SECOND REGULAR SESSION

ONE HUNDRED AND TWELFTH LEGISLATURE

Legislative Document No. 1990

S.P. 791 In Senate, February 7, 1986

Approved for introduction by a majority of the Legislative Council pursuant to Joint Rule 26.

Reference to the Committee on Business and Commerce suggested and ordered printed.

JOY J. O'BRIEN, Secretary of the Senate

Presented by Senator Perkins of Hancock.

Cosponsored by Senator Bustin of Kennebec, Representative Brannigan of Portland and Senator Maybury of Penobscot.

STATE OF MAINE

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

AN ACT Relating to the Update of the Pharmacy Laws.

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

Sec. 1. 3 MRSA §507, sub-§4, ¶B, as repealed and replaced by PL 1981, c. 698, §3, is amended to read:

B. Unless continued or modified by law, the following Group B-2 independent agencies shall terminate, not including the grace period, no later than June 30, 1983. The Maine Health Facilities Authority and the Maine State Housing Authority shall not terminate, but shall be reviewed by the Legislature no later than June 30, 1987:

(1) Board of Chiropractic Examination and Registration;

(2) Board of Dental Examiners;

(3) State Board of Licensure of Administrators of Medical Care Facilities other than Hospitals;

(4) Board of Registration in Medicine;

(5) State Board of Nursing;

(6) State Board of Optometry;

(7) Board of Osteopathic Examination and Registration;

(8) ~~Board of Commissioners of the Profession of Pharmacy~~ Maine State Commission of Pharmacy;

(9) Examiners of Podiatrists;

(10) Maine Health Facilities Cost Review Board;

(11) Maine Medical Laboratory Commission;

(12) State Planning and Advisory Council on Developmental Disabilities;

(13) Maine Committee on Problems of the Mentally Retarded;

(14) Governor's Committee on Employment of the Handicapped;

(15) Division of Community Services;

(16) Maine State Housing Authority; and

(17) Maine Health Facilities Authority.

Sec. 2. 3 MRSA §507-B, sub-§4, ¶B, as amended by PL 1985, c. 441, §1, is further amended to read:

B. Agencies continued as modified by an Act of the Legislature are:

(1) Board of Chiropractic Examination and Registration;

(2) Board of Dental Examiners;

(3) Board of Registration in Medicine;

(4) State Board of Nursing;

(5) State Board of Optometry;

(6) Board of Osteopathic Examination and Registration;

(7) ~~Board of Commissioners of the Profession of Pharmacy~~ Maine State Commission of Pharmacy;

(8) Examiners of Podiatrists;

(9) Governor's Committee on Employment of the Handicapped;

(10) Division of Community Services; and

(11) Board of the Maine Children's Trust Fund.

Sec. 3. 5 MRSA §151, first ¶, as amended by PL 1979, c. 606, §1, is further amended to read:

All money received by the Treasurer of State from the Board of Registration in Medicine, the Board of Examiners in Physical Therapy, the Board of Examiners of Psychologists, the State Board of Nursing, the Board of Examiners of Applicants for Admission to the Bar, the Board of Accountancy, the Board of Veterinary Examiners, the Board of Osteopathic Examination and Registration, the State Board of Funeral Service, the State Board of Registration and Examination in Optometry, the Board of Dental Examiners, the State Board of Registration for Professional Engineers, the State Board of Certification for Geologists and Soil Scientists, the State Board of Licensure of Administrators of Medical Care Facilities other than Hospitals, the State Board of Architects, the Electricians' Examining Board, the Oil and Solid Fuel Board, the Penobscot Bay and River Pilotage Commission, the State Board of Barbers, State Board of Cosmetology, State Board of Registration for Land Surveyors, State

Board of Social Worker Registration, the Examiners of Podiatrists, the Board of Chiropractic Examination and Registration, the Board of Examiners on Speech Pathology and Audiology and the ~~Board of Commissioners of the Profession of Pharmacy~~ Maine State Commission of Pharmacy shall constitute a fund, which shall be a continuous carrying account for the payment of the compensation and expenses of the members, the expenses of the board and for executing the law relating to each board respectively and so much thereof as may be required is appropriated for said purposes. The secretary of each board shall be reimbursed for all expenditures for books, stationery, printing and other necessary expenses actually incurred in the discharge of his duties. All such payments shall be made from the respective funds held in the State Treasury, after the approval of the State Controller. In no event shall such payments exceed the amounts received by the Treasurer of State from the treasurer of each respective board, except that in the discretion of the Chief Justice of the Supreme Judicial Court, and with his written approval, any excess in the compensation and expenses of members of the Board of Examiners of Applicants for Admission to the Bar over the receipts of said board shall be paid and met by transfers of sufficient funds from the appropriations for the Supreme Judicial and Superior Courts. Any balance remaining to the credit of any board at the end of any year shall be carried forward to the next year.

Sec. 4. 5 MRSA §12004, sub-§1, ¶A, sub-¶(29), is repealed and the following enacted in its place:

(29)	Maine State Commission of Pharmacy	$50/Day	32 MRSA §11029

Sec. 5. 17-A MRSA §1102, sub-§4, ¶C, as enacted by PL 1975, c. 499, §1, is amended to read:

C. All nonprescription drugs other than those included in schedules W, X or Y as the ~~Board of Pharmacy~~ Maine State Commission of Pharmacy shall duly designate.

Sec. 6. 17-A MRSA §1113, as repealed and replaced by PL 1977, c. 671, §26, is amended to read:

§1113. Inspection of records

State law enforcement officers, members of the ~~Board of Commissioners of the Profession of Pharmacy~~ Maine State Commission of Pharmacy and pharmacy inspectors shall have the right to inspect the records of any pharmacy which relate to any scheduled drug or any substance designated as a "potent medical substance" under Title 22, section 2201.

Sec. 7. 22 MRSA §2201, as amended by PL 1975, c. 499, §27, is further amended to read:

§2201. Regulations

The ~~Board of Commissioners of the Profession of Pharmacy, hereinafter~~ Maine State Commission of Pharmacy, in this subchapter called the "~~board~~ commission," may from time to time, after notice and hearing, by regulations, designate as potent medicinal substances any compounds of barbituric acid, amphetamines or any other central nervous system stimulants or depressants, psychic energizers or any other drugs having a tendency to depress or stimulate which are likely to be injurious to health if improperly used.

Sec. 8. 22 MRSA §2202, as amended by PL 1971, c. 282, §13, is further amended to read:

§2202. Equipment

There shall be kept in every registered pharmacy a copy of the latest revision of the United States Pharmacopoeia and the latest revision of the National Formulary, modern prescription scales and weights, necessary graduates, mortars and pestles and such other equipment as the ~~board~~ commission may from time to time specify when the same has been duly promulgated by ~~said board~~ the commission, and such United States Pharmacopoeia and National Formulary preparations and other commonly used chemicals, drugs and preparations sufficient to compound ordinary prescriptions as dictated by experience in the community where the pharmacy is located.

22 MRSA §2204-D, as amended by PL 1977, c. 696, §188, is repealed.

Sec. 9. 22 MRSA §2204-E, as amended by PL 1977, c. 696, §189, is repealed.

Sec. 10. 22 MRSA §2204-F, as enacted by PL 1975, c. 257, is repealed.

Sec. 11. 22 MRSA §2207-A, sub-§1, as amended by PL 1977, c. 609, §1, is further amended to read:

1. Physicians, dentists, veterinarians, drug jobbers, drug wholesalers, drug manufacturers, pharmacists and pharmacies registered under Title 32, ~~section 2901~~ chapter 111, and approved animal shelters as provided in Title 7, section 3406, are authorized to deal professionally with dangerous substances.

Sec. 12. 22 MRSA §2207-A, sub-§2, ¶D, as enacted by PL 1975, c. 499, §30, is amended to read:

D. In the case of pharmacies and pharmacists registered under Title 32, ~~section 2901~~ chapter 111,

(1) To sell at retail upon the written order or prescription of a physician, dentist or veterinarian and in good faith to each other and to possess for such purpose; and

(2) To sell at retail in good faith and for the purpose which it is intended, any compound, mixture or preparation containing a dangerous substance which,

(a) Also contains a sufficient quantity of another drug or drugs to cause it to produce an action other than its hypnotic, somnifacent, stimulating or depressant action; or

(b) Is intended for use as a spray or gargle or for external application and contains some other drug or drugs rendering it unfit for internal administration.

Sec. 13. 22 MRSA §2207-A, sub-§3, ¶B, as enacted by PL 1975, c. 499, §30, is amended to read:

B. Any drug bearing on its container the legend "Caution -- federal law prohibits dispensing without prescription," or any veronal or barbital, or any other salts, derivatives or compounds of barbituric acid, or any registered, trademarked or copyrighted preparation registered in the United States Patent Office containing the substances in this paragraph, or any drug designated by the ~~board~~ commission as a "potent medicinal substance;" and

Sec. 14. 22 MRSA §2361, sub-§1, as amended by PL 1971, c. 282, §§12 and 13, is further amended to read:

1. Pharmacist. "Pharmacist" means a licensed pharmacist, as defined by the laws of this State, who prepares, dispenses or sells drugs or medicines and authorized by the ~~board~~ Maine State Commission of Pharmacy to conduct the business of pharmacy and, where the context so requires, the owner of a store or other place of business where narcotic drugs are compounded or dispensed by a licensed pharmacist; but nothing in this chapter shall be construed as conferring on a person, who is not registered nor licensed as a pharmacist, any authority, right or privilege that is not granted to him by the pharmacy laws of this State.

Sec. 15. 22 MRSA §2361, sub-§3 is repealed.

Sec. 16. 22 MRSA §2361, sub-§6 is amended to read.

6. Commission. "Commission" means the Maine ~~Board of Commissioners of the Profession of Pharmacy~~ State Commission of Pharmacy.

Sec. 17. 22 MRSA §2361, sub-§19 is amended to read:

19. Pharmacy. "Pharmacy" means the place registered by the ~~board~~ commission in which drugs, chemicals, medicines, prescriptions or poisons are compounded, dispensed or sold.

Sec. 18. 22 MRSA §2361, sub-§25 is amended to read:

25. Secretary. "Secretary" means the secretary of the ~~Maine Board of Commissioners of the Profession of Pharmacy~~ commission.

Sec. 19. 22 MRSA §2362-D, as enacted by PL 1975, c. 499, §41, is amended to read:

§2362-D. Hypodermic syringes; prescriptions

1. Possession. Hypodermic apparatus may be possessed by a physician, dentist, podiatrist, funeral director, nurse, veterinarian, a manufacturer or dealer in embalming supplies, wholesale druggist, manufacturing pharmacist, pharmacist, manufacturer of surgical instruments, an employee of an incorporated hospital acting under official direction, a carrier or messenger engaged in the transportation of hypodermic apparatus as an agent of any of the above, employees of scientific research laboratories, employees of educational institutions, employees of an agency or organization duly authorized by the Maine ~~Board of Commissioners of the Profession of Pharmacy~~ State Commission of Pharmacy or a person who has received a written prescription issued under subsection 2.

2. Prescriptions. A physician, dentist, podiatrist or osteopathic physician may issue to a patient under his immediate charge a written prescription to purchase a hypodermic apparatus. The ~~Maine Board of Commissioners of the Profession of Pharmacy~~ commission shall, by ~~regulation~~ rule, prescribe the form of prescription that the physician ~~shall~~ may use and the records and information that ~~shall~~ must be kept by the physician and by the pharmacist filling ~~such~~ that prescription.

3. Hypodermic apparatus. As used in this section, "hypodermic apparatus" has the meaning set forth in Title 17-A, ~~chapter 45,~~ section 1101, except that it does not include a syringe, needle or instrument for use on farm animals and poultry.

Sec. 20. 22 MRSA §2364, sub-§4, as enacted by PL 1975, c. 499, §43, is amended to read:

4. The ~~board~~ commission may by ~~regulation~~ rule provide for further authorization to such extent as it determines to be consistent with the public welfare, pharmaceutical preparations found by the ~~board~~ commission after due notice and opportunity for hearing:

A. Either to possess no addiction-forming or addiction-sustaining liability sufficient to warrant imposition of all of the requirements of law; and

B. Does not permit recovery of a narcotic drug having such an addiction-forming or addiction-sustaining liability, with such relative technical simplicity and degree of yield as to create a risk of improper use.

In exercising the authority granted in paragraph A, the ~~board by regulation~~ commission by rule and without special findings may grant authorizations relating to such pharmaceutical preparations as determined to be exempt under the federal narcotic law and regulations.

If the ~~board shall~~ commission subsequently ~~determine~~ determines that any such pharmaceutical preparation does possess a degree of addiction liability that, in its opinion, results in abusive use, it shall by ~~regulation~~ rule publish the determination in the state papers. The determination shall be final and the authorization shall cease to apply to the particular pharmaceutical preparation.

Sec. 21. 22 MRSA §2372, sub-§3, as amended by PL 1971, c. 282, §12, is further amended to read:

3. Pharmacists. Pharmacists shall keep records of all narcotic drugs received and disposed of by them in accordance with subsection 5 and Title 32, section 11034, subsection 2, and section 11074.

Sec. 22. 22 MRSA §2374, as amended by PL 1979, c. 541, Pt. A, §147, is further amended to read:

§2374. Records confidential

Prescriptions, orders and records required by this chapter and stocks of narcotic drugs shall be open for inspection only to the ~~board~~ commission and to federal, state, county and municipal officers whose duty it is to enforce the laws of this State or of the United States relating to narcotic drugs. No officer having knowledge by virtue of his office of any such prescription, order or record ~~shall~~ may divulge such knowledge, except in connection with a prosecution or proceeding in court or before a licensing or registration board or officer, to which prosectuion or proceeding the person to whom such prescriptions, orders or records relate is a party.

Sec. 23. 22 MRSA §2379, as amended by PL 1979, c. 541, Pt. A, §148, is further amended to read:

§2379. Enforcement and cooperation

The Bureau of Health, the ~~board~~ commission, their officers, agents, inspectors and representatives, and all peace officers within the State and all county attorneys shall enforce all provisions of this chapter, except those specifically delegated, and shall cooperate with all agencies charged with the enforcement of the laws of the United States, of this State and of all other states relating to narcotic drugs.

Sec. 24. 32 MRSA c. 41, as amended, is repealed.

Sec. 25. 32 MRSA c. 111 is enacted to read:

CHAPTER 111

MAINE PHARMACY ACT

SUBCHAPTER I

TITLE AND DEFINITION

§11001. Short title

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

§11002. Practice of pharmacy

The "practice of pharmacy" means the interpretation and evaluation of prescription orders; the compounding, dispensing, labeling of drugs and devices, except labeling by a manufacturer, packer or distributor of nonprescription drugs and commercially packaged legend drugs and devices; the participation in drug selection and drug utilization reviews; the proper and safe storage of drugs and devices and the maintenance of proper records for these drugs and devices; the responsibility for advising, where necessary or where regulated, of therapeutic values, content, hazards and use of drugs and devices; and the offering or performing of those acts, services, operations or transactions necessary in the conduct, operation, management and control of pharmacy.

§11003. Generic substitution

Every written prescription issued by a physician, osteopath or dentist in this State shall contain in the lower right-hand corner of the prescription form a box at least 1/2 inch by 1/2 inch. The following words must appear to the left of this box: "Any drug which is the generic or chemical equivalent of the drug specified above in this prescription may be dispensed, provided that no check mark ( ) has been handwritten in the box in the lower right-hand corner."

Any pharmacist receiving a prescription in which no check mark ( ) is found in the box provided may substitute a generic or chemically equivalent drug for the drug specified on the prescription, provided that the substituted drug is distributed by a business entity doing business in the United States which is subject to suit and the service of legal process in the United States and that the price of the substituted drug does not exceed the price of the drug specified by the prescribing physician, osteopath or dentist.

Any pharmacist who substitutes a generic or chemically equivalent drug under this section shall inform the person to whom the drug is dispensed of the substitution. When any substitution is made under

this section, the pharmacist shall cause the name or abbreviation of the drug manufacturer or distributor to appear on the container label of the drug dispensed.

This section does not apply to prescriptions ordered by physicians or osteopaths for patients in hospitals when those prescriptions are filled by a hospital pharmacy or in any institution where a formulary system is established.

§11004. Definitions

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

1. Commission. "Commission" means the Maine State Commission of Pharmacy.

2. Deliver or delivery. "Deliver" or "delivery" means the actual, constructive or attempted transfer of a drug or device from one person to another, whether or not for a consideration.

3. Device. "Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component part or accessory, which is required under federal or state law to be prescribed by a practitioner and dispensed by a pharmacist.

4. Dispense or dispensing. "Dispense" or "dispensing" means the preparation and delivery of a prescription drug pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug.

5. Distribute. "Distribute" means the delivery of a drug other than by administering or dispensing.

6. Drug. "Drug" means:

A. Articles recognized as drugs in the official United States Pharmacopoeia/National Formulary,

other drug compendium or any supplement to any of them;

B. Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animal;

C. Articles, other than food, intended to affect the structure or any function of the body of man or other animals; or

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

7. Drug outlet. "Drug outlet" means any pharmacy, nursing home, convalescent home, extended care facility, drug abuse treatment center, penal institution, hospital, family planning clinic, retail store, wholesaler, manufacturer or mail order vendor with facilities located in this State or doing business in this State which is engaged in dispensing, delivery or distribution of drugs.

8. Labeling. "Labeling" means the process of preparing and affixing of a label to the outside of any drug container exclusive, however, of the labeling by a manufacturer, packer or distributor of a nonprescription drug or commercially packaged legend drug or device. Any such label shall include all information required by federal law or regulation and state law or rule.

9. Manufacture. "Manufacture" means the production, preparation, propagation, compounding, conversion or processing of a device or a drug, either directly or indirectly by extraction from substances of natural origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis and includes any packaging or repacking of the substances or labeling or relabeling of its container; except that "manufacture" does not include the preparation or compounding of a drug by an individual for his use or the preparation, compounding, packaging or labeling of a drug:

A. By a pharmacist or practitioner as an incident to his administering or dispensing of a drug in the course of his professional practice; or

B. By a practitioner or by his authorization under his supervision for the purpose of or as an incident to research, teaching or chemical analysis and not for sale.

10. Manufacturer. "Manufacturer" means a person engaged in the manufacture of drugs.

11. Nonprescription drugs. "Nonprescription drugs" means drugs which may be sold without a prescription and which are prepackaged for use by the consumer and labeled in accordance with the requirements of the laws and rules of this State and the Federal Government.

12. Person. "Person" means an individual, corporation, partnership, association or any other legal entity.

13. Pharmacist. "Pharmacist" means an individual licensed by this State to engage in the practice of pharmacy.

A. Chain pharmacist means an individual who is practicing pharmacy within a chain; that is, where there is a corporate grouping of 4 or more stores.

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

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

D. Qualified assistant pharmacist means an individual licensed by this State, prior to 1936, as a qualified assistant apothecary or qualified assistant or assistant pharmacist and shall be synonymous, provided that the license is in full force and effect, except for the right to serve as a "pharmacist in charge."

14. Pharmacist in charge. "Pharmacist in charge" means the pharmacist who is accountable for the day-to-day operation of the pharmacy department.

15. Practitioner. "Practitioner" means a physician, dentist, veterinarian, scientific investigator or other person, other than pharmacists, licensed in the United States and Canada and permitted by the license to dispense, conduct research with respect to or administer drugs in the course of professional practice or research.

16. Prescription drug or legend drug. "Prescription drug" or "legend drug" means a drug which:

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

(1) Caution: Federal law prohibits dispensing without prescription; or

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

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

17. Prescription drug order. "Prescription drug order" means a lawful written or oral order of a practitioner for a drug.

18. Wholesaler. "Wholesaler" means a person who buys drugs for resale and distribution to persons other than consumers.

SUBCHAPTER II

COMMISSION OF PHARMACY

§11021. Designation

The responsibility for enforcement of this Act is vested in the Maine State Commission of Pharmacy as established pursuant to Title 5, chapter 379. The commission has all of the duties, powers and authority specifically granted by and necessary to the enforcement of this Act, as well as such other duties,

powers and authority as it may be granted from time to time by law.

§11022. Membership

The commission shall consist of 6 members, one of whom shall be a representative of the public and the remainder of whom shall be licensed pharmacists who possess the qualifications specified in section 11023. At the time of the appointment, at least one of the licensed pharmacists must be a hospital pharmacist, at least one must be a chain pharmacist and at least one must be an independent pharmacist.

§11023. Qualifications

1. Public member. The public member of the commission must be a resident of this State who has attained the age of majority and shall not be nor shall he ever have been a member of the profession of pharmacy; the spouse of a member of the profession of pharmacy; a person who has ever had any material financial interest in the providing of pharmacy service; or a person who has engaged in any activity directly related to the practice of pharmacy.

2. Licensed pharmacists. The licensed pharmacist members of the commission shall, at the time of their appointment:

A. Be residents of this State;

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

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

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

§11024. Appointment

The Governor shall appoint the members of the commission. Prior to appointing any pharmacist as a member of the commission, the Governor shall solicit recommendations of candidates from the Maine Pharmacy

Association and other pharmaceutical organizations as he deems appropriate.

§11025. Terms of office

1. Length. Except as provided in subsection 2, members of the commission shall be appointed for terms of 5 years, except that members of the commission who are appointed to fill vacancies which occur prior to the expiration of a former member's full term shall serve the unexpired portion of that term.

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

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

B. The present members of the commission shall serve the balance of their terms.

C. Any present commission member appointed initially for a term of less than 5 years shall be eligible to serve 2 additional full terms.

3. Successorship. No member of the commission may serve more than 2 consecutive full terms. The completion of the unexpired portion of a full term shall not constitute a full term for purposes of this section.

4. Commencement. An appointee to a full term on the commission shall be appointed by the Governor before the expiration of the term of the member being succeeded and shall become a member of the commission on the first day of the calendar year next following his appointment. Appointees to unexpired portions of full terms shall become members of the commission on the day next following that appointment. In the event the number of commission members is increased, the term of any new member shall commence at such time as is designated in the law providing for the enlargement of the commission.

5. Expiration. Each term of office on the commission expires at midnight on the last day of the

calendar year in the final year of the commission member's term or on the date his successor is appointed.

§11026. Vacancies

Any vacancy which occurs in the membership of the commission for any reason, including expiration of term, removal, resignation, death, disability or disqualification, shall be filled by the Governor in the manner prescribed by section 11024. The Governor shall fill vacancies which occur by expiration of full terms within 90 days prior to each date of expiration, and shall fill vacancies which occur for any other reason within 60 days after each such vacancy occurs.

§11027. Removal

1. Grounds. The Governor may remove a member of the commission, pursuant to the procedures set forth in subsection 2, upon one or more of the following grounds:

A. The refusal or inability for any reason of a commission member to perform his duties as a member of the commission in an efficient, responsible and professional manner;

B. The misuse of office by a member of the commission to obtain personal, pecuniary or material gain or advantage for himself or another through that office; or

C. The violation, by any member, of this Act or any of the rules adopted under this Act.

2. Procedures. The following procedures shall be utilized to remove a member of the commission from office for any of the grounds specified by subsection 1.

A. Any person, including the Governor or a commission member, may file a complaint with the executive director or secretary of the commission against a member of the commission alleging specific facts which constitute grounds for removal

from the commission. The executive director or secretary shall notify the president of the commission, the accused member and the Governor of the filing of any such allegations and supply each with a copy of the complaint.

B. Upon the written recommendation of the Governor or 2/3 of the members of the commission, a hearing shall be conducted before an impartial hearing officer pursuant to the Maine Administrative Procedure Act, Title 5, chapter 375. The hearing officer shall submit a transcript of the hearing to the Governor and shall recommend whether or not the commission member shall be removed.

C. The Governor shall review the transcript of any such hearing, determine whether there is substantial evidence to support a finding that a member of the commission has engaged in conduct which constitutes grounds for removal from the commission and enter a finding in accordance with his determination. In the event a commission member is removed under this section, his removal shall be effective as of the date of the Governor's finding for removal and a vacancy shall be deemed to exist.

D. Any individual subjected to possible removal under this section is entitled to those privileges, protections and rights granted all persons under the Maine Administrative Procedure Act, Title 5, chapter 375, including the right of a review by a court of competent jurisdiction.

§11028. Organization

1. Officers. The Maine State Commission of Pharmacy shall elect from its members a president and such other officers as it deems appropriate and necessary to the conduct of its business. The President of the Maine State Commission of Pharmacy shall preside at all meetings of the commission and shall be responsible for the performance of all of the duties and functions of the commission required or permitted by this Act. Each additional officer elected by the board shall perform those duties normally associated

with his position and those other duties assigned to him from time to time by the commission.

2. Terms of office. Officers elected by the commission shall serve terms of one year commencing with the day of their elections and ending upon elections of their successors and shall serve no more than 2 consecutive full terms in each office to which they are elected.

3. Executive director. The commission may employ a licensed pharmacist who shall be an ex officio member of the commission without vote to serve as an employee of the commission in the position of executive director. The executive director shall be responsible for the performance of the regular administrative functions of the commission and such other duties as the commission may direct. The executive director shall not perform any discretionary or decision-making functions for which the commission is solely responsible.

§11029. Compensation

1. Commission members. Each member of the commission shall be compensated in accordance with Title 5, chapter 379.

2. Executive director. The executive director of the commission shall receive, as compensation, a salary, the amount of which shall be determined by the commission, and reimbursement for all expenses incurred in connection with performance of his official duties.

3. Secretary. The secretary of the commission shall receive reimbursement for all expenses incurred in connection with performance of his official duties.

§11030. Meetings

1. Number. The commission shall meet at least once every 2 months to transact its business. The December meeting shall be designated as the annual meeting and shall be for the purpose of electing officers and for the reorganization of the commission.

The commission shall meet at such additional times as it may determine. Additional meetings may be called by the president or by 2/3 of the members of the commission.

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

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

4. Quorum. A majority of the members of the commission constitutes a quorum for the conduct of a commission meeting and, except where a greater number is required by this Act or by any rule of the commission, all actions of the commission shall be by a majority of a quorum.

5. Open meeting. All commission meetings and hearings shall be open to the public. The commission may conduct any portion of its meetings in executive session closed to the public.

§11031. Employees

1. Authority. The commission may employ persons in addition to the executive director in such other positions or capacities as it deems necessary to the proper conduct of commission business and to the fulfillment of the commission's responsibilities as defined by this Act.

2. Compensation. The employees of the commission other than the executive director shall receive, as compensation, an annual salary, the amount of which shall be determined by the commission or by law where required, and reimbursement for all expenses incurred in connection with performance of their official duties.

§11032. Rules

The commission shall make, adopt, amend and repeal such rules as may be deemed necessary by the commission, from time to time, for the proper administration and enforcement of this Act. These rules shall be promulgated in accordance with the Maine Administrative Procedure Act, Title 5, chapter 375.

§11033. Licensure and discipline

1. Responsibility. The commission is responsible for the control and regulation of the practice of pharmacy in this State, including, but not limited to, the following:

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

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

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

D. The inspection of any drug outlet as set out in section 11061;

E. The enforcement of those provisions of this Act relating to the conduct or competence of pharmacists practicing in this State, and the suspension, revocation or restriction of licenses to engage in the practice of pharmacy;

F. The rules of the training, qualifications and employment of pharmacy interns and pharmacy students; and

G. The rules of the training, qualifications and employment of pharmacy ancillary personnel.

§11034. Medications, drugs, devices and other materials

1. Responsibility. The commission has the following responsibilities in regard to medications, drugs, devices and other materials used in this State in the diagnosis, mitigation and treatment or prevention of injury, illness and disease:

A. The rules of the sale and the dispensing of medications, drugs, devices and other materials, including the right to seize any such drugs, devices and other materials found to be detrimental to the public health and welfare by the commission after appropriate hearing as required under the Maine Administrative Procedure Act, Title 5, chapter 375;

B. The specifications of minimum professional and technical equipment, environment, supplies and procedures for the compounding or dispensing of medications, drugs, devices and other materials within the practice of pharmacy;

C. The control of the purity and quality of medications, drugs, devices and other materials within the practice of pharmacy;

D. The issuance of renewal of certificates of registration of drug outlets for purposes of ascertaining those persons engaged in the manufacture and distribution of drugs; and

E. The rules of the sale and the dispensing of any medicinal preparation that contains 30 milliliters or, if a solid or semisolid preparation, in 30 grams:

(1) Not more than 130 milligrams of opium;

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

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

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

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

2. Records of sale. A record shall be kept of the sale of exempt narcotic preparations, those records to contain the date of sale, signature and address of the purchaser, name of the preparation, purpose for which purchased and signature of the person making the sale.

§11035. Other duties, powers and authority

The commission has such other duties, powers and authority as may be necessary to enforce this Act and the commission rules made pursuant to this Act, which include, but are not limited to, the following:

1. Professional associations. The commission may join professional organizations and associations organized exclusively to promote the improvement of the standards of the practice of pharmacy for the protection of the health and welfare of the public and whose activities assist and facilitate the work of the commission.

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

3. Seal. The executive director of the commission or the secretary of the commission shall keep the seal of the commission and shall affix it only in such manner as may be prescribed by the commission.

4. Reports. The commission shall submit to the Governor a report summarizing its proceedings and activities during the fiscal year, together with a report of all money received and disbursed by the commission. These reports, or comprehensive summaries or abstracts of the reports, as determined by the commission, shall be made available to the public.

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

A. Examinations and reexaminations, which fee shall not exceed costs of the examination plus an amount not to exceed $100;

B. The issuance of renewal of pharmacists' licenses, which fee shall not exceed $50;

C. The issuance of certificates of registration for new pharmacies, which fee shall not exceed $200;

D. The issuance of certificates of registration for renewal of pharmacy licenses, which fee shall not exceed $150;

E. The issuance of certificates of registration necessitated by a change in the pharmacist responsible for the license, which fee shall not exceed $100; and

F. The certification of approved providers of continuing education courses, which fee shall not exceed $100; provided that approved providers by the American Council of Pharmaceutical Education are exempt from the fee established in this paragraph.

6. Grants. The commission may receive and expend funds, in addition to its annual appropriation, from parties other than the State, provided that:

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

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

C. Activities connected with or occasioned by the expenditures of the funds do not interfere with or impair the performance of the commission's duties and responsibilities and do not conflict with the exercise of the commission's powers as specified by this Act;

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

E. Periodic reports are made to the Governor concerning the commission's receipt and expenditure of the funds.

7. Investigatory powers. The commission or its authorized representatives may investigate and gather evidence concerning alleged violations of this Act or of the rules of the commission. This shall include removal of prescriptions and patient profiles for the purpose of photocopying. An inventory receipt shall be furnished and the articles removed shall be returned within 3 hours. The pharmacist who has custody of the records may accompany the commission's representative so that he may attest to the authenticity and lack of alteration of the records being photocopied.

8. Embargo. The commission may embargo certain drugs or devices as follows.

A. Notwithstanding anything in this Act to the contrary, if a duly authorized representative of the commission finds or has probable cause to believe that any drug or device is adulterated or misbranded within the meaning of the United States Food and Drug Act, he shall affix to that drug or device a tag or other appropriate marking giving notice that the article is or is suspected of being adulterated or misbranded, has been detained or embargoed and warning all persons not to remove or dispose of the article by sale or otherwise until provision for removal or disposal is given by the commission, its agent or the court. No person may remove or dispose of the embargoed drug or device by sale or otherwise without the permission of the commission or its agent or, after summary proceedings have been instituted, without permission from the court.

B. When a drug or device detained or embargoed under paragraph A has been declared by a representative at the commission to be adulterated or misbranded, the commission shall, as soon as practical thereafter, petition the judge of the court in whose jurisdiction the article is detained or embargoed for an order for condemnation of the article. If the judge determines that the

drug or device so detained or embargoed is not adulterated or misbranded, the commission shall direct the immediate removal of the tag or other marking.

C. If the court finds the detained or embargoed drug or device is adulterated or misbranded, that drug or device, after entry of the decree, shall be destroyed at the expense of the owner under the supervision of the commission representative and all court costs and fees, storage and other proper expense shall be borne by the owner of the drug or device. When the adulteration or misbranding may be corrected by proper labeling or processing of the drug or device, the court, after entry of the decree and after the costs, fees and expenses have been paid and a good and sufficient bond has been posted, may direct that the drug or device be delivered to the owner for labeling or processing under the supervision of a commission representative. Expense of the supervision shall be paid by the owner. The bond shall be returned to the owner of the drug or device on representation to the court by the commission that the drug or device is no longer in violation of the embargo and the expense of supervision has been paid.

D. It is the duty of the Attorney General to whom the commission reports any violation of this subsection to cause appropriate proceedings to be instituted in the proper court without delay and to be prosecuted in the manner required by law. Nothing in this subsection requires the commission to report violations whenever the commission believes the public interest will be adequately served in the circumstances by a suitable written notice or warning.

9. Procedure. Except as otherwise provided, the commission shall exercise all of its duties, powers and authority in accordance with the Maine Administrative Procedure Act, Title 5, chapter 375.

SUBCHAPTER III

LICENSING

§11041. Unlawful practice

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

2. Penalties. Any person found by the commission to have unlawfully engaged in the practice of pharmacy shall be subject to a fine to be imposed by the commission not to exceed $1,000 for each offense. Each violation of this chapter or the rules promulgated under this chapter pertaining to unlawfully engaging in the practice of pharmacy shall also constitute a Class E Crime.

§11042. Qualifications for licensure by examination

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

A. Have submitted a written application in the form prescribed by the commission;

B. Have attained the age of 21 years;

C. Be of good moral character and temperate habits;

D. Have graduated and received the first professional undergraduate degree from an accredited pharmacy degree program which has been approved by the commission;

E. Have completed an internship or other program which has been approved by the commission or demonstrated, to the commission's satisfaction, experience in the practice of pharmacy which meets or exceeds the minimum internship requirement of the commission;

F. Have successfully passed an examination given by the commission; and

G. Have paid the fees specified by the commission for examination and issuance of a license.

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

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

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

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

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

B. The commission shall establish standards for internship or any other program necessary to qualify an applicant for the licensure examination and shall also determine the necessary qualifications of any preceptors used in any internship or other program.

§11043. Qualifications for licensure by reciprocity

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

A. Have submitted a written application in the form prescribed by the commission;

B. Have attained the age of 21 years;

C. Be of good moral character and temperate habits;

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

E. Have passed the examination for licensure as administered by the commission;

F. Have presented to the commission proof of initial licensure by examination and proof that the license and any other license or licenses granted to the applicant by any other state or states have not been suspended, revoked, cancelled or otherwise restricted for any reason except nonrenewal or the failure to obtain required continuing education credits in any state where the applicant is licensed, but not engaged in the practice of pharmacy; and

G. Have paid the fees specified by the commission for issuance of a license.

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

3. Falsification of information. The license of any applicant who knowingly withholds or falsifies information on his application shall be automatically suspended upon discovery of the false information.

§11044. Renewal of licenses

1. Annual report. Each pharmacist must apply for renewal of his license annually no later than the last day of June. The commission shall renew the li-

cense of each pharmacist who is qualified to engage in the practice of pharmacy.

2. Fees. The commission shall specify by rule the procedures to be followed, in addition to those specified by section 11045, and the fees to be paid for renewal of licenses.

§11045. Continuing pharmacy education

No annual renewal certificate may be issued by the commission until the applicant submits proof satisfactory to the board that, during the year preceding his application for renewal, he has participated in not less than 15 hours of approved courses of continuing professional pharmaceutical education as set out in this section. The continuing professional pharmaceutical educational courses shall consist of postgraduate studies, institutes, seminars, workshops, lectures, conferences, extension studies, correspondence courses or such other forms of continuing professional pharmaceutical education as may be approved by the commission.

These courses shall consist of subject matter pertinent to the following general areas of professional pharmaceutical education: The socioeconomic and legal aspects of health care; of properties and actions of drugs and dosage forms and the ideology; or characteristics and therapeutics of the disease state. The specific subject matter of the courses may include, but is limited to, pharmacology, biochemistry, physiology, pharmaceutical chemistry, pharmacy administration, pharmacy jurisprudence, public health and communicable diseases, pharmaceutical marketing, professional practice management, anatomy, histology and such other subject matter as represented in curricula of accredited colleges of pharmacy. The content of each course offered for credit under this continuing professional educational program must be approved in advance of the course offered by a committee composed of equal representation from the commission who shall serve for a period of 2 years. The commission may make exceptions from the operation of this section in emergency of hardship cases.

SUBCHAPTER IV

DISCIPLINE

§11051. Grounds

1. Refusal to issue or renew. The commission of pharmacy may refuse to issue or renew or may suspend, revoke or restrict the license of any person, pursuant to the procedures set forth in section 11052, upon one or more of the following grounds:

A. Unprofessional conduct as that term is defined by the rules of the commission;

B. Incapacity of a nature that prevents a pharmacist from engaging in the practice of pharmacy with reasonable skill, competence and safety to the public;

C. Being found guilty by a court of competent jurisdiction of one or more of the following:

(1) Murder or a Class A, Class B or Class C crime;

(2) Any act involving moral turpitude or gross immorality; or

(3) Violations of the pharmacy or drug laws of this State or rules pertaining to those laws, or of statutes or rules of any other state or the Federal Government;

D. Fraud or intentional misrepresentation by a licensee in securing the issuance or renewal of a license;

E. Engaging or aiding and abetting an individual to engage in the practice of pharmacy without a license or falsely using the title of pharmacist; or

F. Being found by the commission to be in violation of this chapter or rules adopted pursuant to this chapter.

2. Grounds for discipline. The board may suspend or revoke a license, pursuant to Title 5, section 10004. The following shall be grounds for an action to refuse to issue, modify, suspend, revoke or refuse to renew the license of a person licensed under this chapter:

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

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

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

D. Aiding or abetting the practice of pharmacy by a person not duly licensed under this chapter and who represents himself to be so;

E. Incompetence in the practice for which he is licensed. A licensee shall be deemed incompetent in the practice if the licensee has:

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

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

F. A licensee shall be deemed to have engaged in unprofessional conduct if he violates any standard of professional behavior which has been established in the practice for which the licensee is licensed;

G. Subject to the limitations of Title 5, chapter 341, conviction of a crime which involves dishonesty or false statement or which relates directly to the practice for which the licensee is licensed, or conviction of any crime for which incarceration for one year or more may be imposed;

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

I. Any violation of this chapter or of the pharmacy laws of the State or of any rule adopted by the commission.

3. Crime in course of business. If any registered pharmacist is convicted in state or federal court of a crime which is committed during the course of his duties as a registered pharmacist or committed by him through the use of the pharmacy in which he is employed, or which he owns or operates, and which demonstrates his unfitness to practice as a pharmacists, including, but not limited to, convictions for defrauding the Medicaid Program and for illegally distributing prescription drugs, he is subject to the following action by the Administrative Court.

A. A pharmacist convicted of such a crime, if it is punishable by a maximum term of imprisonment of less than one year, shall have his registration and certificate suspended for a minimum period of 120 days.

B. A pharmacist convicted of such a crime, if it is punishable by a maximum term of imprisonment equal to or exceeding one year, shall have his registration and certificate suspended for a minimum period of one year and may have his registration and certificate revoked and be permanently barred from reapplying for registration, notwithstanding Title 5, sections 5301 to 5304.

§11052. Disciplinary actions

Disciplinary proceedings and sanctions. The commission shall investigate a complaint, on its own motion or upon receipt of a written complaint filed

with the commission, regarding noncompliance with or violation of this chapter or of any rules adopted by the commission.

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

If, in the opinion of the commission, the factual basis of the complaint is or may be true and it is of sufficient gravity to warrant further action, the commission may request an informal conference with the licensee. The commission shall provide the licensee with adequate notice of the conference and of the issues to be discussed. The conference shall be conducted in executive session of the commission, unless otherwise requested by the licensee. Statements made at the conference may not be introduced at a subsequent formal hearing unless all parties consent.

If the commission finds that the factual basis of the complaint is true and is of sufficient gravity to warrant further action, it may take any of the following actions it deems appropriate:

1. Consent agreement. With the consent of the licensee, enter into a consent agreement which fixes the period and terms of probation best adapted to protect the public health and safety and to rehabilitate or educate the licensee. A consent agreement may be used to terminate a complaint investigation, if entered into by the commission, the licensee and the Attorney General's office;

2. Negotiate stipulations. In consideration for acceptance of a voluntary surrender of the license, negotiate stipulation, including terms and conditions for reinstatement which ensure protection of the public health and safety and which serve to rehabilitate or educate the licensee. These stipulations shall be set forth only in a consent agreement signed by the

commission, the licensee and the Attorney General's office;

3. Adjudicatory hearing. If the commission concludes that modification or nonrenewal of the license might be in order, hold an adjudicatory hearing in accordance with the Maine Administrative Procedure Act, Title 5, chapter 375, subchapter IV; or

4. File complaint in Administrative Court. If the commission concludes that suspension or revocation of the license is in order, file a complaint in the Administrative Court in accordance with Title 4, chapter 25.

§11053. Penalties and reinstatement

1. Penalties. Upon the finding of the existence of grounds for discipline of any person holding a license or seeking a license or a renewal of a license under this chapter, the commission may impose one or more of the following penalties:

A. Suspension of the offender's license for a term to be determined by the commission;

B. Revocation of the offender's license;

C. Restriction of the offender's license to prohibit the offender from performing certain acts or from engaging in the practice of pharmacy in a particular manner for a term to be determined by the commission;

D. Imposition of a fine not to exceed $1,000 for each offense;

E. Refusal to renew offender's license; or

F. Placement of the offender on probation and supervision by the commission for a period to be determined by the commission.

2. Reinstatement. Any person whose license to practice pharmacy in this State has been suspended, revoked or restricted pursuant to this chapter, whether voluntarily or by action of the commission,

may at reasonable intervals petition the commission for reinstatement of the license. The petition must be made in writing in a form prescribed by the commission. Upon investigation and hearing, the commission may grant or deny the petition or it may modify its original finding to reflect any circumstances which have changed sufficiently to warrant those modifications.

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

4. Judicial review. All final decisions by the commission are subject to judicial review pursuant to the Maine Administrative Procedure Act, Title 5, chapter 375.

SUBCHAPTER V

REGISTRATION OF FACILITIES

§11061. Registration

1. Registration. All drug outlets shall annually register with the Commission of Pharmacy.

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

A. Each drug outlet doing business in the State must apply for a certificate of registration in one of the following classifications:

(1) Retail drug outlet;

(2) Institutional drug outlet;

(3) Manufacturing drug outlet;

(4) Wholesale drug outlet;

(5) Rural health center;

(6) Industrial dispensary;

(7) Educational institution dispensary;

(8) Mail-order drug outlet; or

(9) Any other outlet dispensing legend drugs to consumers.

No individual who is employed by a corporation which is registered under any classification listed in this paragraph need register under the provisions of this subchapter.

3. Rules. The commission shall establish by rule under the powers granted to it under sections 11032 and 11034 the criteria which each drug outlet that has employees or personnel engaged in the practice of pharmacy must meet to qualify for registration in each classification designated in subsection 2. The commission may issue various types of certificates with varying restrictions to the outlets referred to in paragraph A where the commission deems it necessary by reason of the type of drug outlet requesting a certificate.

§11062. Application

1. Procedures. The commission shall specify by rule the registration procedures to be followed, including, but not limited to, specification of forms for use in applying for certificates of registration and the times, places and fees for filing an application; provided that the annual fee for an original or renewal certificate shall not exceed $200.

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

A. Ownership;

B. Location; and

C. Identity of pharmacist licensed to practice in the State who shall be the pharmacist in charge of the drug outlet, where one is required

by this chapter, and such further information as the commission may deem necessary. A pharmacist may be the pharmacist in charge for only one drug outlet. The position of pharmacist in charge may not be held by a qualified assistant pharmacist.

3. Transferability. Certificates of registration issued by the commission pursuant to this chapter are not transferable or assignable.

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

5. Minimum inventory. The commission shall ascertain that the applicant has a sufficient amount of prescription inventory on location to appropriately respond to prescription orders.

§11063. Notifications

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

A. Permanent closing: Requires 14 days prior notice to the public and to the commission;

B. Change of ownership: Requires 7 days prior notice to the commission;

C. Change of pharmacist in charge: Requires notice no later than 7 days after the change; or

D. Any and all other matters and occurrences as the commission may require by rule.

2. Other reportable events. Disasters, accidents and emergencies which may affect the strength,

purity or labeling of drugs, medications, devices or other materials used in the diagnosis or the treatment of injury, illness and disease shall be immediately reported to the commission.

§11064. Violations and penalties

1. Unlawful conduct. No drug outlet designated in section 11061 may be operated until a certificate of registration has been issued to that facility by the commission. Upon the finding of a violation of this section, the commission may impose one or more of the penalties enumerated in section 11053.

2. Reinstatement. Reinstatement of a certificate that has been suspended, revoked or restricted by the commission may be granted in accordance with the procedures specified by section 11053, subsection 2.

SUBCHAPTER VI

MISCELLANEOUS PROVISIONS

§11071. Advertising

It is lawful for any pharmacy, pharmacist or other licensee of the Maine State Commission of Pharmacy to advertise to the public the current retail price he charges for any drugs, medicines or appliances as defined in the United States Code Title 21, Section 3211(g) (I) which bears the legend "Caution: Federal law prohibits dispensing without prescription." The advertising may be according to either the brand name or the generic or chemical name of the drugs. No media advertising of any drugs included in the United States Comprehensive Drug Abuse Prevention and Control Act of 1970, 84 Stat. 1236, is permitted.

§11072. Posting prices

Each licensed pharmacy shall maintain on its premises in a conspicuous place a price listing of those 100 drugs sold most frequently in the State during the previous year which bear the legend "Caution: Federal law prohibits dispensing without prescription." This list is not to include any Schedule

II substances, as defined by the Federal Drug Enforcement Administration. This price listing shall be prepared annually by the commission and shall be provided by the commission to each licensed pharmacy in the State on or before September 1st. This price listing shall be prepared in accordance with the following specifications.

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

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

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

4. Generic or chemical name. The list must include the generic or chemical name of each drug when a generic is available.

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

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

Nothing contained in this section prevents a pharmacy from changing the current retail price of any drug at any time, provided that the listed price is simultaneously adjusted to reflect the new current retail price.

Institutional pharmacies are exempt from this price posting requirement.

§11073. Patient information regulation

1. Explanation by pharmacist. With each new prescription dispensed, the pharmacist, in addition to labeling the prescription in accordance with the requirements of the State, must orally explain to the patient or the patient's agent the directions for use

and any additional information, in writing if necessary, to assure the proper utilization of the medication or device prescribed. For those prescriptions delivered outside the confines of the pharmacy, the explanation shall be by telephone or in writing. This section does not apply to those prescriptions for patients in hospitals or institutions where the medication is to be administered by a nurse or other individual licensed to administer medications or to those prescriptions for patients who are to be discharged from a hospital or institution.

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

§11074. Patient profile record system regulation

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

1. Name. The family name and the first name of the person for whom the medication is intended, which is the patient;

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

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

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

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

6. Prescriber's name. Name of the person prescribing the drug or device;

7. Name, strength and quantity of drug. Name, strength and quantity of drug; and

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

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

Upon receipt of a prescription, a pharmacist shall examine the patient's profile record before dispensing the medication to determine the possibility of a harmful drug interaction or reaction. Upon recognizing a potential harmful reaction or interaction, the pharmacist shall take appropriate action to avoid or minimize the problem which may include consultation with the physician.

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

§11075. Identification of persons prescribing medicines on hospital prescription blanks

Any physician, dentist or veterinarian who writes a prescription upon a prescription blank of a hospital or clinic shall sign his name and cause his name to be printed, stamped or typed on the blank.

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

§11076. Hypodermic syringes; prescriptions

1. Possession. Hypodermic apparatus may be possessed by a physician, dentist, podiatrist, funeral director, nurse, veterinarian, manufacturer or dealer in embalming supplies, wholesale druggist, manufacturing pharmacist, pharmacist, manufacturer of surgical instruments, employee of an incorporated hospital acting under official direction, carrier or messenger engaged in the transportation of hypodermic apparatus as an agent of any of the above, employees of scientific research laboratories, employees of educational institutions, employees of an agency or organization duly authorized by the commission or a person who has received a written prescription issued under subsection 2.

2. Prescriptions. A physician, dentist, podiatrist or osteopathic physician may issue to a patient under his immediate charge a written prescription to purchase a hypodermic apparatus. The commission shall, by rule, prescribe the form of prescription that the physician must use and the records and information that must be kept by the physician and by the pharmacist filling that prescription.

3. Hypodermic apparatus. As used in this section, "hypodermic apparatus" has the meaning set forth in Title 17-A, section 1101, except that it does not include a syringe, needle or instrument for use on farm animals and poultry.

SUBCHAPTER VII

SERVICES AT RURAL HEALTH CENTERS

§11081. Definitions

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

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

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

§11082. Center to be licensed

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

2. Notice. Any rural community health center wishing to be licensed under this subchapter shall notify the commission of its intent to establish such a contract and shall apply for a license, submit floor plans of the physical plant and pay the same fee required for a pharmacy under section 11035. The application shall include the name, address and registration number of the provider of pharmaceutical services.

3. Commission action. The commission shall approve or disapprove of the application within 60 days of receipt and shall notify the applicant in writing of its decision and the reason for the decision.

§11083. Scope of license

A licensee under this subchapter shall comply with sections 11073; 11074, subsections 1 to 7; and any applicable rules promulgated by the commission. No licensee may refill a prescription. All orders shall be treated as new orders. In all other respects, notwithstanding any other provision of law, a licensee may provide pharmaceutical services under this subchapter subject to section 11084.

§11084. Rules

The commission shall adopt rules in conformity with the Maine Administrative Procedure Act, Title 5,

chapter 375, to carry out the purposes of this subchapter.

SUBCHAPTER VIII

THIRD-PARTY PRESCRIPTION PROGRAM ACT

§11091. Short title

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

§11092. Definition

As used in this Act, "Third-party prescription program" means any system of providing for the reimbursement of pharmaceutical goods and services under a contractual arrangement or agreement between a provider of goods and services and another party who is not the consumer of those goods and services. These programs include, but are not limited to, insurance plans which provide coverage for prescription drugs or other pharmaceutical services.

§11093. Notice

No Third-party prescription program may be instituted in this State until written notice of the provisions of this program has been filed with the Superintendent of Insurance and given to all pharmacies which are located within the counties covered by the program at least 30 days prior to the commencement of the program. In the case of chain or branch pharmacies, the notice shall be given to the main or headquarters' office. These pharmacies shall have 30 days from the date of notice to enroll in the program.

§11094. Denial of payment

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

§11095. Reimbursement rates

A Third-party prescription program is prohibited from charging a pharmacy a registration fee or other fixed charges, either annually or otherwise, except in cases where a charge is necessary to specifically cover any equipment, forms or materials required by the program.

§11096. Contract renewal and changes

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

§11097. Exceptions

This Act does not apply to any medical assistance or public health programs administered by the Department of Human Services, including, but not limited to, the Maine Medicaid Program, the Catastrophic Illness Program and the Drugs for the Elderly Program.

Sec. 26. 34-B MRSA §5605, sub-§8, ¶F, as enacted by PL 1983, c. 459, §7, is amended to read:

F. Pharmacy services at each residential facility operated by the department shall be directed or supervised by a professionally competent pharmacist licensed according to ~~the provisions of~~ Title 32, chapter ~~41~~ 111.

STATEMENT OF FACT

The practice of pharmacy in the State is a professional practice affecting the public health, safety and welfare and is subject to regulation and control in the public interest. It is a matter of public interest and concern that the practice of pharmacy, as defined in this bill, merit and receive the confidence of the public and that only qualified persons be permitted to engage in the practice of pharmacy in the State.

It is the purpose of the Maine Pharmacy Act created in this bill to promote, preserve and protect the public health, safety and welfare by and through the effective control and regulation of the practice of pharmacy and of the registration of drug outlets engaged in the manufacture, production, sale and distribution of drugs, medications, devices and such other materials as may be used in the diagnosis and treatment of injury, illness and disease.

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