



HEARING AID DISPENSERS MEETING MINUTES
Radisson Hotel/San Francisco Airport
February 6, 2014
5000 Sierra Point Parkway
Brisbane, CA 94005

Committee Members Present

Alison Grimes, Dispensing Audiologist
Marcia Raggio, Dispensing Audiologist
Amnon Shalev, Hearing Aid Dispenser

Committee Members Absent

Deane Manning, Chair, Hearing Aid Dispenser
Rodney Diaz, M.D.
Jaime Lee, Public Member

Staff Present

Breanne Humphreys, Interim Executive Officer
Sabina Knight, Legal Counsel

Guests Present

Kim Craig, KP Public Affairs
Dee Parker, Speech-Language Pathology and Audiology and Hearing Aid Dispensers Board
Cindy Peffers, Hearing Aid Dispenser, HHP
Randall Sager, Hearing Aid Dispenser, HHP
Debbie Snow, Speech-Language Pathology and Audiology and Hearing Aid Dispensers Board
Michael Snow

I. Call to Order

Chairperson Alison Grimes called the meeting to order at 1:45 p.m.

II. Introductions

Those in attendance introduced themselves.

III. Approval of the June 12, 2013 Hearing Aid Dispensers Committee Meeting Minutes

M/S/C Shalev/Raggio

Minutes approved with minor edits.

IV. Development of Proposed Practice Guidelines for Hearing Aid Dispensing

Ms. Humphreys stated that Mr. Manning was still revising the document and would have it available for the May Board meeting.

V. Discussion on Whether a Bone-Anchored Device, External Sound Processor, Requires a License to Dispense

Ms. Grimes gave a background on bone-conduction hearing devices. The devices have been around for over 40 years and are not a new technology. Most hearing aids can be wired to have a bone conduction receiver as opposed to an air conduction receiver. It is still a hearing aid but with a different kind of receiver.

The device is provided to patients in two different types of application. One type of application is by use of a headband without surgery. The device can also be one-half of a two-part integrated system that is surgically implanted. This component is classified as a Class II medical device and is FDA approved for children over the age of five.

Mr. Shalev stated that any device that requires fitting and programming for a specific hearing loss should be performed by a licensed dispenser of hearing aids. Ms. Raggio agreed.

However, the Board has been informed by a manufacturer of this bundled system that the FDA does not require the person fitting the external component to have a hearing aid license. Ms. Raggio stated that since state laws cannot be more stringent than FDA laws, we would have to address this issue with the FDA and obtain a waiver.

Ms. Knight stated this is a scope of practice question. She will contact the FDA for clarification and inquire about the headband versus the bone anchored device.

VI. Update on Exemption Request of the Federal Drug Administration on Mail Order and Catalog Sales of Hearing Aids

Ms. Humphreys reported that our exemption request is currently under review. It was filed on June 4, 2012.

Chairperson Grimes adjourned the meeting.