

SUNSET EVALUATION UPDATE
HEARING AID DEALERS AND FITTERS
Chapter 451A, Hawaii Revised Statutes

A Report to the Governor and the Legislature of the State of Hawaii

Submitted by the
Legislative Auditor of the State of Hawaii

Report No. 85-1
January 1985

FOREWORD

Under the "Sunset Law," licensing boards and commissions and regulated programs are terminated at specified times unless they are reestablished by the Legislature. Hawaii's Sunset Law, or the Hawaii Regulatory Licensing Reform Act of 1977, scheduled for termination 38 occupational licensing programs over a six-year period. These programs are repealed unless they are specifically reestablished by the Legislature. In 1979, the Legislature assigned the Office of the Legislative Auditor responsibility for evaluating each program prior to its repeal.

This report updates our sunset evaluation of the regulation of hearing aid dealers and fitters under Chapter 451A, Hawaii Revised Statutes, which was conducted in 1981. It presents our findings as to whether the program complies with the Sunset Law and whether there is a reasonable need to regulate the occupation to protect public health, safety, or welfare. It includes our recommendation on whether the program should be continued, modified, or repealed.

We acknowledge the cooperation and assistance extended to our staff by the Board of Hearing Aid Dealers and Fitters, the Department of Commerce and Consumer Affairs, and other officials contacted during the course of our examination.

Clinton T. Tanimura
Legislative Auditor
State of Hawaii

January 1985

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Sunset Evaluation Update

HEARING AID DEALERS AND FITTERS

This report evaluates the regulation of hearing aid dealers and fitters under Chapter 451A, Hawaii Revised Statutes, to determine whether the public interest is best served by reenactment, modification, or repeal of Chapter 451A. In January 1981, this office examined the regulation of hearing aid dealers and fitters in its *Sunset Evaluation Report, Hearing Aid Dealers and Fitters, Chapter 451A, Hawaii Revised Statutes*. This update summarizes the background information and findings and recommendations contained in the 1981 report. It then reports on developments since 1981 and presents our current findings and recommendations.

Background on the Regulation of Hearing Aid Dealers

Reports of unethical business practices among hearing aid dealers on the mainland stimulated government regulation of the occupation. Hawaii enacted legislation in 1969 to license the practice of dealing and fitting hearing aids.¹ The practice of “dealing and fitting” is defined statutorily as “the measurement of hearing by an audiometer or other means solely for the purpose of making selections, adaptations, or sales of hearing aids or the manufacture of impressions for earmolds ...and...the administration of audiograms for use in consultation with the hard-of-hearing.”

Hearing aid dealers and fitters are regulated by a seven-member board placed in the Department of Commerce and Consumer Affairs (DCCA). The board must include at least one hearing aid dealer and fitter with five years of experience, one otolaryngologist, and one audiologist.

The board is authorized, among other powers and duties, to adopt rules, develop standards for licensure, prepare and administer examinations, and investigate and conduct hearings regarding any violation.

1. The law took effect July 1, 1970, but the first licenses were not issued until 1974.

To obtain a license, the applicant must be a high school graduate, of good moral character, and must satisfactorily complete written and practical examinations.

An applicant with a license to practice in a state with requirements equivalent to or higher than those in Hawaii may be issued a license (a certificate of endorsement) by the board without the examinations.

The board may also issue a temporary (one year) permit to allow a prospective hearing aid dealer to train under the supervision of an experienced dealer.

The principal standards of practice prescribed by state statute are the requirements for a medical authorization by a physician before a hearing aid can be sold and a detailed receipt of the terms of sale together with specifications of the hearing aid when one is actually sold. The statute also lists a number of grounds for disciplinary actions and specifies certain prohibited acts and practices.

In 1977, the Federal Food, Drug, and Cosmetic Act mandated federal regulation of the labeling of hearing aids and conditions of sale. The federal Food and Drug Administration (FDA) regulations on hearing aids take precedence over any provisions in state law which are different from, or are in addition to, any of the federal requirements. A state may obtain an exemption from federal preemption of state provisions, but it must first apply to the FDA for consideration and approval.

Findings and Recommendations in the 1981 Sunset Evaluation Report

Under the 1977 Sunset Law, the Board of Hearing Aid Dealers and Fitters was scheduled to be terminated at the end of December 1981. Our sunset evaluation of the regulation of hearing aid dealers and fitters at that time concluded as follows:

“1. Some form of regulation over conditions of sale and other business practices of hearing aid dealers and fitters is necessary to protect the public from the potential harm of economic loss, but neither the board nor licensing is necessary to provide such protection.

“2. Federal law and regulations have preempted the Hawaii statute. Because Hawaii has not been granted an exemption from federal standards, its regulatory activities which are different from or are in addition to federal requirements are of doubtful legality.

"3. The failure of the Board of Hearing Aid Dealers and Fitters, 11 years after the Hawaii statute was enacted, to promulgate rules and regulations in accordance with the Hawaii Administrative Procedure Act also makes past and present state regulatory activities of doubtful legality.

"4. The board's performance in regulatory operations has been weak."²

The need for some form of regulation. We found that the primary purpose for regulating hearing aids and their conditions of sale is to protect the public from the potential harm of economic loss. Cases of unscrupulous sales practices on the mainland had led to Congressional hearings and staff studies, and eventually, to federal regulation of hearing aids.

Prior to federal regulation, the 1969 Hawaii State Legislature had enacted legislation to protect the public from economic exploitation. The Hawaii statute, as amended, regulates the business practices of hearing aid dealers in the State by requiring a medical authorization prior to sale of a hearing aid and by prohibiting certain business practices. Further, the State requires licensing of the occupation by a board. In our evaluation of the need for regulating hearing aid dealers and fitters, we concluded that licensing by a board is not necessary to protect the consumer, and enforcement of business practices could be assigned directly to DCCA.

Our conclusion was derived from the finding that the primary purpose of regulating hearing aids and their conditions of sale is to protect the public from the potential harm of economic loss rather than the potential harm of physical injury. We reasoned that where the situation is one of consumer disadvantage in the marketplace and the potential harm is that of possible economic loss, the appropriate form of regulation is to prescribe the practices which are to apply to the particular business, including the practices which are prohibited. While the Hawaii statute does specify what controls are to be applied over the business practices of hearing aid dealers, the statute went too far in requiring licensing by a board.

Federal vs. state regulation. Since 1977, certain provisions in state law have been preempted by federal regulation. We identified at least five areas where state provisions have been preempted. One major difference between federal and state

2. State of Hawaii, Legislative Auditor, *Sunset Evaluation Report, Hearing Aid Dealers and Fitters, Chapter 451A, Hawaii Revised Statutes*, Report No. 81-3, January 1981, p. 13.

requirements is that while both require a medical authorization before a hearing aid is sold, federal regulations allow persons over 18 to sign a medical waiver because of personal or religious beliefs. The State has no provision for such a waiver. Because Hawaii had not applied for an exemption from preemption as allowed by federal law and FDA regulations, the enforcement of certain portions of the Hawaii statute was of doubtful legality.

The lack of action by the Board of Hearing Aid Dealers and Fitters was not due to a lack of awareness of the federal regulations. The board had discussed this issue on four separate occasions between 1977 and 1980 but no action had resulted.

Rules and regulations. Rules and regulations still had not been adopted 11 years after the statute establishing the board was enacted. Operating without rules and regulations, the board's past and present regulatory activities were of doubtful legality.

Regulatory operations. We found that the board's performance in routine regulatory operations of complaint handling, examining applicants, and monitoring hearing aid dealers was weak. More specifically, we noted that while complaints received by the board were few, they were characterized by delays and lack of resolution; the written examination required for licensing had never been validated and was out-of-date; and while state statute requires medical authorization before a hearing aid is sold, no system of compliance had ever been implemented.

Recommendations and responses. On the basis of our evaluation, we recommended that Chapter 451A be modified to delete the board and the licensing of hearing aid dealers and fitters. Both the chairman of the Board of Hearing Aid Dealers and Fitters as well as another board member responded that the report was an accurate assessment of the board but they said that the board should be continued. DCCA responded that it generally agreed with our evaluation.

Subsequent Developments

Following the submission of our sunset report to the 1981 Legislature, hearings were held to determine whether Chapter 451A should be reenacted, modified or repealed. The board, consumers, and some medical professionals testified in favor of reenacting the board and continued licensing of the occupation.

The Board of Hearing Aid Dealers and Fitters testified that licensing was necessary to provide good hearing health care and to assure "at least a minimal competency" of hearing aid dealers for the benefit of the consumer. The board warned that "[i]nappropriate amplification can lead to furthering social isolation, social withdrawal, premature senility and increased psychological depression."³

With regard to the other findings of our report, the board testified that: (1) while it was true that the board had not petitioned the FDA for an exemption from preemption, the FDA was encouraging the states to remain active in regulating the hearing aid industry; (2) the board's rules and regulations were approved at the February 4, 1981, board meeting and would be up for public hearing and possible approval by the Governor later that year; (3) the written and practical examinations were undergoing revision and validation and should be completed in several months; and (4) the board had consulted with DCCA staff regarding monitoring of hearing aid dealer records in the past, but they were informed that DCCA did not have the staff available to do such monitoring.

In its report, the House Committee on Consumer Protection and Commerce stated, "While mindful of the recommendations of the Auditor to deregulate this area, your Committee agrees with the intent of the bill and the oral testimony presented to protect the public's health and welfare, whenever possible, from potential dangers caused by unqualified and unethical hearing aid dealers and fitters."⁴

Consequently, the Legislature passed legislation extending the repeal date of the Board of Hearing Aid Dealers and Fitters from December 31, 1981 to December 31, 1984.⁵ The House Consumer Protection and Commerce Committee reported that "the three-year extension authorized by this bill is also for the purpose of granting the Board ample time to cure the defects in its administration of Chapter 451A, Hawaii Revised Statutes, as pointed out by the Auditor."⁶

3. Testimony on Senate Bill No. 587 and No. 595 submitted by the Board of Hearing Aid Dealers and Fitters, to the Honorable Steve Cobb, Chairman, Senate Committee on Consumer Protection and Commerce, March 2, 1981.

4. House Standing Committee Report No. 877 on Senate Bill No. 587, Regular Session of 1981.

5. Act 34, SLH 1981, subsequently Act 87, SLH 1981, postponed all sunset reports for one year. Board termination date was thus extended to December 31, 1985.

6. House Standing Committee Report No. 877 on Senate Bill No. 587, Regular Session of 1981.

Current Findings and Recommendations

Summary of findings. We find that:

1. Some regulation of hearing aid dealers and fitters is necessary to protect the public but licensing by a board is not needed.
2. The present board has tried to correct the deficiencies in board operations noted in our first sunset evaluation report but problems of examination validity and the failure to monitor compliance still remain.
3. The department and the board did not establish appropriate safeguards to ensure that the handling of a board member's licensure was fair and that the board member was not violating state law on conflicts of interest.

Need for regulation. In our previous evaluation report, we found that some form of regulation is needed to protect the public, but "neither the board nor licensing is necessary."⁷ This is still true.

We noted that the underlying reason for establishing regulation in 1969, at a time when there was no federal regulation, was the Legislature's concern over the potential harm of economic exploitation. To this end, Chapter 451A provides for controls over certain business practices, primarily (1) the requirement for an authorization from a physician before a hearing aid can be sold, (2) grounds for disciplinary action for such practices as fraud, and false and misleading advertising, and (3) the prohibition of door-to-door sales.

The potential danger to the physical health and safety of consumers from hearing aids or incompetent hearing aid dealers remains minimal. We can find no documented cases of physical injury to consumers caused by hearing aid dealers in Hawaii.

There has also been limited documented evidence of injury on the mainland since the FDA hearing aid regulations took effect in 1977. A 1978 Federal Trade Commission report stated that some researchers believe that excessive amplification could damage residual hearing but that it has not been established conclusively that

7. Legislative Auditor, *Sunset Evaluation Report, Hearing Aid Dealers and Fitters*, p. 13.

such damage is an inevitable result of excessive amplification.⁸ An improperly fitted earmold could also cause painful irritation, but overall, these dangers do not appear to pose an imminent or significant health threat to the public. Our current evaluation reaffirms our past finding that the licensing of hearing aid dealers adds little protection to the consumer.

The Board of Hearing Aid Dealers and Fitters disagreed with this finding in 1981 and testified that licensing is necessary to assure "at least minimal competency" of hearing aid dealers for the benefit of the consumer. The principal contribution made by the board in this regard is the examination of licensees. However, as we report in a later section, the examination has not been validated so there is no assurance that it actually measures competency. In addition, there are several deficiencies in the examination process.

The argument for licensure is also contradicted by experience in other states, such as New York, which has a registration program for hearing aid dealers. There are currently about 450 registered dealers in New York (compared to 17 licensed dealers in Hawaii). Hearing aid dealers in that state are merely required to submit an application and pay a fee to register. No examination for competency is required and yet in 1983, there were only 14 complaints against registered dealers in that state. For the most part, the complaints were from dealers questioning the business practices of other dealers.⁹

Federal versus state regulation. In our January 1981 report, we noted that at least five Hawaii statutory provisions were preempted by the federal regulations. The FDA may grant an exemption to the State if the requirement is found to be: (1) more stringent than the federal requirement or (2) required by compelling local conditions, and compliance to the state requirement would not violate any other federal requirement.¹⁰

8. U.S. Federal Trade Commission, *Hearing Aid Industry Staff Report*, Washington, D.C., September 1978, pp. F-39, F-40, F-41.

9. Letter from Willard Roff, Assistant Director, Department of State, State of New York, to Donna Fujimoto, Office of the Legislative Auditor, May 29, 1984.

10. 21 CFR 808.25(g)(2).

Because the State had not been granted an exemption from federal standards, we found that the State's regulatory activities which are different from, or in addition to, federal requirements are of doubtful legality. We recommended that the department petition the FDA to obtain an exemption.

Since our last report, the board has petitioned the FDA to grant Hawaii an exemption for certain preempted state provisions. However, this request was not submitted to the FDA until April 1983, over two years after our report was published. This delay was, for the most part, due to advice to the board from DCCA staff that board rules and regulations were needed before submitting a request for exemption. We were unable to determine the specific basis for the DCCA staff's recommendation.

According to the FDA regulations covering applications for exemptions, "[a]ny State or political subdivision may apply to the Food and Drug Administration for an exemption from preemption for any requirement that it has enacted and that is preempted. An exemption may be granted for a requirement that has been enacted, promulgated, or issued in final form by the authorized body or official of the State or political subdivision so as to have the force and effect of law."¹¹

Since the portions of Hawaii state law which were preempted were enacted statutorily, the need for the FDA to examine board regulations as well as state statute in order to make a decision is questionable. We believe that the additional two-year delay in seeking the exemption was needless and ill-advised.

In response to Hawaii's request, the FDA published on October 1, 1984, proposed rules that would grant exemption from federal preemption for certain of Hawaii's requirements and deny exemption for other of its requirements. In the proposed rules, the FDA plans to exempt two of Hawaii's preempted provisions. It will allow Hawaii to require written authorizations for hearing aids from otorhinolaryngologists for children under ten, and it will allow the State to require the hearing aid dispenser to keep a physician's written authorization on file for five years rather than the three years required by the FDA.

11. 21 CFR 808.20(a).

The FDA plans to deny exemption for the provision requiring a person wishing to purchase a hearing aid to have a written authorization from a physician. The FDA believes that adults should be permitted to waive this requirement if the user has personal or religious objections to a medical evaluation. The FDA also plans to deny exemption for Hawaii's requirement that a medical authorization be required within 90 days prior to the sale of a hearing aid. The proposed rules did not address a fifth preempted requirement relating to itemized receipts.¹² Table 1 summarizes the preempted provisions and the FDA's proposed rule.

Table 1
Review of FDA Proposed Rules on
Hawaii's Requests for Exemption from Federal Preemption

<i>Hawaii Provisions</i>	<i>Food and Drug Administration Decision</i>	
	<i>Exemption Granted</i>	<i>Exemption Denied</i>
Medical authorization required prior to sale of hearing aid with no provisions for a waiver.		FDA believes that any informed adult who objects to medical evaluation for religious or personal reasons should be permitted to waive the medical authorization requirement.
Medical authorization must be signed by a physician. In the case of a child 10 years of age or under, authorization must be from an otolaryngologist.	FDA believes that hearing loss in children can be treated medically or surgically more often than in adults and that otorhinolaryngologists are more knowledgeable about such treatment than other physicians.	
Medical authorization must be given within 90 days of purchase.		FDA believes it is unnecessarily stringent to require medical clearances three months before the sale of a hearing aid.
Records of medical authorizations must be kept for five years.	FDA believes that the provision will help the State in enforcing its statute.	
A person who buys a used hearing aid must be given a receipt which contains, among other things, information that the device is used or reconditioned. The law does not define "used" or "reconditioned."		<i>Not addressed.</i>

Source: *Federal Register*, v. 49, no. 191, October 1, 1984, pp. 38646-38647.

12. *Federal Register*, v. 49, no. 191, October 1, 1984, pp. 38645-38647.

In publishing the proposed rules, the FDA was providing notice to interested persons to present written comments on these proposals and an opportunity to request an oral hearing prior to final adoption of the rules.

Alternatives to state licensure. In view of the proposed FDA ruling which would maintain federal preemption over key Hawaii provisions and the lack of a need for licensing by a board, it would be best to allow Chapter 451A to expire as scheduled.

Even if the board and licensing were to be sunsetted, there would still be safeguards to protect consumers. Certain business practices would still be regulated by federal FDA regulations. Violations of the regulations could be forwarded to the local FDA office for investigation and possible prosecution. Other deceptive business practices would be covered by state statutes on business and commercial frauds which cover deceptive business practices and false advertising.

Should the Legislature wish to add to these controls, it could consider enacting certain statutory requirements now in Chapter 451A that are not covered by FDA regulations, such as the prohibition against soliciting for door-to-door sales. Enforcement of these business standards could be assigned directly to the Department of Commerce and Consumer Affairs.

Should the Legislature decide that some controls should still be exercised over who can conduct business as hearing aid dealers and fitters, it might consider an alternative patterned after New York's registration program where registration, rather than licensing, is in force. According to one expert in occupational licensing:

"Registration is used in situations where the threat to public health, safety, or welfare is minimal. Although it is relatively easy for individuals to become registered, it is equally easy for the authorities to revoke such registrations in response to complaints from the public. Since it is illegal for unregistered individuals to pursue their activities within a given jurisdiction, registration is a useful device for controlling possible 'fly-by-night' operators."¹³

13. Benjamin Shimberg, *Occupational Licensing: A Public Perspective*, Princeton, New Jersey, Educational Testing Service, 1982, p. 18.

With registration, complaints against registered dealers would be received, investigated and prosecuted by DCCA, although complaints relating to violations of FDA regulations would be forwarded to the local FDA office. Decisions on investigations and hearing recommendations would be made by the director of DCCA.

Regulatory operations. In 1981, we characterized the board's performance in regulatory operations as being weak. Although the present board has actively tried to correct most of the deficiencies noted in our first report, some problems remain unresolved.

Rules and regulations. We reported in 1981 that the failure of the board to promulgate rules and regulations made past and present state regulatory activities of doubtful legality. Board rules and regulations were finally adopted in late 1982, 13 years after the establishment of the board.

The rules contain an inappropriate provision that requires applicants for licensure to file a medical report which includes an X-ray examination and a statement by a licensed physician that the applicant is free of communicable and contagious diseases. There is no statutory basis for this requirement and in fact, a legislative committee specifically deleted a provision requiring such verification from the 1969 bill which was enacted to establish the regulation of hearing aid dealers.

Board regulations and the statutory requirement relating to verification of good moral character are also in effect but are not being enforced by the department. In our 1982 evaluation of the professional and vocational licensing program of the then Department of Regulatory Agencies, we found that letters of good moral character probably did little to screen out persons of "bad" character. The department has responded to this finding by not enforcing the requirement for verification of good moral character for prospective hearing aid dealer licensees. The department should propose that the statute be amended instead of simply deciding to not enforce statutory requirements.

Examinations. Our previous evaluation noted that the written examination was not validated, and that the board chairman felt the examination was out of date, that there were more questions on audiometry than hearing aids, and that there should be more input to the examination from related trades and professions.

Though there have been improvements to the board examinations, the problem of test validity remains unresolved. There is no evidence that the examination is of any value in discriminating between competent and incompetent dealers.

There have been three written examinations in the board's history. The examination developed in 1972 was analyzed by the board chairman in 1980. It had 71 fill-in-the-blank and true/false questions totaling 100 points. In July 1981, the board adopted a completely revised version of the written examination which had 100 multiple-choice questions totaling 100 points. The current written examination is a 1983 revision of the 1981 examination.

The practical examination has also been revised by the board since our prior report. The two general areas tested are the use of an audiometer and the manufacture of an earmold impression. In 1982, the board articulated the specific tasks evaluated in these two areas in its regulations. New procedures were also established whereby three board members oversee the practical examination while the written examination is still administered by the examination branch. The three-person examination committee is comprised of an audiologist, a dealer, and a lay person, with the audiologist actually administering the examination. The grading sheet consists of an abbreviated list breaking down the tasks being evaluated into smaller parts equaling a point each. Total possible points for the practical examination equals 100 and passing scores for both the written and practical examinations are set at 70 percent. In order to take the practical, the applicant must first pass the written examination.

There is still reason for concern about test validity. We described test validation in 1981 as follows:

"A test is considered valid if it provides an accurate measurement of the desired criterion, such as potential performance on the job. . . . A test may be validated in several ways. For example, one method of validation is to show that the items are, in fact, representative of the skills that are being measured. Another way is to demonstrate that the test score predicts an individual's ability to successfully perform the job."¹⁴

14. Legislative Auditor, *Sunset Evaluation Report, Hearing Aid Dealers and Fitters*, p. 22.

No formal assessment of test validity has been conducted on the current written and practical examinations. The written examination has not even undergone a statistical reliability test because of the insufficient number of test scores that can be studied. DCCA examination branch must have at least 15-20 examination results in order to conduct a reliability test and only five applicants had taken the current examination at the time this report was prepared.

Should Chapter 451A be reenacted and licensing be maintained, three major tasks must be initiated by the board to validate its examinations. *First*, the board must formally agree upon the specific functions of a hearing aid dealer in order to determine what skills and knowledge must be tested. This is no small feat considering that the hearing aid dispensing system is in a state of flux, with more university educated audiologists entering the field and competing with traditional hearing aid dealers.¹⁵

Nationally, conflict between the two groups has been heated, with each accusing the other of having serious deficiencies in education or experience.¹⁶ It is difficult to find agreement on precisely what skills and knowledge must be possessed by a hearing aid dealer, but some consensus must be reached in order for a valid test to be constructed. Without a formal description of specific hearing aid dealer functions and standards, it is impossible for the board to determine whether its examinations are fair and accurately reflect general hearing aid dealer practices.

Second, the board should develop a more systematic and comprehensive approach to constructing board examinations. Our review of current examination development practices reveals that the use of outside resources is limited. The board has not maximized the probability of constructing valid examinations through rigorous research and analysis, including review and evaluation of examinations and procedures used in other states.

Third, improvements to the current practical examination must be made. More specific examination procedures should be developed to ensure uniformity, avoid the possibility of unfair treatment, and eliminate any potential of conflicts of interest.

15. In Hawaii, 6 of the 17 licensed dealers (as of July 1984) are audiologists.

16. Beverly A. Goldstein, "Factors Contributing to the Changing Hearing Aid Scene," *Ear and Hearing*, v. 2, no. 6, November-December 1981, pp. 263-264.

Precautions are especially necessary in regulating a small occupational group such as hearing aid dealers because examiners are more likely to know and be affected by applicants for licensure.

Complaint handling. We noted in our 1981 evaluation that although the board received few complaints, board action was characterized by delays and lack of resolution. Complaint handling has improved since then, primarily due to changes made under Act 204, SLH 1982. The act transferred a major portion of complaint handling duties from licensing boards to the Regulated Industries Complaint Office (RICO). Currently, the board's main function relating to complaints is making decisions on the recommendations of RICO investigators and board hearings officers.

Improvements to the speed of complaint resolution have been significant. It took over two years for complaints filed in 1980 to be resolved. By comparison, the two complaints initiated in 1983 took seven months and one month, respectively, to be closed.

Monitoring of records. In our 1981 report, we noted that although Hawaii state statute authorizes the board and other law enforcement agencies to inspect medical authorization records, no system of compliance had ever been implemented.

During an October 1982 meeting, the board discussed establishing a program of periodic monitoring of medical authorization and/or waiver records. Some board members felt that inspection of dealer records should be conducted only if there is a basis from consumer complaints. Accordingly, the board decided to appoint an ad hoc committee to develop criteria for monitoring records based upon the degree or the number of complaints against a hearing aid dealer. To date, no such criteria have been developed by the committee of the board.

Possible conflicts of interest. A current member of the Board of Hearing Aid Dealers and Fitters applied for and was issued a hearing aid dealer's license while active on the board. It is apparent that a special situation such as this requires careful handling by the department and the board to ensure that the board member's license was issued fairly and that there was no violation of the conflicts of interest law. We can find no evidence that any such precautions were taken, however. The board member in question applied for a license, took the examinations, and received a license with no indication by the board or the department that such action could be

in violation of state law on standards of conduct. The board member should obtain an advisory opinion from the State Ethics Commission to resolve this matter.

Additionally, the department should work with the State Ethics Commission to develop policies and procedures for handling similar situations that may arise in the future. Once these are developed, the department should initiate a program to familiarize all members of regulatory boards and commissions with these policies and procedures.

Recommendations

We recommend that:

1. *Chapter 451A, Hawaii Revised Statutes, be allowed to expire as scheduled on December 31, 1985, to leave regulation of the business to the Federal Food and Drug Administration.*

2. *If the board and licensing are continued, the Legislature delete the good moral character requirement and the board amend those rules which do not have a statutory basis or which are not being enforced, improve the board examinations, and develop procedures to monitor medical authorization and waiver records.*

3. *The department work with the State Ethics Commission to develop policies and procedures for handling possible conflicts of interest situations, especially those where board members seek licensure for themselves.*

APPENDIX

RESPONSES OF AFFECTED AGENCIES

COMMENTS ON AGENCY RESPONSES

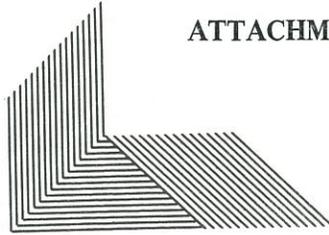
A preliminary draft of this Sunset Evaluation Update was transmitted on November 2, 1984 to the Board of Hearing Aid Dealers and Fitters and the Department of Commerce and Consumer Affairs for their review and comments. A copy of the transmittal letter to the board is included as Attachment 1 of this appendix. A similar letter was sent to the department. The responses from the board and the department are included as Attachments 2 and 3.

The board disagrees with our recommendation that it be eliminated. It says that the report does not give credit to the board for the efforts it has made and that it believes strongly that state regulation is necessary. However, the board acknowledges that problems of examination validity and the monitoring of records remain.

The Department of Commerce and Consumer Affairs responded that it is in general agreement with the observation and evaluation made in the report.

ATTACHMENT 1

THE OFFICE OF THE AUDITOR
STATE OF HAWAII
465 S. KING STREET, RM. 500
HONOLULU, HAWAII 96813



CLINTON T. TANIMURA
AUDITOR

November 2, 1984

COPY

Mrs. June Isono, Chairperson
Board of Hearing Aid Dealers and Fitters
Department of Commerce and Consumer Affairs
State of Hawaii
Honolulu, Hawaii 96813

Dear Mrs. Isono:

Enclosed are eight preliminary copies, numbered 4 through 11, of our *Sunset Evaluation Update, Hearing Aid Dealers and Fitters, Chapter 451A, Hawaii Revised Statutes*. These copies are for review by you, other members of the board, and your executive secretary. This preliminary report has also been transmitted to Russel Nagata, Director, Department of Commerce and Consumer Affairs.

The report contains our recommendations relating to the regulation of nursing home administrators. If you have any comments on our recommendations, we would appreciate receiving them by December 3, 1984. Any comments we receive will be included as part of the final report which will be submitted to the Legislature.

Since the report is not in final form and changes may possibly be made to it, we request that you limit access to the report to those officials whom you wish to call upon for assistance in your response. Please do not reproduce the report. Should you require additional copies, please contact our office. Public release of the report will be made solely by our office and only after the report is published in its final form.

We appreciate the assistance and cooperation extended to us.

Sincerely,

Clinton T. Tanimura
Legislative Auditor

Enclosures

ATTACHMENT 2

GEORGE R. ARIYOSHI
GOVERNOR



RUSSEL S. NAGATA
DIRECTOR

DICK H. OKAJI
LICENSING ADMINISTRATOR

BOARD OF HEARING AID DEALERS AND FITTERS
STATE OF HAWAII
PROFESSIONAL & VOCATIONAL LICENSING DIVISION
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
P. O. BOX 3469
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November 29, 1984

Mr. Clinton T. Tanimura
Legislative Auditor
Office of the Auditor
State of Hawaii
465 South King Street, Room 500
Honolulu, Hawaii 96813

RECEIVED
DEC 3 10 54 AM '84
OFFICE OF THE AUDITOR
STATE OF HAWAII

Dear Mr. Tanimura:

First, I wish to commend the auditor of this report for her in depth research, determination and persistence in obtaining pertinent information. I would like to add, however, that her demeanor while obtaining information was at times prejudgmental, caustic and somewhat unfair. While it is true problems remain in regards to examination validity and record monitoring, the majority of recommendations that the Auditor put forth to the Board in 1981 were completed.

In regards to the petitioning of the FDA, the board was informed by the DCCA that this could not be done without rules and regulations. The rules were finalized by the board by the February 4, 1981 meeting and were at that time changed to the Ramseyer format. It was then sent for review to the Attorney General's Office for legality and approval. Because the rules were originally drawn up by the previous board, rules and regulations concerning federal regulations were included in the proposed rules. The Attorney General then returned the rules for corrections several times and due to the work load of the DCCA (as you know they themselves were undergoing radical changes), these rules were not approved and finalized for public hearing until October 14, 1982. It must be noted that on July 24, 1981, the board finalized the corrections and was anxious to obtain approval by the Attorney General's office. There was much bureaucratic delay in finalizing the rules. The point of the matter remains that not at one point did the Board itself delay the processing of the rules.

Mr. Clinton T. Tanimura
November 29, 1984
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Due to the information given to the Board that petitioning to the FDA could not be completed without rules, the FDA was sent a petition for exemption from preemption. As noted in the auditors report, exemption from preemption was given for medical authorization by and ENT for children under the age of ten, which the board felt was the most important statutory requirement. The important fact is that the board did petition the FDA and a response was obtained.

As to the handling of complaints, it is felt that with the reorganization of the DCCA, complaints are handled more efficiently and with less interference. The board has had no problems with resolving complaints (as noted by the Auditor).

In reference to the examination validity, it is felt that if the DCCA had certain criteria to which examinations should be constructed, these should have been communicated to the board. If review and "rigorous research and analysis" is necessary to design the appropriate examination, the auditor should enlighten us with the where-with-all and the economic resources to do so. Reviews of examinations and procedures used in other states show a diverse number of methods used to determine "competency". The board is currently evaluating other testing procedures that allow for validity. While Texas has just set a precedent by exempting licensed audiologists from hearing aid licensure, the Board feels that this area of competency for the dispensing of hearing aids is a strong criterion to retain the board. As the auditor notes, "this is no small feat."

In regards to the monitoring of records and medical authorizations, the present Board strongly felt that this would be a form of "witch hunting". No other regulatory board does such activity and place licenses on periodical record inspection. The board also feels that monitoring is necessary only when an appropriate complaint occurs. The change will be initiated in the board's rules.

In addition it is felt that other allegations and accusations are irrelevant to the elimination of the board and that the "prejudgemental" philosophy is evident throughout. At no time is credit given for the efforts the Board has put forth to catch up on eleven years of neglect and ineffectiveness. Most board members worked long hours resolving the problems acknowledged by the auditor in 1981, and has done so, leaving only the examination validity and the record monitoring unresolved. The board strongly believes that regulations is necessary at the State level, due to the importance of insuring appropriate amplification and care for children, the prohibition of door-to-door sales and at least to attempt to assure that a very vulnerable population is not taken advantage of. If the Legislature sunsets the board, it is felt

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that some form of state regulation exist. Both the otorhinolaryngological specialists and audiologists firmly believe that licensing is necessary and that the specifics of valid competency is why someone or somebody should work towards resolving these very vital concerns.

Very truly yours,



(Mrs.) June Uyehara-Isono, M.S., C.C.C., A
Chairperson, Board of Hearing Aid
Dealers and Fitters

ATTACHMENT 3



GEORGE R. ARIYOSHI
GOVERNOR

RUSSEL S. NAGATA
Director
COMMISSIONER OF SECURITIES

STATE OF HAWAII
OFFICE OF THE DIRECTOR
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
1010 RICHARDS STREET
P. O. BOX 541
HONOLULU, HAWAII 96809

ROBERT A. ALM
DEPUTY DIRECTOR

November 27, 1984

Mr. Clinton T. Tanimura
Legislative Auditor
Office of the Auditor
State of Hawaii
465 South King Street, Room 500
Honolulu, HI 96813

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Nov 29 10 45 AM '84
OFFICE OF THE AUDITOR
STATE OF HAWAII

Dear Mr. Tanimura:

Thank you for the opportunity to comment on your sunset evaluation report on hearing aid dealers and fitters.

The Department of Commerce and Consumer Affairs is in general agreement with the observation and evaluation you have made of the Board of Hearing Aid Dealers and Fitters. We wish to commend your staff for the thoroughness of the report.

Very truly yours,


Russel S. Nagata
Director