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**DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE
BOARD OF OPTOMETRY**

**MINUTES – DRAFT
GENERAL BUSINESS MEETING**

**Renaissance at Sea World
6677 Sea Harbor Drive
Orlando, FL 32821**

August 23, 2013

14 Agenda items are subject to being taken up at anytime during the meeting. Participants in
15 this public meeting should be aware that these proceedings are being recorded and that an
16 audio file of the meeting will be posted to the board’s website.

17
18 **General Board Business started: 9:07 a.m.**

19
20 **CALL TO ORDER:**

21 Dr. Timothy Underhill, Chairman, called the meeting to order at 9:07 a.m. Those present
22 for all or part of the meeting included the following:

23
24 **BOARD MEMBERS:**

25 Timothy Underhill, O.D., Chair
26 Terrance Naberhaus, O.D., Vice-Chair
27 Tamara Maule, O.D.
28 Stuart Kaplan, O.D.
29 Christopher King, O.D.
30 Rosa McNaughton, Esq.
31 Rod Presnell, R.Ph.

32
33 **BOARD STAFF:**

34 Bill Miller, Executive Director
35 Sharon Guilford, Program Operations Administrator
36 Jose Montalvan, Regulatory Supervisor/Consultant

37
38 **BOARD COUNSEL:**

39 Larry Harris, Assistant Attorney General
40 Office of Attorney General

41
42 **DISCUSSION OF RULE 64B13, FLORIDA ADMINSTRATIVE CODE:**

43
44 **Rule 64B13-5.001, F.A.C. – Hours Requirement**
45

1 **64B13-5.001 Hours Requirement.**

2 (1) As a condition to the renewal of a biennial license, each licensed practitioner shall
3 be required to maintain professional competency by completing 30 clock hours of
4 continuing education in subjects relating to optometry that have been approved by the
5 Board. Licensed practitioners shall not be required to complete the continuing education
6 requirements during the biennium in which they are initially licensed but must complete
7 one hour of approved continuing education in acquired immune deficiency syndrome that
8 complies with the requirements of Section 456.033, F.S. Credit for continuing education
9 will be allowed on the basis of an hour for hour. To receive one hour credit, a licensed
10 practitioner must attend not less than 50 minutes. There will be no fractional hour credits.

11 (a) For licensed practitioners who are certified optometrists, at least 6 of the required
12 30 hours must be of “transcript quality.” For purposes of this rule, the phrase “transcript
13 quality” refers to coursework in ocular and systemic pharmacology and the diagnosis,
14 treatment and management of ocular and systemic conditions and diseases. Transcript
15 quality CE must be sponsored by a school or college of optometry or equivalent
16 educational entity as approved by the Board and must require a test and passing grade.

17 (b) Attendance at a continuing education program must be certified by the lecturer or
18 someone in charge of the program. An instructor of a course may credit the hours taught
19 towards completion of the instructor’s required continuing education only once,
20 regardless of the number of times the course is taught. However, the instructor of a
21 course may not credit the hours taught towards completion of the “transcript quality”
22 portion of the continuing education requirement. Continuing education hours must be
23 obtained during the biennium preceding license renewal.

24 (c) Licensed practitioners shall be permitted to earn two of the 30 clock hours of
25 continuing education credit upon demonstrating successful completion of approved
26 training in cardiopulmonary resuscitation given by the American Heart Association or the
27 American Red Cross.

28 (d) Licensed practitioners shall be permitted to earn two hours of the 30 clock hours
29 in the area of practice management.

30 (e) As part of the 30 clock hours, licensed practitioners shall be required to obtain two
31 hours in the area of Florida jurisprudence.

32 1. No more than two hours of continuing education in the area of Florida
33 jurisprudence may be applied to the 30 clock hour requirement in subsection (1).

34 2. A licensed practitioner may earn two hours in Florida jurisprudence by attending a
35 meeting of the Board for no less than four (4) continuous hours. Licensed practitioners
36 will be required to sign-in and sign-out with board staff. Those licensed practitioners
37 present for disciplinary purposes are not eligible to earn the two clock hours for the
38 Board meeting.

39 3. Out of state licensed practitioners who do not practice in Florida at any time
40 during the biennium, shall be permitted to satisfy the requirement of two hours in Florida
41 jurisprudence by certifying that they have obtained and read a copy of the current
42 provisions of Chapters 456 and 463, F.S., and Rule Chapter 64B13, F.A.C.

43 (f) As part of the 30 clock hours, licensed practitioners are required to complete a 2-
44 hour course relating to prevention of medical errors, as part of the licensure and renewal
45 process. The course shall be approved by the Board and shall include a study of root-
46 cause analysis, error reduction and prevention, and patient safety. If the course is being

1 offered by a facility licensed pursuant to Chapter 395, F.S., for its employees, the Board
2 approves 1 hour of the 2-hour course to be specifically related to error reduction and
3 prevention methods used in that facility. No more than two hours of continuing
4 education relating to the prevention of medical errors may be applied to the 30 clock hour
5 requirement in subsection (1).

6 (2) The Board shall audit an appropriate number of randomly selected licensed
7 practitioners to assure that the reports of completion of continuing education are valid. At
8 the time of audit, each designated licensed practitioner must provide to the Board office
9 appropriate documentation of completion of the required continuing education. All
10 licensed practitioners are responsible for maintaining appropriate records of completed
11 continuing education for the past two bienniums.

12 *Specific Authority 456.013(7), 463.005(1), 463.007(3), (4) FS. Law Implemented*
13 *456.013(7), 463.007 FS. History—New 11-13-79, Amended 5-28-80, 9-16-80, 1-13-81, 2-*
14 *14-82, Formerly 21Q-5.01, Amended 12-16-86, 12-11-88, 4-19-89, 12-20-89, 9-22-92,*
15 *10-28-92, Formerly 21Q-5.001, Amended 8-31-93, Formerly 61F8-5.001, Amended 11-*
16 *29-94, 7-5-95, 8-18-96, Formerly 59V-5.001, Amended 3-21-00, 10-2-01, 1-8-02, 5-8-02,*
17 *3-20-03, 12-25-06,_____.*

18
19 **Dr. Naberhaus moved to approve the above language in Rule 64B13-5.001(1)(e)1**
20 **and (f), F.A.C. The motion was seconded and carried 7/0.**

21
22 **Dr. Kaplan moved that the proposed rule would not have any adverse impacts on**
23 **small businesses and the proposed rule would not be likely to directly or indirectly**
24 **increase regulatory costs to any entity (including government) in excess of \$200,000**
25 **in the aggregate in Florida within 1 year after the implementation of the rule. The**
26 **motion was seconded and carried 7/0.**

27
28 Discussion ensued.

29
30 **Dr. Underhill moved to issue a Notice of Rule Development on Rule 64B13-5.002,**
31 **F.A.C. The motion was seconded and carried 7/0.**

32
33 Mr. John Griffin, with the Florida Optometry Association, stated that the association was
34 against accepting online courses and believed that 64B13-5.001(1)(b), F.A.C. the word
35 attendance means live courses.

36
37 Further discussion ensued and the board requested to hold a Telephone Conference Call
38 to discuss modifications to Rule 64B13-5.002, F.A.C.

39
40 **Rule 64B13-10.001, F.A.C. – Application for Certification**

41
42 **64B13-10.001 Application for Certification.**

43 To be certified to administer and prescribe topical ocular pharmaceutical agents a
44 licensed practitioner must submit a completed application, DH-MQA 1128 (7/2012)
45 DPR/OPT/006(A), revised 1/89, hereby incorporated by reference, provided by the
46 Board; remit the application fee for certification specified in subsection 64B13-

1 6.001(9)(7), F.A.C.; and demonstrate compliance with the following requirements:

2 (1) Successful completion of at least 110 hours of Board approved transcript quality
3 coursework and clinical training in general and ocular pharmacology conducted by an
4 accredited institution which has facilities for both didactic and clinical instruction in
5 pharmacology. The institution must document the applicant's successful completion. The
6 Board will accept coursework and clinical training in general and ocular pharmacology
7 received by the applicant during his or her basic optometric curriculum or at post-
8 graduate courses if this coursework and training was provided by a Board approved
9 school of optometry or equivalent educational entity;

10 (2) Completion of at least one (1) year of supervised experience in differential
11 diagnosis of eye diseases or disorders. The one year of supervised experience shall be
12 received either during optometric training or in a clinical setting as part of optometric
13 experience. The requisite one year of supervised experience in a clinical setting may be
14 obtained in an academic or non-academic environment. For the purpose of this rule, one
15 year of supervised experience in an academic setting is understood to mean three (3)
16 quarters or two (2) semesters and one (1) year of supervised experience in a non-
17 academic setting is understood to mean a twelve month period;

18 (3) Successful completion of part II of the NBEO examination.

19 *Rulemaking Authority 463.005(1), 463.0055 FS. Law Implemented 463.0055, 463.006*
20 *FS. History—New 11-20-86, Amended 7-6-88, 3-16-89, Formerly 21Q-10.001, 61F8-*
21 *10.001, Amended 10-4-94, Formerly 59V-10.001, Amended 7-21-11, _____.*
22

23 **Dr. Underhill moved to Notice for Rule Development and approve the drafted**
24 **language in Rule 64B13-10.001, F.A.C. The motion was seconded and carried 7/0.**
25

26 **Dr. Naberhaus moved that the proposed rule would not have any adverse impacts**
27 **on small businesses and the proposed rule would not be likely to directly or**
28 **indirectly increase regulatory costs to any entity (including government) in excess of**
29 **\$200,000 in the aggregate in Florida within 1 year after the implementation of the**
30 **rule. The motion was seconded and carried 7/0.**
31

32 **Rule 64B13-10.002, F.A.C. – Administration and Prescription of Topical**
33 **Pharmaceutical Agents**
34

35 **64B13-10.002 Administration and Prescription of Ocular Topical**
36 **Pharmaceutical Agents.**

37 (1) Only a certified optometrist may administer and prescribe ~~topical~~ ocular
38 pharmaceutical agents. A licensed practitioner who is not certified may use topically
39 applied anesthetics solely for the purpose of glaucoma examinations, but is otherwise
40 prohibited from administering or prescribing ~~topical~~ ocular pharmaceutical agents.
41 Certified optometrists may administer and prescribe only those ~~topical~~ ocular
42 pharmaceutical agents identified by rule of the Board and oral ocular pharmaceutical
43 agents listed in the statutory formulary.

44 (2) Only certified optometrists who have successfully completed the Board approved
45 pharmaceutical course and examination specified in subsection 463.0055(1)(b),F.S. and
46 provided proof of such to the Department are authorized to administer and prescribe the

1 oral ocular pharmaceutical agents or their therapeutic equivalents specified in subsection
2 463.0055(3),F.S.

3 (3) Controlled substances listed on the statutory formulary of oral ocular
4 pharmaceutical agents may only be administered or prescribed by a certified optometrist
5 who has successfully completed the board approved oral drug course and examination
6 specified in subsection 463.0055(1)(b),F.S., provided proof of such to the Department,
7 and after the certified optometrist has acquired a United States Drug Enforcement
8 Administration registration number.

9 (4)(a)(2) Any prescription for an ocular ~~topical~~ pharmaceutical agent written by a
10 certified optometrist shall contain the following information:

11 1.~~(a)~~ Name of the person for whom the pharmaceutical agent is prescribed;

12 2.~~(b)~~ Full name and address of the prescribing certified optometrist;

13 3.~~(c)~~ Name of the ~~topical~~ ocular pharmaceutical agent prescribed and the strength,
14 quantity, and directions for use thereof; and

15 4.~~(d)~~ Prescriber number and signature of the prescribing certified optometrist.

16 (b) All written prescriptions must comply with the requirements of sections 456.42,
17 F.S. and 893.04, F.S.

18 (5)(3) When an ocular ~~topical~~ pharmaceutical agent is either administered or
19 prescribed to a patient by a certified optometrist, such shall be documented in the patients
20 record.

21 *Rulemaking Authority 463.005(1), 463.0055 FS. Law Implemented 463.0055, 463.012,*
22 *463.0135, 463.016(1)(g), (k) FS. History–New 11-20-86, Formerly 21Q-10.002, 61F8-*
23 *10.002, 59V-10.002, Amended 10-28-09,_____.*

24
25 **Dr. Naberhaus moved to Notice for Rule Development and approve the drafted**
26 **language in Rule 64B13-10.002, F.A.C. The motion was seconded and carried 7/0.**

27
28 **Dr. Kaplan moved that the proposed rule would not have any adverse impacts on**
29 **small businesses and the proposed rule would not be likely to directly or indirectly**
30 **increase regulatory costs to any entity (including government) in excess of \$200,000**
31 **in the aggregate in Florida within 1 year after the implementation of the rule. The**
32 **motion was seconded and carried 7/0.**

33
34 **64B13-10.0011 Administration and Prescription of Oral Pharmaceutical Agents**

35
36 In order to administer or prescribe oral ocular pharmaceutical agents, a Certified
37 Optometrist must submit proof of successful completion of a course and subsequent
38 examination, approved by the Board, on general and ocular pharmaceutical agents and
39 the side effects of those agents.

40 *Rulemaking Authority 463.005(1), 463.0055 FS. Law Implemented 463.0055, 463.006*
41 *FS. History–New*

42
43 **Dr. Naberhaus moved to Notice for Rule Development and approve the drafted**
44 **language in Rule 64B13-10.0011, F.A.C. The motion was seconded and carried 7/0.**

1 **Dr. Kaplan moved that the proposed rule would not have any adverse impacts on**
2 **small businesses and the proposed rule would not be likely to directly or indirectly**
3 **increase regulatory costs to any entity (including government) in excess of \$200,000**
4 **in the aggregate in Florida within 1 year after the implementation of the rule. The**
5 **motion was seconded and carried 7/0.**

6
7 **Rule 64B13-15.005, F.A.C. – Designation of Administrative Violations;**
8 **Major; Minor**
9

10 **64B13-15.005 Designation of Administrative Violations; Major; Minor.**

11 (1) Violations of the following statutory and rule provisions are considered to be
12 Minor Administrative Violations:

13 (a) Section 456.062, F.S., entitled “Advertisement by Health Care Provider of Free or
14 Discounted Services; Required Statement.”

15 (b) Section 456.057, F.S., entitled “Ownership and control of patient records; report
16 or copies of records to be furnished.”

17 (c) Section 463.011, F.S., entitled “Exhibition of License.”

18 (d) Subsection (1), paragraphs (2)(a) and (b) of Section 463.012, F.S., entitled
19 “Prescriptions; Filing; Release; Duplication.”

20 (e) Subsection 463.0135(11), F.S. entitled "Standards of Practice," if the violation is
21 of a technical nature not related to patient care.

22 ~~(f)(e)~~ Paragraphs (1)(d) and (e) of Section 463.014, F.S., entitled “Certain Acts
23 Prohibited.”

24 (g) For the first violation of subsection 463.0141, F.S., entitled "Reports of adverse
25 incidents in the practice of optometry."

26 ~~(h)(f)~~ Subsections (4) and (5) of Section 499.028, F.S., entitled “Drug samples or
27 complimentary drugs; starter packs; permits to distribute” or subsection 465.276(5), F.S.,
28 entitled “Dispensing Practitioner,” if the violation is of a technical nature not related to
29 patient care.

30 ~~(i)(g)~~ Rule 64B13-3.002, F.A.C., entitled “Responsibility to Patient.”

31 ~~(j)(h)~~ Rule 64B13-3.005, F.A.C., entitled “Entrance Sign.”

32 ~~(k)(i)~~ Rule 64B13-3.006, F.A.C., entitled “Licenses and Signs in Office.”

33 ~~(l)(j)~~ Rule 64B13-3.012, F.A.C., entitled “Prescriptions” if the violation consists of
34 failing to release a prescription or technical omissions or errors on the prescription not
35 related to patient care.

36 ~~(m)(k)~~ Section 456.072(1)(nn), F.S., violating any provision of Section 790.338, F.S.

37 (2) Violations of the following statutory and rule provisions are considered to be
38 Major Administrative Violations:

39 (a) Paragraphs 456.072(1)(a), (b), (c), (e), (f), (g), (h), (i), (k), (m), (q), (r), (s), (w),
40 (x), (cc), (gg), (ii), (jj), (kk), (ll), F.S., entitled “Grounds for Discipline; Penalties;
41 Enforcement.”

42 (b) Subsections 463.0055(2)(a), (b) and (c), F.S., entitled “Administration and
43 prescription of topical ocular pharmaceutical agents; ~~committee.~~”

44 (c) Subsections 463.0135(7) and (8), F.S., entitled “Standards of Practice.”

45 (d) Subsection 463.0135(11), F.S. entitled "Standards of Practice," if the violation is
46 substantially likely to affect patient care.

1 ~~(e)(d)~~ Subsections 463.014(1)(a) and (b), F.S., entitled “Certain Acts Prohibited.”

2 ~~(f)~~ For a second or subsequent violation of subsection 463.0141, F.S., entitled
3 “Reports of adverse incidents in the practice of optometry.”

4 ~~(g)(e)~~ Subsections 463.015(1)(a), (b), (c) and (2)(a), (c) and (d), F.S., entitled
5 “Violations and Penalties.”

6 ~~(h)(f)~~ Subsections 463.016(1)(a), (b), (c), (d), (e), (f), (g), (h), (i), (k), (l), (m), (n), (o),
7 (q), (r), and (s), F.S., entitled “Grounds for Disciplinary Action; Action by the Board.”

8 ~~(i)(g)~~ Subsections 499.028(4) and (5), F.S., entitled “Drug samples or complimentary
9 drugs; starter packs; permits to distribute” if the violation is substantially likely to affect
10 patient care.

11 ~~(j)(h)~~ Rule 64B13-3.001, F.A.C., entitled “Confidential Information; Disclosure.”

12 ~~(k)(i)~~ Rule 64B13-3.003, F.A.C., entitled “Patient Records; Transfer or Death of
13 Licensed Practitioner.”

14 ~~(l)(j)~~ Paragraphs (2)(a), (b), (c), (d), (e), (f), and subsections (4), (5), and (6), of Rule
15 64B13-3.009, F.A.C., entitled “False, Fraudulent, Deceptive and Misleading Advertising
16 Prohibited; Policy; Definitions; Affirmative Disclosure.”

17 ~~(m)(k)~~ Rule 64B13-3.012, F.A.C., entitled “Prescriptions” if the violation is
18 substantially likely to affect patient care.

19 ~~(n)(l)~~ Subsection (3) of Rule 64B13-11.001, F.A.C., entitled “Inactive Status.”

20 ~~(o)(m)~~ Rule 64B13-5.001, F.A.C., entitled “Hours Requirement.”

21 (3) For any offense which is not specified above or in subsection (1) or (2) of Rule
22 64B13-15.006, F.A.C., the Board will apply the guideline penalty based on the offense
23 listed which is most comparable to the offense charged.

24 *Rulemaking Authority 456.079, 463.005(1), FS. Law Implemented 456.079, 463.005,*
25 *463.016, FS. History—New 2-24-87, Formerly 21Q-15.005, 61F8-15.005, Amended 8-18-*
26 *96, Formerly 59V-15.005, Amended 5-1-02, 7-6-10, 2-1-12,_____.*

27
28 **Dr. Naberhaus moved to approve the drafted language in Rule 64B13-15.005, F.A.C.**
29 **The motion was seconded and carried 7/0.**

30
31 **Dr. Naberhaus moved that the proposed rule would not have any adverse impacts**
32 **on small businesses and the proposed rule would not be likely to directly or**
33 **indirectly increase regulatory costs to any entity (including government) in excess of**
34 **\$200,000 in the aggregate in Florida within 1 year after the implementation of the**
35 **rule. The motion was seconded and carried 7/0.**

36
37 Mr. Griffin addressed his concerns with the proposed language.

38
39 Discussion ensued.

40
41 **Dr. Naberhaus moved to amend the previous motion to include the new change to**
42 **include (1) and (2) as presented in Rule 64B13-15.005, F.A.C. The motion was**
43 **seconded and carried 7/0.**

44
45 **Dr. Naberhaus moved that the proposed rule would not have any adverse impacts**
46 **on small businesses and the proposed rule would not be likely to directly or**

1 indirectly increase regulatory costs to any entity (including government) in excess of
2 \$200,000 in the aggregate in Florida within 1 year after the implementation of the
3 rule. The motion was seconded and carried 7/0.

4
5 **Rule 64B13-15.006, F.A.C. – Designation of Patient Care Violations; Major;
6 Minor**

7
8 **64B13-15.006 Designation of Patient Care Violations; Major; Minor.**

9 (1) Violations of the following statutory and rule provisions are considered to be
10 Minor Patient Care Violations:

11 (a) Subsections (1) and (8) of Section 463.0135, F.S., entitled “Standards of Practice.”

12 (b) Subsections (1) and (2) of Rule 64B13-3.007, F.A.C., entitled “Minimum
13 Procedures for Comprehensive Eye Examination,” if the violation is a first offense of
14 failing to perform or record.

15 (c) Rule 64B13-3.010, F.A.C., entitled “Standard of Practice for Licensed
16 Optometrists” if the violation does not substantially affect patient care.

17 (2) Violations of the following statutory and rule provisions are considered to be
18 Major Patient Care Violations:

19 (a) Violations of subsections (1), (3), or (4) of Section 463.0055, F.S., entitled
20 “Administration and Prescription of topical ocular pharmaceutical agents; ~~committee,~~”
21 which substantially affect patient care.

22 (b) Violations of Section 463.009, F.S., entitled “Supportive Personnel” which
23 substantially affect patient care.

24 (c) Subsection (1) of Section 463.012, F.S., entitled “Prescriptions; Filing; Release;
25 Duplication” if the violation substantially affects patient care.

26 (d) Subsections (2), (3), (4), (5), (6), and (7) of Section 463.0135, F.S., entitled
27 “Standards of Practice.”

28 (e) Subsections (3) and (4) of 463.014, F.S., entitled “Certain Acts Prohibited.”

29 (f) Paragraph (2)(b) of Section 463.015, F.S., entitled “Violations and Penalties.”

30 (g) Paragraphs (1)(g), (p) and (t) of 463.016, F.S., entitled “Grounds for Disciplinary
31 Action; Action by the Board.”

32 (h) Subsections (1), (2), (3), (4), (5), (6), (7) and (8) of Rule 64B13-3.004, F.A.C.,
33 entitled “Minimum Equipment Requirements.”

34 (i) Subsections (1) and (2) of Rule 64B13-3.007, F.A.C., entitled “Minimum
35 Procedures for Comprehensive Eye Examination,” if the violation is at least a second
36 offense of failing to perform or record.

37 (j) Rule 64B13-3.008, F.A.C., entitled “Corporate, Lay, and Unlicensed Practice of
38 Optometry Prohibited.”

39 (k) Rule 64B13-3.012, F.A.C., entitled “Prescriptions” if the violation involves
40 substantial errors or omissions directly affecting patient care.

41 (l) Rule 64B13-3.010, F.A.C., entitled “Standard of Practice for Licensed
42 Optometrists” if the violation substantially affects patient care.

43 (m) Paragraphs 456.072(1)(d), (j), (l), (n), (o), (p), (u), (y), (z), (aa), (cc), F.S.,
44 entitled “Grounds for Discipline; Penalties; Enforcement.”

45 (n) Section 456.063, F.S., entitled “Sexual Misconduct; Disqualification for License,
46 Certificate or Registration.”

1 (o) Paragraph 456.072(2)(d), F.S., when the offense is found to be fraud or making a
2 false or fraudulent representation.

3 (p) Subsection 893.05(1), F.S., entitled "Practitioners and persons administering
4 controlled substances in their absence."

5 (3) For any offense which is not specified above or in subsection (1) or (2) of Rule
6 64B13-15.005, F.A.C., the Board will apply the guideline penalty based on the offense
7 listed which is most comparable to the offense charged.

8 *Specific Authority 456.079, 463.005(1), FS. Law Implemented 456.079, 463.005,*
9 *463.016, FS. History–New 2-24-87, Formerly 21Q-15.006, 61F8-15.006, 59V-15.006,*
10 *Amended 5-1-02, 10-30-08,_____.*

11
12 **Dr. Maule moved to approve the drafted language in Rule 64B13-15.006, F.A.C.**
13 **The motion was seconded and carried 7/0.**

14
15 **Dr. Naberhaus moved that the proposed rule would not have any adverse impacts**
16 **on small businesses and the proposed rule would not be likely to directly or**
17 **indirectly increase regulatory costs to any entity (including government) in excess of**
18 **\$200,000 in the aggregate in Florida within 1 year after the implementation of the**
19 **rule. The motion was seconded and carried 7/0.**

20 21 **CHAPTER 64B13-18**

22 **TOPICAL OCULAR PHARMACEUTICAL AGENTS**

23 64B13-18.001 Purpose
24 64B13-18.002 Formulary of Topical Ocular Pharmaceutical Agents
25 64B13-18.003 Procedures Regarding Topical Ocular Pharmaceutical Agents

26 27 **64B13-18.001 Purpose.**

28 Subsection 463.0055 (2)(a), F.S., requires the Board to establish a formulary of topical
29 ocular pharmaceutical agents that may be prescribed and administered by a certified
30 optometrist. The formulary is required to consist of those topical ocular pharmaceutical
31 agents which are appropriate to treat or diagnose ocular diseases and disorders that a
32 certified optometrist is qualified to use in the practice of optometry. The Board is
33 required to establish, add to, delete from, or modify the topical formulary by rule. The
34 Legislature, in the Optometry Practice Act, created Section 463.0055(2)(a), F.S., granting
35 authority for certified optometrists to administer and prescribe topical ocular
36 pharmaceutical agents. The Legislature amended Section 463.0055, F.S., to provide for
37 the Board of Optometry to establish a formulary of such medications by rule. This rule
38 lists the approved topical ocular pharmaceutical agents for administration and
39 prescription by certified optometrists.

40 *Rulemaking Authority 463.005, 463.0055(2)(a) FS. Law Implemented 463.0055 FS.*
41 *History–New 3-30-87, Formerly 21-18.001, 21Q-18.001, 61F8-18.001, 59V-18.001,*
42 *Amended_____.*

43 44 **64B13-18.002 Formulary of Topical Ocular Pharmaceutical Agents.**

45 The formulary of topical ocular pharmaceutical agents ~~formulary~~ consists of
46 pharmaceutical agents that are appropriate to treat or diagnose ocular disease and

1 disorders and which a certified optometrist is qualified to administer and prescribe in the
2 practice of optometry pursuant to Section 463.0055(2)(a), F.S. The topical ocular
3 pharmaceutical agents in the formulary include the following legend drugs alone or in
4 combination in concentrations up to those specified, or any lesser concentration ~~that is~~
5 ~~commercially available~~:

6 (1) CYCLOPLEGIC AND MYDRIATICS

- 7 (a) Atropine sulfate – 1.0% (solution and ointment);
- 8 (b) Phenylephrine HCl – 2.5%;
- 9 (c) Cyclopentolate HCl – 0.5%, 1.0%;
- 10 (d) Scopolamine HBr – 0.25%;
- 11 (e) Homatropine HBr – 2.0%, 5.0%;
- 12 (f) Tropicamide – 0.5%, 1.0%; and
- 13 (g) Hydroxyamphetamine HBr – 1.0% plus tropicamide – 0.25%.

14 (2) LOCAL ANESTHETICS

- 15 (a) Tetracaine – 0.5%;
- 16 (b) Proparacaine HCl – 0.5%; and
- 17 (c) Benoxinate HCl – 0.4% (in combination with fluorescein).

18 (3) DIAGNOSTIC PRODUCTS

19 Fluorescein paper strips – 1 mg, 9 mg per strip.

20 (4) ANTIBACTERIAL

- 21 (a) Erythromycin – 0.5%;
- 22 (b) Bacitracin – 400 units/g, 500 units/g (ointment alone and in combination);
- 23 (c) Polymyxin – 10,000 units/g (only in combination);
- 24 (d) Neomycin – 1.75 mg/g, 1.75 mg/ml, 3.50 mg/g (only in combination);
- 25 (e) Gentamicin – 0.3% (solution and ointment);
- 26 (f) Tobramycin – 0.3% (solution and ointment in combination);
- 27 (g) Gramicidin – 0.025 mg/ml (only in combination);
- 28 (h) Ciprofloxacin HCl – 0.3% (solution and ointment);
- 29 (i) Trimethoprim – 1.0 mg/ml (only in combination);
- 30 (j) Ofloxacin – 0.3%;
- 31 (k) Levofloxacin – 1.5%;
- 32 (l) Gatifloxacin – 0.5%;
- 33 (m) Moxifloxacin – 0.5%;
- 34 (n) Sodium sulfacetamide – 10.0% (alone and in combination);
- 35 (o) Azithromycin – 1%; and
- 36 (p) Besifloxacin Ophthalmic Suspension – 0.6%.

37 (5) NON-STEROIDAL AND STEROIDAL ANTI-INFLAMMATORY AGENTS

- 38 (a) Medrysone – 1.0%;
- 39 (b) Prednisolone acetate – 0.12%, 0.125%, 0.2%, 0.5%, 0.6%, 1.0% (alone and in
40 combination);
- 41 (c) Prednisolone sodium phosphate – 0.125%, 0.25%, 1.0% (alone and in
42 combination);
- 43 (d) Fluorometholone – 0.1%, 0.25% (suspension and ointment, alone and in
44 combination);
- 45 (e) Dexamethasone – 0.1%, 1.0% (alone and in combination);
- 46 (f) Dexamethasone sodium phosphate – 0.1% (solution and ointment);

- 1 (g) Fluorometholone acetate – 0.1%;
- 2 (h) Rimexolone – 1.0%;
- 3 (i) Loteprednol etabonate – 0.2%, 0.5% (alone and in combination);
- 4 (j) Diclofenac sodium – 0.1%;
- 5 (k) Ketorolac tromethamine – 0.5%;
- 6 (l) Hydrocortisone – 1.0% (only in combination);
- 7 (m) Bromfenac – .09%;
- 8 (n) Nepafenac – 0.1%; and
- 9 (o) Difluprednate ophthalmic emulsion – .05%
- 10 (6) ANTIHISTAMINES, MAST CELL STABILIZERS AND ANTI-ALLERGY
- 11 AGENTS
- 12 (a) Cromolyn sodium – 4.0%;
- 13 (b) Lodoxamide tromethamine – 0.1%;
- 14 (c) Olopatadine HCl – 0.2%;
- 15 (d) Nedocromil sodium – 2.0%;
- 16 (e) Azelastine HCl – 0.05%;
- 17 (f) Pemirolast potassium – 0.1%;
- 18 (g) Epinastine HCl – 0.05%; and
- 19 (h) Bepotastine besilate – 1.5%.
- 20 (i) Alcaftadine – .25%.
- 21 (7) ANTIVIRAL AGENTS
- 22 (a) Trifluridine – 1.0%; and
- 23 (b) Ganciclovir – 0.15%.
- 24 (8) ANTI-GLAUCOMA AGENTS
- 25 (a) Beta Blockers.
- 26 1. Betaxolol HCl – 0.25%, 0.5%;
- 27 2. Levobunolol HCl – 0.25%, 0.5%;
- 28 3. Metipranolol HCl – 0.3%;
- 29 4. Timolol maleate or hemihydrate – 0.25%, 0.5% (solution and gel, alone and in
- 30 combination); and
- 31 5. Carteolol HCl – 1.0%.
- 32 (b) Miotics, Direct-acting
- 33 1. Carbachol – 0.75%, 1.5%, 3.0%;
- 34 2. Pilocarpine HCl – 0.5%, 1.0%, 2.0%, 4.0%; and
- 35 3. Pilocarpine gel – 4.0%.
- 36 (c) Prostaglandins
- 37 1. Latanoprost – 0.005%;
- 38 2. Bimatoprost – 0.03%; and
- 39 3. Travoprost – 0.004%.
- 40 4. Tafluprost ~~Zioptan~~ – 0.0015%.
- 41 5. Unoprostone Isopropyl - 0.15%
- 42 (d) Alpha₂ Adrenergic Agonist
- 43 1. Brimonidine tartrate – 0.15%, 0.2%; and
- 44 2. Apraclonidine HCl – 0.5%.
- 45 (e) Carbonic Anhydrase Inhibitors (CAI's)
- 46 1. Brinzolamide – 1.0%; and

1 2. Dorzolamide HCl – 2.0% (alone and in combination).

2 (9) MISCELLANEOUS

3 (a) Hydroxypropyl cellulose ophthalmic Insert;

4 (b) Dapiprazole – 0.5%;

5 (c) Cyclosporine emulsion – 0.05%;

6 (d) Polyvinyl pyrrolidone – drops 2.0%; and

7 (e) Bimatoprost – .03%

8 (f) Natamycin Ophthalmic Suspension 5%.

9 *Rulemaking Authority 463.005, 463.0055(2)(a) FS. Law Implemented 463.0055 FS.*
10 *History–New 3-30-87, Amended 4-5-88, 5-7-90, Formerly 21-18.002, Amended 5-10-92,*
11 *1-29-93, Formerly 21Q-18.002, Amended 8-31-93, 7-30-94, Formerly 61F8-18.002,*
12 *Amended 2-11-96, 4-21-96, 1-12-97, 6-8-97, Formerly 59V-18.002, Amended 6-15-00, 6-*
13 *7-05, 6-10-06, 6-26-08, 10-16-08, 3-23-09, 6-28-09, 10-18-09, 4-21-10, 12-26-10, 7-21-*
14 *11, 11-11-12,_____.*

15
16 **64B13-18.003 Procedures Regarding Topical Ocular Pharmaceutical Agents.**

17 ~~(1) Procedure for adding, deleting or modifying agents the existing formulary~~
18 ~~categories.~~

19 ~~(a) No topical ocular pharmaceutical agent within any of the categories of agents on~~
20 ~~the Formulary of Topical Ocular Pharmaceutical Agents shall become part of, deleted~~
21 ~~from or modified on the formulary until the Board has provided sixty days prior written~~
22 ~~notice to each member of the Topical Ocular Pharmaceutical Agent Committee (TOPA~~
23 ~~Committee) by certified mail return receipt requested.~~

24 ~~(b) The sixty day notice that a new agent will be added to the formulary shall not be~~
25 ~~issued before the United States Federal Drug Administration has released the agent for~~
26 ~~sale.~~

27 ~~(c) The sixty day notice period shall begin with the date stated on the notice, which~~
28 ~~date shall be on or after the date the notice was issued. The notice shall advise the TOPA~~
29 ~~Committee that the topical ocular pharmaceutical agent will become part of, deleted from~~
30 ~~or modified on the formulary after sixty days of the date stated in the notice unless the~~
31 ~~TOPA Committee initiates proceedings to review the addition, deletion or modification~~
32 ~~of the agent to the formulary within the sixty day notice period.~~

33 ~~(d) If, during the sixty day notice period, a member of the TOPA Committee requests~~
34 ~~that the TOPA Committee proceedings be initiated to review the addition, deletion or~~
35 ~~modification of the agent to the formulary, the agent shall not become part of, deleted~~
36 ~~from or modified on the formulary until the Board has received and reviewed the~~
37 ~~advisory opinion of the TOPA Committee and the Board has taken any required action.~~

38 ~~(e) Upon request to review the addition, deletion or modification of a topical ocular~~
39 ~~pharmaceutical agent to the formulary, the TOPA Committee shall meet within 30 days~~
40 ~~of the date on the request for TOPA Committee proceedings to review the addition,~~
41 ~~deletion or modification of the agent.~~

42 ~~(f) If there is no request to initiate proceedings to review the addition of the topical~~
43 ~~ocular pharmaceutical agent within the sixty day notice period, the agent shall become~~
44 ~~part of the formulary.~~

45 (1)(2) Procedure for adding, deleting or modifying categories of agents. Requests for
46 the addition, deletion or modification of categories of agents or for the addition of agents

1 ~~which are not within the existing categories on the formulary of topical ocular~~
2 ~~pharmaceutical agents shall be filed with the Board, and shall be referred to the TOPA~~
3 ~~Committee for review and for the issuance of an advisory opinion. The request shall be~~
4 ~~in writing and shall contain the following information:~~

5 (a) the name, address, and telephone number of the individual or entity filing the
6 request;

7 (b) the chemical name of the agent;

8 (c) the brand name(s) of the agent;

9 (d) the concentration of the agent;

10 (e) the United States FDA approved information sheet for the agent;

11 (f) the date the FDA released the agent for sale; and

12 (g) an explanation why the requested addition, deletion or modification is
13 consistent with the provisions of section 463.0055, F.S. and should be made.

14 (2) If, after receipt of a request as specified in subsection (1), the Board determines
15 an addition, deletion, or modification of the formulary should be made, the Board shall
16 initiate rulemaking to accomplish said change.

17 (3) A current list of all topical ocular pharmaceutical agents which certified
18 optometrists are authorized to prescribe or administer shall be maintained by the Board
19 and shall be available upon request.

20 (4) The Board shall cause a notice of each addition, deletion, and modification to the
21 formulary to be distributed to each certified optometrists and to each pharmacy licensed
22 by the State of Florida.

23
24 *Rulemaking Authority 463.0055(2)(a) FS. Law Implemented 463.0055 FS. History--New*
25 *5-15-97, Formerly 59V-18.003, Amended _____.*

26
27 **Dr. King moved to issue a Notice of Rule Development and to approve the changes**
28 **in Rule 64B13-18.001, 18.002 and 18.003, F.A.C. The motion was seconded and**
29 **carried 7/0.**

30
31 **Dr. Naberhaus moved that the proposed rule would not have any adverse impacts**
32 **on small businesses and the proposed rule would not be likely to directly or**
33 **indirectly increase regulatory costs to any entity (including government) in excess of**
34 **\$200,000 in the aggregate in Florida within 1 year after the implementation of the**
35 **rule. The motion was seconded and carried 7/0.**

36
37 The board requested to place on the next agenda the drug formulary strengths.

38 39 **DISCUSSION OF CS/CS/HB/239**

40
41 Information only.

42 43 **• Public Comment**

44
45 Mr. Harris provided drafted language on Public Comment for consideration. He also
46 stated that the Board of Medicine had submitted the language listed below to JAPC and

1 was waiting on a response. Therefore, the board could wait until the Board of Medicine
2 receives their response.

3
4 **64B13-?.???**

5 The Board of Optometry invites and encourages all members of the public to provide
6 comment on matters or propositions before the Board or a committee of the Board. The
7 opportunity to provide comment shall be subject to the following:

- 8 (1) Members of the public will be given an opportunity to provide comment on subject
9 matters before the Board after an agenda item is introduced at a properly noticed
10 board meeting.
11 (2) Members of the public shall be limited to five (5) minutes to provide comment. This
12 time shall not include time spent by the presenter responding to questions posed by
13 Board members, staff or board counsel. The chair of the Board may extend the time
14 to provide comment if time permits.
15 (3) Members of the public shall notify board staff in writing of his or her interest to be
16 heard on a proposition or matter before the Board. The notification shall identify the
17 person or entity, indicate support, opposition, or neutrality, and identify who will
18 speak on behalf of a group or faction of persons consisting of five (5) or more
19 persons. Any person or entity appearing before the Board may use a pseudonym if he
20 or she does not wish to be identified.

21
22 The board requested to postpone the action until the Board of Medicine has received a
23 response from JAPC.

24
25 Mr. Harris recommended adding Public Comment to the next agenda.

26
27 **64B13-16.001, F.A.C. - Branch Office**

28
29 **Dr. Naberhaus moved to withdraw the changes but to leave the rule development**
30 **open in Rule 64B13-16.001, F.A.C. The motion was seconded and carried 7/0.**

31
32 The board requested if the department could perform random inspections.

33
34 Mr. Harris stated that Chapter 456.069, F.S., does not grant the board authority to require
35 inspections, especially random inspections.

36
37 The board requested the department to include in renewals requiring the licensee to
38 indicate compliance with the laws and rules specifically in utilizing the correct equipment
39 for licensed optometrists.

40
41 **General Board Business ended: 12:11 p.m.**

42
43 **ADJOURNMENT:**

44
45 The meeting was adjourned at 12:11 p.m.