ALASKA LEGISLATURE COMMITTEE FILES 1985-1986 8672

3504 HLAB HB 430 - HB 466

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Ear
Nose
Throat
CLINIC

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

Audiologist
Phyllis Cashen Williams

March 26, 1986

Representative Navarre
Pouch V
Juneau, AK 99811

RE: HB 430

Dear Representative:

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

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

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

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

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(1) On page 15. #5 - I feel that providing a statement to the consumer somehow destroys the audiologist-client relationship. If the patient has a complaint about the hearing aid, he should first bring it to the audiologist and almost all problems can be solved. For instance. our audiologist has only had one hearing aid returned because of an unsuccessful fitting in four years. The key to successful fitting of a hearing aid is education of the patient, proper earmolds and if anything goes wrong with the aid. it can be fixed locally and taken care of by the audiologist or hearing aid dealer. Firing complaints off to a state agency because your earmold does not fit is ridiculous.

(2) On page 18, paragraph B - displaying signs about where to make complaints about the product or services that you are selling plants the idea that maybe there will be a problem before any problems actually occur. In general, no one pays much attention to such signs anyway. I have diplomas and licenses all over my office wall and patients never even look at them. Having a sign on the wall is not going to make audiologists and hearing aid dealers more professional or moer competent which is really the key to why this bill is necessary in the first place.

(3) On page 19 concerning the cancellation option - our audiologist tells the patient that if for any reason after adjusting and wearing the hearing aid in the normal routine for a period of time that they are unable to tolerate the aid or it does not help, they are certainly free to return it. We do not want that to happen, of course, and thus give the patient a 3 - 4 day trial with a loaner hearing aid similar to the one that they will be purchasing. Usually after a few days, the patient can tell whether the aid will be helpful and whether they want to go ahead with purchase. This is the way that most reputable audiologists handle hearing aid sales. In the many years that we have been doing this. we have not had a single aid which was kept by the patient and not turned back in - and have only had one aid sold that was ever returned as unsatisfactory. 60 days may be too long a period of time for a person to have a hearing aid and then return it. The major problem that people have with hearing aids is not putting in new batteries, the aids falling off into the sink or toilet. the aids falling off and being stepped on, the dog chewing them up, etc. A lot of trauma can occur in 60 days which is not the fault of manufacturing but is the purchaser's negligence. That is like buying a new car and driving it from Fairbanks to California then driving it back and turning it in because you don't like the color or it doesn't fit your personality but there is nothing mechanically unsound about it. The cancellation contract is fine for the 60 day period if an audiologist or physician tells the patient they didn't need the aid or it was inappropriate. Otherwise, 15 days is reasonable to wear the instrument and then turn it in without too much damage to the goods.

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

(4) On page 22, there is nothing in paragraph stating how to handle a damaged hearing aid that has been returned. Is it your intent that if a person willingly breaks or damages the aid and then decides to return it, it is the dealers responsibility to go the place of residence, collect the broken aid, and give them their money back? Get serious!

(5) On page 24, paragraph 10 - I feel this is a good point in that it will discourage the door-to-door salesmen from the Lower 48 as they are the biggest offenders in this area.

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

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

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

REGULATE DON'T SUFFOCATE!

Sincerely,

Richard P. Raugust M.D.

Richard P. Raugust, M.D.
Otolaryngology

RPR/co

Ear
Nose
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March 26, 1986

Mike Navarre
Pouch V
Juneau, AK 99811

RE: HB #430

Dear Mr. Navarre:

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

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

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

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

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

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(2) On page 17, line 29 should read "I had a medical evaluation by a licensed..." rather than "I had a hearing evaluation by a licensed...".

(3) On page 18, line 2 "or a licensed audiologist" should be omitted.

(4) On page 20. line 27 "will be returned within 10 business days following..." should be changed to "will be returned within 15 business days following...". In the 3 1/2 years that I have been dispensing hearing aids, we have refunded money for returned hearing aids within 30 days. This seems to have worked well and often the refund is made within less than 30 days, however, this gives the business department a chance to research the refund as often an insurance company is involved and refund for the aid not only goes to the client but also to the insurance company. As we often deal with third party payment in the sale of hearing aids, I believe a 15 day time period for refund is not an excessively long period of time.

(5) On page 21, line 3, "if you cancel, you must make available to the..." should be changed to read "if you cancel, you must return to the..." I am really not comfortable with the wording throughout this page in reference to the consumer needing to "make available" the aid to the dealer which he has purchased and now wants refund for. It is the purchasers responsibility to return the aid to the dealer in as good a condition as received less normal wear and tear. It is not the hearing aid dealer or the audiologist's responsibility to retrieve the aid from the purchaser. Throughout the paragraph on page 21, it seems that the responsibility is not placed on the purchaser to return the aid to the dealer. A simple change in wording would make this more clear.

(6) On page 21 line 9 through line 14 "if you make the goods available for the hearing aid dealer to collect after your cancellation and the hearing aid dealer does not collect from you within 20 days of your cancellation, you may retain or dispose of the goods without further obligation to the hearing aid dealer". This entire section should be omitted as it deviates from the intent of the consumers right to cancel. Cancellation of the transaction for purchase of a hearing aid is contingent upon their return of the hearing aid purchased. The responsibility for returning the hearing aid is that of the client or purchaser and is not the responsibility of the hearing aid dealer to collect the aid from the client.

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

(7) On page 21, line 23, I would like to see changed to "written notice together with the hearing aid(s) being returned for refund to (name of hearing aid dealer, at....) which insures that the hearing aid dealer will receive the goods for which he is required to make refund.

(8) On page 22. line 28 and 29 and page 23. line 1 and 2, should be omitted because again it puts the responsibility on the dealer to collect the aid rather than on the consumer to return the aid to the dealer. Written instructions on who and where to return the aid if the consumer wants to cancel the sale are given to the consumer at the time of purchase as stated in the Notice of Right to Cancel on page 20 - 21. The consumer who wants to return a hearing aid for refund should follow this procedure unless as quoted on page 21, line 6 "the dealer notifies you to keep the goods or hold them until the dealer collects them".

(9) On page 22. line 10 "dealer shall and within 10 days of receipt of the notice of cancellation..." should be changed to read "dealer shall and within 15 working days of notice of cancellation..." for the reasons as above.

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

Sincerely.

Phyllis Cashen Williams, MA

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

PCW/co

REPRESENTATIVE
MIKE NAVARRE

DISTRICT 5P

CHAIR, LABOR & COMMERCE
VICE-CHAIR, STATE AFFAIRS

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NAVARRE COPY

House of Representatives

MEMORANDUM

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

FROM: Rep. Mike Navarre

March 18, 1986

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

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

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

The other amendments are mainly housekeeping measures.

Thanks for your assistance in this matter.

Offered by Representative Mike Navarre

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

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

Page 17:

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

Line 7, delete "or an audiologist".

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

Line 10, delete "or the audiologist".

Line 13, delete "or the audiologist".

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

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

Page 18:

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

Line 8, delete "or the audiologist"

Line 9, insert "waiver" before "statement"

Page 22:

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

Page 23:

Revise Sec. 08.55.120 as follows:

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

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

FINAL FDA REG.

...sec. 521, 701, 52 Stat. 1055–1056 as ...ended, 90 Stat. 574 (21 U.S.C. 360k, 371))

Dated: October 5, 1980.

Jere E. Goyan,

Commissioner of Food and Drugs.

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

BILLING CODE 4110-03-M

21 CFR Part 808

[Docket No. 78P–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, 301–427–7174.

SUPPLEMENTARY INFORMATION: In the Federal Register of April 13, 1979 (44 FR 22119), FDA published a proposed regulation responding to applications from Massachusetts and Rhode Island for exemption from Federal preemption for certain hearing aid device requirements. Interested persons were given until June 12, 1979 to submit written comments on the proposal. A public hearing on the proposal was held on October 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 18 other States and the District of Columbia for exemption from preemption for their hearing aid requirements. Some of the issues raised in that proceeding are similar to the issues raised in the comments received on this rule. Because the issues are discussed in greater detail in that regulation, the agency refers interested persons to the preamble to that final rule.

1. One comment objected that the hearing held on the proposed regulation did not comply with the requirements for "informal hearing" specified in section 201(y) of the act (21 U.S.C. 321(y)), especially section 201(y)(1) which requires that the presiding officer be someone who has not participated in any action which is the subject of the hearing and who is not directly responsible to anyone who has participated in any such action. The comment further objected that the hearing officer did not conduct the hearing in an impartial manner.

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

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

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

3. Other comments opposing FDA's proposal to deny exemption from preemption for these waiver provisions argued that hearing aid dealers are abusing the FDA waiver provision. Some of these comments suggested that prospective hearing aid purchasers waive the medical evaluation requirement in 80 to 85 percent of the sales of hearing aids. The Massachusetts Hearing Aid Society surveyed its members and found that 58 percent of the sales of those responding were made to persons who had obtained a prior medical evaluation. The Rhode Island Hearing Aid Society also surveyed its members and found that 62 percent of the sales of those responding were made to persons who had obtained a prior medical evaluation.

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

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

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

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

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

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

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

FDA agrees with this comment. In the final rule responding to applications from 18 other States and the District of Columbia, published elsewhere in this issue of the Federal Register, the agency is exempting from preemption requirements of audiological evaluation for children under the age of 18. Audiologists are specially qualified to assist in the language development and social and educational growth of a child with a hearing loss. Consequently, mandatory audiological evaluation of a minor will serve an important public health purpose. Therefore, the final regulation has been revised to exempt from preemption the Massachusetts hearing test evaluation provision to the extent that it applies to children under the age of 18.

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

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 521, 701, 52 Stat. 1055–1056 as amended, 90 Stat. 574 (21 U.S.C. 360, 371)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Part 808 is amended in Subpart C by adding new §§ 808.71 and 808.89 to read as follows:

§ 808.71 Massachusetts.

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

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

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

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

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

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

§ 808.89 Rhode Island.

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

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

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

Dated: October 5, 1980.

Jere E. Goyan,

Commissioner of Food and Drugs.

[FR Doc. 80-31479 Filed 10-9-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 808

[Docket No. 77N-0333]

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

AGENCY: Food and Drug Administration.

ACTION: Final rule.

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

EFFECTIVE DATE: November 10, 1980.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Bureau of Medical Devices (HFK–70), Food and Drug Administration, 8757 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 33150). Interested persons were initially given until September 26, 1978 to comment on the proposal. In the Federal Register of October 20, 1978 (43 FR 49015), the comment period was extended to December 19, 1978. In the Federal Register of October 20, 1978 (43 FR 49014), the agency also published a proposed regulation addressing a New Jersey requirement that it had not addressed in the July 28 proposal. Interested persons were given until December 19, 1978 to comment on this proposal. FDA held a public hearing on these proposed regulations on October 31 and November 1, 1978.

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

Although FDA is denying exemption from preemption for many State requirements, it encourages the States 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 governmen

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

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

The FTC Rule

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

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

One comment on the FDA proposal said the FTC record is replete with evidence that hearing aid dealers receive little training and so are often incompetent to test hearing and to select and fit hearing aids. The comment also said the FTC record shows that hearing aid dealers do not counsel hearing-impaired persons adequately in adapting to a hearing aid and that they do not repair hearing aids well. Finally, the comment said the FTC record shows that hearing aid dealers abuse home visits. The comment recommended that independent audiological evaluation should be required to remedy these abuses.

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

The Legality and Constitutionality of the Proposed Rule

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

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

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

In section 521 of the act (21 U.S.C. 360k) Congress expressed its purposes and objectives with respect to the preemption of State and local medical device requirements. That section reflects Congress' intent that the Food, Drug, and Cosmetic Act preempt any State or local requirement applicable to a medical device that is different from or in addition to a requirement for the device under the act. The State requirement of audiological evaluation relates to the safety or effectiveness of hearing aids because it is intended to ensure that the purchaser is fitted properly with a hearing aid that will benefit his or her hearing ability. This requirement is in addition to the Federal requirements applicable to hearing aids and would interefere with the execution and accomplishment of the objectives of FDA's hearing aid regulation. Therfore, the State requirement of audiological evaluation is preempted in accordance with both *Hines* v. *Davidowitz* and section 521 of the act.

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

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

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

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

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

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

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

The comment misconceives the law regarding Federal preemption. There are two types of Federal preemption: Express and implied. The standard described in the comment is the test of implied Federal preemption, the test applicable where Congress has not exercised its power under the Commerce clause to expressly declare Federal law paramount to State law. See *Jones* v. *Rath Packing Co.*, 430 U.S. 519 (1977); *Florida Lime & Avocado Growers, Inc.* v. *Paul*, 373 U.S. 132 (1963); *Hines* v. *Davidowitz*, 312 U.S. 52, 66 (1940). In section 521(a) of the act, however, Congress has expressly declared that the Federal Food, Drug, and Cosmetic Act preempts any State or local requirement with respect to the safety or effectiveness of a medical device that is different from or in addition to a requirement under the act applicable to the device. The test of implied Federal preemption therefore, does not apply. Adoption of the standard advanced in the comment would render section 521 of the act meaningless because as argued in the comment the Federal law would preempt only State requirements that directly conflict with the Federal law. Yet, in section 521 of the act Congress established a specific standard of preemption. Under Section 521(a) of the act, preemption is not restricted to State requirements that directly conflict with Federal law, but rather extends to requirements that are different from, or in addition to, any requirement applicable to the device under the act.

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

The authority granted FDA in section 521(b) of the act to exempt State or local requirements from preemption is discretionary. Congress did not specify the criteria that FDA must employ in exercising that discretion. In light of the purpose of the act and the Medical Device Amendments, however, FDA believes that in deciding whether to exempt a State requirement from preemption it is appropriate to consider the effect that granting the exemption would have on the public health. The cost of medical devices and the availability of medical services are relevant factors in assessing the effect that an exemption would have on the public health. Therefore, FDA will consider these factors in determining whether to exempt a particular State requirement from preemption.

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

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

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

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

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

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

An "informal hearing," as defined in section 201(y) of the act, is required only where the term "informal hearing" is specifically used in the act. For example, an "informal hearing" is required under sections 309(g), 515, and 516. An informal hearing is often referred to as a regulatory hearing and is governed by Part 16 of the agency's administrative regulations (21 CFR Part 16). Section 521 of the act provides for the opportunity for an oral hearing, rather than an "informal hearing," on a proposed regulation on an application for exemption from preemption. The public hearing required by section 521 of the act is sometimes referred to as a legislative hearing and is governed by Part 15 (21 CFR Part 15) of the agency's administrative regulations. Indeed, 21 CFR 15.1(b) expressly states that Part 15 governs any hearing relating to exemptions from preemption of requirements for device.

Audiological Evaluation

Almost all the comments on the proposed regulation addressed FDA's proposal to deny exemption from preemption for State laws requiring audiological evaluation before the sale of a hearing aid to an adult. The comments focused on the value, cost, and availability of audiological evaluation.

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

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

After reviewing the conflicting information in the public record regarding the predictive value of audiological testing in determining whether a patient would benefit from a hearing aid, FDA has concluded that audiological evaluation is not necessary to provide reasonable assurance of the safety or effectiveness of hearing aids. There is no evidence that audiological evaluation reduces or eliminates any risk to health presented by a hearing aid. The primary risk to health presented by hearing aids is the possibility that an unnecessary or only partially effective hearing aid will be substituted for necessary medical or surgical treatment, thus depriving the hearing-impared patient of the benefit of appropriate diagnosis and care and resulting in a detriment to health. Medical evaluation by a licensed physician will ensure that all medically treatable conditions are accurately identified and properly treated before a hearing aid is bought. Potential problems involving misevaluation of hearing loss or misfitting of hearing aids will be adequately addressed by strong State and local licensing laws for hearing aid dispensers and by the trial rental period required by the draft final FTC regulation. Moreover, there is no evidence that only audiologists are competent to measure hearing loss and to fit hearing aids. Finally, FDA did not require that conclusive evidence be shown that the patient would benefit from amplification. Rather, the agency concluded that the requirement of mandatory audiological evaluation would increase the cost of obtaining a hearing aid without providing any conclusive assurance that the patient would benefit from amplification.

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

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

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

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

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

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

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

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

The agency would like to set aside a few apparent misconceptions. Neither the FDA regulation on hearing aids nor the agency's decision in this regulation to deny exemption from preemption for state laws requiring mandatory audiological evaluation. Audiologists may continue to test hearing before the sale of a hearing aid. FDA does not question the competency of audiologists. Indeed, FDA recognizes that the audiologist is an important member of the hearing health care team qualified to provide basic audiometric evaluation, hearing aid orientation, auditory training, speech reading, speech conservation, language development, and counseling and guidance services. FDA expects physicians to refer patients to an audiologist when necessary. Likewise, FDA's decision to deny exemption from preemption for these requirements does not constitute a determination that a hearing test is unnecessary before the sale of hearing aid. FDA has determined only that it is not necessary to require that this testing be done by an audiologist to provide reasonable assurance of the safety and effectiveness of hearing aids.

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

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

Waiver

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

Some comments favoring exemption from preemption for State laws limiting or prohibiting waiver of medical evaluation argued that medical evaluation is absolutely necessary and, therefore, that a waiver should not be permitted. Other comments 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 the first time waive medical evaluation. This was confirmed by a limited survey in Massachusetts, which showed that only 8 percent of first-time users of a hearing aid waived the requirement for medical evaluation.

FDA believes that, before purchasing a hearing aid, all prospective hearing 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 aids arises from the failure to obtain beneficial medical treatment rather than from wearing a hearing aid. FDA believes that any informed adult who objects to medical evaluation for religious or personal reasons should be permitted to waive the medical evaluation requirement.

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

...aid dealer licensing boards to ...termine whether they were ...experiencing any problems with ...mpliance with the FDA regulation. Of ...20 States that responded to this ...rvey, only 19 provided FDA with ...formation pertaining to dealer ...compliance with the regulation. Twenty-...ve of these 31 States indicated that ...they had not received complaints or ...other information regarding dealer ...compliance with the regulation, although ...a few of these 25 States related ...unsubstantiated rumors of ...noncompliance. Six of the 31 States ...responding to the survey indicated that ...they had encountered problems ...involving compliance with FDA ...regulation but, of these six, only ...Massachusetts stated that compliance ...problems were more common than ...isolated incidents. Therefore, FDA is ...denying exemption from preemption for ...State laws limiting or prohibiting waiver ...of medical evaluation. Exempting these ...requirements will also permit the ...purchase of a hearing aid in the rare ...circumstance where an individual would ...have great difficulty obtaining a medical ...evaluation because of the lack of a ...physician in the area.

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

16. Many States, while not requiring that the purchaser be examined by a physician, require hearing aid dispensers to advise in writing a prospective purchaser who has one or more of certain listed medical conditions to consult with a physician. Some States also require that the hearing aid dispenser furnish the prospective purchaser with the names and addresses of physicians or otolaryngologists in the area. FDA has proposed to deny exemption from preemptions for these requirements.

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

Disclosure Requirements

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

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

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

Arizona

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

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

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

California

19. Section 26463(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 (e). The User Instructional Brochure accompanying each hearing aid shall contain the following information and instructions for use, to the extent applicable to the particular requirements and characteristics of the hearing aid:

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

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

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

(iv) Specific instructions for:

(a) Use of the hearing aid.

(b) Maintenance and care of the hearing aid, including the procedure to follow in washing the earmold, when replacing tubing on those hearing aids that use tubing, and in storing the hearing aid when it will not be used for an extended period of time.

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

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

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

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

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

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

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

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

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

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

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

WARNING TO HEARING AID DISPENSERS

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

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

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

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

(iv) Acute or chronic dizziness.

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

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

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

(viii) Pain or discomfort in the ear.

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

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

IMPORTANT NOTICE FOR PROSPECTIVE HEARING AID USERS

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

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 all labeling for each type of hearing aid.** Any manufacturer of a hearing aid described in paragraph (a) of this section shall submit to the Food and Drug Administration, Bureau of Medical Devices and 8757 Georgia Ave., Silver Spring, MD 20910, a copy of the User Instructional Brochure described in paragraph (c) of this section and all other labeling for each type of hearing aid on or before August 15, 1977.

§801.421 Hearing aid devices; conditions for sale.

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

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

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

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

(iii) Affords the prospective user the opportunity to sign the following statement:

I have been advised

_____
(Hearing aid dispenser's name)

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

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

(1) Provide the prospective user a copy of the User Instructional Brochure for a hearing aid that has been, or may be selected for the prospective user;

(2) Review the content of the User Instructional Brochure with the prospective user orally, or in the predominate method of communication used during the sale;

(3) Afford the prospective user an opportunity to read the User Instructional Brochure.

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

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

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

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

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

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

March 13, 1986

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

Dear Pat,

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

Sincerely,

David R. Canterbury

Pat

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

Dave
Canterbury

Recommended Changes in CS HB430

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

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

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

Line 9. Delete "or".

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

Line 13. Delete "or the audiologist".

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

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

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

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

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

Sec. 08.55.120. Testing of Hearing
(a) A hearing aid dealer may take threshold measurements to determine the need for hearing aid use, but may not perform other diagnostic procedures to determine the cause of a hearing impairment, the site of lesion or charge a fee for any hearing measurement.

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

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

3/17/86

Mike:

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

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

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

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

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

Dart

CS FOR HB 430 (LABOR & COMMERCE)
SECTIONAL ANALYSIS

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

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

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

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

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

Section 6 adds audiologists to the professional designation requirements.

Section 7 adds the following sections to the chapter:

08.11.010 provides for qualifications for licensing of professional audiologists.

08.11.020 provides for qualifications for licensing of audiologist aides.

08.11.030 addresses temporary license to practice audiology.

08.11.040 provides for duration of licenses.

08.11.050 provides for renewal of licenses.

08.11.060 provides for display of current license.

08.11.070 empowers the department to set fees for licensing.

08.11.080 requires malpractice insurance for audiologists.

08.11.085 allows audiologists to fit and sell hearing aids.

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

08.11.110 lists disciplinary sanctions.

08.11.120 lists prohibited acts.

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

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

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

08.11.200 is the definition section for this chapter.

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

08.55.010 provides for qualifications for license.

08.55.030 provides for duration and renewal of license.

08.55.040 empowers the department to set fees.

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

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

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

08.55.070 provides method of mailing hearing aids to consumer.

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

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

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

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

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

08.55.130 lists grounds for disciplinary sanctions.

08.55.140 lists disciplinary sanctions the department may impose.

08.55.150 lists prohibited acts.

08.55.160 makes violation of prohibited acts a class B misdemeanor.

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

08.55.180 states the Administrative Procedure act applies to this chapter.

08.55,200 is the definition section for this chapter.

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

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

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

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

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

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

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

provision to req individuals to be post a bond Bannister 2/10/86.

Original sponsors: Navarre, Gruenberg, Hurley and Thompson

next

BY THE LABOR AND COMMERCE COMMITTEE

IN THE HOUSE

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

IN THE LEGISLATURE OF THE STATE OF ALASKA

FOURTEENTH LEGISLATURE - SECOND SESSION

A BILL

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

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

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

(b) The purpose of this Act is to establish the procedures necessary to ensure that the public is protected from the incompetent, unprofessional, improper, and unauthorized practice of audiology and dispensing of hearing aids, and to assure the availability of the highest possible quality audiology and hearing aid services for the hearing impaired persons of the state.

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

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

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

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

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

(1) collect fees and issue receipts;

(2) maintain records and files;

(3) issue and receive application forms;

(4) notify applicants of acceptance or rejection of

Bannister
2/10/86

Original sponsors: Navarre, Gruenberg,
Hurley and Thompson

IN THE HOUSE

BY THE LABOR AND
COMMERCE COMMITTEE

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

IN THE LEGISLATURE OF THE STATE OF ALASKA

FOURTEENTH LEGISLATURE - SECOND SESSION

A BILL

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

(1) collect fees and issue receipts;

(2) maintain records and files;

(3) issue and receive application forms;

(4) notify applicants of acceptance or rejection of

applicants as determined by the board or as determined by the department under AS 08.11 for audiologists and audiologist aides or under AS 08.55 for hearing aid dealers;

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

(6) publish notice of examination;

(7) arrange space for holding examinations;

(8) notify applicants of results of examinations;

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

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

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

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

(13) answer routine inquiries;

(14) maintain files relating to individual licensees;

(15) arrange for printing and advertising;

(16) purchase supplies;

(17) employ secretarial help when needed;

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

(19) provide investigative services to the boards established under AS 08.04, AS 08.20, AS 08.36, AS 08.64, AS 08.68, AS 08.70, AS 08.71, AS 08.72, AS 08.80, AS 08.84, and AS 08.86, for the purpose of assisting those boards in matters of professional

discipline and in responding to consumer complaints.

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

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

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

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

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

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

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

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

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

Sec. 08.01.110. DEFINITIONS. In this chapter

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

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

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

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

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

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

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

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

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

CHAPTER 11. AUDIOLOGISTS AND AUDIOLOGIST AIDES.

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

(1) is 18 years of age or older;

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

(3) pays the fee required under AS 08.11.070;

(4) furnishes evidence satisfactory to the department that the person

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

(B) holds a master's degree, doctorate, or the equivalent, in audiology from an accredited educational institution approved by the department; and either has

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

(ii) practiced audiology for two years as of January 1, 1986, or is in the process of completing the year of supervised clinical experience required for the Certificate of Clinical Competence of the American Speech and Hearing Association;

(5) has good moral character; and

(6) files with the department an irrevocable consent to service of process authorizing the department to receive service for the applicant of a notice, process, or pleading in an action or proceding against the applicant based on the practice of audiology by the applicant in the state; service on the department confers personal jurisdiction over the applicant in a court of competent jurisdiction for an action based on the practice of audiology by the applicant in the state.

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

(1) is 18 years of age or older;

(2) has a high school diploma or the equivalent;

(3) applies on a form provided by the department;

(4) meets other minimum qualifications established by the department.

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

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

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

(b) The department may issue a temporary license to the following:

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

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

(B) in cooperation with an audiologist licensed under this chapter;

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

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

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

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

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

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

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

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

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

business of the individual.

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

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

(1) application;

(2) credential review;

(3) audiologist license;

(4) audiologist aide license;

(5) temporary license;

(6) renewal of license;

(7) delinquency;

(8) reinstatement;

(9) duplicate license.

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

Sec. 08.11.085. DEALING IN HEARING AIDS. An audiologist may deal in hearing aids as a hearing aid dealer without being licensed as a hearing aid dealer under AS 08.55, but shall comply with AS 08.55.050 - 08.55.070, 08.55.100 - 08.55.110, and 08.55.130(7) - (13) when dealing in hearing aids.

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

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

misrepresentation;

(2) engaged in deceit, fraud, or intentional misrepresentation in the course of practicing audiology;

(3) advertised professional services in a false or misleading manner;

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

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

(A) professional incompetence;

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

(C) physical or mental disability;

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

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

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

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

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

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

an audiologist has committed an act listed in AS 08.11.090 or an audiologist aide has committed an act listed in AS 08.11.100, the department may impose the following sanctions singly or in combination:

(1) permanently revoke a license to practice;

(2) suspend a license for a determinate period of time;

(3) censure a licensee;

(4) issue a letter of reprimand;

(5) place a licensee on probationary status and require the licensee to

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

(B) limit practice to those areas prescribed;

(C) continue professional education until a satisfactory degree of skill has been attained in those areas determined by the department to need improvement;

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

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

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

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

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

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

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

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

(3) advertise that the person practices audiology.

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

(1) practice audiology;

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

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

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

(1) a physician licensed under AS 08.64;

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

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

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

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

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

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

(b) Notwithstanding the provisions of this chapter,

(1) a nurse licensed under AS 08.68 may perform hearing sensitivity evaluations;

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

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

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

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

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

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

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

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

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

Sec. 08.11.200. DEFINITIONS. In this chapter, unless the context indicates otherwise,

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

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

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

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

Economic Development;

(5) "hearing aid" has the meaning given in AS 08.[illegible].200;

(6) "practice of audiology" means the application of principles, methods, and procedures of measurement, testing, appraisal, prediction, consultation, habilitation, rehabilitation, counseling and instruction related to hearing and hearing impairment for the purpose of modifying communicative disorders involving speech, language, auditory function, including auditory training, speech reading and the recommendation, evaluation, fitting, and sale of hearing aids, including the fitting of ear molds.

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

CHAPTER 55. HEARING AID DEALERS.

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

(1) is 18 years of age or older;

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

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

(4) has good moral character;

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

(6) furnishes evidence satisfactory to the department that the individual has not engaged in conduct that is a ground for imposing disciplinary sanctions under AS 08.55.130;

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

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

embezzlement, or misappropriation of property;

(B) is subject to an injunctive order that is currently in effect from a pending proceeding or action brought by a public agency;

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

(D) has, during the five-year period immediately preceding the date of the application, been reorganized, had a debt adjustment, or has been adjudicated a bankrupt under bankruptcy proceedings due to insolvency or was a principal executive officer or general partner of a business that has been reorganized, had a debt adjustment, or has been adjudicated a bankrupt due to insolvency during the five-year period;

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

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

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

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

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

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

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

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

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

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

(1) application;

(2) hearing aid dealer license;

(3) renewal of license;

(4) renewal delinquency;

(5) duplicate license.

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

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

hearing aid;

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

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

(4) a written statement indicating that the consumer may file a written complaint about a hearing aid or a hearing aid dealer with the department and giving the mailing address and location address of the department.

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

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

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

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

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

(2) does not actively encourage the prospective user to

waive the medical evaluation; and

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

> I have been advised by (HEARING AID DEALER'S NAME) that the State of Alaska has determined that my best interest would be served if I had a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing or leasing a hearing aid.
>
> _____
>
> (PROSPECTIVE USER'S SIGNATURE)

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

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

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

(b) A hearing aid dealer shall prominently display in the business establishment of the dealer a sign indicating that a person may file a complaint with the department about a hearing aid or a hearing aid dealer and giving the mailing and location address of the department.

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

Sec. 08.55.100. CALIBRATION REQUIREMENTS. A hearing aid dealer shall maintain in conformity with the standards set by the American National Standard Institute the calibration of each audiometer used by the hearing aid dispenser.

Sec. 08.55.110. CANCELLATION OPTION. (a) In addition to the cancellation allowed under AS 45.02.350, a person who has purchased or leased a hearing aid from a hearing aid dealer may cancel the sale or lease as provided under (b) of this section or by giving written notice of the intention to cancel the sale or lease to the dealer not later than 30 days following the later of (1) the date the person receives the hearing aid, or (2) the date the hearing aid dealer provides the person with the notice under (c) of this section. The person may use the notice received under (c) of this section to cancel the sale or lease by signing the form where indicated.

(b) In addition to the other rights and remedies the purchaser or lessee of a hearing aid may have, the purchaser or lessee of a hearing aid has the right to cancel the sale or lease by giving written notice of the cancellation to the hearing aid dealer if

(1) a physician licensed under AS 08.64 specializing in diseases of the ear or an audiologist licensed under AS 08.11 advises the person to cancel the sale or lease and specifies in writing the medical or audiological reason for the advice; or

(2) the hearing aid dealer has violated a provision of this chapter in the sale or lease of the hearing aid to the person.

(c) A hearing aid dealer shall give a person who has purchased or leased a hearing aid from the dealer notice of the right to cancel the purchase or lease that is substantially identical to the following form with all of the information filled in except the signature and date lines for the purchaser or lessee:

NOTICE OF RIGHT TO CANCEL

_____

Name of Hearing Aid Dealer

_____

Address of Hearing Aid Dealer

_____

Date of Sale or Lease

You may cancel this transaction, without penalty or obligation, within 30 days from the date you receive the hearing aid or this notice, whichever is later.

If you cancel this transaction, the property you traded in, the payments you made under the sale or lease (less certain costs allowed by state law) and any negotiable instrument executed by you will be returned within 10 business days following receipt by the hearing aid dealer of your cancellation notice, and the hearing aid dealer will cancel any security interest arising out of the sale or lease.

If you cancel, you must make available to the hearing aid dealer, in as good a condition as when received, less normal wear and tear, the goods delivered to you under this sale or lease, unless the dealer notifies you to keep the goods or to hold them until the dealer collects them.

If you make the goods available for the hearing aid dealer to collect after your cancellation, and the hearing aid dealer does not collect

them from you within 20 days of your cancellation, you may retain or dispose of the goods without further obligation to the hearing aid dealer. If you fail to make the goods available for the hearing aid dealer to collect after your cancellation, then the sale or lease is not cancelled and you remain liable for performance of the obligations of the sale or lease.

To cancel this transaction, mail (by certified mail, return receipt request) or deliver a signed and dated copy of this notice or another written notice to (name of hearing aid dealer), at (address of hearing aid dealer's place of business) and (hearing aid dealer's telephone number) no later than midnight of (Date).

I hereby cancel this transaction.

(Date) _____

_____

(Purchaser's or Lessee's signature)

I have read and understand the terms of cancellation of this purchase/lease.

_____

Purchaser's or Lessee's signature

_____

Date

(d) If a purchaser or lessee of a hearing aid cancels the purchase or lease under (a) or (b) of this section, the hearing aid dealer shall and within 10 days of receipt of a notice of the cancellation

(1) refund to the purchaser or lessee all deposits, including the downpayment, less (A) 10 percent of the total purchase price for each 30 days that the purchaser or lessee had the hearing aid, to pay for the reasonable rental value of the hearing aid; (B) the reasonable price of ear molds or custom casings prepared for the purchaser or lessee; and (C) the reasonable costs actually incurred by the hearing aid dealer to make goods that were traded in by the purchaser or lessee ready for sale; the hearing aid dealer may retain the money allowed under this paragraph only up to the amount of a downpayment made by the purchaser or lessee;

(2) return to the purchaser or lessee all goods traded in to the hearing aid dealer as part of the sale or lease;

(3) return to the purchaser or lessee a negotiable instrument signed by the purchaser or lessee; and

(4) cancel a security interest taken by the hearing aid dealer for the purchase or lease.

(e) If a hearing aid dealer fails to collect the hearing aid from the consumer within 20 days of receipt of the cancellation, the purchaser or lessee may retain or dispose of the hearing aid without further obligation to the dealer.

(f) If a purchaser or lessee of a hearing aid fails to make the hearing aid available for the hearing aid dealer to collect, the purchaser or lessee remains liable for the purchase or lease.

(g) To give written notice under this section, a person shall deliver the notice to the hearing aid dealer in person or to the place of business of the dealer, or mail the notice to the place of business of the dealer by certified mail, return receipt requested.

Sec. 08.55.120. TESTING OF HEARING. (a) A hearing aid dealer may take threshhold measurements to determine the degree of hearing

impairment of a person, but may not test or use the threshhold measurements to determine the cause of a hearing impairment or charge a fee for taking the threshhold measurements test.

(b) A hearing aid dealer shall include in every advertisement for the services of the dealer the following statement bordered in black:

Alaska law permits a hearing aid dealer to test hearing only for the purpose of selling or leasing hearing aids; the tests given by a hearing aid dealer are not to be used to diagnose the cause of a hearing impairment.

Sec. 08.55.130. GROUNDS FOR IMPOSITION OF DISCIPLINARY SANCTIONS. After a hearing, the department may impose a disciplinary sanction on an individual licensed under this chapter when the department finds that the person

(1) secured a license through deceit, fraud, or intentional misrepresentation;

(2) engaged in deceit, fraud, or intentional misrepresentation in the course of providing professional services or engaging in professional activities;

(3) advertised professional services in a false or misleading manner;

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

(5) failed to comply with a provision of this chapter or a regulation adopted under this chapter, or an order of the department;

(6) continued to practice after becoming unfit due to

(A) professional incompetence;

(B) addiction to or severe dependency on alcohol or

another drug that impairs the individual's ability to practice safely;

(C) physical or mental disability;

(7) employed a person who did not have a valid current license to deal in hearing aids to perform work covered by this chapter;

(8) failed or refused to honor a representation, promise, agreement or warranty made by the person while dealing in hearing aids;

(9) advertised a model, type, or kind of hearing aid for sale that the person does not sell;

(10) failed to maintain a business address and telephone number at which the individual could normally be reached during regular business hours;

(11) included in a contract or receipt for the purchase or lease of a hearing aid a confession of judgment or a waiver of a right of the consumer under this chapter;

(12) used undue influence, coercion, or other wilful act or representation to interfere with the exercise by the consumer of the rights provided in this chapter;

(13) negotiated, transferred, sold, or assigned a note or other evidence of indebtedness to a finance company or other third party within two months of delivering a hearing aid to a purchaser or lessee of the hearing aid by mail or in person;

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

(15) dealt in hearing aids while suffering from a serious disease that was contagious or infectious.

Sec. 08.55.140. DISCIPLINARY SANCTIONS. (a) When it finds that a licensee has committed an act listed in AS 08.55.130, the department

may impose the following sanctions singly or in combination:

(1) permanently revoke a license to practice;

(2) suspend a license for a determinate period of time;

(3) censure a licensee;

(4) issue a letter of reprimand;

(5) place a licensee on probationary status and require the licensee to

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

(B) limit practice to those areas prescribed;

(C) continue professional education until a satisfactory degree of skill has been attained in those areas determined by the department to need improvement;

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

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

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

(d) The department may reinstate a license that has been suspended or revoked if the department finds after a hearing that the applicant is able to deal in hearing aids with reasonable skill and

safety.

Sec. 08.55.150. PROHIBITED ACTS. (a) Unless a person is licensed under this chapter or AS 08.11, the person may not

(1) deal in hearing aids;

(2) use a title indicating or representing that the person deals in hearing aids or is licensed to deal in hearing aids;

(3) advertise that the person deals in hearing aids.

(b) A person may not

(1) sell, barter, or offer to sell or barter a license issued under this chapter;

(2) purchase or obtain by barter a license issued under this chapter with the intent to use it as evidence of the holder's qualification to deal in hearing aids;

(3) materially alter a license issued under this chapter with fraudulent intent;

(4) use or attempt to use as valid a license to deal in hearing aids that has been purchased, fraudulently obtained, counterfeited, or materially altered.

Sec. 08.55.160. PENALTY. A person who violates AS 08.55.150 is guilty of a class B misdemeanor.

Sec. 08.55.170. NOTICE OF PLACE OF BUSINESS. A person who holds a license under this chapter shall notify the department in writing of the regular address of the place or places where the person deals or intends to deal in hearing aids.

Sec. 08.55.180. PROCEDURES. The Administrative Procedure Act (AS 44.62) applies to regulations and proceedings under this chapter.

Sec. 08.55.200. DEFINITIONS. In this chapter

(1) "dealing in hearing aids" means the sale or lease, or attempted sale or lease of hearing aids, and the recommendation,

selection, fitting, or adaptation of hearing aids;

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

(3) "hearing aid" means a prosthetic instrument or device designed for or represented as aiding, improving, or correcting defective human hearing and the parts, attachments, or accessories of the instrument or device; "hearing aid" does not include cochlear implants, middle-ear implants, vibro-tactile speech-reading aids, other aids for cued speech, or group or individual auditory training units and assistive devices;

(4) "hearing aid dealer" means an individual licensed under AS 08.55.010.

* Sec. 9. AS 09.55.560(1) is amended to read:

(1) "health care provider" means <u>an audiologist and an audiologist aide licensed under AS 08.11;</u> a chiropractor licensed under AS 08.20; a dental hygienist licensed under AS 08.32; a dentist licensed under AS 08.36; a nurse licensed under AS 08.68; a dispensing optician licensed under AS 08.71; an optometrist licensed under AS 08.72; a pharmacist licensed under AS 08.80; a physical therapist licensed under AS 08.84; a physician licensed under AS 08.64; a podiatrist; a psychologist and a psychological associate licensed under AS 08.86; and a hospital as defined in AS 18.20.130, including a governmentally owned or operated hospital; a corporate entity covered under AS 21.88.050(b)(12); and an employee of a health care provider acting within the course and scope of employment;

* Sec. 10. AS 21.88.900(a)(9) is amended to read:

(9) "health care provider" means <u>an audiologist and an audiologist aide licensed under AS 08.11;</u> a chiropractor licensed under AS 08.20; a dental hygienist licensed under AS 08.32; a dentist

licensed under AS 08.36; a nurse licensed under AS 08.68; a dispensing optician licensed under AS 08.71; an optometrist licensed under AS 08.72; a pharmacist licensed under AS 08.80; a physical therapist licensed under AS 08.84; a physician licensed under AS 08.64; a podiatrist; a psychologist and a psychological associate licensed under AS 08.86; a hospital as defined in AS 18.20.130, including a governmentally owned or operated hospital; a corporate entity covered under AS 21.88.050(b)(11); an employee of a health care provider acting within the course and scope of employment;

* Sec. 11. AS 44.62.330(a) is amended by adding new paragraphs to read:

(53) Department of Commerce and Economic Development concerning the licensing and regulation of audiologists and audiologist aides (AS 08.11);

(54) Department of Commerce and Economic Development concerning the licensing and regulation of hearing aid dealers (AS 08.-55).

* Sec. 12. AS 45.50.471(b) is amended by adding a new paragraph to read:

(26) dealing in hearing aids and failing to comply with AS 08.55.

* Sec. 13. AS 45.50.561 is amended by adding new paragraphs to read:

(10) "dealing in hearing aids" has the meaning given in AS 08.55.200;

(11) "hearing aid" has the meaning given in AS 08.55.200.

* Sec. 14. AS 47.17.070(9) is amended to read:

(9) "practitioner of the healing arts" includes chiropractors, [illegible]ygienists, dentists, health aides, nurses, nurse practitioners, optometrists, osteopaths, physical therapists, physicians, physician's assistants, psychiatrists, psychologists, psychological

associates, audiologists and audiologist aides licensed under AS 08.-11, hearing aid dealers licensed under AS 08.55, religious healing practitioners, and surgeons;

CS FOR HB 430 (LABOR & COMMERCE)
SECTIONAL ANALYSIS

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

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

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

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

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

Section 6 adds audiologists to the professional designation requirements.

Section 7 adds the following sections to the chapter:

08.11.010 provides for qualifications for licensing of professional audiologists.

08.11.020 addresses temporary license to practice audiology.

08.11.030 provides for duration and renewal of licenses.

08.11.040 provides for display of current license.

08.11.050 empowers the department to set fees for licensing.

08.11.060 requires malpractice insurance for audiologists.

08.11.070 allows audiologists to fit and sell hearing aids.

08.11.080 define grounds for disciplinary actions against audiologists.

08.11.090 lists disciplinary sanctions.

08.11.100 lists prohibited acts.

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

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

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

08.11.200 is the definition section for this chapter.

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

08.55.010 provides for qualifications for license.

08.55.020 provides for duration and renewal of license.

08.55.030 requires bonding of hearing aid dealers.

08.55.040 empowers the department to set fees.

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

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

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

08.55.070 provides method of mailing hearing aids to consumer.

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

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

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

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

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

08.55.130 lists grounds for disciplinary sanctions.

08.55.140 lists disciplinary sanctions the department may impose.

08.55.150 lists prohibited acts.

08.55.160 makes violation of prohibited acts a class B misdemeanor.

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

08.55.180 states the Administrative Procedure act applies to this chapter.

08.55,200 is the definition section for this chapter.

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

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

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

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

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

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

RECORDS CERTIFICATION

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.

James A. Smith
Signature of Camera Operator

9/5/89
Date

02-519 (REV 8/78)

HOUSE
COMMITTEE REPORT

JUDICIARY

Date referred: 2-7-86

FURTHER REFERRALS: FINANCE

DATE: Feb. 7, 1986

The LABOR & COMMERCE Committee has considered SSHB 466

"An Act relating to Alaskan resident employment preference; and providing for an effective date."

and recommends:

[ ] do pass
[ ] do not pass
[ ] do pass with attached amendment(s)
[ ] no recommendation
[ ] replace with _____ _____ [ ] same title
[ ] new title

and recommends _____

[ ] further referral to the _____ Committee

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

SIGNING DO PASS:

Mike Navarre

SIGNING OTHER RECOMMENDATIONS:

Bryce Hanley - No-Rec

Mike Navarre
Chairman

Cramer
2/5/86
Version #1

Original sponsor: Larson by request

IN THE HOUSE BY THE JUDICIARY COMMITTEE

CS FOR HOUSE BILL NO. 454 (Judiciary)

IN THE LEGISLATURE OF THE STATE OF ALASKA

FOURTEENTH LEGISLATURE - SECOND SESSION

A BILL

For an Act entitled: "An Act relating to compensation of state officers; establishing a commission on compensation of state officers; and providing for an effective date."

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

* Section 1. AS 39.23 is amended by adding new sections to read:

ARTICLE 1. STATE OFFICERS COMPENSATION COMMISSION.

Sec. 39.23.200. COMPENSATION COMMISSION ESTABLISHED. (a) The State Officers Compensation Commission is established. The commission is composed of seven members appointed by the governor subject to confirmation by a majority of the legislature in joint session. Members serve for staggered terms of four years. Commission membership shall include at least one business executive, one representative of a nonpartisan voters' organization, one person with experience in public administration and one representative of a labor organization. A vacancy shall be filled for the balance of the unexpired term.

(b) The commission shall annually elect a member to chair its meetings. A majority of the commission members constitutes a quorum to transact business. The affirmative vote of four members is required to approve the commission's recommendations on compensation.

(c) The commission shall meet at the call of the chair. Notice of a meeting shall be mailed to each member at least 15 days before the date scheduled for the meeting.

(d) The commission shall hold a public hearing to discuss its findings and recommendations before submitting its final report to the

legislature.

(e) The commission shall be established in the Office of the Governor.

Sec. 39.23.210. PROHIBITIONS AGAINST STATE OR MUNICIPAL SERVICE. A member of the commission may not be employed by the state, including the University of Alaska, serve as a member of a state board, commission, or authority, or hold elective state or municipal office during membership on the commission.

Sec. 39.23.220. COMPENSATION. Members of the commission serve without compensation but are entitled to per diem and travel expenses authorized for members of boards and commissions under AS 39.20.180.

Sec. 39.23.230. STAFF. (a) The commission may contract for professional services and may employ staff as it considers necessary.

(b) If requested by the commission, the director of personnel in the Department of Administration shall serve as secretary to the commission.

Sec. 39.23.240. DUTIES OF THE COMMISSION. (a) The commission shall review the salaries, benefits, and allowances of members of the legislature, the governor, lieutenant governor, members of the judiciary, and the head of each principal department and submit a report on its findings at least once every two years, but not more frequently than every year.

(b) The commission shall submit its preliminary findings and recommendations by November 15. The commission shall give reasonable public notice of its preliminary findings and recommendations, solicit public comments, and give due regard to the public comments, before submitting a final report under (c) of this section.

(c) The commission shall make a final report of its findings and recommendations as to the rate and form of compensation, benefits, and

allowances for state officers no later than the 10th day of a legislative session.

(d) The commission may submit to the legislature amendments to the report submitted under (c) of this section.

(e) A commission member who does not concur in the proposed or final recommendations may attach written objections to the commission's report of its findings and recommendations.

Sec. 39.23.250. RECOMMENDATIONS RELATING TO THE JUDICIARY, GOVERNOR, AND LIEUTENANT GOVERNOR. (a) A recommendation of the commission may not have the effect of reducing the compensation or benefits of a member of the judiciary who is a member of the judiciary on the effective date of the commission's recommendation; or reduce, unless consistent with general law applicable to all other salaried officers of the state, except incumbent members of the judiciary, the compensation and benefits of the governor or lieutenant governor who are in office on the effective date of the commission's recommendation.

(b) The commission may recommend reduction in compensation or benefits for individuals who become members of the judiciary or governor or lieutenant governor after the effective date of the commission's recommendation.

Sec. 39.23.260. FILING WITH LIEUTENANT GOVERNOR AND CERTIFICATION. The commission shall, upon transmitting its final recommendations to the legislature, file the recommendations in the office of the lieutenant governor, and upon the recommendations becoming effective the commission shall certify the copy of the recommendations on file in the office of the lieutenant governor.

Sec. 39.23.270. POLICY OF THE LEGISLATURE. It is the policy of the legislature that the commission determine an equitable rate and

form of compensation, benefits, and allowances for state officers.

Sec. 39.23.280. ADMINISTRATIVE PROCEDURE ACT. The regulation-making provisions of the Administrative Procedure Act (AS 44.62) do not apply to proceedings of the commission.

Sec. 39.23.400. DEFINITIONS. In AS 39.23.200 - 39.23.400

(1) "commission" means the State Officers Compensation Commission;

(2) "judiciary" means justices of the supreme court and judges of the court of appeals and the superior and district courts;

(3) "state officer" means members of the legislature, the governor, lieutenant governor, members of the judiciary, and the head of each principal department in the executive branch.

* Sec. 2. AS 39.23.240(c) is amended to read:

(c) The commission shall make a final report of its findings and recommendations as to the rate and form of compensation, benefits, and allowances for state officers no later than the 10th day of a legislative session. A recommendation has the force of law and becomes effective on the first day of the next regular legislative session unless rejected by a concurrent resolution adopted by two-thirds of the members in each house of the legislature.

* Sec. 3. AS 22.05.140(a) is repealed and reenacted to read:

(a) The State Officers Compensation Commission shall set the compensation and geographic cost-of-living adjustment, if any, of each justice under AS 39.23.200 - 39.23.400.

* Sec. 4. AS 22.07.090(a) is repealed and reenacted to read:

(a) The State Officers Compensation Commission shall set the compensation of each judge of the court of appeals under AS 39.23.-200 - 39.23.400.

* Sec. 5. AS 22.10.190(a) is repealed and reenacted to read:

(a) The State Officers Compensation Commission shall set the compensation and geographic cost-of-living adjustment, if any, of each judge of the superior court under AS 39.23.200 - 39.23.400.

* Sec. 6. AS 22.15.220(a) is repealed and reenacted to read:

(a) The State Officers Compensation Commission shall set the compensation and geographic cost-of-living adjustment, if any, of each judge of the district court under AS 39.23.200 - 39.23.400.

* Sec. 7. AS 24.10.100 is repealed and reenacted to read:

Sec. 24.10.100. COMPENSATION OF LEGISLATORS. The State Officers Compensation Commission shall set the compensation of legislators under AS 39.23.200 - 39.23.400.

* Sec. 8. AS 39.20.010 is repealed and reenacted to read:

Sec. 39.20.010. COMPENSATION OF THE GOVERNOR. The State Officers Compensation Commission shall set the compensation of the governor under AS 39.23.200 - 39.23.400.

* Sec. 9. AS 39.20.030 is repealed and reenacted to read:

Sec. 39.20.030. COMPENSATION OF LIEUTENANT GOVERNOR. The State Officers Compensation Commission shall set the compensation of the lieutenant governor under AS 39.23.200 - 39.23.400.

* Sec. 10. AS 39.20.050 is amended to read:

Sec. 39.20.050. EXCLUSIVE COMPENSATION. The compensation fixed by <u>the State Officers Compensation Commission</u> [LAW] for the governor and lieutenant governor is <u>full compensation</u> [IN FULL] for all services rendered by each of them in any official capacity or employment whatsoever during their respective terms of office, and shall be paid throughout their respective terms of office unless the office becomes vacant.

* Sec. 11. AS 39.20.080(a) is repealed and reenacted to read:

(a) The State Officers Compensation Commission shall set the

compensation of the head of each principal executive department under AS 39.23.200 - 39.23.400.

* Sec. 12. Notwithstanding AS 39.05.055(5) and AS 39.23.200, one of the initial members appointed to the commission shall serve a one-year term, two members shall serve two-year terms, two members shall serve three-year terms, and two members shall serve four-year terms.

* Sec. 13. Notwithstanding secs. 3 - 11 and 15 of this Act, the salary established for justices of the supreme court in AS 22.05.140, judges of the court of appeals in AS 22.07.090, judges of the superior court in AS 22.10.190, judges of the district court in AS 22.15.220, legislators in AS 24.10.100, the governor in AS 39.20.010, the lieutenant governor in AS 39.20.030, and heads of each principal executive department in AS 39.-20.080, as those sections existed immediately before the effective date of this section shall remain in effect until the commission has recommended a change in the salary of that office in accordance with AS 39.23.200 - 39.23.400.

* Sec. 14. Notwithstanding the time limit imposed by AS 39.23.240, enacted by sec. 1 of this Act, the commission shall submit its first final report to the legislature by January 10, 1987.

* Sec. 15. AS 22.05.140(c); AS 22.10.190(c); AS 22.15.220(d); AS 39.-20.080(c); and AS 39.23.200(e) are repealed.

* Sec. 16. AS 39.23.260, as enacted by sec. 1 of this Act, and secs. 2 - 11, 13, and 15 of this Act take effect on the effective date of an amendment to the Constitution of the State of Alaska creating a State Officers Compensation Commission.

* Sec. 17. AS 39.23.200 - 39.23.250 and 39.23.270 - 39.23.400 as enacted by sec. 1 of this Act, and secs. 12 and 14 of this Act take effect immediately in accordance with AS 01.10.070(c).

Cramer
2/5/86

Original sponsor: Larson by request

IN THE HOUSE BY THE JUDICIARY COMMITTEE

CS FOR HOUSE JOINT RESOLUTION NO. 54 (Judiciary)

IN THE LEGISLATURE OF THE STATE OF ALASKA

FOURTEENTH LEGISLATURE - SECOND SESSION

Proposing amendments to the Constitution of the State of Alaska establishing a state officers compensation commission.

BE IT RESOLVED BY THE LEGISLATURE OF THE STATE OF ALASKA:

* Section 1. Article XII, Constitution of the State of Alaska, is amended by adding a new section to read:

SECTION 14. STATE OFFICERS COMPENSATION COMMISSION. The state officers compensation commission shall consist of seven members appointed by the governor and subject to confirmation by a majority of the members of the legislature in joint session. The commission may revise the salaries, benefits, and expense allowances of members of the legislature, the governor, lieutenant governor, justices and judges of the court system, and the head of each principal department, by submitting a report to the legislature. The salaries, benefits, and expense allowances established by the commission in the report take effect on the first day of the next regular legislative session after the report is submitted to the legislature. However, the legislature may reject the salaries, benefits, or expense allowances by a concurrent resolution adopted by two-thirds of the members in each house of the legislature. The legislature shall implement this section by law.

* Sec. 2. Article XV, Constitution of the State of Alaska, is amended by adding a new section to read:

SECTION 29. STATE OFFICERS COMPENSATION COMMISSION. If the 1986 amendment creating the state officers compensation commission (art.

To: Rep. Navarre, ch. House L&C
Fr: Sid Billingslea, comm. aide
Dt: 1/18/86
Re: Brief of Robison v. Francis, S-493

FACTS

Francis is a nonresident (hereinafter NR) ironworker who got fired from his public works job because he was a NR.
AS 36.10.010 required 95% of the employees on a public works project be residents (hereinafter R). Figures changed to 90% on projects hiring 10 or fewer employees.

ISSUE

Does AS 36.10.010 violate Francis's federal Privileges & Immunities clause right to travel, his Equal Protection right, and his State equal rights under the Alaska Constitution's equal rights clause?

HOLDING

AS 36.10.010 violates Francis's Privileges and Immunities right.

RULE

Privileges and Immunities (hereinafter P&I) protects fundamental rights.
The Court's level of scrutiny is INTERMEDIATE REVIEW, which means:
The State must have an IMPORTANT PURPOSE and
the means (AS 36.10.010) must be FAIRLY AND SUBSTANTIALLY RELATED to the ends (R employment) (at 11)

The state must have substantial justification for its action. Here, NRs must be a "peculiar source of evil" which the state seeks to remedy. (at10)
The means must be the least onerous to the discriminated group (NRs).

MARKET REGULATER VS. MARKET PARTICIPANT DISTINCTION

Where the state is acting only as a sovereign (regulator) it is afforded little deference in its discriminatory actions, using the "variable standard" (at 12)
In a market participant (e.g. public works project) capacity more leeway is given. Here, the state as market participant used a broad scope of discrimination and extends it to "the fringes of the state's proprietary interests" (at 12). Therefore, little deference is given.

The "broad scope" referred to is the fact the 60-70% of all commercial construction in Alaska was affected by AS 36.01.010.

THE STATE'S JUSTIFICATION

a) Facts: Alaska has higher than national average unemployment, but the state failed to show that NRs were the "peculiar source ofevil" other factors could be climate, lack of training in Rs, lack of construction projects in rural areas. (at 16)

b) Law: Rationale that excluding NRs lets more Rs work* not a "substantial justification" under P&I. The purposes of P&I are to prevent Rs from discriminating against NRs for economic protectionism. (at8); to further the concept of federalism and create a national economic unit. (at9).

RELATION OF MEANS TO ENDS

a) Too broad scope: See Hicklin, which required any R, regardless of qualifications be hired over an NR. (at22) Need less onerous means.

b) See Wyoming case, which upheld a local hire law

c) Sugarman i) rejects under Equal Protection the argument that states interest in restricting resources for the advancement and profit of Rs entitles state to discriminate against aliens for employment purposes. ii) State can restrict employment for aliens, but on a much narrower scope. (at 28)

JUSTICE BURKE'S CONCURRING OPINION

Justice Burke would address the Alaska Const's equal rights provision first because it would preclude further review unless as substantial federal question was left unresolved.

XII, sec. 14) is adopted, the members of the state officers compensation commission appointed under AS 39.23.200 shall become the members of the state officers compensation commission under art. XII, sec. 14, and any action taken by the commission under AS 39.23.200 shall be considered an action taken by the commission under art. XII, sec. 14.

* Sec. 3. The amendments proposed by this resolution shall be placed before the voters of the state at the next general election in conformity with art. XIII, sec. 1, Constitution of the State of Alaska, and the election laws of the state.

Alaska State Legislature

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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: Rep. Mike Navarre, Member
House Labor and Commerce Committee

From: Rep. H.A. "Red" Boucher, Chair
House Labor and Commerce Committee

Date: February 5, 1986

Subject: Expert Witnesses for testimony on HB 466 at Feb. 6 Committee Hearings

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The Alaska Supreme Court decision in the Francis case two weeks ago indicated that unemployment alone is not sufficient grounds for an Alaskan hire law to exist. After conversation last Thursday with Ron Lorenson, Deputy Attorney General, it was established that we need to provide for the legislative committee record findings of information and fact that demonstrate a critical causal link exists between unemployment and various social problems or social ills.

Among the social ills Lorenson pinpointed were alcoholism, suicide, violent crimes, poverty, broken families, and insovlencies/bankruptcies. For the record then, we need to obtain testimony from expert witnesses who can give us insight into the linkages that exist. We have been contacting people we think can shed light on this area, and have asked them to make brief overview presentations of about 5 minutes each, giving an overview of the connection between unemployment and the area they are familiar with and expert in.

We asked them to make reference to specific written documents or publications they are familiar with, on both the federal level and the state level where it exists, and asked them to send that material to us as it becomes available. Some of it will be here in time to include in the record; but if not, we asked them to send it anyway so it could be included later.

Attached, therefore, is a list of expert witnesses that we have contacted and would like to be allowed to present testimony first for the House Labor and Commerce Committee Hearings on Thursday, February 6, 1986 from 1:15 to 2:45 via statewide teleconference.

In a few cases, they requested that they be allowed to testify first because of scheduling conflicts--and we have indicated those. Also, a few of them cannot attend the hearing or a teleconference site because of work conflicts, but are available on a teleconference bridge call. When we are ready for them, please just indicate, and we can take about 30 seconds to call them, and have them dial back into the bridge and hook up to the teleconference for their testimony.

LIST OF EXPERT WITNESSES

1. John Tabor — Director, Division of Public Assistance, Dept. of H & SS, 465-3347. Linking unemployment to poverty. Will be here live; wants to go first due to testimony at 1:45 in another Committee.

2. Michael Price — Director, Division of Family and Youth Services, Dept. of H & SS, 465-3170. Links unemployment to sexual abuse, domestic violence. Wishes to testify early due to a 2:00 Committee hearing. Will be here live.

3. Matt Felix — Coordinator, Office of Alcoholism and Drug Abuse, Dept. of H & SS, 586-6201. Links to alcoholism. Will be here live.

4. Dr. Joesph Cuterichi — Clinical psychologist & head counselor, Vietnam Veteran Center, Anchorage, phone 563-6966. Would like to testify early if possible, around 1:30-2:00. Links to mental health.

5. Dr. Aaron Wolf — Director, Langdon Clinic, Anchorage. Will be calling on a bridge from Kotzebue when we are ready for him. Is also Chief Medical Consultant for Voc. Rehab. Links to mental health.

6. Cecilia Kleinkauf — Social Work Dept. Faculty, U. of Alaska-Anchorage, phone 786-1725. Would like to testify from her office when we are ready for her. Links to broad range of social problems.

7. Dr. Norma Forbes — Acting Director, Division of Mental Health, Dept. of H & SS, will be in Anchorage for meetings and would like to have us call her when ready. Links to suicide, and also studies that show unemployment is a key indicator.

Additional people we have contacted who have not yet committed; but may be able to by Committee meeting time:

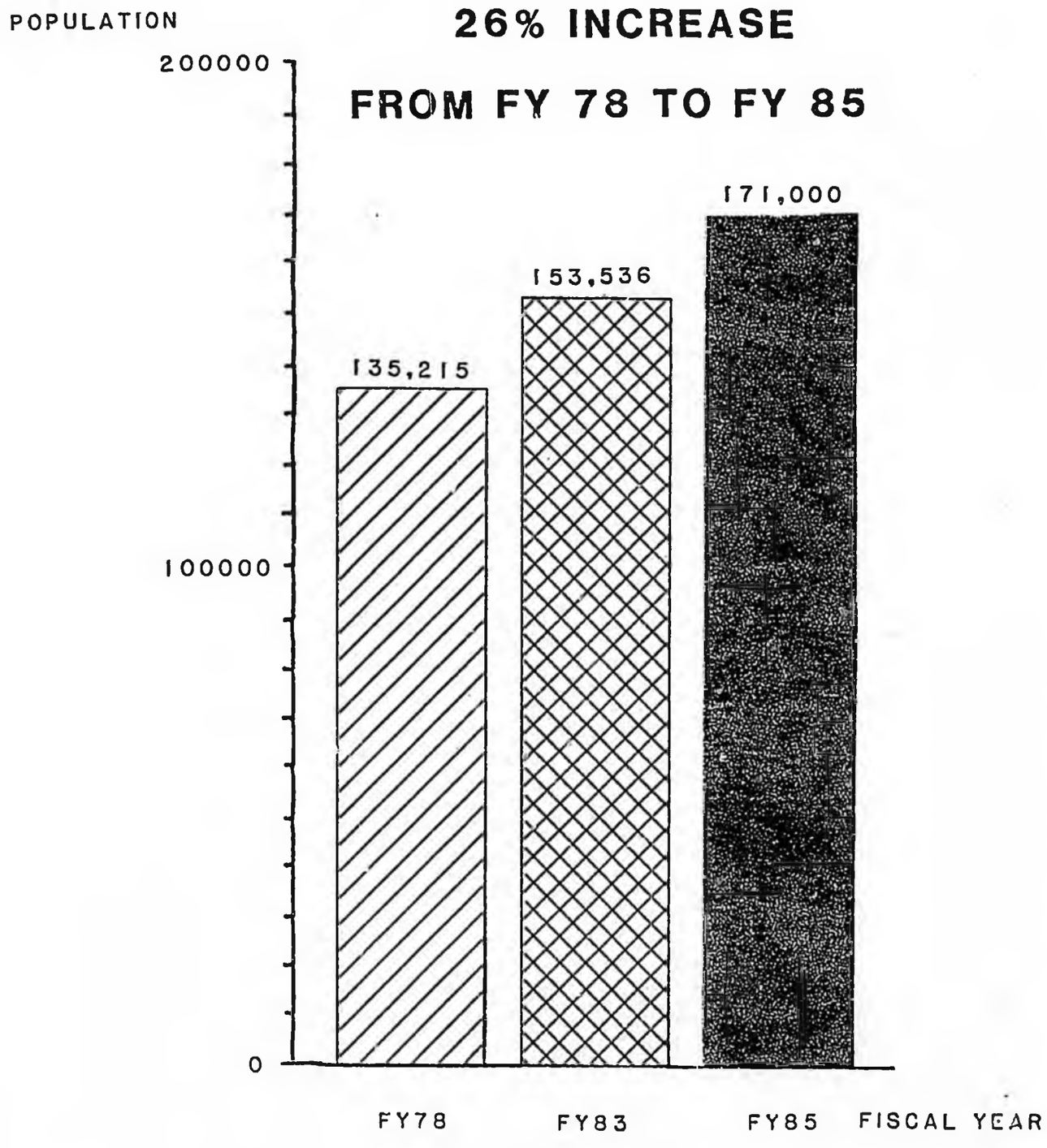
8. Cominco Representative --Lisa Parker, the AA to the President of the Company, may have someone lined up to speak; they have the most liberal policy on Alaskan hire of any company in the state, its even better than any of our past or future state laws; and they have also done some detailed studies linking unemployment to various problems ir both Canada and Alaska.

9. Willis Kirkpatrick -- Dir., Division of Banking, Securities & Corporations, Dept. of Commerce, Links to insolvency and bankruptcy.

10. Shirley Green -- Trying to arrange for someone else from the Women's Resource Center in Anchorage to testify in Heather Flynns abscence on links to sexual abuse and assualt, etc.

11. Dr. Kelso Center for Alcoholism and Addiction STudies, U. of A.-Anchorage.

AT RISK CHILD POPULATION IN ALASKA 0 TO 18



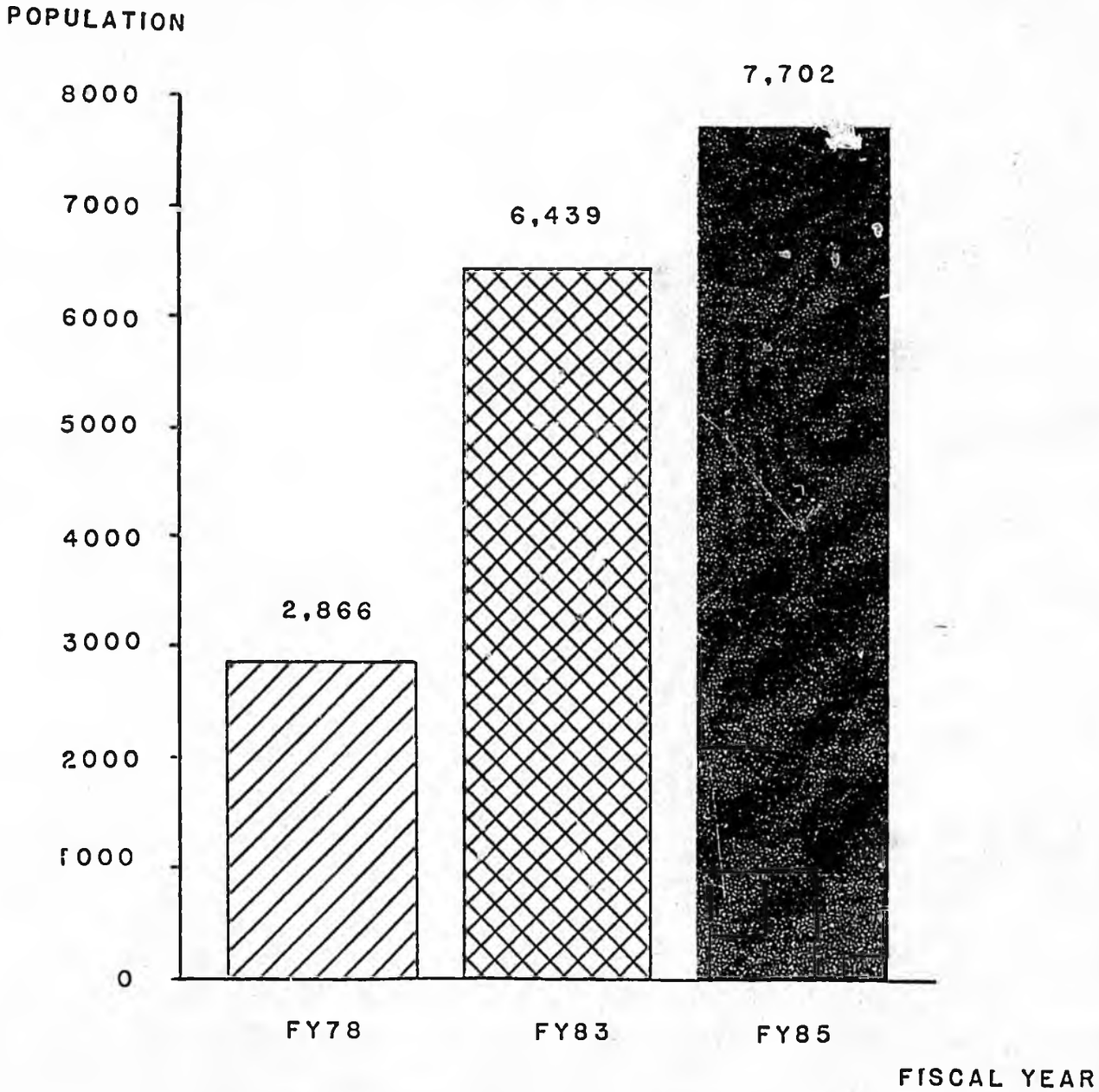
SOURCE: ALASKA DEPARTMENT OF LABOR,

"ALASKA POPULATION OVERVIEW."

CHILD PROTECTIVE SERVICES
INDIVIDUAL CHILDREN SERVED

169% INCREASE OVER FY78

20% INCREASE OVER FY83



CHILDREN SERVED

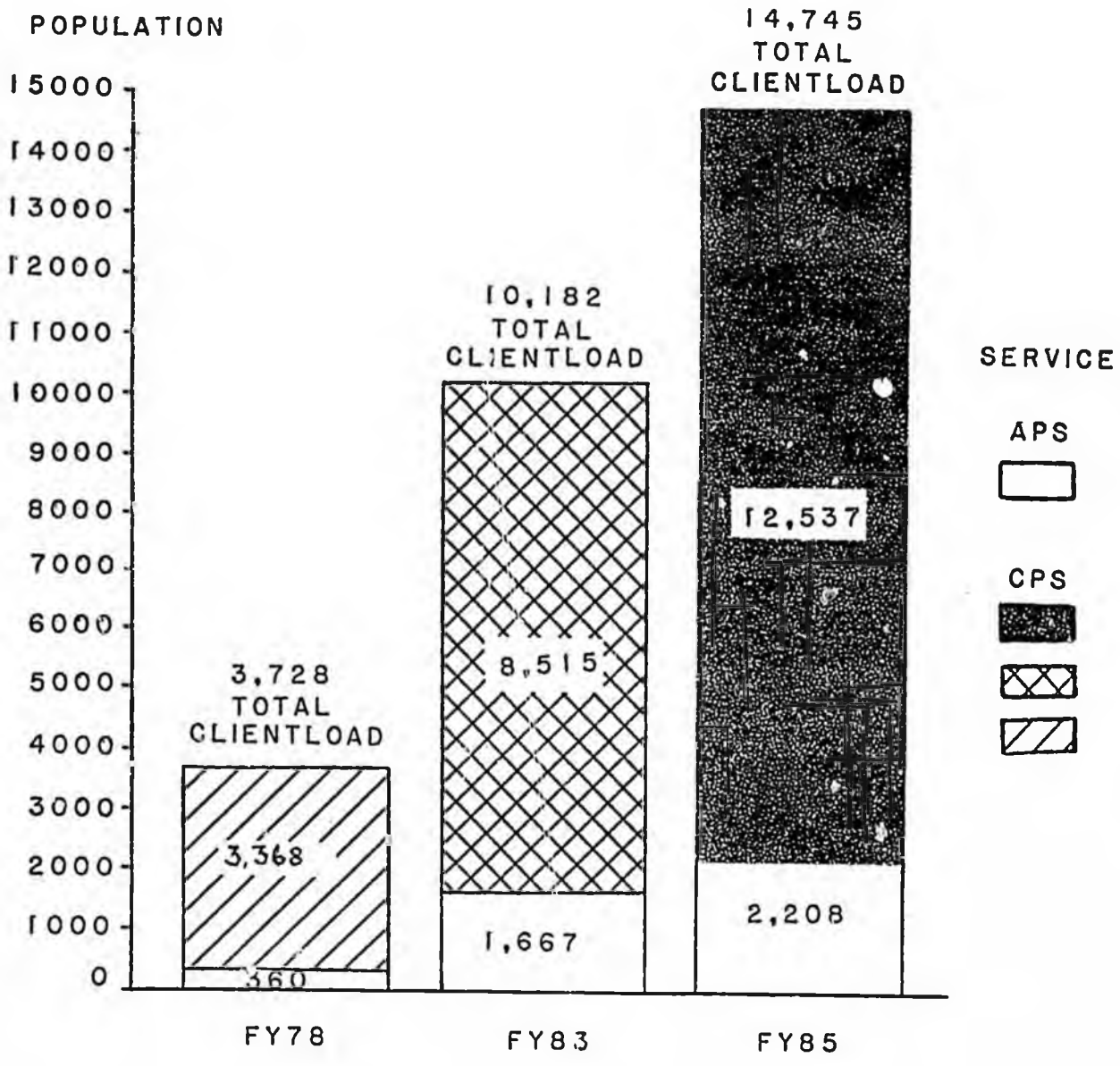
SOURCE: DIVISION OF FAMILY AND YOUTH SERVICES

FY78, 83, AND 85 ANNUAL REPORTS

INDIVIDUALS RECEIVING ADULT OR CHILD PROTECTIVE SERVICES

296% INCREASE OVER FY78

45% INCREASE OVER FY83



SOURCE: DIVISION OF FAMILY AND YOUTH SERVICES

FY78, 83, AND 85 ANNUAL REPORTS

ADDENDUM
to
CHILD ABUSE AND NEGLECT IN ALASKA REPORT

FY 84

The following data updates the charts depicted in the report provided Governor Sheffield on September 18, 1984:

1. Clients Served

Total APS/CPS Clientload = 10,913
Total APS Clients = 1,669
Total CPS Clients = 9,244
Total Children Served = 7,176

From 1983 to 1984 % of Change:
Total Children Served Increased 11%
Total Clientload Increased 7%

2. Reports of Child Abuse and Neglect in Alaska

Total Reports for FY 84 = 9,476
Physical Abuse = 1,929
Sexual Abuse = 1,167
Neglect = 6,380

From 1983 to 1984 % of Change:

Total Reports	Increased 7%
Physical Abuse	Increased 3%
Sexual Abuse	Increased 9%
Neglect	Increased 8%

3. Licensed Facilities in Alaska as of January 1985

Total Facilities = 1,874
Total Capacity = 15,325

Child Care Centers	= 2,860
Family Child Care Homes	= 7,351
Residential Child Care Facilities	= 1,618
Child Foster Homes	= 2,091
Adult Residential Care Facilities	= 369
Adult Foster Homes	= 38

From August 1984 to January 1985 % of Change

Total facilities	Increased 7%
Total Capacity	Increased 21%

SUMMARY OF CLIENTLOAD BY REGION

FAMILY SERVICES APS/CPS CASES

Comparison of January 1983 to January 1985

Region	Total Clients 1983	Total Clients 1985	Social Workers Required 1983	Social Workers Required 1985*	No. of Existing Social Workers	Additional Social Workers Needed	Number of Social Workers Requested in Governor's 86 Budget
Southeastern	912	1,342	20	27	17	10	2
Western	439	587	12	13	12	1	0
Northern	1,809	1,578	37	32	24	8	5
Northwestern	347	399	7	8	9**	0	0
Southcentral	3,386	3,718	72	75	55	20	6.5
Grand Total	6,893	7,624	147	155	117	39	13.5

* Based on 50 clients per social worker.

** Includes 3 Kawerak and 2 Maniilaq line social workers.

Summary of Clientload by Office
Family Services APS/CPS Cases

For January 1983/January 1985

Office	Total Clients 1983	Total Clients 1985	Average Clients/ Soc Worker 1983	Average Clients/ Soc Worker 1985	Total No. of Social Workers Required* 1983	Total No. of Social Workers Required* 1985	No. of Existing Social Workers	Additional Social Workers Needed	Soc. Workers Requested in Governor's FY 86 Budget
Juneau	373	685	62	114	8	14	6	8	1
Sitka	181	153	60	51	4	3	3	0	0
Ketchikan	212	284	42	57	5	6	5	1	1
Petersburg	67	107	67	107	1	2	1	1	0
Wrangell	42	67	42	67	1	1	1	0	0
Craig	37	46	37	46	1	1	1	0	0
Bethel	287	470	47	59	6	9	8**	1	0
Aniak	29	41	29	41	1	1	1	0	0
Alakanuk	14	CLOSED							
Mt. Village	41	31	41	31	1	1	1	0	0
Kwigillingok	41	41	41	41	1	1	1	0	0
Scammon Bay	6	CLOSED							
Grayling	21	4	21	4	1	1	1	0	0
Fairbanks	1,054	894	75	64	21	18	14	4	2
Galena	201	102	100	51	4	2	2	0	1
Ft. Yukon	70	81	70	81	2	2	1	1	0
Barrow	191	215	64	72	4	4	3	1	0
Delta	207	206	70	69	4	4	3	1	1
Nenana	86	80	86	80	2	2	1	1	1
Nome	214	260	71	43	4	5	6***	0	0
Kotzebue	97	135	97	45	2	3	3****	0	0
Unalakleet	36	CLOSED							
Anchorage	1,951	1,993	57	59	39	40	34	6	3
Wasilla/ Palmer	247	301	62	75	5	6	4	2	0
McGrath	28	25	28	25	1	1	1	0	0
Glennallen/ Copper Center	92	51	92	51	2	1	1	0	0
Iliamna	0	CLOSED							
Eagle River	205	291	103	146	4	6	2	4	0
Seward	69	62	69	61	1	1	1	0	0
Kenai	158	158	79	79	3	3	2	1	2
Homer	151	330	151	165	3	7	2	5	1
Dillingham	223	152	112	76	5	3	2	1	0
Valdez	57	46	57	46	2	1	1	0	0.5
Cordova	39	52	39	52	1	1	1	0	0
Unalaska	102	81	102	81	1	2	1	1	0
Kodiak	64	120	32	60	2	2	2	0	0
Naknek	-	52	-	52	1	1	1	0	0
GRAND TOTAL	6,893	7,624			146	155	117	39	13.5

* Based on 50 clients per social worker
** Reflects transfer of Alakanuk and Scammon Bay positions
*** Reflects 3 Kawerak line social workers
**** Reflects 2 Maniilaq line social workers

CHILD ABUSE AND NEGLECT IN ALASKA

A REPORT TO

THE HONORABLE BILL SHEFFIELD

GOVERNOR

STATE OF ALASKA

Revised September 18, 1984

John R. Pugh
Commissioner
Department of Health
and Social Services

Michael L. Price
Director
Division of Family
and Youth Services