

FINAL AND PROPOSAL

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Title 10

MARYLAND DEPARTMENT 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 Final Action

[21-118-F]

On October 14, 2021, the Secretary of Health adopted amendments to Regulations **.01**, **.03**, and **.04**, the repeal of existing Regulations **.05** and **.06**, and amendments to and the recodification of existing Regulation **.07** to be Regulation **.05** under **COMAR 10.28.12 Therapeutic Pharmaceutical Agents**. This action, which was proposed for adoption in 48:18 Md. R. 703—705 (August 27, 2021), has been adopted as proposed.

Effective Date: November 15, 2021.

DENNIS R. SCHRADER
Secretary of Health

PROPOSAL

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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 [repeatably 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)

.03 Requirements for Renewal of Certification.

A.—E. (text unchanged)

F. *TPA Self-Assessment. At the time of license renewal, the therapeutically certified optometrist shall complete a self-assessment checklist provided by the Board to evaluate the following aspects of the optometrist’s practice utilizing TPAs, including but not limited to:*

(1) *Legibility and completeness of TPA records;*

(2) *Documentation of patient visits, services rendered, and communications;*

(3) *Documentation of subjective complaints, objective findings, clinical assessments relating to the findings of the diagnosis, and the plan;*

(4) *A written office plan for handling emergencies;*

- (5) *A system for patients to reach the optometrist, or to access care, in the event of an ocular emergency;*
- (6) *A systematic discarding of expired medications;*
- (7) *Documentation of current CPR certification;*
- (8) *An infection control policy;*
- (9) *Patient confidentiality;*
- (10) *A patient tracking system that enables identification and follow-up to ensure treatment of patients who:*
 - (a) *Are being followed or referred out for emergency sight or life-threatening conditions; or*
 - (b) *Fail to keep appointments;*
- (11) *Procedures for appropriate termination of the doctor-patient relationship when necessary;*
- (12) *Satisfactory explanation of the treatment plan so that the patient knows and understands the nature of the patient's problem or problems and the goals of the treatment regimen; and*
- (13) *Advice to patients regarding the importance of progress examinations and follow-up care.*

.04 Standards of Quality for Therapeutically Certified Optometrists and Optometric Care.

A. The therapeutically certified optometrist shall provide clinical therapeutic eye care consistent with published, [nationally] *universally* accepted practice or clinical guidelines and standards of care.

B. The therapeutically certified optometrist shall adhere to the additional guidelines and standards of care given in [§§C—U] §§C—T of this regulation.

C. (text unchanged)

[D.] D. The therapeutically certified optometrist shall file and label all TPA records in a manner which makes them readily retrievable and available for review.]

[E.] D. The therapeutically certified optometrist shall document the following data, if applicable, for each TPA patient visit or communication:

- (1)—(3) (text unchanged)
- (4) Medication/treatment provided; and
- [(5)] Fee charged; and
- [(6)] (5) (text unchanged)

[F.] E. The therapeutically certified optometrist shall document the following data as part of the patient's permanent file:

- (1)—(2) (text unchanged)
- (3) Name of the doctor to whom the patient is referred, appointment date, and [time of any referrals for consultation or treatment] *documentation that the patient or guardian preferred to schedule the referral appointment on their own;*
- (4)—(6) (text unchanged)

[G.] F.—[K.] J. (text unchanged)

[L.] K. The therapeutically certified optometrist shall maintain a written tracking system to identify patients who are being followed or referred for [disease-risk] *emergency sight or life-threatening* conditions and who fail to keep appointments.

[M.] L. The therapeutically certified optometrist shall [contact] *document that a [disease-risk] patient who fails to keep an appointment for an emergency sight or life-threatening condition was contacted* by [a telephone call and a mailed notice, if needed.]:

- (1) *Telephone;*
- (2) *Electronic mail or other electronic means;*
- (3) *Text message; or*
- (4) *Mail.*

[N.] M.—[O.] N. (text unchanged)

[P.] O. The therapeutically certified optometrist shall remove superficial foreign bodies from the eye in accordance with the applicable standards of care established under Health Occupations Article, Title 11, Annotated Code of Maryland. [A therapeutically certified optometrist may remove superficial foreign bodies from the human eye only if the foreign body:

- (1) May be removed with a cotton-tipped applicator or blunt spatula; and
- (2) Has not penetrated beyond the Bowman's membrane of the cornea and is not within 2.5 millimeters of the visual axis.]

[Q.] P. (text unchanged)

[R.] Q. The therapeutically certified optometrist shall report to the Board, on the form provided by the Board, within 10 working days of the occurrence, an adverse reaction [resulting from administration of a therapeutic pharmaceutical agent or from the removal of a superficial foreign body from the eye]. The therapeutically certified optometrist shall include in the report, at a minimum, the following:

- (1)—(4) (text unchanged)

[S.] R. Glaucoma [Comanagement] *Management.*

- (1) (text unchanged)
- (2) A therapeutically certified optometrist may administer and prescribe topical [therapeutical] pharmaceutical agents for glaucoma only:] *as authorized by law.*

[(a)] For patients with primary open angle glaucoma;

(b) After the optometrist refers the patient to an ophthalmologist; and

(c) After the ophthalmologist and optometrist jointly and promptly develop a written individualized comanagement treatment plan that is signed by the ophthalmologist and optometrist.

(3) The treatment plan may be modified only upon the mutual consultation and consent of the optometrist and ophthalmologist, and the optometrist shall note the modification in the patient's record.

(4) The therapeutically certified optometrist shall refer the patient to an ophthalmologist at least once a year.

(5) The therapeutically certified optometrist shall make available to the ophthalmologist the results of the tests or procedures including visual fields tests, optic nerve photos, or nerve fiber layer photos performed by the optometrist, and the ophthalmologist shall make available to the optometrist the results of tests or procedures performed by the ophthalmologist.

T. The therapeutically certified optometrist and the ophthalmologist shall ensure that the glaucoma comanagement plan includes at least the following:

(1) The tests, examinations, and procedures performed that led to the diagnosis;

(2) An initial schedule of the tests and examinations necessary to treat the patient;

(3) The estimated number of times the patient may need to be seen by the optometrist and the ophthalmologist;

(4) The optometrist's name, address, and license number;

(5) The ophthalmologist's name, address, and license number;

(6) A medication plan;

(7) A target intraocular pressure (IOP) which, if exceeded, requires reassessment of the comanagement plan and appropriate therapeutic intervention to reduce the intra-ocular pressure to an acceptable level; and

(8) Criteria for surgical intervention.]

[U.] S. In developing a [comanagement] *glaucoma* treatment plan that ensures the maximum effectiveness for the patient, the therapeutically certified optometrist [and the ophthalmologist] shall consider the following:

(1) (text unchanged)

(2) Status of the optic nerve structure, function, and its relationship to [IOP] *intraocular pressure*;

(3) Identification of a *target intraocular pressure at or below the target level in* which further optic nerve damage is unlikely to occur;

(4) Maintenance of [IOP] *intraocular pressure* at or below the target level by initiating appropriate therapeutic intervention;

(5) Monitoring of the optic nerve and resetting the target [IOP] *intraocular pressure* if deterioration occurs;

(6) (text unchanged)

(7) Education of the patient in the management of primary open angle glaucoma disease; [and]

(8) Reference to accepted clinical guidelines for glaucoma follow-up management[.]; *and*

(9) *Criteria for surgical intervention.*

T. Laboratory Tests. Laboratory tests shall be ordered by a therapeutically certified optometrist only as provided by law.

[.07] .05 Monitoring of Complaint Investigation.

A. The Board shall review complaints against optometrists relating to ocular therapeutics, [comanagement] *management* of primary open angle glaucoma, removal of superficial foreign bodies, and other aspects of practice by a therapeutically certified optometrist.

B. (text unchanged)

[C. The Board shall submit a report summarizing the Board's investigation of complaints concerning TPAs, the results of the investigations, and actions taken by the Board to the Secretary annually, at the end of the Board's fiscal year. The Board shall ensure that the reports protect the confidentiality of the optometrists and the complainants.]

DENNIS R. SCHRADER
Secretary of Health