STATE OF WISCONSIN
OPTOMETRY EXAMINING BOARD

IN THE MATTER OF RULEMAKING PROCEEDINGS BEFORE THE OPTOMETRY EXAMINING BOARD	:	PROPOSED ORDER OF THE OPTOMETRY EXAMINING BOARD ADOPTING RULES (CLEARINGHOUSE RULE 19-027)

PROPOSED ORDER

An order of the Optometry Examining Board to repeal Opt 6.02 (1m); to renumber and amend Opt 6.02 (1); to amend Opt 6.01 and Opt 6.02 (3) and (6); to repeal and recreate Opt 6.03 and 6.04; and to create Opt 6.01 (Note 1) and (Note 2), 6.02 (1) (a) to (i), 6.02 (1e), (1n), and (1s), 6.025, 6.025 (Note), and 6.05, relating to diagnostic and therapeutic pharmaceutical agents.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: Sections 449.17 and 449.18, Stats.

Statutory authority: Sections 15.08 (5) (b), 449.17 (1m) (a), and 449.18 (2) (a), Stats.

Explanation of agency authority:

Section 15.08 (5) (b), Stats., provides examining boards, "shall promulgate rules for its own guidance and for the guidance of the trade or profession to which it pertains …"

Section 449.17 (1m) (a), Stats., provides that the "examining board shall certify an optometrist to use topical ocular diagnostic pharmaceutical agents …"

Section 449.18 (2) (a), Stats., provides the "examining board shall certify an optometrist to use therapeutic pharmaceutical agents and remove foreign bodies from an eye or from an appendage to the eye …"

Related statute or rule:

Chapter SPS 10, relating to the use of pharmaceutical agents by licensed optometrists

Plain language analysis:

Section 1 is amended to include s. 961.39, Stats., which outlines the limitations on optometrists in the Uniform Controlled Substances Act.

Section 2 adds two notes, one to clarify that Opt 6 is not a chapter for licensure and only applies to those already licensed by Wisconsin, and a second note to cross-reference ch. SPS 10, relating to the use of pharmaceutical agents by licensed optometrists.

Sections 3 and 4 amend the definition of "adverse drug reaction," amending to accommodate the revisions of ch. SPS 10, relating to the use of pharmaceutical agents by licensed optometrists, a concurrent rule project. The definition for "adverse drug reaction" is being repealed from ch. SPS 10, so the content is being moved to ch. Opt 6.

Section 5 repeals the definition for "adverse drug reaction referral plan" because the content of the definition, which previously referenced ch. SPS 10, is being recreated as s. Opt 6.025.

Section 6 moves three new definitions for "approved institution," "classroom hour," and "course of study in pharmacology" into ch. Opt 6, which was previously in ch. SPS 10.

Sections 7 and 9 amend the definitions for "DPA" and "TPA" to correct the reference to the revised ch. SPS 10, a concurrent rule project.

Section 8 repeals the definition for "100 hours of approved study." This definition is unnecessary and the content has been directly incorporated into the recreated s. Opt 6.04.

Section 10 creates a new section in ch. Opt 6 for the Adverse Drug Reaction Referral Plan, this information is moved from ch. SPS 10. It also adds a note to s. Opt 6.025 to state where a user can get the forms necessary to comply with s. Opt 6.025, Adverse Drug Reaction Referral Plan.

Section 11 repeals ss. Opt 6.03 and Opt 6.04 and recreates them. Section Opt 6.03 was a repeat of s. 449.17, Stats. The recreated s. Opt 6.03 distills the statutory language to the process and procedure used by the Optometry Examining Board in certifying optometrists for DPA. Section Opt 6.04 was a repeat of s. 449.18, Stats. The recreated s. Opt 6.04 distills the statutory language to the process and procedure used by the Optometry Examining Board in certifying optometrists for TPA and to remove foreign bodies from eyes.

Section 12 moves a section from ch. SPS 10 into ch. Opt 6 for Prescribing Therapeutic Pharmaceutical Agents.

Summary of, and comparison with, existing or proposed federal regulation:

The federal government schedules therapeutic pharmaceutical agents through the Controlled Substances Act, which categorizes optometrists as mid-level practitioners under Title 21, Code of Federal Regulations, Section 1300.01.

Comparison with rules in adjacent states:
Illinois:

Under Illinois law, optometrists may prescribe Schedule II (hydrocodone products only), III, IV, and V controlled substances and ocular pharmaceutical agents to patients without consulting a physician unless the patient is under 5 years of age. Ocular pharmaceutical agents include topical anesthetics, topical mydriatics, topical cycloplegics, topical miotics and mydriatic reversing agents, anti-infective agents, anti-allergy agents, anti-glaucoma agents (except oral carbonic anhydrase inhibitors, which may be prescribed only in a quantity sufficient to provide treatment for up to 30 days), anti-inflammatory agents (except oral steroids, which may be prescribed only in a quantity sufficient to provide treatment for up to 7 days), over-the-counter agents, analgesic agents, anti-dry eye agents, and agents for the treatment of hypotrichosis. The authority to prescribe a Schedule III, IV, or V controlled substance shall include analgesic agents only in a quantity sufficient to provide treatment for up to 72 hours. The prescription of a Schedule II controlled substance is prohibited, except for Dihydrocodeinone (Hydrocodone) with one or more active, non-narcotic ingredients only in a quantity sufficient to provide treatment for up to 72 hours, and only if such formulations of Dihydrocodeinone are reclassified as Schedule II by federal regulation. The Illinois Optometric Licensing and Disciplinary Board may recommend additional pharmaceutical agents approved by the FDA to the Department of Financial and Professional Regulation, and the Department shall promulgate rules to allow for the prescribing or administering pharmaceutical agents. See 225 ILCS 80/15.1.

The requirements for licensure and certification to use diagnostic and therapeutic pharmaceutical agents in Illinois are substantially equivalent to the requirements in Wisconsin. Both Illinois and Wisconsin require applicants to complete specialized course work relating to the use of diagnostic and therapeutic pharmaceutical agents and to pass a qualifying examination. In reference to continuing education, Illinois requires licensees to complete 24 hours of continuing education. Optometrists who are certified to use therapeutic ocular pharmaceuticals are required to complete an additional 6 hours of continuing education in the treatment of ocular disease. Illinois's administrative rules relating to the practice are found in Title 68: Professions and Occupations, Chapter VII: Department of Financial and Professional Regulation Part 1320, Optometric Practice Act of 1987.

Iowa:
Under Iowa law, the Board of Optometry Examiners is part of the Department of Public Health. An optometrist licensed by the Board of Optometry Examiners may employ all diagnostic and therapeutic pharmaceutical agents for the purpose of diagnosis and treatment of conditions of the human eye and adnexa, excluding the use of injections other than to counteract an anaphylactic reaction, and may without charge supply any of the above pharmaceuticals to commence a course of therapy. Iowa Code § 154.1 3. and 4. Optometrists can prescribe oral medications including antibiotics, antivirals, and DMARDs, prescribe Schedule II, III, IV, and V drugs, and prescribe oral steroids (for a maximum of 14 days) without consultation of a physician. The Board of Pharmacy reviews requests for additions to the controlled substances schedules, and the Board's decision will amend Iowa Code section 124.201, subs. 4. 657-10.37, Iowa Admin. Code.

The requirements for licensure and certification to use diagnostic and therapeutic pharmaceutical agents in Iowa are substantially similar to the requirements in Wisconsin. Both Iowa and Wisconsin require applicants to complete specialized course work relating to the use of diagnostic and therapeutic pharmaceutical agents and to pass a qualifying examination. In reference to continuing education, Iowa and Wisconsin require licensees to complete course work every two years in order to renew their credentials. Iowa requires optometrists who are not certified to use therapeutic pharmaceutical agents to complete 30 hours of continuing education, and optometrists who are certified to use therapeutic pharmaceutical agents to complete 50 hours of continuing education. Iowa's administrative rules relating to the practice of optometry are found in their chapters 179 to 183.

Michigan:
In Michigan, the Board of Optometry requires optometrists to be certified to administer topical ocular diagnostic pharmaceutical agents and to prescribe therapeutic pharmaceutical agents. R 338.315 and R 338.317. The authority to prescribe or administer pharmaceutical agents includes Schedule III, IV, and V drugs and dihydrocodeinone combination drugs. See 333.17401 (f), Michigan Stats. A controlled substances license is required to prescribe controlled substances. A management and emergency plan is also required. See Article 7 of Public Act 3.68 of 1978, as amended.

The requirements for licensure and certification to use diagnostic and therapeutic pharmaceutical agents in Michigan are substantially equivalent to the requirements in Wisconsin. Both Michigan and Wisconsin require applicants to complete specialized course work relating to the use of diagnostic and therapeutic pharmaceutical agents and to pass a qualifying examination. In reference to continuing education, Michigan and Wisconsin require licensees to complete course work every two years in order to renew their credentials. Michigan requires 40 hours of continuing education. Michigan's administrative rules relating to the practice of Optometry are found in their sections R. 338.211 to 338.279 (General Rules) and R 338.291 (Ethical and Unprofessional Conduct).

Minnesota:
Optometrists may prescribe or administer FDA approved drugs to aid in the diagnosis, cure, mitigation, prevention, treatment, or management of disease, deficiency, deformity, or abnormality of the human eye and adnexa included in the curricula of accredited schools or colleges of optometry, and as limited by Minnesota statute and adopted rules by the Board of Optometry. § 148.56 (a), Minn. Stats. Optometrists may not prescribe or administer Schedule II and III oral FDA approved drugs and oral steroids; prescribe oral antivirals for more than ten days; or prescribe or administer oral carbonic anhydrase inhibitors for more than seven days. § 148.56 (b), Minn. Stats. The Board of Pharmacy schedules substances. § 152.02, Minn. Stats.

The requirements for licensure and certification to use diagnostic and therapeutic pharmaceutical agents in Minnesota are substantially equivalent to the requirements in Wisconsin. Both states require applicants to be a graduate of an accredited college of

optometry and to pass a qualifying examination in order to obtain a license. Both states allow for applicants holding equivalent licensure from another jurisdiction to apply for licensure. In addition, both Minnesota and Wisconsin require applicants to complete specialized course work relating to the use of diagnostic and therapeutic pharmaceutical agents and to pass a qualifying examination. In reference to experience required in order to obtain a certification to use therapeutic pharmaceutical agents, Minnesota requires 2 years of supervised clinical experience in differential diagnosis of eye disease or disorders as part of optometric training or one year of that experience and ten years of actual clinical experience as a licensed optometrist. Other than experience or training required in conjunction with an initial optometry degree program, Wisconsin does not require an applicant to complete experience in order to obtain a certificate to use therapeutic pharmaceutical agents. In reference to continuing education, Minnesota and Wisconsin require licensees to complete course work every two years in order to renew their credentials. Minnesota requires 40 hours of continuing education. Minnesota's administrative rules relating to the practice of optometry are under their Chapter 6500.

Summary of factual data and analytical methodologies:

Opt 6, relating to the Use of Diagnostic and Therapeutic Pharmaceutical Agents and Removal of Superficial Foreign Bodies From an Eye or From an Appendage to the Eye, was amended in 2007 to implement 2005 Wisconsin Act 297. The legislation shifted to the Optometry Examining Board from the Department of Safety and Professional Services the authority to determine which licensed optometrists may use pharmaceutical agents. The Department is also amending SPS 10 in order to fully enact 2005 Wisconsin Act 297. Staff have opened Opt 6 and SPS 10 concurrently to accurately and consistently implement this legislative shift. Revisions were reviewed by the Optometry Examining Board and DSPS staff to ensure accuracy.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:

The proposed rules were posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals. No comments were received.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis document is attached.

Effect on small business:

These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Daniel.Hereth@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Helen Leong, Administrative Rule Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-266-0797; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:

Comments may be submitted to Helen Leong, Administrative Rule Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received before 9:00 am on May 30, 2019 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Opt 6.01 is amended to read:

Opt 6.01 Authority. The rules in this chapter are adopted under authority in ss. 15.08 (5) (b), 227.11 (2), 449.17 ~~and~~ , 449.18, and 961.39, Stats.

SECTION 2. Opt 6.01 (Note 1) and (Note 2) are created to read:

Opt 6.01 Note: The rules in this chapter apply only to optometrists licensed by the State of Wisconsin in accordance with ch. Opt 3 or ch. Opt 4, as applicable.

Note: To determine which pharmaceutical agents may be used by licensed optometrists, refer to ch. SPS 10, relating to the use of pharmaceutical agents by licensed optometrists.

SECTION 3. Opt 6.02 (1) is renumbered Opt 6.02 (1) (intro.) and amended to read:

(1) "Adverse drug reaction" ~~has the meaning given under s. SPS 10.01.~~ means an adverse, physical or psychological reaction experienced by a person resulting from diagnostic or therapeutic pharmaceutical agents administered by an optometrist that occurs within 24 hours after the drug is administered. An adverse drug reaction may be indicated by symptoms that include any of the following:

SECTION 4. Opt 6.02 (1) (a) to (i) are created to read:

(a) Red eye.

(b) Painful eye.

(c) Decrease in vision.

(d) Pale or red swelling of the periocular or periorbital tissues.

(e) Nausea.

(f) Vomiting.

(g) Fainting.

(h) Mental confusion.

(i) Cessation of respiration.

SECTION 5. Opt 6.02 (1m) is repealed.

SECTION 6. Opt 6.02 (1e), (1n), and (1s) are created to read:

(1e) "Approved institution" means an institution approved by the board and accredited by a regional or professional accrediting organization which is recognized by the Council for Higher Education Accreditation or its successor or the federal department of education, in accordance with ss. 449.17 (1m) (b) and 449.18 (2) (a) 2., Stats.

(1n) "Classroom hour" means a minimum of 50 minutes of lecture, group discussion, or laboratory. "Classroom hour" does not include time spent working in a clinic other than as part of a laboratory directly associated with a course in pharmacology.

(1s) "Course of study in pharmacology" means a course of study completed in an approved institution after 1973 in general and clinical pharmacology as it relates to optometry with the characteristics described in s. 449.17 (1m) (b), Stats. For a course, such as a continuing education course, that does not lead to a degree in optometry to qualify as part of a course of study in pharmacology, the course must include at least one examination on course content.

SECTION 7. Opt 6.02 (3) is amended to read:

(3) "DPA" or "~~diagnostical~~ diagnostic pharmaceutical agent" ~~has the meaning given under s. SPS 10.01.~~ means an agent authorized under s. SPS 10.02.

SECTION 8. Opt 6.02 (4) is repealed.

SECTION 9. Opt 6.02 (6) is amended to read:

(6) "TPA" or "therapeutic pharmaceutical agent" ~~has the meaning given under s. SPS 10.01.~~ means an agent authorized under s. SPS 10.03.

SECTION 10. Opt 6.025 and Opt 6.025 (Note) are created to read:

Opt 6.025 Adverse drug reaction referral plan. (1) An optometrist who wants to use diagnostic pharmaceutical agents authorized under s. SPS 10.02 or therapeutic pharmaceutical agents authorized under s. SPS 10.03 shall submit an adverse drug reaction referral plan prior to providing pharmaceutical agents. The plan shall be submitted to the department on an approved form in which the optometrist agrees to do all of the following:

(a) Refer any patient who notifies the optometrist of an adverse drug reaction to appropriate medical specialists or facilities.

(b) Routinely advise all patients to immediately contact the optometrist if the patient experiences adverse reactions.

(c) Place in a patient's permanent record information describing any adverse drug reactions experienced by the patient and the date and time that any referral was made.

(2) The plan shall include the names of at least 3 physicians, physician clinics, or hospitals to whom the optometrist agrees to refer patients who experience an adverse drug reaction. At least one of these physicians shall be skilled in the diagnosis and treatment of diseases of the eye.

(3) An optometrist authorized to use diagnostic or therapeutic pharmaceutical agents shall file a revised adverse drug reaction referral plan with the department within 10 working days after the optometrist designates a new physician, physician clinic, or hospital to which the optometrist agrees to refer patients who experience adverse drug reactions.

(4) An optometrist authorized to use therapeutic pharmaceutical agents shall file with the department within 10 working days of its occurrence a report on any adverse drug reaction resulting from the optometrist's administration of the agents. This report shall include all of the following:

(a) The optometrist's name, address, and license number.

(b) The patient's name, address, and age.

(c) The patient's presenting problem, the diagnosis, the agent administered and the method of administration, the reaction, and the subsequent action taken.

Note: The TPA Adverse Reaction Report (Form #1728) and DPA/TPA Certification Application are available on the department's website at dsps.wi.gov, or by request from the Department of Safety and Professional Services, P.O. Box 8935, Madison, Wisconsin 53708, or call (608) 266-2112.

SECTION 11. Opt 6.03 and Opt 6.04 are repealed and recreated to read:

Opt 6.03. Certificate to use diagnostic pharmaceutical agents. (1) A licensed optometrist who has submitted an adverse drug reaction referral plan in accordance with s. Opt 6.025 is authorized to use diagnostic pharmaceutical agents if any of the following applies:

(a) The board initially issued a license to practice optometry to the optometrist on or after August 1, 2006.

(b) The department issued a certificate to the optometrist under s. 449.17, 2003 Stats.

(c) The board issued a certificate under sub. (2) to an optometrist issued a license to practice optometry before August 1, 2006.

(2) An optometrist licensed prior to August 1, 2006 shall be certified by the board to use diagnostic pharmaceutical agents if all of the following are completed:

(a) The optometrist submits an application to the department.

(b) The optometrist submits satisfactory evidence of 60 classroom hours of a course of study that is in accordance with sub. (3) and that was completed prior to entering the examination required in par. (c).

(c) The optometrist submits satisfactory evidence of passing one of the following:

1. Section 9, ocular pharmacology, National Board of Examiners in Optometry administered only after 1981.

2. Parts I and II, National Board of Examiners in Optometry administered only after 1986.

3. An exam administered as part of the course of study under par. (b) that, as determined by the board, satisfactorily assesses competency in the subject matter described in sub. (3). The board may require additional evidence to approve the exam.

(3) A satisfactory course of study under par. (2) (b) at an approved institution shall include at least 30 classroom hours of a course of study in pharmacology and emphasizes the systemic effects of and reactions to pharmaceutical agents, including the treatment of any adverse reactions that may occur, in accordance with s. 449.17 (1m) (b), Stats.

Opt 6.04. Certificate to use therapeutic pharmaceutical agents and remove foreign bodies from eyes. (1) A licensed optometrist who has submitted an adverse drug reaction referral plan in accordance with s. Opt 6.025 is authorized to use therapeutic pharmaceutical agents and remove foreign bodies from an eye or from an appendage to the eye if any of the following applies:

(a) The board initially issued a license to practice optometry to the optometrist on or after August 1, 2006.

(b) The board issued a certificate to the optometrist under s. 449.18, 2003 Stats.

(c) The board issued a certificate under sub. (2) to an optometrist issued a license to practice optometry before August 1, 2006.

(2) An optometrist licensed prior to August 1, 2006 shall be certified by the board to use therapeutic pharmaceutical agents under this section if all of the following are completed:

(a) The optometrist has a certificate to use diagnostic pharmaceutical agents in accordance with s. Opt 6.03.

(b) The optometrist submits an application to the department.

(c) The optometrist has completed all of the following:

1. One hundred classroom hours of post doctorate study in the use of therapeutic pharmaceutical agents and the removal of superficial foreign bodies from an eye or from an appendage to the eye, on or after January 1, 1987 at an approved institution and achieved a minimum passing score.

2. Passed one of the following approved examinations:

a. An exam administered as part of the course of study under subd. 1. that, as determined by the board, satisfactorily assesses competency. The board may require additional evidence to approve the exam.

b. The Treatment and Management of Ocular Disease, TMOD®, National Board of Examiners in Optometry exam administered after 1985 with a minimum passing score as determined by the board in accordance with s. Opt 3.07.

(3) An optometrist authorized under this section may not remove a foreign body from an eye or from an appendage to an eye if the foreign body is deeper than Bowman's layer of the cornea or deeper than the conjunctiva, in accordance with s. 449.18 (5), Stats.

SECTION 12. Opt 6.05 is created to read:

Opt 6.05. Prescribing therapeutic pharmaceutical agents. (1) Therapeutic pharmaceutical agents may be prescribed or administered by an optometrist only for the ocular therapeutic purposes for which the drugs are intended. These drugs shall be prescribed or administered in accordance with minimum standards and procedures established in the optometric profession. An optometrist may not prescribe or administer a therapeutic pharmaceutical agent which is not authorized under s. SPS 10.03. Approved agents may be used in combination only with other approved agents when appropriate.

(2) Prior to prescribing beta blockers or carbonic anhydrase inhibitors for the treatment of glaucoma, any oral antiviral, or any other therapeutic pharmaceutical agent under s. SPS 10.03 that may have significant systemic adverse drug reactions, the optometrist shall inform the patient's primary physician of the treatment plan and document that contact on the patient's chart. If the patient does not identify a primary physician, the patient shall be referred to a physician to determine the presence or absence of any systemic contraindications to the intended therapeutic agent. Following that assessment, and prior to prescribing, the prescribing optometrist shall contact the examining physician, documenting that contact on the patient's chart.

(3) Closed-angle glaucoma shall be considered an emergency in which the treating optometrist shall make immediate referral directly to a physician who specializes in the treatment of diseases of the eye and shall institute any emergency procedures as are directed by that physician.

SECTION 13. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

This Proposed Order of the Optometry Examining Board is approved for submission to the Governor and Legislature.

Dated _____ Agency _____

Chairperson
Optometry Examining Board