

ALASKA LEGISLATURE COMMITTEE FILES 1905-1900 00/2

3215 HHESS HB 426 - HB 430 97



# RECORDS CERTIFICATION



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James O. Smith  
Signature of Camera Operator

7/25/89  
Date

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Version #1  
Bannister  
4/7/86

Original sponsor: Boucher

1 IN THE HOUSE

BY THE HEALTH, EDUCATION AND  
SOCIAL SERVICES COMMITTEE

2 CS FOR HOUSE BILL NO. 426 (HESS)

3 IN THE LEGISLATURE OF THE STATE OF ALASKA

4 FOURTEENTH LEGISLATURE - SECOND SESSION

5 A BILL

6 For an Act entitled: "An Act relating to the regulation of postsecondary  
7 educational institutions."

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

9 \* Section 1. AS 14.42.015(a) is amended to read:

10 (a) There is in the Department of Education the Alaska Commis-  
11 sion on Postsecondary Education consisting of

12 (1) two members of the Board of Regents of the University  
13 of Alaska designated by the members of that body;

14 (2) one person representing private higher education in the  
15 state selected jointly by the Boards of Trustees of Alaska Pacific  
16 University and Sheldon Jackson College from among their membership;

17 (3) one person representing the Department of Education  
18 selected by the state Board of Education;

19 (4) four persons broadly and equitably representative of  
20 the general public appointed by the governor;

21 (5) one member of the state Advisory Council on Vocational  
22 Education designated by the members of that body;

23 (6) one person from [AMONG] the members of the local com-  
24 munity college advisory councils appointed [, INITIALLY,] by the  
25 governor [UNTIL THE STATE ADVISORY COUNCIL ON COMMUNITY COLLEGES IS  
26 ESTABLISHED AND ORGANIZED UNDER AS 14.42.030(b); THEN, ONE MEMBER OF  
27 THE STATE ADVISORY COUNCIL ON COMMUNITY COLLEGES DESIGNATED BY THE  
28 MEMBERS OF THAT BODY];

29 (7) two members from the legislature, one of whom shall be

1 appointed by the president of the senate and one by the speaker of the  
2 house of representatives [DESIGNATED BY THE LEGISLATIVE COUNCIL AND  
3 ONE BY THE LEGISLATIVE BUDGET AND AUDIT COMMITTEE];

4 (8) one person appointed in accordance with (e) of this  
5 section who is a full-time student as defined in AS 14.43.160(2);

6 (9) one administrator appointed by the governor from a  
7 proprietary institution of postsecondary education that has an author-  
8 ization to operate in the state issued under AS 14.48.

9 \* Sec. 2. AS 14.48.060(b) is amended by adding a new paragraph to read:

10 (13) the charges set by the institution for tuition, fees,  
11 books, and supplies are fair and equitable.

12 \* Sec. 3. AS 14.48.100(e) is amended to read:

13 (e) In lieu of the surety bond required in (a) and (b) of this  
14 section, the applicant may file with the commission a cash deposit,  
15 [OR] other negotiable security, or other property, acceptable to the  
16 commission, in the amount specified for the bond [BONDS].

17 \* Sec. 4. AS 14.48.120 is amended to read:

18 Sec. 14.48.120. REVOCATION. An authorization to operate or an  
19 agent's permit may be revoked or conditioned if the commission has  
20 reasonable cause to believe that the holder of the authorization or  
21 permit is violating or has violated this chapter or AS 45.50.471 or  
22 regulations adopted [PROMULGATED] under this chapter or AS 45.50.491.  
23 Except as provided in (b) and (c) of this section, the [THE] Adminis-  
24 trative Procedure Act (AS 44.62) governs the procedure for a revoca-  
25 tion, review of a revocation, or other action under this section.

26 \* Sec. 5. AS 14.48.120 is amended by adding new subsections to read:

27 (b) Authorization for an institution to operate, and a permit  
28 for an agent representing that institution, are revoked 30 days after  
29 the institution ceases to operate. The commission shall give the

1 institution and the agent 15 days' written notice, by certified mail,  
2 sent return receipt requested, to the last addresses of the institu-  
3 tion and agent.

4 (c) The institution and the agent may appeal a revocation under  
5 (b) of this section by filing an appeal in writing with the commission  
6 within 30 days after the revocation.

7 \* Sec. 6. AS 45.50.471(b) is amended by adding a new paragraph to read:

8 (26) failing to comply with AS 14.48.060(b)(13).

9 \* Sec. 7. AS 45.50.481 is amended to read:

10 Sec. 45.50.481. EXEMPTIONS. Nothing in AS 45.50.471 - 45.50.561  
11 applies to

12 (1) an act or transaction regulated under laws administered  
13 by the state, by a [ANY] regulatory board or commission except as  
14 provided by AS 45.50.471(b)(26), or officer acting under statutory  
15 authority of the state or of the United States, unless the law regula-  
16 ting the act or transaction does not prohibit the practices declared  
17 unlawful in AS 45.50.471;

18 (2) an act done by the publisher, owner, agent, or employee  
19 of a newspaper, periodical or radio or television station in the  
20 publication or dissemination of an advertisement, when the owner,  
21 agent or employee did not have knowledge of the false, misleading or  
22 deceptive character of the advertisement or did not have a direct  
23 financial interest in the sale or distribution of the advertised  
24 product or service;

25 (3) an act or transaction regulated under AS 21.36 or  
26 AS 06.05 or a regulation adopted [ANY REGULATIONS PROMULGATED] under  
27 the authority of those chapters.

28 \* Sec. 8. Notwithstanding AS 14.42.015(a)(6) - (7) as amended by sec. 1  
29 of this Act, the existing members of the Alaska Commission on Postsecondary

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Education on the effective date of this Act who were appointed under AS 14.42.015(a)(6) - (7), as those paragraphs existed before the effective date of this Act, shall continue as members of the commission until the normal expiration of the members' terms.



# STATE OF ALASKA 1986 LEGISLATIVE SESSION FISCAL NOTE

Revision Date: 3/25/86

**REQUEST**

Bill/Resolution No. : HB 426  
 Title : Postsecondary Education and Regulation of Institutions  
 Sponsor : Boucner  
 Requestor : House HESS  
 Date of Request : 3/25/86

**FISCAL DETAIL**

Agency Affected : Education  
 BRU : Postsecondary Education  
 Components : General Administration

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

OPERATING	FY 86	FY 87	FY 88	FY 89	FY 90	FY 91
PERSONAL SERVICES						
TRAVEL						
CONTRACTUAL						
SUPPLIES						
EQUIPMENT						
LAND & STRUCTURES						
GRANTS, CLAIMS						
MISCELLANEOUS						
<b>TOTAL OPERATING</b>	<b>N.A.</b>	<b>-0-</b>	<b>-0-</b>	<b>-0-</b>	<b>-0-</b>	<b>-0-</b>

CAPITAL						
---------	--	--	--	--	--	--

REVENUE						
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**FUNDING : (Thousands of Dollars)**

GENERAL FUND	N.A.	-0-	-0-	-0-	-0-	-0-
FEDERAL FUNDS						
OTHER						
<b>TOTAL</b>						

**POSITIONS :**

FULL-TIME						
PART-TIME						
TEMPORARY						

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

The only possible cost would be travel related. This will be absorbed within existing budget for meetings and will essentially be accommodated through Commission vacancy at meetings.

Prepared by: *[Signature]* Phone: 465-2854  
 Division: Commission on Postsecondary Education Date: 3/25/86

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

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

DEPARTMENT OF LAW

POUCH K - STATE CAPITOL  
JUNEAU, ALASKA 99811  
PHONE: (907) 465-3600

OFFICE OF THE ATTORNEY GENERAL

TELECOPIER TRANSMITTAL LETTER

PLEASE DELIVER THE FOLLOWING PAGES TO:

NAME: LINDA O'BANNON  
LOCATION: ANCH PHONE: 270-3550  
TELECOPIER NUMBER: 270-3697  
REMARKS: \_\_\_\_\_

TOTAL NUMBER OF PAGES 5 INCLUDING COVER LETTER.

DATE: 4/3/86 TIME: 9:15 AM  
FROM: HOUSE HESS - NANCY BENNETT  
IN RE SUBJECT/FILE NO. HB 426

CHARGE TO:  100  110  523  
 543  546  674  
 OTHER Legislative Affairs

IF YOU DO NOT RECEIVE ALL THE PAGES OR IF YOU HAVE ANY PROBLEMS,  
PLEASE CONTACT: Nancy Bennett 415-3759  
AT (907) 465-3600 - ATTORNEY GENERAL'S OFFICE - JUNEAU

NOTE: Please fill in ALL of the blanks.

*Scheduled for a hearing 4/7  
pls. call Nancy Bennett 465-3759*

Bannister  
4/2/86 ✓

Original sponsor: Boucher

1 IN THE HOUSE

BY THE HEALTH, EDUCATION AND  
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Please draft a HESS CS with noted changes!

Introduced: 5/7/85  
Referred: Health, Education &  
Social Services

Nancy  
X3759.

1 IN THE HOUSE

BY BOUCHER

2

CS HOUSE BILL NO. 426 (HESS)

3

IN THE LEGISLATURE OF THE STATE OF ALASKA

4

FOURTEENTH LEGISLATURE - FIRST SESSION

5

A BILL

6 For an Act entitled: "An Act adding a member to the Alaska Commission on  
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18 selected by the state Board of Education;

19 (4) four persons broadly and equitably representative of  
20 the general public appointed by the governor;

21 (5) one member of the state Advisory Council on Vocational  
22 Education designated by the members of that body;

23 (6) one person from [AMONG] the members of the local com-  
24 munity college advisory councils appointed [initially] by the governor,  
25 [until the state Advisory Council on Community Colleges is established  
26 and organized under AS 14.42.030(b); then, one member of the state  
27 Advisory Council on Community Colleges designated by the members of  
28 that body];

29 (7) two members from the legislature, one of whom shall be

1 designated by the <sup>President of the Senate</sup> [Legislative Council] and one by the <sup>Speaker of</sup> [Legislative  
2 ~~the House~~ Budget and Audit Committee];

3 (8) one person appointed in accordance with (e) of this  
4 section who is a full-time student as defined in AS 14.43.160(2);

5 (9) one administrator appointed by the governor from a  
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7 ization to operate in the state issued under AS 14.48.

# Alaska State Legislature

POUCH V  
JUNEAU, ALASKA 99811  
(907) 465-4931

DISTRICT 10  
BOX 111038  
ANCHORAGE, ALASKA 99511  
(907) 349-2192



CHAIRMAN  
Special Committee on  
Telecommunications

MEMBER  
Labor and Commerce  
State Affairs  
Finance—Subcommittee Administration

Representative H. A. "Red" Boucher

## M E M O R A N D U M

To: Members, House HFSS Committee

From: Representative H.A. "Red" Boucher  
Sponsor of HB 426

Date: March 20, 1986

Subject: Overview of HB 426, "Membership on the  
Post-Secondary Education Commission"

In 1972, federal law mandated the creation of Postsecondary Education Commissions in each state, as required by Section 1202 of the Education amendments of 1972.

In 1976, the State of Alaska created a Commission under CSHB 143 am S, which became AS 14.42. According to Bettye L. Smith, currently a member of the Commission representing the State Council on Vocational Education, the Commission was created without a member to represent the private proprietary institutions of postsecondary education. Ms. Smith provided detailed testimony on this issue in a presentation before the Commission on September 20, 1977 and again on March 23, 1985, which are in the Committee folders.

The omission of the position was done in spite of the fact that the federal guidelines at the time recommended that such a member be included; and in fact the other 49 states did add such a member to their Commissions. Apparently, the drafters of the bill left off this position because they felt the Commission was too large, and because private proprietary schools were not a large force at that time.

This has all changed. The private proprietary schools are now a sizeable group. The Commission is charged with regulating the private schools, but specifically excludes private higher educational institutions (Alaska Pacific University and Sheldon Jackson College). Thus, the Commission's regulatory function in the private sector is primarily limited to private proprietary schools. Without a member from this group on the Commission, this is "Regulation without Representation."

This bill seeks to rectify this oversight through the addition of a member. The bill was endorsed by the Commission at their February 28-March 1, 1986 quarterly meeting.

BOARD: POSTSECONDARY EDUCATION, ALASKA COMMISSION ON

TITLE: Alaska Commission on Postsecondary Education

DEPT: Department of Education

AUTHORITY: AS 14.42.010

STATUS: ACTIVE

REQUIREMENTS: FINANCIAL DISCLOSURE

PROHIBITIONS: No governing body member, trustee, or employee of post-secondary or higher education institution as public member

TERM: 4 years - staggered, except student members - 2 years

DESCRIPTION: 13 members - 5 appointed by Governor: 4 public; 1 full-time student from nominees (by election); plus 8 with following representation: 2 Board of Regents, 1 private higher education, 1 Dept. of Education, 1 Advisory Council on Vocational Education, 1 from local community college advisory councils, 1 legislative council, and 1 legislative budget and audit committee; serve at pleasure of appointing authority; members elect chair.

SPECIAL FACTS: Quorum - majority; report to Governor/Legislature

FUNCTION: Coordinates development of plans for orderly growth of public/private postsecondary education; recommends new facilities and programs; administers student loan program.

COMPENSATION: Standard travel/per diem

MEETINGS: Quarterly, time/place determined by chair; 10 days maximum

\*FOR FURTHER INFORMATION CONTACT: Executive Director, Commission on Postsecondary Education, Box F, Juneau, AK 99811 - 465-2854

Postsecondary Education

<u>MEMBER</u>	<u>APPT</u>	<u>REAPPT</u>	<u>TERM</u>
Patricia A. Abney 5800 East 142 Avenue Anchorage 99516 Public	83/08/19	84/03/27	88/03/01
Alice J. Bosshard Box 127 Valdez 99686 Community Colleges	85/06/28		89/06/30
Ruth E. Burnett 1901 Crosson Fairbanks 99701 Regents Board	83/04		91/02/01
Patricia C. Clark 612 Sprucewood Fairbanks 99701 Public	83/08/19		86/03/01
Gordon Evans 604 Gold Street Juneau 99801 Regents Board - Chairman	83/04		91/02/01
Ernestine J. Griffin P.O. Box 808 Sitka 99835 Education Board			87/01/31
John E. Havelock 3210 Baxter Road Anchorage 99504 Public	85/05/21		89/03/01
Richard J. Helms P.O. Box 100916 Anchorage 99510-0916 Student Rep.	84/09/07		88/03/01
Jalmar Kerttula Pouch Z Palmer 99645 Legis/S			
Niilo Koponen P.O. Box 252 Fairbanks 99707 Legis/R			

Postsecondary Education - Continued

<u>MEMBER</u>	<u>APPT</u>	<u>REAPPT</u>	<u>TERM</u>
Barbara M. Shaffer 1666 Patterson Street Anchorage 99504-2773 Private/Higher Ed.	85/04/29		89/03/01
Bettye L. Smith 2067 Shepherdia Anchorage 99504 Vocational Ed.	85/06/28		87/05/30
Barbara A. Thompson Dept. of Educ./Pouch F Juneau 99811 Public	83/08/19	84/03/27	82/03/01

1202 COMMISSION  
LACK OF REPRESENTATION BY  
VOCATIONAL-TECHNICAL SCHOOLS

STATEMENTS MADE BY  
BETTYE L. SMITH

TO  
ALASKA POSTSECONDARY COMMISSION  
MARCH 23, 1935

1202 Commission

12

Back in 1977 when the State of Alaska submitted the Alaska Postsecondary plans as required by Section 1202 of the Education Amendments of 1972, I received a letter from the National Association of Trade and Technical Schools which stated - and I quote "Under the plans submitted to the Office of Education by your State, it appears that there is no proprietary representation on the State 1202 Commission as required by Section 1202 of the Education amendments of 1972. You and other schools in your state may wish to look into this matter in depth."

Well NATTS was not bringing to my attention anything I did not already know. During 1973, prior to the passage of HB 180 which created the Alaska Commission on Postsecondary Education, we contacted every member of the legislature including the legislative council that drafted this particular legislation, in particular Mr. Stuart Hall.

In Mr. Hall's judgement there was no obligation whatsoever that proprietary institutions be represented on this Commission. He indicated to me that if our schools were included it would make it too cumbersome - just too many commissioners. However, on page 201 of the Compilation of Higher Education Laws, 1972 of the 92nd Congress, 2d Session it reads: Sec. 1202 (a) Any State which desires to receive assistance under section 1203 or title X shall establish a State Commission or designate an existing State agency or State Commission (to be known as the State Commission) which is broadly and equitably representative of the general public and public and private nonprofit and proprietary institutions of postsecondary education in the State including community colleges (as defined in title X), junior colleges, postsecondary vocational schools, area vocational schools, technical institutes, four year institutions of high education and branches thereof.

As of January 1977, 49 proprietary representatives were serving other states on these very commissions. In fact the Arizona 1202 Commission which I believe you were a part of, Dr. Romesburg, a fellow AICS school manager Mary Willard Hamm was the proprietary representative on that commission.

As the bill stands now, as it did in 1977, not one private proprietary vocational school has any representation on this Commission.

Take a look at the make-up of the commission. Out of 13 commissioners not one person, with any proprietary experience is on that Commission, yet they have the power of life and death over our industry. Take a look at the staff - making life and death recommendations to the commission to vote on. Four year academicians.

We are being governed without representation by those who have acknowledged before us little or no experience or expertise in the private vocational-technical field.

Why can we never get a voice in our governance until we are forced into total frustration with regulations being put into law that have not been widely disseminated and public hearings held in areas that the small private school operators could attend? If appropriate public notification and available public hearings had been held then I would have more appreciation for the statement made by John W. Katz, Director of State/Federal Relations and Special Counsel to Governor Sh- in his February 23, 1985, letter to Congressman Don Young. In this letter he stated, "In addition to expressing their concerns and interests by correspondence, it would seem appropriate for the proprietary schools to voice their opinions and recommendations by participating in the regulatory process. "

This is the first public hearing I am aware of since the September 20, 1977, and we are participating.

We have the desire to serve - or we would not be in this business.  
We have the service to provide - our records show it.  
We have the ability to survive with fair and equitable regulations.  
And - we - will - because - WE CARE FOR OUR STUDENTS!

By the way, what was the Boston Tea Party all about?

92d Congress  
2d Session

JOINT COMMITTEE PRINT

*Please Return  
Budget Smith*

COMPILATION OF HIGHER  
EDUCATION LAWS, 1972

COMMITTEE ON EDUCATION AND LABOR  
HOUSE OF REPRESENTATIVES

COMMITTEE ON LABOR AND PUBLIC WELFARE  
UNITED STATES SENATE



NOVEMBER 1972

Printed for the use of the Committee on Education and Labor  
Carl D. Perkins, *Chairman*

and the

Committee on Labor and Public Welfare  
Harrison A. Williams, Jr., *Chairman*

U.S. GOVERNMENT PRINTING OFFICE

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(d) The term "secondary school" means a school which provides secondary education as determined under State law except that it does not include any education provided beyond grade 12.

(e) The term "Secretary" means the Secretary of Health, Education, and Welfare.

(f) The term "Comissioner" means the Commissioner of Education.

(g) The term "local educational agency" means a public board of education or other public authority legally constituted within a State for either administrative control or direction of, or to perform a service function for, public elementary or secondary schools in a city, county, township, school district, or other political subdivision of a State, or such combination of school districts of counties as are recognized in a State as an administrative agency for its public elementary or secondary schools. Such term also includes any other public institution or agency having administrative control and direction of a public elementary or secondary school.

(h) The term "State educational agency" means the State board of education or other agency or officer primarily responsible for the State supervision of public elementary and secondary schools, or, if there is no such officer or agency, an officer or agency designated by the Governor or by State law.

(i) The term "elementary school" means a school which provides elementary education including education below grade 1, as determined under State law.

(j) The term "combination of institutions of higher education" means a group of institutions of higher education that have entered into a cooperative arrangement for the purpose of carrying out a common objective, or a public or private nonprofit agency, organization, or institution designated or created by a group of institutions of higher education for the purpose of carrying out a common objective on their behalf.

(k) The term "gifted and talented children" means, in accordance with objective criteria prescribed by the Commissioner, children who have outstanding intellectual ability or creative talent.

(l) The term "school or department of divinity" means an institution or a department or a branch of an institution the program of instruction of which is designed for the education of students (A) to prepare them to become ministers of religion or to enter upon some other religious vocation (or to provide continuing training for any such vocation), or (B) to prepare them to teach theological subjects.

(29 U.S.C. 1141) Enacted Nov. 8, 1965, P.L. 89-229, Title VIII, sec. 501, 78 Stat. 1207; amended Oct. 16, 1968, P.L. 90-575, Title II, sec. 251, 263, and 264, 82 Stat. 1012 and 1020-51; amended April 23, 1970, P.L. 91-230, sec. 800(b), 84 Stat. 132; subsection (1) added June 23, 1972, P.L. 92-318, sec. 131(d)(1), 86 Stat. 209.

STATE POSTSECONDARY EDUCATION COMMISSIONS

SEC. 1202. (a) Any State which desires to receive assistance under section 1203 or title X shall establish a State Commission or designate an existing State agency or State Commission (to be known as the State Commission) which is broadly and equitably representative of the general public and public and private nonprofit and proprietary institutions of postsecondary education in the State including com-

*The were  
deliberately  
written out*

(A) makes application to the Board of Regents of the University of Alaska for participation in the community college program;

(B) satisfies educational standards of the University of Alaska according to criteria established by the Board of Regents;

(C) has had an average daily membership during the previous school year of at least 75 high school students, grades 9-12;

(D) has established to the satisfaction of the Board of Regents the practical need for a community college within the district or political subdivision; and

(E) makes arrangements for defraying its proper share of the costs of the operation and maintenance of a community college, as provided by the terms of AS 14.40.560 — 14.40.640;

(3) "board of regents" or "board" means the Board of Regents of the University of Alaska. (§ 2 ch 75 SLA 196.)

Editor's notes. — This section is set out above to correct a typographical error in the title pamphlet.

## Chapter 42. Alaska Commission on Postsecondary Education.

### Section

#### 15. Creation, composition, appointment of members

Sec. 14.42.015. Creation, composition, appointment of members. (a) There is in the Department of Education the Alaska Commission on Postsecondary Education consisting of

(1) two members of the Board of Regents of the University of Alaska designated by the members of that body;

(2) one person representing private higher education in the state selected jointly by the Boards of Trustees of Alaska Pacific University and Sheldon Jackson College from among their membership;

(3) one person representing the Department of Education selected by the state Board of Education;

(4) four persons broadly and equitably representative of the general public appointed by the governor;

(5) one member of the state Advisory Council on Vocational Education designated by the members of that body;

(6) one person from among the members of the local community college advisory councils appointed, initially, by the governor until the state Advisory Council on Community Colleges is established and organized under AS 14.42.030(b); then, one member of the state Advisory Council on Community Colleges designated by the members of that body;

(7) two members from the legislature, one of whom shall be designated by the Legislative Council and one by the Legislative Budget and Audit Committee;

(8) one person appointed in accordance with (e) of this section who is a full-time student as defined in AS 14.43.160(2).

(b) No governing body member, trustee, official or employee of either a public, private or proprietary institution of postsecondary or higher education in the state may be appointed to membership on the commission as representative of the general public for the purpose of (a)(4) of this section.

(c) The governor's appointees are subject to confirmation by the legislature and shall serve at the pleasure of the governor for four-year staggered terms. Members appointed or designated by bodies or agencies other than the governor serve at the pleasure of the appointing authority. Vacancies shall be filled in the same manner as original appointment.

(d) For the purpose of (a)(4) of this section, "broadly and equitably representative of the general public" means that the public membership of the commission shall include adequate representation both on the basis of sex and on the basis of the significant racial, ethnic, geographic and economic groups in the state.

(e) A full-time postsecondary student shall be appointed to the Alaska Commission on Postsecondary Education from a list of nominees submitted to the governor. The governor shall make the appointment from the list within 60 days after it is submitted. The list shall consist of the names of two nominees from Alaska Pacific University, two nominees from Sheldon Jackson College, and two nominees from each campus of the University of Alaska. The nominees shall be selected by the students at Alaska Pacific University, Sheldon Jackson College, and each campus of the University of Alaska. Selections shall be made at elections conducted under rules established by the Office of the Governor. The term of office of the student member of the commission is two years. Membership on the commission is immediately forfeited by a student member who ceases to be a full-time student. Within 60 days after a vacancy occurs, the governor shall appoint a successor from those students appearing on the list of nominees to serve for the unexpired term of the original appointee. The term "campus" used in this subsection means a portion of the University of Alaska designated as a "campus" by the Board of Regents. (§ 4 ch 78 SLA 1974; am §§ 1 — 3 ch 64 SLA 1982; AS 14.40.903; am § 56 ch 6 SLA 1984)

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(B) satisfies educational standards of the University of Alaska according to criteria established by the Board of Regents;

(C) has had an average daily membership during the previous school year of at least 75 high school students, grades 9-12;

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(6) one person from among the members of the local community college advisory councils appointed, initially, by the governor until the state Advisory Council on Community Colleges is established and organized under AS 14.42.030(b); then, one member of the state Advisory Council on Community Colleges designated by the members of that body;

(7) two members from the legislature, one of whom shall be designated by the Legislative Council and one by the Legislative Budget and Audit Committee;

(8) one person appointed in accordance with (e) of this section who is a full-time student as defined in AS 14.43.160(2).

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TESTIMONY  
POSTSECONDARY EDUCATION COMMISSION  
SEPTEMBER 20, 1977

BY  
BETTYE L. SMITH, C. A. M.

Office of Education, Washington, D.C., by the State of Alaska, the National Association of Trade and Technical Schools wrote to me that - and I quote - "Under the plans submitted to the Office of Education by your state, it appears that there is no proprietary representation on the state 1202 Commission as required by Section 1202 of the Education amendments of 1972. You and other schools in your state may wish to look into this matter in depth."

As of January 1977, 49 proprietary representatives were serving other states on these commissions.

As the bill stands now, not one private or proprietary school outside of Sheldon Jackson and Alaska Methodist University has right of representation on the Commission.

Take a look at the makeup of the commission. Out of 13 people not one person with any proprietary experience is on the commission, yet they will have the power of life and death over our industry.

We are going to be governed without representation by those who have acknowledged before us little or no experience or expertise in the private educational field.

Commissioners have informed us that this bill is the intent of the legislature to protect the innocent from the education defrauders.

Testimony, was presented which was given presented by Sharon S. Armstrong, attorney from the Federal Trade Commission, but refers to correspondence schools and other out of state schools. Yet it is the local schools that must pay the price for their misdeeds.

I would like to make available to the commission a report that will shed some additional light on the sources of information used by Sharon Armstrong and the Federal Trade Commission.

Sharon Armstrong indicated the Federal Trade Commission encouraged the State to adopt the Education Commission of the States Model Post Secondary Educational Authorization Act. I have a letter here from the Director of the Education Commission of the States Richard Millard which specifically states "in relation to model legislation I think it should be recognized that its purpose is to serve as a model in terms of raising the essential issues that need be covered. Neither the Task Force nor the Commission would hold to the idea that it should be adopted in toto in every state or necessarily in any state without adaption to the conditions and problems of the particular state. I hope this will clarify the real intent." Signed Richard K. Millard, Director.

I would like to quote the front page of the Times.

"Our main concern is about the educational services promised to the students, such as getting a job after they have completed courses at a business college," said Romesburg.

Being the only business college in the State of Alaska, how can you, Mr. Romesburg, make such a statement without first checking our placement statistics. This to me is a sample of what we private schools can expect in the future.

Our graduate records are public and have had better than 95 - 100% placement. since we started keeping records. These records can be documented.

In 1974, 91.4 percent of the graduates of vocational training available for work were placed in jobs. Sixty to eighty percent of the graduates of the alternative postsecondary institutions have, in recent years, secured jobs directly related to their training. Not only did the majority of those graduated have jobs, but it now appears that their salaries are competitive with those of college graduates.

What job opportunities and advantages are there for the student who obtains a college degree? According to the Bureau of Labor Statistics, the number of graduates will exceed the number of jobs requiring their skills by 800,000 between now and 1981. The United States Census Bureau projects that in the next ten years 800,000 people will graduate from college into a world that doesn't need them.

In 1975, there were 30,000 law school graduates competing for 15,000 jobs. For several years the colleges and universities have been turning out more teachers than there are teaching positions. The Department of Labor reports that three fourths of the social science graduates and two thirds of the humanities graduates who came out of college in the early 1970's have had to take jobs not directly related to their majors. A liberal arts degree has been called a ticket to unemployment.

8

One recent study suggests that as much as 27 percent of the nation's work force may now be made up of people who are "overeducated" for the jobs they hold. The U.S. Office of Education estimates that four out of five jobs created in the 1970's will require vocational or technical training but not a college degree, and the U.S. Department of Labor confirms this with its prediction that 20 percent of the jobs opening in the 1970's will require a four - year college degree while 80% will require a high school diploma or training beyond the high school but less than four years of college. According to the Department of Labor, the biggest demand during the 1970's will be for stenographers and secretaries.

The shorter term program of the proprietary school is possible because of (1) job specific training and (2) intense instructional programs. Colleges provide approximately 512 hours of instruction (16 credit hours times 32 weeks in an academic year), while proprietary schools average about 900 instructional hours per year (this is the minimum required by schools approved by the Veterans Administration). At Alaska Business College ours is higher than that.

The proprietary institutions recognize the need for accountability and believe that the government and taxpayers should be equally concerned with the performance of the institutions they subsidize. The welfare of the student is the primary consideration in education and the student should not be discriminated against because of regulations imposed on the type of school <sup>they choose</sup> to attend.

In recent VA cases, it appears the lack of diligence on the part of the institution in taking classroom attendance resulted in claims of overpayment to the student who is enrolled but not attending classes. If proprietary schools operated

in such a manner, the regulation governing them could not possibly be met. Certainly nonprofit insitiutions should have at least the same scrutiny since they are artifically supported through taxpayers' money and are, therefore, less responsive to the checks and balances of the marketplace.

The Times article continues - Although the University of Alaska is exempt, he said the proposals are not special interest legisiation for the State university. Why should any school in this state be exempt from accountability? With the millions of dollars of tax payers' money pouring into our public postsecondary institutions why should they be above accountability? In addition to the University and all Community Colleges being exempt so are all the trade unions who arc also in the educational business.

BONDING

This type of bonding is a new situation for the insurance companies.

To date my information indicates that any new venture or any school with soft financing would have difficulty getting the institutional bond. Those that could would need \$100,000 net worth and 25,000 working capital. It would cost a soft financed company \$4,500 for a school with 251 - 400 students. At this time Alaska Business College's basic insurance for student protection and other necessary insurance is costing right at \$5,000 for this year, and that does not include institutional or agent bonding. Insurance companies point out such items as on page 4 under Institutional minimum standards and ask by whose standards? That's a value judgment - whose?

It would create the same problem as the medical profession has in Alaska today.

Our alternative to bonding is to put up our own properties - pledging it to the state. Please explain how - when all our assets are pledged to the bonding company or the state - we function with our bankers when we must borrow as all viable businesses must do from time to time? Where are the assets - they are all pledged!

For eighteen years our school has struggled to grow in stature and strength for our graduates. We have exceptional programs, national accreditation, and have been nationally recognized as one of the top quality schools west of the Mississippi; yet you speak of the protection of the students. What about protection from anonymous complaints and open complaints of disgruntled students seeking a diploma without doing the work. My experience has been that we are guilty as charged until proven innocent even to the extent of having to answer to anonymous complaints as we have during a recent commissioner's visit to our school.

In conclusion - Private schools are not fighting accountability. We are asking for fair representation on the Commission. We are asking for the right to operate in a legitimate and fair business climate; not one that expects the small private school operator to be governed by massive, burdensome, restrictive legislation while the University, community colleges, and trade union schools operate without any restrictive legislation just because they are already above legislative control.

Pluralism in education is essential to a free society.

UNAPPROVED MINUTES

February 28-March 1, 1986  
Juneau, Alaska

Alaska Commission on Postsecondary Education  
Box F1  
Juneau, Alaska

February 28-March 1, 1986 Meeting  
MINUTES

LEGISLATIVE CONCERNS

HB 426 - Adding member to Commission on Postsecondary Education.

Commissioner Clark moved that the Commission endorse HB 426. Ms. Smith seconded.  
The motion carried.

# STATE OF ALASKA 1986 LEGISLATIVE SESSION FISCAL NOTE

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

**REQUEST**

Bill/Resolution No. : HB426  
 Title : Adding member to Postsecondary Commission  
 Sponsor : Roucher  
 Requestor : House HESS  
 Date of Request : March 17, 1986

**FISCAL DETAIL**

Agency Affected : Education  
 BRU : Postsecondary Education  
 Components : General Administration

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

OPERATING	FY 86	FY 87	FY 88	FY 89	FY 90	FY 91
PERSONAL SERVICES						
TRAVEL		1.9	2.0	2.1	2.3	2.4
CONTRACTUAL						
SUPPLIES						
EQUIPMENT						
LAND & STRUCTURES						
GRANTS, CLAIMS						
MISCELLANEOUS						
<b>TOTAL OPERATING</b>	<b>N.A.</b>	<b>1.9</b>	<b>2.0</b>	<b>2.1</b>	<b>2.3</b>	<b>2.4</b>

CAPITAL						
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REVENUE						
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**FUNDING : (Thousands of Dollars)**

GENERAL FUND	N.A.	1.9	2.0	2.1	2.3	2.4
FEDERAL FUNDS						
OTHER						
<b>TOTAL</b>						

**POSITIONS :**

FULL-TIME	N.A.	-0-	-0-	-0-	-0-	-0-
PART-TIME						
TEMPORARY						

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

Travel is for Commission meetings only and assumes an Anchorage base. Beyond FY87 is a 6% inflationary increase.

Prepared by : Kerry D. Romesburg, *Kerry Romesburg* Director  
 Division : Alaska Commission on Postsecondary Education  
 Approved by Commissioner : \_\_\_\_\_  
 Agency : \_\_\_\_\_

Phone : 465-2854  
 Date : March 17, 1986  
 Date : March 17, 1986

Distribution (by Agency preparing fiscal note) :

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

Introduced: 5/7/85  
Referred: Health, Education &  
Social Services

1 IN THE HOUSE

BY BOUCHER

2

HOUSE BILL NO. 426

3

IN THE LEGISLATURE OF THE STATE OF ALASKA

4

FOURTEENTH LEGISLATURE - FIRST SESSION

5

A BILL

6 For an Act entitled: "An Act adding a member to the Alaska Commission on  
7 Postsecondary Education."

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

9 \* Section 1. AS 14.42.015(a) is amended to read:

10 (a) There is in the Department of Education the Alaska Commis-  
11 sion on Postsecondary Education consisting of

12 (1) two members of the Board of Regents of the University  
13 of Alaska designated by the members of that body;

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15 state selected jointly by the Boards of Trustees of Alaska Pacific  
16 University and Sheldon Jackson College from among their membership;

17 (3) one person representing the Department of Education  
18 selected by the state Board of Education;

19 (4) four persons broadly and equitably representative of  
20 the general public appointed by the governor;

21 (5) one member of the state Advisory Council on Vocational  
22 Education designated by the members of that body;

23 (6) one person from [AMONG] the members of the local com-  
24 munity college advisory councils appointed, initially, by the governor  
25 until the state Advisory Council on Community Colleges is established  
26 and organized under AS 14.42.030(b); then, one member of the state  
27 Advisory Council on Community Colleges designated by the members of  
28 that body;

29 (7) two members from the legislature, one of whom shall be

## SECTIONAL ANALYSIS

HB 426 - relating to the regulation of postsecondary institutions (note: the provisions of HB 602 have been combined into this bill).

- Section 1 Adds to the Postsecondary Education commission a representative of a proprietary school. Also clarifies two provisions: 6) deletes the state advisory council on community colleges because it does not exist and 7) who appoints legislative members.
- Section 2 Gives the Postsecondary Education Commission the authority to determine if the charges for fees, tuition, books and supplies set by proprietary schools are fair and equitable.
- Section 3 Allows the commission to accept property in lieu of a surety bond for proprietary schools.
- Section 4 Conforming amendment with section 5.
- Section 5 Allows the Commission to revoke a license to operate without completing all steps in the Administrative Procedures Act for a school which has gone out of business.
- Section 6 Places enforcement of the provisions in section 2 under the Consumer Protection Division of the Department of Law.
- Section 7 Conforming amendment with section 6.
- Section 8 Temporary law provision providing that members of the Postsecondary Commission need not be replaced because of the provisions of section 1.

# **CORRECTION**

**THIS DOCUMENT  
HAS BEEN REPHOTOGRAPHED  
TO ASSURE LEGIBILITY**

Introduced: 5/7/85  
Referred: Health, Education &  
Social Services

1 IN THE HOUSE

BY BOUCHER

2

HOUSE BILL NO. 426

3

IN THE LEGISLATURE OF THE STATE OF ALASKA

4

FOURTEENTH LEGISLATURE - FIRST SESSION

5

A BILL

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27 Advisory Council on Community Colleges designated by the members of  
28 that body;

29 (7) two members from the legislature, one of whom shall be

1 designated by the Legislative Council and one by the Legislative  
2 Budget and Audit Committee;

3 (8) one person appointed in accordance with (e) of this  
4 section who is a full-time student as defined in AS 14.43.160(2);

5 (9) one administrator appointed by the governor from a  
6 proprietary institution of postsecondary education that has an author-  
7 ization to operate in the state issued under AS 14.48.

## SECTIONAL ANALYSIS

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# STATE OF ALASKA 1986 LEGISLATIVE SESSION FISCAL NOTE

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

**REQUEST**

Bill/Resolution No. : CSHB 426 (HESS)  
 Title : "An Act Relating to  
 Postsecondary Educational  
 Institutions"  
 Sponsor : Representative Boucher  
 Requestor : House HESS  
 Date of Request : April 7, 1986

**FISCAL DETAIL**

Agency Affected : Department of Law  
 BRU : Consumer Protection  
 \_\_\_\_\_  
 Components : Consumer Protection  
 \_\_\_\_\_

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

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

CAPITAL						
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REVENUE						
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**FUNDING : (Thousands of Dollars)**

GENERAL FUND		-0-	-0-	-0-	-0-	-0-
FEDERAL FUNDS						
OTHER						
<b>TOTAL</b>						

**POSITIONS :**

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

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

Please see attached analysis.

Prepared by : Richard I. Pegues, Director Phone : 465-3672  
 Division : Administrative Services Division Date : 4/7/86

Approved by Commissioner : Richard I. Pegues / Full Date : 4/7/86  
 Agency : Department of Law

Distribution (by Agency preparing fiscal note) :

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

# CONTINUATION of FISCAL NOTE ANALYSIS

For Bill/Resolution No. CSHB 426 (HESS)

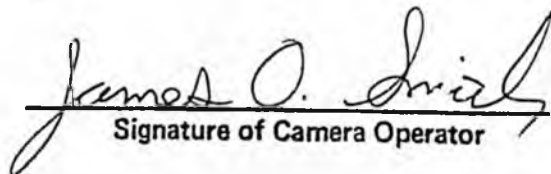
Section 2 and Section 8 of this bill makes charges set by institutions for tuition, fees, books and supplies subject to the unfair trade practices statutes. In view of substantial reductions being made in the consumer protection budget for FY87, the Department of Law will have to rely on the Commission on Postsecondary Education to gather complaints and provide evidence of alleged wrongdoing before the department could take enforcement actions. Likewise, to the extent that any substantial enforcement action becomes necessary, the department would require that the commission transfer funds to the department sufficient to pay for the costs of enforcement, including the personal service costs for the attorneys.

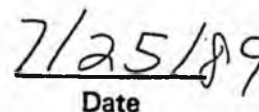


# RECORDS CERTIFICATION



I, the undersigned, an employee of the State of Alaska, do hereby certify that the microfilm images on this microform are accurate reproductions of the original records of the State of Alaska as accumulated during the regular course of business, and that it is the established policy and practice of this State to microfilm its records and to dispose of the original records after microfilm reproductions have been made.

  
Signature of Camera Operator

  
Date

H B

4 5 0

**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  
 Division: Occupational Licensing

Phone: 465-2144

Date: 4/23/86

Approved by Commissioner: [Signature]  
 Agency: Commerce and Economic Development

Date: 4/28/86

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

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

# CONTINUATION of FISCAL NOTE ANALYSIS

For Bill/Resolution No. CSHB 430 (HESS)

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
		\$ 0 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	\$ .0
		+ 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

HEALTH, EDUCATION AND  
The SOCIAL SERVICES

DATE: March 18, 1986

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)
- no recommendation
- replace with CO 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:

SIGNING OTHER RECOMMENDATIONS:

Adrian L. Taylor V.C.  
Katie Purcell  
Miss J. J. [unclear]  
David W. [unclear]  
[unclear]  
Phil E. Kopman

[Signature] no rec

Miss J. J. [unclear]  
 Chairman  
Phil E. Kopman

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:

FULLTIME		0	0	0	0	0
PARTTIME						
TEMPORARY						

ANALYSIS: Attach a separate page if necessary.

The bill charges the department with the responsibility of licensing audiologists and hearing aid dealers. Information received indicates that the number of practitioners affected by the bill are few--12 audiologists and 6-10 legitimate hearing aid dealers. Apparently, fly-by-night individuals have harmed Alaskan consumers as documented by complaints on file with Consumer Protection in the Department of Law,

Prepared by: Jennifer Strickler, Management Analyst  
 Division: Occupational Licensing

Phone: 465-2144  
 Date: 3-5-86

Approved by Commissioner: [Signature]  
 Agency: Commerce and Economic Development

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

Distribution (by Agency preparing fiscal note):

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

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.

# **CORRECTION**

**THIS DOCUMENT  
HAS BEEN REPHOTOGRAPHED  
TO ASSURE LEGIBILITY**

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 legitimate 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  
 Division: Occupational Licensing

Phone: 465-2114  
 Date: 3-5-86

Approved by Commissioner: [Signature]  
 Agency: Commerce and Economic Development

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

Distribution (by Agency preparing fiscal note):

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

# CONTINUATION of FISCAL NOTE ANALYSIS

For Bill/Resolution No. CSHB 430 (L&C) Page 2 of 2

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.

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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08.55.040 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



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

## House of Representatives

### MEMORANDUM

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

FROM: Rep. Mike Navarre

March 18, 1986

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

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

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

The other amendments are mainly housekeeping measures.

Thanks for your assistance in this matter.

Offered by Representative Mike Navarre

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

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

Page 17:

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

Line 7, delete "or an audiologist".

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

Line 10, delete "or the audiologist".

Line 13, delete "or the audiologist".

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

Line 29, delete "hearing", insert "medical" between "&" 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.

Sec. 521, 701, 52 Stat. 1055-1055 as amended, 29 Stat. 574 (21 U.S.C. 360k, 371)

Dated: October 5, 1980.

Jose E. Goyan,  
Commissioner of Food and Drugs.

FD-301 (Rev. 10-29-80) (13)  
CLINIC CODE 4110-03-4

21 CFR Part 803  
(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 82 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 208 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 § 801.423(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.

FD Doc 43-31479 Filed 10-9-80 EJS:smj  
BILLING CODE 4110-03-4

21 CFR Part 208

[Docket No. 77K-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. Saeban, 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 25, 1978 to comment on the proposal. In the Federal Register of October 20, 1978 (43 FR 49015), the comment period was extended to December 19, 1978. In the Federal Register of October 22, 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 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 government

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

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

#### The FTC Rule

1. The Federal Trade Commission (FTC) also has been studying the hearing aid health care delivery system to determine what steps should be taken to protect consumers from unfair or deceptive acts or practices in the sale of hearing aids. In the Federal Register of June 24, 1975 (40 FR 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 aid to select and fit hearing aids. The agency believes that the Federal requirements, along with strong State and local licensing laws, will adequately address the abuses in the hearing aid industry described in the FTC staff report.

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

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

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

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

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

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

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

Congress enacted the Medical Device Amendments of 1976 (Pub. L. 94-285) 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. 291 (1976); *United States v. Dorky*, 312 U.S. 100 (1941). In enacting section 520(e) of the act, Congress determined that the safety and effectiveness of certain medical devices may be ensured only by restricting their sale, distribution, or use. Section 520(e) of the act, therefore, is a valid exercise of congressional authority under the commerce clause. In restricting the sale of hearing aids, FDA acted in accordance with the authority granted it under section 520(e). Therefore, Neither FDA's restrictions on the labeling and conditions for sale of hearing aids nor its decision to deny exemptions from preemption for State

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

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

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

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

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

determining whether to grant an exemption from preemption.

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

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

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

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

7. The comment also stated that proposed § 808.1(d)(5) (21 CFR 808.1(d)(5)), which provides that section 521(a) of the act does not preempt criteria for payment of State or local obligations under Medicaid and similar health care programs, is unlawful because section 521(e) 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 individual 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 preemptive State laws requiring that a hearing aid purchaser be examined by an

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

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

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

An "informal hearing," as defined in section 201(y) of the act, is required only where the term "informal hearing" is specifically used in the act. For example, an "informal hearing" is required under sections 392(g), 515, and 516. An informal hearing is often referred to as a regulatory hearing and is governed by Part 16 of the agency's administrative regulations (21 CFR Part 16). Section 521 of the act provides for the opportunity for an oral hearing, rather than an "informal hearing," on a proposed regulation on an application for exemption from preemption. The public hearing required by section 521 of the act is sometimes referred to as a legislative hearing and is governed by Part 15 (21 CFR Part 15) of the agency's administrative regulations. Indeed, 21 CFR 15.1(b) expressly states that Part 15 governs any hearing relating to exemptions from preemption of requirements for device.

#### Audiological Evaluation

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

#### Waiver

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

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

permitted. Other comments suggested that only persons with religious objections should be permitted to waive the medical examination. Several comments stated that it is easy for hearing aid dealers, eager to make a sale, to induce the purchaser to waive medical evaluation without violating FDA regulation by actively encouraging the waiver. Other comments said that hearing aid dealers are widely abusing the waiver provision. For instance, the Attorney General of Massachusetts asserted that prospective hearing aid purchasers waive the medical evaluation requirement in 65 percent of the sales of hearing aids in Massachusetts.

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

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

FDA has not been presented with 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 the waiver privilege is being exercised in 65 percent of the sales of hearing aids in that Commonwealth. FDA undertook a survey of Attorneys General and

... and dealer licensing boards to determine whether they were experiencing any problems with compliance with the FDA regulation. Of 30 States that responded to this survey, only 19 provided FDA with information pertaining to dealer compliance with the regulation. Twenty-five of these 31 States indicated that they had not received complaints or other information regarding dealer compliance with the regulation, although a few of these 25 States related unsubstantiated rumors of noncompliance. Six of the 31 States responding to the survey indicated that they had encountered problems involving compliance with FDA regulation but of these six, only Massachusetts stated that compliance problems were more common than isolated incidents. Therefore, FDA is denying exemption from preemption for State laws limiting or prohibiting waiver of medical evaluation. Exempting these requirements will also permit the purchase of a hearing aid in the rare circumstance where an individual would have great difficulty obtaining a medical evaluation because of the lack of a physician in the area.

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

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

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

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

#### Disclosure Requirements

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

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

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

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

#### Arizona

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

Several comments opposed FDA's proposal to grant exemption from preemption for A.R.S. Chapter 17, Section 36-1901.7(t) and its implementing regulation, A.C.R.R. Title 9, Article 3, R-9-16-303. These provisions require that a prospective hearing aid user with a significant air bone gap or apparent unilateral sensorineural hearing loss receive an audiological evaluation, although they permit a waiver of this requirement. The comments argued that this State requirement places audiological evaluation on a par with medical evaluation and that this is inconsistent with the position of FDA that audiological evaluation is not necessary to provide reasonable assurance of the safety or effectiveness of hearing aids. One comment argued that this requirement may mislead people into believing that audiological evaluation is as important as medical evaluation.

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

#### California

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

## FDA REGULATIONS FOR HEARING AIDS

§801.420 Hearing aid devices; professional and patient labeling.

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

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

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

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

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

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

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

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

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

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

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

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

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

(iv) Specific instructions for:

(a) Use of the hearing aid.

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

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

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

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

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

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

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

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

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

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

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

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

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

### WARNING TO HEARING AID DISPENSERS

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

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

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

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

(iv) Acute or chronic dizziness.

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

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

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

(viii) Pain or discomfort in the ear

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

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

### IMPORTANT NOTICE FOR PROSPECTIVE HEARING AID USERS

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

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

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

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

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

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

#### Children with Hearing Loss

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

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

- (i) Saturation output curve (SSPL 90 curve).
- (ii) Frequency response curve.
- (iii) Average saturation output (HF-Average SSPL 90)
- (iv) Average full-on gain (HF-Average full-on gain);
- (v) Reference test gain.
- (vi) Frequency range.
- (vii) Total harmonic distortion.
- (viii) Equivalent input noise.
- (ix) Battery current drain.
- (x) Induction coil sensitivity (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 labeling for each type of hearing aid. Any manufacturer of a hearing aid described in paragraph (a) of this section shall submit to the Food and Drug Administration, Department of Health, Education and Welfare, Office of Medical Devices and

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

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

(a) Medical evaluation requirements — (1) General. Except as provided in paragraph (a) (2) of this section, a hearing aid dispenser shall not sell a hearing aid unless the prospective user has presented to the hearing aid dispenser a written statement signed by a licensed physician that states that the patient's hearing loss has been medically evaluated and the patient may be considered a candidate for a hearing aid. The medical evaluation must have taken place within the preceding 6 months.

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

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

I have been advised 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. Virginia Collins  
Rep. Alyce Hanley  
Rep. Drue Pearce  
Rep. Niilo Koponen

FROM: Patrick Malone *PM*  
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 ambiguities.

BILL SHEFFIELD, GOVERNOR

**DEPARTMENT OF ADMINISTRATION**

OLDER ALASKANS COMMISSION

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

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 Chair  
Older Alaskans Commission

cc: Older Alaskans Commission  
Jon Wolfe



(907)  
P.O. Box 102240 • Anchorage, Alaska 99510 • 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

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 distributor 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

BILL SHEFFIELD, GOVERNOR

XX REPLY TO

1021 W 4TH SUITE 110  
ANCHORAGE ALASKA 99501  
PHONE (907) 273-0428

151 NATIONAL CENTER  
100 CUSHMAN SUITE 407  
FAIRBANKS ALASKA 99701  
PHONE (907) 456-8588

U.S. FULLER BLDG  
411 E HARRIS SUITE 214  
POUGH  
JUNEAU ALASKA 99801  
PHONE (907) 465-3692

STATE COURTHOUSE ROOM 26  
P.O. BOX 671  
VALDEZ ALASKA 99586  
PHONE (907) 835-2462

RECEIVED  
Department of Law



JUL 24 1984

CONSUMER COMPLAINT

166393-AP5-AI 46-0

Office of the Attorney General  
Consumer Protection Section  
Anchorage, Alaska

ATTORNEY GENERAL

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 Last First MI <b>HINES LLOYD</b>		2. TODAY'S DATE <b>JULY 20, 1984</b>	
3. MAILING ADDRESS <b>4000 BRYN MAWR CT.</b>		CITY <b>ANCHORAGE</b>	STATE <b>ALASKA</b>
4. HOME ADDRESS (if different)		CITY	STATE
5. HOME TELEPHONE NO. <b>333-7682</b>		6. BUSINESS TELEPHONE NO. <b>333-9411</b>	
7. NAME OF THE PERSON OR COMPANY COMPLAINED ABOUT <b>CUSTOM HEARING AID CENTER</b>		NAME OF SALESPERSON: <b>THOMAS S. GARCIA</b>	
8. COMPANY'S ADDRESS <b>3136 NEW SEWARD HIGHWAY</b>		CITY <b>ANCHORAGE</b>	STATE <b>ALASKA</b>
9. COMPANY'S TELEPHONE NO. <b>274-7330</b>		10. DATE OF TRANSACTION <b>September 6, 1983</b>	
11. WERE YOU ATTRACTED TO THE SERVICE OR PRODUCT BY AN ADVERTISEMENT? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
12. IF YES, WHEN AND WHERE DID YOU SEE THE ADVERTISEMENT?			
13. WAS A WRITTEN CONTRACT SIGNED? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO			
14. HAVE YOU COMPLAINED TO THE INDIVIDUAL OR COMPANY? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		15. IF YES, NAME OF PERSON TO WHOM YOU COMPLAINED.	
16. HAVE YOU CONTACTED A PRIVATE ATTORNEY? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		17. IF YES, NAME OF ATTORNEY.	
18. IS THERE A COURT OR ADMINISTRATIVE PROCEEDING PENDING? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		19. IF YES, NAME COURT OR AGENCY.	

AUTOMOBILE REPAIR ONLY

20. DID YOU REQUEST A SIGNED COPY OF REPAIRS TO BE MADE?	<input type="checkbox"/> YES <input type="checkbox"/> NO	DID YOU RECEIVE IT?	<input type="checkbox"/> YES <input type="checkbox"/> NO
DID YOU REQUEST A WRITTEN PRICE ESTIMATE?	<input type="checkbox"/> YES <input type="checkbox"/> NO	DID YOU RECEIVE IT?	<input type="checkbox"/> YES <input type="checkbox"/> NO
DID COSTS EXCEED WRITTEN ESTIMATE?	<input type="checkbox"/> YES <input type="checkbox"/> NO		
WERE YOU NOTIFIED OF ADDITIONAL COSTS BEFORE WORK WAS DONE?	<input type="checkbox"/> YES <input type="checkbox"/> NO		
DID YOU REQUEST THAT REPLACED PARTS BE RETURNED TO YOU?	<input type="checkbox"/> YES <input type="checkbox"/> NO	RECEIVED/OR ALLOWED TO INSPECT PARTS?	<input type="checkbox"/> YES <input type="checkbox"/> NO
		DID YOU RECEIVE IT?	<input type="checkbox"/> YES <input type="checkbox"/> 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 J. 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, 1988, 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

CONSUMER COMPLAINT

ATTORNEY GENERAL

000395-F85-A-1460

AUG 23 1984

ANCHORAGE

FAIRBANKS

JUNEAU

VALDEZ

Office of the Attorney General  
1031 W. Cushman, Ste. 400  
Suite 110 Anchorage, AK 99501  
279-0428

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 <i>MAHLE PRISILLA</i>	2. TODAY'S DATE <i>August 23 1984</i>
3. MAILING ADDRESS <i>8081 WISTERIA</i>	CITY STATE ZIP CODE <i>ANCHORAGE AK 99501</i>
4. HOME ADDRESS (if different) <i>SAME</i>	CITY STATE ZIP CODE
5. HOME TELEPHONE NO. <i>(907) 243-667</i>	6. BUSINESS TELEPHONE NO.
7. NAME OF THE PERSON OR COMPANY COMPLAINED ABOUT <i>Custom Hushing Center</i>	NAME OF SALESPERSON: <i>Thomas Garcia</i>
8. COMPANY'S ADDRESS <i>3136 New Seward Hwy</i>	CITY STATE ZIP CODE <i>ANCHORAGE AK 99502</i>
9. COMPANY'S TELEPHONE NO. <i>(907) 274-7330</i>	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 NEWS PAPERS*

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?	<input type="checkbox"/> YES <input type="checkbox"/> NO	DID YOU RECEIVE IT?	<input type="checkbox"/> YES <input type="checkbox"/> NO
DID YOU REQUEST A WRITTEN PRICE ESTIMATE?	<input type="checkbox"/> YES <input type="checkbox"/> NO	DID YOU RECEIVE IT?	<input type="checkbox"/> YES <input type="checkbox"/> NO
DID COSTS EXCEED WRITTEN ESTIMATE?	<input type="checkbox"/> YES <input type="checkbox"/> NO		
WERE YOU NOTIFIED OF ADDITIONAL COSTS BEFORE WORK WAS DONE?	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		
DID YOU REQUEST THAT REPLACED PARTS BE RETURNED TO YOU?	<input type="checkbox"/> YES <input type="checkbox"/> NO	RECEIVED/OR ALLOWED TO INSPECT PARTS?	<input type="checkbox"/> YES <input type="checkbox"/> NO
		DID YOU RECEIVE IT?	<input type="checkbox"/> YES <input type="checkbox"/> 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.

*Prisilla 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 JACOBSON  
AT "CUSTOM HEARINGS" 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-WARRANTED DANGER.  
I ALSO WENT BY THEIR SHOP <sup>IT WAS</sup> VACATED.  
THIS HEARING AID IS OF NO USE TO ME  
AS IT DOES NOT WORK AND I CANNOT  
GET IT REPAIRED. I ~~HAVE~~ <sup>WILL BE</sup>  
FORCED TO PURCHASE ANOTHER HEARING  
AID. ~~IN THE PAST~~. SO I WOULD  
LIKE TO BE REIMBURSED FOR MY \$650.00  
FOR <sup>I PAID</sup> DEFECTIVE HEARING AID.

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

I WOULD LIKE MY MONEY REPAID, 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



FEB - 3 1985 CONSUMER COMPLAINT

Office of the Attorney General ATTORNEY GENERAL  
Consumer Protection Section

000864-F-85-A-1 460

<b>ANCHORAGE</b> 1031 W. 4th Suite 110 Anchorage, AK 99501 279-0428	<b>ANCHORAGE</b> 1st National Center 100 Cushman, Ste. 400 Fairbanks, AK 99701 456-8588	<b>JUNEAU</b> S.S. Fuller Bldg. 4th & Harris, Ste. 214 Fouch K Juneau, AK 99811 465-3692	<b>VALDEZ</b> P. O. Box 671 Valdez, AK 99686 835-2462
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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 <u>YAKASOFF Albert J.</u>	2. TODAY'S DATE <u>Feb. 7th 1985</u>
3. MAILING ADDRESS <u>4320 EAST 3rd AVE.</u>	CITY <u>ANCHORAGE</u> STATE <u>AK</u> ZIP CODE <u>99504</u>
4. HOME ADDRESS (if different)	CITY STATE ZIP CODE
5. HOME TELEPHONE NO. <u>(907) 333-6369</u>	6. BUSINESS TELEPHONE NO. <u>NONE - Retire</u>
7. NAME OF THE PERSON OR COMPANY COMPLAINED ABOUT: <u>MIRACLE FEE</u>	NAME OF SALESPERSON: <u>JACK E. HURD</u>
8. COMPANY'S ADDRESS <u>2900 Arctic Blvd.</u>	CITY <u>ANCHORAGE</u> STATE <u>AK</u> ZIP CODE <u>99503</u>
9. COMPANY'S TELEPHONE NO. <u>907-562-4463</u>	10. DATE OF TRANSACTION <u>JAN. 8th 1985</u>
11. WERE YOU ATTRACTED TO THE SERVICE OR PRODUCT BY AN ADVERTISEMENT? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	
12. IF YES, WHEN AND WHERE DID YOU SEE THE ADVERTISEMENT? <u>ANCHORAGE TIMES NEWS PAPER</u>	
13. WAS A WRITTEN CONTRACT SIGNED? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	
14. HAVE YOU COMPLAINED TO THE INDIVIDUAL OR COMPANY? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	15. IF YES, NAME OF PERSON TO WHOM YOU COMPLAINED. <u>JACK HURD - SALESMAN</u>
16. HAVE YOU CONTACTED A PRIVATE ATTORNEY? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	17. IF YES, NAME OF ATTORNEY.
18. IS THERE A COURT OR ADMINISTRATIVE PROCEEDING PENDING? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	19. IF YES, NAME COURT OR AGENCY.

AUTOMOBILE REPAIR ONLY

20. DID YOU REQUEST A SIGNED COPY OF REPAIRS TO BE MADE?	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	DID YOU RECEIVE IT?	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO
DID YOU REQUEST A WRITTEN PRICE ESTIMATE?	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	DID YOU RECEIVE IT?	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
DID COSTS EXCEED WRITTEN ESTIMATE?	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		
WERE YOU NOTIFIED OF ADDITIONAL COSTS BEFORE WORK WAS DONE?	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		
DID YOU REQUEST THAT REPLACED PARTS BE RETURNED TO YOU?	<input type="checkbox"/> YES <input type="checkbox"/> NO	RECEIVED/OR ALLOWED TO INSPECT PARTS?	<input type="checkbox"/> YES <input type="checkbox"/> NO
		DID YOU RECEIVE IT?	<input type="checkbox"/> YES <input type="checkbox"/> 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.
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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)

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But complete.

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Order @ 1 pair of hearing aid, the salesman  
Jack E. Hurd.

Two weeks after order, then - Mr Hurd had  
to come back & take seemed impressed of the  
cost of our ears.

Then I had to wait another couple weeks  
for hearing aid. Then I went to <sup>the</sup> Plesher  
Nations Hospital, and I was told that the  
price was going realistic 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 understand -  
stupid business - if notes they had deposit my  
check here in Anchorage Bank. I don't see  
why that 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.

They are unable with this statement.

I was told by Mr. Hurd - I got a check  
from Company in Minneapolis, Minn.

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)

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