

SUNSET EVALUATION REPORT
PHARMACISTS AND PHARMACY
Chapter 461, 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. 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 These programs are repealed unless they are specifically reestablished by the Legislature.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 evaluates the regulation of pharmacists and pharmacies under Chapter 461, 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 pharmacists and pharmacies 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 It includes our recommendation on whether the program should be continued, modified, or repealed.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 Pharmacy, the Department of Commerce and Consumer Affairs, 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 Each year, six to eight licensing statutes are scheduled to be repealed unless specifically reenacted by the Legislature.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 461, Hawaii Revised Statutes.

Scope of the Evaluation

This report examines the history of the statute on the regulation of pharmacists and pharmacies 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 recommendations.

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

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

encroachment on the right of individuals to pursue an innocent profession.² The court held that mere interest 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 the employer, but the mechanic's workmanship ultimately affects the consumer who brings a car in for repairs or who rents a car from the 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 to adequately 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 a consumer characteristic which may cause the consumer to be at a disadvantage. The highly technical and complex

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

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 461, Hawaii Revised Statutes, regulates the practice of pharmacy in the State. Under the law, only a licensed pharmacist or a qualified assistant under the pharmacist's immediate supervision can legally fill or compound prescriptions. Pharmacists have been regulated in Hawaii since 1903.

Occupational Characteristics

Pharmacy is that health profession concerned with the discovery, development, production, and distribution of drugs used to diagnose, prevent, cure, or relieve the symptoms of disease.¹

The following paragraphs provide a brief history and description of the profession.

History. Although the first known pharmacy was established in Baghdad in the eighth century, the preparation of drugs and medicines to treat injuries and diseases is probably as old as civilization itself. In early times, there was little distinction between the physician and pharmacist. It was not until 1240 A.D. that the two professions were formally separated through an edict by Emperor Frederick II of the Holy Roman Empire. While this separation was to be eventually the pattern in Western society, the two professions are still not separated in some Oriental countries.²

1. *McGraw-Hill Encyclopedia of Science and Technology*, New York, McGraw-Hill, Inc., 1982, p. 119.

2. *The Encyclopedia of Careers and Vocational Guidance*, v. II, Chicago, J.G. Ferguson Publishing Company, 1981, p. 219.

In America, one of the earliest known pharmacists was Governor Winthrop of Massachusetts Bay Colony who learned to compound drugs because there was no other source for obtaining medicines in the colony.³

The first college of pharmacy in the United States was founded in 1821 and is now known as the Philadelphia College of Pharmacy and Science. In 1852, the American Pharmaceutical Association was established.⁴ The first state to establish a commission or board to regulate the profession was Rhode Island in 1870. Between 1870 and 1890, 30 states passed legislation to regulate pharmacists, and by the end of the nineteenth century, 43 states had established pharmacy regulatory boards or commissions.⁵

In Hawaii, three public pharmacies opened in Honolulu in 1847. In that year, Dr. G. Watson advertised his professional services at an "office, next door to C. Brewer and Co.'s, where may be found a general assortment of Drugs and Medicines, Perfumes, Fancy Soaps &c."⁶ In 1903, the first laws to regulate the profession were passed by the Territorial Legislature.

Census statistics on medical and health personnel in Hawaii were first compiled in 1884. The census of that year reported that 23 pharmacists were practicing in Hawaii. By 1940, there were still only 76 pharmacists, but by 1950, the number of pharmacists nearly doubled to 148. In 1970, there were 217 pharmacists.⁷ Today, a little more than a decade later, the number of pharmacists practicing in Hawaii has more than tripled. According to data provided by the Department of Commerce and Consumer Affairs, there are 681 licensed pharmacists in the State.⁸

3. *Ibid.*

4. *The New Encyclopedia Britannica*, v. 14, Chicago, Encyclopedia Britannica, Inc., 1982, pp. 203-204.

5. State of Tennessee, Comptroller of the Treasury, *Program Evaluation on the Board of Pharmacy*, September 1978, p. 7.

6. Robert C. Schmitt, "Health and Medical Firsts in Hawaii," *Hawaii Medical Journal*, September 1981, p. 284.

7. Robert C. Schmitt, "Health Personnel in Hawaii, 1820-1974," *Hawaii Medical Journal*, February 1975, pp. 53-54.

8. State of Hawaii, Department of Commerce and Consumer Affairs, *Geographic Report*, October 1984.

Description of profession. Pharmacists do more than simply fill prescription orders. They are specially trained health professionals knowledgeable about the chemical composition and appropriate use of a wide range of pharmaceutical products.

In addition to dispensing drugs and medicines, pharmacists often advise consumers on the proper use of these drugs. Pharmacists weigh, measure, and mix powders, pills, or liquid medicine and fill bottles or capsules with the right quantity of medicine. They may test drugs to identify what they contain and to determine how pure and strong they are. Some pharmacists do research to develop and test new drugs. Pharmacists also maintain patient medication profiles or records and sometimes assist physicians to properly select and use medicines.

Pharmacists are employed in a variety of different settings. In 1980, there were approximately 140,000 pharmacists in the United States.⁹ About 70 percent of all pharmacists work in community pharmacies—exclusive prescription pharmacy stores or drugstores that sell a variety of items including prescription drugs. Of these, about one-quarter own their own pharmacies. The others work as salaried employees, often for large chain drugstores.

Those not employed in community pharmacies usually work for hospitals, pharmaceutical manufacturers, wholesalers, the state or federal government, or educational institutions. Some community and hospital pharmacists, in addition to their primary jobs, work part time for nursing homes and other health facilities. Generally, pharmacy services in nursing homes are provided by independent pharmacists rather than salaried employees of the nursing homes.

Pharmacists are required to be licensed in all 50 states, the District of Columbia, and Puerto Rico. To qualify for licensure, an applicant must normally graduate from an accredited pharmacy degree program, pass a state board examination, and have a specified amount of practical experience under the supervision of a licensed pharmacist. Today, most states will issue a license without reexamination to qualified pharmacists already licensed in another state.

9. U.S. Bureau of Labor Statistics, *Occupational Outlook Handbook, 1982-83*, Washington, D.C., April 1982, p. 163.

In the United States, there are currently over 70 colleges of pharmacy with degree programs accredited by the American Council on Pharmaceutical Education.¹⁰ Since 1960, five years of study are needed to obtain a bachelor of science or a bachelor of pharmacy degree, the degrees received by most graduates and the minimum educational qualification for most positions in the profession. The basic five-year curriculum usually includes courses in physics, chemistry, biology, bacteriology, physiology, pharmacology, and other specialized areas. Over one-third of the pharmacy schools offer the doctor of pharmacy degree. Advanced degrees are usually required for research work or college teaching.

The American Pharmaceutical Association, with a national membership of about 52,000, represents the major professional society for pharmacists. The local affiliate, the Hawaii Pharmaceutical Association, consists of approximately 130 members.¹¹

Statutory History

Pharmacists have been regulated in Hawaii for over 80 years. With the enactment of Act 70 in 1903, it became "unlawful . . . for any person not licensed as a pharmacist . . . to compound, dispense or sell at retail any drug, chemical or poison upon the prescription of a physician. . . ."¹² The Act created a three-member Board of Pharmacy (one physician and two pharmacists) and established licensing standards.

In passing this legislation, the Senate Committee on Health and Education reported: "Your committee finds that this Act is a very necessary one to be passed as a protection against the indiscriminate sale of poisonous drugs by irresponsible people."¹³

10. There is currently no accredited pharmacy degree program in Hawaii. However, through the Professional Student Exchange Program of the Western Interstate Commission for Higher Education (WICHE), selected students from Hawaii have been able to attend pharmacy schools in other states at reduced tuition.

11. Data provided by Hawaii Pharmaceutical Association, July 19, 1984.

12. Section 1, Act 70, SLH 1903.

13. Territory of Hawaii, Senate Journal, Senate Standing Committee Report, April 15, 1903, p. 547.

Since 1903, the pharmacy law has been amended about two dozen times. In general, these changes were intended to further protect the public, improve the quality of pharmacy practice, and clarify the administration of the law. A few of the more significant amendments are summarized below.

Act 237, SLH 1923, amended the law by prohibiting persons from advertising their businesses as pharmacies or drugstores unless a licensed pharmacist was in charge. The Act also required that the three members of the Board of Pharmacy be licensed pharmacists and residents of the Territory. Additionally, the Act authorized the board to issue temporary licenses to qualified persons.

In its committee report, the House Committee on Judiciary stated: "The purpose of this bill is to protect the public, so far as possible, from the danger of receiving different drugs than are asked for, and to insure that drugs and medicines shall be dispensed or compounded only by those who are familiar with the nature and effects thereof."¹⁴

In 1949, Act 175 provided statutory definitions for "drugs" and "patent medicines;" increased the size of the board from three to five members; required the board to select a chairman, secretary, and a treasurer; authorized the board to suspend or revoke licenses; required every pharmacy to keep a record for at least five years of every prescription compounded or dispensed; and exempted from the law not only physicians and dentists but also practitioners of osteopathy and veterinary medicine.

In 1972, Act 62 raised the qualifying standard for a temporary license by requiring that applicants pass an examination covering laws and public health regulations related to the practice of pharmacy in the State. The House Committee on Public Health, Youth and General Welfare stated in its committee report: "The purpose of this bill is to . . . assure that out-of-state practitioners have the minimum acceptable knowledge of laws relating to the practice of pharmacy in Hawaii. . . ."¹⁵

14. House Standing Committee Report No. 579 on Senate Bill No. 122, Regular Session of 1923.

15. House Standing Committee Report No. 602-72 on Senate Bill No. 1368-72, Regular Session of 1972.

Act 105, SLH 1973, amended the law by removing the requirement that an applicant for a pharmacist license must be a resident of the State for at least one year immediately preceding the granting of the permanent license. The Senate Committee on Judiciary reported: "Residency requirements are constitutionally defective and are unnecessary to insure competent pharmacists."¹⁶

Finally, in 1978, Act 208 amended the law by adding two nonpharmacist, public members to the former five-member board. The Act also required that four board members be residents of the City and County of Honolulu and three members be residents of other counties.

In its committee report, the Senate Committee on Judiciary stated: "Presently, there are certain regulatory boards and commissions . . . all of whose members are persons engaged in the profession regulated by the board. Your Committee finds that it is in the public interest to have persons on a regulatory board or commission who are not professionals regulated by that board or commission."¹⁷

Nature of Regulation

Board of Pharmacy. Under Chapter 461, the licensing of pharmacists is regulated by a seven-member Board of Pharmacy appointed by the Governor and placed for administrative purposes in the Department of Commerce and Consumer Affairs. The department provides staff support to the board.

As required by law, board membership consists of five licensed pharmacists and two public members. Four of the board members must be residents of the City and County of Honolulu and three members must be residents of other counties. From its membership, the board must select a chairman, secretary, and treasurer. The board is required to meet at least twice annually in April and September.

Under Chapter 461, the board is empowered to formulate rules necessary for carrying out the law. It can revoke or suspend the license of a pharmacist or the permit of a pharmacy operator if such persons are guilty of professional misconduct, gross carelessness, manifest incapacity, or violating any provisions of the chapter or

16. Senate Standing Committee Report No. 263 on Senate Bill No. 122, Regular Session of 1973.

17. Senate Standing Committee Report No. 674-78 on House Bill No. 49, Regular Session of 1978.

the rules prescribed by the board. No license or permit can be revoked or suspended until the accused has been given proper notice and the opportunity for a full and fair hearing.

Chapter 461 also empowers the board or any authorized representative of the board to inspect any drug packed, compounded, sold, or offered for sale in the State and to inspect any pharmacy or premises in the State where drugs are packed, compounded, sold, or offered for sale. The board or its authorized representative is also authorized to investigate any violations or suspected violations of Chapter 461 or any of the rules of the board.

Licensing requirements. To be licensed as a pharmacist, an applicant must meet the following requirements: (1) be at least 18 years old; (2) graduate from a school of pharmacy recognized and approved by the American Council of Pharmaceutical Education; (3) have a minimum of one year of practical experience in a pharmacy under the supervision of a licensed pharmacist; and (4) pass the state pharmacy board examination.

An applicant for licensure may take the licensing examination before fulfilling the practical experience requirement. However, those who pass the examination cannot be licensed until the practical experience requirement is met. A licensed pharmacist from any state or territory of the United States who has practiced pharmacy for at least two years is eligible to take the state licensing examination.

Every applicant is required to pass the licensing examination with a general average of at least 70 percent. The examination must cover the following areas: pharmacy, materia medica, chemistry, toxicology, posology (dosages), compounding of prescriptions, identification of drugs, and relevant state laws and public health rules relating to the practice of pharmacy in Hawaii. Examinations are held at least twice a year.

Temporary license; renewals. An applicant for licensure who is already licensed as a pharmacist in another state or territory may be granted a temporary license by the board. To obtain the temporary license, the applicant must pass a preliminary examination covering relevant state laws and public health rules. Applicants may obtain a temporary license which remains valid only until the next

regular licensure examination. The board may extend a temporary license, but normally, an applicant who fails to take or pass the next regular examination must surrender the temporary license.

The law stipulates that every licensed pharmacist, by December 31 of each odd-numbered year, must pay a fee to the board for the biennial renewal of the pharmacist's license. A pharmacist holding an expired license may have the license restored after proper application and payment of all required fees.

Pharmacies. Under Chapter 461, any person establishing or operating a pharmacy in the State must obtain a permit to do so from the Board of Pharmacy. The law also requires that a licensed pharmacist must be in personal and immediate charge of every pharmacy. Additionally, only a licensed pharmacist or an assistant under the pharmacist's immediate supervision can legally fill or compound prescriptions.

Every licensed pharmacist in charge of a pharmacy is responsible for the management of the pharmacy, and every activity subject to Chapter 461 must be under the pharmacist's complete control. Temporary absences of the pharmacist are unlawful except in certain specified situations. During any absence of the pharmacist, prescriptions are not to be filled, compounded, or received by telephone, and prescription drugs cannot be sold. Also, during such absences, the entire stock of prescription drugs must be safely secured and inaccessible to unauthorized persons.

Under Chapter 461, all licensed pharmacists are required to notify the board of any changes of business address within 10 days. Additionally, any proprietor or manager of a pharmacy who fails to place a licensed pharmacist in charge of the pharmacy or who permits an unauthorized person to compound or sell drugs, has violated the law.

The law requires that every pharmacy compounding drugs must be equipped with proper pharmaceutical equipment and specified reference manuals to ensure that prescriptions are properly compounded. Every pharmacy is also required to retain a record for at least five years of every prescription compounded or dispensed. This prescription record is subject to inspection at any time by the board or other law enforcement officers.

Violations; penalties. Under Chapter 461, it is unlawful for:

- (1) any person to sell or offer for sale any drugs at a public auction without first obtaining a permit from the board;
- (2) any person to distribute drug samples or medical supplies without first obtaining a permit from the board; however, drug samples may be furnished directly to physicians, druggists, dentists, and veterinarians for use in their professional practice;
- (3) wholesalers to sell or distribute any drug except to pharmacists, physicians, dentists, veterinarians, or to generally recognized industrial, agricultural, manufacturing, or scientific users for professional or business purposes;
- (4) any person, as a principal or agent, to engage in the business of preparing, manufacturing, compounding, packing, or repacking any drug without first obtaining a permit from the board.

Persons violating any of the provisions of Chapter 461 or any of the rules prescribed by the board are subject to a maximum fine of \$500 or imprisonment up to six months or both. Additionally, the board is authorized to seek a court injunction to restrain any violators of the chapter.

Under the law, legally licensed practitioners of medicine, osteopathy, dentistry, veterinary medicine, and podiatry are exempt from the provisions of Chapter 461 when handling drugs in the course of their professional duties.

Additional state and federal requirements. In addition to Chapter 461, pharmacists in Hawaii are also regulated by other relevant state statutes. These include:

- (1) Chapter 328, Hawaii Revised Statutes, (Hawaii Food, Drug, and Cosmetic Act) which prohibits the adulteration or misbranding of drugs; provides safeguards regarding the sale and distribution of new drugs; prohibits false or misleading drug advertising; and requires pharmacists to offer customers the option to buy lower cost generic drugs.
- (2) Chapter 329, Hawaii Revised Statutes (Uniform Controlled Substances Act) which classifies all dangerous drugs into five classes according to their potential for abuse; requires authorized handlers of these substances

to register with the Department of Health, maintain records, and submit to periodic inventories; and defines and codifies prohibited acts involving controlled substances.

- (3) Chapter 330, Hawaii Revised Statutes, (Poisons) which requires pharmacists who compound or sell any poisonous drugs or substances to maintain a prescription record of these substances.

Finally, Hawaii pharmacists must comply with a variety of federal regulations, the primary ones being those that are enforced by the U.S. Food and Drug Administration (FDA) and the U.S. Drug Enforcement Administration (DEA).

The FDA regulates all drug products dispensed by the pharmacist. The agency enforces laws which require manufacturers, as a condition for marketing a new pharmaceutical drug, to demonstrate that the new drug is safe and effective in treating the medical problem for which it is intended. FDA regulations also ensure the purity, potency, and correct labeling of these pharmaceutical drugs.

The DEA is the lead federal agency in enforcing narcotics and controlled substances laws and regulations. Under the federal Controlled Substances Act of 1970, every pharmacist dispensing controlled substances must register with the DEA and is subject to regulations and inspections by that agency. The DEA can inspect pharmacies handling controlled substances for proper recordkeeping, security, handling, and inventories.

Chapter 3

EVALUATION OF THE REGULATION OF PHARMACISTS

This chapter contains our evaluation of the regulation of pharmacists under Chapter 461, Hawaii Revised Statutes, including our evaluation of the need for regulation and existing regulatory operations. We conclude this report with our recommendations.

Summary of Findings

Our findings are as follows:

1. A clear and significant potential for harm exists with the practice of pharmacy. The absence of regulation would unnecessarily expose the public to possible harm.
2. Existing licensing requirements are unduly restrictive regarding the entry of qualified foreign pharmacy school graduates into the profession.
3. Hawaii is one of only three states which do not allow qualified and licensed out-of-state pharmacists to obtain a license to practice through reciprocity. The restraints on reciprocity are unreasonable and unnecessarily restrictive.
4. Although it is not statutorily authorized, pharmacists often employ pharmacy technicians as support personnel. The unregulated use of these personnel may be compromising the quality and safety of pharmacy services.
5. Because of the increased potential risks involved in prescribing drugs and the limited experience of only a few states in this area, it is premature at this time for the State to grant prescriptive authority to pharmacists.

The Need for Regulation

We find that the continued regulation of pharmacists is necessary to protect the public from untrained and incompetent practitioners. There is a clear and

significant risk to the public's health and safety when unqualified and incompetent pharmacists are allowed to prepare and dispense prescription drugs or advise health personnel and consumers on the safe and appropriate use of these products.

The intent of the original 1903 pharmacy law was to protect the public from improperly filled prescriptions and unsafe or adulterated drugs. Today, most drugs are manufactured in finished form by large pharmaceutical companies which are regulated by the U.S. Food and Drug Administration. Consequently, pharmacists today devote only a very small percentage of their time to compounding drugs. The regulation of pharmacists now focuses primarily on ensuring that prescription drugs are correctly and safely dispensed.

Despite this shift in regulatory focus, conditions existing today indicate that there may be an even greater need to protect the public. Several developments have increased the potential risks for the public. These include the greatly increased use of prescription drugs by consumers, the greater potency of these drugs, and the growing diversion and abuse of prescription drugs.

The expanded use of prescription drugs is reflected in the following statistics. About 60 percent of all visits to the doctor result in the patient receiving an order for one or more prescriptions. Community pharmacists serve about 130 million persons annually, and the typical hospitalized patient receives eight different prescriptions during a hospitalization. Nationally, it has been estimated that approximately three billion prescription orders are dispensed annually to Americans at a cost of about \$20 billion.¹

Because of the potency of modern pharmaceutical drugs, it is essential that prescriptions be filled correctly and that these drugs be dispensed properly and safely. Due to the technical and complex nature of pharmacology, extensive formal training and education are usually necessary before a person can be considered knowledgeable and competent in this field. In most cases, the general public does not have and cannot be expected to have the specialized and technical knowledge to properly evaluate the quality of these pharmaceutical services.

1. T. Donald Rucker, ed., *Pharmacy: Career Planning & Professional Opportunity*, Washington, D.C., AUPHA Press, 1981, p. 12.

The potential hazards in pharmacy are well documented. Generally, the use of any kind of drug can be potentially dangerous. The U.S. Task Force on Prescription Drugs concluded: "There is no known compound which, under certain conditions, cannot injure, destroy tissue, or cause death."²

The *New York Times* published a survey which reported that "30,000 Americans accept the drugs prescribed for them and die as a direct result. Perhaps 10 times as many patients suffer life-threatening and sometimes permanent side effects such as kidney failure, mental depression, internal bleeding, and loss of hearing or vision. These figures are among the more conservative to be found in studies of the prescription drug problem. . . ."³

According to the U.S. National Center for Health Services, adverse drug reactions may be the most common form of iatrogenic (or physician induced) disease in the country.⁴ Estimates of the number of deaths attributed to adverse drug reactions are usually derived from epidemiological studies. The *New York Times* survey reported that for every 18 prescriptions written in a hospital, one adverse drug reaction occurs. Of these, 10 percent of the reactions are major and 1.2 percent are fatal.⁵ Other consequences include extended hospitalization, unnecessary pain, injury and disability, and an increased demand on already limited health resources.

The diversion of controlled substances to illicit drug markets and the misuse of these drugs represents another hazard involved in the use of pharmaceutical drugs.⁶ Licensing pharmacists currently helps to ensure compliance with state and federal requirements regarding the purchase and sale of these controlled drugs. Under these requirements, pharmacists must be licensed by the State and hold a federal permit to dispense controlled drugs.

2. Jeffrey S. Markowitz, Gayle Pearson, Bruce G. Kay, Regina Loewenstein, "Nurses, Physicians, and Pharmacists: Their Knowledge of Hazards of Medications," *Nursing Research*, v. 30, no. 6, November/December 1981, p. 366.

3. "Thousands a Year Killed by Faulty Prescriptions," *New York Times*, January 28, 1976.

4. Markowitz, et al., *Nursing Research*, p. 366.

5. "Thousands a Year Killed by Faulty Prescriptions," *New York Times*.

6. Controlled substances are prescription drugs whose potential for abuse and diversion to illicit markets is high. State and federal laws require that these substances be placed into five schedules or classes based on their potential for abuse and accepted medical safety and use. Specific control procedures apply to each schedule.

State and federal laws require pharmacists to keep stringent records regarding the acquisition, storage, inventory, and disposition of these controlled substances. If pharmacists were not required to be licensed, state and federal enforcement efforts in this area would be seriously undermined, with a greater likelihood of diversion of increased amounts of controlled drugs to illegal markets.

Our examination of formal complaints filed with the Regulated Industries Complaints Office of the Department of Commerce and Consumer Affairs indicates a continued need to provide regulatory safeguards for the public. Since 1980, for example, two dozen complaints have been filed with the department. These complaints include dispensing errors, improper labeling of prescriptions, illegally dispensing dangerous and harmful drugs, operating pharmacies without a permit, overcharging for prescriptions, and improper advertising.

Our review also reveals that several pharmacists have been successfully prosecuted for Medicaid fraud or for illegally selling controlled substances. In 1979, for example, the State Medicaid Fraud Control Unit prosecuted three Maui pharmacists who pleaded guilty to Medicaid fraud. The three pharmacists admitted defrauding the government of \$20,000 in Medicaid funds over a two-year period.⁷ In another case, a Kailua pharmacist pleaded guilty to felony theft for fraudulently obtaining Medicaid funds by doctoring his claims.⁸ Finally, in another example, a Honolulu pharmacist was fined \$5,000 and placed on five years probation for illegally selling controlled substances in 1981.⁹

Our evaluation also indicates that deregulating pharmacists might result in serious economic consequences for the public. The Medicare and Medicaid programs, for example, currently require pharmacists to be licensed for reimbursement. Eliminating state licensure for pharmacists could jeopardize the State's participation in these two programs.

7. "3 Maui Druggists Plead Guilty to Medicaid Fraud," *Honolulu Advertiser*, January 6, 1979; and "3 Pharmacists Sentenced for Medicaid Fraud," *Honolulu Advertiser*, March 9, 1979.

8. "Pharmacist Gets Jail Time, Fine for Fraud," *Honolulu Advertiser*, May 17, 1979.

9. "\$5,000 Fine in Tranquilizer Case," *Honolulu Advertiser*, January 17, 1981.

Without state regulation, then, there would be no formal requirements regarding the training, qualifications, or competence of pharmacists. Consequently, consumers would be subject to a distinct disadvantage in trying to determine the competence of pharmacists and the quality of pharmaceutical services and would face an even greater risk of harm.

Finally, given the highly complex and technical nature of the profession and the significant and immediate potential for harm posed by incompetent or negligent practitioners, we believe that pharmacists warrant continued regulation through licensure as opposed to any less stringent form of regulation. Currently, all 50 states, the District of Columbia, and Puerto Rico continue to regulate pharmacists through licensure.¹⁰

Regulatory Operations

Our evaluation of the board's existing regulatory practices indicates that improvements could be achieved by implementing changes in several key areas. This portion of the report will focus on regulatory operations in the following areas: (1) examinations; (2) licensing; and (3) practice restrictions.

Examinations. The purpose of any licensing examination is to determine whether an applicant possesses the minimum competence necessary to practice without endangering the public's health, safety, or welfare. A good examination must be valid and reliable, and it must be administered fairly. Our evaluation indicates that the licensure examinations for pharmacists are valid and reliable, fairly administered and graded, and do not unfairly restrict entry into the profession.

The licensure examination probably represents one of the most important qualification requirements for entry into the profession. Currently, all states require pharmacist candidates to pass an examination to qualify for initial licensure. Locally, candidates for licensure are required to pass three examinations: (1) the standardized national board examination, the National Association of Boards of Pharmacy Licensure Examination (NABPLEX); (2) the Federal Drug Law

10. U.S. Bureau of Labor Statistics, *Occupational Outlook Handbook, 1982-83*, Washington, D.C., April 1982, p. 163.

Examination (FDLE), also sponsored by the National Association of Boards of Pharmacy (NABP); and (3) the state jurisprudence examination.

In Hawaii, the licensure examinations are conducted at least twice a year, usually in March, June, or September. The examinations are normally given over a two-day period. All of the examinations are multiple-choice, objective examinations. There are no "practical" or oral components to any of the examinations.

The NABPLEX was first developed and utilized in 1970. The primary objective of the examination is to evaluate the candidate's pharmaceutical knowledge and ability to dispense drugs and drug products competently, safely, and legally. The examination contains 460 multiple-choice questions and consists of five parts: practice of pharmacy, pharmacology, pharmacy, mathematics, and chemistry. The NABP currently employs a test contractor (the American College Testing Program, Inc. of Iowa City, Iowa) to help review, validate, administer, and grade the examinations. Currently, all of the states (except for California and Louisiana), the District of Columbia, and Puerto Rico use the NABPLEX.¹¹

The FDLE, the federal jurisprudence examination, is also sponsored by the NABP. The examination focuses specifically on federal drug requirements and is designed to be used in conjunction with the state law examination. Test administrative procedures for the FDLE are consistent with the procedures used for the NABPLEX. The examination consists of 65 multiple-choice questions and covers such areas as: the federal Controlled Substances Act and regulations; the federal Food, Drug, & Cosmetic Act and regulations; and miscellaneous federal regulations. The state jurisprudence examination consists of 20 multiple-choice questions and covers Hawaii pharmacy drug laws and rules.

In the last five years, 189 candidates have taken the required examinations for licensure in Hawaii. Approximately 90 percent of these candidates successfully passed the examinations. In calendar year 1983, examinations were administered in June and September to 48 candidates. Forty-five candidates passed the examination for a passing average of 94 percent.

11. National Association of Boards of Pharmacy, *NABP Board Member Manual*, Chicago, NABP, 1981, p. 17.

Licensing. *Foreign graduate equivalency examination.* Existing licensing requirements appear to be unduly restrictive regarding the entry of qualified foreign pharmacy school graduates into the profession. The law currently requires an applicant for licensure to be a graduate of a pharmacy school or college recognized and approved by the American Council of Pharmaceutical Education (ACPE), the national accrediting body for pharmacy schools. However, no foreign pharmacy schools are currently accredited by the ACPE. Consequently, qualified graduates of these foreign schools are prevented from seeking licensure unless they obtain an additional pharmacy degree from an accredited American school.

Recognizing this problem, the NABP passed a resolution in 1982 to create a Foreign Pharmacy Graduate Examination Commission (FPGEC) to develop an appropriate equivalency examination. This examination would be used to qualify graduates of foreign pharmacy schools to take the standardized national board examination (NABPLEX). Twenty-seven states supported the development of such an equivalency examination.

Recently, the FPGEC successfully developed such an equivalency examination. The FPGEC currently offers the Foreign Pharmacy Graduate Equivalency Examination (FPGEE) to graduates of foreign pharmacy schools seeking an educational equivalency certificate that partially fulfills the requirements to practice pharmacy in the United States.

The equivalency examination is administered for the FPGEC by the American College Testing Program twice a year, usually in April and October, at selected test centers in the United States. The FPGEE is designed to measure an applicant's knowledge of the principles of pharmacy and includes between 300 and 400 multiple-choice questions. The one-day examination is given only in English. One-quarter of the questions cover the basic pharmaceutical services of chemistry, anatomy, physiology, pathology, and microbiology. The remaining questions cover the biomedical sciences, social and behavioral sciences, and pharmaceutical services management.

Foreign applicants who successfully pass the equivalency examination must still meet other requirements before they are awarded a FPGEC certificate. Applicants must be graduates of four-year pharmacy schools listed in the World Directory of Schools of Pharmacy published by the World Health Organization.

Additionally, applicants must provide proof that they have obtained a license or certificate to practice pharmacy in their home country. All documents must be verified by the FPGEC before a certificate is awarded. Applicants must also provide proof that they scored at least 550 on the Test of English as a Foreign Language Examination.

Foreign graduates who obtain a FPGEC certificate become eligible to take the national board examination but only in those states or jurisdictions that recognize and accept the FPGEC certificate. Finally, a foreign graduate seeking pharmacy licensure must meet all of the other licensing requirements of the state in which the foreign graduate is seeking licensure. These requirements, for example, might include internship programs and passing the state jurisprudence examination.

Currently, 21 states accept or recognize the FPGEC certificate. Hawaii, however, is not one of those states. The pharmacy board recently acted to approve draft legislation that would amend the pharmacy law and permit a foreign applicant to take the examination for licensure in Hawaii if the applicant received FPGEC certification and met all other licensing requirements of the State. We support this effort and encourage the Department of Commerce and Consumer Affairs to submit an appropriate measure to the Legislature for consideration.

Reciprocity. Reciprocity is a licensing procedure that permits a person licensed in one state to obtain a license in another state based on that person's credentials and experience and without having to retake the licensure examination. Under current state licensing requirements, a licensed pharmacist from another state cannot obtain a license to practice in Hawaii through reciprocity. Regardless of how highly qualified the licensed out-of-state pharmacist is, the pharmacist is required to retake and pass the national board examination prior to obtaining a permanent license to practice in Hawaii. We believe that this licensing requirement is unreasonable and unnecessarily restrictive.

Reciprocity is currently supported by two major national pharmacy associations, the American Pharmaceutical Association (APhA) and the NABP. The APhA represents the largest professional pharmacist association in the United States. The NABP consists of the boards of pharmacy from each of the 50 states, the District of Columbia, Puerto Rico, the Virgin Islands, and some Canadian provinces. The NABP has developed a model pharmacy law with specific provisions addressing the reciprocity issue.

The NABP administers reciprocity nationally by serving as a central clearinghouse for the reciprocity states. The reciprocity process normally begins when a candidate files a preliminary application with the NABP office. The application is reviewed by the NABP staff, and all credentials are checked and verified by that office. Usually, information is obtained from the candidate's pharmacy school, the various pharmacy boards in which the candidate holds a license, and occasionally, current and former employers.

Candidates seeking licensure through reciprocity must meet the individual qualifying standards of the particular state in which they are seeking licensure and must take the state's jurisprudence examination to demonstrate their knowledge of local statutes and rules. Since all but two states utilize the national board examination (NABPLEX), reciprocity has been greatly standardized and simplified.

Hawaii remains one of only three states that do not allow licensure through reciprocity.¹² California and Florida are the other nonreciprocity states. Local pharmacists defend these licensing restrictions on the grounds that they maintain the high quality of pharmacy services in the State and prevent an influx of transient pharmacists who would come to Hawaii as part-time practitioners. We believe, however, that these restraints on reciprocity are unreasonable and tend to unfairly limit the entry of new pharmacists into local markets.

Such restraints, we believe, tend to reinforce the perception that professional licensing boards are too often more concerned and sympathetic with the needs of the professionals they regulate rather than to the public which they are mandated to protect. A recent pharmacy journal article states, for example: "Professionals have always viewed licensure as a means of protecting the public against untrained and unskilled individuals. . . . But although the public at one time shared this opinion, it appears that it is changing its mind. It now views licensure as a monopoly by which selected groups can regulate entry into their profession. . . ."¹³

12. National Association of Boards of Pharmacy, *NABP Survey of Pharmacy Law, 1983-1984*, Chicago, NABP, 1983, pp. 11-13.

13. Richard P. Penna, "Pharmacy Under Siege: Ensuring Our Professionalism," *American Pharmacy*, v. 19, no. 11, October 1979, p. 45.

There is no reasonable basis for denying a Hawaii license to an already licensed out-of-state pharmacist if evidence is provided that: (1) the pharmacist holds a valid license from another state; (2) the licensing requirements of the pharmacist's home state are equivalent to or more stringent than Hawaii's; (3) the pharmacist is currently a practicing, competent practitioner; (4) the pharmacist has no pending disciplinary action or unresolved complaints; and (5) the pharmacist successfully passes the jurisprudence portion of our licensing examination.

The basic issue in reciprocity is the competency of the pharmacist. While we believe that the board should continue to maintain high licensing standards, we also believe that it would be in the State's best interest to allow licensure through reciprocity when these standards are met.

Practice restrictions. *Pharmacy technicians.* The law currently includes no specific provisions regarding the use of support personnel in pharmacy practice. The board, however, has made provisions for an "assistant" to fill or compound prescriptions under a pharmacist's immediate supervision.¹⁴ These assistants are pharmacy students or recent pharmacy school graduates seeking the necessary practical experience (2,000 hours) required for licensure. Consequently, they are considered interns rather than support personnel.

Nationally, there appears to be a lack of consistency in the regulation of support personnel. Oliver et al. conducted a survey to determine the legal status of pharmacy support personnel in the different states and analyzed the pharmacy laws and regulations from each of the 50 states. The survey found that the majority of states, 31, do not recognize support personnel in their pharmacy laws, four states prohibit their use, and only 15 states permit the use of these personnel.¹⁵

Although it is not always statutorily authorized, pharmacists almost routinely employ such support personnel as pharmacy technicians. Several studies indicate that, regardless of whether existing laws permit the use of pharmacy technicians,

14. The rules define an assistant as "a student or graduate of a school or college of pharmacy recognized and approved by the American Council of Pharmaceutical Education who has been issued a permit to work under the immediate personal supervision of a registered pharmacist." (see: State of Hawaii, Title 16, Department of Commerce and Consumer Affairs, Chapter 95, Pharmacists and Pharmacies, Section 16-95-2).

15. Ernest J. Oliver, Charles D. Mahoney, Louis P. Jeffrey, "State Legislation Pertaining to Supportive Personnel in Pharmacy," *American Journal of Hospital Pharmacy*, v. 37, April 1980, p. 460.

they are being used on a fairly widespread and routine basis. Stolar, for example, reports that 75 percent of the hospital pharmacy directors responding to his survey indicated that they use pharmacy technicians.¹⁶

Despite the questionable legality of using pharmacy technicians, there appears to be little argument that these technicians are providing essential support services. Their services range from typing labels and counting pills to helping prepare and dispense drugs. In addition to helping ensure the economical and efficient provision of pharmacy services to the public, these technicians free the pharmacist to devote more time to clinically oriented services such as monitoring drug usage and consulting with consumers and health professionals on the safe and appropriate use of these drugs.

Aside from the legality issue, a related problem involves identifying and limiting those functions which a technician can safely perform. Dahlin writes: "Few states have acknowledged the supportive person in pharmacy or defined the limits of his responsibilities. This relative lack of recognition, ironically, has been accompanied by extensive employment of assistants and technicians, both in community and in institutional settings. Pharmacists are becoming increasingly aware of the need to address the supportive person and his functions."¹⁷

It appears that most states, Hawaii included, have no regulatory language or only very vague and unclear provisions pertaining to the duties and functions of technicians. The NABP reports that individual state boards of pharmacy have been left to determine allowable functions for pharmacy technicians. Consequently, there exists wide variations regarding the use of these personnel.

The APhA currently endorses the use of support personnel in pharmacy practice but advocates that these personnel "function under written procedures which specify functions and supervisory controls and which assure the efficiency of pharmacy practice while not compromising the quality of pharmaceutical service."¹⁸

16. Michael H. Stolar, "National Survey of Hospital Pharmacy Technician Use," *American Journal of Hospital Pharmacy*, v. 38, August 1981, p. 1133.

17. Patricia A. Dahlin, "Views of Pharmacy Supportive Personnel in Florida," *Drug Intelligence and Clinical Pharmacy*, v. 17, July/August 1983, p. 576.

18. American Pharmaceutical Association, *Policy Statements of the American Pharmaceutical Association, 1963-1977*, Washington, D.C., p. 201.

Additionally, the American Society of Hospital Pharmacists (ASHP) has developed model legislation and minimum competency standards to assist pharmacy boards to standardize guidelines for these personnel.¹⁹

Given the widespread acceptance and use of pharmacy technicians in current pharmacy practice and the acknowledged benefits for both practitioners and the public in utilizing these support personnel, we believe the law should be amended to legally authorize pharmacists to employ these technicians. It is our understanding that the pharmacy board is currently studying this issue and may initiate regulatory changes to allow the use of these support personnel. We encourage this effort.

To ensure necessary safeguards for the public, however, we recommend that any regulatory changes include the following: (1) a clear definition of a pharmacy technician; (2) qualification requirements for these personnel; (3) explicitly stated functions which a technician can legally perform; and (4) necessary supervisory controls. The board may wish to utilize the ASHP's model legislation and minimum competency standards as a basis for its work in this area.

Prescribing authority. Prescriptive authority for pharmacists remains a controversial issue within the profession. Some practitioners believe that pharmacists should be given the authority to prescribe drugs in addition to preparing and dispensing them.²⁰ For many years, prescriptive authority was limited to physicians. Today, in many states, dentists, osteopaths, and veterinarians, among others, also have the right to prescribe. Pharmacists, however, have traditionally been prohibited from prescribing.

Because pharmacists have been prohibited from legally prescribing drugs until very recently, there exists only a very limited amount of evaluative data. The evidence available, however, has generally been positive and suggests that prescribing by clinically trained pharmacists can be safe, effective, and of good quality. Probably the best-known study in this area is the five-year California project that allowed pharmacists to prescribe drugs on an experimental basis.

19. "ASHP Model Amendment to the State Pharmacy Act: Supportive Personnel," no date, and "ASHP Competency Standards for Pharmacy Supportive Personnel," 1977.

20. Prescribing generally refers to the process of designating or ordering the use of a drug or medication. Dispensing involves preparing and distributing drugs or medications to patients based on the exact order of a prescription.

On September 15, 1977, California Assembly Bill 717 was approved. This legislation allowed pharmacists to prescribe drugs in a five-year experimental health manpower project authorized by the Office of Statewide Health Planning and Development of the California State Department of Health Services. The primary purpose of the experimental project was to study the safety, efficacy, and cost-effectiveness of prescribing and dispensing drugs by nontraditional personnel.

Data from the project indicate that pharmacists can prescribe drugs safely and effectively. Independent pharmacist and physician judges, using predetermined criteria and unaware of the identities of the participants, found few differences between prescribing by pharmacists and prescribing by psychiatrists for patients using psychotropic drugs. In some cases, the pharmacists rated better than the psychiatrists in assessing the potential for drug interactions and in providing directions for the patients. In antihypertensive prescribing, no significant differences were found between pharmacists and physicians in terms of prescribing the appropriate quantity and dose, assessing drug interaction potential, and giving directions to patients. However, the pharmacists did considerably better than the physicians in selecting the most appropriate drugs to use.²¹

Partially as a result of the success of this project, California amended its pharmacy law in 1981 by giving pharmacists limited prescriptive authority. The legislation allows pharmacists who work in licensed health-care facilities and who establish a written agreement with a physician and adhere to specific procedures and protocols, to perform routine patient assessments, order drug-related laboratory tests, administer drugs by injection, and adjust the dosage of a patient's drug regimen.

Those who oppose prescribing authority for pharmacists generally cite these arguments: (1) there are still too many pharmacists who are not competent to prescribe drugs; although some pharmacists are qualified to provide sophisticated clinical services, the majority of pharmacists today may not have the necessary skills and qualifications to prescribe drugs; (2) pharmacists are not trained or

21. Timothy R. Covington, "Toward a Rational Approach to the Issue of Prescribing Authority for Pharmacists," *Drug Intelligence and Clinical Pharmacy*, v. 17, September 1983, p. 662.

qualified to diagnose, and diagnosis and treatment cannot be separated; (3) many physicians remain opposed to prescribing by pharmacists; and (4) overall patient care would be further fragmented if pharmacists were allowed to prescribe.

According to the NABP, only two states (Maine and Washington), in addition to California, allow pharmacists to prescribe drugs.²² Given the added risks involved in prescribing drugs and the limited experience of only a very few states, we believe it would be premature at this time for the State to extend prescriptive authority to pharmacists. We encourage the board to monitor the experience of other states; with additional time and experience, the State should be able to make a more informed and reasoned judgment on this issue.

Recommendations

We recommend that:

1. *Chapter 461, Hawaii Revised Statutes, be reenacted to allow for the continued regulation of pharmacists. In reenacting the chapter, consideration be given to the following changes:*

- . Establishing provisions that would allow qualified graduates of foreign pharmacy schools to obtain licensure.*
- . Allowing licensure through reciprocity for qualified and licensed pharmacists from other states whose licensing requirements are equivalent to or more stringent than Hawaii's.*
- . Adding provisions that would allow pharmacists to employ pharmacy technicians as support personnel.*

2. *If the Legislature authorizes the use of pharmacy technicians and consistent with such provisions as may be specified by statute, the board's rules be amended by defining a pharmacy technician, identifying the qualification requirements, specifying those duties which may be legally performed by a technician, and delineating necessary supervisory controls.*

22. National Association of Boards of Pharmacy, *NABP Survey of Pharmacy Law, 1983-1984*, p. 27.

APPENDIX

RESPONSES OF AFFECTED AGENCIES

COMMENTS ON AGENCY RESPONSES

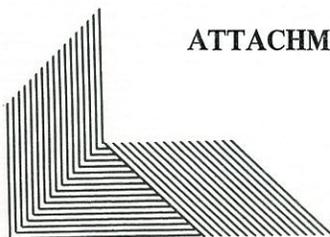
A preliminary draft of this Sunset Evaluation Report was transmitted on November 26, 1984, to the Board of Pharmacy and to the Department of Commerce and Consumer Affairs for their review and comments. A copy of the transmittal letter to the board is included as Attachment 1 of this Appendix. A similar letter was sent to the department. The responses from the board, and the department are included as Attachments 2 and 3.

The board commented on two of the three recommendations made in the report. It said that it is in favor of the recommendation to allow for the licensure of qualified graduates of foreign pharmacy schools, and that it has already submitted a legislative proposal to provide for this. The board is also in agreement with our recommendation to allow for licensure through reciprocity. The board plans to discuss our third recommendation relating to the use of pharmacy technicians at its meeting in January. It will then respond to the recommendation at legislative hearings.

The Department of Commerce and Consumer Affairs stated that it is in general agreement with our evaluation.

ATTACHMENT 1

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



CLINTON T. TANIMURA
AUDITOR

November 26, 1984

COPY

Ms. Mary A. Wahlman, Chairperson
Board of Pharmacy
Department of Commerce and Consumer Affairs
State of Hawaii
Honolulu, Hawaii 96813

Dear Ms. Wahlman:

Enclosed are eight preliminary copies, numbered 4 through 11, of our *Sunset Evaluation Report, Pharmacists and Pharmacy, Chapter 461, 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 pharmacists and pharmacies. If you have any comments on our recommendations, we would appreciate receiving them by December 26, 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 PHARMACY
STATE OF HAWAII
PROFESSIONAL & VOCATIONAL LICENSING DIVISION
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS

P. O. BOX 3469
HONOLULU, HAWAII 96801

December 19, 1984

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OFF. OF THE AUDITOR
STATE OF HAWAII

The Honorable Clinton T. Tanimura
Legislative Auditor
The Office of the Auditor
465 So. King Street, Room 500
Honolulu, Hawaii 96813

Dear Mr. Tanimura:

Thank you for the opportunity to comment on your sunset evaluation report on pharmacists and pharmacy. We found the report comprehensive and agree that regulatory operations of the Board of Pharmacy could be improved by implementing statutory or rule changes in several key areas. At this time we are prepared to offer comments on two of the recommendations which you have proposed.

With regard to the recommendation that we allow for licensure of qualified graduates of foreign pharmacy schools, the board is in favor of this proposal. We have already submitted a legislative proposal that would statutorily recognize and allow for licensure of such individuals. We are pleased with your support in this area as it reinforces our position on this matter.

Further, the board is in agreement with your recommendation to allow for licensure through reciprocity and is prepared to make statutory changes; provided, that the requirements for reciprocity are such that we can be assured of the competency of the pharmacist.

The remaining recommendation regarding a statutory provision to allow pharmacists to employ pharmacy technicians will be discussed at our next meeting scheduled for January 18, 1985. Input from all members will be evaluated and consolidated, and we will be prepared to respond to this recommendation at the legislative hearing.

Very truly yours,

(Ms.) Mary A. Wahlman
Chairman of the Board

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

December 13, 1984

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STATE OF HAWAII

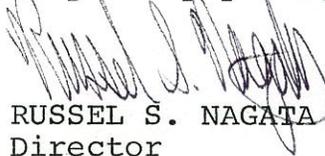
The Honorable Clinton T. Tanimura
Legislative Auditor
The Office of the Auditor
465 So. King Street, Room 500
Honolulu, Hawaii 96813

Dear Mr. Tanimura:

Thank you for the opportunity to comment on your sunset evaluation report on pharmacists and pharmacy.

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

Very truly yours,


RUSSEL S. NAGATA
Director