CR 93-182

CERTIFICATE

STATE OF WISCONSIN

DEPARTMENT OF REGULATION AND LICENSING

TO ALL TO WHOM THESE PRESENTS SHALL COME, GREETINGS:

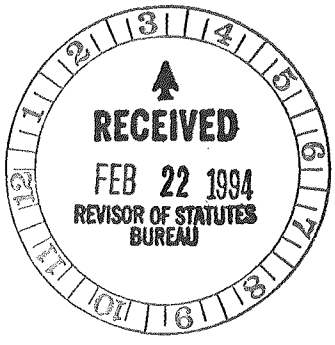
I, Marlene A. Cummings, Secretary of the Wisconsin Department of Regulation and Licensing and custodian of the official records of the Department of Regulation and Licensing, do hereby certify that the annexed rules were duly approved and adopted by the Department of Regulation and Licensing on the 21st day of February, 1994.

I further certify that said copy has been compared by me with the original on file in this office and that the same is a true copy thereof, and of the whole of such original.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the official seal of the Department at 1400 East Washington Avenue, Madison, Wisconsin this 21st day of February, 1994.

Marlene A. Cummings

Marlene A. Cummings
Secretary
Department of Regulation and Licensing



5-1-94

STATE OF WISCONSIN
DEPARTMENT OF REGULATION AND LICENSING

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE DEPARTMENT OF REGULATION AND LICENSING	ORDER OF THE DEPARTMENT OF REGULATION AND LICENSING ADOPTING RULES (CLEARINGHOUSE RULE 93-182)

ORDER

An order of the Department of Regulation and Licensing to repeal RL 10.02 (3); to renumber RL 10.02 (2); to renumber and amend RL 10.02 (1); to amend RL 10.01 (3) and 10.04 (2); to repeal and recreate RL 10.01 (8) (intro.) and (10) (intro.); and to create RL 10.01 (8) (f) and (g), (10) (L), (m) and (n) and 10.02 (1) (a) relating to the use of therapeutic pharmaceutical agents and diagnostic pharmaceutical agents by licensed optometrists.

Analysis prepared by the Department of Regulation and Licensing.

ANALYSIS

Statutes authorizing promulgation: ss. 227.11 (2), 449.17 (5) and 449.18 (8), Stats.

Statutes interpreted: ss. 161.39 (2), 449.01 (1) (a) 2 c, 449.17 and 449.18, Stats.

The Secretary of the Department of Regulation and Licensing is authorized, after consultation with the Medical Examining Board, the Optometry Examining Board and the Pharmacy Examining Board, under ss. 449.17 (5) and 449.18 (8), Stats., to promulgate rules specifying those diagnostic and therapeutic pharmaceutical agents that may or may not be prescribed or administered by licensed optometrists.

Sections 1 and 2

Several definitions contained in s. RL 10.01 are being revised to clarify various aspects concerning institutions which approve coursework relating to the use of diagnostic and therapeutic pharmaceutical agents and relating to the standards and procedures which apply when using such agents.

Section 3

Sections RL 10.01 (8) (f) and (g) are being created to permit the use of any drug which is used for an ophthalmic diagnostic purpose and which has been approved by the Food and Drug Administration pursuant to the Federal Food, Drug, and Cosmetic Act.

Section 4

Sections RL 10.01 (10) (L) (m) and (n) are being created to permit the use of any drug which is used for an ophthalmic therapeutic purpose and which has been approved by the Food and Drug Administration pursuant to the Federal Food, Drug, and Cosmetic Act.

Sections 5, 6, 7 and 8

Section RL 10.02 (1) is being renumbered and amended to clarify the conditions under which pharmaceutical agents may be prescribed and administered by optometrists. The continuing education component is designed to assure that optometrists certified to use pharmaceutical agents have current information relating to the use and application of such agents. Section RL 10.02 (2) is being amended to require an optometrist to inform the department within 10 working days after he or she designates a new physician, physician clinic or hospital to which he or she agrees to refer patients who experience adverse drug reactions.

Section 9

Section RL 10.02 (3) is being repealed. The rule requires optometrists to submit an annual report to the department relating to the use of therapeutic pharmaceutical agents during the specified reporting period. The department has reviewed information submitted by optometrists during the last 2 years and has concluded that removal of the requirement would not be detrimental to the public interest and would in fact benefit the public by focusing reporting only on any adverse reactions encountered.

Section 10

Section RL 10.04 (2) is being amended to provide that applicants will be required to obtain a minimum score of 75 on an examination in pharmacology administered by the national board or an examination prepared, administered and graded by the Optometry Examining Board or, if applying after April 1, 1994, obtain a passing score on Parts I and II of the national examination administered by the National Board of Examiners in Optometry. The national board examination consists of three parts. Prior to December, 1993, the national board provided a separate score for that portion of the examination which related to pharmacology. Starting in 1994, the pharmacology examination score will be included in the final score reported for completion of Parts I and II of the examination.

TEXT OF RULE

SECTION 1. RL 10.01 (3) is amended to read:

RL 10.01 (3) "Approved institution" means ~~the university of Wisconsin extension health sciences unit or any United States~~ a college of optometry accredited by the American council on optometric education approved by the optometry examining board which offers a course of study in general and ocular pharmacology meeting the requirements of s. 449.17 (4), Stats., or a course of study relating to the use of therapeutic pharmaceutical agents and the removal of superficial foreign bodies from an eye or from an appendage to the eye meeting the requirements of s. 449.18 (2), Stats.

Note: The Optometry Examining Board annually reviews for approval the colleges of optometry accredited by the council on optometry education of the American optometric association or other accrediting bodies. A list of board approved colleges of optometry is available from the board upon request.

SECTION 2. RL 10.01 (8) (intro.) and (10) (intro.) are repealed and recreated to read:

RL 10.01 (8) (intro.) "Diagnostic pharmaceutical agent" means any topical ocular diagnostic pharmaceutical agent which is an optometric means used to determine the visual efficiency of the human visual system, including refractive and functional abilities, or to diagnose the presence of ocular disease or ocular manifestations of systemic disease and other departures from normal. "Diagnostic pharmaceutical agents" include but are not limited to:

(10) (intro.) "Therapeutic pharmaceutical agent" means a drug which is prescribed or administered for ocular therapeutic purposes. Therapeutic pharmaceutical agents include but are not limited to:

SECTION 3. RL 10.01 (8) (f) and (g) are created to read:

RL 10.01 (8) (f) Any drug which is used for an ophthalmic diagnostic purpose and which is the subject of a new drug application approved by the food and drug administration under s. 505 (c) (1) of the federal food, drug and cosmetic act, 21 USC s. 355, as amended.

(g) Any drug which is used for an ophthalmic diagnostic purpose and which is generally exempt from the new drug application approval requirement contained in s. 505 of the federal food, drug and cosmetic act, 21 USC s. 355, as amended.

SECTION 4. RL 10.01 (10) (L), (m) and (n) are created:

RL 10.01 (10) (L) Any drug which is used for an ophthalmic therapeutic purpose and which is the subject of a new drug application approved by the food and drug administration under s. 505 (c) (1) of the federal food, drug and cosmetic act, 21 USC s. 355, as amended.

(m) Any drug which is used for an ophthalmic therapeutic purpose and which is generally exempt from the new drug application approval requirement contained in s. 505 of the federal food, drug and cosmetic act, 21 USC s. 355, as amended.

(n) Any drug which is used for an ophthalmic therapeutic purpose and which is certified by the food and drug administration pursuant to s. 507 (a) of the federal food, drug and cosmetic act, 21 USC s. 357, or is exempt from certification under s. 507 (c) of the act, as amended.

NOTE: Section 161.39, Stats., contains certain limitations relating to the prescribing and administering of controlled substances by optometrists certified under s. 449.18, Stats.

SECTION 5. RL 10.02 (1) is renumbered RL 10.02 (1) (b) and amended to read:

RL 10.02 (1) (b) Prescribing. Therapeutic pharmaceutical agents may be prescribed or administered by an optometrist ~~holding a current TPA certificate~~ 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 ~~health care professions~~ optometric profession. An optometrist shall not prescribe or administer a therapeutic pharmaceutical agent which is not ~~listed in~~ allowed under s. RL 10.01 (10).

Approved agents may be used in combination only with other approved agents when appropriate. Prior to prescribing beta blockers or carbonic anhydrase inhibitors for the treatment of glaucoma, or any oral antiviral, or any other therapeutic pharmaceutical agent, as may be identified and designated in the future by the optometry examining board, which might prove to have significant systemic adverse reactions, the optometrist shall inform the patient's primary physician of his/her treatment plans 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. 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 such emergency procedures as are directed by that physician.

SECTION 6. RL 10.02 (1) (a) is created to read:

RL 10.02 RESTRICTIONS AND REPORTS. (1) RESTRICTIONS. (a) Certification and education. Therapeutic pharmaceutical agents may be prescribed or administered by an optometrist who holds a current TPA certificate and who satisfies the continuing education requirements specified in s. Opt 6.04. Diagnostic pharmaceutical agents may be administered by an optometrist who holds a current DPA certificate and who successfully completes biennially a minimum of 1 hour of continuing education approved by the optometry examining board relating to new drugs which are used for ophthalmic diagnostic purposes and which are approved by the food and drug administration, or other topics as designated by the optometry examining board.

NOTE: Completion of the continuing education required in s. Opt 6.04 for TPA certification satisfies the continuing education requirement under this section for an optometrist who holds both a DPA and a TPA certificate.

SECTION 7. RL 10.02 (2) is renumbered RL 10.02 (2) (a).

SECTION 8. RL 10.02 (2) (b) is created to read:

RL 10.02 (2) (b) Any optometrist certified to use diagnostic or therapeutic pharmaceutical agents shall file a revised adverse drug reaction plan with the department within 10 working days after the optometrist designates a new physician, physician clinic or hospital to which he or she agrees to refer patients who experience adverse drug reactions.

SECTION 9. RL 10.02 (3) is repealed.

SECTION 10. RL 10.04 (2) is amended to read:

RL 10.04 (2) Obtained a score of ~~no~~ not less than 75 on the examination in pharmacology which is administered by the national board of examiners in optometry or, if applying after April 1, 1994, obtained a passing score on parts I and II of the examination administered by the national board of examiners in optometry, or obtained a score of not less than 75 on an examination prepared, administered and graded by the optometry examining board; and,

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(END OF TEXT OF RULE)

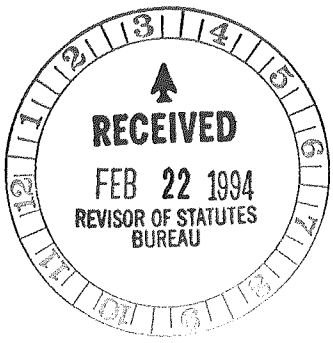
The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin administrative register pursuant to s. 227.22 (2) (intro.), Stats.

Dated 2/21/94

Agency Marlene A. Cummings

Marlene A. Cummings, Secretary
Department of Regulation and Licensing

CORRESPONDENCE/MEMORANDUM **STATE OF WISCONSIN**



DATE: February 22, 1994

TO: Gary Poulson
Assistant Revisor of Statutes

FROM: Pamela Haack, Administrative Assistant
Department of Regulation and Licensing

SUBJECT: Final Rulemaking Order

Agency: DEPARTMENT OF REGULATION AND LICENSING

Clearinghouse Rule: 93-182

Attached is a copy and a certified copy of a final order adopting rules. Would you please publish these rules in the code.

Please stamp or sign a copy of this letter to acknowledge receipt.

Thank you.