BOARD FOR HEARING AID SPECIALISTS AND OPTICIANS MINUTES OF MEETING

The Board for Hearing Aid Specialists and Opticians met on Wednesday, July 12, 2017, at the Offices of the Department of Professional and Occupational Regulation, Perimeter Center, Board Room 3, 2nd Floor, 9960 Mayland Drive, Richmond, Virginia 23233. The following members were present for the meeting:

Judith M. Canty
Pamela S. Chavis, MD
Edward L. DeGennaro
Mark Grohler
Laura Lee Kleiner
Debra Ogilvie, AuD
Arva B. Priola
June H. S. Rogers
Bruce R. Wagner

The following members were not present:

Melissa Gill Eric B. Hecker, PhD L. Frederick Lassen, MD Teresa D. Leeper Bonnie Mayhew

DPOR staff present for all or part of the meeting included:

Jay W. DeBoer, Director Demetrios J. Melis, Executive Director Tamika Rodriguez, Licensing Operations Administrator Cathy Clark, Administrative Assistant

A representative from the Office of the Attorney General was present for the meeting.

Elizabeth B. Peay, Assistant Attorney General

Ms. Canty determined that there was a quorum present, and called the <u>Call to Order</u> meeting to order at 9:02 a.m.

Ms. Canty introduced new Citizen Board member Laura Lee Kleiner. <u>Introduction of New</u>

Board Member

Upon a motion by Ms. Rogers and seconded by Mr. DeGennaro, the Approval of Agenda Board moved to adopt the Agenda.

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The members voting 'yes' were Ms. Canty, Dr. Chavis, Mr. DeGennaro, Mr. Grohler, Ms. Kleiner, Ms. Priola, Ms. Rogers, and Mr. Wagner. There were no negative votes. The motion passed unanimously.

Dr. Ogilvie was not present, did not participate in the discussion, and did not vote on this matter.

Upon a motion by Ms. Rogers and seconded by Mr. DeGennaro, the Board voted to approve the minutes of the April 5, 2017 Ad Hoc Committee on Optician Apprenticeships Meeting and the April 12, 2017 Board for Hearing Aid Specialists and Opticians Meeting.

The members voting 'yes' were Ms. Canty, Dr. Chavis, Mr. DeGennaro, Mr. Grohler, Ms. Kleiner, Ms. Priola, Ms. Rogers, and Mr. Wagner. There were no negative votes. The motion passed unanimously.

Dr. Ogilvie was not present, did not participate in the discussion, and did not vote on this matter.

Dr. Ogilvie arrived at the meeting at 9:08 a.m.

No communications were received by the Board.

Ms. Canty asked for public comments.

Ms. Michelle Nelms, Executive Director of the Opticians Association of Virginia addressed the Board regarding the Request for Proposals (RFP) under consideration for the Optician written and practical examinations. Ms. Nelms provided suggested criteria for the RFP and recommended that a number of licensed Opticians participate on the RFP committee. The Board took Ms. Nelms' remarks under advisement for the discussion that would take place later on the Agenda.

Dr. Ogilvie and Mr. Grohler recused themselves from the meeting.

Case

In the matter of File Number 2017-00327, Kenneth Howard Rossen, the Board reviewed the record which consisted of the Report of

Approval of Minutes: April 5, 2017 Ad Hoc Committee on Optician Apprenticeships Meeting AND April 12, 2017 Board for Hearing Aid Specialists and **Opticians Meeting**

Dr. Ogilvie Arrived at the Meeting

Communications

Public Comment

Dr. Ogilvie and Mr. **Grohler Recused**

File Number 2017-00327, Kenneth

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Findings, transcript, exhibits, and the Summary of the Informal Fact-Finding Conference. Kenneth Howard Rossen did not appear at the meeting in person, by counsel or by any other qualified representative; however, the Board was provided with an emailed letter from Mr. Rossen, which the members reviewed prior to motions and discussion.

Howard Rossen

Concerning Counts 1 and 2, upon a motion by Mr. Wagner and seconded by Ms. Kleiner, the Board adopted the Report of Findings which contains the facts regarding the regulatory and/or statutory issues in this matter, and found substantial evidence that Kenneth Howard Rossen violated the following sections of its Regulations:

Count 1:

18 VAC 80-20-200

Count 2:

18 VAC 80-20-270.1.h

The members voting 'yes' were Ms. Canty, Dr. Chavis, Mr. DeGennaro, Ms. Kleiner, Ms. Priola, Ms. Rogers, and Mr. Wagner. There were no negative votes. The motion passed unanimously.

As Board representatives in this case, Mr. Grohler and Dr. Ogilvie were not present, did not participate in the discussion, and did not vote on this matter.

Mr. Wagner informed the Board that he recalled having provided Mr. Wagner Recused technical assistance to the Board's investigative staff. Mr. Wagner recused himself.

Upon Mr. Wagner's recusal, the Board agreed without objection to reconsider the case.

Concerning Count 1, upon a motion by Ms. Rogers and seconded by Ms. Kleiner, the Board adopted the Report of Findings which contains the facts regarding the regulatory and/or statutory issues in this matter, and found substantial evidence that Kenneth Howard Rossen violated the following section of its Regulations:

Count 1:

18 VAC 80-20-200

The members voting 'yes' were Ms. Canty, Dr. Chavis, Mr. DeGennaro, Ms. Kleiner, Ms. Priola, and Ms. Rogers. There were no negative votes. The motion passed unanimously.

As Board representatives in this case, Mr. Grohler, Dr. Ogilvie, and Mr. Wagner were not present, did not participate in the discussion, and did not vote on this matter.

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Concerning Count 2, upon a motion by Ms. Rogers and seconded by Mr. DeGennaro, the Board adopted the Report of Findings which contains the facts regarding the regulatory and/or statutory issues in this matter, and found substantial evidence that Kenneth Howard Rossen violated the following section of its Regulations:

Count 2:

18 VAC 80-20-270.1.h

The members voting 'yes' were Ms. Canty, Dr. Chavis, Mr. DeGennaro, Ms. Kleiner, Ms. Priola, and Ms. Rogers. There were no negative votes. The motion passed unanimously.

As Board representatives in this case, Mr. Grohler, Dr. Ogilvie, and Mr. Wagner were not present, did not participate in the discussion, and did not vote on this matter.

Concerning Count 1, upon a motion by Ms. Rogers and seconded by Ms. Kleiner, the Board voted to accept the sanction contained in the Recommendation and to impose the following monetary penalty:

Count 1:	18 VAC 80-20-200	\$ 100.00
TOTAL (MONETARY PENALTIES)	\$ 100.00

The members voting 'yes' were Ms. Canty, Dr. Chavis, Mr. DeGennaro, Ms. Kleiner, Ms. Priola, and Ms. Rogers. There were no negative votes. The motion passed unanimously.

As Board representatives in this case, Mr. Grohler, Dr. Ogilvie, and Mr. Wagner were not present, did not participate in the discussion, and did not vote on this matter.

Concerning Count 2, upon a motion by Mr. DeGennaro and seconded by Dr. Chavis, the Board voted to accept the sanction contained in the Recommendation and to impose the following monetary penalty:

Count 1:	18 VAC 80-20-270.1.h	\$ 2,500.00
TOTAL (MONETARY PENALTIES)	\$ 2,500.00

The member voting 'yes' was Dr. Chavis. The members voting 'no' were Ms. Canty, Mr. DeGennaro, Ms. Kleiner, Ms. Priola, and Ms. Rogers. The motion failed.

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As Board representatives in this case, Mr. Grohler, Dr. Ogilvie, and Mr. Wagner were not present, did not participate in the discussion, and did not vote on this matter.

Concerning Count 2, upon a motion by Mr. DeGennaro and seconded by Dr. Chavis, the Board voted to reject the sanction contained in the Recommendation and to impose the following monetary penalty:

Count 1: 18 VAC 80-20-270.1.h \$ 1,500.00 \$1,500.00 TOTAL (MONETARY PENALTIES)

The members voting 'yes' were Ms. Canty, Mr. DeGennaro, Ms. Kleiner, Ms. Priola, and Ms. Rogers. The member voting 'no' was Ms. Chavis. The motion passed by a majority.

As Board representatives in this case, Mr. Grohler, Dr. Ogilvie, and Mr. Wagner were not present, did not participate in the discussion, and did not vote on this matter.

Mr. Grohler, Dr. Ogilvie, and Mr. Wagner returned to the meeting.

Mr. Melis reviewed Hearing Aid Specialists and Opticians licensing Statistics statistics with the Board. (See Addendum 1)

Mr. Melis also reviewed the Hearing Aid Specialists and Opticians examination statistics with the Board for all exams administered between February 1 and June 16, 2017. (See Addendums 2 and 3)

Old Business

Regulations

Mr. Melis reported to the Board that the fee adjustment for Opticians is currently in executive branch review, after which there will be one final public comment period.

OPT Fee Adjustment

Mr. Melis advised the Board that the final action of the Committee will be to work out arrangements for a video to address the surfacing component of the related instruction. Mr. DeGennaro indicated he is in contact with a laboratory that is producing a video which will likely meet the Board's needs. Mr. DeGennaro will report back to staff when more information on the video's progress and availability.

Ad Hoc Committee on Optician **Apprenticeships** Report

As requested by the Board, staff presented a draft letter which will be **Letter to Hearing**

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mailed to all Virginia licensed hearing aid specialists. (See Addendum 4)

Aid Specialists
Regarding FDA
Guidance on Medical
Evaluations

Other Business

Optician Written and Practical Exam
Request for Proposal

Mr. Melis stated it was necessary for the Board to request the Department issue a Request for Proposal (RFP) for the Board's written Optician examination since the contract with the current examination provider was expired. He further stated the Board may wish to consider also including the practical in the RFP. Mr. Melis explained the procurement process generally and advised the Board of the importance of adhering to the Department staff's guidance as it related to the procurement process. The Board agreed to convene a committee to discuss the examination needs. Mr. Melis indicated that he would inquire with the Procurement Division regarding the constituting of the RFP committee.

Following the discussion, upon a motion by Mr. DeGennaro and seconded by Ms. Rogers, the Board voted to submit a Request for Proposals for both a written and a practical Optician examination.

The members voting 'yes' were Ms. Canty, Dr. Chavis, Mr. DeGennaro, Mr. Grohler, Ms. Kleiner, Ms. Priola, Dr. Ogilvie, Ms. Rogers, and Mr. Wagner. There were no negative votes. The motion passed unanimously.

Mr. Melis stated this piece of federal legislation continues to advance. A discussion ensued about potential impacts to Virginia.

Report: Over-the-Counter Hearing Aid Act of 2017 (H.R. 1652)

There being no other business to be brought before the Board, Ms. <u>Adjourn</u> Canty adjourned the meeting at 10:18 a.m.

Judith Canty, Chair

ay W. DeBoer, Secretary

Hearing Aid Specialists and Opticians BOARD STATISTICS

Licenses & Temporary Permits Issued – 4-1-2017 through 6-3	0-2017
Hearing Aid Specialists by Exam	,
Hearing Aid Specialists by Reciprocity	(
Hearing Aid Specialists Temporary Permits	19
Optician by Exam	9
Optician by Reciprocity	C
CLE by Exam	2
CLE by Reciprocity	C
Optician License App Criminal History Review (Pass Matrix)	0
Regulant Population as of 6-1-2017	
Hearing Aid Specialist Temp Permits	58
Hearing Aid Specialists	676
Opticians	1,889
Complaints – 4-1-2017 through 6-30-2017	
New Complaints Received – Hearing Aid Specialists	0
New Complaints Received – Opticians	1
Complaints Pending – Hearing Aid Specialists	0
Complaints Pending – Opticians	0
Complaints Closed – Hearing Aid Specialists	0
Complaints Closed – Opticians	1

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	FINISHIN	FINISHING LAYOUT					80	90	75.00%	

** Above Overall Written Stats**

Breakdown

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Terence R. McAuliffe Governor

July 21, 2017

Todd Haymore Secretary of Commerce and Trade

Jay W. DeBoer Director

Board Guidance

Dear Hearing Aid Specialist:

The Virginia Board for Hearing Aid Specialists and Opticians has issued guidance to hearing aid specialist licensees regarding the December 12, 2016 Food and Drug Administration's (FDA) guidance on "Conditions for Sale for Air-Conduction Hearing Aids." The FDA provided guidance indicating that they were no longer enforcing certain conditions for sales applicable to hearing aids, particularly certain requirements for medical evaluation and recordkeeping. It has come to the Board's attention that some licensees may have interpreted this guidance from the FDA to mean that they no longer need to obtain medical evaluations for aid conduction hearing aids for adults.

Board Regulation 18 VAC 80-20-240 requires licensees and temporary permit holders to recommend the client obtain "a written statement signed by a licensed physician stating that the patient's hearing loss has been medically evaluated within the preceding six months and that the patient may be a candidate for a hearing aid." Should the client decline this recommendation, then a signed medical waiver should be obtained. The FDA guidance does not have any effect on the Board's regulation, and your Virginia regulatory requirement for a medical evaluation or signed medical waiver remains in place.

A copy of the Board's regulation 18 VAC 80-20-240 "Physician Statement Regarding Adult Client's Medical Evaluation of Hearing Loss" has been included in this letter. You can review all the Board's regulations at http://www.dpor.virginia.gov/Boards/HAS-Opticians/. You may contact the Board office by telephone at (804) 367-8590, or by email at https://www.dpor.virginia.gov, with any questions that you may have pertaining to the information provided in this memo.

18VAC80-20-240. Physician Statement Regarding Adult Client's Medical Evaluation of Hearing Loss.

A. Each licensee or holder of a temporary permit, in counseling and instructing adult clients and prospective adult clients related to the testing, fitting, and sale of hearing aids, shall be required to recommend that the client obtain a written statement signed by a licensed physician stating that the patient's hearing loss has been medically evaluated within the preceding six months and that the patient may be a candidate for a hearing aid.

B. Should the client decline the recommendation, a statement of such declination shall be obtained from the client over his signature. Medical waivers that are a part of purchase agreements shall be in a separate section, which shall be signed by the client indicating his understanding of the medical waiver. A separate, additional client signature space shall be provided in all purchase agreements for the client to sign acknowledging his understanding of the purchase terms and conditions established by 18VAC80-20-200.

- 1. Fully informed adult patients (18 years of age or older) may waive the medical evaluation.
- 2. The hearing aid specialist is prohibited from actively encouraging a prospective user to waive a medical examination.

C. The information provided in subsection A of this section must be made a part of the client's record kept by the hearing aid specialist.

Statutory Authority

§ 54.1-201 of the Code of Virginia.

Historical Notes

Derived from VR375-01-02 § 5.8, eff. December 4, 1989; amended, <u>Volume 07, Issue 11</u>, eff. March 27, 1991; <u>Volume 08, Issue 06</u>, eff. January 15, 1992; <u>Volume 11, Issue 22</u>, eff. August 23, 1995; <u>Volume 19, Issue 24</u>, eff. October 1, 2003.