Original: 2278

phaa
PENNSYLVANIA
HEARING AID ALLIANCE

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HARRISBURG, PA 17104
(717) 233-6844

July 19, 2002

Theresa Ritchie
Pennsylvania Dept of Health
132 Kline Plaza, Suite A
Harrisburg PA 17104

Dear Theresa,

On behalf of the members of the Pennsylvania Hearing Aid Alliance, I would like to commend you and your staff for the excellent document you have written as a first draft of the regulations for the revised Hearing Aid Sales Registration Law. This is a well-written document that attempts to follow the letter of the law.

Our organization includes many different types of hearing aid businesses, and each will be affected by these laws in a different way. Many of our members, however, have expressed to our association some questions and reservations about the regulations, particularly about the disclosure agreement and how it will be implemented. We have encouraged them to submit their comments to you.

As a member of the hearing aid advisory council, I look forward to working with you to refine and revise this document.

Respectfully,

Dorothy Kardos, RN, BC-HIS
President, PHAA

Central Pennsylvania Eye and Ear
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Dr. Robert L. Kardos
Optometrist

Dorothy Kardos, RN
Hearing Director

Original: 2278

July 19, 2002

Theresa Ritchie
132 Kline Village, Suite 4
Harrisburg PA 17104

Dear Theresa,

As a hearing aid fitter, dealer, and business owner, I would like to comment on the published regulations.

My primary concern is with the implementation of the disclosure agreement as written in these regulations. It is impossible to know what tests are necessary or the cost of hearing aids when a patient first enters my office. This document and how it is used must be closely reviewed, along with input from registrants as to how it can be revised to be more practical.

My second concern is that the law considers earmolds to be a part of the hearing aids, when, in fact, they are not. Earmolds are an accessory. They can be sold with or without new hearing aids. I understand that this is part of the law, and cannot be changed in the regulations – I just wanted you to know the facts involved! I also wanted to make you aware of the fact that earmolds, once ordered and delivered to the hearing aid fitter, may not returnable to the manufacturer, even if the patient cancels the order (or dies) before delivery.

My third and final concern is the Department's understanding of the cost of hearing aids that are returned for credit. As stated above, earmolds may not be returned for credit. If the hearing aids were received, registrants must also pay airborne delivery charges, which are not refundable. Most important, however, manufacturers keep accurate records for return rates for hearing aids. These rates are used to calculate the cost of a new hearing aid.

In an article published in "The Hearing Review", John Weigand, et al, states the "Clearly it takes time and resources for manufacturers to replace hearing instrument components, and these costs are eventually reflected in the higher initial costs of all hearing instruments." (January 2002)

You should also be aware that per FDA rules, any part of a hearing aid that is returned for credit, even when that hearing aid was never delivered to a patient, may never be reused by the manufacturer in any new hearing aid.

As you have stated, the registrant does not suffer much if the hearing aid is returned, because ultimately it is the hearing impaired patient who will have to pay a higher cost for his hearing aid, based on the return for credit percentage. I know this has nothing to do with the regulations, but I feel very strongly that, as a fitter governed by these laws (most of them very good), it is imperative that I try to inform the lawmakers and those writing and enforcing the regulations, of exactly what I do and how these laws will affect both my business, and the hearing impaired patients I am trying to serve.

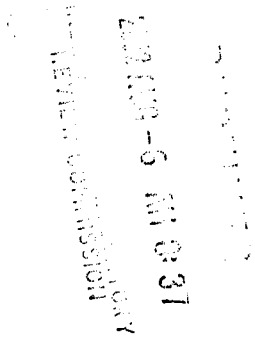
In general, these new regulations are very good. If you have any questions about my comments, please feel free to contact me.

Respectfully,

Dorothy Kardos, RN, BC-HIS
PA Reg # F02828

RAMETTA AUDIOLOGY & HEARING AID CENTER

James P. Rametta, BC-HIS • Michael J. Rametta, M.S. • James P. Rametta, Ph.D.



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July 25, 2002

Theresa Ritchie
132 Kline Village, Suite 4
Harrisburg, PA 17104

Dear Theresa,

Given the fact that I am a 20+ veteran of this industry I feel compelled to comment on the latest proposed regulations. In general the wording is good but I have questions concerning a number of areas.

The regs speaks of a fitter not suffering much if a hearing instrument is returned for credit. I don't feel that some of the people writing these regs have a sufficient amount of knowledge in this industry to understand the inner working and how they effect not only the fitter but more importantly the user.

The most critical part of the use of the disclosure form is the time that it is to be explained to the "potential purchasers". If a person comes to me and tells me that his hearing is fine but is suffering from a sudden decrease in hearing, the first procedure I would perform is an oto scopic inspection of the ear canal to see if wax is the problem. If it is, I would immediately send the patient to a doctor for treatment.

Under the regs, I can not do this without a 15 to 20 minute discussion pertaining to the cost and return of hearing aids when in fact amplification was not called for. This form can best serve all concerned by giving this presentation prior to impression taking or prior to the signing of the purchase agreement.

The amount of testing necessary can not be determined prior to basic examinations. The cost of a hearing aid (1.8 million combinations in the industry) cannot be presented prior to an accurate audiometric evaluation in order to ascertain all of the factors involved in the selection of the proper instrument.

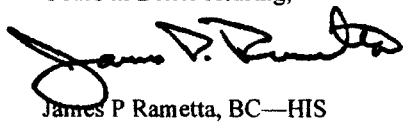
Next item in question pertains to the fact that an ear mold commonly used with BTE type devices are not part of the hearing aid and needs serviced at least once every six months and should be replaced annually. They can not be returned for credit for any reason so this cost should not be included in the price of the hearing instrument nor part of the return fee of $150.00 per aid.

And finally I would like to address the section listed, as 25.217 item 6 stating educational programs shall be open to all persons.... I read this to mean manufacturers that offer continuing education. My question and comment addresses the amount of CEU's that can be acquired from a manufacturer to a select group of fitters. I, as a multi line dispenser, can not go to Beltone or Miracle Ear for their educational seminars. If this be the case than I would recommend that not more thant 1/3 of all CEU's should be allowed to be received from any one manufacturer, and no CEU's should be accepted from any group that does not open their seminars to all fitters.

I appreciate everything you and your staff are doing for us and the hearing impaired and thank you for allowing me to voice my views on this ever important issue.

If you have any questions about my comments please do not hesitate to contact me.

Yours in Better Hearing,



James P Rametta, BC—HIS
PA reg. # F02477