

**REGULATORY REVIEW AND EVALUATION ACT:**

**EVALUATION REPORTS DUE OCTOBER 1, 2017 FOR:**

**Subtitle 31 HEALTH OCCUPATIONS BOARD**

**Subtitle 32 BOARD OF PHYSICIANS**

**Subtitle 33 BOARD OF EXAMINERS OF NURSING HOME  
ADMINISTRATORS**

**Subtitle 34 BOARD OF PHARMACY**

**Subtitle 35 POSTMORTEM EXAMINERS COMMISSION**

**Subtitle 36 BOARD OF EXAMINERS OF PSYCHOLOGISTS**

**SUBMITTED BY:**

**Maryland Department of Health  
Office of Regulation and Policy Coordination  
201 W. Preston Street, Room 512  
Baltimore, Maryland 21201  
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## **EVALUATION REPORTS**

### **Subtitle 31 HEALTH OCCUPATION BOARDS**

COMAR 10.31.01 Code of Conduct for Board Members and Investigators  
COMAR 10.31.02 Tax Compliance Regulations

### **Subtitle 32 BOARD OF PHYSICIANS**

COMAR 10.32.04 Delegation of Duties by a Licensed Physician-Psychiatrist to a Psychiatrist's Assistant  
COMAR 10.32.07 Unlicensed Medical Practitioners  
COMAR 10.32.12 Del. of Acts by a Lic. Physician to an Assistant Not Otherwise Authorized under...Article  
COMAR 10.32.13 Physician License by Conceded Eminence  
COMAR 10.32.14 Unlicensed X-Ray Assistant  
COMAR 10.32.15 Registration of Physicians to Perform Acupuncture  
COMAR 10.32.16 Petition for Declaratory Ruling  
COMAR 10.32.17 Sexual Misconduct  
COMAR 10.32.18 Compelling Purpose Disclosure

### **Subtitle 34 BOARD OF PHARMACY**

COMAR 10.34.02 Examination for Licensure and Professional Experience Programs  
COMAR 10.34.04 Transfer and Outsourcing of Prescriptions and Prescription Orders  
COMAR 10.34.16 Portable Drug Kits for Lic. Home Health Agencies, Hospices, & Home Infusion Providers...  
COMAR 10.34.24 Record of Drug Inventory Acquisition  
COMAR 10.34.26 Patient Safety Improvement  
COMAR 10.34.27 Compelling Purpose Disclosure  
COMAR 10.34.31 Dispensing or Distributing at a Setting That Does Not Possess a Pharmacy Permit

## **EXEMPTIONS REQUESTED**

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

### **Subtitle 32 BOARD OF PHYSICIANS**

10.32.01 General Licensure Regulations	CA 9-29-14
10.32.02 Hearings Before the Board of Physicians	CA 3-2-15
10.32.03 Delegation of Duties by a Licensed Physician—Physician Assistant	CA 10-3-11
10.32.05 Telemedicine	IA 12-28-09
10.32.06 Licensure of Polysomnographic Technologists	CA 5-11-15
10.32.08 Licensure of Athletic Trainers	IA 7-22-13
10.32.09 Delegation...of Cosmetic Medical Procedures & Use of Cosmetic Medical Devices	IA 8-23-10
10.32.10 Lic. of RTs, Radiographers, NMTs and RATs	CA 5-12-2014 and 12-22-14
10.32.11 Licensing of Respiratory Care Practitioners	CA 3-7-11
10.32.19 Disclosure of Records to State Health Agencies	IA 3-3-14
10.32.20 Licensure of Perfusionists	IA 9-15-14
10.32.21 Licensure, Regulation, and Discipline of Naturopathic Doctors	IA 9-12-16
10.32.22 Mandated Reporting to the Board	IA 11-7-16

### **Subtitle 33 BOARD OF EXAMINERS OF NURSING HOME ADMINISTRATORS**

10.33.01 Nursing Home Administrators	CA 3-19-12
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**Subtitle 34 BOARD OF PHARMACY**

10.34.01 Disciplinary Proceedings	CA 1-28-08
10.34.03 Inpatient Institutional Pharmacy	CA 10-1-11
10.34.05 Pharmacy Security	CA 7-1-10
10.34.06 Reporting Phar., Phar. Intern's, & Phar. Tech. Mailing Address & Location of Emp.	CA 7-1-15
10.34.07 Pharmacy Equipment	CA 7-1-10
10.34.08 Information Required on Prescriptions or Patient Drug Profiles	CA 1-28-08
10.34.09 Fees	CA 7-1-15
10.34.10 Pharmacist, Pharmacy Intern, and Pharmacy Technician Code of Conduct	CA 7-1-15
10.34.11 Disciplinary Sanctions Monetary Penalties and Civil Fines	CA 7-1-15
10.34.12 Removal of Expired Medications	CA 7-1-10
10.34.13 Reinstatement of Expired Licenses for Pharmacists	CA 7-1-10
10.34.14 Opening and Closing of Pharmacies	CA 7-8-13
10.34.15 Licensure by Reciprocity	CA 7-1-10
10.34.17 Waiver of Full Service Requirements for Recognized Pharmaceutical Specialties	CA 10-19-09
10.34.18 Continuing Education for Pharmacists	CA 7-1-10
10.34.19 Sterile Pharmaceutical Compounding	CA 2-23-09
10.34.20 Format of Prescription Transmission	CA 10-4-10
10.34.21 Standard of Practice for Unlicensed Personnel	CA 1-28-08
10.34.22 Licensing of Wholesale Prescription Drug or Device Distributors	CA 7-1-14
10.34.23 Pharmaceutical Services to Patients in Comprehensive Care Facilities	CA 6-1-11
10.34.25 Delivery of Prescriptions	CA 3-1-12
10.34.28 Automated Medication Systems	CA 10-1-12
10.34.29 Drug Therapy Management	CA 4-15-13
10.34.30 Change to Permit—Pharmacy or Wholesale Distribution Permit Holder	CA 7-8-13
10.34.32 Pharmacist Administration of Vaccinations	CA 4-28-14
10.34.33 Prescription Drug Repository Program	CA 5-9-16
10.34.34 Pharmacy Technicians	CA 7-1-15
10.34.35 Infusion Pharmacy Services in an Alternate Site Care Environment	IA 3-1-12
10.34.36 Pharmaceutical Services to Residents in Assisted Living Programs & Group Homes	IA 6-15-13
10.34.37 Pharmacy Permit Holder—Wholesale Distribution	IA 7-1-14
10.34.38 Pharmacy Interns	IA 7-1-15
10.34.39 Pharmacist Administration of Self-Administered Drugs	IA 5-9-16

**Subtitle 35 POSTMORTEM EXAMINERS COMMISSION**

10.35.01 Medical Examiner Cases	CA 11-24-14
10.35.02 Testing Blood and Breath for Alcohol	IA 10-4-10

**Subtitle 36 BOARD OF EXAMINERS OF PSYCHOLOGISTS**

10.36.01 Procedures	CA 5-25-15
10.36.02 Continuing Education	CA 5-25-15
10.36.03 Procedure for Board Hearings	CA 5-25-15
10.36.05 Code of Ethics and Professional Conduct	CA 5-25-15
10.36.06 Fee Schedule	CA 5-25-15
10.36.07 Psychology Associate	CA 5-25-15
10.36.08 Disciplinary Sanctions and Monetary Penalties	CA 5-25-15
10.36.09 Child Custody Evaluations in Family Law Proceedings	IA 8-22-11

**CHAPTERS THAT HAVE BEEN TRANSFERRED, REPEALED, OR VACANT****Subtitle 36 BOARD OF EXAMINERS OF PSYCHOLOGISTS**

10.36.04 Expungement of Board Records	Repealed
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**Regulatory Review and Evaluation Act  
Evaluation Report Form  
2012 – 2020**

Chapter Codification:

Chapter Name:

Authority:

Date Originally Adopted or Last Amended:

Purpose:

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

- (1) Do the regulations continue to be necessary for the public interest?  Yes  No
- (2) Do the regulations continue to be supported by statutory authority and judicial opinion?  Yes  No
- (3) Are the regulations obsolete or otherwise appropriate for amendment or repeal?  Yes  No
- (4) Are the regulations effective in accomplishing their intended purpose?  Yes  No

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

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

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

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

- (4) Provide summaries of:  
(a) all comments received from stakeholders, affected units, or the public; and  
(b) the adopting authority's responses to those comments.

No comments received.

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

None

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

N/A

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

Three states have substantively similar regulations in place for at least one health licensing board.

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

None.

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

Has the agency promulgated all regulations required by recent legislation?  Yes  No

Provide explanations of the above responses, as needed:

No legislation has been enacted recently on this topic.

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

XX no action

Summary:

This chapter continues to be supported by statutory authority and is effective in accomplishing its intended purpose. Therefore, no action is required at this time.

Person performing review:

Kristen Neville

Title:

Legislation & Regulations  
Specialist

**Regulatory Review and Evaluation Act  
Evaluation Report Form  
2012 – 2020**

Chapter Codification:

Chapter Name:

Authority:

Date Originally Adopted or Last Amended:

Purpose:

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

- (1) Do the regulations continue to be necessary for the public interest?  Yes  No
- (2) Do the regulations continue to be supported by statutory authority and judicial opinion?  Yes  No
- (3) Are the regulations obsolete or otherwise appropriate for amendment or repeal?  Yes  No
- (4) Are the regulations effective in accomplishing their intended purpose?  Yes  No

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

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

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  - (c) any notice posted on the unit’s website or on a Statewide website created for units to post notices of regulation review;
  - (d) any mailing by the adopting authority; and
  - (e) any public hearing held.

- (4) Provide summaries of:  
(a) all comments received from stakeholders, affected units, or the public; and  
(b) the adopting authority's responses to those comments.

No comments received.

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

None

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

N/A

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

None

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

None.

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

Has the agency promulgated all regulations required by recent legislation?  Yes  No

Provide explanations of the above responses, as needed:

No legislation has been enacted recently on this topic.

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

XX amendment

Summary:

Add four citations to the statutory authority for COMAR 10.31.02. Two cites (Health Occupations Article, §§20–205 and 21–205) are for Boards which were not established at the time that this regulation chapter was originally enacted. The citations Health Occupations Article, §§5–205 and 6–206 were not included in the statutory authority previously and should be added.

Additionally, the exception for the Board of Dietetic Practice, COMAR 10.31.02.01B(1) should be repealed. The Board has always complied with the process prescribed in the regulations, so the exception does not reflect current practice.

Person performing review:

Kristen Neville

Title:

Legislation & Regulations  
Specialist

**Regulatory Review and Evaluation Act  
Evaluation Report Form  
2012 – 2020**

Chapter Codification:

Chapter Name:

Authority:

Date Originally Adopted or Last Amended:

Purpose:

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

- (1) Do the regulations continue to be necessary for the public interest?  Yes  No
- (2) Do the regulations continue to be supported by statutory authority and judicial opinion?  Yes  No
- (3) Are the regulations obsolete or otherwise appropriate for amendment or repeal?  Yes  No
- (4) Are the regulations effective in accomplishing their intended purpose?  Yes  No

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

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

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

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

- (4) Provide summaries of:

- (a) all comments received from stakeholders, affected units, or the public; and
- (b) the adopting authority's responses to those comments.

No comments received.

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

None

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

In review of other states, a "Psychiatric Assistant" seems to encompass a variety of titles, training and educational paths and employment. It appears that there is no provider category with consistent, comparable criteria.

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

Across state lines, a "Psychiatric Assistant" seems to encompass a variety of titles, training and educational paths and employment. It appears that there is no provider category with consistent, comparable criteria.

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

None.

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

Has the agency promulgated all regulations required by recent legislation?  Yes  No  
Provide explanations of the above responses, as needed:

There are no policy statements, guidelines, or standards being applied, nor is there any recent legislation that requires the promulgation of regulations.

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

✓ no action

Summary:

"Psychiatrist's assistant" is defined as an individual who applied for registration on or before October 1, 1993, and was registered by the Board to perform medical duties which would normally be performed by a psychiatrist. Because this particular category of providers has been grandfathered in, there will be no new applications for registration. Recent changes to the regulations eliminated the 3 month grace period for reinstatement. At the same time the Board included amendments to the fees charged these providers.

COMAR 10.32.04.10 states that "The Board shall establish fees for application, registration, re-registration, late registration, and reinstatement of psychiatrist's assistants." To date, the Board has never established fees in regulations, the fee is currently \$20 and is not in alignment with other licensees in other health occupation categories. The Board's 2013 Sunset legislation, Chapter 401 Acts of 2013 (HB 1096) added two requirements related to the establishment of fees; Health Occupations Article §14-205(12) requires the Board to "establish fees that are adequate to fund the effective regulation of physicians and allied health professionals," and §14-205(16) to "develop and adopt a budget that reflects revenues and supports the costs associated with each allied health profession regulated by the Board." The proposed fee provisions of the proposal were not approved.

Given that there are only 10 active registrations with the Board, and the prior effort to amend the regulations was not approved, the Board recommends no action at this time.

Person performing review:

Title:

**Regulatory Review and Evaluation Act  
Evaluation Report Form  
2012 – 2020**

Chapter Codification:

Chapter Name:

Authority:

Date Originally Adopted or Last Amended:

Purpose:

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

- (1) Do the regulations continue to be necessary for the public interest?  Yes  No
- (2) Do the regulations continue to be supported by statutory authority and judicial opinion?  Yes  No
- (3) Are the regulations obsolete or otherwise appropriate for amendment or repeal?  Yes  No
- (4) Are the regulations effective in accomplishing their intended purpose?  Yes  No

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

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

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

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

- (4) Provide summaries of:  
 (a) all comments received from stakeholders, affected units, or the public; and  
 (b) the adopting authority's responses to those comments.

No comments received.

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

None.

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

None found.

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

In a state by state comparison, 17 additional states do not require registration or any other form of licensure for medical school graduates in training.

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

Review of the Federation of State Medical Boards report of resident licensure and other state statutes.

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

Has the agency promulgated all regulations required by recent legislation?  Yes  No

Provide explanations of the above responses, as needed:

There is a current proposal from the Board to repeal COMAR 10.32.07. These regulations are obsolete as a result of the passage of legislation, the Board's Sunset (Senate Bill 549/House Bill 1265) during the 2017 legislative session. In that legislation, a medical student is an exception to licensure, however, the legislation removed the requirement for the Board to perform a criminal history record check. This was the only statutory authority the Board had relative to unlicensed medical practitioners. The other nuance is that the bill as introduced, inserted a new section 14-302.2 which was to further clarify the Board's disciplinary authority over UMPs--that provision was amended out. Other than the CHRC requirement that was in §14-302 and amended out in the Sunset, there is no specific authority in statute for the Board to require registration or charge a fee for that registration required by the regulations.

As a result of the Governor's current moratorium on proposed regulations, a request for an exemption for this proposal was submitted to the Governor's Office on August 15, 2017 and the Department is currently awaiting approval to proceed.

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

✓ repeal

Summary:

COMAR 10.32.07 are not supported by statute and should be repealed.

This proposed action is currently before the Governor's Office for approval to proceed with promulgation (see §C above).

Person performing review:

Wynne E. Hawk

Title:

Manager, Policy & Legislation

**Regulatory Review and Evaluation Act  
Evaluation Report Form  
2012 – 2020**

Chapter Codification: COMAR 10.32.12

Chapter Name: Delegation of Acts by a Licensed Physician to an Assistant Not Otherwise Authorized under the Health Occupations Article or the Education Article

Authority: Health General Article, §§19-114 and 19-118; Health Occupations Article, §14-306; Annotated Code of Maryland

Date Originally Adopted or Last Amended: Effective June 12, 2000, last amended March 2016

Purpose: This chapter governs the delegation of acts by a physician to an assistant not otherwise authorized under the Health Occupations Article or the Education Article, Annotated Code of Maryland.

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

- (1) Do the regulations continue to be necessary for the public interest?  Yes  No
- (2) Do the regulations continue to be supported by statutory authority and judicial opinion?  Yes  No
- (3) Are the regulations obsolete or otherwise appropriate for amendment or repeal?  Yes  No
- (4) Are the regulations effective in accomplishing their intended purpose?  Yes  No

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

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

The regulations were posted on the Board website for 30 days in August/September 2016 inviting all stakeholders to submit comments for consideration.

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

In October 2016 a communication was sent out to DHMH internal units, other affected units and state agencies for comment.

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

The regulations were published in the Md. Register, Volume 43, Issue 19, page 1069 and also posted on the Board of Physician's website for 30 days during August 2016 to September 2016.

- (4) Provide summaries of:  
(a) all comments received from stakeholders, affected units, or the public; and  
(b) the adopting authority's responses to those comments.

No comments received.

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

None.

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

None found.

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

Across state lines, the criteria for how and to whom a Licensed Physician delegates to an Assistant Not Otherwise Authorized seems to encompass a variety of titles, training, educational paths and employment. This is not a provider category with consistent, comparable criteria.

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

None.

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

Has the agency promulgated all regulations required by recent legislation?  Yes  No

Provide explanations of the above responses, as needed:

There are no policy statements, guidelines, or standards being applied or enforced which should be promulgated as regulations. In terms of recent legislation that requires the promulgation of regulations, there is a pending proposal to amend the regulations, which is under consideration as of the publication of this evaluation.

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

✓ no action

Summary:

The Board has consistently amended and updated these provisions as needed. Currently, the Board has proposed to amend COMAR 10.32.12 to allow for the delegation of certain steps in the dispensing of prescription drugs by a physician to an unlicensed assistant, so this COMAR chapter is not in conflict with State statute and other proposed regulations.

Given that there are current pending regulations under consideration by the Department, the Board recommends no further action at this time.

Person performing review:

Title:

**Regulatory Review and Evaluation Act  
Evaluation Report Form  
2012 – 2020**

Chapter Codification:	COMAR 10.32.13
Chapter Name:	Physician License by Conceded Eminence
Authority:	Health Occupations Article, §§14-205, 14-206, 14-301, 14-302, 14-307—319, Annotated Code of Maryland; Chapter 273 (1993)
Date Originally Adopted or Last Amended:	Effective date: November 22, 1993
Purpose:	These regulations establish the qualifications for an individual to become licensed in Maryland to practice medicine by virtue of conceded eminence and authority in the profession and to set limits on the license.

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

- (1) Do the regulations continue to be necessary for the public interest?  Yes  No
- (2) Do the regulations continue to be supported by statutory authority and judicial opinion?  Yes  No
- (3) Are the regulations obsolete or otherwise appropriate for amendment or repeal?  Yes  No
- (4) Are the regulations effective in accomplishing their intended purpose?  Yes  No

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

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

The regulations were posted on the Board website for 30 days in August/September 2016 inviting all stakeholders to submit comments for consideration.

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

In October 2016 a communication was sent out to DHMH internal units, other affected units and state agencies for comment.

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

The regulations were published in the Md. Register, Volume 43, Issue 19, page 1069 and also posted on the Board of Physician's website for 30 days during August 2016 to September 2016.

- (4) Provide summaries of:
  - (a) all comments received from stakeholders, affected units, or the public; and

(b) the adopting authority's responses to those comments.

No comments received.

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

None.

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

None found.

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

Licensure is a state medical board function and a review of other states laws identifies 9 states, in addition to Maryland, that have this type of medical license.

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

None.

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

Has the agency promulgated all regulations required by recent legislation?  Yes  No

Provide explanations of the above responses, as needed:

The Board made a policy decision to comprehensively amend the Conceded Eminence regulations in 2017. As of the preparation of this evaluation, the regulations are in the final stages of approval and therefore the anticipated amended and revised regulations continue to be effective in accomplishing the intended purpose of the regulations.

As a result of the Governor's current moratorium on proposed regulations, a request for an exemption for this proposal was submitted to the Governor's Office on August 15, 2017 and the Department is currently awaiting approval to proceed.

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

✓ amendment

Summary:

The Board is in the final stages of amending and updating these regulations. This proposed action is currently before the Governor's Office for approval to proceed with promulgation (see §C above).

Person performing review: Wynee E. Hawk

Title: Manager, Policy & Legislation

**Regulatory Review and Evaluation Act  
Evaluation Report Form  
2012 – 2020**

Chapter Codification:

Chapter Name:

Authority:

Date Originally Adopted or Last Amended:

Purpose:

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

- (1) Do the regulations continue to be necessary for the public interest?  Yes  No
- (2) Do the regulations continue to be supported by statutory authority and judicial opinion?  Yes  No
- (3) Are the regulations obsolete or otherwise appropriate for amendment or repeal?  Yes  No
- (4) Are the regulations effective in accomplishing their intended purpose?  Yes  No

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

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

The regulations were posted on the Board website for 30 days in August/September 2016 inviting all stakeholders to submit comments for consideration. Also the Board reached out to the Maryland Radiological Society (MRS) via telephone and email asking for input on the need to retain the regulations. MRS submitted the issue for discussion at their monthly Board meeting and the communication to the Board was to retain the regulations.

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

In October 2016 a communication was sent out to DHMH internal units, other affected units and state agencies for comment.

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

The regulations were published in the Md. Register, Volume 43, Issue 19, page 1069 and also posted on the Board of Physician's website for 30 days during August 2016 to September 2016.

- (4) Provide summaries of:  
(a) all comments received from stakeholders, affected units, or the public; and  
(b) the adopting authority's responses to those comments.

No comments received other than MRS as discussed in (1).

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

None

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

None found.

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

Certification of unlicensed X-Ray Assistants is authorized under Maryland State law. Across state lines, an "Unlicensed X-Ray Assistant" seems to encompass a variety of health occupations, titles, training and educational paths and employment. It appears that there is no provider category with consistent, comparable criteria.

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

None.

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

Has the agency promulgated all regulations required by recent legislation?  Yes  No

Provide explanations of the above responses, as needed:

There are no policy statements, guidelines, or standards being applied, nor is there any recent legislation that requires the promulgation of regulations.

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

✓ no action

**Summary:**

The Board was considering a recommendation to repeal these regulations based on the fact that the Board has not received any requests or notifications from the Maryland Radiological Society (MRS) since 2002, and no certifications have been issued since 2002. Additionally, while the Board issues a certification, there is no ongoing oversight of these practitioners. MRS, however, is concerned that they may get a request in the future, and has requested this option not be repealed at this time.

Person performing review:

Wynee E. Hawk

Title:

Manager, Policy & Legislation

**Regulatory Review and Evaluation Act  
Evaluation Report Form  
2012 – 2020**

Chapter Codification:	COMAR 10.32.15
Chapter Name:	Registration of Physicians to Perform Acupuncture
Authority:	Health Occupations Article, §14-504, Annotated Code of Maryland
Date Originally Adopted or Last Amended:	Effective date: September 11, 1995
Purpose:	The regulations require a physician to register to perform acupuncture, and meet certain training qualifications to qualify for registration.

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

- (1) Do the regulations continue to be necessary for the public interest?  Yes  No
- (2) Do the regulations continue to be supported by statutory authority and judicial opinion?  Yes  No
- (3) Are the regulations obsolete or otherwise appropriate for amendment or repeal?  Yes  No
- (4) Are the regulations effective in accomplishing their intended purpose?  Yes  No

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

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

The regulations were posted on the Board website for 30 days in August/September 2016 inviting all stakeholders to submit comments for consideration.

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

In October 2016 a communication was sent out to DHMH internal units, other affected units and state agencies for comment.

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

The regulations were published in the Md. Register, Volume 43, Issue 19, page 1069 and also posted on the Board of Physician's website for 30 days during August 2016 to September 2016.

- (4) Provide summaries of:  
(a) all comments received from stakeholders, affected units, or the public; and  
(b) the adopting authority's responses to those comments.

No comments received.

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

None.

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

None found.

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

The statutory requirements for specific hours and acupuncture training are decided on a state by state basis. States determine the legal standards for all licensed acupuncturists, including medical acupuncturists. Most states have legal requirements based on the guidelines put forth by the World Health Organization (WHO) and World Federation of Acupuncture and Moxibustion Societies (WFAS). Those organizations drafted the WHO and WFAS Guidelines on Basic Training & Safety in Acupuncture in 1996 (printed in 1999). Those guidelines explain the difference in educational requirements between physician acupuncturists and other licensed acupuncturists. There is variability between states on the requirements.

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

None.

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

Has the agency promulgated all regulations required by recent legislation?  Yes  No

Provide explanations of the above responses, as needed:

There are no policy statements, guidelines, or standards being applied, nor is there any recent legislation that requires the promulgation of regulations.

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

✓ no action

Summary:

COMAR 10.32.15 continue to be effective in accomplishing the intended purpose and the Board recommends that no action is needed at this time.

Person performing review: Wynee E. Hawk

Title: Manager, Policy & Legislation

**Regulatory Review and Evaluation Act  
Evaluation Report Form  
2012 – 2020**

Chapter Codification:

Chapter Name:

Authority:

Date Originally Adopted or Last Amended:

Purpose:

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

- (1) Do the regulations continue to be necessary for the public interest?  Yes  No
- (2) Do the regulations continue to be supported by statutory authority and judicial opinion?  Yes  No
- (3) Are the regulations obsolete or otherwise appropriate for amendment or repeal?  Yes  No
- (4) Are the regulations effective in accomplishing their intended purpose?  Yes  No

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

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

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

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

- (4) Provide summaries of:  
(a) all comments received from stakeholders, affected units, or the public; and  
(b) the adopting authority's responses to those comments.

No comments received.

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

None.

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

None found.

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

A declaratory ruling is a statutorily prescribed administrative procedure with respect an inquiry related to the manner in which the Board would apply a regulation, order or statute. There is variability among states in how these issues are decided, and the required process for the interested party and the agency.

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

None.

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

Has the agency promulgated all regulations required by recent legislation?  Yes  No

Provide explanations of the above responses, as needed:

There are no policy statements, guidelines, or standards being applied, nor is there any recent legislation that requires the promulgation of regulations.

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

✓ no action

Summary:

COMAR 10.32.16 continue to be effective in accomplishing the intended purpose and the Board recommends that no action is needed at this time.

Person performing review: Wynee E. Hawk

Title: Manager, Policy & Legislation

**Regulatory Review and Evaluation Act  
Evaluation Report Form  
2012 – 2020**

Chapter Codification:

Chapter Name:

Authority:

Date Originally Adopted or Last Amended:

Purpose:

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

- (1) Do the regulations continue to be necessary for the public interest?  Yes  No
- (2) Do the regulations continue to be supported by statutory authority and judicial opinion?  Yes  No
- (3) Are the regulations obsolete or otherwise appropriate for amendment or repeal?  Yes  No
- (4) Are the regulations effective in accomplishing their intended purpose?  Yes  No

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

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

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

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

- (4) Provide summaries of:  
(a) all comments received from stakeholders, affected units, or the public; and  
(b) the adopting authority's responses to those comments.

No comments received.

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

None.

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

None.

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

Sexual misconduct by physicians is an issue that affects all geographic jurisdictions, however, it is regulated by state medical boards versus the federal government. It is within each state medical board's responsibility to protect the public it serves. The Federation of State Medical Boards (FSMB) has compiled guidelines to provide a framework for discipline in dealing with sexual misconduct cases, including efforts to educate licensees. Additionally, the Board has reviewed other state regulations to evaluate the need to update language and terminology in the current Maryland regulations.

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

The Board's most recent Sunset Review in December 2016 was reviewed as it raised issues related to the Board's sexual misconduct reporting. Greater transparency and more specificity in reporting was recommended and ultimately included in the Sunset legislation that passed. The Board plans to evaluate the regulations, processes, and utilize the existing statutory authority in Health Occupations, §1-212, Md. Code Annotated to strengthen oversight and enhance transparency.

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

Has the agency promulgated all regulations required by recent legislation?  Yes  No

Provide explanations of the above responses, as needed:

There are no policy statements, guidelines, or standards being applied, nor is there any recent legislation that requires the promulgation of regulations.

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

✓ amendment

Summary:

The Board is planning to review and evaluate COMAR 10.32.17 in light of the 2016 Sunset recommendations for transparency, the FSMB guidelines, and a comparison to other states regulations. The current regulations have not been amended since enacted in 2000. The ongoing objective is to strengthen the Board's oversight of sexual misconduct cases to better serve the public.

Person performing review:

Wynee E. Hawk

Title:

Manager, Policy & Legislation

**Regulatory Review and Evaluation Act  
Evaluation Report Form  
2012 – 2020**

Chapter Codification:

Chapter Name:

Authority:

Date Originally Adopted or Last Amended:

Purpose:

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

- (1) Do the regulations continue to be necessary for the public interest?  Yes  No
- (2) Do the regulations continue to be supported by statutory authority and judicial opinion?  Yes  No
- (3) Are the regulations obsolete or otherwise appropriate for amendment or repeal?  Yes  No
- (4) Are the regulations effective in accomplishing their intended purpose?  Yes  No

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

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

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

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

- (4) Provide summaries of:  
(a) all comments received from stakeholders, affected units, or the public; and  
(b) the adopting authority's responses to those comments.

No comments received.

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

None.

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

None.

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

The provisions in the regulations are consistent with other state board disclosure regulations.

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

None.

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

Has the agency promulgated all regulations required by recent legislation?  Yes  No

Provide explanations of the above responses, as needed:

There are no policy statements, guidelines, or standards being applied, nor is there any recent legislation that requires the promulgation of regulations.

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

✓ no action

Summary:

COMAR 10.32.18 continue to be effective in accomplishing the intended purpose and no action is recommended.

Person performing review: Wynee E. Hawk

Title: Manager, Policy & Legislation

**Regulatory Review and Evaluation Act  
Evaluation Report Form  
2012 – 2020**

Chapter Codification:

Chapter Name:

Authority:

Date Originally Adopted or Last Amended:

Purpose:

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

- (1) Do the regulations continue to be necessary for the public interest?  Yes  No
- (2) Do the regulations continue to be supported by statutory authority and judicial opinion?  Yes  No
- (3) Are the regulations obsolete or otherwise appropriate for amendment or repeal?  Yes  No
- (4) Are the regulations effective in accomplishing their intended purpose?  Yes  No

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

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

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

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

(4) Provide summaries of:  
(a) all comments received from stakeholders, affected units, or the public; and

(b) the adopting authority's responses to those comments.

(a) MPhA- The language related to the English Competency exam needs to be updated to comply with 2016 HB 117.

(b) The Board acknowledges that the referenced chapter be amended, specifically, amending COMAR 10.34.02.03 D. Proof of Proficiency in English. The Board at a previous meeting approved to amend this section. This amendment was printed as a proposal in the March 31, 2017 Maryland Register and was adopted in the June 23, 2017 Md.R. with an effective date of July 3, 2017.

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

No interunit conflict was reported.

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

No relevant data was found.

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

There are no corresponding regulations under the federal regulations. Checked surrounding states and found no significant differences.

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

No other relevant information was gathered.

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

Has the agency promulgated all regulations required by recent legislation?  Yes  No

Provide explanations of the above responses, as needed:

HB 227 and SB 469 was enacted into law under Chapters 475 and 476 of the 2016 Legislative Session which required Pharmacy license applicants, graduate from a English-speaking professional school accredited by the Accreditation Council for Pharmacy Education as acceptable proof of proficiency in the oral communication of the English language. This amendment was printed as a proposal in the March 31, 2017 Maryland Register and was adopted in the June 23, 2017 Maryland Register with an effective date of July 3, 2017.

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

X no action

Summary:

The Board reviewed and discussed the need for regulatory review at its September 21, 2016 public Board meeting. After the proposed review was posted in the Maryland Register, one comment was received. The Board voted on the approved response at its December 21, 2016 public Board meeting and, as a result the proposal as discussed in §B(4) and §C was subsequently adopted and is currently in effect.

Person performing review:

Brian K. Logan

Title:

Legislative Liaison

**Regulatory Review and Evaluation Act  
Evaluation Report Form  
2012 – 2020**

Chapter Codification:

Chapter Name:

Authority:

Date Originally Adopted or Last Amended:

Purpose:

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

- (1) Do the regulations continue to be necessary for the public interest?  Yes  No
- (2) Do the regulations continue to be supported by statutory authority and judicial opinion?  Yes  No
- (3) Are the regulations obsolete or otherwise appropriate for amendment or repeal?  Yes  No
- (4) Are the regulations effective in accomplishing their intended purpose?  Yes  No

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

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

Maryland Pharmacy Association, all licensees, registrants and permit holders, notice placed on Board's web site August 22, 2016.

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

No other agencies were affected.

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

Email blast sent to all licensees, registrants and permit holders, notice placed on Board's web site August 22, 2016. Published in the October 14, 2016 Maryland Register.

- (4) Provide summaries of:  
(a) all comments received from stakeholders, affected units, or the public; and  
(b) the adopting authority's responses to those comments.

(a) CVS- need language to address transfer of new or unfilled prescription, clarity of what method of communication, address a valid new/unfilled prescription and the date the prescription was first filled.  
(b) The Board is satisfied with the current language of this section.

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

There was no interunit conflict.

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

No relevant data was found.

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

There are no corresponding regulations under the federal regulations. Checked surrounding States and found no significant differences.

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

No other relevant information was gathered.

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

Has the agency promulgated all regulations required by recent legislation?  Yes  No

Provide explanations of the above responses, as needed:

The Board currently does not have any existing policy statements, guidelines or standards which should be promulgated into regulations at this time.

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

X no action

Summary:

In response to the questions presented by CVS, the Board is satisfied with the current language of this chapter which the Board voted on at the December 21, 2016 public Board Meeting. Therefore, the Board recommends no action regarding this chapter at this time.

Person performing review:

Brian K. Logan

Title:

Legislative Liaison

**Regulatory Review and Evaluation Act  
Evaluation Report Form  
2012 – 2020**

Chapter Codification:

Chapter Name:

Authority:

Date Originally Adopted or Last Amended:

Purpose:

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

- (1) Do the regulations continue to be necessary for the public interest?  Yes  No
- (2) Do the regulations continue to be supported by statutory authority and judicial opinion?  Yes  No
- (3) Are the regulations obsolete or otherwise appropriate for amendment or repeal?  Yes  No
- (4) Are the regulations effective in accomplishing their intended purpose?  Yes  No

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

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

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

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

- (4) Provide summaries of:  
(a) all comments received from stakeholders, affected units, or the public; and  
(b) the adopting authority's responses to those comments.

No comments were received regarding this chapter.

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

There was no interunit conflict.

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

No relevant data was found.

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

There are no corresponding regulations under the federal regulations. Checked surrounding States but could find no corresponding regulations concerning portable drug kits in Home Health Care Settings.

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

No other relevant information was gathered.

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

Has the agency promulgated all regulations required by recent legislation?  Yes  No

Provide explanations of the above responses, as needed:

The Board currently does not have existing policy statements, guidelines or standards which should be promulgated into regulations at this time.

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

X no action

Summary:

There were no comments received regarding this chapter. In addition, the Board did review the chapter and determined that no changes were required at this time.

Person performing review: Brian K. Logan

Title: Legislative Liaison

**Regulatory Review and Evaluation Act  
Evaluation Report Form  
2012 – 2020**

Chapter Codification:

Chapter Name:

Authority:

Date Originally Adopted or Last Amended:

Purpose:

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

- (1) Do the regulations continue to be necessary for the public interest?  Yes  No
- (2) Do the regulations continue to be supported by statutory authority and judicial opinion?  Yes  No
- (3) Are the regulations obsolete or otherwise appropriate for amendment or repeal?  Yes  No
- (4) Are the regulations effective in accomplishing their intended purpose?  Yes  No

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

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

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

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

- (4) Provide summaries of:  
(a) all comments received from stakeholders, affected units, or the public; and  
(b) the adopting authority's responses to those comments.

(a) MPhA-COMAR 10.34.24.04B - Record of Drug Inventory Acquisition – This section could use clarification, specifically related to the term "replaced." Is this an acquisition that is replaced by the distributor or returned to the distributor?

(b) The Board is reviewing the regulatory history regarding the use of the term "replaced" and will consider its use.

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

There were no interunit conflict.

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

No relevant data was found.

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

There are no corresponding regulations under the federal regulations. Checked surrounding States but could not find any regulation that were more stringent.

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

No other relevant information was gathered.

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

Has the agency promulgated all regulations required by recent legislation?  Yes  No

Provide explanations of the above responses, as needed:

The Board currently does not have any existing policy statements, guidelines or standards which should be promulgated into regulations at this time.

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

X no action

Summary:

There was one comment received regarding this chapter. The Board did review the comment at the December 21, 2016 public Board meeting and voted to consider the use of the term "replaced" after researching the history and intent of the regulations. Therefore the Board recommends no action at this time.

Person performing review:

Brian K. Logan

Title:

Legislative Liaison

**Regulatory Review and Evaluation Act  
Evaluation Report Form  
2012 – 2020**

Chapter Codification:

Chapter Name:

Authority:

Date Originally Adopted or Last Amended:

Purpose:

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

- (1) Do the regulations continue to be necessary for the public interest?  Yes  No
- (2) Do the regulations continue to be supported by statutory authority and judicial opinion?  Yes  No
- (3) Are the regulations obsolete or otherwise appropriate for amendment or repeal?  Yes  No
- (4) Are the regulations effective in accomplishing their intended purpose?  Yes  No

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

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

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

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

- (4) Provide summaries of:  
(a) all comments received from stakeholders, affected units, or the public; and  
(b) the adopting authority's responses to those comments.

No comments were received.

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

There was no interunit conflict.

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

No relevant data was found.

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

There is the Food and Drug Administration Safety and Innovation Act (FDASIA) which addresses continual safety improvement.

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

No other relevant information was gathered.

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

Has the agency promulgated all regulations required by recent legislation?  Yes  No

Provide explanations of the above responses, as needed:

The Board currently does not have any existing policy statements, guidelines or standards which should be promulgated into regulations at this time.

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

X no action

Summary:

There were no comments received regarding this chapter. In addition, the Board did review the chapter at the September 21, 2016 public Board meeting and determined that no changes were required.

Person performing review: Brian K. Logan

Title: Legislative Liaison

**Regulatory Review and Evaluation Act  
Evaluation Report Form  
2012 – 2020**

Chapter Codification:

Chapter Name:

Authority:

Date Originally Adopted or Last Amended:

Purpose:

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(4) Provide summaries of:  
(a) all comments received from stakeholders, affected units, or the public; and

(b) the adopting authority's responses to those comments.

No comments were received.

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

There was no interunit conflict.

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

No relevant data was found.

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

No relevant information has been gathered from other states or the federal government.

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

No other relevant information was gathered.

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

Has the agency promulgated all regulations required by recent legislation?  Yes  No

Provide explanations of the above responses, as needed:

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X no action

Summary:

There were no comments received regarding this chapter. In addition, the Board did review the chapter at the September 21, 2016 public Board meeting and determined that no changes were required.

Person performing review:

Brian K. Logan

Title:

Legislative Liaison

**Evaluation Report Form  
2012 – 2020**

Chapter Codification:

Chapter Name:

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Date Originally Adopted or Last Amended:

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- (4) Provide summaries of:  
(a) all comments received from stakeholders, affected units, or the public; and  
(b) the adopting authority's responses to those comments.

No comments were received.

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

There was no interunit conflict.

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

No relevant data was found.

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

There is no relevant information gathered from other states or the federal government.

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

No other relevant information was gathered.

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

Has the agency promulgated all regulations required by recent legislation?  Yes  No

Provide explanations of the above responses, as needed:

The Board currently does not have any existing policy statements, guidelines or standards which should be promulgated into regulations at this time.

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

X no action

Summary:

There were no comments received regarding this chapter. In addition, the Board did review the chapter at the September 21, 2016 public Board meeting and determined that no changes were required.

Person performing review: Brian K. Logan

Title: Legislative Liaison