

MAINE STATE LEGISLATURE

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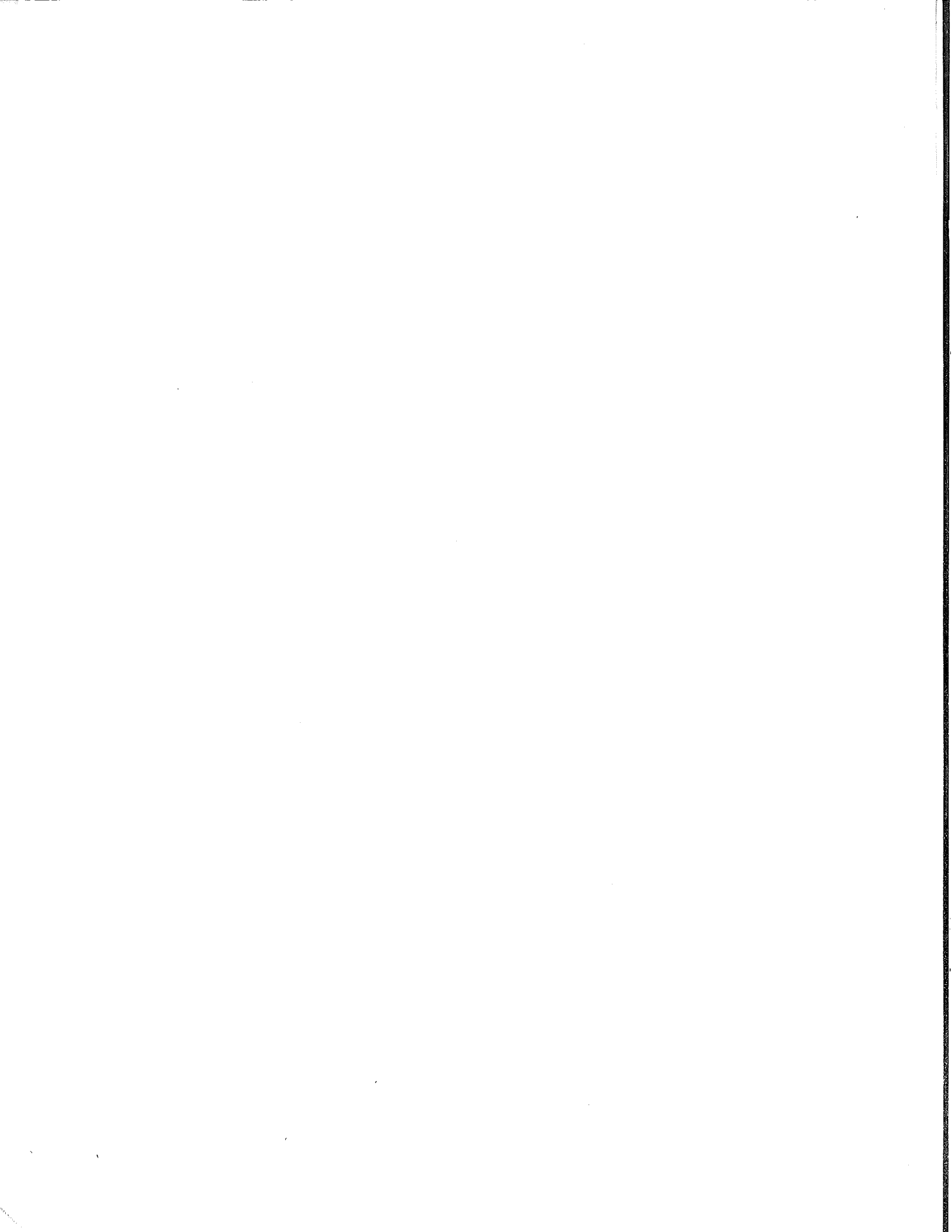
Review of

- Board of Commissioners of the Profession of Pharmacy
- Arborist Examining Board

Joint Standing Committee on Audit and Program Review

1987 - 1988



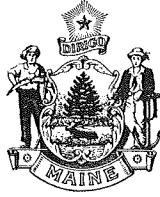


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STATE OF MAINE
ONE HUNDRED AND THIRTEENTH LEGISLATURE
COMMITTEE ON AUDIT AND PROGRAM REVIEW

April 14, 1988

Honorable Charles P. Pray, Chair
Honorable John L. Martin, Vice-Chair
Legislative Council
113th Legislature
Augusta, Maine

Dear Senator Charles Pray and Representative John Martin;

Pursuant to 3 MRSA, Chapter 23, we are pleased to transmit the fourth and final volume of the Committee's 1987-1988 report to you and the Council on:

- The Board of Commissioners of the Profession of Pharmacy; and
- The Arborist Examining Board

In addition to the diligent work of the Committee members, we would like to thank Rep. Carol Allen and members of the Joint Standing Committee on Business Legislation with whom we worked closely during the course of the review.

The Committee's recommendations will serve to improve professional regulation in our state by increasing management and fiscal accountability, resolving complex regulatory issues, clarifying Legislative intent, and increasing Legislative oversight.

Sincerely,

Handwritten signature of Beverly M. Bustin in cursive.

Beverly M. Bustin
Senate Chair

Handwritten signature of Neil Rolde in cursive.

Neil Rolde
House Chair

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Committee Organization

**AUDIT & PROGRAM REVIEW
SUBCOMMITTEE #2**

**Board of Commissioners of the
Profession of Pharmacy
Arborist Examining Board**

Members:

**Senator Beverly M. Bustin, Chair
Representative Neil Rolde, Chair
Senator Mary-Ellen Maybury
Representative Ruth Joseph
Representative Phyllis Erwin
Representative Ada K. Brown
Representative Harriet Ketover
Representative Eleanor Murphy
Representative Wesley Farnum**

Adjunct Members:

Representative Charlene B. Rydell
Joint Standing Committee on
Banking and Insurance
Representative Carol M. Allen
Joint Standing Committee on
Business Legislation
Representative Margaret Pruitt Clark
Joint Standing Committee on
Human Resources
Representative Jo Anne D. Lapointe
Joint Standing Committee on
Human Resources
Representative Jean T. Dellert
Joint Standing Committee on
Human Resources



THE COMMITTEE PROCESS

The Joint Standing Committee on Audit & Program Review was created in 1977 to administer Maine's Sunset Act which "requires the Legislature to evaluate the need for and performance of present and future departments and agencies on a periodic basis." (3 MRSA Ch. 23) To carry out its mandate, the overriding goal of the Audit Committee is to increase governmental efficiency by recommending improvements in agency management, organization, program delivery, and fiscal accountability.

The Committee process unfolds in five distinct phases, which can be briefly described as follows:

PHASE ONE: RECEIPT OF PROGRAM REPORTS

The law requires that agencies due for review must submit a Program Report to the Committee in the year prior to review. The Program, or Justification, Report prepared by the agency provides baseline data used to orient staff and Committee to the agency's programs and finances.

PHASE TWO: REVIEW BEGINS

At the start of each review, the Committee Chairs divide the full Committee into subcommittees, appoint subcommittee chairs and assign each subcommittee responsibility for a portion of the total review. Each subcommittee is augmented by at least one member from the committee of jurisdiction in the Legislature; i.e. the subcommittee reviewing the administration and management of the professional regulatory boards will include a member of the Committee on Business Legislation.

The Committee review process includes state-wide solicitation of comment from the agency's constituents and other interested parties; a review of the literature, including other state legislative sunset reports, state audit reports, annual reports, public rules and publications from the professional field. In addition, the Committee conducts surveys, interviews agency employees, conducts site reviews, analyzes the fiscal and programmatic impact of current programs, including a cost-benefit analysis of these programs in terms of current state needs and priorities and compares the laws and procedures of this agency to other state and federal agencies.

PHASE THREE: SUBCOMMITTEE MEETINGS

The subcommittees created by the Committee meet frequently when the Legislature is in session and every three to four weeks between the sessions to discuss issues regarding the agency and make recommendations for change. Staff will prepare material for the subcommittee's deliberation and present it to the subcommittee in one of several forms; as an option paper, discussion paper, or information paper. The Committee has found that these formats facilitate its process by cogently and objectively describing the topic for discussion and the points necessary for expeditious decision-making. These subcommittee meetings are not formal hearings but are open to the public and are usually well attended by interested parties. The subcommittees conduct their business in an open manner, inviting comment and providing a forum for all views to be heard and aired.

PHASE FOUR: FULL COMMITTEE MEETINGS

The full Audit and Program Review Committee considers the recommendations made by each subcommittee. These meetings are another opportunity for the public to express its views.

PHASE FIVE: THE LEGISLATURE

Following the full Committee's acceptance of subcommittee recommendations, Committee staff prepare a text and draft a bill containing all the Committee's recommendations for change. The Committee introduces its bill into the Legislative session in progress and the bill is then referred to the Audit and Program Review Committee. As a final avenue for public comment prior to reaching the floor, the Committee holds public hearings and work sessions on all its recommendations. After the Committee concludes deliberations and amendments, the bill is reprinted and placed on the agenda for consideration by the entire Legislature.

Summary of Recommendations

The Committee categorizes its changes into Statutory and Administrative Recommendations. The Committee's bill consists of the Statutory Recommendations. Administrative recommendations are implemented by the Agencies under review without statutory changes. In some instances, the Committee includes a finding which requires no further action but which highlights a particular situation. Recommendations include, where possible, the proposed change and the reason for this change. For more specific detail, refer to the narrative of the recommendations.

BOARD OF COMMISSIONERS OF THE PROFESSION OF PHARMACY

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| STATUTORY | 1. | Increase Board membership by adding a second public member to increase public perspective. |
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| STATUTORY | 2. | Decrease the length of an appointment to the Board of Commissioners of the Profession of Pharmacy to 3 years. |
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| STATUTORY | 3. | Establish that Board members may serve a maximum of 3 terms. |
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| STATUTORY | 4. | Define "quorum" as a majority of the Board members. Further, require Board actions to be taken by a majority of the quorum. |
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| STATUTORY | 5. | Place the Board of Commissioners of the Profession of Pharmacy within the Department of Professional and Financial Regulation to promote public accessibility and to increase standardization of the Board's administrative procedures. |
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STATUTORY 6. Authorize the Pharmacy Board to hire the staff necessary to carry out its statutory duties.

STATUTORY 7. Require the Pharmacy Board to notify the Attorney General's Office upon the receipt of a complaint or the discovery of a possible violation. Further, require the Attorney General's Office to notify the department within a timely period if a violation requires a criminal investigation.

ADMINISTRATIVE 8. Direct the Board of Commissioners of the Profession of Pharmacy and the Attorney General's Office to develop guidelines for identifying potential criminal activity.

ADMINISTRATIVE 9. Direct the Pharmacy inspector to refer any possible violations involving other state regulated health professionals to the Attorney General's office for reference to the appropriate licensing board.

ADMINISTRATIVE 10. Direct the Board of Commissioners of the Profession of Pharmacy, with the assistance of the Bureau of Human Resources, to revise the pharmacy inspector's job description. Further, the Pharmacy Board should report on this revision during the 1988 Compliance Review.

STATUTORY 11. Establish statutory caps for licensing fees administered by the Board of Commissioners of the Profession of Pharmacy to provide the Board with necessary flexibility.

STATUTORY 12. Repeal the reference to specific pharmaceutical manuals from the requirements for pharmacy permit renewals.

ADMINISTRATIVE 13. Amend the pharmacy permit and inspection forms to reflect the broader permit renewal criteria.

ADMINISTRATIVE 14. Direct the Board of Commissioners of the Profession of Pharmacy to review and improve its current procedures for issuing reciprocal licenses to pharmacists.

STATUTORY 15. Require all mail order pharmacies that dispense prescription drugs to patients residing in Maine to be licensed by the Board of Commissioners of the Profession of Pharmacy. Further, authorize the Board to enter into reciprocal inspection agreements with the state in which the facility is located.

STATUTORY 16. Require all drug manufacturers and wholesalers whose products are distributed in the State to register with the Pharmacy Board. Further establish a statutory cap for the required registration fee.

ADMINISTRATIVE 17. Direct the Department of Human Services to incorporate state pharmacy regulations in state health facility licensing reviews.

ADMINISTRATIVE 18. Authorize the Pharmacy Board to continue to inspect pharmacies in state-licensed facilities but require it to refer any related complaints to the Department of Human Services for regulatory enforcement action.

ADMINISTRATIVE 19. Direct the Department of Human Services to report to the Board its findings on cases referred by the Board.

ARBORIST EXAMINING BOARD

STATUTORY	20.	Continue the Arborist Examining Board under the provisions of the Maine Sunset law for ten years.
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STATUTORY	21.	Enact a number of statutory changes to promote clarity, expand certain licensing exemptions, revise the appointment and status of certain Board members and make a number of minor technical changes.
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BOARD OF COMMISSIONERS OF THE PROFESSION OF PHARMACY

BOARD OF COMMISSIONERS OF THE PROFESSION OF PHARMACY

The Board of Commissioners of the Profession of Pharmacy was established in 1877 as the Commission of Pharmacy. The Board is comprised of 6 members who represent the following categories (32 MRSA § 2851):

- 1 hospital pharmacist;
- 1 chain pharmacist;
- 3 pharmacists; and
- 1 public member.

Members of the Board are gubernatorially appointed for 5 year terms. The number of terms they may serve is currently unlimited. Compensation for board service is \$25 a day.

The Board has no central office. Central office functions are carried out at several locations. Currently, the Board's legal address is that of the pharmacy which employs the Board secretary. Board records are kept at this pharmacy and in an office in the Secretary's home. Records of public business are filed in the Secretary of State's office and the monthly Board meetings are held at the Augusta Civic Center.

BOARD EMPLOYEES

The Board is authorized to employ a drug inspector and a secretary. (32 MRSA §2853)

The drug inspector works full-time out of her home and is a licensed pharmacist whose responsibilities include:

- inspecting pharmacies;
- destroying outdated medications;
- following up complaints; and
- coordinating information between the pharmacy board and other agencies.

The Board secretary is part-time and is responsible for typing and filing board materials at the Board's legal address.

The Board also contracts with a former board member to act as Secretary for the Board. He is a full-time pharmacist who maintains board records and is responsible for the following:

- handling most correspondence;
- handling all invoices and expense accounts;

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- handling routine requests for information;
 - supervising the inspector on a daily basis; and
 - conferring with the Federal Drug Enforcement Agency (FDEA) and the DHS regularly on pharmacy license numbers.

RELATIONSHIP WITH A STATE AGENCY

The Board of Commissioners of the Profession of Pharmacy is affiliated with the Department of Professional and Financial Regulation. As in the case of all regulatory boards, the Commissioner of Professional and Financial Regulation is the authorized liaison between the Board and Governor but has no authority to interfere with the Board's exercise of power. The Board's only relationship to the department is that it submits its budget through the Department's financial system.

Since the board is not internal to the department, the Board of Commissioners of the Profession of Pharmacy receives no office space and no clerical or administrative services from the department. In addition, the department offices maintain no records of Board activities and has very little formal contact with this licensing board. Public records are sent to the Secretary of State's office for public accessibility.

REGULATORY AUTHORITY

The Board is statutorily authorized to issue rules and administer the licensing regulations which govern pharmacists and pharmacies (32 MRSA ch. 41); the state regulation of narcotics (22 MRSA ch. 551); and the state regulation of drugs (22 MRSA ch. 557). Among its responsibilities are the following:

- issuing and renewing licenses of pharmacists' and assistant pharmacists';
- administering the pharmacists' licensing exam;
- issuing permits for pharmacies, wholesaling companies, and rural health centers;
- inspecting during business hours, all pharmacies, dispensaries, stores, hospital pharmacies, extended care facilities, boarding homes, nursing homes or places that manufacture, store, distribute, compound, dispense or retail drugs or medicines;

- securing and analyzing drug samples; and
- controlling the distribution, sale, character, and standard of all drugs, poisons and medicines compounded, dispensed or distributed in the state.

According to current statute, the Board is **not responsible** for the regulation of:

- physicians;
- hospitals and sanatoriums who supply medicine to their bona fide patients;
- non-poisonous patent or proprietary medicine sold in original and unbroken packages;
- properly labeled bug and fungi killers; or
- miscellaneous remedies, including petroleum jelly, cream of tartar, borax, baking soda, castor oil, flax seed, bicarbonate of soda, saltpeter, aromatic spirits, essence of peppermint, and other unregulated substances.

PHARMACY LICENSING REQUIREMENTS

Pharmacy is a field which requires state licensure in order to authorize practitioners. The Board of Commissioners of the Profession of Pharmacy issued the following number of licenses in fiscal year 1987:

<u>Type of License</u>	<u># Issued</u>	<u>Current Fee</u>
• Pharmacists:	886	\$30
• Reciprocal Pharmacists:	22	\$150
• Assistant Pharmacists:	21	\$ 30
• Inactive Pharmacists:		
under 65:	43	\$ 30
over 65:	24	\$ 10

In addition to licensing pharmacists, the Board issues permits for the following types of facilities:

• Pharmacy	293	\$100;
• Wholesaler	126	\$100;
• Rural Health Center	7	\$100.

A. Pharmacists

The Board issues several types of pharmacist licenses, including registered pharmacists, assistant pharmacists, reciprocal pharmacists and inactive licenses.

Registered pharmacists are required to meet the following criteria in order to be licensed in Maine:

- completion of a national pharmacy exam;
- completion of a state exam on state pharmacy laws;
- graduation from an accredited department or college of pharmacy; and
- payment of a \$100 fee;
- one year's employment in a pharmacy during or after college;
- attainment of 18 years of age;
- Good moral character; and
- U.S. citizenship.

In addition to new college graduates entering the field, the board also issues pharmacist licenses to certain registered assistant pharmacists who have passed the state pharmacy exam. The board renews assistant pharmacist licenses but this licensing category can not be entered today.

The Board issues reciprocal licenses to applicants who meet the following requirements:

- proof of registration as a pharmacist in another state which has similar standards of competency;

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- completion of the state pharmacy exam;
 - payment of a \$150 fee.

Renewal of all pharmacists' licenses require the following:

- annual payment of \$30-\$60 depending on whether the license is renewed within 30 days of expiration; and
- 15 hours of continuing education.

The Board of Commissioners of the Profession of Pharmacy issues 2 types of inactive license renewals for registered pharmacists who are not practicing pharmacy within the state at the time of registration. One license is for the non-practitioner who is over 65 and the second license is for the non-practitioner who is under 65. These licenses allow pharmacists to maintain their Maine state license regardless of whether they are currently living in the state or under a consent agreement with the Board.

Requirements for the non-active license renewals include annual payments to the Board in the following amounts:

- over 65 years of age - \$10;
- under 65 years of age - \$30;

If the licensee requests re-activation of their license they must also document 15 hours of continuing education in the year immediately preceding application for license re-instatement.

B. Facilities

Current law requires all businesses of pharmacy, (not including hospitals, physicians or sanatoriums directly supplying their patients) to be registered with the board and to meet the following requirements:

- under the personal control and supervision of a registered pharmacist;
- have a store license issued under the pharmacists' name;
- payment of a \$100 fee with individual applications per store;

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- dispensing of pharmaceuticals must be legally and safely conducted;
 - conspicuous display of pharmacy permits; and
 - latest revised edition of the U.S. Pharmacopoeia and National Formulary available.

Pharmacy licenses are annually renewed following documentation of the latest edition of the U.S. Pharmacopoeia and National Formulary and payment of \$100.

In addition, companies that sell prescription drugs at wholesale must be registered with the board. Registration criteria include submitting a state permit which identifies a responsible company contact and other pertinent information and paying a \$100 fee.

DISCIPLINARY AUTHORITY

The Board of Commissioners of the Profession of Pharmacy are given the following disciplinary authority. (32 MRSA §2856-A)

- investigate complaints of non-compliance or violation of board rules or statutes including the state laws on drugs and narcotics;
- enter into consent agreements with the licensee, the board and the Attorney General's office; or
- file a complaint in the Administrative Court to suspend or revoke a license.

Licenses may be suspended for licensing fraud, habitual substance abuse, professional misconduct or incompetent practice, conviction of a crime, or violation of board rules.

OTHER AGENCIES RELATED TO DRUG INVESTIGATIONS

The Pharmacy Board is responsible for regulating **controlled substances** and **dispensers of controlled substances**. As controlled substances require appropriate prescriptions for release from a controlled and physically secured area, violations in the field of pharmacy can result in criminal proceedings. Therefore, the Board of Pharmacy must work in conjunction with the law enforcement agencies. An

investigation of professional malpractice may result in not only disciplinary action by the regulatory board but also in criminal investigation by law enforcement agents. Some of the other related government agencies who may be working with the Board or separately investigating a member of the Board's profession include the following:

- state Department of Public Safety
- federal Department of Drug Enforcement Administration
- state Department of Human Services Division of Medical Services
- Attorney General's Office of Fraud Investigation
- Other regulatory Boards whose professions may prescribe or handle prescription drugs (Board of Registration of Medicine, Board of Nursing, Board of Osteopaths, Board of Veterinary Medicine, Board of Dentistry).

BOARD FINANCES:

The Board of Commissioners of the Profession of Pharmacy operates on a budget of dedicated revenues. These revenues are collected for the specific purpose of funding regulatory activities in the field of pharmacy. These funds must be allocated by the Legislature and are based on budgets submitted through the Department of Professional and Financial Regulation.

In 1987, the Board's total budget was as follows:

• Total Revenues	\$76,053
• Total Expenditures	\$87,203
• Ending Balance	\$35,342

A. Income Sources:

The following displays the sources of income for the Board of Commissioners of the Profession of Pharmacy between fiscal years 1983 and 1987.

<u>Type of Income</u>	<u>FY 1987</u>	<u>FY 1986</u>	<u>FY 1985</u>	<u>FY 1984</u>	<u>FY 1983</u>
Application & Exam Fees	\$ 900	\$11,000	\$14,140	\$ 5,601	\$ 2,750
Registration Fees	12,784	3,630	61,313	59,079	71,488
Miscellaneous Income	59,152	60,196	2,914	16,190	
Other Services & Fees	3,217	2,004	0	20	30
Total Income	\$76,053	\$76,830	\$78,367	\$80,890	\$74,180
Ending Balance	\$35,341	\$46,492	\$44,400	\$51,968	41,165

B. Primary Areas of Expense:

The following lists the primary areas of board expenditures between FY 1987 and FY 1983.

<u>Type of Expense</u>	<u>FY 1987</u>	<u>FY 1986</u>	<u>FY 1985</u>	<u>FY 1984</u>	<u>FY 1983</u>
Travel/Auto Mileage	\$14,304	\$11,447	\$18,018	\$16,083	\$17,478
Per Diem	1,400	7,437	11,025	11,557	12,937
Misc. Prof Fees	14,381	7,410	7,016	1,776	942
Part-Time Emp. Salary	5,483	6,639	5,021	644	0
Full-Time Emp. Salary	25,080	19,280	22,982	21,902	21,864
Overtime	2,741	1,243	211	0	0
Telephone	1,476	1,603	2,928	2,185	2,405
Rent Bldgs & Office	178	1,040	864	719	374
Total Expenses	87,203	74,680	85,959	69,187	69,140

The Committee, in reviewing the operations and management of the Board of Commissioners of the Profession of Pharmacy, has issued the following recommendations. The first set of recommendations address issues related to the Board's composition. The second set addresses administrative procedures, particularly as they relate to state administrative practices and current law enforcement efforts. The last set of recommendations reviews the current licensing requirements of practitioners and facilities which distribute prescription items in Maine.

COMMITTEE RECOMMENDATIONS

STATUTORY 1. Increase Board membership by adding a second public member to increase public perspective.

Currently, the Board of Commissioners of the Profession of Pharmacy is comprised of the following 6 members:

- 1 hospital pharmacist;
- 1 chain pharmacist;
- 3 registered pharmacists; and
- 1 public member.

Current law defines a public member as having,

"no substantial financial interest in the profession regulated by the Board to which they have been appointed, nor shall that person possess or have ever possessed the degree or degrees of regulation bestowed by that particular board." (5 MRSA §12004, sub-§ 1.)

Historically, a public member has served to provide an objective regulatory perspective to a board that is otherwise comprised of "professional experts."

The Committee reviewed the composition of Maine's other health and human service regulatory boards and found that 40% of these boards had two public members. Specifically, the health and human service boards were comprised as follows:

One public member (12)

- Physical Therapists
- Administrators of Nursing Homes
- Hearing Aid Dealers
- Occupational Therapists
- Veterinarians
- Radiologists
- Pharmacists
- Dentists
- Optometrists
- Osteopath Physicians
- Chiropractors
- Podiatrists

Two public members (8)

- Psychologists
- Social Workers
- Speech Pathologists & Audiologists
- Substance Abuse Counselors
- Dietetic Practitioners
- Respiratory Care Practitioners
- Registration in Medicine
- Nurses

The Committee finds that adding another public member would increase the public participation and be consistent with other health and human service regulatory boards. The Committee further finds that adding another public member to the Board will result in a total of 7 members and that it is important for Boards to have an odd number of members in order to facilitate decision-making based on a clear majority.

Therefore, to provide increased public participation, the Committee recommends that the Board membership be increased by adding a second public member.

STATUTORY	2.	Decrease the length of an appointment to the Board of Commissioners of the Profession of Pharmacy to 3 years.
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STATUTORY	3.	Establish that Board members may serve a maximum of 3 terms.
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Members of the Board of Commissioners of the Profession of Pharmacy are currently appointed for 5 year terms and are able to serve an unlimited number of terms in office. Current board members have served for the following number of terms:

- 2 Registered Pharmacists - 1 term;
- 1 Registered Pharmacist - 2 terms;
- 1 Chain Pharmacist - 1 term;
- 1 Hospital Pharmacist - 2 terms;
- 1 Public Representative - 2 terms;

The Board Secretary, prior to becoming an employee of the Board, had served 4 terms, or 20 years, as a Board Member.

Of the estimated 40 professional licensing boards in Maine, 18 have appointment terms of 3 years. Furthermore, 11 of the state boards limit Board members to a maximum of 3 terms.

- 20 boards have 2 maximum terms;
- 11 boards have 3 maximum terms;
- 1 board has 4 maximum terms; and
- 8 boards have unlimited terms of service.

Upon review, the Committee finds that shorter terms would serve to:

- enable a greater number of professionals to serve on the Board;
- encourage the involvement of more professionals on the Board;
- encourage fresh perspectives in the regulation of this field; and
- allow more frequent gubernatorial review of Board appointments.

Furthermore, the Committee finds that lengthening the number of allowable terms of service from 2 to 3 years will help provide the continuity necessary for the Board to protect the public health and welfare.

Therefore, the Committee recommends that appointments to the Board of Commissioners of the Profession of Pharmacy should be decreased to 3 year appointments and that the maximum limit on the number of appointments should be increased to 3 terms.

STATUTORY

4.

Define "quorum" as a majority of the Board members. Further, require Board actions to be taken by a majority of the quorum.

Webster's dictionary defines a quorum as the minimum number of members who must be present for the valid transaction of business.

The statutes vary by regulatory Board in defining the number of Board members required to constitute a quorum. However, the Pharmacy Board and the Auctioneers Advisory Board are the only state boards that have no definition of a quorum in statute.

The Committee found that defining a quorum in statute is beneficial to state government. Furthermore, the Committee found that a majority of the Board is appropriate for a quorum and is consistent with the definition used in other regulatory fields.

Therefore, the Committee recommends that the statutes define a quorum as a majority of the pharmacy board and further require board actions to be taken by a majority of the quorum.

STATUTORY 5. Place the Board of Commissioners of the Profession of Pharmacy within the Department of Professional and Financial Regulation to promote public accessibility and to increase standardization of the Board's administrative procedures.

The State of Maine currently has more than 40 professional regulatory boards. Twenty-nine of these boards are internal to the Department of Professional and Financial Regulation. The Board of Commissioners of the Profession of Pharmacy is not currently one of the internal boards.

The Department of Professional and Financial Regulation is responsible for providing procedural assistance to agencies internal to the department in such matters as: (10 MRSA §8003)

- personnel civil service;
- budgeting and finance;
- purchasing of goods;
- clerical services;
- office support services;
- complaint investigation;
- disciplinary actions and enforcement;
- licensing examinations; and
- computer services.

The bureaus, boards and commissions that are internal to the Department of Professional and Financial Regulation have the following authorities:

- sole authority to regulate the profession, occupations and industries;
- authority to suspend a license for up to 90 days or impose a civil penalty of up to \$500 for legal or regulatory violations; and
- authority to execute a consent agreement with the consent of all parties, and the Attorney General's counsel.

The Committee found that placing the Board of Commissioners of the Profession of Pharmacy within the Department of Professional and Financial Regulation will result in the following administrative changes.

- **Personnel:** All Board personnel will be classified state employees of the Department of Professional and Financial Regulation hired by the Commissioner with the advice of the Board. Employee records will be kept using standard weekly time sheets and activity reports. The inspector will be under the specific direction of the Board members with immediate supervision/scheduling provided by the department, in conjunction with the Attorney General's Office.
- **Budgeting and Finance:** Budgets will be submitted in accordance with state budget procedures, including quarterly workplans.
- **Purchasing of Goods:** Board requests for purchasing items will be submitted through the department's administrative office using the state's administrative procedures.
- **Clerical and Support Services:** A state classified board clerk will type, file, keep board minutes and respond to licensing application requests in an immediate and standard state manner; public queries will be logged, reported to the Board and placed on the next meeting agenda; the department will provide a centralized public office with 40 hour/week drop-in center and telephone answering service, a central repository for the public record of Board activities and a widely publicized state phone number.
- **Complaint Investigations:** The Department logs all complaints, schedules the inspectors, and confers with the Attorney General's Office to identify and separate criminal investigations from the department's regulatory investigations. The Board is notified of all complaints and the inspector's findings. The Board is responsible for taking regulatory action.

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- **Disciplinary Actions:** The Department initiates the administrative procedures necessary for disciplinary action. These procedures are defined in statute under the state Administrative Procedures Act and require the scheduling of a hearing date, the issuing of subpoenas to bring in witnesses, and the scheduling of a hearing room, etc in order to facilitate appropriate procedures in the Board's hearing of a disciplinary case. In addition, internal boards have the authority to revoke or suspend a license or impose a fine. These authorities are concurrent with that of the Administrative Court.
 - **Licensing Examinations:** The Department of Professional and Financial Regulations provides public examination rooms for Boards to test licensing applicants.

The Committee finds that having a centralized, accessible public office is essential to the Board's operations. Further, the Committee finds that the Board would benefit from administrative support and guidance in state policies and procedures and would be better able to address questions of state pharmaceutical policy if these administrative matters were handled in a standard manner.

Therefore, the Committee recommends that the Board of Commissioners of the Profession of Pharmacy be placed within the Department of Professional and Financial Regulation in order to increase the accessibility and standardization of the Board's administrative procedures.

STATUTORY

6. Authorize the Pharmacy Board to hire the staff necessary to carry out its statutory duties.
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Current law authorizes the Board to employ a drug inspector and a secretary. (32 MRSA §2853)

The Board currently employs a full-time inspector and a part-time secretary. In addition, the Board contracts with a former board member to act as an administrative Secretary to the Board and to provide supervision to the Board inspector.

The Board's pharmacy inspector is a full-time state employee paid at range 22.

The Board estimates that during the past year, the current inspector:

- inspected 10 - 16 pharmacies a month;
- conducted 40 - 55 complaint investigations; and
- traveled approximately 22,000 miles

The Committee found that the current inspector spends the following amounts of time on the respective types of activities:

- 1 - 2 days a week on report writing, answering the telephone calls, researching the answer to questions;
- 3 -5 days a week traveling to either conduct regularly scheduled pharmacy inspections, investigate complaints, or make site visits in order to answer specific questions.

Currently, the inspector has been unable to complete annual inspections of the 250 pharmacies in the state. This is due to several factors:

- geographic distances require extensive travel time;

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- inspection schedules are disrupted due to incoming complaints, requests for information and requests for other official services, such as legally destroying outdated narcotics; and
 - the inspector is responsible for all related support services such as report typing, researching answers to phone call inquiries, and answering phone calls left on her answering machine.

The Committee finds that it may be appropriate for the Board to hire at least another part-time inspector in the coming year to assist in carrying out all of the responsibilities assigned to the inspector for the following reasons:

- the inspector's annual inspections are important as they ensure that pharmacists are enforcing state laws and regulations;
- the state inspections provide pharmacists with individual feedback regarding their own practices and recent changes in the field; and
- the inspector is currently unable to visit every pharmacy in the state.

Although the Committee finds that there is a clear need for another part-time inspector, the Committee also made a number of recommendations which will result in a more efficient and effective operating system for the Board's inspectors:

- have the Attorney General's Office determine whether a case requires civil or criminal investigation. This will eliminate the inspector's initial work in those cases which require criminal investigation.
- require the inspector to refer cases that involve other professionals to the AG's Office for reference to the appropriate board. The inspector will no longer be involved with the practices of physicians and other licensed professionals authorized to handle drugs.

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- bring the board into the Department of Professional and Financial Regulation as an internal board. As a part of the department, the Board's inspectors will have clerical assistance in typing reports, logging complaints, and in relaying policy questions from pharmacists to board members.

However, the Committee realizes that the inspector may still need assistance in annually inspecting all of the state pharmacies. Furthermore, the Committee recognizes in the future, the Board may need additional administrative assistance and finds that the Department of Professional and Financial Regulation is capable of assessing these needs.

Therefore, the Committee recommends that the board be authorized to hire the necessary staff required to carry out the purposes of this chapter.

STATUTORY

7. Require the Pharmacy Board to notify the Attorney General's Office upon the receipt of a complaint or the discovery of a possible violation. Further, require the Attorney General's Office to notify the department within a timely period if a violation requires a criminal investigation.
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ADMINISTRATIVE

8. Direct the Board of Commissioners of the Profession of Pharmacy and the Attorney General's Office to develop guidelines for identifying potential criminal activity.
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The Board of Commissioners of the Profession of Pharmacy is authorized to enforce and investigate any violations of the state pharmacy laws, narcotic laws and drug laws. This authority is vested in the Board inspector when they inspect pharmacies and conduct complaint investigations.

Currently, the Pharmacy Inspector is responsible for annually inspecting Maine's pharmacies to review their record-keeping, drug storage and distribution practices. The state inspections include a review of the facility and the pharmacy's distribution and patient records to see that they meet the state's legal requirements.

The Board also receives complaints regarding pharmacy practices in Maine. Complaints are received directly by several individuals - the inspector may receive calls, a Board member may receive a call, or the Board office may receive a call. The complaint is then investigated by the inspector.

Two types of complaints may be received by the Board or its personnel:

- regulatory complaints regarding the practice of an individual pharmacy or pharmacist; or
- criminal complaints, such as the overprescription of a local doctor or the overdispensing of a local pharmacist to an individual.

If the inspector finds a possible violation during an inspection or complaint investigation, the inspector will:

- consult with Board members and the Board secretary to determine the next appropriate step in her investigation.
- carry out the direction of the Board members and the secretary keeping them informed of any findings prior to her monthly report to the Board.
- report on the inspector's activities at the monthly meeting; and
- carry out further direction as provided at the Board meeting.

The inspector is currently advised by the Board to gather facts about these complaints before they are determined to be of a regulatory or a criminal nature. Therefore, investigations may already be in the "fact-finding" stages before the Attorney General has advised on whether a possible violation requires a trained criminal investigator or the Board's trained regulatory investigator.

Secondly, if the inspector finds a clear violation of statute, the inspector may immediately act on it and then report this activity to the Board in the monthly inspector's report. An example of this is the use of pre-printed prescription pads. It is illegal to issue prescriptions on pre-printed prescription pads and when found in pharmacy files, the inspector will call the prescribing physician to bring this pharmacy regulation to their attention.

Until recently, the Pharmacy Board has been the primary state agent for investigating pharmaceutical problems. However, with the recent increased public attention being devoted to drug abuse, several other public agencies have increased their involvement in drug investigations. The spectrum of drug investigators today include the following:

- the pharmacy board and its inspector conduct facility inspections and civil licensing investigations of pharmacists;
- related licensing boards conduct civil licensing investigations of their professionals involved in a drug diversion crime or a pharmacy-related action;
- state and local police and the Attorney General's Office conduct criminal investigations using criminal standards of evidence to determine if a crime has been committed involving pharmaceuticals.

The Committee finds that in the course of inspecting pharmacies and answering complaints, the Board frequently encounters possible violations which may constitute criminal activity. However, the Committee further finds that the Pharmacy Board should not be responsible for the investigation of potentially criminal activities nor for civil investigations that relate to other health professionals.

In addition, the Committee found that a model for conducting concurrent civil and criminal investigations has been established by the Attorney General's office and the Department of Human Services in their investigations of child abuse. Specifically, these 2 state agencies have developed guidelines to aid DHS caseworkers in identifying circumstances that could require a criminal investigation. The Committee finds that it is important to the effectiveness of the state's law enforcement efforts and to the protection of individual rights of due process that drug investigations be appropriately conducted in order to safeguard any concurrent or subsequent criminal investigations.

Therefore, the Committee finds that the Board should be advised by the Attorney General's Office of whether a possible violation requires criminal investigation. Further, the Committee finds that it would be mutually beneficial for the Board of Commissioners of the Profession of Pharmacy and the Attorney General's Office to develop guidelines for identifying potential criminal activity.

Accordingly, the Committee recommends that the Pharmacy Board be required to notify the Attorney General's Office upon the receipt of a complaint or the discovery of a possible violation. Further, the Attorney General's Office be required to notify the department within a timely period if a violation requires a criminal investigation. Furthermore, the Committee recommends that the Attorney General's Office and the Board should work together to develop guidelines for identifying potential criminal activity.

ADMINISTRATIVE 9.

Direct the Pharmacy inspector to refer any possible violations involving other state regulated health professionals to the Attorney General's office for reference to the appropriate licensing board.

The Pharmacy Board is currently responsible for the control and distribution of controlled pharmaceutical substances in Maine. This responsibility is carried out by the board inspector in reviewing pharmacy patient and dispensing records for possible violations of current law and regulations. During the course of a review, the inspector may find possible violations which could reflect a health professional's ignorance of a patient's drug habit or it could be the result of intentional, criminal drug diversion.

An example of this is in the case of a patient who "doctor shops". The patient may visit several doctors to receive multiple prescriptions for a controlled substance. The inspector, upon finding excessive amounts documented in the patient's profiles at the pharmacy, may then visit the prescribing physician and bring it to their attention.

If the Doctor were unaware of the patient's drug habit, the inspector's visit could serve to end the problem simply by bringing it to the physician's attention. On the other hand, if the doctor is aware that their patient is a drug abuser and is intentionally prescribing drugs with that knowledge, then they are actively participating in criminal activity and the inspector's visit may inadvertently harm a criminal investigation.

The Committee recognizes that the inspector can serve as an educator in visiting other related health professional. However, the Committee finds that it is not appropriate for the Pharmacy Board inspector to visit other related health professionals for the following reasons:

- The inspector may inadvertently interfere with an on-going criminal investigation by alerting the prescriber that they may be under criminal investigation;
- The pharmacy inspector is representing the State Board of Pharmacy when conducting these visits and the Board has no jurisdiction over these other health professionals;
- The related health boards which have jurisdiction over these professionals have a criminally trained complaint investigator assigned to them in the Attorney General's office.

Therefore the Committee recommends that the pharmacy inspector should refer any possible violations involving other state regulated health professionals to the Attorney General's Office for reference to the appropriate licensing board.

ADMINISTRATIVE 10.

Direct the Board of Commissioners of the Profession of Pharmacy, with the assistance of the Bureau of Human Resources, to revise the pharmacy inspector's job description. Further, the Pharmacy Board should report on this revision during the 1988 Compliance Review.

The Board's pharmacy inspector is currently responsible for several facets of drug compliance and inspection. The inspector's largest responsibility is to annually inspect Maine pharmacies to review their record-keeping, drug storage and distribution practices. In addition to the annual inspections, all new or re-located pharmacies must be inspected for compliance with state laws before a pharmacy can be opened.

Pharmacy inspections are conducted using a standard inspection form which includes a review of pharmacy records to:

- compare the federal distribution records of scheduled drugs with local pharmacy distribution records;
- compare individual patient records to see that appropriate amounts of drugs and appropriate remedies have been dispensed to an individual during a year's period; and
- compare patient records regionally to see if a drug abuser has been visiting several pharmacies or several doctors to receive excessive drug prescriptions.

The inspector also reviews the dispensing facility to see that drug storage and handling practices meet legal standards such as:

- proper security of controlled substances;
- proper storage of all prescription drugs;
- proper disposal of all scheduled drugs; and
- proper patient files recording amounts and types of individual prescriptions.

The inspector also serves as the state's primary pharmacy expert and as such, receives questions on the compliance of physical facilities, security of drug storage practices and other related regulatory compliance questions. In addition, the inspector is one of three available resources for legally destroying outdated narcotics.

Lastly, the inspector often represents the Board in responding to drug complaints. This may involve answering questions over the phone, visiting pharmacies or contacting other officials for further information.

Two types of complaints may be received by the Board or its personnel:

- regulatory complaints regarding the practice of an individual pharmacy or pharmacist; or
- criminal complaints, such as the overprescription of a local doctor or the overdispensing of a local pharmacist to an individual.

Until recently, the Pharmacy Board has been the primary state agent for investigating all pharmaceutical problems. However, with the recent increased attention to drug abuse, law enforcement agents have increased their participation in drug investigations. In addition, the Attorney General's investigative unit has added investigators to work with some of the regulatory boards. This increased participation by criminal investigators has reduced the pharmacy board inspector's responsibility for investigating all complaints related to pharmaceuticals and has eliminated the need to contact related health professionals other than pharmacists.

The Committee has issued several related recommendations which will impact the inspector's current responsibilities as defined in the job description. For example, the Committee has recommended that:

- the pharmacy board should only be conducting civil investigations and should be legally advised as to whether a finding requires a civil or criminal investigation.
- the Board should not be conducting civil investigations that relate to other health professionals.
- the board should be authorized to inspect pharmacies in health facilities licensed by the Department of Human Services for compliance with state pharmacy laws but complaints should be referred to the DHS for regulatory action.

Accordingly, the Committee finds that the Board of Commissioners of the Profession of Pharmacy, with the assistance of the Bureau of Human Resources, should revise the pharmacy inspector's job description to reflect these changes in Board authority and responsibility. Further, the Pharmacy Board should report on these efforts during the 1988 Compliance Review.

STATUTORY 11. Establish statutory caps for licensing fees administered by the Board of Commissioners of the Profession of Pharmacy to provide the Board with necessary flexibility.

Current law (32 MRSA ch.41, sub-ch. III.) authorizes the Board to charge the following amounts for pharmacist and pharmacy licensing fees:

- \$100 for pharmacist application fee;
- \$ 30 for annual pharmacist license renewal; and
- \$100 for annual pharmacy permit.

In Fiscal Year 1987, these fees totaled \$56,580, and amounted to 75% of the Board's revenues. The other 25% of the Board's revenues were derived from issuing qualified assistant pharmacist licenses, reciprocal licenses, inactive pharmacists licenses and wholesalers permits.

In reviewing the Board's budget between 1983 and 1987, the Committee found that the Board has consistently had expenditures that were slightly higher than revenues. However, the board's budget has been balanced each year due to an ending balance of \$35,000-\$45,000 which has consistently been carried forward.

In 1987, the Board's total budget was as follows:

• Total Revenues	\$76,053
• Total Expenditures	\$87,203
• Carry over Ending Balance	\$35,342

Therefore, in light of the board's current level of expenditures, and the potentially increased future costs, the Committee recommends amending the statutes to establish a statutory cap of \$100 for pharmacist licenses and \$200 for pharmacy permit fees.

STATUTORY 12. Repeal the reference to specific pharmaceutical manuals from the requirements for pharmacy permit renewals.

ADMINISTRATIVE 13. Amend the pharmacy permit and inspection forms to reflect the broader permit renewal criteria.

The state law has 3 sections of law regulating pharmaceuticals and their distribution:

1. Title 32, which defines pharmacy and pharmacist licensing regulations;
2. Title 22, which defines the State Drug Act in accordance with the Federal Food and Drug Act; and
3. Title 22, which defines the Narcotics Laws.

Pharmacy reference materials are identified and required in 2 sections of law. The pharmacy licensing law, in Title 32 requires all pharmacies to maintain current reference materials on drug interactions (32 MRSA §2911). The state drug laws in Title 22 require the reference materials to be the latest revision of the U.S. Pharmacopoeia (USP) and the National Formulary (NF) (22 MRSA §2202).

The annual license renewal form requires each pharmacy to include the serial numbers for the latest copy of the U.S. Pharmacopoeia and National Formulary. Accordingly, each pharmacy must purchase a new set of these reference books every year in order to be relicensed.

Furthermore, the pharmacy inspection sheets include a category which requires the inspector to check for these specific references. A pharmacy can be cited for failure to have an up-to-date set of materials.

The Committee finds that the USP and NF are only 2 of the available and accepted pharmaceutical reference books. The Committee further finds that:

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- these specific references are not as valuable to today's retail pharmacy as in the past, but due to current law, pharmacists must purchase copies of these specific references in addition to the reference manuals that are essential to today's retail pharmacist;
 - the USP and NF are expensive; and
 - these references are contained within a section of statute which also requires some obsolete pharmaceutical equipment.

Further, the Committee finds that the public health and welfare would be better protected if the pharmacy law were amended to replace references to specific materials with the following language:

"Establish the specifications of minimum professional and technical equipment, environment, supplies and procedure for the compounding or dispensing of medications, drugs, devices and other materials within the practice of pharmacy."

Therefore, the Committee finds that the law, the permit and the inspection forms should be amended to repeal the requirements for specific reference materials in the pharmacy permit renewal process.

ADMINISTRATIVE	14.	Direct the Board of Commissioners of the Profession of Pharmacy to review and improve its current procedures for issuing reciprocal licenses to pharmacists.
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Current law authorizes the Board to issue reciprocal pharmacy licenses on the following basis:(32 MRSA §2902)

- upon payment of \$150 from the applicant to the secretary of the Board; and
- upon proof of licensure from states which require a comparable degree of competency.

State regulations further require the applicant to:

- have a year's experience;
- be licensed in a state which has reciprocity with Maine;
- appear for a personal interview with a member of the Board of Commissioners of the Profession of Pharmacy; and
- complete an exam on state and federal pharmacy laws.

The National Association of State Licensing Boards of Pharmacy (NABP) facilitates the reciprocal licensing process by providing a national clearinghouse for reciprocal pharmacy licenses. NABP provides each participating state, including Maine, with reciprocal licensing application forms, application reviews and individual reference validations. This process takes 4 to 6 weeks. Applicants are notified of whether they qualify to take the state examination 6 to 10 weeks after the application is returned to the Maine state Board. Following satisfactory completion of an examination, the applicant may be issued immediately a temporary license to practice. The Board then issues the applicant's annual license at the next board meeting.

The Committee found that the Board requires 6-10 weeks in addition to the NABP process due to the following factors:

- the state must contact the pharmacist's references; and
- references are requested through the mail and 6 to 8 weeks is allowed before telephone follow-up is initiated.

The Committee finds that careful review of applicants licensing references is important to the public health and safety. However, the Committee also finds that reciprocal licenses are essential to the state's ability to fill pharmacy vacancies and protect the public health and welfare.

Therefore, the Committee recommends that the Board of Commissioners of the Profession of Pharmacy should review and improve its current procedures for issuing reciprocal licenses to pharmacists.

STATUTORY

15.

Require all mail order pharmacies that dispense prescription drugs to patients residing in Maine to be licensed by the Board of Commissioners of the Profession of Pharmacy. Further, authorize the Board to enter into reciprocal inspection agreements with the state in which the facility is located.

Upon review, the Committee found that current law contains no provisions to regulate the distribution of prescription items directly from out-of-state pharmaceutical companies to Maine patients/consumers.

However, in order to protect the health and welfare of Maine citizens, Maine law requires in-state pharmacists to meet laws and regulations designed to protect the public health and welfare. For example, pharmacists in Maine are required to personally provide information to their patients about the medication being dispensed, meet certain recordkeeping requirements, and follow certain administrative and personnel procedures to dispense these drugs.

The Committee finds that these regulations are essential in protecting the public health and welfare of Maine clients. Furthermore, the Committee finds that mail order companies that dispense prescription items directly to Maine residents should be required to institute similar safeguards to protect Maine's patients.

For practical purposes, the Committee finds that these standards could best be assured through recognition of facility licenses in states with similar licensing standards. In the absence of such licensure, the Committee finds that the Board should be authorized to enter into reciprocal inspection agreements with the state in which the facility is located.

Therefore, the Committee recommends that all mail order pharmacies that dispense prescription drugs to patients in Maine should be licensed in Maine. Further, for practical purposes, the Committee recommends that the board be authorized to enter into reciprocal inspection agreements with the state in which the facility is located.

STATUTORY

16.

Require all drug manufacturers and wholesalers whose products are distributed in the State to register with the Pharmacy Board. Further establish a statutory cap for the required registration fee.

Current state law requires that all wholesalers of prescription drugs, whether within or without this state, be registered with the Board before making any sales. "Wholesaler" is defined as a person who manufactures, bottles, packs or purchases drugs, medical devices or cosmetics for the purpose of selling these prescription items to retailers. (32 MRSA §2904) The process of registration currently includes an annual registration fee of \$100.

Current law requires anyone selling directly to a dispenser to be registered in Maine as a wholesaler. This includes 2 different types of companies:

1. Wholesale companies that buy drugs from manufacturers and sell to dispensers; and
2. Manufacturing companies that sell directly to dispensers.

Current law does not require registration of manufacturers that sell their product to wholesale companies for resale to the retailers.

After much deliberation, the Committee found that it is important to the public health and welfare to know what companies are distributing drugs into Maine and to identify a representative of the company as the state contact. The Committee further found that registration of the manufacturing companies was sufficient control of the salespeople's distribution of sample size prescription items.

Accordingly, the Committee finds that in light of the increased drug regulations the current law is inadequate to protect the public health and welfare and that state law would be more effective if it provided a registration cap instead of a defined fee.

Therefore, the Committee finds that all drug manufacturers and wholesalers whose products are distributed in the state should register with the Board of Commissioners of the Profession of Pharmacy. Further, the statutes should include a statutory cap in place of the required registration fee.

ADMINISTRATIVE 17. Direct the Department of Human Services to incorporate state pharmacy regulations in state health facility licensing reviews.

ADMINISTRATIVE 18. Authorize the Pharmacy Board to continue to inspect pharmacies in state-licensed facilities but require it to refer any related complaints to the Department of Human Services for regulatory enforcement action.

ADMINISTRATIVE 19. Direct the Department of Human Services to report to the Board its findings on cases referred by the Board.

Current law authorizes the board to register retail pharmacies, wholesale pharmacies and rural health centers. However, physicians, hospitals and sanatoriums who supply medicine to their bona fide patients are specifically excluded from required registration with the pharmacy board. (32 MRSA § 2801)

According to 32 MRSA §2851, sub-§3, the board is authorized to inspect all pharmacies, dispensaries, stores, hospital pharmacies, extended care facilities, boarding homes, nursing homes, or places in which drugs or medicines are manufactured, stored, distributed, compounded, dispensed or retailed. This includes those facilities which are excluded from Board registration.

According to the State's current human service laws, all "hospitals, sanatoriums, convalescent homes, rest homes, nursing homes and other institutions for the hospitalization or nursing care of human beings **must be licensed** (by the DHS) to operate."(22 MRSA §1811)

Furthermore, the law provides the DHS with the following regulatory authority if facilities fail to meet licensing requirements:

"when a health care institution fails to meet all of the legal or regulatory requirements for licensure, the DHS may either issue a temporary 90 day license or a conditional license until the facility comes into compliance with regulatory or licensing requirements." (22 MRSA §1817)

In determining the need for board registration of the pharmacies in these state-licensed facilities, the Committee reviewed the facility licensing practices of the Department of Human Services. The DHS Division of Licensing and Certification has a licensing team comprised of:

- a pharmacist;
- an internist;
- a surgeon;
- several nurses;
- a dietician;
- a social worker; and
- a sanitarian.

This team conducts institutional reviews which average 3 - 5 days in length and focus on the facility as a whole, including a review of the practices of individual departments and how the departments interact with other institutional units in providing individual client services.

The Committee found that this multi-disciplinary team reviews the following topics as it assesses a facility's use of pharmaceuticals:

- appropriateness of drug use, administration, storage, accessibility and security;
- audits of the scheduled drugs;

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- review of the pharmacy's patient profiles and physician's orders;
 - visibility of a pharmacist's license; and
 - review of policies and procedures on the organization of the facility, its staff, its methods for stop-orders of discharged patients and expired drugs and practices for emergency room drug use and dispensing.

If the DHS finds health care practices that do not meet the state regulatory standards the facility is cited and must correct the problem before a permanent annual facility license is issued.

If an individual health care professional is at fault in a facility licensing citation, the DHS contacts the appropriate regulatory board to investigate licensing action against the professional.

The DHS licensing team reviews these facilities for state licensure every 2.5 years. In addition, these facilities are also subject to federal regulation. In providing care to Medicare patients, all hospitals are required to be accredited by the Joint Commission on Accreditation of Hospitals (JCAH), the Osteopath Accreditation of Hospitals (OAH) or to be annually certified by state Medicare and Medicaid survey teams. The accreditation process includes a 3-day site review by the JCAH or OAH every three years. The certification process is required annually in order to facilitate federal reimbursements to the hospitals.

The Committee finds current law to be appropriate in providing the DHS with licensing enforcement authority for entire facilities, including the facilities' pharmacies for the following reasons:

- current DHS licensing procedures include regular facility reviews which contain a specific pharmacy component;
- the pharmacy component includes inspection for compliance with state pharmaceutical laws and regulations;
- the facilities are further reviewed for compliance with federal licensing requirements, such as Medicaid and Medicare;

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- the facilities are reviewed tri-annually for continuing accreditation by the Joint Commission of Accreditation of Hospitals (JCAH) and the Osteopath Accreditation of Hospitals (OAH);
 - federal regulation is designed to specifically review drug distribution in the context of an institutional environment; and
 - regulation by both the DHS and the Board of Pharmacy would be duplicative and cause an undue burden on the health facilities.

However, the Committee also finds that the current law which authorizes the Board of Commissioners of the Profession of Pharmacy to inspect these facilities is appropriate and valuable. The Committee finds that it is important for the licensed pharmacists within these institutions to have a direct and open line of communication with the state regulatory board.

The Committee finds that due to a lack of clarity, the Board has no established procedures for reporting poor institutional pharmacy practices to the DHS for enforcement action. Furthermore, the Committee finds that the DHS lacks a system to report to the board its findings on referred cases.

Therefore, the Committee finds that administrative procedures should be improved to ensure that the DHS continues to incorporate pharmacy regulations in facility licensing reviews; the Board continues to inspect these facilities but refers complaints to the DHS and the DHS should report its findings to the pharmacy board on referred cases.



ARBORIST EXAMINING BOARD

ARBORIST EXAMINING BOARD

STATUTORY 20. Continue the Arborist Examining Board under the provisions of the Maine Sunset law for ten years.

The Arborist Examining Board exists to administer state regulation of the arborist profession. Current Maine Law (32 MRSA §§1951-2961) requires that those persons who conduct the various aspects of tree care and maintenance must have a state arborist license to practice that profession. The statutes presently define "arborist" as follows:

"Arborist" means a person who, for compensation, diagnoses or evaluates the condition of shade or ornamental trees; or solicits, recommends or supervises the treatment of such trees; or in any manner or for any purpose treats or cares for such trees or parts thereof; or takes down or fells such trees by topping or by sections, except pursuant to a permit issued under section 2051-A; or for control of any diseases, injuries or insects, sprays or treats by any other method such trees or forest trees.
(32 MRSA §1951 (1))

Present law contains a number of significant exemptions regarding licensure as arborists. These exemptions include the following:

- municipalities with a population less than 2,500 persons; i.e. the arborist profession may be practiced in these towns without a state license;
- personnel employed and supervised by a licensed arborist;
- public employees who perform arborist related duties in the course of their normal job responsibilities; and

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- general contractors who perform arborist related duties in the course of their normal job responsibilities.

The Arborist Examining Board was established in 1933 by the Maine State Legislature. Since 1978, the Board has been an "internal" Board of the Department of Professional and Financial Regulation. In that relationship, the Board receives centralized administrative and support services but retains autonomy in its discretionary licensing authority.

The Board is comprised of the following 6 members:

- 2 licensed arborists, appointed by the Governor;
- 1 plant pathologist employed by either the University of Maine or the State; appointed by the Governor;
- 1 public member; appointed by the Governor; and
- 2 non-voting, ex-officio members are appointed by the Director of the Bureau of Forestry from that Bureau.

Board members are appointed for 5 year terms by using a staggered system which helps to ensure some Board continuity. Board members receive \$25 per day in compensation for their duties.

The Board uses the part-time services of one clerk from the Division of Licensing and Enforcement. In recent years, the Board's clerk has averaged 5 hours per week on the Board. In addition, the Director of that Division processes complaints for the Board.

By law, the Board is required to meet at least once yearly. In 1987, the Board met 6 times. The Committee notes that this figure is significantly higher than in other recent years and represents a more active board.

The Committee found that the Director of the Division of Licensing and Enforcement receives an average of 6 complaints per year regarding unlicensed practice for arborists. These complaints tend not to be filed by members of the general public, but by licensed arborists who report unlicensed practice of competitors. These complaints appear to be resolved through letters written by the division director to the complainants.

For FY 1987, the board had:

- anticipated revenues of \$9,707;
- budgeted expenditures of \$7,200; and
- projected balance of \$2,507.

The Committee also notes that these figures represent a financial turnaround for the Arborist Examining Board. Prior to the last several years, the Board had struggled to generate revenues to adequately cover expenditures. The Board's improved financial status is attributable in part to recently increased licensing fees, and in part to a renewed enthusiasm from the Board.

During last year's review process, the Committee had recommended a one year continuation of the Board. Since that time, the Committee finds that the Board appears to have been reinvigorated and have approached their responsibilities with a new sense of dedication and interest. The Committee commends the Board for their renewed interest and recent accomplishments and finds that the public health and welfare continues to require state regulation of the arborist profession.

Therefore, the Committee now recommends that the Arborist Examining Board be continued for ten years under the provisions of the Maine Sunset Law.

STATUTORY	21.	Enact a number of statutory changes to promote clarity, expand certain licensing exemptions, revise the appointment and status of certain Board members and make a number of minor technical changes.
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During its 1986 review, the Committee reviewed the Arborist Examining Board and recommended its continuation for one year. In brief, the Committee continued the Board for only one year in order to give the Board a chance to improve its operations and formulate recommendations for needed statutory changes for consideration by the Committee. The Committee stipulated that the Board report back by January 1, 1988 on their progress.

As mentioned in the previous recommendation, the Board has acted to significantly improve its operations. The Board also submitted, as requested, a list of proposed statutory changes to the Committee.

After careful consideration, the Committee is recommending that several proposed changes received from the Board be enacted into law. These recommended changes are summarized as follows:

- clarification of a number of existing definitions;
- expansion of current licensing exemptions to specify that any personnel may perform arborist tasks under the on-site supervision of a licensed arborist;
- expansion of current licensing exemptions to allow unlicensed individuals to perform arborist duties in times of public emergencies;
- increase the number of voting Board members from four to six. Presently, two board members have a non-voting, ex-officio status and are appointed by the Director of the Bureau of Forestry. The Committee recommends that the Governor be authorized to appoint all six members, and that all members have full voting privileges. The final recommended change in this area is that the two ex-officio members, presently required to be from the Bureau of Forestry, will now have differently mandated places of employment. First, one member having expertise in urban forestry shall be appointed from the Bureau of Forestry. The other member shall be an employee of the Department of Agriculture and Rural Resources who is involved with the State Board of Pesticides Control;
- provide the Board with the flexibility to offer whatever form of examination that it deems to be appropriate. Presently, the Board is limited to written examinations. The Committee finds that a more flexible examination process will help to ensure that appropriately qualified individuals will have the opportunity for licensure as arborists; and

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- enact a number of minor technical amendments to existing laws.

Accordingly, the Committee recommends that these specified changes be enacted into law to promote clarity, expand certain licensing exemptions, revise the appointment and status of certain Board members and make a number of minor technical changes.