CR 90-76

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, do hereby certify that the annexed rules were duly approved and adopted by the Department of Regulation and Licensing on the 28th day of September, 1990.

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 28th day of September, 1990.

Marlene A. Cummings
Secretary
Department of Regulation and Licensing

12-1-90

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 90-76)

ORDER

An order of the Department of Regulation and Licensing to renumber and amend RL 10.02 and RL 10.03; to amend RL 10 (title), RL 10.01 (intro.), (1) and (8); and to create RL 10.01 (9) and (10) and RL 10.02 of the administrative code 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) (a), 449.18 (8), Stats., as affected by 1989 Wisconsin Act 31.

Statutes interpreted: ss. 161.39 (2), 449.01 (1) (a) 2 c, 449.19, Stats., as affected by 1989 Wisconsin Act 31.

These rules result from changes in the law enacted as part of 1989 Wisconsin Act 31. This law amended the definition of the practice of optometry to permit optometrists to prescribe and administer drugs for ocular therapeutic purposes and to remove superficial foreign bodies from the eye or an appendage of the eye. The law also requires the Secretary of the Department of Regulation and Licensing to promulgate rules specifying those therapeutic pharmaceutical agents that may or may not be prescribed or administered. In three instances limitations are placed on the use of therapeutic pharmaceutical agents by optometrists. The authority of the Secretary to limit the use as provided in the rules is derived from the broader statutory authority in s. 449.18 (8), Stats., to specify drugs that may or may not be prescribed or administered, and from s. 227.11 (2) (a), Stats., as these limitations are necessary to properly effectuate the statute.

These rules were drafted based on information developed through an advisory committee comprised of two optometrists, two ophthalmologists, one optician, two public members, one representing the rural elderly and the other urban minority communities, and one representative each from the Optometry, Medical and Pharmacy Examining Boards. The committee met on October 4, 1989, November 2, 1989, December 7, 1989 and January 3, 1990. The advice of the Medical Examining Board, Optometry Examining Board and Pharmacy Examining Board was received in the process of writing the rules.

The significant factors used in selecting therapeutic drugs for this list were:

1. The frequency or prevalence of ocular conditions requiring treatment by this agent.

    a. Are the conditions chronic, requiring long term, frequent treatment?

    b. Will the conditions likely recur?

2. The risk of visual impairment or visual loss without treatment of such conditions.

3. What is the availability of alternative sources of care if the agent is not available to optometrists?

4. How successful is this agent in the treatment of such ocular conditions?

5. What are the risks to the consumer associated with receiving treatment by this agent?

    a. What is the probability of serious side effects?

    b. What is the ability of the TPA certified optometrist to monitor and treat side effects?

    c. What is the probability of adverse interactions with systemic medications used to treat other organs?

    d. What is the ability of the TPA certified optometrist to monitor adverse interactions with other systemic medications used to treat other organs?

    e. May the condition to be treated by this agent be a part of a general medical condition affecting different organs of the body?

6. Does data from other states document risk to the consumer when this agent is used by TPA certified optometrists?

The impact on consumer choice and consumer safety of permitting or prohibiting these specific therapeutics was also considered.

The drugs included on the list and permitted for use by certified optometrists are categorized as follows: oral analgesics; topical decongestant agents and decongestant combinations; antiallergy agents; artificial tear solutions, ophthalmic irrigants and ocular lubricants; topical hyperosmotic agents; miscellaneous preparations and products; topical anesthetics; antibiotics; anti-inflammatory agents; topical anticholinergic agents; and antiglaucomatous agents.

Topical beta-adrenergic blocking agents and oral carbonic anhydrase inhibitors, antiglaucomatous agents, are approved for treatment of open-angle glaucoma with certain restrictions. Closed-angle glaucoma is referred to in the rules as an emergency requiring special procedures.

Section RL 10.01 (8) is amended to delete unnecessary punctuation. Section RL 10.02 is renumbered and amended to include statement of approval required to receive a TPA certificate from the Optometry Examining Board. The newly created RL 10.02 specifies the restrictions placed on the use of topical beta-adrenergic blocking agents and oral carbonic anhydrase inhibitors for the treatment of glaucoma and with the use of any oral antiviral. RL 10.03 is renumbered and the title is amended to be consistent with proposed rules of the Optometry Examining Board relating to requirements for licensed optometrists to obtain certificates to use therapeutic pharmaceutical agents.

TEXT OF RULE

SECTION 1. Chapter RL 10 (title) is amended to read:

CHAPTER RL 10 (title)
USE OF ~~DIAGNOSTIC~~ PHARMACEUTICAL
AGENTS BY LICENSED OPTOMETRISTS

SECTION 2. RL 10.01 (intro.) and (1) are amended to read:

RL 10.01 (intro.) DEFINITIONS. As used in the rules in this chapter ~~and in the interpretation and administration of chapter 280, Laws of 1977~~:

(1) "Adverse drug reaction" means an adverse, physical or psychological reaction experienced by a person resulting from diagnostic or therapeutic pharmaceutical agents administered by an optometrist which occurs within 24 hours after the drug is administered. An adverse drug reaction may be indicated by symptoms which include, but are not limited to, the following: red eye, painful eye, decrease in vision, pale or red swelling of the periocular or periorbital tissues, nausea, vomiting, fainting, mental confusion or cessation of respiration.

SECTION 3. RL 10.01 (8) is amended to read:

RL 10.01 (8) "Diagnostic pharmaceutical agent" means any of the topical, ocular, diagnostic, pharmaceutical agents listed below if used in accordance with the following conditions: agents may be used in strengths no greater than the strengths indicated in the list; may be used by the optometrist only and may not be dispensed by the optometrist to patients for self-administration.

SECTION 4. RL 10.01 (9) and (10) are created to read:

RL 10.01 (9) "TPA certificate" means a certificate granted by the optometry examining board to an optometrist as evidence that the optometrist is certified to use therapeutic pharmaceutical agents in accordance with s. 449.18, Stats.

(10) "Therapeutic pharmaceutical agent" means any of the topical or oral ocular therapeutic pharmaceutical agents listed in pars. (a) to (k).

(a) Oral analgesics.

1. Acetaminophen.

2. Aspirin.

3. Salicylates.

4. Schedule III, IV and V narcotic analgesics.

(b) Topical decongestant agents and decongestant combinations.

1. Epinephrine HCl.

2. Hydroxyamphetamine HBr.

3. Naphazoline HCl.

4. Oxymetazoline HCl.

5. Phenylephrine HCl.

6. Tetrahydrozoline HCl.

7. Combinations of the above agents with antihistamines or zinc sulfate.

(c) Antiallergy agents.

1. 'Topical and oral antihistamine agents in the following drug categories.'

a. Alkyamines.

b. Ethanolamines.

c. Ethylenediamines.

d. Phenothiazines.

e. Piperazines.

f. Piperidines.

g. Terfenadines.

2. 'Cromolyn sodium, a mast cell stabilizing agent.'

(d) Artificial tear solutions, ophthalmic irrigants and ocular lubricants.

(e) Hypertonic sodium chloride, a topical hyperosmotic agent.

(f) Yellow mercuric oxide, a miscellaneous preparation and product.

(g) Topical anesthetics.

1. Benoxinate HCl.

2. Benoxinate HCl and sodium fluorescein.

3. Proparacaine HCl.

4. Tetracaine HCl.

(h) Antibiotics.

1. 'Topical antibiotics.'

a. Aminoglycosides.

b. Bacitracin.

c. Cephalosporins.

d. Erythromycin.

e. Gramicidin.

f. Penicillins.

g. Polymyxin B.

h. Sulfonamides.

i. Tetracyclines.

j. Trimethoprim.

k. Zinc sulfate.

2. 'Oral antibiotics.'

a. Erythromycin.

b. Tetracycline.

3. 'Topical antiviral agents.'

a. Acyclovir.

b. Idoxuridine.

c. Trifluridine.

d. Vidarabine.

4. 'Acyclovir, an oral antiviral agent.'

(i) Anti-inflammatory agents.

1. 'Oral non-steroidal anti-inflammatory agents.'

a. Fenoprofen.

b. Ibuprofen.

c. Ketoprofen.

d. Naproxen.

2. 'Topical corticosteroid agents.'

a. Dexamethasone.

b. Fluoromethalone.

c. Medrysone.

d. Prednisolone.

e. Prednisolone and atropine combinations.

f. Topical corticosteroid and antibiotic combinations.

g. Topical corticosteroid and mydriatic combinations.

(j) Topical anticholinergic agents.

1. Atropine.

2. Atropine sulfate.

3. Cyclopentolate.

4. Homatropine.

5. Homatropine hydrogen bromide.

6. Scopolamine.

7. Tropicamide.

(k) Antiglaucomatous agents.

1. 'Sympathomimetics.'

a. Dipivefrin.

b. Epinephrine.

2. 'Miotics, direct acting.'

a. Acetylcholine.

b. Carbachol.

c. Pilocarpine.

3. 'Miotics, cholinesterase inhibitors.'

a. Demecarium bromide.

b. Echothiophate.

c. Isoflurophate.

d. Physostigmine.

4. 'Topical beta-adrenergic blocking agents.'

a. Betaxolol.

b. Levobunolol.

c. Timolol.

5. 'Oral carbonic anhydrase inhibitors.'

a. Acetazolamide.

b. Dichlorphenamide.

c. Methazolamide.

SECTION 5. RL 10.02 is renumbered 10.03 and amended to read:

RL 10.03 STATEMENT OF APPROVAL REQUIRED. A licensed optometrist may not use diagnostic pharmaceutical agents in the practice of optometry unless the optometrist has completed an application form and received a DPA certificate from the department. An application for a certificate shall be granted or denied within 15 business days after receipt of a completed application. A licensed optometrist may not use therapeutic pharmaceutical agents in the practice of optometry unless the optometrist has completed an application form, met the requirements under s. 449.18, Stats., and received a TPA certificate from the optometry examining board.

SECTION 6. RL 10.02 is created to read:

RL 10.02 RESTRICTIONS AND REPORTS. (1) PRESCRIBING RESTRICTIONS. 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. An optometrist shall not prescribe or administer a therapeutic pharmaceutical agent which is not listed in 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, 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.

(2) REPORTING REQUIRED. Any optometrist certified to use therapeutic pharmaceutical agents shall file with the department within 10 working days of its occurrence a report on any adverse reaction resulting from the optometrists's administration of such agents. This report shall include the optometrist's name, address and license number, the patient's name, address and age, the patient's presenting problem, the diagnosis, the agent administered and the method of administration, the reaction and the subsequent action taken.

(3) ANNUAL REPORT. Any optometrist certified to use therapeutic pharmaceutical agents shall file with the department by January 31 of each year a report on the optometrist's usage of such agents. This report shall include the optometrist's name, address and license number, the number of TPA administrations, and for each administration the patient's age and presenting problem, the diagnosis, the agent administered and the method of administration, and the benefits achieved or problems encountered.

SECTION 7. RL 10.03 is renumbered 10.04 and 10.04 (title) is amended to read:

RL 10.04 (title) APPLICATION FOR CERTIFICATE.

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

Dated 9/28/90

Agency Marlene D. Cummings

Marlene A. Cummings, Secretary
Department of Regulation
and Licensing

CORRESPONDENCE/MEMORANDUM **STATE OF WISCONSIN**

DATE: September 28, 1990

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: 90-76

Attached is a copy and a certified copy of a final order adopting rules.

Would you please publish these rules in the code.

Thank you.