MAINE STATE LEGISLATURE

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FIRST REGULAR SESSION

ONE HUNDRED AND THIRTEENTH LEGISLATURE

Legislative Document No. 1581

S.P. 529

13

Sec. 4.

In Senate, May 15, 1987

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

JOY J. O'BRIEN, Secretary of the Senate Presented by Senator BALDACCI of Penobscot. Cosponsored by Senator GOULD of Waldo.

STATE OF MAINE

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

1 2	AN ACT to Reform the Pharmacy Laws.
3 4	Be it enacted by the People of the State of Maine as follows:
5 6	Sec. 1. 5 MRSA $\S12004$, sub- $\S1$, \PA , sub- $\P(29)$ is amended to read:
7 8 9	(29) Board of Commis- \$25/Day 32-MRSA-\$2851 sioners of the Pro- \$35/Day 32 MRSA \$11521 fession of Pharmacy
10 11	Sec. 2. 22 MRSA c. 551, sub-c.II, as amended, is repealed.
12	Sec 3 22 MPSA c 557 as amended is repealed

32 MRSA c. 41, as amended, is repealed.

1	Sec. 5. 32 MRSA c. 113 is enacted to read:
2	CHAPTER 113
3	MAINE PHARMACY ACT
4	SUBCHAPTER I
5	TITLE AND DEFINITIONS
6	§11501. Short title
7 8	This Act shall be known and may be cited as the "Maine Pharmacy Act."
9	§11502. Definitions
10 11 12	As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings.
13 14	1. Board. "Board" means the Board of Commissioners of the Profession of Pharmacy.
15 16 17 18	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.
19 20 21 22 23 24	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.
25 26 27 28 29 30 31	4. Dispense or dispensing. "Dispense" or "dispensing" means the preparation and delivery of a prescription drug in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug pursuant to a lawful order of a practitioner.
32 33	5. Distribute. "Distribute" means the delivery of a drug other than by administering or dispensing.

	1	6. Drug. "Drug" means:
	2 3 4 5	A. Articles recognized as drugs in the official United States Pharmacopeia and National Formulary, other drug compendia or any supplement to any of them;
	6 7 8	B. Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animal;
	9 10 11	C. Articles, other than food, intended to affect the structure or any function of the body of mar or other animal; and
	12 13	D. Articles intended for use as a component of any articles specified in paragraphs A to C.
	14	7. Drug outlet. "Drug outlet" means:
<u> </u>	15 16 17 18 19 20 21	A. Any pharmacy located in an extended care facility, drug abuse treatment center, penal institution, hospital, retail store, mail order business or any other auxiliary dispensing facility with facilities located in this State which is engaged in dispensing, delivering or distributing of prescription drugs; or
	22 23 24 25 26	B. Any wholesaler, manufacturer or rural health center with facilities located in this State or doing business in this State which is engaged in dispensing, delivering or distributing of prescription drugs.
	27 28 29 30 31 32 33	8. Labeling. "Labeling" means the process of preparing and affixing a label to the outside of any drug container, exclusive 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.
、 シ ノ	34 35 36 37 38	9. Manufacture. "Manufacture" means the production, preparation, propagation, compounding, conversion or processing of a device or drug, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemi-

- cal 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:
- 8 A. By a pharmacist or practitioner incidental to
 9 his administering or dispensing of a drug in the
 10 course of his professional practice; or
- B. By a practitioner or by his authorization under his supervision for the purpose of or incidental to research, teaching or chemical analysis and not for sale.

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- 10. Manufacturer. "Manufacturer" means a person engaged in the manufacture of prescription drugs.
- 17 <u>ll. Nonprescription drugs. "Nonprescription</u>
 18 drugs" means nonnarcotic drugs which may be sold
 19 without a prescription and which are prepackaged for
 20 use by the consumer and labeled in accordance with
 21 the requirements of the laws and rules of this State
 22 and the Federal Government.
- 23 <u>12. Person. "Person" means an individual, corpo-</u>
 24 <u>ration, partnership, association or any other legal</u>
 25 <u>entity.</u>
- 26 13. Pharmacist. "Pharmacist" means an individual 27 licensed by this State to engage in the practice of 28 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.
- 33 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.

1 2 3	D. "Qualified assistant pharmacist" means an in
2	dividual licensed by this State as a qualifie
	assistant apothecary or qualified assistant o assistant pharmacist, provided that the licens
4	assistant pharmacist, provided that the licens
5 6	is in full force and effect, except for the righ
6	to serve as a "pharmacist in charge."
7	14. Pharmacist in charge. "Pharmacist in charge
8	means the pharmacist who is responsible for the li
9	censing of the prescription department.
,	censing of the prescription department.
10	15 Deschios of whomas "Deschios of whomas
	15. Practice of pharmacy. "Practice of pharmacy
11	means the interpretation and evaluation of prescrip-
12	tion drug orders; the compounding, dispensing, label
13	ing of drugs and devices, except labeling by a manu-
14	facturer, packer or distributor of nonprescription
15	drugs and commercially packaged legend drugs and de-
16	vices; the participation in drug selection and drug
17	utilization reviews; the proper and safe storage of
18	utilization reviews; the proper and safe storage of drugs and devices and the maintenance of proper
19	records for these drugs and devices; the responsibil-
20	ity for advising, when necessary or regulated, of
21	therapeutic values, content, hazards and use of drugs
22	and devices; and the offering or performing of those
23	and devices, and the offering of performing of those
	acts, services, operations or transactions necessary
24	in the conduct, operation, management and control of
25	a pharmacy.
26	16. Practitioner. "Practitioner" means a physi-
27	cian, dentist, veterinarian, scientific investigator or other person, other than pharmacists, licensed in
28	or other person, other than pharmacists, licensed in
29	the United States and Canada and permitted by the li-
30	cense to dispense, conduct research with respect to
31	or administer drugs in the course of professional
32	practice or research.
33	17. Prescription drug or legend drug. "Prescrip-
34	tion drug" or "legend drug" means a drug which:
24	cion didd of legend didd means a didd which.
35	A Under federal law is required prior to be
	A. Under federal law, is required, prior to be-
36	ing dispensed or delivered, to be labeled with
37	either of the following statements:

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

1 [.] 2 3	ţ	(2) "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."; or
4 5 6		B. Is required by an applicable federal or state law or rule to be dispensed on prescription only or is restricted to use by practitioners only.
7 8 9		18. Prescription drug order. "Prescription drug order" means a lawful written or oral order of a practitioner for a drug.
10 11 12		19. Wholesaler. "Wholesaler" means a person who buys prescription drugs for resale and distribution to persons other than consumers.
1:3		SUBCHAPTER II
14		BOARD OF COMMISSIONERS OF THE PROFESSION OF PHARMACY
15		§11521. Designation
16 17 18 19 20 21 22 23		The responsibility for enforcement of this Act is in part vested in the Board of Commissioners of the Profession of Pharmacy as established pursuant to Title 5, chapter 379. The board 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.
24		§11522. Membership
25 26 27 28 29 30 31 32		The board 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 11523. 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.
33		§11523. Qualifications
34 35 36		1. Public member. The public member of the board must be a resident of this State who has attained the age of majority and shall not be, nor ever have been,

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)	1	a member of the profession of pharmacy, the spouse of
	2	a member of the profession of pharmacy, a person who
	3	has ever had any material financial interest in the
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	4.4	providing of pharmacy service or a person who has en-
	5	gaged in any activity directly related to the prac-
	6	tice of pharmacy.
)	7	2. Licensed pharmacists. The licensed pharmacist
	8	members of the board shall, at the time of their ap-
	9	members of the board sharp, at the of their ap
	3	pointment:
	10	A. Be residents of this State;
		1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
	11	B. Be licensed and in good standing to engage in
	12	the practice of pharmacy in this State;
	12,	the practice of pharmacy in this state,
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	13	C. Be engaged in the practice of pharmacy in
	14	this State; and
	15	D. Have 5 years of experience in the practice of
	16	pharmacy in this State after licensure.
	10	pharmacy in this beate after freehaute.
	17	§11524. Appointment
	18	The Governor shall appoint the members of the
	19	board. Prior to appointing any pharmacist as a member
	20	of the board, the Governor shall solicit recommenda-
	21	tions of candidates from the Maine Pharmacy Associa-
	22	tion and other physical examination as he
		tion and other pharmaceutical organizations as he
	23	deems appropriate.
	24	§11525. Terms of office
	25	1. Length. Except as provided in subsection 2,
	26	members of the board shall be appointed for terms of
	27	
		5 years; except that members of the board who are ap-
	28	pointed to fill vacancies which occur prior to the
	29	expiration of a former member's full term shall serve
	30	the unexpired portion of that term.
	31	2. Staggered terms. The terms shall be staggered
	32	
	32	as follows:
	33	A. The terms of the members of the board shall
	34	be staggered so that the terms of no more than 2
- \.	35	members shall expire in any year.
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B. The present members of the board shall serve the balance of their terms.

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- C. Any present board 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 board 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 board shall be appointed by the Governor before the expiration of the term of the member being succeeded and shall become a member of the board on the first day of the calendar year next following his appointment or day of his appointment if that appointment is made after January 1st. Appointees to unexpired portions of full terms shall become members of the board on the day of that appointment. In the event the number of board 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 board.
 - 5. Expiration. Each term of office on the board expires at midnight on the last day of the calendar year in the final year of the board member's term or on the date his successor is appointed, whichever occurs later.
- 6. Vacancies. Any vacancy which occurs in the membership of the board 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 11524. 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 the vacancy occurs.
- 39 7. Grounds for removal. The Governor may remove 40 a member of the board for cause.

§11526. Organization

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- 2 1. Officers. The board shall elect from 3 members a president and such other officers as it deems appropriate and necessary to the conduct of its business. The president of the board shall preside at 4 5 6 all meetings of the board and shall be responsible 7 for the performance of all of the duties and functions of the board required or permitted by this Act. 8 9 Each additional officer elected by the board shall 10 perform those duties normally associated with his position and those other duties assigned to him from 11 12 time to time by the board.
 - 2. Terms of office. Officers elected by the board 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.
- 19 Executive director. The board may employ a 20 licensed pharmacist who shall be an ex officio member 21 of the board without a vote to serve as an employee 22 of the board in the position of executive director. 23 The executive director shall be responsible for performance of the regular administrative functions of the board and such other duties as the board may 24 25 26 direct. The executive director shall not perform any 27 discretionary or decision-making functions for which 28 the board is solely responsible.

§11527. Compensation

- 1. Members. Each member of the board shall be compensated in accordance with Title 5, chapter 379.
- 2. Executive director. The executive director of the board shall receive, as compensation, a salary, the amount of which shall be determined by the board, and reimbursement for all expenses incurred in connection with performance of his official duties.
- 37 3. Secretary. The secretary of the board shall receive reimbursement for all expenses incurred in connection with performance of his official duties.

§11528. Meetings

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- 1. Number. The board 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 board. The board 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 board.
- 2. Place. The board 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 board 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 board constitutes a quorum for the conduct of a board meeting and, except when a greater number is required by this Act or by any rule of the board, all actions of the board shall be by a majority of a quorum.
 - 5. Open meeting. All board meetings and hearings shall be open to the public. The board may conduct portions of its meetings in executive session pursuant to the freedom of access laws, Title 1, section 405.

30 §11529. Employees

- 1. Authority. The board may employ persons in addition to the executive director in such other positions or capacities as it deems necessary to the proper conduct of board business and the fulfillment of the board's responsibilities as defined by this Act.
- 37 2. Compensation. The employees of the board oth-38 er than the executive director shall receive, as compensation, an annual salary, the amount of which

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1 2 3 4	shall be determined by the board or by law where required, and reimbursement for all expenses incurred in connection with performance of their official duties.
5	§11530. Rules
6 7 8 9 10	The board shall make, adopt, amend and repeal such rules as may, from time to time, be determined necessary by the board 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.
12	§11531. Licensure and discipline
13 14 15 16	l. Responsibility. The board's responsibility for the control and regulation of the practice of pharmacy in this State includes, but is not limited to, the following actions:
17 18 19	A. The licensing by examination or by reciprocity of applicants who are qualified to engage in the practice of pharmacy under this Act;
 20 21	B. The renewal of licenses to engage in the practice of pharmacy;
22 23 24 25 26 27 28	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;
29 30	D. The inspection and registration of any drug outlet as set out in section 11561;
31 32 33 34 35 36	E. The enforcement of those provisions of this Act relating to the conduct or competence of pharmacists practicing in this State and the processing of complaints which could lead to the suspension, revocation or restriction of licenses to engage in the practice of pharmacy;

1 2 3,	F. The rules of the training, qualification and employment of pharmacy interns and pharmacy students; and
4 5	G. The rules of the training, qualification and employment of pharmacy ancillary personnel.
6 <u>§11</u>	532. Medications, drugs, devices and other mate- rials
$ \begin{array}{ccc} 10 & \overline{\text{vic}} \\ 11 & \overline{\text{dia}} \end{array} $	1. Responsibility. The board has the following ponsibilities in regard to medications, drugs, dees and other materials used in this State in the gnosis, mitigation and treatment or prevention of ury, illness and disease. The board shall:
13 14 15 16 17 18 19	A. Promulgate rules concerning 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 board after appropriate hearing as required under the Maine Administrative Procedure Act, Title 5, chapter 375;
21 22 23 24 25	B. Establish the specifications of minimum professional and technical equipment, environment, supplies and procedure for the compounding or dispensing of medications, drugs, devices and other materials within the practice of pharmacy;
26 27 28	C. Assure the purity and quality of medications, drugs, devices and other materials within the practice of pharmacy;
29 30 31 32	D. Issue and renew certificates of registration of drug outlets for purposes of ascertaining those persons engaged in the manufacture and distribution of drugs;
33 34 35 36 37	E. Promulgate rules concerning the sale and the dispensing of any exempt narcotic preparation. An "exempt narcotic preparation" means any medicinal preparation that contains in 30 milliliters or, if a solid or semisolid preparation, in 30 grams:
38	(1) Not more than 130 milligrams of opium;

	1 2	(2) Not more than 15 milligrams of morphine or any of its salts;
	3 4	(3) Not more than 65 milligrams of codeine or any of its salts;
	5 6	(4) Not more than 30 milligrams of dihydrocodeine or any of its salts; or
	7 8	(5) Not more than one of the drugs named in subparagraphs (1) to (4).
	9 10 11 12 13 14	A record shall be kept of the sale of exempt narcotic preparations. The record must 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; and
	15 16 17 18 19 20 21	F. After notice and hearing, 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.
\mathcal{L}	22	§11533. Other duties, powers and authority
	23 24 25 26	The board has such other duties, powers and authority as may be necessary to enforce this Act and the board rules made pursuant to this Act, which include, but are not limited to, the following.
	27 28 29 30 31 32	1. Professional associations. The board 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 board.
	33 34 35 36	2. Bond. In addition to any statutory requirements, the board 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 discussing funds.

1 2 3 4	3. Seal. The executive director of the board or the secretary of the board shall keep the seal of the board and shall affix it only in such manner as may be prescribed by the board.
5 6 7 8	4. Reports. The board 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 board.
9 10 11	5. Fees. The board shall determine within 30 days prior to the beginning of each state fiscal year the fees to be collected for:
12 13 14	A. An examination and reexamination, which fee shall not exceed costs of the examination plus an amount not to exceed \$100;
15 16	B. The issuance of a pharmacist's license, by reciprocity, which fee shall not exceed \$150;
17 18	C. The issuance of renewal of a pharmacist's license, which fee shall not exceed \$50;
19 20 21 22	D. The issuance of a nonactive pharmacist's license, which fee shall not exceed \$15 if he is 65 years of age or older, or which fee shall not exceed \$50 if he is under 65;
23 24 25	E. The issuance of a certificate of registration for a new pharmacist, which fee shall not exceed \$200;
26 27 28	F. The issuance of a certificate of registration for renewal of a drug outlet license, which fee shall not exceed \$150;
29 30 31 32	G. The issuance of a certificate of registration necessitated by a change in the pharmacist responsible for the license, which fee shall not exceed \$100; and
33 34 35 36 37	H. The certification of an approved provider of continuing education courses, which fee shall not exceed \$100, provided that a provider approved by the American Council of Pharmaceutical Education is exempt from the fee established in this para-

graph.

	. 1	6. Grants. The board may receive and expend
	2	funds, in addition to its annual appropriation, from
	3	parties other than the State, provided that:
	4	A. The funds are awarded for the pursuit of a
)	. 5 6	specific objective which the board is authorized
	7	to accomplish by this Act or which the board is qualified to accomplish by reason of its juris-
	8	diction or professional expertise;
	_	
	9	B. The funds are expended for the pursuit of the
	10	objective for which they are awarded;
	1 7	C Ballantin annual della del annual della
	11 12	C. Activities connected with or occasioned by the expenditures of the funds do not interfere
	13	with or impair the performance of the board's du-
	14	ties and responsibilities and do not conflict
	15	with the exercise of the board's powers as speci-
	16	fied by this Act;
		· · · · · · · · · · · · · · · · · · ·
	17	D. The funds are kept in a separate, special
	18	state account; and
	19	E. Periodic reports are made to the Governor
	20 21	concerning the board's receipt and expenditure of
)	21	the funds.
	22	7. Investigatory powers. The board or its autho-
	23	rized representatives may investigate and gather evi-
	24	dence concerning alleged violations of this Act or of
	25	the rules of the board. The board may remove certain
	26	records, including, but not limited to, prescription
	27	records, patient profiles, inventories and other drug
	28	records for the purposes of photocopying and further-
	29	ing the investigation. An inventory receipt shall be
	30	furnished and the articles removed shall be returned
	31 32	within 3 hours. The pharmacist who has custody of the records may accompany the board's representatives so
	33	that he can attest to the authenticity and lack of
	34	alteration of the records being photocopied.
	J.	arteriation of the records being photocopical
	35	A. Prescriptions, orders and records required by
	36	this chapter and stocks of narcotic drugs shall
	37	be open for inspection only to the board and to
	38	federal, state, county and municipal officers
)	39	whose duty it is to enforce the laws of this
	40	State or of the United States relating to narcot-

- 1 ic drugs. No officer having knowledge by virtue 2 of his office of any such prescription, order 3 record may divulge that knowledge, except in connection with a prosecution or proceeding in court 4 5 or before a licensing or registration board or 6 officer, to which prosecution or proceeding the 7 person to whom such prescriptions, orders or 8 records relate is a party.
- 9 The Bureau of Health, the board, their offi-10 cers, agents, inspectors and representatives, all 11 peace officers within the State and all county 12 attorneys shall enforce all provisions of this chapter, except those specifically delegated, and 13 shall cooperate with all agencies charged with 14 15 the enforcement of the laws of the United States, 16 of this State and of all other states relating to 17 narcotic drugs.
- 18 <u>8. Embargo. The board may embargo certain drugs</u>
 19 or devices as follows.
- 20 Notwithstanding anything in this Act to the 21 contrary, if a duly authorized representative of 22 the board finds or has probable cause to believe 23 drug or device is adulterated or misany 24 branded within the meaning of the United States Food and Drug Act, he shall affix to the drug or 25 device a tag or other appropriate marking giving 26 notice that the article is or is suspected of be-27 28 ing adulterated or misbranded and has been de-29 tained or embargoed, and warning all persons or dispose of the article by sale or 30 remove 31 otherwise until provision for removal or disposal 32 is given by the board, its agent or the court. No person may remove or dispose of the embargoed drug or device by sale or otherwise without the 33 34 35 permission of the board or its agent or, 36 summary proceedings have been instituted, without 37 permission from the court.
 - B. When a drug or device detained or embargoed under paragraph A has been declared by a representative of the board to be adulterated or misbranded, the board shall, as soon as practical, report the declaration to the Attorney General's office, along with sufficient information to per-

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mit the Attorney General to bring a petition for an injunction to the judge of the court in whose jurisdiction the article is detained or embargoed. If the judge determines that the drug or device so detained or embargoed is not adulterated or misbranded, the board shall direct the immediate removal of the tag or other marking.

If the court finds the detained or embargoed drug or device is adulterated or misbranded, that drug or device, after entry of the decree, be destroyed at the expense of the owner under the supervision of the board representative all court costs and fees, storage and other propexpense shall be borne by the owner of the drug or device. When the adulteration or branding 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 beling or processing under the supervision of a board representative. The 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 board that the drug or device is no longer in violation of the embargo and the expense of supervision has paid.

9. Records and reports. The board shall keep a record of the names of all persons examined and registered and a record of all money received and disbursed by the board. A duplicate of the record shall always be open to inspection in the office of the Secretary of State. The board shall make a report annually in July to the Commissioner of Human Services stating the condition of pharmacy in the State, with a full and complete record of all its official acts during the year and of the receipts and disbursements of the board to the last day of the preceding month.

10. Budget. The board shall submit to the Commissioner of Human Services its budgetary requirements in the same manner as is provided in Title 5, section 1665, and the commissioner shall in turn

- transmit these requirements to the Bureau of the Budget without any revision, alteration or change.
 - ll. Procedure. Except as otherwise provided, the board shall exercise all of its duties, powers and authority in accordance with the Maine Administrative Procedure Act, Title 5, chapter 375.

SUBCHAPTER III

8 <u>LICENSING</u>

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- 9 §11541. Unlawful practice; penalties; injunctions
- 10 1. Applicability. It is unlawful for any person 11 to engage in the practice of pharmacy unless licensed 12 to practice under this Act; provided that physicians, veterinarians, osteopaths or other practi-13 dentists, tioners of the healing arts who are licensed 14 15 of this State may dispense and administer the laws prescription drugs to their patients in the practice 16 of their respective professions where specifically 17 18 authorized to do so by law.
- 2. Authorization to deal with dangerous substances. Physicians, dentists, veterinarians, drug
 jobbers, drug wholesalers, drug manufacturers, pharmacists and pharmacies registered under chapter 111,
 and approved animal shelters as provided in Title 7,
 section 3406, are authorized to deal professionally
 with dangerous substances.
- 3. Violation. Any person who violates this chapter commits a Class E crime and, notwithstanding Title 17-A, section 1301, may be punished by a fine of not more than \$1,000. Each violation of each section of this chapter constitutes a separate offense.
- 31 Violation; suspension; penalty. For any vio-32 lation of this chapter, in addition to other disciplinary action which may be taken by the board, the 33 34 board may suspend the violator's license for up to 90 days or impose a civil penalty of up to \$500, or both, for each violation of each section of this 35 36 chapter. The jurisdiction to suspend a license for up 37 38 to 90 days shall be concurrent with that of 39 ministrative Court.

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	1	5. Action to enjoin. The State may bring an ac-
	2	tion to enjoin any licensee or person from violating
-	3	this chapter, regardless of whether proceedings have been or may be instituted in the Administrative Court
	4	been or may be instituted in the Administrative Court
	5	or whether criminal proceedings have been or may be
	6	instituted.
1	7	6. Fees; fines; forfeitures. All fees, fines and
<i>.</i>	8	forfeitures under this chapter shall be paid to the
-	9	Treasurer of State and shall be considered funds of
	10	the board, to be expended by them for the enforcement
	11	of laws relating to pharmacists and for expenses in
	12	carrying out the duties of the board.
		The state of the s
	13	§11542. Qualifications for licensure by examination
	14	1. Requirements. To obtain a license to engage
	15	in the practice of pharmacy, an applicant for licen-
	16	sure by examination must:

	17	A. Have submitted a written application in the
	18	form prescribed by the board;
		Control of the Contro
	19	B. Have attained the age of 21 years;
, comments of	20	C. Have demonstrated good moral character and
	21	temperate habits;
)		
	22	D. Have graduated and received the first profes-
	23	sional undergraduate degree from an accredited
	24	pharmacy degree program which has been approved
	25	by the board;
	26	E. Have completed an internship or other program
	27	which has been approved by the board or demon-
	28	strated, to the board's satisfaction, experience
	29	in the practice of pharmacy which meets or ex-
	30	ceeds the minimum internship requirement of the
	31	board;
	32	F. Have successfully passed an examination given
	33	by the board; and
	- ·	
	34	G. Have paid the fees specified by the board for
	35	examination and issuance of a license.
	26	O Harristian Paristration - 1977 to 1980
)	36	2. Examinations. Examinations shall be prepared
	37	and administered according to this subsection.

1 2 3 4 5 6 7 8	A. The examination shall be prepared to measure the competence of the applicant to engage in the practice of pharmacy. The board 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.
9 10 11 12 13 14	B. The examination for licensure shall be given by the board at least 2 times during each fiscal year of the State. The board 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.
16 17 18	3. Internship and other training programs. Internship and practical experience requirements shall be determined as follows.
19 20 21 22 23	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 board may determine.
24 25 26 27 28 29	B. The board 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.
30	§11543. Qualifications for licensure by reciprocity
31 32 33	l. Requirements. To obtain a license as a pharmacist by reciprocity an applicant for licensure must:
34 35	A. Have submitted a written application in the form prescribed by the board;
36	B. Have attained the age of 21 years;
37 38	C. Have demonstrated good moral character and temperate habits;

i	1	D. Have possessed at the time of initial licen-
	2	sure as a pharmacist such other qualifications
	3	necessary to have been eligible for licensure at
	4	that time in this State;
	•	The state of the s
	5	E. Have engaged in the practice of pharmacy for
	6	a period of at least one year or have met the in-
)	7	ternship requirements of this State within the
2	8	one-year period immediately previous to the date
	9	of the application;
	10	F. Have passed the state pharmacy law exam as
	11	administered by the board;
	12	G. Have presented to the board proof of initial
	13	licensure by examination and proof that the li-
	14	cense and any other license or licenses granted
	15	to the applicant by any other state or states
	16 17	have not been suspended, revoked, canceled or otherwise restricted for any reason except nonre-
	18	newal or the failure to obtain required continu-
	19	ing education credits in any state where the ap-
	20	plicant is licensed, but not engaged in the prac-
	21	tice of pharmacy; and
	21	tice of pharmacy, and
	22	H. Have paid the fees specified by the board for
1	23	issuance of licenses.
į.		
	24	2. Eligibility. No applicant is eligible for li-
	25	censure by reciprocity unless the state in which the
	26	applicant was initially licensed as a pharmacist also
	27	grants reciprocal licensure to pharmacists duly li-
	28	censed by examination in this State under like cir-
	29	cumstances and conditions.
	30	§11544. Renewal of licenses
	0.1	
	31	1. Annual report. Each pharmacist must apply for
	32	renewal of his license annually no later than the
	33	last day of June. The board shall renew the license
	34 35	of each pharmacist who is qualified to engage in the
	35	practice of pharmacy.
	36	2. Nonactive renewal registration. Every regis-
	37	tered pharmacist not practicing pharmacy within this
	38	State shall pay annually, on or before the last day
ì	39	of June, a renewal fee to the secretary of the board,
;		The state of the s

- in return for which a nonactive renewal registration
 shall be issued.
- 3 Every registered pharmacist holding a nonactive renewal registration who desires to practice pharmacy 4 in this State shall be required to submit proof 5 isfactory to the board that, during the calendar year preceding his application for active registration, he 6 7 has participated in not less than 15 hours of ap-8 proved courses of continuing professional pharmaceutical education as defined in section 11545. The board may make exceptions from the operation of the 9 10 11 continuing education requirement of this section in 12 13 emergency or hardship cases.
- If any person fails or neglects to procure his annual nonactive renewal registration, notice of that failure having been mailed to his post office address by the board, after the expiration of 30 days following the issue of notice, his original registration shall expire. That person, in order to regain registration, shall be required to pay one renewal fee in addition to the sum of all fees that person may be in arrears.
- 22 3. Fees. The board shall specify by rule the procedures to be followed, in addition to those specified by section 11545, and the fees to be paid for renewal of licenses.

§11545. Continuing pharmacy education

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certificate may be issued by 27 No annual renewal 28 the board until the applicant submits proof satisfactory to the board that, during the year preceding his 29 30 application for renewal, he has participated in less than 15 hours of approved courses of continuing 31. 32 professional pharmaceutical education as set out in 33 this section. The continuing professional pharmaceu-34 tical educational courses shall consist of postgradu-35 ate studies, institutes, seminars, workshops, tures, conferences, extension studies, correspondence courses or such other forms of continuing profession-36 37 38 al pharmaceutical education as may be approved by the 39 board.

These courses shall consist of subject matter pertinent to the following general areas of profes-

1	sional pharmaceutical education: The socioeconomic
2	and legal aspects of health care; the properties and
3	actions of drugs and dosage forms; and the ideology,
4	characteristics and therapeutics of the disease
5	state. The specific subject matter of the courses may
6	include, but is not limited to, pharmacology, bio-
7	chemistry, physiology, pharmaceutical chemistry,
8	pharmacy administration, pharmacy jurisprudence, pub-
9	lic health and communicable diseases, pharmaceutical
10	marketing, professional practice management, anatomy,
11	histology and such other subject matter as repre-
12	sented in curricula of accredited colleges of pharma-
13	cy. The content of each course offered for credit un-
14	der this continuing professional educational program
15	must be approved in advance of the course by a com-
16	mittee composed of equal representation from the
17	board, hospital pharmacy and retail pharmacy within
18	the State. The number and members of the committee
19	shall be selected by the board and shall serve for a
20	period of 2 years. The board may make exceptions from
21	the operation of this section in emergency or hard-
22	ship cases.

SUBCHAPTER IV

DISCIPLINE

§11551. Disciplinary actions

The board shall, on its own motion or upon receipt of a written complaint filed with the board, investigate a complaint regarding noncompliance with or violation of this chapter or of any rules adopted by the board.

The board 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 board 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 board, the factual basis of the complaint is or may be true and it is of

sufficient gravity to warrant further action, the board may request an informal conference with the licensee. The board 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 board, 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 board 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:

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- 2. 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 board, the licensee and the Attorney General's office;
- 24 3. Negotiate stipulations. In consideration for acceptance of a voluntary surrender of the license, 25 26 negotiate stipulations, including terms and condi-27 tions for reinstatement which ensure protection of 28 the public health and safety and which serve to rehabilitate or educate the licensee. These stipulations 29 30 shall be set forth only in a consent agreement signed 31 by the board, the licensee and the Attorney General's 32 office;
 - 4. Adjudicatory hearing. If the board 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
- 5. File complaint in Administrative Court. If the board 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.

/	1	§11552. Grounds for discipline
	2 3 4	1. Suspension or revocation. The board may suspend or revoke a license, pursuant to Title 5, section 10004.
A cu	5 6 7 8	2. Grounds for action. The following shall be grounds for an action to refuse to issue for modification of the license or for refusal to renew the license of a person licensed under this chapter:
	9 10 11 12	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;
	13 14 15 16 17	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;
)	19 20 21 22 23	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;
	24 25 26	D. Aiding or abetting the practice of pharmacy by a person not duly licensed under this chapter and who represents himself as duly licensed;
	27 28 29	E. Incompetence in the practice for which he is licensed. A licensee shall be deemed incompetent in the practice if the licensee has:
	30 31 32 33	(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
)	34 35 36 37	(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;

1 2 3 4	F. Engaging in unprofessional conduct by violating any standard of professional behavior which has been established in the practice for which the licensee is licensed;
5 6 7 8 9 10	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 convicted of any crime for which incarceration for one year or more may be imposed;
12 13	H. Engaging in false, misleading or deceptive advertising; or
14 15	I. Any violation of this Act or of any rule adopted by the board.
16 17 18 19 20 21 22 23 24 25 26 27	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 pharmacist, including, but not limited to, convictions for defrauding the Medicaid program and for illegally distributing prescription drugs, his license is subject to suspension or revocation by the Administrative Court.
28	§11553. Penalties and reinstatement
29 30 31 32 33	1. Penalties. Upon finding grounds for discipline of any person holding a license or seeking a license or a renewal of a license under this chapter, the board may take one or more of the following actions:
34 35 36	A. Request the Attorney General's office to institute appropriate judicial proceedings which may lead to suspension or revocation of license;
37 38 39	B. Restrict the offender's license to prohibit the offender from performing certain acts or from engaging in the practice of pharmacy in a partic-

)	· 1 2	ular manner for a term to be determined by the board; or
	3 4	C. Hold an adjudication hearing which may result in:
\	5	(1) Refusal to renew offender's license; or
j /	6 7 8	(2) Placement of the offender on probation and supervision by the board for a period to be determined by the board.
	9 10 11 12 13 14 15 16 17 18	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 board, may at reasonable intervals petition the board for reinstatement of the license. The petition must be made in writing in a form prescribed by the board. Upon investigation and hearing, the board 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.
)	20 21 22 23 24	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.
	25 26 27 28	4. Judicial review. All final decisions by the board are subject to judicial review pursuant to the Maine Administrative Procedure Act, Title 5, chapter 375.
	29	SUBCHAPTER V
	30	REGISTRATION OF FACILITIES
	31	§11561. Registration
	32 33 34	l. Registration. All drug outlets shall annually register with the Board of Commissioners of the Pro- fession of Pharmacy.
`)	35 36	 Classifications. Drug outlets shall be registered in classifications set out in this subsection.

	1	2. Required information. Applications for cer-
)	2	tificates of registration shall include the following
/	- 3	information about the proposed drug outlet:
	4	A. Ownership;
	•	Juni 197
	5	B. Location; and
	*	
)	6 . 7	C. Identity of the pharmacist licensed to practice in the State who shall be the pharmacist in
	. 8	charge of the drug outlet, where one is required
	9	by this chapter, and such further information as
	10	the board may deem necessary. A pharmacist may be
	11	the pharmacist in charge for only one drug out-
	12 13	let. The position of pharmacist in charge may not be held by a qualified assistant pharmacist.
	1.3	be need by a quarrilled assistant pharmacist.
	14	3. Transferability. Certificates of registration
	15	issued by the board pursuant to this chapter are not
	16	transferable or assignable.
	17	4. Professional responsibility. The board shall
	18	specify by rule minimum standards for the profession-
	19	al responsibility in the conduct of any drug outlet
,	20	that has employees or personnel engaged in the practice of pharmacy. The board may require that the por-
	21 22	tion of the facility to which the certificate of reg-
1	23	istration applies be operated only under the direct
Ĵ	24	supervision of no less than one pharmacist licensed
	25	to practice in this State and not otherwise and to
	26	provide such other special requirements as necessary.
	27	5. Minimum inventory. The board shall ascertain
	28	that the applicant has a sufficient amount of pre-
	29	scription inventory on location to appropriately re-
	30	spond to prescription orders.
	31	§11563. Notifications
	32	1. Changes. All registered drug outlets shall
	33	report to the board, by registered mail, the occur-
	34	rence of any of the following changes:
	35	A. Permanent closing which requires 14 days'
	36	prior notice to the public and to the board;
	37	B. Change of ownership which requires 7 days'
)	38	prior notice to the board;

2	notice no later than 7 days after the change; and
-	notice no racer enam , days areer ene enamye, and
3	D. Any other matters and occurrences as the
4	board may require by rule.
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5 6	2. Other reportable events. Disasters, accidents
7	and emergencies which may affect the strength, purity or labeling of drugs, medications, devices or other
8	materials used in the diagnosis or the treatment of
9	injury, illness and disease shall be immediately re-
10	ported to the board.
_	Management of the second of th
11	§11564. Violations and penalties
12	1. Unlawful conduct. No drug outlet designated
13	in section 11561 may be operated until a certificate
14	of registration has been issued to that facility by
15	the board. Upon the finding of a violation of this
16 17 · ·	section, the board may impose one or more of the pen- alties enumerated in section 11541 or 11553.
Ι,	arties enumerated in section 11541 of 11553.
18	2. Reinstatement. Reinstatement of a certificate
19	that has been suspended, revoked or restricted by the
20	board may be granted in accordance with the proce-
21	dures specified by section 11553, subsection 2.
22	SUBCHAPTER VI
23	SERVICES AT RURAL HEALTH CENTERS
23	BERVICES AT RORAL HEADIR CENTERS
24	§11571. Definitions
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25	As used in this subchapter, unless the context
26	otherwise indicates, the following terms have the
27	following meanings.
28	1. Pharmacy provider. "Pharmacy provider" means
29	a pharmacy licensed in this State participating with
30	a rural community health center under this subchap-
31	ter.
32	2. Rural community health center. "Rural commu-
33	nity health center" means an incorporated nonprofit
34	health facility which provides comprehensive primary
35	health care to citizens in rural areas without a
36 37	pharmacy or in a community where available pharmacy services cannot meet the documented need.
/ د	services cannot meet the documented need.

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/	1	§11572. Center to be licensed
	2	1. License required. A rural community health
	3	center that desires to contract for pharmaceutical
	. 4	
		service with a pharmacy must be licensed by the board
	5	and shall abide by the rules of the board. These
)	. 6	rules may be no more restrictive than those regu-
/	7	lating private pharmacy practice in the State.
	8	2. Notice. Any rural community health center
	9	wishing to be licensed under this subchapter shall
	10	notify the board of its intent to establish such a
	11	contract and shall apply for a license, submit floor
	12	plane of the share and plane and the same feet
		plans of the physical plant and pay the same fee re-
	13	quired for a pharmacy under section 11533. The appli-
	14	cation shall include the name, address and registra-
	15	tion number of the provider of pharmaceutical ser-
	16	vices.
		And the second s
	17	3. Board action. The board shall approve or dis-
	18	approve of the application within 60 days of receipt
	19	and shall notify the applicant in writing of its de-
	20	
		cision and the reason for the decision.
	21	§11573. Scope of license
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<i>).</i>	22	A licensee under this subchapter shall comply
	23	with sections 11594; 11595, subsections 1 to 7; and
	24	any applicable rules promulgated by the board. No li-
	25	censee may refill a prescription and all orders shall
	26	be treated as new orders. In all other respects, not-
	27	withstanding any other provision of law, a licensee
		withstanding any other provision of law, a litensee
	28	may provide pharmaceutical services under this sub-
	29	chapter subject to section 11574.
	30	§11574. Rules
	31	The board shall adopt rules in conformity with
	32	the Maine Administrative Procedure Act, Title 5,
	33	chapter 375, to carry out the purposes of this sub-
	34	chapter.
	24	Chapter.
	2.5	
	35	SUBCHAPTER VII

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§11581. Short title

THIRD-PARTY PRESCRIPTION PROGRAM ACT

36

- This subchapter shall be known and may be cited as the "Third-party Prescription Program Act."
 - §11582. Definitions

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- As used in this section, unless the context otherwise indicates, the following terms have the following meanings.
- 7 3rd party prescription program. "3rd party prescription program" means any system of providing for the reimbursement of pharmaceutical goods and services under a contractual arrangement or agreement 8 9 10 11 between a provider of goods and services and another 12 party who is not the consumer of those goods and ser-13 vices. These programs include, but are not limited 14 to, insurance plans which provide coverage for pre-15 scription drugs or other pharmaceutical services.
- 16 <u>§11583</u>. Notice
- 17. No 3rd-party prescription program may be instituted in this State until written notice of the pro-18 19 visions of the program has been filed with the Super-20 intendent 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 21 22 23 program. In the case of chain or branch 24: pharmacies, the notice shall be given to the main headquarters' office. These pharmacies shall have 30 25 26 days from the date of notice to enroll in the pro-27 gram.
 - §11584. Denial of payment
- 29 No program administrator may deny to any pharmacy 30 payment for services which may have resulted from the fraudulent or illegal use 31 of an identification 32 card by any person, unless the pharmacy has been no-3.3 tified that the card has been canceled or discontin-34 ued and that the program administrator has been un-35 successful in attempting to regain possession of card. 36
- 37 §11585. Reimbursement rates

)	1	A 3rd-party prescription program is prohibited
1	1 2	from charging a pharmacy a registration fee or other
	3	fixed charge, either annually or otherwise, except in
	4	cases where a charge is necessary to specifically
	5	cover any equipment, forms or materials required by
	. 6	the program.
·**	. 0	che program.
1	7	\$11506
الر	/	§11586. Contract renewal and changes
	8	Any changes in benefits or provisions in any con-
	9	tract may not be made unilaterally by either the pro-
	10	gram administrator or the pharmacy. Any change in a
	11	contract offered to one pharmacy shall be offered to
	12	all the state pharmacies participating in the pro-
	13	gram.
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	14	S11597 Eventions
	7.4	§11587. Exceptions
	7.5	
	15	This Act does not apply to any medical assistance
	16	or public health programs administered by the Depart-
	17	ment of Human Services, including, but not limited
	18	to, the Medicaid program, the Catastrophic Illness
	19	Program and the Drugs for the Elderly Program.
	20	SUBCHAPTER VIII
		AND
À	21	MISCELLANEOUS PROVISIONS
	22	§11591. Generic substitution
		grissi. deneric subscriberon
	23	From white promise is and by a proti
	24	Every written prescription issued by a practi-
	24 25	tioner in this State shall contain in the lower
•		right-hand corner of the prescription form a box at
	26	least $1/2$ inch by $1/2$ inch. The following words must
	27	appear to the left of this box: "Any drug which is
	28	the generic or chemical equivalent of the drug speci-
	29	fied above in this prescription may be dispensed,
	30	provided that no check mark () has been handwritten
	31	in the box in the lower right-hand corner."
		·
	32	Any pharmacist receiving a prescription in which
	33	no handwritten check mark () is found in the box
	34	provided may substitute a generic or chemically
	35	equivalent drug for the drug aposified on the area
	36	equivalent drug for the drug specified on the pre-
	36 37	scription, provided that the substituted drug is dis-
1		tributed by a business entity doing business in the United States which is subject to suit and the ser-
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vice 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.

§11592. Advertising

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It is lawful for any pharmacy, pharmacist or other licensee of the board to advertise to the the current retail price he charges for any drugs, in medicines or appliances defined as the United States Code, Title 21, Section 3211 (g) (1) which bears the legend "Caution: Federal law prohibits dispensing without prescription." The advertising may be according to either the brand name or the generic chemical name of the drug. No media advertising of any drugs included in the United States Comprehensive Drug Abuse Prevention and Control Act Stat. 1236, is permitted.

§11593. 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 bears 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 board and shall be provided by the board to each licensed pharmacy in the State

1	on or before September 1st. This price listing shall
2	be prepared in accordance with the following specifi-
3	cations.
4	1. Size of list. The list must be of uniform
5	size and shall be no smaller than 36 inches wide by
6	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.
- 11 3. Services. The list must include the profes-12 sional services and nonprofessional convenience ser-13 vices provided by the pharmacy.

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- 14 4. Generic or chemical name. The list must in-15 clude the generic or chemical name of each drug when 16 a generic is available.
- 5. Type of print. The list must be printed in type sufficiently large to be easily read.
- 19 <u>6. Alphabetical listing. The list must be com-</u> 20 piled alphabetically.
- Nothing in this section prevents a pharmacy from changing the current retail price of any drug at any time, provided that the listed price is simultaneous—ly adjusted to reflect the new current retail price.
- 25 <u>Institutional drug outlets are exempt from this</u> 26 price-posting requirement.

§11594. 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.
- 7 2. Maintenance of current reference material. To
 8 ensure that proper information is available to each
 9 pharmacist, each pharmacy or pharmacist shall main10 tain current reference material on drug interactions.
 - §11595. Patient profile record system regulation

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- 12 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 to enable the immediate re-13 14 15 16 trieval of information necessary for the dispensing pharmacist to identify previously dispensed medication at the time a prescription is presented for dispensing. One profile record or document may be main-17 18 19 tained for all members of a family living at the same 20 address and possessing the same family name. The following information shall be recorded: 21 22
 - 1. Name. The family name and the first name of the person for whom the medication is intended, which is the patient;
- 26 <u>2. Address. The address to correspond to the</u> 27 name in subsection 1;
- 28 <u>3. Age group. An indication of the patient's age</u> 29 group, that is, infant, child or adult;
- 30 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;
- 35 <u>6. Prescriber's name. The name of the person</u> 36 prescribing the drug or device;
- 37 7. Drug information. The name, strength and quantity of the drug; and

	1 2 3 4 5	8. Initials of pharmacist; date of refill. The initials of the dispensing pharmacist and the date of dispensing the medication as a renewal or refill, if those initials and that date are not recorded on the back of the original prescription.
	6 7 8 9	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.
	11 12 13 14 15 16 17	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 potentially harmful reaction or interaction, the pharmacist shall take appropriate action to avoid or minimize the problem which may include consultation with the physician.
	19 20 21	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.
	22 23	§11596. Identification of persons prescribing medicines on hospital prescription blanks
1	24 25 26 27	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.
	28 29 30 31 32 33	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.
	35	§11597. Hypodermic syringes; prescriptions
	36 37 38 39	1. Possession. A 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, an employee of an incorporated hospital acting under official direction, carrier or messenger engaged in the transportation of a hypodermic apparatus as an agent of any of the persons named in this subsection, employees of scientific research laboratories, employees of educational institutions, employees of an agency or organization duly authorized by the board 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 board shall, by rule, prescribe the form of prescription that the physician shall 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, subsection 2, except that it does not include a syringe, needle or instrument for use on farm animals and poultry.

§11598. Sale of poisonous drugs

 Each licensed pharmacist who sells arsenic, carbolic acid, chloroform, corrosive sublimate, cyanide of potassium or sodium, strychnine or its salts shall affix to the package sold by him a label plainly marked with the name and address of the store and the word "POISON" and the name of the poison sold, and shall enter at the time of sale in a permanently bound book to be kept for that purpose the name and address of the purchaser, the date of sale, the name of the poison and the quantity sold and the person making the sale shall sign the entry. This section shall not apply to sales on prescription of physicians, dentists, podiatrists or veterinarians, sales at wholesale to pharmacists or sales to hospitals, colleges or public institutions.

§11599. Possession of drug samples

1	No person may purchase manufacturers' drug sam-
2 -	ples from any person for purposes of resale. If those
3	samples are given gratuitously to a registered phar-
4	macist, qualified assistant pharmacist or medical
5	practitioner, he may give any such sample to any per-
6	son, provided that any such sample is kept in con-
7	tainers suitably labeled to conform to the Federal
8	Food and Drug Act and the state food and drug laws
9	and provided that such gift shall be subject to the
10	laws relating to the sale of drugs.
11	§11600. Using drugs not in prescription
	<u> </u>
12	If a pharmacist knowingly uses any drugs or in-
13	gredients in preparing or compounding a written or
14	oral prescription of any physician different from
15 16	those named in the prescription, that use shall con-
17	stitute a civil violation for which a forfeiture of not more than \$1,000 nor less than \$50 may be ad-
18	judged.
10	<u>Juagea:</u>
19	§11601. Return of drugs prohibited
20	A drug or pharmaceutical preparation which has
21	been dispensed on prescription shall not be returned
22	to pharmacy stock after being in possession and under
23	the control of another person and shall not be dispensed again, unless the drug is packaged in an un-
24	pensed again, unless the drug is packaged in an un-
25	broken, sealed container or unless, in the case of a
26	hospital, a licensed pharmacist determines that the
27	drug has not been impaired.
28	§11602. Sale by certain methods prohibited
29	It shall be unlawful for any person to sell, dis-
30	tribute, vend or otherwise dispose of any drug, medi-
31	cine or pharmaceutical or medical preparation by
32	means of any public exhibition, entertainment, per-
33	formance, carnival or by vending machines.
34	§11603. Adulterating and selling drugs
35	Whoever fraudulently adulterates, for the purpose

Whoever fraudulently adulterates, for the purpose of sale, any drug or medicine or sells any fraudulently adulterated drug or medicine, knowing the same to be adulterated, shall be punished by a fine of not more than \$1,000 or by imprisonment for not more than

Ι.	II months. These adulterated drugs and medicines
2	shall be forfeited and destroyed under the direction
3	of the court.
4	§11604. Labeling of prescriptions
5	Every drug dispensed pursuant to prescription,
6	whether for a legend drug or not, shall carry on the
. 7	label the following information: The prescription
8	number, the date of original filling, the patient's
9	name, directions for use, the name of the medical
10	practitioner prescribing the drug and the name and
11	address of the pharmacy where the prescription was
12	compounded and dispensed.

13 STATEMENT OF FACT

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