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Summary: Compounding pharmacies

**HISTORY OF LEGISLATIVE ACTIONS**

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12/15/2022 House Prefiled

12/15/2022 House Referred to Committee on **Medical, Military, Public and Municipal Affairs**

1/10/2023 House Introduced and read first time ([House Journal‑page 221](h:\hj\20230110.docx))

1/10/2023 House Referred to Committee on **Medical, Military, Public and Municipal Affairs** ([House Journal‑page 221](h:\hj\20230110.docx))

5/3/2023 House Committee report: Favorable with amendment **Medical, Military, Public and Municipal Affairs** ([House Journal‑page 58](h:\hj\20230503.docx))

5/4/2023 House Amended ([House Journal‑page 53](h:\hj\20230504.docx))

5/4/2023 House Read second time ([House Journal‑page 53](h:\hj\20230504.docx))

5/4/2023 House Roll call Yeas-101 Nays-0 ([House Journal‑page 54](h:\hj\20230504.docx))

5/4/2023 House Unanimous consent for third reading on next legislative day ([House Journal‑page 55](h:\hj\20230504.docx))

5/5/2023 House Read third time and sent to Senate ([House Journal‑page 4](h:\hj\20230505.docx))

5/9/2023 Senate Introduced and read first time ([Senate Journal‑page 9](h:\sj\20230509.docx))

5/9/2023 Senate Referred to Committee on **Medical Affairs** ([Senate Journal‑page 9](h:\sj\20230509.docx))

1/18/2024 Senate Committee report: Favorable with amendment **Medical Affairs** ([Senate Journal‑page 8](h:\sj\20240118.docx))

1/19/2024 Scrivener's error corrected

2/27/2024 Senate Committee Amendment Adopted ([Senate Journal‑page 18](h:\sj\20240227.docx))

2/27/2024 Senate Amended ([Senate Journal‑page 18](h:\sj\20240227.docx))

2/27/2024 Senate Read second time ([Senate Journal‑page 18](h:\sj\20240227.docx))

2/27/2024 Senate Roll call Ayes-43 Nays-0 ([Senate Journal‑page 18](h:\sj\20240227.docx))

2/28/2024 Senate Read third time and returned to House with amendments ([Senate Journal‑page 23](h:\sj\20240228.docx))

3/20/2024 House Concurred in Senate amendment and enrolled ([House Journal‑page 71](h:\hj\20240320.docx))

3/20/2024 House Roll call Yeas-109 Nays-0 ([House Journal‑page 71](h:\hj\20240320.docx))

5/8/2024 Ratified R 147

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**VERSIONS OF THIS BILL**

[12/15/2022](https://www.scstatehouse.gov/sess125_2023-2024/prever/3592_20221215.docx)

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**NOTE: THIS IS A TEMPORARY VERSION. THIS DOCUMENT WILL REMAIN IN THIS VERSION UNTIL FINAL APPROVAL BY THE LEGISLATIVE COUNCIL.**

(R147, H3592)

AN ACT TO AMEND THE SOUTH CAROLINA CODE OF LAWS BY AMENDING SECTION 40‑43‑30, RELATING TO DEFINITIONS IN THE PHARMACY PRACTICE ACT, SO AS TO REMOVE CERTAIN DEFINITIONS; BY AMENDING SECTION 40‑43‑86, RELATING TO COMPOUNDING OF MEDICATIONS BY PHARMACIES, SO AS TO REVISE REQUIREMENTS FOR COMPOUNDING PHARMACIES; BY AMENDING SECTION 40‑43‑87, RELATING TO NUCLEAR/RADIOLOGIC PHARMACY PRACTICES, SO AS TO REMOVE REQUIREMENTS CONCERNING NUCLEAR PHARMACY FACILITIES; BY AMENDING SECTION 40‑43‑88, RELATING TO STANDARDS FOR PREPARATION, LABELING, AND DISTRIBUTION OF STERILE PRODUCTS BY PHARMACIES, SO AS TO REMOVE CERTAIN STANDARDS; BY ADDING SECTION 40‑43‑197 SO AS TO PROVIDE PERSONS OR ENTITIES AUTHORIZED TO DISPENSE DRUGS MAY ACQUIRE CERTAIN DRUGS COMPOUNDED OR REPACKAGED BY AN OUTSOURCING FACILITY DIRECTLY FROM THE OUTSOURCING FACILITY WITHOUT AN ORDER AND MAY DISPENSE THE DRUGS TO THE SAME EXTENT AS AUTHORIZED FOR OTHER AUTHORIZED MEANS; AND TO PROVIDE THE BOARD OF PHARMACY MUST PROMULGATE CERTAIN RELATED REGULATIONS.

Be it enacted by the General Assembly of the State of South Carolina:

Definitions

SECTION 1. Section 40‑43‑30 of the S.C. Code is amended to read:

Section 40‑43‑30. 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) “Aseptic preparation” means the technique involving procedures designed to preclude contamination of drugs, packaging, equipment, or supplies by microorganisms during processing.

(3) “Biological product” has the same meaning as defined in 42 U.S.C. Section 262.

(4) “Board” or “Board of Pharmacy” means the State Board of Pharmacy.

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

(6) “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).

(7) “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.

(8) “Compounding” (sterile and nonsterile) 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 “nonsterile 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. The term “sterile compounding” does not include mixing, reconstituting, or other such acts with nonhazardous agents that are preformed in accordance with directions contained in approved labeling provided by the product’s manufacturer for immediate use.

(9) “Compounded sterile preparation” or “CSP” means a compounded biologic, diagnostic, drug, nutrient, or radiopharmaceutical that must be sterile when administered to a patient. Among other things, CSPs include:

(a) aqueous bronchial and nasal inhalations;

(b) baths and soaks for live organs and tissues;

(c) injections, such as colloidal dispersions, emulsions, solutions, suspensions, among others;

(d) irrigations for wounds and body cavities;

(e) ophthalmic drops and ointments; and

(f) tissue implants.

(10) “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 well‑being, and to other persons or governmental agencies authorized by law to receive such confidential information.

(11) “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.

(12) “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.

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

(14) “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.

(15) “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.

(16) “Distribute” means the delivery of a drug or device other than by administering or dispensing.

(17) “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 subitem (a), (b), or (c) of this subsection.

(18) “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.

(19) “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.

(20) “Enteral” means within or by way of the intestine.

(21) “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.

(22) “Expiration date” means the maximum time period that a manufactured, compounded, or repackaged product may be used based on specified storage requirements.

(23) “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.

(24) “Generic names” means the official compendia names or United States Adopted Names (USAN).

(25) “Hazardous drug” means a drug that has at least one of the following properties: carcinogenicity; teratogenicity or developmental toxicity; reproductive toxicity in humans; organ toxicity at low doses in humans or animals; genotoxicity; or new drugs that mimic existing hazardous drugs in structure or toxicity.

(26) “Health care provider” includes a pharmacist who provides health care services within the pharmacist’s scope of practice pursuant to state law and regulation.

(27) “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.

(28) “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.

(29) “Institutional consultant pharmacist” means a pharmacist licensed in this State who acts as a consultant for institutional facilities.

(30) “Interchangeable biological product” means a biological product that the federal Food and Drug Administration has:

(a) licensed and determined to meet the standards of “interchangeability” pursuant to 42 U.S.C. Section 262(k)(4); or

(b) determined to be therapeutically equivalent by the federal Food and Drug Administration.

(31) “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.

(32) “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.

(33) “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.

(34) “Manufacturer” means a person engaged in the manufacture of prescription drugs or devices.

(35) “Material safety data sheet” or “MSDS” means a resource that provides information concerning a chemical, including:

(a) the identity, physical and chemical characteristics, physical and health hazards, primary routes of entry, and exposure limits of the chemical;

(b) whether the chemical is a carcinogen;

(c) precautions for safe handling and use of the chemical;

(d) control measures;

(e) emergency and first aid procedures;

(f) the latter of the date the MSDS was prepared or last modified; and

(g) the name, address, and telephone number of the manufacturer, importer, or employer who distributes the MSDS.

(36) “Medical order” means a lawful order of a practitioner which may or may not include a prescription drug order.

(37) “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.

(38) “Nonresident pharmacy” means a pharmacy located outside this State.

(39) “Parenteral” means a sterile preparation of drugs for injection through one or more layers of the skin.

(40) “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.

(41) “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.

(42) “Person” means an individual, sole‑proprietorship, corporation, partnership, association, or any other legal entity including government.

(43) “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.

(44) “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.

(45) “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.

(46) “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.

(47) “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.

(48) “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”.

(49) “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.

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

(51) “Preparation” means a drug or nutrient compounded in a licensed pharmacy or licensed health care facility.

(52) “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 or compounded preparations 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.

(53) “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.

(54) “Product” means a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. A product is accompanied by FDA‑approved manufacturer labeling or a product package insert.

(55) “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.

(56) “Pyrogen” means a substance or agent that tends to cause a rise in body temperature or fever.

(57) “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.

(58) “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.

(59) “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.

Compounding pharmacy practices

SECTION 2. Section 40‑43‑86(CC) of the S.C. Code is amended to read:

(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 in facilities permitted by the Board of Pharmacy shall operate in conformance with regulations promulgated by the Board of Pharmacy, which shall be based upon a review of available compendia literature, medical or scientific literature, and/or practical experience in the art of compounding. The board shall:

(i) develop these regulations based on a review of available compendia literature, medical or scientific literature, and/or practical experience in the art of compounding; and

(ii) promulgate these regulations within eighteenth months after the effective date of this section.

(iii) Until regulations are promulgated by the Board of Pharmacy as provided in this subsubitem, compounding pharmacies shall comply with the compounding standards in the State in use on the effective date of this subsubitem as outlined in the Non‑Sterile Compounding Pharmacy and Sterile Compounding Pharmacy Inspection Forms in use on the effective date of this subsubitem as published by the Board of Pharmacy, unless the Pharmacy is held to a higher standard of another body such as an accrediting body.

(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 for which the components are commercially available.

(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) A compounder shall first attempt to use components manufactured in an FDA‑registered facility. When components cannot be obtained from an FDA‑registered facility, a compounder shall use his professional judgment in selecting an acceptable and reliable source and shall establish purity and safety by reasonable means, to include Certificate of Analysis, manufacturer reputation, and reliability of source.

(e) For components that do not have expiration dates assigned by the manufacturer or supplier, a compounder shall label the container with the date of receipt and assign a conservative expiration date, not to exceed three years after receipt of the component based on the nature of the component and its degradation mechanism, the container in which it is packaged, and the storage conditions.

(f) Pharmacists may not offer compounded medications to other pharmacies for resale; however, pharmacists may compound preparations based on an order from a practitioner for administration to a patient in institutional or office settings.

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

(h) Physicians who administer compounded medications in an office or licensed ambulatory surgical facility setting shall be allowed to order and purchase those medications from the compounding pharmacy, store them in the office for future use but not for resale, and administer those medications according to their usual physician/patient/pharmacy practice relationship. A prescription for an individual patient for each administration of the drug shall not be required.

(i) Institutional pharmacies may order and store compounded preparations, both sterile and nonsterile, from compounding pharmacies in anticipation of patient orders based on the existence of a pharmacist/patient/practitioner relationship for regularly observed prescribing patterns. A chart order from a practitioner will be required for administration in an institutional facility.

(3) 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. The pharmacist must perform the final check of the compounded preparation to determine if the preparation is ready to dispense.

(4)(a) 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.

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

(5) The pharmacist shall keep records of all compounded preparations 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. Additionally, statistical reports related to these prescription records may be required to be reported to the Board of Pharmacy periodically to enable the board to meet various statutory and regulatory requirements. These records are subject to duplication by photocopying or other means of reproduction as part of the inspection.

Nuclear/radiologic pharmacies

SECTION 3. Section 40‑43‑87 of the S.C. Code is amended to read:

Section 40‑43‑87. (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) 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.

Sterile preparations

SECTION 4. Section 40‑43‑88 of the S.C. Code is amended to read:

Section 40‑43‑88. (A) All sterile pharmaceuticals prepared for dispensing must be labeled in accordance with Section 40‑43‑86 and include:

(1) name, address, and telephone number of the pharmacy for outpatients and name of the facility for inpatients;

(2) dating of a nonadditive solution if the manufacturer’s protective cover, if applicable, is removed before dispensing;

(3) name of prescribing physician;

(4) room number and bed of patient, if applicable; and

(5) special handling, storage requirements, or both.

(B) Bulk or unformulated drug substances and added substances or excipients must be stored in tightly closed containers under temperature, humidity, and lighting conditions that are either indicated in official monographs or approved by suppliers. The date of receipt by the compounding facility must be clearly and indelibly marked on each package of ingredients. After receipt by the compounding facility, packages of ingredients that lack a supplier’s expiration date cannot be used after one year unless either appropriate inspection or testing indicates that the ingredient has retained its purity and quality for use in CSPs.

(C) 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, such as anaphylactic shock.

(D) A licensed health care professional may possess noncontrolled legend drugs or devices such as water for injection, normal saline for an IV, and heparin flushes to facilitate in the administration of prescribed CSPs.

(E) There must be a system that requires an institutional or home infusion pharmacist to be available twenty‑four hours a day for a patient, nursing agency, or physician to which the pharmacy is providing services.

Definition

SECTION 5. Section 40‑43‑30 of the S.C. Code is amended by adding:

(93) “Outsourcing facility” means a facility registered with the United States Food and Drug Administration to operate under Section 503B of the Federal Food and Cosmetic Act.

Authorized dispensation of drugs, outsourcing facilities

SECTION 6. Chapter 43, Title 40 of the S.C. Code is amended by adding:

Section 40‑43‑197. Any person or entity authorized to dispense drugs including, but not limited to, a pharmacy, institutional pharmacy, or practitioner, may:

(1) purchase or otherwise acquire drugs compounded or repackaged by an outsourcing facility directly from the outsourcing facility without an order from a practitioner other than, when applicable, the practitioner purchasing or acquiring the drug; and

(2) administer and dispense drugs purchased or acquired pursuant to item (1) to the same extent as drugs acquired through other authorized means.

Outsourcing facility regulations

SECTION 7. The Board of Pharmacy must promulgate regulations for outsourcing facilities as defined in Section 40‑43‑30. The board must:

(1) develop these regulations based on a review of available compendia literature, medical or scientific literature, and/or practical experience in the art of compounding; and

(2) promulgate these regulations within eighteen months after the effective date of this act.

Time effective

SECTION 8. This act takes effect upon approval by the Governor.

Ratified the 8th day of May, 2024.

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President of the Senate

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Speaker of the House of Representatives

Approved the \_\_\_\_\_\_\_\_\_\_\_\_\_ day of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_2024.

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Governor

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