Sunset Evaluation Update:

Pharmacists and Pharmacy

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



The Office of the Auditor

The missions of the Office of the Auditor are assigned by the Hawaii State Constitution (Article VII, Section 10). The primary mission is to conduct post audits of the transactions, accounts, programs, and performance of public agencies. A supplemental mission is to conduct such other investigations and prepare such additional reports as may be directed by the Legislature.

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Under its assigned missions, the office conducts the following types of examinations:

- Financial audits attest to the fairness of the financial statements of agencies. They
 examine the adequacy of the financial records and accounting and internal controls, and
 they determine the legality and propriety of expenditures.
- 2. Management audits, which are also referred to as performance audits, examine the effectiveness of programs or the efficiency of agencies or both. These audits are also called program audits, when they focus on whether programs are attaining the objectives and results expected of them, and operations audits, when they examine how well agencies are organized and managed and how efficiently they acquire and utilize resources.
- Sunset evaluations are conducted of professional and occupational licensing programs
 to determine whether the programs should be terminated, continued, or modified. These
 evaluations are conducted in accordance with a schedule and criteria established by
 statute.
- 4. Sunrise analyses are similar to sunset evaluations, but they apply to proposed rather than existing regulatory programs. Before a new professional and occupational licensing program can be enacted, the statutes require that the measure be analyzed by the Office of the Auditor as to its probable effects.
- Health insurance analyses are conducted on bills which propose to mandate certain
 health insurance benefits. Such bills cannot be enacted unless they are referred to the
 Office of the Auditor for an assessment of the social and financial impact of the
 proposed measure.
- Special studies are conducted when they are requested by both houses of the Legislature. The studies usually address specific problems for which the Legislature is seeking solutions.

Hawaii's laws provide the Auditor with broad powers to examine all books, records, files, papers, and documents and all financial affairs of every agency. The Auditor also has the authority to summon persons to produce records and to question persons under oath. However, the Office of the Auditor exercises no control function, and its authority is limited to reviewing, evaluating, and reporting on its findings and recommendations to the Legislature and the Governor.



Kekuanao'a Building 465 South King Street, Suite 500 Honolulu, Hawaii 96813 Report No. 93-6 September 1993

OVERVIEW

THE AUDITOR STATE OF HAWAII

Sunset Evaluation Update: Pharmacists and Pharmacy

Summary

We evaluated the regulation of pharmacists and pharmacy under Chapter 461, Hawaii Revised Statutes, and conclude that the public interest is best served by reenactment of the statute. We found that continued regulation of pharmacists and pharmacy is needed. If practiced incompetently, the occupation has a significant potential for harm to consumers.

Pharmacists measure, count, mix, and dispense drugs prescribed by physicians, podiatrists, dentists, and veterinarians. They also advise medical practitioners about drug selection, help customers choose over-the-counter medications, and maintain patient medication profiles.

A seven-member Board of Pharmacy regulates the occupation. The board is administratively attached to the Department of Commerce and Consumer Affairs. The department's Professional and Vocational Licensing Division provides administrative services to the board, and the Regulated Industries Complaints Office handles consumer complaints and pursues legal action when appropriate.

Since our first sunset evaluation in 1985, improvements have been made in the regulatory program. Additional improvements are needed in several areas. The statute contains licensing requirements that are restrictive (2,000 hours of practical experience instead of the more common 1,500) and unnecessary (a state jurisprudence examination). In addition, the Board of Pharmacy is attempting to expand the scope of regulation unnecessarily by regulating nonresident pharmacies, imposing additional requirements on pharmacist assistants (interns), and taking over certain regulatory responsibilities of the Department of Health. Finally, the board's manual and licensing forms contain inaccuracies, and the requirement that applicants submit a personal photograph has the potential for discrimination.

Recommendations and Response

We recommend that the Legislature reenact Chapter 461, Hawaii Revised Statutes, to continue the regulation of pharmacists and pharmacy. In reenacting the statute, the Legislature should consider amending it to reduce the practical experience requirement from 2,000 to 1,500 hours and delete the requirement of a state jurisprudence examination.

Report No. 93-6 September 1993

The Board of Pharmacy should abandon its efforts to regulate further nonresident pharmacies, impose unnecessary requirements on pharmacist assistants, and take over certain regulatory responsibilities of the Department of Health. The department should work with the board to correct the inaccuracies in the board's operational manual and delete the requirement of a personal photograph.

The Board of Pharmacy concurs that Chapter 461 should be reenacted, the practical experience requirement reduced to 1,500 hours, and the jurisprudence examination deleted. It points out that Act 259 of 1993 requires regulation of nonresident pharmacies. To clarify, we are simply saying that the board should not pursue additional regulation of these pharmacies.

The board says that its experience requirements for pharmacy interns will apply to all license applicants and it will exercise its authority carefully. It does not agree that the board should abandon efforts to take over certain responsibilities currently exercised by the health department. We believe that abandoning these efforts is necessary.

The board says that corrections in its operational manual and application forms have already been made. It agrees that the photograph requirement should be deleted, not because of discrimination, but because it is neither necessary nor efficient.

Marion M. Higa State Auditor State of Hawaii Office of the Auditor 465 South King Street, Room 500 Honolulu, Hawaii 96813 (808) 587-0800 FAX (808) 587-0830

Sunset Evaluation Update: Pharmacists and Pharmacy

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

Submitted by

THE AUDITOR STATE OF HAWAII

Report No. 93-6 September 1993

Foreword

The Sunset Law, or the Hawaii Regulatory Licensing Reform Act of 1977, schedules regulatory programs for termination on a periodic cycle. Unless specifically reestablished by the Legislature, the programs are repealed. The State Auditor is responsible for evaluating each program for the Legislature prior to the date of repeal.

This report evaluates the regulation of pharmacists and pharmacy under Chapter 461, Hawaii Revised Statutes. It presents our findings as to whether the program complies with policies in the Sunset Law and whether there is a reasonable need to regulate pharmacists and pharmacy to protect the health, safety, and welfare of the public. It includes our recommendation on whether the program should be continued, modified, or repealed. In accordance with Section 26H-5, HRS, the report incorporates in the Appendix the draft legislation intended to improve the regulatory program.

We acknowledge the cooperation of the Department of Commerce and Consumer Affairs, the Board of Pharmacy, and others whom we contacted during the course of our evaluation. We appreciate the assistance of the Legislative Reference Bureau, which drafted the recommended legislation.

Marion M. Higa State Auditor

Table of Contents

Chapter 1	Introduction	
	Background on Pharmacists and Pharmacy Objectives of the Evaluation Scope and Methodology	. 2
Chapter 2	Findings and Recommendations	
	Summary of Findings	. 5
	State Should Continue To Regulate Pharmacists and Pharmacy	
	Some Statutory Provisions Are Restrictive or Unnecessary	
	Efforts To Expand Regulation Are Unnecessary	
	Board Manual and Licensing Forms Need Revision	
	Recommendations	10
Notes		11
Responses	of the Affected Agencies	13
Appendix: Pro	posed Legislation	21

Chapter 1

Introduction

The Sunset Law, or the Hawaii Regulatory Licensing Reform Act, Chapter 26H, Hawaii Revised Statutes, establishes policies for occupational licensing and schedules the repeal of licensing statutes according to a timetable. The law directs the State Auditor to evaluate each licensing statute prior to the repeal date and to determine whether the health, safety, and welfare of the public are best served by reenactment, modification, or repeal.

This report evaluates whether the regulation of pharmacists and pharmacy under Chapter 461, HRS, complies with policies for occupational licensing in the Sunset Law.

Background on Pharmacists and Pharmacy

Pharmacists measure, count, mix, and dispense drugs prescribed by physicians, podiatrists, dentists, and veterinarians. Other duties include advising medical practitioners about the selection, dosage, and effects of drugs, and helping customers find appropriate over-the-counter medicines. Pharmacists also maintain patient medication profiles to prevent harmful drug interactions and to ensure that patients comply with prescribing doctors' instructions. Pharmacists may specialize in drug therapy as pharmacotherapists, in radioactive drugs as radiopharmacists, and in nutrition as nutrition support pharmacists.

Pharmacists earn a Bachelor of Science or a Bachelor of Pharmacy degree with five years of study at one of 74 accredited colleges of pharmacy in the United States. For more specialized work they earn a Master of Science or Ph.D. in pharmacy.

Pharmacists work in community pharmacies, hospitals, health maintenance organizations (HMOs), clinics, and other settings. In March 1993, there were 1,137 pharmacists licensed in Hawaii. Of these, 664 lived in Hawaii. There were 195 pharmacy establishments in the state.¹

Regulatory program

Chapter 461, HRS governs the regulatory program. The law requires the Board of Pharmacy to license pharmacists and wholesale drug distributors, and to issue permits to pharmacies. The board is administratively attached to the Department of Commerce and Consumer Affairs and consists of seven members: five pharmacists and two public

members. An executive secretary in the department's Professional and Vocational Licensing Division serves as staff to the board and administers its day-to-day operations.

The department's Regulated Industries Complaints Office (RICO) mediates and resolves consumer complaints, pursues disciplinary action against licensees, and seeks court injunctions and fines against unlicensed practitioners. Final disciplinary decisions are made by the board following a recommended decision from the department's Office of Administrative Hearings. RICO also inspects new pharmacies seeking permits.

Previous sunset report

Our first sunset evaluation in 1985 recommended that Chapter 461 be reenacted to continue the regulation of pharmacists and pharmacy.² We found existing licensing requirements to be restrictive and recommended amending the law to allow licensure of qualified graduates of foreign pharmacy schools and pharmacists from other states with licensing requirements equivalent to or more stringent than Hawaii's.

We found that the use of pharmacy technicians was unregulated, which could compromise quality and safety. We suggested amending the statute so that pharmacists could employ them as support personnel. We recommended that the board's rules define pharmacy technicians, set their qualifications, and specify their duties and how they are to be supervised.

Objectives of the Evaluation

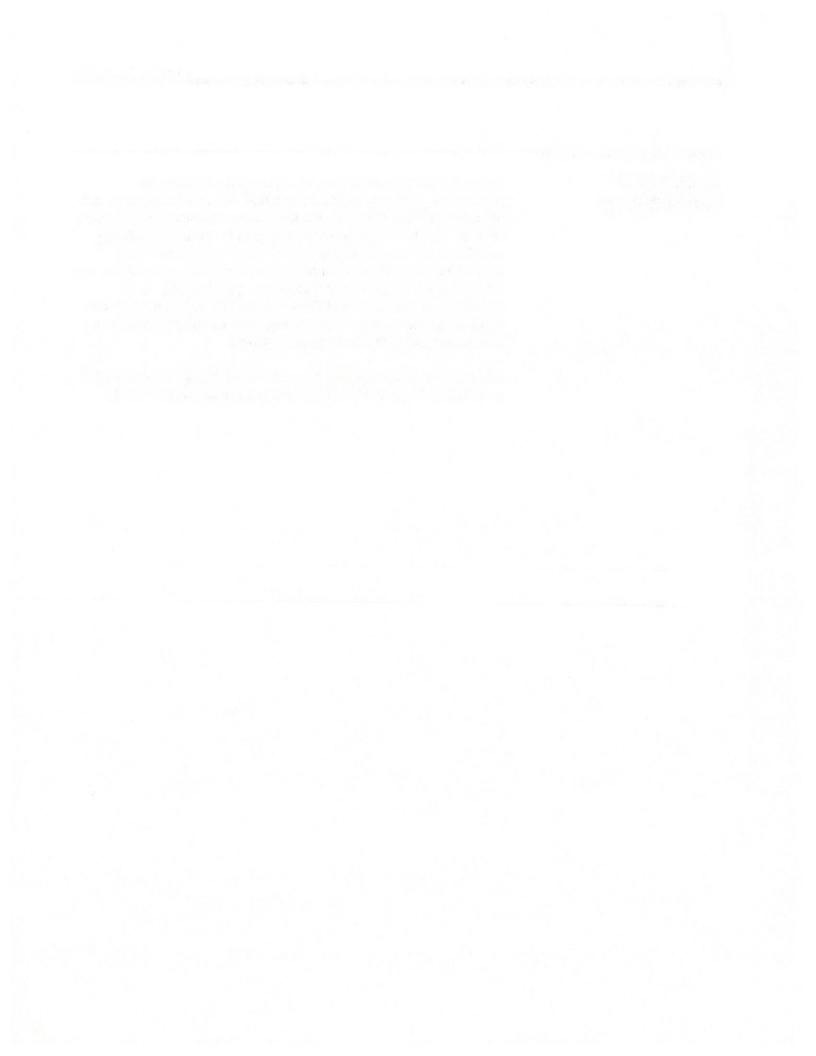
This evaluation sought to determine whether the regulation of pharmacists and pharmacy complies with policies in the Sunset Law. Specifically, the objectives were to:

- 1. Determine whether there is a reasonable need to regulate pharmacists and pharmacy to protect the health, safety, and welfare of the public;
- 2. Determine whether current regulatory requirements are appropriate for protecting the public;
- 3. Establish whether the regulatory program is being implemented effectively and efficiently; and
- 4. Make recommendations based upon findings in these areas.

Scope and Methodology

To accomplish these objectives, we reviewed the literature on pharmacists, pharmacy, and their regulation. We reviewed statutes and rules in Hawaii and the changes in these since our last sunset evaluation in 1985. We also reviewed evidence of harm to consumers including complaints. We interviewed members of the Board of Pharmacy, personnel from the Department of Commerce and Consumer Affairs and the Department of Health, and professional organizations. At the Department of Commerce and Consumer Affairs, we reviewed files on licensing, enforcement, correspondence, and board operations. Finally, we observed one of the licensing examinations.

Our work was performed from December 1992 through August 1993 in accordance with generally accepted government auditing standards.



Chapter 2

Findings and Recommendations

Our past recommendations have been implemented. The Legislature has authorized licensure of qualified graduates of foreign pharmacy schools, licensure by reciprocity with other states, and the use of pharmacy technicians. Some additional improvements, however, could be made in the statutes, rules, and administration of the licensing program.

Summary of Findings

- 1. The State should continue to regulate pharmacists and pharmacy to protect the public's health, safety, and welfare.
- 2. The statute contains provisions that are restrictive or unnecessary.
- 3. The Board of Pharmacy is unnecessarily attempting to expand the scope of regulation.
- 4. The board's manual and the licensing applications need revision.

State Should Continue To Regulate Pharmacists and Pharmacy

The Legislature should reenact Chapter 461, Hawaii Revised Statutes, to continue the regulation of pharmacists and pharmacy. The practice of pharmacy could harm the public's health, safety, and welfare.

Pharmacists who incorrectly dispense drugs or advise consumers may cause serious physical, emotional, and financial harm. The wrong medication can be fatal. Since consumers are not in a position to judge the competence of pharmacists, the State must regulate pharmacists and ensure that they meet such standards of competency so as to safeguard the public.

Regulating pharmacists also helps to ensure their compliance with the state and federal requirements designed to prevent the misuse of controlled substances and their diversion to illegal markets.

All 50 states, the District of Columbia, and U.S. territories regulate pharmacists through licensure.¹ These jurisdictions require that applicants graduate from an accredited pharmacy program, pass examinations, and have practical experience.

Evidence of harm

There is evidence that pharmacists have caused harm in Hawaii. Since 1989, complainants filed approximately 35 cases against pharmacists and pharmacies with the department's Regulated Industries Complaints Office (RICO). Some of the cases were closed for lack of evidence, but others demonstrated the need for regulation.

For example, RICO found that pharmacists filled prescriptions incorrectly, changed prescriptions, dispensed drugs without prescriptions, allowed unlicensed persons to dispense drugs, prescribed controlled substances for their own use, and failed to disclose that they had been disciplined by another state.

RICO has notified licensees of possible violations and requested corrective action, reached settlement agreements that included fines, and, in one case, recommended that a license be revoked by the Board of Pharmacy.

The board has taken disciplinary actions against licensees. One pharmacist forfeited his license for violating the conditions of his probation in another state. The board revoked the license of another for stealing prescription pads and dispensing controlled substances to herself. It fined a pharmacy \$5,000 for allowing a pharmacy technician to dispense prescription drugs. It required a pharmacist who incorrectly filled a prescription to pay the complainant \$3,500 in damages.

Some Statutory Provisions Are Restrictive or Unnecessary

Regulatory statutes should not unnecessarily restrict practice. They should contain only those provisions necessary to protect the public. The regulation of pharmacists would be improved if the statute were amended to correct two deficiencies. One provision requires applicants to have more practical experience than do other states. A second provision requires applicants to pass an unnecessary state jurisprudence examination.

Excessive experience requirement

All states require license applicants to have a certain amount of practical experience. In Hawaii, the statutory requirement is 2,000 hours of practical experience. This requirement appears excessive and restricts entry into the profession. Hawaii is one of only three states to require so much.² Other jurisdictions require 1,500 hours or less; most jurisdictions (37) require 1,500 hours. The law should be amended to reduce the practical experience requirement to 1,500 hours.

Unnecessary jurisprudence examination

Section 461-6(a) of the statute requires license applicants to pass three examinations: (1) the National Association of Boards of Pharmacy Licensure Examination, (2) the Federal Drug Law Examination, and (3)

the state jurisprudence examination. The state jurisprudence examination is both deficient and unnecessary.

The jurisprudence examination contains 25 multiple-choice questions on Hawaii pharmacy laws and rules. We found some questions based on outdated rules. In addition, licensing examinations that test knowledge of statutes and rules are not necessary. Many of the regulatory programs in Hawaii do not require an examination on state jurisprudence. For example, the dental hygienist licensing program has abandoned its laws exam due to ambiguous questions. The jurisprudence examination is an added burden on the program and on applicants. Since the exam for pharmacists is both deficient and unnecessary, we recommend that it be terminated.

Efforts To Expand Regulation Are Unnecessary

A regulatory program should extend only as far as is necessary to protect the public. The Board of Pharmacy wants to regulate nonresident pharmacies, impose new restrictions on pharmacist assistants, and take over certain responsibilities of the Department of Health. These efforts increase regulation without adding any protection to consumers.

No clear harm from nonresident pharmacies

The board has been trying to regulate nonresident pharmacies that do business in Hawaii. Nonresident pharmacies differ from local pharmacies in three respects. First, they allow consumers to order prescription drugs through the mail; second, they usually offer drugs at a lower cost; and third, they are typically high-volume businesses with little or no personal consumer contact.

The board believes that regulation of nonresident pharmacies is needed to protect Hawaii consumers. In a 1992 report, the Legislative Reference Bureau recommended some regulation of nonresident pharmacies because of the potential harm from prescription drug errors.³ The bureau concluded that requirements should be imposed such as having them verify their out-of-state license, submit a copy of their most recent regulatory inspection, and operate a toll-free hotline for patient consultation.

Regulation was expanded by Act 259 of 1993. It requires nonresident pharmacies to obtain a permit from the board; identify their principal corporate officers; attest that neither they nor their employees have been found in violation of any drug laws; verify their out-of-state license; and employ a registered pharmacist. The board had favored even broader regulation including requirements that the nonresident pharmacies operate a toll-free hotline and agree to abide by Hawaii's laws and rules.

However, we found no clear evidence that nonresident pharmacies are any less safe than local pharmacies. We found the evidence of harm to be inconclusive. Nonresident pharmacies are already regulated in their home states. This should be sufficient to protect Hawaii consumers and the board should not seek additional regulation beyond that imposed by Act 259.

Unnecessary efforts to increase pharmacist assistant regulation

The administrative rules authorize the board to issue permits to students or graduates of pharmacy schools to work as pharmacist assistants. By working as pharmacist assistants, these individuals can acquire the hours of practical experience needed to obtain a pharmacist license. However, the board is attempting to impose some unnecessary requirements on pharmacist assistants.

The pharmacist assistant permits are useful in enabling the board to document the hours of practical experience acquired. But the board is trying to expand the rules to regulate what types of skills are to be acquired through practical experience. Such regulation would verify that the pharmacist assistant knows how to detect errors in a prescription, select the correct drug product, and maintain prescription records. This exceeds the board's responsibility to ensure that pharmacist assistants obtain a basic level of experience. It is also unfair because it would apply only to individuals gaining their experience in Hawaii.

Act 112 of 1993 clarified that pharmacist assistants must have a board permit to practice. The Act also renamed pharmacist assistants as pharmacy interns and required the board to adopt rules on their functions, permit requirements, and supervision. We encourage the board to exercise this authority with restraint and not impose unnecessary requirements.

Consolidation of regulation unwarranted

The board wants to take on certain regulatory responsibilities that are being carried out by the Department of Health. But these efforts to consolidate regulation are unwarranted.

Chapter 461, HRS, gives the board responsibilities for regulating the pharmacist occupation, including licensing and professional discipline. Chapter 328, HRS, gives the health department responsibilities for regulating certain industry practices such as prescription drug labeling, maintenance of prescription records, advertising, the drug formulary,⁴ and the offering of lower cost equivalent drugs. The board has established an ad hoc committee to work with the Department of Health on transferring these regulatory responsibilities to the board.

Currently, the committee is focusing on transferring authority over prescription drug labeling, defining what constitutes a valid prescription, and how lower cost equivalent drugs can be substituted for brand name drugs on written prescriptions. But these efforts should cease because neither the board nor the health department reports any problems that would warrant a change in the current arrangement.

Board Manual and Licensing Forms Need Revision

To ensure efficient, effective, and lawful program operations, the department should make sure that key documents are accurate and up-to-date. We found that the board's operations manual and the licensing forms do not match the statutes and rules. Also, the personal photograph requirement on the license application is unwarranted and could be discriminatory.

Inaccurate operations manual

The operations manual for the Board of Pharmacy contains four inaccuracies:

- The manual states that a valid board decision requires the concurrence of a majority of the members *present*. Yet Section 92-15, HRS requires the concurrence of a majority of *all* the members of the board.
- The manual says that graduates of foreign pharmacy schools must pass *either* the Test of Spoken English (TSE) *or* the Test of English as a Foreign Language (TOEFL). Yet the rules require such applicants to pass *both* of these exams.
- The manual describes the state jurisprudence examination as having 20 multiple-choice questions when actually it has 25.
- The manual says that applicants for a temporary pharmacist's license must have two years of experience in another state. The statute and rules have no such requirement.

The department, with the board, should revise the manual to prevent possibly erroneous decisions.

Deficient licensing forms

Two licensing forms need revision to match the licensing statute and administrative rules:

• The pharmacist application asks applicants to verify that they worked as a *full-time* pharmacist for 2,000 hours or more in the past five years. Neither the statute nor the rules require full-time work.

• The pharmacist assistant application asks graduates of foreign schools to verify that they passed the Foreign Graduate Equivalency Examination, the Test of English as a Foreign Language, and the Test of Spoken English. The statute and rules do not require these exams for assistants.

The department should work with the board to correct these documents as well.

Unwarranted personal photograph

The license application requires applicants to provide a recent photograph. The purpose of this requirement is unclear. The licensing division already requires applications to be notarized. Furthermore, applicants are required to present an official photo identification at state examinations, such as a driver's license or passport. These procedures should be sufficient to verify the identity of the applicant and ensure that no substitute takes the exam.

By revealing the applicant's race, color, national origin, age, and gender, the photograph requirement could lead to discrimination or accusations of discrimination. The department has been examining whether photographs are necessary. We recommend that the department work with the board to delete the photograph requirement.

Recommendations

- The Legislature should reenact Chapter 461, Hawaii Revised Statutes, to continue the regulation of pharmacists and pharmacy. In reenacting the statute, the Legislature should consider amending it to:
 - a. Reduce the practical experience requirement from 2,000 to 1,500 hours.
 - b. Delete the requirement for applicants to pass a state jurisprudence examination.
- The Board of Pharmacy should abandon its efforts to regulate further nonresident pharmacies, to impose unnecessary requirements on pharmacist assistants, and to take over certain regulatory responsibilities of the Department of Health.
- 3. The department should work with the board to correct the inaccuracies in the board's operational manual and licensing forms, and to delete the requirement of a personal photograph.

Notes

Chapter 1

- 1. Hawaii, Department of Commerce and Consumer Affairs, *Summary/Geographic Report* (printout), March 5, 1993, p. 30.
- 2. Hawaii, Legislative Auditor, *Sunset Evaluation Report:*Pharmacists and Pharmacy, Report No. 85-4, Honolulu, January 1985.

Chapter 2

- 1. National Association of Boards of Pharmacy, 1992-1993 National Association of Boards of Pharmacy Survey of Pharmacy Law, Washington, D.C., 1993, p. 9.
- 2. Florida requires 2,080 hours. Arkansas requires one year of experience which at 40 hours a week is equivalent to 2,080 hours of experience.
- 3. Hawaii, Legislative Reference Bureau, *Mail Order Pharmacy: First Class or Second Rate?*, Report No. 8, 1992, Honolulu.
- 4. The Drug Product Selection Board, administratively placed in the Department of Health, establishes and maintains a state drug formulary that specifies which drugs are therapeutically equivalent, safe, and effective.

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Responses of the Affected Agencies

Comments on Agency Responses

We transmitted a draft of this report to the Board of Pharmacy and to the Department of Commerce and Consumer Affairs on July 30, 1993. A copy of the transmittal letter to the board is included as Attachment 1. A similar letter was sent to the department. The response from the board is included as Attachment 2. The department did not submit a separate response.

The board agrees with our recommendation to reenact Chapter 461, Hawaii Revised Statutes, to continue the regulation of pharmacists and pharmacy. It also concurs with our recommendation to reduce the practical experience requirement from 2,000 to 1,500 hours and delete the requirement for appplicants to pass a state jurisprudence examination. The board says it is unclear about our recommendation that it abandon its efforts to regulate nonresident pharmacies, since Act 259 of 1993 now regulates them. We have amended our draft to clarify that the board should not pursue additional regulation beyond that imposed by the new law.

Concerning our recommendation that the board not impose unnecessary requirements on pharmacy assistants, the board responds that these requirements will apply to all license applicants and that it will exercise its authority with care. Arguing for greater consolidation and efficiency, the board disagrees with our recommendation that it cease trying to take over certain responsibilities of the Department of Health in regulating the pharmacy industry. We believe, however, that there is no sufficient reason to change the division of responsibility.

Concerning our recommendation that the board correct inaccuracies in its operational manual and license application forms, the board says that corrections have already been made. Concerning our finding that the application forms ask pharmacist assistant applicants who are graduates of foreign schools to take examinations in English proficiency although the statutes and rules do not require these examinations, the board believes that Section 461-5(b), HRS and Act 112 of 1993 authorize such examinations. We point out that Section 461-5(b) applies to pharmacists, not pharmacist assistants, and Act 112 only took effect on May 17, 1993.

Finally, the board agrees that the personal photograph requirement should be deleted, but not because of potential discrimination. Instead,

the board says that the photograph is no longer needed for enforcement purposes and eliminating it would streamline operations.

The board notes that several improvements in the program were made in May 1993 or thereafter (following completion of our fieldwork).

STATE OF HAWAII OFFICE OF THE AUDITOR

465 S. King Street, Room 500 Honolulu, Hawaii 96813-2917



MARION M. HIGA State Auditor

(808) 587-0800 FAX: (808) 587-0830

July 30, 1993

C O P Y

The Honorable Clifford K. Higa, Director Department of Commerce and Consumer Affairs 1010 Richards Street Honolulu, Hawaii 96813

Dear Mr. Higa:

Enclosed for your information are three copies, numbered 6 to 8 of our draft report, Sunset Evaluation Update: Pharmacists and Pharmacy. We ask that you telephone us by Tuesday, August 3, 1993, on whether you intend to comment on our recommendations. If you wish your comments to be included in the report, please submit them no later than Monday, August 30, 1993.

The Board of Pharmacy, Governor, and presiding officers of the two houses of the Legislature have also been provided copies of this draft report.

Since this report is not in final form and changes may be made to it, access to the report should be restricted to those assisting you in preparing your response. Public release of the report will be made solely by our office and only after the report is published in its final form.

Sincerely,

Marion M. Higa State Auditor

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Enclosures

JOHN WAIHEE



CLIFFORD K. HIGA DIRECTOR

NOE NOE TOM 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

September 2, 1993

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OFC. OF THE AUDITOR STATE OF HAWAII

The Honorable Marion M. Higa, State Auditor Office of the Auditor State of Hawaii 465 S. King Street, Room 500 Honolulu, Hawaii 96813-2917

Dear Ms. Higa:

The Board of Pharmacy ("Board") thanks you for the opportunity to respond to the Sunset Evaluation Update on Pharmacists and Pharmacy. The Board appreciates the report's acknowledgement that the recommendations of the 1985 sunset evaluation have been implemented. The Board also appreciates the report's strong statements in support of the regulatory protection afforded consumers through Chapter 461, Hawaii Revised Statutes (HRS). We will comment on the recommendations as they appear chronologically on page 10 of the report.

- 1. "The Legislature should reenact Chapter 461, Hawaii Revised Statutes, to continue the regulation of pharmacists and pharmacy." The Board concurs with this recommendation.
 - "In reenacting the statute, the Legislature should consider amending it to:"
 - "a. Reduce the practical experience requirement from 2,000 to 1,500 hours."

The Board is in agreement with the recommendation of reducing the practical experience requirement from 2,000 to 1,500 hours to follow the national trend.

The Honorable Marion M. Higa, State Auditor Page Two September 2, 1993

However, the Board does not feel that this requirement, while it may have appeared to be excessive and restrictive, was in actuality excessive or restrictive. For the most part, students in pharmacy school coordinated externships and clinical clerkship programs, which the Board accepts, obtain close to 1,500 hours of practical experience not including summer or part-time employment. Thus, requiring additional hours outside of the experience gained in a school curriculum is not, in the Board's view, excessive or restrictive licensure requirements.

"b. Delete the requirement for applicants to pass a state jurisprudence examination."

The Board is in agreement with the recommendation to delete the jurisprudence examination provided applicants attest to the fact that they have read and understood the Board's laws and rules and the laws and rules of the Department of Public Safety and the Department of Health pertaining to the practice of pharmacy. The Board feels strongly that the knowledge of these applicable laws and rules is important and warrants addressing. The Board also feels that the criticism aimed at the jurisprudence examination (that it is deficient due to outdated rules) fails to consider pertinent information that would have negatively impacted applicants. It is our understanding that the exam was reviewed by your office in January 1993. Although new rules were adopted on December 24, 1992, the exam administered in January 1993 was not changed because applicants would not have had the time to acquire and study the new rules. Immediately after the January 1993 examination administration, the exam was revised to reflect information from the December 1992 newly adopted rules. Therefore, the examination is not deficient and is based on current rules.

2. "The Board of Pharmacy should abandon its efforts to regulate nonresident pharmacies, to impose unnecessary requirements on pharmacist assistants, and to take over certain regulatory responsibilities of the Department of Health." The Honorable Marion M. Higa, State Auditor Page Three September 2, 1993

The Board is unclear as to the auditor's recommendation regarding nonresident pharmacies because of inconsistent and conflicting language in your report. On page 10 it is recommended that the Board "abandon its efforts to regulate nonresident pharmacies," yet on page 8, the Board is told that they "should not seek additional regulation beyond that imposed by Act 259." The matter of regulating nonresident pharmacies has already been decided by the Legislature and the Board will carry out the provisions of Act 259.

On the issue of the requirements for "pharmacist assistants" (which should be corrected to read "pharmacy intern" because of Act 112, SLH 1993) it is the Board's intent to ensure a basic level of meaningful experience for the intern. During the months of the auditor's review, the Board did extensive brainstorming to develop experience requirements for pharmacy interns. As with all brainstorming, it becomes more focused over time. Unfortunately, your staff had exited before this point and your report does not reflect the Board's current position. The Board is in fact developing experience requirements applicable to all candidates. Your concern on page 8 regarding the Board's direction has long since been changed and is in-line with your position. The Board will continue to clarify the experience requirements, keeping it at minimal level but still ensuring the intern acquires meaningful uniform experience. The Board will, as it always has, be very careful when exercising their authority, and would like to assure the auditor that they do so with due consideration. The Board has not exceeded its authority, as confirmed by the attorney general's office.

The Board disagrees with the recommendation that they abandon their efforts to take over certain regulatory responsibilities of the Department of Health (DOH), and with the statement that their efforts to consolidate regulation are unwarranted. Current budgetary and fiscal restraints make it unlikely that consolidation will occur in the near future; however, the Board will continue to strive in the future to obtain efficiency (even if it entails consolidation) to avoid duplicative efforts by two departments.

The Honorable Marion M. Higa, State Auditor Page Four September 2, 1993

3. "The department should work with the board to correct the inaccuracies in the board's operational manual and licensing forms, and to delete the requirement of a personal photograph."

The operational manual is an internal tool prepared for board members by the department and is updated in July of each year to incorporate any changes which occurred during the year and to provide newly appointed board members the most current information. Had your review of the manual been done in July 1993, you would not have found any inaccuracies.

The Board responds as follows with regard to the auditor's finding of alleged inaccuracies on the licensing forms (as stated in your report):

- a. The Board had already revised the application form to delete the "full-time" requirement back in May 1993.
- b. The Board believes it is within their authority to require proof of English proficiency by examination from foreign pharmacy intern applicants as they do from foreign pharmacist applicants pursuant to §461-5(b), HRS, and Act 112, SLH 1993.

The Board is in agreement with deleting the personal photograph requirement for reasons that it is no longer necessary for enforcement purposes (which was its purpose) and to support the department's effort to streamline aspects of its document processing to enhance efficiency. The Board and the department feel that these are more relevant and accurate reasons to eliminate the photograph rather than unfounded inferences of potential discriminatory use.

The Board appreciates the opportunity to comment on the findings and recommendations of this sunset evaluation report.

Very truly yours,

Gerry Fujii Chairperson

PROPOSED LEGISLATION

SEVENTEENTH LEGISLATURE, 1994 STATE OF HAWAII

A BILL FOR AN ACT

RELATING TO PHARMACY.

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

- 1 SECTION 1. Section 26H-4, Hawaii Revised Statutes, is
- 2 amended as follows:
- 3 1. By amending subsection (a) to read as follows:
- 4 "(a) The following chapters are hereby repealed effective
- 5 December 31, 1994:
- 6 (1) Chapter 447 (Dental Hygienists)
- 7 (2) Chapter 457 (Board of Nursing)
- 8 (3) Chapter 457A (Nurse Aides)
- 9 (4) Chapter 457B (Board of Examiners of Nursing Home
- 10 Administrators)
- 11 [(5) Chapter 461 (Board of Pharmacy)
- 12 (6)] (5) Chapter 468L (Travel Agencies)"
- 13 2. By amending subsection (g) to read as follows:
- 14 "(q) The following chapters are hereby repealed effective
- 15 December 31, 2000:
- 16 (1) Chapter 439 (Board of Cosmetology)
- 17 (2) Chapter 448F (Electrologists)
- 18 (3) Chapter 454 (Mortgage Brokers and Solicitors)
- 19 (4) Chapter 454D (Real Estate Collection Servicing Agents)

- 1 (5) Chapter 466 (Board of Public Accountancy)
- 2 (6) Chapter 467 (Real Estate Commission)
- 3 (7) Chapter 461 (Pharmacists and Pharmacy)"
- 4 SECTION 2. Section 461-5, Hawaii Revised Statutes, is
- 5 amended by amending subsection (a) to read as follows:
- 6 "(a) Any applicant for a license as a pharmacist shall
- 7 submit an application on a form prescribed by the board and shall
- 8 provide evidence to the board that the applicant:
- 9 (1) Is at least eighteen years of age;
- 10 (2) Holds a degree from a school or college of pharmacy or
- department in a university, which school or college or
- 12 department is recognized and accredited by the American
- 13 Council of Pharmaceutical Education;
- 14 (3) Has a minimum of [two thousand] fifteen hundred hours
- 15 practical experience in any state of the United States
- in a pharmacy under the supervision of a registered
- 17 pharmacist. Service and experience in a pharmacy under
- 18 the supervision of a registered pharmacist as required
- in this section shall be predominantly related to the
- 20 selling of drugs, compounding prescriptions, preparing
- 21 pharmaceutical preparations, and keeping records and
- 22 making reports required under state and federal

- 1 statutes. In the event an applicant has no practical
- 2 experience as required, the applicant may take the
- 3 examination and upon passing the examination, shall not
- 4 receive a license until after the fulfillment of the
- 5 practical experience requirement; and
- 6 (4) Has passed an examination as may be prescribed by the
- 7 board."
- 8 SECTION 3. Section 461-6, Hawaii Revised Statutes, is
- 9 amended as follows:
- 10 l. By amending subsection (a) to read as follows:
- 11 "(a) Every applicant for a license as a pharmacist shall
- 12 pass the National Association of Boards of Pharmacy Licensure
- 13 Examination (NABPLEX) [with a score of not less than seventy-
- 14 five,] and the Federal Drug Law Examination (FDLE), with a score
- 15 on each of not less than seventy-five[, and the state
- 16 jurisprudence examination with a score of not less than seventy-
- 17 fivel."
- 18 2. By amending subsection (d) to read as follows:
- "(d) Applicants who fail the NABPLEX[,] or FDLE[, or state
- 20 jurisprudence] examination shall file an application for
- 21 reexamination in the examination for which a passing score was
- 22 not achieved and shall not be licensed until the applicant

- 1 successfully passes [all] both of the licensure examinations."
- 2 SECTION 4. Section 461-7, Hawaii Revised Statutes, is
- 3 amended by amending subsection (a) to read as follows:
- 4 "(a) A registered pharmacist of any state or territory of
- 5 the United States who is not eligible for licensure by
- 6 reciprocity under section 461-8.5 may be granted a temporary
- 7 license by the board[; provided that the person shall first pass
- 8 the state jurisprudence examination with a score of not less than
- 9 seventy-five]."
- 10 SECTION 5. Section 461-8.5, Hawaii Revised Statutes, is
- 11 amended by amending subsection (a) to read as follows:
- 12 "(a) Any pharmacist who is registered or licensed under the
- 13 laws of any state or territory of the United States with
- 14 qualifications for licensure which equal or exceed those of this
- 15 State, shall be eligible for licensure; provided that:
- 16 (1) [the] The pharmacist possesses a current valid license;
- 17 (2) The pharmacist has practiced as a registered pharmacist
- for [two thousand] fifteen hundred hours or more within
- 19 the five years preceding the date of application;
- 20 (3) [there is no] No disciplinary action [pending] or other
- 21 unresolved complaints are pending against the
- 22 pharmacist in any state or territory; and

1	(4) [the] $\underline{\text{The}}$ laws of the other state or territory grant
2	reciprocal treatment to licensees of this State. [The
3	board may examine such licensees only as to knowledge
4	of this State's statutes and rules.]"
5	SECTION 6. Statutory material to be repealed is bracketed.
6 N	New statutory material is underscored.
7	SECTION 7. This Act shall take effect upon its approval.
8	
9	INTRODUCED BY:

