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COMMITTEE REPORT  
HOUSE

3/7  
HEALTH, EDUCATION AND  
SOCIAL SERVICES

(7)

FURTHER: FINANCE

5/9/85

Date: May 9 1985

The Committee on LABOR & COMMERCE has had HB 430

"An Act regulating audologists, hearing aid dealers and the dispensing of hearing aids."

under consideration and recommends:

- do pass  do not pass
- do pass with attached amendments(s)
- replace with CS for HR 430 (LVC)  same title  
and recommends to pass  new title
- AND attaches a "Letter of Intent"  New Fiscal Note
- reports it back without recommendation  Zero Fiscal Note Attached
- referred to the \_\_\_\_\_ Committee *sup 95*

MEMBERS SIGNING  
DO PASS

MEMBERS HAVING  
OTHER RECOMMENDATIONS:

*W. J. ...*

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*W. J. ...*  
CHAIRMAN

# STATE OF ALASKA 1986 LEGISLATIVE SESSION FISCAL NOTE

Revision Date : 4/3/86

**REQUEST**

Bill/Resolution No. : CSHB 430 (HESS)  
 Title : Regulating audiologists,  
 hearing aid dealers & dispensing  
 of hearing aids  
 Sponsor : House HESS  
 Requestor : House Finance Committee  
 Date of Request : 4/3/86

**FISCAL DETAIL**

Agency Affected : Commerce & Econ. Dev.  
 BRU : Occupational Licensing  
 Components : \_\_\_\_\_

**EXPENDITURES/REVENUES : (Thousands of Dollars)**

OPERATING	FY 86	FY 87	FY 88	FY 89	FY 90	FY 91
PERSONAL SERVICES		0	0	0	0	0
TRAVEL		0	0	0	0	0
CONTRACTUAL		0	0	0	0	0
SUPPLIES		0	0	0	0	0
EQUIPMENT		0	0	0	0	0
LAND & STRUCTURES		0	0	0	0	0
GRANTS, CLAIMS		0	0	0	0	0
MISCELLANEOUS		0	0	0	0	0
TOTAL OPERATING		0	0	0	0	0

CAPITAL		0	0	0	0	0
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REVENUE		10.3	2.7	3.1	3.5	10.1
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**FUNDING : (Thousands of Dollars)**

GENERAL FUND		0	0	0	0	0
FEDERAL FUNDS		0	0	0	0	0
OTHER		0	0	0	0	0
TOTAL		0	0	0	0	0

**POSITIONS :**

FULL-TIME		0	0	0	0	0
PART-TIME		0	0	0	0	0
TEMPORARY		0	0	0	0	0

**ANALYSIS :** Attach a separate page if necessary

The \$100 estimated as needed for printing of applications and statute booklets can be absorbed within the Department's FY 87 budget.

*APA*

Prepared by : Al Adams, Chair Phone : 465-3706  
 Division : House Finance Committee Date : 4/3/86

Approved by Commissioner : \_\_\_\_\_ Date : \_\_\_\_\_  
 Agency : \_\_\_\_\_

**Distribution (by Agency preparing fiscal note) :**

- Legislative Finance
- Legislative Sponsor
- Requestor
- Office of Management and Budget
- Impacted Agency(ies)

STATE OF ALASKA 1986 LEGISLATIVE SESSION  
FISCAL NOTE

Revision Date: \_\_\_\_\_

**REQUEST**

Bill/Resolution No.: CSHB 430 (HESS)  
 Title: Regulating Audiologists, Hearing Aid Dealers and dispensing of hearing aids;  
 Sponsor: House HESS  
 Requester: House Finance  
 Date of Request: 4/2/86

**FISCAL DETAIL**

Agency Affected: Commerce & Econ. Dev.  
 BRU: Occupational Licensing  
 Components: \_\_\_\_\_

**EXPENDITURES / REVENUES : (Thousands of Dollars)**

OPERATING	FY 86	FY 87	FY 88	FY 89	FY 90	FY 91
PERSONAL SERVICES		-0-	-0-	-0-	-0-	-0-
TRAVEL		-0-	-0-	-0-	-0-	-0-
CONTRACTUAL		.1	-0-	-0-	-0-	-0-
SUPPLIES		-0-	-0-	-0-	-0-	-0-
EQUIPMENT		-0-	-0-	-0-	-0-	-0-
LAND & STRUCTURES		-0-	-0-	-0-	-0-	-0-
GRANTS, CLAIMS						
MISCELLANEOUS						
TOTAL OPERATING		.1	-0-	-0-	-0-	-0-

CAPITAL						
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REVENUE		10.3	2.7	3.1	3.5	10.1
---------	--	------	-----	-----	-----	------

**FUNDING: (Thousands of dollars)**

GENERAL FUND		.1	-0-	-0-	-0-	-0-
FEDERAL FUNDS						
OTHER						
TOTAL		.1	-0-	-0-	-0-	-0-

**POSITIONS:**

FULLTIME		-0-	-0-	-0-	-0-	-0-
PARTTIME						
TEMPORARY						

**ANALYSIS:** Attach a separate page if necessary.

The bill charges the department with the responsibility of licensing audiologists and hearing aid dealers. Information received indicates that the number of practitioners affected by the bill are few -- 12 audiologists and 10 legitimate hearing aid dealers. Apparently, fly-by-night individuals have harmed Alaskan consumers as documented by complaints on file with Consumer

Prepared by: Jennifer Strickler Management Analyst  
 Division: Occupational Licensing

Phone: 465-2144  
 Date: 4-3-86

Approved by Commissioner: Lois L. Lounsbury  
 Agency: Commerce and Economic Development

Date: 4/3/86

**Distribution (by Agency preparing fiscal note):**

- Legislative Finance
- Legislative Sponsor
- Requestor
- Office of Management and Budget
- Impacted Agency(ies)

# CONTINUATION of FISCAL NOTE ANALYSIS

For Bill/Resolution No. CSHB 430 (HESS)

Protection in the Department of Law, the Office of the Ombudsman, and the Department of Health and Social Services, Communicable Disease Control Section. Licensing of Audiologists and hearing aid dealers may be one instance where the need for licensure out-weighs the small number of practitioners.

An estimate of operating costs derived from comparing qualifications and numbers of practitioners with a similar existing license function indicate the costs to total \$4.5 each year. Of the yearly costs; \$.1 is expected to be new costs as a result of this legislation, for printing of application and statute booklets. The remainder of \$4.4 consists largely of personal services costs which would be absorbed by the division through funding already included in the agency's operating budget.

The following fee schedule was developed so that fees generated over the four-year renewal cycle would match, as closely as possible, costs over the same period.

Revenues were estimated on the following fee schedule:

Application Fee	\$ 30	
Credentials Review Fee	20	
Temporary Permit Fee	100	
Audiologist:		
License & Renewal Fee	520	quadrennially (\$130 annually)
Hearing Aid Dealers	200	annually

As a result of quadrennial licenses issued to Audiologists, revenues collected in FY 87 essentially covers a portion of the costs in FY 88 to FY 90. A detailed description follows:

FY 87:			Distribution across
12 Audiologists seeking licensure	\$ 6.2		quadrennial renewal:
10 Hearing Aid Dealers	2.0		
22 Application/Credentials Review	1.1		
	<u>\$ 9.3</u>		\$ 9.3
			- 4.5 costs
			<u>\$ 4.8</u> balance
FY 88:			
Assuming there will be two new applicants seeking Audiology temporary permits	\$ .2		
2 new Hearing Aid Dealers:			
Application & Credentials Review Fee	.1		
License fee	.4		
10 Hearing Aid Dealers renewing	2.0		\$ 4.8 balance forward
	<u>\$ 2.7</u>		.27
			<u>\$ 7.5</u>
			- 4.5 costs
			<u>\$ 3.0</u> balance

# CONTINUATION of FISCAL NOTE ANALYSIS

For Bill/Resolution No. CSHB 430 (HESS)

FY 89:

Assuming there will be two new applicants seeking Audiology temporary permits	\$ .2		
2 new Hearing Aid Dealers:			
Application & Credentials Review Fee	.1		
License Fee	.4		
12 Hearing Aid Dealers	2.4		
	\$ 3.1	\$ 3.0	balance forward
		3.1	
		\$ 6.1	
		- 4.5	costs
		\$ 1.6	balance

FY 90:

Assuming there will be two new applicants seeking Audiology temporary permits	\$ .2		
2 new Hearing Aid Dealers:			
Application & Credentials Review Fee	.1		
License Fee	.4		
14 Hearing Aid Dealers renewing	2.8		
	\$ 3.5	\$ 1.6	balance forward
		3.5	
		\$ 5.1	
		- 4.5	costs
		\$ .6	balance

FY 91 will be the start of a new quadrennial license period for Audiologists, and is the reason for revenues increasing from \$3.5 in FY 90 to \$10.1 in FY 91.

FY 91:

Assuming there will be one new applicant seeking licensure as an Audiologist	\$ .5		
2 new Hearing Aid Dealers, license fee	.4		
Application & Credentials fee for 3 new applicants	.2		
12 Audiologists renewing	6.2		
14 Hearing Aid Dealers renewing	2.8		
	\$10.1		



# Illinois Hearing Aid Consumer Protection

A consumer protection service provided through  
the Illinois Department of Public Health - IDPH.

CALL TOLL-FREE 1-800-572-3270

VOLUME 85-1

## The Illinois Hearing Aid Consumer Protection Program

"A Hearing Aid Can Be A Good Sound Investment." This is the promotional theme for the new Illinois law designed to promote the benefits of hearing aids and protect the public from fraudulent dispensing practices which threaten the health, safety and welfare of Illinois citizens.

The Illinois Hearing Aid Consumer Protection Act (HACPA-Supplement to Ill. Rev. Stat. 1983, chap. 111, par. 7403 et seq.) supports sound hearing aid dispensing practices through the certification of dispensers and the follow-up of complaints and/or inquiries. The Illinois Department of Public Health is responsible for administering the provisions of the Hearing Aid Consumer Protection Act (HACPA) by initiating a four component action plan which focuses on:

1. health promotion/  
consumer education;
2. continuing education services for  
hearing aid dispensers;
3. certification of dispensers; and
4. follow-up of inquiries and com-  
plaints.

The Illinois Department of Public Health has developed and implemented a system to follow-up consumer inquiries and problems. Inquiries can be received by the toll-free action line or by

mail. Program staff are available to respond to all inquiries and initiate follow-up activities, whether received by the toll-free action line or by mail. Should a reconciliation be unattainable, the individual case and all documentation will be forwarded to the Department and after review, if warranted, to the Board. The Board has the authority, by mandate, to conduct hearings and make recommendations to the Director, should disciplinary action be indicated. The Board is comprised of:

Jack D. Clemis, M.D.  
Board Chairman, Otolaryngologist,  
Chicago, Illinois

Thomas Regnier, Hearing Aid  
Dispenser, Illinois Society of  
Hearing Aid Specialists, Peoria,  
Illinois

Gail Gudmundsen, Hearing Aid  
Dispenser, Illinois Speech, Hearing  
and Language Association, Hoffman  
Estates, Illinois

Bee White, Senior Advocate,  
Springfield, Illinois\*

To facilitate the promotion of the HACPA, its provisions, and the service it provides to consumers, program staff are currently developing a statewide networking effort to involve all state and community programs which provide a link to the senior citizens. By successfully educating these interested allied agencies to the services and provision of the HACPA, a larger population of hearing aid consumers can be served.

\* One Board position is currently vacant due to the recent resignation of Richard Gelula, Chicago Hearing Society, Chicago, Illinois.



## THE ILLINOIS HEARING AID DISPENSERS EXAMINATION

To carry out the requirements for the hearing aid dispensers examinations as stated in the Illinois Hearing Aid Consumer Protection Act, the Department of Public Health convened a statewide committee of hearing aid dispensers to review available tests and decide upon a test for Illinois hearing aid dispensers. This committee chose to work with the Educational Testing Service (ETS) to develop the Illinois Hearing Aid Dispensers' Examination. Guided by the committee, ETS designed a job analysis survey that was completed by over half of the practicing dispensers in Illinois. Based on the survey results and the committee's recommendations, ETS developed multiple forms of a 75-question exam, using questions drafted by the committee.

This first examination is intended for temporary certificate holders. Those temporary certificate holders who registered with IDPH on or before May 31, 1985 will be notified by ETS regarding the examination scheduled for August 24, 1985. On this date, two examinations will be conducted simultaneously in Springfield and Chicago. The times and locations will be announced in registration packages. Registration packages must be completed and returned to ETS so that an entrance ticket to the examination can be mailed to each registrant.

The examination will consist of multiple-choice questions. Each question will have four options and only one correct answer. Test-takers are encouraged to choose the option they think is more than likely correct when they do

not know the correct answer. There is no penalty for guessing on this examination.

Test-takers will have ample time to complete this exam. The three and one-half hours scheduled for the test should allow sufficient time for all test-takers. You need only bring one or two #2 pencils. No notes, dictionaries, etc., will be allowed in the test room. You may bring a silent, hand-held calculator. Calculators, however, are not really needed for this exam.

The examination questions will cover the following subjects:

1. ACOUSTICS
2. NATURE OF THE EAR  
(normal ear, hearing process, disorders of the ear)
3. HEARING MEASUREMENT  
(data collection and measurement)
4. HEARING AID TECHNOLOGY
5. SELECTION OF HEARING AIDS
6. DISPENSING AND SERVICING HEARING AIDS
7. CONSUMER PROTECTION REGULATIONS  
--(Federal and State)

In developing this examination, the committee has made every effort to limit the examination to basic information that all hearing aid dispensers should know so that the public may be adequately protected.

The passing score on the examination will be set in a meeting of the committee on July 11. The committee, in reviewing the test, will define what it expects a person to know in order to be minimally qualified as a hearing aid dispenser.

Test-takers will be informed of the passing score as they begin the examination on August 24. Again, the purpose of the passing score will be to assure that the public is adequately protected. This is not a competitive examination in which the top group passes and the rest fail. If all test-takers are minimally qualified, as defined above, all will pass this examination.

The practicum component of the examination is only available to those who successfully complete the written examination. (The written exam will be offered October 19, 1985 only, at the ETS Headquarters in Evanston for those who fail the written component and wish to retake the examination.) The practicums will be comprised of eight stations each, manned by two examiners (certified hearing aid dispensers). All examiners will be trained by ETS to objectively and uniformly evaluate the practicum performance. This examination component is scheduled to take approximately one hour per person. Admission tickets with the assigned date and location will be mailed with notifications of passing the written examination. The practicums will be conducted:

October 22, 23, 24, 25 and December 4  
(Chicago Metropolitan Area)

November 12, 13, (Springfield)



AT YOUR FINGER TIPS:

A toll-free action line was established earlier this year to facilitate

the consumer service component of the Hearing Aid Consumer Protection Act (HACPA). Since its development, over 400 calls have been received by the Illinois Department of Public Health. A majority of the calls received focused on consumer education and awareness about the newly enacted program.

The toll-free telephone line (1-800-572-3270) is provided to respond to problems, questions, or about hearing aid goods and services. In addition, a telecommunication device for the deaf (TDD) can be accessed through this same number. Program staff are available 8:30 a.m. - 5:00 p.m. Monday - Friday to accept calls. A telephone answering device will accept telephone calls received after work hours. The toll-free action line is being promoted on posters and pamphlets developed and disseminated by the Hearing Aid Consumer Protection Program. Copies are available upon request by contacting the toll-free action line. All telephone calls are forwarded to IDPH Vision and Hearing Regional Consultants, for follow-up.

#### "CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT"

The Consumer Fraud and Deceptive Business Practices Act protects consumers, borrowers, and businessmen against fraud, unfair methods of competition and deceptive acts or practices in the conduct of any trade or commerce. It also clarifies the powers of the Attorney General. For these reasons, it is crucial that hearing aid dispensers and consumers understand the Consumer Fraud and Deceptive Business Practices Act. Several major points of this Act are identified below.

1. If a sale of merchandise involving \$25 or more is made or contracted to be made to a consumer as a result of or in connection with a person's contact

with or call on the consumer, that consumer may void the contract or transaction by notifying the seller within three full business days following that day on which the contract was signed or the sale was made. In addition, the consumer must return in its original condition, any merchandise delivered to the consumer under the contract or sale.

2. At the time of a transaction, the dispenser should furnish the consumer with a completed receipt or contract containing a "Notice of Cancellation" informing the consumer that the transaction may be cancelled within three days.
3. The following statement shall be, located near the consumer's signature on the contract or on the front page of the receipt (if a contract is not used) in at least 10-point type.

"YOU, THE CONSUMER, MAY CANCEL THIS TRANSACTION AT ANY TIME PRIOR TO MIDNIGHT OF THE THIRD BUSINESS DAY AFTER THE DATE OF THIS TRANSACTION. SEE THE ATTACHED NOTICE OF CANCELLATION FORM FOR AN EXPLANATION OF THIS RIGHT."

4. Attached to the receipt or contract shall be a completed form in duplicate, captioned "NOTICE OF CANCELLATION", which shall be easily detachable and shall contain in 10-point bold face type the information identified in the Consumer Fraud and Deceptive Business Practices Act.

These points are provided only to highlight a few of the major issues contained in this Act. If you would like to obtain a copy of this Act, contact the Illinois Department of Public Health.

#### ROSTER OF PREFERRED MAILING ADDRESSES FOR HEARING AID DISPENSER APPLICANTS

If the place of business of a certificant is changed from that address provided on the certificate and maintained on file by the Illinois Department of Public Health (IDPH), the certificant should notify IDPH in writing within 10 working days of the change. After a change in the business location, the dispenser should leave a forwarding address with the post office for one year and a forwarding telephone number for six months where the consumer can contact the dispenser.

A roster of preferred mailing addresses for Certified and Temporary Hearing Aid Dispenser applicants is now available to the general public. This list identifies each applicant's preferred mailing address and the dispenser's certification status.

The cost of the roster is 25c/page which covers duplication, postage and handling expenses.

To obtain this list, contact the HACP Action Line by calling 1-800-572-3270.

#### IDPH WORKSHOP Hearing Aid Dispensing Practices: An Overview

The Illinois Department of Public Health is offering a workshop entitled "Hearing Aid Dispensing Practices: An Overview," to orient hearing aid dispensers to the use of acceptable and appropriate dispensing practices. Especially designed for Temporary Certified Dispensers, the workshop was created to augment the skill and knowledge of dispensers. Experts from the field of medicine and the hearing aid industry will provide information regarding hearing aid selection and

fitting. The workshop will be offered at two locations:

August 1, 1985  
Holiday Inn East  
3100 S. Dirksen Parkway  
I-55 Junction By Pass 66  
Stevenson Drive  
Audiovisual Room  
Springfield, Illinois

August 2, 1985  
Holiday Inn  
4400 Frontage Road  
Churchill Room  
Hillside, Illinois

 AGENDA 

- |            |  |   |
|------------|--|---|
| 8:00 a.m.  | Registration   |   |
| 8:30 a.m.  | Consumer Protection: The Responsibilities of the Dispenser.                | James R. Nelson, Chief, Division of Health Promotion and Screening, IDPH  |
| 9:00 a.m.  | Shall I Sign the Medical Waiver?   | Leonard Rybak, M.D., Ph.D.<br>Otolaryngologist, Springfield Memorial Medical Center (Springfield)<br><br>Richard Wiet, M.D.,<br>Otolaryngologist, Hinsdale, IL (Hillside) |
| 10:00 a.m. | BREAK  |   |
| 10:15 a.m. | Hearing Aid Selection: Options and Alternatives                            | Ronald Regan, President, Argosy Electronics, Edina, Minnesota   |
| 11:45 a.m. | LUNCH  |   |
| 1:00 p.m.  | Earmolds: Making a Good Impression   | Marie Jablin, Vice President Marketing & Audiological Research, Audiovox, Bensonville, IL   |
| 2:45 p.m.  | BREAK  |   |
| 3:00 p.m.  | The Educational Testing Service (ETS): Test Preparation and Administration | Terri Strand, Ph.D., Professional Associate, ETS, Evanston, IL (Springfield)  |

3:00 p.m. (Continued)

George Elford, Director, Mid-  
western Region, Educational  
Testing Service, Evanston,  
Illinois (Hillside)

4:00 p.m. Laboratory Session: Introduction IDPH Staff  
to the Qualitone Acoustic Appraiser  
and the Bioacoustic Audiometric  
Simulator\*

5:00 p.m. CLOSURE

\* This equipment will be used in the practicum component of the  
Illinois Hearing Aid Dispenser Examination.

Those interested in attending this workshop should complete the  
following registration form.

#### REGISTRATION

Hearing Aid Dispensing Practices: An Overview

Please check the date and location you plan to attend. Advance registration  
fee is \$40.00 (includes lunch, coffee and materials). At site registration  
will be \$50.00.

\_\_\_\_ August 1, 1985 (Springfield) .      \_\_\_\_ August 2, 1985 (Hillside)

Please type or print

NAME: \_\_\_\_\_

CERTIFICATION I.D. NUMBER: \_\_\_\_\_

BUSINESS ADDRESS: \_\_\_\_\_

HOME TELEPHONE: (    ) \_\_\_\_\_ WORK TELEPHONE: (    ) \_\_\_\_\_

Please make checks payable to: IDPH/Hearing Aid Program  
(Your cancelled check is your receipt)

Mail registration to: Hearing Aid Program  
Division of Health Promotion and Screening  
Illinois Department of Public Health  
535 West Jefferson Street  
Springfield, Illinois 62761

NO REFUNDS WILL BE AVAILABLE AFTER JULY 19, 1985

such receipt in Court shall be grounds for dismissal of the action.

*For repeal of Act, see note preceding § 7001 of this chapter.*

7025.16. Penalties

§ 25.16. Any person who is found to have violated any provision of this Act is guilty of a Class A misdemeanor. On conviction of a second or subsequent offense, the violator shall be guilty of a Class 4 felony.

*For repeal of Act, see note preceding § 7001 of this chapter.*

7026. State powers and functions

§ 26. It is declared to be the public policy of this State, pursuant to paragraphs (h) and (i) of Section 6 of Article VII of the Illinois Constitution of 1970, that any power or function set forth in this Act to be exercised by the State is an exclusive State power or function. Such power or function shall not be exercised concurrently, either directly or indirectly, by any unit of local government, including home rule units, except as otherwise provided in this Act.

*For repeal of Act, see note preceding § 7001 of this chapter.*

7027. Administrative Procedure Act

§ 27. "The Illinois Administrative Procedure Act", approved September 22, 1975, as amended,<sup>1</sup> is hereby expressly adopted and incorporated herein as if all of the provisions of such Act were included in this Act, except that the provision of paragraph (c) of Section 16 of "The Illinois Administrative Procedure Act", as amended,<sup>2</sup> which provides that at hearings the licensee has the right to show compliance with all lawful requirements for retention, or continuation or renewal of the license, is specifically excluded, and for the purpose of this Act the notice required under Section 10 of "The Illinois Administrative Procedure Act", as amended,<sup>3</sup> is considered sufficient when mailed to the last known address of a party.

<sup>1</sup> Chapter 127, § 1001 et seq.

<sup>2</sup> Chapter 127, § 1016.

<sup>3</sup> Chapter 127, § 1010.

*For repeal of Act, see note preceding § 7001 of this chapter.*

7028. Rights under prior laws

§ 28. Rights and obligations incurred and any actions commenced under the "Veterinary Medicine and Surgery Practice Act", approved August 14, 1961, as amended,<sup>1</sup> as it existed prior to the effective date of this Act shall not be impaired by the enactment of this Act. Rules adopted under the former Act, unless clearly inconsistent with the provisions of this Act, shall remain in effect until amended or rescinded.

All licenses heretofore legally issued in this State permitting the holder thereof to practice veterinary medicine and surgery and valid and in effect on the taking effect of this Act shall have the same force, and be subject to the same authority of the Department to revoke or suspend them as licenses issued under this Act.

<sup>1</sup> Paragraph 6901 et seq. (repealed) of this chapter.

*For repeal of Act, see note preceding § 7001 of this chapter.*

HEARING AID CONSUMER PROTECTION ACT

AN ACT to regulate the selling, practice of fitting, dispensing or servicing of hearing aids in the State of Illinois. P.A. 83-928, am. veto overridden Nov. 1, 1983, eff. July 1, 1984.

Repeal of Act

*P.A. 81-999, the Regulatory Agency Sunset Act, eff. Sept. 22, 1979, which provides for the legislative review of programs and agencies which regulate professions, occupations, business, industry and trade in Illinois, as amended by P.A. 83-928, § 37, eff. July 1, 1984, provided in section 4.8 of the Act for repeal of "The Hearing Aid Consumer Protection Act", enacted by the 13rd General Assembly, as now or hereafter amended", effective Dec. 31, 1995. For complete text of the Regulatory Agency Sunset Act, see § 1901 et seq. of chapter 127.*

7401. Purpose

*Paragraph effective July 1, 1984.*

§ 1. The purpose of this Act is to protect the hearing-impaired public from incompetent and dishonest dispensers of hearing aids who could endanger the health, safety and welfare of the People of this State. The Federal Food and Drug Administration has recommended that State legislation is necessary in order to establish standards of competency and to impose stringent penalties for those who violate the public trust in this field of health care.

*For repeal of Act, see note preceding this paragraph.*

7402. Short title

*Paragraph effective July 1, 1984.*

§ 2. This Act shall be known as the Hearing Aid Consumer Protection Act.

*For repeal of Act, see note preceding § 7401 of this chapter.*

7403. Definitions

*Paragraph effective July 1, 1984.*

§ 3. As used in this Act, except as the context requires otherwise:

(a) "Department" means the Department of Public Health.

(b) "Director" means the Director of the Department of Public Health.

(c) "Certification" means a certificate issued by the State under this Act to a hearing aid dispenser.

(d) "Temporary certificate" means a certificate issued while the applicant is in training or is qualifying to become a certified hearing aid dispenser.

(e) "Clinical Audiologist" means a person with a Masters Degree in Audiology who holds a certificate of clinical competence in Audiology from the American Speech and Hearing Association or its equivalent.

(f) "Hearing Aid Audiologist" means a person who has been so certified after qualification by examination and experience by the National Board of Certification of the National Hearing Aid Society.

(g) "Licensed Physician" means a physician licensed to practice medicine in all of its branches.

*Amended 10/7/95 Act 1*

(h) "Board" means the Hearing Aid Consumer Protection Board.

(i) "Hearing aid" means any instrument or device designed, intended or offered for the purpose of effectively compensating for impaired human hearing and any parts, attachments or accessories, including earmold. However, batteries, cords and individual or group auditory training devices and any instrument or device used by a public utility in providing telephone or other communication services are excluded.

(j) "Practice of fitting, dispensing and servicing of hearing aids" means the selection, adaptation, sale and service of hearing aids and include the testing of hearing by means of an audiometer properly calibrated to American National Standard Institute standards.

(k) "Sell" or "sale" means any transfer of title or of the right to use by lease, bailment, or any other contract, excluding wholesale transactions with distributors or dealers.

*For repeal of Act, see note preceding § 7401 of this chapter.*

7404. Consumer information—Medical evaluation—Waiver—Complaint procedure—Liability insurance  
Paragraph effective July 1, 1984.

§ 4. Every person fitted and sold a hearing aid shall be given, at no charge, the "User Instructional Brochure", supplied by all hearing aid manufacturers, containing advice to the user regarding requirements for evaluation by licensed physicians, specific waivers to the medical evaluation requirements, hearing aid manufacturer evaluations, purchase privileges and technical data.

Any person who fits, dispenses, services or sells hearing aids shall deliver to each person supplied with a hearing aid, which shall contain the seller's signature, the manufacturer's specifications, the model and serial number of the hearing aid furnished and the full sales terms clearly stated. If a used hearing aid is sold, the receipt and the container thereof shall be clearly marked as "used" or "reconditioned", whichever is applicable, with terms of guarantee, if any.

A hearing aid dispenser shall not sell a hearing aid unless the prospective user has presented to the hearing aid dispenser a written statement signed by a licensed physician which states that 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 6 months immediately preceding the time the written statement is presented by the prospective hearing aid user to the hearing aid dispenser. If the prospective hearing aid user is 18 years of age or older, the hearing aid dispenser may afford the prospective user an opportunity to waive the medical evaluation requirement of this Section, provided that the hearing aid dispenser:

- (i) informs the prospective user that the exercise of the waiver is not in the user's best health interest;
- (ii) Does not in any way actively encourage the prospective user to waive such a medical evaluation; and
- (iii) affords the prospective user the opportunity to sign the following statement:

I have been advised by \_\_\_\_\_ (Hearing aid dispenser's name) that the Food and Drug Administration has determined that my best 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 hearing aid dispenser shall retain such proof of medical examination or waiver for at least 4 years.

If the parent or guardian of any individual under the age of 18 years is a member of any church or religious denomination, whose tenets and practices include reliance upon spiritual means through prayer alone and objects to medical treatment and so states in writing to the hearing aid dispenser, such individual shall undergo a hearing examination as provided by this Section, but no proof, ruling out any medically treatable problem causing hearing loss, shall be required.

All persons certified under this Act shall have conspicuously displayed in their business establishment a sign indicating that formal complaints regarding hearing aid goods or services may be made to the Department. Such sign shall give the address of the Department. All persons purchasing hearing aids shall be provided with a written statement indicating that formal complaints regarding hearing aid goods or services may be made to the Department and shall give the address of the Department.

Any person wishing to make a complaint, against a hearing aid dispenser under this Act, shall file it with the Department within 3 years from the date of the action upon which the complaint is based. The Department shall investigate all such complaints.

All persons certified under this Act shall maintain liability insurance as set forth by rule and shall be responsible for the annual calibration of all audiometers in use by such persons. Such annual calibrations shall be in conformance with the standards set by American National Standard Institute.

*For repeal of Act, see note preceding § 7401 of this chapter.*

7405. Certified hearing aid dispensers

Paragraph effective July 1, 1984.

§ 5. No person shall engage in the selling, practice of fitting, dispensing or servicing hearing aids or display a sign, advertise or represent oneself as a person who practices the fitting and selling of hearing aids after January 1, 1985, unless such person holds a current certificate issued by the Department as provided in this Act. For purposes of this Act, such person shall be known as a certified hearing aid dispenser. The certificate shall be conspicuously displayed in the place of business. Duplicate certificates shall be issued by the Department to valid certificate holders operating more than one office, with such additional payment as may be required.

Nothing in this Act shall prohibit a corporation, partnership, trust, association or other organization maintaining an established business address, from engaging in the business of fitting and selling or offering for sale hearing aids at retail without a certificate, provided it employs only certified individuals in the direct fitting and dispensing of such products. Each such corporation, partnership, trust, association or other organization shall file annually, with the Department, a list of all certified hearing aid dispensers employed by it. Such organizations shall also file with the Department a statement that they comply with this Act, the rules issued pursuant to it and the regulations of the Federal Food and Drug Administration.

and the Federal Trade Commission insofar as they are applicable.

For repeal of Act, see note preceding § 7401 of this chapter.

7406. Sale of hearing aids by business organizations—Registration—Disclosure statement—Consent to service of process—Right of cancellation by consumer of mail order—Other requirements

Paragraph effective July 1, 1984.

§ 6. Nothing in this Act shall prohibit a corporation, partnership, trust, association or other organization maintaining an established business address, from engaging in the business of selling or offering for sale hearing aids at retail by mail to persons 18 years of age or older who have not been examined by a licensed physician or tested by a certified hearing aid dispenser provided that:

(a) Each such organization is registered by the Department prior to engaging in business in this State.

(b) Each such organization files with the Department, prior to registration and annually thereafter, a Disclosure Statement containing the following:

(1) the name under which the organization is doing or intends to do business and the name of any affiliated company which the organization recommends or will recommend to persons as a supplier of goods or services or in connection with other business transactions of the organization;

(2) the organization's principal business address and the name and address of its agent in this State authorized to receive process;

(3) the business form of the organization, whether corporate, partnership, or otherwise and the state of other sovereign power under which the organization is organized;

(4) the names of the directors or persons performing similar functions and names and addresses of the chief executive officer, and the financial, accounting, sales, and other principal executive officers, if the organization is a corporation, association, or other similar entity; of all general partners, if the organization is a partnership; and of the owner, if the organization is a sole proprietorship, together with a statement of the business background during the past 5 years for each such person;

(5) a statement as to whether the organization or any person identified in the disclosure statement:

(i) has during the 5 year period immediately preceding the date of the disclosure statement been convicted of a felony, pleaded nolo contendere to a felony charge, or been held liable in a civil action by final judgment, if such felony or civil action involved fraud, embezzlement, or misappropriation of property, and a description thereof; or

(ii) is subject to any currently effective injunctive or restrictive order as a result of a proceeding or pending action brought by any public agency or department, and a description thereof; or

(iii) is a defendant in any pending criminal or material civil action relating to fraud, embezzlement, misappropriation of property or violations of the antitrust or trade regulation laws of the United States or any state, and a description thereof; or

(iv) has during the 5 year period immediately preceding the date of the disclosure statement had entered against

such person or organization a final judgment in any material civil proceeding, and a description thereof; or

(v) has during the 5 year period immediately preceding the date of the disclosure statement been adjudicated a bankrupt or reorganized due to insolvency or was a principal executive officer or general partner of any company that has been adjudicated a bankrupt or reorganized due to insolvency during such 5 year period, and a description thereof;

(6) the length of time the organization and any predecessor of the organization has conducted a business dealing with hearing aid goods or services;

(7) a financial statement of the organization audited by an independent certified public accountant, as of the close of the most recent fiscal year of the organization. If the financial statement is filed later than 120 days following the close of the fiscal year of the organization it must be accompanied by a statement of the organization of any material changes in the financial condition of the organization. The Department may in its discretion waive the requirement for audited statements for organizations who have not previously had such certified audits, if the unaudited financial statement is prepared by an independent certified public accountant. If the unaudited financial statement is filed later than 120 days following the close of the fiscal year of the organization, it must be accompanied by a statement of the organization of any material changes in the financial condition of the organization;

(8) a general description of the business, including without limitation a description of the goods, training programs, supervision, advertising, promotion and other services provided by the organization;

(9) a statement of any compensation or other benefit given or promised to a public figure arising, in whole or in part, from (i) the use of the public figure in the name or symbol of the organization or (ii) the endorsement or recommendation of the organization by the public figure in advertisements;

(10) a statement setting forth such additional information and such comments and explanations relative to the information contained in the disclosure statement as the organization may desire to present.

(c) Each such organization files with the Department prior to registration and annually thereafter a statement that they comply with the Act, the rules issued pursuant to it and the regulations of the Federal Food and Drug Administration and the Federal Trade Commission insofar as they are applicable.

(d) Each such organization files with the Department at the time of registration an irrevocable consent to service of process authorizing the Department and any of its successors to be served any notice of process or pleading in any action or proceeding against such organization arising out of or in connection with any violation of this Act. Such service shall have the effect of conferring personal jurisdiction over such organization in any court of competent jurisdiction.

(e) Each such organization affords the prospective user an opportunity to waive the medical evaluation requirement of Section 4 of this Act and the testing requirement of subsection (j) of Section 3 and subsection (z) of Section 18 provided that the organization:

(1) informs the prospective user that the exercise of the waiver is not in the user's best health interest;

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2) does not in any way actively encourage the prospective user to waive such a medical evaluation or test; and  
3) affords the prospective user the opportunity to sign following statement:

"I have been advised by \_\_\_\_\_ (Hearing Aid dispenser's name) that the Food and Drug Administration and the State of Illinois have determined that my best interest could be served if I had a medical evaluation by a licensed physician, preferably a physician who specialized in diseases of the ear, before purchasing a hearing aid; or a test by a certified hearing aid dispenser utilizing established procedures and instrumentation in the fitting of hearing aids. I do not wish either a medical evaluation or test before purchasing a hearing aid".

(c) Where a sale, lease, or rental of hearing aids is sold or contracted to be sold to a consumer by mail order, that consumer may avoid the contract or sale by notifying the seller within 45 full business days following that day on which the hearing aids were mailed by the seller to the consumer and by returning to the seller in its original condition, any hearing aid delivered to the consumer under the contract or sale. At the time the hearing aid is mailed the seller shall furnish the consumer with a fully completed receipt or copy of any contract pertaining to such sale containing a "Notice of Cancellation" informing the consumer that he may cancel the sale at any time within such 45 days and which shows the date of the mailing and contains the name, address and telephone number of the seller, and in immediate proximity to the space reserved in the contract for the signature of the consumer or on the front page of the receipt if a contract is not used and in bold face type of a minimum size of 10 points, a statement in substantially the following form:

"You, the buyer, may cancel this transaction at any time prior to midnight of the 45th business day after the date of this transaction. See the attached notice of cancellation form for an explanation of this right".

Attached to the receipt or contract shall be a completed form in duplicate, captioned "NOTICE OF CANCELLATION" which shall be easily detachable and which shall contain in 10 point bold face type the following information and statements in the same language as that used in the contract:

**NOTICE OF CANCELLATION**  
enter date of transaction

\_\_\_\_\_  
(DATE)

YOU MAY CANCEL THIS TRANSACTION, WITHOUT ANY PENALTY OR OBLIGATION, WITHIN 45 BUSINESS DAYS FROM THE ABOVE DATE.

IF YOU CANCEL ANY PROPERTY TRADED IN, ANY PAYMENTS MADE BY YOU UNDER THE CONTRACT OR SALE, AND ANY NEGOTIABLE INSTRUMENT EXECUTED BY YOU WILL BE RETURNED WITHIN 10 BUSINESS DAYS FOLLOWING RECEIPT BY THE SELLER OF YOUR CANCELLATION NOTICE, AND ANY SECURITY INTEREST ARISING OUT OF THE TRANSACTION WILL BE CANCELLED.

IF YOU CANCEL, YOU MUST MAKE AVAILABLE TO THE SELLER AT YOUR RESIDENCE, IN SUBSTANTIALLY AS GOOD CONDITION AS WHEN RECEIVED, ANY GOODS DELIVERED TO YOU UNDER THIS CONTRACT OR SALE, OR YOU MAY IF YOU WISH, COMPLY WITH THE INSTRUCTIONS OF THE

SELLER REGARDING THE RETURN SHIPMENT OF THE GOODS AT THE SELLER'S EXPENSE AND RISK. IF YOU DO MAKE THE GOODS AVAILABLE TO THE SELLER AND THE SELLER DOES NOT PICK THEM UP WITHIN 20 DAYS OF THE DATE OF YOUR NOTICE OF CANCELLATION, YOU MAY RETAIN OR DISPOSE OF THE GOODS WITHOUT ANY FURTHER OBLIGATION. IF YOU FAIL TO MAKE THE GOODS AVAILABLE TO THE SELLER, OR IF YOU AGREE TO RETURN THE GOODS TO THE SELLER AND FAIL TO DO SO, THEN YOU REMAIN LIABLE FOR PERFORMANCE OF ALL OBLIGATIONS UNDER THE CONTRACT.

TO CANCEL THIS TRANSACTION, MAIL OR DELIVER A SIGNED AND DATED COPY OF THIS CANCELLATION NOTICE OR ANY OTHER WRITTEN NOTICE, OR SEND A TELEGRAM, TO (name of seller), AT (address of seller's place of business) AND (seller's telephone number) NO LATER THAN MIDNIGHT OF \_\_\_\_\_ (date).

I HEREBY CANCEL THIS TRANSACTION.  
\_\_\_\_\_  
(Date)

\_\_\_\_\_  
(Buyers Signature)

Such written "Notice of Cancellation" may be sent by the consumer to the seller to cancel the contract. The 45 day period provided for in this Section does not commence until the consumer is furnished the Notice of Cancellation, the address and phone number at which such notice to the seller can be given is furnished.

If the conditions of this Section are met, the seller must return to the consumer the full amount of any payment made or consideration given under the contract or for the merchandise.

It is an unlawful practice within the meaning of this Act for a seller to: (1) mail hearing aids to a consumer other than by certified mail; (2) fail, before furnishing copies of the "Notice of Cancellation" to the consumer, to complete both copies by entering the name of the seller, the address of the seller's place of business, the seller's telephone number, the date of the mailing, and the date, not earlier than the 45th business day following the date of the mailing, by which the consumer may give notice of cancellation; (3) include in any contract or receipt any confession of judgment or any waiver of any of the rights to which the consumer is entitled under this Section including specifically his right to cancel the sale in accordance with the provisions of this Section; (4) misrepresent in any manner the consumer's right to cancel; (5) use any undue influence, coercion, or any other wilful act or representation to interfere with the consumer's exercise of his rights under this Section; (6) fail or refuse to honor any valid notice of cancellation by a consumer and within 10 business days after the receipt of such notice, to (i) Refund all payments made under the contract or sale, (ii) return any goods or property traded in, in substantially as good condition as when received by the person, (iii) cancel and return any negotiable instrument executed by the consumer in connection with the contract or sale and take any action necessary or appropriate to terminate promptly any security interest created in the transaction; (7) negotiate, transfer, sell or assign any note or other evidence of indebtedness to a finance company or other third party prior to midnight of the 50th business day following the day of the mailing; or (8) fail, within 10 business days of receipt of the consumer's notice of cancellation, to notify him whether

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e: the seller intends to repossess or to abandon any stopped or delivered goods.

(g) Each such organization employs only certified individuals in the dispensing of hearing aids and files annually with the Department, a list of all certified hearing aid dispensers employed by it.

<sup>1</sup> Paragraph 7404 of this chapter.

<sup>2</sup> Paragraph 7403 of this chapter.

<sup>3</sup> Paragraph 7418 of this chapter.

For repeal of Act, see note preceding § 7401 of this chapter.

7407. Exemptions

Paragraph effective July 1, 1984.

§ 7. The following are exempt from this Act:

(a) Persons who measure human hearing and who fit hearing aids for the sole purpose of audiological evaluations. Such persons shall not sell or dispense hearing aids or accessories thereto unless certified under this Act.

(b) Licensed physicians.

(c) Persons who only repair or manufacture hearing aids and their accessories.

For repeal of Act, see note preceding § 7401 of this chapter.

7408. Examination of hearing aid dispensers—Requirements of applicants

Paragraph effective July 1, 1984.

§ 8. In order to protect the hearing-impaired individual the Department shall authorize or shall conduct an appropriate examination for persons who dispense, fit or service hearing aids. The Department may use the test prepared by the National Institute for Hearing Instruments Studies. Those who successfully pass such an examination shall be issued a certificate as a hearing aid dispenser which shall be effective for a 2-year period. Applicants shall be:

- (1) At least 18 years of age;
- (2) Of good moral character;
- (3) A high school graduate or the equivalent;
- (4) Free of contagious or infectious disease; and
- (5) A citizen or person who has the status as a legal alien.

An applicant for certification by examination shall, by means of written and practical tests, demonstrate that such person is qualified to practice the fitting, selling and servicing of hearing aids.

The renewal of a certificate shall be contingent upon compliance with the continuing education requirement as determined by the Board.

For repeal of Act, see note preceding § 7401 of this chapter.

7409. Matters included in examination

Paragraph effective July 1, 1984.

§ 9. The examination required by Section 8<sup>1</sup> shall demonstrate the applicant's technical qualifications by:

(a) Tests of knowledge in the following areas as they pertain to the fitting and selling of hearing aids:

- (1) Characteristics of sound;
- (2) The nature of the ear; and

(3) The function and maintenance of hearing aids.

(b) Practical tests of proficiency in the following techniques as they pertain to the fitting of hearing aids:

(1) Pure tone audiometry including air conduction testing and bone conduction testing;

(2) Live voice or recorded voice speech audiometry, including speech reception, threshold testing and speech discrimination testing;

(3) Masking;

(4) Proper selection and adaptation of a hearing aid in relation to the above procedure;

(5) Taking earmold impressions;

(6) Proper maintenance procedures; and

(7) A general knowledge of the medical and physical contraindications to the use and fitting of a hearing aid.

(c) Knowledge of the general medical and hearing rehabilitation facilities in the area being served.

<sup>1</sup> Paragraph 7408 of this chapter.

For repeal of Act, see note preceding § 7401 of this chapter.

7410. Provisional certificates

Paragraph effective July 1, 1984.

§ 10. For the period of 6 months immediately following the effective date of this Act, an applicant for certification shall be issued a certificate, provided the applicant:

(a) Has been engaged, at a place of business in Illinois, as a hearing aid dispenser for a total of at least 2 years within the 5-year period immediately prior to July 1, 1984;

(b) Is a person of good moral character;

(c) Is 18 years of age or older;

(d) Is free of contagious or infectious disease;

(e) Agrees, in writing, to comply with the provisions of this Act, the rules issued hereunder and the applicable regulations of the Federal Food and Drug Administration and the Federal Trade Commission;

(f) Pays the appropriate fee; and

(g) Is a citizen or has the status of a legal alien.

However, within 3 years of the effective date of this Act, all persons granted a certificate under this Section shall be required to pass the examination required by Section 8.<sup>1</sup> Those who do not pass the examination within this period shall immediately surrender their certificate to the Department and cease operating as a hearing aid dispenser. Upon failure to do so, the Department shall seize the certificate.

<sup>1</sup> Paragraph 7408 of this chapter.

For repeal of Act, see note preceding § 7401 of this chapter.

7411. Temporary certificates

Paragraph effective July 1, 1984.

§ 11. An applicant who fulfills the requirements regarding age, character, education and health, as set forth in Section 8,<sup>1</sup> may obtain a temporary certificate upon application to the Department. Previous experience or a waiting period shall not be a requirement to obtain a temporary or qualifying certificate. Upon receiving such application, when accompanied by the appropriate fee, the Department shall issue a temporary certificate which entitles the applicant to engage in the fitting, dispensing and

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ing of hearing aids for a period not to exceed one year. A temporary certificate shall not be renewable and the applicant must take the examination within a year after receiving the temporary certificate. All applicants for a temporary certificate shall be employed by a person who has a certificate as a hearing aid dispenser. Such person shall be responsible for the supervision and training of the applicant and shall maintain personal contact and records.

The Department may issue a temporary certificate to an applicant starting a hearing aid dealership as sole owner, principal of a firm, or employee-manager for a corporation if the applicant's training is provided by a manufacturer or by a person who holds a valid certificate issued under this Act and if the new dealer, not later than 5 days prior to the commencement of operation under a temporary certificate, obtains and files with the Department a surety bond in the sum of at least \$5,000, which shall be conditioned on the satisfactory performance, pursuant to and in accordance with this Act and the rules hereunder, during the period covered by the temporary certificate.

<sup>1</sup> Paragraph 7402 of this chapter.

*For repeal of Act, see note preceding § 7401 of this chapter.*

7412. Registration of person licensed or certified in another state

*Paragraph effective July 1, 1984.*

§ 12. The Department may register as a hearing aid dispenser without examination, but upon payment of the required fee, an applicant who has a certificate or license in good standing to practice in another state, if the requirements in such state are substantially equal to the requirements imposed by this Act. Applicants who meet such endorsement requirements may practice in this State pending action on their application. If the application is denied, their right to practice ceases on the date of denial.

*For repeal of Act, see note preceding § 7401 of this chapter.*

7413. Expiration and renewal of certificates

*Paragraph effective July 1, 1984.*

§ 13. The expiration date and renewal period for each certificate issued under this Act shall be set by rule. A hearing aid dispenser whose certificate has expired may have it reinstated within 5 years after the expiration thereof, by making a renewal application therefor and by paying the required fee. However, any hearing aid dispenser whose certificate expired while: (1) on active duty with the Armed Forces of the United States, or the State Militia called into service or training, or (2) in training or education under the supervision of the United States preliminary to induction into the military service, may have the certificate renewed, reinstated or restored without paying any lapsed renewal fees if, within 2 years after honorable termination of such service, training or education, except under conditions other than honorable, such person must furnish the Department with satisfactory evidence of being so engaged and that the service, training or education has been terminated.

If the hearing aid dispenser has not practiced for 5 years or more, the Board shall determine, by an evaluation program established by rule, such person's fitness to resume active status and may require the hearing aid

dispenser to complete a period of evaluated experience and may require successful completion of the examination.

Any hearing aid dispenser whose certificate has expired for more than 5 years prior to July 1, 1984 may have it restored by making application, and filing acceptable proof, to the Department of his fitness to have such certificate restored, including sworn evidence certifying to active practice in another jurisdiction and by paying the required restoration fee.

*For repeal of Act, see note preceding § 7401 of this chapter.*

7414. Powers and duties of department

*Paragraph effective July 1, 1984.*

§ 14. The powers and duties of the Department are: (a) To supervise issuance of certificates and to administer examinations to applicants. However, the Department may authorize a testing service to provide this function or it may use the test prepared by the National Institute for Hearing Instruments Studies.

(b) To certify persons who are qualified to engage in the fitting, selling and dispensing of hearing aids;

(c) To provide the equipment and facilities necessary for the examination;

(d) To issue and to renew certificates;

(e) To suspend or revoke certificates or to take such other disciplinary action as provided in this Act;

(f) To consider all recommendations of the Board and to inform it of all actions of the Department insofar as hearing aid dispensers are concerned, including any instances where the actions of the Department are contrary to the recommendations of the Board; and

(g) To promulgate rules necessary to implement this Act.

*For repeal of Act, see note preceding § 7401 of this chapter.*

7415. Fees—Disposition of fees

*Paragraph effective July 1, 1984.*

§ 15. (a) The following are fees to be charged and are not refundable:

(1) The fee for application for a certificate is \$25.

(2) In addition to the application fee, applicants for any examination shall be required to pay, either to the Department or to the designated testing service, a fee covering the actual cost of the examination. Failure to appear for the examination on the scheduled date, at the time and place specified, after the applicant's application and fee for the examination has been received and acknowledged by the Department or the designated testing service, shall result in the forfeiture of the fee.

(3) The fee for the renewal of a certificate shall be \$30 per year.

(4) The fee for the reinstatement of a certificate which has expired for not more than 5 years is \$10, plus payment of all lapsed renewal fees.

(5) The fee for the restoration of a certificate which has expired for more than 5 years is \$100.

(6) The fee for the issuance of a duplicate certificate, for the issuance of a replacement certificate which has been lost or destroyed or for the issuance of a certificate with a change of name or address, other than during the renewal

period is \$10. No fee is required for name and address changes on Department records when no duplicate certificate is issued.

(7) The fee for a certification of a registrant's record for any purpose is \$10.

(8) The fee to have the scoring of an examination administered by the Department reviewed and verified is \$10, plus any fee charged by the testing service.

(9) The fee for a wall certificate shall be the actual cost of such certificate.

(10) The fee for a roster of persons registered as hearing aid dispensers shall be the actual cost of such roster.

(b) The moneys received as license fees by the Department of Public Health under this Act shall be deposited in the Hearing Aid Dispenser Examining and Certification Fund, which is hereby created as a special fund in the State Treasury, and shall be used only for the administration of this Act, including: (1) costs directly related to certification of persons under this Act; and (2) by the Hearing Aid Consumer Protection Board in the exercise of its powers and performance of its duties, and such use shall be made by the Department of Public Health with full consideration of all recommendations of the Hearing Aid Consumer Protection Board.

For the fiscal year beginning July 1, 1984, the moneys deposited in the Hearing Aid Dispenser Examining and Certification Fund shall be appropriated to the Department for expenses of the Department and the Hearing Aid Consumer Protection Board in the administration of this Act.

Moneys in the Hearing Aid Dispenser Examining and Certification Fund may be invested and reinvested, with all earnings received from such investment to be deposited in the Hearing Aid Dispenser Examining and Certification Fund and used for the same purposes as fees deposited in such fund.

Upon the completion of any audit of the Department as prescribed by the Illinois State Auditing Act,<sup>1</sup> which audit includes an audit of the Hearing Aid Dispenser Examining and Certification Fund, the Department shall make a copy of the audit open to inspection by any interested person, which copy shall be submitted to the Department by the Auditor General, in addition to the copies of audit reports required to be submitted to other State officers and agencies by Section 3-14 of the Illinois State Auditing Act.<sup>2</sup>

<sup>1</sup> Chapter 15. § 301-1 et seq.

<sup>2</sup> Chapter 15. § 303-14.

*For repeal of Act, see note preceding § 7401 of this chapter.*

#### 7416. Hearing aid consumer protection board—Establishment—Members

*Paragraph effective July 1, 1984.*

§ 16. There shall be established a Hearing Aid Consumer Protection Board which shall assist, advise and make recommendations to the Department pursuant to this Act.

The Board shall consist of 5 members who shall be residents of Illinois. One shall be a licensed physician who specializes in otology or otolaryngology; one shall be a member of a consumer-oriented organization concerned with the hearing impaired; one shall be from the general public, preferably a senior citizen; and 2 shall be certified hearing aid dispensers. Each such certified hearing aid

dispenser shall have at least 5 years of experience, excepting those appointed to the first Board. One of the certified hearing aid dispensers shall be a Certified Clinical Audiologist, the other shall be a Certified Hearing Aid Audiologist.

Members of the Board shall be appointed by the Director. The term of office of each shall be 4 years, except for those of the first Board, 2 shall be appointed for 2 year terms. Before a member's term expires, the Director shall appoint a successor to assume member's duties at the expiration of his predecessor's term. A vacancy shall be filled by appointment for the unexpired term. The members shall annually designate one member as chairman. No member of the Board who has served 2 or more successive and full terms may be reappointed. The Director may remove members for good cause.

Members of the Board shall receive reimbursement for actual and necessary travel and for other expenses, not to exceed the limit established by the Department.

*For repeal of Act, see note preceding § 7401 of this chapter.*

#### 7417. Duties of board

*Paragraph effective July 1, 1984.*

§ 17. The Board shall advise the Department in all matters relating to this Act and shall assist as requested by the Director.

The Board shall respond to issues and problems relating to the improvement of services to the hearing-impaired and shall make such recommendations as it considers advisable. It shall file an annual report with the Director and shall meet at least twice a year.

The Board shall recommend specialized education programs for persons wishing to become certified as hearing aid dispensers and shall, by rule, establish minimum standards of continuing education required for certificate renewal.

The Board shall hear charges brought against hearing aid dispensers and shall recommend disciplinary action to the Director.

*For repeal of Act, see note preceding § 7401 of this chapter.*

#### 7418. Disciplinary actions by department—Grounds

*Paragraph effective July 1, 1984.*

§ 18. The Department may refuse to issue or renew a certificate or it may revoke, suspend, place on probation, censure or reprimand a certificate holder for any of the following:

(a) Material misstatement in furnishing information to the Department

(b) Violations of this Act, or the rules promulgated hereunder;

(c) Conviction of any crime under the laws of the United States or any state or territory thereof which is a felony or misdemeanor, an essential element of which is dishonesty, or of any crime which is directly related to the practice of the profession;

(d) Making any misrepresentation for the purpose of obtaining a certificate or renewing a certificate, including falsification of the continuing education requirement;

(e) Professional incompetence;

(f) Malpractice;

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- (g) Aiding or assisting another person in violating any provision of this Act or the rules promulgated hereunder;
- (h) Failing, within 60 days, to provide information in response to a written request made by the Department;
- (i) Engaging in dishonorable, unethical or unprofessional conduct which is likely to deceive, defraud or harm the public;
- (j) Knowingly employing, directly or indirectly, any suspended or unregistered person to perform any services covered by this Act;
- (k) Habitual intoxication or addiction to the use of drugs;
- (l) Discipline by another state, the District of Columbia, territory, or a foreign nation, if at least one of the grounds for the discipline is the same or substantially equivalent to those set forth herein;
- (m) Directly or indirectly giving to or receiving from any person, firm, corporation, partnership or association any fee, commission, rebate or other form of compensation for any professional services not actually rendered;
- (n) A finding by the Board that the registrant, after having his certificate placed on probationary status has violated the terms or probation;
- (o) Willfully making or filing false records or reports;
- (p) Willfully failing to report an instance of suspected child abuse or neglect as required by the "Abused and Neglected Child Reporting Act", approved June 26, 1975, as amended;<sup>1</sup>
- (q) Physical illness, including but not limited to, deterioration through the aging process, or loss of motor skill which results in the inability to practice the profession with reasonable judgment, skill or safety;
- (r) Solicitation of professional services other than by permitted advertising;
- (s) Participating in subterfuge or misrepresentation in the fitting and servicing of a hearing aid;
- (t) Advertising a particular model or type of hearing aid for sale when prospective purchasers cannot purchase the advertised model or type, where it is established that the purpose of the advertisement is to obtain prospects for the sale of a different model or type than that advertised;
- (u) Representing that the services of a licensed physician will be used or made available in the fitting, adjustment, maintenance or repair of hearing aids when that is not true, or using the words "doctor", "audiologist", "clinic", "Clinical Audiologist", "Certified Hearing Aid Audiologist", "State Certified", "Certified Hearing Aid Dispenser" or any other term, abbreviation or symbol when it would give the impression that service is being provided by persons awarded that degree or title, or that the person's service who is holding the certificate has been recommended by a governmental agency, when such is not the case;
- (v) Advertising a manufacturer's product or using a manufacturer's name or trademark implying a relationship which does not exist;
- (w) Directly or indirectly giving or offering anything of value to any person who advises another in a professional capacity, as an inducement to influence the purchase of a product sold or offered for sale by a hearing aid dispenser or influencing persons to refrain from dealing in the products of competitors;

(x) Conducting business while suffering from a contagious disease;

(y) Engaging in the fitting and sale of hearing aids under a name with fraudulent intent;

(z) Dispensing a hearing aid to a person who has not been given tests utilizing appropriate established procedures and instrumentation in the fitting of hearing aids, except where there is the replacement of a hearing aid, of the same make and model;

(aa) Unavailability or unwillingness to adequately provide for service and repair of hearing aids fitted and sold by a dispenser;

(bb) Violating the regulations of the Federal Food and Drug Administration or the Federal Trade Commission as they affect hearing aids;

(cc) Violating any provision of the "Consumer Fraud and Deceptive Business Practices Act", approved July 24, 1961, as amended.<sup>2</sup>

<sup>1</sup> Chapter 23, § 2051 et seq.

<sup>2</sup> Chapter 121 1/2, § 261 et seq.

*For repeal of Act, see note preceding § 7401 of this chapter.*

#### 7419. Dispensing of hearing aids without certificate—Injunction—Costs

*Paragraph effective July 1, 1984.*

§ 19. The practice of fitting, dispensing and servicing hearing aids by any person not at that time holding a valid and current certificate under this Act is hereby declared to be inimical to the public welfare and constitutes a public nuisance. The Director of the Department, through the Attorney General or the State's Attorney of any county, may maintain an action in the name of the people of the State of Illinois and may apply for an injunction in the circuit court to enjoin any such person from engaging in such practice. Upon the filing of a verified petition in such court, the court, if satisfied by affidavit, or otherwise, that such person has been engaged in such practice without a current certificate to do so, may issue a temporary injunction without notice or bond, joining the defendant from any such further practice. A copy of the verified complaint shall be served upon the defendant and the proceedings shall thereafter be conducted as other civil cases. If it is established that the defendant has been, or is engaged in any unlawful practice, the court may enter an order or judgment perpetually enjoining the defendant from further such practice. In all proceedings hereunder, the court, in its discretion, may apportion the costs among the parties interested in the suit, including cost of filing complaint, service of process, witness fees and expenses, court reporter charges and reasonable attorneys fees. In case of violation of any injunction issued pursuant to this Section, the court may try and punish the offender for contempt of court. Such injunction proceedings shall be in addition to all penalties and other remedies in this Act.

*For repeal of Act, see note preceding § 7401 of this chapter.*

#### 7420. Inactive status

*Paragraph effective July 1, 1984.*

§ 20. Any hearing aid dispenser who notifies the Department, on the prescribed forms, may place such certificate on inactive status and shall be exempt from payment of renewal fees until such person notifies the Department

*M. J. D. [Signature]*

cate to the Department and if such person fails to do so, the Department shall seize such certificate.

*For repeal of Act, see note preceding § 7401 of this chapter.*

#### 7427. Restoration of certificate

*Paragraph effective July 1, 1984.*

§ 27. At any time after the suspension or revocation of any certificate, the Department may restore it to the accused person, upon the written recommendation of the Board.

*For repeal of Act, see note preceding § 7401 of this chapter.*

#### 7428. Payment of costs—Filing or receipt

*Paragraph effective July 1, 1984.*

§ 28. The Department shall not be required to certify any record to the Court or to file any answer in court or otherwise appear in any court in a judicial review proceeding, unless there is filed in the court, with the complaint, a receipt from the Department acknowledging payment of the costs of furnishing and certifying the record, which costs shall be computed at the rate of 20 cents per page of such record. Failure on the part of the plaintiff to file such receipt in court shall be grounds for dismissal of the action.

*For repeal of Act, see note preceding § 7401 of this chapter.*

#### 7429. Certain orders as prima facie proof

*Paragraph effective July 1, 1984.*

§ 29. An order or a certified copy thereof, over the seal of the Department and purporting to be signed by the Director, shall be prima facie proof:

- (a) That such signature is the signature of the Director;
- (b) That the Director is duly appointed and qualified; and
- (c) That the Board, and the members thereof, are qualified to act.

*For repeal of Act, see note preceding § 7401 of this chapter.*

#### 7430. Determination of mental illness—Automatic suspension of certificate

*Paragraph effective July 1, 1984.*

§ 30. The determination by a circuit court that a certificate holder is subject to involuntary admission or judicial admission, as provided in the "Mental Health and Developmental Disabilities Code", approved September 5, 1978, as amended,<sup>1</sup> operates as an automatic suspension of the holder's certificate. Such suspension will end upon a finding by a court that the patient is no longer subject to involuntary admission or judicial admission and the court issues an order so finding and discharging the patient and upon the recommendation of the Board to the Director that the registrant be allowed to resume his practice.

<sup>1</sup> Chapter 91½, § 1-100 et seq.

*For repeal of Act, see note preceding § 7401 of this chapter.*

#### 7431. Applicability of Administrative Procedure Act—Review under Administrative Review Law

*Paragraph effective July 1, 1984.*

§ 31. The provisions of "The Illinois Administrative Procedure Act", approved September 22, 1975, as amended,<sup>1</sup> shall apply to this Act. All final administrative decisions of the Department are subject to judicial review pursuant to the provisions of Article 3 of the "Code of Civil Procedure", approved August 19, 1981, as amended.<sup>2</sup> Any circuit court, upon the application of the certificate holder or the Department, may order the attendance of witnesses and the production of relevant records in any Departmental hearing relative to the application for or refusal, recall, suspension or revocation of a certificate.

<sup>1</sup> Chapter 137, § 1001 et seq.

<sup>2</sup> Chapter 110, §§ 1-101 et seq.

*For repeal of Act, see note preceding § 7401 of this chapter.*

#### 7432. Public policy

*Paragraph effective July 1, 1984.*

§ 32. It is declared to be the public policy of this State, pursuant to paragraphs (h) and (i) of Section 6 of Article VII of the Illinois Constitution of 1970, that any power or function set forth in this Act to be exercised by the State is an exclusive State power or function. Such power or function shall not be exercised concurrently, either directly or indirectly, by any unit of local government, including home rule units, except as otherwise provided in this Act.

*For repeal of Act, see note preceding § 7401 of this chapter.*

#### 7433. Violations of act—Unlawful practice under Consumer Fraud and Deceptive Business Practices Act

*Paragraph effective July 1, 1984.*

§ 33. The advertising, offering for sale, sale or distribution of hearing aid goods and services to consumers by any person in violation of any of the provisions of this Act is an unlawful practice pursuant to Section 20 of the "Consumer Fraud and Deceptive Business Practices Act"; approved July 24, 1961, as amended.<sup>1</sup>

<sup>1</sup> Chapter 121½, § 262a.

*For repeal of Act, see note preceding § 7401 of this chapter.*

#### 7434. Powers of attorney general—Award of actual damages

*Paragraph effective July 1, 1984.*

§ 34. All remedies, penalties and authority granted to the Attorney General by the "Consumer Fraud and Deceptive Practices Act", approved July 24, 1961, as now or hereafter amended,<sup>1</sup> shall be available to him for the enforcement of this Act, and Sections 3, 4, 5, 6, 6.1, 7 and 10 of that Act<sup>2</sup> are hereby incorporated by reference into this Act. In addition, in any action brought by the Attorney General to enforce this Act, the court may order that persons who incurred actual damages be awarded the amount at which actual damages are assessed.

<sup>1</sup> Chapter 121½, § 261 et seq.

<sup>2</sup> Chapter 121½, §§ 263 to 267 and 170.

*For repeal of Act, see note preceding § 7401 of this chapter.*

in writing, of his intention to resume the practice of fitting, dispensing and servicing hearing aids and pays the current renewal fee. However, if such period of inactive status is more than 5 years, the hearing aid dispenser shall also provide the Department with sworn evidence certifying to active practice in another jurisdiction that is satisfactory to the Department. If such person has not practiced in any jurisdiction for 5 years or more, he shall be required to restore his certificate as provided in this Act. Any hearing aid dispenser whose certificate has an inactive status shall not practice in Illinois.

*For repeal of Act, see note preceding § 7401 of this chapter.*

**7421. Investigation by department—Notice of charges—Hearing**

*Paragraph effective July 1, 1984.*

§ 21. The Department may investigate the actions of any applicant or any person holding or claiming to hold a certificate. The Department shall, before refusing to issue a certificate or disciplining a registrant, notify, in writing, at least 10 days prior to the date set for the hearing, the applicant for, or holder of, a certificate. The notification shall set forth the charges and the date of the hearing. The hearing shall determine whether the applicant or holder is entitled to hold such certificate, and shall afford such person an opportunity to be heard in person or by counsel. Such written notice may be served by certified or registered mail to the respondent at his last known address. At the time and place fixed in the notice, the Board shall hear the charges and the parties shall be accorded opportunity to present such statements, testimony and evidence as may be pertinent to the charges or defenses. The Board may continue such hearing from time to time. Pursuant to rule, the Director may conduct informal hearings, and shall so inform the Board.

*For repeal of Act, see note preceding § 7401 of this chapter.*

**7422. Findings and recommendation of board**

*Paragraph effective July 1, 1984.*

§ 22. At the conclusion of the hearing, the Board shall present to the Director a written report of its finding and recommendation as to whether or not the accused person violated this Act or failed to comply with the conditions required in this Act or any rule promulgated pursuant hereto. The Board shall specify the nature of the violation or failure to comply and shall make its recommendations to the Director.

The report of findings and recommendation of the Board shall be the basis for the Department's action with respect to certificates or the imposition of any disciplinary action. The findings are not admissible in evidence against the person in a criminal prosecution brought for the violation of this Act, but the hearing and findings are not a bar to a criminal prosecution brought for violating this Act.

*For repeal of Act, see note preceding § 7401 of this chapter.*

**7423. Record of proceedings—Service upon respondent of copy of board's report—Motion for rehearing—Order**

*Paragraph effective July 1, 1984.*

§ 23. The Department, at its expense, shall preserve a record of all proceedings at the formal hearing of any case

involving the refusal to issue a certificate or to discipline a registrant. The notice of hearing, the complaint and all other documents in the nature of pleadings and written motions filed in the proceedings, the transcript of testimony, the report of the Board and the orders of the Department shall be the record of such proceeding.

In any case involving the refusal to issue a certificate or to discipline a registrant, a copy of the Board's report shall be served upon the respondent by the Department, as provided in this Act for the service of the notice of hearing. Within 20 days after such service, the respondent may present to the Department a motion in writing for a rehearing, which motion shall specify the particular grounds therefor. If no motion for rehearing is filed, then upon the expiration of the time specified for filing such a motion, or if a motion for rehearing is denied, then upon such denial, the Director may enter an order in accordance with recommendations of the Board. If the respondent orders and pays for a transcript of the record within the time for filing a motion for rehearing, the 20-day period within which such a motion may be filed shall commence upon the delivery of the transcript to the respondent.

Whenever the Director is satisfied that substantial justice has not been done either in an examination or in the revocation, suspension or refusal to issue a certificate, the Director may order a re-examination or rehearing.

*For repeal of Act, see note preceding § 7401 of this chapter.*

**7424. Violations of act—Injunctions**

*Paragraph effective July 1, 1984.*

§ 24. If any registrant violates any provision of this Act, the Director may, through the Attorney General, petition, for an order enjoining such violation or for an order enforcing compliance with this Act or any rule issued pursuant hereto. Upon the filing of a verified petition in such court, the court may issue a temporary injunction, without notice or bond, enjoining such continued violation, and if it is established that such person has violated or is violating the injunction, the Court may punish the offender for contempt of court. Proceedings under this Section shall be in addition to all other remedies and penalties.

*For repeal of Act, see note preceding § 7401 of this chapter.*

**7425. Powers of circuit court**

*Paragraph effective July 1, 1984.*

§ 25. Any circuit court may, upon application of the prosecutor or of the applicant or registrant against whom disciplinary proceedings are pending, enter an order requiring the attendance of witnesses and their testimony, and the production of documents, papers, files, books and records in connection with any hearing or investigation. The court may compel obedience to its order by proceedings for contempt.

*For repeal of Act, see note preceding § 7401 of this chapter.*

**7426. Surrender of certificate**

*Paragraph effective July 1, 1984.*

§ 26. Upon the revocation or suspension of any certificate, the registrant shall forthwith surrender the certifi-

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*Department of Human Resources*

**HEALTH DIVISION**

Board of Examiners for Speech Pathology  
and Audiology

1400 S.W. 5th AVENUE, PORTLAND, OREGON 97201 PHONE

228-6479

November 15, 1982

TO: Oregon Licensed Audiologists

FROM: Duane Anderson, Executive Secretary, Board of Examiners  
for Speech Pathology and Audiology

SUBJECT: Law concerning use of the term "Audiologist"

On July 1, 1983 the Board mailed the attached memos to all Oregon registered hearing aid dealers. During their October 15, 1983 meeting the Board requested that we mail copies of this material to all licensed audiologists in Oregon. The Board plans to pursue legal action against any person in Oregon who uses the term "Audiologist" in any context and is not licensed as an audiologist under ORS 601.

attachment

AN EQUAL OPPORTUNITY EMPLOYER

Mailing Address: P.O. Box 231, Portland, Oregon 97207  
EMERGENCY PHONE (503) 229-5599

228-6479

July 1, 1983

TO: Oregon Registered Hearing Aid Dealers  
FROM: Board of Examiners for Speech Pathology and Audiology  
SUBJECT: Use of the Term "Audiologist" and Related Words

During the last few years the Board of Examiners for Speech Pathology and Audiology has made numerous attempts to discourage hearing aid dealers from using the term "audiologist" and related terms in their telephone directory and newspaper advertising. In addition, several hearing aid dealers are displaying their NHAS certificate which identifies them as a "Certified Hearing Aid Audiologist".

Recently we requested an advisory statement on this matter from the Consumer Protection Section of the Department of Justice. The attached memo from their office should resolve any misunderstandings which may currently exist. If you have any questions, please feel free to contact our office or the Consumer Protection Section of the Department of Justice.

attachment



## STATE OF OREGON

## INTEROFFICE MEMO

TO: Board of Examiners for Speech Pathology and Audiology DATE: June 15, 1983

FROM: Daryl Dodson Wilson  
Assistant Attorney General

SUBJECT: Hearing Aid Dealer's Use of the Term "Audiology" and Related Words

A review of ORS Chapter 681 and ORS Chapter 694 shows that a hearing aid dealer who falsely represents that the services of an audiologist are available, or who claims to be giving "audiological testing" when no licensed audiologist is performing the test, may be in violation of several statutes. The penalties may be cumulative.

1. Hearing aid dealers are generally governed by ORS Chapter 694.

ORS 694.015(5) anticipates that hearing aid dealers will be conducting some hearing tests in conjunction with the provision of hearing aids. These tests include evaluation or measurement of the powers or range of human hearing. In offering these tests, a dealer may not advertise that the services of either an "audiologist" or "clinical audiologist" is available for selection, fitting, adjustment, maintenance or repair of hearing aids, when no properly licensed audiologist is performing the service. A dealer may have his or her license suspended or revoked or may be put on probation for these false representations. ORS 694.136(8).

A problem may arise when a dealer offers "audiological" testing without having a licensed audiologist performing the test. Even though "audiological" and related terms may have trade or common meaning, these words should only be used in advertisements in Oregon in accordance with the definition in ORS 681.205 (see 2. below). It would seem that the Oregon statutory scheme anticipates that only licensed audiologists may conduct "audiological" tests.

ORS Chapter 694 also provides criminal sanctions for some misrepresentations. A false claim that an audiologist's services will be used, are used, or made available may be punishable by up to a \$500 fine and up to 90 days of imprisonment. ORS 694.911(1).

A hearing aid dealer should also be concerned that no false, misleading or deceptive name is used in his or her business. ORS 694.136(11). A dealer would also violate the

To: Board of Examiners for Speech Pathology and Audiology  
Page 2  
June 15, 1983

statutes by making a false, misleading or deceptive representation regarding any guarantee or services provided.  
ORS 694.136(2).

2. ORS Chapter 681 dealing with audiologists and speech pathologists may also be of concern to hearing aid dealers.

Both hearing aid dealers and audiologists measure the powers or range of human hearing. See ORS 694.015(5) and ORS 681.205(4). However, the focus and extent of the testing and evaluation are quite different. ORS Chapter 681 provides that only a licensed audiologist may represent that he or she is engaged in the practice of audiology.

Although many of the terms used in these statutes may have meanings in the hearing aid trade, the statutory definition takes precedence in Oregon. Thus, the terms "audiology" and "practice of audiology" carry a particular meaning, whether used by audiologists or by hearing aid dealers. See ORS 681.205(1) and (4). Any person holding him or herself out as a "hearing clinician", "hearing therapist" or "audiologist" or a similar title or description of service must be a licensed audiologist. ORS 681.250(2). Similar titles or descriptions of service might include "audiological testing" and "audiological service". Remember, the common meaning of these words must give way when the statute provides a definition.

It is a misdemeanor to falsely use any of these titles or descriptions of service. ORS 681.991. The District Attorney's office would prosecute the case. Class A misdemeanor carries a penalty of a maximum \$2,500 fine and a maximum one year in prison. See ORS 161.555(3) and ORS 161.615 and 161.635.

3. The Oregon Unlawful Trade Practices Act (UTPA)  
ORS 646.605 to 646.638 governs some activities of hearing aid dealers.

A variety of unconscionable tactics and unlawful trade practices are prescribed by the UTPA. A hearing aid dealer might be in conflict with the Unlawful Trade Practices Act if he or she said that "audiological testing services" were available when no licensed audiologist actually performed the services. The unlawful business practice in that case might include causing a likelihood of confusion or misunderstanding as to the affiliation, connection or association with another; or representing that services have quantities or qualities that they do not have or that a person has a status or qualification or connection that he does not have. See ORS 646.608(1)(c) and (e).

To: Board of Examiners for Speech Pathology and Audiology  
Page 3  
June 15, 1983

A hearing aid dealer who said that audiological testing was performed, when no licensed audiologist performed those tests, might be found in violation of the Unlawful Trade Practices Act for that false advertising, as well as being in violation of ORS Chapter 681 and ORS Chapter 694. The penalties for violation of the Unlawful Trade Practices Act include injunction, restitution for actual damages, possible punitive damages, attorneys fees and other relief granted by the court. The statute provides for suit by the Attorney General the District Attorney or by a private citizen. This is the area of concern to the Consumer Protection Division (Financial Fraud Unit) of the Department of Justice.

4. Other regulations are also pertinent to hearing aid dealers.

Oregon common law and statutes provide other remedies for a person who has been defrauded. Separate statutes cover home solicitations. See ORS 646.611 and 83.720. A dealer might want to take extra steps to check compliance with these laws before sales are made.

kp

You can call the Illinois Department of Public Health toll-free

**1-800-572-3270**  
**(TDD OR VOICE AVAILABLE)**



**IF...**

**YOU  
PURCHASE  
WISELY**

Division of Health Promotion and Screening  
Illinois Department of Public Health  
535 West Jefferson  
Springfield, Illinois 62761

Printed by Authority of the State of Illinois

6/85

A consumer protection service  
provided through the Hearing Aid  
Consumer Protection Program

**Illinois Department of Public Health**

# Remember these important facts:

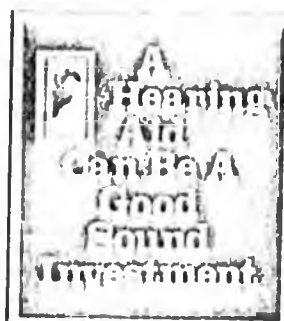
1. **MEDICAL CLEARANCE** from a licensed physician should be obtained before buying a hearing aid. This identifies medically treatable conditions which affect your hearing.
2. Obtain a **HEARING EVALUATION** from a certified dispenser or clinical audiologist before purchasing a hearing aid.
3. Be sure the hearing aid dispenser is **CERTIFIED** by the Illinois Department of Public Health.
4. Ask if a **TRIAL PERIOD OR RETURN PRIVILEGE** is offered. If so, make sure that this and the cost of this trial period are stated in the contract.
5. Ask if the hearing aid has a **MANUFACTURER'S WARRANTY** and/or **SERVICE CONTRACT**. Find out what services each provide, what costs are involved and the time period they cover.
6. Illinois Law requires a dispenser who sells hearing aids door-to-door or in a customer's home to give a **NOTICE OF CANCELLATION** to the buyer. The Notice explains the legal right of the buyer to cancel the purchase within three days of the sale.
7. Make sure that the **DELIVERY DATE** of the hearing aid is written in the contract.
8. If possible, do not pay the full price of the hearing aid in advance. Make a **DEPOSIT** and pay the balance when the hearing aid is delivered.
9. If the hearing aid is uncomfortable, causing problems or not working properly, **CONTACT YOUR DISPENSER** immediately.
10. Ask about the dispenser's **REPAIR POLICY**. Can repairs be done at the office or must hearing aids be mailed to the manufacturer? How long will these repairs take and are "loaner" aids available?
11. Keep all information received as

**RECORD OF PURCHASE**, such as receipts, warranties, etc., for future reference.

12. You may want to **BRING A FRIEND** along to assist you when you purchase a hearing aid.
13. A hearing aid is an important investment. Don't be afraid to **ASK QUESTIONS** or seek a second opinion.

There is a law to protect Illinois consumers from dishonest and incompetent hearing aid dispensing practices. The **ILLINOIS HEARING AID CONSUMER PROTECTION ACT**, administered by the Illinois Department of Public Health, requires that:

1. All dispensers must be **CERTIFIED** to dispense hearing aids, and
2. Should a consumer have an **INQUIRY** or **COMPLAINT** regarding a hearing aid and/or dispenser, the **ILLINOIS DEPARTMENT OF PUBLIC HEALTH** will investigate and offer assistance.



## Illinois Hearing Aid Consumer Protection

your hearing protection services provided through  
the Illinois Department of Public Health - IDPH

CALL TOLL FREE 1-800-572-3270

IF YOU HAVE ANY QUESTIONS ABOUT THE HEARING AID CONSUMER PROTECTION ACT, OR WOULD LIKE A COPY OF THIS ACT, PLEASE CONTACT THE VISION/HEARING CONSULTANT AT ONE OF THE OFFICES LISTED BELOW.

Region 1

Illinois Department of Public Health  
4302 N. Main Street  
Rockford, Illinois 61105  
815/987-7511

Region 2

Illinois Department of Public Health  
5415 University  
Peoria, Illinois 61614  
309/691-2200, ext. 312

Region 3

Illinois Department of Public Health  
4500 South Sixth Street Road  
Springfield, Illinois 62706  
217/786-6345

Region 4

Illinois Department of Public Health  
Cottonwood Road  
Edwardsville, Illinois 62025  
618/288-5756

Region 5

Illinois Department of Public Health  
2209 Main Street  
Marion, Illinois 62959  
618/997-4371

Region 6

Illinois Department of Public Health  
2125 South First Street  
Champaign, Illinois 61820  
217/333-6914

Region 7

Illinois Department of Public Health  
245 West Roosevelt Road  
Bldg. 5  
West Chicago, Illinois 60185  
312/293-6842

Region 8

Illinois Department of Public Health  
160 N. LaSalle, Room 1112  
Chicago, Illinois 60601  
312/793-3880



ILLINOIS DEPARTMENT OF PUBLIC HEALTH  
DIVISION OF HEALTH PROMOTION AND SCREENING  
535 WEST JEFFERSON STREET  
SPRINGFIELD, ILLINOIS 62761

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State of Illinois  
5/84

## A SYNOPSIS OF THE HEARING AID CONSUMER PROTECTION ACT

PUBLIC ACT 83-0928

EFFECTIVE JULY 1, 1984

For more information call  
1-800-572-3270  
(Voice or TDD)

Illinois Department of Public Health  
Division of Health Promotion and Screening  
Hearing Aid Consumer Program

### HEARING AID CONSUMER PROTECTION ACT

The Illinois "Hearing Aid Consumer Protection Act" was enacted into law by the 83rd General Assembly. The purpose of the Act is to protect the hearing impaired public from incompetent and dishonest dispensers of hearing aids who could endanger the health, safety and welfare of the people of this State.

### ILLINOIS DEPARTMENT OF PUBLIC HEALTH

The Illinois Department of Public Health is mandated to supervise the issuance of certificates to hearing aid dispensers, administer examinations to applicants for the hearing aid dispenser certificate, suspend or revoke certificates or take such other disciplinary action, if the provisions of the Act are violated, and to promulgate rules necessary to implement this Act, which becomes effective July 1, 1984.

Under the direction of the Division of Health Promotion and Screening, Vision and Hearing Section, the Department will initiate a four point action plan to implement Public Act 83-0928:

1. Health Promotion - Consumer Education
2. Continuing Education for Dispenser of Hearing Aids
3. Certification of Dispensers of Hearing Aids
4. Follow-up and Investigation of Complaints

### WHAT THE CONSUMER SHOULD KNOW ABOUT THE HEARING AID CONSUMER PROTECTION ACT

1. No person shall engage in the selling, practice of fitting, dispensing or servicing hearing aids, or display signs, advertise, or represent oneself as a person who practices the fitting and selling of hearing aids after January 1, 1985, unless such holds a current certificate issued by the Department as provided in this Act.
2. The certificate shall be conspicuously displayed in the place of business. A sign must be conspicuously displayed in the dispenser's business and a written statement must be given to each hearing aid purchaser indicating that complaints regarding hearing aids may be made to the Illinois Department of Public Health.
3. Every person fitted and sold a hearing aid shall be given, at no charge, the "User Instructional Brochure" supplied by the manufacturer.
4. The dispenser shall provide a receipt to each hearing aid purchaser with the seller's signature, phone number, the manufacturer's specifications, the make, model and serial number of the hearing aid furnished, the dispenser's certification number, and the full sales term clearly stated. The receipt and container for a used hearing aid shall be clearly marked as such.
5. A hearing aid dispenser shall not sell a hearing aid unless the prospective user presents to the dispenser a written statement signed by a licensed physician which states that the patient's hearing loss has been medically evaluated.

The medical waiver requirement may only be waived by the patient when the patient is 18 years or older. The dispenser must inform the user that the exercise of the waiver is not in the user's best health interest; and the dispenser cannot in any way encourage the buyer to waive medical evaluation.

Ear  
Nose  
Throat  
CLINIC

March 26, 1986

Representative Navarre  
Pouch V  
Juneau, AK 99811

RE: HB 430

Otolaryngologists  
Ronald E. Tinsley, M.D.  
Richard P. Raugust, M.D.  
Bruce G. Whipple, M.D.

Audiologist  
Phyllis Cashen Williams

Dear Representative:

HB 430 has recently been brought to my attention by several audiologists in the Fairbanks community. For the past ten years, I have practiced otolaryngology-head/neck surgery in Alaska and have seen numerous problems with the sale and fitting of hearing aids. Without exception, these problems have come from hearing aid dealers and never from audiologists. Some hearing aid dealers are quite reputable and seem to do a good job for the general public. However, there are an unscrupulous many who have fly-by-night operations and come to the community as door-to-door salesmen selling aids out of hotel rooms and then retreating back to the Lower 48 after robbing the public of many thousands of dollars.

I have seen patients who were sold hearing aids when they are totally deaf secondary to skull fracture with fracture of the inner ear or tumor of the inner ear which has destroyed the inner ear to the point that no hearing aid, no matter how powerful, would benefit the patient. I have also seen many patients with chronic, draining ears from active otitis media infection who have had their ear canals plugged with hearing aids which only aggravates the infectious process and further destroys their hearing. All of these patients should have had medical clearance before hearing aid fitting as many will never be a hearing aid candidate and could have had their hearing improved by medical treatment.

One of the greatest tragedies is that the patient is sold a hearing aid for well over \$1000 from a door-to-door salesman when the same type of aid could be purchased locally from a reputable audiologist for \$300 - 400.

In view of the abuse which I have seen, I am certainly in favor of a bill to license and regulate audiologists, hearing aid dealers, and the dispensing of hearing aids. After review of HB430, I agree with most of it except for a few glaring exceptions as listed below:

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Drawer 42  
Fairbanks, Alaska 99701  
(907) 456-7767

- (1) On page 15, #5 - I feel that providing a statement to the consumer somehow destroys the audiologist-client relationship. If the patient has a complaint about the hearing aid, he should first bring it to the audiologist and almost all problems can be solved. For instance, our audiologist has only had one hearing aid returned because of an unsuccessful fitting in four years. The key to successful fitting of a hearing aid is education of the patient, proper earmolds and if anything goes wrong with the aid, it can be fixed locally and taken care of by the audiologist or hearing aid dealer. Firing complaints off to a state agency because your earmold does not fit is ridiculous.
- (2) On page 18, paragraph B - displaying signs about where to make complaints about the product or services that you are selling plants the idea that maybe there will be a problem before any problems actually occur. In general, no one pays much attention to such signs anyway. I have diplomas and licenses all over my office wall and patients never even look at them. Having a sign on the wall is not going to make audiologists and hearing aid dealers more professional or more competent which is really the key to why this bill is necessary in the first place.
- (3) On page 19 concerning the cancellation option - our audiologist tells the patient that if for any reason after adjusting and wearing the hearing aid in the normal routine for a period of time that they are unable to tolerate the aid or it does not help, they are certainly free to return it. We do not want that to happen, of course, and thus give the patient a 3 - 4 day trial with a loaner hearing aid similar to the one that they will be purchasing. Usually after a few days, the patient can tell whether the aid will be helpful and whether they want to go ahead with purchase. This is the way that most reputable audiologists handle hearing aid sales. In the many years that we have been doing this, we have not had a single aid which was kept by the patient and not turned back in - and have only had one aid sold that was ever returned as unsatisfactory. 60 days may be too long a period of time for a person to have a hearing aid and then return it. The major problem that people have with hearing aids is not putting in new batteries, the aids falling off into the sink or toilet, the aids falling off and being stepped on, the dog chewing them up, etc. A lot of trauma can occur in 60 days which is not the fault of manufacturing but is the purchaser's negligence. That is like buying a new car and driving it from Fairbanks to California then driving it back and turning it in because you don't like the color or it doesn't fit your personality but there is nothing mechanically unsound about it. The cancellation contract is fine for the 60 day period if an audiologist or physician tells the patient they didn't need the aid or it was inappropriate. Otherwise, 15 days is reasonable to wear the instrument and then turn it in without too much damage to the goods.

My biggest problem with the cancellation option is that there are several phrases regarding the hearing aid dealer collecting the goods. I cannot believe that you feel the audiologist or hearing aid dealer must go to the patient's house and collect the aid. It should be the responsibility of the purchaser to return the goods to the dealer either in person or by mail with a letter stating why it is being returned.

- (4) On page 22, there is nothing in paragraph 8 stating how to handle a damaged hearing aid that has been returned. Is it your intent that if a person willingly breaks or damages the aid and then decides to return it, it is the dealers responsibility to go the place of residence, collect the broken aid, and give them their money back? Get serious!
- (5) On page 24, paragraph 10 - I feel this is a good point in that it will discourage the door-to-door salesmen from the Lower 48 as they are the biggest offenders in this area.

To reiterate, I am generally in favor of HB430 particularly with respect to controlling hearing aid dealers, but I do not wish the law to be at the expense of reputable audiologists. As far as I know, all of them are doing an excellent job. They do not deserve to be harassed in such a manner. They are already awash in a sea of paperwork and requiring more forms and paperwork would not benefit the client in the least but merely makes health care providers more angry, hostile, and disgusted at the State bureaucracy.

We hope that you will revise the bill to benefit the consumer and the health care provider.

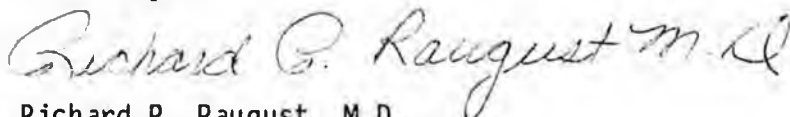
As you may or may not know, your current Health and Social Services budget for the Handicapped Children's Program is already broke. There is no money left to fix the ears and cleft palates of children in Alaska who do not have insurance until after the beginning of the new fiscal year. Creating new jobs in Juneau to watchdog audiologists and hearing aid dealers will just take more money away from children who need immediate health care.

REGULATE

DON'T

SUFFOCATE!

Sincerely,



Richard P. Raugust, M.D.  
Otolaryngology

RPR/co

Ear  
Nose  
Throat  
CLINIC

March 26, 1986

Mike Navarre  
Pouch V  
Juneau. AK 99811

RE: HB #430

Otolaryngologists

Ronald E. Tinsley, M.D.  
Richard P. Raugust, M.D.  
Bruce G. Whipple, M.D.

Audiologist

Phyllis Cashen Williams

Dear Mr. Navarre:

In reference to HB430 "An Act regulating audiologists, hearing aid dealers and the dispensing of hearing aids". I would like to offer the following information.

As an audiologist with a Master's degree in Audiology and a Certificate of Clinical Competence in Audiology from the American Speech & Language Hearing Association, I was born and raised in Fairbanks and have practiced audiology for the past 11 1/2 years in the private sector. During the past 3 1/2 years, my practice has also included the dispensing of hearing aids.

Generally, I am in support of HB430. During my years as an audiologist in Alaska, I have come into contact with several people who have purchased hearing aids from out of city or out of state hearing aid dealers who come to Fairbanks for 2 - 3 day periods to test hearing and take orders for hearing aids. Oftentimes the hearing aid is mailed to the person rather than being fit on the person which means that often the aid is not adjusted correctly for the person's hearing loss and little or no counseling is given on hearing aid care and use. Consumers often find themselves with a hearing aid that they cannot wear.

However, I do have some concerns with HB430 as it now reads:

- (1) On page 16, line 27, #5 under Section 8.55.050 "items to be provided by hearing aid dealers". I believe audiologists should be exempt as they are professionals trained in evaluation of hearing and selection of hearing aids. By handing out this written statement at the time of hearing aid sales, it somehow appears to negate the confidence that an audiologist wants to give their client - that they have been fit with the best hearing aid for their hearing loss. If audiologists were exempt, then on page 14, line 27, should be changed to read "comply with AS 08.55.050 #1 - 4". Another suggestion would be to re-word #5 above to read "If the consumer has a complaint about a hearing aid or a hearing aid dealer and has notified or attempted to notify the hearing aid dealer without resolution of the complaint, the hearing aid dealer shall give the consumer the mailing address and the location address of the department upon request of the consumer".

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Page 2

- (2) On page 17, line 29 should read "I had a medical evaluation by a licensed..." rather than "I had a hearing evaluation by a licensed...".
- (3) On page 18, line 2 "or a licensed audiologist" should be omitted.
- (4) On page 20, line 27 "will be returned within 10 business days following..." should be changed to "will be returned within 15 business days following...". In the 3 1/2 years that I have been dispensing hearing aids, we have refunded money for returned hearing aids within 30 days. This seems to have worked well and often the refund is made within less than 30 days, however, this gives the business department a chance to research the refund as often an insurance company is involved and refund for the aid not only goes to the client but also to the insurance company. As we often deal with third party payment in the sale of hearing aids, I believe a 15 day time period for refund is not an excessively long period of time.
- (5) On page 21, line 3, "if you cancel, you must make available to the..." should be changed to read "if you cancel, you must return to the..." I am really not comfortable with the wording throughout this page in reference to the consumer needing to "make available" the aid to the dealer which he has purchased and now wants refund for. It is the purchasers responsibility to return the aid to the dealer in as good a condition as received less normal wear and tear. It is not the hearing aid dealer or the audiologist's responsibility to retrieve the aid from the purchaser. Throughout the paragraph on page 21, it seems that the responsibility is not placed on the purchaser to return the aid to the dealer. A simple change in wording would make this more clear.
- (6) On page 21 line 9 through line 14 "if you make the goods available for the hearing aid dealer to collect after your cancellation and the hearing aid dealer does not collect from you within 20 days of your cancellation, you may retain or dispose of the goods without further obligation to the hearing aid dealer". This entire section should be omitted as it deviates from the intent of the consumers right to cancel. Cancellation of the transaction for purchase of a hearing aid is contingent upon their return of the hearing aid purchased. The responsibility for returning the hearing aid is that of the client or purchaser and is not the responsibility of the hearing aid dealer to collect the aid from the client.

To continue with line 14, "if you fail to make the goods available..." should be changed to "if you fail to return the goods to the hearing aid dealer after your cancellation...". Again, the reason for suggesting this change is that it puts the responsibility on the purchaser to return the aid in order to get refund as requested. I believe it would be most unusual for a person to cancel a transaction in which he paid for a hearing aid and expect a refund and not expect to have to return the aid back to the dealer.

Page 3

- (7) On page 21, line 23, I would like to see changed to "written notice together with the hearing aid(s) being returned for refund to (name of hearing aid dealer, at....) which insures that the hearing aid dealer will receive the goods for which he is required to make refund.
- (8) On page 22, line 28 and 29 and page 23, line 1 and 2, should be omitted because again it puts the responsibility on the dealer to collect the aid rather than on the consumer to return the aid to the dealer. Written instructions on who and where to return the aid if the consumer wants to cancel the sale are given to the consumer at the time of purchase as stated in the Notice of Right to Cancel on page 20 - 21. The consumer who wants to return a hearing aid for refund should follow this procedure unless as quoted on page 21, line 6 "the dealer notifies you to keep the goods or hold them until the dealer collects them".
- (9) On page 22, line 10 "dealer shall and within 10 days of receipt of the notice of cancellation..." should be changed to read "dealer shall and within 15 working days of notice of cancellation..." for the reasons as above.

Thank you for your consideration of my suggested changes. I believe that these changes would mean a fair and just bill for all involved in the sale and purchase of hearing aids.

Sincerely,

*Phyllis Cashen Williams, M.A.*

Phyllis Cashen Williams, M.A.  
Audiologist - CCC-A

PCW/co

Alaska State Legislature

REPRESENTATIVE  
MIKE NAVARRE

DISTRICT 5A

CHAIR, LABOR & COMMERCE  
VICE-CHAIR, STATE AFFAIRS



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WHILE IN SESSION  
POUCH V  
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NAVARRE  
COPY

House of Representatives

MEMORANDUM

TO: House Health, Education and Social Services Committee  
Rep. Max Gruenberg, Co-Chair  
Rep. Niilo Koponen, Co-Chair  
Rep. Robin Taylor, Vice Chair  
Rep. Alyce Hanley  
Rep. Katie Hurley  
Rep. Fritz Pettyjohn  
Rep. Dave Thompson

FROM: Rep. Mike Navarre

March 18, 1986

Subject: CS for HB 430 (L&C), sponsor offered amendments

Attached is a list of proposed amendments for the CS for House Bill 430 (L & C).

The primary amendment deals with the "prior hearing evaluation" language in the bill. After this bill passed from the Labor & Commerce Committee, it came to my attention that Section 08.55.060 (page 17) is in conflict with Federal Regulations requiring a prior medical evaluation. The current language in the bill broadens the prior evaluation requirement to allow a prior hearing evaluation by a licensed physician or audiologist. In an effort to head off any potential conflict, I feel the language should be tightened up to conform with the Federal regulations (pertinent pages of the Federal Register attached).

The other amendments are mainly housekeeping measures.

Thanks for your assistance in this matter.

Offered by Representative Mike Navarre

Proposed Amendments to CS FOR HOUSE BILL 430 (L&C)

Page 08, Line 18, delete "for the audiologist who works for the audiologist"

Page 17:

Line 6, Section title: delete "HEARING", insert "MEDICAL" between "PRIOR" and "EVALUATION".

Line 7, delete "or an audiologist".

Lines 9 and 10, delete "or an audiologist".

Line 10, delete "or the audiologist".

Line 13, delete "or the audiologist".

Line 25, delete "is not a physician or an audiologist".

Line 29, delete "hearing", insert "medical" between "a" and "evaluation".

Page 18:

Lines 2 & 3, delete "or a licensed audiologist"

Line 8, delete "or the audiologist"

Line 9, insert "waiver" before "statement"

Page 22:

Line 29, insert "or provide written mailing instructions (by certified mail) for the hearing aid to the consumer" between "consumer" and "within".

Page 23:

Revise Sec. 08.55.120 as follows:

TESTING OF HEARING. (a) A hearing aid dealer may take threshold measurements to determine the need for hearing aid use [DEGREE OF HEARING IMPAIRMENT OF A PERSON], but may not perform other diagnostic procedures [TEST OR USE THE THRESHOLD MEASUREMENTS] to determine the cause of a hearing impairment or charge a fee for any hearing measurement [TAKING THE THRESHOLD MEASUREMENTS TEST].

Line 15, insert "printed" between "every" and "advertisement".

Sec. 521, 701, 52 Stat. 1055-1056 as amended, 20 Stat. 574 (21 U.S.C. 360k, 371)  
Dated: October 5, 1980  
Jesse E. Goyan,  
Commissioner of Food and Drugs.  
HLLING CODE #110-03-4

21 CFR Part 603  
(Docket No. 79P-0222)

Medical Devices; Applications for Exemption From Federal Preemption of State and Local Hearing Aid Requirements

AGENCY: Food and Drug Administration.  
ACTION: Final rule.

SUMMARY: Massachusetts and Rhode Island have applied to the Food and Drug Administration for exemptions from Federal preemption of their State hearing aid requirements. In this rule the agency is responding to these applications.

EFFECTIVE DATE: November 10, 1980.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Bureau of Medical Devices (H7K-70), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7174.

SUPPLEMENTARY INFORMATION: In the Federal Register of April 13, 1979 (44 FR 22119), FDA published a proposed regulation responding to applications from Massachusetts and Rhode Island for exemption from Federal preemption for certain hearing aid device requirements. Interested persons were given until June 12, 1979 to submit written comments on the proposal. A public hearing on the proposal was held on October 18, 1979, and interested persons were given until November 15, 1979, to submit written comments on matters raised at the hearing.

Elsewhere in this issue of the Federal Register the agency is publishing a final rule responding to applications from 18 other States and the District of Columbia for exemption from preemption for their hearing aid requirements. Some of the issues raised in that proceeding are similar to the issues raised in the comments received on this rule. Because the issues are discussed in greater detail in that regulation, the agency refers interested persons to the preamble to that final rule.

1. One comment objected that the hearing held on the proposed regulation did not comply with the requirements for "informal hearing" specified in section 201(y) of the act (21 U.S.C. 321(y)), especially section 201(y)(1)

which requires that the presiding officer be someone who has not participated in any action which is the subject of the hearing and who is not directly responsible to anyone who has participated in any such action. The comment further objected that the hearing officer did not conduct the hearing in an impartial manner.

Section 201(y) of the act, which sets forth the definition of "informal hearing," does not apply to a hearing conducted under section 521 of the act (21 U.S.C. 360k). An "informal hearing" is required only where that term is specifically used in the act. Section 521 of the act provides for the opportunity for an "oral hearing", rather than an "informal hearing." The agency believes that the record shows that the hearing was conducted fairly and that all parties had an adequate opportunity to present their views.

2. Several comments objected to FDA's proposal to deny exemption from preemption for the Massachusetts provision permitting waiver of the requirement of medical evaluation only if the purchaser's religious beliefs preclude consultation with a physician. Comments also objected to the agency's proposal to deny exemption from preemption for the Rhode Island law, which does not permit a waiver of the requirement of medical evaluation under any circumstances. The FDA regulation (21 CFR 801.420) allows an informed adult 18 years of age or older to waive medical evaluation. Some of the comments argued that medical evaluation is absolutely necessary and, therefore, that no waiver should be permitted. Other comments suggested that only persons with religious objections should be permitted to waive the medical evaluation. Opposing comments agreed with FDA that informed adults should have the freedom to waive medical evaluation. Others suggested that waiver is appropriate in at least certain situations, such as where a purchaser objects to the evaluation for religious reasons or when purchasing replacement hearing aids.

The agency believes that examination by a physician is necessary to ensure that the organic causes of hearing loss are diagnosed and treated properly. The agency, therefore, believes, however, that any informed adult who objects to medical evaluation for religious or personal reasons should be permitted to waive the requirement.

3. Other comments opposing FDA's proposal to deny exemption from preemption for these waiver provisions argued that hearing aid dealers are abusing the FDA waiver provision. Some of these comments suggested that

prospective hearing aid purchasers waive the medical evaluation requirement in 80 to 85 percent of the sales of hearing aids. The Massachusetts Hearing Aid Society surveyed its members and found that 58 percent of the sales of those responding were made to persons who had obtained a prior medical evaluation. The Rhode Island Hearing Aid Society also surveyed its members and found that 62 percent of the sales of those responding were made to persons who had obtained a prior medical evaluation.

FDA has not been presented with any convincing evidence that the waiver provision is being widely abused by hearing aid dealers. The agency conducted a survey of State officials to determine whether they were experiencing any problems with compliance with the FDA hearing aid regulation. Of the 39 States that responded to the survey, only Massachusetts stated that it had encountered major problems with regard to compliance. However, Massachusetts did not document its assertion. Therefore, FDA is denying exemption from preemption for the Massachusetts and Rhode Island waiver provisions.

4. Several comments objected to FDA's proposal to deny exemption from preemption for the Massachusetts provision requiring a hearing test evaluation before the sale of a hearing aid. The Massachusetts law requires that the hearing test be conducted by an otolaryngologist, a physician, or an audiologist. Some comments argued that hearing aid dealers are not qualified to perform the necessary testing and that evaluation by a physician or an audiologist is necessary. Opposing comments argued that hearing aid dealers are qualified to perform the necessary testing. One comment noted that the requirement of medical evaluation is sufficient to ensure that audiometric testing is done as part of the diagnostic process.

There is no evidence that only physicians or audiologists are competent to measure hearing loss. Therefore, the agency does not believe that it is appropriate to require a hearing test evaluation by a physician or an audiologist before every sale of a hearing aid. Problems regarding the competency of hearing aid dealers to measure hearing loss will be adequately addressed by strong State and local licensing provisions.

5. Several comments objecting to FDA's proposal to deny exemption from preemption for the Massachusetts provision requiring that a hearing test evaluation be conducted by an audiologist or a physician argued that

hearing aid dealers are primarily interested in selling hearing aids and, therefore, cannot be expected to perform unbiased testing. Opposing comments disputed the implication that many hearing aid dealers sell hearing aids when the testing shows that an aid is not required. Several comments also noted that some physicians and audiologists now sell hearing aids and, if Massachusetts were permitted to require hearing test evaluation, probably more would sell them.

Although the agency is aware that there are some abuses in the hearing aid industry, it has not been shown that these abuses are so widespread as to justify requiring a hearing test evaluation by a physician or an audiologist before every sale of a hearing aid. The agency believes that the Federal requirements along with stringent State and local licensing laws will adequately address abuses in the hearing aid industry.

6. One comment suggested that FDA should grant Massachusetts an exemption from preemption for its hearing test evaluation requirement as it applies to children under the age of 18. This comment said that granting such an exemption would be consistent with the agency's decisions concerning similar provisions of other State statutes.

FDA agrees with this comment. In the final rule responding to applications from 18 other States and the District of Columbia, published elsewhere in this issue of the Federal Register, the agency is exempting from preemption requirements of audiological evaluation for children under the age of 18.

Audiologists are specially qualified to assist in the language development and social and educational growth of a child with a hearing loss. Consequently, mandatory audiological evaluation of a minor will serve an important public health purpose. Therefore, the final regulation has been revised to exempt from preemption the Massachusetts hearing test evaluation provision to the extent that it applies to children under the age of 18.

7. FDA is granting an exemption from preemption for Chapter 93, Section 74 of the Massachusetts General Laws, which requires the disclosure of certain information to hearing aid purchasers, on the condition that in enforcing this provision, Massachusetts apply the definition of "used hearing aid" contained in the FDA regulation. There were no comments on this provision.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 521, 701, 52 Stat. 1055-1056 as amended, 90 Stat. 574 (21 U.S.C. 360, 371)) and under authority delegated to the Commissioner

of Food and Drugs (21 CFR 5.1), Part 808 is amended in Subpart C by adding new §§ 808.71 and 808.89 to read as follows:

§ 808.71 Massachusetts.

(a) The following Massachusetts medical device requirements are enforceable notwithstanding section 521 of the act because the Food and Drug Administration has exempted them from preemption under section 521(b) of the act:

(1) Massachusetts General Laws, Chapter 93, Section 72, to the extent that it requires a hearing test evaluation for a child under the age of 18.

(2) Massachusetts General Laws, Chapter 93, Section 74, except as provided in paragraph (6) of the Section, on the condition that, in enforcing this requirement, Massachusetts apply the definition of "used hearing aid" in § 801.420(a)(6) of this chapter.

(b) The following Massachusetts medical device requirements are preempted by section 521(a) of the act, and the Food and Drug Administration has denied them exemptions from preemption under section 521(b) of the act:

(1) Massachusetts General Laws, Chapter 93, Section 72, except as provided in paragraph (a) of this section.

(2) Massachusetts General Laws, Chapter 93, Section 74, to the extent that it requires that the sales receipt contain a statement that State law requires a medical examination and a hearing test evaluation before the sale of a hearing aid.

§ 808.89 Rhode Island.

The following Rhode Island medical device requirements are preempted by section 521(a) of the act, and the Food and Drug Administration has denied them an exemption from preemption under section 521(b) of the act: Rhode Island General Laws, Section 5-49-2.1, and Section 2.2, to the extent that Section 2.2 requires hearing aid dispensers to keep copies of the certificates of need.

*Effective date.* This regulation is effective November 10, 1980.

(Secs. 521, 701, 52 Stat. 1055-1056 as amended, 90 Stat. 574 (21 U.S.C. 360, 371))

Dated: October 5, 1980.

Jer E. Goyar,

Commissioner of Food and Drugs.

FD Docket 80-3179 Filed 10-9-80 2:43 am

REGULING CODE 4110-13-94

21 CFR Part 208

[Docket No. 77N-0533]

Exemption From Preemption of State and Local Hearing Aid Requirements; Applications for Exemption

AGENCY: Food and Drug Administration.  
ACTION: Final rule.

**SUMMARY:** Various States have applied to the Food and Drug Administration for exemptions from Federal preemption of their State hearing aid requirements. In this rule the agency grants exemptions for some State hearing aid requirements and denies exemptions for others.

**EFFECTIVE DATE:** November 10, 1980.

**FOR FURTHER INFORMATION CONTACT:** Joseph M. Sheehan, Bureau of Medical Devices (HFK-70), Food and Drug Administration, 5757 Georgia Ave., Silver Spring, MD 20910, 301-427-7114.

**SUPPLEMENTARY INFORMATION:** The proposal upon which this final regulation is based was published in the Federal Register of July 28, 1978 (43 FR 33160). Interested persons were initially given until September 25, 1978 to comment on the proposal. In the Federal Register of October 20, 1978 (43 FR 49015), the comment period was extended to December 19, 1978. In the Federal Register of October 23, 1978 (43 FR 49014), the agency also published a proposed regulation addressing a New Jersey requirement that it had not addressed in the July 28 proposal. Interested persons were given until December 19, 1978 to comment on this proposal. FDA held a public hearing on these proposed regulations on October 31 and November 1, 1978.

A proposed regulation responding to applications from Massachusetts and Rhode Island for exemption from preemption for their State hearing aid requirements was published in the Federal Register of April 13, 1979 (44 FR 22113). Interested persons were given until June 12, 1979 to comment on the proposed regulation. This final rule does not include the agency's response to the applications from these two States which is set forth in a final rule published elsewhere in this issue of the Federal Register.

Although FDA is denying exemption from preemption for many State requirements, it encourages the States remain active in regulating the hearing aid industry. FDA particularly encourages the States to adopt strict licensing laws to establish and maintain minimum competency requirements for persons who test for hearing loss and select and fit hearing aids. FDA also encourages State and local government

to educate consumers about the value of medical evaluation prior to the purchase of a hearing aid and to furnish them with the information they need for proper hearing health care. States may assist in enforcing the FDA hearing aid regulations by adopting requirements identical to the FDA requirements.

In addition to the testimony at the public hearing, the agency received more than 300 comments on the proposed regulation. Most of these comments addressed the issue of mandatory audiological evaluation. Many comments also addressed waiver of medical evaluation, disclosure requirements, and the California provision restricting the advertising of hearing aids. The following is a summary of the comments and the agency's response to them.

#### The FTC Rule

1. The Federal Trade Commission (FTC) also has been studying the hearing aid health care delivery system to determine what steps should be taken to protect consumers from unfair or deceptive acts or practices in the sale of hearing aids. In the Federal Register of June 24, 1975 (40 FR 26646), the FTC published an "initial notice" of a proposed trade regulation rule for the hearing aid industry. Public hearings on the proposed rule were held in various cities from April to August of 1976. The presiding officer at these hearings reported his findings and conclusions on August 1, 1977. The staff then analyzed the record and made its report and recommendation to the FTC on September 25, 1978. Interested persons were given 60 days to comment on the staff report. The rule is now awaiting final action by the FTC.

The most important provision of the proposed rule is a requirement that the purchaser of a hearing aid be given the right to cancel the purchase for any reason at any time within 30 days of delivery, and receive a refund of most of the purchase price (in effect, a mandatory trial rental period). Other important features of the rule are that it would prohibit certain misleading claims and sales practices with respect to hearing aids and would require the hearing aid dealer to obtain prior express written consent to a sales visit in the buyer's home or office.

One comment on the FDA proposal said the FTC record is replete with evidence that hearing aid dealers receive little training and so are often incompetent to test hearing and to select and fit hearing aids. The comment also said the FTC record shows that hearing aid dealers do not counsel hearing-impaired persons adequately in

adapting to a hearing aid and that they do not repair hearing aids well. Finally, the comment said the FTC record shows that hearing aid dealers abuse home visits. The comment recommended that independent audiological evaluation should be required to remedy these abuses.

The FTC record does indeed contain evidence of many abuses in the hearing aid industry. It should be noted, however, that most of the evidence in the FTC record was gathered before the FDA regulation became effective on August 25, 1977. FDA believes that its regulation has already reduced some abuses in the industry and that adoption of the FTC rule would reduce these abuses even further. FDA also believes that stringent State and local licensing laws will ensure that hearing aid dealers are competent to test hearing and to select and fit hearing aids. The agency believes that the Federal requirements, along with strong State and local licensing laws, will adequately address the abuses in the hearing aid industry described in the FTC staff report.

#### The Legality and Constitutionality of the Proposed Rule

2. One person combined comments on the proposal with a petition to amend the FDA hearing aid regulation.

FDA will respond to the petition separately in a letter to the petitioner and will place a copy of the response on file with the Hearing Clerk, Food and Drug Administration.

3. One comment argued that the regulation is illegal and unconstitutional in several respects. First, the comment argued that the FDA regulation does not preempt State requirements for audiological evaluation because the constitutional requirements for preemption set forth in *Hines v. Davidowitz* (312 U.S. 52 (1941)) are not satisfied—specifically, that a State requirement is preempted only if it obstructs the "accomplishment and execution of the full purposes and objectives of an act of Congress." The comment reasoned that the requirement of audiological evaluation before the sale of a hearing aid does not relate to the safety or effectiveness of hearing aids and, consequently, does not interfere with the Federal regulation.

In section 521 of the act (21 U.S.C. 360k) Congress expressed its purposes and objectives with respect to the preemption of State and local medical device requirements. That section reflects Congress' intent that the Food, Drug, and Cosmetic Act preempt any State or local requirement applicable to a medical device that is different from or in addition to a requirement for the

device under the act. The State requirement of audiological evaluation relates to the safety or effectiveness of hearing aids because it is intended to ensure that the purchaser is fitted properly with a hearing aid that will benefit his or her hearing ability. This requirement is in addition to the Federal requirements applicable to hearing aids and would interfere with the execution and accomplishment of the objectives of FDA's hearing aid regulation. Therefore, the State requirement of audiological evaluation is preempted in accordance with both *Hines v. Davidowitz* and section 521 of the act.

4. The comment further argued that the Tenth amendment, which reserves to the States those powers not specifically granted to the Federal government, limits the power of Congress to regulate interstate commerce in areas traditionally regulated by the States, such as occupational licensing and consumer protection. The comment stated that audiological evaluation does not involve interstate commerce. The comment also objected that FDA is requiring the States to enforce the Federal regulatory scheme by changing their State laws to prohibit audiological evaluations, contrary to the holdings in *Brown v. Environmental Protection Agency*, 521 F.2d 827 (9th Cir. 1975) and *District of Columbia v. Train*, 521 F.2d 97 (D.C. Cir. 1975).

Congress enacted the Medical Device Amendments of 1976 (Pub. L. 94-295) pursuant to its authority to regulate interstate commerce under Article 1, Section 8 of the United States Constitution. The purpose of the amendments is to ensure that medical devices are safe and effective. When Congress determines that it is necessary to regulate a particular area of interstate commerce, it may also regulate any incidental aspects of that area that it believes may affect interstate commerce. *Heart of Atlanta Motel v. United States*, 379 U.S. 241 (1964); *Katzenbach v. McClung*, 379 U.S. 294 (1976); *United States v. Dary*, 312 U.S. 100 (1941). In enacting section 520(e) of the act, Congress determined that the safety and effectiveness of certain medical devices may be ensured only by restricting their sale, distribution, or use. Section 520(e) of the act, therefore, is a valid exercise of congressional authority under the commerce clause. In restricting the sale of hearing aids, FDA acted in accordance with the authority granted it under section 520(e). Therefore, neither FDA's restrictions on the labeling and conditions for sale of hearing aids nor its decision to deny exemptions from preemption for State

requirements of amendatory audiological evaluation is in violation of the Tenth amendment.

FDA's action is not contrary to the holdings in *Brown v. EPA* and *District of Columbia v. Train*. FDA is not requiring the States to enforce a Federal regulatory scheme, nor is it requiring them to prohibit audiological evaluation. The effect of FDA's denying an exemption from preemption for the requirement of audiological evaluation is to make such evaluations optional for the patient. By denying exemption for this requirement, the agency is recognizing Congress' intent that FDA regulations applicable to devices, such as hearing aids, preempt State and local requirements that are different from or in addition to the FDA requirements.

5. The comment also noted that under section 520(e) of the act, FDA may restrict the use of a device to persons with specific training, skill, education, or experience only if it determines that such a restriction is necessary to ensure the safe and effective use of the device. The comment argued that FDA has made no such finding with respect to the use of hearing aids by audiologists.

FDA is not excluding audiologists from the use of hearing aids. Because the FDA hearing aid regulation preempts State laws requiring audiological evaluation, the States may not require, as a condition to the purchase of a hearing aid, that the prospective purchaser receive an audiological evaluation. However, audiologists may continue to conduct hearing tests.

6. The comment also argued that, even if Congress did intend to preempt State laws requiring audiological evaluation, the procedures in Part 808 (21 CFR Part 808), pursuant to which FDA has considered the applications that are the subject of this rule, are unconstitutional and unlawful because the criteria for determining whether to grant an exemption are not in accord with the constitutional standard for preemption. The comment stated that the correct standard for the agency to apply is first to determine whether there is a congressional intent to occupy the field, and then to determine whether the State policy obstructs the full purpose and objectives of the act or whether Federal and State policies seek the same objectives and can coexist. The comment also stated that in denying an exemption FDA must show that a conflict between Federal and State regulation would necessarily result if the exemption were granted. Finally, the comment stated that FDA has no authority to consider factors such as cost and availability of services in

determining whether to grant an exemption from preemption.

The comment misconceives the law regarding Federal preemption. There are two types of Federal preemption: Express and implied. The standard described in the comment is the test of implied Federal preemption, the test applicable where Congress has not exercised its power under the Commerce clause to expressly declare Federal law paramount to State law. See *Jones v. Rath Packing Co.*, 430 U.S. 519 (1977); *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132 (1963); *Hines v. Davidowitz*, 312 U.S. 52, 55 (1940). In section 521(a) of the act, however, Congress has expressly declared that the Federal Food, Drug, and Cosmetic Act preempts any State or local requirement with respect to the safety or effectiveness of a medical device that is different from or in addition to a requirement under the act applicable to the device. The test of implied Federal preemption therefore, does not apply. Adoption of the standard advanced in the comment would render section 521 of the act meaningless because as argued in the comment the Federal law would preempt only State requirements that directly conflict with the Federal law. Yet, in section 521 of the act Congress established a specific standard of preemption. Under Section 521(a) of the act, preemption is not restricted to State requirements that directly conflict with Federal law, but rather extends to requirements that are different from, or in addition to, any requirement applicable to the device under the act.

The comment's contention that, in denying an exemption, FDA must show that a conflict between Federal and State regulation would necessarily result if an exemption were granted confuses the test of preemption with the standard FDA must apply in deciding whether to exempt State and local requirements from preemption. As stated above, section 521(a) of the act specifies the type of State or local requirement that is preempted. In section 521(b) of the act, Congress authorized FDA to exempt a State or local requirement from Federal preemption if it is more stringent than the Federal requirement or if it is required by compelling local conditions and compliance with the requirement would not cause the device to be in violation of the act. Thus, FDA is not required to show that a conflict between Federal and State law would necessarily result if a State requirement were exempted from preemption.

The authority granted FDA in section 521(b) of the act to exempt State or local

requirements from preemption is discretionary. Congress did not specify the criteria that FDA must employ in exercising that discretion. In light of the purpose of the act and the Medical Device Amendments, however, FDA believes that in deciding whether to exempt a State requirement from preemption it is appropriate to consider the effect that granting the exemption would have on the public health. The cost of medical devices and the availability of medical services are relevant factors in assessing the effect that an exemption would have on the public health. Therefore, FDA will consider these factors in determining whether to exempt a particular State requirement from preemption.

7. The comment also stated that proposed § 808.1(d)(5) (21 CFR 808.1(d)(5)), which provides that section 521(a) of the act does not preempt criteria for payment of State or local obligations under Medicaid and similar health care programs, is unlawful because section 521(a) of the act preempts all State or local requirements relating to medical devices.

Under section 521(a) of the act, the Food, Drug, and Cosmetic Act preempts only State or local requirements that relate to the safety or effectiveness of medical devices. In order for a State provision to be a requirement with respect to a device within the meaning of section 521 of the act—and thereby a candidate for preemption—it must relate to the device itself. Rules or requirements established by Federal, State, or local agencies to control the expenditure of public funds for purchasing hearing aids and hearing health care services for the hearing impaired, i.e., third-party payment programs, typically establish standards for the screening and diagnosis of individuals who will receive hearing aids through publicly funded programs. These requirements are designed to ensure the proper use of public funds. Rules and requirements for the expenditure of public funds for hearing aids are payment criteria established by the payer or purchaser and are not "requirements with respect to a device" within the meaning of section 521(a) of the act. Consequently, these requirements are not preempted under section 521(a). It should be noted, however, that regardless of the criteria for payment, the hearing aid dispenser is required to comply with the FDA regulation.

8. The same comment also argued that the proposal to exempt from preemption State laws requiring that a hearing aid purchaser be examined by an

Otolaryngologist violated section 520(e) of the act. Section 520(e)(1) of the act provides that no restriction placed on a device under section 520(e)(1)(B) may exclude a person from using a device solely because the person does not have the training or experience to be eligible for certification by a certifying board recognized by the American Board of Medical Specialties or has not been certified by such a board.

Section 520(e) of the act limits the restrictions that FDA may place on the sale, distribution, or use of a device. That section does not limit FDA's authority to exempt State or local requirements from preemption, nor does it provide that FDA may exempt from preemption only requirements that it has the authority to impose. In any event, although FDA believes that it has the authority to exempt from preemption the requirement of examination by an otolaryngologist, it is denying exemption for this requirement because it may be a barrier to the receipt of a hearing aid in areas where otolaryngologists are not readily available.

9. Finally, the same comment objected that the hearing held on the proposed regulation did not comply with the requirements of an "informal hearing" specified in section 201(y) of the act (21 U.S.C. 321(y)), especially section 201(y)(5), which requires that the presiding officer prepare a written report of the hearing to which he or she shall attach all written material presented at the hearing.

An "informal hearing," as defined in section 201(y) of the act, is required only where the term "informal hearing" is specifically used in the act. For example, an "informal hearing" is required under sections 505(g), 515, and 516. An informal hearing is often referred to as a regulatory hearing and is governed by Part 16 of the agency's administrative regulations (21 CFR Part 16). Section 521 of the act provides for the opportunity for an oral hearing, rather than an "informal hearing," on a proposed regulation on an application for exemption from preemption. The public hearing required by section 521 of the act is sometimes referred to as a legislative hearing and is governed by Part 15 (21 CFR Part 15) of the agency's administrative regulations. Indeed, 21 CFR 15.1(b) expressly states that Part 15 governs any hearing relating to exemptions from preemption of requirements for device.

#### Audiological Evaluation

Almost all the comments on the proposed regulation addressed FDA's proposal to deny exemption from preemption for State laws requiring

audiological evaluation before the sale of a hearing aid to an adult. The comments focused on the value, cost, and availability of audiological evaluation.

10. Many comments in favor of exempting from preemption State laws requiring mandatory audiological evaluation objected to FDA's conclusion that audiological evaluation would not provide conclusive assurance that the patient would benefit from amplification. Some argued that FDA should not require that such conclusive assurance be shown. Many comments stated that there is widespread misevaluation of hearing loss by hearing aid dealers. The comments also argued that audiologists are better qualified than are hearing aid dealers to test hearing and that, because audiologists do not sell hearing aids, their evaluations are unbiased and, hence, more reliable.

Comments supporting FDA's proposal to deny exemption to these requirements stated that mandatory audiological evaluation would be superfluous because only physicians can perform the necessary medical tests and hearing aid dealers can perform the audiometric tests. These comments also disputed the contention that there is widespread misevaluation of hearing loss by hearing aid dealers. Several comments pointed out that not all audiologists are unbiased testers because some audiologists sell hearing aids and, if audiological evaluation were mandatory, probably more audiologists would begin selling them.

After reviewing the conflicting information in the public record regarding the predictive value of audiological testing in determining whether a patient would benefit from a hearing aid, FDA has concluded that audiological evaluation is not necessary to provide reasonable assurance of the safety or effectiveness of hearing aids. There is no evidence that audiological evaluation reduces or eliminates any risk to health presented by a hearing aid. The primary risk to health presented by hearing aids is the possibility that an unnecessary or only partially effective hearing aid will be substituted for necessary medical or surgical treatment, thus depriving the hearing-impaired patient of the benefit of appropriate diagnosis and care and resulting in a detriment to health. Medical evaluation by a licensed physician will ensure that all medically treatable conditions are accurately identified and properly treated before a hearing aid is bought. Potential problems involving misevaluation of

hearing loss or misfitting of hearing aids will be adequately addressed by strong State and local licensing laws for hearing aid dispensers and by the trial rental period required by the draft final FTC regulation. Moreover, there is no evidence that only audiologists are competent to measure hearing loss and to fit hearing aids. Finally, FDA did not require that conclusive evidence be shown that the patient would benefit from amplification. Rather, the agency concluded that the requirement of mandatory audiological evaluation would increase the cost of obtaining a hearing aid without providing any conclusive assurance that the patient would benefit from amplification.

11. Many comments challenged FDA's conclusion that mandatory audiological evaluation would increase the cost of a hearing aid. These comments reasoned that if an audiological evaluation were done, the hearing aid dealer would not have to perform further testing. Other comments noted the low cost of hearing aids in certain public dispensing programs that require audiological evaluation, such as the Veteran's Administration. Many comments argued that mandatory audiological evaluation would result in a net savings to the consumer because the better testing provided by audiologists would result in fewer misevaluations and, therefore, fewer sales of hearing aids to persons who could not benefit from them.

Many comments supported FDA's proposal to deny exemption from preemption for State laws requiring mandatory audiological evaluation. Many hearing aid dealers stated that they do not reduce the cost of a hearing aid by the cost of an audiological evaluation if such an evaluation has already been made because they cannot rely on testing done by an audiologist with whom they are not familiar. Consequently, hearing aid dealers frequently perform hearing tests even after an audiological evaluation has been made. Many comments also disagreed with the contention that mandatory audiological evaluation would result in fewer misevaluations of hearing loss and therefore a net savings to the consumer.

The evidence whether mandatory audiological evaluation would increase the cost of a hearing aid is conflicting and inconclusive. Some hearing aid dealers said they would reduce the cost of a hearing aid if the prospective purchaser had an audiological evaluation; others said they would not. Many of the comments that purported to show that audiological evaluation would reduce the cost of a hearing aid actually

described governmental or clinical programs where any savings were attributable to the fact that the program was nonprofit and not to the fact that an audiological evaluation had been made. Thus, it appears that mandatory audiological evaluation would result in an increase in cost in some cases and a decrease (or at least no increase) in cost in other cases. It is not clear what the predominant effect of such a requirement would be. FDA believes that the amount of unnecessary costs that may be incurred as a result of misvaluation of misfitting would be reduced more efficiently by stricter State licensing laws and a trial rental period as required in the draft final FTC regulation than by mandatory audiological evaluation.

12. Many comments agreed with FDA's conclusion that audiologists are not readily available in certain areas of the country. Many comments noted that while audiologists may be available in urban areas they are scarce in rural areas. Some comments pointed out that few audiologists are engaged in private practice and, therefore, few are available to conduct hearing tests for the general public.

Many comments disputed FDA's conclusion that audiologists are scarce in certain areas of the country. Comments from various States said that audiologists are widely available in their jurisdictions. Many of these comments cited statistics or supported their claims in other ways.

There is conflicting evidence with respect to the availability of audiologists. Although audiologists may be readily available in and around large cities, it appears from the comments that they are scarce in most rural areas. Many elderly people could not easily travel 25 or 50 miles to visit an audiologist. Mandatory audiological evaluation, therefore, would sometimes prohibit a patient who could be helped by a hearing aid from obtaining one.

After considering all the factors discussed above, FDA has decided to deny exemption from preemption for State and local laws requiring audiological evaluation before the sale of a hearing aid to an adult. It has not been shown that audiological evaluation is necessary to provide reasonable assurance of the safety or effectiveness of hearing aids. Furthermore, mandatory audiological evaluation may increase the cost of a hearing aid and create an additional barrier to the receipt of a hearing aid in those areas of the country where audiological services are scarce.

The agency would like to set aside a few apparent misconceptions. Neither the FDA regulation on hearing aids nor

the agency's decision in this regulation to deny exemption from preemption for state laws requiring mandatory audiological evaluation. Audiologists may continue to test hearing before the sale of a hearing aid. FDA does not question the competency of audiologists. Indeed, FDA recognizes that the audiologist is an important member of the hearing health care team qualified to provide basic audiometric evaluation, hearing aid orientation, auditory training, speech reading, speech conservation, language development, and counseling and guidance services. FDA expects physicians to refer patients to an audiologist when necessary. Likewise, FDA's decision to deny exemption from preemption for these requirements does not constitute a determination that a hearing test is unnecessary before the sale of hearing aid. FDA has determined only that it is not necessary to require that this testing be done by an audiologist to provide reasonable assurance of the safety and effectiveness of hearing aids.

13. Comments from physicians, audiologists, and hearing aid dealers supported FDA's proposal to exempt from preemption State requirements of audiological evaluation for children.

FDA agrees with these comments and, therefore, is granting exemption from preemption to State laws requiring audiological evaluation before the sale of a hearing aid to a minor. Audiologists are specially qualified to assist in the language development and educational and social growth of a child with hearing loss. Consequently, mandatory audiological evaluation of a minor will serve an important public health purpose.

#### Waiver

14. Many comments addressed the issue of waiver of medical evaluation. The FDA regulation permits any informed adult 18 years or older to waive the medical evaluation requirement. Some State laws do not permit a waiver of the medical evaluation requirement under any circumstances. Others permit a waiver only if the prospective purchaser objects to medical evaluation for religious reasons. FDA proposed to deny exemptions from preemption for those State and local requirements that either do not permit a waiver of a medical evaluation requirement or permit a waiver for religious reasons only.

Some comments favoring exemption from preemption for State laws limiting or prohibiting waiver of medical evaluation argued that medical evaluation is absolutely necessary and, therefore, that a waiver should not be

permitted. Other comments suggested that only persons with religious objections should be permitted to waive the medical examination. Several comments stated that it is easy for hearing aid dealers, eager to make a sale, to induce the purchaser to waive medical evaluation without violating FDA regulation by actively encouraging the waiver. Other comments said that hearing aid dealers are widely abusing the waiver provision. For instance, the Attorney General of Massachusetts asserted that prospective hearing aid purchasers waive the medical evaluation requirement in 85 percent of the sales of hearing aids in Massachusetts.

The comments supporting FDA's proposal to deny exemption from preemption for State requirements limiting or prohibiting waiver of medical evaluation generally agreed with FDA that informed adults should have the freedom to waive medical evaluation. One religious group argued that failure to allow waiver of medical evaluation would violate the rights of its members. Many comments disputed the content that the waiver provision is being widely abused. One comment pointed out that most of the waivers identified in a recent New York study were exercised by persons who already owned a hearing aid, and that only 6 percent of the persons purchasing a hearing aid the first time waive medical evaluation. This was confirmed by a limited survey in Massachusetts, which showed that only 8 percent of first-time users of a hearing aid waived the requirement for medical evaluation.

FDA believes that, before purchasing a hearing aid, all prospective hearing users should obtain a medical evaluation of hearing loss to determine whether any conditions exist that could be corrected by medical treatment or surgery. FDA recognizes, however, that the risk to health posed by hearing aid arises from the failure to obtain beneficial medical treatment rather than from wearing a hearing aid. FDA believes that any informed adult who objects to medical evaluation for religious or personal reasons should be permitted to waive the medical evaluation requirement.

FDA has not been presented with a convincing evidence that the waiver provision is being widely abused by hearing aid dealers. The Attorney General of Massachusetts provided no evidence to support its claim that the waiver privilege is being exercised in percent of the sales of hearing aids in that Commonwealth. FDA undertook a survey of Attorneys General and

hearing aid dealer licensing boards to determine whether they were experiencing any problems with compliance with the FDA regulation. Of the 31 States that responded to this survey, only 19 provided FDA with information pertaining to dealer compliance with the regulation. Twenty-five of these 31 States indicated that they had not received complaints or other information regarding dealer compliance with the regulation, although a few of these 25 States related unsubstantiated rumors of noncompliance. Six of the 31 States responding to the survey indicated that they had encountered problems involving compliance with FDA regulation but, of these six, only Massachusetts stated that compliance problems were more common than isolated incidents. Therefore, FDA is denying exemption from preemption for State laws limiting or prohibiting waiver of medical evaluation. Exempting these requirements will also permit the purchase of a hearing aid in the rare circumstance where an individual would have great difficulty obtaining a medical evaluation because of the lack of a physician in the area.

15. In the proposed regulation, FDA proposed to grant exemptions from preemption for requirements that prohibit a waiver when certain medical conditions are found to exist in the prospective purchaser. Comments have persuaded FDA to deny exemption from preemption for these State requirements. FDA believes that an informed adult should be permitted to waive a medical evaluation even if one of these conditions is present. The existence of such a condition does not necessarily mean that the individual could not safely benefit from using a hearing aid. Moreover, the FDA hearing aid regulation requires that the User Instructional Brochure contain a statement warning hearing aid dispensers to advise a prospective purchaser to consult promptly with a licensed physician (preferable a physician who specializes in diseases of the ear) if the dispenser learns of the existence of any of eight specified medical conditions. FDA expects that hearing aid dispensers will be conscientious in impressing the importance of a medical examination upon prospective users exhibiting any of these symptoms.

16. Many States, while not requiring that the purchaser be examined by a physician, require hearing aid dispensers to advise in writing a prospective purchaser who has one or more of certain listed medical

conditions to consult with a physician. Some States also require that the hearing aid dispenser furnish the prospective purchaser with the names and addresses of physicians or otolaryngologists in the area. FDA has proposed to deny exemption from preemption for these requirements.

These requirements are more stringent than the FDA regulation because they require the dispenser to advise the prospective purchaser in writing. This requirement places only a slight additional burden on the dispenser and does not conflict with the FDA requirement. Therefore, the agency is exempting these requirements from preemption. FDA's requirements with respect to medical evaluation and waiver still apply in these States.

#### Disclosure Requirements

17. Many State regulations require that the hearing aid dispenser provide the purchaser with certain information at the time of sale. Most States require that this information be included in a sales receipt, while some States require that the information be included on the package. Much of the required information relates to the terms of sale and not to the safety or effectiveness of hearing aids. To this extent, these provisions are not preempted and, consequently, are not candidates for exemption. Many of these provisions, however, do relate to the safety or effectiveness of hearing aids and, therefore, are preempted. These preempted provisions generally require that the receipt state whether the hearing aid is new, used, or reconditioned. Many States also require that the receipt or packaging include a statement that a hearing aid will not prevent or improve organic causes of hearing loss.

Several comments objected to FDA's proposal to grant exemptions to the preempted State requirements described above. The comments argued that the User Instructional Brochure required by the FDA regulation contains all of the information the consumer needs and, consequently, that it is unnecessary to require that the information be included on the sales receipt and on the packaging as well. Manufacturers of hearing aids also objected that permitting certain States to require that specific statements be placed on the packaging of a hearing aid would create an unreasonable burden because they do not always know the ultimate destination of every hearing aid package.

These requirements are more stringent than the Federal requirements. FDA believes that the additional information

required by these State provisions may be useful to the consumer and will not impose a significant burden on the hearing aid dispenser or manufacturer. Although some of the information required to be included on the receipt is also contained in the User Instructional Brochure, FDA believes that inclusion of the information in both places will increase the likelihood that it is brought to the attention of the consumer. Moreover, the additional information required to be included on the packaging can be added at the time of sale. Therefore, FDA is granting exemption from preemption for these requirements. To ensure uniformity, the agency is requiring that the States apply the Federal definition of "used hearing aid" (21 CFR 801.420(a)(6)) in enforcing their disclosure requirements.

#### Arizona

18. As proposed, FDA is denying exemption from preemption for Arizona Revised Statutes (A.R.S.), Chapter 17, Section 36-1901.7(s) and its implementing regulation, Arizona Code of Revised Regulations (A.C.R.R.), Title 9, Article 3, R-9-16-303. These provisions are less stringent than the FDA regulation because they allow the dispensing of a hearing aid to a child 14 years of age or under by permitting the parent or guardian of the child to waive the medical evaluation requirement.

Several comments opposed FDA's proposal to grant exemption from preemption for A.R.S. Chapter 17, Section 36-1901.7(t) and its implementing regulation, A.C.R.R. Title 9, Article 3, R-9-16-304. These provisions require that a prospective hearing aid user with a significant air bone gap or apparent unilateral sensorineural hearing loss receive an audiological evaluation, although they permit a waiver of this requirement. The comments argued that this State requirement places audiological evaluation on a par with medical evaluation and that this is inconsistent with the position of FDA that audiological evaluation is not necessary to provide reasonable assurance of the safety or effectiveness of hearing aids. One comment argued that this requirement may mislead people into believing that audiological evaluation is as important as medical evaluation.

FDA agrees with these comments and, therefore, is denying exemption from preemption for these provisions.

#### California

19. Section 26453(m) of the California Health and Safety Code provides that it is unlawful to advertise any drug or device represented to have an effect on

## FDA REGULATIONS FOR HEARING AIDS

§801.420 Hearing aid devices; professional and patient labeling.

(a) Definitions for the purposes of this section and §801.421. (1) "Hearing aid" means any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing.

(2) "Ear specialist" means any licensed physician who specializes in diseases of the ear and is medically trained to identify the symptoms of deafness in the context of the total health of the patient, and is qualified by special training to diagnose and treat hearing loss. Such physicians are also known as otolaryngologists, otologists, and otorhinolaryngologists.

(3) "Dispenser" means any person, partnership, corporation, or association engaged in the sale, lease, or rental of hearing aids to any member of the consuming public or any employee, agent, sales person, and/or representative of such a person, partnership, corporation, or association.

(4) "Audiologist" means any person qualified by training and experience to specialize in the evaluation and rehabilitation of individuals whose communication disorders center in whole or in part in the hearing function. In some states audiologists must satisfy specific requirements for licensure.

(5) "Sale" or "purchase" includes any lease or rental of a hearing aid to a member of the consuming public who is a user or prospective user of a hearing aid.

(6) "Used hearing aid" means any hearing aid that has been worn for any period of time by a user. However, a hearing aid shall not be considered "used" merely because it has been worn by a prospective user as a part of a bona fide hearing aid evaluation conducted to determine whether to select that particular hearing aid for that prospective user, if such evaluation has been conducted in the presence of the dispenser or a hearing aid health professional selected by the dispenser to assist the buyer in making such a determination.

(b) Label requirements for hearing aids. Hearing aids shall be clearly and permanently marked with:

(1) The name of the manufacturer or distributor, the model name or number, the serial number, and the year of manufacture.

(2) A "+" symbol to indicate the positive connection for battery insertion, unless it is physically impossible to insert the battery in the reversed position.

(c) Labeling requirements for hearing aids — (1) General. All labeling information required by this paragraph shall be included in a User Instructional Brochure that shall be developed by the manufacturer or distributor, shall accompany the hearing aid, and shall be provided to the prospective user by the dispenser of the hearing aid in accordance with §802.421 (c). The User Instructional Brochure accompanying each hearing aid shall contain the following information and instructions for use, to the extent applicable to the particular requirements and characteristics of the hearing aid:

(i) An illustration(s) of the hearing aid, indicating operating controls, user adjustments, and battery compartment.

(ii) Information on the function of all controls intended for user adjustment.

(iii) A description of any accessory that may accompany the hearing aid, e.g., accessories for use with a television or telephone.

(iv) Specific instructions for:

(a) Use of the hearing aid.

(b) Maintenance and care of the hearing aid, including the procedure to follow in washing the earmold, when

replacing tubing on those hearing aids that use tubing, and storing the hearing aid when it will not be used for an extended period of time.

(v) Replacing or recharging the batteries, including a generic designation of replacement batteries.

(vi) Information on how and where to obtain repair service, including at least one specific address where the users can go, or send the hearing aid to, to obtain such repair service.

(vii) A description of commonly occurring avoidable conditions that could adversely affect or damage the hearing aid, such as dropping, immersing, or exposing the hearing aid to excessive heat.

(viii) Identification of any known side effects associated with the use of a hearing aid that may warrant consultation with a physician, e.g., skin irritation and accelerated accumulation of cerumen (ear wax).

(ix) A statement that a hearing aid will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions.

(x) A statement that in most cases infrequent use of a hearing aid does not permit a user to attain full benefit from it.

(xi) A statement that the use of a hearing aid is only part of hearing habilitation and may need to be supplemented by auditory training and instruction in lipreading.

(xii) The warning statement required by paragraph (c) (2) of this section.

(xiii) The notice for prospective hearing aid users required by paragraph (e) (3) of this section.

(xiv) The technical data required by paragraph (c) (4) of this section, unless such data is provided in separate labeling accompanying the device.

(2) Warning statement. The User Instructional Brochure shall contain the following warning statement:

### WARNING TO HEARING AID DISPENSERS

A hearing aid dispenser should advise a prospective hearing aid user to consult promptly with a licensed physician (preferably an ear specialist) before dispensing a hearing aid if the hearing aid dispenser determines through inquiry, actual observation, or review of any other available information concerning the prospective user, that the prospective user has any of the following conditions:

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

(ii) History of active drainage from the ear within the previous 90 days.

(iii) History of sudden or rapidly progressive hearing loss within the previous 90 days.

(iv) Acute or chronic dizziness.

(v) Unilateral hearing loss of sudden or recent onset within the previous 90 days.

(vi) Audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz.

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

(viii) Pain or discomfort in the ear.

Special care should be exercised in selecting and fitting a hearing aid whose maximum sound pressure level exceeds 132 decibels because there may be risk of impairing the remaining hearing of the hearing aid user. (This provision is required only for those hearing aids with a maximum sound pressure capability greater than 132 decibels (dB).

(3) Notice for prospective hearing aid users. The User Instructional Brochure shall contain the following notice:

### IMPORTANT NOTICE FOR PROSPECTIVE HEARING AID USERS

Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. Licensed physicians who specialize in diseases of the ear

otolaryngologists. The purpose of medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased.

Following the medical evaluation, the physician will give you a written statement that states that your hearing loss has been medically evaluated and that you may be considered a candidate for a hearing aid. The physician will refer you to an audiologist or a hearing aid dispenser, as appropriate, for a hearing aid evaluation.

The audiologist or hearing aid dispenser will conduct a hearing aid evaluation to assess your ability to hear with and without a hearing aid. The hearing aid evaluation will enable the audiologist or dispenser to select and fit a hearing aid to your individual needs.

If you have reservations about your ability to adapt to amplification, you should inquire about the availability of a trial-rental or purchase-option program. Many hearing aid dispensers now offer programs that permit you to wear a hearing aid for a period of time for a nominal fee after which you may decide if you want to purchase the hearing aid.

Federal law restricts the sale of hearing aids to those individuals who have obtained a medical evaluation from a licensed physician. Federal law permits a fully informed adult to sign a waiver statement declining the medical evaluation for religious or personal beliefs that preclude consultation with a physician. The exercise of such a waiver is not in your best health interest and its use is strongly discouraged.

#### Children with Hearing Loss

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

(4) Technical data. Technical data useful in selecting, fitting, and checking the performance of a hearing aid shall be provided in the User Instructional Brochure or in separate labeling that accompanies the device. The determination of technical data values for the hearing aid labeling shall be conducted in accordance with the test procedures of the Acoustical Society of America Standard for Specification of Hearing Aid Characteristics, ASA STD 7-1976. As a minimum, the User Instructional Brochure or such other labeling shall include the appropriate values or information for the following technical data elements as these elements are defined or used in such standard:

- (i) Saturation output curve (SSPL 90 curve).
- (ii) Frequency response curve.
- (iii) Average saturation output (HF-Average SSPL 90)
- (iv) Average full-on gain (HF-Average full-on gain);
- (v) Reference test gain.
- (vi) Frequency range.
- (vii) Total harmonic distortion.
- (viii) Equivalent input noise.
- (ix) Battery current drain.
- (x) Induction coil sensitivity (tel. phone coil aids only).
- (xi) Input-output curve (ACG aids only).
- (xii) Attack and release times (ACG aids only).

(5) Statement if hearing aid is used or rebuilt. If a hearing aid has been used or rebuilt, this fact shall be declared on the container in which the hearing aid is packaged and on a tag that is physically attached to such hearing aid. Such fact may also be stated in the User Instructional Brochure.

(6) Statements in User Instructional Brochure other than those required. A User Instructional Brochure may contain statements or illustrations in addition to those required by paragraph (c) of this section if the additional statements:

- (i) Are not false or misleading in any particular, e.g., diminishing the impact of the required statements; and
- (ii) Are not prohibited by this chapter or by regulations of the Federal Trade Commission.

(d) Submission of all labeling for each type of hearing aid. Any manufacturer of a hearing aid described in paragraph (a) of this section shall submit to the Food and Drug Administration, Bureau of Medical Devices and

8757 Georgia Ave., Silver Spring, MD 20910, a copy of the User Instructional Brochure described in paragraph (c) of this section and all other labeling for each type of hearing aid on or before August 15, 1977.

#### 801.421 Hearing aid devices; conditions for sale.

(a) Medical evaluation requirements — (1) General. Except as provided in paragraph (a) (2) of this section, a hearing aid dispenser shall not sell a hearing aid unless the prospective user has presented to the hearing aid dispenser a written statement signed by a licensed physician that states that 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 6 months.

(2) Waiver to the medical evaluation requirements. If the prospective hearing aid user is 18 years of age or older, the hearing aid dispenser may afford the prospective user an opportunity to waive the medical evaluation requirement of paragraph (a) (1) of this section provided that the hearing aid dispenser:

- (i) Informs the prospective user that the exercise of the waiver is not in the user's best health interest;
- (ii) Does not in any way actively encourage the prospective user to waive such a medical evaluation; and
- (iii) Affords the prospective user the opportunity to sign the following statement:

I have been advised)

(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 by 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.

(b) Opportunity to review User Instructional Brochure. Before signing any statement under paragraph (a) (2) (iii) of this section and before the sale of a hearing aid to a prospective user, the hearing aid dispenser shall:

(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.

(c) Availability of User Instructional Brochure — (1) Upon request by an individual who is considering purchase of a hearing aid, a dispenser shall, with respect to any hearing aid that he dispenses, provide a copy of the User Instructional Brochure for the hearing aid or the name and address of the manufacturer or distributor from whom a User Instructional Brochure for the hearing aid may be obtained.

(2) In addition to assuring that a User Instructional Brochure accompanies each hearing aid, a manufacturer or distributor shall with respect to any hearing aid that he manufactures or distributes:

(i) Provide sufficient copies of the User Instructional Brochure to sellers for distribution to users and prospective users;

(ii) Provide a copy of the User Instructional Brochure to any hearing aid professional, user, or prospective user who requests a copy in writing.

(d) Recordkeeping. The dispenser shall retain for 3 years after the dispensing of a hearing aid a copy of any written statement from a physician required under paragraph (a) (1) of this section or any written statement waiving medical evaluation required under paragraph (a) (2) (iii) of this section.

(e) Exemption for group auditory trainers. Group auditory trainers, defined as a group amplification system purchased by a qualified school or institution for the purpose of communicating with and educating individuals with hearing impairments, are exempt from the requirements of this section.

March 13, 1986

Pat Malone  
c/o Representative Navarre  
State Legislature  
Juneau, AK 99811

Dear Pat,

Attached are the items I promised you regarding CS HB430. If you have any questions, give me a call.

Sincerely,

David R. Canterbury

Pat

The reference I made to requiring audiological evaluations for children under 18 years is explained in the FDA testimony attached. This would provide some safeguard against improper fitting to children but it may not need to be stated as such because the "60 day" return rule with medical or audiological writers statements may well be enough.

Dave  
Canterbury

Recommended Changes in CS HB430

Page 08, Line 18. Delete ..... "for the audiologist who works for the audiologist".

Page 15, Line 23. Raise \$5,000.00 bond to \$10,000.00. Justification: Hearing aids often cost consumers \$900.00 to \$1,200.00 each. A higher bond coverage would insure that more than a few consumers might be covered.

Page 17, Line 7. Delete "who is not a physician or audiologist".

Line 9. Delete "or".

Line 10. Delete "an audiologist" and " or the audiologist".

Line 13. Delete "or the audiologist".

Line 25. Delete "is not a physician or an audiologist".

Page 18, Line 8. Delete "or the audiologist".

Line 9. Insert "waiver" before..... "statement".

Page 22, Line 29. Insert "or provide written mailing instructions (by certified mail)" after..... from the consumer.

Page 23, Lines 10 to 14. Change wording to:

Sec. 08.55.120. Testing of Hearing

(a) A hearing aid dealer may take threshold measurements to determine the need for hearing aid use, but may not perform other diagnostic procedures to determine the cause of a hearing impairment, the site of lesion or charge a fee for any hearing measurement.

Line 17. Insert "in no smaller than 12 point print".

Page 29, Lines 16 and 17. Delete "hearing aid dealers licensed under AS 08.55".

3/17/86

Mike:

Most of the amendments required for HB 430 in HESS are actually minor.

On page 17 & 18, the amendments delete audiologists from the prior evaluation language, making it a medical evaluation, not a hearing evaluation. This brings the bill in line with current Federal Food & Drug Administration regulations, according to Dr. Dave Canterbury. He's sending the material, I just haven't seen it yet. It actually limits the audiologists a little.

Page 22, the language is made a little more liberal, allowing the hearing aid dealer to provide mailing instructions to a dissatisfied consumer, rather than having to chase around and pick up the hearing aids. This makes life a little easier for them.

Page 23: the language defining what type of hearing testing a hearing aid dealer may perform is cleaned up.

One change suggested by Canterbury <sup>(NOT INCLUDED)</sup> is to require a minimum 8 point (roughly typewriter print) letter size for the statement on page 23. The reasoning here is to keep the fine print from being so small that a consumer (especially an elderly one) can't read it. The only problem I can see with that is you might be forcing a dealer into buying a 1/2 page Yellow Page ad.

*Pat*

CS FOR HB 430 (LABOR & COMMERCE)  
SECTIONAL ANALYSIS

Section 1 states the legislative findings and purpose of the bill.

Section 2 adds audiologists, audiologist aides and hearing aid dealers to the centralized licensing chapter.

Section 3 adds audiologists, audiologist aides and hearing aid dealers to those others provided with services by the department, without requiring a board or commission.

Section 4 adds audiologists, audiologist aides and hearing aid dealers to those subject to investigation and enforcement procedures required by the department.

Section 5 redefines "license" and "occupation" to include trades or professions listed in the amended centralized licensing chapter that are not covered by a board or commission.

Section 6 adds audiologists to the professional designation requirements.

Section 7 adds the following sections to the chapter:

08.11.010 provides for qualifications for licensing of professional audiologists.

08.11.020 provides for qualifications for licensing of audiologist aides.

08.11.030 addresses temporary license to practice audiology.

08.11.040 provides for duration of licenses.

08.11.050 provides for renewal of licenses.

08.11.060 provides for display of current license.

08.11.070 empowers the department to set fees for licensing.

08.11.080 requires malpractice insurance for audiologists.

08.11.085 allows audiologists to fit and sell hearing aids.

08.11.090 and 08.11.100 define grounds for disciplinary actions against audiologists and audiologist aides.

08.11.110 lists disciplinary sanctions.

08.11.120 lists prohibited acts.

08.11.130 makes violations of prohibited acts a class B misdemeanor (actual penalties defined elsewhere).

08.11.140 provides for exemptions under this chapter; prevents those individuals who may be exempt, but who are not audiologists, from holding forth as an audiologist.

08.11.150 states the Administrative Procedure Act applies to regulations under this chapter.

08.11.200 is the definition section for this chapter.

Section 8 adds a new chapter to AS 08, addressing hearing aid dealers. The following sections are within this chapter:

08.55.010 provides for qualifications for license.

08.55.030 provides for duration and renewal of license.

08.55.040 empowers the department to set fees.

08.55.050 requires a hearing aid dealer, when entering a contract with a consumer for the purchase or lease of a hearing aid, to provide the consumer with an instructional brochure; registration number, specifications, make, model and serial number of the hearing aid; a clear statement of the full terms of the contract; written information on the consumer's right to file a complaint, including the address of the department;

also requires that any used or reconditioned hearing aid be clearly labeled as such, and what guarantee may be offered.

08.55.060 requires a medical evaluation prior to the sale or lease of a hearing aid; allows the consumer, if 18 years of age or older, to waive the medical evaluation by signing a statement; requires the hearing aid dealer to retain statement or medical evaluation for four years after sale date of hearing aid.

08.55.070 provides method of mailing hearing aids to consumer.

08.55.080 provides the consumer may file a complaint with the department within three years of purchase date; requires dealer to post notice of consumer's right to file complaint.

08.55.090 requires liability insurance for hearing aid dealers; empowers department to set insurance requirements.

08.55.100 requires hearing aid dealers keep audiometers calibrated to national standards.

08.55.110 provides dealer will inform consumer of consumer's right to cancel purchase or lease of hearing aid; lists valid reasons for cancellation; provides facsimile of "notice of right to cancel" form hearing aid dealer must provide, form provides for terms of cancellation; provides for refund of purchase price less reasonable costs incurred by dealer; return of goods traded as part of sale or lease, return of negotiable instruments signed by the purchaser as part of sale or lease, cancellation of security interest taken by dealer as part of sale or lease; requires a dealer to collect a hearing aid from the consumer within 20 days of receipt of the cancellation or else consumer can retain possession; requires consumer make hearing aid available for dealer to collect, or else cancellation is void; provides notice of cancellation requirements.

08.55.120 restricts type of hearing testing allowed by hearing aid dealers; requires all dealers to specify, in their advertising, what type of hearing testing they are allowed to perform.

08.55.130 lists grounds for disciplinary sanctions.

08.55.140 lists disciplinary sanctions the department may impose.

08.55.150 lists prohibited acts.

08.55.160 makes violation of prohibited acts a class B misdemeanor.

08.55.170 requires a hearing aid dealer to notify the department of the address of their regular place of business.

08.55.180 states the Administrative Procedure act applies to this chapter.

08.55,200 is the definition section for this chapter.

Section 9 adds audiologists and audiologist aides to the definition of "health care provider" under AS 09.55.560.

Section 10 adds audiologists and audiologist aides to the definition of "health care provider" under AS 21.88.900.

Section 11 adds audiologists and audiologist aides to AS 44.62.330(a), application of procedure by boards, commissions & officers.

Section 12 adds failure to comply with AS. 08.55 to AS 45.50.471(b), the unlawful acts and practices section of Trade & Commerce.

Section 13 adds "dealing in hearing aids" and "hearing aid" to the AS 45.50.561, the definitions section of Trade and Commerce.

Section 14 adds "audiologists and audiologist aides" and "hearing aid dealers" to AS 47.17.090(9) as "practitioners of the healing arts".

... Hearing audiology aides is unusual - usually is an assistant

propn to req individuals to post a bond

Bannister  
2/10/86.

Original sponsors: Navarre, Gruenberg,  
Hurley and Thompson

next

BY THE LABOR AND  
COMMERCE COMMITTEE

1 IN THE HOUSE

2 CS FOR HOUSE BILL NO. 430 (L&C)

3 IN THE LEGISLATURE OF THE STATE OF ALASKA

4 FOURTEENTH LEGISLATURE - SECOND SESSION

5 A BILL

6 For an Act entitled: "An Act regulating audiologists, hearing aid dealers  
7 and the dispensing of hearing aids."

8 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:

9 \* Section 1. LEGISLATIVE FINDINGS, PURPOSE. (a) The legislature finds  
10 that the practice of audiology and the dispensing of hearing aids affects  
11 the health, safety and welfare of the public and requires regulation and  
12 control by the state in the public interest.

13 (b) The purpose of this Act is to establish the procedures necessary  
14 to ensure that the public is protected from the incompetent, unprofession-  
15 al, improper, and unauthorized practice of audiology and dispensing of  
16 hearing aids, and to assure the availability of the highest possible quali-  
17 ty audiology and hearing aid services for the hearing impaired persons of  
18 the state.

19 \* Sec. 2. AS 08.01.010 is amended by adding new paragraphs to read:

20 (24) regulation of audiologists and audiologist aides under  
21 AS 08.11;

22 (25) regulation of hearing aid dealers under AS 08.55.

23 \* Sec. 3. AS 08.01.050(a) is amended to read:

24 (a) The department shall provide the following administrative  
25 and budgetary services when appropriate:

26 (1) collect fees and issue receipts;

27 (2) maintain records and files;

28 (3) issue and receive application forms;

29 (4) notify applicants of acceptance or rejection of

Original sponsors: Navarre, Gruenberg,  
Hurley and Thompson

BY THE LABOR AND  
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1 IN THE HOUSE

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29 (4) notify applicants of acceptance or rejection of

1 applicants as determined by the board or as determined by the depart-  
2 ment under AS 08.11 for audiologists and audiologist aides or under  
3 AS 08.55 for hearing aid dealers;

4 (5) designate dates examinations are to be held and notify  
5 applicants;

6 (6) publish notice of examination;

7 (7) arrange space for holding examinations;

8 (8) notify applicants of results of examinations;

9 (9) issue licenses and certificates or temporary licenses  
10 or certificates as authorized by the board or as authorized by the  
11 department under AS 08.11 for audiologists and audiologist aides or  
12 under AS 08.55 for hearing aid dealers;

13 (10) issue duplicate licenses or certificates upon proof by  
14 the licensee of loss of the original and payment by the licensee of a  
15 fee of \$2 except as otherwise provided in this title;

16 (11) notify licensees of renewal dates at least 30 days  
17 before the expiration date of their licenses;

18 (12) compile and maintain current a register of licenses;

19 (13) answer routine inquiries;

20 (14) maintain files relating to individual licensees;

21 (15) arrange for printing and advertising;

22 (16) purchase supplies;

23 (17) employ secretarial help when needed;

24 (18) perform other services that [WHICH] may be requested by  
25 the board;

26 (19) provide investigative services to the boards estab-  
27 lished under AS 08.04, AS 08 20, AS 08.36, AS 08.64, AS 08.68, AS 08.-  
28 70, AS 08.71, AS 08.72, AS 08.80, AS 08.84, and AS 08.86, for the  
29 purpose of assisting those boards in matters of professional

1 discipline and in responding to consumer complaints.

2 \* Sec. 4. AS 08.01.087 is amended to read:

3 Sec. 08.01.087. POWERS AND DUTIES OF DEPARTMENT. (a) The  
4 department may, upon its own motion, conduct investigations to deter-  
5 mine whether a [ANY] person has violated a provision of this chapter  
6 or a regulation adopted under it, or a provision of [A CHAPTER IN]  
7 this title or regulation adopted under this title dealing with an  
8 occupation or board [ONE OF THE BOARDS] listed in AS 08.01.010 [OR A  
9 REGULATION ADOPTED BY ONE OF THOSE BOARDS], or to secure information  
10 useful in the administration of this chapter.

11 (b) If it appears to the commissioner that a person has engaged  
12 in or is about to engage in an act or practice in violation of a  
13 provision of this chapter or a regulation adopted under it, or a  
14 provision of this title or regulation adopted under this title dealing  
15 with an occupation or board [OR ANY OF THE LAWS PERTAINING TO OR  
16 REGULATIONS ADOPTED BY THE BOARDS] listed in AS 08.01.010, the commis-  
17 sioner may, if the commissioner considers it in the public interest,  
18 and after notification of a proposed order or action by telephone or  
19 telegraph to all board members, if a board regulates the act or prac-  
20 tice involved, [BY TELEPHONE OR TELEGRAPH OF A PROPOSED ORDER OR  
21 ACTION] unless a majority of the members of the board object within 10  
22 days,

23 (1) issue an order directing the person to stop the act or  
24 practice; however, reasonable notice of and an opportunity for a  
25 hearing must first be given to the person, except that the commis-  
26 sioner may issue a temporary order before a hearing is held; a tempo-  
27 rary order remains in effect until a final order affirming, modifying,  
28 or reversing the temporary order is issued or until 15 days after the  
29 person receives the notice and has not requested a hearing by that

1 time; a temporary order becomes final if the person to whom the notice  
2 is addressed does not request a hearing within 15 days after receiving  
3 the notice; the commissioner or the commissioner's designee shall be  
4 the hearing officer at the hearing and shall issue a final order  
5 within 10 days after the hearing;

6 (2) bring an action in the superior court to enjoin the  
7 acts or practices and to enforce compliance with this chapter, a  
8 regulation adopted under it, [OR] an order issued under it, or with a  
9 provision of this title or regulation adopted under this title dealing  
10 with an occupation or board [OR ANY OF THE LAWS PERTAINING TO OR  
11 REGULATIONS ADOPTED BY THE BOARDS] listed in AS 08.01.010;

12 (3) examine or have examined the books and records of a  
13 [ANY] person whose business activities require licensure by a board  
14 listed in AS 08.01.010, or whose occupation is listed in AS 08.01.010;  
15 the commissioner [AND HE] may require the [THAT] person to pay the  
16 reasonable costs of the examination; and

17 (4) issue subpoenas for the attendance of witnesses, and  
18 the production of books, records and other documents.

19 \* Sec. 5. AS 08.01.110 is amended to read:

20 Sec. 08.01.110. DEFINITIONS. In this chapter

21 (1) "board" includes the boards and commissions listed in  
22 AS 08.01.010;

23 (2) "department" means the Department of Commerce and  
24 Economic Development;

25 (3) "commissioner" means the commissioner of commerce and  
26 economic development;

27 (4) "license" means a [ANY] license, certificate, permit,  
28 or registration or similar evidence of authority issued for an occupa-  
29 tion or board [BY ONE OF THE BOARDS] listed in AS 08.01.010;

1 (5) "licensee" means a [ANY] person who holds a license;

2 (6) "occupation" means a trade or profession [ANY OF THE  
3 TRADES OR PROFESSIONS FOR WHICH LICENSURE IS REQUIRED BY ONE OF THE  
4 BOARDS] listed in AS 08.01.010.

5 \* Sec. 6. AS 08.02.010(a) is amended to read:

6 (a) An audiologist licensed under AS 08.11, a [A] person li-  
7 censed in the state as a chiropractor under AS 08.20, a dentist under  
8 AS 08.36, a medical practitioner or osteopath under AS 08.64, a regis-  
9 tered nurse under AS 08.68, an optometrist under AS 08.72, a regis-  
10 tered pharmacist under AS 08.80, a registered physical therapist under  
11 AS 08.84, or a psychologist under AS 08.86, shall use as professional  
12 identification appropriate letters or a title after that person's name  
13 which represents that person's specific field of practice. The letters  
14 or title shall appear on all signs, stationery or other advertising in  
15 which the person offers or displays personal professional services to  
16 the public. In addition, a person engaged in the practice of medicine  
17 or osteopathy under AS 08.64.380(2), or a person engaged in any manner  
18 in the healing arts who diagnoses, treats, tests, or counsels other  
19 persons in relation to human health or disease and uses the letters  
20 "M.D." or the title "doctor" or "physician" or another [ANY OTHER]  
21 title that [WHICH] tends to show that the person is willing or qual-  
22 ified to diagnose, treat, test, or counsel another person, shall  
23 clarify the letters or title by adding the appropriate specialist  
24 designation, if any, such as "dermatologist", "radiologist", "audio-  
25 logist", "naturopath", or the like.

26 \* Sec. 7. AS 08 is amended by adding a new chapter to read:

27 CHAPTER 11. AUDIOLOGISTS AND AUDIOLOGIST AIDES.

28 Sec. 08.11.010. QUALIFICATIONS FOR LICENSE. (a) The department  
29 shall issue a license to practice audiology to an individual who

- 1 (1) is 18 years of age or older;  
2 (2) applies on a form provided by the department;  
3 (3) pays the fee required under AS 08.11.070;  
4 (4) furnishes evidence satisfactory to the department that  
5 the person

6 (A) has not engaged in conduct that is a ground for  
7 imposing disciplinary sanctions under AS 08.11.090;

8 (B) holds a master's degree, doctorate, or the equiva-  
9 lent, in audiology from an accredited educational institution  
10 approved by the department; and either has

11 (i) a Certificate of Clinical Competence in  
12 Audiology from the American Speech and Hearing Association  
13 or the equivalent of the certificate; or

14 (ii) practiced audiology for two years as of  
15 January 1, 1986, or is in the process of completing the year  
16 of supervised clinical experience required for the Certifi-  
17 cate of Clinical Competence of the American Speech and  
18 Hearing Association;

19 (5) has good moral character; and

20 (6) files with the department an irrevocable consent to  
21 service of process authorizing the department to receive service for  
22 the applicant of a notice, process, or pleading in an action or pro-  
23 ceeding against the applicant based on the practice of audiology by the  
24 applicant in the state; service on the department confers personal  
25 jurisdiction over the applicant in a court of competent jurisdiction  
26 for an action based on the practice of audiology by the applicant in  
27 the state.

28 Sec. 08.11.020. AUDIOLOGIST AIDES. (a) The department shall  
29 issue an audiologist aide license to an individual who

1 (1) is 18 years of age or older;  
2 (2) has a high school diploma or the equivalent;  
3 (3) applies on a form provided by the department;  
4 (4) meets other minimum qualifications established by the  
5 department.

6 (b) An audiologist aide may practice audiology only if the  
7 audiologist aide works under the direct supervision of an audiologist.

8 (c) The practice of audiology by an audiologist aide is the  
9 direct responsibility of the audiologist supervising the audiologist  
10 aide.

11 Sec. 08.11.030. TEMPORARY LICENSE TO PRACTICE AUDIOLOGY AS AN  
12 AUDIOLOGIST. (a) Pending disposition of the application the depart-  
13 ment shall issue a temporary license for the practice of audiology as  
14 an audiologist to an individual who is licensed to practice audiology  
15 in another state and has submitted to the department an application  
16 for a license under AS 08.11.010.

17 (b) The department may issue a temporary license to the follow-  
18 ing:

19 (1) an individual from another state for the practice of  
20 audiology as an audiologist in this state

21 (A) for five days or less in a calendar year; and

22 (B) in cooperation with an audiologist licensed under

23 this chapter;

24 (2) a nonresident for the practice of audiology as an  
25 audiologist in the state for 30 days or less in a calendar year, if  
26 the individual is licensed to practice audiology in another state,  
27 territory of the United States, foreign country, or province that has  
28 requirements for a license to practice audiology that are substan-  
29 tially equivalent to or higher than the requirements of AS 08.11.010.

1 (3) a nonresident for the practice of audiology as an  
2 audiologist in the state for 30 days or less in a calendar year, if  
3 the individual meets the qualifications and requirements for a license  
4 under AS 08.11.010, and resides in a state or territory of the United  
5 States or a foreign country or province that does not license indi-  
6 viduals to practice audiology.

7 (c) The department may impose limitations that it determines  
8 appropriate on a temporary license issued under this section.

9 Sec. 08.11.040. DURATION OF LICENSE. A license issued under  
10 this chapter is valid until January 30 of the year following its  
11 issuance, and is subject to renewal.

12 Sec. 08.11.050. RENEWAL OF LICENSES. (a) The department shall  
13 renew the license of an individual licensed under this chapter if the  
14 individual submits to the department on or before January 30 of each  
15 year an application for renewal and pays the renewal fee.

16 (b) If an individual fails to renew a license under (a) of this  
17 section, the license lapses.

18 (c) The department may reinstate a lapsed license if the license  
19 has lapsed for less than two years and if the individual submits to  
20 the department an application for renewal and pays a delinquency fee  
21 in addition to the renewal fee.

22 (d) A suspended license is subject to expiration and must be  
23 renewed as provided in this section, but the renewal does not entitle  
24 the individual while the license remains suspended to practice audiol-  
25 ogy or to engage in other activity or conduct that violates the order  
26 or judgment that suspended the license.

27 Sec. 08.11.060. DISPLAY OF LICENSE. (a) An individual licensed  
28 to practice audiology as an audiologist or audiologist aide in the  
29 state shall display the license in a prominent place at each place of

1 business of the individual.

2 (b) If an audiologist has more than one place of business, the  
3 department shall, on request and payment of a fee, issue a duplicate  
4 license for each place of business of the individual.

5 Sec. 08.11.070. FEES. The department shall set fees under  
6 AS 08.01.065 for each of the following:

- 7 (1) application;
- 8 (2) credential review;
- 9 (3) audiologist license;
- 10 (4) audiologist aide license;
- 11 (5) temporary license;
- 12 (6) renewal of license;
- 13 (7) delinquency;
- 14 (8) reinstatement;
- 15 (9) duplicate license.

16 Sec. 08.11.080. MALPRACTICE INSURANCE. An audiologist shall  
17 maintain insurance against liability for negligence in the practice of  
18 audiology for the audiologist and for each audiologist aide who works  
19 for the audiologist.

20 Sec. 08.11.085. DEALING IN HEARING AIDS. An audiologist may  
21 deal in hearing aids as a hearing aid dealer without being licensed as  
22 a hearing aid dealer under AS 08.55, but shall comply with AS 08.55.-  
23 050 - 08.55.070, 08.55.100 - 08.55.110, and 08.55.130(7) - (13) when  
24 dealing in hearing aids.

25 Sec. 08.11.090. GROUNDS FOR IMPOSITION OF DISCIPLINARY SANCTIONS  
26 ON AN AUDIOLOGIST. After a hearing, the department may impose a  
27 disciplinary sanction on an audiologist when the department finds that  
28 the licensee

- 29 (1) secured a license through deceit, fraud, or intentional

1 misrepresentation;

2 (2) engaged in deceit, fraud, or intentional misrepresenta-  
3 tion in the course of practicing audiology;

4 (3) advertised professional services in a false or mislead-  
5 ing manner;

6 (4) has been convicted of a felony or other crime that  
7 affects the person's ability to continue to practice competently and  
8 safely;

9 (5) continued to practice audiology after becoming unfit  
10 due to

11 (A) professional incompetence;

12 (B) addiction to or severe dependency on alcohol or  
13 another drug that impairs the person's ability to practice  
14 safely;

15 (C) physical or mental disability;

16 (6) permitted another person to use the licensee's license;

17 (7) employed a person who does not have a valid current  
18 license to practice audiology or a valid audiology aide license to  
19 perform work covered by this chapter;

20 (8) failed to supervise an audiologist aide who worked for  
21 the audiologist;

22 (9) failed to comply with a provision of this chapter or a  
23 regulation adopted under this chapter, or an order of the department.

24 Sec. 08.11.100. GROUNDS FOR IMPOSITION OF DISCIPLINARY SANCTIONS  
25 ON AN AUDIOLOGIST AIDE. After a hearing, the department may impose a  
26 disciplinary sanction on an audiologist aide under this chapter when  
27 the department finds that the licensee committed an act listed in  
28 AS 08.11.090(1), (2), (4) - (6), or (9).

29 Sec. 08.11.110. DISCIPLINARY SANCTIONS. (a) When it finds that

1 an audiologist has committed an act listed in AS 08.11.090 or an  
2 audiologist aide has committed an act listed in AS 08.11.100, the  
3 department may impose the following sanctions singly or in combina-  
4 tion:

5 (1) permanently revoke a license to practice;  
6 (2) suspend a license for a determinate period of time;  
7 (3) censure a licensee;  
8 (4) issue a letter of reprimand;  
9 (5) place a licensee on probationary status and require the  
10 licensee to

11 (A) report regularly to the department on matters  
12 involving the basis of probation;

13 (B) limit practice to those areas prescribed;

14 (C) continue professional education until a satisfac-  
15 tory degree of skill has been attained in those areas determined  
16 by the department to need improvement;

17 (6) impose limitations or conditions on the practice of a  
18 licensee.

19 (b) The department may withdraw a limitation, condition, or  
20 probationary status if it finds that the deficiency that required the  
21 sanction has been remedied.

22 (c) The department may summarily suspend a license before final  
23 hearing or during the appeals process if the department finds that the  
24 licensee poses a clear and immediate danger to the public welfare and  
25 safety if the licensee continues to practice. An individual whose  
26 license is suspended under this subsection is entitled to a hearing by  
27 the department no later than seven days after the effective date of  
28 the order. The individual may appeal the suspension after the hearing  
29 to the superior court.

1 (d) The department may reinstate a license that has been sus-  
2 pended or revoked if the department finds after a hearing that the  
3 individual is able to practice with reasonable skill and safety.

4 (e) One year after revocation of a license issued under this  
5 chapter, the individual whose license was revoked may reapply for the  
6 license. The department may require an examination for reinstatement.

7 Sec. 08.11.120. PROHIBITED ACTS. (a) Unless a person is an  
8 audiologist under this chapter, the individual may not

9 (1) practice audiology unless the person is an audiologist  
10 aide practicing under the direct supervision of an audiologist;

11 (2) use a title indicating or representing that the person  
12 practices as an audiologist;

13 (3) advertise that the person practices audiology.

14 (b) Unless a person is licensed as an audiologist aide under  
15 this chapter, the person may not

16 (1) practice audiology;

17 (2) use a title indicating or representing that the person  
18 practices or is licensed to practice audiology as an audiology aide.

19 Sec. 08.11.130. PENALTY. A person who violates AS 08.11.120 is  
20 guilty of a class B misdemeanor.

21 Sec. 08.11.140. EXEMPTIONS. (a) This chapter does not apply to  
22 an individual who practices audiology consistent with the accepted  
23 standards and code of ethics of the individual's profession and as  
24 part of the individual's duties as

25 (1) a physician licensed under AS 08.64;

26 (2) an employee of the federal government who is required  
27 to practice audiology during the employment, if

28 (A) the employer maintains appropriate supervision of  
29 the individual's practice of audiology;

1 (B) the individual practices audiology as part of the  
2 duties for which the individual is employed;

3 (C) the individual practices audiology in the facility  
4 where the individual is employed or under the supervision of the  
5 federal governmental unit where the individual is employed; and

6 (D) the individual does not render or offer to render  
7 audiology services to the public for compensation in addition to  
8 the salary the individual receives from the federal governmental  
9 unit;

10 (3) a student, intern, or resident pursuing a course of  
11 study in audiology at an accredited college or a clinical training  
12 facility approved by the department, if the activities of the student,  
13 intern, or resident constitute part of a supervised course of study  
14 and the student, intern, or resident is designated as an "audiology  
15 intern," "audiology trainee," or other title approved by the depart-  
16 ment that clearly indicates that the person is training to be an  
17 audiologist or an audiologist aide.

18 (b) Notwithstanding the provisions of this chapter,

19 (1) a nurse licensed under AS 03.68 may perform hearing  
20 sensitivity evaluations;

21 (2) an individual licensed as a hearing aid dealer under  
22 AS 08.55 may deal in hearing aids;

23 (3) an individual holding a class A certificate issued by  
24 the Conference of Executives of American Schools of the Deaf may teach  
25 the hearing impaired;

26 (4) an individual may engage in the testing of hearing as  
27 part of a hearing conservation program that complies with the regu-  
28 lations of the Occupational Safety and Health Administration of the  
29 federal government if the individual is certified to do the testing by

1 a state or federal agency acceptable to the Occupational Safety and  
2 Health Administration.

3 (c) An individual who is not an audiologist, but who is exempt  
4 under this section may not use a title or description stating or  
5 implying that the person is an audiologist.

6 (d) An individual who is not an audiologist aide, but who is  
7 exempt under this section may not use a title or description stating  
8 or implying that the person is an audiologist aide.

9 (e) An individual exempt under (a)(2) of this section may con-  
10 sult with and disseminate research findings and scientific information  
11 to accredited academic institutions or governmental agencies, and  
12 offer lectures to the public for a fee, monetary or otherwise, without  
13 being licensed under this chapter.

14 (f) An individual who is not licensed under this chapter but who  
15 teaches the practice of audiology in an audiologist training program  
16 at a college or university may use the title "audiologist" but may not  
17 practice audiology or supervise an audiologist aide.

18 Sec. 08.11.150. PROCEDURES. The Administrative Procedure Act  
19 (AS 44.62) applies to regulations and proceedings under this chapter.

20 Sec. 08.11.200. DEFINITIONS. In this chapter, unless the con-  
21 text indicates otherwise,

22 (1) "audiologist" means an individual who is licensed under  
23 AS 08.11.010 to practice audiology in the state;

24 (2) "audiologist aide" means an individual who is licensed  
25 under AS 08.11.020 to practice audiology in the state under the direct  
26 supervision of an audiologist;

27 (3) "dealing in hearing aids" has the meaning given in  
28 AS 08.55.200;

29 (4) "department" means the Department of Commerce and

1 Economic Development;

2 (5) "hearing aid" has the meaning given in AS 08.55.200;

3 (6) "practice of audiology" means the application of prin-  
4 ciples, methods, and procedures of measurement, testing, appraisal,  
5 prediction, consultation, habilitation, rehabilitation, counseling and  
6 instruction related to hearing and hearing impairment for the purpose  
7 of modifying communicative disorders involving speech, language,  
8 auditory function, including auditory training, speech reading and the  
9 recommendation, evaluation, fitting, and sale of hearing aids, includ-  
10 ing the fitting of ear molds.

11 \* Sec. 8. AS 08 is amended by adding a new chapter to read:

12 CHAPTER 55. HEARING AID DEALERS.

13 Sec. 08.55.010. QUALIFICATIONS FOR LICENSE. (a) The department  
14 shall issue a license to act as a hearing aid dealer to an individual  
15 who

16 (1) is 18 years of age or older;

17 (2) applies on a form provided by the department;

18 (3) has a high school diploma or the equivalent;

19 (4) has good moral character;

20 (5) has a business license issued under AS 43.70.020;

21 (6) furnishes evidence satisfactory to the department that  
22 the individual has not engaged in conduct that is a ground for impos-  
23 ing disciplinary sanctions under AS 08.55.130;

24 (7) submits with the application a statement disclosing  
25 whether the applicant

26 (A) has, during the five-year period immediately  
27 preceding the date of the application been convicted of a felony,  
28 or had a final judgment entered against the applicant in a civil  
29 action, if the felony or civil action involved fraud,

1           embezzlement, or misappropriation of property;

2           (B) is subject to an injunctive order that is current-  
3 ly in effect from a pending proceeding or action brought by a  
4 public agency;

5           (C) is a defendant in a pending criminal or civil  
6 action relating to fraud, embezzlement, misappropriation of  
7 property, or the antitrust or trade regulation laws of the United  
8 States or a state;

9           (D) has, during the five-year period immediately  
10 preceding the date of the application, been reorganized, had a  
11 debt adjustment, or has been adjudicated a bankrupt under bank-  
12 ruptcy proceedings due to insolvency or was a principal executive  
13 officer or general partner of a business that has been reor-  
14 ganized, had a debt adjustment, or has been adjudicated a bank-  
15 rupt due to insolvency during the five-year period;

16           (8) furnishes a description of each item in (7) of this  
17 subsection that the applicant disclosed as being applicable to the  
18 applicant;

19           (9) furnishes an irrevocable consent to service of process  
20 authorizing the department to be served a notice, process, or pleading  
21 in an action or proceeding against the applicant arising out of a  
22 violation of this chapter; service on the department confers personal  
23 jurisdiction over the applicant in a court of competent jurisdiction.

24           (b) A person who is licensed as an audiologist under AS 08.11  
25 may deal in hearing aids without being licensed under this chapter,  
26 but shall comply with AS 08.55.050 - 08.55.070, 08.55.100 - 08.55.110,  
27 and 08.55.130(7) - (13) when dealing in hearing aids.

28           (c) If an individual licensed under this chapter has more than  
29 one place of business, the department shall, on request and payment of

1 a fee, issue a duplicate license for each place of business of the  
2 individual.

3 Sec. 08.55.030. DURATION AND RENEWAL OF LICENSE. (a) A license  
4 to act as a hearing aid dealer is valid for one year and is subject to  
5 renewal.

6 (b) On or before the expiration of one year after the issuance  
7 of a license under this chapter, a licensee may apply for renewal of  
8 the license, and the department shall renew the license if the li-  
9 censee pays the renewal fee and provides evidence satisfactory to the  
10 department that the individual has not engaged in conduct that is a  
11 ground for imposing disciplinary sanctions under AS 08.55.130.

12 (c) If a licensee fails to renew a license under (b) of this  
13 section, the license lapses.

14 (d) The department may reinstate a lapsed license under (b) of  
15 this section if the license has not lapsed for more than two years and  
16 if the person pays a delinquency fee in addition to the renewal fee.

17 Sec. 08.55.040. FEES. The department shall set fees under  
18 AS 08.01.065 for each of the following:

- 19 (1) application;  
20 (2) hearing aid dealer license;  
21 (3) renewal of license;  
22 (4) renewal delinquency;  
23 (5) duplicate license.

24 Sec. 08.55.050. ITEMS TO BE PROVIDED BY HEARING AID DEALER. (a)  
25 A hearing aid dealer shall give the following items to a consumer at  
26 the time the consumer contracts with the hearing aid dealer to buy or  
27 lease a hearing aid:

28 (1) an instructional brochure that contains operating  
29 instructions, purchase privileges, and performance data for the

1 hearing aid;

2 (2) a statement of the registration number, manufacturer's  
3 specifications, make, model, and serial number for the hearing aid;

4 (3) a clear statement of the full terms of the contract;  
5 and

6 (4) a written statement indicating that the consumer may  
7 file a written complaint about a hearing aid or a hearing aid dealer  
8 with the department and giving the mailing address and location ad-  
9 dress of the department.

10 (b) Before the sale of a used hearing aid, the hearing aid  
11 dealer shall clearly mark the receipt and the container for the hear-  
12 ing aid as "used" or "reconditioned," whichever is applicable, and  
13 with the terms of a guarantee that the dealer provides.

14 Sec. 08.55.060. MEDICAL EVALUATION. (a) A hearing aid dealer  
15 may not sell or lease a hearing aid unless the prospective user of the  
16 hearing aid presents to the hearing aid dealer a written statement  
17 signed by a physician licensed under AS 08.64 stating that the physi-  
18 cian has medically evaluated the prospective user's hearing loss and  
19 that the prospective user is a candidate for a hearing aid.

20 (b) The medical exam on which the physician bases the statement  
21 required in (a) of this section must have occurred within the six  
22 months immediately preceding the date when the prospective user pre-  
23 sents the statement to the hearing aid dispenser.

24 (c) If the prospective user is 18 years of age or older, the  
25 hearing aid dealer may afford the prospective user an opportunity to  
26 waive the medical evaluation in writing if the hearing aid dealer

27 (1) informs the prospective user that the exercise of the  
28 waiver is not in the best interest of the prospective user's health;

29 (2) does not actively encourage the prospective user to

1 waive the medical evaluation; and

2 (3) affords the prospective user the opportunity to sign  
3 the following statement:

4 I have been advised by (HEARING AID DEALER'S  
5 NAME) that the State of Alaska has determined  
6 that my best interest would be served if I  
7 had a medical evaluation by a licensed physi-  
8 cian (preferably a physician who specializes  
9 in diseases of the ear) before purchasing or  
10 leasing a hearing aid.

11 \_\_\_\_\_  
12 (PROSPECTIVE USER'S SIGNATURE)

13 (d) The hearing aid dealer shall retain the medical evaluation  
14 statement or the prospective user's signed statement for four years  
15 after the date of the sale of the hearing aid.

16 Sec. 08.55.070. TRANSMITTAL OF HEARING AID BY MAIL. If a hear-  
17 ing aid dealer mails a hearing aid to a customer, the dealer shall  
18 send the hearing aid by certified mail.

19 Sec. 08.55.080. COMPLAINTS. (a) A person may file a complaint  
20 with the department about a hearing aid or a hearing aid dealer within  
21 three years from the date of the cause of the complaint.

22 (b) A hearing aid dealer shall prominently display in the busi-  
23 ness establishment of the dealer a sign indicating that a person may  
24 file a complaint with the department about a hearing aid or a hearing  
25 aid dealer and giving the mailing and location address of the depart-  
26 ment.

27 Sec. 08.55.090. INSURANCE REQUIREMENTS. A hearing aid dealer  
28 shall maintain liability insurance for dealing in hearing aids in an  
29 amount that the department determines by regulation to be appropriate.

1           Sec. 08.55.100. CALIBRATION REQUIREMENTS. A hearing aid dealer  
2 shall maintain in conformity with the standards set by the American  
3 Nationa' Standard Institute the calibration of each audiometer used by  
4 the hearing aid dispenser.

5           Sec. 08.55.110. CANCELLATION OPTION. (a) In addition to the  
6 cancellation allowed under AS 45.02.350, a person who has purchased or  
7 leased a hearing aid from a hearing aid dealer may cancel the sale or  
8 lease as provided under (b) of this section or by giving written  
9 notice of the intention to cancel the sale or lease to the dealer not  
10 later than 30 days following the later of (1) the date the person  
11 receives the hearing aid, or (2) the date the hearing aid dealer  
12 provides the person with the notice under (c) of this section. The  
13 person may use the notice received under (c) of this section to cancel  
14 the sale or lease by signing the form where indicated.

15           (b) In addition to the other rights and remedies the purchaser  
16 or lessee of a hearing aid may have, the purchaser or lessee of a  
17 hearing aid has the right to cancel the sale or lease by giving writ-  
18 ten notice of the cancellation to the hearing aid dealer if

19                   (1) a physician licensed under AS 08.64 specializing in  
20 diseases of the ear or an audiologist licensed under AS 08.11 advises  
21 the person to cancel the sale or lease and specifies in writing the  
22 medical or audiological reason for the advice; or

23                   (2) the hearing aid dealer has violated a provision of this  
24 chapter in the sale or lease of the hearing aid to the person.

25           (c) A hearing aid dealer shall give a person who has purchased  
26 or leased a hearing aid from the dealer notice of the right to cancel  
27 the purchase or lease that is substantially identical to the following  
28 form with all of the information filled in except the signature and  
29 date lines for the purchaser or lessee:

1 NOTICE OF RIGHT TO CANCEL

2 \_\_\_\_\_  
3 Name of Hearing Aid Dealer

4 \_\_\_\_\_  
5 Address of Hearing Aid Dealer

6 \_\_\_\_\_  
7 Date of Sale or Lease

8 You may cancel this transaction, without  
9 penalty or obligation, within 30 days from the  
10 date you receive the hearing aid or this notice,  
11 whichever is later.

12 If you cancel this transaction, the property  
13 you traded in, the payments you made under the  
14 sale or lease (less certain costs allowed by state  
15 law) and any negotiable instrument executed by you  
16 will be returned within 10 business days following  
17 receipt by the hearing aid dealer of your cancel-  
18 lation notice, and the hearing aid dealer will  
19 cancel any security interest arising out of the  
20 sale or lease.

21 If you cancel, you must make available to the  
22 hearing aid dealer, in as good a condition as when  
23 received, less normal wear and tear, the goods  
24 delivered to you under this sale or lease, unless  
25 the dealer notifies you to keep the goods or to  
26 hold them until the dealer collects them.

27 If you make the goods available for the  
28 hearing aid dealer to collect after your cancella-  
29 tion, and the hearing aid dealer does not collect

1 them from you within 20 days of your cancellation,  
2 you may retain or dispose of the goods without  
3 further obligation to the hearing aid dealer. If  
4 you fail to make the goods available for the  
5 hearing aid dealer to collect after your cancel-  
6 lation, then the sale or lease is not cancelled  
7 and you remain liable for performance of the  
8 obligations of the sale or lease.

9 To cancel this transaction, mail (by cer-  
10 tified mail, return receipt request) or deliver a  
11 signed and dated copy of this notice or another  
12 written notice to (name of hearing aid dealer), at  
13 (address of hearing aid dealer's place of busi-  
14 ness) and (hearing aid dealer's telephone number)  
15 no later than midnight of (Date).

16 I hereby cancel this transaction.

17 (Date) \_\_\_\_\_  
18 \_\_\_\_\_

19 (Purchaser's or Lessee's signature)

20 I have read and understand the terms of  
21 cancellation of this purchase/lease.  
22

23 \_\_\_\_\_  
Purchaser's or Lessee's signature

24 \_\_\_\_\_  
25 Date

26 (d) If a purchaser or lessee of a hearing aid cancels the pur-  
27 chase or lease under (a) or (b) of this section, the hearing aid  
28 dealer shall and within 10 days of receipt of a notice of the cancel-  
29 lation

1 (1) refund to the purchaser or lessee all deposits, in-  
2 cluding the downpayment, less (A) 10 percent of the total purchase  
3 price for each 30 days that the purchaser or lessee had the hearing  
4 aid, to pay for the reasonable rental value of the hearing aid; (B)  
5 the reasonable price of ear molds or custom casings prepared for the  
6 purchaser or lessee; and (C) the reasonable costs actually incurred by  
7 the hearing aid dealer to make goods that were traded in by the pur-  
8 chaser or lessee ready for sale; the hearing aid dealer may retain the  
9 money allowed under this paragraph only up to the amount of a down-  
10 payment made by the purchaser or lessee;

11 (2) return to the purchaser or lessee all goods traded in  
12 to the hearing aid dealer as part of the sale or lease;

13 (3) return to the purchaser or lessee a negotiable instru-  
14 ment signed by the purchaser or lessee; and

15 (4) cancel a security interest taken by the hearing aid  
16 dealer for the purchase or lease.

17 (e) If a hearing aid dealer fails to collect the hearing aid  
18 from the consumer within 20 days of receipt of the cancellation, the  
19 purchaser or lessee may retain or dispose of the hearing aid without  
20 further obligation to the dealer.

21 (f) If a purchaser or lessee of a hearing aid fails to make the  
22 hearing aid available for the hearing aid dealer to collect, the  
23 purchaser or lessee remains liable for the purchase or lease.

24 (g) To give written notice under this section, a person shall  
25 deliver the notice to the hearing aid dealer in person or to the place  
26 of business of the dealer, or mail the notice to the place of business  
27 of the dealer by certified mail, return receipt requested.

28 Sec. 08.55.120. TESTING OF HEARING. (a) A hearing aid dealer  
29 may take threshold measurements to determine the degree of hearing

1 impairment of a person, but may not test or use the threshold mea-  
2 surements to determine the cause of a hearing impairment or charge a  
3 fee for taking the threshold measurements test.

4 (b) A hearing aid dealer shall include in every advertisement  
5 for the services of the dealer the following statement bordered in  
6 black:

7 Alaska law permits a hearing aid dealer to test hearing  
8 only for the purpose of selling or leasing hearing aids;  
9 the tests given by a hearing aid dealer are not to be  
10 used to diagnose the cause of a hearing impairment.

11 Sec. 08.55.130. GROUNDS FOR IMPOSITION OF DISCIPLINARY SANC-  
12 TIONS. After a hearing, the department may impose a disciplinary  
13 sanction on an individual licensed under this chapter when the depart-  
14 ment finds that the person

15 (1) secured a license through deceit, fraud, or intentional  
16 misrepresentation;

17 (2) engaged in deceit, fraud, or intentional misrepresenta-  
18 tion in the course of providing professional services or engaging in  
19 professional activities;

20 (3) advertised professional services in a false or mislead-  
21 ing manner;

22 (4) has been convicted of a felony or other crime that  
23 affects the individual's ability to continue to practice competently  
24 and safely;

25 (5) failed to comply with a provision of this chapter or a  
26 regulation adopted under this chapter, or an order of the department;

27 (6) continued to practice after becoming unfit due to

28 (A) professional incompetence;

29 (B) addiction to or severe dependency on alcohol or

1 another drug that impairs the individual's ability to prac-  
2 tice safely;

3 (C) physical or mental disability;

4 (7) employed a person who did not have a valid current  
5 license to deal in hearing aids to perform work covered by this chap-  
6 ter;

7 (8) failed or refused to honor a representation, promise,  
8 agreement or warranty made by the person while dealing in hearin'  
9 aids;

10 (9) advertised a model, type, or kind of hearing aid for  
11 sale that the person does not sell;

12 (10) failed to maintain a business address and telephone  
13 number at which the individual could normally be reached during regu-  
14 lar business hours;

15 (11) included in a contract or receipt for the purchase or  
16 lease of a hearing aid a confession of judgment or a waiver of a right  
17 of the consumer under this chapter;

18 (12) used undue influence, coercion, or other wilful act or  
19 representation to interfere with the exercise by the consumer of the  
20 rights provided in this chapter;

21 (13) negotiated, transferred, sold, or assigned a note or  
22 other evidence of indebtedness to a finance company or other third  
23 party within two months of delivering a hearing aid to a purchaser or  
24 lessee of the hearing aid by mail or in person;

25 (14) permitted another person to use the licensee's license;

26 (15) dealt in hearing aids while suffering from a serious  
27 disease that was contagious or infectious.

28 Sec. 08.55.140. DISCIPLINARY SANCTIONS. (a) When it finds that  
29 a licensee has committed an act listed in AS 08.55.130, the department

1 may impose the following sanctions singly or in combination:

- 2 (1) permanently revoke a license to practice;
- 3 (2) suspend a license for a determinate period of time;
- 4 (3) censure a licensee;
- 5 (4) issue a letter of reprimand;
- 6 (5) place a licensee on probationary status and require the

7 licensee to

- 8 (A) report regularly to the department on 5  
9 involving the basis of probation;
- 10 (B) limit practice to those areas prescribed;
- 11 (C) continue professional education until a satisfac-  
12 tory degree of skill has been attained in those areas determined  
13 by the department to need improvement;

14 (6) impose limitations or conditions on the practice of a  
15 licensee.

16 (b) The department may withdraw a limitation, condition, or  
17 probationary status if it finds that the deficiency that required the  
18 sanction has been remedied.

19 (c) The department may summarily suspend a license before final  
20 hearing or during the appeals process if the department finds that the  
21 licensee poses a clear and immediate danger to the public welfare and  
22 safety if the licensee continues to practice. A person whose license  
23 is suspended under this subsection is entitled to a hearing by the de-  
24 partment no later than seven days after the effective date of the  
25 order. The person may appeal the suspension after the hearing to the  
26 superior court.

27 (d) The department may reinstate a license that has been sus-  
28 pended or revoked if the department finds after a hearing that the  
29 applicant is able to deal in hearing aids with reasonable skill and

1 safety.

2 Sec. 08.55.150. PROHIBITED ACTS. (a) Unless a person is li-  
3 censed under this chapter or AS 08.11, the person may not

4 (1) deal in hearing aids;

5 (2) use a title indicating or representing that the person  
6 deals in hearing aids or is licensed to deal in hearing aids;

7 (3) advertise that the person deals in hearing aids.

8 (b) A person may not

9 (1) sell, barter, or offer to sell or barter a license  
10 issued under this chapter;

11 (2) purchase or obtain by barter a license issued under  
12 this chapter with the intent to use it as evidence of the holder's  
13 qualification to deal in hearing aids;

14 (3) materially alter a license issued under this chapter  
15 with fraudulent intent;

16 (4) use or attempt to use as valid a license to deal in  
17 hearing aids that has been purchased, fraudulently obtained, counter-  
18 feited, or materially altered.

19 Sec. 08.55.160. PENALTY. A person who violates AS 08.55.150 is  
20 guilty of a class B misdemeanor.

21 Sec. 08.55.170. NOTICE OF PLACE OF BUSINESS. A person who holds  
22 a license under this chapter shall notify the department in writing of  
23 the regular address of the place or places where the person deals or  
24 intends to deal in hearing aids.

25 Sec. 08.55.180. PROCEDURES. The Administrative Procedure Act  
26 (AS 44.62) applies to regulations and proceedings under this chapter.

27 Sec. 08.55.200. DEFINITIONS. In this chapter

28 (1) "dealing in hearing aids" means the sale or lease, or  
29 attempted sale or lease of hearing aids, and the recommendation,

1 selection, fitting, or adaptation of hearing aids;

2 (2) "department" means the Department of Commerce and  
3 Economic Development;

4 (3) "hearing aid" means a prosthetic instrument or device  
5 designed for or represented as aiding, improving, or correcting defec-  
6 tive human hearing and the parts, attachments, or accessories of the  
7 instrument or device; "hearing aid" does not include cochlear im-  
8 plants, middle-ear implants, vibro-tactile speech-reading aids, other  
9 aids for cued speech, or group or individual auditory training units  
10 and assistive devices;

11 (4) "hearing aid dealer" means an individual licensed under  
12 AS 08.55.010.

13 \* Sec. 9. AS 09.55.560(1) is amended to read:

14 (1) "health care provider" means an audiologist and an  
15 audiologist aide licensed under AS 08.11; a chiropractor licensed  
16 under AS 08.20; a dental hygienist licensed under AS 08.32; a dentist  
17 licensed under AS 08.36; a nurse licensed under AS 08.68; a dispensing  
18 optician licensed under AS 08.71; an optometrist licensed under  
19 AS 08.72; a pharmacist licensed under AS 08.80; a physical therapist  
20 licensed under AS 08.84; a physician licensed under AS 08.64; a podia-  
21 trist; a psychologist and a psychological associate licensed under  
22 AS 08.86; and a hospital as defined in AS 18.20.130, including a  
23 governmentally owned or operated hospital; a corporate entity covered  
24 under AS 21.88.050(b)(12); and an employee of a health care provider  
25 acting within the course and scope of employment;

26 \* Sec. 10. AS 21.88.900(a)(9) is amended to read:

27 (9) "health care provider" means an audiologist and an  
28 audiologist aide licensed under AS 08.11; a chiropractor licensed  
29 under AS 08.20; a dental hygienist licensed under AS 08.32; a dentist

1 licensed under AS 08.36; a nurse licensed under AS 08.68; a dispensing  
2 optician licensed under AS 08.71; an optometrist licensed under  
3 AS 08.72; a pharmacist licensed under AS 08.80; a physical therapist  
4 licensed under AS 08.84; a physician licensed under AS 08.64; a podia-  
5 trist; a psychologist and a psychological associate licensed under  
6 AS 08.86; a hospital as defined in AS 18.20.130, including a govern-  
7 mentally owned or operated hospital; a corporate entity covered under  
8 AS 21.88.050(b)(11); an employee of a health care provider acting  
9 within the course and scope of employment;

10 \* Sec. 11. AS 44.62.330(a) is amended by adding new paragraphs to read:

11 (53) Department of Commerce and Economic Development con-  
12 cerning the licensing and regulation of audiologists and audiologist  
13 aides (AS 08.11);

14 (54) Department of Commerce and Economic Development con-  
15 cerning the licensing and regulation of hearing aid dealers (AS 08.-  
16 55).

17 \* Sec. 12. AS 45.50.471(b) is amended by adding a new paragraph to  
18 read:

19 (26) dealing in hearing aids and failing to comply with  
20 AS 08.55.

21 \* Sec. 13. AS 45.50.561 is amended by adding new paragraphs to read:

22 (10) "dealing in hearing aids" has the meaning given in  
23 AS 08.55.200;

24 (11) "hearing aid" has the meaning given in AS 08.55.200.

25 \* Sec. 14. AS 47.17.070(9) is amended to read:

26 (9) "practitioner of the healing arts" includes chiroprac-  
27 tors, hygienists, dentists, health aides, nurses, nurse practi-  
28 tioners, optometrists, osteopaths, physical therapists, physicians,  
29 physician's assistants, psychiatrists, psychologists, psychological

1 associates, audiologists and audiologist aides licensed under AS 08.-  
2 11, hearing aid dealers licensed under AS 08.55, religious healing  
3 practitioners, and surgeons;  
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CS FOR HB 430 (LABOR & COMMERCE)  
SECTIONAL ANALYSIS

Section 1 states the legislative findings and purpose of the bill.

Section 2 adds audiologists and hearing aid dealers to the centralized licensing chapter.

Section 3 adds audiologists and hearing aid dealers to those others provided with services by the department, without requiring a board or commission.

Section 4 adds audiologists and hearing aid dealers to those subject to regulation, investigation and enforcement procedures required by the department.

Section 5 redefines "license" and "occupation" to include trades or professions listed in the amended centralized licensing chapter that are not covered by a board or commission.

Section 6 adds audiologists to the professional designation requirements.

Section 7 adds the following sections to the chapter:

08.11.010 provides for qualifications for licensing of professional audiologists.

08.11.020 addresses temporary license to practice audiology.

08.11.030 provides for duration and renewal of licenses.

08.11.040 provides for display of current license.

08.11.050 empowers the department to set fees for licensing.

08.11.060 requires malpractice insurance for audiologists.

08.11.070 allows audiologists to fit and sell hearing aids.

08.11.080 define grounds for disciplinary actions against audiologists.

08.11.090 lists disciplinary sanctions.

08 11.100 lists prohibited acts.

08.11.110 makes violations of prohibited acts a class B misdemeanor (actual penalties defined elsewhere).

08.11.120 provides for exemptions under this chapter; prevents those individuals who may be exempt, but who are not audiologists, from holding forth as an audiologist.

08.11.130 states the Administrative Procedure Act applies to regulations under this chapter.

08.11.200 is the definition section for this chapter.

Section 8 adds a new chapter to AS 08, addressing hearing aid dealers. The following sections are within this chapter:

08.55.010 provides for qualifications for license.

08.55.020 provides for duration and renewal of license.

08.55.030 requires bonding of hearing aid dealers.

08.55.040 empowers the department to set fees.

08.55.050 requires a hearing aid dealer, when entering a contract with a consumer for the purchase or lease of a hearing aid, to provide the consumer with an instructional brochure; the dealer's registration number, specifications, make, model and serial number of the hearing aid; a clear statement of the full terms of the contract; written information on the consumer's right to file a complaint, including the address of the department;

also requires that any used or reconditioned hearing aid be clearly labeled as such, and what guarantee may be offered.

08.55.060 requires a medical evaluation prior to the sale or lease of a hearing aid; allows the consumer, if 18 years of age or older, to waive the medical evaluation by signing a statement; provides language for the evaluation waiver statement form; requires the hearing aid dealer to retain statement or medical evaluation for four years after sale date of hearing aid.

08.55.070 provides method of mailing hearing aids to consumer.

08.55.080 provides the consumer may file a complaint with the department within three years of purchase date; requires dealer to post notice of consumer's right to file complaint.

08.55.090 requires liability insurance for hearing aid dealers; empowers department to set insurance requirements.

08.55.100 requires hearing aid dealers keep audiometers calibrated to national standards.

08.55.110 provides dealer will inform consumer of consumer's right to cancel purchase or lease of hearing aid; lists valid reasons for cancellation; provides facsimile of "notice of right to cancel" form hearing aid dealer must provide, form provides for terms of cancellation; provides for refund of purchase price less reasonable costs incurred by dealer; return of goods traded as part of sale or lease, return of negotiable instruments signed by the purchaser as part of sale or lease, cancellation of security interest taken by dealer as part of sale or lease; requires a dealer to collect a hearing aid from the consumer within 20 days of receipt of the cancellation or else consumer can retain possession; requires consumer make hearing aid available for dealer to collect, or else cancellation is void; provides notice of cancellation requirements.

08.55.120 restricts type of hearing testing allowed by hearing aid dealers; requires all dealers to specify, in their advertising, what type of hearing testing they are allowed to perform.

08.55.130 lists grounds for disciplinary sanctions.

08.55.140 lists disciplinary sanctions the department may impose.

08.55.150 lists prohibited acts.

08.55.160 makes violation of prohibited acts a class B misdemeanor.

08.55.170 requires a hearing aid dealer to notify the department of the address of their regular place of business.

08.55.180 states the Administrative Procedure act applies to this chapter.

08.55,200 is the definition section for this chapter.

Section 9 adds audiologists to the definition of "health care provider" under AS 09.55.560.

Section 10 adds audiologists to the definition of "health care provider" under AS 21.88.900.

Section 11 adds audiologists to AS 44.62.330(a), application of procedure by boards, commissions & officers.

Section 12 adds failure to comply with AS. 08.55 to AS 45.50.471(b), the unlawful acts and practices section of Trade & Commerce.

Section 13 adds "dealing in hearing aids" and "hearing aid" to the AS 45.50.561, the definitions section of Trade and Commerce.

Section 14 adds "audiologists and audiologist aides" and "hearing aid dealers" to AS 47.17.090(9) as "practitioners of the healing arts".



# RECORDS CERTIFICATION



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James O. Smith  
Signature of Camera Operator

9/5/89  
Date