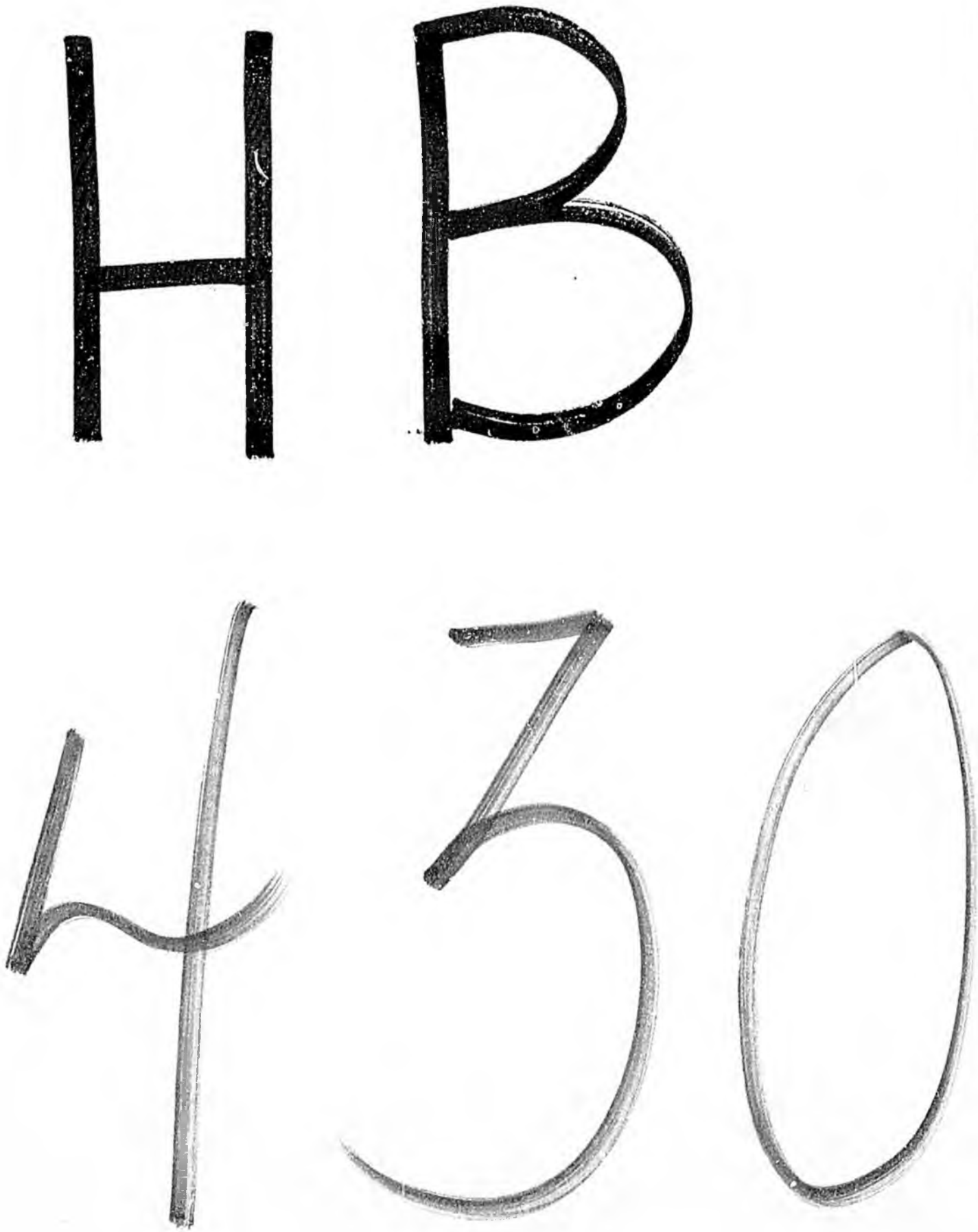
HB
430

STATE OF ALASKA 1986 LEGISLATIVE SESSION
FISCAL NOTE

Revision Date: 4/23/86

REQUEST

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

FISCAL DETAIL

Agency Affected: Commerce & Economic 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						
MISCELLANEOUS						
TOTAL OPERATING		-0-	-0-	-0-	-0-	-0-
CAPITAL						
REVENUE		1.8	1.1	1.3	2.0	1.6

FUNDING: (Thousands of dollars)

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

POSITIONS:

FULL-TIME		-0-	-0-	-0-	-0-	-0-
PART-TIME						
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 Protection in the

Prepared by: Jennifer Strickler, Management Analyst Phone: 465-2144
Division: Occupational Licensing Date: 4/23/86

Approved by Commissioner: Loren D. Lounsbury Date: 4/28/86
Agency: Commerce and Economic Development

Distribution (by Agency preparing fiscal note):
- Legislative Finance
- Legislative Sponsor
- Requestor
- Office of Management and Budget
- Impacted Agency(ies)

10/25/85

CONTINUATION of FISCAL NOTE ANALYSIS

For Bill/Resolution No. CSHB 430 (HESS)

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 $1.4 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 consists largely of personal services costs which would be absorbed by the division through funding already included in the agency's operating budget. The fiscal note will be zero.

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. These fees are still estimates at this time.

Revenues were estimated on the following fee schedule:

Application/Credentials Review fee	$20
Temporary Permit fee	$25
Audiologists License/Renewal fee	$50 - quadrennially
Hearing Aid Dealers License/Renewal	$80 - 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 91. A detailed description follows:

FY 87:

		Distribution across quadrennial renewal:
12 Audiologists seeking licensure ($50 x 12) =	$ .6	
10 Hearing Aid Dealers ($80 x 10) =	.8	
22 Application/Credentials Review ($20 x 22) =	.4	
	$ 1.8	$ 1.8
		- 1.4 costs
		$ .4 balance

FY 88:

Assuming there will be two new applicants seeking Audiology Temporary Permits ($25 x 2)	$ .05	
2 new Hearing Aid Dealers:		
Application/Credentials Review Fee ($20 x 2)	.04	
Hearing Aid Dealers License ($80 x 2)	.2	
10 Hearing Aid Dealers renewing ($80 x 10)	.8	
	$ 1.1	$ .4
		+ 1.1
		$ 1.5
		- 1.4 costs
		$ .1 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 ($25 x 2)	$ .05	
2 new Hearing Aid Dealers:		
Application/Credentials Review Fee ($20 x 2)	.04	
Hearing Aid Dealers License ($80 x 2)	.2	
12 Hearing Aid Dealers renewing ($80 x 12)	1.0	
	$ 1.3	$ .1 balance forward
		+ 1.3
		$ 1.4
		- 1.4 costs
		$ Ø balance

FY 90:

Assuming there will be two new applicants seeking Audiology Temporary Permits ($25 x 2)	$ .05	
2 new Hearing Aid Dealers:		
Application/Credentials Review Fee ($20 x 2)	.04	
Hearing Aid Dealers License ($80 x 2)	.2	
12 Audiologists renewing ($50 x 12)	.6	
14 Hearing Aid Dealers renewing ($80 x 14)	1.1	
	$ 2.0	$.Ø
		+ 2.0
		$ 2.0
		- 1.4 costs
		$ .6 balance

FY 91:

Assuming there will be one new applicant seeking licensure as an Audiologist ($50 x 1)	$ .05	
2 new Hearing Aid Dealers ($80 x 2)	.2	
3 paying Application/Credentials Review ($20 x 3)	.06	
16 Hearing Aid Dealers renewing ($80 x 16)	1.3	
	$ 1.6	$ .6
		+ 1.6
		$ 2.2
		- 1.4 costs
		$ .8 balance

NOTE:

The revision in this fiscal note from the previous version is in the total estimated annual costs to administer the function. The original estimate was based on $4.5 annually. As a result of adjusting costs in relation to the number of licensees, this revised fiscal note is based on $1.4 annual expenditures.

HOUSE COMMITTEE REPORT

(7)

Date referred: 3/1/86

FURTHER REFERRALS: FINANCE

DATE: March 18, 1986

The HEALTH, EDUCATION AND SOCIAL SERVICES Committee has considered HB 430

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

and recommends:

[ ] do pass

[ ] do not pass

[ ] do pass with attached amendment(s)

[X] no recommendation

[√] replace with CS HB 430 (HESS) [√] same title

[ ] new title

and recommends do pass

[ ] further referral to the _____ _____ Committee

and attaches:
[ ] letter of intent
[ ] first fiscal note
[ ] new fiscal note
[ ] zero fiscal note

SIGNING DO PASS:

Edwin L. Taylor V.C.

Katie Hensley

Mary Lynn Byrd

David W. Thompson

Wayne Hensley

Willie E. Kopman

SIGNING OTHER RECOMMENDATIONS:

Bettye Fossett no rec

Chairman: Mary Lynn Byrd

Willie E. Kopman

From Rep. Navarre

3/17/86

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.

STATE OF ALASKA 1986 LEGISLATIVE SESSION
FISCAL NOTE

Revision Date: _____

REQUEST Page 1 of 2

Bill/Resolution No.: CSHB 430 (L&C)
Title: Regulating Audiologists, hearing aid dealers and dispensing of hearing aids
Sponsor: House Labor & Commerce
Requester: _____
Date of Request: _____

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						
GRANTS, CLAIMS						
MISCELLANEOUS						
TOTAL OPERATING		-0-	-0-	-0-	-0-	-0-
CAPITAL						
REVENUE		***				

FUNDING: (Thousands of dollars)

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

POSITIONS:

FULL-TIME		0	0	0	0	0
PART-TIME						
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 6-10 ligitimate hearing aid dealers. Apparently, fly-by-night individuals have harmed Alaskan consumers as documented by complaints on file with Consumer Protection in the Department of Law,

Prepared by: Jennifer Strickler, Management Analyst Phone: 465-2144
Division: Occupational Licensing Date: 3-5-86

Approved by Commissioner: _____ Date: _____
Agency: Commerce and Economic Development

Distribution (by Agency preparing fiscal note):
- Legislative Finance
- Legislative Sponsor
- Requestor
- Office of Management and Budget
- Impacted Agency(ies)

10/25/85

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.

***Operating costs to license 22 people would be minimal. Licensing fees would also be established to cover the costs of the licensing function.

From Rep. Navarre

3/17/86

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.

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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.

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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".

REPRESENTATIVE
MIKE NAVARRE

DISTRICT 5A

CHAIR, LABOR & COMMERCE
VICE-CHAIR, STATE AFFAIRS

Alaska State Legislature

House of Representatives

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WHILE IN SESSION
POUCH V
JUNEAU, ALASKA 99811
(907) 465-3893

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 10, delete "10", replace with "20".

Line 28, delete subsection (e) and reword as follows:

(e) The purchaser or lessee may retain or dispose of the hearing aid if within 20 days of receipt of the notice of cancellation, the hearing aid dealer fails

(1) to collect the hearing aid from the consumer or

(2) to provide the consumer with instructions for returning the hearing aid by mail.

more...

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".

FINAL FDA REG.

...Stat. 701, 52 Stat. 1055–1055 as ...ended, 90 Stat. 574 (21 U.S.C. 360k, 371))

Dated: October 5, 1980.

Jere E. Goyan,

Commissioner of Food and Drugs.

[FR Doc. 80-31473 Filed 10-9-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 808

[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 (HFK–70), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7114.

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 16, 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 10 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, also 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.

Jere E. Goyan,

Commissioner of Food and Drugs.

[FR Doc. 80-31379 Filed 10-9-80; 8:45 am]

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21 CFR Part 808

[Docket No. 77N-0333]

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, 6757 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 26, 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 22119). 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 exemptions from preemption for many State requirements, it encourages the States to 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 governments

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 26546), 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 interefere 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 goverment, 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. *Darby*, 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, 66 (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 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 Specialities 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 301(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-impared 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 misevaluation 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 evaulation 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 evaulation 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 suggest that only persons with religious objections should be permitted to w the medical examination. Several comments stated that it is easy for hearing aid dealers, eager to make a sale, to induce the purchaser to wa medical evaluation without violating FDA regulation by actively encour the waiver. Other comments said th hearing aid dealers are widely abus the waiver provision. For instance, t Attorney General of Massachusetts asserted that prospective hearing ai purchasers waive the medical evaluation requirement in 65 percen 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 med evaluation generally agreed with FD that informed adults should have th freedom to waive medical evaluatio One religious group argued that fail to allow waiver of medical evaluatio would violate the rights of its mem Many comments disputed the conte that the waiver provision is being widely abused. One comment point out that most of the waivers identifi a recent New York study were exer by persons who already owned a hearing aid, and that only 6 percent the persons purchasing a hearing aid the first time waive medical evalua This was confirmed by a limited sur in Massachusetts, which showed tha only 8 percent of first-time users of a hearing aid waived the requirement medical evaluation.

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

FDA has not been presented with convincing evidence that the waiver provision is being widely abused by hearing aid dealers. The Attorney General of Massachusetts provided evidence to support its claim that th waiver privilege is being exercised percent of the sales of hearing aids that Commonwealth. FDA undertoo survey of Attorneys General and

...ing aid dealer licensing boards to ...termine whether they were ...experiencing any problems with ...mpliance with the FDA regulation. Of ... States that responded to this ...vey, 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 preemptions 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 26493(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 in storing the hearing aid when it will not be used for an extended period of time.

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

(v) 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.

(vi) 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.

(vii) 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).

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

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

(x) 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.

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

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

(xiii) 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

ot-rhinolaryngologists. 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 (telephone 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 [illegible] 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 of 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 by

_____
(Hearing aid dispenser's name)

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

MEMORANDUM

TO: House Labor & Commerce Committee
Rep. Mike Navarre, Chair
Rep. Mike Davis, Vice-Chair
Rep. Virgina Collins
Rep. Alyce Hanley
Rep. Drue Pearce
Rep. Niilo Koponen

FROM: Patrick Malone
Aide to Rep. Navarre

March 5, 1986

Attached is the latest draft of the proposed CS for HB430. The draft incorporates the changes recommended by the Department of Commerce and Economic Development, Division of Occupational Licensing. The substantive changes are:

The language that required the Department to act as a "middleman" between the audiologist or hearing aid dealer and a claimant has been removed. Occupational licensing felt this language was confusing. In addition, it placed the division in a position that shouldn't be required of them.

Temporary licensure of audiologists- The redundant 5 day temporary licensure language has been removed.

Duration and renewal of Audiologist's licenses: The license is now a 4 year license.

It was decided that "Audiologist Aides" should be removed from the bill. Occupational licensing felt uncomfortable with licensure of possibly unqualified subprofessionals. An audiologist may still have a person working under their direct supervision whose actions would be the audiologist's responsibility, but there is really no need to address these individuals in statute.

For the protection of the hearing aid dealer, the "right to cancel" on the advice of a physician or audiologist is limited to 60 days from receipt of the hearing aid. Previously, there was no time limit on cancellation for this reason.

A $ 5000.00 security or cash bond is now required of hearing aid dealers.

All other changes are not substantial, but merely clarify or clear up amibiguities.

BILL SHEFFIELD, GOVERNOR

DEPARTMENT OF ADMINISTRATION

POUCH C, M.S. 0209
JUNEAU, ALASKA 99811
PHONE: (907) 465-3250

OLDER ALASKANS COMMISSION

February 12, 1986

Representative Navarre
Alaska State Legislature
Pouch V
Juneau, Alaska 99811

Dear Representative Navarre:

The Older Alaskans Commission appreciates your sponsorship of House Bill No. 430 to regulate audiologists, hearing aid dealers and the dispensing of hearing aids. The Commission endorsed protective legislation for consumers of these products and professions last fall. This action was taken due to our personal knowledge of significant problems in this area.

We will inform older Alaskans of the importance of supporting the effort now represented by this bill. Do not hesitate to contact our executive director, Jon Wolfe for any assistance we may provide.

Sincerely,

Peggy Burgin

Peggy Burgin Chair
Older Alaskans Commission

cc: Older Alaskans Commission
Jon Wolfe

02-825LH

Senior Voice OPAG
P.O. Box 102240 • Anchorage, Alaska 99510 • (907) 277-0787

Rebecca J. Goodman
Associate editor, Senior Voice
P.O. Box 211604
Auke Bay, Alaska 99821

Pat Malone
Legislative aide
House of Representatives
Alaska State Legislature
Pouch V (MS 3100)
Juneau, Alaska 99811

Dear Mr. Malone:

I wish Older Persons Action Group could tell you exactly how many older consumers have been victimized by unscrupulous hearing aid dealers in Alaska. Unfortunately, no one knows for certain the extent of the problem. Not many "victims" find it easy to admit that they've been "taken" and not many are willing to admit that they have a hearing problem.

However, what we do know about the problem is this: Nearly a dozen older consumers have contacted Older Persons Action Group offices in Anchorage over the past two years to complain that they lost money (in amounts ranging from $800 to $2,000) to hearing aid salespeople (both "established" businesses and door-to-door salesmen) for worthless aids or non-delivery of aids.

One older woman told us she'd lost more than $1,800 to hearing aid dealer Louis DeLegge of Anchorage, who skipped town with her money and failed to deliver the purchased aid. DeLegge was responsible for a majority of complaints OPAG received last year regarding hearing aid fraud, but DeLegge is by no means the only culprit involved in these scams. It's important to note that without consumer protections in place in Alaska, these abuses could easily happen again and again to consumers. For this reason, Older Persons Action Group supports Rep. Mike Navarre's efforts to bring about strong legislative measures to regulate hearing aid sales practices in the state.

Sincerely,

Rebecca J. Goodman
SENIOR VOICE / OPAG
ph. 364-3874

STATE OF ALASKA

BILL SHEFFIELD, GOVERNOR

REPLY TO
XX 1031 W. 4th, SUITE 110
ANCHORAGE, ALASKA 99501
PHONE (907) 279-0428

1st NATIONAL CENTER
100 CUSHMAN, SUITE 400
FAIRBANKS, ALASKA 99701
PHONE (907) 456-8592

S.S. FULLER BLDG
4th & HARRIS, SUITE 214
POUCH P
JUNEAU, ALASKA 99811
PHONE (907) 465-3692

STATE COURTHOUSE, ROOM 28
P.O. BOX 671
VALDEZ, ALASKA 99686
PHONE (907) 835-2462

DEPARTMENT OF LAW
OFFICE OF ATTORNEY GENERAL
CONSUMER PROTECTION SECTION

September 23, 1985

Department of Health
and Social Services
Communicative Disorders Program
1231 Gambell Street
Anchorage, AK 99501-4627

Attention: Dr. David Canterbury

RE: Hearing and Consumer Complaints

Dear Sir:

Enclosed please find copies of consumer complaints received by our office during fiscal year '85 that involve hearing aids. All of these complaints (except the Wrangell Publishing, Inc. complaint) have been either resolved, or closed/unresolved due to our inability to locate the respondent or elicit his cooperation.

We noticed your article in the August edition of the "Senior Voice", and believe these complaints may support you and your efforts with respect to HB-430. For your information, a major problem is that the businesses are often closed and the owner somewhere out-of-state by the time the complaint reaches our office. Needless to say, this situation interferes with, and sometimes precludes any efforts on our part to resolve these matters. If the complaint involves defective merchandise, we are sometimes able to obtain restitution through the manufacturer. However, if the problem is with a distributer who has accepted partial or full payment for merchandise not delivered, there is little this office can do.

We hope this information is helpful to you. If you have any questions, please feel free to call.

Sincerely,

HAROLD M. BROWN
ATTORNEY GENERAL

By: Duane L. Sipary
Duane L. Sipary
Paralegal Assistant

DLS/np

RECEIVED
Department of Law

JUL 24 1984

CONSUMER COMPLAINT

ATTORNEY GENERAL

Office of the Attorney General
Consumer Protection Section
Anchorage, Alaska

ANCHORAGE		JUNEAU	VALDEZ
1031 W. 4th Suite 110 Anchorage, AK 99501 279-0428	1st National Center 100 Cushman, Ste.400 Fairbanks, AK 99701 456-8588	S.S. Fuller Bldg. 4th & Harris,Ste.214 Pouch K Juneau, AK 99811 465-3692	P. O. Box 671 Valdez, AK 99686 835-2462

I WISH TO FILE A CONSUMER COMPLAINT AGAINST THE PERSON OR COMPANY NAMED IN 7 BELOW. I REALIZE THAT A COPY OF THIS COMPLAINT WILL BE SENT TO THE PERSON OR BUSINESS I HAVE COMPLAINED OF. (PLEASE TYPE OR PRINT)

1. NAME HINES (Last) LLOYD (First) W. (MI)	2. TODAY'S DATE JULY 20, 1984
3. MAILING ADDRESS 4000 BRYN MAWR CT.	CITY ANCHORAGE STATE ALASKA ZIP CODE 99504
4. HOME ADDRESS (If different)	CITY STATE ZIP CODE
5. HOME TELEPHONE NO. 333-7682	6. BUSINESS TELEPHONE NO. 333-9411
7. NAME OF THE PERSON OR COMPANY COMPLAINED ABOUT. CUSTOM HEARING AID CENTER	NAME OF SALESPERSON: THOMAS S. GARCIA
8. COMPANY'S ADDRESS. 3136 NEW SEWARD HIGHWAY	CITY ANCHORAGE STATE ALASKA ZIP CODE 99503
9. COMPANY'S TELEPHONE NO. 274-7330	10. DATE OF TRANSACTION September 6, 1983

11. WERE YOU ATTRACTED TO THE SERVICE OR PRODUCT BY AN ADVERTISEMENT? ☐ YES ☒ NO

12. IF YES, WHEN AND WHERE DID YOU SEE THE ADVERTISEMENT?

13. WAS A WRITTEN CONTRACT SIGNED? ☒ YES ☐ NO

14. HAVE YOU COMPLAINED TO THE INDIVIDUAL OR COMPANY? ☐ YES ☒ NO	15. IF YES, NAME OF PERSON TO WHOM YOU COMPLAINED.
16. HAVE YOU CONTACTED A PRIVATE ATTORNEY? ☐ YES ☒ NO	17. IF YES, NAME OF ATTORNEY.
18. IS THERE A COURT OR ADMINISTRATIVE PROCEEDING PENDING? ☐ YES ☒ NO	19. IF YES, NAME COURT OR AGENCY.

AUTOMOBILE REPAIR ONLY

20. DID YOU REQUEST A SIGNED COPY OF REPAIRS TO BE MADE? ☐ YES ☐ NO DID YOU RECEIVE IT? ☐ YES ☐ NO

DID YOU REQUEST A WRITTEN PRICE ESTIMATE? ☐ YES ☐ NO DID YOU RECEIVE IT? ☐ YES ☐ NO

DID COSTS EXCEED WRITTEN ESTIMATE? ☐ YES ☐ NO

WERE YOU NOTIFIED OF ADDITIONAL COSTS BEFORE WORK WAS DONE? ☐ YES ☐ NO

DID YOU REQUEST THAT REPLACED PARTS BE RETURNED TO YOU? ☐ YES ☐ NO RECEIVED/OR ALLOWED TO INSPECT PARTS? ☐ YES ☐ NO

DID YOU RECEIVE IT? ☐ YES ☐ NO

Please state the year, make, model name and V.I.N. (Vehicle Identification No.) of your auto. (Check your registration papers.)

Year	Make	Model	V.I.N.

I hereby certify that I have read the information contained in this complaint and that all of the information I have given is true and complete to the best of my knowledge, information and belief. I further authorize the Attorney General to use this information as he deems necessary and proper.

Lloyd W. Hines
Signature

On the reverse side of this form
Summarize your complaint. Be brief,
But complete.

HOW TO WRITE YOUR COMPLAINT:

Start at the beginning. Describe all the events in the order they happened.

Put down the names of any witnesses.

Please attach copies of any documents which explain or support your complaint, including the cancelled checks, copies of advertisements, letters, etc.

I HAVE A HEARING LOSS AND I'M WEARING HEARING AIDS, BUT ALWAYS SEARCHING FOR SOMETHING BETTER. THOMAS S. GARCIA, WHO CALLS HIMSELF "CUSTOM HEARING AID CENTER" STATED HIS HEARING AIDS WERE COMPUTERS. AFTER TRYING THEM OUT, I FOUND THEM TO BE VERY INFERIOR TO WHAT I HAD BEEN USING, DUE TO THE FACT THEY DID NOT FILTER OUT BACKGROUND NOISE. I FINALLY RETURNED THESE HEARING AIDS TO HIM.

AFTER SEVERAL CALLS BACK TO HIM, HE COULD NOT TALK ME INTO CONTINUING WITH THEM, SO HE FINALLY AGREED TO PREPARE ANOTHER PAIR. I INFORMED HIM I WAS GOING SOUTH FOR A FEW MONTHS, AND HE AGREED TO SEND THE NEW ONES TO ME. I NEVER RECEIVED THE HEARING AIDS AND UPON RETURN TO ANCHORAGE, APPROXIMATELY MAY 1, 198· MR. GARCIA, OFFICE & ALL WERE GONE AND HE LEFT NO FORWARDING ADDRESS.

I AGREED TO PAY HIM HIS PRICE OF $1300.00, 50% DOWN, CHECK No. 662 DATED SEPTEMBER 6, 1983 FOR $650.00.

I AM NOW DESIROUS OF RECOVERING THE ABOVE PAYMENT, SINCE I HAVE TOTALLY LOST CONFIDENCE IN HIS PROFESSIONAL ABILITY AS WELL AS HIS HONESTY.

WHAT TYPE OF SETTLEMENT DO YOU WISH THIS OFFICE TO ATTEMPT TO OBTAIN?

(Please use additional sheets if necessary)

RECEIVED
Department of Law
AUG 23 1984
Office of the Attorney General
Consumer Protection Section
Anchorage, AK

CONSUMER COMPLAINT

ATTORNEY GENERAL

2C03 85-F85-A-I460

ANCHORAGE	FAIRBANKS	JUNEAU	VALDEZ
1031 W. 4th Avenue	Regional Center	S.S. Fuller Bldg.	P. O. Box 671
Suite 110	Cushman, Ste.400	4th & Harris,Ste.214	Valdez, AK
Anchorage, AK	Fairbanks, AK	Pouch K	99686
99501	99701	Juneau, AK 99811	835-2462
279-0428	456-8588	465-3692	

I WISH TO FILE A CONSUMER COMPLAINT AGAINST THE PERSON OR COMPANY NAMED IN 7 BELOW. I REALIZE THAT A COPY OF THIS COMPLAINT WILL BE SENT TO THE PERSON OR BUSINESS I HAVE COMPLAINED OF. (PLEASE TYPE OR PRINT)

1. NAME (Last) MAHLE (First) PRISCILLA	2. TODAY'S DATE August 23, 1984
3. MAILING ADDRESS 8081 WISTERIA	CITY ANCHORAGE STATE AK ZIP CODE 99504
4. HOME ADDRESS (if different) SAME	CITY STATE ZIP CODE
5. HOME TELEPHONE NO. (907) 243-6667	6. BUSINESS TELEPHONE NO.
7. NAME OF THE PERSON OR COMPANY COMPLAINED ABOUT Custom Hearing Center	NAME OF SALESPERSON: Thomas Garcia
8. COMPANY'S ADDRESS 3136 New Seward Hiway	CITY Anchorage STATE AK ZIP CODE 99502
9. COMPANY'S TELEPHONE NO. (907) 274-7330	10. DATE OF TRANSACTION

11. WERE YOU ATTRACTED TO THE SERVICE OR PRODUCT BY AN ADVERTISEMENT? ☒ YES ☐ NO

12. IF YES, WHEN AND WHERE DID YOU SEE THE ADVERTISEMENT?

LOCAL NEWSPAPERS

13. WAS A WRITTEN CONTRACT SIGNED? ☒ YES ☐ NO

14. HAVE YOU COMPLAINED TO THE INDIVIDUAL OR COMPANY? ☒ YES ☐ NO	15. IF YES, NAME OF PERSON TO WHOM YOU COMPLAINED. Thomas Garcia
16. HAVE YOU CONTACTED A PRIVATE ATTORNEY? ☐ YES ☒ NO	17. IF YES, NAME OF ATTORNEY.
18. IS THERE A COURT OR ADMINISTRATIVE PROCEEDING PENDING? ☐ YES ☒ NO	19. IF YES, NAME COURT OR AGENCY.

AUTOMOBILE REPAIR ONLY

20. DID YOU REQUEST A SIGNED COPY OF REPAIRS TO BE MADE?	☐ YES	☐ NO	DID YOU RECEIVE IT?	☐ YES	☐ NO
DID YOU REQUEST A WRITTEN PRICE ESTIMATE?	☐ YES,	☐ NO	DID YOU RECEIVE IT?	☐ YES	☐ NO
DID COSTS EXCEED WRITTEN ESTIMATE?	☐ YES	☐ NO			
WERE YOU NOTIFIED OF ADDITIONAL COSTS BEFORE WORK WAS DONE?	☐ YES	☐ NO			
DID YOU REQUEST THAT REPLACED PARTS BE RETURNED TO YOU?	☐ YES	☐ NO	RECEIVED/OR ALLOWED TO INSPECT PARTS?	☐ YES	☐ NO
			DID YOU RECEIVE IT?	☐ YES	☐ NO

Please state the year, make, model name and V.I.N. (Vehicle Identification No.) of your auto. (Check your registration papers.)

Year	Make	Model	V.I.N.

I hereby certify that I have read the information contained in this complaint and that all of the information I have given is true and complete to the best of my knowledge, information and belief. I further authorize the Attorney General to use this information as he deems necessary and proper.

Priscilla Mahle
Signature

On the reverse side of this form
Summarize your complaint. Be brief,
But complete.

HOW TO WRITE YOUR COMPLAINT:

Start at the beginning. Describe all the events in the order they happened.

Put down the names of any witnesses.

Please attach copies of any documents which explain or support your complaint, including the cancelled checks, copies of advertisements, letters, etc.

I PURCHASED HEARING AID FROM TOM JARCIA AT CUSTOM HEARING FOR $650.00 AFTER A FEW MONTHS IT BEGAN TO FAIL AND FINALLY IT QUIT ALTOGETHER I TRIED CALLING COMPANY BUT WAS TOLD THIS WAS A NON WORKING NUMBER I ALSO WENT BY THEIR SHOP IT WAS VACATED. THIS HEARING AID IS OF NO USE TO ME AS IT DOES NOT WORK AND I CAN NOT GET IT REPAIRED. I WILL BE FORCED TO PURCHASE ANOTHER HEARING AID, SO I WOULD LIKE TO BE REIMBURSED FOR MY $650.00 I PAID FOR DEFECTIVE HEARING AID

WHAT TYPE OF SETTLEMENT DO YOU WISH THIS OFFICE TO ATTEMPT TO OBTAIN?

I WOULD LIKE MY MONEY REFUNDED, I NEED A NEW HEARING AID, AS I CANNOT HEAR WITHOUT IT, AND I HAVE NO MONEY TO PURCHASE ONE.

(Please use additional sheets if necessary)

RECEIVED

Department of L

2/11/85
LP

FEB - 3 1985

CONSUMER COMPLAINT

ATTORNEY GENERAL

cc 0864-85-A-I 46-0

Office of the Attorney General
Consumer Protection Section

ANCHORAGE	FAIRBANKS	JUNEAU	VALDEZ
1031 W. 4th Suite 110 Anchorage, AK 99501 279-0428	1st National Center 100 Cushman, Ste.400 Fairbanks, AK 99701 456-8588	S.S. Fuller Bldg. 4th & Harris, Ste.214 Pouch K Juneau, AK 99811 465-3692	P. O. Box 671 Valdez, AK 99686 835-2462

I WISH TO FILE A CONSUMER COMPLAINT AGAINST THE PERSON OR COMPANY NAMED IN 7 BELOW. I REALIZE THAT A COPY OF THIS COMPLAINT WILL BE SENT TO THE PERSON OR BUSINESS I HAVE COMPLAINED OF. (PLEASE TYPE OR PRINT)

1. NAME Last: YAKASOFF First: Albert M.I.: J.	2. TODAY'S DATE: Feb. 7th 1985
3. MAILING ADDRESS: 4322 East 3rd Ave.	CITY: Anchorage STATE: Ak. ZIP CODE: 99504
4. HOME ADDRESS (If different)	CITY STATE ZIP CODE
5. HOME TELEPHONE NO.: (907) 333-6369	6. BUSINESS TELEPHONE NO.: NONE — Retire
7. NAME OF THE PERSON OR COMPANY COMPLAINED ABOUT: Miracle Ear	NAME OF SALESPERSON: Jack E. Hurd
8. COMPANY'S ADDRESS: 7505 Artic Blvd.	CITY: Anchorage STATE: Ak ZIP CODE: 99503
9. COMPANY'S TELEPHONE NO.: 907) 562-4463	10. DATE OF TRANSACTION: JAN. 8th 1985

11. WERE YOU ATTRACTED TO THE SERVICE OR PRODUCT BY AN ADVERTISEMENT? ☒ YES ☐ NO

12. IF YES, WHEN AND WHERE DID YOU SEE THE ADVERTISEMENT?
ANCHORAGE TIMES NEWS PAPER

13. WAS A WRITTEN CONTRACT SIGNED? ☒ YES ☐ NO

14. HAVE YOU COMPLAINED TO THE INDIVIDUAL OR COMPANY? ☒ YES ☐ NO	15. IF YES, NAME OF PERSON TO WHOM YOU COMPLAINED. JACK HURD — SALESMAN
16. HAVE YOU CONTACTED A PRIVATE ATTORNEY? ☐ YES ☒ NO	17. IF YES, NAME OF ATTORNEY.
18. IS THERE A COURT OR ADMINISTRATIVE PROCEEDING PENDING? ☐ YES ☒ NO	19. IF YES, NAME COURT OR AGENCY.

AUTOMOBILE REPAIR ONLY

20. DID YOU REQUEST A SIGNED COPY OF REPAIRS TO BE MADE?	☐ YES	☒ NO	DID YOU RECEIVE IT?	☐ YES	☒ NO
DID YOU REQUEST A WRITTEN PRICE ESTIMATE?	☒ YES	☐ NO	DID YOU RECEIVE IT?	☒ YES	☐ NO
DID COSTS EXCEED WRITTEN ESTIMATE?	☐ YES	☒ NO			
WERE YOU NOTIFIED OF ADDITIONAL COSTS BEFORE WORK WAS DONE?	☐ YES	☒ NO			
DID YOU REQUEST THAT REPLACED PARTS BE RETURNED TO YOU?	☐ YES	☐ NO	RECEIVED/OR ALLOWED TO INSPECT PARTS?	☐	☐ NO
			DID YOU RECEIVE IT?	☐ YES	☐ NO

Please state the year, make, model name and V.I.N. (Vehicle Identification No.) of your auto. (Check your registration papers.)

Year Make Model V.I.N.

I hereby certify that I have read the information contained in this complaint and that all of the information I have given is true and complete to the best of my knowledge, information and belief. I further authorize the Attorney General to use this information as he deems necessary and proper.

Albert J. Yakasoff
Signature

(over)

On the reverse side of this form
Summarize your complaint. Be brief,
But complete.

HOW TO WRITE YOUR COMPLAINT:

Start at the beginning. Describe all the events in the order they happened.

Put down the names of any witnesses.

Please attach copies of any documents which explain or support your complaint, including the cancelled checks, copies of advertisements, letters, etc.

Order (2) pairs of hearing aid, the salesman: Jack E. Hurd.

two weeks after I order them - Mr Hurd had to come back & take second impress of the canal of my ears.

Then I had to wait another couple weeks for hearing aid. Then I went to Alaska Native Hospital, And I was told that the price [illegible] paying realities too much for them.

So I called Mr Hurd. Asked him to return my down payment. And he said he would. But I would have to wait for my money. this what I do not under-stand. Because I notice they had deposit my check here in Anchorage Bank. I don't see why they can't make out Anchorage Bank check to me.

I gave them $1,000.00 & I expect to get back $800.00 as agreed upon.

Copy are enclosed with this statement.

I was told by Mr. Hurd - I get a check from Company in Minneapolis, Mn.

WHAT TYPE OF SETTLEMENT DO YOU WISH THIS OFFICE TO ATTEMPT TO OBTAIN?

Return of $800.00 as I agreed to in their contract.

(Please use additional sheets if necessary)

RECEIVED

RECEIVED
Department of Law
Office of the Attorney General
Consumer Protection Section
Anchorage, Alaska

JUN 17 1985

CONSUMER COMPLAINT
ATTORNEY GENERAL

2 40

CP14L5-F85-A-I 46.0

ANCHORAGE	FAIRBANKS	JUNEAU	VALDEZ
1031 W. 4th	...onal Center	S.S. Fuller Bldg.	P. O. Box 672
Suite 110	...Cushman, Ste.400	4th & Harris, Ste.214	Valdez, AK
Anchorage, AK	Fairbanks, AK	Pouch K	99686
99501	99701	Juneau, AK 99811	835-2462
279-0428	456-8588	465-3692	

I WISH TO FILE A CONSUMER COMPLAINT AGAINST THE PERSON OR COMPANY NAMED IN 7 BELOW. I REALIZE THAT A COPY OF THIS COMPLAINT WILL BE SENT TO THE PERSON OR BUSINESS I HAVE COMPLAINED OF. (PLEASE TYPE OR PRINT)

1. NAME (Last, First, M.I.)	2. TODAY'S DATE 6-17-85
3. MAILING ADDRESS Powell Margaret K. 617 N. Lane ST.	CITY / STATE / ZIP CODE
4. HOME ADDRESS (If different) Anchorage AK. 99502	CITY / STATE / ZIP CODE
5. HOME TELEPHONE NO. 277-1774	6. BUSINESS TELEPHONE NO.
7. NAME OF THE PERSON OR COMPANY COMPLAINED ABOUT. Alaska Hearing Center	NAME OF SALESPERSON: Lou Neleqqe
8. COMPANY'S ADDRESS 120 5 Tudor rd. Anch. AK.	CITY Anchorage STATE Alaska ZIP CODE
9. COMPANY'S TELEPHONE NO. 561-5639	10. DATE OF TRANSACTION 5-16-85

11. WERE YOU ATTRACTED TO THE SERVICE OR PRODUCT BY AN ADVERTISEMENT? ☐ YES ☒ NO

12. IF YES, WHEN AND WHERE DID YOU SEE THE ADVERTISEMENT?

13. WAS A WRITTEN CONTRACT SIGNED? ☒ YES ☐ NO

14. HAVE YOU COMPLAINED TO THE INDIVIDUAL OR COMPANY? ☐ YES ☒ NO	15. IF YES, NAME OF PERSON TO WHOM YOU COMPLAINED.
16. HAVE YOU CONTACTED A PRIVATE ATTORNEY? ☐ YES ☒ NO	17. IF YES, NAME OF ATTORNEY.
18. IS THERE A COURT OR ADMINISTRATIVE PROCEEDING PENDING? ☐ YES ☒ NO	19. IF YES, NAME COURT OR AGENCY.

AUTOMOBILE REPAIR ONLY

20. DID YOU REQUEST A SIGNED COPY OF REPAIRS TO BE MADE?	☐ YES	☐ NO	DID YOU RECEIVE IT?	☐ YES	☐ NO
DID YOU REQUEST A WRITTEN PRICE ESTIMATE?	☐ YES	☐ NO	DID YOU RECEIVE IT?	☐ YES	☐ NO
DID COSTS EXCEED WRITTEN ESTIMATE?	☐ YES	☐ NO			
WERE YOU NOTIFIED OF ADDITIONAL COSTS BEFORE WORK WAS DONE?	☐ YES	☐ NO			
DID YOU REQUEST THAT REPLACED PARTS BE RETURNED TO YOU?	☐ YES	☐ NO	RECEIVED/OR ALLOWED TO INSPECT PARTS?	☐ YES	☐ NO
			DID YOU RECEIVE IT?	☐ YES	☐ NO

Please state the year, make, model name and V.I.N. (Vehicle Identification No.) of your auto. (Check your registration papers.)

Year Make Model V.I.N.

I hereby certify that I have read the information contained in this complaint and that all of the information I have given is true and complete to the best of my knowledge, information and belief. I further authorize the Attorney General to use this information as he deems necessary and proper.

Margaret K. Powell
Signature

On the reverse side of this form
Summarize your complaint. Be brief,
But complete.

HOW TO WRITE YOUR COMPLAINT:

Start at the beginning. Describe all the events in the order they happened.

Put down the names of any witnesses.

Please attach copies of any documents which explain or support your complaint, including the cancelled checks, copies of advertisements, letters, etc.

~~I~~ I paid The Alaska Hearing center $450.00 down to make me Two hearing aids with a Balance of $750.00 left to Pay also he has another of my hearing aids to fix which should be worth about $350.00 when fixed. I called The Alaska hearing center 6-14-25 to see if my aids where ready & Shawn Clark answered she said she was Taking his Messages. I ask her where my aids where at had been a whole month since orders they were to be Delivered in 2 weeks. Shawn said she would call me back. She did & Told me that Lou Nelegge had closed his office & was selling & my things & Better start Doing something. He is getting ready to leave Town

WHAT TYPE OF SETTLEMENT DO YOU WISH THIS OFFICE TO ATTEMPT TO OBTAIN? I would like my $450.00 Back & my hearing aid which I figure is worth about $350.00

(Please use additional sheets if necessary)

RECEIVED
Department of Law
MAR - 0 1984

CONSUMER COMPLAINT

ATTORNEY GENERAL

7110-FPV-A— 46.0

ANCHORAGE Office of the Attorney General
Consumer Protection Section
1031 W. 4th Anchorage, Alaska
Suite 110
Anchorage, AK
99501
279-0428

FAIRBANKS
National Center
100 Cushman, Ste.400
Fairbanks, AK
99701
456-8588

JUNEAU
S.S. Fuller Bldg.
4th & Harris, Ste.214
Pouch K
Juneau, AK 99811
465-3692

VALDEZ
P. O. Box 671
Valdez, AK
99686
5-2462

I WISH TO FILE A CONSUMER COMPLAINT AGAINST THE PERSON OR COMPANY NAMED IN 7 BELOW. I REALIZE THAT A COPY OF THIS COMPLAINT WILL BE SENT TO THE PERSON OR BUSINESS I HAVE COMPLAINED OF. (PLEASE TYPE OR PRINT)

1. NAME Merv (Last) Ruby (First) M.I.	2. TODAY'S DATE 1-5-84
3. MAILING ADDRESS 3500 Glc Dr.	CITY Anchorage STATE ALASKA ZIP CODE 99504
4. HOME ADDRESS IF DIFFERENT Same	CITY Same STATE ZIP CODE
5. HOME TELEPHONE NO. 338-5830	6. BUSINESS TELEPHONE NO.
7. NAME OF THE PERSON OR COMPANY COMPLAINED ABOUT. Custom Hearing Aid Center	NAME OF SALESPERSON: Bill Lyons
8. COMPANY'S ADDRESS. 3196 New Seward Highway	CITY Anchorage STATE ALASKA ZIP CODE 99503
9. COMPANY'S TELEPHONE NO. 274-7330	10. DATE OF TRANSACTION 3-24-83

11. WERE YOU ATTRACTED TO THE SERVICE OR PRODUCT BY AN ADVERTISEMENT? ☒ YES ☐ NO

12. IF YES, WHEN AND WHERE DID YOU SEE THE ADVERTISEMENT?
March-83 in Daily Papper

13. WAS A WRITTEN CONTRACT SIGNED? ☒ YES ☐ NO

14. HAVE YOU COMPLAINED TO THE INDIVIDUAL OR COMPANY? ☒ YES ☐ NO	15. IF YES, NAME OF PERSON TO WHOM YOU COMPLAINED. Thomas S. Garcia
16. HAVE YOU CONTACTED A PRIVATE ATTORNEY? ☐ YES ☒ NO	17. IF YES, NAME OF ATTORNEY.
18. IS THERE A COURT OR ADMINISTRATIVE PROCEEDING PENDING? ☐ YES ☒ NO	19. IF YES, NAME COURT OR AGENCY.

AUTOMOBILE REPAIR ONLY

20. DID YOU REQUEST A SIGNED COPY OF REPAIRS TO BE MADE?	☐ YES	☐ NO	DID YOU RECEIVE IT?	☐ YES ☐ NO
DID YOU REQUEST A WRITTEN PRICE ESTIMATE?	☐ YES	☐ NO	DID YOU RECEIVE IT?	☐ YES ☐ NO
DID COSTS EXCEED WRITTEN ESTIMATE?	☐ YES	☐ NO		
WERE YOU NOTIFIED OF ADDITIONAL COSTS BEFORE WORK WAS DONE?	☐ YES	☐ NO		
DID YOU REQUEST THAT REPLACED PARTS BE RETURNED TO YOU?	☐ YES	☐ NO	RECEIVED/OR ALLOWED TO INSPECT PARTS?	☐ YES ☐ NO
			DID YOU RECEIVE IT?	☐ YES ☐ NO

Please state the year, make, model name and V.I.N. (Vehicle Identification No.) of your auto. (Check your registration papers.)

Year	Make	Model	V.I.N.

I hereby certify that I have read the information contained in this complaint and that all of the information I have given is true and complete to the best of my knowledge, information and belief. I further authorize the Attorney General to use this information as he deems necessary and proper.

Ruby M. Merv
Signature

On the reverse side of this form
Summarize your complaint. Be brief,
But complete.

HOW TO WRITE YOUR COMPLAINT:

Start at the beginning. Describe all the events in the order they happened.

Put down the names of any witnesses.

Please attach copies of any documents which explain or support your complaint, including the cancelled checks, copies of advertisements, letters, etc.

Subject: Custom Hearing Aid — Purchased - 24 March 1983

Salesman - Bill Lyons

Secretary - Thomas S. Garcia

I purchased Two (2) hearing aids from Custom Hearing Aid Center 3136 New Seward Highway Anchorage, Alaska 99503

The Salesman was Bill Lyons, about 3 weeks after they delivered them, they had to send one (Left) to Florida, as it did not fit.

About 4 weeks later delivered it to me & it did not work due to the inside parts. They took it in again & about 3 weeks returned it again (Same Aid - Left Ear) Seems to work except it has been using batteries at the rate of one battery every 5 days for the last 2 mo.

I have been trying to reach Bill or Thomas for 2 months. My son went by his office & left word and my daughter & son-in law have called - No one there has returned my calls.

The girl who answers the phone there claims she doesn't know where they can be reached or when they will return.

I would like the hearing aid replaced or a full refund of my purchase price.

I am a Senior Citizen on a fixed income

My witness - Mr & Mrs M. Hartsock 338-5836

Dan C. Tilery

Florence Tilery 562-7114

WHAT TYPE OF SETTLEMENT DO YOU WISH THIS OFFICE TO ATTEMPT TO OBTAIN?

Replacement or Refund!

(Please use additional sheets if necessary)

7/11/84 ZGA
16
3B

RECEIVED
Department of Law
JUL 17 1984
ATTORNEY GENERAL

CONSUMER COMPLAINT

CC M52-F85-A-I460

Office of the Attorney General
Consumer Protection Section
Anchorage Alaska

ANCHORAGE	FAIRBANKS	JUNEAU	VALDEZ
1031 W. 4th Suite 110 Anchorage, AK 99501 279-0428	National Center 100 Cushman, Ste.400 Fairbanks, AK 99701 456-8588	S.S. Fuller Bldg. 4th & Harris, Ste.214 Pouch K Juneau, AK 99811 465-3692	P. O. Box 671 Valdez, AK 99686 835-2462

I WISH TO FILE A CONSUMER COMPLAINT AGAINST THE PERSON OR COMPANY NAMED IN 7 BELOW. I REALIZE THAT A COPY OF THIS COMPLAINT WILL BE SENT TO THE PERSON OR BUSINESS I HAVE COMPLAINED OF. (PLEASE TYPE OR PRINT)

1. NAME (Last) DEANDA (First) JAMES (MI)	2. TODAY'S DATE 5-27-84
3. MAILING ADDRESS 6153 E 32ND. AVE.	CITY ANCHORAGE STATE AK ZIP CODE 99504
4. HOME ADDRESS (If different) SAME	CITY STATE ZIP CODE
5. HOME TELEPHONE NO. 333-0676	BUSINESS TELEPHONE NO.
7. NAME OF THE PERSON OR COMPANY COMPLAINED ABOUT. CUSTOM HEARING AID SERVICES	NAME OF SALESPERSON: GLEN MILLER
8. COMPANY'S ADDRESS. MOSS BAY BLDG SUITE 20, 135 LAKE ST	CITY KIRKLAND STATE WASHINGTON ZIP CODE 98033
9. COMPANY'S TELEPHONE NO. 206-822-1230	10. DATE OF TRANSACTION 4-6-83

11. WERE YOU ATTRACTED TO THE SERVICE OR PRODUCT BY AN ADVERTISEMENT? ☒ YES ☐ NO

12. IF YES, WHEN AND WHERE DID YOU SEE THE ADVERTISEMENT?
NEWSPAPER AD

13. WAS A WRITTEN CONTRACT SIGNED? ☒ YES ☐ NO

14. HAVE YOU COMPLAINED TO THE INDIVIDUAL OR COMPANY? ☒ YES ☐ NO	15. IF YES, NAME OF PERSON TO WHOM YOU COMPLAINED. SANDY (NO LAST NAME GIVEN)
16. HAVE YOU CONTACTED A PRIVATE ATTORNEY? ☐ YES ☒ NO	17. IF YES, NAME OF ATTORNEY.
18. IS THERE A COURT OR ADMINISTRATIVE PROCEEDING PENDING? ☐ YES ☐ NO	19. IF YES, NAME COURT OR AGENCY.

AUTOMOBILE REPAIR ONLY

20. DID YOU REQUEST A SIGNED COPY OF REPAIRS TO BE MADE?	☐ YES ☐ NO	DID YOU RECEIVE IT?	☐ YES	☐ NO
DID YOU REQUEST A WRITTEN PRICE ESTIMATE?	☐ YES ☐ NO	DID YOU RECEIVE IT?	☐ YES	☐ NO
DID COSTS EXCEED WRITTEN ESTIMATE?	☐ YES ☐ NO			
WERE YOU NOTIFIED OF ADDITIONAL COSTS BEFORE WORK WAS DONE?	☐ YES ☐ NO			
DID YOU REQUEST THAT REPLACED PARTS BE RETURNED TO YOU?	☐ YES ☐ NO	RECEIVED/OR ALLOWED TO INSPECT PARTS?	☐ YES	☐ NO
		DID YOU RECEIVE IT?	☐ YES	☐ NO

Please state the year, make, model name and V.I.N. (Vehicle Identification No.) of your auto. (Check your registration papers.)

Year	Make	Model	V.I.N.

I hereby certify that I have read the information contained in this complaint and that all of the information I have given is true and complete to the best of my knowledge, information and belief. I further authorize the Attorney General to use this information as he deems necessary and proper.

James Deanda
Signature

On the reverse side of this form
Summarize your complaint. Be brief,
But complete.

HOW TO WRITE YOUR COMPLAINT:

Start at the beginning. Describe all the events in the order they happened.

Put down the names of any witnesses.

Please attach copies of any documents which explain or support your complaint, including the cancelled checks, copies of advertisements, letters, etc.

Received hearing aids on 5/27/93. Had recurring problems with them and they were returned to Washington for repairs three separate times. In November '93 the right hearing aid was returned for repairs and I have not yet received it back. I have placed four call to the company trying to locate the hearing aid. The Company called me twice & on the last occasion told me they had located the hearing aid & it was being mailed to Anchorage. As of this date 5/27/94 I have not received the hearing aid. Also the other hearing aid for the left ear is not working and I was instructed by the Company not to return it to them until I received the right one.

In my conversations with the Company I was told that a Mr. Jose Garcia had taken over their Anchorage office. I have tried to locate Mr. Garcia but have been unable to do so.

I also received a call from a gentleman who works for Senior Citizens, Bill O'Connor 279-2332, who told me a lot of other people were having trouble with the same hearing aid people.

WHAT TYPE OF SETTLEMENT DO YOU WISH THIS OFFICE TO ATTEMPT TO OBTAIN? I would like to have my money refunded and will return the hearing aids to the Company.

(Please use additional sheets if necessary)

RECEIVED
Department of Law
AUG - 3 1984

16

CONSUMER COMPLAINT

ATTORNEY GENERAL

nc 0140-785AL 46.0

Office of the Attorney General
Consumer Protection Unit
Anchorage, Alaska

ANCHORAGE	FAIRBANKS	JUNEAU	VALDEZ
1031 W. 4th Suite 110 Anchorage, AK 99501 279-0428	1st National Center 100 Cushman, Ste.400 Fairbanks, AK 99701 456-8588	S.S. Fuller Bldg. 4th & Harris, Ste.214 Pouch K Juneau, AK 99811 465-3692	P. O. Box 671 Valdez, AK 99686 835-2462

I WISH TO FILE A CONSUMER COMPLAINT AGAINST THE PERSON OR COMPANY NAMED IN 7 BELOW. I REALIZE THAT A COPY OF THIS COMPLAINT WILL BE SENT TO THE PERSON OR BUSINESS I HAVE COMPLAINED OF. (PLEASE TYPE OR PRINT)

1. NAME JERDE, (Last) RUTH (First) E. (M.I.)	2. TODAY'S DATE July 31, 1984
3. MAILING ADDRESS P. O. Box 2012 Palmer, Alaska	CITY Palmer STATE Alaska ZIP CODE 99645
4. HOME ADDRESS (if different) MRN Sarasota Drive, Shorewood, Sub.	CITY Palmer STATE Alaska ZIP CODE 99645
5. HOME TELEPHONE NO. 745-1797	6. BUSINESS TELEPHONE NO. None
7. NAME OF THE PERSON OR COMPANY COMPLAINED ABOUT Fifth Avenue Hearing Center - Miracle Ear	NAME OF SALESPERSON: Mr. Steve Kaufman and [illegible]
8. COMPANY'S ADDRESS 1415	CITY Anchorage STATE Alaska ZIP CODE 99501
9. COMPANY'S TELEPHONE NO. (Seattle 206-623-0555) 907-562-4463	10. DATE OF TRANSACTION October 19, 1984

11. WERE YOU ATTRACTED TO THE SERVICE OR PRODUCT BY AN ADVERTISEMENT? ☒ YES ☐ NO

12. IF YES, WHEN AND WHERE DID YOU SEE THE ADVERTISEMENT?
Fall of 1983, in Anchorage Daily News and the Anchorage Times - it was an insert - such as the one sent last week in both papers.

13. WAS A WRITTEN CONTRACT SIGNED? ☒ YES ☐ NO

14. HAVE YOU COMPLAINED TO THE INDIVIDUAL OR COMPANY?	15. IF YES, NAME OF PERSON TO WHOM YOU COMPLAINED.
☒ YES ☐ NO	Miracle Ear, P.O. Box 549, Minneapolis, Minn. and by phone - Mr. Steve Kaufman in Anchorage
16. HAVE YOU CONTACTED A PRIVATE ATTORNEY? ☐ YES ☒ NO	17. IF YES, NAME OF ATTORNEY.
18. IS THERE A COURT OR ADMINISTRATIVE PROCEEDING PENDING? ☐ YES ☒ NO	19. IF YES, NAME COURT OR AGENCY.

AUTOMOBILE REPAIR ONLY

20. DID YOU REQUEST A SIGNED COPY OF REPAIRS TO BE MADE?	☐ YES	☐ NO	DID YOU RECEIVE IT?	☐ YES	☐ NO
DID YOU REQUEST A WRITTEN PRICE ESTIMATE?	☐ YES	☐ NO	DID YOU RECEIVE IT	☐ YES	☐ NO
DID COSTS EXCEED WRITTEN ESTIMATE?	☐ YES	☐ NO			
WERE YOU NOTIFIED OF ADDITIONAL COSTS BEFORE WORK WAS DONE?	☐ YES	☐ NO			
DID YOU REQUEST THAT REPLACED PARTS BE RETURNED TO YOU?	☐ YES	☐ NO	RECEIVED/OR ALLOWED TO INSPECT PARTS?	☐ YES	☐ NO
			DID YOU RECEIVE IT?	☐ YES	☐ NO

Please state the year, make, model name and V.I.N. (Vehicle Identification No.) of your auto. (Check your registration papers.)

Year	Make	Model	V.I.N.

I hereby certify that I have read the information contained in this complaint and that all of the information I have given is true and complete to the best of my knowledge, information and belief. I further authorize the Attorney General to use this information as he deems necessary and proper.

Ruth E. Jerde
Signature

On the reverse side of this form
Summarize your complaint. Be brief,
But complete.

HOW TO WRITE YOUR COMPLAINT:

Start at the beginning. Describe all the events in the order they happened.

Put down the names of any witnesses.

Please attach copies of any documents which explain or support your complaint, including the cancelled checks, copies of advertisements, letters, etc.

In the fall of 1983 I answered an ad in the Anchorage papers. it was an insert for Miracle Hearing Aid.

On October 19 a Mr. Steve Kaufman and Lou ? reps of the Fifth Avenue Hearing Aid Centers in Seattle came to our home and sold me two Dahlberg hearing aid units to the cost of $1100 for bo

Mr. Steve Kaufman being advised we were leaving for 4-1/2 mos. and would return March 23 stated if I didn't like the hearing aid in my right ear, he would refund the money upon our return or by April 1, 1984. He also stated he would be in touch with us before A[illegible] 1 to follo up on the aids. However, he did no follow up at all.

While in Seattle on March 12, 1984 one hearing aid was defective. I called the Seattle office ~~of the Fifth Avenue Hearing Aid that Mr. Kaufman represented. I asked for a warranty booklet,~~ and also a cap for the volume control knob and also other items pertaining to the aids working. ~~These were never received.~~

~~April 3, 1984 I contacted the Seattle office again as I was unable to obtain Mr. Steve Kaufman~~ here in the Anchorage area. I called for his telephone number, and again they stated they would ~~send me the volume control cap and warranty booklet. I was having other problems with the unit~~ as it wouldn't hold the battery in place... I contacted the Anchorage office this same day, but received no answer.

April 19, 1984 I again, called the Anchorage office and the ~~receptionist~~ fellow Lou told me he would come out and make the service call and follow up call before April 26, which was the date I was leaving to care for my invalid Mother from an emergency doctors call to me. No call or attempt to contact me.

While in Minneapolis, someone called my husband here and told him (my husband) they were too late I had already left.

May 4, I contacted the St. Cloud Hearing Aid Service Center in Minnesota to please fix my hearing aid. This the man came out and temporarily fixed it, and again they called the Dahlberg rep in Mineapolis. The Minneapolis rep told me in no way did the Dahlberg reps act this way, and to contact the home office. I didn't know where it was, and accidently left the reps name from the Minneapolis area out or at my mothers place.

After my return to Anchorage, on July 16, I called Mr. Steve' Kaufman's office. I was advised ~~by the receptionist that Mr. Kaufman was in town and also started up another office of Miracle~~ Ear and Fifth Avenue Hearing Center. I asked the girl to please have Mr. Kaufman or someone ~~contact me before the end of that week July 20, or I would have no other recourse but to~~ file with the Anchorage Consumer Protection office here in Alaska. To date there has been ~~no contact or answer to my July 16 call.~~

~~While talking to this Lou on April 19, I advised him I knew of 4 more hearing aids th could~~ sell here to one person in the valley.. He wanted to know to whom and I told him when he came to repair and fix my aid I would advise him of such.

Of course, since this shoddy way of treating [illegible] who put out $1100. I wouldn't recommend them to anyone. I feel senior citizens of Alaska deserve better treatment than this one and they should be made aware of the fly-by-night service and selling procedures.

WHAT TYPE OF SETTLEMENT DO YOU WISH THIS OFFICE TO ATTEMPT TO OBTAIN?

Either refund of both aides, or repair of same. Preferrably refund

(Please use additional sheets if necessary)

MY ONLY WITNESS IS MY HUSBAND:
WALTER E. LEEDE

CC 10 17-F85-A-I 46.8

RECEIVED
Department of Law

MAR 11 1985

Office of the Attorney General
Consumer Protection Section
Anchorage, Alaska

P. O. Box 62
Valparaiso, Florida 32580
March 5, 1985

The Consumer Protection Agency
1031 W. 4th Avenue, Suite 110
Anchorage, Alaska 99501

Gentlemen:

I have been having a problem for some time now with Miracle Ear Hearing Center, located at 2909 Arctic Boulevard, Suite 101, Anchorage, 99503, telephone number 562-4425.

The facts in this case are the following, substantiated by the attached documentation. I am seeking the return of $2,000.00 (what I paid cash for this (these) hearing aids), plus the $190.00 discount I was due for paying cash for the items at the time of purchase, September 5, 1984. I purchased this (these) hearing aid(s), in a hurry before leaving Anchorage for Florida, where we generally stay through February of each year. After having received no answer to my last two letters to them requesting a refund (see Atchmnts 6 and 8), I decided to wait until our return to Anchorage in early March but now find we will have to remain here longer than expected. That is why I am now writing you to see if you can help me.

At the time I purchased these items I was assured by Jerry Callahan, the salesman, that I had thirty days in which to try them and if I was not totally satisfied I could return them and get full reimbursement. Because of the rush we were in to leave Anchorage at the time of purchase, I neglected to deduct the $190.00 discount which was stated on the contract (Atch 1 below) at the time of purchase. I, therefore, paid them $2000.00 which I should only have paid them $1810.00. Jerry Callahan should have known this at the time I signed the contract but said nary a word. Of course, he had come to the house about 10 in the morning to put me through a series of tests and then had given me the usual salesman's spiel and by that time I was weary, and hungry, and simply forgot the pitch about the $190.00 discount for cash. I should add that I am 74 years of age and, while my hearing is impaired, I am doing very nicely without any kind of a hearing aid at this time.

Listed in chronological order by attachments are the following:

Atch #1 -- Contract for Purchase, dated September 5, 1984. This shows the $190.00 discount I was due for paying cash. Please note I had 30 days in which to try the merchandise and "if for any reason a refund will be made if not satisfied."

Atch #2 -- copy of my check for $2,000.00 with endorsement on reverse.

Atch #3 -- letter dated October 17, 1984, wherein I asked for a 30-day extension trial period because I was having trouble with bleeding and "squealing" in my left ear.

Atch #4 -- statement from Eglin Air Force Regional Hospital personnel that I not wear the hearing aids for two weeks to allow recovery.

Atch #5 -- letter dated October 29, 1984, from Miracle Ear granting me a 30-day extension, through November 30, 1984, telling me where to go for assistance and my notes talking with the Miracle Ear people in Tallahassee, Florida, the closest place they advised I could have the ear molds made and/or pared down or modified to fit my ear.

Atch #6 -- letter dated November 17, 1984, from me to Miracle Ear, explaining the problem I was having getting a new mold made and the requirement they were placing on me to travel back and forth to Tallahassee for assistance. Please note that in the next to the last paragraph I stated I was returning the hearing aids and asked for a refund of my money. This was within the 30 day extension granted in Atch #5.

dated November 20, 1984,

Atch #7 -- registered receipt number R125714026/for return of the hearing aids, insured for $2000.00 and receipt from them dated November 26, 1984.

Atch #8 -- letter dated January 18, 1985, from me to them asking what had happened to my request for reimbursement and again asking for reimbursement.

I have received no replies to either of the letters mentioned in Atchs. 6 and 8 above.

I thought I was dealing with reputable people but I am now convinced these people are frauds. I want the return of my money in the amount of $12,000.00 plus the $190.00 discount I was supposed to have gotten for a cash payment of $2,000.00.

If I have come to the wrong people in this matter then please direct this request to the proper persons who will ensure that a consumer is not bilked by a supposedly reputable company.

Thanking you in advance, I am,

Sincerely yours

Gladys M. Thomas

(Mrs.) Jay N. Thomas

Atch #9 -- receipt from Miracle Ear dated January 24, 1985, showing they received my letter of January 18, 1985 (Atch #8 above)

ALASKA TREATMENT CENTER
3710 E. 20th Avenue • Anchorage, AK 99504 • (907) 272-0586

Dear Dave

here is another letter of dissatisfaction
& dealers to add to the collection.

Geri

ALASKA TREATMENT CENTER

3710 E. 20th Avenue • Anchorage, AK 99504 • (907) 272-0586

Dear Sir
I don't mind spending my money but
I don't like to be Jurjured out of it
I have spent approximately $1,200 for
Hearing aids. That have never worked Right
I Think That are just a pile of Junk.
at an unreasonable price.

A. G. Kimbrel
PO. 13 or 61
Saldotna Ak
99669

Phone 262-4994

(Alaska opticians)

RENDEZVOUS
P.O. Box 9382
Ketchikan, Alaska 99901
(907) 225-6837

June 13, 1985

David Canterbury, ED, CCCA
Chief of Communicative Disorders Program
State of Alaska
Depart. of Health and Social Service
3401 E. 42nd St.
Anchorage, Alaska 99504

Dear Mr. Canterbury:

At the present time I am director of an adult day care center here in Kethcikan and had the opportunity to meet Susan Bunting, regional Audiologist, during her recent visit to Ketchikan.

I had accompanied one of our participants for her hearing evaluation. This woman, Caroline Thompson, had purchased two hearing aids from Miracle Ear Hearing Center, Dahlbery hearing systems, 2909 Arctic Blvd. Suite 101, Anchorage, Alaska 99503. Their representative Jack Hurd sold these two hearing aids to Caroline 8-9-84 and finalized the contract 10-9-84 to the total sum of $1400.00. $700 paid initiallly and the other $700 C.O.D. Needless to say Caroline expected miracles from these hearing aids but the miracle did not occur. All through the winter the hearing aides have buzzed and cuase general discomfort.

After meeting Ms. Bunting severalitems were clarified:

1. The hearing aid is a Dahlberg not a Miracle Ear
2. The fit is not correct for Caroline. New molds were made.
3. The price was excessive.
4. The dealer is from out of town thereby eliminating any follow up contact for problems or questions

The consumer must be protected, especially our senior citizens, from this type of fraud through proper legislation. Better educating of our population in the above matters is imperative, and we need more audiologist to serve the Alaskan population.

Caroline already suffers from low self-esteem and chronic depression and lives on a marginal income and to be taken advantage of hurts deeply.

If action can be taken and the problems remedied then our seniors will be better served.

Sincerely,

Patricia Fordney

Patricia Fordney, R.N.
Program Director

From Rep. Navarre

Oct 2-25

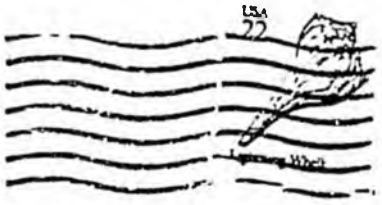
Dear Dr. Canterbury,

I had a fraud dealing with hearing aids. The Alaska Hearing center received $450.00 check from me for a hearing aid & also took my old one to be repaired which I had only bought two years before for $600.00. So I do strongly support the legislation to regulate the dispensing of hearing aids. I have made my complaint to the consumer protection section. I am out my money & no hearing aids. which I need for both ears. I would like to find this guy whose name is Lou Delegge. I even wrote to Dear Bud but he didn't put my letter in the paper. this Happened 5-16-25.

Sincerely
Margaret R. Powell
617 N. Lane St.
Anchorage, Ak.
99502

MARGARET POWELL
617 N. LANE ST.
ANCHORAGE, AK 99508

MARGARET POWELL
617 N. LANE ST.
ANCHORAGE, AK 99508



State of Alaska
Dept. of Health & Social Services
ATTN: Dr. canterbury
1231 Gambell St.
Anchorage, Ak. 99501

ALASKA TREATMENT CENTER

3710 E. 20th Avenue • Anchorage, AK 99508 • (907) 272-0586

May 7, 1985

David Canterbury
Chief of Communicative Disorders Program
Department of Health and Social Services
3401 E. 42nd Avenue
Anchorage, Alaska 99504

Dear Mr. Canterbury:

Enclosed is a receipt for a used hearing aid sold to an elderly woman on Medicaid. She did understand the aid was used when she purchased it. There is no indication as to the make or age of the aid or if it had been reconditioned prior to the sale.

A visual check revealed this to be a modular unit that snapped into an "all purpose" ear mold. The model of this aid could not be determined.

This aid fit very poorly resulting in discomfort and feedback. The consumer had used a kitchen knife to try and modify the mold so that it fit comfortably. She and her family were extremely dissatisfied with this aid as well as the method of sale.

Through this Center, she was fit with a postauricular aid with good subjective and objective results.

I will send further documentation of abuse as received.

Sincerely,

Jeri Powers

Jeri Powers, MS
Audiologist

JP/vm

Anchorage Hearing Aids

3605 S. Arctic Blvd.
Box 281
Anchorage, Alaska 99503
(907) 333-0978

office 338-7827

Model	SERIAL NO.	POWER CODE	TONE	RESPONSE	COLOR INSTRU.	TEMPLE COLOR	LENGTH OF TEMPLE	BATTERY NO.	DELIVERY DATE	☐ NEW ☒ USED
Right		Rt.								
Left	X	Lt.								

TESTING . . . . . $ N.C.

CUSTOM EAR MOLD . . . . . $ N.C.

LAB FEE . . . . . $ N.C.

TOTAL . . . . . $ —

CREDITS:

Amount of Trade-In . . . . . $ —

Make of Trade-In . . . . . $ —

Balance . . . . . $ —

Sales Tax . . . . . $ —

Cash Price . . . . . $ Paid

Down Payment . . . . . $ —

Unpaid Cash Price . . . . . $ —

FINANCE CHARGE . . . . . $ —

BALANCE DUE . . . . . $ —

Aid to be Used by _____
Mr. Mrs. Miss

_____
Address Street City

SPECIAL COMMENTS

ONE USED AID

X _____

Client's Signature (in ink) MARGARET Schenck

(Print Client's Full Name)

Street BARTLETT

Street

City HOMER State AK Zip 99603

Telephone 235 7625

Consultant Byron Selmyer

Date 12-15-92

Check No. _____ For Amount _____

or

Amount Cash Received _____ By _____

BUYER'S RIGHT TO CANCEL — If this Agreement was solicited at a residence other than that of the Seller and you do not want the goods or services, you may cancel this Agreement by mailing a notice to the Seller. The notice must say that you do not want the goods or services and must be mailed before 12 midnight of the fifth business day after you sign this Agreement.

NORTON SOUND
HEALTH CORPORATION

P.O. BOX 966
NOME, ALASKA 99762
(907) 443-5411

June 25, 1985

David Canterbury, Ed.D.
Communicative Disorders Program
3401 E. 42nd Ave.
Anchorage, Alaska 99504

RE: House Bill 430

Dear Dave:

Thank you for providing me with a copy of the above House Bill. I am encouraged by this Bill in that better regulation of hearing aid dispensing will be enforced. It's frustrating when someone from your region ends up with hearing aids that are inappropriate or monstrously expensive or unreturnable! I assume most States have this kind of regulation (at least they do where I've been), and it's about time Alaska quit hiding behind that "wilderness-anything-goes" excuse.

After reading this comprehensive bill, I find only one area of possible conflict. Under Section 08.11.110 Exemptions is listed "a physician..." Usually, physicians are their own employers, so I don't see who is going to supervise their audiological procedures. I would think that a physician would either make an appropriate referral to an audiologist, or only practice limited hearing screening procedures (unless he/she is also a certified audiologist).

I think it is important to set up a supervision structure for those held exempt from licensure - perhaps with the State?

Let me know if any further comments are needed. I know you'll keep me informed.

Sincerely,

NORTON SOUND REGIONAL HOSPITAL

Beverly

Beverly Short
Audiologist

BS/kn

cc: File

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 complaints.

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 1. 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 at 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 applicants 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	August 2, 1985
Holiday Inn East 3100 S. Dirksen Parkway I-55 Junction By Pass 66 Stevenson Drive Audiovisual Room Springfield, Illinois	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. Otolaryngologist, Springfield Memorial Medical Center (Springfield) Richard Wiet, M.D., 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, Midwestern Region, Educational Testing Service, Evanston, Illinois (Hillside)
4:00 p.m.	Laboratory Session: Introduction to the Qualitone Acoustic Appraiser and the Bioacoustic Audiometric Simulator*	IDPH Staff
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

Illinois –

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,[1] 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,[2] 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,[3] is considered sufficient when mailed to the last known address of a party.

[1] Chapter 127, ¶ 1001 et seq.

[2] Chapter 127, ¶ 1016.

[3] 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,[1] 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.

[1] Paragraph 4901 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 83rd 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.

(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 a receipt which shall contain the seller's signature, purchaser, the manufacturer's specifications, the make, 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 corporations, partnerships, trusts, associations or other organizations 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, 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 [1] Section 4 of this Act [1] and the testing requirement of subsection (j) of Section 3 [2] and subsection (z) of Section 18 [3] provided that the organization:

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

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 a 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 interests would 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".

(f) Where a sale, lease, or rental of hearing aids is solicited 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 issued 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

er the seller intends to repossess or to abandon any shipped 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.

[1] Paragraph 7404 of this chapter.

[2] Paragraph 7403 of this chapter.

[3] Paragraph 7418 of this chapter.

For repeal of Act, see note preceding ¶ 7101 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 ¶ 7101 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 ¶ 7101 of this chapter.

7409. Matters included in examination

Paragraph effective July 1, 1984.

§ 9. The examination required by Section 8[1] 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 contra-indications to the use and fitting of a hearing aid.

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

[1] Paragraph 7408 of this chapter.

For repeal of Act, see note preceding ¶ 7101 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.[1] 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.

[1] Paragraph 7408 of this chapter.

For repeal of Act, see note preceding ¶ 7101 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,[1] 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

...ising of hearing aids for a period not to exceed one ...r. A temporary certificate shall not be renewable and ...e applicant must take the examination within a year ...ter receiving the temporary certificate. All applicants ...a temporary certificate shall be employed by a person ...o has a certificate as a hearing aid dispenser. Such ...erson shall be responsible for the supervision and train... of the applicant and shall maintain personal contact ...d records.

The Department may issue a temporary certificate to an ...pplicant starting a hearing aid dealership as sole owner, ...incipal of a firm, or employee-manager for a corporation ...f the applicant's training is provided by a manufacturer ...r 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 condi...tioned on the satisfactory performance, pursuant to and in ...accordance with this Act and the rules hereunder, during ...the period covered by the temporary certificate.

[1] 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,[1] 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.[2]

[1] Chapter 15, ¶ 301-1 et seq.

[2] 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;

(j) Aiding or assisting another person in violating any provision of this Act or the rules promulgated hereunder;

(k) Failing, within 60 days, to provide information in response to a written request made by the Department;

(l) Engaging in dishonorable, unethical or unprofessional conduct which is likely to deceive, defraud or harm the public;

(m) Knowingly employing, directly or indirectly, any suspended or unregistered person to perform any services covered by this Act;

(n) Habitual intoxication or addiction to the use of drugs;

(o) 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;

(p) 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;

(q) A finding by the Board that the registrant, after having his certificate placed on probationary status has violated the terms of probation;

(r) Willfully making or filing false records or reports;

(s) 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; [1]

(t) 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;

(u) Solicitation of professional services other than by permitted advertising;

(v) Participating in subterfuge or misrepresentation in the fitting and servicing of a hearing aid;

(w) 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;

(x) Representing that the service 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;

(y) Advertising a manufacturer's product or using a manufacturer's name or trademark implying a relationship which does not exist;

(z) 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;

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

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

(cc) 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;

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

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

(ff) Violating any provision of the "Consumer Fraud and Deceptive Business Practices Act", approved July 24, 1961, as amended.[2]

[1] Chapter 23, ¶ 2051 et seq.

[2] Chapter 121½, ¶ 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, enjoining 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

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,[1] 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.

[1] 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,[1] 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.[2] 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.

[1] Chapter 127, ¶ 1001 et seq.

[2] Chapter 110, ¶ 3-101 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 2H of the "Consumer Fraud and Deceptive Business Practices Act", approved July 24, 1961, as amended.[1]

[1] 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,[1] 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[2] 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.

[1] Chapter 121½, ¶ 261 et seq.

[2] Chapter 121½, ¶¶ 263 to 267 and 270.

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-

Department of Human Resources
HEALTH DIVISION
1400 S.W. 5th AVENUE, PORTLAND, OREGON 97201 PHONE

Board of Examiners for Speech Pathology and Audiology
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 681.

attachment

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 serivce. 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

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).

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)

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
6/89

IF...

YOU PURCHASE WISELY

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.

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 61103
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.