–3301, 13-3302 and 13–3309, Annotated Code of Maryland

.01 Definitions.

- A. In this chapter, the following terms have the meaning indicated. B. Terms Defined.
- (1) "License" means a license issued by the Commission to operate as a processor.
 - (2) "Licensee" means a licensed processor.

.02 Premises Generally.

- A. The premises of a licensee shall be located within Maryland.
- B. The premises and operations of a licensee shall conform to all local zoning and planning requirements.
- C. A processor license shall be displayed at each location where the licensee is authorized to operate.
- D. No major renovation or modification shall be undertaken without notification to the Commission.

.03 Security of Premises.

The premises of a licensee shall be constructed to prevent unauthorized entry.

.04 Security Lighting.

Lighting fixtures of the licensee shall be designed and installed to ensure proper surveillance.

.05 Security Alarm Systems.

- A. A licensee shall maintain a security alarm system that covers all perimeter entry points and windows at all premises.
 - B. The security alarm system shall be:
 - (1) Continuously monitored;
 - (2) Capable of detecting smoke and fire;
 - (3) Capable of detecting power loss.
- C. The security alarm system shall include panic alarm devices mounted at convenient, readily-accessible locations throughout the licensed premises.
 - D. A second, independent alarm system shall be used to protect:
 - (1) The location where records are stored on-site;
 - (2) The location where records are stored off-site; and
 - (3) Any room that holds medical cannabis.
- E. The security alarm system shall remain operational until the premises of the licensee no longer have any medical cannabis on the premises.
- F. All security alarm systems shall be equipped with auxiliary power sufficient to maintain operation for at least 48 hours.

.06 Video Surveillance Requirements.

- A. A licensee shall maintain a motion activated video surveillance recording system at all premises that:
- (1) Records all activity in images of high quality and high resolution capable of clearly revealing facial detail;
- (2) Operates 24-hours a day, 365 days a year without interruption; and
 - (3) Provides a date and time stamp for every recorded frame.
- B. A licensee shall post appropriate notices advising visitors of the video surveillance.
- C. A surveillance camera shall be located and operated to capture activity at each exit from the premises.
- D. A surveillance camera shall capture activity at each entrance to an area where medical cannabis is processed, tested, packaged, and stored.

- E. A recording of all images captured by each surveillance camera shall be kept at:
 - (1) The licensed premises; and
 - (2) An off-site location.
 - F. Recordings of security video surveillance shall be:
 - (1) Access-limited;
- (2) Secured by a security alarm system that is independent of the main premises security alarm system;
- (3) In a format that can be easily accessed for investigational purposes; and
 - (4) Retained for a minimum of 30 calendar days.
- G. Any recording of security video surveillance shall be made available to the Commission or law enforcement agency for just cause as requested.

.07 Visitor to the Premises.

- A. When a visitor is admitted to a non-public area of the premises of a licensee, a registered processor agent shall:
 - (1) Log the visitor in and out;
- (2) Retain with the log a photocopy of the visitor's governmentissued identification;
- (3) Continuously visually supervise the visitor while on the premises; and
- (4) Ensure that the visitor does not touch any plant or medical cannabis.
- B. The licensee shall maintain a log of all visitors to non-public areas for 2 years.

10.62.22 Medical Cannabis Processor Operations

Authority: Health General Article, §§13–3301, 13-3302, 13-3306(b) and (e), 13-3307(f), 13-3309 and 13-3311(c), Annotated Code of Maryland

.01 Definitions.

- A. In this chapter, the following terms have the meaning indicated.
- B. Term Defined.
 - (1) "Licensee" means a licensed processor.
- (2) "Processor supervisor" means the registered processor agent designated by the licensed processor to supervise processor operations.
- (3) "Receiving licensee" means the licensee that receives the shipment.
- (4) "Shipping licensee" means the licensee that initiates the shipment.

$.02\ Standard\ Operating\ Procedures.$

- A. A licensee shall:
- (1) Establish standard operating procedures for all aspects of the receipt, processing, storage, packaging, labeling, handling, tracking and shipping of products containing cannabis and medical cannabis waste;
- (2) Create and use a perpetual inventory control system that identifies and tracks the licensee's stock of medical cannabis from the time it is delivered or produced to the time it is delivered to another licensee, a licensed grower, or a qualifying patient or caregiver; and
- (3) Train each registered processor agent in the standard operating procedureand retain attendance records.
- B. A copy of the standard operating procedure shall be readily available on site for inspection by the Commission.

.03 Receipt of Products Containing Cannabis.

- A. A licensee may not:
- (1) Acquire medical cannabis from an individual or entity in Maryland other than a licensee;
- (2) Acquire medical cannabis from outside of Maryland unless authorized by the Commission; or

- (3) Transport medical cannabis to any place outside of Maryland.
- B. A receiving licensee shall detail in the standard operating procedure the steps set forth in §C, D and H of this regulation, or their equivalent, and a shipping licensee shall detail in its standard operating procedure the steps set forth in §C—H of this regulation, or their equivalent, to assure:
- (1) The integrity of the shipment of products containing cannabis;
- (2) The integrity of the electronic manifest and inventory control system; and
 - (3) The quality of the products in the shipment.
- C. Upon arrival of a medical cannabis transport vehicle, the transportation agent shall notify an appropriate registered processor agent to continue the chain of custody of the shipment of products containing cannabis.
 - D. An agent of the receiving licensee shall:
 - (1) Log into the electronic manifest;
- (2) Take custody of a shipment of products containing cannabis;
 - (3) Confirm that:
- (a) The transportation agent is carrying appropriate identification;
- (b) The packaging is secure, undamaged, and appropriately labeled;
- (c) Each package in the shipment is labeled as described in the electronic manifest; and
- (d) The contents of the shipment are as described in the electronic manifest;
 - (4) Record the confirmations in the electronic manifest;
- (5) Obtain in the electronic manifest the signature or identification number of the transportation agent who delivers the shipment;
- (6) Record in the electronic manifest the date and time the receiving agent takes custody of the shipment;
- (7) Enter the products containing cannabis into the inventory control system;
- (8) Segregate the items in the shipment from the inventory until the item can be inspected;
- (9) Inspect each item to ensure that the packaging of each item is undamaged, accurate and complete; and
- (10) Upon determining the item passes inspection, release the item into the stock.
- E. The transportation agent shall provide a copy of the electronic manifest for the shipment to the receiving licensee.
- F. The transportation agent shall provide the completed electronic manifest to the shipping licensee.
- G. The shipping licensee shall retain the electronic manifest for the shipment for 5 years.
 - H. Discrepancy in the Shipment.
- (1) A discrepancy between the electronic manifest and the shipment, identified by either a transportation agent or a receiving agent, shall be reported by each agent to each agent's supervisor.
- (2) If a discrepancy can be immediately rectified, the accepting processor supervisor shall record the rectification in the electronic manifest.
- (3) A discrepancy that cannot be immediately rectified shall be reported to the Commission by the receiving licensee within 24 hours of the observation of the discrepancy and an investigation of the discrepancy shall be initiated by the shipping licensee.
 - (4) The shipping licensee shall submit to the Commission:
- (a) Within 7 business days of the observation of the discrepancy, a preliminary report of an investigation of a discrepancy; and

(b) Within 30 business days a final report of the investigation.

.04 Sanitary Storage of Medical Cannabis.

- A. A licensee's standard operating procedure shall provide for maintaining the cleanliness of any building or equipment used to store or display medical cannabis.
 - B. A licensee shall have a standard operating procedure to:
- (1) Maintain the medical cannabis free from contamination; and
- (2) Require a processor agent to report any personal health condition that might compromise the cleanliness or quality of the medical cannabis the processor agent might handle.
- C. A licensee's standard operating procedure shall provide for disposal and segregated storage of any medical cannabis:
- (1) That is outdated, damaged, deteriorated, misbranded, or adulterated; or
- (2) Whose containers or packages have been improperly or accidentally opened.

.05 Equipment Sanitation, Accuracy and Maintenance Logs.

- A. A licensee's standard operating procedure shall provide for maintaining the sanitation of equipment that comes in contact with medical cannabis.
 - B. The licensee shall ensure that:
- (1) Automatic, mechanical, or electronic equipment is routinely calibrated and periodically checked to ensure proper performance; and
- (2) Any scale, balance, or other measurement device is routinely calibrated and periodically checked to ensure accuracy.
 - C. The licensee shall maintain an accurate log recording the:
 - (1) Cleaning of equipment;
 - (2) The maintenance of equipment; and
 - (3) The calibration of equipment.

.06 Report of Products Offered for Distribution.

A licensee shall submit to the Commission at the end of the month following each calendar quarter a list of the products and the products' specifications that the licensee offered for distribution in the previous calendar quarter.

10.62.23 Medical Cannabis Concentrates and Medical Cannabis-Infused Products

Authority: Health General Article, §§13-3301, 13-3302, 13-3309, and 13-3311, Annotated Code of Maryland

.01 Definitions.

- A. In this chapter, the following terms have the meanings indicated.
 - B. Terms Defined.
- (1) "License" means a license issued by the Commission to operate as a processor.
 - (2) "Licensee" means a licensed processor.
- (3) "Tincture" means a cannabis-infused solution derived either directly from the cannabis plant or from a processed cannabis extract and typically combined with alcohol, glycerin, or vegetable oils.

.02 Controls for Processing of Medical cannabis Concentrates and Medical cannabis-Infused Products.

- A. A licensed processor of medical cannabis concentrates and medical cannabis-infused products shall:
- (1) Develop standard operating procedures, good manufacturing practices, and a training plan before producing medical cannabis concentrates and medical cannabis-infused products;

- (2) Require that any person involved in processing medical cannabis concentrates and medical cannabis-infused products is:
- (a) Appropriately trained in accordance to their job description to safely operate and maintain the system used for processing and attendance records are retained;
- (b) Has direct access to applicable material safety sheets and labels; and
- (c) Follows OSHA protocols for handling and storage of all chemicals:
- (3) Assign a unique lot number to each lot of medical cannabis concentrate or medical cannabis-infused product; and
- (4) Carry out a validation process on the first 10 lots of any new medical cannabis concentrate, medical cannabis-infused product, or process, to establish the validity of the production process.
- B. A processor shall establish a standard operating procedure for the methods, equipment, solvents, and gases when processing medical cannabis concentrates and medical cannabis-infused products.
- C. If a licensee uses a solvent-based extraction method the solvents shall be at least 99 percent pure.
- D. A standard operating procedure of a licensed processor shall require:
- (1) Use of solvents in a professional grade, closed-loop extraction system designed to recover the solvents;
- (2) Work in a spark-free environment with proper ventilation;
- (3) Following all applicable OSHA regulations, and local fire, safety and building codes in the processing and storage of the solvents.
- E. If a licensee uses carbon dioxide gas extraction the standard operating procedure shall require:
- (1) Every vessel be rated to a minimum of 900 pounds per square inch;
 - (2) Use a professional grade, closed-loop system;
- (3) Follow all applicable OSHA regulations, and local fire, safety and building codes in the processing and the storage of the solvents; and
 - (4) Use carbon dioxide that is at least 99 percent pure.
- F. A licensed processor may use heat, screens, presses, steam distillation, ice water, and other methods to produce medical cannabis concentrates.

.03 Independent Testing Laboratory Selection and Responsibility.

Upon successful completion of a validation process, the licensee shall use an independent testing laboratory:

- A. That has adopted a standard operating procedure to test medical cannabis and medical cannabis concentrate that is approved by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement:
- B. To have an agent of the independent testing laboratory obtain samples according to a statistically valid sampling method for each lot;
 - C. To analyze the samples according to
- (1) The most current version of the cannabis Inflorescence monograph published by the American Herbal Pharmacopeia (AHP); or
- (2) A scientifically valid methodology that is equal or superior to that of the AHP monograph;
- D. In the event of a test result which falls out of specification, the laboratory shall follow their standard operating procedure to confirm or refute the original result;
- E. To destroy the remains of the sample of medical cannabis after analysis is completed; and

F. To destroy the remains of the sample of medical cannabis after analysis is completed.

.04 Contents of Certificate of Analysis.

- A. An independent testing laboratory shall issue a certificate of analysis for each lot, with supporting data, to report:
- (1). Whether the chemical profile of the lot conforms to the specifications for the lot for the following compounds:
 - (a) Δ9-Tetrahydrocannabinol (THC);
 - (b) Tetrahydrocannabinolic Acid (THCA);
 - (c) Cannabidiol (CBD);
 - (d) Cannabidiolic Acid (CBDA);
- (e) The terpenes described in the most current version of the cannabis Inflorescence monograph published by the American Herbal Pharmacopeia (AHP);
 - (f) Cannabigerol (CBG); and
 - (g) Cannabinol (CBN); and
- (2) That the presence of the following contaminants do not exceed the levels as required by the AHP monograph:
 - (a) Any residual solvent or processing chemicals;
- (b) Foreign material such as hair, insects, or any similar or related adulterant;
 - (c) Any microbiological impurity, including:
 - (i) Total aerobic microbial count (TAMC);
 - (ii) Total yeast mold count (TYMC);
 - (iii) P. aeruginosa;
 - (iv) Aspergillus spp.;
 - (v) S. aureus;
 - (vi) Aflatoxin B1, B2, G1, and G2; and
 - (vii) Ochratoxin A.; and
 - (d) Whether the batch is within specification for:
 - (i) Odor; and
 - (ii) Appearance.
- B. Residual levels of volatile organic compounds (VOCs) shall be below the specifications as set by the United States Pharmacoepia (USP Chapter 467).

.05 Licensed Processor Determination That a Lot May be Released.

- A. If a licensed processor, upon review of the certificate of analysis, determines that a lot meets the specification for the product, the licensed processor may:
 - (1) Assign an expiration date to the lot;
 - (2) Release the lot for distribution; and
 - (3) Revise the status of the lot in the inventory control.
- B. If a licensed processor receives test results that the lot does not meet specifications, the licensed processor may rework or reprocess the lot according to their standard operating procedure.
- C. The reworked or reprocessed lot shall be resampled and retested by the independent testing laboratory to meet all required specifications.
 - D. A licensee shall retain every certificate of analysis.

.06 Stability Testing and Retention Sampling.

- A. A licensee shall provide a sample from each released lot to an independent testing laboratory sufficient to perform stability testing at 6-month intervals to:
 - (1) Ensure product potency and purity; and
 - (2) Provide support for expiration dating.
 - B. A licensee shall retain a sample from each released lot:
 - (1) Sufficient to provide for follow-up testing if necessary; and
- (2) Properly store the sample for 1 year past the date of expiration of the lot.

.07 Report of Products Offered for Distribution.

A licensee shall submit to the Commission within 30 days following the end of a quarter a list of the products and the products' specifications that the licensee offered for distribution in the quarter.

10.62.24 Medical Cannabis Finished Products Packaging

Authority: Health General Article, §§13-3301, 13-3302, 13-3307, and 13-3309, Annotated Code of Maryland

.01 Packaging of Medical Cannabis Finished Product.

- A. All items shall be individually packaged at the original point of processing.
- B. Packaging Requirements. A package of medical cannabis finished product shall:
 - (1) Be plain;
 - (2) Be opaque;
- (3) Be tamper-evident, and if applicable or appropriate, child-resistant;
 - (4) Bear a finished-product lot number and an expiration date;
 - (5) Bear a clear warning that:
- (a) The contents may be lawfully consumed only by a qualifying patient named on an attached label;
- (b) It is a illegal for any person to possess or consume the contents of the package other than the qualifying patient; and
- (c) It is a illegal to transfer the package or contents to any person other than a transfer by a caregiver to a qualifying patient;
- (6) Bear a clear warning to keep the package and its contents away from children other than a qualifying patient;
- (7) Bear the Maryland Poison Control Center emergency telephone number;
- (8) Bear the name of the licensee that packaged the medical cannabis finished product and the telephone number of the licensee for reporting an adverse patient event;
 - (9) Bear any allergen warning required by law;
 - (10) Bear a listing of the non-medical cannabis ingredients;
- (11) Bear an itemization, including weight, of all cannabinoid and terpene ingredients specified for the product, and concentrates of any cannabinoid of less than one percent shall be printed with a leading zero before the decimal point; and
- (12) Leave space for a licensed dispensary to attach a personalized label for the qualifying patient.
- C. Packaging Prohibitions. A package of medical cannabis finished product may not bear any:
- (1) Resemblance to the trademarked, characteristic or productspecialized packaging of any commercially available candy, snack, baked good or beverage;
- (2) Statement, artwork or design that could reasonably mislead any person to believe that the package contains anything other a medical cannabis finished product;
- (3) Seal, flag, crest, coat of arms, or other insignia that could reasonably mislead any person to believe that the product has been endorsed, manufactured, or used by any State, county or municipality or any agency thereof; and
- (4) Cartoon, color scheme, image, graphic or feature that might make the package attractive to children.

10.62.25 Medical Cannabis Dispensary License

Authority: Health General Article, §§13–3301, 13-3302 and 13–3307, Annotated Code of Maryland

.01 Definitions.

A. In this chapter the following terms have the meanings indicated.

- B. Terms Defined.
- (1) "Audited financial statement" means an audited financial statement that is performed by a certified public accountant licensed or with practice privileges in Business Occupations and Professions Article, Title 2, Annotated Code of Maryland, that is prepared in accordance with the Professional Standards of the American Institute of Certified Public Accountants and in the case of a publicly owned corporation in conformity with the standards of the Public Company Oversight Board.
- (2) "License" means a license issued by the Commission to operate as a licensed dispensary.
 - (3) "Licensee" means a licensed dispensary.

.02 Application.

- A. An applicant shall submit to the Commission a application for a license for each Senatorial district in which it is competing for a license.
- B. An application on a form developed by the Commission shall be completed and submitted to the Commission for consideration. In addition to the application form, the applicant shall submit the following documents to be included as addenda to the application form:
- (1) A list identifying the applicant's potential dispensary agents;
- (2) A list identifying each individual investor with 5 percent or more of investment known at the time of application;
 - (3) A detailed business plan including an organizational chart;
 - (4) Documentation and source of adequate capitalization;
- (5) If the applicant is a corporation, a copy of the articles of incorporation and authorization to do business in Maryland;
- (6) Evidence that no tax obligation is in arrears in any jurisdiction on the part of the applicant and any investor with 5 percent or more of investment known at the time of application;
- (7) A description of the proposed premises, including a preliminary site plan;
 - (8) A security plan;
 - (9) A plan for quality control;
- (10) A plan for inventorying, safekeeping and tracking medical cannabis from entry into inventory to sale or disposal of medical cannabis waste;
 - (11) A plan for the disposal of medical cannabis waste;
 - (12) A plan for training employees and volunteers;
- (13) A plan for counseling qualifying patients and caregivers in the use of medical cannabis; and
- (14) A plan of the medical cannabis and medical cannabisinfused products proposed to be dispensed with the proposed cannabinoid profiles.
- C. The application shall be accompanied by the stage I application fee specified in COMAR 10.62.35.
- D. An applicant shall amend an application within 3 business days to include the name and documentation of a request to forward the criminal history record information and audited financial statement to the Commission of a new individual investor of an interest of 5 percent or more, or another manager or director of the entity, even after a license is issued.
- E. Any party applying for a license shall have an interest in only one license.

.03 Criminal History Record Request.

For each individual identified in the application specified in Regulation .02B(1) and (2) of this chapter, an applicant shall provide to the Director of the Central Repository:

A. Two sets of legible fingerprints taken in a format approved by the Director of CJIS and the Director of the FBI and the fee authorized under Criminal Procedure Article, §10-221(B)(7), Annotated Code of Maryland, for access to State criminal history and records for each dispensary agent and investor identified in the application; and

B. A request that the individual's state and national criminal history record information be forwarded to the Commission.

.04 Consent for Investigation.

- A. An individual who is required to provide personal and background information under this chapter shall provide a statement that irrevocably gives consent to the Commission and persons authorized by the Commission to:
- (1) Verify all information provided in the application documents; and
 - (2) Conduct a background investigation of the individual.
- B. An applicant shall waive any contractual, statutory, or common law obligation of confidentiality and authorize any government agency in any jurisiction to release to and provide access to the Commission of any and all information the applicant has provided to any other jurisdiction while seeking a cannabis-related license in that other jurisdiction, as well as the information obtained by that other jurisdiction during the course of any investigation it may have conducted regarding the applicant.
- C. An applicant shall release all financial institutions, fiduciaries, and other parties from any contractual, statutory or common law obligation of confidentiality to provide financial, personal and background information to the Commission relevant to the applicant's capacity to manage a licensed dispensary and the applicant's good moral character.

.05 Application Review.

- A. The burden of proving an applicant's qualifications rests on the applicant.
- B. The Commission may deny an application that contains a misstatement, omission, misrepresentation, or untruth.
 - C. An application shall be complete in every material detail.
- D. The Commission may request any additional information the Commission determines is necessary to process and fully investigate an application.
- E. The applicant shall provide requested additional information by the close of business of the 14th business day after the request has been received by the applicant.
- F. If the applicant does not provide the requested information within 14 business days, the Commission may consider the application to be suspended.
- G. The Commission intends to award the licenses to the best applications that most efficiently and effectively ensure public safety and safe access to medical cannabis and medical cannabis-infused products.
- H. The Commission shall provide guidelines and detailed instructions for submitting the application form for the Commission's consideration.
- I. The Commission, or a Commission independent contractor, shall review for a pre-approval for a license the submitted applications, as described in Regulations .02B and .05E of this chapter, for each Senatorial district. The applications shall be ranked based on the following weighted criteria:
- (1) Operational factors will be afforded 20 percent weight, including:
- (a) A detailed operational plan for the dispensing of medical cannabis extracts and medical cannabis-infused products; and
 - (b) Summaries of policies and procedures for:
 - (i) Counseling and educating patients and caregivers;
 - (ii) Packaging; and
 - (iii) Labeling;

- (2) Safety and security factors will be afforded 20 percent weight, including:
- (a) Detailed plan or information describing the security features and procedures;
- (b) Detailed plan describing how the dispensary will prevent diversion; and
 - (c) Detailed plan describing safety procedures;
- (3) Medical cannabis professionalism factors will be afforded 15 percent weight, including:
- (a) Experience, knowledge and training in training dispensary agents in the science and use of medical cannabis; and
 - (b) Use of a clinical director;
- (4) Retail management factors will be afforded 15 percent weight, including:
- (a) A detailed plan to preserve the quality of the medical cannabis;
- (b) A plan to minimize any negative impact on the surrounding community and businesses;
 - (c) A detailed inventory control plan; and
 - (d) A detailed medical cannabis waste disposal plan;
- (5) Business and economic factors will be afforded 15 percent weight, including:
 - (a) A business plan:
 - (i) Demonstrating a likelihood of success;
- (ii) Demonstrating a sufficient business ability and experience on the part of the applicant; and
- (iii) Providing for appropiate employee working conditions, benefits and training;
 - (b) Demonstration of adequate capitalization; and
- (c) A detailed plan evidencing how the dispensary will enforce the alcohol and drug free workplace policy;
- (6) Additional factors that will be afforded 15 percent weight, including:
- (a) Demonstrated Maryland residency among the owners and investors;
- (b) Evidence that applicant is not in arrears regarding any tax obligation in Maryland and other jurisdictions; and
- (c) The medical cannabis extracts and medical cannabisinfused products proposed to be dispensed with proposed cannabinoid profiles, including varieties with high cannabidiol content, and the varieties of routes of administration.
- J. An applicant that is ranked first or second in more than one senatorial district may elect to move to stage 2 of the application process in only one district.
- K. In a Senatorial district in which the top ranking applicants chose not to move to phase 2, lesser ranked applicants will move up in rank.

.06 Pre-Approval of License Application.

- A. Number of Pre-approvals. In consideration of the ranking of the applications in accordance with Regulation .05, the Commission may issue pre-approvals of up to two licensed dispensaries per Senatorial district, other than the number of licenced grower dispensary facilities located in the Senatorial district.
- B. If there are more qualified applications than the number of licenses available and there is a numerical tie for the last license to be issued, the last pre-approved license shall be determined by public lottery.
- C. The Commission may deny issuing a pre-approval of a license if, for any individual identified in the application specified in Regulation .02B(1) and (2) of this chapter:
- (1) The criminal history record information or background information demonstrate an absence of good moral character; or
 - (2) The payment of taxes due in any jurisdiction is in arrears.

- D. Within 10 business days of the Commission's decision, the Commission shall notify applicants who have been pre-approved for a license.
- E. The Commission may rescind pre-approval of a dispensary license if the dispensary is not operational within 1 year of pre-approval.

.07 Issuance of License.

- A. After an applicant has been issued a pre-approval for a license under this chapter the applicant shall submit to the Commission, as part of its application:
- (1) An audited financial statement for the applicant and for each individual, partnership, corporation, or other entity review that has invested, or is proposed to invest, 5 percent or more of the capital of the applicant;
- (2) Payment of the stage 2 application fee specified in COMAR 10.62.35.
- B. The Commission may issue a dispensary license on a determination that:
- (1) The criminal history background check and background investigation reveal no evidence that demonstrates the absence of good moral character;
- (2) All inspections are passed and all of the applicant's operations conform to the specifications of the application as preapproved pursuant to Regulation .06 of this chapter;
 - (3) The proposed premises:
 - (a) Are under the legal control of the applicant;
 - (b) Comply with all zoning and planning requirements; and
- (c) Conform to the specifications of the application as preapproved pursuant to Regulation .07 of this chapter; and
- (4) The first year's license fee specified in COMAR 10.62.35 has been paid.

.08 Change of Ownership of License.

- A. No interest of 5 percent or more of a license issued pursuant to this chapter shall be assignable or transferable unless:
- (1) The Commission has received notice of the intent of the owner of the interest, or of the estate of the owner of the interest, to transfer or assign an interest in a license to another party;
- (2) The transferee has had forwarded the criminal history record information and audited financial statement to the Commission of the transferee;
- (3) The Commission does not object to the transfer or assignment within 45 days of its receipt of notice; and
- (4) The transferee has paid the required fee specified in COMAR 10.62.35.
- B. The Commission may deny transfer of an interest in a license if, for any proposed transferee:
- (1) The criminal history record information or the background investigation demonstrate an absence of good moral character; or
 - (2) The payment of taxes due in any jurisdiction is in arrears.

.09 Change of Location.

- A. A licensee may apply to change the location of the licensee's operation.
- B. The licensee shall submit an application to the Commission along with the fee specified in COMAR 10.62.35.
- C. A licensee may not begin dispensing medical cannabis at a new location until all inspections have been passed.

.10 Renewal of License.

- A. A licensee is eligible to apply to renew a license every 2 years.
- B. Ninety days before the expiration of a license, the Commission shall notify the licensee of the:
 - (1) Date on which the license expires;
 - (2) Process and the fee required to renew the license; and

- (3) Consequences of a failure to renew the license.
- C. At least 30 business days before a license expires a licensee shall submit:
 - (1) The renewal application as provided by the Commission;
- (2) Proof that fingerprints have been submitted to CJIS and the FBI for every processor agent and investor of an interest of 5 percent or more;
- (3) To full inspection of the operation, unless a full inspection was satisfactorily completed within 3 months before the date of the license expiration; and
 - (4) Payment of the fee specified in COMAR 10.62.35.
- D. The Commission shall renew a license that meets the requirements for renewal as stated in §C of this regulation.
- E. If the Commission does not renew a license due to a failed inspection or an inadequate application for renewal, the licensee may apply for reinstatement by:
- (1) Submitting a plan to correct the deficiencies noted during an inspection; and
 - (2) Amending the application for renewal.
 - F. The Commission may decline to renew a license if:
- (1) The plan to correct deficiencies identified in an inspection is deficient;
 - (2) The amended application for renewal is deficient; or
 - (3) The licensee has repeatedly failed inspections.
- G. A licensee who fails to apply for renewal of a license by the date specified by the Commission, or whose license was not renewed by the Commission:
 - (1) Shall cease operations at all premises; and
 - (2) May not provide medical cannabis to any entity or person.
 - H. A license may be reinstated upon:
- (1) Payment of the reinstatement fee specified in COMAR 10.62.35; and
- (2) Submission of a reinstatement application approved by the Commission.

10.62.26 Registered Dispensary Agent

Authority: Health General Article, \$\$13–3301, 13-3302, 13-3307 and 13–3308, Annotated Code of Maryland

.01 Definitions.

- A. In this chapter, the following terms have the meaning indicated. B. Terms Defined.
- (1) "License" means a license issued by the Commission to operate as a licensed dispensary.
 - (2) "Licensee" means a licensed dispensary.

.02 Dispensary Agent Generally.

A dispensary agent shall be 21 years old or older.

.03 Dispensary Agent Registration and Criminal History Record.

- A. A dispensary agent shall be registered with the Commission before the agent may volunteer or work for a licensee.
- B. A licensee shall apply to register a dispensary agent by submitting to the Commission:
- (1) The name, address, date of birth and Social Security Number of a dispensary agent;
- (2) Documentation of the submission of fingerprints of the dispensary agent to the Central Registry; and
- (3) The request for the criminal history record information of the dispensary agent to be forwarded to the Commission.
- C. A prospective registered dispensary agent may not be registered by the Commission if the prospective registered dispensary agent has ever been convicted of a felony drug offense.

D. The Commission, after review of the criminal history record information, may disqualify any prospective registered dispensary agent from registration for an absence of good moral character.

.04 Registered Dispensary Agent Identification Cards.

- A. The Commission shall issue to each registered dispensary agent a identification card that shall include a photograph of the face of the registered dispensary agent taken no more than 6 months before the date of the application.
- B. At all times at the premises of a licensee every registered dispensary agent shall visibly wear the identification card issued to the registered dispensary agent by the Commission.
 - C. The identification card shall be renewed every 2 years.
- D. If a registered dispensary agent's identification card is lost, destroyed or stolen, within 24 hours of becoming aware of the loss, destruction or theft, the licensee shall:
 - (1) Report the loss, destruction or theft to a the Commission;
 - (2) Apply for a replacement card; and
 - (3) Pay a replacement card fee specified in COMAR 10.62.35.
- E. An identification card remains the property of the Commission and the Commission may order the return or seizure of an identification card if the registration is revoked or expires.
- F. If a registered dispensary agent's identification card is lost, destroyed, or stolen, a copy of notification to the Commission shall be evidence of registration until a new card is obtained from the Commission.

.05 Termination.

- A. As soon as possible upon termination of a registered dispensary agent's association with a licensee, the licensee shall:
- (1) Take custody of the terminated registered dispensary agent's identification card;
- (2) Obtain any keys or other entry devices from the terminated registered dispensary agent; and
- (3) Ensure the terminated registered dispensary agent can no longer gain access to the premises of the licensee.
- B. Within 1 business day of the termination of a registered dispensary agent's association with a licensee, the licensee shall:
 - (1) Notify the Commission:
- (a) Of the termination and the circumstances of a termination; and
- (b) Whether the terminated registered dispensary agent has returned the agent's identification card; and
- (2) Initiate delivery of the terminated registered dispensary agent's identification card to the Commission.
- C. The Commission shall revoke a identification card of a dispensary agent upon receiving notification that a dispensary agent is no longer associated with a licensee.
- D. If a registered dispensary agent did not return the agent's identification card within 30 days, the Commission shall notify the Maryland State Police and place a notice in the register of that fact.

.06 Prospective Dispensary Agent Drug Screen.

- A. The licensee shall require a prospective dispensary agent to submit to a drug screen before commencement of association.
- B. The drug screen shall be carried out following the procedures set forth in COMAR 17.04.09.04—.08.
- C. In addition to the drugs to be be screened in accordance with the procedures set forth in COMAR 17.09.04-.08, the screen shall include any other drugs as required by the Commission.
- D. Unless medically justified, a prospective dispensary agent who has a positive response to any tested substance on a drug screen that meets the requirements of COMAR 17.04.09.07 may not be registered by the Commission.

.07 Registered Dispensary Agent Training.

- A. The licensee shall train all registered dispensary agents on:
- (1) Federal and State medical cannabis laws and regulations and other laws and regulations pertinent to the dispensary agent's responsibilities;
 - (2) Standard operating procedures;
 - (3) Detection and prevention of diversion of medical cannabis;
 - (4) Security procedures; and
 - (5) Safety procedures, including responding to;
 - (a) A medical emergency;
 - (b) A fire;
 - (c) A chemical spill; and
 - (d) A threatening event such as:
 - (i) An armed robbery;
 - (ii) An invasion;
 - (iii) A burglary; or
 - (iv) Any other criminal incident.
- B. Every 12 months registered dispensary agents shall be educated on the most recent data regarding:
 - (1) The pharmacology of cannabis and its active components;
- (2) The potential therapeutic and adverse effects of medical cannabis;
- (3) Dosage forms of medical cannabis and their pharmacodynamic impact;
- (4) Potential drug interactions and consumer safety issues with marijuana use; and
- (5) Recognition of symptoms of substance use disorders and acute intoxication.
- C. The licensee shall retain training materials and attendance records and make the training materials available for inspection by the Commission.

.08 Alcohol and Drug Free Workplace Policy.

- A. A registered dispensary agent shall declare in writing that the registered dispensary agent shall adhere to the State alcohol and drug free workplace policy, as identified in COMAR 21.11.08.03.
- B. The licensee shall retain the declaration in the registered dispensary agent's personnel record.

.09 Annual Verification of Registered Dispensary Agents.

Every year, on a date determined by the Commission, the licensee shall notify the Commission that the licensee has verified that no registered dispensary agent has been convicted of a felony drug offense.

10.62.27 Licensed Dispensary Premises

Authority: Health General Article, §§13–3301, 13-3302 and 13–3307, Annotated Code of Maryland

.01 Definitions.

- A. In this chapter, the following terms have the meaning indicated.
- B. Terms Defined.
- (1) "License" means a license issued by the Commission to operate as a dispensary.
 - (2) "Licensee" means a licensed dispensary.

.02 Premises Generally.

- A. The premises of a licensee shall be located within Maryland.
- B. The premises of a licensed dispensary shall be separate from the premises of a licensed processor.
- C. The dispensary license shall be displayed at the location where the licensee is authorized to operate.
- D. The premises and operations of a licensee shall conform to all local zoning and planning requirements.
- E. No major renovation or modification shall be undertaken without notification to the Commission.

.03 Security of Premises.

The premises of a licensee shall be constructed to prevent unauthorized entry.

.04 Secure Room.

- A. A licensed dispensary shall contain a secure room to store the medical cannabis inventory.
 - B. The secure room:
- (1) Shall be constructed of concrete or similar building material that prevents unauthorized entry;
- (2) May not be placed adjacent to an exterior wall of the premises; and
 - (3) Shall have only one entrance door that:
 - (a) Meets commercial security standards;
- (b) Is equipped with a cipher or chip-activated keyed lock or equivalent; and
 - (c) Is not visible from public areas of the premises.
- C. Other than while the licensed dispensary is open for business and 1 hour before and 1 hour after, the inventory of medical cannabis shall be stored in the secure room.

.05 Security Lighting.

Lighting fixtures of the licensee shall be designed and installed to ensure proper surveillance.

.06 Security Alarm Systems.

- A. A licensee shall maintain a security alarm system that covers all perimeter entry points, windows and portals at the premises.
 - B. The security alarm system shall be:
 - (1) Continuously monitored;
 - (2) Capable of detecting smoke and fire;
 - (3) Capable of detecting power loss.
- C. The security alarm system shall include panic alarm devices mounted at convenient, readily-accessible locations throughout the licensed premises.
 - D. A second, independent alarm system shall be used to protect:
 - (1) The location where records are stored on-site;
 - (2) The location where records are stored off-site; and
 - (3) Any secure room that holds medical cannabis.
- E. The security alarm system shall remain operational until the premises of the licensee no longer have any medical cannabis on the premises.
- F. All security alarm systems shall be equipped with auxiliary power sufficient to maintain operation for at least 48 hours.

.07 Video Surveillance Requirements.

- A. A licensee shall maintain a motion-activated video surveillance recording system at the premises that:
- (1) Records all activity in images of high quality and high resolution capable of clearly revealing facial detail;
- (2) Operates 24-hours a day, 365 days a year without interruption; and
 - (3) Provides a date and time stamp for every recorded frame.
- B. A licensee shall post appropriate notices advising visitors of the video surveillance.
- C. A surveillance camera shall be located and operated to capture activity at each exit from the premises.
- D. A surveillance camera shall capture activity at each entrance to an area where medical cannabis is packaged, tested, processed, stored or dispensed.
- E. A recording of all images captured by each surveillance camera shall be kept at:
 - (1) The licensed premises; and
 - (2) An off-site location.
 - F. Recordings of security video surveillance shall be:
 - (1) Access-limited;

- (2) Secured by a security alarm system that is independent of the main premises security alarm system;
- (3) In a format that can be easily accessed for investigational purposes; and
 - (4) Retained for a minimum of 30 calendar days.
- G. Any recording of security video surveillance shall be made available to the Commission or law enforcement agency for just cause as requested.

.08 Licensed Dispensary Premises Organization.

- A. A licensee shall divide the licensed dispensary premises between a public zone and an operations zone.
 - B. Public Zone.
 - (1) The public zone shall have:
 - (a) A waiting area open to the general public; and
- (b) A service area in which a qualifying patient or caregiver may consult with a registered dispensary agent and receive medical cannabis.
- (2) The licensed dispensary shall restrict entry into the service area to qualifying patients and caregivers.
- (3) The licensed dispensary's hours of business shall be displayed at the entrance to the public zone.
 - C. Operations Zone.
- (1) All operations other than consulting with qualifying patients and caregivers and dispensing medical cannabis shall be carried out in the operations zone.
- (2) The operations zone shall be appropriately divided into separate areas for:
 - (a) Medical cannabis storage;
 - (b) Medical cannabis preparation and packaging;
 - (c) Use by dispensary agents for breaks; and
 - (d) Changing clothing and dispensary agent lockers.
- (3) Tamper-evident logbooks or electronic identification logs shall document the movement of persons to and from the operations zone.
 - D. Appropriate signage shall clearly delineate the separate zones.
 - E. Doors and other access points between zones shall be secured.
- F. Security alarms systems and video surveillance, as described in Regulations .06 and .07 of this chapter, shall be used to monitor the separation between zones.
- G. All medical cannabis, other than that being displayed, being processed, or being dispensed during business hours, shall be kept in a secure room.
- H. No individual other than a registered dispensary agent may handle the inventory in a display case or elsewhere in the dispensary until dispensed.

.09 Visitor to a Non-Public Area of the Premises.

- A. When a visitor is admitted to a non-public area of the premises of a licensee, a registered dispensary agent shall:
 - (1) Log the visitor in and out;
- (2) Retain with the log a photocopy of the visitor's governmentissued identification;
- (3) Continuously visually supervise the visitor while on the premises; and
- (4) Ensure that the visitor does not touch any medical cannabis.
- B. The licensee shall maintain a log of all visitors to non-public areas for 2 years.

10.62.28 Licensed Dispensary Operations

Authority: Health General Article, §§13–3301, 13-3302 and 13–3307, Annotated Code of Maryland

.01 Definitions.

- A. In this chapter, the following terms have the meaning indicated. B. Terms Defined.
- (1) "Dispensary supervisor" means the registered dispensary agent designated by the licensed dispensary to supervise dispensary operations.
 - (2) "Licensee" means a licensed dispensary.
- (3) "Receiving licensee" means the licensee that receives the shipment.
- (4) "Shipping licensee" means the licensee that receives the shipment.

.02 Standard Operating Procedure.

- A. A licensee shall:
- (1) Establish a standard operating procedure for all aspects of the receipt, storage, packaging, labeling, handling, tracking and dispensing of products containing medical cannabis and medical cannabis waste;
- (2) Create and use a perpetual inventory control system that identifies and tracks the licensee's stock of medical cannabis from the time it is delivered or produced to the time it is delivered to another licensee, a licensed grower, or a qualifying patient or caregiver; and
- (3) Train each registered dispensary agent in the standard operating procedure and retain attendance records.
- B. A copy of the standard operating procedure shall be readily available on site for inspection by the Commission.

.03 Receipt of Products Containing Cannabis.

- A. A licensee or licensed grower that dispenses medical cannabis to patients may not:
- (1) Acquire medical cannabis from an individual or entity in Maryland other than a licensee;
- (2) Acquire medical cannabis from outside of Maryland unless authorized by the Commission; or
- (3) Transport medical cannabis to any place outside of Maryland.
- B. A receiving licensee shall detail in the standard operating procedure the steps set forth in §\$C, D, and H of this regulation, or their equivalent, and a shipping licensee shall detail in its standard operating procedure the steps set forth in \$C—H of this regulation, or their equivalent, to assure:
- (1) The integrity of the shipment of products containing cannabis;
- (2) The integrity of the electronic manifest and inventory control system; and
 - (3) The quality of the products in the shipment.
- C. Upon arrival of a medical cannabis transport vehicle, the transportation agent shall notify an appropriate registered dispensary agent or registered grower agent to continue the chain of custody of the shipment of products containing cannabis.
 - D. An agent of the receiving licensee shall:
 - (1) Log into the electronic manifest;
- (2) Take custody of a shipment of products containing cannabis;
 - (3) Confirm that:
- (a) The transportation agent is carrying appropriate identification;
- (b) The packaging is secure, undamaged, and appropriately labeled;
- (c) Each package in the shipment is labeled as described in the electronic manifest; and

- (d) The contents of the shipment are as described in the electronic manifest;
 - (4) Record the confirmations in the electronic manifest;
- (5) Obtain in the electronic manifest the signature or the identification number of the transportation agent who delivers the shipment;
- (6) Record in the electronic manifest the date and time the receiving agent takes custody of the shipment;
- (7) Enter the products containing cannabis into the inventory control system;
- (8) Segregate the items in the shipment from the inventory until the item can be inspected;
- (9) Inspect each item to ensure that the packaging of each item is undamaged, accurate and complete; and
- (10) Upon determining the item passes inspection, release the item into the inventory.
- E. The transportation agent shall provide a copy of the electronic manifest for the shipment to the receiving licensee.
- F. The transportation agent shall provide the completed electronic
- manifest to the shipping licensee.

 G. The shipping licensee shall retain the electronic manifest for the shipment for 5 years.
 - H. Discrepancy in the Shipment.
- (1) If the licensee finds evidence of a theft or diversion within 1 business day the licensee shall report the theft or diversion to the Commission and to the Maryland State Police.
- (2) Within 30 business days of discovering the discrepancy, the licensee shall:
 - (a) Complete an investigation;
- (b) Amend the licensee's standard operating procedures, if necessary; and
 - (c) Send a report of the investigation to the Commission.
 - (3) The shipping licensee shall submit to the Commission:
- (a) Within 7 business days of the observation of the discrepancy, a preliminary report of an investigation of a discrepancy; and
- (b) Within 30 business days a final report of the investigation.

.04 Sanitary Storage of Medical Cannabis.

- A. A licensee shall maintain the cleanliness of any building or equipment used to store or display medical cannabis.
 - B. A registered dispensary agent shall:
- (1) Comply with the standard operating procedure to maintain the medical cannabis free from contamination; and
- (2) Report to a supervisor any personal health condition that might compromise the cleanliness or quality of the medical cannabis the dispensary agent might handle.
- C. A licensee shall separately store in the secure room until disposed of any medical cannabis:
- (1) That is outdated, damaged, deteriorated, misbranded, or adulterated; or
- (2) Whose containers or packages have been improperly or accidentally opened.

.05 Equipment Sanitation, Accuracy and Maintenance Logs.

- A. The licensee shall maintain the sanitation of equipment that comes in contact with medical cannabis to prevent contamination in accordance with the approved standard operating procedure.
- B. Pursuant to the approved standard operating procedure, the licensee shall require that:
- (1) Automatic, mechanical, or electronic equipment is routinely calibrated and periodically checked to ensure proper performance; and
- (2) Any scale, balance, or other measurement device is routinely calibrated and periodically checked to ensure accuracy.

- C. Pursuant to the approved standard operating procedure, the licensee shall maintain an accurate log recording the:
 - (1) Cleaning of equipment;
 - (2) The maintenance of equipment; and
 - (3) The calibration of equipment.

10.62.29 Licensed Dispensary Packaging and Labeling for Distribution

Authority: Health General Article, §§13–3301, 13-3302 and 13–3307, Annotated Code of Maryland

.01 Packaging Medical Cannabis for Distribution to a Qualifying Patient or Caregiver.

- A. A licensed dispensary may only distribute medical cannabis in a package that complies with the requirements and restrictions of §B—F of this regulation.
- B. Packaging Requirements. A package of medical cannabis for distribution to a qualifying patient or caregiver shall:
 - (1) Be plain;
 - (2) Be opaque;
- (3) If appropriate or requested by a qualifying patient or caregiver, be child-resistant;
- (4) Identify the licensee that produced the medical cannabis finished product or that grew the medical cannabis in the package;
 - (5) Bear a finished-product lot number and an expiration date;
 - (6) Bear a clear warning that:
- (a) The contents may be lawfully consumed only by the qualifying patient named on the attached label;
- (b) It is illegal for any person to possess or consume the contents of the package other than the qualifying patient; and
- (c) It is illegal to transfer the package or contents to any person other than for a caregiver to transfer it to a qualifying patient;
- (7) Bear a clear warning to keep the package and its contents away from children;
- (8) Bear the Maryland Poison Control Center emergency telephone number;
- (9) Bear the telephone number of the licensee to call to report an adverse patient event;
- (10) If applicable, bear any allergen warning or nutrition labeling required by law;
- ${\it (11) If applicable, bear a listing of the non-medical cannabis ingredients;}$
- (12) Bear a conspicuous itemization, including weight, of all cannabinoid and terpene ingredients specified for the product; and
 - (13) Bear a personalized label for the qualifying patient.
- C. Packaging Prohibitions. A package of medical cannabis for distribution to a qualifying patient or caregiver may not:
- (1) Bear any resemblance to the trademarked, characteristic or product-specialized packaging of any commercially available candy, snack, baked good or beverage;
- (2) Bear any statement, artwork or design that could reasonably mislead any person to believe that the package contains anything other an a medical cannabis finished product;
- (3) Bear any seal, flag, crest, coat of arms, or other insignia that could reasonably mislead any person to believe that the product has been endorsed, manufactured, or used by any State, county or municipality or any agency thereof; or
- (4) Bear any cartoon, color scheme, image, graphic or feature that might make the package attractive to children.
- D. Information printed on the package shall be in English, in letters at least one-sixteenth of an inch high.
- E. If a statement of the presence of any cannabinoid is expressed as a percentage of the total weight of the contents and the

concentration of the cannabinoid is less than 1 percent, the percentage shall be written with a leading zero before the decimal point.

F. At a licensed dispensary medical cannabis may only be prepared or re-packaged in an area of the operations zone designed, maintained, and used exclusively for such purposes.

.02 Label for Distribution to a Qualifying Patient.

- A. A licensee shall print a label for a package of medical cannabis for a qualifying patient in English in letters no less than one-sixteenth of an inch high. If requested by a qualifying patient or caregiver, the licensee may also print a label in another language.
- B. A licensee may not distribute a package of medical cannabis without a label securely attached.
- C. A licensee shall state on a label of a package of medical cannabis:
 - (1) The name of the qualifying patient;
 - (2) The name of the certifying physician;
 - (3) The name of the licensee where the product was dispensed;
 - (4) The date that the medical cannabis was dispensed;
 - (5) The name of the product;
- (6) The strength of applicable cannabinoid and terpene compounds:
 - (a) Displayed in units appropriate to the dosage form; and
- (b) Concentrations of any cannabinoid of less than one percent shall be printed with a leading zero before the decimal point;
- (7) The quantity of medical cannabis dispensed, displayed in units appropriate to the dosage form;
 - (8) Any directions for use of the product; and
- (9) The instructions for proper storage or handling of the product.
- D. Any other information required by the dispensary at its discretion may be provided in a patient insert.
 - E. The label may not:
 - (1) Contain any false or misleading statement or design; or
- (2) Include any statement, image or design that may not be included on the package.

10.62.30 Dispensing Medical Cannabis

Authority: Health General Article, §§13–3301, 13-3302, 13-3307, 13-3313 and 13–3314, Annotated Code of Maryland

.01 Use of Written Certification.

A dispensary shall notify the Commission that a qualifying patient or caregiver has presented a written certification at that dispensary or has requested a delivery based upon a written certification.

.02 Visitor and Activity at a Licensed Dispensary.

- A. In the service area of a licensed dispensary, a registered dispensary agent shall:
 - (1) Escort a member of the public; and
 - (2) Maintain visual contact at all times.
- B. A licensed dispensary may not permit the consumption of medical cannabis at the licensed premises.

.03 Procedure for Dispensing Medical Cannabis.

- A. A registered dispensary agent shall dispense medical cannabis only to a qualifying patient or caregiver who has presented a government-issued identification card.
- B. Before any distribution of medical cannabis, a dispensary agent shall query the Commission data network and verify that:
 - (1) The qualifying patient or caregiver is currently registered;
- (2) A certifying physician issued a valid written certification to the qualifying patient, and
- (3) The amount of medical cannabis that has already been dispensed pursuant to the written certification.

- C. A dispensary agent may provide information on:
- (1) The available types of medical cannabis, cannabis varieties, and medical cannabis finished products;
 - (2) Methods by which medical cannabis can be taken; and
 - (3) How unused cannabis may be returned for disposal.
 - D. 30-Day Supply.
- (1) A qualifying patient or caregiver may obtain a portion of a 30-day supply at any time once the written certification is presented to a licensed dispensary, provided the portion being sought when added to portions previously obtained does not exceed a 30-day supply.
- (2) The dispensary agent shall enter the weight of usable cannabis or the weight of $\Delta 9$ -Tetrahydrocannabinol (THC) dispensed in the Commission data network.
- E. A registered dispensary agent may decline to dispense medical cannabis to a qualifying patient or caregiver if, in the professional opinion of the registered dispensary agent, the patient or caregiver appears to be currently under the influence of drugs or alcohol.
- F. A licensed dispensary may not distribute a sample of medical cannabis.
- G. If not used to purchase medical cannabis within 120 days of issuance, a written certification becomes null and void.

.04 Delivery of Medical Cannabis to a Qualifying Patient or Caregiver.

- A. A qualifying patient or caregiver shall first telephone a registered dispensary to request the delivery of medical cannabis:
- (1) The qualifying patient or caregiver shall provide identification that a dispensary agent can verify by means established by the Commission; and
- (2) The qualifying patient or caregiver shall also provide a complete and verifiable delivery address.
- B. During the telephone conversation with the qualifying patient or caregiver, a registered dispensary agent may provide information on:
- (1) The available types of medical cannabis, cannabis varieties, and medical cannabis finished products:
 - (2) Methods by which medical cannabis can be used; and
 - (3) How unused cannabis may be returned for disposal.
- C. Before any delivery of medical cannabis, a dispensary agent shall query the Commission data network and verify that:
- (1) The qualifying patient or caregiver is currently registered;
- (2) A certifying physician issued a valid written certification to the qualified patient; and
- (3) The amount of medical cannabis requested does not exceed the 30-day supply;
 - D. 30-Day Supply.
- (1) A qualifying patient or caregiver may obtain by delivery a portion of a 30-day supply at any time once the written certification is presented to a licensed dispensary, provided the portion being sought for delivery when added to portions previously obtained does not exceed a 30-day supply.
- (2) The dispensary agent shall enter the weight dispensed in the Commission data network prior to delivery.
- E. Only a qualified patient or caregiver may accept delivery of medical cannabis.
- F. Only a registered dispensary agent may deliver medical cannabis.

.05 Attestation by Qualifying Patient or Caregiver.

- A. Before medical cannabis is dispensed, either in person or by delivery, a qualifying patient or caregiver shall attest that the qualifying patient or caregiver understand that the qualifying patient and caregiver are not immune from the imposition of any civil, criminal, or other penalties for the following:
- (1) Operating, navigating, or being in actual physical control of any motor vehicle, aircraft, or boat while under the influence of medical cannabis:
 - (2) Smoking medical cannabis in any public place;
 - (3) Smoking medical cannabis in a motor vehicle; or
- (4) Undertaking any task under the influence of medical cannabis, when doing so would constitute negligence or professional malpractice;
 - (5) Smoking medical cannabis on a private property that:
 - (a) Is rented from a landlord; and
- (b) Is subject to a policy that prohibits the smoking of medical cannabis or marijuana on the property; or
- (6) Smoking medical cannabis on a private property that is subject to a policy that prohibits the smoking of medical cannabis on the property of an attached dwelling adopted by:
- (a) The board of directors of the council of unit owners of a condominium regime; or
 - (b) The governing body of a homeowners association.
- B. As used in §A(5) and (6) of this regulation, vaporization of medical cannabis is not smoking.
- C. Before medical cannabis is dispensed, a qualifying patient or caregiver shall attest that the qualifying patient or caregiver understands that:
 - (1) The qualifying patient or caregiver shall:
- (a) Keep all medical cannabis away from children other than the qualifying patient; and
- (b) Take steps to prevent children from obtaining or using medical cannabis;
- (2) It is illegal to transfer medical cannabis to any person, other than the transfer by a caregiver to a qualifying patient;
- (3) Obtaining medical cannabis does not exempt a qualifying patient or caregiver from prosecution under Federal law and the penalties provided by Federal law;
- (4) Scientific research has not established the safety of the use of medical cannabis by pregnant women; and
- (5) The use of medical cannabis to treat a medical condition is not approved by the U.S. Food and Drug Administration.

.06 Dispensing Controls.

- A. In cases of delivery, at the point of delivery a qualified patient or caregiver shall display identification to the delivering dispensary agent.
- B. The qualifying patient or caregiver shall sign a receipt for the medical cannabis.
- C. The dispensary agent and the qualifying patient or caregiver shall each retain a copy of the receipt.
- D. A registered dispensary agent shall record in the inventory control and in the Commission data network each item dispensed including lot and batch number and the weight of medical cannabis that was dispensed.

.07 Limit on Transfer of Medical Cannabis.

A licensee or registered dispensary agent may not transfer any medical cannabis to any person if the licensee or registered dispensary agent knows, or may have reason to know, that the transfer or the medical cannabis does not comply with any provision of the Health – General Article, Title 13, Subtitle 33, Annotated Code of Maryland or this subtitle.

.08 Report of Products Offered for Distribution.

A licensee shall submit to the Commission on the last day of the month following each quarter a list of the products and the products' specifications that the licensee offered for distribution in the quarter.

.09 Disposal of Green Waste.

A licensee may either ship any medical cannabis that is surplus or out of date or that is waste from processing or repackaging:

- A. To a licensed grower for disposal; or
- B. Dispose of such material in accordance with the licensee's approved waste disposal plan.

10.62.31 Licensed Dispensary Clinical Director

Authority: Health General Article, §§13–3301, 13-3302, 13-3307 and 13–3314, Annotated Code of Maryland

.01 Clinical Director Responsibilities.

A licensed dispensary may appoint an individual who is a Maryland-licensed physician, nurse practitioner or pharmacist to function as clinical director.

10.62.32 Records

Authority: Health General Article, §§13-3301, 13-3302, 13-3306, 13-3309 and 13-3311, Annotated Code of Maryland

.01 Definition.

In this chapter, "Licensee" means a licensed grower, a licensed processor, and a licensed dispensary.

.02 Licensee Records.

- A. A licensee shall maintain, independent of the inventory control, a searchable, secure, tamper-evident record of each distribution that contains:
 - (1) The name and address of the recipient;
 - (2) The quantity delivered; and
- (3) The name, strength, batch number and lot number of the product.
- B. Upon request, a licensee shall provide in a reasonable time and manner to a certifying physician a copy of the record of each distribution by the licensee to a qualifying patient of the certifying physician of the quantity delivered, name, strength, batch number and lot number of medical cannabis.
- C. A licensee shall retain the records of production and distribution of each batch and lot and of daily checklists to maintain uniformity from batch to batch, and lot to lot.
- D. A licensee shall maintain a record of test methods and test results for each batch and lot, including graphs, charts, or spectra from laboratory instrumentation.
- E. A licensee shall maintain a log of individuals visiting each premises.
- F. A licensee shall maintain a duplicate set of all records at a secure, off site location.

.03 Record Retention.

Unless otherwise specified, a licensee, or a certifying physician shall retain a record for a period of 5 years.

10.62.33 Inspection

Authority: Health General Article, §\$13-3301, 13-3302 13-3306, 13-3307, 13-3309, and 13-3311, Annotated Code of Maryland

.01 Definition.

In this chapter, "Inspector" means any member of the Commission or any State employee or contractor designated by the Commission to carry out an inspection under this chapter.

.02 Consent to Inspection.

Submission of an application to be a licensed grower, licensed processor, or licensed dispensary, independent testing laboratory irrevocably gives the Commission consent to conduct all inspections necessary to ensure compliance with State law and regulations.

.03 Inspection of Applicants.

- A. The Commission may inspect all premises of an applicant to be:
 - (1) A licensed grower;
 - (2) A licensed processor;
 - (3) A licensed dispensary; or
 - (4) A independent testing laboratory.
- B. The Commission shall inspect all aspects of an applicant's operation to make a determination that the operation conforms to the terms of the application.
- C. In the case of an inspection before the issuance of a license, the Commission shall arrange the inspection to take place at a mutually agreeable time.

.04 Announced and Unannounced Inspections.

- A. The Commission may conduct announced and unannounced inspections of the facilities of licensed growers, licensed processors, licensed dispensaries, and independent testing laboratories subject to the Commission's regulation, mission, and function, to determine compliance with statute and regulations.
- B. Failure by a licensed grower, licensed processor, licensed dispensary or registered independent testing laboratory to provide the Commission with immediate access to any part of a premises, requested material, information, or agent as part of an inspection may result in the imposition of a civil fine, suspension of license, or revocation of license.
 - C. During an inspection, the Commission may:
 - (1) Review and make copies of all records;
- (2) Enter any place, including a vehicle, in which medical cannabis is held, dispensed, sold, produced, tested, delivered, transported, manufactured or otherwise disposed of;
- (3) Inspect all equipment, raw and processed material, containers and labeling, and all things therein including:
 - (a) Records;
 - (b) Files:
 - (c) Financial data;
 - (d) Sales data;
 - (e) Shipping data;
 - (f) Pricing data;
 - (g) Employee data;
 - (h) Research;
 - (i) Papers;
 - (j) Processes;
 - (k) Controls; and
 - (l) Facilities;
 - (4) Inventory any medical cannabis;
- (5) Inspect any equipment, instruments, tools or machinery used to process:
 - (a) Medical cannabis;
 - (b) Medical cannabis concentrate; or
 - (c) Medical cannabis-infused product; and
- (6) Question personnel present at the location and any agent of the licensee.

.05 Sample Collection and Testing as Part of Inspection.

- A. During an inspection, the Commission may obtain samples for testing of any:
 - (1) Cannabis;
 - (2) Medical cannabis concentrate;
 - (3) Medical cannabis-infused product;
 - (4) Media used to grow cannabis;

- (5) Chemicals or solvents used to process medical cannabis concentrate;
 - (6) Labels or containers for cannabis;
 - (7) Paraphernalia;
 - (8) Any waste material; and
 - (9) Raw or processed material.
- B. If the inspector has grounds to question the quality of any medical cannabis, the inspector may contract with an independent testing laboratory to analyze the samples for any deviation from specification questioned by the inspector.
- C. Analysis of cannabis shall conform to the most current version of the cannabis Inflorescence monograph published by the American Herbal Pharmacopeia (AHP) or a scientifically valid methodology that is equal or superior to that of the AHP monograph.
- D. Analysis of other materials shall conform to a scientifically valid methodology for the analysis of such material.
- E. A written report of the testing under this regulation shall be provided to the inspector.

.06 Action Upon Findings in Inspection.

In the event that an inspector has reasonable suspicion of an operational failure or of conditions that create a likelihood of diversion, contamination, or a risk to the public health:

- A. An inspector may:
- Suspend the distribution of some or all medical cannabis from the licensed or registered premises;
- (2) Order immediate evacuation of the premises and seal the entry door; or
 - (3) Quarantine some or all medical cannabis;
- B. The Commission shall undertake a review of the inspection findings and may:
 - (1) Request a recall of the medical cannabis;
 - (2) Request independent testing of affected medical cannabis;
 - (3) Approve a procedure to reprocess the medical cannabis;
 - (4) Notify the Maryland State Police if diversion is suspected;
- (5) Order the destruction of contaminated or substandard medical cannabis; and
- C. The inspector or Commission may notify the local fire department or police department, or appropriate regulatory agency, regarding a risk to public health and safety.

.07 Receipt and Chain of Custody for Materials Removed.

The Commission shall leave a receipt and create a documented chain of custody for anything removed in the course of an inspection.

.08 Report of Inspection.

- A. An inspector shall:
 - (1) Prepare a report of:
 - (a) The observations and findings of the inspection; and
 - (b) Any suggestions or demands for corrective action;
- (2) Deliver a copy of the report to the inspected entity and obtain a receipt for the delivery; and
- (3) If possible, discuss the inspection and inspection report with the licensee.
- B. If an inspection report contains a suggestion or demand for corrective action, within 10 business days from the delivery of the report, the inspected entity shall:
- (1) Respond in writing to every suggestion or demand for corrective action; and
- (2) Set forth the plan for corrective action to be taken and the timetable for correction.
- C. If an inspector finds evidence of operational failures or conditions that create a likelihood of diversion, contamination, or the risk to public health, an inspector may direct that the licensed premises may not distribute or participate in the distribution of any

medical cannabis until the violation has been corrected and the premises pass re-inspection.

10.62.34 Discipline and Enforcement

Authority: Health General Article, § 13-3301, 13-3302, 13-3304, 13-3306, 13-3307, 13-3309, 13-3311 Annotated Code of Maryland

.01 Operational Failure Risking Diversion or Endangering Health.

In the event the Commission finds there is a reasonable likelihood of diversion, contamination of medical cannabis, or any risk to the health of a patient or any other individual, after written notice and a hearing in accordance with the State Government Article, §§10-201—10-226, Annotated Code of Maryland, the Commission may:

- A. Impose a fine of up to \$10,000 per violation on a licensed grower, licensed processor, licensed dispensary or registered independent testing laboratory;
 - B. Deny the license or registration;
- C. Suspend the license, licensee, agent, employee, registration or registrant; or
- D. Revoke the licenses, licensee, agent, employee, registration or registrant.

.02 Pattern of Deviation from Standard Operating Procedure.

In the event the Commission finds there is a pattern of deviations from standard operating procedures or the terms set forth in the application or the license but the pattern does not directly create a risk of endangering the health or safety of a patient, after written notice and a hearing in accordance with the State Government Article, §§10-201—10-226, Annotated Code of Maryland, the Commission may:

- A. Impose a fine of up to \$5,000 per violation on a licensed grower, licensed processor, licensed dispensary, or independent testing laboratory;
 - B. Deny the license or registration;
- C. Suspend the license, registration, licensee, registrant, or agent;
- D. Revoke the license or registration.

.03 Violation of Requirements.

In the event the Commission finds that a licensee, registrant, agent or employee violated a requirement of this subtitle, after written notice and a hearing in accordance with the State Government Article, §§10-201—10-226, Annotated Code of Maryland, the Commission may:

- A. Impose a fine of up to \$5,000 per violation on a licensed grower, licensed processor, licensed dispensary or independent testing laboratory;
- B. Suspend the license, registration, licensee, registrant, employee or agent; or
 - C. Revoke the license or registration.

.04 Action Against a Physician.

- A. After written notice and a hearing in accordance with the State Government Article, §§10-201—10-226, Annotated Code of Maryland, the Commission may deny a certifying physician's application for registration, or revoke registration to certify if the physician:
 - (1) Fraudulently applied for approval;
 - (2) Fraudulently issued a written certification; or
 - (3) Failed to comply with this chapter.
- B. The Commission shall report to the Maryland Board of Physicians any instance of fraud or conduct that threatens public health by a certifying physician.

10.62.35 Fee Schedule

Authority: Health General Article, §§13-3301, 13-3302, 13-3303, 13-3304, 13-3306, 13-3307, 13-3309, and 13-3311, Annotated Code of Maryland

.01 Fees.

- A. The following fees are established by the Commission:
 - (1) Grower fees:
 - (a) License as Grower-only:
 - (i) Application fee \$6,000 (Stage 1: \$2,000; Stage 2:

\$4,000);

- (ii) Annual license fee \$125,000;
- (b) License as Grower and Dispensary:
- (i) Application fee \$11,000 (Stage 1: \$3,000; Stage 2: \$8,000):
 - (ii) Annual licensing fee \$165,000;
 - (2) Grower agent fees:
 - (a) Registration fee \$200;
 - (b) Replacement identification card fee \$100;
 - (3) Licensed Processor fees:
- (a) Application fee \$6,000 (Stage 1: \$2,000; Stage 2: \$4,000);
 - (b) Annual license fee \$40,000;
 - (4) Processor Agent fees:
 - (a) Registration fee \$200;
 - (b) Replacement identification card fee \$100;
 - (5) Licensed Dispensary fees;
- (a) Application fee \$5,000 (Stage 1: \$1,000; Stage 2: \$4,000);
 - (b) Annual license fee \$40,000;
 - (6) Dispensary agent fees:
 - (a) Registration fee \$200;
 - (b) Replacement identification card fee \$100,
 - (7) Qualifying patient and caregiver fees:
 - (a) Identification card base fee \$50;
 - (b) Replacement identification card fee \$100;
 - (8) Independent Testing Laboratory fees:
 - (a) Registration fee \$100;
 - (b) Renewal fee \$100;
 - (9) Independent Testing Laboratory Employee fees:
 - (a) Registration fee \$200;
 - (b) Replacement identification card fee \$100;
 - (10) Miscellaneous fees:
- (a) Transfer of ownership of grower license, processor or dispensary license \$7,000;
- (b) Change in the location of grower, processor or dispensary premises \$7,000; and
 - (c) License reinstatement fee \$2,000.

VAN T. MITCHELL Secretary of Health and Mental Hygiene

Title 17 DEPARTMENT OF BUDGET AND MANAGEMENT

Subtitle 04 PERSONNEL SERVICES AND BENEFITS

17.04.02 Position Classifications and Compensation

Authority: State Personnel and Pensions Article, Titles 4, 6, and 8, Annotated Code of Maryland

Notice of Proposed Action

[15-153-P]

The Secretary of Budget and Management proposes to amend Regulation .09 under COMAR 17.04.02 Position Classifications and Compensation.

Statement of Purpose

The purpose of this action is to fulfill the statutory mandate of State Personnel and Pensions Article, §8-106(b), Annotated Code of Maryland, which provides that the Secretary shall adopt regulations requiring automatic increases, from minimum to maximum steps in a pay grade, of the pay rates set by the Standard Pay Plan for an employee under certain circumstances.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

The proposed action has no economic impact.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Jennifer P. Hine, Personnel Director, Department of Budget and Management, 301 W. Preston Street, Room 602, Baltimore, MD 21201, or call 410 767-4718, or email to jennifer.hine@maryland.gov, or fax to 410 333-5262. Comments will be accepted through July 27, 2015. A public hearing has not been scheduled.

.09 Standard Salary Plan Actions.

- A.—C. (text unchanged)
- D. Increments or merit increases are:
- (1) Granted January 1 to an employee who was appointed on or between January 1 and June 30, or July 1 to an employee who was appointed on or between July 1 and December 31, unless delayed by an act of the legislature or an executive order;
- (2) Provided to an employee whose overall performance is rated satisfactory or above on the employee's annual performance appraisal; and
 - (3) Subject to the availability of funding in the State budget.

DAVID R. BRINKLEY

Secretary of Budget and Management

Title 23 BOARD OF PUBLIC WORKS

Subtitle 03 PUBLIC SCHOOL CONSTRUCTION

Notice of Proposed Action

[15-152-P-I]

The Board of Public Works proposes to:

- (1) Amend Regulations .05 and .06 under COMAR 23.03.02 Administration of the Public School Construction Program:
- (2) Amend Regulation .02 under COMAR 23.03.05 Alternative Financing; and
- (3) Adopt new Regulations .01—.03 under a new chapter, COMAR 23.03.06 Relocatable Classroom Indoor Environmental Quality Standards.

This action was considered at a Board of Public Works meeting held on April 1, 2015.

Statement of Purpose

The purpose of this action is to: (a) update the State-local cost share percentages applicable to State-funded public school construction projects; (b) correct certain technical errors in current regulations; and (c) implement in accordance with statute new regulations regarding the indoor air quality of relocatable classroom buildings.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

I. Summary of Economic Impact. COMAR 23.03.06 may increase the cost of construction of relocatable classrooms; however, it would require a detailed study by a cost estimator to separate the cost increase due to these regulations from other factors that affect construction cost.

	Revenue (R+/R-)	W. Jane
II. Types of Economic Impact.	Expenditure (E+/E-)	Magnitude
A. On issuing agency: B. On other State	NONE	
agencies:	NONE	
C. On local governments:	(E+)	Moderate
	Benefit (+) Cost (-)	Magnitude
D. On regulated industries or trade groups:	NONE	Unknown
E. On other industries or trade groups:	NONE	Unknown
F. Direct and indirect effects on public:	(+)	Improvement
III. Assumptions. (Identic	fied by Impact Lette	er and Number fror

- **III. Assumptions.** (Identified by Impact Letter and Number from Section II.)
- C. There may be a modest increase of cost to relocatable classrooms in order to meet the indoor air requirements of the regulations. The cost impact cannot be known at this time, since it will depend on several factors:
 - How many new relocatable classrooms each local board of

- education will require.
- To what extent the manufacturers of relocatable classrooms already meet the requirements of the regulation, including restrictions on volatile organic compounds (VOCs).
- Other market and regulatory factors that may increase costs that would need to be differentiated from the impacts of the new regulations.
- D. As in C above, the cost impacts on the relocatable classroom manufacturers cannot be known at this time. These cost impacts, however, will be passed on to the local boards of education that purchase the relocatable classroom units.
- E. As in C above, the cost impacts on other industries, e.g. vendors of electrical, mechanical, sitework, concrete, etc. services, cannot be known at this time.
- F. The regulation will improve the indoor air quality of relocatable classrooms. Maryland currently has almost 3,000 relocatable classrooms, with indications that the number will grow in future years. Currently, the relocatable fleet has the capacity to house about 67,600 students, or approximately 8% of the total student population of the state. If the number of relocatables continues to grow, many students will benefit from the improved indoor air quality that will result from the regulations. Studies have generally found that the quality of indoor air has an effect on the alertness and productivity of building occupants, and on avoidance of respiratory problems that can lead to loss of productivity and time spent on task. It is difficult to quantify the economic impact of these improvements, particularly in the case of students whose economic contributions will come later in life.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has an impact on individuals with disabilities as follows:

Because Chapter 23.03.06 Relocatable Classroom Indoor Environmental Quality Standards will lead to an improvement in the indoor air quality of relocatable classrooms, it will have a positive effect on students and adults who suffer from respiratory ailments and sensitivities. It is estimated that at this time, the relocatable classrooms in Maryland have the capacity to house up to 67,000 students, or approximately 8% of the total public student population of the state.

Opportunity for Public Comment

Comments may be sent to David Lever, Executive Director, Public Schools Construction Program, 200 West Baltimore Street, Baltimore, MD 21201, or call 410-767-0610 TTY: 410-333-6442, or email to dlever@msde@state.md.us, or fax to 410-333-6522. Comments will be accepted through July 27, 2015. A public hearing has not been scheduled.

Editor's Note on Incorporation by Reference

Pursuant to State Government Article, §7-207, Annotated Code of Maryland, the Maryland Green Building Council International Green Construction Code (IgCC) Supplement has been declared a document generally available to the public and appropriate for incorporation by reference. For this reason, it will not be printed in the Maryland Register or the Code of Maryland Regulations (COMAR). Copies of this document are filed in special public depositories located throughout the State. A list of these depositories was published in 42:1 Md. R. 9 (January 9, 2015), and is available online at www.dsd.state.md.us. The document may also be inspected at the office of the Division of State Documents, 16 Francis Street, Annapolis, Maryland 21401.

23.03.02 Administration of the Public School Construction Program

Authority: Education Article, §§4-126, 5-112, and 5-301; State Finance and Procurement Article, §5-7B-07; Annotated Code of Maryland

.05 State Cost Share Percentage.

- A. (text unchanged)
- B. Percentages
 - (1) (text unchanged)
- (2) The maximum State share of public school construction funding for eligible costs of approved projects beginning Fiscal Year 2019 is 98 percent.
- [(2)] (3) For Fiscal Year [2013] 2016 through Fiscal Year [2015] 2018, the State share percentages of public school construction funding for eligible costs of approved projects are as follows:

(existing table proposed for repeal)

County	FY 2016	FY 2017	FY 2018
Allegany	88%	83%	83%
Anne Arundel	50%	50%	50%
Baltimore City	93%	93%	93%
Baltimore	52%	52%	52%
Calvert	53%	53%	53%
Caroline	80%	80%	80%
Carroll	59%	59%	59%
Cecil	64%	63%	63%
Charles	61%	61%	61%
Dorchester	76%	76%	76%
Frederick	64%	64%	64%
Garrett	50%	50%	50%
Harford	63%	63%	63%
Howard	55%	55%	55%
Kent	50%	50%	50%
Montgomery	50%	50%	50%
Prince George's	63%	63%	63%
Queen Anne's	50%	50%	50%
St. Mary's	59%	58%	58%
Somerset	100%	100%	100%
Talbot	50%	50%	50%
Washington	71%	71%	71%
Wicomico	97%	97%	97%
Worcester	50%	50%	50%

- [(3)] (4) (text unchanged)
- (5) The Sate share percentage for the Maryland School for the Blind shall be 93 percent of eligible costs of approved projects.
 - C. (text unchanged)

.06 Maximum State Construction Allocation.

- A.—G. (text unchanged)
- H. Renovation.
- (1) The maximum State construction allocation for projects proposed to renovate buildings or portions of buildings, 16 years old or older, is calculated according to either:
 - (a) The following formula:
 - (i) (text unchanged)
- (ii) Multiply the eligible square footage for each age group by the average Statewide per square-foot building cost, and then multiply each product by the percentage in [\$G(1)(a)(iii)] \$H(1)(a)(iii) of this regulation;
 - (iii) (text unchanged)
- (iv) Add the products calculated in [§G(1)(a)(ii)] $\S H(1)(a)(ii)$ of this regulation;

- (v) Next, add site development costs, figured as a percentage of total building costs set forth in $[\S G(1)(a)(iv)]$ $\S H(1)(a)(iv)$ of this regulation;
- (vi) Then, add the contingency amount, figured as a percentage of the sum of [\$G(1)(a)(iv) and (v)] \$H(1)(a)(iv) and (v) of this regulation; and
 - (vii) (text unchanged)
- (b) The estimated or actual cost of construction multiplied by the State cost share percentage, not to exceed the amount calculated in $[\S G(1)(a)] \S H(1)(a)$ of this regulation.
 - (2)—(3) (text unchanged)
 - I.—O. (text unchanged)

23.03.05 Alternative Financing

Authority: Education Article, §§4-126, 5-112, and 5-301, Annotated Code of Maryland

.02 Alternative Project [Delivery] Proposal Review Assistance. (text unchanged)

23.03.06 Relocatable Classroom Indoor Environmental Quality Standards

Authority: Education Article, and §5-301(b-1), Annotated Code of Maryland

.01 Definitions.

- A. In this regulation, the following terms have the meanings indicated.
 - B. Terms Defined.
- (1) "Locally-constructed relocatable classroom" means a relocatable classroom that is constructed at the school site.
- (2) "Model Performance Code" means the construction standards stated in COMAR 05.02.01.03:
- (3) "Pre-manufactured unit" means a relocatable classroom that is constructed off-site and transported to the school site.
- (4) "Relocatable classroom" means a classroom unit that is capable of being disconnected and transported from one school site and reinstalled at another school site.

.02 Relocatable Classrooms Indoor Environmental Quality Standards.

- A. All relocatable classrooms used for student instruction at public schools must conform to Indoor Environmental Quality Standards that meet the Maryland Green Building Council International Green Construction Code (IgCC) Supplement, Chapter 8, Section 801 through 806, which is incorporated by reference; and
 - B. One of the following:
 - (1) The Model Performance Code for pre-manufactured units; or
- (2) Local building codes for locally-constructed relocatable classrooms.

.03 Exceptions.

This chapter does not apply to relocatable classrooms constructed before July 1, 2015.

SHEILA McDONALD Executive Secretary

Title 26 DEPARTMENT OF THE ENVIRONMENT

Subtitle 11 AIR QUALITY

26.11.19 Volatile Organic Compounds from Specific Processes

Authority: Environment Article, §§1-101, 1-404, 2-101—2-103, 2-301—2-303, 10-102, and 10-103, Annotated Code of Maryland

Notice of Proposed Action

[15-148-P]

The Secretary of the Environment proposes to amend Regulation .26 and adopt new Regulation .26-1 under COMAR 26.11.19 Volatile Organic Compounds from Specific Processes.

Statement of Purpose

The purpose of this action is to adopt the requirements of the EPA's Control Techniques Guidelines (CTG) for Fiberglass Boat Manufacturing. The new regulation COMAR 26.11.19.26-1, Control of Volatile Organic Compounds from Fiberglass Boat Manufacturing, adopts the requirements of the EPA's CTG for this category. EPA develops CTGs as guidance on control requirements for various source categories. States can follow the CTGs or adopt more restrictive standards. MDE proposes to adopt new volatile organic compound (VOC) limits, standards for application methods, and work practice requirements which are consistent with the most recent CTG recommendations applicable to fiberglass boat manufacturing. The new regulation affects manufacturers of fiberglass boats. COMAR 26.11.19.26 Control of Volatile Organic Compounds from Reinforced Plastic Manufacturing is amended to exempt fiberglass boat manufacturing. This amendment and new regulation will be submitted to the U.S. Environmental Protection Agency (EPA) as a revision to Maryland's State Implementation Plan (SIP).

Background

The EPA first published an assessment of VOC emissions from fiberglass boat manufacturing in 1990. This assessment evaluated VOC emissions from fiberglass boat manufacturing and potential control options. The National Emission Standards for Hazardous Air Pollutants for Boat Manufacturing, 40 CFR part 63, subpart VVVV (2001 NESHAP) were promulgated in 2001. Emission standards under the 2001 NESHAP were for organic hazardous air pollutants (HAPs) based on low-HAP resins and gel coats and low-emitting resin application technology. In July 2008, the EPA published a new CTG for Fiberglass Boat Manufacturing Materials. The CTG was developed based on the 1990 VOC assessment, the 2001 NESHAP, existing state VOC emission reduction approaches such as California, and in consideration of information obtained since the issuance of the 2001 NESHAP.

Requirements

Resins containing styrene and gel coats containing both styrene and methyl methacrylate (MMA) are the main contributors of VOC emissions at fiberglass boat manufacturing facilities. The proposed standards are designed to reduce VOC emissions during fiberglass boat manufacturing operations. Not all the VOCs in the materials used are emitted to the atmosphere, as some of the VOCs are used in cross linking reactions of polymers and are retained in the finished material. Thus, an overall reduction of VOC content in production

materials reduces potential emissions from extraneous VOCs during the manufacturing process.

Cleaning activities other than surface preparation also occur at facilities engaged in fiberglass boat manufacturing. Cleaning materials are used to remove residue or other unwanted materials from equipment related to manufacturing operations such as molds and prototypes, as well as the cleaning of application equipment, transfer lines and other ancillary equipment. These cleaning materials are typically mixtures of VOC containing solvents. The proposed regulation includes emission control requirements for cleaning materials consistent with those in the CTG.

Expected Emissions Reductions

The proposed regulation sets standards for fiberglass boat manufacturing operations. Emissions of VOCs from fiberglass boat manufacturing operations are expected to be reduced by approximately forty percent nationally. Maryland only has one known source that may, on occasion, assemble fiberglass boats from premanufactured hulls and decks. Therefore Maryland VOC emission benefits will be negligible. The coatings industry already has products available to meet VOC standards contained in the CTG and proposed regulation. The maximum benefit from VOC reductions will be provided during the ozone season when VOCs readily combine with NOx to form the pollutant ground level ozone.

Comparison to Federal Standards

There is a corresponding federal standard to this proposed action, but the proposed action is not more restrictive or stringent.

Estimate of Economic Impact

I. Summary of Economic Impact. The proposed new regulation adopts the requirements of the CTG for fiberglass boat manufacturing. EPA estimated the economic impact of this regulation on a national level at a cost effectiveness approximately \$ 4,200/ton of VOC controlled. The standards and requirements of the CTG have already been implemented in other states and as a result cost of production of compliant materials has come down from initial phase of implementation. As the CTGs are implemented nationally, the costs of compliant materials are expected to be reduced further. Due to the limited number of affected sources, the economic impact in MD will be minimal.

II. Types of Economic Impact.	Revenue (R+/R-) Expenditure (E+/E-)	Magnitude
A. On issuing agency:	NONE	
B. On other State agencies:	NONE	
C. On local governments:	NONE	
	Benefit (+) Cost (-)	Magnitude
D. On regulated industries or trade groups:	(-)	Minimal
E. On other industries or trade groups:	NONE	
F. Direct and indirect effects on public:	NONE	
III. Assumptions. (Identified by I	mpact Letter and I	Number from

III. Assumptions. (Identified by Impact Letter and Number from Section II.)

D. Minimal impact on affected sources.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

The Department of the Environment will hold a public hearing on the proposed action on July 28, 2015 at 10:00 a.m. at the Department of the Environment, 1800 Washington Boulevard, 1st Floor Conference Rooms, Baltimore, Maryland 21230-1720. Interested persons are invited to attend and express their views. Comments may be sent to Mr. Randy Mosier, Chief of the Regulation Division, Air and Radiation Management Administration, Department of the Environment, 1800 Washington Boulevard, Suite 730, Baltimore, Maryland 21230-1720, or emailed to randy.mosier@maryland.gov. Comments must be received not later than July 28, 2015, or be submitted at the hearing. For more information, call Randy Mosier at (410) 537-4488.

Copies of the proposed action and supporting documents are available for review at the following locations:

- The Department of the Environment's website at: http://www.mde.state.md.us/programs/regulations/air/Pages/req comments.aspx
 - The Air and Radiation Management Administration Office in Baltimore; and
 - The regional offices of the Department in Cumberland and Salisbury.

Anyone needing special accommodations at the public hearing should contact the Department's Fair Practices Office at (410) 537-3964. TTY users may contact the Department through the Maryland Relay Service at 1-800-735-2258.

.26 Control of Volatile Organic Compound Emissions from Reinforced Plastic Manufacturing.

A. Applicability.

- (1)—(2) (text unchanged)
- (3) The requirements in this regulation do not apply to any fiberglass boat manufacturing facility as defined in Regulation .26-1B(5) of this chapter.
 - B.—D. (text unchanged)

.26-1 Control of Volatile Organic Compound Emissions from Fiberglass Boat Manufacturing.

A. Applicability.

- (1) This regulation applies to any fiberglass boat manufacturing facility where the total actual VOC emissions, before add-on controls, from all fiberglass boat manufacturing is 15 pounds or more per day as determined on a monthly average.
- (2) VOC emissions from polyester resins, tooling resins and gel coats, ancillary parts production, touch-up, clean-up, and repair are to be included in determining VOC emissions pursuant to $\S(A)(1)$ of this regulation.
- B. Definitions. In this regulation, the following terms have the meanings indicated:
 - ${\it (1)}\ Atomized\ Resin\ Application.$
- (a) "Atomized resin application" means a resin application technology in which the resin leaves the application equipment and breaks into droplets or an aerosol as it travels from the application equipment to the surface of the part.
- (b) "Atomized resin application" includes, but is not limited to, resin spray guns and resin chopper spray guns.
 - (2) Clear Gel Coat.
- (a) "Clear gel coat" means a gel coat that is clear or translucent such that underlying colors are visible.

- (b) "Clear gel coat" does not include tooling gel coats used to build or repair molds.
 - (3) Closed Molding.
- (a) "Closed molding" means any molding process that has the following characteristics:
- (i) Pressure is used to distribute the resin through the reinforcing fabric placed between two mold surfaces to either saturate the fabric or fill the mold cavity; and
- (ii) Clamping pressure, fluid pressure, atmospheric pressure, or vacuum pressure are applied either alone or in combination.
- (b) "Closed molding" includes, but is not limited to, compression molding with sheet molding compound, infusion molding, resin injection molding (RIM), vacuum assisted resin transfer molding (VARTM), resin transfer molding (RTM), and vacuum assisted compression molding.
 - (c) "Closed molding" does not include:
- (i) Processes in which a closed mold is used only to compact saturated fabric or remove air or excess resin from the fabric (such as in vacuum bagging); or
- (ii) Open molding steps such as application of a gel coat or skin coat layer by conventional open molding prior to a closed molding process.
- (4) "Fiberglass boat" means any type of vessel, other than a seaplane, that can be used for transportation on the water, in which either the hull or deck is built from a composite material consisting of a polyester resin or other thermosetting resin matrix reinforced with fiberglass (glass fibers), inert filler or other reinforcing materials such as fibers of carbon or aramid.
 - (5) Fiberglass Boat Manufacturing Facility.
- (a) "Fiberglass boat manufacturing facility" means a facility that manufactures hulls or decks of fiberglass boats, assembles fiberglass boats from premanufactured hulls and decks, or builds molds to make hulls or decks of fiberglass boats.
- (b) "Fiberglass boat manufacturing facility" does not include a facility which:
- (i) Manufactures ancillary parts for fiberglass boats (such as hatches, seats, or lockers) or boat trailers; and
- (ii) Does not manufacture hulls or decks of fiberglass boats, assemble fiberglass boats from premanufactured hulls and decks, or build molds for fiberglass boat hulls or decks.
- (6) "Filled resin" means a resin to which an inert material has been added to change viscosity, density, shrinkage, or other physical properties.
- (7) "Gel coat" means a thermosetting resin surface coating containing styrene (Chemical Abstract Service (CAS No. 100–42–5) or methyl methacrylate (CAS No. 80–62–6) that:
- (a) Provides a cosmetic enhancement or improves resistance to degradation from exposure to the elements;
 - (b) Does not contain any reinforcing fibers; and
- (c) Is applied directly to mold surfaces or to a finished laminate.
- (8) "Mold" means the cavity or surface into or on which gel coat, resin, and fibers are placed and from which finished fiberglass parts take their form.
- (9) "Monomer" means a low molecular weight organic compound that reacts with itself or other similar compounds to produce a polymer such as a polyester or vinylester resin.
 - (10) Nonatomized Resin Application.
- (a) "Nonatomized resin application" means any application technology in which the resin is not broken into droplets or an aerosol as it travels from the application equipment to the surface of the part.
- (b) "Nonatomized resin application" includes, but is not limited to, flowcoaters, chopper flowcoaters, pressure fed resin

rollers, resin impregnators, and hand application by paint brush or paint roller.

- (11) "Non-monomer" means any low molecular weight organic compound that does not react with itself or other similar compounds to produce a polymer and is assumed to be emitted fully as a VOC into the atmosphere.
 - (12) "Non-VOC cleanup material" means a material that:
- (a) Is used to clean products, tools, process equipment, and other equipment used in the manufacture of fiberglass boats; and
- (b) Either contains less than 5 percent VOC by weight or has a VOC composite vapor pressure of no more than 0.5 millimeters of mercury at 68 degrees Fahrenheit.
 - (13) Open Molding and Gel Coat Operations.
- (a) "Open molding and gel coat operation" means any process in which the reinforcing fibers and resin are placed in the mold and are open to the surrounding air while the reinforcing fibers are saturated with resin.
- (b) "Open molding and gel coat operation" includes operations in which a vacuum bag or similar cover is used to compress an uncured laminate to remove air bubbles or excess resin, or to achieve a bond between a core material and a laminate.
 - (14) Pigmented Gel Coat.
 - (a) "Pigmented gel coat" means an opaque gel coat.
- (b) "Pigmented gel coat" does not include tooling gel coats used to build or repair molds.
 - (15) Production Resin.
- (a) "Production resin" means any resin used to manufacture parts for sale.
- (b) "Production resin" does not include tooling resins used to build or repair molds, or assembly adhesives.
- (16) "Pure, 100-percent, vinylester resin used for skin coats" means resins containing only vinylester resin and does not include any resin containing blends of vinylester and polyester resins.
- (17) "Resin and gel coat mixing operation" means any operation in which a resin or gel coat is combined with additives that include, but are not limited to, fillers, promoters, or catalysts, and includes operations making putties or polyputties used to assemble parts of fiberglass boats and to fill gaps between parts.
- (18) "Skin coat" means a layer of resin and fibers applied over a gel coat to protect the gel coat from being deformed by an additional laminate layer or layers.
- (19) "Tooling" means the production of molding tools such as shapes, matrixes, molds, or other instruments and utensils that are used during manufacturing of fiberglass boats.
- (20) "Tooling resin" means, for the purposes of \$C(1) of this regulation, the resin used to build or repair molds (also known as tools) or prototypes (also known as plugs) from which molds will be made.
- (21) "Tooling gel coat" means, for the purposes of SC(1) of this regulation, the gel coat used to build or repair molds (also known as tools) or prototypes (also known as plugs) from which molds will be made.
- (22) "Total VOC Content (percent by weight)" means the sum of the monomer content (percent by weight) determined according to \$D(1) of this regulation and of the weight percent of the non-monomer VOC determined by \$D(3) of this regulation.
 - (23) Vacuum Bagging.
- (a) "Vacuum bagging" means any molding technique in which the reinforcing fabric is saturated with resin and then covered with a flexible sheet that is sealed to the edge of the mold and where a vacuum is applied under the sheet to compress the laminate, remove excess resin, or remove trapped air from the laminate during curing.

- (b) "Vacuum bagging" does not include closed molding.
- (24) "Vinylester resin" means a thermosetting resin containing esters of acrylic or methacrylic acids and having double-bond and ester linkage sites only at the ends of the resin molecules.

C. Requirements.

- (1) A person who owns or operates a fiberglass boat manufacturing facility subject to this regulation shall:
- (a) Not cause or permit the discharge into the atmosphere of any VOC from resin and gel coat operations in excess of the following standards, except as provided in C(3) of this regulation:

Ţ	Operation	Application	Total	Total VOC
		Method	Monomer	Content
1			Content	(percent by
			(percent by	weight)
			weight)	
Ī	Production	Atomized resin	28	33
	resin	application		
		(spray)		
Ī	Production	Nonatomized	35	40
	resin	resin		
		application		
ſ	Pigmented gel	Atomized or	33	38
	coat	nonatomized		
	200	resin		
		application		
ş	Clear gel coat	Atomized or	48	53
ã		nonatomized		
2	F 1200022	resin		
5		application		
	Tooling resin	Atomized resin	30	35
u		application		
J	BEAR SHEET SA	(spray)		
	Tooling resin	Nonatomized	39	44
	III VALLED	resin		
3	The state of the s	application		
	Tooling gel	Atomized or	40	45
	coat	nonatomized		
	- 3//	resin		
1	136	application		
L		Tr	l	l

- (b) Notwithstanding \$C(3)(a) and (b) of this regulation, use nonatomizing resin application equipment when applying production resins (including skin coat resins) pursuant to \$C(3)(a) of this regulation, and pure,100-percent vinylester resins pursuant to \$C(3)(b) of this regulation.
- (c) Not cause or permit the discharge into the atmosphere of any VOC from any resin and gel coat mixing operation unless all mixing containers with a capacity equal to or greater than 208 liters (55 gallons), including those used for on-site mixing of putties and polyputties, have a cover with no visible gaps in place at all times except when material is being manually added to or removed from the container, or when mixing or pumping equipment is being placed in or removed from the container.
 - (d) Only use non-VOC cleanup materials.
 - (2) Alternative Compliance Option.
- In lieu of meeting the standards of SC(1)(a) of this regulation, a person who owns or operates a fiberglass boat manufacturing facility subject to this regulation may cause or permit the discharge into the atmosphere of any VOC from filled resins provided that such emissions do not exceed the following non-monomer VOC content and as-applied monomer VOC emission rates

calculated using the equation in $\S D(3)$ of this regulation:

Type of Filled Resin	Monomer Rate in kg Monomer VOC per Megagram of Filled Resin as Applied	Non-monomer VOC Content Limit of Unfilled Resin
Production	46	5%
Tooling	54	5%

- (3) Exemptions. The standards in C(1)(a) of this regulation do not apply to:
- (a) Production resins (including skin coat resins) that meet specifications for use in military vessels or must be approved by the U.S. Coast Guard for use in the construction of lifeboats, rescue boats, and other life-saving appliances approved under 46 CFR Chapter I, Subchapter Q, or the construction of small passenger vessels as regulated by 46 CFR Chapter I, Subchapter T;
- (b) Pure, 100-percent vinylester resins used for skin coats where the total quantity of such resins used is less than or equal to 5 percent by weight of all resin used at a fiberglass boat manufacturing facility on a 12-month rolling average basis, as reported in §§E(5)—(7) of this regulation;
- (c) Production and tooling resins, and pigmented, clear, and tooling gel coats, which are used for touch up and repair of parts or molds and which are used in quantities less than or equal to 1 percent by weight of all resin used at a fiberglass boat manufacturing facility on a 12-month rolling average basis, as reported in \$E(1) of this regulation;
 - (d) Resins used in closed molding;
- (e) Polyester resins used for tooling or touch-up and repair during a manufacturing process that is not fiberglass boat manufacturing;
 - (f) Coatings applied to fiberglass boats; and
 - (g) Adhesives used in the assembly of fiberglass boats.
 - D. Test Methods and Compliance Procedures.
- (1) A person who owns or operates a fiberglass boat manufacturing facility subject to this regulation shall determine the monomer VOC content of any resin or gel coat applied at the facility using:
- (a) South Coast Air Quality Management District (SCAQMD) Method 312-91, Determination of Percent Monomer in Polyester Resins, revised April 1996; or
 - (b) Manufacturer's formulation data.
- (2) In the event of a conflict between the monomer VOC content of any resin or gel coat indicated by the manufacturer's formulation data and the results of a test using the method referenced in SD(1)(a) of this regulation, the test results shall be used for the purpose of determining compliance with this regulation.
- (3) A person meeting the alternative emission rates in \$C(2) of this regulation shall compute the as-applied monomer VOC emission rate for the filled production resin or tooling resin, in kilograms monomer VOC per megagram of filled material, using the following equation:

$$PV_F = PV_u \ times \ (100 - Filler \ pct)$$

100

Where

 PV_F is the as-applied monomer VOC emission rate for the filled production resin or tooling resin, kilograms monomer VOC per megagram of filled material.

 PV_u is the monomer VOC emission rate for the neat (unfilled) resin, before filler is added, as calculated using the formulas in the table in $\S D(4)$ of this regulation.

Filler pct is the weight-percent of filler in the as-applied filled resin system.

(4) The monomer VOC emission rate for the neat (unfilled) resin, before filler is added, PV_w shall be calculated using the formulas in the following table:

Monomer VOC Emis	sion Rate Formulas for C	Open Molding and Gel					
Coat Operations							
Material	Application Method	Formula to					
		Calculate					
		the Monomer VOC					
		Emission					
		$Rate^{I}$					
Production resin or	Atomized resin	0.014 x (Resin					
tooling resin	application	VOC%) ^{2.425}					
	Atomized resin	0.01185 x (Resin					
	application, plus	$VOC\%)^{2.425}$					
	vacuum bagging	,					
	with roll-out						
	Atomized resin	0.00945 x (Resin					
	application, plus	$VOC\%)^{2.425}$					
	vacuum bagging	,					
	without roll-out						
	Nonatomized resin	0.014 x (Resin					
	application	VOC%) ^{2.425}					
	Nonatomized resin	0.0110 x (Resin					
	application plus	$VOC\%)^{2.275}$					
10	vacuum bagging	·					
13/100	with roll-out						
CENT 1.1	Nonatomized resin	0.0076 x (Resin					
10/1	application plus	$VOC\%)^{2.275}$					
1011	vacuum bagging						
121	without roll-out						
Pigmented gel coat,	All methods	0.445 x (Gel coat					
clear gel coat,		VOC%) ^{1.675}					
tooling gel coat							
A SECURE AND ADDRESS OF THE PARTY OF THE PAR							

- Where the resin VOC% is the monomer VOC content as supplied, expressed as a weight-percent value between 0 and 100 percent.
- (5) A person meeting the alternative emission rates in \$C(2) shall demonstrate the as-applied non-monomer VOC content of resins and gel coats using the test method prescribed in COMAR 26.11.19.02D(1), and for this purpose, resins and gel coats shall be considered coatings.
- (6) For the purpose of demonstrating that a cleanup material is a non-VOC cleanup material, a person shall:
- (a) Perform a test using the method prescribed in COMAR 26.11.19.02D(1), where the cleanup material shall be considered a coating; and
- (b) Determine the composite vapor pressure of organic-compounds in a cleanup material using the calculation prescribed in COMAR 26.11.19.02E(3).
- E. Record Keeping. A person who owns or operates a fiberglass boat manufacturing facility subject to this regulation shall maintain for not less than 3 years, and shall make available to the Department upon request, records that provide the following information:
- (1) A description of each polyester or vinylester resin material used including:
 - (a) The manufacturer's name;
- (b) The type (e.g. production resin, production gel coat, tooling resin, tooling gel coat);
- (c) The amount of each of the polyester or vinylester resin materials used;
- (d) The weight (in percent) of monomer for each polyester resin materials and filler or fillers used;

- (e) The weight percent of VOC that is not monomer or the total weight percent of the VOC content; and
 - (f) The type of application method used with each resin;
- (2) On a quarterly basis, the total weight and the monomer content and VOC content of each polyester and vinylester resin material;
- (3) On a quarterly basis, the total weight and the monomer content and VOC content of each polyester and vinylester resin material used under the exemption of \$C(3)(a), including a description or identification (military specifications, 46 CFR Subchapter Q, or 46 CFR subchapter T) of the exemption;
- (4) On a monthly basis, the total weight, monomer content, and VOC content of each polyester and vinylester resin material used for closed molding under the exemption of $\S C(3)(d)$;
- (5) On a monthly basis, the total weight, monomer content, and VOC content of each pure,100-percent vinylester resin used under the exemption of SC(3)(b);
 - (6) On a monthly basis, the total weight of all resins used;
- (7) On a monthly basis, the total weight of pure, 100-percent vinylester resins used under the exemption of SC(3)(b) over the preceding 12 months divided by total weight of all resins used over the preceding 12 months;
- (8) On a daily basis, the total weight, monomer content, and VOC content of each resin used for touch up and repair of parts or molds under the exemption of SC(3)(c);
- (9) For filled resins for which compliance is demonstrated under alternative compliance option of SC(2) of this regulation:
- (a) The total weight and non-monomer VOC content of each polyester and vinylester resin material used; and
- (b) The monomer emission rate computed in accordance with \$D(3) of this regulation in kg monomer VOC per megagram of filled resin as applied.
 - (10) On a monthly basis, the total clean-up materials used.

BENJAMIN H. GRUMBLES Secretary of the Environment

Subtitle 12 RADIATION MANAGEMENT

26.12.01 Radiation Protection

Authority: Environment Article, §§8-106, 8-301, and 8-304, Annotated Code of Maryland

Notice of Proposed Action

[15-169-P-I]

The Secretary of the Environment proposes to amend Regulation .01 under COMAR 26.12.01 Radiation Protection.

Statement of Purpose

The purpose of this action is to update COMAR 26.12.01.01, Incorporation by Reference, to include (a) one U.S. Nuclear Regulatory Commission regulation establishing additional security requirements for use and transport of risk significant quantities of radioactive material, (b) prohibition of use of a radiation machine prior to facility registration, and (c) miscellaneous corrections.

Comparison to Federal Standards

There is a corresponding federal standard to this proposed action, but the proposed action is not more restrictive or stringent.

Estimate of Economic Impact

The proposed action has no economic impact.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Michael D. Kurman, Regulations Coordinator, Radiological Health Program, 1800 Washington Boulevard, Suite 750, Baltimore, Maryland 21230, or e-mail to michael.kurman@maryland.gov, or call 410-537-3208, or fax to 410-537-3198. Comments will be accepted through July 27, 2015. A public hearing has not been scheduled.

The proposed regulation may be viewed on the MDE Website at http://www.mde.state.md.us/programs/Air/RadiologicalHealth/Regul ationsforControlofIonizingRadiation/Pages/Programs/AirPrograms/R adiological_Health/Regulations/index.aspx, or at official depository libraries throughout the State. A listing of these depository libraries is available at http://www.dsd.state.md.us/Depositories.aspx or call 410-974-2486 or 800-633-9657.

Editor's Note on Incorporation by Reference

Pursuant to State Government Article, §7-207, Annotated Code of Maryland, Regulations for the Control of Ionizing Radiation (1994), as amended by Supplements 1—26, has been declared a document generally available to the public and appropriate for incorporation by reference. For this reason, it will not be printed in the Maryland Register or the Code of Maryland Regulations (COMAR). Copies of this document are filed in special public depositories located throughout the State. A list of these depositories was published in 42:1 Md. R. 9 (January 9, 2015), and is available online at www.dsd.state.md.us. The document may also be inspected at the office of the Division of State Documents, 16 Francis Street, Annapolis, Maryland 21401.

.01 Incorporation by Reference.

All provisions of the "Regulations for the Control of Ionizing Radiation (1994)" as amended by Supplement 1 through Supplement [25] 26 are incorporated by reference.

BENJAMIN H. GRUMBLES Secretary of the Environment

Title 30 MARYLAND INSTITUTE FOR EMERGENCY MEDICAL SERVICES SYSTEMS (MIEMSS)

Subtitle 01 GENERAL

30.01.02 Documents Incorporated by Reference

Authority: Education Article, §13-516, Annotated Code of Maryland

Notice of Proposed Action

[15-134-P-I]

The Maryland State Emergency Medical Services Board proposes to amend Regulation .01 under COMAR 30.01.02 Documents Incorporated by Reference. This action was considered and approved by the State Emergency Medical Services Board at its

regular meeting on April 14, 2015, notice of which was given by publication in 42:6 Md. R. 539 (March 20, 2015) under General Provisions Article, §3-302(c), Annotated Code of Maryland.

Statement of Purpose

The purpose of this action is to incorporate by reference the current Maryland Medical Protocols for Emergency Medical Services Providers.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

I. Summary of Economic Impact. The 2015 Maryland Medical Protocols for Emergency Medical Services Providers will require each of approximately 204 public safety basic life support ambulances to carry one unit of naloxone plus a syringe at a cost of approximately \$59 per ambulance plus training costs.

Revenue (R+/R-) Expenditure

II. Types of Economic Impact.

(E+/E-) Magnitude

A. On issuing agency: NONE
B. On other State agencies: NONE

C. On local governments: NONE

Benefit (+) Cost (-)

Magnitude

\$59.00 per BLS ambulance

D. On regulated industries or trade groups:

Naloxone plus syringe (-)

E. On other industries or

trade groups: NONE

F. Direct and indirect effects on public:

Will provide prompt

administration of naloxone (+) Uncertain

- $\boldsymbol{III.}$ Assumptions. (Identified by Impact Letter and Number from Section II.)
- D. Assumes BLS ambulance will carry one dose of naloxone plus syringe.
 - F. Will increase prompt treatment of certain episodes of overdose.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to E. Fremont Magee, Assistant Attorney General, Maryland Institute for Emergency Medical Services Systems, 653 West Pratt Street, Baltimore, Maryland 21201, or call 410-706-8531, or email to fmagee@miemss.org, or fax to 410-706-2138. Comments will be accepted through July 27, 2015. A public hearing has not been scheduled.

Editor's Note on Incorporation by Reference

Pursuant to State Government Article, §7-207, Annotated Code of Maryland, the Maryland Medical Protocols for Emergency Medical Services Providers (MIEMSS July 1, 2015 Edition) has been declared a document generally available to the public and appropriate for incorporation by reference. For this reason, it will not be printed in the Maryland Register or the Code of Maryland Regulations (COMAR). Copies of this document are filed in special public depositories located throughout the State. A list of these depositories was published in 41:1 Md. R. 9 (January 10, 2014), and is available online at www.dsd.state.md.us. The document may also be inspected at the office of the Division of State Documents, 16 Francis Street, Annapolis, Maryland 21401.

.01 Incorporation by Reference.

- A. (text unchanged)
- B. Documents Incorporated.
- (1) "Maryland Medical Protocols for Emergency Medical Services Providers (MIEMSS July 1, [2014] 2015 Edition)". This document can be obtained through the Maryland Institute for Emergency Medical Services Systems at 653 W. Pratt Street, Baltimore, Maryland 21201 (410-706-4449).
 - (2) (4) (text unchanged)

KEVIN G. SEAMAN, M.D., F.A.C.E.P.

Executive Director

Title 36 MARYLAND STATE LOTTERY AND GAMING CONTROL AGENCY

Subtitle 05 TABLE GAMES

36.05.06 Poker Rules

Authority: State Government Article, §§9-1A-02(b) and 9-1A-04(d), Annotated Code of Maryland

Notice of Proposed Action

[15-157-P]

The Maryland Lottery and Gaming Control Agency proposes to amend Regulation .08 under COMAR 36.05.06 Poker Rules. This action was considered at the Maryland Lottery and Gaming Control Commission open meeting held on September 25, 2014, notice of which was given pursuant to General Provisions Article, §3-302(c), Annotated Code of Maryland.

Statement of Purpose

The purpose of this action is to update the regulation of the Maryland Lottery and Gaming Control Agency to reflect the table game procedures for placing bets during Poker games.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

The proposed action has no economic impact.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to James B. Butler, Director of Legislative and Policy Affairs, Maryland Lottery and Gaming Control Agency, 1800 Washington Blvd., Suite 330, Baltimore, MD 21230, or call 410-230-8781, or email to jbutler@maryland.gov, or fax to 410-230-8727. Comments will be accepted through July 27, 2015. A public hearing has not been scheduled.

.08 Placing Bets; Minimum and Maximum Bets.

- A. (text unchanged)
- B. A player may participate in the betting during a round of play in accordance with the following requirements:
 - (1)—(5) (text unchanged)
- (6) If a player indicates an intent to temporarily leave a Poker table during a round of play without relinquishing his seat at the table, at the player's request a floorperson or above shall:
 - (a)—(b) (text unchanged)
 - C.—F. (text unchanged)
- G. Subject to the posted table betting limits, a player who announces "raise" [may continue to bet value chips, tournament chips or plaques until both of his hands come to rest in front of the pot] must state the amount the player is raising or put all of the chips in the pot at once.
 - H.—K. (text unchanged)



Special Documents

DEPARTMENT OF TRANSPORTATION

MARYLAND TRANSPORTATION AUTHORITY

Public Notice — New Lower Toll Rates Effective July 1, 2015

The Maryland Transportation Authority (MDTA), the State agency that owns, finances, operates and maintains Maryland's toll facilities, APPROVED at its May 7, 2015, public meeting the following changes to its toll structure **effective July 1, 2015**:

William Preston Lane, Jr., Memorial (Bay) Bridge (US 50/301)*

Increased E-ZPass Maryland discount from 10% to 37.5% Decreased Cash/Base, Commuter and Shoppers rates by 33%

Ca	Cash/Base Rates								
		Current	7	/1/2015					
2-axle	\$	6.00	\$	4.00					
3-axle	\$	12.00	\$	8.00					
4-axle	\$	18.00	\$	12.00					
5-axle	\$	36.00	\$	24.00					
6+-axle	\$	45.00	\$	30.00					

E-ZPass Maryland Rates						
		Current	7)	1/2015		
Commuter	\$	2.10	\$	1.40		
2-axle	\$	5.40	\$	2.50		
Shoppers	\$	3.00	\$	2.00		

Video Toll Rates								
		Current	7	/1/2015				
2-axle	\$	9.00	\$	6.00				
3-axle	\$	18.00	\$	12.00				
4-axle	\$	27.00	\$	18.00				
5-axle	\$	51.00	\$	36.00				
6+-axle	\$	60.00	\$	45.00				

Baltimore Harbor Tunnel (I-895), Fort McHenry Tunnel (I-95/I-395) and Francis Scott Key Bridge (I-695) Increased E-ZPass Maryland discount from 10% to 25%

E-ZPass Maryland Rates						
	10	Current	7/	1/2015		
2-axle	\$	3.60	\$	3.00		

John F. Kennedy Memorial Highway (I-95)*
Increased E-ZPass Maryland discount from 10% to 25%

E-ZPass Maryland Rates						
		Current	71	1/2015		
2-axle	\$	7.20	\$	6.00		

Thomas J. Hatem Memorial Bridge (US 40)*
Increased *E-ZPass* Maryland discount from 10% to 25%
30% discount for 3- and 4-axle vehicles

E-ZPass Maryland Rates							
		Current	7	/1/2015			
2-axle	\$	7.20	\$	6.00			
3-axle	\$	16.00	\$	11.20			
4 axle	\$	24 00	\$	16 80			

Gov. Harry W. Nice Memorial Bridge (US 301)*
Increased E-ZPass Maryland discount from 10% to 25%

E-ZPa	ss N	larylan	d Ra	ates	
	- 0	Current	7,	/1/2015	* toll collected in one
2-axle	\$	5.40	\$	4.50	direction only

Intercounty Connector (ICC)/MD 200 I-95 Express Toll Lanes (ETL) Reduced 2-axle rate ranges by \$0.03/mile

	e Rates		
	Current	7	/1/2015
2-axle			
Peak	\$ 0.25	\$	0.22
Off-peak	\$ 0.20	\$	0.17
Overnight	\$ 0.10	\$	0.07
3-axle			
Peak	\$ 0.75	\$	0.44
Off-peak	\$ 0.60	\$	0.34
Overnight	\$ 0.30	\$	0.14
4-axle			
Peak	\$ 1.125	\$	0.66
Off-peak	\$ 0.90	\$	0.51
Overnight	\$	\$	0.21
5-axle			
Peak	\$ 1.50	\$	1.32
Off-peak	\$ 1.20	\$	1.02
Overnight	\$ 0.60	\$	0.42
6+-axle			
Peak	\$ 1.875	\$	1.65
Off-peak	\$ 1.50	\$	1.275
Overnight	\$ 0.75	\$	0.525

Video Toll Rates are 1.5 times the *E-ZPass* toll rates with a minimum of \$1/maximum of \$15 above the *E-ZPass* rates.

Additional approved changes effective July 1, 2015:

- No \$1.50 *E-ZPass* monthly account maintenance fee for Maryland addresses and for out-of-state addresses with three or more trips at Maryland toll facilities in the previous statement period.
- Increase E-ZPass Maryland supplemental rebate program by 5 percentage points per trip level for vehicles with 5+ axles.

Supplemental Rebate Program (%)					
Current	7/1/2015	Trips			
5	10	60-79			
10	15	80-99			
15	20	100+			

Additional approved changes effective January 1, 2016:

• **Decrease toll rates to \$2 per axle** for commercial vehicle drivers with *E-ZPass* Maryland using the Childs Street (I-895) and Francis Scott Key Bridge (I-695) turnaround exits.

New Childs Street and I-695 Turnaround Discount							
		Current	1/1/2016				
3-axle	\$	8.00	\$	6.00			
4-axle	\$	12.00	\$	8.00			
5-axle	\$	24.00	\$	10.00			
6+-axle	\$	30.00	\$	12.00			

For a full list of toll rates, ICC/ETL pricing periods and additional information, visit mdta.maryland.gov.

General Notices

Notice of ADA Compliance

The State of Maryland is committed to ensuring that individuals with disabilities are able to fully participate in public meetings. Anyone planning to attend a meeting announced below who wishes to receive auxiliary aids, services, or accommodations is invited to contact the agency representative at least 48 hours in advance, at the telephone number listed in the notice or through Maryland Relay.

ATHLETIC COMMISSION

Subject: Public Meeting

Date and Time: July 20, 2015, 2 — 5 p.m. Place: 500 N. Calvert St., 3rd Fl. Conf.

Rm., Baltimore, MD

Contact: Patrick Pannella (410) 230-6223

[15-13-28]

BOARD OF COSMETOLOGISTS

Subject: No Meeting Notice Date and Time: July 6, 2015, 10 a.m. Place: 500 N. Calvert St., Baltimore, MD **Contact:** Shirley Leach (410) 230-6195 [15-13-25]

COMMISSION ON CRIMINAL SENTENCING POLICY

Subject: Public Meeting

Date and Time: July 14, 2015, 5:30 —

7:30 p.m.

Place: Judiciary Education and Conference Center, 2009D Commerce Park Dr.,

Annapolis, MD

Contact: David Soule (301) 403-4165

[15-13-35]

BOARD OF DIETETIC PRACTICE

Subject: Public Meeting

Date and Time: July 16, 2015, 12:30 —

3:30 p.m.

Place: 4201 Patterson Ave., Rm. 106,

Baltimore, MD

Contact: Lenelle Cooper (410) 764-4733

[15-13-26]

STATEWIDE EMERGENCY MEDICAL SERVICES ADVISORY **COUNCIL (SEMSAC)**

Subject: Public Meeting

Date and Time: July 2, 2015, 1 — 3 p.m. **Place:** 653 W. Pratt St., Ste. 212,

Baltimore, MD

Add'l. Info: The State Emergency Medical Services Advisory Committee (SEMSAC) meets regularly on the 1st Thursday of each

month.

Contact: Leandrea Gilliam (410) 706-4449

[15-13-09]

EMERGENCY MEDICAL SERVICES **BOARD**

Subject: Public Meeting

Date and Time: July 14, 2015, 9 — 11 a.m.; part of the meeting may include a closed session

Place: 653 W. Pratt Street, Ste. 212,

Baltimore, MD

Add'l. Info: The State Emergency Medical Services Board (EMS Board) meets regularly on the 2nd Tuesday of each month.

Contact: Leandrea Gilliam (410) 706-4449 [15-13-06]

MARYLAND INSTITUTE FOR EMERGENCY MEDICAL SERVICES SYSTEMS (MIEMSS)

Subject: Public Meeting

Date and Time: July 8, 2015, 10 a.m. 12 p.m.

Place: 653 W. Pratt St., Ste. 212, Baltimore, MD

Add'l. Info: The Protocol Review Committee meets regularly on the 2nd Wednesday of every other month.

Contact: Leandrea Gilliam (410) 706-4449

[15-13-08]

BOARD FOR PROFESSIONAL ENGINEERS

Subject: Public Meeting

Date and Time: July 9, 2015, 9 a.m. Place: 500 N. Calvert St., 3rd Fl. Conf.

Rm., Baltimore, MD

Contact: Pamela J. Edwards (410) 230-

6262

[15-13-46]

COMMISSIONER OF FINANCIAL REGULATION

Subject: Bank Merger

Add'l. Info: On May 18, 2015, Hamilton Bancorp, Inc. submitted an application to the Commissioner of Financial Regulation, pursuant to Financial Institutions Article, §§3-703 and 5-904, Annotated Code of Maryland, requesting approval to acquire Fairmount Bancorp, Inc., and subsequently merge Fairmount Bank, a Maryland-chartered bank, with and into Hamilton Bank, a federally-chartered savings bank. Both banks headquartered in Baltimore, Maryland. The surviving bank will be Hamilton Bank.

The public file on this application is available at the Office of Commissioner of Financial Regulation, 500 North Calvert Street, Suite 402, Baltimore, Maryland 21202. Comments regarding application must be submitted in writing and must be received by the Commissioner within 20 calendar days of the publication of this notice.

For further information, contact Marcia Ryan, Assistant Commissioner, at 410-230-6104.

Contact: Marcia Ryan (410) 230-6104 [15-13-40]

COMMISSIONER OF FINANCIAL REGULATION

Subject: Bank Merger

Add'l. Info: On June 3, 2015, Kopernik Bank, a Maryland-chartered mutual savings bank, filed an application pursuant to Financial Institutions Article, §3-703, Annotated Code of Maryland, requesting approval to merge with Kosciuszko Federal Savings Bank. Both banks are located in Baltimore, Maryland. The surviving institution will be Kopernik Bank.

The public file on this application is available at the Office of Commissioner of Financial Regulation, 500 North Calvert Street, Suite 402, Baltimore, Maryland 21202. Comments regarding application must be submitted in writing and must be received by the Commissioner within 20 calendar days of the publication date of this notice.

For further information, contact Marcia Ryan, Assistant Commissioner, at 410-230-6104.

Contact: Marcia Ryan (410) 230-6104 [15-13-41]

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subject: Call for Physician Nominations for Maryland's Drug Utilization Review Board

Add'l. Info: The Maryland Department of Health and Mental Hygiene Drug Utilization Review (DUR) Board is currently recruiting for one physician to serve on the Maryland DUR Board beginning in September 2015.

The implementation of the Omnibus Budget Reconciliation Act of 1990 requires that the Maryland Department of Health and Mental Hygiene establish a DUR Board. The DUR Board is comprised of both physicians and pharmacists and has been in operation since November 1992. The activities of the DUR Board include:

- Overseeing retrospective and prospective DUR within the Maryland Medicaid Program.
- · Approving DUR criteria and standards.
- Making recommendations concerning education and other types of interventions based on prospective and retrospective DUR findings.
- Preparing an annual report for submission to the Centers for Medicare and Medicaid (CMS) describing the nature and scope of the DUR program, summarizing educational/interventional strategies used, and estimating cost savings generated.
- Reviewing individual recipient profiles and make recommendations to restrict patients who might be abusing Medicaid prescription drugs.

The DUR Board has quarterly 3-hour meetings in the Baltimore area. Meetings are normally scheduled on a Thursday morning during the months of March, June, September, and December. Members serve terms of 3 years from the date of their appointment with the option to serve an additional 3 year term.

The membership of the Maryland DUR Board includes health care professionals who have recognized knowledge and expertise in at least one of the following areas:

- The clinically appropriate prescribing of outpatient drugs.
- The clinically appropriate dispensing and monitoring of outpatient drugs.
- Drug use review, evaluation and intervention.
- Medical quality assurance.

For an application packet, please contact Gina Homer at The Maryland Medicaid Pharmacy Program at 410-767-1749 or via email at Gina. Homer@Maryland.gov. The application deadline is July 17, 2015. Contact: Gina Homer (410) 767-1749

[15-13-23]

DEPARTMENT OF HEALTH AND MENTAL HYGIENE/OFFICE OF **HEALTH SERVICES**

Subject: Public Notice for Developmental Disabilities Administration Targeted Case Management Reimbursement Rate

Add'l. Info: Developmental Disabilities Administration Targeted Case Management: For dates service of beginning July 1, 2015, the Maryland Medical Assistance reimbursement rate for Developmental Disabilities Administration (DDA) targeted case management (TCM) providers will increase by 3 percent. These TCM services are also called coordination of community services. DDA TCM services target three populations of individuals with developmental disabilities: (1) individuals on the Developmental Disabilities Administration Waiting List; (2) individuals needing community coordination services; and (3) individuals transitioning to the community. The rate will be \$17.39 per unit. This represents an estimated \$1,163,867 total fund increase (50% General Funds/50% federal funds) cost for the program between July 1, 2015 and June 30, 2016.

Copies of the proposed changes are available for public review at the local health department in each county and Baltimore City. Written comments may be sent to Michael Cimmino, Office of Health Services, DHMH, 201 W. Preston St., Room 128D, Baltimore, MD 21201, or call 410-767-0579 or email Michael.Cimmino@maryland.gov.

Contact: Nina McHugh (410) 767-5003

[15-13-47]

DEPARTMENT OF HEALTH AND MENTAL HYGIENE/OFFICE OF **HEALTH SERVICES**

Subject: Public Notice Reminder for Maryland Medical Assistance's Cost-Sharing and Premium Exclusion Information

Add'l. Info: Some adult participants enrolled in Maryland Medical Assistance (MA) or HealthChoice managed care organizations (MCOs) are subject to minimal cost sharing for prescription medications — \$1 for generic drugs and \$3for name brand drugs. Certain individuals are excluded from pharmacy cost sharing charges. A participant is exempt if he or she is:

- 1. Under age 21;
- 2. A pregnant woman;
- 3. Receiving MA because of the state's election to extend coverage to the Certain Individuals Needing Treatment for Breast and Cervical Cancer;

- 4. An Indian who is currently receiving or has ever received an item or service furnished by an Indian health care provider or through referral under contract health services: or
- 5. Unable to pay the cost-sharing charge.

If a participant belongs to one of the above categories, then the participant must identify themselves as belonging to an exempt category. For example, if you are a pregnant woman simply inform the pharmacist that you are pregnant, and therefore, not required to pay the costsharing charge.

At this time there is no anticipated fiscal note to this cost-sharing policy. This public notices serves are a reminder to MA participants, providers and pharmacies that the above mentioned categories of MA participants are exempt from prescription cost-sharing allowances.

Copies of the proposed changes are available for public review at the local health department in each county and Baltimore City. Written comments may be sent to Michael Cimmino, Office of Health Services, DHMH, 201 W. Preston St., Room 128D, Baltimore, MD 21201, or call 410-767-0579 or email Michael.Cimmino@maryland.gov.

Contact: Nina McHugh (410) 767-5003

[15-13-48]

BOARD OF HEATING. VENTILATION, AIR-CONDITIONING, AND REFRIGERATION CONTRACTORS (HVACR)

Subject: Public Meeting

Date and Time: July 8, 2015, 10:30 a.m. — 12 p.m.

Place: 500 N. Calvert St., 3rd Fl. Conf.

Rm., Baltimore, MD

Contact: Robin Bailey (410) 230-6160

[15-13-11]

FACILITIES ADVISORY BOARD — JUVENILE SERVICES

Subject: Public Meeting

Date and Time: July 11, 2015, 10 a.m. —

Place: 300 N. Gay St, 2nd Fl. Large Conf.

Rm., Baltimore, MD

Contact: Bridgett Tucker (410) 752-

3500x130

[15-13-39]

COMMISSION ON KIDNEY DISEASE

Subject: Public Meeting

Date and Time: July 16, 2015, 2 — 5 p.m. **Place:** 4201 Patterson Ave., Rm. 110,

Baltimore, MD

Add'l. Info: Please note the meeting date was changed from July 23, 2015. A portion of this meeting is closed for administrative

session.

Contact: Eva Schwartz (410) 764-4799

[15-13-12]

DIVISION OF LABOR AND INDUSTRY/BOARD OF BOILER RULES

Subject: Public Meeting

Date and Time: July 16, 2015, 10 a.m. —

12 p.m.

Place: Maryland Occupational Safety and Health Training Rm., 312 Marshall Ave.,

Rm. 600, Laurel, MD

Add'l. Info: The Board of Boiler Rules will meet to discuss issues relating to boiler and pressure vessel safety and may consider requests for variance. Interested persons should call the contact person to confirm meeting.

Contact: Melissa Myer (410) 767-2182

[15-13-27]

DIVISION OF LABOR AND INDUSTRY/MARYLAND APPRENTICESHIP AND TRAINING COUNCIL

Subject: Public Meeting

Date and Time: July 14, 2015, 9 a.m. —

12 p.m.

Place: Associated Builders and Contractors, Inc., Metropolitan Washington Chapter, 6901 Muirkirk Meadows Dr., Ste. F. Beltsville, MD

Add'l. Info: The Apprenticeship and Training Council will consider the approval and registration of new apprenticeship programs, revisions to presently approved apprenticeship programs and other business which may come before the Council.

Contact: C. Edward Poarch II (410) 767-2246

[15-13-43]

BOARD FOR PROFESSIONAL LAND SURVEYORS

Subject: Public Meeting

Date and Time: July 7, 2015, 10 a.m. **Place:** 500 N. Calvert St., 3rd Fl. Conf.

Rm., Baltimore, MD

Contact: Pamela J. Edwards (410) 230-

6262

[15-13-44]

LAND SURVEYORS CPC COMMITTEE

Subject: Public Meeting

Date and Time: July 7, 2015, 1 p.m. **Place:** 500 N. Calvert St., 3rd Fl. Conf.

Rm., Baltimore, MD

Contact: Pamela J. Edwards (410) 230-

6262

[15-13-45]

MARYLAND HEALTH CARE COMMISSION

Subject: Public Meeting

Date and Time: July 16, 2015, 1 p.m. **Place:** Maryland Health Care Commission, 4160 Patterson Ave., Conf. Rm. 100,

Baltimore, MD

Contact: Valerie Wooding (410) 764-3460

[15-13-10]

MARYLAND HEALTH CARE COMMISSION

Subject: Formal Start of Review

Add'l. Info: The Maryland Health Care Commission (MHCC) hereby gives notice of docketing of the following application for Certificate of Need:

Anne Arundel Medical Center — Docket No. 15-02-2360 — Establish a cardiac surgery, research and training program in partnership with Johns Hopkins Medicine at the hospital located Annapolis; Proposed Cost: \$2,500,000.

Baltimore Washington Medical Center — Docket No. 15-02-2361 — Establish a cardiac surgery services program at the hospital in Glen Burnie, as a third location for the existing University of Maryland Cardiac Surgery Services Program; Proposed Cost: \$1,259,117.

MHCC shall review the applications under Health-General Article, §19-101 et seq., Annotated Code of Maryland, COMAR 10.24.01, and the applicable State Health Plan standards.

Any affected person may make a written request to the Commission to receive copies of relevant notices concerning the applications. All further notices of proceedings on the applications will be sent only to affected persons who have registered as interested parties.

Persons desiring to become interested parties in the Commission's review of the above-referenced applications must meet the requirements of COMAR 10.24.01.01B(2) and (20) and must also submit written comments to the Commission no later than close of business July 27, 2015. These comments must state with particularity the State Health Plan standards or review criteria that you believe

have not been met by the applicants as stated in COMAR 10.24.01.08F.

Please refer to the Docket Number listed above in any correspondence on the applications. Copies of the application are available for review in the office of MHCC during regular business hours by appointment. All correspondence should be addressed to Paul E. Parker, Director, Center for Health Care Facilities Planning & Development, Maryland Health Care Commission, 4160 Patterson Avenue, Baltimore, Maryland 21215.

Contact: Ruby Potter (410) 764-3276

[15-13-34]

MARYLAND HEALTH CARE COMMISSION/PROVIDER CARRIER WORKGROUP SELF REFERRAL STUDY

Subject: Public Meeting

Date and Time: July 22, 2015, 3 — 5 p.m. **Place:** Maryland Health Care Commission, 4160 Patterson Ave., Conf. Rm. 100, Baltimore, MD

Add'l. Info: Existing shared savings

programs and opportunities. **Contact:** Erin Dorrien (410) 764-3284

[15-13-31]

BOARD OF PODIATRIC MEDICAL EXAMINERS

Subject: Public Meeting

Date and Time: July 9, 2015, 1 p.m. **Place:** 4201 Patterson Ave., Rm. 110,

Baltimore, MD

Contact: Sheri Henderson (410) 764-4785

[15-13-03]

BOARD OF PODIATRIC MEDICAL EXAMINERS

Subject: Public Meeting

Date and Time: September 10, 2015, 1

p.m.

Place: 4201 Patterson Ave., Baltimore,

MD

Contact: Sheri Henderson (410) 764-4785

[15-13-14]

BOARD OF PODIATRIC MEDICAL EXAMINERS

Subject: Public Meeting

Date and Time: October 8, 2015, 1 p.m. **Place:** 4201 Patterson Ave., Baltimore,

MD

Contact: Sheri Henderson (410) 764-4785

[15-13-15]

BOARD OF PODIATRIC MEDICAL EXAMINERS

Subject: Public Meeting

Date and Time: November 12, 2015, 1

p.m.

Place: 4201 Patterson Ave., Baltimore,

MD

Contact: Sheri Henderson (410) 764-4785

[15-13-16]

BOARD OF PODIATRIC MEDICAL EXAMINERS

Subject: Public Meeting

Date and Time: December 10, 2015, 1

p.m.

Place: 4201 Patterson Ave., Baltimore,

MD

Contact: Sheri Henderson (410) 764-4785

[15-13-18]

BOARD OF PODIATRIC MEDICAL EXAMINERS

Subject: Public Meeting

Date and Time: January 14, 2016, 1 p.m. **Place:** 4201 Patterson Ave., Baltimore,

MD

Contact: Sheri Henderson (410) 764-4785

[15-13-19]

BOARD OF PODIATRIC MEDICAL EXAMINERS

Subject: Public Meeting

Date and Time: February 11, 2016, 1 p.m. **Place:** 4201 Patterson Ave., Baltimore,

MD

Contact: Sheri Henderson (410) 764-4785

[15-13-20]

BOARD OF EXAMINERS OF PSYCHOLOGISTS

Subject: Public Meeting

Date and Time: July 10, 2015, 9 a.m. — 1

p.m.

Place: 4201 Patterson Ave., Conf. Rm.

110, Baltimore, MD

Add'l. Info: Sign language interpreters/other appropriate accommodations for qualified individuals with disabilities will be provided upon request.

upon request.

Contact: Dorothy Kutcherman (410) 764-

4703

[15-13-24]

RACING COMMISSION

Subject: Public Meeting

Date and Time: July 21, 2015, 12:30 — 1

p.m.

Place: Laurel Park, Laurel, MD

Contact: J. Michael Hopkins (410) 296-

9682

[15-13-13]

RACING COMMISSION

Subject: Public Meeting

Date and Time: July 21, 2015, 12:30 — 1

p.m

Place: Ocean Downs Raceway, Berlin, MD **Contact:** J. Michael Hopkins (410) 296-

9682

[15-13-29]

REAL ESTATE COMMISSION

Subject: Public Meeting

Date and Time: July 15, 2015, 10:30 a.m. **Place:** Dept. of Labor, Licensing, and Regulation, 500 N. Calvert St., 3rd Fl.

Conf. Rm., Baltimore, MD

Contact: Charlene Faison (410) 230-6199

[15-13-21]

REAL ESTATE COMMISSION

Subject: Public Hearing

Date and Time: July 15, 2015, 12:30 p.m. **Place:** Dept of Labor, Licensing,

Regulation

500 N. Calvert St., 3rd Fl. Conf. Rm.,

Baltimore, MD

Contact: Charlene Faison (410) 230-6199

[15-13-22]

PROTOCOL FOR SEXUAL ASSAULT MEDICAL FORENSIC EXAMINATIONS AND PLANNING COMMITTEE

Subject: Public Meeting

Date and Time: July 9, 2015, 10 a.m. -

12 p.m.

Place: Columbia Gateway Bldg., 6751 Columbia Gateway Dr., Rm. 401,

Columbia, MD

Contact: Joyce Dantzler (410) 767-1372

[15-13-01]

STATE TREASURER'S OFFICE

Subject: Public Meeting

Date and Time: September 2, 2015, 2 p.m. **Place:** Louis L. Goldstein Treasury Bldg., 80 Calvert St., Assembly Rm. 114—116, Annapolis, MD

Add'l. Info: Legislative review and the size and condition of tax-supported debt **Contact:** Nikki Griffith (410) 260-7920 [15-13-36]

WORKERS' COMPENSATION COMMISSION

Subject: Public Meeting

Date and Time: July 9, 2015, 9 — 11 a.m. **Place:** 10 E. Baltimore St., Baltimore, MD **Add'l. Info:** Portions of this meeting may

be held in closed session.

Contact: Amy Lackington (410) 864-5300

[15-13-05]

WORKERS' COMPENSATION COMMISSION

Subject: Public Meeting

Date and Time: August 17, 2015, 3 — 5

p.m.

Place: Workers' Compensation Commission, 10 E. Baltimore St., 3rd Fl.,

Baltimore, MD

Add'l. Info: Medical Fee Guide

Committee Meeting

Contact: Regina Brown (410) 864-5327

[15-13-37]

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