CR92-218

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 7th day of May, 1993.

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 7th day of May, 1993.

Marlene A. Cummings
Secretary
Department of Regulation
and Licensing

7-1-93

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 92-218)

ORDER

An order of the Department of Regulation and Licensing to create RL 10.01 (8) (d) 2 and (e), RL 10.01 (10) (h) 1 cm and 1 em, and RL 10.01 (10) (k) 4 am and 4 bm of the administrative code relating to use of diagnostic pharmaceutical agents and therapeutic pharmaceutical agents by licensed optometrists.

Analysis prepared by the Department of Regulation and Licensing.

ANALYSIS

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

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

Section 449.17, Stats., permits an optometrist certified under that section to use topical ocular diagnostic pharmaceutical agents ("DPA"). Certified optometrists are required to establish a plan approved by the Secretary of the Department of Regulation and Licensing for the referral of patients who experience adverse reactions from the application of such agents to appropriate medical services. The Secretary is authorized under s. 449.17 (5), Stats., after consultation with the Optometry Examining Board, the Medical Examining Board and the Pharmacy Examining Board, to promulgate rules specifying the topical ocular diagnostic pharmaceutical agents which optometrists may utilize in this state.

Section 449.18, Stats., permits an optometrist certified under that section to use therapeutic pharmaceutical agents ("TPA") and to remove foreign bodies from an eye or from an appendage to the eye. The Secretary is authorized under s. 449.18 (8), Stats., after consultation with the Optometry Examining Board, the Medical Examining Board and the Pharmacy Examining Board, to promulgate rules specifying those therapeutic pharmaceutical agents that may or may not be prescribed or administered by certified optometrists.

The current rules specifying the diagnostic and therapeutic pharmaceutical agents which may be used by certified optometrists are contained in s. RL 10.01 (8) and (10). These rules are being proposed by the Optometry Examining Board for purposes of adding "Rose Bengal," "Dapiprazole HCl" and "Pilocarpine .125%" to the list of approved diagnostic pharmaceutical agents and "Ciprofloxacin," "Norfloxacin," "Diclofenac sodium," "Carteolol" and "Metipranolol HCl" to the list of approved therapeutic pharmaceutical agents. The Optometry Examining Board has determined, based upon the extensive research and analysis conducted by the Drug Review Committee appointed by the board, that the addition of these agents to the approved list would provide substantial benefits to consumers in Wisconsin. In addition, the proposals were presented to the Pharmacy Examining Board and the Medical Examining Board for their review and comment prior to final consideration by the department.

The significant factors used in selecting diagnostic pharmaceutical agents and therapeutic pharmaceutical agents for inclusion on the 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 the therapeutic pharmaceutical agents was also considered.

The following is a section analysis of the proposed rules:

SECTION 1. This section creates s. RL 10.01 (8) (d) 2 and (e) for purposes of adding "Rose Bengal," "Dapiprazole HCl" and "Pilocarpine .125%" to the list of approved diagnostic pharmaceutical agents.

SECTION 2. This section creates s. RL 10.01 (10) (h) 1 cm and 1 em for purposes of adding two new topical antibiotics, "Ciprofloxacin" and "Norfloxacin," to the list of approved therapeutic pharmaceutical agents.

SECTION 3. This section creates s. RL 10.01 (10) (i) 3 for purposes of adding a topical non-steroidal agent, "Diclofenac sodium" to the list of approved therapeutic pharmaceutical agents.

SECTION 4. This section creates s. RL 10.01 (10) (k) 4 am and 4 bm for purposes of adding two new topical beta-adrenergic blocking agents, "Carteolol" and "Metipranolol HCl" to the list of approved therapeutic pharmaceutical agents.

TEXT OF RULE

SECTION 1. RL 10.01 (8) (d) 2 and (e) are created to read:

RL 10.01 (8) (d) 2 Rose Bengal.

(e) Miotics.

1. Dapiprazole HCl.

2. Pilocarpine .125%.

SECTION 2. RL 10.01 (10) (h) 1 cm and 1 em are created to read:

RL 10.01 (10) (h) 1 cm Ciprofloxacin HCl.

em Norfloxacin.

SECTION 3. RL 10.01 (10) (i) 3 is created to read:

RL 10.01 (10) (i) 3 Topical non-steroidal agent, diclofenac sodium.

SECTION 4. RL 10.01 (10) (k) 4 am and 4 bm are created to read:

RL 10.01 (10) (k) 4 am Carteolol HCl.

bm Metipranolol HCl.

(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 5/7/93

Agency Marlene A. Cummings

Marlene A. Cummings, Secretary
Department of Regulation
and Licensing

CORRESPONDENCE/MEMORANDUM **STATE OF WISCONSIN**

DATE: May 7, 1993

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: 92-218

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.