SUNSET EVALUATION REPORT

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

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FOREWORD

Under the "sunset law," licensing boards and commissions and regulated programs are terminated at specified times unless they are reestablished by the Legislature. Nationally, the first sunset law was passed in 1976. Within three years, 30 more states had enacted similar legislation. The rapid spread of sunset legislation reflects increasing public concern with what it sees as unwarranted government interference in everyday activities.

Hawaii's Sunset Law, or the Hawaii Regulatory Licensing Reform Act of 1977, terminated 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 These programs are repealed unless they are specifically reestablished by the Legislature.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 evaluates the regulation of hearing aid dealers and fitters under Chapter 451A, Hawaii Revised Statutes. It presents our findings as to whether the program complies with the Sunset Law and whether there is a reasonable need to regulate hearing aid dealers and fitters to protect public health, safety, or welfare. It includes our recommendation on whether the program should be continued, modified, or repealed.

Our approach to the evaluation of the regulation of hearing aid dealers and fitters is described in Chapter 1 of this report under "Framework for Evaluation." That framework will also serve as the framework for conducting subsequent evaluations. We used the policies enunciated by the Legislature in the Sunset Law to develop our framework for evaluation. The first and basic test we applied was whether there existed an identifiable potential danger to public health, safety, or welfare arising from the conduct of the occupation or profession being regulated. Then the other criteria for evaluation were applied.

We acknowledge the cooperation and assistance extended to our staff by the Department of Regulatory Agencies and other officials contacted during the course of our examination.

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Chapter 1

INTRODUCTION

The Hawaii Regulatory Licensing Reform Act of 1977, or Sunset Law, repeals statutes concerning 38 state licensing boards and commissions over a six-year period. Each year, six to eight licensing statutes are scheduled to be repealed unless specifically reenacted by the Legislature.

In 1979, the Legislature amended the law to make the Legislative Auditor responsible for evaluating each licensing program prior to its repeal and to recommend to the Legislature whether the statute should be reenacted, modified, or permitted to expire as scheduled. In 1980, the Legislature further amended the law to require the Legislative Auditor to evaluate the effectiveness and efficiency of the licensing program, even if he determines that the program should not be reenacted.

Objective of the Evaluation

The objective of the evaluation is: To determine whether, in light of the policies set forth in the Sunset Law, the public interest is best served by reenactment, modification or repeal of Chapter 451A.

Scope of the Evaluation

This report examines the history of the statute on licensing of hearing aid dealers and fitters and the public health, safety, or welfare that the statute was designed to protect. It then assesses the effectiveness of the statute in preventing public injury and the continuing need for the statute.

Organization of the Report

This report consists of three chapters: Chapter 1, this introduction and the framework developed for evaluating the licensing program; Chapter 2, background information on the regulated industry and the enabling legislation; and Chapter 3, our evaluation and recommendation.

Framework for Evaluation

Hawaii's Regulatory Licensing Reform Act of 1977, or Sunset Law, reflects rising public antipathy toward what is seen as unwarranted government interference in citizens' lives. The Sunset Law sets up a timetable terminating various occupational licensing boards. Unless reestablished, the boards disappear or "sunset" at a prescribed moment in time.

In the Sunset Law, the Legislature established policies on the regulation of professions and vocations. The law requires that each occupational licensing program be assessed against these policies in determining whether the program should be reestablished or permitted to expire as scheduled. These policies, as amended in 1980, are:

1. The regulation and licensing of professions and vocations by the State shall be undertaken only where reasonably necessary to protect the health, safety, or welfare of consumers of the services; the purpose of regulation shall be the protection of the public welfare and not that of the regulated profession or vocation.

2. Where regulation of professions and vocations is reasonably necessary to protect consumers, government regulation in the form of full licensure or other restrictions on the professions or vocations should be retained or adopted.

3. Professional and vocational regulation shall be imposed where necessary to protect consumers who, because of a variety of circumstances, may be at a disadvantage in choosing or relying on the provider of the services.

4. Evidence of abuses by providers of the services shall be accorded great weight in determining whether government regulation is desirable.

5. Professional and vocational regulation which artificially increases the costs of goods and services to the consumer should be avoided.

6. Professional and vocational regulation should be eliminated where its benefits to consumers are outweighed by its costs to taxpayers.

7. Regulation shall not unreasonably restrict entry into professions and vocations by all qualified persons.

We translated these policy statements into the following framework for evaluating the continuing need for the various occupational licensing statutes.

Licensing of an occupation or profession is warranted if:

1. There exists an identifiable potential danger to public health, safety, or welfare arising from the operation or conduct of the occupation or profession.

2. The public that is likely to be harmed is the consuming public.

3. The potential harm is not one against which the public can reasonably be expected to protect itself.

4. There is a reasonable relationship between licensing and protection of the public from potential harm.

5. Licensing is superior to other optional ways of restricting the profession or vocation to protect the public from the potential harm.

6. The benefits of licensing outweigh its costs.

The potential harm. For each regulatory program under review, the initial task is to identify the purpose of regulation and the dangers from which the public is intended to be protected.

Not all potential dangers warrant the exercise of the State's licensing powers. The exercise of such powers is justified only when the potential harm is to public health, safety, or welfare. "Health" and "safety" are fairly well understood. "Welfare" means well-being in any respect and includes physical, social, and economic well-being.

This policy that the potential danger be to the public health, safety, or welfare is a restatement of general case law. As a general rule, a state may exercise its police power and impose occupational licensing requirements only if such requirements tend to promote the public health, safety, or welfare. Under particular fact situations and statutory enactments, courts have held that licensing requirements for paperhangers, housepainters, operators of public dancing schools, florists, and private land surveyors could not be justified.[1] In Hawaii, the State Supreme Court in 1935 ruled that legislation requiring photographers to be licensed bore no reasonable relationship to public health, safety, or welfare and constituted an unconstitutional encroachment on the right of individuals to pursue an innocent profession.[2] The court held that mere interest in

1. See discussion in 51 *American Jurisprudence*, 2d., "Licenses and Permits", Sec. 14.

2. *Terr. v. Fritz Kraft*, 33 Haw. 397.

maintaining honesty in the practice of photography or in ensuring quality in professional photography did not justify the use of the State's licensing powers.

The public. The Sunset Law states that for the exercise of the State's licensing powers to be justified, not only must there be some potential harm to public health, safety, or welfare, but also the potential harm must be to the health, safety, or welfare of that segment of the public consisting mainly of consumers of the services rendered by the regulated occupation or profession. The law makes it clear that the focus of protection should be the consuming public and not the regulated occupation or profession itself.

Consumers are all those who may be affected by the services rendered by the regulated occupation or profession. Consumers are not restricted to those who purchase the services directly. The provider of services may have a direct contractual relationship with a third party and not with the consumer, but the criterion set forth here may be met if the provider's services ultimately flow to and adversely affect the consumer. For example, the services of an automobile mechanic working for a garage or for a U-drive establishment flow directly to his employer, but his workmanship ultimately affects the consumer who brings a car in to his employer for repairs or who rents a car from his employer. If all other criteria set forth in the framework are met, the potential danger of poor workmanship to the consuming public *may* qualify an auto mechanic licensing statute for reenactment or continuance.

Consumer disadvantage. The consuming public does not require the protection afforded by the exercise of the State's licensing powers if the potential harm is one from which the consumers can reasonably be expected adequately to protect themselves. Consumers are expected to be able to protect themselves unless they are at a disadvantage in selecting or dealing with the provider of services.

Consumer disadvantage can arise from a variety of circumstances. It may result from a characteristic of the consumer or from the nature of the occupation or profession being regulated. Age is an example of consumer characteristic which may cause the consumer to be at a disadvantage. Highly technical and complex nature of the occupation is an illustration of occupational character that may result in the consumer being at a disadvantage. Medicine and law fit into the latter illustration. Medicine and law were the first occupations to be licensed on the theory that the general public lacked sufficient knowledge about medicine and law to enable them to make judgments about the relative competencies of doctors and lawyers and about the quality of services provided them by the doctors and lawyers of their choice.

However, unless otherwise indicated, consumers are generally assumed to be knowledgeable and able to make rational choices and to assess the quality of services being provided them.

Relationship between licensing and protection. Occupational licensing cannot be justified unless it reasonably protects the consumers from the identified potential harm. If the potential harm to the consumer is physical injury arising from possible lack of competence on the part of the provider of service, the licensing requirement must ensure the competence of the provider. If, on the other hand, the potential harm is the likelihood of fraud, the licensing requirements must be such as to minimize the opportunities for fraud.

Alternatives. Depending on the harm to be protected against, licensing may not be the most suitable form of protection for the consumers. Rather than licensing, the prohibition of certain business practices, governmental inspection, or the inclusion of the occupation within some other existing business regulatory statute may be preferable, appropriate, or more effective in providing protection to the consumers. Increasing the powers, duties, or role of the consumer protector is another possibility. For some programs, a nonregulatory approach may be appropriate, such as consumer education.

Benefit-costs. Even when all other criteria set forth in this framework are met, the exercise of the State's licensing powers may not be justified if the costs of doing so outweigh the benefits to be gained from such exercise of power. The term, "costs," in this regard means more than direct money outlays or expenditure for a licensing program. "Costs" includes opportunity costs or all real resources used up by the licensing program; it includes indirect, spillover, and secondary costs. Thus, the Sunset Law asserts that regulation which artificially increases the costs of goods and services to the consumer should be avoided; and regulation should not unreasonably restrict entry into professions and vocations by all qualified persons.

Chapter 2

BACKGROUND

Chapter 451A, Hawaii Revised Statutes, makes it unlawful for any person to engage in the sale or practice of dealing and fitting of hearing aids without a license issued by the Board of Hearing Aid Dealers and Fitters. The practice of "dealing and fitting" is statutorily defined 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."

Occupational Characteristics

There are approximately 60,000 people in Hawaii with hearing impairments.[1] Some conditions can be corrected by medical treatment. Other hearing losses can be rectified by a hearing aid. But, in certain cases, hearing cannot be restored by either medical treatment or a hearing aid.

The hearing aid. The hearing aid is an instrument which transmits sound to the listener's ear. The major components of a hearing aid are a microphone to pick up sound, an amplifier to increase the loudness of the sound, a receiver to deliver the sound, and a battery for power. An additional common component of nearly all hearing aids is the ear mold. It is usually a plastic insert device designed to conduct amplified sound from the hearing aid receiver into the ear canal. An impression for the ear mold is made by the hearing aid dealer and sent to laboratories for manufacturing of the ear mold.

The hearing aid dealer. Hearing aids were initially sold by salespersons representing the hearing aid manufacturers. Today, they are usually sold in independent retail outlets by an estimated 12,000 to 15,000 hearing aid dealers in the United States.

1. D. Robert Frisina, *The Survey of Programs and Services for the Hearing Impaired in Hawaii*, Health and Community Services Council of Hawaii, April 1976, Appendix B, p. 41.

Hawaii has ten licensed dealers who represent four business establishments on the islands of Oahu and Hawaii. It is estimated that 1800 to 2100 hearing aids are sold each year in the State at retail prices ranging from $300 to $550. These prices include the cost of the ear mold and examinations relating to the fitting and adjusting of the hearing aid.

A hearing aid dealer may use the audiometer to fit a hearing aid.[2] The dealer makes the impression for the ear mold and all necessary adjustments to fit the hearing aid to the individual. Instructions are also given by the dealer to the customer on the use and care of the hearing aid.

There are no formal educational programs for prospective hearing aid dealers. Most learn the business by training under the supervision of an experienced dealer.

Regulation of Hearing Aid Dealers

Reports of unethical business practices among hearing aid dealers on the mainland stimulated government regulation of this occupation. There were incidents of bait and switch advertising, price fixing, territorial restrictions, high pressure selling, and other unethical sales practices. The U.S. Senate started congressional hearings on the problem in 1968. Federal legislation was later enacted to prevent abusive sales practices.

Meanwhile, Oregon had become, in 1960, the first state to enact a licensing program for hearing aid dealers, and there are now 44 states that license or register hearing aid dispensers.

Regulation in Hawaii. Hawaii enacted legislation in 1969 to license the practice of dealing and fitting of hearing aids.[3] The purpose of regulation was to protect the hearing-impaired population from "dealers whose prime concern is economic gain."[4] Although it had no documented cases of abuse, the Department of Health (DOH) testified that it had been informed of "high pressure selling (some by itinerant mainland people in Hawaii briefly) and sale of devices which may not have been suited to the purchaser."[5]

The law enacted in 1969 included specific prohibited business practices such as making a sale by fraud or misrepresentation; using misleading, deceptive, or untruthful

2. An audiometer is an instrument used to measure the acuity of hearing.

3. Act 205, SLH 1969.

4. Senate Standing Committee Report No. 591 on S.B. No. 995, 1969.

5. Walter B. Quisenberry, Testimony on S.B. 995, Senate Committee on Public Health, Welfare and Housing, April 11, 1969.

advertising; and selling a hearing aid to a person who has not been given appropriate tests. The Legislature amended the law in 1974 to require that customers have medical authorizations prior to the purchase of a hearing aid and to prohibit house-to-house solicitation by dealers of hearing aids.[6]

The 1969 and 1974 laws are codified under Chapter 451A, Hawaii Revised Statutes. The main provisions of the chapter are discussed in the ensuing sections.

Board and authority. Regulation of hearing aid dealers and fitters is under a seven-member board placed in the Department of Regulatory Agencies (DRA). Membership must include at least one hearing aid dealer and fitter with five years of experience, one otolaryngologist and one audiologist.[7]

The powers and duties of the board are to adopt rules and regulations; develop standards for licensure; prepare and administer examinations; issue, renew, suspend, and revoke licenses; register applicants and holders of a license, permit, and certification of endorsement; investigate and conduct hearings regarding any violation; maintain a record of its proceedings; and generally do all things necessary to carry out the functions, powers, and duties set forth in Chapter 451A. The board is required to meet at least once each year.

License requirements. To obtain a license, the applicant must be a high school graduate, of good moral character, and must satisfactorily complete written and practical examinations. By law, the written test must include subjects dealing with basic physics of sound, anatomy and physiology of the ear, and the function of hearing aids. In the practical examination, the applicant must demonstrate proficiency in several techniques, such as pure tone audiometry, live voice or recorded voice speech audiometry, and taking ear mold impressions.

The initial license fee is $5 with a $10 biennial renewal fee every odd-numbered year.

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.

6. Act 167, SLH 1974.

7. An otolaryngologist is a physician who is an ear, nose, and throat specialist; an audiologist is a person skilled in the science of hearing.

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. There are no requirements for this permit beyond application and payment of $5.

Standards of practice. The principal standards prescribed by statute are the requirement 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.

- *Medical authorization.* Before a hearing aid can be offered or sold, the dealer must have a written authorization by a physician that the potential purchaser has been examined and that a hearing device has been prescribed or approved. The authorization must be signed by the physician within 90 days prior to the date of offer or sale.[8] Children who are 10 or younger are required to be examined by an otorhinolaryngologist.[9] A record of every authorization must be kept by the dealer for a period of at least five years. The records are to be open to inspection by the board or other law enforcement agencies.

- *Sales receipt.* The dealer is required to give the purchaser a receipt containing certain prescribed information including specifications as to the make and model of the hearing aid and the terms of the sale. The receipt must also include a statement that the purchaser has been advised that any examination or representation by the dealer is not to be considered a medical opinion.

- *Grounds for discipline and prohibited practices.* The law lists a number of practices which are grounds for denial, revocation, or suspension of any license, certificate of endorsement, or temporary permit. These include advertising a particular model or type of hearing aid which is not immediately available to obtain prospects for the sale of a different model; using symbols related to the medical profession, such as "doctor" or "clinic"; and committing gross incompetence or negligence in fitting and selling hearing aids. The law also cites several prohibited practices, including the prohibition of house-to-house solicitation.

Federal Regulation. Since 1977, hearing aids have been subject to the Federal Food, Drug, and Cosmetic Act and its regulations on the labeling of hearing aids and conditions for sale.

8. The 90-day limit does not apply if the authorization states that a return visit of the patient is not necessary for subsequent purchases.

9. A physician whose specialty is dealing with the ear, nose, and throat.

Unless a state applies for and is granted an exemption by the Food and Drug Administration (FDA), the FDA regulations supersede provisions of the state law which are different from, or are in addition to, any requirement applicable under federal regulations and which relate to the safety or effectiveness of the device or other matters included in the hearing aid requirements. The following is a summary of the major provisions of the federal requirements.

Labeling requirements. Hearing aid manufacturers must conform to FDA's labeling regulations for the appliance and provide consumers with prescribed information in a user instructional brochure which must accompany each hearing aid. Hearing aids must be marked with specific information which includes the name of the manufacturer or distributor, model name, serial number, and year of manufacture. The user instructional brochure must contain information on the use and care of the aid, how and where to obtain repair service, importance of a medical evaluation, the federal requirement for a medical evaluation, etc. Consumers are advised to inquire about a trial-rental or purchase-option program if they have reservations about their abilities to adapt to amplification. Children are directed to have an audiologic as well as medical evaluation about their abilities to adapt to amplification. Manufacturers are required to submit device labels to the FDA. If there is reason to believe that devices are adulterated or misbranded, the FDA may order "administrative detention" of the devices.

Conditions of sale. The hearing aid dealer cannot sell a hearing aid unless the customer has a medical evaluation written within the preceding six months. Prospective hearing aid users 18 years of age or older may sign a waiver for the medical evaluation. Waivers are permitted provided that the dealer: (1) explains to the customer that the waiver is not in the customer's best health interest, (2) does not encourage the prospective user to waive the medical evaluation, and (3) obtains the customer's signature on a waiver form which includes an acknowledgment that the customer understands the importance of the medical evaluation but wishes to waive the requirement.

Dealers must review the contents of a user instructional brochure with the customer and provide copies of the brochure to users and prospective users. A record of all medical evaluations and waivers must be kept by dealers for three years after dispensing the hearing aids.

Chapter 3

EVALUATION OF THE REGULATION OF HEARING AID DEALERS AND FITTERS

This chapter contains our evaluation of the regulation of hearing aid dealers and fitters under Chapter 451A, Hawaii Revised Statutes, including evaluation of the need for regulation, the effects of federal law and regulations versus the Hawaii statute, regulatory operations, and our recommendations concerning regulation.

Summary of Findings

We find that:

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.

The Need for Some Form of Regulation

From our review of the origins of federal regulation and the history of the Hawaii statute, it is evident 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.

Unscrupulous sales practices on the mainland often resulted in unwary consumers purchasing hearing aids from which they could not benefit or being sold expensive models when cheaper ones could have served the purpose. Congressional hearings and staff studies prior to federal regulation fully documented these and other practices which exploited consumers. Because the hearing aid is designed to correct a health impairment, there were, of course, health considerations in federal regulation, but these concerns were not directly related to the hearing aid itself. As the U.S. Food and Drug Commissioner reported to a congressional committee:

> "Although there are certain instances in which excessive amplication may result in a harmful threshold shift in hearing, the primary health concern underlying the medical clearance recommendation is not directly related to the safety of the hearing aid. Rather, this recommendation (to require a medical clearance) is essentially based upon the recognition that unnecessary or partially effective hearing aids may be substituted for primary medical or surgical treatment, thus depriving the hearing impaired individual of the benefits to be derived from appropriate medical diagnosis and care. In addition to delaying proper medical diagnosis and possibly reducing the efficacy of corrective treatment, the purchase of an ineffective aid undoubtedly involves high and unnecessary cost to the consumer." [1]

Likewise, at the state level, the underlying reason for the initiation of regulation in 1969, at a time when there was no federal regulation, was the Legislature's concern over the potential harm of economic exploitation. A legislative committee report stated:

> ". . . although the local hearing dealers are competent individuals . . . there are a few dealers whose prime concern is economic gain. The rapid growth of the State is attracting additional hearing aid dealers and fitters. It is from these that the consumer must be protected." [2]

At both the federal and state levels, the conclusion was reached that consumer disadvantage in hearing aid transactions warranted some form of government regulation to protect the public from the potential harm of economic losses. That conclusion appears to be still valid. However, the question arises, at the state level, whether licensing by a board is an appropriate form of protection against the potential harm of economic exploitation by unscrupulous dealers.

1. Letter, Dr. Alexander M. Schmidt to Senator Charles Percy, January 2, 1976, included in *Hearings before the Permanent Subcommittee on Investigations of the Committee on Government Operations*, April 1 and 2, 1976 (U.S. Government Printing Office, Washington: 1977), p. 88.

2. Standing Committee Report No. 491 on S.B. No. 995, Senate Committee on Public Health, Welfare, and Housing, 1969 Regular Session.

In our framework for evaluation described in Chapter 1, we stated:

> "Depending on the harm to be protected against, licensing may not be the most suitable form of protection to the consumers. Rather than licensing, the prohibition of certain business practices, governmental inspection, or the inclusion of the occupation within some other existing business regulatory statute may be preferable, appropriate, or more effective in providing protection to the consumers. Increasing the powers, duties, or role of the consumer protector is another possibility." [3]

Where the situation is one of consumer disadvantage in the marketplace and the potential harm is that of possible economic loss, an appropriate form of regulation would be to prescribe the practices which are to apply to the business or occupation, including those practices which are prohibited. Chapter 451A does take the foregoing approach. The principal statutory provisions which provide for controls over the hearing aid business are: (1) the requirement of authorization from a physician before a hearing aid can be sold; (2) grounds for disciplinary action which include, among others, false or misleading advertising and sale of a hearing aid to a person who has not been given appropriate tests; and (3) prohibited acts and practices, especially the provision which prohibits house-to-house sales.

Controls over the business practices of hearing aid dealers are what provides substance to Hawaii's statute. However, the statute goes further in requiring licensing by a board. In our view, licensing adds little protection to the consumer. If licensing were eliminated, there would, of course, be no need for the board. Enforcement of business practices could be assigned directly to the Department of Regulatory Agencies (DRA) or the Office of Consumer Protection (OCP).

Federal Versus State Regulation

In Chapter 2, we reported that federal regulation has preempted state law in controls over hearing aids and their conditions of sale in those areas where state provisions are different from or in addition to federal requirements. While federal law and regulations issued by the Food and Drug Administration (FDA) allow for state and local governments to apply for exemption from preemption, Hawaii has not done so. Therefore, the enforcement of certain portions of the Hawaii statute would be of doubtful legality.

3. Page 5, *supra*.

Federal preemption authority is expressed in Section 521 of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 360k). Section 521(a) of the act provides that no state or local government may establish or continue in effect any requirement with respect to the safety and effectiveness of a device or to any other requirement applicable to the device under the act, if such requirement is different from or in addition to the requirements applicable to the device. Section 521(b) allows the FDA Commissioner, upon application of a state or local government, to exempt a requirement from preemption if a state or local requirement is more stringent than the requirements imposed by FDA or if the requirement is necessitated by compelling local conditions and compliance would not violate a federal requirement.[4]

While, at first glance, it might appear that federal preemption focuses on requirements for the hearing aid itself, the FDA regulations also cover conditions of sale and other aspects. The FDA staked out the scope of its preemption authority in ruling on one state's requirement for an audiological evaluation before the sale of a hearing aid. It stated:

> ". . . the Food, Drug, and Cosmetic Act preempt(s) any State or local requirement applicable to a medical device that is different from or in addition to a requirement for the device under the act. The State requirement of audiological evaluation relates to the safety or effectiveness of hearing aids because it is intended to ensure that the purchaser is fitted properly with a hearing aid that will benefit his or her hearing ability. This requirement is in addition to the Federal requirements applicable to hearing aids and would interfere with the execution and accomplishment of the objectives of FDA's hearing aid regulation. Therefore, the State requirement of audiological evaluation is preempted . . . ."[5]

Preemption of state provisions. Our review of the federal regulation and the Hawaii statute indicates that there are at least five areas where state provisions have been preempted. These state provisions are those which are covered by federal regulation but which impose different requirements. Table 1 compares the state and federal provisions:

4. *Federal Register*, February 15, 1977, Part IV, p. 9293.

5. *Federal Register*, October 10, 1980, p. 67327.

Table 1

Comparison of Federal and State Requirements

	Federal		*State*
1.	Medical authorization before a hearing aid is sold with a waiver for persons over 18 because of personal or religious beliefs.	1.	Medical authorization before a hearing aid is sold with no provisions for a waiver.
2.	Medical authorization must be signed by a licensed physician.	2.	Medical authorization must be signed by a physician. In the case of a child ten years of age or under, authorization must be from an otorhinolaryngologist.
3.	Medical authorization must be given within six months prior to the purchase of a hearing aid.	3.	Medical authorization must be given within 90 days of purchase.
4.	Records of medical authorizations must be kept for three years.	4.	Records of medical authorization must be kept for five years.
5.	A "used hearing aid" means any hearing aid that has been worn for any period of time by the user. This fact must be declared on the container in which the hearing aid is packaged and on a tag physically attached to the hearing aid.	5.	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."

In addition to the provisions listed in Table 1, federal regulations contain requirements which are not in the state law, including the requirements for the provision of user instructional brochures with each hearing aid and oral review of these instructions by the dealer to each prospective purchaser. State law, in turn, prohibits a number of business practices which, except for misleading labels, are not addressed by the regulations of the FDA. Chapter 451A prohibits the following:

- Soliciting for the sale of hearing aids house to house;
- Obtaining a fee or the making of a sale by fraud or misrepresentation;
- Applying, causing or promoting for advertising, the use of any matter, promotional literature, testimonial, guarantee, warranty, label, brand, insignia, or any other representation which is misleading, deceptive, or untruthful;
- Advertising a particular model or type of hearing aid for sale which in fact is not immediately available and where it is established that the purpose was to obtain prospects for the sale of a different model or type;
- Representing that the service or advice of a person licensed to practice medicine will be used or made available in the selection, fitting, adjustment, maintenance, or repair of hearing aids when that is not true, or using the words "doctor," "clinic," or similar words, abbreviations, or symbols related to the medical profession when it is not accurate;

- Advertising a product or using a manufacturer's name or trademark which implies a relationship which in fact does not exist;

- Giving or offering to give, directly or indirectly, money or anything of value to any person who advises another in a professional capacity as an inducement to influence him or have him influence others to purchase or contract to purchase products sold or offered for sale by a hearing aid dealer or fitter, or influencing persons to refrain from dealing in the products of competitors;

- Engaging in the fitting and selling of hearing aids under a false name or alias with fraudulent intent;

- Selling a hearing aid to a person who has not been given tests utilizing appropriate established procedures and instrumentation in fitting of hearing aids; and

- Committing gross incompetence or negligence in fitting and selling hearing aids.

From the foregoing, it can be seen that Hawaii's law differs from federal requirements in a number of material respects. If the Hawaii provisions are to have any force at all, the State must pursue the required course of action, which is to apply to the FDA for exemption from preemption.

Exemption from preemption. The general guidelines for exemption from preemption and application procedures have been established by FDA regulation.[6] A large number of states and the District of Columbia have applied for exemption from preemption of various provisions. Some have been granted and others have been denied.

One of the general guidelines for exemption, set forth in federal statute and FDA regulation, is that an exemption from preemption would be allowed if the state or local requirement is more stringent than the federal requirement. However, FDA's rulings have not followed this guideline in at least one crucial area: the requirement for a medical authorization before a hearing aid can be sold.

As noted in Item 1 of Table 1, federal regulation requires a medical authorization before a hearing aid can be sold, but it allows a person over 18 to waive the requirement on the basis of "religious" or "personal" beliefs. In effect, this permits any adult to waive the requirement.

6. *Code of Federal Regulations, Food and Drugs*, No. 21, Parts 800 to 1299, revised as of April 1, 1980, pp. 44–49.

The counterpart Hawaii provision allows for no waiver. Every prospective purchaser of a hearing aid must have obtained a medical authorization within 90 days prior to the purchase, and in the case of a child 10 years or younger, the authorization must be by an otorhinolaryngologist. This requirement was determined to be so crucial for the protection of consumers as to require a special amendment in 1974. In justifying the requirement, the Legislature reported that:

> "The addition of this requirement to the provisions of Chapter 451A would protect the hard-of-hearing public from purchasing hearing aid from which they cannot benefit. According to testimony received, a substantial number of the patients who consult physicians cannot benefit from a hearing device at all. A further benefit of a medical examination prior to sale is that such an examination often uncovers other related health problems which might otherwise go untreated."[7]

This amendment is preempted by federal regulation and is apparently non-enforceable. FDA's early position was that: "The [FDA] Commissioner believes that, in general, an informed adult who has religious or personal objections to medical examination should be permitted to waive the medical evaluation requirement. Therefore, he is proposing to deny exemption from preemption for those State and local requirements that either do not permit any waiver of a medical evaluation requirement, or permit a waiver only for religious reasons."[8]

Apparently, FDA's position remains unchanged. In October 1980, FDA ruled on a number of applications for exemption from preemption. Among the jurisdictions applying for exemptions, West Virginia had a medical authorization requirement quite similar to Hawaii's with no provision for waiver. The District of Columbia had a provision for waiver but for religious reasons only. Both applications for exemption from preemption of these provisions were denied by FDA.[9]

It is, of course, speculative as to how FDA might rule in the specific case of Hawaii's key requirement for medical authorization or in the case of the other provisions which are at variance with or in addition to federal requirements. The point is that, for having

7. Conference Committee Report No. 4 on H.B. No. 2941–74, 1974 Regular Session.

8. *Federal Register*, July 28, 1978, Part V, p. 33181.

9. *Federal Register*, October 10, 1980, pp. 67335–67337.

failed to present its case for exemption from preemption to FDA, as so many other jurisdictions have done, Hawaii simply does not know where it stands and a good portion of its regulatory activities is of questionable legality.

Position of the board. The lack of action on the part of the Board of Hearing Aid Dealers and Fitters is not due to nonawareness of federal regulation. From our review of the minutes of the board for the past several years, we find that there has been discussion from time to time concerning federal regulation and preemption but no action. Thus, the record shows:

- On July 28, 1977, there was discussion on the federal regulation which was to become effective shortly, and a member of the board agreed to look into the relation of the state law to FDA regulations.

- On December 29, 1977, an ad hoc committee of the board reported that the FDA regulations superseded the State's laws and that the committee was taking a "wait and see" position (in the words of the minutes of the meeting) before submitting a recommendation as to whether the board should file a petition for exemption.

- On December 19, 1979, there was some discussion on the federal regulations and the necessity to consider them in drafting state rules and regulations.

- On June 10, 1980, the board considered the differences between state law and the federal regulation, and noted again that "FDA regulations supersede Hawaii State statutes where they differ," and that a statement to this effect would be in the rules and regulations.

There, the matter apparently rests. Nothing in the record shows that the board thoroughly analyzed the issue of federal preemption or that it was prepared to press a case for exemption for those state provisions which are different from or in addition to federal requirements. The "wait and see" position taken by the board meant, in effect, doing nothing.

Rules and Regulations

More than 11 years since Chapter 451A was enacted, rules and regulations still have not been adopted. The adoption of rules and regulations in accordance with the Hawaii Administrative Procedure Act to carry out the purposes of Chapter 451A is a specific

duty assigned by law to the Board of Hearing Aid Dealers and Fitters.[10] The requirement for rules and regulations, of course, is there for a purpose. A licensing board affects the rights of and procedures available to the public. Its decisions may have the force of law. Without rules or regulations promulgated and made available in accordance with the Administrative Procedure Act, no agency rule, order, or opinion can be valid or effective against any person or party nor can it be invoked by the agency for any purpose.[11]

Operating as it has without rules and regulations and considering the law as well as court decisions, the board's past and present regulatory activities are of doubtful legality. In a case involving the University of Hawaii, the Hawaii State Supreme Court decided that provisions which the university contended were rules did not have the force of law since there was no showing of compliance with the Hawaii Administrative Procedure Act.[12] In a recent circuit court case, the court reversed a decision of the Motor Vehicle Licensing Board because it did not have current rules and regulations concerning the procedures it and members of the general public must follow in contested cases.[13]

Proposed rules and regulations for Chapter 451A were drafted in 1971 and redrafted, public hearings were held in 1971 and 1974, committees of the board have studied the proposed rules, the board has discussed them, proposed amendments have been considered, but the fact remains that rules and regulations have never been adopted. As far as we can determine, there is no timetable for their completion and adoption.

Regulatory Operations

While the failure to deal squarely with the issue of federal preemption and to adopt rules and regulations constitute the board's greatest deficiencies in making and executing policy, there are also indicators of desultory performance in the more routine regulatory operations of complaint handling, examining applicants, and monitoring hearing aid dealers. In making this assessment, we have reviewed regulatory performance since the enactment and implementation of Chapter 451A. Over the years, the composition of the

10. Section 451A-5(1), HRS.

11. Section 91-2(b), HRS.

12. *Abramson vs. Board of Regents*, 46 Hawaii 689 (1976).

13. *Tony Honda Corporation, dba Tony Honda of Waipahu vs. Motor Vehicle Industry Licensing Board*, Civil No. 49645 (March 4, 1980).

board has changed and so has DRA staff support to the board. Thus, we are not critical of any particular board, and it would not be correct to fix all of the responsibility for deficiencies on the present board. In some instances, the present board, under the leadership which recently took office, appears to be aware of some of the problems underlying its operations, and there is some movement to deal with them.

Complaint handling. Since the enactment of Chapter 451A, there have not been many complaints against hearing aid dealers, but the few that have been handled have been characterized by delays and lack of resolution.

In June 1974, the OCP referred a complaint against a hearing aid dealer to the board's executive secretary. At that time, OCP had informed the executive secretary that OCP had received a number of complaints against the same dealer and that some action should be taken. The complaint was not presented to the board that year (1974). No board meetings were held in 1975. At the next board meeting in December 1976, the board minutes indicate that the hearing aid dealer had gone out of business and that the case was thus not resolved.

Only three complaints have reached the board in the past five years, all against one hearing aid dealer. One complaint, filed in September 1976, was closed in July 1977 when the complainant decided not to pursue the matter further. Two complaints, both filed in May 1980, have not been resolved and are still pending.

Examination. Applicants must pass a written and practical examination as a condition for licensing. The written examination consists of 71 items totaling 100 points. It was prepared by a former audiologist board member in 1972 to assess applicants' knowledge of basic physics of sound, anatomy, physiology of the ear, and functions of hearing aids. However, the examination has never been validated.

A test is considered valid if it provides an accurate measure of the desired criterion, such as potential performance on the job or performance in graduate school. A test may be validated in several ways. For example, one method of validation is to show that the test 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.

We acknowledge that this is a matter which is receiving the attention of the present board. The chairperson of the board feels that the present examination is out-of-date, that there are more questions on audiometry than there are on hearing aids, and that there should be more input to the examination from related trades and professions. As a result, the chairperson of the board is heading an ad hoc committee for revision of the examination. [14]

Monitoring records. As previously noted in this chapter, one of the crucial controls governing the hearing aid business is the requirement for a medical authorization before a hearing aid is sold. Each dealer is required to keep a record of every authorization for at least five years, and the record is subject to inspection by the board and other law enforcement agencies.

No system for compliance has ever been implemented. A periodic inspection program came up for discussion in October 1974,[15] but that is as far as the matter went. Because of the small number of hearing aid businesses and the simplicity of the task of checking hearing aid sales against medical authorizations, a monitoring program should be neither time-consuming nor costly. It is an assignment which could well be delegated by the board to the DRA staff.

Conclusion

Chapter 451A was enacted to protect the public from the potential of economic loss in hearing aid transactions. The thrust of regulation has been to prohibit or curb unscrupulous business practices. There are a number of good features in the Hawaii statute, but federal preemption casts a legal cloud over regulatory activities under state law. The Legislature has two basic alternatives. It could, upon review of the Hawaii statute and upon likewise finding that it has desirable features, direct the state agency to petition to the Food and Drug Administration for exemption from preemption. This would appear to be the most appropriate course of action. Alternatively, the Legislature, could, if it desired, pull the State out of the hearing aid regulatory business and leave regulation in the hands of the federal government. In neither alternative, however, do we find licensing or a board necessary to protect consumer interests.

14. Board of Hearing Aid Dealers and Fitters. Minutes. October 29, 1980.

15. Board of Hearing Aid Dealers and Fitters, Minutes, October 10, 1974.

Recommendations

We recommend the following:

1. Chapter 451A be modified to delete the board and the licensing of hearing aid dealers and fitters.

2. The Legislature direct the Department of Regulatory Agencies to petition the Food and Drug Administration for exemption from preemption of those state requirements which are different from or in addition to federal requirements.

3. If the board and licensing are continued, the board adopt rules and regulations forthwith and develop and implement procedures for timely and effective handling of complaints, construct a valid examination, and institute a system of periodic monitoring of the medical clearance records of hearing aid dealers.

APPENDIX

RESPONSES OF AFFECTED AGENCIES

COMMENTS ON AGENCY RESPONSES

A preliminary draft of this Sunset Evaluation Report was transmitted on January 9, 1981 to the Board of Hearing Aid Dealers and Fitters and the Department of Regulatory Agencies. We asked them for their comments on the recommendations contained in the report.

A copy of the transmittal letter to the Board of Hearing Aid Dealers and Fitters is included as Attachment 1 of this appendix. A similar letter was sent to the Department of Regulatory Agencies.

We were informed that the board could not secure a quorum to respond to the report. We did, however, receive separate responses, included in this appendix as Attachments 2 and 3, from the chairperson and one member of the board.

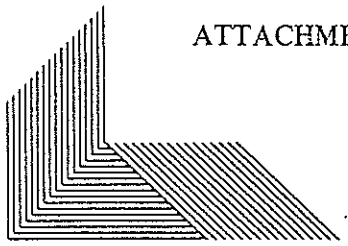
Both responses state that the report is an accurate assessment of the board. However, both the chairperson and the member disagree with the report's recommendation to delete the board and the licensing of hearing aid dealers and fitters.

As to other recommendations, the two responses collectively indicate that the board intends to take action to validate and update the licensing examination, complete the promulgation of rules and regulations, and implement a system to monitor hearing aid dealers. If the board is continued, it should also address the issue of federal preemption of state requirements and the development of procedures for timely and effective handling of complaints, aspects covered in the report but not in the responses.

The response of the Department of Regulatory Agencies, included as Attachment 4, states that the department is in general agreement with the report's observation and evaluation.

ATTACHMENT 1

THE OFFICE OF THE AUDITOR
STATE OF HAWAII
465 S. KING STREET, RM. 500
HONOLULU, HAWAII 96813
(808) 548-2450



CLINTON T. TANIMURA
AUDITOR
RALPH W. KONDO
DEPUTY AUDITOR

January 9, 1981

Ms. June Uyehara-Isono, Chairman
Board of Hearing Aid Dealers and Fitters
Department of Regulatory Agencies
State of Hawaii
Honolulu, Hawaii

COPY

Dear Ms. Uyehara-Isono:

Enclosed are seven preliminary copies, numbered 6 through 12, of our *Sunset Evaluation Report on Hearing Aid Dealers and Fitters.* These copies are for review by you and other members of the board. This preliminary report has also been transmitted to Mr. Tany S. Hong, Director, Department of Regulatory Agencies.

The report contains recommendations relating to the regulation of hearing aid dealers and fitters. We would appreciate receiving your written comments on the recommendations by January 19, 1981. Your comments 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, access to this report should be restricted solely to board members and those officials whom you might wish to call upon to assist you in your response. We request that you exercise controls over access to the report and ensure that the report will not be reproduced. 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

JUNE
UYEHARA
ISONO
M.S.C.C.C.-A
Certified Clinical Audiologist

January 16, 1981

RECEIVED
JAN 20 7 59 AM '81
OFC. OF THE AUDITOR
STATE OF HAWAII

Legislative Auditor
465 S. King Street
Honolulu, HI 96813

Attention: Mr. Clinton T. Tanimura
Auditor

Gentlemen:

Subject: Sunset Evaluation Report, Hearing Aid Dealers and Fitters, Chapter 451A, HRS

My response to the sunset evaluation report is based not only from my short experience as a board member, but as a professional who is concerned about good hearing health care. There is little doubt that the auditor's report accurately describes the status of the board and the lack of action from the board in the past. I can neither justify nor rationalize the actions of the board in the past, and I certainly feel frustrated at the inability of the board to act upon certain issues.

The major concern of professionals in the hearing health care field is not particularly over the sale of the hearing aid but the ability of the individual who sells the aid to provide the proper rehabilitative services necessary to utilize amplification effectively. The main purpose of the hearing aid is to increase communicative function. Therefore, it is vitally important to insure the public that the person who sells the aid has the knowledge to deal with the psychological aspects of hearing loss as well as the side effects of hearing loss, such as social isolation. I feel that the only way to help to insure the competency of the individual in dealing with the hearing impaired and avoiding psychological harm is by examination or licensing. Although the examinations have not been reviewed recently, the present board is working on validating and updating the written and practical exams.

The rules and regulations for Chapter 451A are all but ready for public hearing and the governor's office. It is felt that the lack of action of the board members on the rules and regulations cannot be theirs alone; responsibility also lies with administrative personnel.

1201 Hind Uka Drive · Honolulu, HI 96821 · Phone: (808) 373-2614

It could also be postulated that the complaints against hearing aid dealers are few because of the licensure requirement. The elimination of licensing will allow unqualified individuals to exploit a handicap that sometimes has no solution. It is a fact that a hearing aid cannot bring back normal hearing.

It is strongly felt that licensure is vitally important for the protection of the consumer not only for the probable economic loss that will follow but also the perpetuation of the frustration and psychological isolation that all hearing impaired individuals experience. Unless the individual selling the aid is knowledgeable about the aid and the hearing process, the public will continue to buy aids and place them in drawers.

I can only state that the present board is trying as diligently as possible to solve the problems of the examination, complaints, exemption from preemption and finalizing the rules and regulations. To terminate the board at this point in time would be unfortunate. The hearing aid industry is undergoing radical changes which will have a profound effect upon the consumer. It is important that these changes are monitored in the best interest of the public.

Sincerely,

(Mrs.) June Uyehara-Isono
MSCCC

ATTACHMENT 3

January 19, 1981

Legislative Auditor
465 S. King Street
Honolulu, HI 96813

Attention: Mr. Clinton T. Tanimura, Auditor

Gentlemen:

SUBJECT: SUNSET EVALUATION REPORT,
HEARING AID DEALERS AND FITTERS,
CHAPTER 451A, HRS

Herewith are presented my views on the Sunset Evaluation report on the Hearing Aid Dealers and Fitters.

I acknowledge that the auditor's report presents an accurate assessment of the current situation as it exists with the Board of Hearing Aid Dealers and Fitters.

The present board does recognize the problems facing it and have been working to get them resolved. For example, the rules and regulations are all but ready for public hearing and subsequent submittal to the governor.

The examination for licensing is in the process of being revised and updated to relate more meaningfully to the work of those engaged in the fitting of hearing aids.

The monitoring of dealers to check for compliance with the laws has been discussed by the board and will be the responsibility of the investigative staff of the Department of Regulatory Agencies.

The elimination of the board and licensing would open the door to anyone without proper training and qualifications to sell hearing aids. This would not only leave the consumer unprotected for possible economic loss but may also prevent him from getting the medical attention which he might need rather than the use of a hearing aid.

Licensing is needed also so that those who decide to engage in the fitting of hearing aids can at least be judged as to their qualifications and competence by taking a written and practical examination.

Admittedly the board has been slow if not remiss in handling its responsibilities to date. There is definite affirmation by members of the present board however that the situation will change and definite actions will be taken to not only make it more viable but also better serve the interests of hearing aid purchasers.

Any action to eliminate the board at this time would, in my opinion, be premature and tragic. Especially when one considers the changes that are taking place in the hearing aid industry which will more than likely bring many more matters of vital concern to the board for consideration and action.

Sincerely,

TERUO HASEGAWA

ATTACHMENT 4

GEORGE R. ARIYOSHI
GOVERNOR

STATE OF HAWAII
OFFICE OF THE DIRECTOR
DEPARTMENT OF REGULATORY AGENCIES
1010 RICHARDS STREET
P. O. BOX 541
HONOLULU, HAWAII 96809

TANY S. HONG
DIRECTOR
BANK EXAMINER
COMMISSIONER OF SECURITIES
INSURANCE COMMISSIONER

DONALD D.H. CHING
DEPUTY DIRECTOR

January 20, 1981

Mr. Clinton T. Tanimura
Legislative Auditor
Office of the Auditor
465 S. King Street, Ste. 500
Honolulu, Hawaii 96813

Dear Mr. Tanimura:

Thank you for the opportunity to comment on your "Sunset Evaluation Report on Hearing Aid Dealers and Fitters."

The Department of Regulatory Agencies is in general agreement with the observation and evaluation you have made of the Board of Hearing Aid Dealers and Fitters. You and your staff should be commended for the accurate and thorough assessment of the board.

Very truly yours,

DONALD D. H. CHING
Deputy Director

cc: Tany S. Hong, Director