

South Carolina Board of Pharmacy

Title 40 - Professions and Occupations

CHAPTER 43.

SOUTH CAROLINA PHARMACY PRACTICE ACT

SECTION 40-43-10. Short title; purpose of chapter; severability.

This chapter may be cited as the "South Carolina Pharmacy Practice Act". The purpose of this chapter is to promote, preserve, and protect the public health, safety, and welfare by and through the effective control and regulation of the practice of pharmacy; the licensure of pharmacists; the licensure, permitting, control, and regulation of all sites or persons, in or out of this State, that distribute, manufacture, possess, or sell drugs or devices within this State, as may be used in the diagnosis, treatment, and prevention of injury, illness, and disease of a patient or other individual.

The practice of pharmacy shall center around the provision of pharmacy care services and assisting the patient to achieve optimal therapeutic outcomes.

If a provision of this chapter is declared unconstitutional or illegal, or the applicability of this chapter to a person, pharmacy, or circumstance is held invalid by a court of competent jurisdiction, the constitutionality or legality of the remaining provisions of this chapter and the application of this chapter to other persons, pharmacies, and circumstances are not affected and shall remain in full force and effect without the invalid provision or application.

HISTORY: 1998 Act No. 366, Section 1.

SECTION 40-43-20. License required.

Except as otherwise provided in this chapter, it is unlawful for an individual to engage in the practice of pharmacy unless currently licensed pursuant to this chapter.

HISTORY: 1998 Act No. 366, Section 1.

SECTION 40-43-30. Definitions.

For purposes of this chapter:

(1) "Administer" means the direct application of a drug or device pursuant to a lawful order of a practitioner to the body of a patient by injection, inhalation, ingestion, topical application, or any other means.

(2) "Biological safety cabinet" means a containment unit suitable for the preparation of low-to-moderate risk agents where there is a need for protection of the product, personnel, and environment, according to National Sanitation Foundation Standard 49.

(3) "Board" or "Board of Pharmacy" means the State Board of Pharmacy.

(4) "Brand name" means the proprietary or trade name placed upon a drug, its container, label, or wrapping at the time of packaging.

(5) "Chart order" means a lawful order from a practitioner for a drug or device for patients of a hospital or extended care facility, or such an order prepared by another person and signed by a practitioner either immediately or at another time, issued for a legitimate medical purpose within the practitioner's course of legitimate practice and including orders derived on behalf of a practitioner from a practitioner approved drug therapy management.

(6) "Class 100 environment" means an atmospheric environment which contains less than one hundred particles 0.5 microns in diameter per cubic foot of air.

(7) "Compounding" means the preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis, or the preparation, mixing, assembling, packaging, or labeling of a drug or device 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 for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing. Compounding also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns. The term compounding does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.

(8) "Confidential information" means information maintained in a patient's records or which is communicated to a patient as part of patient counseling, which is privileged and may be released only to the patient, to those practitioners and pharmacists where, in the pharmacist's professional judgment, release is necessary to protect the patient's health and wellbeing, and to other persons or governmental agencies authorized by law to receive such confidential information.

(9) "Cytotoxic agent" means a drug that has the capability of killing living cells.

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

(11) "Designated agent" means a person employed by an authorized practitioner to transmit, either orally or electronically, a prescription drug order on behalf of the authorized practitioner to the pharmacist. The authorized practitioner accepts the responsibility for the correct transmission of the prescription drug order.

(12) "Designated pharmacist" means an individual currently licensed by the Board of Pharmacy in this State who certifies internship training.

(13) "Device" means an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including any component part or accessory, which is required under federal law to bear the label: "Caution: Federal law restricts this device for sale by or on the order of a _____", the blank to be filled with the word physician, dentist, veterinarian, or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device; or "Federal law prohibits dispensing without prescription"; or any products deemed to be a public health threat after notice and public hearing as designated by the board.

(14) "Dispense" means the transfer of possession of one or more doses of a drug or device by a licensed pharmacist or person permitted by law, to the ultimate consumer or his agent pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to, or use by, a patient. As an element of dispensing, the dispenser shall, before the actual physical transfer, interpret and assess the prescription order for potential adverse reactions or side effects, interactions, allergies, dosage, and regimen the dispenser considers appropriate in the exercise of his professional judgment, and the dispenser shall determine that the drug or device called for by the prescription is ready for dispensing. The dispenser shall also provide counseling on proper drug usage, either orally or in writing, as provided in this chapter. The actual sales transaction and delivery of a drug or device is not considered dispensing and the administration is not considered dispensing.

(15) "Distribute" means the delivery of a drug or device other than by administering or dispensing.

(16) "Drug" or "medicine" means:

(a) articles recognized as drugs in an official compendium, or supplement to a compendium, including, but not limited to, USP/NF designated from time to time by the board for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;

(b) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;

(c) articles, other than food, or nonprescription vitamins intended to affect the structure or a function of the human body or other animals; and

(d) articles intended for use as a component of any articles specified in item (a), (b), or (c) of this subsection.

(17) "Drug regimen review" includes, but is not limited to, the following activities:

(a) evaluation of prescription drug orders and pharmacy patient records for:

(i) known allergies;

(ii) rational therapy-contraindications;

(iii) reasonable dose and route of administration; and

(iv) reasonable directions for use.

(b) evaluation of prescription drug orders and pharmacy patient records for duplication of therapy.

(c) evaluation of prescription drug orders and pharmacy patient records for interactions:

(i) drug-drug;

(ii) drug-food;

(iii) drug-disease, if available; and

(iv) adverse drug reactions.

(d) evaluation of prescription drug orders and pharmacy patient records for proper utilization, including over-utilization or under-utilization, and optimum therapeutic outcomes.

(18) "Drug therapy management" is that practice of pharmacy which involves the expertise of the pharmacist in a collaborative effort with the practitioner and other health care providers to ensure

the highest quality health care services for patients.

(19) "Enteral" means within or by way of the intestine.

(20) "Equivalent drug product" means a drug product which has the same established name and active ingredients to meet the same compendia or other applicable standards, but which may differ in characteristics such as shape, scoring configuration, packaging, excipient (including colors, flavors, preservatives), and expiration time. Pharmacists may utilize as a basis for the determination of generic equivalency Approved Drug Products with Therapeutic Equivalence Evaluations and current supplements published by the Federal Food and Drug Administration, within the limitations stipulated in that publication.

(21) "Extern" means an individual currently enrolled in an approved college or school of pharmacy who is on required rotations for obtaining a degree in pharmacy.

(22) "Generic names" mean the official compendia names or United States Adopted Names (USAN).

(23) "Health care provider" includes a pharmacist who provides health care services within the pharmacist's scope of practice pursuant to state law and regulation.

(24) "Institutional facility" means an organization whose primary purpose is to provide a physical environment for patients to obtain health care services and shall not include those places where physicians, dentists, veterinarians, or other practitioners, who are duly licensed, engage in private practice.

(25) "Institutional pharmacy" means the physical portion of an institutional facility that is engaged in the compounding, dispensing, and distribution of drugs, devices, and other materials, hereinafter referred to as "drugs", used in the diagnosis and treatment of injury, illness, and disease and which is permitted by the State Board of Pharmacy.

(26) "Institutional consultant pharmacist" means a pharmacist licensed in this State who acts as a consultant for institutional facilities.

(27) "Intern" means an individual who is currently registered by certificate in this State to engage in the practice of pharmacy while under the personal supervision of a pharmacist and is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist.

(28) "Labeling" means the process of preparing and affixing a label which includes all information required by federal and state law to a drug container exclusive of the labeling by a

manufacturer, packer, or distributor of a nonprescription drug or commercially packaged legend drug or device.

(29) "Manufacturing" of products means the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis, or from bulk chemicals, and includes any packaging or repackaging of the substances or labeling or relabeling of its container, if these actions are followed by the promotion and marketing of the drugs or devices for resale to pharmacies, practitioners, or other persons.

(30) "Manufacturer" means a person engaged in the manufacture of prescription drugs or devices.

(31) "Medical order" means a lawful order of a practitioner which may or may not include a prescription drug order.

(32) "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 of this State and the federal government.

(33) "Nonresident pharmacy" means a pharmacy located outside this State.

(34) "Parenteral" means a sterile preparation of drugs for injection through one or more layers of the skin.

(35) "Patient counseling" means the oral or written communication by the pharmacist to a patient or caregiver providing information on the proper use of drugs and devices.

(36) "Permit consultant pharmacist" means a pharmacist licensed in this State who acts as a consultant for a permit holder other than a pharmacy or institution.

(37) "Person" means an individual, sole-proprietorship, corporation, partnership, association, or any other legal entity including government.

(38) "Pharmacy care" is the direct provision of drug therapy and other pharmacy patient care services through which pharmacists, in cooperation with the patient and other health care providers, design, implement, monitor, and manage therapeutic plans for the purpose of improving a patient's quality of life. Objectives include cure of disease, elimination or reduction of a patient's symptomatology, arresting or slowing a disease process, or prevention of a disease or symptomatology. The process includes three primary functions:

(a) identifying potential and actual drug-related problems;

(b) resolving actual drug-related problems; and

(c) preventing potential drug-related problems.

(39) "Pharmacist" means an individual health care provider licensed by this State to engage in the practice of pharmacy. A pharmacist is a learned professional authorized to provide patient care services within the scope of his knowledge and skills.

(40) "Pharmacist-in-charge" means a pharmacist currently licensed in this State who accepts responsibility for the operation of a pharmacy in conformance with all laws pertinent to the practice of pharmacy and the distribution of drugs and who is in full and actual charge of the pharmacy and personnel.

(41) "Pharmacy" means a location for which a pharmacy permit is required and in which prescription drugs and devices are maintained, compounded, and dispensed for patients by a pharmacist. This definition includes a location where pharmacy-related services are provided by a pharmacist.

(42) "Pharmacy technician" means an individual other than an intern or extern, who assists in preparing, compounding, and dispensing medicines under the personal supervision of a licensed pharmacist and who is required to register as a pharmacy technician.

(43) "Poison" means:

(a) a drug, chemical, substance, or preparation which, according to standard works on medicine, materia medica, or toxicology, is liable to be destructive to adult human life in doses of sixty grains or less; or

(b) a substance recognized by standard authorities on medicine, materia medica, or toxicology as poisonous; or

(c) any other item enumerated in this chapter; or

(d) a drug, chemical, substance, or preparation which is labeled "Poison".

(44) "Practice of pharmacy" means the interpretation, evaluation, and dispensing of prescription drug orders in the patient's best interest; participation in drug and device selection, drug

administration, prospective drug reviews, and drug or drug-related research; provision of patient counseling and the provision of those acts or services necessary to provide pharmacy care and drug therapy management; and responsibility for compounding and labeling of drugs and devices, (except labeling by a manufacturer, repackager, or distributor or nonprescription drugs and commercially packaged legend drugs and devices) proper and safe storage of drugs and devices and maintenance of proper records for them; or the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, education, management, and control of pharmacy.

(45) "Practitioner" means a physician, dentist, optometrist, podiatrist, veterinarian, or other health care provider authorized by law to diagnose and prescribe drugs and devices.

(46) "Prescription drug" or "legend drug" means:

(a) a drug which, under federal law, is required, prior to being dispensed or delivered, to be labeled with any of the following statements:

(i) "Caution: Federal law prohibits dispensing without prescription";

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

(iii) "Rx only"; or

(b) a drug which is required by any applicable federal or state law to be dispensed pursuant only to a prescription drug order or is restricted to use by practitioners only;

(c) any drug products considered to be a public health threat, after notice and public hearing as designated by the board; or

(d) any prescribed compounded prescription is a prescription drug within the meaning of this act.

(47) "Prescription drug order" means a lawful order from a practitioner for a drug or device for a specific patient, issued for a legitimate medical purpose within the prescriber's course of legitimate practice and including orders derived from collaborative pharmacy practice.

(48) "Prospective drug use review" means a review of the patient's drug therapy and prescription drug order before dispensing the drug as part of a drug regimen review.

(49) "Significant adverse drug reaction" means a drug-related incident that may result in serious harm, injury, or death to the patient.

(50) "Sterile pharmaceutical" means a dosage form devoid of viable micro-organisms.

(51) "Therapeutically equivalent" means a drug product with the same efficacy and toxicity when administered to an individual as the originally prescribed drug as provided for in Section 39-24-40.

(52) "Wholesale distributor" means a person engaged in wholesale distribution of prescription drugs or devices including, but not limited to, manufacturers; repackagers; own-label distributors; private-label distributors; jobbers; brokers; warehouses including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions. "Wholesale distributor" does not include:

(a) intracompany sales, being defined as a transaction or transfer between a division, subsidiary, parent, or affiliated or related company under the common ownership and control of a corporate entity;

(b) the purchase or other acquisition by a hospital or other health care entity that is a member of a group-purchasing organization of a drug for its own use from the group-purchasing organization or from other hospitals or health care entities that are members of such organizations;

(c) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1986 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(d) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control. For purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract, or otherwise;

(e) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons. For purposes of this section, "emergency medical reasons" includes the transfer of legend drugs by a licensed pharmacy to another licensed pharmacy or a practitioner licensed to possess prescription drugs to alleviate a temporary shortage, except that the gross dollar value of the transfers may not exceed five percent of the total legend drug sales revenue of either the transferor or the transferee pharmacy during a consecutive twelve-month period;

(f) the sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription; or

(g) the sale, purchase, or trade of blood and blood components intended for transfusion.

(53) "Revocation" means the cancellation or withdrawal of a license, permit, or other authorization issued by the board either permanently or for a period specified by the board before the person shall be eligible to apply anew. A person whose license, permit, or other authorization has been permanently revoked by the board shall never again be eligible for a license or permit of any kind from the board.

(54) "Certified pharmacy technician" means an individual who is a registered pharmacy technician and who has completed the requirements provided for in Section 40-43-82(B).

HISTORY: 1998 Act No. 366, Section 1; 1999 Act No. 76, Sections 1, 2; 2002 Act No. 314, Section 2.

SECTION 40-43-40. State Board of Pharmacy; creation; membership; terms; qualifications; vacancies; removal.

(A) There is created the State Board of Pharmacy to be composed of nine members, appointed by the Governor with advice and consent of the Senate, one of whom must be a lay member from the State at large, one of whom must be a pharmacist from the State at large, and seven of whom must be pharmacists representing each of the seven congressional districts. However, if no hospital pharmacist is selected to represent any of the seven congressional districts, the Governor shall appoint a hospital pharmacist as the pharmacist at large.

(B) The pharmacist at large and the lay member shall serve coterminously with the appointing Governor and until their successors are appointed and qualify. The board shall conduct an election to nominate three pharmacists from each congressional district to be submitted to the Governor for consideration for appointment. The Governor shall appoint one pharmacist to represent each congressional district from among the nominees submitted for that district. The election shall provide for participation by all pharmacists currently licensed and residing in the congressional district for which the nomination is being made. The pharmacists must be residents of the congressional district they represent, licensed, in good standing to practice pharmacy in this State, and actively engaged in the practice of pharmacy in this State. The members of the board representing the seven congressional districts shall serve terms of six years and until their successors are appointed and qualify. No member may serve more than two successive terms of office except that a member serving an unexpired term may be reelected and reappointed for two successive terms.

(C) Before December first in the year in which the term expires for a member representing a congressional district, a qualified pharmacist desiring to be a candidate for the board shall submit to the administrator of the board a biography and a petition bearing the signatures of a minimum of fifteen pharmacists practicing in that pharmacist's congressional district. The administrator shall prepare ballots for mailing to all pharmacists licensed and residing in the congressional district for which the nomination is being made. The ballots must be in a form so as to make tabulation quick and easy and shall contain the names of the nominees in alphabetical order. Enclosures to accompany the ballots shall include the envelope in which the ballot is to be sealed and an envelope addressed to the secretary of the board. The addressed envelope shall contain a statement headed "information required" on which must be typed or printed the name of the voter and a space for the voter's signature certifying that the voter:

(1) is the person whose name appears on the statement;

(2) is eligible to vote in this election;

(3) has personally cast the ballot.

(D) All ballots must be mailed by the administrator before January fifteenth to the last known mailing address of all pharmacists residing in the congressional district for which the nomination is being made and must be returned to the administrator postmarked before February fifteenth and received by the office before February twenty-fifth. The administrator of the board shall certify these ballots to be true and valid.

(E) Before March first, the board shall certify in writing to the Governor the name of the three persons winning the election and the name of the person the nominee replaces on the board, and the member, when appointed by the Governor, takes office the first of July of that year.

(F) Notwithstanding subsection (B), if a nominee is judged unfit by the Governor, the board must be informed and other nominees must be submitted in like manner.

(G) Vacancies must be filled in the manner of the original appointment for the unexpired portion of the term.

(H) The Governor may remove a member of the board who is guilty of continued neglect of board duties or who is found to be incompetent, unprofessional, or dishonorable. No member may be removed without first giving the member an opportunity to refute the charges filed against that member.

HISTORY: 1998 Act No. 366, Section 1; 2012 Act No. 222, Section 6, eff June 7, 2012.

SECTION 40-43-50. Board meetings; quorum; chair and vice chair.

(A) The board is styled the "Board of Pharmacy" and shall meet in the City of Columbia or any other place in the State designated by the board at least three times a year. The board may meet additionally for administrative purposes at the call of the chairman or of two-thirds of its members.

(B) A simple majority of the appointed members of the board constitutes a quorum for the transaction of business. The board shall elect a chairman and a vice chairman.

HISTORY: 1998 Act No. 366, Section 1.

SECTION 40-43-60. Chief drug inspector; staff inspectors; duties; violation corrections or prosecution; duties of board; adulterated or misbranded drugs; destruction at owner's expense; seal of drugs and devices under control of licensee when license suspended or revoked; complimentary drug samples; optometric supplies.

(A) There must be an administrator of the Board of Pharmacy who must be a pharmacist licensed in the State of South Carolina and who must be the chief drug inspector. When a vacancy occurs, the position of administrator of the Board of Pharmacy shall be filled in accordance with Section 40-1-50.

(B) The Board of Pharmacy shall have its own staff of inspectors who must be pharmacists licensed in South Carolina and shall conduct all pharmacy inspections and investigations and shall report to and be supervised by the administrator of the Board of Pharmacy.

(C) The chief drug inspector, or his designee, shall visit biennially all permitted facilities in this State and inspect them to see that the laws relating to the licensing of pharmacists are obeyed and to see that all of the provisions of this chapter are obeyed and carried out by the permitted facilities and pharmacists of this State. If a violation of this chapter is discovered, the inspector either shall require the pharmacist or permit holder of the permitted facility in default immediately to correct the violation or shall prosecute the offender under the law, using his discretion after consulting with the board if considered necessary. The inspector or his designee may swear out warrants for offenders who violate the provisions of this chapter.

(D) The board shall:

(1) regulate the practice of pharmacy;

- (2) regulate the sale and dispensing of drugs, poisons, and devices;
- (3) regulate the supervision and training of pharmacy interns and technicians in pharmacies;
- (4) investigate alleged violations of this chapter or any other law in the State pertaining to, or in connection with, persons licensed by the board or otherwise authorized by state laws to manufacture, sell, distribute, dispense, or possess drugs, medicines, poisons, or devices, or as related to misbranded or counterfeit drugs, or any regulations promulgated by the board under this chapter; conduct hearings when, in its discretion, it appears to be necessary; and bring violations to the notice of the prosecuting attorney of the court of competent jurisdiction in which a violation takes place or to the notice of the Attorney General;
- (5) establish the minimum specifications for the physical facilities, technical equipment, environment, supplies, personnel, and procedures for the storage, compounding or dispensing, or both, of drugs or devices, and for the monitoring of drug therapy;
- (6) confine at any time to prescription order only the dispensing of a drug found to be potentially dangerous to public safety if dispensed without prescription;
- (7) seize any drugs and devices found by the board to constitute an imminent danger to the public health and welfare;
- (8) promulgate regulations which the board, in its judgment, considers necessary for the carrying out of the purposes of this chapter;
- (9) license in accordance with this chapter pharmacists who shall practice in this State and permit all facilities which possess or dispense drugs in this State, except as provided in subsections (H) and (I) of this section, and as otherwise provided for in this chapter and except as to those entities and persons authorized to obtain and possess drugs pursuant to Section 47-3-420(A)(1)(i) and to suspend, revoke, or cancel a license or permit in accordance with law;
- (10) adopt rules of professional conduct for pharmacists which must be appropriate to the establishment and maintenance of a high standard of integrity and dignity in the profession; and
- (11) to have such powers and authority as may be necessary and proper to accomplish the foregoing or as may be prescribed by law.

(E) The board may:

(1) join professional organizations and associations organized exclusively to promote the improvement of the standards of the practice of pharmacy for the protection of the health and welfare of the public or whose activities assist and facilitate the work of the board, or both;

(2) establish a bill of rights for patients concerning the health care services a patient may expect in regard to pharmacy care.

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

(1) When a drug or device detained or embargoed under this subsection has been declared by a representative to be adulterated or misbranded, the board shall, as soon as is practical, petition the court in which jurisdiction the article is detained or embargoed for an order for condemnation of the article. If the court determines that the drug or device so detained or embargoed is not adulterated or misbranded, the board shall direct the immediate removal of the tag or other marking.

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

(3) It is the duty of the Attorney General to whom the board reports any violation of this subsection to cause appropriate proceedings to be instituted in the proper court without delay and to be prosecuted in the manner required by law. Nothing in this subitem shall be construed to

require the board to report violations whenever the board believes the public's interest will be adequately served in the circumstances by a suitable written notice or warning.

(G) The board may place under seal all drugs or devices that are owned by or in the possession, custody, or control of a licensee at the time the license is suspended or revoked or at the time the board refuses to renew the license. Except as otherwise provided in this section, drugs or devices so sealed shall not be disposed of until appeal rights under the Administrative Procedures Act have expired, or an appeal filed pursuant to that act has been determined. The court involved in an appeal filed pursuant to the Administrative Procedures Act may order the board, during the pendency of the appeal, to sell drugs that are perishable. The proceeds of the sale must be deposited with that court.

(H) Nothing in this chapter shall be construed to require a permit of or to prevent a licensed practitioner as defined under Section 40-43-30(45) from possessing or administering drugs or devices, or compounding drugs used for administration in the regular course of professional practice.

(I) This chapter does not require a permit of or prevent a licensed practitioner, as defined under Section 40-43-30(45), from dispensing drugs or devices that are the lawful property of the practitioner or a partnership or corporate entity which is fully owned by licensed practitioners or from dispensing a free complimentary trial supply of drugs owned by a person or institution authorized to possess medication under state or federal law for indigent patients with guidelines equal to or equivalent to Section 340B of the Public Health Service Act. Drugs or medicine dispensed must comply with the labeling requirements of state and federal laws and regulations.

(J) The possession of complimentary drug samples intended for distribution, and stock bottles and legend devices intended for remuneration or demonstration by manufacturer's representatives as allowed by the federal Food and Drug Administration and the actual distribution of them to pharmacists licensed to dispense and to practitioners in this State who are legally authorized to prescribe does not require a permit within the meaning of this chapter.

(K) A physician may dispense noncontrolled prescription drugs at an entity that provides free medical services for indigent patients if no pharmacist is available. All such drugs must be labeled as required by this chapter.

(L) Nothing in this chapter prohibits an optometrist from purchasing, possessing, administering, selling, prescribing, or dispensing either directly or through a licensed manufacturer contact lenses, contact lens solutions, and topically applied dyes or applies to the practice of opticianry.

(M) Nothing in this chapter may be construed to prevent, restrict, or in any manner interfere with

the sale by a retail merchant of nonnarcotic nonprescription drugs which may be lawfully sold without a prescription under the United States Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq. as now or hereafter amended) or the laws of this State.

HISTORY: 1998 Act No. 366, Section 1; 1999 Act No. 76, Section 3; 2000 Act No. 340, Sections 1, 7; 2002 Act No. 314, Section 3.

SECTION 40-43-70. Federally qualified health centers.

(A) For purposes of this section:

(1) "Board" means the South Carolina Board of Pharmacy.

(2) "Federally qualified health center" or "FQHC" means an entity funded by the Bureau of Primary Health Care (BPHC) under Section 330 of the Public Health Service Act as amended by the Health Centers Consolidation Act of 1996.

(3) "Health center delivery site" means a physical location where a licensed practitioner duly employed by or under contract with an FQHC provides primary and preventative health care services to patients of that FQHC. An FQHC may have multiple health center delivery sites.

(B) This section does not prevent a licensed practitioner, as defined in Section 40-43-30(45), from dispensing a drug or device for a patient of an FQHC if:

(1) a drug dispensed by the FQHC is properly labeled in accordance with state and federal law;

(2) the patient is given a choice of receiving the drug or device from the FQHC or from another provider;

(3) as it pertains to an FQHC without a retail pharmacy, the FQHC must obtain and maintain an FQHC permit as designated by this section; and

(a) monthly shall conduct and submit to the Board of Pharmacy self-inspections and maintain written checklists that are readily available to the Board of Pharmacy for on-site visits; and

(b) designate a pharmacist duly licensed by and in good standing with the Board of Pharmacy as a consultant pharmacist to be responsible for the duties stated in this section at the FQHC permit holder's location. A consultant pharmacist shall sign a new or renewal application along with the FQHC permit holder and agree in writing to assume the responsibilities of a consultant pharmacist. The consultant pharmacist shall perform and maintain written quarterly inspections

that are readily available. The FQHC permit holder and consultant pharmacist shall notify the board in writing within ten days of a change of consultant pharmacist. A designation of an individual as a consultant pharmacist or delegation of duties to a consultant pharmacist by a holder of an FQHC permit may not relieve the permit holder of the FQHC permit holder's duties under state or federal laws or regulations;

(4) as it pertains to a health center delivery site established after January 1, 2011, by an FQHC without a retail pharmacy, as a condition of permitting by the board pursuant to item (3) of subsection (B), this FQHC must certify to the board that it made a good faith effort but was unable to reach an agreement with an existing retail pharmacy located within five miles of the FQHC health center delivery site pursuant to which the existing retail pharmacy would provide prescription drugs to all FQHC patients at the same cost, convenience, and efficacy provided by the proposed new FQHC health center delivery site;

(5) as it pertains to an FQHC with a permitted retail pharmacy:

(a) the FQHC's retail pharmacy must be permitted pursuant to Section 40-43-83;

(b) the FQHC must obtain and maintain an FQHC permit for its affiliated health center delivery sites without an on-site pharmacy; and

(i) those affiliated delivery sites will be subject to the inspection requirements outlined in item (3) of this subsection; and

(ii) the FQHC pharmacist may serve as the consultant pharmacist for the FQHC's affiliated delivery sites;

(c) with prior approval of the Board of Pharmacy, the FQHC pharmacist may serve as the pharmacist in charge for more than one pharmacy at a time and need not be physically present in the pharmacy to serve as its pharmacist in charge.

(C) The Board of Pharmacy shall promulgate regulations needed to effectuate the purposes of this section.

HISTORY: 2010 Act No. 194, Section 1, eff May 28, 2010.

SECTION 40-43-80. Qualifications of applicants for pharmacy license examination.

To obtain a license to engage in the practice of pharmacy, an applicant for licensure by examination shall:

- (1) have submitted a written application in the form prescribed by the Board of Pharmacy;
- (2) have received a Bachelor of Science in pharmacy or Doctor of Pharmacy degree from an accredited college or school of pharmacy or department of pharmacy of a university which is recognized by the board, the recognition to be established by the board on the basis of uniform and reasonable standards of educational requirements to be observed by a school or college of pharmacy or department of pharmacy of a university or have received the Foreign Pharmacy Graduate Equivalency Certification. The accrediting agency may include, but is not limited to, the American Council on Pharmaceutical Education. The school or college of pharmacy or department of pharmacy of universities referred to in this item must be examined and inspected by the Board of Pharmacy of South Carolina or its accrediting agency and approved by the board periodically to see that the school or college of pharmacy of the universities comply with the standards of the board and its accrediting agency as to the purpose of the college, the faculty, teaching load, size of classes, curriculum, and degrees, admission requirements, attendance, promotion and graduation, student load, instruction, library, administration, finance, physical plant, extra-curricular activities, miscellaneous factors, and annual progress report.
- (3) have completed an internship or other program that has been approved by the Board of Pharmacy or demonstrated to the board's satisfaction experience in the practice of pharmacy which meets or exceeds the minimum internship requirements of the board;
- (4) have successfully passed the North American Pharmacist Licensure Examination (NAPLEX) and the Multistate Pharmacy Jurisprudence Examination (MPJE);
- (5) have paid all the appropriate fees.

HISTORY: 1998 Act No. 366, Section 1; 2000 Act No. 340, Section 2.

SECTION 40-43-81. Transfer of pharmacist licenses from other jurisdictions; reciprocity required.

(A) In order for a pharmacist currently licensed in another jurisdiction to obtain a license as a pharmacist by license transfer in this State, an applicant shall:

- (1) have submitted a written application in the form prescribed by the Board of Pharmacy;
- (2) have possessed at the time of initial licensure as a pharmacist all qualifications necessary to have been eligible for licensure at that time in this State;

(3) have presented to the board proof of initial licensure by examination and proof that such license is in good standing;

(4) have presented to the board proof that any other license granted to the applicant by any other state has not been suspended, revoked, or otherwise restricted for any reason except nonrenewal or for the failure to obtain the required continuing education credits in any state where the applicant is currently licensed but not engaged in the practice of pharmacy;

(5) have paid the fees specified by the board;

(6) have passed the Multistate Pharmacy Jurisprudence Examination; and

(7) be interviewed by members of the board.

(B) No applicant is eligible for license transfer unless the state in which the applicant was initially licensed as a pharmacist also grants licensure transfer to pharmacists duly licensed by examination in this State, under like circumstances and conditions.

HISTORY: 1998 Act No. 366, Section 1; 2000 Act No. 340, Section 3.

SECTION 40-43-82. Pharmacy technicians; registration; approval of training programs; minimum requirements; pharmacists previously disciplined not eligible to be technicians; volunteers at free medical clinics.

(A)(1) The Board of Pharmacy shall register pharmacy technicians who are performing pharmacy functions under the supervision of a pharmacist.

(2) A registration is valid from July one through June thirtieth and is renewable on dates as prescribed by the department with the consent of the board. An application for renewal must be on a board approved form provided by the department and must be submitted and accompanied by an annual fee in an amount established in accordance with Section 40-1-50. A pharmacy technician who has failed to properly renew a registration before July first shall immediately cease practice and refrain from performing any duties as a pharmacy technician. Reinstatement of a registration must be granted upon the board receiving a renewal application and renewal and penalty fees.

(3) A pharmacy technician shall display his or her current registration in a conspicuous place in the primary pharmacy or drug outlet in which the technician is employed, so that the current registration is easily and readily observable by the public. A technician working in a pharmacy or drug outlet where the technician's registration is not posted must have his or her wallet

registration card with him or her.

(B)(1) An individual may be certified by the board as a pharmacy technician if the individual has:

(a) worked for fifteen hundred hours under the supervision of a licensed pharmacist as a registered pharmacy technician or has completed a Board of Pharmacy approved pharmacy technician course as provided for in subsection (D); however, beginning July 1, 2004, to be certified as a pharmacy technician an individual must have worked for one thousand hours under the supervision of a licensed pharmacist as a technician and must have completed a Board of Pharmacy approved technician course as provided for in subsection (D);

(b) a high school diploma or equivalent; and

(c) passed the National Pharmacy Technician Certification Board exam or a Board of Pharmacy approved exam and has maintained current certification; and

(d) fulfilled continuing education requirements as provided for in Section 40-43-130(G).

(2) The pharmacist-in-charge shall verify compliance with the requirements of item (a) of subsection (B)(1) and maintained a record of this requirement in a readily retrievable manner for inspection.

(C) Notwithstanding any other provision of this chapter, a supervising pharmacist may authorize a certified pharmacy technician to:

(1) receive and initiate verbal telephone orders;

(2) conduct one time prescription transfers;

(3) check a technician's refill of medications if the medication is to be administered by a licensed health care professional in an institutional setting;

(4) check a technician's repackaging of medications from bulk to unit dose in an institutional setting.

(D) A formal academic pharmacy technician training program that leads to a certificate, diploma, or higher degree may be approved by the board if it includes at a minimum:

(1) introduction to pharmacy and health care systems;

- (2) pharmacy law and ethics;
- (3) pharmacy calculations;
- (4) pharmacology;
 - (a) anatomy and physiology;
 - (b) therapeutic agents;
 - (c) prescription drugs;
 - (d) nonprescription drugs;
- (5) pharmacy operations;
 - (a) drug distribution systems;
 - (b) records management and inventory control;
 - (c) ambulatory and institutional practice;
- (6) compounding;
 - (a) aseptic technique;
 - (b) nonsterile compounding;
- (7) general education;
 - (a) medical terminology;
 - (b) interpersonal relations;
 - (c) communications;
 - (d) computers/keyboarding;
- (8) problem solving/critical thinking;

(9) experiential training (practical experience).

(E) A pharmacist whose license has been denied, revoked, suspended, or restricted for disciplinary purposes is not eligible to be registered as a pharmacy technician.

(F) Notwithstanding the requirements of this section or any other provision of law or regulation, an individual who works as an unpaid volunteer under the personal supervision of a licensed pharmacist or who handles legend drugs in a pharmacy department of a free medical clinic staffed by a licensed pharmacist may be registered as a pharmacy technician and may perform pharmacy functions as a pharmacy technician without payment of a registration fee or filing with the board; provided, that a register is maintained in the pharmacy department of the free medical clinic bearing the name of every such volunteer performing pharmacy functions as a pharmacy technician and documenting each volunteer's period of service. This special registration is valid only in the free medical clinic. The register must be kept for a period of three years. For the purposes of this section, "free medical clinic" means a permitted facility that provides medical services, including the dispensing of legend drugs and other medications, free of any charge to members of the public.

HISTORY: 1998 Act No. 366, Section 1; 2000 Act No. 297, Section 1; 2002 Act No. 314, Section 4.

SECTION 40-43-83. In-state facilities dealing with prescription drugs; out-of-state facilities in mail order pharmacy service; permits; registered agents; required pharmacist-in-charge; display of permit; penalty; refusal of permit if not in public interest.

(A) All facilities located within this State engaging in the manufacture, production, sale, distribution, possession, or dispensing of prescription drugs or devices and all facilities located outside of this State whose primary business is mail order pharmacy service engaging in the sale, distribution, or dispensing of prescription drugs or devices in this State must be permitted by the Board of Pharmacy, and annually shall renew the permit by June first. Where operations are conducted at more than one location, each location must be permitted by the Board of Pharmacy.

This subsection does not apply to a college or university athletic department that dispenses prescription drugs or devices.

(B) Each permittee located outside of this State who ships, mails, distributes, or delivers prescription drugs or devices in this State and every pharmacy located outside of this State who ships, mails, distributes, or delivers prescription drugs or devices in this State shall designate a registered agent in this State for service of process. Any such permittee or pharmacy who does

not so designate a registered agent is deemed to have designated the Secretary of State of this State to be its true and lawful attorney, upon whom may be served all legal process in any action or proceeding against such permittee growing out of or arising from such delivery. A copy of any such service of process shall be mailed to such permittee or pharmacy by the board by certified mail, return receipt requested, postage prepaid, at the address such permittee has designated on its application for licensure in this State. If any such person is not permitted in this State, service on the Secretary of State only is sufficient service.

(C) The board shall determine and promulgate the permit classifications of all permits by regulation under this chapter and establish minimum standards for such permits.

(D) Each pharmacy shall have a pharmacist-in-charge; however, a college or university athletic department pharmacy is not required to have a pharmacist-in-charge. Whenever an applicable rule requires or prohibits action by a pharmacy, responsibility is that of the permit holder and the pharmacist-in-charge of the pharmacy, whether the ownership is a sole proprietor, partnership, association, corporation, or otherwise.

(E) The board may enter into agreements with other states or with third parties for the purpose of exchanging information concerning the permitting and inspection of entities located in this jurisdiction and those located outside this State.

(F) Permits issued under this section must be displayed in a conspicuous place in the permitted facility for which it was issued in such a manner that will enable an interested person to determine the name of the permittee, permit number, and permit expiration date. The permits are not transferable.

(G) This section must not be construed as precluding any person from owning or being a permit holder if all of the dispensing, compounding, and retailing of prescription drugs in it are under the supervision and direction of a licensed pharmacist.

(H) The Board of Pharmacy may deny or refuse to renew a permit if it determines that the granting or renewing of such permit would not be in the public interest. If an application is refused, the board shall notify the applicant in writing of its decision and the reasons for its decision.

(I) A permit is required for the sale, distribution, possession, or dispensing of drugs bearing the legend "Caution: Federal law prohibits dispensing without a prescription" including, but not limited to, pharmacies (institutional or community, public or private), nursing homes, hospitals, convalescent homes, extended care facilities, family planning clinics, public or private health clinics, infirmaries, wholesalers, correctional institutions, industrial health clinics, mail order

vendors, and manufacturers within or outside this State.

(J) The board shall assess a civil penalty in the amount of fifty dollars for failure to display a permit as required by this section.

(K) The Department of Health and Environmental Control is exempt from the provisions of this section that require facilities distributing or dispensing prescription drugs to be permitted by the Board of Pharmacy and from the provisions of this section that require each pharmacy to have a pharmacist-in-charge; however, each health district in this State must have a permit to distribute or dispense prescription drugs.

HISTORY: 1998 Act No. 366, Section 1; 2000 Act No. 340, Section 8; 2002 Act No. 356, Section 1, Part II.H(1),(2); 2007 Act No. 49, Section 3.A.

SECTION 40-43-84. Internship and externship certificates; program requirements; intern and extern restrictions; requirements for supervisory site and pharmacist.

(A) All applicants for licensure by examination shall obtain one thousand five hundred hours of practical experience in the practice of pharmacy. The board shall establish certificate requirements for interns/externs and standards for internship, or any other experiential program necessary to qualify an applicant for licensure. The board shall issue an intern certificate to a qualified applicant. No intern/extern may receive credit for practical experience unless he has been issued a certificate by the board. Such certificate must be granted only to individuals who have been accepted by or graduated from an approved college of pharmacy, but no sooner than three months before beginning pharmacy school. No credit shall be given for internships worked more than three months before beginning pharmacy school or if the student does not matriculate. A foreign pharmacy graduate may secure a certificate of registration as a pharmacy intern upon presenting to the board proof of graduation from a pharmacy school located in a foreign country and a statement of his intent to complete the requirements of the Foreign Pharmacy Graduate Equivalency Examination (FPGEE).

(B) An intern/extern may not represent himself as a pharmacist. The board shall issue to an intern/extern a certificate for purposes of identification and verification of his role as an intern/extern. The internship certificate must be displayed in the pharmacy or site in which the experience is being gained. No individual who has not been issued a certificate by the board as an intern/extern shall take, use, or exhibit the title of intern/extern, or any other term of similar like or import.

(C) An intern/extern may engage in the practice of pharmacy if such activities are under the direct supervision of a licensed pharmacist. A pharmacist must be in continuous personal eye and

voice contact with, and actually giving instructions to, the intern/extern during all professional activities throughout the entire period of the internship/externship. The pharmacist shall physically review the prescription drug order and the dispensed product before the product is delivered to the patient or the patient's agent. The pharmacist is responsible for the work of the intern/extern. A pharmacist may not supervise more than one intern at any one time.

Pharmacy interns/externs shall not be left in sole charge of a prescription department or other approved site at any time. Violation of this may result in cancellation of any and all internship/externship hours toward licensure that may have been accrued by the intern/extern, and may, in the discretion of the board, cause the board after sufficient notice to the pharmacy intern/extern, to revoke or suspend the internship certificate as provided above. The supervising pharmacist or designated pharmacist may also be subject to disciplinary action by the board.

An applicant for licensure, who is guilty of compounding or dispensing a prescription of a practitioner or selling legend drugs or medicines while not under the supervision of a licensed pharmacist may be refused licensure.

(D) All interns shall notify the board of any change of employment or residence address within ten days.

(E) Credit for claims of practical experience required under the pharmacy laws will not be recognized by the board unless such claims are corroborated by records on file in the board office, showing the beginning and ending of the practical experience claimed as supplied by the applicant during the training period and by the pharmacist who supervised the practical experience during the training period.

(F) The pharmacy, site, or program in which practical experience is being obtained shall have a current, valid pharmacy permit, as required by this chapter, and the designated pharmacist shall hold a current, valid license to practice pharmacy.

HISTORY: 1998 Act No. 366, Section 1; 1999 Act No. 76, Section 4.

SECTION 40-43-85. Notification form regarding internship; practical experience; experience gained outside State; credit for externship programs; requirements for site and supervising pharmacists.

(A) An intern shall notify the Board of Pharmacy within ten days after the beginning and again within ten days after the ending of each and every calendar year, if the intern is employed, and within ten days after the beginning of each new employment and within ten days after the ending of each employment, on forms provided by the board, of the identity of the internship site and of

the designated pharmacist. This form must be certified by the designated pharmacist. The pharmacy intern is responsible for the submission of the appropriate forms within the time limits as set.

(B) An intern may gain practical experience toward licensure as a pharmacist in accordance with this section and as may otherwise be required by this chapter.

(C) Where practical experience is gained in a pharmacy, other site, or program located outside of the State, the board has the discretion to determine whether such experience meets the requirements of the board. The applicant shall submit from the secretary of the Board of Pharmacy of the state in which practical experience was gained certification of the validity of the supervising pharmacist's license and the pharmacy permit.

(D) A minimum of five hundred hours of practical experience must be obtained in a retail or institutional pharmacy. Approval of all experience gained is left to the discretion of the board after receiving a description of the experience by the intern and the designated pharmacist.

(E) Students enrolled in an approved program leading to a bachelor of science degree in pharmacy may receive practical experience credit for up to five hundred hours for participation in an externship program upon completion of the program. Hours earned must be certified by the college of pharmacy, none of which may be used to fulfill the requirement in subsection (D).

(F) Students enrolled in an approved doctor of pharmacy program consisting of six or more years of collegiate studies may receive practical experience credit for up to one thousand hours for practice related experiences upon completion of such program, the number of hours certified by the college of pharmacy, none of which shall be used to fulfill the requirements in subsection (D).

(G) A pharmacy, site, or program offering interns/externs practical experience toward licensure as a pharmacist shall conform to the best traditions of pharmacy, shall have available all necessary reference books, in addition to the official standards and current professional journals and periodicals, and must be operated at all times under the supervision of a licensed pharmacist as required by law. The designated pharmacist must signify willingness to train interns/externs desiring to obtain practical experience in accordance with this chapter. The pharmacy at which an intern/extern is being trained shall provide an environment that is conducive to the learning of the practice of pharmacy by an intern/extern. It is expected that the intern/extern will be exposed to all facets of the practice of pharmacy in that setting including, but not limited to:

(1) evaluation of prescription drug orders;

(2) preparation and labeling of drugs;

(3) dispensing of drugs;

(4) patient profile update and review;

(5) drug use review;

(6) patient counseling; and

(7) proper and safe storage of drugs.

(H) No more than forty hours per week of internship training may be allowed.

HISTORY: 1998 Act No. 366, Section 1; 1999 Act No. 76, Section 5.

SECTION 40-43-86. Facility requirements for pharmacies; presence of pharmacist-in-charge; consultant pharmacists; prescription drug orders; transferring of prescriptions; substitution of drugs; label requirements; patient records and counseling; policies and requirements for automated systems; unlawful practices; sales to optometrists and home medical equipment providers; code of ethics; sale of poisons and returned medications; permit fees; compounding regulations and restrictions.

(A) A pharmacy, at a minimum, shall:

(1) be of sufficient size to allow for the safe and proper storage of prescription drugs and for the safe and proper compounding and preparation of prescription drug orders;

(2) maintain an area designated for the provision of patient counseling services. This area must be designed to provide a reasonable expectation of privacy;

(3) maintain on file current drug reference materials. The references should enable the user to find information using the brand name, generic name, pharmacologic group, therapeutic group, and synonym;

(4) update drug monographs at least quarterly, which include the following prescribing information: actions, indications, contradictions, warning and precautions, drug interactions, adverse reactions, patient information, overdose, administration, and dosage;

(5) update this product information at least quarterly:

- (a) products grouped by dosage or strength;
 - (b) identical brand name products;
 - (c) distributor name;
 - (d) package sizes for all dosage forms;
 - (e) product identification;
 - (f) whether prescription or nonprescription;
 - (g) controlled substance schedule;
 - (h) combination products comparison;
 - (i) products with identical formulations.
- (6) update new development information at least quarterly:
- (a) significant recent drug therapy developments;
 - (b) information on investigational agents;
 - (c) recent new product information and product listing changes.
- (7) maintain a copy of Equivalent Drug Product Evaluations or equivalent reference;
- (8) have a current copy of the South Carolina Pharmacy Practice Act, South Carolina Controlled Substances Act and Regulations, South Carolina Drug Act, and South Carolina Board of Pharmacy Newsletter;
- (9) maintain patient-oriented reference material for guidance in proper drug usage;
- (10) maintain storage areas at temperatures which shall ensure the integrity of the drugs prior to their dispensing as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling;
- (11) have access to a sink with hot and cold running water that is in the compounding area;

(12) have a pharmacist who, while on duty, is responsible for the security of the pharmacy department including provision of effective control against theft or diversion of drugs or devices, or both;

(13) have secured its pharmacy by either a physical barrier with suitable locks or an electronic barrier, or both, to detect entry at a time the pharmacist, or a person authorized by the pharmacist on duty or the pharmacist-in-charge, is not present. The barrier must be approved by the Board of Pharmacy before being put into use;

(14) display, when the pharmacy department is closed or in the absence of the licensed pharmacist, a sign stating "Pharmacy Department Closed, Pharmacist Not On Duty" displayed during the absence of the licensed pharmacist;

(15) carry, utilize, and maintain according to manufacturer's specifications the equipment and supplies necessary to conduct a pharmacy in a manner that is in the best interest of the patients served and to comply with all state and federal laws;

(16) maintain the area and equipment in which prescriptions are compounded and dispensed in a clean and orderly condition and:

(a) the prescription department must be kept dry and well ventilated, free from obnoxious odors, and equipped with adequate lighting facilities;

(b) drugs, pharmaceuticals, and chemicals must be arranged in a neat, orderly manner, free from dust, insects, rodents, or any type of contamination;

(c) all outdated, damaged, defaced, or unlabeled drugs, pharmaceuticals, biologicals, and chemicals must be removed from active stock;

(d) pharmaceuticals and biologicals requiring refrigeration must be kept stored in a refrigerator at the specified temperature;

(e) all stocks and materials used in the compounding of prescriptions must be labeled and conform in purity and strength as required by law;

(f) the prescription counter area upon which prescriptions are compounded must be used for no other purpose than for compounding prescriptions;

(g) the prescription department shall maintain only such instruments, equipment, materials, drugs, pharmaceuticals, biologicals, chemicals, and medicines as are necessary in the

compounding and dispensing of prescriptions and pharmaceutical preparations;

(h) all instruments, articles, and containers used in the compounding and dispensing of prescriptions and pharmaceutical preparations must be clean and free from all foreign substances;

(i) the sink, with hot water connection, of the prescription department must be used for no other purpose than for cleaning of instruments and materials used in the compounding and dispensing of prescriptions and medicines, or the cleansing of the hands of those preparing and compounding;

(j) all pharmacists, before compounding prescriptions, and supportive personnel assisting pharmacists, shall thoroughly cleanse their fingernails and wash their hands;

(k) the storing of drugs, medicines, pharmaceuticals, or consumable materials used in compounding and dispensing prescriptions and pharmaceutical preparations in the washroom or toilet of a pharmacy is prohibited.

(B)(1) No person may operate a pharmacy without a pharmacist-in-charge. The pharmacist-in-charge of a pharmacy must be designated in and sign the application for the pharmacy permit, and in each renewal thereof. A pharmacist may not serve as pharmacist-in-charge unless he is physically present in the pharmacy a sufficient amount of time to provide supervision and control. A pharmacist may not serve as pharmacist-in-charge for more than one pharmacy at any one time without written permission from the board.

Subsection (B)(1) does not apply to a college or university athletic department pharmacy.

(2) Each institutional pharmacy shall be directed by a pharmacist, hereinafter referred to as the pharmacist-in-charge who is licensed to engage in the practice of pharmacy in this State.

(3) The pharmacist-in-charge shall have the following responsibilities:

(a) assuring that all pharmacists, technicians, and interns employed at the pharmacy are currently licensed, certified, or registered and that interns and technicians wear proper identification while on duty;

(b) notifying the Board of Pharmacy immediately of any of the following changes:

(i) change of employment or responsibility as the pharmacist-in-charge;

(ii) change of ownership of the pharmacy;

(iii) change of address of the pharmacy; or

(iv) permanent closing of the pharmacy;

(c) making or filing any reports required by state or federal laws and regulations;

(d) responding to the Board of Pharmacy regarding any violations brought to the pharmacist-in-charge's attention.

(4) The pharmacist-in-charge must be assisted by a sufficient number of licensed pharmacists and registered pharmacy technicians as may be required to competently and safely provide pharmacy services.

(a) The pharmacist-in-charge shall maintain and file with the board of pharmacy, on a form provided by the board, a current list of all pharmacy technicians assisting in the provision of pharmacy services.

(b) The pharmacist-in-charge shall develop and implement written policies and procedures to specify the duties to be performed by pharmacy technicians. The duties and responsibilities of these personnel shall be consistent with their training and experience. These policies and procedures shall, at a minimum, specify that pharmacy technicians are to be personally supervised by a licensed pharmacist who has the ability to control and who is responsible for the activities of pharmacy technicians and that pharmacy technicians are not assigned duties that may be performed only by a licensed pharmacist. One pharmacist may not supervise more than three pharmacy technicians at a time; through June 30, 2006, at least one of these three technicians must be state-certified, and after June 30, 2006, at least two of these three technicians must be state-certified. If a pharmacist supervises only one or two pharmacy technicians, these technicians are not required to be state-certified. Pharmacy technicians do not include personnel in the prescription area performing only clerical functions, including data entry up to the point of dispensing, as defined in Section 40-43-30(14).

(c) For the purpose of dispensing by institutional pharmacies to institutional facility in-patients the pharmacist to technician ratio may not exceed a one to three employment ratio. The allowable employment ratio for a site is determined by comparing the number of pharmacists employed at the site to the number of pharmacy technicians employed at the site. The day to day operational pharmacist to technician personal supervision ratio is to be determined by the pharmacist-in-charge.

(5) The pharmacist-in-charge shall develop or implement, or both, a procedure for proper management of drug recalls which may include, where appropriate, contacting patients to whom the recalled drug products have been dispensed.

(6) The pharmacist-in-charge of an institutional pharmacy shall establish or implement, or both, written policies and procedures for provision of drugs to the medical staff and other authorized personnel whenever a licensed pharmacist is not physically present in an institutional facility by use of night cabinets and/or by access to the pharmacy. A licensed pharmacist must be on call at all times.

(a) In the absence of a pharmacist, only specifically authorized personnel shall have access by key or combination to the night cabinets. Such enclosures, which are to be located outside of the pharmacy, must be sufficiently secure to prevent access by unauthorized persons.

(b) The pharmacist-in-charge, in conjunction with the appropriate committee of the institutional facility, shall develop inventory listings of those drugs to be included in the cabinet and determine who may have access and ensure that:

(i) the drugs are properly labeled;

(ii) only prepackaged drugs are available, in amounts sufficient for immediate therapeutic requirements;

(iii) whenever access to the cabinet occurs, written practitioner's orders and proofs of use are provided;

(iv) all drugs therein are inventoried no less than once a week;

(v) a complete audit of all activity concerning the cabinet is conducted no less than once a month; and

(vi) written policies and procedures are established to implement the requirements of this section.

(c) If a drug is not available from floor supplies or night cabinets, and the drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, the drug may be obtained from the pharmacy only by authorized personnel. Removal of a drug from the pharmacy must be recorded on a suitable form showing patient name, room number, name of drug, strength, amount, date, time, and signature of authorized personnel. The form must be left with the container from which the drug was removed and must be reviewed by a licensed pharmacist within seventy-two hours.

(d) For an institutional facility that does not have an institutional pharmacy, drugs may be provided for use by authorized personnel in emergency kits located at the facility. The kits must meet the following requirements:

(i) emergency kit drugs must be those drugs which may be required to meet the immediate therapeutic needs of patients and which are not available from any other authorized source in sufficient time to prevent risk of harm to patients by delay resulting from obtaining the drugs from the other sources;

(ii) all emergency kit drugs must be provided and sealed by a pharmacist;

(iii) the supplying pharmacist and the medical staff of the institutional facility shall jointly determine the drugs, by identity and quantity, to be included in emergency kits;

(iv) emergency kits must be stored in secured areas to prevent unauthorized access, and to ensure a proper environment for preservation of the drugs within them;

(v) the exterior of each emergency kit must be labeled to clearly indicate that it is an emergency drug kit for use in emergencies only. The label shall contain a listing of the drugs contained in the kit, including name, strength, and quantity of the contents, and the name, address, and telephone number of the supplying pharmacist;

(vi) drugs must be removed from emergency kits only pursuant to a valid medical order;

(vii) whenever an emergency kit is opened, the supplying pharmacist must be notified and the pharmacist shall restock and reseal the kit within a reasonable time to prevent risk of harm to patients; and

(viii) the expiration date of an emergency kit is the earliest date of expiration of a drug or device supplied in the kit. Upon the occurrence of the expiration date, the supplying pharmacist shall replace the expired drug or device.

(C) Except for a pharmacy, wholesaler, or a permitted facility that supplies only oxygen, every holder of a permit from the board shall designate a pharmacist duly licensed by the Board of Pharmacy as a consultant pharmacist to be responsible for the duties as stated in this chapter at the permit holder's location. The consultant pharmacist shall sign a new or renewal application along with the permit holder and agree in writing to assume the responsibilities of consultant pharmacist.

(1) The consultant pharmacist must be consistent with the accepted standards of professional conduct and practice and responsible for compliance with all applicable laws and regulations including:

(a) establishing as applicable to the permit, policies, and procedures for the procurement, storage, compounding, dispensing, and distribution of drugs;

(b) establishing and supervising the recordkeeping system for the purchase, sale, possession, storage, safekeeping, and return of drugs;

(c) facilitating drug recalls and the removal of outdated and adulterated drugs;

(d) supervising all employees of the permit holder whose duties relate to the procurement, compounding, sale, distribution, and storage of drugs;

(e) acting as a drug information resource for the staff by bringing new and current drug information to their attention and being available by phone for questions;

(f) performing written monthly inspections that are readily available.

(2) The outgoing consultant pharmacist and the permit holder shall notify the board in writing within ten days of a change of consultant pharmacist.

(3) No designation of an individual as a consultant pharmacist or delegation of duties to a consultant pharmacist by a holder of a pharmacy permit shall relieve the permit holder of any of the permit holder's duties under state or federal laws or regulations.

(4) Emergency medical services licensed by the Department of Health and Environmental Control are exempt from permit fees and the provisions of this section requiring a consultant pharmacist to perform the duties set forth in this chapter at the permit holder's location, and the medical director or a consultant pharmacist may perform the duties of the consultant pharmacist pursuant to this chapter.

(5) A facility supplying durable medical equipment is exempt from the provisions of this section requiring a consultant pharmacist to perform the duties set forth in this chapter at the permit holder's location, and a medical director, respiratory therapist, registered nurse, or consultant pharmacist may perform the duties of the consultant pharmacist pursuant to this chapter.

(D) In addition to the duties and responsibilities contained in this section, a consultant pharmacist for an institutional facility shall review the record of each institutional resident

receiving medication for potential adverse reactions, allergies, interactions, and laboratory test modification and advise the physician of any recommended changes in the medication regimen. This review must be conducted monthly and documented on the resident's medical record.

(E) A prescription drug order shall contain at a minimum, the:

(1) full name and address of the patient;

(2) name, address, telephone number, and degree classification of the prescriber; license number, and Drug Enforcement Agency registration number of the prescribing practitioner where required by law;

(3) date of issuance;

(4) name, strength, dosage form, and quantity of drug prescribed;

(5) directions for use;

(6) number of refills authorized. No prescription marked "PRN" or any other nonspecified number of refills may be refilled more than two years beyond the date it was originally written. Nothing in this subsection abridges the right of a pharmacist to refuse to fill or refill a prescription; and

(7) a written order signed by the prescriber, which shall bear the name of the patient; name, strength, and quantity of the drug or device prescribed; directions for use; date of issue; and, either rubber stamped, typed, printed by hand, or typeset, the name, address, telephone number, and degree classification of the prescriber; and, if a controlled substance is prescribed, the prescriber's federal registration number;

(8) only one drug and set of instructions for each blank, if preprinted;

(9) a chart order is exempt from the requirements of this subsection.

(F) A prescription drug order must be issued for a legitimate medical purpose by a practitioner acting within the course of legitimate professional practice. The prescription drug order must be received at the pharmacy as it was originally transmitted. Each prescription drug order becomes part of a permanent record and must be readily retrievable. The institutional pharmacist must review the physician's drug order, or a direct copy, prior to dispensing any drug (except for emergency use). Electronically transmitted prescription drug orders shall meet these requirements:

(1) must be sent only to a pharmacy of the patient's choice;

(2) must be received at the pharmacy as it was originally transmitted by facsimile or computer and shall include the name and address of the practitioner, the phone number for verbal confirmation, the time and date of transmission, and the name of the pharmacy intended to receive the transmission, as well as any other information required by federal or state law;

(3) a pharmacist may dispense prescription drug orders transmitted electronically only when transmitted by an authorized practitioner or his designated agent;

(4) the pharmacist shall exercise professional judgment regarding the accuracy or authenticity of the transmitted prescription drug order consistent with existing federal or state laws and regulations;

(5) any alterations of electronic transfer of a prescription drug order or information constitutes an unlawful act which will be prosecuted by the Attorney General of this State;

(6) the prescribing practitioner may authorize his agent to transmit a prescription drug order orally or electronically to the pharmacy provided that the identity of the transmitting agent is included in the order.

(G)(1) The transfer of original prescription information for the purpose of dispensing refills is permissible between licensed or permitted pharmacies subject to these requirements:

(a) The transfer must be communicated directly between two pharmacists and not by one pharmacist accessing an information file containing data for several locations, unless all locations accessed are under common ownership or accessed pursuant to contractual agreement of the pharmacies.

(b) The transferring pharmacist shall void any remaining refills and so mark the face of the prescription retained by the transferring pharmacist or record information electronically.

(c) The transferring pharmacist shall record the name and address of the pharmacy to which the prescription was transferred and the name of the pharmacist receiving the prescription information on the reverse side of the transferred prescription or record information electronically.

(2) The transferring pharmacist shall record in writing the date of the transfer and the name of the pharmacist transferring the information or record information electronically.

(3) The transferring pharmacist shall record on the prescription transferred or record information electronically that the receiving pharmacist is authorized to dispense all remaining refills based on the original prescription, if such is the case.

(4) The pharmacist receiving the transferred prescription information shall record in writing or electronically the following:

(a) the word "transfer" on the face of the transferred prescription;

(b) any information required to be on a prescription, including:

(i) the date of issuance of the original prescription;

(ii) the date and time of transfer;

(iii) the pharmacy's name, address, and original prescription number from which the prescription information was transferred;

(c) the name of the transferring pharmacist;

(d) the manufacturer or brand name of drug dispensed; and

(e) documentation that the receiving pharmacist shall dispense refills based on the transferring pharmacist's certification under subsection (G)(3).

(5) The requirements of this section may be facilitated by use of a computer, data, or facsimile.

(6) All records pertinent to this section must be readily available.

(7) Both the original and transferred prescription drug order must be maintained for a period of two years from the date of last refill.

(8) The transfer must be in compliance with current state and federal laws on controlled substances.

(9) The transfer of prescription information for the purpose of dispensing authorized refills is permissible between pharmacies where all pharmacies are under common ownership and access prescription information through a common computerized data system, subject to subsection (G)(1)(c), (G)(2), (G)(5), (G) (6), (G)(7), and (G)(8).

(H)(1) Upon receiving a prescription for a brand name product, a registered pharmacist may in his professional judgment substitute an equivalent drug product as provided in this subsection.

(2) Every oral or written drug prescription shall provide an authorization from the practitioner as to whether or not an equivalent drug product may be substituted.

(3) A written prescription shall have two signature lines at opposite ends on the bottom of the form. Under the line at the left side shall be clearly printed the words "Dispense As Written". Under the line at the right side shall be clearly printed the words "Substitution Permitted". The practitioner shall communicate the instructions to the pharmacist by signing on the appropriate line. No written prescription is valid without the signature of the practitioner on one of these lines.

(4) An oral prescription from the practitioner shall instruct the pharmacist as to whether or not an equivalent drug product may be substituted. The pharmacist shall note the instructions on the file copy of the prescription and retain the prescription form for the period as prescribed by law.

(5) The pharmacist shall note the brand name or the manufacturer of the substituted drug dispensed on the file copy of a written or oral prescription or record this information electronically, or both. If a pharmacist substitutes a generic drug for a name brand prescribed drug when dispensing a prescribed medication, the brand name and the generic name of the drug and its manufacturer, with an explanation of "generic for" or similar language to indicate substitution has occurred, must appear on the prescription label and be affixed to the container or an auxiliary label, unless the prescribing practitioner indicated that the name of the drug may not appear upon the prescription label.

(6) Substitution may not occur unless the pharmacist advises the patient or the patient's agent that the practitioner has authorized substitution and the patient, or patient's agent, consents. A Medicaid recipient whose prescription is reimbursed by the South Carolina Medicaid Program is deemed to have consented to the substitution of a less costly equivalent generic drug product.

(I)(1) All drugs dispensed for use by inpatients of a hospital or other health care facility, where the drug is not in the possession of the ultimate user prior to administration, shall meet these requirements:

(a) The label of a single unit package of an individual-dose or unit-dose system of packaging of drugs shall include:

(i) the nonproprietary or proprietary name of the drug;

(ii) the route of administration, if other than oral;

(iii) the strength and volume, where appropriate, expressed in the metric system whenever possible;

(iv) the control number and expiration date;

(v) special storage conditions, if required.

(b) A log book must be maintained identifying the repackager, the name of the drug, the lot number, the manufacturer, the facility control number, the expiration date, the quantity, and the initials of the pharmacist.

(c) When a multiple-dose drug distribution system is utilized, including dispensing of single-unit packages, the drugs must be dispensed in a container to which is affixed a label containing the:

(i) patient's name;

(ii) date of dispensing;

(iii) nonproprietary or proprietary name of the drug dispensed, or both; and

(iv) strength, expressed in the metric system whenever possible.

(2) All drugs dispensed to inpatients for self-administration shall be labeled in accordance with item (4).

(3) If any drugs are added to parenteral solutions, these admixtures shall bear a distinctive label indicating:

(a) name of solution and volume of solution;

(b) patient's name;

(c) infusion rate;

(d) bottle sequence number or other system control method;

(e) name and quantity of each additive;

(f) date of preparation;

(g) beyond-use date and time of parenteral admixture;

(h) ancillary precaution labels; and

(i) identity of preparer and checking pharmacist.

(4) All drugs dispensed to ambulatory or outpatients shall contain a label affixed to the container in which the drug is dispensed including:

(a) the name and address of the pharmacy dispensing the drug;

(b) the name of the patient for whom the drug is prescribed;

(c) the name of the prescribing practitioner;

(d) such directions as may be stated on the prescription drug order;

(e) the date of dispensing;

(f) any cautions which may be required by federal or state law;

(g) the serial number of the prescription drug order;

(h) the name or initials of the dispensing pharmacist;

(i) the proprietary or generic name of the drug dispensed and its strength, if more than one strength of the drug is marketed;

(j) the brand name of the drug product dispensed or the generic name of the drug product dispensed and its manufacturer or labeler, either written in full or appropriately abbreviated;

(k) when dispensing a prescribed medication, if a pharmacist selects an equivalent drug product for a name-brand prescribed drug, the generic drug name must either be listed on the prescription label first followed by the name-brand prescribed drug, or this information must be affixed to the container on an auxiliary label.

(5) Drugs other than sample medication provided by a manufacturer to a prescriber for patient

use shall meet all requirements of labeling.

(6) No radiopharmaceutical may be dispensed unless a label is affixed to the immediate container bearing:

- (a) the standard radiation symbol;
- (b) the words "Caution--Radioactive Material"; and
- (c) the prescription number.

(7) No radiopharmaceutical may be dispensed unless a label is affixed to the outer or delivery container bearing the:

- (a) standard radiation symbol;
- (b) words "Caution--Radioactive Material";
- (c) radionuclide and chemical form;
- (d) activity and date and time of assay;
- (e) volume if in liquid form;
- (f) requested activity and the calibrated activity;
- (g) prescription number;
- (h) patient name or space for patient name. Where the patient's name is not available at the time of dispensing, a seventy-two hour exemption is allowed to obtain the name of the patient. No later than seventy-two hours after dispensing the radiopharmaceutical, the patient's name shall become a part of the prescription drug order to be retained for two years;
- (i) name and address of the nuclear pharmacy;
- (j) name of the practitioner; and
- (k) lot number of the prescription.

(8) A package prepared by a pharmacist containing two or more drugs prescribed for a specific

patient shall meet USP labeling requirements.

(J)(1) A pharmacy patient record system must be maintained by all pharmacies for patients for whom prescription drug orders are dispensed. The pharmacy patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing. The pharmacist shall make a reasonable effort to obtain, record, and maintain the:

(a) full name of the patient for whom the drug is intended;

(b) address and telephone number of the patient;

(c) patient's age or date of birth;

(d) patient's gender;

(e) list of all prescription drug orders obtained by the patient at the pharmacy during the two years immediately preceding the most recent entry showing the prescription number, name, and strength of the drug, the quantity and date received, the number of refills given, the date of each refill, the identity and quantity of each refill if different from the prescribed quantity, the identity of dispensing pharmacist and the name of the practitioner; and

(f) pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(2) The pharmacist shall make a reasonable effort to obtain information from the patient or the patient's agent regarding any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other drugs, including over-the-counter drugs, or devices currently being used by the patient which may relate to prospective drug review. This information shall be recorded in the patient's record.

(3) A pharmacy patient record must be maintained for a period of not less than two years from the date of the last entry in the profile record. This record may be a hard copy or a computerized form.

(K) A pharmacist shall review the pharmacy patient record and each prescription drug order presented for dispensing for purposes of promoting therapeutic appropriateness by identifying:

(1) over-utilization or under-utilization;

- (2) therapeutic duplication;
- (3) drug-disease contraindications;
- (4) drug-drug interactions;
- (5) incorrect drug dosage or duration of drug treatment;
- (6) drug-allergy interactions;
- (7) clinical abuse/misuse.

Upon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the problem which shall, as appropriate, include consultation with the practitioner.

(L)(1) Upon receipt of a prescription drug order for a new medication and following review of the patient's pharmacy record, the pharmacist shall personally offer counseling to the patient or the patient's agent. Using his best professional judgment, the pharmacist's counseling shall include a discussion of those matters that the pharmacist considers appropriate for the patient or patient's agent in that particular situation.

The discussion must be in person, whenever practicable, or by telephone and shall include appropriate elements of patient counseling. The elements may include:

- (a) the name and description of the drug;
- (b) the dosage form, dose, route of administration, and duration of drug therapy;
- (c) intended use of the drug and expected action;
- (d) special directions and precautions for preparation, administration, and use by the patient;
- (e) potentially serious side effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
- (f) techniques for self-monitoring drug therapy;
- (g) proper storage;
- (h) prescription refill information;

(i) action to be taken in the event of a missed dose; and

(j) pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(2) Alternative forms of patient information may be used to supplement patient counseling when appropriate including, but not limited to, written information leaflets, pictogram labels, or video programs.

(3) Patient counseling is not required for inpatients or emergency department patients of a hospital or institution where other licensed health care professionals are authorized to administer the drug.

(4) A pharmacist is not required to counsel a patient or caregiver when the patient or caregiver refuses the consultation.

(M) Significant adverse drug reactions must be reported to the prescriber immediately upon discovery. Appropriate entry on the patient's record also must be made.

(N) Records of dispensing, which are readily retrievable within twenty-four hours, for all drugs or devices are to be made and kept by pharmacies for two years and shall include, but are not limited to:

(1) quantity dispensed for original and refills, if different from original;

(2) date of dispensing;

(3) serial number or equivalent if an institution;

(4) the identification of the pharmacist responsible for dispensing;

(5) name and manufacturer of drug dispensed if drug product selection occurs; and

(6) records of refills to date.

(O)(1) An up-to-date policy and procedure manual must be maintained by the pharmacist-in-charge that explains the operational aspects of an automated system and shall:

(a) include examples of all required output documentation provided by the automated system;

(b) outline steps to be followed when the automated system is not operational due to scheduled or unscheduled system interruption;

(c) outline regular and routine backup file procedure and file maintenance;

(d) outline audit procedures, personnel code assignments, and personnel responsibilities;

(e) provide a quality assurance mechanism for data entry validation.

(2) The automated system shall have the capability of producing sight-readable information on all original and refill prescription drug orders. The term "sight-readable" means that an authorized individual must be able to examine the record and read the information from the cathode ray tube (CRT), microfiche, microfilm, printout, or other method acceptable to the Board of Pharmacy.

The automated system shall provide on-line retrieval (via CRT display or hard-copy printout) of original prescription drug order information. The information shall include, but is not limited to, the prescription drug order requirements and records of dispensing.

The automated system shall have the capability of producing a printout of any prescription drug order data. The system shall provide a refill-by-refill audit trail for any specified strength and dosage form of any drug. The audit trail must be by printout and shall include the name of the prescribing practitioner, name and location of the patient, quantity dispensed on each refill, date of dispensing of each refill, name or identification code of the dispensing pharmacist, and unique identifier of the prescription drug order.

A facility maintaining centralized prescription records must be capable of sending a requested printout to the pharmacy within seventy-two hours.

(3) To maintain the confidentiality of patient records, the system shall have adequate security and systems safeguards to prevent unauthorized access, modification, or manipulation of pharmacy patient records. Once the drug has been dispensed, any alterations in prescription drug order data must be documented including the identification of the pharmacist responsible for the alteration.

(4) In the event of an unscheduled system interruption, sufficient patient data and prescription drug order data must be available to permit reconstruction of such data within a two-hour time period for the pharmacist to dispense drugs with sound professional judgment.

An auxiliary system shall be established for the documentation of refills if the automated data processing system is inoperative for any reason and to ensure that all refills are authorized by the original prescription drug order and that the maximum number of refills is not exceeded.

The auxiliary system shall be in place to provide for the maintenance of all necessary patient drug information until the automated system becomes operational. However, nothing in this subsection shall preclude the pharmacist from using professional judgment for the benefit of a patient's health and safety.

When the automated system is restored to operation, the information regarding prescription drug orders dispensed and refilled during the inoperative period must be entered into the automated system.

Routine backup systems and procedures (hard copy, copy, disc, etc.) must be in place and operational to ensure against loss of patient data.

In the event that permanent dispensing information is lost due to unscheduled system interruption, the Board of Pharmacy must be notified within seventy-two hours of the loss or of the discovery of the loss.

(P) If a pharmacist receives a request for a prescription refill and the pharmacist is unable to obtain refill authorization from the prescriber, the pharmacist may dispense a one-time emergency refill of up to a seventy-two hour supply of the prescribed medication if:

- (1) the prescription is not for a controlled substance;
- (2) the medication is essential to the maintenance of life or to the continuation of therapy;
- (3) in the pharmacist's professional judgment, continuing the therapy for seventy-two hours will produce no undesirable health consequences or cause physical or mental discomfort;
- (4) the pharmacist properly records the dispensing; and
- (5) the dispensing pharmacist notifies the prescriber of the emergency dispensing within seventy-two hours after the one-time emergency refill dispensing.

(Q) Machines used in the prescription drug distribution process must be under the control of and are the responsibility of a licensed pharmacist.

Drugs brought into an institutional facility by a patient may not be administered unless they can

be identified. If such drugs cannot be administered, then according to pharmacy procedures specified in writing, the drugs must be turned into the pharmacy which shall package and seal them and return them to an adult member of the patient's immediate family, or store and return them to the patient upon discharge.

Investigational drugs which are used within an institutional facility must be stored in and dispensed from the pharmacy only.

All information with respect to investigational drugs must be maintained in the pharmacy.

All drug storage areas must be routinely inspected by pharmacy personnel to ensure that no outdated or unusable items are present, and that all stock items are properly labeled and stored.

A written stop-order policy or other system must be established by the institutional pharmacists-in-charge to ensure that drug orders are not inappropriately continued.

There must be a written policy and procedure for providing pharmacy services in the event of a disaster. This shall be reviewed annually by all pharmacy staff members and so documented.

(R)(1) It is unlawful for a person, except a pharmacist licensed under this chapter and pursuant to the regulations of the board of pharmacy to:

(a) take, use, or exhibit the title "pharmacist", "druggist", "pharmacy", "drugstore", "drugs", "prescriptions", or any other title, sign, display, or declaration that tends to lead the public to believe that the person is engaged in the business of selling, compounding, or dispensing any prescription drugs; or

(b) have charge of, engage in, or carry on, for himself or another, the dispensing, compounding, or sale of any prescription drugs anywhere within this State.

(2) Except as prescribed by this chapter, it is unlawful for a person to practice as a pharmacist or to advertise or represent himself by a title, sign, display, declaration, or other item to be a pharmacist or to engage in, conduct, carry on, or be employed in the dispensing, compounding, or retailing of any prescription drugs within this State.

(3) Notwithstanding any other provision of law or regulation, pharmacies and apothecaries are permitted to advertise the retail price of all drugs sold by prescription.

(4) Those merchants selling varieties of health and beauty needs, including that class of personal care products and nonprescription drugs which do not require a prescription for sale at retail,

may use and display the term "drug-sundries" in advertising, if these conditions are met:

- (a) the word "drug-sundries" is a hyphenated word;
- (b) the word "drug-sundries" must appear all on one line;
- (c) the two parts of the word must be of equal size lettering, of the same color, and the same style print or script; and
- (d) no effort may be made to mislead the public that there is a full drug and prescription service available.

(5) Nothing in this section authorizes the board to promulgate regulations concerning the prices of goods or drugs sold by outlets, the hours that the business may be operated, or the hours of work of the employees of the businesses.

(S) Licensed pharmacists may sell pharmaceutical agents, other than controlled substances as defined in Section 44-53-110, to optometrists who are diagnostically certified by the South Carolina Board of Examiners in Optometry for diagnostic purposes in the practice of optometry in accordance with Section 40-37-105(A). For these purposes, "pharmaceutical agent" means anesthetics, mydriatics, cyclopegics, miotics, dyes, and over-the-counter drugs.

Licensed pharmacists may sell pharmaceutical agents, other than Schedule I and Schedule II controlled substances as defined in Section 44-53-110, to optometrists who are therapeutically certified by the South Carolina Board of Examiners in Optometry for diagnostic and therapeutic purposes in the practice of optometry in accordance with Section 40-37-105(B).

(T) Duties that must be performed by a licensed pharmacist or a pharmacy intern or extern within the practice of pharmacy, to exclude Home Medical Equipment providers, include, but are not limited to:

- (1) the interpretation and evaluation of medical orders;
- (2) participation in drug and device selection;
- (3) provision of patient counseling;
- (4) performing drug regimen reviews;
- (5) provision of pharmacy care; and

(6) receiving telephone or verbal medical orders from licensed practitioners.

A licensed pharmacist shall supervise the activities of a pharmacy technician to ensure all activities are performed completely, safely, and without risk of harm to patients.

(U) Nonprescription drugs may be sold by any retailer in their original, unbroken prepackaged containers and no rule or regulation shall be adopted by the Board of Pharmacy which shall require the sale of nonprescription drugs by a licensed pharmacist or in a pharmacy. However, nonprescription drugs may also be dispensed and profiled by pharmacists pursuant to a practitioner's prescription, and when dispensed in this manner by a pharmacist, the drug must be treated in all respects as a prescription drug and all prescription drug counseling and labeling requirements shall apply.

(V) A manufacturer or wholesaler shall supply insulin only to persons or entities that can legally possess prescription drugs.

(W) The American Pharmaceutical Association Code of Ethics will be adopted as the code of ethics for pharmacists in this State.

(X)(1) Physicians who are in charge or who directly supervise the operation of emergency rooms may dispense legend drugs in order to meet the immediate needs of the patient. The amount dispensed may not exceed an amount equal to a seventy-two hour supply. Records of drugs dispensed must be maintained. A valid physician-patient relationship shall exist between the emergency room physician and the patient before dispensing legend drugs in the emergency room.

(2) Physicians who are in charge of or who directly supervise the operation of college and university athletics department training rooms may dispense in the training room prescription drugs owned by the facility in order to meet the needs of the student-athletes participating in athletic department activities or programs. College and university athletic departments are exempt from Section 40-43-83, as it relates to the Board of Pharmacy and the requirement that each pharmacy must have a pharmacist-in-charge. Records of drugs dispensed must be maintained and properly accounted for by the athletic department physician. A valid physician-patient relationship must exist between the athletics department physician and the student-athlete before dispensing prescription drugs in the athletics department training room. Drugs dispensed by the athletic department physician must be properly labeled in accordance with federal and state law.

(Y) It is unlawful for a person to deliver prescription drugs to any permitted facility, at any time

when the facility is not open for business, unless shipments are received by an authorized employee of the facility or into a secure area, or both.

(Z) A current record showing disposition of all restricted pharmaceutical preparations, such as federal legend drugs, exempt class V, insulin, controlled substances, poisons and any other drugs so designated by the board, dispensed or sold to physicians, dentists, veterinarians, pharmacies, hospitals, or other persons authorized by law to possess drugs restricted to sale on prescription only, must be maintained for two years in the prescription files or in the records of the permitted facility showing the name of the person to whom dispensed or sold, the name, strength, and quantity dispensed or sold, and the date of the transaction.

Every pharmacist or other person selling nonlegend poison must be satisfied that the purchase is made for legitimate purposes and keep a book on file in which must be recorded every sale of the following articles: arsenic and its preparations, all metallic cyanides and cyanides of potassium, tartar emetic, corrosive sublimate, aconite and alkaloids, and their salts, and hydrocyanic acid. The record shall exhibit the name of the person to whom the poison was sold and the purpose of purchase stated. The book or file must be kept at all times subject to inspection of the coroner of the county and the solicitor or inspector of the Board of Pharmacy or any other person as either of them may designate.

These above-named poisons, and oxalic acid, chloroform, or any other poisonous articles that may be added to the list by the board, must be securely labeled "Poison" when sold in the permitted facility.

Nothing in this section may be construed to apply to the filling of prescriptions written by physicians.

(AA) No pharmacist or permit holder shall reuse, sell, or offer for sale a prescription or other medication intended for internal or external use which has been returned unless the pharmacist accepting the medication determines in his best professional judgment that the strength, potency, and stability of the medication have not been adversely affected or contaminated.

(BB) Applicants and licensees must pay fees for new and renewed permits, licenses, registrations, and certifications. Fees shall be established and adjusted, as provided by Section 40-1-50. Among other things provided in this chapter, fees may be established by regulation and assessed for a:

(1) new pharmacy permit for renewal;

(2) new nondispensing drug outlet permit or permit renewal;

(3) new medical gases or legend devices drug outlet permit or permit renewal;

(4) new nonresident pharmacy permit or permit renewal;

(5) new out-of-state wholesale distributor permit or permit renewal;

(6) relocation permit within the same city;

(7) six-year intern certificate;

(8) application for complete licensure examination;

(9) application for licensure by score transfer;

(10) application for licensure by licensure transfer;

(11) pharmacist's license or license renewal; and

(12) pharmacy technician registration or registration renewal.

(CC)(1) The provisions of this subsection only apply to the compounding of medication by pharmacies permitted in the State of South Carolina.

(2) The following are the minimum current good compounding practices for the preparation of medications by pharmacists licensed in the State for dispensing or administering, or both, to humans or animals:

(a) Pharmacists engaged in the compounding of drugs shall operate in conformance with applicable laws regulating the practice of pharmacy;

(b) Based on the existence of a pharmacist/patient/practitioner relationship and the presentation of a valid prescription, or in anticipation of prescription medication orders based on routine, regularly observed prescribing patterns, pharmacists may compound, for an individual patient medications that are commercially available in the market place;

(c) Pharmacists shall receive, store, or use drug substances for compounding that meet official compendia requirements, or of a chemical grade in one of the following categories: chemically pure (CP), analytical reagent (AR), American Chemical Society (ACS), or, if other than this, drug substances that meet the accepted standard of the practice of pharmacy;

(d) Pharmacists may compound drugs before receiving a valid prescription based on a history of receiving valid prescriptions that have been generated solely within an established pharmacist/patient/practitioner relationship, for all such products compounded at the pharmacy as required by the Board of Pharmacy;

(e) Pharmacists may not offer compounded medications to other pharmacies for resale; however, pharmacists may compound products based on an order from a practitioner for use by practitioners for patient use in institutional or office settings. Compounding pharmacies/pharmacists may advertise or otherwise promote the fact that they provide prescription compounding services, e.g., chemicals, devices, and information, when requested; however, they may not solicit business by promoting to compound specific drug products, e.g., like a manufacturer;

(f) The compounding of drugs in anticipation of receiving prescriptions without a historical basis or the distribution of compounded products without a patient/practitioner/pharmacist relationship is considered manufacturing.

(3) Pharmacists engaging in compounding shall maintain proficiency through current awareness and training. Continuing education shall include training in the art and science of compounding and the rules and regulations of compounding.

Pharmacy technicians may assist the pharmacist in compounding. The pharmacist is responsible for training and monitoring the pharmacy technician. The pharmacy technician's duties must be consistent with the training received.

Personnel engaged in the compounding of medications shall wear clean clothing appropriate to the operation being performed. Protective apparel, such as coats, jackets, aprons, gowns, hand or arm coverings, or masks must be worn as necessary to protect personnel from chemical exposure and medication or chemical contamination.

Only personnel authorized by the responsible pharmacist may be in the immediate vicinity of the drug compounding operation. A person shown at any time, either by medical examination or pharmacist determination, to have an apparent illness or open lesions that may adversely affect the safety or quality of a drug product being compounded must be excluded from direct contact with components, medication containers, closures, in-process materials, and medication products until the condition is corrected or determined by competent medical personnel not to jeopardize the safety or quality of the products being compounded. All personnel who assist the pharmacists in compounding procedures must be instructed to report to the pharmacist any health conditions that may have an adverse effect on drug products.

(4) Pharmacists engaging in compounding shall have a specifically designated and adequate area (space) for the orderly compounding of prescriptions that is maintained in a good state of repair for the placement of material and equipment. Sterile compounding must be performed in a separate area in compliance with Section 40-43-88.

Bulk medications and other chemicals or materials used in the compounding of medication must be stored in adequately labeled containers in a clean, dry, and temperature-controlled area or, if required, under proper refrigeration.

Adequate lighting and ventilation must be provided in all drug compounding areas. Potable water must be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to a compounded drug product. Adequate washing facilities, easily accessible to the compounding areas of the pharmacy, must be provided. These facilities shall include, but are not limited to, hot and cold water, soap or detergent, and air-dryers or single-use towels.

The area used for the compounding of drugs must be maintained in a clean and sanitary condition. It must be free of infestation by insects, rodents, and other vermin. Trash must be held and disposed of in a timely and sanitary manner. Sewage and other refuse in and from the pharmacy and immediate medication compounding areas must be disposed of in a safe and sanitary manner.

If sterile products are being compounded, the pharmacist shall comply with Section 40-43-88 as applicable to the procedure.

If radiopharmaceuticals are being compounded, the pharmacist shall comply with Section 40-43-87 as applicable to the procedure.

If drug products with special precautions for contamination, such as penicillin, are involved in a compounding procedure, appropriate measures, including either the dedication of equipment or meticulous cleaning of contaminated equipment before its use for the preparation of other drugs, must be utilized in order to prevent cross-contamination.

(5) Equipment and utensils used for compounding must be of appropriate design and capacity and stored in a manner to protect from contamination. In addition, all equipment and utensils must be cleaned and sanitized before use to prevent contamination that would alter the safety or quality of the drug product beyond that desired. The pharmacist is responsible for determining suitability for use. In the case of sterile compounding, the pharmacist shall comply with Section 40-43-88 as applicable to equipment and utensils.

Automatic, mechanical, electronic, or other equipment used in compounding must be routinely inspected, calibrated, if necessary, or checked to ensure proper performance.

The pharmacist shall ensure that the proper container is selected to dispense the finished compounded prescription, whether sterile or nonsterile.

(6) The pharmacist shall ensure that there are formulas and logs maintained either electronically or manually. Formulas must be comprehensive and include ingredients, amounts, methodology, and equipment, if needed, and special information regarding sterile compounding.

The pharmacist shall ensure that components used in compounding are accurately weighed, measured, or subdivided as appropriate at each stage of the compounding procedure to conform to the formula being prepared. Any chemical transferred to a container from the original container must be labeled with the same information as on the original container and the date of transfer placed on the label.

The pharmacist shall establish and conduct procedures so as to monitor the output of compounded prescriptions, i.e., capsule weight variation, adequacy of mixing, clarity, pH of solutions, and, where appropriate, procedures to prevent microbial contamination of medications purported to be sterile.

(7) The pharmacist shall label any excess compounded product so as to reference it to the formula used and the assigned control number and the estimated beyond-use date based on the pharmacist's professional judgment, appropriate testing, or published data. The product must be stored appropriately.

At the completion of compounding the prescription, the pharmacist shall examine the prescription for correct labeling.

(8) The pharmacist shall keep records of all compounded products for a period of time as other prescriptions as required by the Board of Pharmacy. These records must be readily available for authorized inspection during the retention period at the establishment. These records are subject to duplication by photocopying or other means of reproduction as part of the inspection.

(DD) Unprofessional conduct includes, but is not limited to, the following acts by a pharmacist, permit holder, pharmacy technician, or the owner of a permitted facility:

(1) publishing or circulating false, misleading, or otherwise deceptive statements concerning the practice of pharmacy;

(2) attempting to circumvent the patient counseling requirements, or discouraging the patient from receiving patient counseling concerning their prescription drug orders;

(3) divulging or revealing to unauthorized persons patient information or the nature of professional pharmacy services rendered without the patient's express consent, or without order or direction of a court. Authorized persons include:

(a) a patient, or patient's agent, or another pharmacist acting on behalf of a patient;

(b) the practitioner who issued the prescription drug order;

(c) certified/licensed health care personnel who are responsible for the care of the patient;

(d) an inspector, agent, or investigator of the Board of Pharmacy or any federal, state, county, or municipal officer whose duty is to enforce the laws of this State or the United States relating to drugs or devices and who is engaged in a specific investigation involving a designated person or drug;

(e) an agency of government charged with the responsibility of providing medical care for the patient upon written request by an authorized representative of the agency requesting the information;

(4) selling, giving away, or otherwise disposing of accessories, chemicals, or drugs or devices found in illegal drug traffic when the pharmacist knows or should have known of their intended use in illegal activities;

(5) engaging in conduct likely to deceive, defraud, or harm the public, or demonstrating a wilful or careless disregard for the health, welfare, or safety of a patient, or engaging in conduct which substantially departs from the standards of care ordinarily exercised by a pharmacist;

(6) selling a drug for which a prescription drug order from a practitioner is required without having received a prescription drug order for the drug;

(7) wilfully and knowingly failing to maintain complete and accurate records of all drugs received, dispensed, or disposed of in compliance with the federal laws and regulations and state laws and regulations;

(8) obtaining any remuneration by fraud, misrepresentation, or deception;

(9) using a system providing for the electronic transfer of information that infringes on a patient's freedom of choice as to the provider of pharmacy care.

(EE) Except as provided in subsection (S), it is unlawful for a person to possess, dispense, or distribute in this State, except on a prescription of a licensed practitioner, any drug or device, as defined in Section 39-23-20, bearing on its manufacturer's or distributor's original commercial container the legend, "Caution: Federal law prohibits dispensing without prescription", "Rx Only", "Caution: Federal law restricts this drug to use by, or on the order of, a licensed veterinarian", or "Caution: Federal law restricts device for sale by or on the order of a _____".

A person who violates this subsection is guilty of a misdemeanor and, upon conviction, must be fined not more than five hundred dollars or imprisoned not more than two years, or both.

(FF) The Department of Health and Environmental Control is exempt from the provisions of this section that prohibit a pharmacist from serving as a pharmacist-in-charge unless he is physically present in the pharmacy and that prohibits a pharmacist from serving as a pharmacist-in-charge for more than one pharmacy at a time, so that one pharmacist-in-charge may be designated by the department to serve more than one health district.

HISTORY: 1998 Act No. 366, Section 1; 1999 Act No. 76, Sections 6 to 12; 2000 Act No. 340, Sections 4, 9 and 10; 2002 Act No. 314, Sections 5, 6, 7; 2002 Act No. 356, Section 1, Part II.H(3); 2004 Act No. 251, Section 1; 2005 Act No. 18, Section 1; 2007 Act No. 49, Section 3.B; 2008 Act No. 353, Section 2, Part 4.A.

SECTION 40-43-87. Nuclear/radiologic pharmacy practice; regulations set by Nuclear Regulatory Commission; revocation of materials license; inspections; hearings regarding violations of state or federal law; space and equipment requirements.

(A) Nuclear/radiologic pharmacy practice refers to a patient-oriented service that embodies the scientific knowledge and professional judgment required to improve and promote health through the assurance of the safe and efficacious use of radiopharmaceuticals and other drugs. Nuclear/radiologic pharmacies also shall adhere to the regulations established by the Nuclear Regulatory Commission as they pertain to the practice of nuclear pharmacy.

The pharmacist-in-charge of a nuclear pharmacy must be a qualified nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radiopharmaceuticals and ancillary drugs must be under the direct supervision of a qualified nuclear pharmacist.

(B) Revocation of the radioactive materials license from the Department of Health and

Environmental Control voids the pharmacy permit immediately and the permit must be returned to the board within ten days.

(C) Copies of all regulatory inspection reports must be made available upon request for board inspection.

(D) The nuclear pharmacist-in-charge shall notify the Board of Pharmacy by letter of the outcome of any hearings that are conducted pursuant to citations for violations of state or federal laws or regulations governing radioactive materials. Notification must be within thirty days of the date of the hearing.

(E) Space and equipment must be adequate to the scope of services required and provided. All nuclear pharmacy facilities shall have a radiopharmaceutical preparations/dispensing area, a radioactive material shipping/receiving area, and a radioactive waste decay area. Airflow hoods must be certified annually for operational efficiency in accordance with federal standards by a qualified technician and must be recertified each time the hood is moved. Certification must be attached to the front of the hood and shall state the date certification was granted. Prefilters must be changed in accordance with manufacturer's specifications. Changes must be documented by date and initials. Documentation must be retained for two years.

(F) For purposes of this section, "qualified nuclear pharmacist" means a pharmacist who holds a current license issued by the South Carolina Board of Pharmacy, and who is either certified as a nuclear pharmacist by the Board of Pharmaceutical Specialties, or meets minimal standards of training for status as an authorized user of radioactive material, as specified by the Nuclear Regulatory Commission.

HISTORY: 1998 Act No. 366, Section 1.

SECTION 40-43-88. Standards for preparation, labeling, and distribution of sterile products by pharmacies.

(A) The purpose of this section is to provide standards for the preparation, labeling, and distribution of sterile products by pharmacies, pursuant to or in anticipation of a prescription drug order for a patient in home health care.

(B) The pharmacy shall have a separate area designated for placement of the Class 100 laminar airflow hood, which must:

(1) be constructed so as to allow visual observation;

(2) not be a thruway for traffic;

(3) have walls, floor, ceiling, and work surfaces constructed of materials that are nonporous and do not produce particulate matter;

(4) be ventilated in a manner that will not interfere with the outward flow of air from the hood;

(5) not be used for unpacking bulk supplies;

(6) not be used for storage of bulk supplies and materials; and

(7) have an eye wash station and sink readily accessible to the area.

(C)(1) All sterile pharmaceuticals must be prepared within the airflow hood work surface.

(2) Work surfaces of the airflow hood must be cleaned with seventy percent isopropyl alcohol or an equivalent disinfectant every eight-hour work shift and as needed for microbial, drug, and particulate matter removal. This cleaning must be documented by date, time, and initials. Documentation must be retained for two years.

(3) The airflow hood must be certified by a qualified technician every twelve months and must be recertified each time the hood is moved for operational efficiency in accordance with federal standards. The certification must be attached to the front of the hood and shall state the date the certification was performed. Certification documents must be retained for two years.

(4) The sterile product preparation area must be cleaned and disinfected weekly with appropriate agents according to written policy and procedures. This must be documented by date and initials and retained for two years.

(5) Prefilters must be changed in accordance with manufacturer's specifications. Changes must be documented by date and initials and documentation must be retained for two years.

(6) Work surfaces inside the airflow hood must be clear of drugs, records, labels, and equipment unrelated to work in process.

(7) All solutions, additive and nonadditive, must be checked by a pharmacist before dispensing. The checking pharmacist's initials must appear on either the prescription or medical order, the patient's profile, a compounding record, or label. Only one system must be used. Initials may be computer produced or stamped for solutions containing noncontrolled additives.

(8) Sterile pharmaceuticals returned by an outpatient or the outpatient's agent must be destroyed. Supplies and equipment designed by the manufacturer for one time use may not be reused. Returned sterile pharmaceuticals containing controlled substances must be destroyed in accordance with federal and state requirements.

(9) A sink with hot and cold running water readily accessible to the sterile products preparation area with immediate availability of germicidal skin cleanser and either a warm air blower or nonshedding single-use towels for hand drying must be available to all personnel preparing sterile pharmaceuticals.

(10) Adverse drug reactions sustained by patients must be documented in the patient's profile. Significant untoward reactions must be reported to the Food and Drug Administration and the manufacturer.

(D)(1) Compounding shall involve aseptic manipulations that are properly and promptly executed.

(2) Closed system transfers must be used in compounding sterile pharmaceuticals, except for initial withdrawals from ampules.

(a) All container closures shall remain intact throughout the aseptic process, except for the penetration of sterile, pyrogen-free, and particulate matter-free needles or cannulas through the designated stopper or port.

(b) Ancillary devices used to facilitate the transfer, withdrawal, or delivery of sterile solutions must be sterile, free of pyrogen and particulate matter, and used in accordance with the manufacturer's labeled instructions.

(3) Compounded sterile pharmaceuticals must be stored immediately according to published and professional guidelines.

(4) Administration must be initiated in accordance with stability standards.

(5) If products are prepared from nonsterile ingredients, these products must be appropriately sterilized before dispensing.

(E) In addition to reference books currently required in a pharmacy, at least one current reference on compatibility and stability of sterile pharmaceuticals must be available.

(F) All sterile pharmaceuticals prepared for dispensing shall have an adhesive label affixed

which shall contain the following:

- (1) name, address, and telephone number of pharmacy for outpatients and name of facility for inpatients;
 - (2) if additive, the date solution was prepared. Nonadditive solutions must be dated if the manufacturer's protective cover is removed before dispensing;
 - (3) name of physician;
 - (4) name of patient;
 - (5) room number and bed of patient, if applicable;
 - (6) serial number of prescription or other identifying number;
 - (7) if additive solution, the name and amount of additive. If additives are identified by their generic name, the manufacturer must be identified on either the prescription, the patient's profile, or compounding record;
 - (8) name of basic solution;
 - (9) name or initials of individual preparing sterile pharmaceutical on either the prescription or medical order, the patient's profile, compounding record, or label. For solutions containing noncontrolled additives, the initials may be imprinted;
 - (10) expiration date and, if applicable, the expiration time of the solution in accordance with the manufacturer's specifications or research-supported standard of practice;
 - (11) frequency and rate of administration;
 - (12) precautionary statements, auxiliary labels, or warning labels in keeping with current standards or practice;
 - (13) special handling or storage requirements, or both;
- (G) There must be a system for a pharmacist to be available twenty-four hours a day for a patient, nursing agency, or physician to which the pharmacy is providing services.
- (H) A profile or medical record must be maintained for each patient. This profile must be

maintained for two years after the last dispensing activity. It shall contain at a minimum:

(1) patient's name, address, telephone number and, if applicable, the patient's bed or room number;

(2) age or date of birth, weight, height, and sex of patient;

(3) identity of the health care agency, if applicable;

(4) itemization of sterile pharmaceuticals dispensed with prescription number or other identifying number, including date dispensed and the name and amount of additives;

(5) drug and food allergies;

(6) primary diagnosis;

(7) prescription and nonprescription drugs and home remedies the patient is receiving; and

(8) documentation by a pharmacist of the resolution of other potential drug related problems.

(I)(1) All cytotoxic solutions must be compounded in a Class II, biological safety cabinet. No other products may be compounded in this cabinet.

(2) Protective apparel must be worn by personnel compounding cytotoxic agents including gloves, closed front gowns with tight cuffs, and masks. Written procedures for handling spills of cytotoxic agents must be developed.

(3) There must be immediate access to emergency spill supplies wherever cytotoxic drugs are prepared.

(4) Prepared solutions must be identified with warning labels in accordance with state and federal requirements.

(5) Prepared solutions must be packaged for handling and delivery in a manner that minimizes the risk of rupture of the primary container and ensures the stability and potency of the solution.

(6) Documentation that personnel have been trained in the compounding, handling, and destruction of cytotoxic agents must be available. This documentation must be obtained annually.

(7) Documentation that personnel have been informed of the carcinogenic, mutagenic, and teratogenic nature of the cytotoxic agents handled must be available. This documentation must be updated annually by all personnel.

(8) Class II safety cabinets must be certified by a qualified technician every twelve months and must be recertified each time the hood is moved for operational efficiency. Earlier recertification may be required if dictated by federal or state requirements or manufacturer's specifications due to workload.

(J) All waste materials must be disposed of in accordance with federal, state, and local requirements.

(K) A policy and procedure manual must be available in the pharmacy. The manual shall include policies and procedures as applicable for the following:

(1) quality control;

(2) sterile technique;

(3) destruction of returned solutions;

(4) labeling of injectable solutions;

(5) drug recall procedures;

(6) investigational drugs;

(7) handling and disposal of hazardous waste;

(8) cytotoxic agents;

(9) maintenance of patient profiles; and

(10) material safety data sheets.

(L) When sterile pharmaceuticals are provided to home care patients, the dispensing pharmacy may supply a nurse with emergency drugs if a physician has authorized the use of these drugs by a protocol or prescription drug order for use in an emergency situation, e.g., anaphylactic shock.

(M) A licensed health care professional may possess noncontrolled prescribed legend drugs or

devices such as water for injection, normal saline for IV, and heparin flush used in the administration of sterile pharmaceuticals.

(N) If appropriate, the pharmacist shall demonstrate or document the patient's training and competency in managing therapy provided by the pharmacist to the patient in the home environment. A pharmacist must be involved in the patient training process in any area that relates to drug compounding, labeling, administration, storage, stability, compatibility, or disposal. The pharmacist is responsible for seeing that the patient's competency in the above areas is reassessed on an ongoing basis.

(O) There must be a documented, ongoing, quality assurance control program that monitors patient care and pharmacy care outcomes, including but not limited to:

(1) routine performance of prospective drug use review and patient monitoring functions by a pharmacist;

(2) patient-monitoring plans that include written outcome measures and systems for routine patient assessment including, but not limited to, infection rates, rehospitalization rates, and the incidence of adverse drug reactions;

(3) documentation of patient training as specified in subsection (N);

(4) appropriate collaboration with other health care professionals.

HISTORY: 1998 Act No. 366, Section 1.

SECTION 40-43-89. Wholesale distributor permits and renewals; required information; changes; forms; personnel and facility requirements; recordkeeping; disposal of outdated, damaged, impure, or unsealed drugs; adherence to policies and procedures; inspections and audits; application of federal, state, and local laws; mail order prescription services; grounds for denial or suspension of permit.

(A)(1) The following information must be provided to the board with an application for a wholesale distributor permit, and for any subsequent permit renewals:

(a) name, full business address, and telephone number of the applicant;

(b) all trade or business names used by the applicant;

(c) addresses, telephone numbers, and the names of contact persons for the facility used by the

applicant for storage, handling, and distribution of drugs;

(d) the type of ownership or operation, i.e., partnership, corporation, or sole proprietorship; and

(e) name of the owner and/or operator of the applicant, including:

(i) if a person, the name, address, and social security number or date of birth, or both, of the person;

(ii) if a partnership, the name, address, and social security number or date of birth, or both, of each partner, and the name of the partnership;

(iii) if a corporation, the name, address, social security number or date of birth, or both, and title of each corporate officer and director, the corporate names, the name of the state of incorporation, and the name of the parent company, if any; the name, address, and social security number of each shareholder owning ten percent or more of the voting stock of the corporation, including over-the-counter stock, unless the stock is traded on a major stock exchange and not over-the-counter;

(iv) if a sole proprietorship, the full name, address, and social security number or date of birth, or both, of the sole proprietor and the name of the business entity.

(2) Changes in any information in this subsection must be submitted to the Board of Pharmacy within thirty days of the change.

(3) Pursuant to Section 40-43-83(E) and Section 40-43-90, the information required for initial permitting or renewal of a permit of a wholesale distributor must be submitted on forms prepared by the Board of Pharmacy or by the National Association of Boards of Pharmacy which shall act as a clearinghouse of applications for the board and must be submitted to the board or NABP accompanied by the applicable fee.

(4) The board may suspend, revoke, deny, or refuse to renew the permit of wholesale drug distributors other than pharmacies dispensing or distributing drugs or devices directly to patients.

(B) The licensed wholesale distributor shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in the wholesale distribution of drugs.

(C) All facilities where drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(1) be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(2) have storage areas big enough to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened;

(4) be maintained in a clean and orderly condition; and

(5) be free from infestation by insects, rodents, birds, or vermin of any kind.

(D)(1) All facilities used for wholesale drug distribution must be secure from unauthorized entry, access from outside the premises must be kept to a minimum and well controlled, the outside perimeter of the premises must be well lighted, and entry into areas where prescription drugs are held must be limited to authorized personnel.

(2) All facilities must be equipped with an alarm system to detect entry after hours.

(3) All facilities must be equipped with a security system that provides suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(E) All drugs must be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium.

If no storage requirements are established for a drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

Temperature and humidity must be automatically documented by electronic recording devices.

The recordkeeping requirements in subsection (I) must be followed for all stored drugs.

(F) Upon receipt, each outside shipping container must be visually examined for identity and to prevent the acceptance of contaminated drugs or drugs that are otherwise unfit for distribution. This examination must be adequate to reveal container damage that would suggest possible

contamination or other damage to the contents.

Each outgoing shipment must be carefully inspected for identity of the drug products and to ensure that there is no delivery of drugs that has been damaged in storage or held under improper conditions.

The recordkeeping requirements in subsection (I) must be complied with for all incoming and outgoing drugs.

(G)(1) Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be quarantined and physically separated from other drugs until they are destroyed or returned to their supplier.

(2) A drug whose immediate or sealed outer or sealed secondary containers have been opened or used must be identified as such and must be quarantined and physically separated from other drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the drug must be destroyed or returned to the supplier unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(4) The recordkeeping requirements in subsection (I) must be complied with for all outdated, damaged, deteriorated, misbranded, or adulterated drugs.

(H)(1) Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs. These records shall include:

(a) the source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

(b) the identity and quantity of the drugs received and distributed or disposed of; and

(c) the dates of receipt and distribution or other disposition of the drugs.

(2) Inventories and records must be made available for inspection and photocopying by any authorized official of any governmental agency charged with enforcement of this chapter for a period of two years following disposition of the drugs.

(3) Records described in this subsection that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means must be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable must be available for inspection within two working days of a request by an authorized official of any governmental agency charged with enforcement of this chapter.

(I) Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures which shall be followed for the receipt, security, storage, inventory, and distribution of drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies and procedures:

(1) a procedure whereby the oldest approved stock of a drug product is distributed first. The procedure may permit deviation from this requirement if such deviation is temporary and appropriate;

(2) a procedure to be followed for handling recalls and withdrawals of drugs. The procedure must be adequate to deal with recalls and withdrawals due to:

(a) any action initiated at the request of the Food and Drug Administration or other federal, state, or local law enforcement or other government agency, including the Board of Pharmacy;

(b) any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(c) any action undertaken to promote public health and safety by the replacing of existing merchandise with an improved product or new package design;

(3) a procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of a strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency;

(4) a procedure to ensure that outdated drugs are segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated drugs which must be maintained for two years after disposition of the

outdated drugs.

(J) Wholesale distributors shall establish and maintain a current list of officers, directors, managers, and other individuals in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

(K) Wholesale distributors shall permit the Board of Pharmacy and authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

Wholesale distributors that deal in controlled substances shall register with the appropriate state-controlled substance authority and with the Drug Enforcement Administration, and shall comply with all applicable state, local, and DEA requirements.

(L) Wholesale distributors are subject to the provisions of any applicable federal, state, or local laws or regulations that relate to drug product salvaging or reprocessing.

(M) This chapter may not be construed to prevent licensed pharmacists from filling, as otherwise provided by law, prescriptions originating outside the boundaries of this State and official United States government prescriptions issued by authorized governmental officials.

(N)(1) A facility located outside this State, whose primary business is mail order prescription service, shall have a permit issued by the board to ship, mail, or deliver a controlled substance or dangerous drug or device into this State pursuant to a prescription of a licensed practitioner. The facility shall report to the board:

(a) information on the location, names, and titles of all principal corporate officers and pharmacists who are dispensing controlled substances or dangerous drugs or devices to residents of this State. The report must be updated annually and within thirty days of a change of permit holder or pharmacist-in-charge;

(b) that it complies with the applicable laws for operation in the state in which it is located and with the provisions of this section. The facility shall have a valid unexpired license, permit, or registration in compliance with the laws of the state in which it is located and must be constantly under the personal and immediate supervision of a licensed pharmacist. The facility shall submit to the board with its initial application and with each renewal application a copy of its most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located. These inspections are deemed to meet all inspection requirements contained in this chapter;

(c) that it maintains its records of controlled substances or dangerous drugs or devices dispensed to patients in this State so that the records are readily retrievable.

(2) Nothing in this chapter requires that pharmacists employed by facilities located in other states and who are not engaged in the practice of pharmacy in this State be licensed in this State.

(3) If the state in which the facility is located does not establish, by statute or regulation, a ratio describing the number of auxiliary personnel that a pharmacist may supervise, or otherwise define the role of the pharmacist in the compounding and dispensing of prescription drugs, then that facility may not allow a pharmacist to supervise more than two pharmacy technicians at any time in the compounding and dispensing of prescription drugs.

(4) A pharmacy, as described in this section, during its regular hours of operation but not less than six days or forty hours a week, shall provide a toll-free telephone service to facilitate communication between patients in this State and a pharmacist at the pharmacy who has access to their records. This telephone number must be printed on a label affixed to the container for the substance, drug, or device.

(5) The board may deny, revoke, suspend, or otherwise take action against a facility permit issued under the provisions of this section for:

(a) failure to comply with the requirements of:

(i) this section;

(ii) portions of this chapter dealing with prescription drug orders, drug product selection, labeling, patient records, drug review, drug dispensing, patient counseling, emergency refills, and advertisements;

(iii) subchapter 1, Chapter 13, Title 21 (Federal Controlled Substance Act);

(iv) Chapter 2, Title 21 of the Code of Federal Regulations (Federal Controlled Substance Regulation);

(b) conduct which causes serious bodily or serious psychological injury to a resident of this State if the board has referred the matter to the regulatory or licensing agency under which the pharmacy operates in the state in which it is located and that agency fails to initiate an investigation within forty-five days of the referral. The board shall maintain a record of referrals pursuant to this item and action taken on them.

(6) A facility required to obtain a permit pursuant to this subsection but which has not been issued a permit, may not advertise its services in this State, and a resident of this State may not advertise the services for the facility.

(7) A permit issued pursuant to this section is not evidence that the pharmacy is doing business within this State.

(8) A permit issued pursuant to this section is not evidence that the pharmacy is doing business within this State.

HISTORY: 1998 Act No. 366, Section 1; 2002 Act No. 314, Section 8.

SECTION 40-43-90. Permit requirements for applicants; permits not transferrable or assignable.

(A) To obtain a permit, an applicant shall:

(1) submit an application in the form prescribed by the Board of Pharmacy at least forty-five days before the opening date of the facility;

(2) pass an inspection conducted by inspectors of the Board of Pharmacy or a pharmacist designee; and

(3) pay all required fees.

(B) Each facility shall apply individually and obtain a separate permit for each location.

(C) A permit issued by the board pursuant to this chapter is not transferable or assignable and expires annually on June thirtieth.

(D) A permit renewal application, including the required fee, must be submitted to the board before June first. If not postmarked before June first, a penalty of fifty dollars must be assessed. For permits not renewed by the expiration date, the board may charge an additional ten dollars a day until the permit is reinstated. A permit which has not been renewed before July first is a lapsed permit. A permit holder who allows a site to operate with a lapsed permit is in violation of Section 40-43-83.

(E) Upon the occurrence of any of the following, an existing permit is void and a new permit must be applied for:

(1) change of ownership:

(a) any change of ownership in the case of a sole proprietorship;

(b) a gain or loss of a partner in the case of a partnership;

(c) a change of ownership of fifty percent or more of stock in the case of a corporation;

(2) change of name; or

(3) change of location from one city to another.

HISTORY: 1998 Act No. 366, Section 1; 2002 Act No. 314, Section 9.

SECTION 40-43-91. Reports to Board of Pharmacy regarding thefts, convictions, changes in ownership or pharmacy employment, disasters, and accidents; return of permit; penalty for failure to comply.

(A) A permit holder shall report to the Board of Pharmacy within thirty working days of the discovery of the occurrence of:

(1) theft or loss of drugs or devices; or

(2) conviction of any employee of any state or federal drug law.

(B) All permit holders shall report to the Board of Pharmacy within ten working days of the discovery of the occurrence of any of the following:

(1) permanent closing;

(2) change of ownership, management, location, consultant pharmacists, or pharmacist-in-charge of a pharmacy;

(3) change in employment of pharmacists or pharmacy technicians within a pharmacy permitted by the board;

(4) disasters, accidents, destruction, or loss of records required to be maintained by state or federal law.

(C) Upon permanent closing a permittee shall return the permit to the board within thirty days.

(D) The board may assess a civil penalty of not more than one hundred dollars upon any individual who fails to comply with the rules as provided in this section.

(E) Any currently licensed pharmacist or pharmacy technician who changes his mailing address must notify the board in writing within ten days listing his name, license or registration number, and new mailing address.

(F) When a licensed pharmacist in the employ of or in charge of the pharmacy duties of a permitted facility within this State leaves the employ of or ceases to have charge of the pharmacy duties of the permitted facility, he shall notify the board in writing within ten days of the change, giving the name and address of the permitted facility at which he was last employed. When a licensed pharmacist or registered pharmacy technician within this State makes any change in employment from one permitted facility to another, he shall notify the board of the change within ten days, listing the name and address of the permitted facility at which he was last employed and of the facility to which he expects to move.

HISTORY: 1998 Act No. 366, Section 1; 2002 Act No. 314, Section 10.

SECTION 40-43-110. License expiration; license renewals; lapsed licenses.

(A) A license issued by the board pursuant to this chapter expires annually on April thirtieth.

(B) A pharmacist who wishes to renew his license in an active status must submit a renewal application to the board. If mailed, the board must receive the application before April first, including all required fees, data, and certification of acceptable continuing education. If not postmarked before April first, a penalty of fifty dollars must be assessed.

(C) A pharmacist who wishes to renew his license in an inactive status must submit a renewal application to the board. If mailed, the board must receive the application before April first, including all required fees and data; however, no continuing education is required. If not postmarked before April first a penalty of fifty dollars must be assessed. The license certificate must be prominently marked as an inactive license, and the holder may not practice pharmacy under any conditions in this or any state based on the South Carolina license. If the pharmacist wishes to reactivate the license, he shall complete the required continuing education for license renewal, plus an additional fifteen hours which must have been obtained during the calendar year immediately preceding the date of the reactivation application.

(D) A license which has not been renewed before May first is a lapsed license. A person who practices pharmacy with a license that has lapsed is practicing without a license. Reinstatement

of a lapsed license must be granted upon evidence satisfactory to the board, subject to disciplinary actions for the failure to renew the license within the prescribed period, and payment of the renewal fee and a penalty of fifty dollars and any other required penalty.

(E) A pharmacist whose license has lapsed for three years or less may reinstate his license by applying to the board, submitting proof of completion of fifteen hours of acceptable continuing education for each year the license has been lapsed, and paying the renewal fee and any applicable penalty.

(F) A pharmacist whose license has lapsed for more than three years and who has been actively practicing pharmacy in another state may reinstate his license by applying to the board, submitting evidence of at least one thousand hours of out-of-state employment in the practice of pharmacy within the last three years, official verification of a current license in another state, proof of completion of sixty hours of acceptable continuing education, and paying the renewal fee and any applicable penalty.

(G) A pharmacist whose license has lapsed for more than three years and who has not been actively practicing pharmacy in another state may reinstate his license by applying to the board, demonstrating to the board evidence of at least one thousand hours of practice under the on-site supervision of a pharmacist licensed in this State, successfully passing the Multistate Pharmacy Jurisprudence Examination, submitting proof of completion of sixty hours of acceptable continuing education, and paying the renewal fee and any applicable penalty.

(H) An assistant pharmacist currently licensed has all the rights and privileges of a licensed pharmacist.

(I) The board may not issue temporary licenses.

HISTORY: 1998 Act No. 366, Section 1; 2002 Act No. 314, Section 11.

SECTION 40-43-130. Continuing education; topics; hours; carry over of hours; exemption period following examination; certificate of completion; authority to grant exemption for postgraduate degree work.

(A) Topics and formats of study for continuing education shall include subject matter designed to maintain the professional competence of pharmacists licensed to practice and to improve their professional skills in order to protect the public health and safety.

(B) Each licensed pharmacist, as a condition of an active status license renewal, shall complete fifteen hours (1.5 CEU's) of American Council on Pharmaceutical Education (ACPE) accredited

continuing pharmacy education or continuing medical education (CME), Category I, or both, each license year. Of the fifteen hours, a minimum of six hours must be obtained through attendance at lectures, seminars, or workshops. At least fifty percent of the total number of hours required must be in drug therapy or patient management.

(C) All hours completed in any license year in excess of the requirement may be carried forward for credit in the next license year but may not be carried forward for more than one license year.

(D) Upon licensure in this State by examination or by license transfer, pharmacists are exempt from continuing education requirements for the first renewal period.

(E) A statement certifying completion of the required continuing education must be submitted as a part of the annual license renewal application, and no renewal of an active license may be issued without the certification. The board shall conduct an audit of continuing education credits of ten percent of the licensees, randomly selected, of the total number of active pharmacists.

(F) An exemption may be granted by the board for pharmacists enrolled in an approved pharmacy postgraduate degree program. Application must be made to the board and a current official transcript must be submitted to the board.

(G)(1) As a condition of registration renewal, a registered pharmacy technician shall complete ten hours of American Council on Pharmaceutical Education or CME I approved continuing education each year, beginning with the next renewal period after June 30, 2003. A minimum of four hours of the total hours must be obtained through attendance at lectures, seminars, or workshops.

(2) Topics and formats of study for continuing education must include subject matter designed to maintain the professional competence of pharmacy technicians registered with the board and to improve their professional skills in order to protect the public health and safety.

(3) Certification of completion of the required continuing education must be made on the annual registration renewal application, and no renewal may be issued without this certification. The board shall conduct an audit of continuing education credits of ten percent, randomly selected, of the total number of pharmacy technicians renewing.

(4) All hours completed in any registration year in excess of the requirements may be carried forward for credit in the next registration year but may not be carried forward for more than one registration year.

HISTORY: 1998 Act No. 366, Section 1; 2000 Act No. 340, Section 5; 2002 Act No. 314,

Section 12.

SECTION 40-43-140. Grounds for suspension, revocation, denial, or refusal of board to renew permit or imposition of disciplinary action; penalties for persons distributing or delivering drugs or devices not in accordance with this chapter.

(A)(1) The board may suspend, revoke, deny, or refuse to renew the permit of a permittee or impose disciplinary action authorized by this chapter for:

(a) violations of any of the provisions of this chapter or any regulations promulgated pursuant to this chapter;

(b) retaining as an employee a person who wilfully or habitually violates any of the state or federal laws applicable to a permitted facility or its operation.

(2) A person who distributes or delivers drugs or devices to a person not permitted in accordance with this chapter is subject to a fine to be imposed by the board not to exceed one thousand dollars for each offense in addition to such other disciplinary action the board may take under this chapter. Each violation constitutes a misdemeanor punishable by a fine not to exceed five thousand dollars or imprisonment not to exceed one year, or both.

(3) Facilities requiring permits may not operate unless a permit has been issued by the board.

(4) Except where otherwise allowed by law, it is unlawful for a manufacturer or a wholesale distributor to distribute or deliver drugs or devices to any person in this State not permitted under this chapter.

(a) conviction for a violation of any federal, state, or local law relating to the practice of pharmacy, drug samples, wholesale or retail drug or device distribution, or illegal use of or distribution of controlled substances;

(b) the furnishing of false or fraudulent material in any application made in connection with drug or device manufacturing or distribution;

(c) suspension or revocation by federal, state, or local government of any permit or license currently or previously held by the applicant for the manufacture or distribution of any drugs or devices, including controlled substances;

(d) obtaining remuneration by fraud, misrepresentation, or deception;

(e) dealing with drugs or devices that they know or should have known are stolen drugs or devices.

HISTORY: 1998 Act No. 366, Section 1.

SECTION 40-43-150. Procedures for investigations, hearings, injunctive actions, and disciplinary actions; voluntary surrender of license; appeal.

(A) Investigations and hearings must be conducted in accordance with the provisions of Section 40-1-80.

(B) Restraining orders and cease and desist orders shall be issued in accordance with the provisions of Section 40-1-100.

(C) Upon determination by the board that one or more of the grounds for disciplining a licensee or permittee exists, as provided for in Section 40-1-110, the board may, in addition to the actions provided for in Section 40-1-120, impose a fine not to exceed an amount set by the board in regulation.

(D) A licensee or permittee who is under investigation for any of the grounds provided for in Section 40-1-110 for which the board may take disciplinary action must voluntarily surrender his license or permit to the board in accordance with Section 40-1-150.

(E) A person aggrieved by an action of the board may seek review of the decision in accordance with Section 40-1-160.

HISTORY: 1998 Act No. 366, Section 1; 2000 Act No. 340, Section 6.

SECTION 40-43-160. Unlawful practice of pharmacy following hearing; fine; penalty.

(A) An individual who, after a hearing, shall be found by the board to have unlawfully engaged in the practice of pharmacy is subject to a fine to be imposed by the board not to exceed an amount set by the board in regulation for each offense.

(B) Each violation of this chapter or the regulations promulgated under this chapter pertaining to unlawfully engaging in the practice of pharmacy shall also constitute a misdemeanor and, upon conviction, is punishable as provided in Section 40-1-210.

HISTORY: 1998 Act No. 366, Section 1.

SECTION 40-43-170. State of Emergency; prerequisites to emergency refills; dispensing of medications by pharmacists not licensed in this State.

(A) When the Governor issues a "State of Emergency":

(1) A pharmacist may work in the affected county and may dispense a one-time emergency refill of up to a fifteen-day supply of a prescribed medication if:

(a) the pharmacist has all prescription information necessary in order to accurately refill the prescription and;

(b) in the pharmacist's professional opinion the medication is essential to the maintenance of life or to the continuation of therapy and;

(c) the pharmacist reduces the information to a written prescription marked "Emergency Refill", files the prescription as required by law and notifies the prescribing physician within fifteen days of the emergency refill and;

(d) the prescription is not for a controlled substance.

(2) A pharmacist not licensed in South Carolina but currently licensed in another state, may in a state of emergency dispense prescription medications in those affected counties without being licensed in South Carolina during the time that a state of emergency exists if:

(a) the pharmacist has some type of identification to verify current licensure in another state and;

(b) the pharmacist is engaged in a legitimate relief effort during an emergency situation.

(B) This disaster preparedness ends with the state of emergency.

HISTORY: 1998 Act No. 366, Section 1; 1999 Act No. 76, Section 13.

SECTION 40-43-180. Construction of chapter; third party payors not required to provide service or pay for services provided for in this chapter.

Nothing in this chapter may be construed to require a health maintenance organization, a self-funded plan, an accident and health insurer, or any other third party payor to provide services or to pay for services provided for in this chapter.

HISTORY: 1998 Act No. 366, Section 1.

SECTION 40-43-190. Protocol for pharmacists to administer influenza vaccines and certain medications without order of practitioner; informed consent; records.

(A)(1) The Board of Medical Examiners shall issue a written protocol for the administration of influenza vaccines by pharmacists without an order of a practitioner. The administration of influenza vaccines as authorized in this section must not be to persons under the age of eighteen years.

(2) The written protocol must further authorize pharmacists to administer without an order of a practitioner those medications necessary in the treatment of adverse events. These medications must be used only in the treatment of adverse events and must be limited to those delineated within the written protocol.

(3) The written protocol must be issued no later than January 1, 2011.

(B) The written protocol must provide that:

(1) A pharmacist seeking authorization to administer influenza vaccines as authorized in this section shall successfully complete a course of training accredited by the Accreditation Council for Pharmacy Education or a similar health authority or professional body approved by the Board of Pharmacy and the Board of Medical Examiners. Training must comply with current Centers for Disease Control guidelines and must include study materials, hands-on training, and techniques for administering influenza vaccines and must provide instruction and experiential training in the following content areas:

(a) mechanisms of action for influenza vaccines, contraindications, drug interactions, and monitoring after vaccine administration;

(b) standards for adult immunization practices;

(c) basic immunology and vaccine protection;

(d) vaccine-preventable diseases;

(e) recommended immunization schedules;

(f) vaccine storage management;

(g) biohazard waste disposal and sterile techniques;

- (h) informed consent;
- (i) physiology and techniques for vaccine administration;
- (j) prevaccine and postvaccine assessment and counseling;
- (k) immunization record management;
- (l) management of adverse events, including identification, appropriate response, emergency procedures, documentation, and reporting;
- (m) understanding of vaccine coverage by federal, state, and local entities;
- (n) needle stick management.

(2) A pharmacist administering an influenza vaccine without an order of a practitioner pursuant to this section shall:

- (a) obtain the signed written consent of the person being vaccinated or that person's guardian;
- (b) maintain a copy of the vaccine administration in that person's record and provide a copy to the person or the person's guardian;
- (c) notify that person's designated physician or primary care provider of any influenza vaccine administered;
- (d) report administration of an influenza vaccine to any statewide immunization registry established by the Department of Health and Environmental Control as the department may require;
- (e) maintain a current copy of the written protocol at each location at which a pharmacist administers an influenza vaccine pursuant to this section.

(3) A pharmacist may not delegate the administration of influenza vaccines to a pharmacy technician as defined in Section 40-43-30 or any other person who is not a pharmacist.

(4) A pharmacist administering influenza vaccines shall, as part of the current continuing education requirements pursuant to Section 40-43-130, complete no less than one hour of continuing education each license year regarding administration of influenza vaccines.

(C) Informed consent must be documented in accordance with the written protocol for influenza vaccine administration issued pursuant to this section.

(D) All records required by this section must be maintained in the pharmacy for a period of at least six years.

HISTORY: 2010 Act No. 224, Section 1, eff July 1, 2010.

SECTION 40-43-200. Joint Pharmacist Administered Influenza Vaccines Committee; meetings, quorum, and chairperson; duties of committee.

(A) There is created a Joint Pharmacist Administered Influenza Vaccines Committee as a committee to the Board of Medical Examiners which consists of seven members with experience regarding influenza vaccines. The committee is comprised of two physicians selected by the Board of Medical Examiners, two pharmacists selected by the Board of Pharmacy, and two advanced practice nurse practitioners selected by the Board of Nursing. One member of the Department of Health and Environmental Control designated by the commissioner of the department also shall serve on the committee. Members of the committee may not be compensated for their service on the board and may not receive mileage, per diem, and subsistence as otherwise authorized by law for members of state boards, committees, and commissions.

(B) The committee shall meet at least once annually and at other times as may be necessary. Five members constitute a quorum for all meetings. At its initial meeting, and at the beginning of each year thereafter, the committee shall elect from its membership a chairperson to serve for a one year term.

(C) The committee shall assist and advise the Board of Medical Examiners in establishing a written protocol for the purpose of authorizing pharmacists to administer influenza vaccines without an order of a practitioner as authorized by Section 40-43-190 and shall provide a suggested written protocol to the board no later than four months after the passage of this act.

Frequently Asked Questions

Can a registered pharmacist be a consultant pharmacist at more than one location?

Yes, a registered pharmacist can be a consultant pharmacist at more than one location. According to §40-43-86(C)(1) of the South Carolina Pharmacy Practice Act, "The consultant pharmacist must be consistent with the accepted standards of professional conduct and practice, and be responsible for compliance with all applicable laws and regulations including:" those specified under §40-43-86(C) and (D).

What are the requirements in the event of loss or theft of legend drugs or legend devices at a permitted facility?

According to § 40-43-91 (A) of the South Carolina Pharmacy Practice Act, " All permit holders shall report to the Board of Pharmacy within thirty working days of the discovery of the occurrence of:

- (1) theft or loss of drugs or devices
 - (2) conviction of any employee of any state or federal drug laws."
- § 40-43-86 (B)(3) states that "The pharmacist §in-charge shall have the following responsibilities:
- (d) making or filing any reports required by state or federal laws and regulations.

Any time your pharmacy or drug outlet experiences a loss or theft of legend drugs or legend devices, the Board of Pharmacy requires a written notification.

Section 147 of Regulation 61-4 (South Carolina Controlled Substances Regulations) requires that a loss or theft of controlled substances must be reported to the DHEC Division of Drug Control, on a DEA Form 106, not later than 30 days after the discovery of the loss or theft.

How much time must the pharmacist-in-charge actually work in the pharmacy?

According to §40-43-86(B) of the South Carolina Pharmacy Practice Act, "A pharmacist may not serve as pharmacist-in-charge unless he is physically present in the pharmacy a sufficient amount of time to provide supervision and control." Therefore, the pharmacist-in-charge must be in the pharmacy enough time to allow him/her to fulfill all of the requirements pertaining to the pharmacist-in-charge's duties as defined in §40-43-86 and be responsible for all professional duties connected with the proper and lawful conduct of the pharmacy. §40-43-30(40) defines a pharmacist-in-charge as "a pharmacist currently licensed in this State who accepts responsibility for the operation of a pharmacy in conformance with all laws pertinent to the practice of pharmacy and the distribution of drugs and who is in full and actual charge of the pharmacy and personnel."

What are the requirements on labels for prescriptions for brand name medications when substitution has been authorized and has occurred?

The prescription label shall contain the generic name of the drug and its manufacturer listed first, followed by the words 'substituted for' and the brand name prescribed drug. This information must be affixed to the container or an auxiliary label, unless the prescribing practitioner indicated that the name of the drug may not appear on the prescription label. §40-43-86(H)(5)

What are the requirements to close a pharmacy or drug outlet permanently?

According to §40-43-91(B) of the South Carolina Pharmacy Practice Act, "All permit holders shall report to the Board of Pharmacy within ten working days of the discovery of the occurrence of any of the following: (1) permanent closing"

(C) Upon permanent closing a permittee shall return the permit to the Board within thirty days.

§ 40-43-86 (B)(3) The pharmacist-in-charge shall have the following responsibilities: (c) notifying the Board of Pharmacy immediately of any of the following changes: (iv) permanent closing of the pharmacy.

All pharmacy signs and symbols must be removed; all drugs must be transferred, returned to vendors or disposed of properly prior to returning your permit. If you intend to close a pharmacy, please allow sufficient time to meet these requirements.

The South Carolina Controlled Substances Registration Certificate must be returned to the DHEC Division of Drug Control, along with a letter of explanation as to the transfer or disposal of the controlled substance inventory. The DEA Registration Certificate, along with any unused DEA 222 forms, must be returned to the Drug Enforcement Administration.

Whose responsibility is it to assure that all pharmacy interns and technicians wear proper identification?

According to §40-43-86 (B)(3) of the South Carolina Pharmacy Practice Act, "the pharmacist-in-charge shall have the following responsibilities:

(b) assuring that all pharmacists, technicians, and interns employed at the pharmacy are currently licensed, certified, or registered and that interns and technicians wear proper identification while on duty;"

Board inspectors will be monitoring these requirements while conducting site inspections.

What are the requirements for patient counseling?

Upon receipt of a prescription for a new medication and following review of the patients' pharmacy record, the pharmacist shall personally offer counseling to the patient or the patient's agent. If accepted, this discussion must be in person, whenever practicable, or by telephone and shall include appropriate elements of patient counseling. §40-43-86(L). As provided in §40-43-

86(T), under the direct supervision of a licensed pharmacist, pharmacy interns and extern may provide patient counseling.

Who is allowed to call in prescriptions to a pharmacy from a doctor's office?

Drug order may be directly transmitted orally or electronically from the practitioner or his "designated agent" to the pharmacy. The "designated agent" is a ". . . person employed by an authorized practitioner to transmit, either orally or electronically, a prescription drug order on behalf of the authorized practitioner to the pharmacist. The authorized practitioner accepts responsibility for the correct transmission of the prescription drug order." [Emphasis Added]
§40-43-30(11)