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Pursuant to State Government Article, §7-206, Annotated Code of Maryland, this issue contains all previously unpublished documents required to be published, and filed on or before August 9, 2021, 5 p.m.

Pursuant to State Government Article, §7-206, Annotated Code of Maryland, I hereby certify that this issue contains all documents required to be codified as of August 9, 2021.

Gail S. Klakring
Administrator, Division of State Documents
Office of the Secretary of State



(2) *A cottage food business may request a unique identification number from the Department which can be used in lieu of the address of the cottage food business on the product label required under §C(1) of this regulation.*

[(2)] (3)—[(5)] (6) (text unchanged)

[(6)] (7) The owner of a cottage food business may not sell or offer for sale a cottage food product to a retail food store until notified by the Department, in writing, that the requirements stated in [§C(5)] §C(6) of this regulation are satisfactorily met.

D. (text unchanged)

DENNIS R. SCHRADER
Secretary of Health

Subtitle 26 BOARD OF ACUPUNCTURE

Notice of Proposed Action

[21-107-P]

The Secretary of Health proposes to:

(1) Amend Regulations **.02—**.05 and adopt new Regulation **.08** under **COMAR 10.26.02 General Regulations**; and

(2) Adopt new Regulations **.01—**.03 under a new chapter, **COMAR 10.26.06 Continuing Education**.

This action was considered by the Board of Acupuncture at public meetings held on November 12, 2019, March 10, 2020, November 10, 2020, and March 9, 2021, notice of which was given by publication on the Board’s website at <https://health.maryland.gov/bacc/Pages/index.aspx> pursuant to General Provisions Article, §3–302(c), Annotated Code of Maryland.

Statement of Purpose

The purpose of this action is to:

(1) Update the definition of “practice acupuncture” as a result of Ch. 543, Acts of 2019;

(2) Add language that an applicant shall have graduated from a master’s level program or its equivalent in acupuncture, as a result of Ch. 543, Acts of 2019;

(3) Remove obsolete language and make clarifying changes;

(4) Define and establish qualifications and procedures for acupoint injection therapy; and

(5) Establish a new chapter for continuing education requirements.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

The proposed action has no economic impact.

Economic Impact on Small Businesses

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

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Jason Caplan, Director, Office of Regulation and Policy Coordination, Maryland Department of Health, 201 West Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499 (TTY 800-735-2258), or email to mdh.regs@maryland.gov, or fax to 410-767-6483. Comments will be accepted through September 27, 2021. A public hearing has not been scheduled.

10.26.02 General Regulations

Authority: Agriculture Article, §§2-301(g) and 2-304; Health Occupations Article, §§1-211, 1A-205, 1A-301, 1A-302, 1A-306, 1A-307, and 1A-316; Annotated Code of Maryland

.02 Definitions.

A. (text unchanged)

B. Terms Defined.

(1) (text unchanged)

(2) *“Acupoint injection therapy” means a form of acupuncture that utilizes therapeutic and natural injectable fluids in place of traditional needles.*

[(2)] (3) *“Acupuncture” means a form of health care[,] based on [a theory] East Asian medical theories of energetic physiology[,] that [describes] describe the interrelationship of the body organs [or] and functions of a human or animal [with an associated point or combination of points].*

[(3)] (4)—[(7)] (8) (text unchanged)

[(8)] (9) *“Practice acupuncture” means the use of [oriental] East Asian medical therapies for the purpose of normalizing energetic physiological functions including pain control, and for the promotion, maintenance, and restoration of health including, but not limited to:*

(a) Stimulation of [points of] a human or animal body by the insertion of [acupuncture] needles;

(b) The application of moxibustion; [and]

(c) [Manual, mechanical, thermal, or electrical] *The following therapies, practices, and remedies only when performed in accordance with the principles of [oriental acupuncture] East Asian medical theories[.] such as:*

(i) *Manual therapies;*

(ii) *Mechanical therapies;*

(iii) *Thermal therapies;*

(iv) *Acupoint injection therapy in accordance with Regulation .08 of this chapter;*

(v) *Hot and cold therapy;*

(vi) *Therapeutic exercise and stretching;*

(vii) *Electric stimulation;*

(viii) *Light and cold laser;*

(ix) *Herbal remedies;*

(x) *Mindfulness practices; and*

(xi) *Nutritional and lifestyle counseling; and*

(d) *The utilization of the findings or results of clinical data to engage in the practice of acupuncture as defined in Health Occupations, §1A-101 et seq., Annotated Code of Maryland, which may include traditional or modern diagnostic methods such as:*

(i) *Lab testing; and*

(ii) *Diagnostic imaging.*

[(9)] (10)—[(10)] (11) (text unchanged)

.03 Application for License.

A.—C. (text unchanged)

D. The applicant shall provide documentary evidence of having met one of the following standards for education, training, or demonstrated experience:

(1) Graduation from [a course of training of at least 1,800 hours in acupuncture, including 300 clinical hours,] *at least a master’s level program or its equivalent in acupuncture that is:*

(a)—(b) (text unchanged)

(c) Found by the Board to be equivalent to a course approved [by the ACAOM] *or accredited by the authority listed under §D(1)(a) or (b) of this regulation; or*

(2) (text unchanged)

E. An applicant shall demonstrate proof of proficiency in the written and oral communication of the English language by providing documentary evidence that *the applicant has*:

(1) [The applicant has completed] *Completed* at least 60 classroom credits from an English-speaking undergraduate school or English-speaking professional school; [or]

(2) [The applicant has achieved] *Achieved* a passing score on the TOEFL within the 2 years preceding license application[.]; *or*

(3) *Passed the NCCAOM written and practical examination components in English.*

[F. Proof of proficiency in the English language does not apply to an individual who was in possession of a valid Maryland acupuncture license by March 1, 1996, or had applied by that date and subsequently met all requirements for licensure.]

.04 Approval of Applicant for Licensure.

A.—D. (text unchanged)

[E. For each individual registered with the State Board of Physician Quality Assurance to perform acupuncture as of July 1, 1994, the Board shall consider the individual licensed until December 31, 1995.]

.05 Term, Renewal, Reinstatement, and Inactive Status.

A.—E. (text unchanged)

[F. Continuing Education.

(1) A licensee applying for renewal shall complete 30 hours of relevant continuing education during the 2-year period preceding the expiration of the license which include the following:

(a) At least 20 hours in formally organized programs which are relevant to the practice of acupuncture and Oriental medicine and are approved by the Board or sponsored by, but not limited to, the following organizations and their member organizations:

- (i) American Academy of Medical Acupuncture;
- (ii) American Association of Acupuncture and Oriental Medicine (AAAOM);
- (iii) Council of Colleges of Acupuncture and Oriental Medicine (CCAOM);
- (iv) Colleges and universities accredited by the Accreditation Commission for Acupuncture and Oriental Medicine (ACAOM);
- (v) National Commission for the Certification of Acupuncture and Oriental Medicine (NCCAOM);
- (vi) Society for Acupuncture Research; or
- (vii) The National Acupuncture Detoxification Association;

(b) Not more than 10 hours of formally organized training programs in Western science and medical practices, medical ethics, medical research, or cardiopulmonary resuscitation which are relevant to the practice of acupuncture and are sponsored by, but not limited to, organizations listed in §F(1)(a) of this regulation and the following organizations:

- (i) World Health Organization (WHO);
- (ii) National Institutes of Health (NIH);
- (iii) American Medical Association (AMA);
- (iv) American Nurses Association (ANA);
- (v) American Psychiatric Association (APA);
- (vi) Red Cross;
- (vii) Local colleges; or
- (viii) Local hospitals;

(c) Not more than 10 hours of training in approved programs which will assist a licensee to carry out the licensee's professional responsibilities, including, but not limited to:

- (i) Management courses for a school administrator;
- (ii) Foreign language training for translators of relevant

texts;

(iii) Educational methodology for teachers of acupuncture;

(d) Not more than 10 hours teaching acupuncture and related Oriental medical therapies in an accredited school or in a program approved for acupuncture continuing education;

(e) Not more than 7 hours of pro bono work as outlined in §F(3) of this regulation; or

(f) Not more than 7 hours in published writing or articles in acupuncture and Oriental medicine that are:

- (i) Peer-reviewed research or peer-reviewed clinically relevant articles in acupuncture and Oriental medicine; and
- (ii) Limited to 4 hours per article.

(2) Pro Bono Work.

(a) Pro bono work shall earn 1 credit hour for each 3 hours of pro bono activity up to a maximum of 7 credit hours per renewal cycle.

(b) Pro bono work shall be for the provision of acupuncture services provided through an organization offering humanitarian services such as, but not limited to:

- (i) Domestic or international victims in an emergency situation or disaster area;
- (ii) Low income or underserved areas or populations;
- (iii) Special needs populations; or
- (iv) United States military personnel.

(c) Upon completion of the pro bono work, the licensee shall obtain from the facility written documentation of completion of pro bono hours including:

- (i) The name of the facility;
- (ii) The address where the pro bono work was provided;
- (iii) The type of work that was done;
- (iv) The number of hours of actual work provided for which the licensee desires credit hours; and
- (v) A statement guaranteeing that the work provided no financial benefit to licensee.

(3) Licensees shall maintain the documentation of their continuing education credits for 4 years from the date of their acupuncture renewal.

(4) If requested by the Board, a licensee shall provide proof of continuing education attendance by providing documentation of:

- (a) Name of the program;
- (b) Date of the program;
- (c) Number of continuing education hours earned; and
- (d) Name of the sponsoring organization.]

.08 Acupoint Injection Therapy.

A. *Registration. To obtain the required registration from the Board as qualified to practice acupoint injection therapy, an applicant shall:*

- (1) *Possess a current acupuncture license in good standing;*
- (2) *Successfully complete a Board-approved specialty training program in acupoint injection therapy that consists of a minimum of 20 hours of theory and clinical training, which include each of the following topics:*

- (a) *Uses and contraindications for injectable substances;*
- (b) *Proper storage and disposal of injection syringes and injection compounds;*
- (c) *Safety and emergency procedures;*
- (d) *Administration and practical injection skills, including injection technique;*
- (e) *Universal precautions including management of:*
 - (i) *Blood borne pathogens; and*
 - (ii) *Biohazardous waste; and*
- (f) *Clinical training;*

(3) Possess a current certification in basic life support or cardiopulmonary resuscitation (CPR) approved by the American Heart Association or American Red Cross; and

(4) Complete and submit an application provided by the Board.

B. Practice. To practice acupoint injection therapy, the licensed acupuncturist:

(1) Shall:

(a) Possess a registration for acupoint injection therapy from the Board;

(b) Explain acupoint injection therapy to the patient in advance of treatment;

(c) Obtain written informed consent specific to acupoint injection therapy that shall be included in the patient's medical record;

(d) Only perform subcutaneous or intramuscular injection in accordance with the principles of acupuncture and East Asian medical theories;

(e) Have an adverse event or emergency plan in place for allergic reactions to injected substances;

(f) Maintain professional liability coverage for this procedure;

(g) Only use prepackaged acupoint injectable therapeutic substances that are:

(i) Acquired from an appropriately licensed entity in compliance with federal and state law;

(ii) Sterile from the appropriately licensed entity; and

(iii) Stored in accordance to manufacturer's specifications;

(2) May use the following acupoint injectable therapeutic substances without further approval:

(a) Water;

(b) Saline;

(c) Dextrose;

(d) Glucose;

(e) Procaine; or

(f) Lidocaine;

(3) May use acupoint injectable therapeutic substances from the following categories only with Board approval:

(a) Vitamins;

(b) Amino acids;

(c) Proteins;

(d) Sugars; or

(e) Homeopathic substances; and

(4) May not:

(a) Administer compounds for which the licensed acupuncturist has not been appropriately trained in accordance with this regulation;

(b) Give an injectable substance to a patient for self-injection; or

(c) Administer intravenous injections.

C. The Board shall maintain a list of all:

(1) Licensed acupuncturists registered by the Board as qualified to practice acupoint injection therapy;

(2) Board-approved acupoint injection therapy training programs; and

(3) Formularies of Board-approved acupoint injectable therapeutic substances from the categories listed in §B(3) of this regulation.

D. On or after the effective date of this regulation, unless the person is registered by the Board as qualified to practice acupoint injection therapy, an individual may not:

(1) Represent to the public that the individual is an acupoint injection therapy registered acupuncturist; or

(2) Practice acupoint injection therapy.

E. Violation of this regulation constitutes unprofessional conduct and may result in disciplinary action as set forth in Health Occupations Article, §4-315, Annotated Code of Maryland.

10.26.06 Continuing Education

Authority: Health Occupations Article, §§1A-205 and 1A-306, Annotated Code of Maryland

.01 Scope.

This regulation governs all acupuncturists licensed to practice in the State of Maryland.

.02 Definitions.

A. In this chapter, the following term has the meaning indicated.

B. Term Defined. "Board" means the State Board of Acupuncture.

.03 Licensure Renewal.

A. A licensee applying for renewal shall complete 30 hours of relevant continuing education during the 2-year period preceding the expiration of the license which include the following:

(1) At least 20 hours in formally organized programs approved by the Board which are relevant to the practice of acupuncture and East Asian medicine;

(2) Not more than 10 hours of formally organized training programs in Western science and medical practices, medical ethics, medical research, or cardiopulmonary resuscitation which are relevant to the practice of acupuncture and East Asian medicine;

(3) Not more than 10 hours of training in approved programs which will assist a licensee to carry out the licensee's professional responsibilities, including, but not limited to:

(a) Management courses for a school administrator;

(b) Foreign language training for translators of relevant texts; or

(c) Educational methodology for teachers of acupuncture;

(4) Not more than 10 hours teaching acupuncture and related East Asian medical therapies in an accredited school or in a program approved for acupuncture continuing education;

(5) Not more than 7 hours of pro bono work as outlined in §B of this regulation;

(6) Not more than 7 hours in published writing or articles in acupuncture and East Asian medicine that are:

(a) Peer-reviewed research or peer-reviewed clinically relevant articles in acupuncture and East Asian medicine; and

(b) Limited to 4 hours per article;

(7) Not more than 20 hours for passage of the NCCAOM exam within the 2-year period preceding the expiration of the license; or

(8) Not more than 10 hours serving on a professional board involving:

(a) Acupuncture; or

(b) East Asian medicine.

B. Pro Bono Work.

(1) Pro bono work shall:

(a) Earn 1 credit hour for each 3 hours of pro bono activity up to a maximum of 7 credit hours per renewal cycle; and

(b) Be for the provision of acupuncture services provided through an organization offering humanitarian services such as, but not limited to:

(i) Domestic or international victims in an emergency situation or disaster area;

(ii) Low-income or underserved areas or populations;

(iii) Special needs populations; or

(iv) United States military personnel.

(2) Upon completion of the pro bono work, the licensee shall obtain from the facility written documentation of completion of pro bono hours including:

- (a) The name of the facility;
- (b) The address where the pro bono work was provided;
- (c) The type of work that was done;
- (d) The number of hours of actual work provided for which the licensee desires credit hours; and
- (e) A statement guaranteeing that the work provided no financial benefit to the licensee.

C. Licensees shall maintain the documentation of their continuing education credits for 4 years from the date of their acupuncture renewal.

D. If requested by the Board, a licensee shall provide proof of continuing education attendance by providing documentation of the:

- (1) Name of the program;
- (2) Date of the program;
- (3) Number of continuing education hours earned; and
- (4) Name of the sponsoring organization.

DENNIS R. SCHRADER
Secretary of Health

Subtitle 28 BOARD OF EXAMINERS IN OPTOMETRY

10.28.12 Therapeutic Pharmaceutical Agents

Authority: Health Occupations Article, §§11-101, 11-205, 11-302—11-309, 11-401.1, 11-404, and 11-404.1, Annotated Code of Maryland

Notice of Proposed Action

[21-118-P]

The Secretary of Health proposes to amend Regulations .01, .03, and .04, repeal existing Regulations .05 and .06, and amend and recodify existing Regulation .07 to be Regulation .05 under **COMAR 10.28.12 Therapeutic Pharmaceutical Agents**. This action was considered by the Board of Examiners in Optometry at a public meeting held on July 29, 2020, notice of which was given by publication on the Board’s website at <https://health.maryland.gov/optometry/Pages/index.aspx> pursuant to General Provisions Article, §3–302(c), Annotated Code of Maryland.

Statement of Purpose

The purpose of this action is to:

- (1) Add clarifying language to the definitions;
- (2) Establish evaluation standards for therapeutically certified optometrists utilizing therapeutic pharmaceutical agents (TPAs);
- (3) Remove obsolete language; and
- (4) Repeal existing Regulations .05 and .06.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

The proposed action has no economic impact.

Economic Impact on Small Businesses

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

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Jason Caplan, Director, Office of Regulation and Policy Coordination, Maryland Department of Health, 201 West Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499 (TTY 800-735-2258), or email to mdh.regs@maryland.gov, or fax to 410-767-6483. Comments will be accepted through September 27, 2021. A public hearing has not been scheduled.

.01 Definitions.

A. (text unchanged)

B. Terms Defined.

(1) (text unchanged)

(2) “Adverse reaction” means the unintended or unexpected effect of treatment on a patient caused by or resulting from:

(a) An adverse drug reaction; [or]

(b) The removal of a superficial foreign body from the eye[.]; or

(c) The ordering of a laboratory test.

(3) (text unchanged)

[(4) “Comanagement plan” means the formal, written individualized treatment plan signed and agreed to by an ophthalmologist and an optometrist with TPA certification for the treatment and management of primary open angle glaucoma.]

[(5)] (4) “Diagnostic pharmaceutical agent (DPA)” means a medication [which directly or indirectly affects] *that*:

(a) *Directly or indirectly affects* the pupil of the eye *as defined in COMAR 10.28.11*; [or]

(b) *Directly or indirectly affects* the sensitivity of the cornea *as defined in COMAR 10.28.11*[.]; or

(c) *Stains the ocular surface*.

[(6)] (5) “Ophthalmologist” means a physician[:

(a) Who] *who* practices in the specialty of ophthalmology and who is licensed by the Maryland Board of Physicians[;

(b) Licensed in an adjoining state who practices the specialty of ophthalmology and meets the following requirements:

(i) The physician’s participation in the comanagement plan has been requested by a Maryland TPA-certified optometrist and a justification for the request has been submitted to the Board, and

(ii) The Board concludes that the physician’s participation is permitted by State law and no other means of meeting patient care needs is reasonably available].

[(7)] (6) “Primary open angle glaucoma” means glaucomatous changes characterized by:

(a)—(b) (text unchanged)

(c) One or more of the following:

(i) The appearance of optic disc damage or optic nerve fiber layer damage as evidenced by the size or shape of the optic disc cup, thinning or notching of the optic disc rim, progressive changes in the appearance of the optic disc cup, optic disc hemorrhage, or nerve fiber layer defects, *seen clinically or via imaging*;

(ii) The presence of abnormalities in the visual field including arcuate defect, nasal step, paracentral scotoma, or general depression, in the absence of other causes or explanations for a visual field defect[.]; or

(iii) Intraocular pressure [repeatedly above 21mm Hg (by Goldmann applanation or its equivalent) at some course during observation which] *that* is thought to pose a threat to the health of the optic nerve.

[(8) “Quality assurance program” means the process which includes peer review, record review, self-assessment, and data collection.]

[(9)] (7)—[(13)] (11) (text unchanged)