STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE AND CONSUMER SERVICES AGENCY • GOVERNOR EDMUND G. BROWN JR.
SPEECH-LANGUAGE PATHOLOGY & AUDIOLOGY & HEARING AID DISPENSERS BOARD
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HEARING AID DISPENSERS PRACTICE COMMITTEE MEETING MINUTES

January 26, 2011
Kensington Park Hotel
450 Post Street
"Sherwood Room"
San Francisco, CA
(916) 263-2666

Committee Members Present
Deane Manning, Hearing Aid Dispenser
Robert Green, Au.D.
Sandra Danz, Hearing Aid Dispenser
Alison Grimes, Au.D.

Staff Present
Annemarie Del Mugnaio, Executive Officer
LaVonne Powell, Legal Counsel
Cynthia Alameda, Staff
Yvonne Crawford, Staff
Debbie Newcomer, Staff

Board Members Present
Carol Murphy, M.A.
Monty Martin, M.A.

Board Members Absent
Rodney Diaz, M.D.

Guests Present
Cynthia Peffers, HHP CA
Jody Winzelberg, Director of Rehabilitative Services, Lucile Packard Children's Hospital at Stanford
Marcia Raggio, California Academy of Audiology (CAA)
Rebecca Bingea, University of California, San Francisco (UCSF)
Randy Sager, HHP CA
Chelsea Diles, InSound Medical

I. Call To Order

Deane Manning called the meeting to order at 1:00 p.m.

II. Introductions

Those in attendance introduced themselves.

III. Proposed Regulation Amendments Pertaining to Continuing Education Requirements for Licensed Hearing Aid Dispensers – California Code of Regulations Section 1399-140-1399.143

Ms. Del Mugnaio explained that the proposed regulations were discussed at previous meetings. She stated that the Committee has discussed the need to include provisions related to self-study courses, stating that "self-study" does not include live or interactive courses offered through electronic means. The added provisions should assist in educating practitioners that web-based courses that include attendee participation and an instructor are not categorized as self-study courses and are not deemed independent learning.

Mr. Manning asked about the definition of on-demand courses.

Ms. Grimes responded that on-demand courses provided through such sites as Audiology Online are pre-recorded courses and are not interactive.

The Committee discussed the proposed self-study definition and agreed to strike "tape recorded" courses and "videotaped materials" from the language.

Ms. Del Mugnaio suggested the language, "Any interactive course that provides an opportunity for participation is not deemed self-study and not limited to the three hour maximum described in Subsection (1)."

Ms. Del Mugnaio mentioned another section of the proposed regulations that was previously discussed related to the waiver, and it was recommended at the last meeting that the waiver language be retained at this point. The waiver allows that a dispenser who does not complete all of the required CE hours in the one-year license renewal period be allowed to make up the deficiency during the next renewal period.

Ms. Grimes suggested changing the word "pragmatic" to "practical" under Section 1399.140.1 (a) (2).

Ms. Del Mugnaio reviewed the proposed changes pursuant to discussion at this meeting, which included:

- Changing the term "pragmatic" to "practical" in Section 1399.140.1(a) (2)
- Amending Section 1399.140(a)(2) to include a qualifier regarding self-study courses as follows: "Any interactive course that provides opportunity for participation is not deemed self-study and is not limited to the three hour maximum described in Subsection (1)"
- Striking antiquated language, such as "recorded courses" and "video-tape materials" from the existing definition of self-study.

M/S/C: Grimes/Danz

The Committee moved to recommend the full Board approve the continuing education amendments discussed above and notice the proposed regulatory changes for public hearing.

IV. Regulatory Proposal re Song-Beverly Consumer Warranty Act (California Code of Regulations Section 1399-140-1399.143)

Ms. Del Mugnaio referenced a draft regulatory proposal she prepared related to the provisions of the Song-Beverly Consumer Warranty Act, which includes information provided by Committee members Robert Green and Deane Manning and incorporates background information regarding longstanding legal issues with how Song-Beverly has been misinterpreted. She stated that the draft regulatory proposal outlines return and refund provisions and would provide an exception/exemption within the Civil Code for right-of-return provisions for hearing aids. Ms. Del Mugnaio stated that the draft proposal is a working document that the Board may present to the Legislature to explain the intent of the amendments to Civil Code Section a1793.02 (i), which would provide the Board with regulatory authority to adopt specific provisions for return and refund policies related to the dispensing of hearing aids. She asked the Committee to review the draft and provide advice/recommendations as to whether the proposal addresses the long-standing legal issues. Ms. Del Mugnaio stated that the Board has not been able to secure an author for the legislative proposal to date, as the amendments are not deemed omnibus in nature, and it may be necessary to seek assistance from the professional association.

Mr. Manning mentioned that it was his understanding that Section (a)(1) was included in order to make it less confusing for consumers and hearing aid dispensers to interpret Song-Beverly. He suggested that the regulatory proposal include a flat fee that could be charged to a consumer for services rendered related to the dispensing of the hearing aid.

Mr. Green agreed that a list of what the fee may include should be identified.

Ms. Winzelberg mentioned that other states have done this on a percentage of the sale instead of a flat fee.

Ms. Del Mugnaio stated that this language was modeled after other states' provisions, where a list of items deemed non-refundable was included in the provisions, and a limit on the total dollar amount or a percentage was noted. She suggested that the draft regulatory document be viewed as a fluid discussion document.

Discussion ensued related to how fees retained by dispensers should be included, concerns related to percentage of costs, defining an exclusionary list of services, etc. The Committee agreed that a specific amount that can be retained by the hearing aid dispenser should be identified.

Ms. Del Mugnaio suggested the following: "Provider is permitted to retain an amount not to exceed $200.00 per hearing aid upon return of the device for costs incurred in the dispensing of the hearing aid. She indicated this could be a place holder and could be revised later.

The Committee suggested the language regarding a consumer's responsibility for retrieving a hearing aid from the provider upon request be changed from two (2) business days to seven (7) business days.

Ms. Del Mugnaio added that there is also a provision regarding the information that should be documented on the purchase agreement, which states: "The hearing aid dispenser shall provide the consumer with a written purchase agreement signed by both the dispenser and consumer that contains the following: the specified date the device was purchased (the Committee requested that purchased be changed to delivered), the date(s) the device was returned to the hearing aid dispenser for service or adjustment, and the date(s) the device was retrieved by the consumer."

She stated that date the consumer was informed the hearing aid was available for delivery could be included.

Discussion ensued regarding the charging of a flat fee, including an explanation of the charges not to exceed $200.00 per aid.

Ms. Del Mugnaio asked all Committee members to bring unbundled costs and documentation to the next meeting from each of the following settings: a hearing aid dispenser office, a dispensing audiologist's office, and a UC system clinic.

M/S/C: Grimes/Green
The Committee recommended the full Board to approve the draft regulatory document as a working document to provide to interested parties during the Legislative discussions regarding the amendments to the Song-Beverly Consumer Warranty Act.

V. Hearing Aid Dispensers Examination Program – 2011 Occupational Analysis

Ms. Del Mugnaio requested that the Committee members provide the Board with references of individuals who may serve as Subject Matter Experts (SMEs) for the Occupational Analysis (OA) study beginning in June 2011. She explained that funding was provided for an OA study for the hearing aid dispensers examination program as part of the merger of the Speech-Language Pathology and Audiology Board with the Hearing Aid Dispensers Bureau. The Board is moving forward with the OA, which typically takes about a year and a half to complete. Any changes to the examination format/content would be implemented in 2013. There is a series of workshops, questionnaires, interviews, and items-writing tasks that must occur in order for the Office of Professional Examination Services (OPES) to determine if the exam is a valid in terms of testing for entry-level practice for hearing aid dispensers. The OPES will begin conducting workshops and interviews for which a diverse group of subject matter experts representing a range of practice settings and professional experience will be utilized to assist in crafting a comprehensive knowledge, skills, and abilities survey form. The survey will then be distributed to the licensee population for rating. The returned information is compiled and analyzed to determine its congruence to the current examination content. Ms. Del Mugnaio asked the Committee to provide names of individuals they believe may be well suited for the assignment and provide their names to Debbie Newcomer. She commented that dispensing audiologists who participate in this process must remember that this is an entry-level exam for hearing aid dispensers, so audiology practice cannot factor into the professional input.

Additionally, Ms. Del Mugnaio explained that an OA is required every five to seven years, and the last hearing aid dispenser OA was done in 2007, which was about 4 years ago. She stated that the 2011 OA is being conducted in response to concerns that were raised during the legislative discussions of the Board/Bureau. Ms. Del Mugnaio stated that the funding provided for the OA must be applied to the project during this budget year.

Ms. Del Mugnaio announced that the first OA Workshop will be held June 23, 2011. Ms. Newcomer responded that the June 23 workshop is already full, and no other workshop dates have been scheduled at this time. Ms. Newcomer added that there will be several workshops: three prior to the survey and two after. Approximately 10-20 SMEs will be needed for interviews, and approximately 40 SMEs will be needed for the workshops. Ms. Newcomer explained that the

survey will be condensed to make it less time-consuming for licensees than in the past, and will be available on-line. She explained the shortened survey, and that readily available access should encourage more licensees to provide input.

Ms. Del Mugnaio explained that the Board will be the decision-maker when the validation study is complete, and will have to vote to adopt or not adopt the final report.

Ms. Powell stated there is a Department policy regarding Board members participation in an OA and the exam process. It was explained that Board Member will be recruiters and decision makers, and recruitment of SMEs will be done by Board staff contacting licensees by phone.

Ms. Winzelberg asked if the information and a request for interested individuals could be added to the Board's Web site.

Ms. Del Mugnaio indicated that the announcement will be placed on the Board's website.

VI. Scope of Practice Limitations on Deep Insertion Hearing Aid Devices

Ms. Del Mugnaio stated that it has come to the attention of the Board that there have been some issues and filed a complaint about deep-insertion hearing aids, where the aids are inserted deeper into the ear canal than a traditional hearing aid. This issue had come up previously as a Song-Beverly issue related to return rights. At that time, these aids were fit only by physicians, but are now being fit by physicians, audiologists, and hearing aid dispensers. Therefore, the Board needs to address whether the deep-insertion procedure constitutes a consumer protection issue that is outside the scope of practice for hearing aid dispensers and possibly audiologists.

Mr. Manning brought a letter from the Federal Drug Administration that states that the devices should be fit by physicians, audiologists, and hearing aid specialists, but that does not mean that the scope of practice defined by the state regulatory board for hearing aid dispensers and audiologists allows this type of service.

Ms. Powell asked if deep-insertion aids were fit beyond the eardrum.

Committee members responded that they are fit millimeters from the eardrum, and they are not implantable.

Ms. Grimes added that an ear impression for a traditional hearing aid can also go beyond the second bend of the ear canal.

Discussion pursued regarding the placement of deep-insertion and extended-wear hearing aids.

Ms. Crawford reviewed the issues that have been brought previously to the Bureau regarding deep-insertion hearing aids, which included warranty issues, potential consumer harm, bait and switch, and training received related to fitting deep-insertion hearing aids. She also explained that the Board is not aware of any hearing aid dispensers fitting deep insertion hearing aids at this time.

Ms. Powell responded that there may be a standard of care issue rather than a scope of practice issue, as the law does not differentiate between deep-insertion hearing aids and non-deep insertion hearing aids. She stated that standard of care provisions may be added to the regulations; however,

as professional services and technology continue to evolve, changes to the regulations would be necessary.

Ms. Grimes explained that there are two events involved here: the taking of ear impressions and prolonged use of the hearing aids. She commented that setting limitations on how deep an ear impression can be inserted would be unreasonable, as each individual's ear canal and hearing loss is unique, and impressions vary for each individual situation. Ms. Grimes commented that the more pressing issue would be the length of time, often three months, which the deep-insertion hearing aid remains in the ear canal.

Ms. Powell commented that this is an FDA issue. Discussion ensued regarding the FDA's approval of deep-insertion hearing aids, consumer protection issues that may arise, complaints regarding deep-insertion hearing aids, and physicians' involvement in inserting the hearing aids.

Ms. Powell responded that the Board should refer cases to an SME to determine if the subject followed the standard of care; then, based on the recommendation of the SME, the Board may adopt or not adopt whether the standard of care was appropriate and move forward with regulations.

The Committee agreed that staff should pursue this matter using the assistance of an SME.

The Committee adjourned at 3:00 p.m.