

4747-1-19

Rules on appropriate test procedures.

For the purpose of dealing in or fitting of hearing aids the following test procedures performed bilaterally are considered to be appropriate, and as prescribed by division (J) of section 4747.12 of the Revised Code.

(A) Tests of threshold.

(1) Puretone air threshold tests must be performed at least at two hundred fifty, five hundred, one thousand, two thousand, three thousand, four thousand, and six thousand Hertz. Bone-conduction threshold tests must be performed at least at five hundred, one thousand, two thousand, and four thousand. On clients whose bone-conduction thresholds have been previously measured, and those measures are part of the client's permanent record, new bone-conduction testing may be omitted if there has been no change in the air conduction thresholds greater than 5dB. Appropriate masking shall be used, with levels indicated on the test record, whenever necessary to obtain valid results.

(B) Test of tolerance includes most comfortable listening level (MCL) and uncomfortable listening level (UCL).

(C) Test of speech awareness or speech reception threshold, and speech understanding or speech discrimination. All such tests are to be recorded in writing, and if the examiner was unable to complete any tests because of the client's inability to perform for any reason, that inability should be clearly stated and the reasons fully noted on the test record. All testing should be done only for the purpose of dealing in or fitting of hearing aids utilizing traditional state-of-the-art procedures. Appropriate masking must be used, with levels indicated on the test record, whenever necessary to obtain valid results. Measuring instruments other than audiometers may be used under division (J) of section 4747.12 of the Revised Code, provided they are used with an audiometer either separately or together.

(D) Test environment.

(1) The test environment should meet "American national standards institute" (ANSI) standards (SID 1996) or latest revision as adopted; otherwise, the test environment must be described on the test record as quiet, average, or noisy.

(E) Symbols.

(1) Symbols used in recording test results must appear in a legend on the face of the test record.

(F) View of ear canal:

(1) The licensee or trainee shall use an otoscope to complete an ear canal inspection of both ears. Any identified abnormalities shall be noted on the test record.

(G) Calibration of equipment:

(1) Electroacoustic analysis and calibration of testing equipment shall be completed annually on any test equipment, which record shall be kept for two years.

(H) Medical referral:

(1) A licensee should advise a prospective hearing aid user to consult promptly with a licensed physician (preferably an ear specialist) before dispensing a hearing aid to the perspective hearing aid user, and promptly document the fact that such a referral was made in the individual's case record, if it is determined through documented case history, actual observation, or review of any other available information concerning the prospective user, that any of the following conditions exist:

(a) Visible congenital or traumatic deformity of the ear.

(b) Visible evidence of cerumen accumulation or a foreign body in the ear canal.

(c) History of active drainage from the ear within the previous ninety days.

(d) Acute or chronic dizziness.

(e) Unilateral hearing loss of sudden or recent onset within the previous ninety days.

(f) History of sudden or rapidly progressive hearing loss within the previous ninety days.

(g) Pain or discomfort in the ear.

(h) Audiometric air-bone gap equal to or greater than fifteen decibels at five hundred, one thousand, and two thousand Hertz.

(I) Except as noted in paragraph (J) of this rule, a licensee shall not sell a hearing aid unless the prospective user has presented to the licensee a written statement signed by a licensed physician that states the patient's hearing loss has been medically evaluated and the patient may be considered a candidate for a hearing aid. The medical evaluation must have taken place within the preceding six months.

(J) An exception to medical referral can be made only if the prospective hearing aid user is eighteen years of age or older and following viewing of the ear canals, taking a case history and completing appropriate testing. The licensee may, in such cases, afford the prospective user an opportunity to waive the medical evaluation provided that the licensee:

- (1) Informs the prospective user that the exercise of the waiver is not in the user's best health interest;
- (2) Does not in any way actively encourage the prospective user to waive such medical evaluation; and
- (3) Affords the prospective user the opportunity to sign a waiver stipulating to the above. The waiver shall be printed in bold-face type of the minimum size of ten points to include the following statements:

" I have been advised by

(Hearing Aid Dispenser's Name)

that the Food and Drug Administration has determined that my best health interest would be served if I had a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. I do not wish a medical evaluation before purchasing a hearing aid."

The licensee or trainee must provide the prospective hearing aid user with a copy of this signed waiver.

~~(A) For the purpose of dealing in or fitting of hearing aids the following test procedures performed bilaterally are considered to be appropriate, and as prescribed by division (J) of section 4747.12 of the Revised Code:~~

~~(1) Tests of threshold:~~

~~(a) Puretone air and bone conduction threshold tests must be performed at least at two hundred fifty, five hundred, one thousand, two thousand, and four thousand Hertz. On clients whose bone conduction thresholds have been previously measured, and those measures are a part of the client's permanent record, new bone conduction testing may be omitted if there has been no change in the air conduction thresholds greater than five dB.~~

~~(2) Test of tolerance:~~

~~(3) Test of speech awareness or speech reception threshold, and speech understanding or speech discrimination. All such tests are to be recorded in writing, and if the examiner was unable to complete any tests because of the client's inability to perform for any reason, that inability should be clearly stated and the reasons fully noted on the test record. All testing should be~~

~~done only for the purpose of dealing in or fitting of hearing aids utilizing traditional state-of-the-art procedures. Appropriate masking must be used, with levels indicated on the test record, whenever necessary to obtain valid results. Measuring instruments other than audiometers (such as master hearing aids) may be used under division (J) of section 4747.12 of the Revised Code, provided they are used with an audiometer either separately or together.~~

~~(4) Test environment:~~

~~(a) The test environment should meet "American National Standards Institute" (ANSI) standards (S 3. 1-1960) or latest revision as adopted; otherwise, the test environment must be described on the test record as quiet, average, or noisy.~~

~~(5) Symbols:~~

~~(a) Symbols used in recording test results must appear in a legend on the face of the test record.~~

~~(6) View of ear canal:~~

~~(a) The licensee or trainee shall use an otoscope to complete an ear canal inspection of both ears. Any identified abnormalities shall be noted on the test record.~~

~~(7) Calibration of equipment:~~

~~(a) Electroacoustic analysis and calibration of testing equipment shall be completed annually on any test equipment, which record shall be kept for two years.~~

~~(8) Medical referral:~~

~~(a) A licensee should advise a prospective hearing aid user to consult promptly with a licensed physician (preferably an ear specialist) before dispensing a hearing aid if it is determined through documented case history, actual observation, or review of any other available information concerning the prospective user, that any of the following conditions exist:~~

~~(i) Visible congenital or traumatic deformity of the ear.~~

~~(ii) Visible evidence of cerumen accumulation or a foreign body in the ear canal.~~

~~(iii) History of active drainage from the ear within the previous ninety~~

days.

~~(iv) Acute or chronic dizziness.~~

~~(v) Unilateral hearing loss of sudden or recent onset within the previous ninety days.~~

~~(vi) History of sudden or rapidly progressive hearing loss within the previous ninety days.~~

~~(vii) Pain or discomfort in the ear.~~

~~(viii) Audiometric air bone gap equal to or greater than fifteen decibels at five hundred, one thousand, and two thousand, Hertz.~~

~~(9) Except as noted in paragraph (A)(10) of this rule, a licensee shall not sell a hearing aid unless the prospective user has presented to the licensee a written statement signed by a license physician that states the patient's hearing loss has been medically evaluated and the patient may be considered a candidate for a hearing aid. The medical evaluation must have taken place within the preceding six months.~~

~~(10) An exception to medical referral can be made only if the prospective hearing aid user is eighteen years of age or older and following viewing of the ear canals, taking a case history and completing appropriate testing. The licensee may, in such cases, afford the prospective user an opportunity to waive the medical evaluation provided that the licensee:~~

~~(a) Informs the prospective user that the exercise of the waiver is not in the user's best health interest;~~

~~(b) Does not in any way actively encourage the prospective user to waive such medical evaluation; and;~~

~~(c) Affords the prospective user the opportunity to sign a waiver stipulating to the above. The waiver shall be printed in bold face type of the minimum size of ten points to include the following statements:~~

~~"I have been advised by~~

~~_____~~

~~(Hearing Aid Dispensers's Name)~~

~~that the Food and Drug Administration has determined that my best health interest would be served if I had a medical evaluation by a licensed physician (preferably a physician who specializes in diseases~~

~~of the ear) before purchasing a hearing aid. I do not wish a medical evaluation before purchasing a hearing aid."~~

~~The licensee or trainee must provide the prospective hearing aid user with a copy of this signed waiver.~~

~~(B) Normally, the board will consider a complaint of a sufficiently serious nature as to warrant a hearing if it is based on the evidence that appropriate procedures were not followed during the sale or attempt to fit or sell a hearing aid and/or evidence that the hearing aid was fit inappropriately.~~

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