



State of North Carolina

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December 5, 2011

James P. Young, Chair
North Carolina State Board of Hearing Aid Dealers and Fitters
Post Office Box 97833
Raleigh, North Carolina 27624-7833

Re: Advisory Letter: Request for Opinion as to Whether Hearing Aids Specialists
Licensed under Chapter 93D May Fit Hearing Aids on a Minor

Dear Mr. Young:

You have requested an opinion as to whether a Hearing Aid Specialist may fit hearing aids on a minor according to Federal Guidelines 21 C.F.R. 801.420 and 21 C.F.R. 801.421 and state laws.

As you note, the HADF Board is charged with administering Chapter 93D of the North Carolina General Statutes and the rules duly adopted pursuant to the statutory authority contained in Chapter 93D. As you further note, the federal government, as part of a larger regulatory effort regarding Medical Devices, has also established two regulations which purport to regulate both the "conditions for sale" of hearing aid devices, 21 C.F.R. 801.421, and the labeling of those devices, 21 C.F.R. 801.420.

The "conditions for sale" regulation requires a patient under the age of 18 be medically evaluated to determine whether the patient may be considered a candidate for a hearing aid within 6 months of purchasing a hearing aid. Further, the regulation requires that the prospective user (or presumably the user's parents/guardians) present the dispenser with a signed statement by a physician to that effect. 21 C.F.R. 801.421(a)(1)-(2).

The "labeling" regulation is primarily directed at hearing aid manufacturers. This regulation only requires that the "User Instructional Brochure" which is prepared by the manufacturer and accompanies the hearing aid contain the following language:

CHILDREN WITH HEARING LOSS

In addition to seeing a physician for a medical evaluation, a child

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with a hearing loss should be directed to an audiologist for evaluation and rehabilitation since hearing loss may cause problems in language development and the educational and social growth of a child. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of a child with a hearing loss.

21 C.F.R. 801.420(c)(3).

The “conditions of sale” regulation does require that before selling the hearing aid, a dispenser must

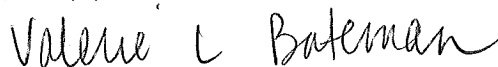
- (1) Provide the prospective user a copy of the User Instructional Brochure for a hearing aid that has been, or may be selected for the prospective user;
- (2) Review the content of the User Instructional Brochure with the prospective user orally, or in the predominate method of communication used during the sale;
- (3) Afford the prospective user an opportunity to read the User Instructional Brochure.

21 C.F.R. 801.421(b)(1)-(3).

Other than the requirement that the dispenser review the contents of the User Instructional Brochure with the prospective user (or presumably the parents/guardians of the prospective user), there are no restrictions or prescriptions applicable to the dispenser in the labeling regulation. Thus, so long as a hearing aid dispenser complies with the requirements of the Code of Federal Regulations and the State statutes and rules governing the fitting and selling of hearing aids with regard to a sale to a person under the age of 18, a hearing aid dispenser is allowed by law to fit and sell a hearing aid to a person under the age of 18.

This is an advisory letter. It has not been reviewed and approved in accordance with procedures for issuing an Attorney General's opinion. Nonetheless, I trust this letter has been helpful and responsive to your inquiry.

Very truly yours,



Valerie L. Bateman
Special Deputy Attorney General