West's Annotated Code of Maryland Currentness
Health Occupations (Refs & Annos)
Title 12. Pharmacists and Pharmacies (Refs & Annos)
Subtitle 1. Definitions; General Provisions (Refs & Annos)
§ 12-101. Definitions

In general

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

Authorized prescriber

(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 or devices.

Board

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

Compounding

(d)(1) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device:

(i) As the result of a practitioner's prescription drug order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice; or

(ii) For the purpose of, or incident to, research, teaching, or chemical analysis and not for the sale or dispensing of the drug or device.

(2) "Compounding" includes the preparation of drugs or devices in anticipation of a prescription drug order based on routine, regularly observed prescribing patterns.

Delegated pharmacy act

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(e)(1) “Delegated pharmacy act” means an activity that constitutes the practice of pharmacy delegated by a licensed pharmacist under this title and regulations adopted by the Board.

(2) “Delegated pharmacy act” does not include:

(i) An act within the parameters of a therapy management contract as provided under Subtitle 6A of this title;

(ii) The administration of an influenza vaccination in accordance with § 12-508 of this title;

(iii) The delegation of a pharmacy act by a registered pharmacy technician, pharmacy student, or pharmacy technician trainee;

(iv) A pharmacy activity performed by a pharmacy student in accordance with § 12-301(b) of this title;

(v) A pharmacy activity performed by an applicant for a license to practice pharmacy in accordance with regulations adopted by the Board; or

(vi) The performance of other functions prohibited in regulations adopted by the Board.

Device

(f)(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.

Direct supervision

(g) “Direct supervision” means that a licensed pharmacist is physically available on-site to supervise the

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performance of delegated pharmacy acts.

Dispense, dispensing

(h) “Dispense” or “dispensing” means the procedure which results in the receipt of a prescription or nonprescription drug or device by a patient or the patient's agent and which entails the:

(1) Interpretation of an authorized prescriber's prescription for a drug or device;

(2) Selection and labeling of the drug or device prescribed pursuant to that prescription; and

(3) Measuring and packaging of the prescribed drug or device in accordance with State and federal laws.

Distribute

(i)(1) “Distribute” means the process resulting in the provision of a prescription or nonprescription drug or device to a separate, intervening individual, licensed and practicing under this article, prior to administration of the provided drug or device 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 § 12-6C-03 of this title.

License

(j) “License” means, unless the context requires otherwise, a license issued to a pharmacist by the Board to practice pharmacy.

Licensed pharmacist

(k) “Licensed pharmacist” means, unless the context requires otherwise, a pharmacist who is licensed by the Board to practice pharmacy.

Nonprescription drug

(l) “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.

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Nonresident pharmacy

(m) “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 or devices to a person in this State pursuant to a prescription.

Pharmaceutical care

(n) “Pharmaceutical care” means the provision of a patient's drug regimen for the purpose of achieving definite outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process by identifying, resolving, or preventing actual or potential drug therapy problems and which may include patient counseling and providing information to licensed and certified health care providers.

Pharmacist

(o) “Pharmacist” means an individual who practices pharmacy regardless of the location where the activities of practice are performed.

Pharmacy

(p) “Pharmacy” means an establishment in which prescription or nonprescription drugs or devices are compounded, dispensed, or distributed.

Pharmacy permit

(q) “Pharmacy permit” means a permit issued by the Board to establish and operate a pharmacy.

Pharmacy student

(r) “Pharmacy student” means an individual who is enrolled as a student in a school or college of pharmacy approved by the Board or accredited by the Accreditation Council for Pharmacy Education.

Pharmacy technician trainee

(s) “Pharmacy technician trainee” means an individual engaged in a Board approved pharmacy technician training program.

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Practice pharmacy

(t)(1) “Practice pharmacy” means to engage in any of the following activities:

(i) Providing pharmaceutical care;

(ii) Compounding, dispensing, or distributing prescription drugs or devices;

(iii) Compounding or dispensing nonprescription drugs or devices;

(iv) Monitoring prescriptions for prescription and nonprescription drugs or devices;

(v) Providing information, explanation, or recommendations to patients and health care practitioners about the safe and effective use of prescription or nonprescription drugs or devices;

(vi) Identifying and appraising problems concerning the use or monitoring of therapy with drugs or devices;

(vii) Acting within the parameters of a therapy management contract, as provided under Subtitle 6A of this title;

(viii) Administering an influenza vaccination, a vaccination for pneumococcal pneumonia or herpes zoster, or any vaccination that has been determined by the Board, with the agreement of the Board of Physicians and the Board of Nursing, to be in the best health interests of the community in accordance with § 12-508 of this title;

(ix) Delegating a pharmacy act to a registered pharmacy technician, pharmacy student, or an individual engaged in a Board approved pharmacy technician training program;

(x) Supervising a delegated pharmacy act performed by a registered pharmacy technician, pharmacy student, or an individual engaged in a Board approved pharmacy technician training program; or

(xi) Providing drug therapy management in accordance with § 19-713.6 of the Health--General Article.

(2) “Practice pharmacy” does not include the operations of a person who holds a permit issued under § 12-6C-03 of this title.

Registered pharmacy technician

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(u) “Registered pharmacy technician” means an individual who is registered with the Board to perform delegated pharmacy acts.

Registration

(v) “Registration” means, unless the context requires otherwise, a registration issued by the Board to perform delegated pharmacy acts under the supervision of a licensed pharmacist.

Supervision

(w) “Supervision” means reviewing the work, guiding and directing the activities, and monitoring the performance of an individual.

§ 12-102. Right to practice pharmacy, pharmaceutical care

Definitions

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

(2) “In the public interest” means the dispensing of drugs or devices 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.

In general

(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.

Preparation, dispensing of prescriptions, generally

(c) This title does not prohibit:

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(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 or devices by the dentist, physician, or podiatrist is in the public interest;

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

4. Posts a sign conspicuously positioned and readable regarding the process for resolving incorrectly filled prescriptions or includes written information regarding the process with each prescription dispensed;

(ii) The person for whom the drugs or devices 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 dispensing and labeling requirements of this title;

2. Records the dispensing of the prescription drug or device 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 and in accordance with § 12-102.1 of this subtitle;

4. On inspection by the Division of Drug Control, signs and dates an acknowledgment form provided by the Division of Drug Control relating to the requirements of this section;

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

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6. Does not direct patients to a single pharmacist or pharmacy in accordance with § 12-403(b)(8) of this title;

7. Does not receive remuneration for referring patients to a pharmacist or pharmacy;

8. Complies with the child resistant packaging requirements regarding prescription drugs under Title 22, Subtitle 3 of the Health--General Article;

9. Complies with drug recalls;

10. Maintains biennial inventories and complies with any other federal and State record-keeping requirements relating to controlled dangerous substances;

11. Purchases prescription drugs from a pharmacy or wholesale distributor who holds a permit issued by the Board of Pharmacy, as verified by the Board of Pharmacy;

12. Annually reports to the respective board of licensure whether the dentist, physician, or podiatrist has personally prepared and dispensed prescription drugs within the previous year; and

13. Completes ten continuing education credits over a 5-year period relating to the preparing and dispensing of prescription drugs, offered by the Accreditation Council for Pharmacy Education (ACPE) or as approved by the Secretary, in consultation with each respective board of licensure, as a condition of permit renewal; or

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

Dispensing drugs, samples

(d) This title does not prohibit:

(1) A licensed veterinarian from personally dispensing a drug or device sample to a patient of the veterinarian; or

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

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

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

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

Administering prescription drugs

(e)(1) This title does not prohibit a dentist, physician, or podiatrist from administering a prescription drug or device 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 or device at a given time, whether by injection or other means, and whether in liquid, tablet, capsule, or other form.

Labeling requirements

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

(i) The starter dosage complies with the labeling requirements of § 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 or device sufficient to begin therapy:

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

(ii) Prior to obtaining a larger quantity of the drug or device to complete the therapy.

Medical facilities

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

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

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

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

General merchants

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

(1) Any nonprescription drug or device;

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

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

Dispensing permits

Reporting requirements

(i) The Board of Pharmacy, the Board of Dental Examiners, the Board of Physicians, and the Board of Podiatric Medical Examiners annually shall report to the Division of Drug Control:

(1) The names and addresses of its licensees who are authorized to personally prepare and dispense prescription drugs; and

(2) The names and addresses of its licensees who have reported, in accordance with subsection (c)(2)(iv)12 of this section, that they have personally prepared and dispensed prescription drugs within the previous year.

Revocation of dispensing permit

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

(1) Have the dispensing permit revoked; and

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

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➡ § 12-102.1. Inspection of offices with dispensing permits

In general

(a) The Division of Drug Control shall enter and inspect the office of a dentist, physician, or podiatrist who holds:

(1) An initial dispensing permit:

(i) Within 6 months after receiving the report required under § 12-102(i)(1) of this subtitle; and

(ii) At least one more time during the duration of the permit; and

(2) A renewed dispensing permit at least two times during the duration of the permit.

Results of inspections

(b) The Division of Drug Control promptly shall report the results of the inspections required under subsection (a) of this section to the respective board of licensure.

➡ § 12-102.2. Fees charged to dentists , physicians, or podiatrists

In general

(a) The Board of Dental Examiners, the Board of Physicians, and the Board of Podiatric Medical Examiners shall charge a fee to a dentist, physician, or podiatrist who holds a dispensing permit in an amount that will produce funds to approximate but not exceed the documented costs to the Division of Drug Control for inspections of dispensing permit holders.

Revenues paid to General Fund

(b) Revenues collected by the Board of Dental Examiners, the Board of Physicians, and the Board of Podiatric Medical Examiners under this section shall be paid into the General Fund of the State.

Subtitle 2. State Board of Pharmacy (Refs & Annos)

➡ § 12-201. State Board of Pharmacy

There is a State Board of Pharmacy in the Department.

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➡ § 12-202. Board members

Composition

(a)(1) The Board consists of twelve members.

(2) Of the twelve Board members:

(i) Ten shall be licensed pharmacists, including:

1. Two who at the time of appointment practice primarily in chain store pharmacies;

2. Two who at the time of appointment practice primarily in independent pharmacies;

3. Two who at the time of appointment practice primarily in an acute-care hospital;

4. One who at the time of appointment practices primarily in a pharmacy that provides services to a long-term care facility;

5. One who at the time of appointment practices primarily in a pharmacy that specializes in the provision of home infusion/home care services; and

6. Two pharmacists at-large; and

(ii) Two shall be consumer members.

(3)(i) The Governor shall appoint the chain store pharmacist members, with the advice of the Secretary, from a list of names submitted to the Secretary and the Governor by the Maryland Association of Chain Drug Stores.

(ii) The Governor shall appoint the independent pharmacist members, with the advice of the Secretary, from a list of names submitted to the Secretary and the Governor by the Maryland Pharmacists Association and the Maryland Pharmaceutical Society.

(iii) The Governor shall appoint the acute-care hospital pharmacist members, with the advice of the Secretary, from a list of names submitted to the Secretary and the Governor by the Maryland Society of Health-System Pharmacists.

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(iv) The Governor shall appoint the long-term care facility pharmacist member, with the advice of the Secretary, from a list of names submitted to the Secretary and the Governor by the Maryland Chapter of the American Society of Consultant Pharmacists.

(v) The Governor shall appoint the home infusion/home care pharmacist member, with the advice of the Secretary, from a list of names submitted to the Secretary and the Governor by the Maryland Society of Health-System Pharmacists.

(vi) The Governor shall appoint the at-large pharmacist members, with the advice of the Secretary, from a list of all names submitted to the Maryland Pharmacists Association, and then forwarded to the Secretary and the Governor.

(vii) Except for the at-large vacancies, the number of names on each list submitted to the Secretary and the Governor under this paragraph shall be three times the number of vacancies.

(4) For each pharmacist vacancy:

(i) The Board shall notify all licensed pharmacists and other interested parties of record in the State of the vacancy to solicit nominations to fill the vacancy and provide information for contacting a representative of the group that submits the list of names to the Governor under paragraph (3) of this subsection; and

(ii) Except for the at-large vacancies, each association that is responsible for submitting a list of nominees to the Secretary and the Governor under this section shall:

1. Issue a nomination form upon the request of any licensed pharmacist and consider all nominations received by the association's deadline;

2. Form a committee, which recognizes diversity within the State in geographic distribution, sex, race, and age, comprised of at least five pharmacists to review nominations, interview all qualified nominees in a meeting open to the public, and select three names for each vacancy to be submitted to the Secretary and the Governor; and

3. In the event that fewer than three qualified nominees are submitted to the association, select any additional names that are needed to complete the list required to be submitted to the Secretary and the Governor under this section.

(5) The Governor shall appoint the consumer members with the advice of the Secretary and the advice and consent of the Senate.

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(6) Each member of the Board shall be a resident of this State.

(7) A member of the Board shall be recused from all aspects of the licensing exam if that Board member:

(i) Is a member of the board of trustees at a school of pharmacy;

(ii) Is a teacher at a school of pharmacy; or

(iii) Acquires the member's primary source of income through employment by a school of pharmacy.

Pharmacist members

(b) Each pharmacist member of the Board shall:

(1) Be skilled and competent in practicing pharmacy; and

(2) Have at least 5 years of active pharmacy practice.

Consumer members

(c) Each consumer member of the Board:

(1) Shall be a member of the general public;

(2) May not be or ever have been a pharmacist or in training to become a pharmacist;

(3) May not have a household member who is a pharmacist or in training to become a pharmacist;

(4) May not participate or ever have participated in a commercial or professional field related to practicing pharmacy;

(5) May not have a household member who participates in a commercial or professional field related to practicing pharmacy; and

(6) May not have had within 2 years before appointment a substantial financial interest in a person regulated by the Board.

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Financial interests

(d) While a member of the Board, a consumer member may not have a substantial financial interest in a person regulated by the Board.

Oath

(e) Before taking office, each appointee to the Board shall take the oath required by Article I, § 9 of the Maryland Constitution.

Term

(f)(1) The term of a member is 4 years.

(2) The terms of members are staggered as required by the terms provided for members of the Board on July 1, 1981.

(3) At the end of a term, a member continues to serve until a successor is appointed and qualifies.

(4) A member who is appointed after a term has begun serves only for the rest of the term and until a successor is appointed and qualifies.

(5) To the extent practicable, the Governor shall fill any vacancy on the Board within 60 days of the date of the vacancy.

(6) A member may not serve more than 2 consecutive full terms.

Removal

(g)(1) The Governor may remove a member for incompetence or misconduct.

(2) Upon the recommendation of the Secretary, the Governor may remove a member whom the Secretary finds to have been absent from 2 successive Board meetings without adequate reason.

➡ **§ 12-203. Officers**

In general

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(a) From among its pharmacist members, the Board annually shall elect a president, a secretary, and a treasurer.

Election and duties

(b) The Board shall determine:

(1) The manner of election of officers; and

(2) The duties of each officer.

§ 12-204. Meetings, compensation, and staff

In general

(a) A majority of the members then serving on the Board is a quorum to do business.

Time and location of meetings

(b) The Board shall determine the times and places of its meetings.

Compensation and reimbursement for expenses

(c) Each member of the Board is entitled to:

(1) Compensation in accordance with the budget of the Board; and

(2) Reimbursement for expenses at a rate determined by the Board.

Staff

(d)(1) The Board may employ a staff in accordance with the budget of the Board.

(2) The Board may designate 1 of its staff as an executive director.

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§ 12-205. Additional powers and duties of Board

In general

(a) In addition to the powers set forth elsewhere in this title, the Board may adopt:

(1) Rules and bylaws that are necessary to do its business;

(2) Rules and regulations to carry out the provisions of this title;

(3) Rules and regulations that are necessary to protect the public health, safety, and welfare and that establish standards for practicing pharmacy and operating pharmacies, including rules and regulations that govern:

(i) Methods of advertising and promotion; and

(ii) Standards for filling and refilling prescriptions; and

(4) A code of conduct that specifies which behaviors are either required or prohibited in the practice of pharmacy.

Recordkeeping requirements

(b) In addition to the duties set forth elsewhere in this title, the Board shall:

(1) Keep a record that includes:

(i) The name and place of the business or the home address of each licensed pharmacist and each registered pharmacy technician;

(ii) The facts concerning the issuance of that pharmacist's license; and

(iii) The facts concerning the issuance of that pharmacy technician's registration;

(2) Prepare and deliver to the Governor, the Secretary, and the Maryland Pharmacists Association an annual report that:

(i) Summarizes the condition of pharmacy in this State; and

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(ii) Includes a record of the proceedings of the Board; and

(3) Disclose any information contained in a record to any health occupations regulatory board or agency of this State or another state if the health occupations regulatory board or agency of this State or another state requests the information in writing.

Public information, protection

(c) In addition to the duties set forth elsewhere in this title, the Board may initiate such programs and projects as deemed necessary to inform or protect the public.

Examinations

(d)(1) The Board shall adopt standards for approving examinations under § 12-6B-02(b)(4) of this title.

(2) The Board shall approve any examination that meets the standards adopted under paragraph (1) of this subsection including:

(i) Employer based pharmacy technician examinations;

(ii) Nationally recognized pharmacy technician examinations; and

(iii) Examinations for certification as a pharmacy technician.

§ 12-206. State Board of Pharmacy Fund

In general

(a) There is a State Board of Pharmacy Fund.

Fees

(b)(1) The Board may set reasonable fees for the issuance and renewal of licenses and registrations and its other services.

(2) The fees charged shall be set so as to produce funds to approximate the cost of maintaining the Board.

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(3) Funds to cover the compensation and expenses of the Board members shall be generated by fees set under this section.

Funds paid to Comptroller

(c)(1) The Board shall pay all funds collected under this title to the Comptroller of the State.

(2) The Comptroller shall distribute the fees to the State Board of Pharmacy Fund.

Fund to cover direct and indirect costs of Board

(d)(1) The Fund shall be used to cover the actual documented direct and indirect costs of fulfilling the statutory and regulatory duties of the Board as provided by the provisions of this article.

(2) The Fund is a continuing, nonlapsing fund, not subject to § 7-302 of the State Finance and Procurement Article.

(3) Any unspent portions of the Fund may not be transferred or revert to the General Fund of the State, but shall remain in the Fund to be used for the purposes specified in this article.

(4) No other State money may be used to support the Fund.

Administration

(e)(1) A designee of the Board shall administer the Fund.

(2) Moneys in the Fund may be expended only for any lawful purpose authorized under the provisions of this article.

Pharmacist rehabilitation committee

(f) The Board may allocate moneys from the Fund to a pharmacist rehabilitation committee described in § 12-317 of this title.

Audits

(g) The Legislative Auditor shall audit the accounts and transactions of the Fund as provided in § 2-1220 of

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the State Government Article.

§ 12-207. Immunity from liability

A person shall have the immunity from liability described under § 5-713 of the Courts and Judicial Proceedings Article for giving information to the Board or otherwise participating in its activities.

Subtitle 3. Licensing (Refs & Annos)

§ 12-301. License requirements

In general

(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.

Experiential learning programs

(b) This section does not apply to a pharmacy student participating in an experiential learning program of a college or school of pharmacy under the supervision of a licensed pharmacist.

§ 12-302. License qualifications

In general

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

Good moral character

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

Age

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

Education

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(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 professional experience program that the Board requires.

Examination

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

Foreign schools

(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.

Oral competency

(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

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licensing procedures.

§ 12-303. License application

In general

(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 the application fees set by the Board.

Signed and verified application

(b) An application shall be signed and verified by the applicant as to completion of the required professional experience program.

§ 12-304. License examination

In general

(a) An applicant who otherwise qualifies for a license is entitled to be examined as provided in this section.

Time and place of exam

(b) The Board shall give examinations to applicants at least twice a year, at the times and places that the Board determines.

Notification

(c) The Board shall notify each qualified applicant of the time and place of examination.

Subjects, scores

(d) The Board shall determine the subjects, scope, form, and passing score for examinations given under this subtitle.

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§ 12-305. Examination waivers; foreign licenses

In general

(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.

Waivers

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

(1) Is of good moral character;

(2) Pays the application 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.

Regulations

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

§ 12-306. Issuance of license

The Board shall issue a license to any applicant who meets the requirements of this title.

§ 12-307. Practice of pharmacy, authorized activities

In general

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

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(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)(1) 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.

(2) The Board shall adopt regulations that authorize a pharmacist to dispense or distribute from a remote location for the benefit of a health care facility that uses a remote automated medication system in accordance with § 12-605 of this title.

Delegation of duties

(d) A licensed pharmacist may delegate pharmacy acts to a registered pharmacy technician, pharmacy student, or pharmacy technician trainee provided that the delegated pharmacy acts:

(1) Are directly supervised by a licensed pharmacist;

(2) Are not required to be performed by a licensed pharmacist;

(3) Are within the education, training, experience, and area of practice of the delegating licensed pharmacist; and

(4) Are appropriate to the education, training, and experience of the registered pharmacy technician, pharmacy student, or pharmacy technician trainee.

➡ § 12-308. Expiration, renewal of license

In general

(a)(1) A license expires on the date set by the Board unless it is renewed for an additional term as provided in this section.

(2) A license may not be renewed for a term longer than 2 years.

Renewal notice

(b)(1) Except as provided in paragraph (2) of this subsection, the Board shall send to each licensee, at least 1 month before a license expires, a renewal notice by first-class mail to the last known address of the licensee.

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(2) If requested by a licensee, the Board shall send to the licensee, at least two times within the month before a license expires, a renewal notice by electronic means to the last known electronic address of the licensee.

(3) If a renewal notice sent by electronic means under paragraph (2) of this subsection is returned to the Board as undeliverable, the Board shall send to the licensee a renewal notice by first-class mail to the last known address of the licensee.

(4) A renewal notice sent under this subsection shall state:

(i) The date on which the current license 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 license expires; and

(iii) The amount of the renewal fee.

Fees, requirements

(c) Before the license expires, the licensee periodically may renew it for an additional term set by the Board in its regulations, if the licensee:

(1) Otherwise is entitled to be licensed;

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

(3) Submits to the Board:

(i) A renewal application on the form that the Board requires; and

(ii) Satisfactory evidence of compliance with the continuing education requirements set under this subtitle for license renewal.

Renewal certificate

(d) The Board shall renew the license of and issue a renewal certificate to each licensee who meets the requirements of this section.

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§ 12-309. Continuing pharmaceutical education; renewals

In general

(a) Except as permitted in subsections (b) and (c) of this section, the Board may not renew the license and issue a certificate of renewal to any pharmacist until the pharmacist presents evidence of having completed 30 hours of approved continuing pharmaceutical education within the preceding 2 years.

Renewal certificate

(b) The Board may renew the license and issue a certificate of renewal to a pharmacist who presents acceptable evidence that the pharmacist was unable to comply with subsection (a) of this section.

First renewal period

(c) The Board may renew the license and issue a certificate of renewal for the first renewal period following the issuance of the original license without requiring a pharmacist to complete any continuing pharmaceutical education, if the pharmacist obtains a license within 1 year of the completion of the pharmacist's pharmaceutical education.

Program approval

(d) The Board shall evaluate and approve programs of continuing pharmaceutical education submitted to the Board by the person who intends to offer the program.

One unit equals one hour of participation

(e) Each program of continuing pharmaceutical education shall consist of at least 1 continuing education unit, which is 1 hour of participation in an organized continuing educational experience, including postgraduate studies, institutes, seminars, lectures, conferences, workshops, correspondence courses, cassette programs, programmed learning courses, audiovisual programs, and any other form of presentation that is approved by the Board.

Subject of program

(f) Any aspect of the practice of pharmacy may be the subject of a program of continuing pharmaceutical education, including pharmaceutics (compounding), pharmacology, pharmaceutical chemistry, biochemistry, physiology, microbiology, pharmacy administration, and professional practice management.

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Criteria for program approval

(g) Each program of continuing pharmaceutical education submitted to the Board of Pharmacy for approval shall:

(1) Have a definite stated objective;

(2) Be presented in an organized manner by a qualified instructor or resource person; and

(3) Include a method of program evaluation that is suitable to the type of program being presented.

Registration, documentation

(h) Each person who offers a program of continuing pharmaceutical education shall:

(1) Provide a means for registration by the participants;

(2) Maintain a record of participation for at least 3 years; and

(3) Furnish each participant with adequate documentation of satisfactory completion of the program, including:

(i) The name of the participant;

(ii) The name of the sponsor;

(iii) The type of program completed;

(iv) The number of continuing education hours or units completed; and

(v) The date of completion.

Evaluations

(i) For purposes of evaluation, members of the Board may attend and participate in any continuing pharmaceutical education program approved for credit.

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Request for approval

(j) A pharmacist who completes a program of continuing pharmaceutical education that is not previously approved by the Board may request the Board, in writing, to approve the program for credit.

Regulations

(k) The Board shall adopt regulations that are necessary to carry out the purposes of this section.

Automatic qualification

(l) Any continuing education program that is currently approved by the American Council on Pharmaceutical Education automatically qualifies for continuing education credit.

§ 12-310. License reinstatement after expiration

Expired less than two years

(a) The Board shall reinstate the license of a pharmacist whose license has been expired for less than 2 years, if the pharmacist:

(1) Meets the renewal and reinstatement requirements set by rule and regulation of the Board; and

(2) Pays to the Board the reinstatement fee set by the Board.

Expired two years or more

(b) The Board shall reinstate the license of a pharmacist whose license has been expired for 2 years or more if the pharmacist:

(1) Meets the reinstatement requirements established by the Board in its rules or regulations; and

(2) Satisfies the requirements of subsection (a) of this section.

§ 12-311. Display of license

Each licensee shall display the license conspicuously in the office or place of business of the licensee.

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§ 12-312. Surrender of license

In general

(a) Unless the Board agrees to accept the surrender of a license, a licensed pharmacist may not surrender the license nor may the license lapse by operation of law while the licensee is under investigation or while charges are pending against the pharmacist.

Conditions

(b) The Board may set conditions on its agreement with the pharmacist under investigation or against whom charges are pending to accept surrender of the pharmacist's license.

§ 12-313. License denial, suspension, or revocation

Convicted defined

(a) In this section, “convicted” includes a determination of guilt, a guilty plea, or a plea of nolo contendere followed by a sentence.

In general

(b) Subject to the hearing provisions of § 12-315 of this subtitle, the Board, on the affirmative vote of a majority of its members then serving, may deny a license to any applicant for a pharmacist's license, reprimand any licensee, place any licensee on probation, or suspend or revoke a license of a pharmacist if the applicant or licensee:

(1) Fraudulently or deceptively obtains or attempts to obtain a license for the applicant or licensee or for another;

(2) Fraudulently or deceptively uses a license;

(3) Aids an unauthorized individual to practice pharmacy or to represent that the individual is a pharmacist or a registered pharmacy technician;

(4) Delegates pharmacy acts to an unauthorized individual;

(5) Provides professional services while:

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(i) Under the influence of alcohol; or

(ii) Using any narcotic or controlled dangerous substance, as defined in § 5-101 of the Criminal Law Article, or other drug that is in excess of therapeutic amounts or without valid medical indication;

(6) Submits a false statement to collect a fee;

(7) Willfully makes or files a false report or record as part of practicing pharmacy;

(8) Willfully fails to file or record any report that is required by law;

(9) Willfully impedes or obstructs the filing or recording of any report that is required by law;

(10) Willfully induces another to fail to file or record any report that is required by law;

(11) Provides or causes to be provided to any authorized prescriber prescription forms that bear the name, address, or other means of identification of a pharmacist or pharmacy;

(12) Provides remuneration to an authorized prescriber for referring an individual to a pharmacist or pharmacy for a product or service to be provided by that pharmacist or pharmacy;

(13) Agrees with an authorized prescriber or registered pharmacy technician to prepare or dispense a secret formula prescription;

(14) Except as to an association that has remained in continuous existence since July 1, 1963, associates as a partner, coowner, or employee of a pharmacy that is owned wholly or substantially by an authorized prescriber or group of authorized prescribers;

(15) Dispenses any drug, device, or diagnostic for which a prescription is required without a written, oral, or electronically transmitted prescription from an authorized prescriber;

(16) Except as provided in § 12-506 of this title, unless an authorized prescriber authorizes the refill, refills a prescription for any drug, device, or diagnostic for which a prescription is required;

(17) Violates any provision of § 12-505 of this title, which concerns the labeling requirements for prescriptions for drugs, devices, or diagnostics;

(18) Violates any provision of § 12-603 of this title, which concerns the home dialysis distribution program;

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(19) Advertises or otherwise publicly claims to dispense prescriptions or practice pharmacy in a superior manner;

(20) Advertises in a manner that tends to deceive or defraud the public;

(21) Is professionally, physically, or mentally incompetent;

(22) Is convicted of or pleads guilty or nolo contendere to a felony or to a crime involving moral turpitude, whether or not any appeal or other proceeding is pending to have the conviction or plea set aside;

(23) Is convicted of a violation of this title;

(24) Is disciplined by a licensing or disciplinary authority of any state or country or convicted or disciplined by a court of any state or country for an act that would be grounds for disciplinary action under the Board's disciplinary statutes;

(25) Violates any rule or regulation adopted by the Board;

(26) Refuses, withholds from, denies, or discriminates against an individual with regard to the provision of professional services for which the licensee is licensed and qualified to render because the individual is HIV positive;

(27) Violates any provision of § 12-507 of this title;

(28) Provides or causes to be provided confidential patient information to any person without first having obtained the patient's consent, as required by § 12-403(b)(13) of this title and by Title 4, Subtitle 3 of the Health--General Article;

(29) Fails to cooperate with a lawful investigation conducted by the Board or the Division of Drug Control;

(30) Delegates pharmacy acts to a registered pharmacy technician, pharmacy student, or a pharmacy technician trainee outside the scope of education, training, experience, and area of practice of a licensed pharmacist;

(31) Delegates pharmacy acts that are inappropriate for a registered pharmacy technician, pharmacy student, or pharmacy technician trainee who does not have the education, training, or experience to perform the delegated pharmacy acts; or

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(32) Fails to dispense or dispose of prescription drugs or medical supplies in accordance with Title 15, Subtitle 6 of the Health--General Article.

Criminal convictions

(c)(1) The Board shall revoke the license of a licensee who is convicted under § 5-702 of the Criminal Law Article.

(2) The Board may reinstate the license of a person whose license has been revoked under this section in accordance with the regulations adopted by the Board.

➡ § 12-314. Fines and penalties

In general

(a) If after a hearing under § 12-315 of this subtitle the Board finds that there are grounds under § 12-313 of this subtitle to reprimand any licensee, place any licensee on probation, or suspend or revoke a license, the Board may impose a penalty not exceeding $10,000:

(1) Instead of reprimanding the licensee, placing the licensee on probation, or suspending or revoking the license; or

(2) In addition to reprimanding the licensee, placing the licensee on probation, or suspending or revoking the license.

Rules and regulations

(b) The Board shall adopt rules and regulations to set standards for the imposition of penalties under this section.

Penalties paid to General Fund

(c) The Board shall pay any penalty collected under this section into the General Fund of this State.

➡ § 12-315. Notice and hearing

In general

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(a) Except as otherwise provided in the Administrative Procedure Act, [FN1] before the Board takes any action under § 12-313 of this subtitle or § 12-6B-09 of this title, it shall give the individual against whom the action is contemplated an opportunity for a hearing before the Board.

Application of Administrative Procedure Act

(b) The Board shall give notice and hold the hearing in accordance with the Administrative Procedure Act.

Notice

(c) The hearing notice to be given to the individual shall be sent by certified mail, return receipt requested, bearing a postmark from the United States Postal Service, to the last known address of the individual at least 20 days before the hearing.

Counsel

(d) The individual may be represented at the hearing by counsel.

Subpoenas, oaths

(e) Over the signature of an officer or the executive director of the Board, the Board may issue subpoenas and administer oaths in connection with any investigation under this title and any hearings or proceedings before it.

Contempt of court

(f) If, without lawful excuse, a person disobeys a subpoena from the Board or an order by the Board to take an oath or to testify or answer a question, then, on petition of the Board, a court of competent jurisdiction may punish the person as for contempt of court.

Absence of individual

(g) If after due notice the individual against whom the action is contemplated fails or refuses to appear, nevertheless the Board may hear and determine the matter.

Procedural defects

(h) The hearing of charges against a person may not be stayed or challenged by procedural defects alleged to

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have occurred prior to filing of the charges.

Records not discoverable or admissible

(i)(1) This subsection does not apply to a civil action brought by a party to a proceeding before the Board who claims to be aggrieved by the decision of the Board.

(2) Except by the express stipulation and consent of all parties to a proceeding before the Board or any of its investigatory bodies, in a civil or criminal action:

(i) The proceedings, records, or files of the Board or any of its investigatory bodies are not discoverable and are not admissible in evidence; and

(ii) Any order passed by the Board is not admissible in evidence.

(3) If any medical or hospital record or any other exhibit is subpoenaed and otherwise is admissible in evidence, the use of that record or exhibit in a proceeding before the Board or any of its investigatory bodies does not prevent its production in any other proceeding.

[FN1] State Government § 10-101 et seq.

§ 12-316. Appeals

In general

(a) Except as provided in this section for an action under § 12-313 of this subtitle or § 12-6B-09 of this title, any person aggrieved by a final decision of the Board in a contested case, as defined in the Administrative Procedure Act, [FN1] may:

(1) Appeal that decision to the Board of Review; and

(2) Then take any further appeal allowed by the Administrative Procedure Act.

Direct judicial appeals

(b)(1) Any person aggrieved by a final decision of the Board under § 12-313 of this subtitle or § 12-6B-09 of this title may not appeal to the Secretary or Board of Review but may take a direct judicial appeal.

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(2) The appeal shall be made as provided for judicial review of final decisions in the Administrative Procedure Act.

[FN1] State Government § 10-101 et seq.

§ 12-317. Pharmacist rehabilitation committee

Pharmacist rehabilitation committee defined

(a) In this section, "pharmacist rehabilitation committee" means a group, the majority of which is comprised of pharmacists, that is recognized by the Board.

In general

(b) For purposes of this section, a pharmacist rehabilitation committee evaluates and provides assistance to any pharmacist or registered pharmacy technician in need of treatment and rehabilitation for alcoholism, drug abuse, chemical dependency, or other physical, emotional, or mental condition.

Records not discoverable or admissible

(c)(1) Except as otherwise provided in this section, the proceedings, records, and files of a pharmacist rehabilitation committee are not discoverable and are not admissible in evidence in any civil action arising out of matters that are being or have been reviewed and evaluated by the pharmacist rehabilitation committee.

(2) Paragraph (1) of this subsection does not apply to any record or document that is considered by the pharmacist rehabilitation committee and that otherwise would be subject to discovery and introduction into evidence in a civil trial.

(3) For purposes of this subsection, civil action does not include a proceeding before the Board or judicial review of a proceeding before the Board.

Civil liability

(d) A person who acts in good faith and within the scope of jurisdiction of a pharmacist rehabilitation committee is not civilly liable for any action as a member of the pharmacist rehabilitation committee or for giving information to, participating in, or contributing to the function of the pharmacist rehabilitation committee.

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➡ § 12-318. Pharmacy review committee

In general

(a) In this section, “pharmacy review committee” means an advisory committee appointed by the Board from a pool of Board approved pharmacists to aid the Board in licensing and disciplinary matters.

Role of committee

(b) A pharmacy review committee shall:

(1) Evaluate and seek to improve the quality of pharmaceutical care provided by providers of pharmaceutical care;

(2) Evaluate the need for and the level of performance of pharmaceutical care provided by providers of pharmaceutical care;

(3) Evaluate the qualifications, competence, and performance of providers of pharmaceutical care; or

(4) Evaluate and act on matters that relate to the discipline of any provider of pharmaceutical care.

Records not discoverable or admissible

(c)(1) This subsection does not apply to:

(i) A civil action brought by a party to the proceedings of the pharmacy review committee who claims to be aggrieved by the decision of the pharmacy review committee; or

(ii) Any record or document that is considered by the pharmacy review committee and that otherwise would be subject to discovery and introduction into evidence in a civil trial.

(2) The proceedings, records, and files of a pharmacy review committee are not discoverable and are not admissible in evidence in any civil action arising out of matters that are being reviewed and evaluated by the pharmacy review committee.

Civil liability

(d) A person who acts in good faith and within the scope of jurisdiction of a pharmacy review committee is

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not civilly liable for any action as a member of the pharmacy review committee or for giving information to, participating in, or contributing to the function of the pharmacy review committee.

§ 12-319. Injunctions

In general

(a) An action may be maintained in the name of this State or the Board to enjoin:

(1) The unauthorized practice of pharmacy; or

(2) Conduct that is a ground for disciplinary action under § 12-313 of this subtitle or § 12-6B-09 of this title.

Movants

(b) An action may be brought by:

(1) The Board, in its own name;

(2) The Attorney General, in the name of the State; or

(3) The State's Attorney, in the name of the State.

Venue

(c) An action under this section shall be brought in the county where the defendant resides or engages in the actions sought to be enjoined.

Damages

(d) Proof of actual damages or that a person will sustain damage if an injunction is not granted is not required for an action under this section.

Criminal prosecutions

(e) An action under this section is in addition to and not instead of criminal prosecution for unauthorized practice of pharmacy under § 12-701 of this title or disciplinary action under § 12-313 of this subtitle or §

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12-6B-09 of this title.

§ 12-320. Examination by health care provider; possible harm to public

In general

(a) In investigating an allegation brought against a licensee or registered pharmacy technician under this title, if the Board has reason to believe that a licensee or registered pharmacy technician may cause harm to a person affected by the licensee's practice or the acts of a registered pharmacy technician, the Board on its own initiative may direct the licensee or registered pharmacy technician to submit to an appropriate examination by a health care provider designated by the Board.

Consent to examination

(b) In return for the privilege given to a licensee to practice pharmacy or a registered pharmacy technician to perform delegated pharmacy acts in the State, the licensee or registered pharmacy technician is deemed to have:

(1) Consented to submit to an examination under this section, if requested by the Board in writing; and

(2) Waived any claim of privilege as to the testimony or examination reports of a health care provider.

Failure or refusal to submit to examination

(c) The failure or refusal of a licensee or registered pharmacy technician to submit to an examination required under this section is prima facie evidence of the licensee's inability to practice pharmacy competently or the registered pharmacy technician's inability to perform delegated pharmacy acts, unless the Board finds that the failure or refusal was beyond the control of the licensee or registered pharmacy technician.

Cost

(d) The Board shall pay the cost of any examination made under this section.

Subtitle 4. Pharmacy Permits (Refs & Annos)

§ 12-401. Pharmacy permits; requirements

Permit required

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(a) A person shall hold a pharmacy permit issued by the Board before the person may establish or operate a pharmacy in this State.

Multiple permits

(b) A separate pharmacy permit is required for each pharmacy that a person establishes or operates.

§ 12-402. Pharmacy permits; qualifications

To qualify for a pharmacy permit, an applicant shall satisfy the Board that the pharmacy for which the application is made will be operated in accordance with the standards specified in § 12-403 of this subtitle.

§ 12-403. Nonresident pharmacies; rules and regulations

In general

(a) This section does not require a nonresident pharmacy to violate the laws or regulations of the state in which it is located.

Rules and regulations

(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 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;

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

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(6) 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;

(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;

(8) May not make any agreement that denies a patient a free choice of pharmacist or pharmacy services;

(9) May not participate in any activity that is a ground for Board action against a licensed pharmacist under § 12-313 of this title or a registered pharmacy technician under § 12-6B-09 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 or devices properly and safely subject to the rules and regulations adopted by the Board;

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(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 or devices 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) Except as otherwise provided under federal law, shall establish and maintain mechanisms to ensure that all prescription drugs or devices 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;

(16) Shall provide such personnel, automation, and technology as are necessary to comply with the labeling requirements specified in § 12-505 of this title;

(17) With regard to a prescription drug that is delivered in this State by the United States mail, a common carrier, or a delivery service and is not personally hand delivered directly to a patient or to the agent of the patient at the residence of the patient or at another location designated by the patient, shall:

(i) Provide a general written notice in each shipment of a prescription drug that alerts a consumer that, under certain circumstances, a medication's effectiveness may be affected by exposure to extremes of heat, cold, or humidity; and

(ii) Provide a specific written notice in each shipment of a prescription drug that provides a consumer with a toll-free or local consumer access telephone number accessible during regular hours of operation, which is designed to respond to consumer questions pertaining to medications;

(18)(i) May maintain a record log of any prescription that is requested to be filled or refilled by a patient in accordance with the provisions of Title 4, Subtitle 3 of the Health--General Article;

(ii) If the prescription record of a patient includes the patient's Social Security number, shall keep the Social

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Security number confidential;

(iii) May not list in the record log the type of illness, disability, or condition that is the basis of any dispensing or distribution of a drug by a pharmacist; and

(iv) May not list a patient's Social Security number, illness, disability, or condition, or the name and type of drug received in the record log if the log is available to other pharmacy customers;

(19) May not allow an unauthorized individual to represent that the individual is a pharmacist or registered pharmacy technician;

(20) Shall provide information regarding the process for resolving incorrectly filled prescriptions in accordance with existing regulations by:

(i) Posting a sign that is conspicuously positioned and readable by consumers at the point where prescription drugs are dispensed to consumers; or

(ii) Including written information regarding the process with each prescription dispensed; and

(21) Shall dispense or dispose of prescription drugs or medical supplies in accordance with Title 15, Subtitle 6 of the Health--General Article.

Waivers

(c)(1) The Board may waive any of the requirements of this section for the University of Maryland School of Pharmacy, for nuclear pharmacy and dental pharmacy experimental and teaching programs.

(2) The Board may waive the requirements of subsection (b)(5) and (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.

(3) The Board may waive the requirements of subsection (b)(3) through (6) and (15) of this section for pharmacies that only dispense devices in accordance with rules and regulations adopted by the Board.

(4) The Board shall waive the requirements of subsection (b)(20) of this section for a pharmacy owned and operated by a hospital, nursing facility, or clinic to which the public does not have access to purchase pharmaceuticals on a retail basis.

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Permits

(d) A nonresident pharmacy shall:

(1) Hold a pharmacy permit issued by the Board; and

(2) Have a pharmacist on staff who is:

(i) Licensed by the Board; and

(ii) Designated as the pharmacist responsible for providing pharmaceutical services to patients in the State.

Pharmacy permits

(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.

Compliance with home state laws

(f) Notwithstanding subsection (a) of this section, a nonresident pharmacy shall:

(1) Comply with the requirements of subsection (b)(2), (7) through (12), and (19) of this section when:

(i) Dispensing prescription drugs or prescription devices to a patient in this State; or

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(ii) Otherwise engaging in the practice of pharmacy in this State;

(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 or devices 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 or devices 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 or an individual who:

(i) Has access to the patient's prescription records; and

(ii) Is required to refer patients in the State to the responsible pharmacist licensed in the State, as appropriate;

(7) Disclose its toll-free telephone number on a label affixed to each container of drugs or devices;

(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; and

(9) Comply with the requirements of subsection (b)(17) and (20) of this section.

Suspensions for noncompliance

(g) Subject to the hearing provisions of § 12-411 of this subtitle, 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.

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Waiver of requirements for nonresident pharmacies

(h) The Board may waive the following requirements for nonresident pharmacies that only dispense devices in accordance with rules and regulations adopted by the Board:

(1) Subsections (d)(2) and (f)(6)(ii) of this section; and

(2) If not applicable, subsections (e)(1)(iii) and (f)(4) of this section.

§ 12-404. Pharmacy permits; applications

In general

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

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

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

Multiple permits

(b) For each pharmacy permit for which a person applies, the person shall submit a separate application and pay a separate application fee.

§ 12-405. Issuance of permit

In general

(a) The Board shall issue a pharmacy permit to any applicant who meets the requirements of this title.

Denials

(b) If the Board denies a pharmacy permit to an applicant, it shall give the applicant written notice of its decision and the reasons for the denial.

§ 12-406. Pharmacy permits; authorized activities

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In general

(a) A pharmacy permit authorizes the pharmacy permit holder to establish and operate the pharmacy while the pharmacy permit is effective.

Wholesale distribution business

(b)(1) Subject to paragraphs (2) and (3) of this subsection, a pharmacy permit holder may conduct wholesale distribution, if:

(i) The wholesale distribution business does not exceed 5% of the pharmacy permit holder's annual sales; and

(ii) The pharmacy permit holder:

1. Maintains records of wholesale distribution separately from its other records; and

2. Makes the records of wholesale distribution available for inspection by the Board.

(2) A pharmacy permit holder that obtains a waiver from the Board under § 12-403(c) of this subtitle may conduct wholesale distribution only with another pharmacy permit holder.

(3) A retail pharmacy that holds a pharmacy permit may conduct wholesale distribution only with:

(i) Another pharmacy permit holder; and

(ii) A wholesale distributor if the retail pharmacy:

1. Reports to the Board that the retail pharmacy is conducting wholesale distribution with a wholesale distributor; and

2. A. Maintains records of wholesale distribution with wholesale distributors separately from its records of wholesale distribution with pharmacy permit holders; and

B. Makes the records of wholesale distribution available for inspection by the Board.

➡ **§ 12-407. Expiration, renewal of pharmacy permit**

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Expiration date

(a) A pharmacy permit expires on the May 31 after its effective date, unless the pharmacy permit is renewed for a 2-year term as provided in this section.

Renewal notice

(b)(1) Except as provided in paragraph (2) of this subsection, on or before March 1 of the year the permit expires, the Board shall send to each pharmacy permit holder a renewal notice for each pharmacy permit by first-class mail to the last known address of the pharmacy permit holder.

(2) If requested by a pharmacy permit holder, the Board shall send to the pharmacy permit holder, at least two times within the month before a pharmacy permit expires, a renewal notice for each pharmacy permit by electronic means to the last known electronic address of the pharmacy permit holder.

(3) If a renewal notice sent by electronic means under paragraph (2) of this subsection is returned to the Board as undeliverable, the Board shall send to the pharmacy permit holder a renewal notice for each pharmacy permit by first-class mail to the last known address of the pharmacy permit holder.

(4) A renewal notice sent under this subsection shall state:

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

(iii) The amount of the renewal fee.

Permit renewals

(c) Before the pharmacy permit expires, the pharmacy permit holder periodically may renew it for an additional 2-year term, if the pharmacy permit holder:

(1) Otherwise is entitled to the pharmacy permit;

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

(3) Submits a renewal application to the Board on the form that the Board provides.

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Duty of Board to renew

(d) The Board shall renew the pharmacy permit of each pharmacy permit holder who meets the requirements of this section.

Applications

(e) If application for renewal is not made on or before May 1, the pharmacy permit shall expire on the last day of its term and the Board may not reinstate the pharmacy permit unless the applicant:

(1) Provides reason, sufficient to the Board, for the failure to file within the time required; and

(2) Pays, in addition to the renewal fee, a late fee set by the Board.

§ 12-408. Transferability, display of permit

Permits not transferable

(a) A pharmacy permit is not transferable.

Display

(b) Each pharmacy permit shall be displayed conspicuously in the pharmacy for which it is issued.

§ 12-409. Suspension or revocation of permit

In general

(a) Subject to the hearing provisions of § 12-411 of this subtitle, the Board may suspend or revoke any pharmacy permit, if the pharmacy:

(1) Is conducted so as to endanger the public health or safety;

(2) Violates any of the standards specified in § 12-403 of this subtitle; or

(3) Otherwise is not conducted in accordance with the law.

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Nonresident pharmacies

(b)(1) A nonresident pharmacy is subject to the disciplinary actions stated in this subtitle.

(2) The Board may fine a nonresident pharmacy in accordance with § 12-410 of this subtitle or deny, revoke, or suspend the permit of a nonresident pharmacy for any violation of § 12-403(d) through (g) of this subtitle.

§ 12-410. Fines and penalties

In general

(a) If after a hearing under § 12-411 of this subtitle the Board finds that there are grounds under § 12-409 of this subtitle to suspend or revoke a permit, the Board may impose a penalty not exceeding $10,000:

(1) Instead of suspending the permit; or

(2) In addition to suspending or revoking the permit.

Rules and regulations

(b) The Board shall adopt rules and regulations to set standards for the imposition of penalties under this section.

Penalties paid to General Fund

(c) The Board shall pay any penalty collected under this section into the General Fund of this State.

§ 12-411. Notice and hearing

In general

(a) Except as otherwise provided in the Administrative Procedure Act, [FN1] before the Board takes any action under § 12-409 of this subtitle or any action to suspend or revoke a pharmacy permit under any other section of this title, it shall give the person against whom the action is contemplated an opportunity for a hearing before the Board.

Application of Administrative Procedure Act

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(b) The Board shall give notice and hold the hearing in accordance with the Administrative Procedure Act.

Absence of individual

(c) If after due notice the person against whom the action is contemplated fails or refuses to appear, nevertheless the Board may hear and determine the matter.

[FN1] State Government § 10-101 et seq.

§ 12-412. Appeals

In general

(a) Any person whose application for a pharmacy permit has been denied or whose pharmacy permit has been suspended or revoked under this title may:

(1) Appeal that action to the Board of Review; and

(2) Then take any further appeal allowed by the Administrative Procedure Act. [FN1]

Stays pending appeal

(b) If an appeal is taken under this section, the Board may stay its order of suspension or revocation pending the decision of the court.

[FN1] State Government § 10-101 et seq.

§ 12-413. Inspection of pharmacies

In general

(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 or devices, 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

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(3) The facility.

Warrants

(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.

Hindrances prohibited

(c) A person may not hinder an inspection or an investigation conducted under this section.

Subtitle 4A. Sterile Compounding Permits (Refs & Annos)

§ 12-4A-01. Definitions

In general

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

Compounding

(b) “Compounding” means the preparation, mixing, assembling, packaging, or labeling of a drug only:

(1) As the result of a practitioner's prescription drug order or initiative based on the practitioner/patient relationship in the course of professional practice;

(2) For the purpose of, or incidental to, research, teaching, or chemical analysis and not for the sale or dispensing of the drug or device; or

(3) In anticipation of a prescription drug order based on routine, regularly observed prescribing patterns.

Designee

(c) “Designee” means a public agency or private entity approved by the Board to conduct inspections of sterile compounding facilities or entities that prepare sterile drug products.

Sterile compounding

(d) “Sterile compounding” means compounding of biologics, diagnostics, drugs, nutrients, and

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radiopharmaceuticals that, under USP 797, must be prepared using aseptic techniques.

Sterile compounding facility

(e) “Sterile compounding facility” means a pharmacy, a health care practitioner's office, or any other setting in which sterile compounding is performed.

Sterile drug product

(f) “Sterile drug product” means a drug product that:

(1) Must be prepared using aseptic techniques; and

(2) Is not required to be prepared in response to a patient specific prescription.

USP 797

(g) “USP 797” means the standards set forth in the United States Pharmacopeia, General Chapter 797, “Pharmaceutical Compounding--Sterile Preparations”.

➡ § 12-4A-02. Permit required for sterile compounding facility to perform sterile compounding

In general

(a) A sterile compounding facility shall hold a sterile compounding permit issued by the Board before the sterile compounding facility may perform sterile compounding in the State.

Other permits or licenses held by facility

(b) A sterile compounding permit is required in addition to and does not replace any other permit or license a sterile compounding facility holds.

Performance of sterile compounding outside State

(c) A sterile compounding facility that performs sterile compounding outside the State shall hold a sterile compounding permit issued by the Board before the sterile compounded preparations of the sterile compounding facility are dispensed in the State.

Separate permits required for multiple sites

(d) A separate sterile compounding permit is required for each site at which sterile compounding is performed.

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Permit not transferable

(e) A sterile compounding permit is not transferable.

Preparation and distribution of sterile drug products

(f) A person that prepares and distributes sterile drug products into or within the State:

(1) Is not required to hold a sterile compounding permit under subsection (a) or (c) of this section; and

(2) Shall hold:

(i) A manufacturer's permit or other permit designated by the U.S. Food and Drug Administration to ensure the safety of sterile drug products; and

(ii) A wholesale distributor's permit issued by the Board under Subtitle 6C of this title.

Waiver of permit requirements

(g)(1) The Board may waive any requirements of this subtitle, including the requirements of subsection (f) of this section, in accordance with regulations adopted by the Board.

(2) A waiver may be issued to a sterile compounding facility or a person described in subsection (f) of this section only:

(i) For specified sterile compounded preparations or sterile drug products for which there is a clinical need, as determined by the Board with input from health care providers in the State;

(ii) In exigent circumstances that, as determined by the Board, otherwise prevent health care providers from obtaining, in the size and strength needed, the specified sterile compounded preparations or sterile drug products under item (i) of this paragraph; and

(iii) If the sterile compounding facility or person described in subsection (f) of this section meets requirements established by the Board, including:

1. Provision of:

A. Reports of inspections conducted by a designee or the U.S. Food and Drug Administration;

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B. A statement of compliance with USP 797; and

C. A review of adverse regulatory action; and

2. Any other requirement as determined by the Board.

(3)(i) The Board shall post on its Web site any waiver issued under this subsection.

(ii) For each waiver posted on its Web site, the Board shall include:

1. The name of the sterile compounding facility or other person receiving the waiver;

2. The sterile compounded preparation or sterile drug product for which the waiver is issued;

3. The basis for issuing the waiver;

4. The duration of the waiver; and

5. Any other information relating to the waiver or limitations on the waiver determined appropriate by the Board.

(4) Any waiver issued by the Board:

(i) May not exceed 2 years in duration;

(ii) May be renewed by the Board; and

(iii) May be rescinded by the Board if the Board finds that any requirements of this subtitle are not met.

(5)(i) The Board shall include in the regulations adopted under paragraph (1) of this subsection requirements for documenting, in a record acceptable to the Board, the administration to a patient of a sterile compounded preparation or sterile drug product obtained under a waiver issued under this subsection.

(ii) The requirements shall include:

1. Documentation of the lot number or other mechanism for identifying the sterile compounded preparation or sterile drug product for the purpose of tracing the sterile compounded preparation or sterile

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drug product back to the sterile compounding facility or other person that prepared it; or

2. If documentation of the lot number or other identification mechanism is not feasible, documentation of the source of the sterile compounded preparation or sterile drug product for the purpose of tracking the sterile compounded preparation or sterile drug product back to the sterile compounding facility or other person that prepared it.

➡ § 12-4A-03. Permit qualifications

In general

(a) To qualify for a sterile compounding permit, an applicant shall satisfy the Board that the applicant will perform sterile compounding in accordance with the requirements of this subtitle.

Regulations based on risk

(b) The Board shall establish, by regulation, requirements for applicants based on risk.

➡ § 12-4A-04. Permit applications

Application fee and form

(a) To apply for a sterile compounding permit, an applicant shall:

(1) Pay to the Board an application fee set by the Board; and

(2) Submit an application to the Board on the form that the Board requires.

Inspection of facility applying for permit

(b) The Board may not issue a sterile compounding permit to an applicant unless the Board or its designee:

(1) Conducts an inspection of the sterile compounding facility applying for the permit; and

(2) Finds that the sterile compounding facility meets the Board's requirements.

Duty of Board to issue permit to qualified applicants

(c) The Board shall issue a sterile compounding permit to any applicant that meets the requirements of this section.

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➡ § 12-4A-05. Expiration and renewal of permit

Expiration date

(a) A sterile compounding permit expires on May 31 of the next even- numbered year after its effective date, unless the sterile compounding permit is renewed for a 2-year term as provided in this section.

Renewal term

(b) Before a sterile compounding permit expires, the sterile compounding permit may be renewed for an additional 2-year term if the applicant:

(1) Otherwise is entitled to the permit;

(2) Pays to the Board the renewal fee set by the Board in regulation; and

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

Duty of Board to renew permit

(c) The Board shall renew a permit if the applicant meets the requirements of this section.

➡ § 12-4A-06. Regulations relating to compliance, reporting requirements, and quality and safety standards

In general

(a) The Board shall adopt regulations to carry out this subtitle.

Compliance and reporting requirements

(b) The regulations shall:

(1) Require compliance with USP 797;

(2) Require each sterile compounded preparation to be dispensed or administered in accordance with a prescription from an authorized prescriber;

(3) Include:

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(i) In accordance with §§ 12-4A-07 and 12-4A-08 of this subtitle, requirements for:

1. Inspections;

2. Reporting of adverse events and evidence of environmental contamination; and

3. Reporting of deficiencies, disciplinary action, or changes in accreditation status;

(ii) Quality and safety standards; and

(iii) Initial permit and permit renewal fees; and

(4) Require a sterile compounding permit holder to ensure that personnel engaging in sterile compounding are trained and demonstrate competence in the safe handling and compounding of sterile preparations.

➡ § 12-4A-07. Inspection of sterile compounding permit holder

Scope of inspection

(a) Subject to subsection (b) of this section, the Board:

(1) Shall inspect a sterile compounding permit holder with a frequency based on risk as set forth in regulations adopted by the Board;

(2) Shall include, in all inspections under item (1) of this subsection, a review in accordance with regulations adopted by the Board, of:

(i) Quality assurance testing reports; and

(ii) Microbial testing of a sampling of the compounded preparations of the sterile compounding permit holder; and

(3) May inspect a sterile compounding permit holder at any time:

(i) To verify compliance with permit requirements; or

(ii) To investigate a complaint.

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Performance of sterile compounding outside State

(b)(1) If an applicant or permit holder is performing sterile compounding outside the State, the Board may rely on an inspection conducted by a designee to conduct inspections under this subtitle.

(2) The Board may approve a designee to conduct inspections of applicants or permit holders outside the State only if the inspections are conducted in accordance with this subtitle and the regulations adopted by the Board.

(3) An applicant or permit holder outside the State is responsible for obtaining an inspection from a designee to meet the requirements of this subtitle.

➡§ 12-4A-08. Reporting requirements relating to adverse events and evidence of environmental contamination

Determination of adverse events and evidence of environmental contamination

(a) The Board shall:

(1) Determine the adverse events and evidence of environmental contamination that must be reported by a sterile compounding permit holder; and

(2) Require a sterile compounding permit holder to report to the Board the adverse events or evidence of environmental contamination within 5 calendar days after becoming aware of the adverse events or evidence.

Determination of reporting requirements

(b)(1) The Board shall:

(i) Determine the deficiencies, disciplinary actions, and changes in accreditation status described in paragraph (2) of this subsection that must be reported by a sterile compounding permit holder; and

(ii) Require a sterile compounding permit holder to report to the Board the deficiencies, disciplinary actions, and changes in accreditation status within 5 calendar days after becoming aware of the deficiencies, disciplinary actions, or changes in accreditation status.

(2) The Board may require a sterile compounding permit holder to report under paragraph (1) of this subsection:

(i) A deficiency noted during an inspection, during an accreditation site visit, or in official correspondence

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from a State or federal agency, a professional association, or an accreditation organization;

(ii) Disciplinary action by a State or federal agency, including a revocation, suspension, probation, censure, reprimand, or restriction placed on a license, a permit, or any other authorization of the sterile compounding permit holder or a health care practitioner who is an owner, operator, or employee of a sterile compounding permit holder; or

(iii) A change in accreditation status issued by a professional association or an accreditation organization relating to the sterile compounding permit holder.

➡ § 12-4A-09. Denial, suspension, or revocation of permit

In general

(a)(1) Subject to the hearing provisions of subsection (c) of this section, for a violation of this subtitle or any regulation adopted under this subtitle, the Board may:

(i) Deny a permit to an applicant;

(ii) Reprimand a permit holder;

(iii) Place a permit holder on probation; or

(iv) Suspend or revoke a permit.

(2) Instead of or in addition to a reprimand, probation, suspension, or revocation, the Board may impose a fine not exceeding $10,000 for any violation of this subtitle or any regulation adopted under this subtitle.

(3) Each violation of this subtitle or any regulation adopted under this subtitle is grounds for a separate fine.

Payment of fines to State Board of Pharmacy Fund

(b) The Board shall pay any fine collected under this section into the State Board of Pharmacy Fund.

Notice and opportunity for hearing

(c)(1) Before the Board takes any action under subsection (a) of this section, it shall give the applicant or permit holder an opportunity for a hearing before the Board.

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(2) The Board shall give notice and hold the hearing in accordance with the Administrative Procedure Act.

(3) Any applicant or permit holder aggrieved by a final decision of the Board may appeal as provided under the Administrative Procedure Act.

Notice to public of applicant or permit holder discipline

(d) The Board shall report on its Web site and make available to the public on request:

(1) Within 5 calendar days after taking the action, information relating to a suspension or revocation of a permit; and

(2) Within 30 calendar days after taking the action, information relating to any other formal action against an applicant or permit holder.

➡ § 12-4A-10. Permit required to operate sterile compounding facility or allow distribution of sterile drug products

Operation of sterile compounding facility

(a) Except as provided in subsection (c) of this section, a sterile compounding facility may not operate in the State or allow the sterile compounded preparations of the sterile compounding facility to be dispensed in the State unless the sterile compounding facility holds a sterile compounding permit issued by the Board.

Distribution of sterile drug products

(b) Except as provided in subsection (c) of this section, a person may not distribute sterile drug products in the State unless the sterile drug products are produced in a facility that holds a manufacturer's permit or other permit designated by the U.S. Food and Drug Administration to ensure the safety of sterile drug products.

Waiver of requirements

(c) A person may dispense or distribute sterile compounded preparations or sterile drug products in the State without meeting the requirements of subsection (a) or (b) of this section only in accordance with a waiver issued by the Board under § 12-4A-02 of this subtitle.

➡ § 12-4A-11. Permit holder names and addresses

The Board shall maintain and submit annually to the Secretary information relating to each sterile compounding permit holder, including:

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(1) The permit holder's name and address;

(2) The permit holder's permit category; and

(3) Any disciplinary actions taken against the permit holder during the reporting period.

Subtitle 5. Practice of Pharmacy and Operation of Pharmacies (Refs & Annos)

➡ § 12-501. Refusal to dispense or refill prescriptions

In general

(a) A pharmacist may refuse to dispense or refill a prescription if the decision is based on professional judgment, experience, knowledge, or available reference materials.

Notification of prescriber

(b)(1) Except as provided in paragraph (2) of this subsection, if a pharmacist refuses to dispense or refill a prescription, the pharmacist shall, to the extent practicable, notify the authorized prescriber that the prescription or refill was refused within 72 hours after the refusal.

(2) Paragraph (1) of this subsection does not apply if a pharmacist is unable to determine the name of the authorized prescriber.

➡ § 12-502. Information regarding drugs and medication; price, potential side effects

In general

(a) In the operation of a pharmacy, only a licensed pharmacist or an individual engaging in a 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 or devices including information as to their therapeutic values, potential side effects, and use in the treatment and prevention of diseases.

Price

(b) A licensed pharmacist shall give a patient who requests, in person or by telephone, the current price of a prescription drug or device that the pharmacy offers for sale to the public.

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§ 12-503. Date of prescription; restrictions

In general

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

Restrictions

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

§ 12-504. Generically equivalent drugs

Brand name defined

(a) In this section, “brand name” means the proprietary name a manufacturer places on a drug or device product or its container.

Duty to inform of generic equivalents

(b)(1) Subject to the provisions of this subtitle, a pharmacist, or the pharmacist's designee, who is under the direct supervision of the pharmacist, shall inform a retail consumer to the best of the pharmacist's or the pharmacist's designee's knowledge of the availability of a generically equivalent drug and shall inform a retail consumer of the approximate cost difference as compared to the brand name drug.

(2) The Board shall adopt procedures for:

(i) A consumer to notify the Board when a pharmacist fails to provide the information required under paragraph (1) of this subsection; and

(ii) Advising a pharmacist to bring the pharmacist into compliance with the requirements of paragraph (1) of this subsection.

(3) Paragraph (1) of this subsection does not apply:

(i) To a prescription that is written for a generic drug;

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(ii) When the authorized prescriber states expressly that the prescription is to be dispensed only as directed;

(iii) To a pharmacist who works in a pharmacy, whether centralized or decentralized, which primarily serves public or private institutional recipients; or

(iv) When the cost of the prescription is reimbursed by a third party payer, including medical assistance.

Substitution of generic drug or device

(c) A pharmacist may substitute a generically equivalent drug or device product, of the same dosage form and strength, for any brand name drug or device 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 or device products with therapeutic equivalence evaluations; and

(3) The consumer is charged less for the substituted drug or device than the price of the brand name drug or device.

Notification of substitution

(d) If a drug or device product is substituted under this section, the pharmacist shall:

(1) Notify the patient in writing that the drug or device product dispensed is a generic equivalent of the prescribed drug or device product; and

(2) Record on the prescription and keep a record of the name and manufacturer of the substituted drug or device product.

List of approved generic drugs

(e) The Department may list any additional drug or device 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.

Disqualification of generic drugs

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(f) The Department may disqualify a drug or device 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 or device is therapeutically nonequivalent or has a negative physical or biological effect on the consumer of that drug or device 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 or device 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 or device product; and

(ii) After providing an opportunity for public comment, determines whether the drug or device product should remain disqualified.

Reinstatement of generic drugs

(g) For a drug or device product that the Department has disqualified from being used in Maryland as a generic substitute under subsection (f) 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 or device product for use in Maryland as a generic substitute.

Liability for substitutions

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

§ 12-505. Labeling regulations, generally

In general

(a) Except for a drug or device dispensed to an inpatient in a hospital or related institution, each container of a drug or device dispensed shall be labeled in accordance with this section.

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Contents of label

(b) In addition to any other information required by law, the label shall include:

(1) The date the prescription is filled; and

(2) Unless otherwise required by the prescriber:

(i) An expiration date of the drugs or devices which shall be the lesser of:

1. 1 year from the date of dispensing;

2. The month and year when the drugs or devices expire;

3. The appropriate expiration date for repackaged drugs or devices; or

4. A shorter period as determined by the pharmacist;

(ii) Any appropriate special handling instructions regarding proper storage of the drugs or devices; and

(iii) Subject to the provisions of subsection (c) of this section, the name and strength of the drugs or devices.

Name of drug or device

(c)(1) Except as provided in paragraph (2) of this subsection, the label shall indicate the same name for the drug or device as that used by the authorized prescriber.

(2) If, under § 12-504 of this subtitle, the pharmacist substitutes a drug or device product for that named by the authorized prescriber, the label shall indicate both the name of the drug or device product and the name of the manufacturer or distributor of the drug or device dispensed.

Prescription, expiration dates

(d)(1) Except as provided in this subsection, if an authorized prescriber dispenses a drug or device, the prescriber shall label each container of the drug or device.

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

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(i) The name and strength of the drug or device;

(ii) The date the prescription is dispensed;

(iii) An expiration date of the drug or device which shall be the lesser of:

1. 1 year from the date of dispensing;

2. The month and year when the drug or device expires; or

3. A shorter period as determined by the authorized prescriber; and

(iv) Any appropriate special handling instructions regarding proper storage of the drug or device.

(3) The labeling requirements of this subsection do not apply if the authorized prescriber dispenses the drug or device:

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

(ii) In an emergency situation; or

(iii) As a sample drug or device dispensed in the regular course of the authorized prescriber's practice.

Alterations, defacement of label

(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.

§ 12-506. Unauthorized refill of prescription

In general

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

(1) The pharmacist:

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(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 or device is essential to the maintenance of life;

(4)(i) The drug or device 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 or device 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 or device.

Restrictions

(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 14-day supply or unit of use.

Emergencies

(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;

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

(3) The quantity dispensed does not exceed a 14-day supply or unit of use; and

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

§ 12-507. Prescription consultation services

In general

(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.

Offers to discuss

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

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(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.

Refusal of consultation

(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.

Records

(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.

Medical assistance recipients

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

Refill prescriptions

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

Regulations

(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.

§ 12-508. Influenza vaccinations

In general

(a)(1) A pharmacist may administer an influenza vaccination to an individual who is at least 9 years old, in accordance with regulations adopted by the Board, in consultation with the Department.

(2) A pharmacist may administer a vaccination that is listed in the Centers for Disease Control and Prevention's Recommended Immunization Schedule to an individual who:

(i) Is at least 11 years old but under the age of 18 years; and

(ii) Has a prescription from an authorized prescriber.

(3)(i) Subject to subparagraph (ii) of this paragraph, a pharmacist may administer to an adult a vaccination that is:

1. Listed in the Centers for Disease Control and Prevention's Recommended Immunization Schedule; or

2. Recommended in the Centers for Disease Control and Prevention's Health Information for International Travel.

(ii) A pharmacist shall administer a vaccination under subparagraph (i) of this paragraph under a written protocol that:

1. Is vaccine specific; and

2. Meets criteria established by the Department, in consultation with the Board, the Board of Physicians, and the Board of Nursing, in regulation.

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(4) A pharmacist shall:

(i) Report all vaccinations administered by the pharmacist to the ImmuNet Program established under § 18-109 of the Health--General Article;

(ii) If the vaccination has been administered in accordance with a prescription, document at least one effort to inform the individual's authorized prescriber that the vaccination has been administered; and

(iii) For a vaccination administered under paragraph (2) or (3) of this subsection, if the authorized prescriber is not the individual's primary care provider or if the vaccination has not been administered in accordance with a prescription, document at least one effort to inform the individual's primary care provider or other usual source of care that the vaccination has been administered.

Fees

(b) The Board shall:

(1) Set reasonable fees for the administration of vaccinations under this section; and

(2) Adopt regulations that require a pharmacist to submit a registration form to the Board that includes verification that the pharmacist:

(i) Has successfully completed a certification course approved by the Board that included instruction in the guidelines and recommendations of the Centers for Disease Control and Prevention regarding vaccinations; and

(ii) Is certified in basic cardiopulmonary resuscitation and obtained the certification through in-person classroom instruction.

➡ § 12-509. Renumbered as Health Occupations § 12-505 by Acts 1997, c. 614, § 1, eff. Oct. 1, 1997

➡ § 12-510. Repealed by Acts 1997, c. 614, § 1, eff. Oct. 1, 1997

➡ § 12-511. Renumbered as Health Occupations § 12-506 by Acts 1997, c. 614, § 1, eff. Oct. 1, 1997

➡ § 12-512. Renumbered as Health Occupations § 12-507 by Acts 1997, c. 614, § 1, eff. Oct. 1, 1997

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Subtitle 6. Board Regulation of Drugs, Medicines, and Other Products (Refs & Annos)

➡ § 12-601. Denial, suspension, or revocation of permit

In general

(a) Subject to the hearing provisions of § 12-315 of this title, for a violation of this subtitle, Subtitle 6C of this title, or any regulation adopted under Subtitle 6C of this title, the Board may:

(1) Deny a permit to an applicant;

(2) Reprimand a permit holder;

(3) Place a permit holder on probation; or

(4) Suspend or revoke a permit.

Appeals

(b) A person aggrieved by a final action of the Board under this subtitle or Subtitle 6C of this title may not appeal to the Secretary or the Board of Review but may appeal as provided under Title 10, Subtitle 2 of the State Government Article.

➡ § 12-601.1. Renumbered as Health Occupations 14-601 by Acts 2002, c. 157, § 2, eff. July 1, 2002

➡ § 12-602. Repealed by Acts 2007, c. 352, § 1; Acts 2007, c. 353, § 1, eff. July 1, 2007

➡ § 12-603. Home dialysis permits; regulations

Definitions

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

(2) “Dialysis drugs and devices” means:

(i) Dialysate and dialysis solutions;

(ii) Dialyzers, delivery systems, and their accessory equipment necessary to administer these products;

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(iii) Heparin;

(iv) Local anesthetics and any other drugs and devices approved by the Board under subsection (g) of this section;

(v) Needles;

(vi) Syringes; and

(vii) Sterile sodium chloride and sterile potassium chloride.

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

Permit required for home dialysis

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

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

Compliance with section

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

Applications

(d) To apply for a home 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.

Issuance of permit

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

Authorized activities

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

Rules and regulations

(g)(1) The Board may approve local anesthetics and other drugs and devices for distribution as dialysis drugs and devices under this section.

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

(i) Maintaining facilities that are adequate to assure proper security and control of dialysis drugs and devices;

(ii) Keeping records;

(iii) Labeling dialysis drugs and devices;

(iv) Receipts and returns from patients for dialysis drugs and devices;

(v) Reports to the Board; and

(vi) Restrictions on specific dialysis drugs or devices, including limitations on the amounts that may be distributed.

Approval of drugs and devices

(h) A person authorized to distribute dialysis drugs and devices under this section may distribute only 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;

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(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 irreversibly lost function of the individual's kidneys and requires regular treatment; and

(ii) Who has completed a full course of training in providing the individual's own dialysis treatment given by:

1. A home dialysis training facility; or

2. 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.

Suspension or revocation of permit

(i) Subject to the Administrative Procedure Act, [FN1] the Board may suspend or revoke the home dialysis distribution permit of any home dialysis distribution permit holder who fails to comply with subsection (h) of this section.

[FN1] State Government § 10-101 et seq.

§ 12-604. Inspection of pharmaceuticals, generally

In general

(a) The Secretary, the Board, or the agents of either, during business hours, may:

(1) Enter any place where drugs, devices, diagnostics, cosmetics, dentifrices, domestic remedies, or toilet articles are manufactured, packaged, stocked, or offered for sale; and

(2) Inspect the drugs, devices, diagnostics, cosmetics, dentifrices, domestic remedies, and toilet articles there.

Annual inspections

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(b)(1) A pharmacy in this State issued a permit by the Board and subject to inspection under subsection (a) of this section shall be inspected annually.

(2) A nonresident pharmacy:

(i) Is subject to inspection under subsection (a) of this section by the Secretary, the Board, or the agents of either; and

(ii) On application for and renewal of a pharmacy permit in this State, shall 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.

Hindrances prohibited

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

§ 12-605. Remote automated medication systems; pharmacist duties

Definitions

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

(2) "Health care facility" means a related institution as defined in § 19-301 of the Health--General Article.

(3) "Remote automated medication system" means an automated mechanical system that is located in a health care facility that does not have an on-site pharmacy and in which medication is stored in a manner that may be patient-specific.

(4) "Starter dose" means a dose of medication removed from a remote automated medication system within the first 24 hours after it is ordered.

Responsibility for system

(b)(1) A pharmacist shall be responsible for the safe and efficient dispensing, repackaging, delivery, control, bar coding, transaction records, dispensation records, labeling, and accountability for all medications in a remote automated medication system located in a health care facility that does not have a pharmacy present on-site.

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(2) If a pharmacist is not physically present where the remote automated medication system is located in a health care facility, the pharmacist shall have access to the system by electronic and visual means in order to ensure the safe and efficient dispensing, repackaging, delivery, control, bar coding, transaction records, dispensation records, labeling, and accountability for all medications in the system.

Review of medication orders

(c) If a health care facility uses a remote automated medication system, a pharmacist shall review for accuracy, completeness, and appropriateness all medication orders after being entered into the system.

Remote automated system requirements

(d)(1) If a remote automated medication system, the pharmacy permit holder that manages the system, and the health care facility where the system is located meet the requirements of this subsection:

(i) A health care facility that uses a system does not need to have a pharmacist physically present to review the selection, packaging, or repackaging of medications by the system;

(ii) If the starter dose is reviewed by a pharmacist within 24 hours of delivery from a system, a system may deliver a starter dose or a dose in response to an emergency without prior review by a pharmacist; and

(iii) A system may allow simultaneous access to multiple drug strengths, dosage forms, or drug entities if contained within a patient-specific package.

(2) A remote automated medication system shall at least:

(i) Use bar code technology to ensure accuracy in loading and selection of medications in the system;

(ii) Have electronic reporting capability regarding the identity of all persons with access to the system and regarding all medications removed from the system; and

(iii) Before administration of a medication to a patient by an individual authorized to administer medication under this article, provide:

1. A picture of the medication if available; or

2. If a picture is not available, a written report that describes the medication.

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(3) The health care facility where the system is located shall have at least:

(i) A pharmacist available for consultation 24 hours per day;

(ii) Technical assistance regarding operation of the system available 24 hours per day; and

(iii) A quality assurance program as described under subsection (e) of this section.

(4) The pharmacy permit holder that manages a remote automated medication system shall provide a comprehensive training program to all persons with access to the system.

Quality assurance programs

(e)(1) A pharmacist that operates a remote automated medication system, in consultation with the health care facility where the system is located, shall develop and implement a quality assurance program in accordance with regulations adopted by the Board.

(2) The quality assurance program developed under this subsection shall include:

(i) Policies and procedures at both the pharmacy where the system receives an order and the health care facility where the system administers the medication regarding operation of the system;

(ii) Daily inspection of the integrity of the system;

(iii) A plan for addressing medication errors;

(iv) A plan for reviewing incidents regarding inappropriate use and access to the system;

(v) Proper labeling procedures that comply with applicable State and federal laws;

(vi) Policies and procedures for the safe handling and return of unused medications; and

(vii) Any other requirements determined by the Board and set forth in regulations.

Access to system

(f)(1) A pharmacist that operates a remote automated medication system shall limit access to the system to

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individuals authorized to access the system by requiring individual security codes for all functions.

(2) A record shall be kept of each transaction containing user identification information.

Maintenance logs and repair records

(g)(1) A pharmacist who operates a remote automated medication system shall maintain maintenance logs and repair records for the system.

(2) In a power outage or otherwise unforeseen situation, a pharmacist shall ensure that:

(i) A back-up power source for the system is available by a connection with the health care facility's generator; and

(ii) Only a registered nurse or a licensed practical nurse has access to the medications contained within the system.

Subtitle 6A. Therapy Management Contracts (Refs & Annos)

➡ **§ 12-6A-01. Definitions**

In general

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

Group model health maintenance organization

(b) "Group model health maintenance organization" has the meaning stated in § 19-713.6 of the Health--General Article.

Health maintenance organization

(c) "Health maintenance organization" has the meaning stated in § 19-701(g) of the Health--General Article.

Institutional facility

(d)(1) "Institutional facility" means a facility other than a nursing home whose primary purpose is to provide a

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physical environment for patients to obtain inpatient or emergency care.

(2) “Institutional facility” does not include an urgent care facility that is not part of a facility.

Licensed physician

(e) “Licensed physician” means an individual who is licensed to practice medicine under Title 14 of this article.

Physician-pharmacist agreement

(f) “Physician-pharmacist agreement” means an agreement between a licensed physician and a licensed pharmacist that is disease-state specific and specifies the protocols that may be used.

Protocol

(g) “Protocol” means a course of treatment predetermined by the licensed physician and licensed pharmacist according to generally accepted medical practice for the proper completion of a particular therapeutic or diagnostic intervention.

Therapy management contract

(h)(1) “Therapy management contract” means a voluntary, written arrangement that is disease-state specific signed by each party to the arrangement between:

(i) One licensed pharmacist and the licensed pharmacist's designated alternate licensed pharmacists;

(ii) One licensed physician and alternate designated licensed physicians involved directly in patient care; and

(iii) One patient receiving care from a licensed physician and a licensed pharmacist pursuant to a physician-pharmacist agreement and protocol under this subtitle.

(2) A therapy management contract shall be related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or limitations for the purpose of improving patient outcomes.

➡ **§ 12-6A-02. Therapy management contracts not required**

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A therapy management contract is not required for the management of patients in an institutional facility or in a group model health maintenance organization.

§ 12-6A-03. Physician-pharmacist agreement

In general

(a) A licensed physician and a licensed pharmacist who wish to enter into therapy management contracts shall have a physician-pharmacist agreement.

Agreement submitted to Board of Physicians and Board of Pharmacy

(b)(1) A licensed physician who has entered into a physician-pharmacist agreement shall submit to the Board of Physicians a copy of the physician-pharmacist agreement and any subsequent modifications made to the physician-pharmacist agreement or the protocols specified in the physician-pharmacist agreement.

(2) A licensed pharmacist who has entered into a physician-pharmacist agreement shall submit to the Board of Pharmacy a copy of the physician-pharmacist agreement and any subsequent modifications made to the physician-pharmacist agreement or the protocols specified in the physician-pharmacist agreement.

§ 12-6A-04. Physician-pharmacist agreements; eligibility of pharmacist

A pharmacist is authorized to enter into a physician-pharmacist agreement if the pharmacist:

(1) Is a licensed pharmacist;

(2) Has a Doctor of Pharmacy Degree or equivalent training as established in regulations adopted under this subtitle;

(3) Is approved by the Board to enter into a physician-pharmacist agreement with a licensed physician in accordance with this subtitle; and

(4) Meets the requirements that are established by regulations adopted under this subtitle.

§ 12-6A-05. Therapy management contracts; in general

In general

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(a) Subject to the regulations adopted under this subtitle, a licensed pharmacist may enter into a therapy management contract initiated by a licensed physician.

Economic incentives

(b) A licensed pharmacist may not employ or provide economic incentives to a licensed physician for the purpose of entering into a physician-pharmacist agreement or a therapy management contract.

§ 12-6A-06. Protocols

In general

(a) A protocol under this subtitle:

(1) May authorize:

(i) The modification, continuation, and discontinuation of drug therapy under written, disease-state specific protocols;

(ii) The ordering of laboratory tests; and

(iii) Other patient care management measures related to monitoring or improving the outcomes of drug or device therapy; and

(2) May not authorize acts that exceed the scope of practice of the parties to the therapy management contract.

Drug substitutions

(b) A protocol shall prohibit the substitution of a chemically dissimilar drug product by the pharmacist for the product prescribed by the physician, unless permitted in the therapy management contract.

§ 12-6A-07. Therapy management contracts; terms, fees

In general

(a) A therapy management contract shall apply only to conditions for which protocols have been agreed to by a licensed physician and a licensed pharmacist in accordance with the regulations adopted under this subtitle.

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Contract length

(b) A therapy management contract shall terminate 1 year from the date of its signing, unless renewed by the licensed physician, licensed pharmacist, and patient.

Contract terms

(c) A therapy management contract shall include:

(1) A statement that none of the parties involved in the therapy management contract have been coerced, given economic incentives, excluding normal reimbursement for services rendered, or involuntarily required to participate;

(2) Notice to the patient indicating how the patient may terminate the therapy management contract;

(3) A procedure for periodic review by the physician, of the drugs modified pursuant to the agreement or changed with the consent of the physician; and

(4) Reference to a protocol, which will be provided to the patient upon request.

Termination

(d) Any party to the therapy management contract may terminate the contract at any time.

Fees

(e) The Board of Pharmacy may assess a fee, as established in regulation, for approval of a pharmacist to enter into a physician-pharmacist agreement.

§ 12-6A-08. Therapy management contracts; patient records

In general

(a) The physician shall maintain complete patient records with respect to the therapy management contract.

Timely updated records

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(b) The licensed physician's patient record shall be fully updated in writing by the licensed pharmacist in a timely manner, as provided in the physician-pharmacist agreement.

§ 12-6A-09. Application of Criminal Law § 5-902

Nothing in this subtitle supersedes the provisions of § 5-902 of the Criminal Law Article.

§ 12-6A-10. Board of Pharmacy, Board of Physicians; joint regulations

In general

(a) Subject to subsection (b) of this section, the Board of Pharmacy, together with the Board of Physicians, shall jointly develop and adopt regulations to implement the provisions of this subtitle.

Subjects

(b) The regulations adopted under subsection (a) of this section:

(1) Shall include provisions that:

(i) Define the criteria for physician-pharmacist agreements; and

(ii) Establish guidelines concerning the use of protocols, including communication, documentation, and other relevant factors; and

(2) May not require the Board of Physicians or the Board of Pharmacy to approve a physician-pharmacist agreement or the protocols specified in a physician-pharmacist agreement.

Subtitle 6B. Registered Pharmacy Technicians (Refs & Annos)

§ 12-6B-01. Registration as pharmacy technician required; exceptions

In general

(a) Except as otherwise provided in this title, on or after January 1, 2007, an individual shall be registered and approved by the Board as a pharmacy technician before the individual may perform delegated pharmacy acts.

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Exceptions

(b) This section does not apply to:

(1) A pharmacy student performing delegated pharmacy acts under the direct supervision of a licensed pharmacist and in accordance with regulations adopted by the Board;

(2) A pharmacy technician trainee under the direct supervision of a licensed pharmacist provided that the individual does not perform delegated pharmacy acts for more than 6 months; or

(3) An applicant for a license to practice pharmacy under the direct supervision of a licensed pharmacist provided that the applicant does not perform delegated pharmacy acts for more than 10 months.

§ 12-6B-02. Registration requirements

In general

(a) To qualify for registration an applicant shall be an individual who:

(1) Is currently certified by a national pharmacy technician certification program and complies with subsection (b)(6) of this section; or

(2) Meets the requirements of this section.

Requirements

(b) The applicant shall:

(1) Be of good moral character;

(2) Be at least 17 years old;

(3)(i) 1. Be a high school graduate or have attained a high school equivalency; or

2. Be enrolled and in good standing at a high school; or

(ii) Meet the requirements in subsection (d) of this section;

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(4) Have successfully passed an examination approved by the Board;

(5) Complete a pharmacy technician training program approved by the Board that:

(i) Includes 160 hours of work experience; and

(ii) Is no longer than 6 months' duration; and

(6) Submit a request for a State criminal history records check.

Criminal history check

(c) The Board may not approve an application until the State criminal history records check is completed.

Exceptions

(d) If an applicant does not meet the requirements of subsection (b)(3) through (5) of this section, the applicant qualifies for registration if:

(1) The applicant has worked in the pharmacy area of a pharmacy operated by the same pharmacy permit holder since January 1, 2006;

(2) The pharmacy permit holder for whom the applicant works attests in writing that the applicant has worked in the pharmacy area operated by the pharmacy permit holder continuously since January 1, 2006;

(3) A pharmacist who has supervised the applicant for at least 6 months attests in writing that the individual has performed competently; and

(4) The applicant otherwise meets the requirements of subsection (b) of this section.

Age

(e) An individual, at least 16 years and 6 months old, may begin fulfilling the pharmacy technician registration requirements under this subtitle.

Waivers

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(f)(1) Subject to the provisions of this subsection, the Board may waive any requirement of this subtitle for an individual who is registered as or has worked as a pharmacy technician in another state.

(2) The Board may grant a waiver under this subsection only if the applicant:

(i) Pays the application fee required under § 12-6B-03 of this subtitle; and

(ii) 1. Provides sufficient evidence that the applicant was registered in a state with registration or licensing requirements that are substantially similar to the registration requirements of this subtitle; or

2. Has worked as a pharmacy technician in another state and satisfies any additional requirements established by the Board in regulation.

§ 12-6B-03. Registration application

In general

(a) An applicant for registration shall:

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

(2) Unless otherwise qualified under § 12-6B-02(a) or (d) of this subtitle, provide documentation of the completion of a pharmacy technician training program under § 12-6B-02(b)(5) of this subtitle;

(3) Unless otherwise qualified under § 12-6B-02(a) or (d) of this subtitle, provide documentation of having successfully completed an examination approved by the Board;

(4) Submit to a request for a State criminal history records check; and

(5) Pay the application fees set by the Board.

Signed application

(b) The application shall be signed by the applicant.

§ 12-6B-04. Pharmacy technician registration; fees

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In general

(a) The Board shall register as a pharmacy technician any applicant who meets the requirements of this subtitle.

Fees

(b)(1) The Board may set reasonable fees for the issuance and renewal of registrations and other services.

(2) The fees charged shall be set so as to approximate the cost of registering pharmacy technicians.

§ 12-6B-05. Notification of criminal convictions

In general

(a) A registered pharmacy technician shall notify the Board of each plea of guilty for, conviction of, or entry of a plea of nolo contendere for a felony or a crime involving moral turpitude, regardless of whether:

(1) An adjudication of guilt or sentencing or imposition of sentence is withheld; or

(2) Any appeal or other proceeding is pending regarding the matter.

Timeliness of notification

(b) The registered pharmacy technician shall notify the Board within 7 days of the conviction or entry of the plea.

§ 12-6B-06. Authorization to perform delegated pharmacy acts

In general

(a) Registration authorizes a registered pharmacist technician to perform delegated pharmacy acts as defined in § 12-101 of this title while the registration is effective.

Exceptions

(b) A registered pharmacy technician or a pharmacy technician trainee may not:

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(1) Act within the parameters of a therapy management contract as provided under Subtitle 6A of this title;

(2) Administer an influenza vaccination in accordance with § 12-508 of this title;

(3) Delegate a pharmacy act that was delegated to the registered pharmacy technician or individual engaging in a Board approved technician training program; or

(4) Perform other functions prohibited by regulations adopted by the Board.

§ 12-6B-07. Renewal of registration

In general

(a)(1) Unless the registration is renewed for an additional term as provided in this section, registration expires on the date set by the Board.

(2) The ability of a registered pharmacy technician to function as a pharmacy technician terminates on the date of expiration of the pharmacy technician's registration unless renewed.

(3) Registration may not be renewed for a term longer than 2 years.

Renewal notice

(b)(1) Except as provided in paragraph (2) of this subsection, the Board shall send to each registered pharmacy technician, at least 1 month before a registration expires, a renewal notice by first-class mail to the last known address of the registered pharmacy technician.

(2) If requested by a registered pharmacy technician, the Board shall send to the registered pharmacy technician, at least two times within the month before a pharmacy technician registration expires, a renewal notice by electronic means to the last known electronic address of the registered pharmacy technician.

(3) If a renewal notice sent by electronic means under paragraph (2) of this subsection is returned to the Board as undeliverable, the Board shall send the registered pharmacy technician a renewal notice by first-class mail to the last known address of the registered pharmacy technician.

(4) A renewal notice sent under this subsection shall state:

(i) The date on which the current registration expires;

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

(iii) The amount of the renewal fee.

Renewals

(c) A registered pharmacy technician periodically may renew a pharmacy technician's registration for an additional 2-year term, if the registered pharmacy technician:

(1) Otherwise is entitled to be registered as a pharmacy technician;

(2) Submits to the Board a renewal application on the form that the Board requires;

(3) Meets the continuing education requirements set by the Board under this section; and

(4) Pays to the Board a renewal fee set by the Board.

Continuing education requirements

(d) In addition to any other qualifications and requirements established by the Board, the Board shall establish continuing education requirements as a condition to the renewal of registrations under this section.

Duty of Board to renew

(e) The Board shall renew the registration of each pharmacy technician who meets the requirements of this section.

Termination dates

(f)(1) Except as provided in paragraph (2) of this subsection, the registration of a pharmacy technician who qualified for registration under § 12-6B-02(d) of this subtitle permanently expires on the date the registered pharmacy technician's employment terminates with the pharmacy permit holder that made the attestation required under § 12-6B-02(d) of this subtitle.

(2) Paragraph (1) of this subsection does not apply to the registration of a pharmacy technician who:

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(i) At the time of termination, notifies the Board of the termination date;

(ii) Resumes working as a pharmacy technician within 1 year of the termination date; and

(iii) Notifies the Board of the date the registered pharmacy technician begins employment after the termination date.

§ 12-6B-08. Display of registration; identification

In general

(a) Each registered pharmacy technician shall:

(1) Display the pharmacy technician's registration in the office or place of business in which the pharmacy technician is working; or

(2) Have the registration on the pharmacy technician's person available for viewing.

Identification

(b) When performing delegated pharmacy acts, the registered pharmacy technician shall wear identification that conspicuously identifies the registered pharmacy technician as a registered pharmacy technician.

§ 12-6B-09. Denial, suspension, or revocation of registration

Subject to the hearing provision of § 12-315 of this title, the Board may deny a pharmacy technician's registration to any applicant, reprimand a registered pharmacy technician, place any pharmacy technician's registration on probation, or suspend or revoke a pharmacy technician's registration if the applicant or pharmacy technician registrant:

(1) Performs an act that is restricted to a licensed pharmacist;

(2) Fraudulently or deceptively obtains or attempts to obtain a pharmacy technician's registration for the applicant or assists or attempts to assist another in fraudulently or deceptively obtaining a pharmacy technician's registration;

(3) Fraudulently uses a pharmacy technician's registration;

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(4) Knowingly aids an unauthorized individual to practice pharmacy or to represent that the individual is a licensed pharmacist or registered pharmacy technician;

(5) Performs delegated pharmacy acts while:

(i) Under the influence of alcohol; or

(ii) Using any narcotic or controlled dangerous substance, as defined in § 5-101 of the Criminal Law Article, or other drug that is in excess of therapeutic amounts or without valid medical indication;

(6) Submits a false statement to collect a fee;

(7) Willfully makes or files a false report or record as part of the registered pharmacy technician's duties or employment;

(8) Willfully fails to file or record any report that is required by law;

(9) Willfully impedes or obstructs the filing or recording of any report that is required by law;

(10) Willfully induces another to fail to file or record any report that is required by law;

(11) Provides or causes to be provided to any authorized prescriber prescription forms that bear the name, address, or other means of identification of a pharmacist or pharmacy;

(12) Provides remuneration to an authorized prescriber for referring an individual to a licensed pharmacist, registered pharmacy technician, or pharmacy for a product or service to be provided by that licensed pharmacist, registered pharmacy technician, or pharmacy;

(13) Agrees with an authorized prescriber or pharmacist to prepare or dispense a secret formula prescription;

(14) Except as to an association that has remained in continuous existence since July 1, 1963, associates as a partner, co-owner, or employee of a pharmacy that is owned wholly or substantially by an authorized prescriber or group of authorized prescribers;

(15) Knowingly aids a pharmacist in dispensing any drug, device, or diagnostic for which a prescription is required without a written, oral, or electronically transmitted prescription from an authorized prescriber;

(16) Unless an authorized prescriber authorizes the refill, refills a prescription for any drug, device, or

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diagnostic for which a prescription is required;

(17) Violates any labeling requirements in this title;

(18) Violates any provision of § 12-603 of this title, which concerns the home dialysis distribution program;

(19) Advertises or otherwise publicly claims to dispense prescriptions in a superior manner;

(20) Advertises in a manner that tends to deceive or defraud the public;

(21) Is physically or mentally incompetent;

(22) Pleaded guilty or nolo contendere to, or has been found guilty of, a felony or a crime involving moral turpitude, regardless of whether:

(i) An adjudication of guilt or sentencing or imposition of sentence is withheld; or

(ii) Any appeal or other proceeding is pending regarding the matter;

(23) Violates any provision of this title;

(24) Is disciplined by a licensing, registering, or disciplinary authority of any state or country or convicted or disciplined by a court of any state or country for an act that would be grounds for disciplinary action under the Board's disciplinary statutes;

(25) Violates any regulation adopted by the Board;

(26) Refuses, withholds from, denies, or discriminates against an individual with regard to the provision of professional services for which the registered pharmacy technician is registered and qualified to render because the individual is HIV positive;

(27) Participates in any activity that is grounds for Board action under § 12-313 or § 12-409 of this title;

(28) Provides or causes to be provided confidential patient information to any person without first having obtained the patient's consent, as required by § 12-403(b)(13) of this title and by Title 4, Subtitle 3 of the Health--General Article;

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(29) Fails to cooperate with a lawful investigation conducted by the Board or the Division of Drug Control;

(30) Performs delegated pharmacy acts in an incompetent manner; or

(31) Performs delegated pharmacy acts that are inappropriate based on the registered pharmacy technician's education, training, and experience.

§ 12-6B-10. Suspension or revocation of registration; probation, fines

In general

(a) If after a hearing under § 12-315 of this title, the Board finds that there is a ground under § 12-6B-09 of this subtitle to reprimand a registered pharmacy technician, place a pharmacy technician's registration on probation, or suspend or revoke a pharmacy technician's registration, the Board may impose a penalty not exceeding $2,500:

(1) Instead of reprimanding the registered pharmacy technician, placing the registered pharmacy technician on probation, or suspending or revoking the pharmacy technician's registration; or

(2) In addition to reprimanding the registered pharmacy technician, placing the registered pharmacy technician on probation, or suspending or revoking the pharmacy technician's registration.

Regulations

(b) The Board shall adopt regulations to set standards for the imposition of penalties under this section.

Penalties paid to General Fund

(c) The Board shall pay any penalty collected under this section into the General Fund of this State.

§ 12-6B-11. Surrender of registration

In general

(a) Unless the Board agrees to accept the surrender of a pharmacy technician's registration, a registered pharmacy technician may not surrender the pharmacy technician's registration nor may the pharmacy technician's registration lapse by operation of law while the registered pharmacy technician is under investigation or while charges are pending against the registered pharmacy technician.

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Conditions

(b) The Board may set conditions on its agreement with the registered pharmacy technician under investigation or against whom charges are pending to accept the surrender of the pharmacy technician's registration.

§ 12-6B-12. Working without registration prohibited

Except as otherwise provided in this title, an individual may not work, attempt to work, or offer to work as a registered pharmacy technician in this State unless registered with the Board.

§ 12-6B-13. False representations made to obtain registration

In general

(a) An individual may not obtain a pharmacy technician's registration by making a false representation.

Convictions

(b) On conviction of an individual for making a false representation to the Board in order to register as a pharmacy technician, the pharmacy technician's registration is void.

§ 12-6B-14. Representations to the public, practice as pharmacy technician

In general

(a) Except as otherwise provided in this subtitle, an individual may not represent to the public by title, by description of services, methods, or procedures, or otherwise, that the individual is registered to work as a registered pharmacy technician unless registered in accordance with this subtitle.

Misleading terms

(b) Except as otherwise provided in this subtitle, an individual may not use the terms “registered pharmacy technician” or “pharmacy technician” with the intent to represent that the individual is authorized to work as a registered pharmacy technician unless registered as a pharmacy technician under this subtitle.

Subtitle 6C. Wholesale Distributor Permitting and Prescription Drug Integrity Act (Refs & Annos)

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§ 12-6C-01. Definitions

In general

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

Authenticate

(b) “Authenticate” means to affirmatively verify, before any wholesale distribution of a prescription drug occurs, that each transaction listed on the pedigree for the prescription drug has occurred.

Authorized distributor of record

(c) “Authorized distributor of record” means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug.

Co-licensed partner

(d) “Co-licensed partner” means a person in a relationship in which two or more persons have the right to engage in the manufacturing or marketing of a prescription drug, consistent with the U.S. Food and Drug Administration's implementation of the federal Prescription Drug Marketing Act.

Co-licensed product

(e) “Co-licensed product” means a product of co-licensed partners.

Designated representative

(f) “Designated representative” means an individual who:

(1) Is designated by a wholesale distributor;

(2) Serves as the primary contact of the wholesale distributor with the Board; and

(3) Is actively involved in and aware of the daily operation of the wholesale distributor.

Drop shipment

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(g) “Drop shipment” means the sale of a prescription drug:

(1) To a wholesale distributor by:

(i) The manufacturer of the prescription drug; or

(ii) The manufacturer's co-licensed partner, third party logistics provider, or manufacturer's exclusive distributor; and

(2) Through which:

(i) The wholesale distributor or a pharmacy warehouse takes title to but not physical possession of the prescription drug;

(ii) The wholesale distributor invoices the pharmacy, pharmacy warehouse, or other person authorized by law to dispense or administer the prescription drug to a patient; and

(iii) The pharmacy, pharmacy warehouse, or other authorized person receives delivery of the prescription drug directly from:

1. The manufacturer; or

2. The manufacturer's third party logistics provider or the manufacturer's exclusive distributor.

Facility

(h) “Facility” means a facility of a wholesale distributor where prescription drugs are stored, handled, repackaged, or offered for sale.

Intracompany sales

(i) “Intracompany sales” means a:

(1) Transaction or transfer of prescription drugs between a division, subsidiary, parent, or affiliated or related company under common ownership and control of a corporate entity, other than a transaction or transfer of prescription drugs from a pharmacy to a wholesale distributor; or

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(2) Transaction or transfer of a co-licensed product between co-licensed partners.

Manufacturer

(j) “Manufacturer” means a person licensed or approved by the U.S. Food and Drug Administration to engage in the manufacture of prescription drugs or prescription devices, consistent with the definition of “manufacturer” under the U.S. Food and Drug Administration's regulations and guidelines implementing the Prescription Drug Marketing Act.

Manufacturer's exclusive distributor

(k) “Manufacturer's exclusive distributor” means a person who:

(1) Contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer; and

(2) Takes title to the manufacturer's prescription drug, but does not have general responsibility to direct the sale or disposition of the manufacturer's prescription drug.

Normal distribution channel

(l) “Normal distribution channel” means a chain of custody for a prescription drug that, directly or by drop shipment, goes:

(1) From:

(i) A manufacturer of the prescription drug; or

(ii) The manufacturer's co-licensed partner, third party logistics provider, or manufacturer's exclusive distributor; and

(2) To:

(i) A pharmacy or other designated person authorized by law to dispense or administer the prescription drug to a patient;

(ii) A wholesale distributor to a pharmacy or other designated person authorized by law to dispense or administer the prescription drug to a patient;

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(iii) A wholesale distributor to a pharmacy warehouse to the pharmacy warehouse's intracompany pharmacy or other designated person authorized by law to dispense or administer the prescription drug to a patient;

(iv) A pharmacy warehouse to the pharmacy warehouse's intracompany pharmacy or other designated person authorized by law to dispense or administer the prescription drug to a patient; or

(v) An authorized distributor of record to another authorized distributor of record solely for distribution to an office-based health care practitioner authorized by law to dispense or administer the prescription drug to a patient.

Ongoing relationship

(m) “Ongoing relationship” means a relationship that exists between a wholesale distributor, including any affiliated group of the wholesale distributor, as defined in § 1504 of the Internal Revenue Code, and a manufacturer when the wholesale distributor:

(1) Has a written agreement currently in effect with the manufacturer evidencing the ongoing relationship; and

(2) Is listed on the manufacturer's current list of authorized distributors of record.

Pedigree

(n) “Pedigree” means a document or electronic file containing information that records each wholesale distribution of a prescription drug.

Pharmacy warehouse

(o) “Pharmacy warehouse” means a physical location for storage of prescription drugs that:

(1) Serves as a central warehouse; and

(2) Performs intracompany sales or transfers of the prescription drugs to a group of pharmacies that are under common ownership and control with the pharmacy warehouse.

Prescription device

(p) “Prescription device” means any device required by federal law or regulation to be dispensed only by a prescription.

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Prescription drug

(q)(1) “Prescription drug” means any drug required by federal law or regulation to be dispensed only by a prescription.

(2) “Prescription drug” includes:

(i) A biological product; and

(ii) Finished dosage forms and bulk drug substances subject to § 503(b) of the Federal Food, Drug, and Cosmetic Act.

(3) “Prescription drug” does not include blood and blood components intended for transfusion or biological products that are also medical devices.

Repackage

(r)(1) “Repackage” means to repackage or otherwise change the container, wrapper, or labeling of a prescription drug to further the distribution of the prescription drug.

(2) “Repackage” does not include changes to a container, wrapper, or labeling of a prescription drug completed by the pharmacist responsible for dispensing the prescription drug to a patient.

Repackager

(s) “Repackager” means a person who repackages prescription drugs.

Third party logistics provider

(t) “Third party logistics provider” means a person who:

(1) Contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer; but

(2) Does not take title to the prescription drug or have general responsibility to direct the prescription drug's sale or disposition.

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Wholesale distribution

(u)(1) “Wholesale distribution” means the distribution of prescription drugs or prescription devices to persons other than a consumer or patient.

(2) “Wholesale distribution” does not include:

(i) Intracompany sales;

(ii) The sale, purchase, distribution, trade, or transfer of a prescription drug or an offer to sell, purchase, distribute, trade, or transfer a prescription drug for emergency medical reasons;

(iii) The sale, purchase, distribution, trade, or transfer of a prescription drug or prescription device by the Department for public health purposes;

(iv) The distribution of samples of a prescription drug by a manufacturer's representative;

(v) Prescription drug returns conducted by a hospital, health care entity, or charitable institution in accordance with 21 C.F.R. § 203.23;

(vi) The sale of minimal quantities of prescription drugs by retail pharmacies to licensed health care practitioners for office use;

(vii) The sale, purchase, or trade of a prescription drug, an offer to sell, purchase, or trade a prescription drug, or the dispensing of a prescription drug in accordance with a prescription;

(viii) The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy to or with another pharmacy, whether accomplished as a purchase and sale of stock or business assets;

(ix) The sale, purchase, distribution, trade, or transfer of a prescription drug from one authorized distributor of record to one additional authorized distributor of record if:

1. The manufacturer has stated in writing to the receiving authorized distributor of record that the manufacturer is unable to supply the prescription drug; and

2. The supplying authorized distributor of record states in writing that the prescription drug being supplied had until that time been exclusively in the normal distribution channel;

(x) The delivery of, or offer to deliver, a prescription drug by a common carrier solely in the common

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carrier's usual course of business of transporting prescription drugs, if the common carrier does not store, warehouse, or take legal ownership of the prescription drug; or

(xi) The sale or transfer from a pharmacy or pharmacy warehouse of expired, damaged, returned, or recalled prescription drugs to:

1. The original wholesale distributor;

2. The original manufacturer; or

3. A third party returns processor.

Wholesale distributor

(v)(1) “Wholesale distributor” means a person that is engaged in the wholesale distribution of prescription drugs or prescription devices.

(2) “Wholesale distributor” includes:

(i) A manufacturer;

(ii) A repackager;

(iii) An own-label distributor;

(iv) A private-label distributor;

(v) A jobber;

(vi) A broker;

(vii) A warehouse, including a manufacturer's or distributor's warehouse;

(viii) A manufacturer's exclusive distributor or an authorized distributor of record;

(ix) A drug wholesaler or distributor;

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(x) An independent wholesale drug trader;

(xi) A third party logistics provider;

(xii) A pharmacy that conducts wholesale distribution, if the wholesale distribution business accounts for more than 5% of the pharmacy's annual sales; and

(xiii) A pharmacy warehouse that conducts wholesale distribution.

Wholesale distributor permit

(w) “Wholesale distributor permit” means a permit issued by the Board under this subtitle to distribute prescription drugs or prescription devices into, out of, or within the State as a wholesale distributor.

§ 12-6C-02. Distributions exempt from Act

This subtitle 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.

§ 12-6C-03. Permit requirements; wholesale distributors

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Wholesale distributors

(a) A wholesale distributor shall hold a permit issued by the Board before the wholesale distributor engages in wholesale distribution in the State.

Manufacturers

(b)(1) A manufacturer engaged in wholesale distribution shall hold a wholesale distributor permit issued under this subtitle.

(2) Notwithstanding paragraph (1) of this subsection, the information and qualification requirements for obtaining a permit under this subtitle, beyond that required by federal law, do not apply to:

(i) A manufacturer that distributes its own prescription drugs that are approved by the U.S. Food and Drug Administration; or

(ii) A manufacturer that distributes its own prescription devices that are approved or authorized by the U.S. Food and Drug Administration.

Exclusive distributors, third-party logistics provider

(c) A manufacturer's exclusive distributor and a third-party logistics provider shall hold a wholesale distributor permit issued under this subtitle.

Display of permit

(d) A wholesale distributor permit shall be displayed conspicuously in the place of business for which the permit is issued.

Transferability of permit

(e) A wholesale distributor permit is not transferable.

Purchases from authorized sellers

(f) Subject to any other restriction provided by law, a person may not purchase or obtain a prescription drug or prescription device unless the prescription drug or prescription device is purchased or obtained from a person who holds a wholesale distributor permit, a licensed pharmacist, or an authorized prescriber.

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§ 12-6C-03.1. Prescription drugs and devices for public health purposes

Purchase and distribution by Department

(a) The Department may purchase and distribute prescription drugs and prescription devices for public health purposes.

Regulations

(b) The Department shall adopt regulations, in consultation with the Board, to implement this section.

§ 12-6C-03.2. Reporting requirements relating to inspections

Inspections conducted by U.S. Food and Drug Administration or Board designee

(a) Notwithstanding any other provision of this subtitle, a wholesale distributor applicant or permit holder that prepares sterile drug products shall submit to the Board a report of an inspection conducted by the U.S. Food and Drug Administration or a Board designee:

(1) At the time of application; and

(2) On renewal.

Nature of inspection report

(b) The inspection report required under subsection (a) of this section shall be:

(1) Conducted within 1 year before the date of application or renewal; and

(2) Demonstrate compliance with applicable federal good manufacturing practice standards or USP 797, as defined in § 12-4A-01 of this title.

Inspection requirements

(c) An applicant or permit holder is responsible for obtaining an inspection to meet the requirements of this section.

§ 12-6C-04. Permits by reciprocity; accreditation standards

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Definitions

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

(2) “Accreditation organization” means a private entity that:

(i) Is recognized by the Board; and

(ii) Conducts inspections and surveys of wholesale distributors based on nationally recognized and developed standards.

(3) “Deemed status” means a status under which a wholesale distributor may be exempt from initial and routine inspection requirements under this subtitle.

Wholesale distributor permit

(b) The Board may only grant deemed status to a wholesale distributor that is:

(1) Currently accredited by an accreditation organization, wherever the wholesale distributor is located; or

(2) Located in a state that has requirements that:

(i) Are substantially equivalent to the requirements of this State; and

(ii) Include pedigrees, routine inspections of wholesale distributors, operation of wholesale distributors in a commercial nonresidential facility, and security measures.

Receipt of permit by reciprocity

(c)(1) The Board may issue a wholesale distributor permit by reciprocity to a wholesale distributor who holds a license or permit under the laws of another state if the Board determines that the requirements of that state are substantially equivalent to the requirements of this State.

(2) A wholesale distributor that receives a permit by reciprocity shall comply with the requirements of § 12-6C-05(e) and (f) of this subtitle.

(3) In addition to meeting the requirements under this subtitle, a wholesale distributor located out-of-state that is not eligible for reciprocity shall be accredited by an accreditation organization.

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(4) The Board shall grant deemed status to a wholesale distributor that:

(i) Is currently accredited by an accreditation organization; or

(ii) Has been granted reciprocity by the Board.

Inspections

(d) The Board or its designee may inspect a wholesale distributor who is accredited or has been issued a permit by reciprocity to:

(1) Determine compliance with any permit requirement under this subtitle; or

(2) Investigate a complaint.

§ 12-6C-05. Permit application

In general

(a) To apply for a wholesale distributor permit, an applicant shall:

(1) Pay to the Board an application fee set by the Board; and

(2) Submit an application to the Board on the form that the Board requires.

Identifying information

(b) The application shall include the following:

(1) The name, full business address, and telephone number of the applicant;

(2) All trade or business names used by the applicant;

(3) Addresses, telephone numbers, and the names of contact persons for the facility used by the applicant for the storage, handling, and distribution of prescription drugs;

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(4) The type of business form under which the applicant operates, such as partnership, corporation, or sole proprietorship;

(5) The name of each owner and operator of the applicant, including:

(i) If an individual, the name of the individual;

(ii) If a partnership, the name of the partnership and of each partner;

(iii) If a corporation, the name of the corporation, the name and title of each corporate officer and director, and the state of incorporation; and

(iv) If a sole proprietorship, the full name of the sole proprietor and the name of the sole proprietor's business entity;

(6) A list of all licenses and permits issued to the applicant by any other state that authorizes the applicant to purchase or possess prescription drugs;

(7) For the designated representative and the immediate supervisor of the designated representative at the applicant's place of business, the following:

(i) Name;

(ii) Places of residence for the past 7 years;

(iii) Date and place of birth;

(iv) The name and address of each business where the individual was employed during the past 7 years, and the individual's job title or office held at each business;

(v) A statement of whether, during the past 7 years, the individual has been the subject of any proceeding for the revocation of any professional or business license or any criminal violation and, if so, the nature and disposition of the proceeding;

(vi) A statement of whether, during the past 7 years, the individual has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating any federal or state law regulating the possession, control, or distribution of prescription drugs, together with details concerning the event;

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(vii) A description of any involvement, including any investments other than the ownership of stock in a publicly traded company or mutual fund, by the individual during the past 7 years with any business that manufactures, administers, prescribes, distributes, or stores prescription drugs, and any lawsuits in which the business was named as a party;

(viii) 1. A description of any misdemeanor or felony offense of which the individual, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the individual pled guilty or nolo contendere; and

2. If the individual indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal, within 15 days after the disposition of the appeal, a copy of the final written order of disposition; and

(ix) A photograph of the individual taken in the previous 180 days.

Oath

(c) The information required under subsection (b) of this section shall be provided under oath.

Inspection of facilities

(d) The Board may not issue a wholesale distributor permit to an applicant unless the Board or its designee:

(1) If the applicant holds prescription drugs or devices, conducts a physical inspection of the applicant's place of business, including any facility of the applicant;

(2) Finds that the place of business and facility, if any, meets the Board's requirements;

(3) Determines that the designated representative of the applicant meets the following qualifications:

(i) Is at least 21 years of age;

(ii) Has been employed full time for at least 3 years in a pharmacy or with a wholesale distributor in a capacity related to the dispensing and distribution of, and record keeping relating to, prescription drugs;

(iii) Is employed by the applicant full time in a managerial level position;

(iv) Is actively involved in and aware of the daily operation of the wholesale distributor;

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(v) Is physically present, except for an authorized absence such as sick leave or vacation leave, at the facility of the applicant during regular business hours;

(vi) Is serving as a designated representative for only one applicant at a time, or for two or more wholesale distributors who are located in the same facility and are members of an affiliated group, as defined in § 1504 of the Internal Revenue Code;

(vii) Does not have any convictions for a violation of any federal, state, or local laws relating to wholesale or retail prescription drug distribution or distribution of controlled substances; and

(viii) Does not have any convictions for a felony under federal, state, or local laws; and

(4) Determines that the immediate supervisor of the designated representative of the applicant meets the following qualifications:

(i) Is at least 21 years of age;

(ii) Has been employed full time for at least 3 years in a pharmacy or with a wholesale distributor in a capacity related to the dispensing and distribution of, and record keeping relating to, prescription drugs;

(iii) Is employed by the applicant full time in a managerial level position;

(iv) Is actively involved in and aware of the daily operation of the wholesale distributor;

(v) Does not have any convictions for a violation of any federal, state, or local laws relating to wholesale or retail prescription drug distribution or distribution of controlled substances; and

(vi) Does not have any convictions for a felony under federal, state, or local laws.

Criminal history records check

(e) The designated representative and the immediate supervisor of the designated representative of an applicant shall submit to a criminal history records check in accordance with § 12-6C-05.1 of this subtitle.

Exceptions

(f)(1) In this subsection, “gross receipts” means gross receipts from sales of prescription drugs and devices in the State.

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(2) This subsection does not apply to a pharmacy warehouse that is not engaged in wholesale distribution.

(3)(i) An applicant for a wholesale distributor permit shall submit a surety bond or other equivalent means of security acceptable to the State, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to the State Board of Pharmacy to be deposited into an account established by the State under paragraph (7) of this subsection.

(ii) The surety bond or other security shall be in the amount of:

1. $100,000, if the annual gross receipts of the applicant for the previous tax year are $10,000,000 or more; or

2. $50,000, if the annual gross receipts of the applicant for the previous tax year are less than $10,000,000.

(iii) The Board may require by regulation documentation for the gross receipts of the wholesale distributor to qualify for a surety bond or other security in the amount of $50,000.

(4) The purpose of the surety bond is to secure payment of any fines or penalties imposed by the Board and any fees and costs incurred by the State relating to the permit that:

(i) Are authorized under State law; and

(ii) Are not paid by the permit holder within 30 days after the fines, penalties, fees, or costs become final.

(5) The State may make a claim against the surety bond or other security until 2 years after the permit holder's permit ceases to be valid.

(6) A single surety bond shall cover all facilities operated by the applicant in the State.

(7) The Board shall establish an account, separate from its other accounts, in which to deposit the applicant's surety bond or other security.

Multiple facilities

(g) If a wholesale distributor distributes prescription drugs or prescription devices from more than one facility, the wholesale distributor shall obtain a permit for each facility.

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Notification of results

(h) Within 30 days after the date the Board receives a completed application, including the results of all required criminal history records checks, the Board shall notify the applicant of the Board's acceptance or rejection of the application.

➡ § 12-6C-05.1. Criminal history records checks

In general

(a)(1) In this subsection, "Central Repository" means the Criminal Justice Information System Central Repository of the Department of Public Safety and Correctional Services.

(2) This subsection applies to applicants located in the State.

(3) As part of an application to the Central Repository for a State and national criminal history records check, the designated representative and the immediate supervisor of the designated representative of an applicant shall submit to the Central Repository:

(i) Two complete sets of legible fingerprints taken on forms approved by the director of the Central Repository and the Director of the Federal Bureau of Investigation;

(ii) The fee authorized under § 10-221(b)(7) of the Criminal Procedure Article for access to State criminal history records; and

(iii) The processing fee required by the Federal Bureau of Investigation for a national criminal history records check.

(4) In accordance with §§ 10-201 through 10-228 of the Criminal Procedure Article, the Central Repository shall forward the criminal history records information of the designated representative and the immediate supervisor of the designated representative of an applicant to the Board and the applicant.

(5) The Board shall ensure that information obtained from the Central Repository under this subsection:

(i) Is kept confidential;

(ii) Is not redisseminated; and

(iii) Is used only for the permitting purpose authorized by this subtitle.

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(6) The subject of a criminal history records check under this subsection may contest the contents of the printed statement issued by the Central Repository as provided in § 10-223 of the Criminal Procedure Article.

Applicants located outside State

(b)(1) This subsection applies to applicants located outside the State.

(2) The designated representative and the immediate supervisor of the designated representative of an applicant shall submit to a criminal history records check by the applicant's state of residence, in accordance with the laws of the applicant's state of residence.

(3) The criminal history records check shall consist of:

(i) A state criminal history records check for the applicant's state of residence; and

(ii) A national criminal history records check.

(4) The designated representative and the immediate supervisor of the designated representative of an applicant shall request the appropriate entity in the applicant's state of residence to forward the results of the criminal history records check to the Board and the applicant.

(5) The Board shall ensure that information obtained under this subsection:

(i) Is kept confidential;

(ii) Is not redisseminated; and

(iii) Is used only for the permitting purpose authorized by this subtitle.

➡ § 12-6C-06. Expiration, renewal of permits

In general

(a) A wholesale distributor permit expires on May 31 after its effective date, unless the wholesale distributor permit is renewed for an additional 2-year term as provided in this section.

Renewal notice

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(b)(1) Except as provided in paragraph (2) of this subsection, at least 1 month before a wholesale distributor permit expires, the Board shall send to the wholesale distributor permit holder a renewal notice by first-class mail to the last known address of the permit holder.

(2) If requested by a wholesale distributor permit holder, the Board shall send to the permit holder, at least two times within the month before a wholesale distributor permit expires, a renewal notice by electronic means to the last known electronic address of the permit holder.

(3) If a renewal notice sent by electronic means under paragraph (2) of this subsection is returned to the Board as undeliverable, the Board shall send to the wholesale distributor permit holder a renewal notice by first-class mail to the last known address of the permit holder.

(4) A renewal notice sent under this subsection shall state:

(i) The date on which the current wholesale distributor 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 current wholesale distributor permit expires; and

(iii) The amount of the renewal fee.

(5) Before a wholesale distributor permit expires, a wholesale distributor permit holder periodically may renew it for an additional 2-year term, if the wholesale distributor permit holder:

(i) Otherwise is entitled to a wholesale distributor 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.

(6)(i) The renewal application form shall set forth the information that the wholesale distributor provided under § 12-6C-05 of this subtitle.

(ii) Within 30 days after receiving the form, the wholesale distributor shall identify and state under oath to the Board all changes or corrections to the information that was provided under § 12-6C-05 of this subtitle.

(7) The Board shall renew the wholesale distributor permit of a wholesale distributor permit holder who meets the requirements of this subtitle and any regulations adopted under this subtitle.

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(8) The Board may deny, suspend, or revoke the permit of a wholesale distributor if the Board determines that the wholesale distributor no longer qualifies for a permit.

§ 12-6C-07. Inspections

The Board:

(1) Shall adopt regulations that require routine inspections of wholesale distributor facilities; and

(2) May adopt regulations establishing:

(i) Minimum requirements for the receipt, storage, and handling of prescription drugs or prescription devices, security precautions, quality control, record keeping, and procedures, policy, and responsibilities of personnel; and

(ii) Education and experience requirements for personnel employed in positions responsible for carrying out the duties:

1. Referenced in item (i) of this item; or

2. Related to State permit requirements under this subtitle.

§ 12-6C-08. Disclosure of information

Information provided by a wholesale distributor or an applicant for a wholesale distributor permit under this subtitle may not be disclosed to any person or entity except a State licensing or permitting authority, State board, or government agency that needs the information for licensing, permitting, monitoring, or law enforcement purposes.

§ 12-6C-09. Returns or exchanges of prescription drugs; wholesale distributors

In general

(a)(1) A wholesale distributor shall receive prescription drug returns or exchanges from a pharmacy or pharmacy warehouse according to the terms and conditions of the agreement between the wholesale distributor and the pharmacy or pharmacy warehouse.

(2) Returns of expired, damaged, recalled, or otherwise nonsaleable prescription drugs shall be distributed by

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the receiving wholesale distributor only to either the original manufacturer or a third party returns processor.

(3) Returns or exchanges of prescription drugs, saleable or otherwise, including any redistribution by a receiving wholesaler, are not subject to the pedigree requirements of § 12-6C-10 of this subtitle if they are exempt from the pedigree requirement of the U.S. Food and Drug Administration's currently applicable Prescription Drug Marketing Act guidelines.

(4) Wholesale distributors and pharmacies shall be accountable for:

(i) Administering their returns process; and

(ii) Ensuring that the returns process is secure and does not permit the entry of adulterated and counterfeit product.

Supply of drugs to authorized persons

(b) A wholesale distributor may supply prescription drugs only to a person authorized by law to dispense or receive prescription drugs.

Authorized persons or agents

(c)(1) Except as provided in paragraph (2) of this subsection, a wholesale distributor may deliver prescription drugs only to:

(i) The premises listed on the recipient's license or permit; or

(ii) An authorized person or an agent of an authorized person at the premises of the wholesale distributor if:

1. The identity and authorization of the person or agent is properly established; and

2. This method of delivery is employed only to meet the immediate needs of a particular patient of the authorized person.

(2)(i) Prescription drugs may be supplied to a hospital pharmacy receiving area if a pharmacist or authorized receiving personnel of the hospital pharmacy signs, at the time of delivery, a receipt showing the type and quantity of the prescription drug received.

(ii) Any discrepancy between the type and quantity of the prescription drug indicated on the receipt and the

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type and quantity of the prescription drug received:

1. Shall be reported to the delivering wholesale distributor by the next business day after the delivery to the hospital pharmacy receiving area; and

2. May be reported to the Board for investigation.

Payments

(d)(1) A wholesale distributor may not accept payment or allow the use of a person's credit to establish an account for the purchase of prescription drugs from any person other than the owner of record, the chief executive officer, or the chief financial officer listed on the license or permit of a person legally authorized to receive prescription drugs.

(2) Any account established for the purchase of prescription drugs shall bear the name of the license or permit holder.

Residence

(e) A wholesale distributor may not operate out of a residence.

§ 12-6C-10. Pedigree requirements; contents

Pedigree required

(a) A person who is engaged in the wholesale distribution of a prescription drug that leaves, or has ever left, the normal distribution channel shall provide, before each wholesale distribution of the prescription drug, a pedigree to the person who receives the prescription drug.

Compliance

(b) A retail pharmacy or pharmacy warehouse shall comply with the requirements of this section only if the pharmacy or pharmacy warehouse engages in the wholesale distribution of a prescription drug in the State.

Normal distribution channel defined

(c)(1) To be considered part of the normal distribution channel, a wholesale distributor, a manufacturer's exclusive distributor, and a manufacturer's third party logistics provider also must be an authorized distributor

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of record.

(2) Notwithstanding paragraph (1) of this subsection, a pharmacy warehouse that is not an authorized distributor of record shall be considered part of the normal distribution channel.

Authentication

(d) Each person who engages in the wholesale distribution of a prescription drug, including repackagers but excluding the original manufacturer of the finished form of the prescription drug, who is provided a pedigree for the prescription drug and attempts to further distribute the prescription drug, shall authenticate, before any distribution of the prescription drug occurs, that each transaction listed on the pedigree has occurred.

Contents of pedigree

(e) The pedigree shall include:

(1) All necessary identifying information relating to each sale in the chain of distribution of the prescription drug from the manufacturer or the manufacturer's third party logistics provider, co-licensed partner, or manufacturer's exclusive distributor, through acquisition and sale by any wholesale distributor or repackager, until final sale to a pharmacy or other person dispensing or administering the prescription drug, including:

(i) The name, address, telephone number, and if available, electronic mail address, of each owner and each wholesale distributor of the prescription drug;

(ii) The name and address of each location from which the prescription drug was shipped, if different from the owner's;

(iii) Transaction dates; and

(iv) Certification that each recipient has authenticated the pedigree;

(2) The name of the prescription drug;

(3) The dosage form and strength of the prescription drug;

(4) The size of the container;

(5) The number of containers;

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(6) The lot number and National Drug Code of the prescription drug; and

(7) The name of the manufacturer of the finished dosage form.

Maintenance

(f) Each pedigree for a prescription drug shall be:

(1) Maintained by the purchaser and the wholesale distributor for 3 years from the date of sale or transfer; and

(2) Available for inspection or use within 5 business days on request of the Board, the Board's designee, or an authorized law enforcement officer.

§ 12-6C-11. Violations; factors in determining fines

Knowing violations

(a)(1) If a person knowingly violates any provision of this subtitle or any regulation adopted under this subtitle, the Board may impose a fine not to exceed $500,000.

(2) Before the Board imposes a fine, the Board shall consider the appropriateness of the fine in relation to:

(i) The size of the wholesale distributor;

(ii) The gravity of the violation for which the fine is to be imposed;

(iii) The good faith of the wholesale distributor; and

(iv) Any previous violations by the wholesale distributor.

Other drug laws

(b) In addition to the penalty provided in subsection (a) of this section, the Board also may take disciplinary action against a permit holder who is convicted of or pleads guilty or nolo contendere to a violation of State, federal, or local drug laws.

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§ 12-6C-12. Board regulations

On or before January 1, 2008, the Board shall adopt regulations to implement this subtitle.

§ 12-6C-13. Reporting requirements

On or before January 1, 2008, and on or before January 1 of each subsequent year, the Board shall report to the Governor and, in accordance with § 2-1246 of the State Government Article, to the General Assembly on the implementation of this subtitle.

Subtitle 7. Prohibited Acts; Penalties (Refs & Annos)

§ 12-701. License required to practice pharmacy

Except as otherwise provided in this title, a person may not practice, attempt to practice, or offer to practice pharmacy in this State unless licensed by the Board.

§ 12-702. False representations used to obtain license

In general

(a) A person may not obtain a license by making any false representation.

Convictions

(b) On conviction of a person for obtaining a license by false representation, the license held by that person is void.

§ 12-703. Pharmacy permit required in order to operate pharmacy

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.

§ 12-704. Representations to the public, practice of pharmacy

Practice of pharmacy

(a)(1) Unless authorized to practice pharmacy under this title, a person may not represent to the public by title,

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by description of services, methods, or procedures, or otherwise, that the person is authorized to practice pharmacy in this State.

(2) Unless authorized to practice pharmacy under this title, a person may not use the terms “pharmacist” or “druggist” with the intent to represent that the person practices pharmacy.

Status as pharmacy

(b)(1) Unless an establishment has a pharmacy permit, a person may not represent to the public by title, by description of services, methods, or procedures, or otherwise, that the establishment is a pharmacy.

(2) The acts prohibited by this subsection include using, with the intent to misrepresent that an establishment is a pharmacy, the terms “pharmacy” or “drugstore”, the characteristic show bottles or globes filled with colored water, or any other term or symbol traditionally associated with practicing pharmacy.

➡ §§ 12-705, 12-706. Reserved

➡ §§ 12-705, 12-706. Reserved

➡ § 12-707. Fines and penalties

In general

(a) A person who violates any provision of the following subtitles or sections of this title is guilty of a misdemeanor and on conviction is subject to a fine not exceeding $1,000:

(1) § 12-311 (“Display of licenses”);

(2) Subtitle 4 (“Pharmacy permits”);

(3) § 12-502(b) (“Pharmaceutical information”);

(4) § 12-505 (“Labeling requirements for prescription medicines”); and

(5) § 12-604 (“General power to inspect drugs, devices, and other products”).

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Misdemeanor convictions

(b) A person who violates any provision of the following sections of this title is guilty of a misdemeanor and on conviction is subject to a fine not exceeding $1,000 or imprisonment not exceeding 1 year or both:

(1) § 12-4A-10 ("Operating a sterile compounding facility without permit");

(2) § 12-701 ("Practicing pharmacy without license");

(3) § 12-702 ("License obtained by false representation");

(4) § 12-703 ("Operating a pharmacy without permit");

(5) § 12-704 ("Misrepresentations"); and

(6) § 12-6B-12 ("Working as an unregistered pharmacy technician").

Separate offenses

(c) Each day that a violation of any section of Subtitle 4 of this title continues constitutes a separate offense.

Report of conviction

(d) Within 10 days after a court renders the conviction, the court shall report to the Board each conviction of a pharmacist or registered pharmacy technician for:

(1) Any crime regarding the pharmacy or drug laws that involves professional misconduct; or

(2) Any crime that involves the State law regarding controlled dangerous substances or the federal narcotic laws.

Penalties paid to State Board of Pharmacy Fund

(e)(1) Any person who violates § 12-4A-10 ("Operating a sterile compounding facility without permit"), § 12-701 ("Practicing pharmacy without a license"), § 12-703 ("Operating a pharmacy without a permit"), or § 12-6B-12 ("Working as an unregistered pharmacy technician") of this title is subject to a civil fine of not more than $50,000 to be assessed by the Board.

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(2) The Board shall pay any penalty collected under this subsection into the State Board of Pharmacy Fund.

Subtitle 8. Short Title; Termination of Title (Refs & Annos)

§ 12-801. Short title

This title may be cited as the “Maryland Pharmacy Act”.

§ 12-802. Termination of title

Subject to the evaluation and reestablishment provisions of the Program Evaluation Act, [FN1]this title and all rules and regulations adopted under this title shall terminate and be of no effect after July 1, 2023.

[FN1] State Government, § 8-401 et seq.

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