**South Carolina General Assembly**

125th Session, 2023-2024

**H. 3592**

**STATUS INFORMATION**

General Bill

Sponsors: Reps. Hyde and Carter

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Introduced in the House on January 10, 2023

Introduced in the Senate on May 9, 2023

Last Amended on February 27, 2024

Currently residing in the House

Summary: Compounding pharmacies

**HISTORY OF LEGISLATIVE ACTIONS**

Date Body Action Description with journal page number

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))

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**VERSIONS OF THIS BILL**

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

[05/04/2023](https://www.scstatehouse.gov/sess125_2023-2024/prever/3592_20230504.docx)

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[02/27/2024](https://www.scstatehouse.gov/sess125_2023-2024/prever/3592_20240227.docx)

Indicates Matter Stricken

Indicates New Matter

Committee Amendment Adopted and Amended

February 27, 2024

H. 3592

Introduced by Reps. Hyde and Carter

S. Printed 02/27/24--S.

Read the first time May 09, 2023

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A bill

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; and 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.

Amend Title To Conform

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

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) “Ante area” means an ISO 8 or greater area where personnel perform hand hygiene, garbing, and stage components. An ante area precedes a buffer area, provided:

(a) a buffer area must be separated by a wall from an ante area if high‑risk preparations are compounded; and

(b) if only low‑risk and medium‑risk preparations are compounded, separating an ante room from a buffer area is recommended.

(3) “Aseptic preparation” means the technique involving procedures designed to preclude contamination of drugs, packaging, equipment, or supplies by microorganisms during processing.

(4) “Beyond‑use date” or “BUD” means the date or time after which a compounded preparation is recommended not to be dispensed or used. The date is determined from the date or time the preparation is compounded.

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

(6) “Biological safety cabinet” or “BSC” means a containment unit suitable for the preparation of agents where there is a need for protection of the preparation, personnel, and environment, according to National Sanitation Foundation Standard 49.

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

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

(9) “Buffer area” means an area where the primary engineering control is physically located. Activities that occur in this area include the preparation and staging of components and supplies used when compounding sterile preparations.

(106) “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).

(117) “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.

(12) “Class 100 environment” or “ISO 5” means an atmospheric environment which contains less than one hundred particles 0.5 microns in diameter per cubic foot of air.

(13) “Closed‑system transfer device” or “CSTD” means a closed‑system hazardous drug handling device comprising a number of interlocking parts for reconstituting, injecting, and administering doses of hazardous drugs.

(14) “Colony‑forming unit” or “CFU” means an estimate of cell quantity.

(158) “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.

(169) “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.

(17) “Compounding aseptic containment isolator” or “CACI” means a completely enclosed isolating cabinet that makes use of airtight glove ports designed to protect the user from exposure to airborne drugs and other agents during the compounding and material transfer processes. A CACI also provides an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur in a CACI unless the air is first passed through a HEPA minimum, microbial retentive filter system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where volatile hazardous drugs are prepared, the exhaust air from the isolator should be appropriately removed by properly designed building ventilation.

(18) “Compounding aseptic isolator” or “CAI” means a completely enclosed isolating cabinet that makes use of airtight glove ports designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer process. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a HEPA minimum, microbial retentive filter. A CAI is primarily used for nonhazardous drug preparations.

(1910) “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.

(20) “Critical site” means an opening that provides a direct pathway between a CSP and the environment or any surface coming in contact with the preparation or environment.

(2111) “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.

(2212) “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.

(2313) “Designated pharmacist” means an individual currently licensed by the Board of Pharmacy in this State who certifies internship training.

(2414) “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.

(25) “Disinfectant” means an agent that frees from infection, usually a chemical agent but sometimes a physical one, and that destroys disease‑causing pathogens or other harmful microorganisms but may not kill bacterial and fungal spores. It refers to substances applied to inanimate objects.

(2615) “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.

(2716) “Distribute” means the delivery of a drug or device other than by administering or dispensing.

(2817) “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.

(2918) “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.

(3019) “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.

(3120) “Enteral” means within or by way of the intestine.

(3221) “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.

(3322) “Expiration date” means the maximum time period that a manufactured, compounded, or repackaged product may be used based on specified storage requirements.

(3423) “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.

(35) “First air” means the air exiting the HEPA filter in a unidirectional airstream that is essentially particulate‑free.

(3624) “Generic names” mean the official compendia names or United States Adopted Names (USAN).

(37) “Glove fingertip test” means a test where the gloved fingertips and thumb are lightly pressed into appropriate agar plates. The plates are incubated for an appropriate time period and at an appropriate temperature.

(3825) “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.

(3926) “Health care provider” includes a pharmacist who provides health care services within the pharmacist's scope of practice pursuant to state law and regulation.

(40) “High‑efficiency particulate arrestor” or “HEPA” means a type of air filter that must satisfy certain efficiency standards set by the United States Department of Energy. A filter that qualifies as a HEPA is subject to interior classifications.

(4127) “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.

(4228) “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.

(4329) “Institutional consultant pharmacist” means a pharmacist licensed in this State who acts as a consultant for institutional facilities.

(4430) “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.

(4531) “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.

(46) “ISO” means the International Organization for Standardization.

(47) “ISO 5 environment” means an atmospheric environment that contains fewer than 3,520 particles no greater than 0.5 millimeters in diameter per cubic meter of air. The previous designation of this environment was known as Class 100.

(48) “ISO 7 environment” means an atmospheric environment that contains fewer than 352,000 particles no greater than 0.5 millimeters in diameter per cubic meter of air. The previous designation of this environment was known as Class 10,000.

(49) “ISO 8 environment” means an atmospheric environment that contains fewer than 3,520,000 particles no greater than 0.5 millimeters in diameter per cubic meter of air. The previous designation of this environment was known as Class 100,000.

(50) “Isolator” means a self‑contained primary engineering control defined by having fixed walls, a floor, and a ceiling, and includes barriers such as gloves, sleeves, and air locks that separate transfers of materials into and out of the environment. The use of an isolator can be an alternative to a buffer area for sterile preparations.

(5132) “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.

(52) “Laminar air flow workbench” or “LAFW” means a primary engineering control that uses an ISO 5 controlled environment created by a HEPA filter to retain airborne particles and microorganisms, and has horizontal air flow or vertical air flow.

(5333) “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.

(5434) “Manufacturer” means a person engaged in the manufacture of prescription drugs or devices.

(5535) “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.

(56) “Media‑fill test” means a test to evaluate the aseptic technique of:

(a) compounding personnel; and

(b) a process to ensure that the process used can produce sterile preparation that has no microbial contamination.

(5736) “Medical order” means a lawful order of a practitioner which may or may not include a prescription drug order.

(58) “Negative pressure” means a room or device that is at a lower pressure than adjacent space; the air flow moves into the room or device.

(5937) “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.

(6038) “Nonresident pharmacy” means a pharmacy located outside this State.

(6139) “Parenteral” means a sterile preparation of drugs for injection through one or more layers of the skin.

(6240) “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.

(6341) “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.

(6442) “Person” means an individual, sole‑proprietorship, corporation, partnership, association, or any other legal entity including government.

(65) “Personal protective equipment” or “PPE” means a gown, glove, mask, hair cover, shoe cover, eye shield, and similar items intended to protect the compounder from hazards and minimize particle shedding.

(6643) “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.

(6744) “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.

(6845) “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.

(6946) “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.

(7047) “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.

(7148) “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”.

(72) “Positive pressure” means a room or device with higher pressure than adjacent space so that air flow moves out of, rather than into, the room or device.

(7349) “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.

(7450) “Practitioner” means a physician, dentist, optometrist, podiatrist, veterinarian, or other health care provider authorized by law to diagnose and prescribe drugs and devices.

(7551) “Preparation” means a drug or nutrient compounded in a licensed pharmacy or licensed health care facility.

(7652) “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.

(7753) “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.

(78) “Primary engineering control” or “PEC” means a device, such as a laminar airflow workbench or an isolator, or a room that provides an ISO 5 environment.

(79) “Process verification and validation” means the process:

(a) used to evaluate whether a preparation, service, or system meets specifications and fulfills its intended purpose; and

(b) of establishing evidence that provides a high degree of assurance that a preparation, service, or system accomplishes its intended requirements.

(8054) “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.

(8155) “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.

(8256) “Pyrogen” means a substance or agent that tends to cause a rise in body temperature or fever.

(8357) “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.

(84) “Secondary engineering control” means a buffer area and an ante area that meet the designated ISO classification.

(85) “Segregated compounding area for compounding sterile product preparations” means a designated space:

(a) confined to a room or a demarcated area;

(b) restricted to preparing low‑risk CSPs with a twelve hour or less beyond‑use time;

(c) containing a device that provides unidirectional air flow of ISO 5 air quality;

(d) free of materials extraneous to sterile compounding; and

(e) not used for other activities or purposes.

(86) “Significant adverse drug reaction” means a drug‑related incident that may result in serious harm, injury, or death to the patient.

(87) “Sterile pharmaceutical” means a dosage form devoid of viable microorganisms.

(88) “Sterility test” means a process designed to determine the presence of bacteria or fungi in or on a test device or solution.

(8958) “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.

(90) “Velocity” means the displacement air flow across the line of demarcation between a buffer area into the ante area in a single room.

(9159) “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.

(92) “Zone of turbulence” means the pattern of flow of air from the HEPA filter created behind an object placed within the LAFW pulling or allowing contaminated room air into the aseptic environment.

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 shall operate in conformance with applicable laws regulating the practice of pharmacyin 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 subitem, compounding pharmacies shall comply with the compounding standards in the State in use on the effective date of this subitem as outlined in the Non-Sterile Compounding Pharmacy and Sterile Compounding Pharmacy Inspection Forms in use on the effective date of this subitem 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)(a) Pharmacists engaging in compounding shall achieve competence and maintain proficiency through current awareness training and annual competency assessment in the art and science of compounding and the rules and regulations of compounding.

(b) 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.

(c) Personnel engaged in the compounding of medications shall wear clean clothing appropriate to the operation being performed. Protective apparel must be worn as necessary to protect personnel from chemical exposure and medication or chemical contamination.

(d) 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 preparation being compounded must be excluded from direct contact with components, medication containers, closures, in‑process materials, and medication preparations until the condition is corrected or determined by competent medical personnel not to jeopardize the safety or quality of the preparations 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 preparations.

(4)(a) Pharmacists engaging in compounding shall have an adequate area for the complexity level of compounding that is maintained for the placement of material and equipment. Sterile compounding must be performed in a separate area in compliance with Section 40‑43‑88.

(b) 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.

(c) 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 preparation. 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.

(da) 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.

(e) If sterile preparations are being compounded, the pharmacist shall comply with Section 40‑43‑88 as applicable to the procedure.

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

(g) If drug products with special precautions for contamination, such as penicillin or hazardous drugs, 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)(a) 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 preparation 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.

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

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

(6)(a) 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.

(b) 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.

(c) 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)(a) The pharmacist shall label any excess compounded preparation so as to reference it to the formula used and the assigned control number and the beyond‑use date based on appropriate testing or published data. In the absence of stability information applicable to the specific compound, the maximum BUD must be determined by:

(i) the type of formulation, such as nonaqueous, water containing, or topical; and

(ii) professional judgment.

(b) The preparation must be stored appropriately.

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

(85) 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.

(9) All significant procedures performed in the compounding area must be covered in written policies and procedures. These procedures must be developed for the facility, equipment, personnel, preparation, packaging, and storage of compounded preparations and ingredients to ensure accountability, accuracy, quality, safety, and uniformity in compounding as appropriate for the level of compounding performed at the facility.

(10) Safety data sheets should be readily accessible from an Internet website or otherwise to all personnel working with drug substances or bulk chemicals located on the compounding facility premises, and personnel should be instructed on how to retrieve needed information.

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) 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.

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

Section 40‑43‑88. (A) The purpose of this section is to provide standards for the preparation, labeling, storing, dispensing and distribution of sterile preparations by pharmacies and other facilities permitted by the board.

(B) Compounded sterile preparation (CSP) microbial contamination risk level is assigned according to the corresponding probability of contamination.

(1) A low‑risk level CSP is compounded under the following conditions:

(a) The CSP must be compounded with aseptic manipulations entirely within ISO Class 5 or better air quality using only sterile ingredients, products, components, and devices with the exception of radiopharmaceuticals as stated in Section 40‑43‑87.

(b) The compounding only may involve transfer, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile products and not more than two entries into one sterile container or package of sterile product or administration container or device to prepare the CSP.

(c) For a low‑risk level preparation, in the absence of passing a sterility test or process validation, the storage periods should not exceed the following time periods before administration and with proper storage:

(i) not more than forty‑eight hours at controlled room temperature;

(ii) not more than fourteen days at a cold temperature; and

(iii) not more than forty‑five days in solid frozen state.

(2) A low‑risk level CSP prepared in a PEC and that cannot be located within an ISO Class 7 or better buffer area requires a twelve‑hour or less BUD. A low‑risk level CSP with a BUD of twelve hours or less must meet the following criteria:

(a) PECs must be certified and maintain ISO Class 5 for exposure to critical sites and must be in a segregated compounding area restricted to sterile compounding activities that minimize the risk of CSP contamination.

(b) The segregated compounding area must not be in a location that has unsealed windows or doors that connect to the outdoors or high traffic flow, or that is adjacent to construction sites, warehouses, or food preparation.

(c) Personnel shall follow all procedures outlined in subsection (F) prior to compounding. A sink may not be located adjacent to the ISO Class 5 PEC and must be separated from the immediate area of the ISO Class 5 PEC device.

(d) The specifications for cleaning and disinfecting the sterile compounding area, personnel training and responsibilities, aseptic procedures, and air sampling must be followed as described in subsection (F).

(3) A medium‑risk level CSP occurs under low‑risk conditions when one or more of the following conditions exist:

(a) Multiple individual or small doses of sterile products are combined or pooled to prepare CSPs that will be administered either to multiple patients or to one patient on multiple occasions.

(b) The compounding process includes complex aseptic manipulations other than the single‑volume transfer.

(c) The compounding process requires an unusually long duration, such as that required to complete dissolution or homogeneous mixing.

(d) In the absence of passing a sterility test or process validation, the storage periods should not exceed the following time periods before administration and with proper storage:

(i) not more than thirty hours at controlled room temperature;

(ii) not more than nine days at a cold temperature; and

(iii) not more than forty‑five days in solid frozen state.

(4) A CSP is considered high‑risk if it is compounded under the following conditions due to contamination or high risk of becoming contaminated:

(a) Nonsterile ingredients and products are incorporated or a nonsterile device is employed before terminal sterilization.

(b) Any of the following are exposed to air quality worse than ISO Class 5 for more than one hour:

(i) sterile contents of commercially manufactured products;

(ii) CSPs that lack effective antimicrobial preservatives; and

(iii) sterile surfaces of devices and containers for the preparation, transfer, sterilization, and packaging of CSPs.

(c) Presterilization procedures for high‑risk level CSP, such as weighing and mixing, are completed in an ISO Class 8 or better environment.

(d) Preparations are appropriately sterilized before dispensing.

(e) For a high‑risk level preparation, in the absence of passing a sterility test or process validation, the storage periods should not exceed the following time periods before administration and with proper storage:

(i) not more than twenty‑four hours at controlled room temperature;

(ii) not more than three days at a cold temperature; and

(iii) not more than forty‑five days in solid frozen state.

(5) The immediate‑use CSP provision stated here only may be used for situations where a need for emergency or immediate patient administration of a CSP exists. An immediate‑use preparation may not include a medium‑risk level or a high‑risk level CSP. An immediate‑use CSP is exempt from the requirements described in subsection (B)(1) if:

(a) The compounding process involves simple transfer of commercially manufactured packages of sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers into any one container or package of sterile infusion solution or administration container or device.

(b) The compounding procedure is a continuous process not to exceed one hour unless otherwise required for preparation.

(c) During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix‑ups with other CSPs, and direct contact of outside surfaces.

(d) Administration begins no later than one hour following the start of the preparation of the CSP.

(e) Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP must bear a label listing the patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact one‑hour BUD and time.

(f) If administration has not begun within one hour following the start of preparing the CSP, the CSP must be discarded.

(C) The compounding area of the facility must meet the facility requirements relative to the risk level of preparations they prepare.

(1) Facility design and environmental control must be designed to minimize airborne contamination from contacting critical sites.

(a) A PEC must maintain ISO Class 5 or better conditions while compounding.

(b) The PEC HEPA‑filtered air must be supplied in critical areas at a velocity sufficient to sweep particles away from the compounding area.

(2) The buffer area must maintain at least ISO Class 7 conditions under dynamic operating conditions.

(a) The room must be segregated from surrounding, unclassified spaces to reduce the risk of contaminants being blown, dragged, or otherwise introduced into the HEPA‑filtered airflow environment.

(b) For buffer areas not physically separated from the ante areas, the principle of displacement airflow must be employed. The displacement concept shall not be used for high‑risk compounding.

(c) The PEC must be placed out of the traffic flow in a manner to avoid conditions that could adversely affect its operation.

(d) Cleaning materials must be nonshedding and dedicated for use only in the sterile compounding area.

(e) Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed may be brought into the buffer area, and they must be nonpermeable, nonshedding, cleanable, and resistant to disinfectants. They must be cleaned, then disinfected before brought into the area.

(f) The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area must be smooth, impervious, and nonshedding in order to promote cleanliness.

(g) The buffer area shall not contain sources of water or floor drains with the exception of emergency safety devices.

(3) An ISO Class 7 buffer area and ante area supplied with HEPA‑filtered air must have air changes per hour (ACPH) of not less than thirty.

(4) HEPA‑filtered supply air should be introduced at the ceiling and returns must be mounted low on the wall, creating a general top‑down dilution of area air.

(5) The floors in the clean and ante areas are cleaned by sweeping and mopping on each day of operation when no aseptic operations are in progress.

(6) The environment for compounding must contain an ante area that is ISO Class 8 quality air or better. Areas participating in high‑risk compounding must have a separate ante area. Supplies and equipment must be removed from shipping cartons outside of the ante area, and must be wiped with a sanitizing agent before being transported to the clean room.

(7) Placement of a PEC must be based on the following:

(a) an LAFW, BSC, CAI, and CACI only may be located within a restricted access ISO Class 7 buffer area; and

(b) a CAI and CACI only may be placed in an ISO Class 7 buffer area unless the isolator maintains ISO Class 5 during dynamic operating conditions.

(8) The buffer area designated for placement of the ISO Class 5 PEC must be constructed to allow visual observation.

(9) The buffer area may not be used for storage of bulk supplies and materials.

(10) Maintain areas at temperatures and humidity levels to ensure the integrity of the drugs prior to their dispensing as stipulated by the USP/NF or the labeling of the manufacturer or distributor, or both.

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

(D) Environmental quality and control practices include:

(1) Giving the highest priority in a sterile compounding practice to the protection of critical sites by precluding physical contact and airborne contamination.

(2) Performing viable and nonviable environmental air sampling testing every six months as part of a comprehensive quality management program and:

(a) as part of the commissioning and certification of new facilities and equipment;

(b) as part of the recertification of facilities and equipment; or

(c) in response to identified problems with the sterility of end preparations.

(3) Engineering control performance verification procedures must be performed by a qualified individual no less than every six months and when the device or room is relocated or altered. Certification documents must be retained for two years.

(4) Certification that each ISO classified area is within established guidelines for total particle counts must be performed no less than every six months and whenever the LAFW, BSC, CAI, or CACI is relocated or the physical structure of the buffer area or ante area has been altered. Testing must be performed by qualified operators.

(5) All certification records must be maintained and reviewed by pharmacy personnel to ensure that the controlled environments are in compliance.

(6) A pressure gauge or velocity meter must be installed to monitor the pressure differential or airflow between the buffer area and the ante area and between the ante area and the general environment outside the compounding area.

(a) The pressure between the positive ISO Class 7 or better buffer area, the ante area, and the general pharmacy area may not be less than a 0.02 inch water column.

(b) The pressure between the negative ISO Class 7 or better buffer area, the ante area, and the general pharmacy area may not be less than a ‑0.01inch water column. For negative pressure buffer areas, the ante area must be ISO Class 7 or better.

(c) The results must be reviewed and documented on a log maintained either electronically or manually at least every work shift or by a continuous recording device.

(7) An appropriate facility‑specific environmental sampling procedure must be followed for airborne viable particles based on a risk assessment of compounding activities performed.

(a) The documentation must include sample location, method of collection, volume of air sampled, time of day, and action levels.

(b) Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments, including LAFWs, CAIs, clean room or buffer areas, and ante areas, must be performed by properly trained individuals for all compounding risk levels. Impaction is the preferred method of volumetric air sampling.

(c) For all compounding risk levels, air sampling must be performed at locations prone to contamination during compounding activities and during other activities such as staging, labeling, gowning, and cleaning. Locations must include zones of turbulence within LAFW and other areas where air turbulence may enter the compounding area.

(d) Corrective actions must be taken when CFU counts for each ISO classification are exceeded, or when microorganisms are identified that are potentially harmful to patients receiving CSPs.

(E)(1) All hazardous CSPs must be compounded and prepared in an ISO Class 5 environment in a BSC or CACI with the exception of radiopharmaceuticals as stated in Section 40‑43‑87. Hazardous drugs may not be prepared in a laminar airflow workbench or a compounding aseptic isolator.

(2) Appropriate personal protective equipment must be worn by personnel compounding hazardous agents.

(3) Written procedures for disposal and handling spills of hazardous agents must be developed.

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

(5) A hazardous CSP must be identified with warning labels in accordance with state and federal requirements.

(6) A hazardous CSP must be packaged for handling and delivery in a manner that minimizes the risk of rupture of the primary container and ensures the stability, sterility, and potency of the solution.

(7) A hazardous drug must be handled with caution at all times during receiving, distribution, stocking, inventorying, preparation for administration, and disposal.

(8) Documentation that personnel have been trained in the compounding, handling, and disposal of hazardous agents must be available. This documentation must be updated annually. The training must include the following if applicable:

(a) safe aseptic manipulation practices;

(b) negative pressure techniques when utilizing a BSC or CACI;

(c) correct use of CSTD devices;

(d) containment, cleanup and disposal procedures for breakages and spills; and

(e) treatment of personnel contact and inhalation exposure.

(F) Policies and procedures must be developed and implemented for the pharmacy. These policies and procedures must include the following as applicable:

(1) annual training and evaluation of sterile compounding personnel to include skills observation of antiseptic hand cleansing, other personnel cleansing, media‑fill challenge, glove fingertip testing, cleaning of compounding environment, donning protective garb, maintaining or achieving sterility of CSPs;

(2) semiannual media‑fill test representative of high‑risk compounding must be performed by all personnel authorized to prepare high‑risk CSPs;

(3) cleaning and disinfecting of the sterile compounding areas and devices with supporting documentation;

(4) ensuring identity, quality, and purity of ingredients;

(5) sterilization methods for high‑risk CSPs;

(6) establishment of appropriate storage requirements and BUDs;

(7) measuring, mixing, dilution, purification, packaging, and labeling;

(8) unpackaging and introducing supplies into the sterile compounding environment;

(9) compounding activities that require the manipulation and disposal of a hazardous material;

(10) expiration dating of single‑dose and multiple‑dose containers;

(11) quality control and quality assurance of CSP processes;

(12) material safety data sheets;

(13) use of investigational drugs;

(14) written procedures outlining required equipment calibration, maintenance, monitoring for proper function, and controlled procedures for use of the equipment and specified time frames for these activities must be established and followed. Results from the equipment calibration, semiannual certification reports, and routine maintenance must be kept on file for two years;

(15) patient training and competency in managing therapy in the home environment;

(16) safety measures to ensure accuracy of CSPs; and

(17) compounding logs for nonpatient‑specific CSPs.

(G) Compounding personnel:

(1) may not introduce food or drinks into the ante areas, buffer areas, or segregated compounding areas; and

(2) shall ensure that all CSPs are checked by a pharmacist before dispensing.

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

(I) 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.

(JB) 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.

(KC) 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.

(LD) 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.

(ME) 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.

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.

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.

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.

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

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