



HEARING AID DISPENSERS MEETING MINUTES

January 13, 2012

Department of Consumer Affairs
2005 Evergreen Street
"Hearing Room"
Sacramento, CA

Committee Members Present

Deane Manning, Chair, Hearing Aid Dispenser
Robert Green, Au.D.
Sandra Danz, Hearing Aid Dispenser
Alison Grimes, Au.D.
Rodney Diaz, M.D.

Staff Present

Annemarie Del Mugnaio, Executive Officer
Claire Yazigi, Legal Counsel
Breanne Humphreys, Staff
Yvonne Crawford, Staff
Ily Mason, Staff

Board Members Present

Monty Martin, M.A.
Lisa O'Connor, M.A.

Board Members Absent

Carol Murphy, M.A.

Guests Present

Cynthia Peffers, HHP CA
Tricia Hunter, HHP CA
Rebecca Bingea, UCSF
Marcia Raggio, CSHA, SFSU
Patti Solomon-Rice, CSHA
Bill Barnaby, CSHA

I. Call to Order

Deanne Manning called the meeting to order at 9:13 a.m.

II. Introductions

Those in attendance introduced themselves.

III. Review Public Comments to Amendments to the Hearing Aid Dispenser's Advertising Regulations and Related Guidelines (California Code of Regulations Section 1399.127)

Ms. Del Mugnaio referenced a public notice included in the meeting packets which invites licensees and consumers to provide input to the current advertising provisions for hearing aid dispensing. She explained that the notice was emailed to a number of consumer groups and professional associations including, the Hearing Healthcare Providers of CA, the California Academy of Audiology, and the California Speech-Language Hearing Association. Ms. Del Mugnaio explained that since the email was recently distributed

she had only received on comment thus far. She stated that the request for public comment is due by January 31, 2012.

Chairperson Manning stated that he received feedback from a few professionals who assumed that the public notice was more of an announcement that regulations changes to the current advertising provisions had already occurred instead of the notice being a request for public comment. He stated that since the final comment deadline is not until the end of January, the issue should be revisited at the next scheduled Committee meeting in order to consider further public input.

IV. Review Existing Laws on Internet Sale of Hearing Aid Devices- Discuss Relevant Consumer Protection Issues

Ms. Del Mugnaio reported that the Board is currently addressing the issue of hearing aids sold over the Internet. She stated that California law does not specifically address the sale of hearing aids over the Internet, but instead regulates the sale of hearing aids by catalog or direct mail. Ms. Del Mugnaio stated that the Board faces significant legal challenges in attempting to restrict the sale of hearing aids over the Internet, not only due to the fact that California law is silent on the issue, but also because federal regulations do not restrict the sale of hearing aids over the Internet and federal law prevent states from implementing laws that are more stringent or restrictive than federal rule. As such, the Board is dealing with a preemption issue. Ms. Del Mugnaio explained that states may request an exemption from federal regulations to implement provisions that exceed federal rule if the provisions are deemed necessary for protection of the public.

Ms. Yazigi explained that if the Board chooses to move forward with regulating the Internet sale of hearing aids, the term Internet sale must be included in the statute which would require a legislative change. She stated that the second layer required for the Board to regulate the Internet sale of hearing aids is to seek a federal exemption. Ms. Yazigi stated that if the Board directs her to move forward with seeking an exemption, she will correspond with the Federal Drug Administration (FDA) on exempting current law regarding hearing aids sold by catalog and direct mail as federal regulations do not restrict hearing aids sold by catalog or direct mail, and it would be in the Board's best interest to determine how the FDA will respond to the request for the exemption to the current statute prior to moving forward with a legislative change to include the sale of hearing aids over the Internet to California provisions. Ms. Yazigi reviewed current statute with the Board and explained provisions in California law which are already more restrictive than federal regulation and which the Board has not yet sought an exemption from the FDA; Business and Professions Code Section 2538.23 regarding the sale of hearing aids by catalog or direct mail is one such statute.

Chairperson Manning inquired about California law verses the FDA regulations in terms of observation of the purchaser's ear canal and mandatory referrals for a medical assessment should the seller identify one of the conditions listed in California law and federal regulations.

Ms. Yazigi explained that California law does require actual inspection of the ear canal and a written notification from the seller to the purchaser that the ear canal has been examined and that conditions requiring further medical treatment have been ruled out. Whereas, FDA regulations only require the seller to obtain a signed waiver from the purchaser regarding the specified seven (7) conditions and informing the purchaser that a medical assessment conducted by a physician is in their best interest. She stated the FDA regulations require the seller to include a warning statement in their hearing aid pamphlet about the specified seven (7) medical conditions which are listed in both federal regulations and also codified in state law.

Ms. Grimes inquired about a pending issue where WalMart has corresponded with the Board and challenged the Board's laws restricting the sale of hearing aids by a licensed hearing aid dispenser where the business transaction occurs via the Internet.

Ms. Yazigi stated that many of the authority issues raised by WalMart are pre-emption issues the Board must address with the FDA prior to pursuing any legal challenges.

The Committee discussed the process of selling hearing aids over the Internet and that it seems to be a product business transaction with no controls over the health care needs of the purchaser.

M/SC: Grimes/Danz

The Committee voted to recommend to the full Board that the Board delegate to Ms. Yazigi the task of preparing an exemption request to the FDA regarding the regulation of hearing aids sold over the Internet.

Chairperson Manning inquired about companies that sell hearing aids over the Internet and contract with licensed hearing aid dispensers to provide fitting and adjustment services and what liability the licensee has with respect to the refund of the hearing aid if that becomes an issue.

Ms. Del Mugnaio responded and stated that depending on the specific facts of the case, the licensee may be held accountable for securing a refund.

Ms. Bingea commented and stated that some consumers purchase hearing aids from a company/corporation and then once in possession of the device, independently seek out a dispenser to fit and adjust the hearing aid, but the dispenser has no contractual relationship with the company who sold the hearing aid to the consumer.

Ms. Del Mugnaio replied and stated that the Board would not take legal action against a dispenser who had no knowledge or business relationship with the company who sold a hearing aid to a consumer but failed to provide the appropriate refund.

Ms. Peffers inquired whether the Board has considered communicating with other states' licensing boards to determine whether other states are pursuing similar exemption requests of the FDA, or facing similar legal challenges in regulating hearing aids sold over the Internet and possibly collaborating with interested states on a joint communication to the FDA.

Ms. Yazigi commented that it may be helpful for the Board to communicate with the other states about their experiences with the issue, but that since each state has separate and distinct licensing provisions, it may not be possible to craft a joint exemption request letter.

The Committee agreed that the Board should communicate with other states regarding California's efforts to regulate the sale of hearing aids over the Internet and to gain information from the other states about their efforts regarding the same.

Chairperson Manning adjourned the meeting at 10:15 a.m.