APRIL 1, 2008

REGULATORY REVIEW AND EVALUATION ACT

EVALUATION REPORTS FOR:

Subtitle 10 LABORATORIES
Subtitle 11 MATERNAL AND CHILD HEALTH
Subtitle 12 ADULT HEALTH
Subtitle 13 DRUGS
Subtitle 14 CANCER CONTROL
Subtitle 50 TISSUE BANKS

SUBMITTED BY:

Department of Health and Mental Hygiene
Office of Regulation & Policy Coordination
201 W. Preston Street, Room 512
Baltimore, Maryland 21201
Phone: (410) 767-6499
Email: regs @dhmh.state.md.us

EXEMPTIONS

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

Subtitle 10 LABORATORIES
10.10.01 General (C.A.: 12-13-99)
10.10.02 Medical Laboratories—General (IA: 12-13-99)
10.10.03 Medical Laboratories—Licenses (IA: 12-13-99)
10.10.04 Medical Laboratories—Fees (IA: 12-13-99)
10.10.05 Medical Laboratories—Proficiency Testing (IA: 12-13-99)
10.10.06 Medical Laboratories—Quality Assurance (IA: 12-13-99)
10.10.07 Medical Laboratories—Personnel (IA: 12-13-99)
10.10.08 Medical Laboratories—Sanctions (IA: 12-13-99)
10.10.09 Law Enforcement Laboratories—Personnel Certification & Approval of Laboratory Procedures (IA: 12-13-99)
10.10.10 Job-Related Alcohol and Controlled Dangerous Substances Testing (IA: 12-13-99)
10.10.11 Biological Agents Registry Program (CA 7-31-06)
10.10.12 Medical Laboratories—Public Health HIV Testing Programs (IA: 3-14-05)

Subtitle 11 MATERNAL AND CHILD HEALTH
10.11.03 Children's Medical Services Program (Will be CA by Late Spring 2007)
10.11.04 Lead Poisoning Screening Program (IA: 5-12-03)

Subtitle 12 ADULT HEALTH
10.12.02 Rape and Sexual Offenses—Physician and Hospital Charges (CA: 7-5-04)
10.12.04 Day Care for the Elderly and Medically Handicapped Adults (CA: 11-13-06)

Subtitle 13 DRUGS
10.13.08 Sale of Needles and Syringes or Other Paraphernalia (CA: 3-6-00)
10.13.12 Impoundment and Disposal of Drugs and Prescription Records (IA: 6-24-02)

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

Subtitle 50 TISSUE BANKS
10.50.01 Tissue Banks (CA: 3-15-04)

CHAPTERS THAT HAVE BEEN REPEALED

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

Subtitle 12 ADULT HEALTH
10.12.01 Abortion Referral Services
10.12.03 Expanded Maternity Plan

Subtitle 13 DRUGS
10.13.02 Retail Sales or Use of Hydrocyanic Acid and its Salts, Compounds, and Preparations
10.13.03 Sale of Sodium Fluoride or Hydrofluoric Acid Preparations for Use as Insecticides
10.13.04 Labeling of Prescriptions for Drugs (Other Than Narcotic Drugs) That May be Dispensed Only on Prescription
10.13.06 Acceptance of Oral Prescriptions for Certain Narcotic Drugs
10.13.07 Sale of Dihydrocodeinone or any of its Salts
10.13.09 Sale of Nitrous Oxide
10.13.10 Prescribing, Administering, and Dispensing of Amphetamines and Methamphetamines

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Chapter Codification: 10.11.01

Chapter Name: Identification of Infants

Authority: Health-General Article, § 2-104(b), 20-401, and 20-402, Annotated Code of Maryland

Date Originally Adopted or Last Amended: December 25. 1989

Purpose: These regulations specify the types of procedures to identify a newborn infant to be used by all institutions or related facilities with obstetrical services. The regulations also specify the information that must be included in each identification procedure and requirements for verification that the identification procedure was performed.

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

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

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

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

(4) Are the regulations effective in accomplishing their intended purpose? [X] Yes [ ] No

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

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

Representatives from the American Academy of Pediatrics, the Obstetrical & Gynecologic Society of Maryland, and the American College of Obstetricians and Gynecologists were invited to comment on the regulations. No comments were received.

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

Representatives from the Family Health Administration's Office for Genetics and Children with Special Health Care Needs, the Maryland Hospital Association, the Office of the Attorney General, the State Laboratory Administration, and the local health departments were invited to comment on the regulations. No comments were received.

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

Comments from the public were solicited by publishing a public notice in the Maryland Register. The comment period ended March 15, 2007.

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

No comments were received.

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

None

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

The American Academy of Pediatrics and the American College of Obstetricians and Gynecologists recommend placing matching wrist / ankle bands with a unique identifier on mother and infant in the delivery room immediately after birth as the primary procedure for infant identification (*Guidelines for Perinatal Care, 6th edition, 2007*). This same practice is also recommended as the first step to be taken to assure infant identification by the National Center for Missing and Exploited Children (*For Healthcare Professionals: Guidelines on Prevention of and Response to Infant Abductions, 8th edition, 2005*), supported by the Association of Women's Health, Obstetric and Neonatal Nurses; the National Association of Neonatal Nurses; the Academy of Neonatal Nursing; and the International Association for Healthcare Security and Safety. Secure banding of mother and infant is also recommended by the Joint Commission (*Sentinel Event Alert, Issue 9, 1999*). This practice is not currently included in Maryland regulation.

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

There are no relevant federal regulations. State statutes found that address infant identification or prevention of infant abduction include the measures currently outlined in Maryland regulation. Some include additional security measures to prevent infant abduction.

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

An informal survey of Maryland birthing hospitals revealed that placement of secure numbered bands on both mother and infant in the delivery room is the standard practice for infant identification in Maryland. This is not reflected in the current regulation.

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

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

Provide explanations of the above responses, as needed:

N/A

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

no action

amendment **X**

repeal

repeal and adopt new regulations

reorganization

Summary:

It is recommended that these regulations be amended to reflect the recommendations of professional and regulatory organizations, as well as the common practice within the State, and to incorporate a primary recommendation that secure banding of mother and infant be done in the delivery room immediately after birth.

Person performing review: Dr. S. Lee Woods

Title: Medical Director
CMCH
FHA

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Chapter Codification: 10.11.02

Chapter Name: Program for Hearing-Impaired Infants

Authority: Health-General Article, §§ 13-601--13-605, Annotated Code of Maryland

Date Originally Adopted or Last Amended: January 20, 1992

Purpose: The Chapter provides guidelines and procedures for implementing the Program for Hearing Impaired Infants in order to facilitate the early identification and follow-up of hearing impaired infants and infants who are at risk of developing a hearing impairment. The chapter also specifics the responsibilities of the Advisory Council for Hearing-Impaired Infants which provides consultation and support to the Program.

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

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

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

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

(4) Are the regulations effective in accomplishing their intended purpose? [ ] Yes [X] No

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

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

Representatives from the Maryland Speech and Hearing Association, Maryland Academy of Audiology, A.G. Bell Association, Maryland Academy of Pediatrics, Maryland School for the Deaf, Maryland State Department of Education, Maryland Coalition of the Deaf and Hard of Hearing, Maryland Association of the Deaf, Maryland Society of Otolaryngology, and the Universal Newborn Hearing Screening Advisory Council were invited to comment on these regulations. Their comments are detailed below.

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

Representatives from the Family Health Administration, the Maryland Hospital Association, the Office of the Attorney General, and the local health departments were invited to comment on the regulations.

(3) Describe the process used to solicit public comment, including:

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

Comments from the public were solicited by publishing a public notice in the Maryland Register. The comment period ended March 16, 2007.

(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.

Two groups commented. The Maryland School for the Deaf suggested changing the wording in the purpose section to eliminate the potentially offensive term "debilitating effects of hearing loss." They also wanted to add "Maryland School for the Deaf" to various places throughout the regulations, including defining it in the definition section. They also recommended changing "TDD" to "tty."

The other group to comment was the Advisory Council for the Universal Newborn Hearing Screening Program. They advised making various changes that would update the regulations, including updating colloquial terms; updating the names of certain programs and offices; eliminating the High Risk Questionnaire requirement and replacing it with a Departmental reporting form; and adding a reporting requirement that certain data collected by the Department would be reported quarterly to the Advisory Council.

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

In response to eliminating the term "debilitating effects of hearing loss," the Department agrees that term should be removed and plans to do so while updating other archaic language. Likewise, "TDD" will be changed to "tty." The regulations will not specifically add "Maryland School for the Deaf" however, as Regulation .06E already addresses "existing State and local education agency programs" which would include the Maryland School for the Deaf.

In response to the changes suggested by the Advisory Council for the Universal Newborn Hearing Screening Program, all of their changes will be made with the exception of adding the reporting requirement. This change will not be made because this data is reported annually to the National Center for Hearing Assessment and Management (NCHAM) and the Directors of Speech and Hearing Programs in State Health and Welfare Agencies (DSHPSHWA) and shared with the Advisory Council on an annual basis. Annual reporting is more appropriate for a condition in which the diagnostic cascade is at least three months long and the target age for intervention is six months.

(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.

In March 1993, the NIH Consensus Development Conference recommended that all babies be screened for hearing loss before being discharged from the hospital. At that time, only two states, Hawaii and Rhode Island, had legislative mandates, passed in 1990 and 1992 respectively, requiring newborn hearing screening for all babies born in the state. As an increasing number of newborn hearing screening programs were implemented and policy makers and the public became more aware of the benefits associated with such programs, legislative actions increased. Now there are 37 states (plus the District of Columbia and Puerto Rico) with statutes related to universal newborn hearing screening. Only 22 of 37 statutes (59%) require screening of all babies. Twenty-four of 37 statutes (65%) require hospitals to report data from newborn hearing screening to the State Department of Health, thus underscoring the intent of making newborn hearing screening a public health program.

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

N/A

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

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

Provide explanations of the above responses, as needed:

N/A

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

no action

amendment X

repeal

repeal and adopt new regulations

reorganization

Summary:

These regulations will be amended primarily to update what is now to considered archaic language. Certain procedures also need to be updated to reflect current practices, including screening and diagnostic practices as recommended in the 2007 Joint Committee on Infant Hearing position statement, and upgraded reporting procedures. Further, high-risk registries are no longer used, and therefore language referring to the High Risk Questionnaire in Regulation .05 and references which follow, will be deleted. Additionally, regulations regarding the Advisory Council for Hearing Impaired Infants need to be amended to outline length of terms, and appropriate meeting and reporting responsibilities.

Person performing review: Dr. Susan Panny

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

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Chapter Codification: 10.12.05

Chapter Name: Breast Implantation

Authority: Health-General Article, § 20-114, Annotated Code of Maryland

Date Originally Adopted or Last Amended: September 3, 1990

Purpose: This chapter requires the Department of Health and Mental Hygiene to provide and distribute a written summary that contains information and cautions on breast implantation. The chapter also describes the requirements of physicians to provide this summary to patients receiving breast implants.

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

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

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

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

(4) Are the regulations effective in accomplishing their intended purpose? [X] Yes [ ] No

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

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

Representatives from Breast Cancer Awareness, Cumberland Valley, Arm in Arm, Anne Arundel Medical Center, Cancer Information Service, Women Supporting Women, Sisters Network, and The Center for Women's Health & Medicine at Mercy Hospital were invited to comment on the regulations. No comments were received.

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

Representatives from the Family Health Administration, the Maryland Hospital Association, the Office of the Attorney General, and the local health departments were invited to comment on the regulations. No comments were received.

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

(e) any public hearing held.

Comments from the public were solicited by publishing a public notice in the Maryland Register. The comment period ended March 1, 2007.

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

No comments were received.

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

None

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

N/A

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

The Federal Food and Drug Administration requires manufacturers of breast implants to: "Distribute approved patient labeling to women considering silicone gel-filled implants as part of a formal informed decision process, and monitor the process to ensure that patients are being informed of the risks and benefits."

Illinois requests that a standardized written summary outlining methods for the early detection and diagnosis of breast cancer be provided to all women having breast augmentation surgery. The summary shall contain information on breast reconstructive surgery, including, but not limited to, the use of breast implants and their side effects. Illinois uses the "Informed Consent-Augmentation Mammaplasty" resource book from the American Society of Plastic Surgeons.

Massachusetts requires that except in the cases of emergency surgery, any facility providing breast implants must inform the patients of the disadvantages and risks associated with breast implantation at least 10 days before the physician operates. The information shall include, but not be limited to, the standardized written statement provided by the Department of Health. The patient shall sign a statement acknowledging receipt of the standardized summary. Additionally the Department of Health shall: 1) develop a standardized written summary; 2) update the summary as necessary; 3) distribute the written summary to each facility that performs implants; and 4) provide the physician inserting the breast implant with a statement to be signed by the patient acknowledging receipt of the standardized written summary.

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

N/A

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

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

Provide explanations of the above responses, as needed:

N/A

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

no action **X**

amendment

repeal

repeal and adopt new regulations

reorganization

Summary:

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

Person performing review: Donna Gugel

Title: Acting Director, Center for Cancer Surveillance & Control

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Chapter Codification: COMAR 10.13.01

Chapter Name: Dispensing of Prescription Drugs by a Licensee

Authority: Health Occupations Article, §12-102, Annotated Code of Maryland

Date Originally Adopted or Last Amended: March 6, 2000

Purpose: The purpose of this chapter is to define the parameters under which a licensed dentist, physician or podiatrist may dispense prescription drugs in accordance with Health Occupations Article, § 12-102, Annotated Code of Maryland.

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

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

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

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

(4) Are the regulations effective in accomplishing their intended purpose? [X] Yes [ ] No

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

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

Licensees of the Board of Pharmacy, Board of Dental Examiners, Board of Physicians and Board of Podiatric Medical Examiners
The public through publication in the Maryland Register
4 comments received from pharmacists and associations

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

The Board of Dental Examiners
The Board of Podiatric Medical Examiners
The Board of Physicians

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

A notice was published in 34:9 Md.R. 822 (April 27, 2007)
A notice was published on the MD Board of Pharmacy website on April 23, 2007 -
A notice was published in the MD Board of Pharmacy Newsletter Spring 2007 Edition
A notice was submitted to the Board of Physicians, the Board of Dental Examiners and the Board of Podiatric Medical Examination for posting on their websites and in their newsletter. As of April 17, 2007 all three Boards responded that they received the notice.

(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)
1) Comment submitted by Chandra Mouli, Deputy Chief, Division of Drug Control
Mr. Mouli suggests adding that a permit be issued only pursuant to an inspection by the Division of Drug Control to ensure that the applicant has provided effective controls and procedures to guard against theft and unlawful diversion of prescription drugs and controlled dangerous substances.

2) Comment submitted by Michael Souranis, Pharmacist
i) Recommends amending the regulation so that when a licensed pharmacy is available or physically located within the same facility or premises, practitioner licensee dispensing will be limited to dispensing samples without charge;

ii) Recommends amending the regulation to prohibit practitioner dispensing permits if a pharmacy is located within 5 miles of the practitioner licensee;
iii) Recommends amending the regulation so that the Board of Pharmacy is notified when a dispensing permit is issued to a practitioner licensee;
iv) Concerns regarding the lack of inspections for licensee dispensers;
v) Concerns regarding the ambiguity of the definition of "public interest" and the factors to be determined solely in the discretion of the patient concerning whether a pharmacy is conveniently located for the patient;
vi) Concerns regarding the lack of tracking dispensing practices of physicians; and
vii) Concerned that current regulations do not include: procedural requirements regarding storage, security of drug inventory, over prescribing, dispensing expired drugs, diversion, refills, ancillary personnel dispensing, repackaging, child-resistant packaging, biennial inventories maintained, drug recalls, lack of pharmacy choice, reporting of medication errors, limited inventory for drug selection and conflicts of interest.

3) Comment submitted by Howard Schiff, Executive Director, Maryland Pharmacists Association (MPhA)
The MPhA has concerns that dispensing physicians have never been inspected by the Division of Drug Control. The suggestion of MPhA is to rewrite the regulation with more specific requirements for 10.13.01.04J which allows a licensee to dispense prescription drugs to a patient only when a pharmacy is not conveniently available to the patient. The section places the decision whether a pharmacy is conveniently available to the patient based upon factors to be determined solely in the discretion of the patient.

The MPhA also recommends a more vigorous enforcement of 10.13.01.04K and L. .04K requires a form in each patient's chart indicating that a pharmacy is not conveniently available to the patient; states that the determination that a pharmacy is not conveniently available was made solely by the patient; and is signed and dated by the patient before dispensing prescription drugs to the patient for the first time. .04L requires the licensee to display prominently a sign which informs the patient that prescription drugs can be purchased from the permit holder if the patient determines that a pharmacy in not conveniently available to the patient.

4) Comment submitted by the National Association of Boards of Pharmacy
NABP understands and supports the proposed intent of the regulation to increase and improve the access to medications for patients in rural areas where pharmacist and pharmacy services may not be readily available. However, information which NABP received from other states regarding similar initiatives and regulations indicates that the desired outcome of increasing access and resolving a mal-distribution of pharmacist care and pharmacy services were not achieved when such regulations were adopted and implemented in other states. Instead, licensees other than pharmacists empowered to engage in dispensing activities remained concentrated in urban areas where their present practice sites and patients were based and there exists well documented access to pharmacist care and pharmacy services.

NABP and its member state boards of pharmacy feel strongly that allowing the dispensing of medications by licensees other than pharmacists, absent the requirements in place for pharmacists and the practice of pharmacy, poses a significant risk to the safety of the patient. Similarly, allowing the dispensing of medications pursuant to this regulation when pharmacist and pharmacy services are readily available and duly sanctioned and regulated by the State of Maryland inappropriately applies the regulation and again places patients in unnecessary jeopardy.

Based on the above NABP noted through resolution that the NABP opposes the dispensing of medications by practitioners other than pharmacists except when the dispensers comply with all applicable federal and state recordkeeping, packaging, labeling, and patient care requirements.

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

The Board responded by sending identical responses to Chandra Mouli, Deputy Chief, Division of Drug Control; Michael Souranis, Pharmacist; Howard Schiff, Executive Director, Maryland Pharmacists Association (MPhA); and the National Association of Boards of Pharmacy. The response summarized the four comments received and indicated that the Board would form a subcommittee to address their concerns. The text of the responses is as follows (NOTE: Original copies can be obtained upon request):

"Thank you for submitting comments to the Maryland Board of Pharmacy (the "Board") regarding COMAR 10.13.01 Dispensing of Prescription Drugs by a Licensee. The Board is currently reviewing and evaluating COMAR 10.13.01 in accordance with the Regulatory Review and Evaluation Act, State Government Article, §§10-130—10-139, Annotated Code of Maryland.

The Board received comments that focused on two topic areas. The first topic area concerned enforcement of the current regulations. Although the regulations allow for the Division of Drug Control to enter and inspect the licensee's office at all reasonable hours, no inspections have ever taken place. If a dispensing licensee is obtaining, storing and dispensing prescription medications, they should be held to the same standards as a licensed pharmacy. Additionally the regulations require that the dispensing licensee maintain a single form in

each patient's chart that indicates that a pharmacy is not conveniently available to the patient; that the determination that a pharmacy in not conveniently available was made solely by the patient; and be signed and dated by the patient before dispensing prescription drugs to the patient for the first time. Finally a dispensing licensee should display prominently a sign which informs patients that prescription drugs can be purchased from the permit holder if patients determine that a pharmacy is not conveniently available to the patient. The comments emphasized that since there have been no inspections of dispensing licensees, there is no way to know if there has been compliance with these requirements.

The second topic area concerned revisions to the current regulations that address patient safety and the juxtaposition of pharmacies and dispensing licensees. The suggested revisions include:

- Add a section to the regulations that requires an inspection of the dispensing licensee's office as a condition for obtaining a dispensing permit;
- Clearly define the term "conveniently available to the patient" since that is the condition for a dispensing licensee to dispense;
- Amend the regulations so that when a licensed pharmacy is physically located within the same facility or premises, the practitioner licensee dispensing will be limited to samples;
- Amend the regulations to prohibit dispensing permits for a practitioner licensee if a pharmacy is located within 5 miles of the practitioner licensee;
- Amend the regulations to address the large number of dispensing permits issued to practitioner licensees in urban areas where numerous pharmacies are also located;
- Amend the regulation so that the Board is notified when a dispensing permit is issued to a practitioner licensee; and
- Amend the regulations to include procedural requirements regarding storage, security of drug inventory, over prescribing, dispensing expired drugs, diversion, refills, ancillary personnel dispensing, repackaging, child-resistant packaging, maintenance of biennial inventories, drug recalls, reporting of medication errors, limited inventory for drug selection and conflicts of interest.

The Board would like to thank you again for submitting comments regarding COMAR 10.13.01 Dispensing of Prescription Drugs by a Licensee, pursuant to the Regulatory Review and Evaluation Act. As a result of the comments received, the Board will form a subcommittee to consider comments and recommend any necessary revisions to address enforcement and patient safety issues.

Should you have questions or additional concerns, please feel free to contact Anna D. Jeffers, Legislation and Regulations Manager at (410) 764-4794.

Sincerely,
LaVerne G. Naesea
Executive Director"

(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.

The Maryland Board of Physicians Drug Dispensing Permit List as of December 5, 2007 is 871 physicians. Most of the physicians listed are in zip-code areas where pharmacies are also located.

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

The National Association of Boards of Pharmacy publishes an annual Survey of Pharmacy Law and includes in their survey the health care practitioners with dispensing authority in the United States and U.S. Territories. Of those 53 jurisdictions, only one, Puerto Rico, restricts all dispensing to a pharmacist. Twelve jurisdictions, including Maryland, place restrictions on physicians, podiatrists and dentists who dispense. Utah allows only physicians, podiatrists and dentists to dispense samples. Several states, Maryland, Michigan, Missouri and Ohio, restrict dispensing by a physician, podiatrist or dentist to their own patients. Texas severely restricts dispensing by health care practitioners, except for veterinarians. North Carolina, North Dakota and Virginia do not allow dispensing by a podiatrist. North Carolina and North Dakota prohibit dispensing by a dentist.
The survey indicates that roughly 24% of the jurisdictions have placed some restrictions on dispensing by a physician, podiatrist or dentist.

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

A report, Physician Drug Dispensing, An Overview of State Regulation, prepared by the Office of the Inspector General, Office of Analysis and Inspections, at the U.S. Department of Health and Human Services made three recommendations regarding physician dispensing:
1) State Governments should take initiatives to promote stronger, more effective regulation of physician dispensing;
2) State Governments should take steps to strengthen their enforcement of regulation governing physician dispensing; and
3) The Federation of State Medical Boards and the National Association of Boards of Pharmacy should work together in helping states to promote stronger, more effective regulation governing physician dispensing. oig.hhs.gov/oei/reports/oai-01-88-00590.pdf

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 [X]

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

Provide explanations of the above responses, as needed:

COMAR 10.34.33 Prescription Drug Repository Program, Effective January 29, 2007, pursuant to SB 1059, Prescription Drug Repository Program, 2006
COMAR 10.34.34 Pharmacy Technicians, Effective January 28, 2008, pursuant to SB 371, State Board of Pharmacy - Registration of Pharmacy Technicians, 2006
COMAR 10.34.22 Licensing of Wholesale Prescription Drug or Device Distributors, Proposal Published February 1, 2008, pursuant to SB 759, Wholesale Distribution Permitting and Prescription Drug Integrity Act, 2007.

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

no action

√ amendment

repeal

repeal and adopt new regulations

reorganization

Summary:

The Board received comments that focused on two topic areas. The first topic area concerned enforcement of the current regulations. The second topic area concerned revisions to the current regulations that address patient safety and the juxtaposition of the locations of pharmacies and dispensing licensees. As a result of the comments received, the Board will form a subcommittee to consider comments and recommend any necessary revisions.

Person performing review: Anna D. Jeffers

Title: Legislation and Regulations Manager, Maryland Board of Pharmacy

Regulatory Review and Evaluation Act
Evaluation Report Form
2003 – 2011

Chapter Codification: COMAR 10.13.05

Chapter Name: AIDS Education Program for Persons Convicted of Drug/Sex Related Crimes

Authority: Health General Article, §18-339; Criminal Law Article §5-906

Date Originally Adopted or Last Amended: January 12, 2001

Purpose: Enumerate responsibilities of DHMH, local health departments, contractors, and persons sentenced by the judiciary to attend the education program about HIV/AIDS.

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

(1) Do the regulations continue to be necessary for the public interest? ☐ Yes ☒ No

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

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

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

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

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

Requests were made of the Judiciary to confirm that the number referrals to the program, the alternatives to the program, and their opinion of the program. There were no other stakeholders affected by 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.

Requests were made of the Judiciary to confirm that the number referrals to the program, the alternatives to the program, and their opinion of the program. There were no other agencies affected by the regulations.

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

None

(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.

No potential conflict was identified.

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

The program has never been scientifically evaluated.

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

Other states integrate the prevention aspects of the program into a comprehensive Drug Court curriculum.

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

No other relevant information was obtained.

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

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

Provide explanations of the above responses, as needed:

Maryland law continues to permit judges to sentence persons to attend and to mandate that DHMH conduct the program. However, a participant has not been referred to the program in at least three years. Additionally, the funding for the program does not exist within the Department's current budget. Furthermore, alternative programs have been developed within the State that provide comprehensive services, including HIV prevention (e.g., Drug Court).

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

X no action

amendment

repeal

repeal and adopt new regulations

reorganization

Summary:

The Agency believes that this regulation is necessary given the presence of the statute authorizing the program. However, the Judiciary is not utilizing the program.

Person performing review: William Honablew

Title: AIDS Administration

Regulatory Review and Evaluation Act
Evaluation Report Form
2003 – 2011

Chapter Codification:	COMAR 10.13.11
Chapter Name:	Exemption to Allow Sale of Drugs in Vending Machines
Authority:	Health-General Article §21-1111(c), Annotated Code of Maryland

Date Originally Adopted or Last Amended:

Originally adopted on September 15, 1994; Effective Date: October 10, 1994 (21:20 Md.R. 1732)

Purpose:

COMAR 10.13.11.01 allows the vending machine sale of non-prescription pain relievers by providing an exemption to the State's prohibition on the sale of any drug by use of a vending machine under Health-General Article §21-1111(b). The authority for the exemption is Health-General Article §21-1111(c), which allows the Secretary of Health and Mental Hygiene by regulation to exempt from the prohibition any commodity if the Secretary finds that the commodity may be dispensed by vending machine without danger to the public health.

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
(see recommended amendments at section D)

(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.

John Laura, BuyRite Vending Company, 800-690-1810
Doug Lang, Protocol, Inc., St. Paul, MN, 800-227-5336
Don Reckerman, Relief Services, Inc., Maryland, 410-398-7800
Managers of the following businesses where vending machines are located:
LaQuinta Inn and Suites at BWI, 1734 W. Nursery Road, Linthicum, MD 21090, 410-859-2333
Inn at the Colonnade, 4 W. University Parkway, Baltimore, MD 21218, 410-235-5400
Arundel Mills Mall, 7000 Arundel Mills Circle, Hanover, MD 21076, 410-540-5110

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

The Maryland Board of Pharmacy (the "Board") was invited to participate in the review of COMAR 10.13.11. The Board's Practice Committee reviewed this chapter and the Committee's comments and findings were subsequently approved by the full Board during its February 2008 meeting.

Describe the process used to solicit public comment:

Names and contact information for the businesses involved with vending machine drug sales were obtained directly from identification labels on vending machines located in Maryland, and were also researched and obtained from the internet.

(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.

There was universal agreement from all the stake-holders that the exemption provided by COMAR 10.13.11 regulation should be maintained. This regulatory exemption allowing for the vending machine sale of non-prescription pain relievers is useful for both the businesses that operate the vending machines, the businesses where the vending machines are located, and for Maryland consumers. We had direct contact with two national vending companies one from New York (BuyRite Vending), and another from Minnesota (Protocol, Inc.) that supply vending equipment to clients in many states, including Maryland. Over-the-counter drug vending machines provide easy and affordable access to a variety of medications. These vending machines are found identified as Fast-Aid Medical Center, Health-Aid center, MiniDrug, 'Lil' Drug Store, Medic-Aid Drug Store, etc. One such machine found in Maryland is called MediKwic Plus, and provides the automated sale of Advil®, Motrin® IB, Tylenol® products including Cold, PM, and Extra Strength. Comments were also solicited from the Maryland Board of Pharmacy, and it recommended broadening the current exemption to include more over-the-counter medications in addition to pain relievers. This would include products such as sinus and allergy medications, anti-diarrheals, anti-nausea and "heart-burn" medicines.

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

None

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

N/A

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

The U.S. Food and Drug Administration does not require human interaction in the sale of over-the-counter pain medications. The only federal vending machine enforcement is the age limit on the sale of nicotine products. Two states (Arizona and Oregon) actually regulate and require a license to sell non-prescription drugs with vending machines. Maryland remains in the clear majority of states that either exempt or simply do not regulate the sale of non-prescription drugs via a vending machine.

Without COMAR 10.13.11 Maryland would be more strict than any other state because Health-General Article §21-1111(b) prohibits the sale of any drug by means of a vending machine. However, Health-General Art. §21-1111(c) allows the Secretary of Health and Mental Hygiene (the "Secretary") to exempt from the prohibition any commodity if the Secretary finds that the commodity may be dispensed by vending machine without danger to the public health. It is COMAR 10.13.11.01 adopted by the Secretary that provides the exemption in Maryland to sell non-prescription drugs that alleviate pain by vending machine.

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

Background: The market place for non-prescription medicines commonly referred to as over-the-counter (OTC) drugs is national in scope and includes a wide variety of pain relievers and other medicines. The vending companies were found to be national distributors that have local owners who manage the vending machines and their individual vending routes. The placement of the OTC medicine vending machines is tailored such that operators can make a successful business out of this type of vending machine operation. These so-called automated sales sites are found free-standing and wall mounted in a variety of venues including shopping malls, gas stations, grocery stores, airport lobbies, beauty shops, convenience stores, and hotels. To ensure their success these machines are often placed in locations where there are no nearby twenty-four-hour drug stores, and thus provide consumers with a valuable service that can be very useful in an emergency.

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

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

Provide explanations of the above responses, as needed:

N/A

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

☐ no action

☒ amendment: It is recommended that the words "that alleviate pain" be removed from §§A and B of 10.13.11.01 which will allow additional OTC medicines to be sold via vending machine.

☐ repeal

☐ repeal and adopt new regulations

☐ reorganization

Summary:

COMAR 10.13.11 continues to be necessary for the public interest by providing a regulatory exemption that allows the sale of OTC pain relievers by vending machine. This chapter benefits both the businesses that operate the vending machines and the businesses where the vending machines are located, and Maryland consumers who find themselves in need of off-hour or convenient access to OTC medications. This chapter continues to be highly effective in accomplishing its purpose. However, over the past decade many additional OTC medications have become available to consumers such as sinus and allergy medications, and anti-diarrheal, anti-nausea and "heart-burn" medicines making this chapter ripe for amendment. These additional OTC medications can be made available for sale by vending machine by removing the words "that alleviate pain" from §§A and B of COMAR 10.13.11.01 as suggested by the Maryland Board of Pharmacy.

Person performing review:	Michael Wajda
Title:	Deputy Director for Administrative and Regulatory Programs

Regulatory Review and Evaluation Act
Evaluation Report Form
2003 – 2011

Chapter Codification: 10.14.03

Chapter Name: Breast Cancer Treatment Methods

Authority: Health-General Article, § 20-113, Annotated Code of Maryland

Date Originally Adopted or Last Amended: Last Amended January 20, 1992

Purpose:

This chapter requires the Department of Health and Mental Hygiene (DHMH) to provide and distribute a written summary that contains certain breast cancer-related information to all hospitals, clinics, other facilities, and physician's offices that perform breast cancer treatment. The information must describe: (1) effective methods of breast cancer treatment; and (2) the advantages, disadvantages, risks, and procedures associated with each treatment method. The chapter also describes the requirements of physicians to provide this written summary to patients diagnosed with breast cancer.

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

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

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

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

(4) Are the regulations effective in accomplishing their intended purpose? [X] Yes [ ] No

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

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

Representatives from Susan G. Komen Breast Cancer Foundation, American Cancer Society, Arm in Arm, Anne Arundel Medical Center, Men Against Breast Cancer, Nubian Women, Sinai Hospital, The Center for Women's Health & Medicine at Mercy Hospital, Chase Brexton Health Services, the Maryland Hospital Association, and the Hoffberger Breast Center were invited to comment on the regulations. One comment was received (described below in # (4)).

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

Representatives from the Family Health Administration, the Office of the Attorney General, and the local health departments were invited to comment on the regulations. No comments were received.

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

Comments from the public were solicited by publishing a public notice in the Maryland Register. The comment period ended March 1, 2007.

(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.

One comment was received from Hoffberger Breast Center, questioning the implementation of the distribution requirement. The Center employee questioned what the DHMH booklet was, and was concerned that the booklets were not actually being distributed.

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

It was clarified to the above stakeholder that while DHMH once authored its own booklet, the booklets now distributed by DHMH are "Breast Cancer Treatment Guidelines for Patients" (published by American Cancer Society and National Comprehensive Cancer Network), "What You Need to Know About Breast Cancer," and "Surgery Choices for Women with Early Stage Breast Cancer" (published by National Institute of Health/National Cancer Institute). Physicians may choose which of these booklets to give their patients, and DHMH will mail free copies to doctors who request copies of them. The above stakeholder had been looking for a booklet written by DHMH, and once it was clarified that the DHMH-provided booklets are those cited above, it was agreed that the relevant facilities do in fact have copies of the necessary material.

(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.

In statutes dating primarily from the mid-1980s, 14 states require that physicians inform patients of the advantages, disadvantages, and risks of medically viable therapies options for the treatment of breast cancer. These laws may require use of a standardized written summary prepared by a state agency or the posting of signs outlining these options. Some states also require the use of written consent for treatment forms signed by all breast cancer patients, verifying that they have received the information mandated by these statutes.

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

Note that the formerly distributed booklet entitled "Understanding Breast Cancer" is no longer printed and will be replaced with two other booklets, both National Institute of Health/National Cancer Institute publications. The title of the chapter was changed from "Alternative Methods of Breast Cancer Treatment" to "Breast Cancer Treatment Methods."

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

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

Provide explanations of the above responses, as needed:

N/A

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

no action X

amendment

repeal

repeal and adopt new regulations

reorganization

Summary:

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

Person performing review:	Donna Gugel
Title:	Acting Director, Center for Cancer Surveillance & Control