

CR 86-6

RECEIVED

CERTIFICATE

MAY 30 1986
3:25 pm
Revisor of Statutes
Bureau

STATE OF WISCONSIN)
) SS
OPTOMETRY EXAMINING BOARD)

TO ALL TO WHOM THESE PRESENTS SHALL COME, GREETINGS:

I, Barbara Livingston, director of the Bureau of Health Professions in the Department of Regulation and Licensing, and custodian of the official records of the Optometry Examining Board, do hereby certify that the rules relating to written disclosure to accompany the dispensing of extended-wear contact lenses were duly approved and adopted by this board on April 17, 1986.

I further certify that said copy has been compared by me with the original on file in this board 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 board at 1400 East Washington Avenue, Madison, Wisconsin, this 27th day of May, A.D. 1986.



Barbara Livingston
Bureau Director

BL:DD:rjt
pc6469

47-1-86

RECEIVED

MAY 30 1986

Revisor of Statutes
Bureau

STATE OF WISCONSIN
BEFORE THE OPTOMETRY EXAMINING BOARD

IN THE MATTER OF RULEMAKING : ORDER OF THE OPTOMETRY
PROCEEDINGS BEFORE THE : EXAMINING BOARD REPEALING,
OPTOMETRY EXAMINING BOARD : AMENDING OR ADOPTING RULES

AN ORDER to renumber Opt 6.02(1) to (3); and, create Opt 6.02(1) and 6.14 relating to the provision of written disclosure to accompany the dispensing of extended wear contact lenses.

ANALYSIS

In this order, the optometry examining board adopts ss. Opt 6.02(1) and Opt 6.14 which defines the term, "extended-wear contact lenses" and requires an optometrist to provide written disclosures to a patient receiving extended-wear lenses. The disclosure informs the individual of the risk of potentially serious complications. It lists warning signs of complications and includes a recommended wearing schedule. The form also requires scheduling of follow up care.

Current ss. Opt 6.02(1) to (3) are renumbered ss. Opt 6.02(2) to (4) to retain in alphabetical order the terms defined.

The rules proposed interpret ss. 449.07(1)(f) and 449.08, Stats., relating to denial, limitation, suspension, revocation and reprimand and unprofessional conduct.

The rules in this proposal became effective as emergency rules on December 17, 1985.

ORDER

Pursuant to the authority vested in the optometry examining board in ss. 15.08(5)(b), 227.014(2)(a), 449.01(1)(a)2, 449.07(1)(f) and 449.08, Stats., the optometry examining board hereby adopts rules interpreting ss. 449.07(1)(f) and 449.08, Stats., as follows:

SECTION 1. Opt 6.02(1) to (3) are renumbered 6.02(2) to (4).

SECTION 2. Opt 6.02(1) is created to read:

Opt 6.02 DEFINITIONS. (1) "Extended-wear contact lenses" as used in s. Opt 6.14 means contact lenses which have received federal food and drug administration approval for marketing for extended wear and are prescribed for use on an extended wear (overnight) schedule.

Note: Extended-wear contact lenses require premarket approval under section 515 of the Federal Food, Drug and Cosmetic Act, 21 USC 360e (1985). A copy of this provision is available at the board office, 1400 East Washington Avenue, Madison, Wisconsin 53702.

SECTION 3. Opt 6.14 is created to read:

Opt 6.14 DISCLOSURE. (1) It shall be unprofessional conduct for an optometrist to fail to provide to any patient receiving extended-wear contact lenses a separate, written disclosure in not less than 12 point type, which includes the following language:

"As with any other drug or device, the use of extended-wear contact lenses is not without risk. A small, but significant, percentage of individuals wearing extended-wear lenses develop potentially serious complications which can lead to permanent eye damage.

If you have any unexplained eye pain or redness, watering of the eye or discharge, cloudy or foggy vision, decrease in vision or sensitivity to light, remove your lenses and make arrangements to see your eye-care professional before wearing your lenses again.

Regular inspection by a licensed eye-care professional is important to evaluate your eyes' tolerance of extended wear lenses."

(2) The disclosure shall in addition indicate that a regular schedule of cleaning and disinfection is necessary and indicate a recommended schedule of follow-up appointments for evaluation of adaptation to contact lens wear.

(3) Information about replacement lenses, service agreements, warranties, refunds and other business items should not be part of the required disclosure. Instructions for proper lens care and recommended solutions should also be distributed separately.

(4) The disclosure shall be signed by the patient prior to the patient's receipt of the lenses. If the patient is a minor or incompetent, the patient's parent or legal guardian shall sign the disclosure. The patient or legal guardian shall be given a copy of the disclosure, and a signed copy of the disclosure shall be placed in the patient record of the individual for whom the lenses are dispensed.

(5) An optometrist may dispense replacement extended-wear lenses without providing the written disclosure required in sub. (1), if the patient for whom the lenses are dispensed already has a signed disclosure form in his or her patient file.

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. 227.026(1)(intro.), Stats.

Dated this 30 day May, 1986.

By:


Lloyd Milavitz, O.D., Chairperson
Optometry Examining Board

FISCAL ESTIMATE

There is no statewide or local fiscal effect.

REGULATORY FLEXIBILITY ANALYSIS

The rules proposed will have no significant economic impact on small businesses, as defined in s. 227.016(1)(a), Stats.

Questions on the proposed rules may be directed to Wilma Morris, 266-3423.

WM:cls
RULCTR-N
3/20/86