

MAINE STATE LEGISLATURE

The following document is provided by the
LAW AND LEGISLATIVE DIGITAL LIBRARY
at the Maine State Law and Legislative Reference Library
<http://legislature.maine.gov/lawlib>



Reproduced from scanned originals with text recognition applied
(searchable text may contain some errors and/or omissions)

(Emergency)
(New Draft of S.P. 529, L.D. 1581)
SECOND REGULAR SESSION

ONE HUNDRED AND THIRTEENTH LEGISLATURE

Legislative Document

No. 2555

S.P. 963

In Senate, March 21, 1988

Reported by Senator WHITMORE of Androscoggin for the
Committee on Business Legislation and printed under Joint Rule
2. Original Bill sponsored by Senator BALDACCI of Penobscot.
Cosponsored by: Senator GOULD of Waldo.

JOY J. O'BRIEN, Secretary of the Senate

STATE OF MAINE

IN THE YEAR OF OUR LORD
NINETEEN HUNDRED AND EIGHTY-EIGHT

AN ACT to Reform the Pharmacy Laws.

1
2

3 **Emergency preamble.** Whereas, Acts of the
4 Legislature do not become effective until 90 days
5 after adjournment unless enacted as emergencies; and

6 Whereas, the pharmacy board and the Department of
7 Professional and Financial Administration need the
8 recodified laws in force in time to prepare for the
9 next fiscal year; and

1 Whereas, in the judgment of the Legislature, these
2 facts create an emergency within the meaning of the
3 Constitution of Maine and require the following
4 legislation as immediately necessary for the
5 preservation of the public peace, health and safety;
6 now, therefore,

7 Be it enacted by the People of the State of Maine as
8 follows:

9 Sec. 1. 5 MRSA §12004, sub-§1, ¶A, sub-¶(29) is
10 amended to read:

11 (29) Board of Commis- \$25/Day 32-MRSA-§2851
12 sioners of the Pro- \$35/Day 32 MRSA §13711
13 fession of Pharmacy

14 Sec. 2. 22 MRSA c. 551, sub-c. II, as amended,
15 is repealed.

16 Sec. 3. 22 MRSA c. 557, as amended, is repealed.

17 Sec. 4. 32 MRSA c. 41, as amended, is repealed.

18 Sec. 5. 32 MRSA c. 117 is enacted to read:

19 CHAPTER 117

20 MAINE PHARMACY ACT

21 SUBCHAPTER I

22 TITLE AND DEFINITIONS

23 §13701. Short title

24 This chapter shall be known and may be cited as
25 the "Maine Pharmacy Act."

26 §13702. Definitions

27 As used in this chapter, unless the context
28 otherwise indicates, the following terms have the
29 following meanings.

- 1 1. Board. "Board" means the Board of
2 Commissioners of the Profession of Pharmacy.
- 3 2. Commissioner. "Commissioner" means the
4 Commissioner of the Department of Professional and
5 Financial Regulation.
- 6 3. Dangerous substance. "Dangerous substance"
7 means a substance defined in section 11541, subsection
8 2.
- 9 4. Deliver or delivery. "Deliver" or "delivery"
10 means the actual, constructive or attempted transfer
11 of a drug or device from one person to another,
12 whether or not for a consideration.
- 13 5. Department. "Department" means the Department
14 of Professional and Financial Regulation.
- 15 6. Device. "Dèvice" means an instrument,
16 apparatus, implement, machine, contrivance, implant,
17 in vitro reagent or other similar or related article,
18 including any component part or accessory, which is
19 required under federal or state law to be prescribed
20 by a practitioner and dispensed by a pharmacist.
- 21 7. Dispense or dispensing. "Dispense" or
22 "dispensing" means the preparation and delivery of a
23 prescription drug in a suitable container
24 appropriately labeled for subsequent administration to
25 or use by a patient or other individual entitled to
26 receive the prescription drug pursuant to a lawful
27 order of a practitioner.
- 28 8. Distribute. "Distribute" means the delivery of
29 a drug other than by administering or dispensing.
- 30 9. Drug. "Drug" means:
31 A. Articles recognized as drugs in the official
32 United States Pharmacopeia and National Formulary,
33 other drug compendiums or any supplement to any of
34 them;

1 B. Articles intended for use in the diagnosis,
2 cure, mitigation, treatment or prevention of
3 disease in humans or other animals;

4 C. Articles, other than food, intended to affect
5 the structure or any function of the body of
6 humans or other animals; and

7 D. Articles intended for use as a component of
8 any articles specified in paragraphs A to C.

9 10. Drug outlet. "Drug outlet" means:

10 A. Any pharmacy located in a retail store, mail
11 order business or rural health center with
12 facilities located in this State which is engaged
13 in dispensing, delivering or distributing
14 prescription drugs; or

15 B. Any mail order prescription company, or
16 wholesaler, with facilities located in this State
17 or doing business in this State which is engaged
18 in dispensing, delivering or distributing
19 prescription drugs.

20 11. Generic and therapeutically equivalent drug.
21 "Generic" and "therapeutically equivalent drug" means
22 any drug which has identical amounts of the same
23 active ingredients in the same dosage form and in the
24 same concentration which, when administered in the
25 same amounts, will produce or can be expected to have
26 the same therapeutic effect as the drug prescribed.

27 12. Labeling. "Labeling" means the process of
28 preparing and affixing a label to the outside of any
29 drug container, exclusive of the labeling by a
30 manufacturer, packer or distributor of a
31 nonprescription drug or commercially packaged legend
32 drug or device. Any such label shall include all
33 information required by federal law or regulation and
34 state law or rule.

35 13. Mail order prescription pharmacy. A "mail
36 order prescription pharmacy" means an entity that
37 dispenses prescription medications by mail or carrier

1 from a facility not located in this State to a patient
2 who resides in Maine.

3 14. Manufacture. "Manufacture" means the
4 production, preparation, propagation, compounding,
5 conversion or processing of a device or drug, either
6 directly or indirectly, by extraction from substances
7 of natural origin or independently by means of
8 chemical synthesis or by a combination of extraction
9 and chemical synthesis and includes any packaging or
10 repacking of the substances or labeling or relabeling
11 of its container, except that manufacture does not
12 include the preparation or compounding of a drug by an
13 individual for personal use or the preparation,
14 compounding, packaging or labeling of a drug:

15 A. By a pharmacist or practitioner incidental to
16 administering or dispensing a drug in the course
17 of professional practice; or

18 B. By a practitioner or by authorization under
19 the practitioner's supervision for the purpose of
20 or incidental to research, teaching or chemical
21 analysis and not for sale.

22 15. Manufacturer. "Manufacturer" means a person
23 engaged in the manufacture of prescription drugs.

24 16. Nonprescription drugs. "Nonprescription
25 drugs" means nonnarcotic drugs which may be sold
26 without a prescription and which are prepackaged for
27 use by the consumer and labeled in accordance with the
28 requirements of the laws and rules of this State and
29 the Federal Government.

30 17. Person. "Person" means an individual,
31 corporation, partnership, association or any other
32 legal entity.

33 18. Pharmacist. "Pharmacist" means an individual
34 licensed by this State to engage in the practice of
35 pharmacy.

36 A. "Chain pharmacist" means an individual who is
37 practicing pharmacy within a chain; that is, where

1 there is a corporate grouping of 4 or more stores.

2 B. "Hospital pharmacist" means an individual who
3 is practicing pharmacy in a hospital setting.

4 C. "Independent pharmacist" means an individual
5 who is practicing pharmacy in an independent
6 pharmacy; that is, where there are fewer than 4
7 pharmacies under the same ownership.

8 D. "Qualified assistant pharmacist" means an
9 individual licensed by this State as a qualified
10 assistant apothecary, qualified assistant or
11 assistant pharmacist, provided that the license is
12 in full force and effect, except for the right to
13 serve as a "pharmacist in charge."

14 19. Pharmacist in charge. "Pharmacist in charge"
15 means the pharmacist who is responsible for the
16 licensing of the prescription department.

17 20. Physician. "Physician" means an allopathic
18 physician or osteopathic physician.

19 21. Poison. "Poison" means an agent that when
20 ingested, inhaled or otherwise absorbed by a living
21 organism is capable of producing a deleterious
22 response seriously injuring function or producing
23 death.

24 22. Practice of pharmacy. "Practice of pharmacy"
25 means the interpretation and evaluation of
26 prescription drug orders; the compounding, dispensing,
27 labeling of drugs and devices, except labeling by a
28 manufacturer, packer or distributor of nonprescription
29 drugs and commercially packaged legend drugs and
30 devices; the participation in drug selection and drug
31 utilization reviews; the proper and safe storage of
32 drugs and devices and the maintenance of proper
33 records for these drugs and devices; the
34 responsibility for advising, when necessary or
35 regulated, of therapeutic values, content, hazards and
36 use of drugs and devices; and the offering or
37 performing of those acts, services, operations or
38 transactions necessary in the conduct, operation,

1 management and control of a pharmacy.

2 23. Practitioner. "Practitioner" means a
3 physician, dentist, podiatrist, veterinarian,
4 scientific investigator or other person, other than
5 pharmacists, licensed in the United States and Canada
6 to dispense, conduct research with respect to or
7 administer drugs in the course of professional
8 practice or research.

9 24. Prescription drug or legend drug.
10 "Prescription drug" or "legend drug" means a drug
11 which:

12 A. Under federal law, is required, prior to being
13 dispensed or delivered, to be labeled with either
14 of the following statements:

15 (1) "Caution: Federal law prohibits
16 dispensing without prescription."; or

17 (2) "Caution: Federal law restricts this
18 drug to use by or on the order of a licensed
19 veterinarian."; or

20 B. Is required by an applicable federal or state
21 law or rule to be dispensed on prescription only
22 or is restricted to use by practitioners only.

23 25. Prescription drug order. "Prescription drug
24 order" means a lawful written or oral order of a
25 practitioner for a drug.

26 26. Wholesaler. "Wholesaler" means a person who
27 buys prescription drugs for resale and distribution to
28 persons other than consumers.

29 SUBCHAPTER II

30 BOARD OF COMMISSIONERS OF THE PROFESSION OF PHARMACY

31 §13711. Establishment

32 There is established, within the department, in
33 accordance with Title 5, chapter 379, the Board of

1 Commissioners of the Profession of Pharmacy. The
2 board has all of the duties, powers and authority
3 specifically granted by and necessary to the
4 enforcement of this Act.

5 §13712. Membership

6 The board shall consist of 7 members, two of whom
7 shall be representatives of the public and the
8 remainder of whom shall be licensed pharmacists who
9 possess the qualifications specified in section 11523.
10 At the time of the appointment, at least one of the
11 licensed pharmacists must be a hospital pharmacist, at
12 least one must be a chain pharmacist and at least one
13 must be an independent pharmacist.

14 §13713. Qualifications

15 1. Public members. The public members of the
16 board must be residents of this State who are at least
17 21 years of age and shall not be, nor ever have been,
18 members of the profession of pharmacy, the spouse of a
19 member of the profession of pharmacy, a person who has
20 ever had any material financial interest in providing
21 pharmacy services or a person who has engaged in any
22 activity directly related to the practice of pharmacy.

23 2. Licensed pharmacists. The licensed pharmacist
24 members of the board shall, at the time of their
25 appointment:

26 A. Be residents of this State;

27 B. Be licensed and in good standing to engage in
28 the practice of pharmacy in this State;

29 C. Be engaged in the practice of pharmacy in this
30 State; and

31 D. Have 5 years of experience in the practice of
32 pharmacy in this State after licensure.

33 §13714. Appointment

34 The Governor shall appoint the members of the

1 board. Prior to appointing any pharmacist as a member
2 of the board, the Governor may solicit recommendations
3 of candidates from the Maine Pharmacy Association and
4 other pharmaceutical organizations as appropriate.

5 §13715. Terms of office

6 1. Length. Except as provided in subsection 2,
7 members of the board shall be appointed for terms of 3
8 years; except that members of the board who are
9 appointed to fill vacancies which occur prior to the
10 expiration of a former member's full term shall serve
11 the unexpired portion of that term.

12 2. Staggered terms. The terms shall be staggered
13 as follows.

14 A. The terms of the members of the board shall be
15 staggered so that the terms of no more than 2
16 members shall expire in any year.

17 B. The present members of the board shall serve
18 the balance of their terms.

19 C. Any present board member appointed initially
20 for a term of less than 3 years shall be eligible
21 to serve 3 additional full terms.

22 3. Successorship. No member of the board may
23 serve more than 3 consecutive full terms. The
24 completion of the unexpired portion of a full term
25 shall not constitute a full term for purposes of this
26 section.

27 4. Commencement. An appointee to a full term on
28 the board shall be appointed by the Governor before
29 the expiration of the term of the member being
30 succeeded and shall become a member of the board on
31 the first day of the calendar year next following
32 appointment or day of appointment if that appointment
33 is made after January 1st. Appointees to unexpired
34 portions of full terms shall become members of the
35 board on the day of that appointment. If the number of
36 board members is increased, the term of any new member
37 shall commence at such time as is designated in the

1 law providing for the enlargement of the board.

2 5. Expiration. Each term of office on the board
3 expires at midnight on the last day of the calendar
4 year in the final year of the board member's term or
5 on the date a successor is appointed, whichever occurs
6 later.

7 6. Vacancies. Any vacancy which occurs in the
8 membership of the board for any reason, including
9 expiration of term, removal, resignation, death,
10 disability or disqualification, shall be filled by the
11 Governor in the manner prescribed by section 11524.
12 The Governor shall fill vacancies which occur by
13 expiration of full terms within 90 days prior to each
14 date of expiration and shall fill vacancies which
15 occur for any other reason within 60 days after the
16 vacancy occurs.

17 7. Grounds for removal. The Governor may remove a
18 member of the board for cause.

19 §13716. Organization

20 1. Officers. The board shall elect from its
21 members a president and other officers as it deems
22 appropriate and necessary to the conduct of its
23 business. The president of the board shall preside at
24 all meetings of the board and shall be responsible for
25 the performance of all of the duties and functions of
26 the board required or permitted by this Act. Each
27 additional officer elected by the board shall perform
28 those duties normally associated with that position
29 and those other duties assigned from time to time by
30 the board.

31 2. Terms of office. Officers elected by the board
32 shall serve terms of one year commencing with the day
33 of their elections and ending upon elections of their
34 successors and shall serve no more than 3 consecutive
35 full terms in each office to which elected.

36 3. Executive director. The department may employ,
37 with the advice of the board, a licensed pharmacist
38 who shall be an ex officio member of the board without

1 a vote to serve as an employee of the board in the
2 position of executive director. The executive director
3 shall be responsible for the performance of the
4 regular administrative functions of the board and
5 other duties as the board may direct. The executive
6 director shall not perform any discretionary or
7 decision-making functions for which the board is
8 solely responsible.

9 §13717. Compensation

10 1. Members. Each member of the board shall be
11 compensated in accordance with Title 5, chapter 379.

12 2. Secretary. The secretary of the board shall
13 receive reimbursement for all expenses incurred in
14 connection with performance of official duties.

15 §13718. Meetings

16 1. Number. The board shall meet at least once
17 every 2 months to transact its business. The December
18 meeting shall be designated as the annual meeting and
19 shall be for the purpose of electing officers and for
20 the reorganization of the board. The board shall meet
21 at additional times as it may determine. Additional
22 meetings may be called by the president or by 2/3 of
23 the members of the board.

24 2. Place. The board shall meet at such place as
25 it may from time to time determine. The place for each
26 meeting shall be determined prior to giving notice of
27 the meeting and shall not be changed after the notice
28 is given without adequate subsequent notice.

29 3. Notice. Notice of all meetings of the board
30 shall be given in the manner and pursuant to
31 requirements prescribed by the State's applicable laws
32 and rules.

33 4. Quorum. A majority of the members of the board
34 constitutes a quorum for the conduct of a board
35 meeting and, except when a greater number is required
36 by this Act or by any rule of the board, all actions
37 of the board shall be by a majority of a quorum.

1 5. Open meeting. All board meetings and hearings
2 shall be open to the public. The board may conduct
3 portions of its meetings in executive session pursuant
4 to the freedom of access laws, Title 1, section 405.

5 §13719. Employees

6 With the advice of the board, the commissioner may
7 appoint, subject to the Civil Service Law, such
8 employees as may be necessary to carry out this
9 chapter. Any person so employed shall be located in
10 the department and under the administrative and
11 supervisory direction of the commissioner.

12 §13720. Rules

13 The board shall make, adopt, amend and repeal such
14 rules as may, from time to time, be determined
15 necessary by the board for the proper administration
16 and enforcement of this Act. These rules shall be
17 promulgated in accordance with the Maine
18 Administrative Procedure Act, Title 5, chapter 375.

19 §13721. Licensure and discipline

20 1. Responsibility. The board's responsibility for
21 the control and regulation of the practice of pharmacy
22 in this State includes, but is not limited to, the
23 following actions:

24 A. The licensing by examination or by reciprocity
25 of applicants who are qualified to engage in the
26 practice of pharmacy under this Act;

27 B. The renewal of licenses to engage in the
28 practice of pharmacy;

29 C. The determination and issuance of standards
30 for recognition and approval of degree programs of
31 schools and colleges of pharmacy whose graduates
32 shall be eligible for licensure in this State and
33 the specification and enforcement of requirements
34 for practical training, including internship;

1 D. The inspection during business hours of all
2 pharmacies, dispensaries, stores, hospital
3 pharmacies, extended care facilities, boarding
4 homes, nursing homes, drug abuse treatment
5 centers, penal institutions, family planning
6 centers or other drug outlets in which drugs or
7 medicines are manufactured, stored, distributed,
8 compounded, dispensed or retailed in this State;

9 E. The registration of any drug outlet as set out
10 in section 11561 and any manufacturer or
11 wholesaler whose products are distributed in this
12 State;

13 F. The enforcement of those provisions of this
14 Act relating to the conduct or competence of
15 pharmacists practicing in this State and the
16 processing of complaints which could lead to the
17 suspension, revocation or restriction of licenses
18 to engage in the practice of pharmacy;

19 G. The rules of the training, qualification and
20 employment of pharmacy interns and pharmacy
21 students; and

22 H. The rules of the training, qualification and
23 employment of pharmacy ancillary personnel.

24 2. Reciprocal inspections. The Board of
25 Commissioners of the Profession of Pharmacy may enter
26 into reciprocal inspection agreements with any state
27 in which a Maine licensed mail order prescription
28 facility is located. The purpose of this agreement is
29 to authorize the state in which the facility is
30 located to inspect the facility for compliance with
31 Maine laws and rules.

32 §13722. Medications, drugs, devices and other
33 materials

34 1. Responsibility. The board has the following
35 responsibilities in regard to medications, drugs,
36 devices and other materials used in this State in the
37 diagnosis, mitigation and treatment or prevention of
38 injury, illness and disease. The board shall:

1 A. Promulgate rules concerning the sale and
2 dispensing of medications, drugs, devices and
3 other materials, including the right to seize any
4 such drugs, devices and other materials found to
5 be detrimental to the public health and welfare by
6 the board after appropriate hearing as required
7 under the Maine Administrative Procedure Act,
8 Title 5, chapter 375;

9 B. Establish the specifications of minimum
10 professional and technical equipment, environment,
11 supplies and procedure for the compounding or
12 dispensing of medications, drugs, devices and
13 other materials within the practice of pharmacy;

14 C. Assure that standards for purity and quality
15 of medications, drugs, devices and other materials
16 within the practice of pharmacy are met;

17 D. Issue and renew certificates of registration
18 for purposes of ascertaining those persons engaged
19 in the manufacture and distribution of drugs;

20 E. Promulgate rules concerning the sale and the
21 dispensing of any exempt narcotic preparation. An
22 "exempt narcotic preparation" means any medicinal
23 preparation that contains in 30 milliliters or, if
24 a solid or semisolid preparation, in 30 grams:

25 (1) Not more than 130 milligrams of opium;

26 (2) Not more than 15 milligrams of morphine
27 or any of its salts;

28 (3) Not more than 65 milligrams of codeine
29 or any of its salts;

30 (4) Not more than 30 milligrams of
31 dihydrocodeine or any of its salts; or

32 (5) Not more than one of the drugs named in
33 subparagraphs (1) to (4).

34 A record shall be kept of the sale of exempt

1 narcotic preparations. The record must contain the
2 date of sale, signature and address of the
3 purchaser, name of the preparation, purpose for
4 which purchased and signature of the person making
5 the sale; and

6 F. After notice and hearing, designate as potent
7 medicinal substances any compounds of barbituric
8 acid, amphetamines or any other central nervous
9 system stimulants or depressants, psychic
10 energizers or any other drugs having a tendency to
11 depress or stimulate which are likely to be
12 injurious to health if improperly used.

13 §13723. Other duties, powers and authority

14 The board has such other duties, powers and
15 authority as may be necessary to enforce this Act and
16 the board may adopt rules pursuant to this Act, which
17 include, but are not limited to, the following.

18 1. Professional associations. The board may join
19 professional organizations and associations organized
20 exclusively to promote the improvement of the
21 standards of the practice of pharmacy for the
22 protection of the health and welfare of the public and
23 whose activities assist and facilitate the work of the
24 board.

25 2. Bond. In addition to any statutory
26 requirements, the board may require such surety bonds
27 as it deems necessary to guarantee the performance and
28 discharge of the duties of any officer or employee
29 receiving and disbursing funds.

30 3. Seal. The executive director of the board or
31 the secretary of the board shall keep the seal of the
32 board at the department and shall affix it only in
33 such manner as may be prescribed by the board.

34 4. Reports. The board shall submit to the
35 commissioner no later than August 1st of each year a
36 report summarizing its proceedings and activities
37 during the fiscal year, together with a report of all
38 money received and disbursed by the board.

1 5. Fees. The board shall determine within 30 days
2 prior to the beginning of each state fiscal year the
3 fees to be collected for:

4 A. An examination and reexamination, which fee
5 shall not exceed costs of the examination, plus an
6 amount not to exceed \$100;

7 B. The issuance of a pharmacist's license, by
8 reciprocity, which fee shall not exceed \$150;

9 C. The issuance of renewal of a pharmacist's
10 license, which fee shall not exceed \$100;

11 D. The issuance of a nonactive pharmacist's
12 license, which fee shall not exceed \$15 if the
13 nonactive pharmacist is 65 years of age or older,
14 or which fee shall not exceed \$50 if the nonactive
15 pharmacist is under 65;

16 E. The issuance of a certificate of registration
17 for a new drug outlet, manufacturer or wholesaler
18 license, which fee shall not exceed \$200;

19 F. The issuance of a certificate of registration
20 for renewal of a drug outlet, manufacturer or
21 wholesaler license, which fee shall not exceed
22 \$200;

23 G. The issuance of a certificate of registration
24 necessitated by a change in the pharmacist
25 responsible for the license, which fee shall not
26 exceed \$100; and

27 H. The certification of an approved provider of
28 continuing education courses, which fee shall not
29 exceed \$100 per year, provided that a provider
30 approved by the American Council of Pharmaceutical
31 Education is exempt from the fee established in
32 this paragraph.

33 6. Grants. The board may receive and expend
34 funds, in addition to its annual allocation, from
35 parties other than the State, provided that:

1 A. The funds are awarded for the pursuit of a
2 specific objective which the board is authorized
3 to accomplish by this Act or which the board is
4 qualified to accomplish by reason of its
5 jurisdiction or professional expertise;

6 B. The funds are expended for the pursuit of the
7 objective for which they are awarded;

8 C. Activities connected with or occasioned by the
9 expenditures of the funds do not interfere with or
10 impair the performance of the board's duties and
11 responsibilities and do not conflict with the
12 exercise of the board's powers as specified by
13 this Act;

14 D. The funds are kept in a separate, special
15 state account; and

16 E. Periodic reports are made to the commissioner
17 concerning the board's receipt and expenditure of
18 the funds.

19 7. Investigatory powers. The board shall notify
20 the Department of the Attorney General upon receipt of
21 a complaint. Upon receipt of the notifications, the
22 Attorney General shall notify the department within a
23 timely period if the alleged violation requires
24 criminal investigation. If a case does not require
25 criminal investigation, the board or its authorized
26 representatives may investigate and gather evidence
27 concerning alleged violations of this Act or of the
28 rules of the board. The board may remove certain
29 records, including, but not limited to, prescription
30 records, patient profiles, inventories and other drug
31 records for the purposes of photocopying and
32 furthering the investigation. An inventory receipt
33 shall be furnished and the articles removed shall be
34 returned within 3 hours. The pharmacist who has
35 custody of the records may accompany the board's
36 representatives so that the pharmacist can attest to
37 the authenticity and lack of alteration of the records
38 being photocopied.

1 A. Prescriptions, orders and records required by
2 this chapter and stocks of narcotic drugs shall be
3 open for inspection only to the board and to
4 federal, state, county and municipal officers
5 whose duty it is to enforce the laws of this State
6 or of the United States relating to narcotic
7 drugs. No officer having knowledge by virtue of
8 the officer's office of any such prescription,
9 order or record may divulge that knowledge, except
10 in connection with a prosecution or proceeding in
11 court or before a licensing or registration board
12 or officer, to which prosecution or proceeding the
13 person to whom such prescriptions, orders or
14 records relate is a party.

15 B. The Bureau of Health, the board, their
16 officers, agents, inspectors and representatives,
17 all peace officers within the State and all county
18 attorneys shall enforce all provisions of this
19 chapter, except those specifically delegated, and
20 shall cooperate with all agencies charged with the
21 enforcement of the laws of the United States, of
22 this State and of all other states relating to
23 narcotic drugs.

24 8. Embargo. The board may embargo certain drugs
25 or devices as follows.

26 A. Notwithstanding anything in this Act to the
27 contrary, if a duly authorized representative of
28 the board finds or has probable cause to believe
29 that any drug or device is adulterated or
30 misbranded within the meaning of the United States
31 Food and Drug Act, the board representative shall
32 affix to the drug or device a tag or other
33 appropriate marking giving notice that the article
34 is or is suspected of being adulterated or
35 misbranded and has been detained or embargoed, and
36 warning all persons not to remove or dispose of
37 the article by sale or otherwise until provision
38 for removal or disposal is given by the board, its
39 agent or the court. No person may remove or
40 dispose of the embargoed drug or device by sale or
41 otherwise without the permission of the board or
42 its agent or, after summary proceedings have been

1 instituted, without permission from the court.

2 B. When a drug or device detained or embargoed
3 under paragraph A has been declared by a
4 representative of the board to be adulterated or
5 misbranded, the board shall, as soon as practical,
6 report the declaration to the Attorney General's
7 office, along with sufficient information to
8 permit the Attorney General to bring a petition
9 for an injunction to the judge of the court in
10 whose jurisdiction the article is detained or
11 embargoed. If the judge determines that the drug
12 or device so detained or embargoed is not
13 adulterated or misbranded, the board shall direct
14 the immediate removal of the tag or other marking.

15 C. If the court finds the detained or embargoed
16 drug or device is adulterated or misbranded, that
17 drug or device, after entry of the decree, shall
18 be destroyed at the expense of the owner under the
19 supervision of the board representative and all
20 court costs and fees, storage and other proper
21 expense shall be borne by the owner of the drug or
22 device. When the adulteration or misbranding may
23 be corrected by proper labeling or processing of
24 the drug or device, the court, after entry of the
25 decree and after the costs, fees and expenses have
26 been paid and a good and sufficient bond has been
27 posted, may direct that the drug or device be
28 delivered to the owner for labeling or processing
29 under the supervision of a board representative.
30 The expense of the supervision shall be paid by
31 the owner. The bond shall be returned to the owner
32 of the drug or device on representation to the
33 court by the board that the drug or device is no
34 longer in violation of the embargo and the expense
35 of supervision has been paid.

36 9. Budget. The board shall submit to the
37 Commissioner of Human Services its budgetary
38 requirements in the same manner as is provided in
39 Title 5, section 1665, and the commissioner shall in
40 turn transmit these requirements to the Bureau of the
41 Budget without any revision, alteration or change.

1 10. Procedure. Except as otherwise provided, the
2 board shall exercise all of its duties, powers and
3 authority in accordance with the Maine Administrative
4 Procedure Act, Title 5, chapter 375.

5 SUBCHAPTER III

6 LICENSING

7 §13731. Unlawful practice; penalties; injunctions

8 1. Applicability. It is unlawful for any person
9 to engage in the practice of pharmacy unless licensed
10 to practice under this Act; provided that physicians,
11 dentists, veterinarians or other practitioners of the
12 healing arts who are licensed under the laws of this
13 State may dispense and administer prescription drugs
14 to their patients in the practice of their respective
15 professions where specifically authorized to do so by
16 law.

17 2. Authorization to deal with dangerous
18 substances. Practitioners, drug jobbers, drug
19 wholesalers, drug manufacturers, pharmacists and
20 pharmacies registered under this chapter and approved
21 animal shelters as provided in Title 7, section 3913,
22 are authorized to deal professionally with dangerous
23 substances. A dangerous substance is:

24 A. Any substance listed under the Federal Uniform
25 Controlled Substance Act, sections 1 through 5; or

26 B. Anything deemed to be dangerous by the Federal
27 Drug Administration, other federal agency, or the
28 Attorney General of the United States.

29 3. Violation. Any person who violates this
30 chapter commits a Class E crime and, notwithstanding
31 Title 17-A, section 1301, may be punished by a fine of
32 not more than \$1,000. Each violation of each section
33 of this chapter constitutes a separate offense.

34 4. Violation; suspension; penalty. For any
35 violation of this chapter, in addition to other
36 disciplinary action which may be taken by the board,

1 the board may suspend the violator's license for up to
2 90 days or impose a civil penalty of up to \$500, or
3 both, for each violation of each section of this
4 chapter. The jurisdiction to suspend a license for up
5 to 90 days shall be concurrent with that of the
6 Administrative Court.

7 5. Action to enjoin. The State may bring an
8 action to enjoin any licensee or person from violating
9 this chapter, regardless of whether proceedings have
10 been or may be instituted in the Administrative Court
11 or whether criminal proceedings have been or may be
12 instituted.

13 6. Fees; fines; forfeitures. All fees, fines and
14 forfeitures under this chapter shall be paid to the
15 Treasurer of State and shall be considered funds of
16 the board to be expended by them for the enforcement
17 of laws relating to pharmacists and for expenses in
18 carrying out the duties of the board. The money shall
19 not lapse but shall be carried forward.

20 §13732. Qualifications for licensure by examination

21 1. Requirements. To obtain a license to engage in
22 the practice of pharmacy, an applicant for licensure
23 by examination must:

24 A. Have submitted a written application in the
25 form prescribed by the board;

26 B. Have attained the age of 21 years;

27 C. Have demonstrated good moral character and
28 temperate habits;

29 D. Have graduated and received the first
30 professional undergraduate degree from a pharmacy
31 degree program accredited by the American Council
32 on Pharmaceutical Education or have received a
33 degree from an equivalent program, which has been
34 approved by the board, from a school outside the
35 United States;

36 E. Have completed an internship or other program

1 which has been approved by the board or
2 demonstrated, to the board's satisfaction,
3 experience in the practice of pharmacy which meets
4 or exceeds the minimum internship requirement of
5 the board;

6 F. Have successfully passed an examination given
7 by the board; and

8 G. Have paid the fees specified by the board for
9 application, examination and issuance of a license.

10 2. Examinations. Examinations shall be prepared
11 and administered according to this subsection.

12 A. The examination shall be prepared to measure
13 the competence of the applicant to engage in the
14 practice of pharmacy. The board may employ and
15 cooperate with any organization or consultant in
16 the preparation and grading of an appropriate
17 examination, but shall retain the sole discretion
18 and responsibility of determining which applicants
19 have successfully passed the examination.

20 B. The examination for licensure shall be given
21 by the board at least 2 times during each fiscal
22 year of the State. The board shall determine the
23 content and subject matter of each examination,
24 the place, time and date of administration of the
25 examination and those persons who have
26 successfully passed the examination.

27 3. Internship and other training programs.
28 Internship and practical experience requirements shall
29 be determined as follows.

30 A. All applicants for licensure by examination
31 must obtain practical experience in the practice
32 of pharmacy concurrent with or after college
33 attendance under such terms and conditions as the
34 board may determine.

35 B. The board shall establish standards for
36 internship or any other program necessary to
37 qualify an applicant for the licensure examination

1 and shall also determine the necessary
2 qualifications of any preceptors used in any
3 internship or other program.

4 §13733. Qualifications for licensure by reciprocity

5 1. Requirements. To obtain a license as a
6 pharmacist by reciprocity an applicant for licensure
7 must:

8 A. Have submitted a written application in the
9 form prescribed by the board;

10 B. Have attained the age of 21 years;

11 C. Have demonstrated good moral character and
12 temperate habits;

13 D. Have possessed at the time of initial
14 licensure as a pharmacist such other
15 qualifications necessary to have been eligible for
16 licensure at that time in this State;

17 E. Have engaged in the practice of pharmacy for a
18 period of at least one year or have met the
19 internship requirements of this State within the
20 one-year period immediately previous to the date
21 of the application;

22 F. Have passed the state pharmacy law exam as
23 administered by the board;

24 G. Have presented to the board proof of initial
25 licensure by examination and proof that the
26 license and any other license or licenses granted
27 to the applicant by any other state or states have
28 not been suspended, revoked, canceled or otherwise
29 restricted for any reason except nonrenewal or the
30 failure to obtain required continuing education
31 credits in any state where the applicant is
32 licensed, but not engaged in the practice of
33 pharmacy; and

34 H. Have paid the fees specified by the board for
35 issuance of licenses.

1 2. Eligibility. No applicant is eligible for
2 licensure by reciprocity unless the state in which the
3 applicant was initially licensed as a pharmacist also
4 grants reciprocal licensure to pharmacists duly
5 licensed by examination in this State under like
6 circumstances and conditions.

7 §13734. Renewal of licenses

8 1. Annual renewal. A license shall expire
9 annually on December 31st or on such other date as the
10 commissioner may determine. Notice of expiration
11 shall be mailed to each licensee's last known address
12 at least 30 days in advance of the expiration of the
13 license. The notice shall include any requests for
14 information necessary for renewal.

15 Licenses may be renewed up to 90 days after the date
16 of expiration upon payment of a late fee of \$10 in
17 addition to the renewal fee. Any person who submits
18 an application for renewal more than 90 days after the
19 license renewal date shall be subject to all
20 requirements governing new applicants under this
21 chapter, except that the board may, giving due
22 consideration to the protection of the public, waive
23 examination if that renewal application is made within
24 2 years from the date of that expiration.

25 2. Nonactive renewal registration. Every
26 registered pharmacist not practicing pharmacy within
27 this State shall pay annually, on or before December
28 31st or on another date as determined by the
29 commissioner, a renewal fee to the secretary of the
30 board, in return for which a nonactive renewal
31 registration shall be issued.

32 Every registered pharmacist holding a nonactive
33 renewal registration who desires to practice pharmacy
34 in this State shall be required to submit proof
35 satisfactory to the board that, during the calendar
36 year preceding application for active registration,
37 the pharmacist has participated in not less than 15
38 hours of approved courses of continuing professional
39 pharmaceutical education as defined in section 13735.

1 The board may make exceptions from the operation of
2 the continuing education requirement of this section
3 in emergency or hardship cases.

4 If any person fails or neglects to procure the annual
5 nonactive renewal registration, notice of that failure
6 having been mailed to that person's last known address
7 by the board, after the expiration of 30 days
8 following the issue of notice, that person's original
9 registration shall expire. That person, in order to
10 regain registration, shall be required to pay one
11 renewal fee in addition to the sum of all fees that
12 person may be in arrears.

13 3. Fees. The board shall specify by rule the
14 procedures to be followed, in addition to those
15 specified by section 11545, and the fees to be paid
16 for renewal of licenses.

17 §13715. Continuing pharmacy education

18 No annual renewal certificate may be issued by the
19 board until the applicant submits proof satisfactory
20 to the board that, during the year preceding an
21 application for renewal, the applicant has
22 participated in not less than 15 hours of approved
23 courses of continuing professional pharmaceutical
24 education as set out in this section. The continuing
25 professional pharmaceutical educational courses shall
26 consist of postgraduate studies, institutes, seminars,
27 workshops, lectures, conferences, extension studies,
28 correspondence courses or such other forms of
29 continuing professional pharmaceutical education as
30 may be approved by the board.

31 These courses shall consist of subject matter
32 pertinent to the following general areas of
33 professional pharmaceutical education: The
34 socioeconomic and legal aspects of health care; the
35 properties and actions of drugs and dosage forms; and
36 the ideology, characteristics and therapeutics of the
37 disease state. The specific subject matter of the
38 courses may include, but is not limited to,
39 pharmacology, biochemistry, physiology, pharmaceutical
40 chemistry, pharmacy administration, pharmacy

1 jurisprudence, public health and communicable
2 diseases, pharmaceutical marketing, professional
3 practice management, anatomy, histology and such other
4 subject matter as represented in curricula of
5 accredited colleges of pharmacy. The content of each
6 course offered for credit under this continuing
7 professional educational program must be approved in
8 advance of the course by a committee composed of equal
9 representation from the board, hospital pharmacy and
10 retail pharmacy within the State. The number and
11 members of the committee shall be selected by the
12 board and shall serve for a period of 2 years. The
13 board may make exceptions from the operation of this
14 section in emergency or hardship cases.

15 SUBCHAPTER IV

16 DISCIPLINE

17 §13741. Disciplinary actions

18 The board shall investigate civil complaints
19 regarding noncompliance with or violation of this
20 chapter or of any rules adopted by the board.

21 The board shall notify the licensee of the content
22 of a complaint filed against the licensee as soon as
23 possible, but in no event later than within 60 days of
24 receipt of this information. The licensee shall
25 respond within 30 days. If the licensee's response to
26 the complaint satisfies the board that the complaint
27 does not merit further investigation or action, the
28 matter may be dismissed, with notice of the dismissal
29 to the complainant, if any.

30 If, in the opinion of the board, the factual basis
31 of the complaint is or may be true and it is of
32 sufficient gravity to warrant further action, the
33 board may request an informal conference with the
34 licensee. The board shall provide the licensee with
35 adequate notice of the conference and of the issues to
36 be discussed. The conference shall be conducted in
37 executive session of the board, unless otherwise
38 requested by the licensee. Statements made at the
39 conference may not be introduced at a subsequent

1 formal hearing unless all parties consent.

2 If the board finds that the factual basis of the
3 complaint is true and is of sufficient gravity to
4 warrant further action, it may take any of the
5 following actions it deems appropriate as set forth in
6 Title 10, section 8003, subsection 5 and including:

7 1. Warning. Warning, censuring or reprimanding
8 the licensee;

9 2. Consent agreement. With the consent of the
10 licensee, entering into a consent agreement which
11 fixes the period and terms of probation best adapted
12 to protect the public health and safety and to
13 rehabilitate or educate the licensee. A consent
14 agreement may be used to terminate a complaint
15 investigation if entered into by the board, the
16 licensee and the Attorney General's office;

17 3. Negotiate stipulations. In consideration for
18 acceptance of a voluntary surrender of the license,
19 negotiating stipulations, including terms and
20 conditions for reinstatement which ensure protection
21 of the public health and safety and which serve to
22 rehabilitate or educate the licensee. These
23 stipulations shall be set forth only in a consent
24 agreement signed by the board, the licensee and the
25 Attorney General's office; or

26 4. Adjudicatory hearing. If the board concludes
27 that modification or nonrenewal of the license might
28 be in order, holding an adjudicatory hearing in
29 accordance with the Maine Administrative Procedure
30 Act, Title 5, chapter 375, subchapter IV.

31 §13742. Grounds for discipline

32 1. Suspension or revocation. The board may
33 suspend or revoke a license, pursuant to Title 5,
34 section 10004.

35 2. Grounds for action. The following shall be
36 grounds for an action to refuse to issue a
37 modification of the license or for refusal to renew

1 the license of a person licensed under this chapter:

2 A. The practice of fraud or deceit in obtaining a
3 license under this chapter or in connection with
4 service rendered within the scope of the license
5 issued;

6 B. Habitual intemperance in the use of alcohol or
7 the habitual use of narcotic, hypnotic or other
8 substances, the use of which has resulted or may
9 result in the licensee performing duties in a
10 manner which endangers the health or safety of the
11 patients;

12 C. A professional diagnosis of a mental or
13 physical condition which has resulted or may
14 result in the licensee performing duties in a
15 manner which endangers the health or safety of the
16 patients;

17 D. Aiding or abetting the practice of pharmacy by
18 a person not duly licensed under this chapter and
19 who was represented as duly licensed;

20 E. Incompetence in the practice for which
21 licensed. A licensee shall be deemed incompetent
22 in the practice if the licensee has:

23 (1) Engaged in conduct which evidences a
24 lack of ability or fitness to discharge the
25 duty owed by the licensee to a client,
26 patient or the general public; or

27 (2) Engaged in conduct which evidences a
28 lack of knowledge or inability to apply
29 principles or skills to carry out the
30 practice for which licensed;

31 F. Engaging in unprofessional conduct by
32 violating any standard of professional behavior
33 which has been established in the practice for
34 which the licensee is licensed;

35 G. Subject to the limitations of Title 5, chapter
36 341, conviction of a crime which involves

1 dishonesty or false statement or which relates
2 directly to the practice for which the licensee is
3 licensed or conviction of any crime for which
4 incarceration for one year or more may be imposed;

5 H. Engaging in false, misleading or deceptive
6 advertising; or

7 I. Any violation of this Act or of any rule
8 adopted by the board.

9 3. Crime in course of business. If any registered
10 pharmacist is convicted in state or federal court of a
11 crime which is committed during the course of duties
12 performed as a registered pharmacist or committed
13 through the use of the pharmacy in which the
14 pharmacist is employed, or which the pharmacist owns
15 or operates, and which demonstrates unfitness to
16 practice as a pharmacist, including, but not limited
17 to, convictions for defrauding the Medicaid program
18 and for illegally distributing prescription drugs, the
19 pharmacist's license is subject to suspension or
20 revocation as set forth in section 13741.

21 §13743. Penalties and reinstatement

22 1. Penalties. Upon finding grounds for discipline
23 of any person holding a license or seeking a license
24 or a renewal of a license under this chapter, the
25 board may take one or more of the following actions:

26 A. Request the Attorney General's office to
27 institute appropriate judicial proceedings which
28 may lead to suspension or revocation of license;

29 B. Restrict the offender's license to prohibit
30 the offender from performing certain acts or
31 engaging in the practice of pharmacy in a
32 particular manner for a term to be determined by
33 the board; or

34 C. Hold an adjudication hearing which may result
35 in:

36 (1) Refusal to renew offender's license; or

1 (2) Placement of the offender on probation
2 and supervision by the board for a period to
3 be determined by the board.

4 2. Reinstatement. Any person whose license to
5 practice pharmacy in this State has been suspended,
6 revoked or restricted pursuant to this chapter,
7 whether voluntarily or by action of the board, may at
8 reasonable intervals petition the board for
9 reinstatement of the license. The petition must be
10 made in writing in a form prescribed by the board.
11 Upon investigation and hearing, the board may grant or
12 deny the petition or it may modify its original
13 finding to reflect any circumstances which have
14 changed sufficiently to warrant those modifications.

15 3. Criminal prosecutions. Nothing in this chapter
16 bars criminal prosecution for any violation of this
17 chapter where that violation is a criminal offense
18 under the laws of this State or of the United States.

19 4. Judicial review. All final decisions by the
20 board are subject to judicial review pursuant to the
21 Maine Administrative Procedure Act, Title 5, chapter
22 375.

23 SUBCHAPTER V

24 REGISTRATION OF FACILITIES

25 §13751. Registration

26 1. Registration. All drug outlets, manufacturers
27 or wholesalers shall annually register with the board.

28 2. Classifications. Drug outlets shall be
29 registered in classifications set out in this
30 subsection.

31 Each drug outlet must apply for a certificate of
32 registration in one of the following classifications:

33 A Retail drug outlet;

1 B Mail order prescription drug outlet;

2 C Wholesale drug outlet; or

3 D Rural health center.

4 3. Rules. The board shall establish by rule the
5 criteria which each drug outlet must meet to qualify
6 for registration in each classification designated in
7 subsection 2. The board may issue various types of
8 certificates with varying restrictions to the outlets
9 referred to in subsection 2, paragraph A when the
10 board determines it necessary by reason of the type of
11 drug outlet requesting a certificate.

12 4. Nonprescription drugs. It shall be lawful for
13 a person to sell and distribute nonprescription drugs.
14 Any person engaging in the sale and distribution of
15 those items shall not be deemed to be improperly
16 engaged in the practice of pharmacy. No rule may be
17 adopted by the board under this Act which requires the
18 sale of nonprescription drugs by a licensed pharmacist
19 or under the supervision of a licensed pharmacist or
20 otherwise applies to or interferes with the sale and
21 distribution of those medicines.

22 §13752. Application

23 1. Procedures. The board shall specify by rule
24 the registration procedures to be followed, including,
25 but not limited to, specification of forms for use in
26 applying for certificates of registration and the
27 times, places and fees for filing an application,
28 provided that the annual fee for an original or
29 renewal certificate does not exceed \$200.

30 2. Required information. Applications for
31 certificates of registration shall include the
32 following information about the proposed drug outlet:

33 A. Ownership;

34 B. Location; and

35 C. Identity of the pharmacist licensed to

1 practice in the State who shall be the pharmacist
2 in charge of the drug outlet, when one is required
3 by this chapter, and such further information as
4 the board may deem necessary. A pharmacist may be
5 the pharmacist in charge for only one drug outlet.
6 The position of pharmacist in charge may not be
7 held by a qualified assistant pharmacist.

8 3. Transferability. Certificates of registration
9 issued by the board pursuant to this chapter are not
10 transferable or assignable.

11 4. Professional responsibility. The board shall
12 specify by rule minimum standards for the professional
13 responsibility in the conduct of any drug outlet that
14 has employees or personnel engaged in the practice of
15 pharmacy. The board may require that the portion of
16 the facility to which the certificate of registration
17 applies be operated only under the direct supervision
18 of no less than one pharmacist licensed to practice in
19 this State and not otherwise and to provide such other
20 special requirements as necessary.

21 5. Minimum inventory. The board shall ascertain
22 that the applicant has a sufficient amount of
23 prescription inventory on location to respond
24 appropriately to prescription orders.

25 §13753. Notifications

26 1. Changes. All registered drug outlets shall
27 report to the board, by registered mail, the
28 occurrence of any of the following changes:

29 A. Permanent closing which requires 14 days'
30 prior notice to the public and to the board;

31 B. Change of ownership which requires 7 days'
32 prior notice to the board;

33 C. Change of pharmacist in charge which requires
34 notice no later than 7 days after the change; and

35 D. Any other matters and occurrences as the board
36 may require by rule.

1 2. Other reportable events. Disasters, accidents
2 and emergencies which may affect the strength, purity
3 or labeling of drugs, medications, devices or other
4 materials used in the diagnosis or the treatment of
5 injury, illness and disease shall be immediately
6 reported to the board.

7 §13754. Violations and penalties

8 1. Unlawful conduct. No drug outlet registered
9 pursuant to section 13751 may be operated until a
10 certificate of registration has been issued to that
11 facility by the board. Upon the finding of a violation
12 of this section, the board may impose one or more of
13 the penalties enumerated in section 13731 or 13743.

14 2. Reinstatement. Reinstatement of a certificate
15 that has been suspended, revoked or restricted by the
16 board may be granted in accordance with the procedures
17 specified by section 13743, subsection 2.

18 SUBCHAPTER VI

19 MANUFACTURERS AND WHOLESALERS WITHOUT
20 FACILITIES IN THIS STATE

21 §13758. Registration

22 1. Purpose; statement of intent. The purpose of
23 this section is to require registration of
24 manufacturers and wholesalers without facilities in
25 this State. The intent of the Legislature is that the
26 board shall not promulgate rules regarding companies
27 without wholesale facilities or manufacturers'
28 facilities located in this State which are more
29 restrictive than federal law or regulation.

30 2. Registration, manufacturers and wholesalers.
31 All manufacturers and wholesalers whose products are
32 distributed in the State in any manner shall register
33 with the Board of Commissioners of the Profession of
34 Pharmacy.

35 3. Registration, individuals. No individual who

1 is employed by a manufacturer or wholesaler which is
2 registered under this subchapter need register under
3 this subchapter.

4 4. Form. Registration forms shall state:
5 Applicant's name; address; day phone; 24-hour phone;
6 ownership status; manufacturer or wholesaler
7 designation; Drug Enforcement Agency and Federal Drug
8 Administration members; and date executed.
9 Registration forms shall be executed by an owner or
10 officer of the entity, providing printed name and
11 title.

12 5. Fees. Each registrant shall pay a fee not to
13 exceed \$200.

14 6. Violations. It shall be unlawful for
15 manufacturers or wholesale companies to distribute
16 prescription drugs in this State unless registered
17 under the provisions of this subchapter or subchapter
18 V.

19 SUBCHAPTER VII

20 SERVICES AT RURAL HEALTH CENTERS

21 §13761. Definitions

22 As used in this subchapter, unless the context
23 otherwise indicates, the following terms have the
24 following meanings.

25 1. Pharmacy provider. "Pharmacy provider" means a
26 pharmacy licensed in this State participating with a
27 rural community health center under this subchapter.

28 2. Rural community health center. "Rural
29 community health center" means an incorporated
30 nonprofit health facility which provides comprehensive
31 primary health care to citizens in rural areas without
32 a pharmacy or in a community where available pharmacy
33 services cannot meet the documented need.

34 §13762. Center to be licensed

1 1. License required. A rural community health
2 center that desires to contract for pharmaceutical
3 services with a pharmacy must be licensed by the board
4 and shall abide by the rules of the board. These rules
5 may be no more restrictive than those regulating
6 private pharmacy practice in the State.

7 2. Annual renewal. Licenses shall expire
8 annually on December 31st or on such other date as the
9 commissioner determines. Notice of expiration shall
10 be mailed to each licensee's last known address at
11 least 30 days in advance of the expiration of the
12 license. The notice shall include any requests for
13 information necessary for renewal.

14 Licenses may be renewed up to 90 days after the date
15 of expiration upon payment of a late fee of \$10 in
16 addition to the renewal fee. Any person who submits
17 an application for renewal more than 90 days after the
18 license renewal date shall be subject to all
19 requirements governing new applicants under this
20 chapter.

21 3. Notice. Any rural community health center
22 wishing to be licensed under this subchapter shall
23 notify the board of its intent to establish such a
24 contract and shall apply for a license, submit floor
25 plans of the physical plant and pay the same fee
26 required for a pharmacy under section 13723. The
27 application shall include the name, address and
28 registration number of the provider of pharmaceutical
29 services.

30 4. Board action. The board shall approve or
31 disapprove of the application within 60 days of
32 receipt and shall notify the applicant in writing of
33 its decision and the reason for the decision.

34 §13763. Scope of license

35 A licensee under this subchapter shall comply with
36 sections 13784; 13785, subsections 1 to 7; and any
37 applicable rules promulgated by the board. No licensee
38 may refill a prescription and all orders shall be
39 treated as new orders. In all other respects,

1 notwithstanding any other provision of law, a licensee
2 may provide pharmaceutical services under this
3 subchapter subject to section 13764.

4 §13764. Rules

5 The board shall adopt rules in conformity with the
6 Maine Administrative Procedure Act, Title 5, chapter
7 375, to carry out the purposes of this subchapter.

8 SUBCHAPTER VIII

9 THIRD-PARTY PRESCRIPTION PROGRAM ACT

10 §13771. Short title

11 This subchapter shall be known and may be cited as
12 the "Third-party Prescription Program Act."

13 §13772. Definitions

14 As used in this subchapter, unless the context
15 otherwise indicates, the following terms have the
16 following meanings.

17 1. Third-party prescription program.
18 "Third-party prescription program" means any system of
19 providing for the reimbursement of pharmaceutical
20 goods and services under a contractual arrangement or
21 agreement between a provider of goods and services and
22 another party who is not the consumer of those goods
23 and services. These programs include, but are not
24 limited to, insurance plans which provide coverage for
25 prescription drugs or other pharmaceutical services.

26 §13773. Notice

27 No 3rd-party prescription program may be
28 instituted in this State until written notice of the
29 provisions of the program has been filed with the
30 Superintendent of Insurance and given to all
31 pharmacies which are located within the counties
32 covered by the program at least 30 days prior to the
33 commencement of the program. In the case of chain or
34 branch pharmacies, the notice shall be given to the

1 main office or headquarters. These pharmacies shall
2 have 30 days from the date of notice to enroll in the
3 program.

4 §13774. Denial of payment

5 No program administrator may deny to any pharmacy
6 payment for services which may have resulted from the
7 fraudulent or illegal use of an identification card by
8 any person, unless the pharmacy has been notified that
9 the card has been canceled or discontinued and that
10 the program administrator has been unsuccessful in
11 attempting to regain possession of the card.

12 §13775. Reimbursement rates

13 A 3rd-party prescription program is prohibited
14 from charging a pharmacy a registration fee or other
15 fixed charge, either annually or otherwise, except in
16 cases where a charge is necessary to specifically
17 cover any equipment, forms or materials required by
18 the program.

19 §13776. Contract renewal and changes

20 Any changes in benefits or provisions in any
21 contract may not be made unilaterally by either the
22 program administrator or the pharmacy. Any change in a
23 contract offered to one pharmacy shall be offered to
24 all the state pharmacies participating in the program.

25 §13777. Exceptions

26 This Act does not apply to any medical assistance
27 or public health programs administered by the
28 Department of Human Services, including, but not
29 limited to, the Medicaid program and the Low Cost Drug
30 Program.

31 SUBCHAPTER IX

32 MISCELLANEOUS PROVISIONS

33 §13781. Generic and therapeutically equivalent
34 substitution

1 Every written prescription issued by a
2 practitioner in this State shall contain in the lower
3 right-hand corner of the prescription form a box at
4 least 1/2 inch by 1/2 inch. The following words must
5 appear to the left of this box: "Any drug which is the
6 generic and therapeutic equivalent of the drug
7 specified above in this prescription may be dispensed,
8 provided that no check mark () has been handwritten
9 in the box in the lower right-hand corner."

10 Any pharmacist receiving a prescription in which
11 no handwritten check mark () is found in the box
12 provided may substitute a generic and therapeutically
13 equivalent drug for the drug specified on the
14 prescription, provided that the substituted drug is
15 distributed by a business entity doing business in the
16 United States which is subject to suit and the service
17 of legal process in the United States and that the
18 price of the substituted drug does not exceed the
19 price of the drug specified by the practitioner.

20 Any pharmacist who substitutes a generic drug
21 under this section shall inform the person to whom the
22 drug is dispensed of the substitution. When any
23 substitution is made under this section, the
24 pharmacist shall cause the name or abbreviation of the
25 drug manufacturer or distributor to appear on the
26 container label of the drug dispensed.

27 This section does not apply to prescriptions
28 ordered by practitioners for patients in hospitals
29 when those prescriptions are filled by a hospital
30 pharmacy or in any institution where a formulary
31 system is established.

32 §13782. Advertising

33 It is lawful for any pharmacy, pharmacist or other
34 licensee of the board to advertise to the public the
35 current retail price charged for any drugs, medicines
36 or appliances as defined in the United States Code,
37 Title 21, Section 3211 (g) (1) which bears the legend
38 "Caution: Federal law prohibits dispensing without
39 prescription." The advertising may be according to

1 either the brand name or the generic name of the drug.
2 No media advertising of any drugs included in the
3 United States Comprehensive Drug Abuse Prevention and
4 Control Act of 1970, 84 Stat. 1236, is permitted.

5 §13783. Posting prices

6 Each licensed pharmacy shall maintain on its
7 premises in a conspicuous place a price listing of
8 those 100 drugs sold most frequently in the State
9 during the previous year which bears the legend
10 "Caution: Federal law prohibits dispensing without
11 prescription." This list is not to include any
12 Schedule II substances, as defined by the Federal Drug
13 Enforcement Administration. This price listing shall
14 be prepared annually by the board and shall be
15 provided by the board to each licensed pharmacy in the
16 State by September 1st. This price listing shall be
17 prepared in accordance with the following
18 specifications.

19 1. Size of list. The list must be of uniform size
20 and shall be no smaller than 36 inches wide by 36
21 inches high.

22 2. Contents and price. The list must include the
23 name, strength and quantity of each drug and a space
24 for the insertion of the current retail price of each
25 drug by each licensed pharmacy.

26 3. Services. The list must include the
27 professional services and nonprofessional convenience
28 services provided by the pharmacy.

29 4. Generic name. The list must include the
30 generic name of each drug when a generic and
31 therapeutically equivalent is available.

32 5. Type of print. The list must be printed in
33 type sufficiently large to be easily read.

34 6. Alphabetical listing. The list must be
35 compiled alphabetically.

36 Nothing in this section prevents a pharmacy from

1 changing the current retail price of any drug at any
2 time, provided that the listed price is simultaneously
3 adjusted to reflect the new current retail price.

4 §13784. Patient information regulation

5 1. Explanation by pharmacist. With each new
6 prescription dispensed, the pharmacist, in addition to
7 labeling the prescription in accordance with the
8 requirements of the State, must orally explain to the
9 patient or the patient's agent the directions for use
10 and any additional information, in writing if
11 necessary, to assure the proper utilization of the
12 medication or device prescribed. For those
13 prescriptions delivered outside the confines of the
14 pharmacy, the explanation shall be by telephone or in
15 writing. This section does not apply to those
16 prescriptions for patients in hospitals or
17 institutions where the medication is to be
18 administered by a nurse or other individual licensed
19 to administer medications or to those prescriptions
20 for patients who are to be discharged from a hospital
21 or institution.

22 2. Maintenance of current reference material. To
23 ensure that proper information is available to each
24 pharmacist, each pharmacy or pharmacist shall maintain
25 current reference material on drug interactions.

26 §13785. Patient profile record system regulation

27 A patient profile record system shall be
28 maintained in all pharmacies for persons for whom
29 prescriptions are dispensed. The patient profile
30 record system shall be devised to enable the immediate
31 retrieval of information necessary for the dispensing
32 pharmacist to identify previously dispensed medication
33 at the time a prescription is presented for
34 dispensing. One profile record or document may be
35 maintained for all members of a family living at the
36 same address and possessing the same family name. The
37 following information shall be recorded:

38 1. Name. The family name and the first name of
39 the person for whom the medication is intended;

1 2. Address. The address to correspond to the name
2 in subsection 1;

3 3. Age group. An indication of the patient's age
4 group, that is, infant, child or adult;

5 4. Original date of dispensing. The original date
6 the medication is dispensed pursuant to the receipt of
7 a practitioner's prescription;

8 5. Prescription identification. The number or
9 designation identifying the prescription;

10 6. Prescriber's name. The name of the person
11 prescribing the drug or device;

12 7. Drug information. The name, strength and
13 quantity of the drug; and

14 8. Initials of pharmacist; date of refill. The
15 initials of the dispensing pharmacist and the date of
16 dispensing the medication as a renewal or refill, if
17 those initials and that date are not recorded on the
18 back of the original prescription.

19 The pharmacist shall attempt to ascertain and
20 shall record any allergies and idiosyncrasies of the
21 patient and any chronic conditions which may relate to
22 drug utilization as communicated to the pharmacy by
23 the patient.

24 Upon receipt of a prescription, a pharmacist shall
25 examine the patient's profile record before dispensing
26 the medication to determine the possibility of a
27 harmful drug interaction or reaction. Upon recognizing
28 a potentially harmful reaction or interaction, the
29 pharmacist shall take appropriate action to avoid or
30 minimize the problem which may include consultation
31 with the practitioner.

32 A patient profile record must be maintained for a
33 period of not less than 5 years from the date of the
34 last entry in the profile record.

1 §13786. Identification of persons prescribing
2 medicines on hospital prescription blanks

3 Any practitioner who writes a prescription upon a
4 prescription blank of a hospital or clinic shall sign
5 that practitioner's name and cause that name to be
6 printed, stamped or typed on the blank.

7 This section applies to any physician's assistant
8 or registered nurse who writes a prescription while
9 working under the control or supervision of a
10 physician. In case of the physician's assistant or
11 registered nurse, the name of the physician under whom
12 the assistant or nurse works shall be printed, stamped
13 or typed on the blank.

14 §13787. Hypodermic syringes; prescriptions

15 1. Possession. A hypodermic apparatus may be
16 possessed by a practitioner, funeral director, nurse,
17 manufacturer or dealer in embalming supplies,
18 wholesale druggist, manufacturing pharmacist,
19 pharmacist, manufacturer of surgical instruments, an
20 employee of an incorporated hospital acting under
21 official direction, carrier or messenger engaged in
22 the transportation of a hypodermic apparatus as an
23 agent of any of the persons named in this subsection,
24 employees of scientific research laboratories,
25 employees of educational institutions, employees of an
26 agency or organization duly authorized by the board or
27 a person who has received a written prescription
28 issued under subsection 2.

29 2. Prescriptions. A practitioner may issue to a
30 patient under the practitioner's immediate charge a
31 written prescription to purchase a hypodermic
32 apparatus. The board shall, by rule, prescribe the
33 form of prescription that the practitioner shall use
34 and the records and information that must be kept by
35 the practitioner and by the pharmacist filling that
36 prescription.

37 3. Hypodermic apparatus. As used in this section,
38 "hypodermic apparatus" has the meaning set forth in
39 Title 17-A, section 1101, subsection 2, except that it

1 does not include a syringe, needle or instrument for
2 use on farm animals and poultry.

3 §13788. Sale of poisonous drugs

4 Each licensed pharmacist who sells a poison shall
5 affix to the package sold a label plainly marked with
6 the name and address of the store and the word
7 "POISON" and the name of the poison sold, and shall
8 enter at the time of sale in a permanently bound book
9 to be kept for that purpose the name and address of
10 the purchaser, the date of sale, the name of the
11 poison and the quantity sold and the person making the
12 sale shall sign the entry. This section shall not
13 apply to sales on prescription of practitioners, sales
14 at wholesale to pharmacists or sales to hospitals,
15 colleges or public institutions.

16 §13789. Possession of drug samples

17 No person may purchase manufacturers' drug samples
18 from any person for purposes of resale. If those
19 samples are given gratuitously to a registered
20 pharmacist, qualified assistant pharmacist or medical
21 practitioner, any such sample may be given to any
22 person, provided that any such sample is kept in
23 containers suitably labeled to conform to the Federal
24 Food and Drug Act and the state food and drug laws and
25 provided that this gift shall be subject to the laws
26 relating to the sale of drugs.

27 §13790. Using drugs not in prescription

28 If a pharmacist knowingly uses any drugs or
29 ingredients in preparing or compounding a written or
30 oral prescription of any practitioner different from
31 those named in the prescription, that use shall
32 constitute a civil violation for which a forfeiture of
33 not more than \$1,000 nor less than \$50 may be adjudged.

34 §13791. Return of drugs prohibited

35 A drug or pharmaceutical preparation which has
36 been dispensed on prescription shall not be returned
37 to pharmacy stock after being in possession and under

1 the control of another person and shall not be
2 dispensed again, unless the drug is packaged in an
3 unbroken, sealed container or unless, in the case of a
4 hospital, a licensed pharmacist determines that the
5 drug has not been impaired.

6 §13792. Sale by certain methods prohibited

7 It shall be unlawful for any person to sell,
8 distribute, vend or otherwise dispose of any drug,
9 medicine or pharmaceutical or medical preparation by
10 means of any public exhibition, entertainment,
11 performance, carnival or by vending machines.

12 §13793. Adulterating and selling drugs

13 Whoever fraudulently adulterates, for the purpose
14 of sale, any drug or medicine or sells any
15 fraudulently adulterated drug or medicine, knowing the
16 same to be adulterated, shall be punished by a fine of
17 not more than \$1,000 or by imprisonment for not more
18 than 11 months. These adulterated drugs and medicines
19 shall be forfeited and destroyed under the direction
20 of the court.

21 §13794. Labeling of prescriptions

22 Every drug dispensed pursuant to prescription,
23 whether for a legend drug or not, shall carry on the
24 label the following information: The prescription
25 number; the date of filling; the patient's name;
26 directions for use; the name and strength of the drug
27 and the amount dispensed, including either the brand
28 name of the drug or, if a generic and therapeutically
29 equivalent drug is dispensed, it shall be in
30 accordance with section 13781; the name of the
31 practitioner prescribing the drug; and the name,
32 address and telephone number of the pharmacy where the
33 prescription was compounded and dispensed.

34 **Sec. 6. Appropriation.** The following funds are
35 appropriated from the General Fund to carry out the
36 purposes of this Act.

37

1988-89

| | | |
|----|-----------------------------------|------------------|
| 1 | <u>PROFESSIONAL AND FINANCIAL</u> | |
| 2 | <u>REGULATION, DEPARTMENT OF</u> | |
| 3 | Board of Commissioners of the | |
| 4 | Profession of Pharmacy | |
| 5 | Positions | (1.5) |
| 6 | Personal Services | \$(57,090) |
| 7 | All Other | 85,000 |
| 8 | Capital Expenditures | 5,000 |
| 9 | | |
| 10 | Total | <u>\$32,910</u> |
| 11 | Division of Licensing | |
| 12 | and Equipment | |
| 13 | Positions | (3) |
| 14 | Personal Services | 80,000 |
| 15 | | |
| 16 | TOTAL | <u>\$112,910</u> |

17 **Sec. 7. Transition.**

18 1. Funds transferred. All liabilities and assets
19 shall remain with the Board of Commissioners of the
20 Profession of Pharmacy and the Department of
21 Professional and Financial Regulation.

22 2. Personnel transferred. All employees of the
23 Board of Commissioners of the Profession of Pharmacy
24 shall become employees of the Department of
25 Professional and Financial Regulation. The accrued
26 fringe benefits, including vacation and sick leave,
27 health and life insurance and retirement of these
28 personnel shall remain with those personnel.

29 3. Rules and procedures. All rules and
30 procedures currently in effect and operations
31 pertaining to any unit and which are in compliance
32 with the provisions of this Act shall remain in effect
33 until rescinded or amended as provided by state law.

1 4. Members. Members of the Board of
2 Commissioners of the Profession of Pharmacy who have
3 been appointed to terms extending beyond the effective
4 date of this Act shall continue to serve in their
5 appointed terms of office under the Board of
6 Commissioners of the Profession of Pharmacy and shall
7 serve until their successors are appointed and
8 qualified.

9 **Emergency clause.** In view of the emergency
10 cited in the preamble, this Act shall take effect when
11 approved.

12 STATEMENT OF FACT

13 The purpose of this bill is to recodify and reform
14 the pharmacy laws.

15 4999031688