SENATE BILL 652

Unofficial Copy 1997 Regular Session
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By: Senator Hollinger
Introduced and read first time: January 31, 1997
Assigned to: Economic and Environmental Affairs

A BILL ENTITLED

AN ACT concerning

State Board of Pharmacy - Scope of Practice

FOR the purpose of altering certain provisions of the Maryland Pharmacy Practice Act concerning licensing, permits, the practice of pharmacy, the operation of pharmacies, and the regulation of drugs, devices, and diagnostics; specifying the scope of the Act; requiring a person to have a license to practice pharmacy; specifying the qualifications and application procedure for obtaining a certain license and the scope of the license; specifying the standards applicable to a pharmacy to which a certain permit has been issued, including a nonresident pharmacy; authorizing a certain inspection or investigation of pharmacies by certain State officials and prohibiting a person from hindering that inspection or investigation; providing certain standards concerning certain pharmacy practices relating to drugs, devices, or diagnostics; specifying certain powers and duties of the State Board of Pharmacy; defining certain terms; and generally relating to the practice of pharmacy and the Maryland Pharmacy Practice Act.

BY repealing and reenacting, with amendments,
Article - Health Occupations
Section 12-101, 12-102, 12-301 through 12-303, 12-305, 12-307, 12-403, 12-501, 12-502, 12-507, 12-508, 12-509, 12-512, 12-602, 12-603, and 12-703
Annotated Code of Maryland
(1994 Replacement Volume and 1996 Supplement)

BY repealing
Article - Health Occupations
Section 12-503 through 12-506, 12-510, and 12-511
Annotated Code of Maryland
(1994 Replacement Volume and 1996 Supplement)

BY adding to
Article - Health Occupations
Section 12-413 and 12-506
Annotated Code of Maryland
(1994 Replacement Volume and 1996 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article - Health Occupations

12-101.

(a) In this title the following words have the meanings indicated.

(b) "Authorized prescriber" means any licensed dentist, licensed physician, licensed podiatrist, licensed veterinarian, certified nurse midwife to the extent permitted in § 8-601 of this article, CERTIFIED NURSE PRACTITIONER TO THE EXTENT PERMITTED IN § 8-508 OF THIS ARTICLE, or other individual authorized by law to prescribe PRESCRIPTION OR NONPRESCRIPTION drugs, [medicines, or] devices, OR DIAGNOSTICS.

(c) "Board" means the State Board of Pharmacy.

(D) "COMPOUNDING" MEANS TO ENGAGE IN ANY OF THE FOLLOWING ACTIVITIES:

(1) THE COMBINING OF CHEMICALS, PRESCRIPTION DRUGS, OR NONPRESCRIPTION DRUGS FOR USE BY HUMANS OR ANIMALS PURSUANT TO A PRESCRIPTION WRITTEN FOR A SPECIFIC PATIENT;

(2) THE COMBINING OF CHEMICALS, PRESCRIPTION DRUGS, OR NONPRESCRIPTION DRUGS FOR USE BY HUMANS OR ANIMALS, WHICH COMBINATION IS:

(I) PREPARED IN REASONABLE EXPECTATION OF AN AUTHORIZED PRESCRIBER'S PRESCRIPTIONS WRITTEN FOR SPECIFIC PATIENTS; AND

(II) PREPARED IN QUANTITIES NOT GREATER THAN TWO TIMES THE ANTICIPATED WEEKLY USAGE OF THE FORMULATION BASED ON AN AUTHORIZED PRESCRIBER'S PRESCRIPTIONS WRITTEN FOR SPECIFIC PATIENTS AND FILLED PREVIOUSLY BY THE PHARMACY;

(3) THE CREATION OF A DIFFERENT, DISTINCT DOSAGE FORM, DOSE, OR FORMULATION WHICH IS COMMERCIALLY UNAVAILABLE FOR USE BY HUMANS OR ANIMALS PURSUANT TO AN AUTHORIZED PRESCRIBER'S PRESCRIPTION WRITTEN FOR A SPECIFIC PATIENT; OR

(4) THE SELECTION OF NONTHERAPEUTIC INGREDIENTS TO BE UTILIZED IN THE COMBINING OF CHEMICALS, PRESCRIPTION DRUGS, OR NONPRESCRIPTION DRUGS WHEN THE NECESSARY NONTHERAPEUTIC INGREDIENTS ARE NOT SPECIFIED IN THE AUTHORIZED PRESCRIBER'S PRESCRIPTION.

[(d)] (E) (1) "Device" means a device used in the diagnosis, treatment, or prevention of disease.

(2) "Device" does not include any:

(i) Surgical or dental instrument;

(ii) Physical therapy equipment;

(iii) X-ray apparatus; or

(iv) Component part or accessory of any of these items.

(F) "DISPENSE" OR "DISPENSING" MEANS THE PROCEDURE WHICH RESULTS IN THE RECEIPT OF A PRESCRIPTION OR NONPRESCRIPTION DRUG, DEVICE, OR DIAGNOSTIC BY A PATIENT OR THE PATIENT'S AGENT AND WHICH ENTAILS THE INDEPENDENT:

(1) INTERPRETATION OF AN AUTHORIZED PRESCRIBER'S PRESCRIPTION FOR A DRUG, DEVICE, OR DIAGNOSTIC;

(2) SELECTION AND LABELING OF THE DRUG, DEVICE, OR DIAGNOSTIC PRESCRIBED PURSUANT TO THAT PRESCRIPTION; AND

(3) MEASURING AND PACKAGING OF THE PRESCRIBED DRUG, DEVICE, OR DIAGNOSTIC IN ACCORDANCE WITH STATE AND FEDERAL LAWS.

(G) (1) "DISTRIBUTE" MEANS THE PROCESS RESULTING IN THE PROVISION OF A PRESCRIPTION OR NONPRESCRIPTION DRUG, DEVICE, OR DIAGNOSTIC TO A SEPARATE, INTERVENING INDIVIDUAL, LICENSED AND PRACTICING UNDER THE HEALTH OCCUPATIONS ARTICLE, PRIOR TO ADMINISTRATION OF THE PROVIDED DRUG, DEVICE, OR DIAGNOSTIC TO THE PATIENT PURSUANT TO A PRESCRIPTION ISSUED BY AN AUTHORIZED PRESCRIBER.

(2) "DISTRIBUTE" DOES NOT INCLUDE THE OPERATIONS OF A PERSON WHO HOLDS A PERMIT ISSUED UNDER §§ 12-601 AND 12-602 OF THIS TITLE.

[(e)] (H) "License" means, unless the context requires otherwise, a license issued by the Board to practice pharmacy.

[(f)] (I) "Licensed pharmacist" means, unless the context requires otherwise, a pharmacist who is licensed by the Board to practice pharmacy.

(J) "NONPRESCRIPTION DRUG" MEANS A DRUG WHICH MAY BE SOLD WITHOUT A PRESCRIPTION AND WHICH IS LABELED FOR USE BY THE CONSUMER IN ACCORDANCE WITH THE REQUIREMENTS OF THE LAWS AND REGULATIONS OF THIS STATE AND THE FEDERAL GOVERNMENT.

(K) "NONRESIDENT PHARMACY" MEANS A PHARMACY LOCATED OUTSIDE THIS STATE THAT, IN THE NORMAL COURSE OF BUSINESS, AS DETERMINED BY THE BOARD, SHIPS, MAILS, OR DELIVERS DRUGS, DEVICES, OR DIAGNOSTICS TO A PERSON IN THIS STATE PURSUANT TO A PRESCRIPTION.

(L) "PHARMACEUTICAL CARE" MEANS THE PROVISION OF DRUGS, DEVICES, OR DIAGNOSTICS AND OTHER RELATED SERVICES INTENDED TO ACHIEVE DEFINITE OUTCOMES REGARDING A PATIENT'S HEALTH.

[(g)] (M) "Pharmacist" means an individual who practices pharmacy REGARDLESS OF THE LOCATION WHERE THE ACTIVITIES OF PRACTICE ARE PERFORMED.

[(h)] (N) "Pharmacy" means an establishment in which PRESCRIPTION OR NONPRESCRIPTION drugs, [medicines, or] devices, OR DIAGNOSTICS ARE COMPOUNDED, DISPENSED, OR DISTRIBUTED [are dispensed, sold, or offered for sale].

[(i)] (O) "Pharmacy permit" means a permit issued by the Board to establish and operate a pharmacy.

[(j)] (P) (1) "Practice pharmacy" means to engage in any of the following activities:

(i) [Selecting, preparing, and dispensing drugs, medicines, or devices] PROVIDING PHARMACEUTICAL CARE;

(II) COMPOUNDING, DISPENSING, OR DISTRIBUTING PRESCRIPTION DRUGS, DEVICES, OR DIAGNOSTIC;

(III) COMPOUNDING OR DISPENSING NONPRESCRIPTION DRUGS, DEVICES, OR DIAGNOSTICS;

(IV) MONITORING PRESCRIPTIONS FOR PRESCRIPTION AND NONPRESCRIPTION DRUGS, DEVICES, OR DIAGNOSTICS;

[(ii)] (V) Providing information, [and] explanation, OR RECOMMENDATIONS to patients and health care practitioners about the safe and effective use of PRESCRIPTION OR NONPRESCRIPTION drugs, [medicines, or] devices, OR DIAGNOSTICS; or

[(iii)] (VI) Identifying and appraising problems concerning the use or monitoring of [drug] therapy WITH DRUGS, DEVICES, OR DIAGNOSTICS.

(2) "Practice pharmacy" does not include the operations of a person who holds a permit issued under §§ 12-601 and 12-602 of this title.

12-102.

(a) (1) In this section the following terms have the meanings indicated.

(2) "In the public interest" means the dispensing of drugs, DEVICES, OR DIAGNOSTICS by a licensed dentist, physician, or podiatrist to a patient when a pharmacy is not conveniently available to the patient.

(3) "Personally preparing and dispensing" means that the licensed dentist, physician, or podiatrist:

(i) Is physically present on the premises where the prescription is filled; and

(ii) Performs a final check of the prescription before it is provided to the patient.

(b) This title does not limit the right of an individual to practice a health occupation that the individual is authorized to practice under this article.

(c) This title does not prohibit:

(1) A licensed veterinarian from personally preparing and dispensing the veterinarian's prescriptions;

(2) A licensed dentist, physician, or podiatrist from personally preparing and dispensing the dentist's, physician's, or podiatrist's prescriptions when:

(i) The dentist, physician, or podiatrist:

1. Has applied to the board of licensure in this State which licensed the dentist, physician, or podiatrist;

2. Has demonstrated to the satisfaction of that board that the dispensing of prescription drugs, DEVICES, OR DIAGNOSTICS by the dentist, physician, or podiatrist is in the public interest; and

3. Has received a written permit from that board to dispense prescription drugs, DEVICES, OR DIAGNOSTICS except that a written permit is not required in order to dispense starter dosages or samples without charge;

(ii) The person for whom the drugs, DEVICES, OR DIAGNOSTICS are prescribed is a patient of the prescribing dentist, physician, or podiatrist;

(iii) The dentist, physician, or podiatrist does not have a substantial financial interest in a pharmacy; and

(iv) The dentist, physician, or podiatrist:

1. Complies with the labeling requirements of [§ 12-509] § 12-505 of this title;

2. Records the dispensing of the prescription drug, DEVICE, OR DIAGNOSTIC on the patient's chart;

3. Allows the Division of Drug Control to enter and inspect the dentist's, physician's, or podiatrist's office at all reasonable hours;

4. Except for starter dosages or samples without charge, provides the patient with a written prescription, maintains prescription files in accordance with [§ 12-505] § 12-403(B)(13) of this title, and maintains a separate file for Schedule II prescriptions;

5. Does not direct patients to a single PHARMACIST OR pharmacy [in accordance with § 12-403(a)(7)] § 12-403(B)(8) of this title; and

6. Does not receive remuneration for referring patients to a PHARMACIST OR pharmacy; or

(3) A hospital-based clinic from dispensing prescriptions to its patients.

(d) This title does not prohibit:

(1) A licensed veterinarian from personally dispensing a drug, DEVICE, OR DIAGNOSTIC sample to a patient of the veterinarian; or

(2) A licensed dentist, licensed physician, or licensed podiatrist from personally dispensing a drug, DEVICE, OR DIAGNOSTIC sample to a patient of the licensed dentist, licensed physician, or licensed podiatrist if:

(i) The sample complies with the labeling requirements of [§ 12-509] § 12-505 of this title;

(ii) No charge is made for the sample; and

(iii) The authorized prescriber enters an appropriate record in the patient's chart.

(e) (1) This title does not prohibit a dentist, physician, or podiatrist from administering a prescription drug, DEVICE, OR DIAGNOSTIC in the course of treating a patient.

(2) For the purposes of paragraph (1) of this subsection, "administering" means the direct introduction of a single dosage of a drug, DEVICE, OR DIAGNOSTIC at a given time, whether by injection or other means, and whether in liquid, tablet, capsule, or other form.

(f) (1) This title does not prohibit a dentist, physician, or podiatrist from personally dispensing a starter dosage of a prescription drug, DEVICE, OR DIAGNOSTIC to a patient of the dentist, physician, or podiatrist, provided that:

(i) The starter dosage complies with the labeling requirements of [§ 12-509] § 12-505 of this title;

(ii) No charge is made for the starter dosage; and

(iii) The dentist, physician, or podiatrist enters an appropriate record on the patient's chart.

(2) For the purposes of paragraph (1) of this subsection, "starter dosage" means an amount of drug, DEVICE, OR DIAGNOSTIC sufficient to begin therapy:

(i) Of short duration of 72 hours or less; or

(ii) Prior to obtaining a larger quantity of the drug, DEVICE, OR DIAGNOSTIC to complete the therapy.

(g) This title does not prohibit a dentist, physician, or podiatrist from dispensing a prescription drug, DEVICE, OR DIAGNOSTIC in the course of treating a patient:

(1) At a medical facility or clinic that specializes in the treatment of medical cases reimbursable through workers' compensation insurance;

(2) At a medical facility or clinic that is operated on a nonprofit basis;

(3) At a health center that operates on a campus of an institution of higher education; or

(4) At a public health facility, a medical facility under contract with a State or local health department, or a facility funded with public funds.

(h) This title does not limit the right of a general merchant to sell:

(1) Any nonprescription drug, [medicine, or] device, OR DIAGNOSTIC;

(2) Any commonly used household or domestic remedy; or

(3) Any farm remedy or ingredient for a spraying solution, in bulk or otherwise.

(i) A dentist, physician, or podiatrist who fails to comply with the provisions of this section governing the dispensing of prescription drugs, DEVICES, OR DIAGNOSTICS shall:

(1) Have the dispensing permit revoked; and

(2) Be subject to disciplinary actions by the appropriate licensing board.

12-301.

(a) Except as otherwise provided in this title, an individual shall be licensed by the Board before the individual may practice pharmacy in this State.

(b) This section does not apply to an individual while engaging in a [clinical pharmacy training] PROFESSIONAL EXPERIENCE program under the direct supervision of a licensed pharmacist.

12-302.

(a) To qualify for a license, an applicant shall be an individual who meets the requirements of this section.

(b) The applicant shall be of good moral character.

(c) The applicant shall be at least 18 years old.

(d) The applicant shall:

(1) Be a graduate of a school or college of pharmacy that is approved by the Board or accredited by the American Council on Pharmaceutical Education; and

(2) Have completed the [clinical pharmacy training] PROFESSIONAL EXPERIENCE PROGRAM that the Board requires.

(e) Except as otherwise provided in this title, the applicant shall pass an examination given by the Board under this subtitle.

(f) (1) In this subsection, "foreign school or college of pharmacy" means a school or college of pharmacy that is not located in any state in the United States.

(2) The Board may waive the requirements of subsection (d)(1) of this section for an applicant who is a graduate of a foreign school or college of pharmacy, provided that the applicant passes an examination approved by the Board in addition to the examinations otherwise given by the Board under this subtitle.

(g) (1) The Board shall require, as part of its examination or licensing procedures, an applicant for a license to practice pharmacy to demonstrate an oral competency in the English language by passing a Board approved standardized test of oral competency.

(2) The Board shall adopt regulations that establish a procedure for testing an individual who because of the individual's speech or hearing impairment is unable to complete satisfactorily a Board approved standardized test of oral competency.

(3) If any disciplinary charge or action that relates to a problem with the oral communication of the English language is brought against a licensee under this title, the Board shall require the licensee to pass a Board approved standardized test of oral competency.

(4) The Board may not require an applicant for a license to practice pharmacy, who was previously licensed in another state to practice pharmacy, to demonstrate an oral competency in the English language, if the other state's examination and licensing procedures at the time the applicant was licensed in the other state included an oral competency component similar to the oral competency component in this State's examination and licensing procedures.

12-303.

(a) To apply for a license, an applicant shall:

(1) Submit an application to the Board on the form that the Board requires; and

(2) Pay [to the Board] the application [fee] FEES set by the Board.

(b) An application shall be signed and verified by the applicant as to completion of the required [clinical training] PROFESSIONAL EXPERIENCE PROGRAM.

12-305.

(a) Subject to the provisions of this section, the Board may waive any examination requirement of this title for an applicant who is licensed to practice pharmacy in any other state, if that state grants a similar waiver to licensees of this State.

(b) The Board may grant a waiver under this section only if the applicant:

(1) Is of good moral character;

(2) Pays the application [fee] FEES set by the Board; and

(3) Provides adequate evidence that the applicant:

(i) Meets the qualifications otherwise required by this title; and

(ii) Became licensed or registered in the other state to practice pharmacy only after passing an examination that is approved by the Board.

(c) The Board shall adopt by regulation an examination to be administered to applicants who are licensed to practice pharmacy in any other state.

12-307.

(A) A license authorizes the licensee to practice pharmacy while the license is effective.

(B) EXCEPT AS OTHERWISE PROVIDED IN THIS SECTION, A PHARMACIST MAY ENGAGE IN DISPENSING OR DISTRIBUTING ONLY FROM A PHARMACY HOLDING A PHARMACY PERMIT ISSUED BY THE BOARD.

(C) PURSUANT TO REGULATIONS ADOPTED BY THE BOARD, A LICENSED PHARMACIST MAY ENGAGE IN DISPENSING OR DISTRIBUTING FROM A SETTING NOT HOLDING A PHARMACY PERMIT ONLY UPON RECEIVING THE PRIOR APPROVAL OF THE BOARD.

12-403.

(a) THIS SECTION DOES NOT REQUIRE A NONRESIDENT PHARMACY TO VIOLATE THE LAWS OR REGULATIONS OF THE STATE IN WHICH IT IS LOCATED.

(B) Except as otherwise provided in this section, a pharmacy for which a pharmacy permit has been issued under this title:

(1) Shall be operated in compliance with the law and with the rules and regulations of the Board;

(2) Shall be located and equipped so that the pharmacy may be operated without endangering the public health or safety;

(3) Shall [be constantly under the personal and immediate supervision of a licensed pharmacist] ENSURE THAT A LICENSED PHARMACIST BE IMMEDIATELY AVAILABLE ON THE PREMISES TO PROVIDE PHARMACY SERVICES AT ALL TIMES THE PHARMACY IS IN OPERATION;

(4) SHALL BE SUPERVISED BY A LICENSED PHARMACIST WHO IS RESPONSIBLE FOR THE OPERATIONS OF THE PHARMACY AT ALL TIMES THE PHARMACY IS IN OPERATION;

[(4)] (5) Shall provide complete pharmaceutical service by preparing and dispensing all prescriptions that reasonably may be expected of a pharmacist;

[(5)] (6) [Except for a hospital pharmacy, shall] SHALL provide services to the general public and may not restrict or limit its services to any group of individuals UNLESS GRANTED A WAIVER FROM THIS REQUIREMENT BY THE BOARD;

[(6)] (7) May not offer pharmaceutical services under any term or condition that tends to interfere with or impair the free and complete exercise of professional pharmaceutical judgment or skill;

[(7)] (8) May not make any agreement that denies a patient a free choice of [pharmacists] PHARMACIST OR PHARMACY SERVICES; [and]

[(8)] (9) May not participate in any activity that is a ground for Board action against a licensed pharmacist under § 12-313 of this title[.];

(10) (I) SHALL MAINTAIN AT ALL TIMES A CURRENT REFERENCE LIBRARY THAT IS APPROPRIATE TO MEET THE NEEDS OF:

1. THE PRACTICE SPECIALTY OF THAT PHARMACY; AND

2. THE CONSUMERS THE PHARMACY SERVES; AND

(II) SHALL COMPLY WITH ANY REGULATIONS ADOPTED BY THE BOARD ESTABLISHING THE TYPES OF TEXTS REQUIRED TO BE INCLUDED IN THE REFERENCE LIBRARIES IN EACH OF THE VARIOUS PRACTICE SPECIALTY PHARMACIES;

(11) (I) SHALL MAINTAIN AT ALL TIMES THE MINIMUM PROFESSIONAL AND TECHNICAL EQUIPMENT AND SANITARY APPLIANCES THAT ARE NECESSARY IN A PHARMACY:

1. TO PREPARE AND DISPENSE PRESCRIPTIONS PROPERLY; AND

2. TO OTHERWISE OPERATE A PHARMACY; AND

(II) SHALL:

1. BE EQUIPPED WITH THE MINIMUM EQUIPMENT AND APPLIANCES SPECIFIED BY THE BOARD UNDER THIS SECTION; AND

2. BE KEPT IN A CLEAN AND ORDERLY MANNER;

(12) SHALL STORE ALL PRESCRIPTION OR NONPRESCRIPTION DRUGS, DEVICES, OR DIAGNOSTICS PROPERLY AND SAFELY SUBJECT TO THE RULES AND REGULATIONS ADOPTED BY THE BOARD;

(13) SHALL:

(I) MAKE AND KEEP ON FILE FOR AT LEAST 5 YEARS A RECORD OF EACH PRESCRIPTION PREPARED OR DISPENSED IN THE PHARMACY;

(II) DISCLOSE THE RECORDS AND FILES MAINTAINED OF PRESCRIPTIONS FOR DRUGS, DEVICES, OR DIAGNOSTICS THAT IDENTIFY OR MAY BE READILY ASSOCIATED WITH THE IDENTITY OF A PATIENT ONLY IN ACCORDANCE WITH THE PROVISIONS OF TITLE 4, SUBTITLE 3 OF THE HEALTH - GENERAL ARTICLE; AND

(III) KEEP ADDITIONAL RECORDS AS REQUIRED BY THE RULES AND REGULATIONS ADOPTED BY THE BOARD;

(14) SHALL ESTABLISH AND MAINTAIN MECHANISMS TO ENSURE THAT ALL PRESCRIPTION DRUGS, DEVICES, OR DIAGNOSTICS USED WITHIN INSTITUTIONS THAT PROVIDE ACUTE, SUBACUTE, OR LONG-TERM CARE, OR WITHIN THEIR RELATED CORPORATE SUBSIDIARIES, BUT STORED OUTSIDE A PHARMACY, ARE STORED PROPERLY AND SAFELY, SUBJECT TO RULES AND REGULATIONS ADOPTED BY THE BOARD AND POLICIES ESTABLISHED BY THE INSTITUTION;

(15) SHALL PROVIDE SUCH PERSONNEL, AUTOMATION, AND TECHNOLOGY AS ARE NECESSARY TO ALLOW THE LICENSED PHARMACIST EMPLOYEE SUFFICIENT TIME TO UTILIZE THE PHARMACIST'S KNOWLEDGE AND TRAINING AND TO PERFORM COMPETENTLY THE FUNCTIONS OF A LICENSED PHARMACIST AS REQUIRED BY LAW; AND

(16) SHALL PROVIDE SUCH PERSONNEL, AUTOMATION, AND TECHNOLOGY AS ARE NECESSARY TO ALLOW THE LICENSED PHARMACIST EMPLOYEE TO COMPLY WITH THE LABELING REQUIREMENTS SPECIFIED IN § 12-505.

[(b)] (C) (1) The Board may waive any of the requirements of this section for the University of Maryland School of Pharmacy, for [radio] NUCLEAR pharmacy and dental pharmacy experimental and teaching programs.

(2) The Board may waive the requirements of subsection [(a)(4)] (B)(5) and [(5)] (6) of this section for pharmacies that are engaged in pharmaceutical specialties which are recognized by the Board under rules and regulations adopted by the Board.

(D) A NONRESIDENT PHARMACY SHALL HOLD A PHARMACY PERMIT ISSUED BY THE BOARD.

(E) (1) IN ORDER TO OBTAIN A PHARMACY PERMIT FROM THE BOARD, A NONRESIDENT PHARMACY SHALL:

(I) SUBMIT AN APPLICATION TO THE BOARD ON THE FORM THAT THE BOARD REQUIRES;

(II) PAY TO THE BOARD AN APPLICATION FEE SET BY THE BOARD;

(III) SUBMIT A COPY OF THE MOST RECENT INSPECTION REPORT RESULTING FROM AN INSPECTION CONDUCTED BY THE REGULATORY OR LICENSING AGENCY OF THE STATE IN WHICH THE NONRESIDENT PHARMACY IS LOCATED; AND

(IV) ON THE REQUIRED PERMIT APPLICATION, IDENTIFY THE NAME AND CURRENT ADDRESS OF AN AGENT LOCATED IN THIS STATE OFFICIALLY DESIGNATED TO ACCEPT SERVICE OF PROCESS.

(2) A NONRESIDENT PHARMACY SHALL REPORT A CHANGE IN THE NAME OR ADDRESS OF THE RESIDENT AGENT IN WRITING TO THE BOARD 30 DAYS PRIOR TO THE CHANGE.

(F) A NONRESIDENT PHARMACY SHALL:

(1) COMPLY WITH THE LAWS OF THE STATE IN WHICH IT IS LOCATED;

(2) ON AN ANNUAL BASIS AND WITHIN 30 DAYS AFTER A CHANGE OF OFFICE, CORPORATE OFFICER, OR PHARMACIST, DISCLOSE TO THE BOARD THE LOCATION, NAMES, AND TITLES OF ALL PRINCIPAL CORPORATE OFFICERS AND ALL PHARMACISTS WHO ARE DISPENSING PRESCRIPTIONS FOR DRUGS, DEVICES, OR DIAGNOSTICS TO PERSONS IN THIS STATE;

(3) COMPLY WITH ALL LAWFUL DIRECTIONS AND REQUESTS FOR INFORMATION FROM THE REGULATORY OR LICENSING AGENCY OF THE STATE IN WHICH IT IS LOCATED AND ALL REQUESTS FOR INFORMATION MADE BY THE BOARD PURSUANT TO THIS SECTION;

(4) MAINTAIN AT ALL TIMES A VALID, UNEXPIRED PERMIT TO CONDUCT A PHARMACY IN COMPLIANCE WITH THE LAWS OF THE STATE IN WHICH IT IS LOCATED;

(5) MAINTAIN ITS RECORDS OF PRESCRIPTION DRUGS, DEVICES, OR DIAGNOSTICS DISPENSED TO PATIENTS IN THIS STATE SO THAT THE RECORDS ARE READILY RETRIEVABLE;

(6) DURING ITS REGULAR HOURS OF OPERATION, BUT NOT LESS THAN 6 DAYS A WEEK, AND FOR A MINIMUM OF 40 HOURS PER WEEK, PROVIDE TOLL-FREE TELEPHONE SERVICE TO FACILITATE COMMUNICATION BETWEEN PATIENTS IN THIS STATE AND A PHARMACIST WHO HAS ACCESS TO THE PATIENT'S PRESCRIPTION RECORDS;

(7) DISCLOSE ITS TOLL-FREE TELEPHONE NUMBER ON A LABEL AFFIXED TO EACH CONTAINER OF DRUGS, DEVICES, OR DIAGNOSTICS; AND

(8) COMPLY WITH THE LAWS OF THIS STATE RELATING TO THE CONFIDENTIALITY OF PRESCRIPTION RECORDS IF THERE ARE NO LAWS RELATING TO THE CONFIDENTIALITY OF PRESCRIPTION RECORDS IN THE STATE IN WHICH THE NONRESIDENT PHARMACY IS LOCATED.

(G) SUBJECT TO THE HEARING PROVISIONS OF § 12-411 OF THIS TITLE, IF A PHARMACY OR A NONRESIDENT PHARMACY IS OPERATED IN VIOLATION OF THIS SECTION, THE BOARD MAY SUSPEND THE APPLICABLE PHARMACY PERMIT UNTIL THE PHARMACY COMPLIES WITH THIS SECTION.

12-413.

(A) DURING BUSINESS HOURS, THE SECRETARY, THE BOARD, OR THE AGENTS OF EITHER MAY ENTER ANY PERMIT HOLDER'S PHARMACY AND INSPECT FOR COMPLIANCE WITH FEDERAL AND STATE LAWS AND REGULATIONS:

(1) ANY DRUGS, DEVICES, DIAGNOSTICS, DENTIFRICES, DOMESTIC REMEDIES, AND TOILET ARTICLES THAT ARE IN THE PHARMACY;

(2) ANY RECORDS OR PUBLICATIONS THAT ARE REQUIRED TO BE KEPT BY A PHARMACY UNDER THIS TITLE; AND

(3) THE FACILITY.

(B) AT THE DIRECTION OF THE SECRETARY, THE BOARD, THE CHIEF OF THE DIVISION OF DRUG CONTROL, OR THEIR AGENTS MAY ENTER A PERMIT HOLDER'S PHARMACY AT ANY TIME AND INVESTIGATE WITH LAW ENFORCEMENT OFFICERS PURSUANT TO A VALID WARRANT.

(C) A PERSON MAY NOT HINDER AN INSPECTION OR AN INVESTIGATION CONDUCTED UNDER THIS SECTION.

12-501.

(A) [Whenever a pharmacy is in operation, it shall be constantly under the personal and immediate supervision of a licensed pharmacist] A LICENSED PHARMACIST HAS A DUTY TO EXERCISE INDEPENDENT PROFESSIONAL JUDGMENT IN DECIDING WHETHER OR NOT TO DISPENSE OR REFILL A PRESCRIPTION.

(B) IN REFUSING TO DISPENSE OR REFILL A PRESCRIPTION, THE DECISION OF THE PHARMACIST SHALL NOT BE ARBITRARY BUT SHALL BE BASED ON PROFESSIONAL EXPERIENCE, KNOWLEDGE, OR AVAILABLE REFERENCE MATERIALS.

12-502.

(a) [In the operation of a pharmacy, only] ONLY a licensed pharmacist or an individual engaging in a [clinical pharmacy training] PROFESSIONAL EXPERIENCE program and acting under the direct supervision of a licensed pharmacist may provide information to the public OR A HEALTH CARE PRACTITIONER concerning PRESCRIPTION OR NONPRESCRIPTION drugs, [medicines, and] devices, OR DIAGNOSTICS including information as to their therapeutic values, potential side effects, and use in the treatment and prevention of diseases.

(b) [While on the premises of a pharmacy, a] A licensed pharmacist shall give [an individual] A PATIENT who requests, in person or by telephone, the current price of a prescription drug, DEVICE, OR DIAGNOSTIC that the pharmacy offers for sale to the public.

[12-503.

(a) The Board shall specify the minimum professional and technical equipment and sanitary appliances that are necessary in a pharmacy:

(1) To prepare and dispense prescriptions properly; and

(2) Otherwise to operate a pharmacy.

(b) Each pharmacy shall be:

(1) Equipped with the minimum equipment and appliances specified by the Board under this section; and

(2) Kept in a clean and orderly manner.

(c) Subject to the hearing provisions of § 12-411 of this title, if a pharmacy is operated in violation of this section, the Board may suspend the applicable pharmacy permit until the pharmacy complies with this section.]

[12-504.

(a) In each pharmacy there shall be kept at all times a current reference library that is appropriate to meet the needs of:

(1) The practice specialty of that pharmacy; and

(2) The consumers the pharmacy serves.

(b) The Board shall adopt regulations establishing the types of texts required to be included in the reference libraries in each of the various practice specialty pharmacies.

(c) Subject to the hearing provisions of § 12-411 of this title, if a pharmacy is operated in violation of this section, the Board may suspend the applicable pharmacy permit until the pharmacy complies with this section.]

[12-505.

(a) (1) In each pharmacy, a record of each prescription prepared or dispensed in the pharmacy shall be made and kept on file for at least 5 years.

(2) The records and files maintained by a pharmacy of prescription orders for drugs, medicines, or devices that identify or may be readily associated with the identity of a patient:

(i) Are medical records; and

(ii) May only be disclosed in accordance with the provisions of Title 4, Subtitle 3 of the Health - General Article.

(b) In each pharmacy, additional records also shall be kept as required by the rules and regulations adopted by the Board.]

[12-506.

Subject to the rules and regulations adopted by the Board, all drugs, medicines, and devices held by a pharmacy shall be stored properly and safely.]

[12-507.] 12-503.

(a) An authorized prescriber who issues a prescription shall indicate on the prescription the date of its issuance.

(b) Unless otherwise instructed by the authorized prescriber who issues the prescription, a pharmacist may not dispense any drug, [medicine, or] device, OR DIAGNOSTIC on a prescription presented more than 120 days after the date the prescription was issued.

[12-508.] 12-504.

(a) In this section, "brand name" means the proprietary name a manufacturer places on a drug, DEVICE, OR DIAGNOSTIC product or its container.

(b) A pharmacist may substitute a generically equivalent drug, DEVICE, OR DIAGNOSTIC product, of the same dosage form and strength, for any brand name drug, DEVICE, OR DIAGNOSTIC product prescribed, if:

(1) The authorized prescriber does not state expressly that the prescription is to be dispensed only as directed;

(2) The substitution is recognized in the United States Food and Drug Administration's current list of approved drug, DEVICE, OR DIAGNOSTIC products with therapeutic equivalence evaluations; and

(3) The consumer is charged less for the substituted drug, DEVICE, OR DIAGNOSTIC than the price of the brand name drug, DEVICE, OR DIAGNOSTIC.

(c) If a drug, DEVICE, OR DIAGNOSTIC product is substituted under this section, the pharmacist shall:

(1) Notify the patient in writing that the drug, DEVICE, OR DIAGNOSTIC product dispensed is a generic equivalent of the prescribed drug, DEVICE, OR DIAGNOSTIC product; and

(2) Record on the prescription and keep a record of the name and manufacturer of the substituted drug, DEVICE, OR DIAGNOSTIC product.

(d) The Department may list any additional drug, DEVICE, OR DIAGNOSTIC products that are determined by the Department to meet requirements that are adequate to assure product quality and therapeutic equivalence, after an opportunity for public comment as provided in Title 10, Subtitle 1 of the State Government Article.

(e) The Department may disqualify a drug, DEVICE, OR DIAGNOSTIC product on the United States Food and Drug Administration's current list from being used in Maryland as a generic substitute if the Department determines that the drug, DEVICE, OR DIAGNOSTIC is therapeutically nonequivalent or has a negative physical or biological effect on the consumer of that drug, DEVICE, OR DIAGNOSTIC product:

(1) After providing an opportunity for public comment as provided in Title 10, Subtitle 1 of the State Government Article; or

(2) Prior to providing an opportunity for public comment, if the Department believes that a particular generic drug, DEVICE, OR DIAGNOSTIC product constitutes an imminent danger to the public health, safety or welfare, and the Department:

(i) Provides an opportunity for public comment as provided in Title 10, Subtitle 1 of the State Government Article within 30 days of disqualifying the DRUG, DEVICE, OR DIAGNOSTIC product; and

(ii) After providing an opportunity for public comment, determines whether the DRUG, DEVICE, OR DIAGNOSTIC product should remain disqualified.

(f) For a drug, DEVICE, OR DIAGNOSTIC product that the Department has disqualified from being used in Maryland as a generic substitute under subsection (e) of this section, the Department shall provide an opportunity for public comment as provided in Title 10, Subtitle 1 of the State Government Article before reinstating the drug, DEVICE, OR DIAGNOSTIC product for use in Maryland as a generic substitute.

(g) A pharmacist who substitutes a drug, DEVICE, OR DIAGNOSTIC product in compliance with this section incurs no greater liability in filling the prescription by dispensing the equivalent drug, DEVICE, OR DIAGNOSTIC product than would be incurred in filling the prescription by dispensing the prescribed brand name drug, DEVICE, OR DIAGNOSTIC.

[12-509.] 12-505.

(a) [In this section, "established name" has the meaning stated in the Federal Food, Drug, and Cosmetic Act.]

[(b)] Except for a [medication] DRUG, DEVICE, OR DIAGNOSTIC dispensed to an inpatient in a hospital or related institution, a pharmacist shall label each container of [medication] DRUGS, DEVICES, OR DIAGNOSTICS that the pharmacist dispenses.

[(c)] (B) In addition to any other information required by law, the pharmacist shall include on the label:

(1) The date the prescription is filled; and

(2) Unless otherwise required by the prescriber:

(i) [The month and year when the medication expires, if known;] AN EXPIRATION DATE OF THE DRUGS, DEVICES, OR DIAGNOSTICS WHICH SHALL BE THE LESSER OF:

1. 1 YEAR FROM THE DATE OF DISPENSING;

2. THE MONTH AND YEAR WHEN THE DRUGS, DEVICES, OR DIAGNOSTICS EXPIRE;

3. THE APPROPRIATE EXPIRATION DATE FOR REPACKAGED DRUGS, DEVICES, OR DIAGNOSTICS; OR

4. A SHORTER PERIOD AS DETERMINED BY THE PHARMACIST;

(ii) Any appropriate special handling instructions regarding proper storage of the [medication] DRUGS, DEVICES, OR DIAGNOSTICS; and

(iii) Subject to the provisions of subsection [(d)] (C) of this section, the name and strength of the [medication] DRUGS, DEVICES, OR DIAGNOSTICS.

[(d)] (C) (1) Except as provided in paragraph (2) of this subsection, the pharmacist shall indicate on the label the same name for the [medication] DRUG, DEVICE, OR DIAGNOSTIC as that used by the authorized prescriber.

(2) If, under [§ 12-508] § 12-504 of this subtitle, the pharmacist substitutes a drug, DEVICE, OR DIAGNOSTIC product for that named by the authorized prescriber, the pharmacist shall indicate on the label both the [established] name of the drug, DEVICE, OR DIAGNOSTIC product [prescribed] and the name of the manufacturer or distributor of the drug, DEVICE, OR DIAGNOSTIC dispensed.

[(e)] (D) (1) Except as provided in this subsection, if an authorized prescriber dispenses [medication] A DRUG, DEVICE, OR DIAGNOSTIC, the prescriber shall label each container of the [medication] DRUG, DEVICE, OR DIAGNOSTIC.

(2) In addition to any other information required by law, the authorized prescriber shall include on the label:

(i) The name and strength of the [medication] DRUG, DEVICE, OR DIAGNOSTIC;

(ii) The date the prescription is dispensed;

(iii) [The month and year when the medication expires, if known; and] AN EXPIRATION DATE OF THE DRUG, DEVICE, OR DIAGNOSTIC WHICH SHALL BE THE LESSER OF:

1. 1 YEAR FROM THE DATE OF DISPENSING;

2. THE MONTH AND YEAR WHEN THE DRUG, DEVICE, OR DIAGNOSTIC EXPIRES; OR

3. A SHORTER PERIOD AS DETERMINED BY THE AUTHORIZED PRESCRIBER; AND

(iv) Any appropriate special handling instructions regarding proper storage of the [medication] DRUG, DEVICE, OR DIAGNOSTIC.

(3) The labeling requirements of this subsection do not apply if the authorized prescriber dispenses the [medication] DRUG, DEVICE, OR DIAGNOSTIC:

(i) To an inpatient in a hospital or related institution;

(ii) In an emergency situation; or

(iii) As a sample [medication] DRUG, DEVICE, OR DIAGNOSTIC dispensed in the regular course of the authorized prescriber's practice.

[(f)] (E) So long as any of the original contents remain in the container, a person may not alter, deface, or remove any label required by this section.

[12-510.

(a) The Secretary, the Board, or the agents of either may enter any pharmacy and inspect during business hours:

(1) Any drugs, medicines, devices, dentifrices, domestic remedies, and toilet articles that are in the pharmacy; and

(2) Any records and publications that are required to be kept in a pharmacy under this title.

(b) A person may not hinder an inspection conducted under this section.]

[12-511.

(a) A pharmacist may refill a prescription for a drug for which the refill has not been authorized if:

(1) The pharmacist:

(i) Attempts to obtain an authorization from the authorized prescriber; and

(ii) Is not able readily to obtain the authorization.

(2) The refill of the prescription is not for a controlled dangerous substance;

(3) The drug is essential to the maintenance of life;

(4) (i) The drug is essential to the continuation of therapy in chronic conditions; and

(ii) In the pharmacist's professional judgment, the interruption of the therapy reasonably might produce an undesirable health consequence, be detrimental to the patient's welfare, or cause physical or mental discomfort;

(5) The pharmacist:

(i) Enters on the back of the prescription or on another appropriate uniformly maintained, readily retrievable record, such as a medication record, the date and the quantity of the drug dispensed; and

(ii) Signs or initials the record; and

(6) The pharmacist notifies the authorized prescriber of the refill of the prescription within 72 hours of dispensing the drug.

(b) If a pharmacist refills a prescription under subsection (a) of this section, the pharmacist may provide only 1 refill of the prescription and the refill quantity dispensed shall be in conformity with the prescriber's directions for use and may not exceed a 72-hour period of time.

(c) If the federal or State government declares a state of emergency, a pharmacist working in the area declared an emergency may refill a prescription for a drug for which the refill has not been authorized if:

(1) As a result of the emergency, the pharmacist is unable to obtain an authorization from the authorized prescriber;

(2) The refill of the prescription is not for a controlled dangerous substance;

(3) The quantity dispensed does not exceed a 7-day supply; and

(4) The pharmacist notifies the authorized prescriber of the refill of the prescription within 7 days of dispensing the drug.]

12-506.

(A) A PHARMACIST MAY REFILL A PRESCRIPTION FOR A DRUG, DEVICE, OR DIAGNOSTIC FOR WHICH THE REFILL HAS NOT BEEN AUTHORIZED IF:

(1) THE PHARMACIST HAS, AS PART OF THE RECORDS REQUIRED TO BE KEPT ON FILE UNDER § 12-403(B)(13) OF THIS SUBTITLE:

(I) THE ORIGINAL PRESCRIPTION; OR

(II) A PRESCRIPTION LEGALLY TRANSFERRED ACCORDING TO REGULATIONS ADOPTED BY THE BOARD;

(2) THE REFILL OF THE PRESCRIPTION IS NOT FOR A CONTROLLED DANGEROUS SUBSTANCE;

(3) IN THE PHARMACIST'S PROFESSIONAL JUDGMENT, UPON ASSESSMENT OF THE PATIENT, THE INTERRUPTION OF THE THERAPY REASONABLY MIGHT PRODUCE AN UNDESIRABLE HEALTH CONSEQUENCE, BE DETRIMENTAL TO THE PATIENT'S WELFARE, OR CAUSE PHYSICAL OR MENTAL DISCOMFORT;

(4) THE QUANTITY DISPENSED DOES NOT EXCEED A 30-DAY SUPPLY;

(5) THE PHARMACIST:

(I) ENTERS ON THE BACK OF THE PRESCRIPTION OR ON ANOTHER APPROPRIATE, UNIFORMLY MAINTAINED, AND READILY RETRIEVABLE RECORD, SUCH AS A MEDICATION RECORD, THE DATE AND THE QUANTITY OF THE DRUG DISPENSED; AND

(II) SIGNS OR INITIALS THE RECORD; AND

(6) THE PHARMACIST NOTIFIES THE AUTHORIZED PRESCRIBER OF THE REFILL OF THE PRESCRIPTION WITHIN 72 HOURS OF DISPENSING THE DRUG, DEVICE, OR DIAGNOSTIC.

(B) IF THE FEDERAL, STATE, OR A COUNTY GOVERNMENT DECLARES A STATE OF EMERGENCY, A PHARMACIST WORKING IN THE AREA DECLARED AN EMERGENCY MAY REFILL A PRESCRIPTION FOR A DRUG, DEVICE, OR DIAGNOSTIC FOR WHICH THE REFILL HAS NOT BEEN AUTHORIZED IF:

(1) AS A RESULT OF THE EMERGENCY, THE PHARMACIST IS UNABLE TO OBTAIN AN AUTHORIZATION FROM THE AUTHORIZED PRESCRIBER;

(2) THE QUANTITY DISPENSED DOES NOT EXCEED A 7-DAY SUPPLY OR UNIT-OF-USE;

(3) THE PHARMACIST NOTIFIES THE AUTHORIZED PRESCRIBER OF THE REFILL OF THE PRESCRIPTION WITHIN 7 DAYS OF DISPENSING THE DRUG, DEVICE, OR DIAGNOSTIC; AND

(4) THE REFILL OF THE PRESCRIPTION IS NOT FOR A CONTROLLED DANGEROUS SUBSTANCE.

[12-512.] 12-507.

(a) A pharmacist who provides prescription services to medical assistance recipients shall offer to discuss with each medical assistance recipient or caregiver who presents a prescription order for outpatient drugs any matter which, in the exercise of the pharmacist's professional judgment, the pharmacist deems significant, which may include the following:

(1) The name and description of the medication;

(2) The route, dosage form, dosage, route of administration, and duration of drug therapy;

(3) Special directions and precautions for preparation, administration, and use by the patient;

(4) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(5) Techniques for self-monitoring drug therapy;

(6) Proper storage;

(7) Prescription refill information; and

(8) Action to be taken in the event of a missed dose.

(b) The offer to discuss may be made in the manner determined by the professional judgment of the pharmacist, which shall include either:

(1) A face-to-face communication with the pharmacist; or

(2) At least 2 of the following:

(i) A sign posted so it can be seen by patients;

(ii) A notation affixed to or written on the bag in which the prescription is to be dispensed;

(iii) A notation contained on the prescription container; or

(iv) Communication by telephone.

(c) Nothing in this section shall be construed as requiring a pharmacist to provide consultation if the medical assistance recipient or caregiver refuses the consultation.

(d) A pharmacist must make a reasonable effort to obtain, record, and maintain, at the individual pharmacy, at least the following information regarding a medical assistance recipient:

(1) Name, address, telephone number, date of birth or age, and gender;

(2) Individual history when significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices; and

(3) Pharmacist comments relevant to the individual's drug therapy which may be recorded either manually or electronically in the patient's profile.

(e) This section shall apply only to medical assistance recipients presenting prescriptions for covered outpatient drugs.

(f) The requirements of this section do not apply to refill prescriptions.

(g) The Secretary, after consultation with the Maryland Pharmacists Association and the Maryland Association of Chain Drug Stores, shall adopt regulations in accordance with pharmacy practices in Maryland to implement the provisions of this section.

12-602.

(a) (1) In this section, the following words have the meanings indicated.

(2) "Distribution permit" means a permit issued by the Board under this section to distribute prescription drugs, DEVICES, OR DIAGNOSTICS into, out of, or within the State as a distributor, jobber, manufacturer, or wholesaler, wherever located.

(3) "Prescription drugs, DEVICES, OR DIAGNOSTICS" means any drug, DEVICE, OR DIAGNOSTIC [intended for use by man] that, because of its toxicity or other potential for harmful effect, the method of its use, or the collateral measures necessary for its use, is required by federal law to bear a cautionary label warning against dispensing without a prescription or is designated by the Department as not safe for use except under the supervision of a practitioner licensed to administer drugs, DEVICES, OR DIAGNOSTICS of this nature.

(b) This section does not affect any person while distributing:

(1) Feed for livestock or poultry;

(2) Fertilizers;

(3) Fungicides;

(4) Insecticide;

(5) Land plaster;

(6) Lime;

(7) Seeds; or

(8) Devices, drugs, or supplies of any kind for the treatment, care, or cure of farm animals.

(c) A person shall hold a distribution permit issued by the Board before the person may distribute prescription drugs, DEVICES, OR DIAGNOSTICS as a distributor, jobber, manufacturer, or wholesaler.

(d) To qualify for a distribution permit, an applicant shall:

(1) Satisfy the Board that the applicant will distribute prescription drugs, DEVICES, OR DIAGNOSTICS in compliance with the restrictions specified in subsection (e) of this section; and

(2) Comply with any pertinent regulations adopted under subsection (i) of this section.

(e) A distribution permit holder may distribute prescription drugs, DEVICES, OR DIAGNOSTICS only:

(1) To the following persons:

(i) An authorized prescriber;

(ii) A pharmacy permit holder;

(iii) A distribution permit holder; or

(iv) Any other person approved by the Board; and

(2) In compliance with any rules and regulations adopted under this section.

(f) To apply for a distribution permit, an applicant shall:

(1) Submit an application to the Board on the form that the Board provides; and

(2) Pay to the Board an application fee set by the Board.

(g) The Board shall issue a distribution permit to any applicant who meets the requirements of this section.

(h) A distribution permit issued under this section authorizes the distribution permit holder to distribute prescription drugs, DEVICES, OR DIAGNOSTICS as a distributor, jobber, manufacturer, or wholesaler while the distribution permit is effective.

(i) To protect the public health and safety, the Board may adopt rules and regulations regarding the distribution of prescription drugs, DEVICES, OR DIAGNOSTICS including regulations regarding:

(1) Qualifications and information required from an applicant seeking issuance or renewal of a distribution permit;

(2) Minimum requirements for the receipt, storage, and handling of prescription drugs, DEVICES, OR DIAGNOSTICS, security precautions, quality control, recordkeeping, and establishment of written procedures, policy, and responsibilities of personnel;

(3) The education and experience of personnel employed in positions responsible for duties referenced in paragraph (2) of this subsection and generally responsible for carrying out those duties that are subject to State licensure requirements under this subtitle; and

(4) Disciplinary action to be taken against a permit holder who is convicted of or pleads guilty or nolo contendere to a violation of State, federal, or local drug laws or who violates regulations promulgated by the Board under this section.

(j) (1) A distribution permit expires on the December 31 after its effective date, unless the distribution permit is renewed for a 1-year term as provided in this subsection.

(2) At least 1 month before a distribution permit expires, the Board shall send to the distribution permit holder, by first-class mail to the last known address of the distribution permit holder, a renewal notice that contains a statement of:

(i) The date on which the current distribution permit expires;

(ii) The date by which the renewal application must be received by the Board for the renewal to be issued and mailed before the distribution permit expires; and

(iii) The amount of the renewal fee.

(3) Before a distribution permit expires, a distribution permit holder periodically may renew it for an additional 1-year term, if the distribution permit holder:

(i) Otherwise is entitled to a distribution permit;

(ii) Pays to the Board a renewal fee set by the Board; and

(iii) Submits to the Board a renewal application on the form that the Board requires.

(4) The Board shall renew the distribution permit of each distribution permit holder who meets the requirements of this section and any regulation adopted under this section.

(k) Each distribution permit shall be displayed conspicuously in the place for which it is issued.

(l) A distribution permit is not transferable.

(m) Subject to any other restriction provided by law, a person may not purchase or obtain any prescription drugs, DEVICES, OR DIAGNOSTICS unless the drug, DEVICE, OR DIAGNOSTIC is obtained from a distribution permit holder, a licensed pharmacist, or an authorized prescriber.

(n) A person may not violate any rule or regulation adopted under this section.

(o) A distribution permit is void on conviction of the distribution permit holder for any violation of:

(1) This section; or

(2) Any rule or regulation adopted by the Board under this section.

12-603.

(a) (1) In this section the following words have the meanings indicated.

(2) "[Hemodialysis] DIALYSIS drugs and devices" means:

(i) Dialysate AND DIALYSIS SOLUTIONS;

(ii) Dialyzers, delivery systems, and their accessory equipment NECESSARY TO ADMINISTER SUCH PRODUCTS;

(iii) Heparin;

(iv) Local anesthetics AND OTHER DRUGS AND DEVICES approved by the Board under subsection (g) of this section;

(v) Needles;

(vi) Syringes; and

(vii) Sterile sodium chloride, [0.9%] AND STERILE POTASSIUM CHLORIDE.

(3) "Home [hemodialysis] DIALYSIS distribution permit" means a permit issued by the Board to distribute [hemodialysis] DIALYSIS drugs and devices to the homes of [hemodialysis] DIALYSIS patients.

(b) (1) Except as provided under this subsection, a person shall hold a home [hemodialysis] DIALYSIS distribution permit issued by the Board before the person may distribute [hemodialysis] DIALYSIS drugs and devices to the home of a [hemodialysis] DIALYSIS patient.

(2) A licensed pharmacist may distribute [hemodialysis] DIALYSIS drugs and devices under this section without the home [hemodialysis] DIALYSIS distribution permit otherwise required by this section.

(c) To qualify for a home [hemodialysis] DIALYSIS distribution permit, an applicant shall satisfy the Board that the applicant will distribute [hemodialysis] DIALYSIS drugs and devices in compliance with subsection (h) of this section.

(d) To apply for a home [hemodialysis] DIALYSIS distribution permit, an applicant shall:

(1) Submit an application to the Board on the form that the Board requires; and

(2) Pay to the Board a fee set by the Board.

(e) The Board shall issue a home [hemodialysis] DIALYSIS distribution permit to any applicant who meets the requirements of this section.

(f) A home [hemodialysis] DIALYSIS distribution permit issued under this section authorizes the home [hemodialysis] DIALYSIS distribution permit holder to distribute [hemodialysis] DIALYSIS drugs and devices to the home of a [hemodialysis] DIALYSIS patient while the home [hemodialysis] DIALYSIS distribution permit is effective.

(g) (1) The Board may approve local anesthetics AND OTHER DRUGS AND DEVICES for distribution as [hemodialysis] DIALYSIS drugs AND DEVICES under this section.

(2) The Board may adopt rules and regulations to assure safe, proper, and uninterrupted distribution of [hemodialysis] DIALYSIS drugs and devices, including rules and regulations as to:

(i) Maintaining facilities that are adequate to assure proper security and control of [hemodialysis] DIALYSIS drugs and devices;

(ii) Keeping records;

(iii) Labeling [hemodialysis] DIALYSIS drugs and devices;

(iv) Receipts AND RETURNS from patients for [hemodialysis] DIALYSIS drugs and devices;

(v) Reports to the Board; and

(vi) Restrictions on specific [hemodialysis] DIALYSIS drugs or devices, including limitations on the amounts that may be distributed.

(h) A person authorized to distribute [hemodialysis] DIALYSIS drugs and devices under this section may distribute only [hemodialysis] DIALYSIS drugs and devices:

(1) That the Board, after consultation with the State Commission on Kidney Disease, has approved as effective and safe for their intended use;

(2) Under supervision of a person who the Board considers qualified to safeguard and protect the public health;

(3) To an individual:

(i) Who has permanently lost the function of the individual's kidneys and requires regular treatment [with a kidney machine]; and

(ii) Who has completed a full course of training in providing the individual's own [hemodialysis] DIALYSIS treatment GIVEN BY:

1. [Given by a] A home dialysis training facility; [and] OR

2. [With another individual personally committed to the treatment of the individual who has permanently lost kidney function; and] AN END STAGE RENAL DISEASE CLINIC CERTIFIED UNDER MEDICARE; AND

(4) In compliance with the rules and regulations adopted by the Board under this section.

(i) Subject to the Administrative Procedure Act, the Board may suspend or revoke the home [hemodialysis] DIALYSIS distribution permit of any home [hemodialysis] DIALYSIS distribution permit holder who fails to comply with subsection (h) of this section.

12-703.

A person may not establish or operate a pharmacy in this State OR A NONRESIDENT PHARMACY unless the person holds a pharmacy permit issued by the Board.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 1997.