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LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
NEW JERSEY STATE BOARD OF OPTOMETRISTS

Readoption with Amendments: N.J.A.C. 13:38

New Jersey State Board of Optometrists Rules

Proposed: April 4, 2011 at 43 N.J.R. 822(a).

Adopted: September 21, 2011 by the State Board of Optometrists, Mitchell Fink, O.D., President.

Filed: March 15, 2012 as R.2012 d.077, **with substantial changes** not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3), **with the proposed amendments to N.J.A.C. 13:38-1.4(b)3 and 2.1(c) not adopted.**

Authority: N.J.S.A. 45:12-1 et seq.

Effective Dates: March 15, 2012, Readoption;

April 16, 2012, Amendments.

Expiration Date: March 15, 2019.

Summary of Public Comments and Agency Responses:

The official comment period ended June 3, 2011. The Board received 10 comments from the following individuals:

1. Charles H. Fitzpatrick, O.D., President of New Jersey Society of Optometric Physicians (NJSOP)
2. Matthew S. Halpin, Opticians Association of New Jersey

1. COMMENT: Dr. Fitzpatrick commented on N.J.A.C. 13:38-1.4, which regulates practice under assumed names and requires disclosure of practice names. He expressed concern that the word "advertising" referred to in paragraph (b)1 should be more specific as to the media format included. Furthermore, he was concerned that the reporting requirement to the Board specified paragraph (b)3 appeared burdensome and duplicative because every registered corporation pursuant to the Professional Services Corporation Act, is required to file the identical information with the State each year. He also expressed concern that subsection (c) is unclear as to whether each individual corporate officer must comply with the filing requirement or whether each officer is responsible that this filing has been accomplished for the entity each year.

RESPONSE: The Board believes that the term "advertising" should remain broad so that new advertising formats that may become available in the future would be regulated under this section.

The Board agrees with Dr. Fitzpatrick that the reporting requirement to the Board specified in paragraph (b)3 is duplicative and burdensome to licensees. Licensees are required to file with the Board the same information that they must provide to the State pursuant to the Professional Services Corporation Act. Additionally, the Board does not use this information in its regulation of licensees. The Board is therefore not adopting the amendment proposed at paragraph (b)3 and is deleting existing paragraph(b)3 in its entirety upon adoption. Additional public notice and comment pursuant to N.J.A.C. 1:30-6.3 regarding this change is not required because the effect of the change is to relieve licensees of a ministerial requirement; the public would not be prejudiced because this information is still required by other means and would still be available as a public record.

2. COMMENT: Dr. Fitzpatrick commented on N.J.A.C. 13:38-2.1(c), the general rules of optometric practice. NJSOP believes that revisions to this subsection should reflect advances in technology, current practice patterns, and the use of ancillary personnel all designed to improve the accuracy and quality of the optometric eye examination and improve office efficiency to the benefit of the consumer. NJSOP believes that the proposed revision to this subsection is

overreaching and regressive. Dr. Fitzpatrick expressed concern that the requirement that "any procedure involving contact with the surface of the eye shall be performed only by the optometrist" constitutes a substantive change from the existing language with broader implications than the presumed intent of the original rule. He points out that the new restriction ignores established technology, which already allows for safe, accurate, and benign measurement and routine office procedures to be performed by others who do not have a doctoral degree. Modern optometric practice is equipped with several modalities of measurement of ocular anatomy and performance that employ mechanical transducers, ultrasound, and laser technologies, some of which approximate but do not deform the ocular tissues. He believes that there is no reason why a properly trained technician under the direct supervision of an optometric physician cannot safely and accurately perform these measurements or continue to safely perform other routine office procedures. He believes that this revision adds no real benefit to the consumer but will add to the cost of patient care.

RESPONSE: As stated in the Summary in the notice of proposal, the Board proposed to amend the existing language in N.J.A.C. 13:38-2.1(c) in order to clarify that optometrists may not delegate to ancillary personnel any duties that involve contact tonometry. However, it appears from the comment that this change has created additional confusion over which tests must be performed by optometrists and which tests may be performed by trained technicians. The Board notes that the existing language, which requires any procedure involving contact tonometry be performed by an optometrist, has been sufficient to protect New Jersey consumers from harm. Therefore, the Board is not adopting the proposed amendment to N.J.A.C. 13:38-2.1(c).

3. COMMENT: Dr. Fitzpatrick commented on N.J.A.C. 13:38-2.3, the section requiring optometrists to prepare, and maintain for at least seven years, contemporaneous, legible, and permanent professional treatment and billing records made to patients or third-party carriers for professional services. He expressed concern that the proposed revision of the rule calls for more burdensome paperwork and record archiving for a period of time well beyond what is required in the normal course of business. He pointed out that, in many settings, the clinical record is maintained separately from the claim history and financial record of the practice or retail establishment. The HINT legislation and the Health Claims Authorization, Processing and Payment Act, N.J.S.A. 17B:30-48, call for a maximum look-back period on claim submission and claim payment review/recovery of three years. He states that no sensible explanation has been offered as to why the proposed revision should exceed industry standards.

RESPONSE: The Board considers the billing record to be part of the patient record, and the Board has always required that patient records be retained for seven years, as do most healthcare boards. Consumers frequently have questions about current and past bills, and the Board [page=1273] requires that patient billing records be available for its review. Furthermore, the Board notes that the HINT legislation and the Health Claims Authorization, Processing and Payment Act retention provisions would not apply to an optometrist who does not accept insurance payments.

4. COMMENT: With respect to N.J.A.C. 13:38-2.4, which establishes rules relating to prescription writing, Dr. Fitzpatrick proposed that N.J.A.C. 13:38-2.4(a)4 be revised to clarify that the 72-hour time requirement to report an altered, lost, or stolen New Jersey Prescription Blank should start after discovery of the lost New Jersey Prescription Blank.

He also expressed concern that proposed N.J.A.C. 13:38-2.4(k) requires an optometrist to have a Drug Enforcement Administration Registration Number (DEA number) in order to transmit a prescription to a pharmacist telephonically or electronically. He points out that while the major electronic prescribing intermediaries do require that the prescriber have a DEA number to register, there is no requirement that an optometric physician possess a DEA number in order to prescribe oral or topical pharmaceutical agents to New Jersey patients. Many optometrists have chosen not to obtain a DEA registration based upon their mode of practice and the infrequent use of controlled dangerous substances in their practice. Dr. Fitzpatrick also points out that in addition to being very expensive to maintain registration, the DEA strongly opposes use of a DEA registration number other than for the purpose of providing certification of DEA registration in transactions involving controlled dangerous substances. He suggests that a more appropriate alternative would be to request the provider's National Provider Identifier (NPI) number in place of the DEA number in N.J.A.C. 13:38-2.4(k).

Dr. Fitzpatrick and NJSOP also proposed that N.J.A.C. 13:38-2.4(c)2, which time-limits the quantity of drug dispensed to a 72-hour supply, be modified to conform to the current statute and reflect the fact that the optometric physician may now supply a newly created pharmaceutical device that administers a sustained dose of a drug while sequestered within a contact lens. He points out that N.J.S.A. 45:12-9.11 was modified on May 6, 2010 to permit an optometrist to dispense a pharmaceutical agent to a patient through a contact lens at a charge to the patient.

RESPONSE: The Board agrees with Dr. Fitzpatrick's comment that N.J.A.C. 13:38-2.4(a)4 should be revised to clarify that the 72-hour time requirement to report an altered, lost, or stolen New Jersey Prescription Blank should start after discovery of the lost New Jersey Prescription Blank.

The Board's intent when it proposed N.J.A.C. 13:38-2.4(k) was to permit electronic transmission of prescriptions. The Board agrees that it is not necessary for an optometrist to have a DEA number. The Board is changing this section to permit electronic and telephonic transmission of prescriptions, and is deleting any reference to the requirement to provide a DEA registration number and license number. Deleting the reference to providing a DEA number in order to transmit a prescription electronically does not change the effect of this rule, which is to permit electronic transmission of prescriptions. The change only lessens the financial burden on licensees who use this means of transmission. The Board discussed Dr. Fitzpatrick's comment on N.J.A.C. 13:38-2.4(c)2, which time-limits the quantity of drug dispensed to a 72-hour supply in accordance with N.J.S.A. 45:12-9.11a. The Board recognized that this rule may be confusing in light of the amendment to N.J.S.A. 45:12-9.11b, which permits an optometrist to dispense a pharmaceutical agent that is delivered to the eye by a contact lens at a charge to the patient. However, in this instance, the Board has chosen not to follow a new procedure authorized by P.L. 2011, c. 33 to make substantial changes on adoption, so that the amendments proposed as part of the readoption can become effective without waiting for the notice and the 60-day comment period under the new procedure. The Board will develop a separate notice of proposal to address the issue.

5. COMMENT: Dr. Fitzpatrick commented on N.J.A.C. 13:38-6.1, the section concerned with records and the release of information as required by Federal statute. He points out that the proposed revision in N.J.A.C. 13:38-6.1(c) requires an optometrist to release a copy of a patient's contact lens prescription to a "patient's authorized representative." He expressed concern that because the prefatory language to the proposed amendments stated that the Board believes that there are certain circumstances in which it is appropriate and necessary to permit a patient's authorized representative to receive a copy of the patient's contact lens or eyeglass prescription, the Board's intent is to broaden the implied definition of "authorized representative" beyond the original intent of the regulation. He states that this may be subject to abuse, and that the change exceeds statutory authority. He points out that the Contact Lens Dispenser Act does not contain this provision. Additionally, he believes that Fairness to the Contact Lens Consumer Act, the authorizing Federal regulation, in stipulating contact lens prescription release to the "contact lens seller" presumed that the optical supplier was a licensed optometrist, physician, or ophthalmic dispenser, the three licensees who may dispense a contact lens in New Jersey. However, he states that this assumption is no longer valid, and the unsupervised distribution of contact lenses poses a grave and immediate risk to New Jersey citizens. He also expressed concern about the same release provisions of the spectacle prescription to a "patient's authorized representative." NJSOP believes that this will abet the unregulated supply of spectacle lenses and frames, contrary to existing rules. NJSOP believes that the fitting, fabrication, verification, and supply of prescription ophthalmic eyeglasses should be regulated for the public welfare. NJSOP is concerned that the extension of the prescription release to a "patient's authorized representative" without knowing if that party is competent to deliver American National Standards Institute (ANSI)-approved materials, is ill advised and NJSOP is also concerned about the proliferation of out-of-State and off-shore internet-based virtual retailers who are outside of the jurisdiction of New Jersey law enforcement and consumer protection. NJSOP has requested that this subsection of the revised rule be expunged.

RESPONSE: The Board disagrees with Dr. Fitzpatrick's assessment that this amendment will encourage the unauthorized dispensing of contact lenses and eyeglasses. The Board recognizes that there may be some confusion over the term "authorized representative" because the under the Fairness to Contact Lens Consumers Act and the Contact Lens Rule, a contact lens seller may be considered to be a person designated to act on behalf of a patient. However, the Board has not incorporated the Fairness to Contact Lens Consumers Act and the Contact Lens Rule into its rules either directly or by reference. The Board notes that the term "authorized representative" is defined in N.J.A.C. 13:38-6.1(a) and includes the patient's insurance carrier, attorney, or in the case of a minor, a parent or guardian. The Board's intent when it amended this rule was to make it easier for foster parents and guardians of children to obtain copies of the prescriptions for eyeglasses and contact lenses for children in their care.

6. COMMENT: Mr. Halpern offered a comment relating to proposed N.J.A.C. 13:38-2.1(c), which clarifies that any procedure that has contact with the surface of the eye must be performed only by an optometrist. The Opticians Association of New Jersey (OANJ) wants to know if, under this amendment, anyone other than an optometrist can teach contact lens insertion and removal.

RESPONSE: As stated in response to a prior comment, the Board has decided to keep the existing version of N.J.A.C. 13:38-2.1(c), which permits only optometrists to perform contact tonometry.

7. COMMENT: Mr. Halpern and the OANJ expressed concern that N.J.A.C. 13:38-2.10 match the minimum standards and tolerances of those stated in N.J.A.C. 13:35-5.2, Minimum standards and tolerances.

RESPONSE: The standards set forth in N.J.A.C. 13:38-2.10(a)7 vary slightly from the standards set forth in N.J.A.C. 13:35-5.2(a)7, relating to prism power and center location of specified optical center. Additionally, there is no

corresponding standard in N.J.A.C. 13:35-5.2 to the standard relating to frame selection and fit, which appears in N.J.A.C. 13:38-2.10(a)13. However, the Board believes that the standards recited in N.J.A.C. 13:38-2.10 are the same standards issued by ANSI.

8. COMMENT: Mr. Halpern and the OANJ suggested that the term "direct supervision" as used in N.J.A.C. 13:38-2.11 be further clarified to mean "in the presence of an optometrist" when ancillary personnel are conducting activities otherwise reserved for individuals licensed by the State. They expressed concern that without the appropriate levels of direct supervision, patient safety can be compromised.

RESPONSE: The term "direct supervision" is defined in N.J.A.C. 13:38-2.11(a)2 as "the continuous physical presence of the optometrist [page=1274] who is in a supervisory status at the office location and who is available on-site for the consultation, guidance, and instruction during the performance of any delegable procedures by ancillary personnel." The Board does not believe that it is necessary to amend the rules to require an optometrist to stand next to a technician performing a procedure. The Board believes that the existing definition is satisfactory and does not compromise patient care.

9. COMMENT: Mr. Halpern and the OANJ commend the Board for the proposed change to N.J.A.C. 13:38-6.1(d) to permit a prescription for eyeglasses to be provided to a patient's authorized representative upon the patient's request.

RESPONSE: The Board thanks Mr. Halpern and the OANJ for their support.

10. COMMENT: Mr. Halpern and the OANJ commented on the Jobs Impact language in the prefatory to the proposed amendments. They expressed concern that any expansion of delegation of duties to ancillary personnel would have an impact on jobs for licensed ophthalmic dispensers.

RESPONSE: The Board does not agree with Mr. Halpern, because the proposed amendments do not expand the delegation of duties to ancillary personnel.

Federal Standards Statement

These rules comport with the Fairness to Contact Lens Consumers Act § 4(f), 15 U.S.C. § 7603(f), and the Contact Lens Rule, 16 CFR Part 315. There are no other applicable Federal laws or standards.

Full text of the readopted rules can be found in the New Jersey Administrative Code at N.J.A.C. 13:38.

Full text of the adopted amendments follows (additions to proposal indicated in boldface with asterisks ***thus***; deletions from proposal indicated in brackets with asterisks *[thus]*):

SUBCHAPTER 1. ADVERTISEMENTS AND SOLICITATION

(OFFICE OF ADMINISTRATIVE LAW NOTE: As the Board is deleting existing N.J.A.C. 13:38-1.4(b)3 upon adoption, the non-adoption of the proposed amendments to the paragraph is not depicted below.)

13:38-1.3 Permissible business structures; referral fees

(a) As used in this section, the following words and terms shall have the following meanings unless the context clearly indicates otherwise.

...

"Closely allied health care professional" means an individual who provides professional services and is licensed in New Jersey by a professional or occupational licensing board or other State agency, in any of the following fields pursuant to N.J.S.A. 14A:17-3(b): optometry, ophthalmic dispensers, dentistry, registered professional nursing, physical therapy or any branch of medicine or surgery.

...

(b)-(f) (No change.)

13:38-1.4 Optometric practice under assumed names and disclosure of practitioner names

(a) (No change.)

(b) A licensed optometrist who is also an officer of a professional service corporation which renders optometric service or sells ophthalmic materials shall:

1. Disclose conspicuously the name of at least one corporate officer who is licensed to practice optometry within this State in all advertising of the corporation; ***and***

2. Display the names of all optometrists conspicuously at the entrance where the optometric services are rendered*[*; and]**.*

[3. File with the Board of Optometrists by March 31 of each year a copy of that report required to be filed pursuant to N.J.S.A. 14A:17-15 showing the names and post office addresses of all shareholders, directors, and officers of such corporation. In addition thereto, the report shall include the names and post office addresses of all licensed optometrists employed by the corporation.]

(c) All corporate officers holding licenses shall comply with this section.

(d)-(e) (No change.)

(f) A sole practitioner of optometry and all licensed optometrists offering services as partners in a partnership shall display their names conspicuously at the entrance of the facility.

SUBCHAPTER 2. GENERAL RULES OF OPTOMETRIC PRACTICE

13:38-2.1 Minimum examination; record of conditions

(a)-(b) (No change.)

[(c) Any procedure involving contact with the surface of the eye shall be performed only by the optometrist.]

(c) Where any form of contact tonometry is used in procedure (a)11 above, only the optometrist shall perform the procedure.

(d)-(e) (No change.)

(f) Nothing contained in this chapter shall be construed to prohibit vision screening under the direct supervision of an optometrist for the purpose of determining the advisability of a complete optometric examination. For purposes of this section, "direct supervision" means the continuous physical presence of the optometrist who is in a supervisory status at the office location and who is available on-site for consultation, guidance and instruction during the performance of any delegable procedures conducted by ancillary personnel.

13:38-2.3 Records of examinations and prescriptions; computerized records

(a) Licensees shall prepare and maintain contemporaneous, legible, permanent professional treatment and billing records made to patients or third-party carriers for professional services. All treatment records, bills and claim forms shall accurately reflect the treatment of services rendered. Treatment and billing records shall be maintained for a period of not less than seven years from the date of the most recent entry.

(b)-(d) (No change.)

13:38-2.4 Requirements for issuing prescriptions and dispensing medications

(a) Written prescriptions shall be issued only on New Jersey Prescription Blanks (NJPB).

1. All prescription blanks shall be numbered consecutively and shall be printed on non-reproducible, non-erasable safety paper bearing the optometrist's license number and National Provider Identifier Number, if applicable;
2. All prescription blanks shall be secured from a vendor approved by the Division of Consumer Affairs in the Department of Law and Public Safety;
3. A record shall be maintained of the receipt of New Jersey Prescription Blanks; and
4. The Office of Drug Control in the Division of Consumer Affairs shall be notified as soon as possible but no later than 72 hours **[if]** ***from the time that the optometrist becomes aware that*** a New Jersey Prescription Blank has been altered, lost^{*},^{*} or stolen from the optometrist's possession.

(b) Every optometrist shall provide the following information on all prescriptions:

1.-4. (No change.)

Recodify existing (b)-(d) as (c)-(e) (No change in text.)

(f)-(g) (No change.)

(h) Each prescription for a controlled dangerous substance shall be written on a separate NJPB.

1. (No change.)

2. An NJPB that contains a prescription for only one controlled dangerous substance and contains other medication(s) shall not be valid.

(i)-(j) (No change.)

(k) An optometrist may transmit a prescription to a pharmacist telephonically or electronically **[if the optometrist's Drug Enforcement Administration Registration Number and license number is provided]**.

SUBCHAPTER 5. FEE SCHEDULE

13:38-5.1 Fee schedule

(a) The following fees shall be charged by the Board:

1.-2. (No change.)

3. Biennial renewal fee--active license: \$ 250.00;

4. Biennial renewal fee--inactive license \$ 100.00;

5.-12. (No change.)

13. (No change in text.)

14. Letter of certification:

i. (No change.)

Recodify existing 16. and 17. as 15. and 16. (No change in text.)

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SUBCHAPTER 6. RECORDS

13:38-6.1 Availability of records

(a)-(b) (No change.)

(c) An optometrist shall, free of charge, release the contact lens prescription directly to the patient upon completion of the contact lens fitting. An optometrist shall, free of charge, release a copy of a patient's contact lens prescription directly to a licensed ophthalmologist, optometrist, ophthalmic dispenser or patient's authorized representative, upon either the verbal or written request of a patient. Upon the release of a contact lens prescription directly to a patient, an optometrist, shall provide the patient with a written warning, which shall include the following language in boldface, underlined and in capital letters (Lexis.com Note: Due to system limitations, the following written warning is recreated in bold italic, *thus*, rather than bold underline.):

WARNING: YOU SHOULD BE AWARE THAT YOUR EYES MAY CHANGE WITH TIME AND CONTACT LENSES THAT WERE INITIALLY FITTING PROPERLY MAY NO LONGER BE APPROPRIATE AND MAY ENDANGER YOUR EYE HEALTH. YOU SHOULD SEE YOUR EYE DOCTOR PERIODICALLY TO ENSURE YOUR LENSES ARE FITTING PROPERLY.

1. (No change.)

(d) After the completion of a patient's comprehensive eye examination, and upon the patient's request, a copy of the patient's prescription for eyeglasses shall be given, free of charge, to the patient, the patient's authorized representative or to another optometrist, ophthalmologist or ophthalmic dispenser acting on the patient's behalf.

(e) (No change.)

SUBCHAPTER 7. CONTINUING PROFESSIONAL OPTOMETRIC EDUCATION

13:38-7.2 Inactive license renewal and reactivation of license; continuing education requirement

(a) Any licensee who has an inactive license shall be exempt from the continuing professional optometric education requirements set forth in this subchapter.

(b) Any licensee seeking to reactivate an inactive license shall provide the Board with evidence of having maintained proficiency by completing the professional optometric education requirements set forth at N.J.A.C. 13:38-7.3(a) during the two calendar years immediately preceding the application for reactivation.