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Indicates New Matter

RECALLED

April 18, 2017

**H. 3926**

Introduced by Rep. Spires

S. Printed 4/18/17--H.

Read the first time March 7, 2017.

**STATEMENT OF ESTIMATED FISCAL IMPACT**

**Explanation of Fiscal Impact**

**Introduced March 7, 2017**

**State Expenditure**

This bill amends the S.C. Pharmacy Practice Act to add definitions, provide specific guidelines, health and safety standards, and procedures for compounding pharmacies and pharmacists regarding the preparation of compounded medications. The bill lists the current good pharmacy practices for the preparation and dispensing of compounded products, workplace safety, equipment maintenance, record-keeping, and consumer protection. The bill also provides public health standards for the compounding area environment, preparation, labeling, storing, dispensing, and distribution of sterile preparations.

**Department of Labor, Licensing and Regulation**. The department reports that this bill would have no expenditure impact on the general fund, federal funds, or other funds. The bill revises compounding pharmacy standards but places no additional regulatory duties on the Board of Pharmacy which already regulates compounding pharmacies.

**Department of Health and Environmental Control**. The department indicates that this bill would have no expenditure impact on the general fund, federal funds, or other funds as the department does not operate any compounding pharmacies.

Frank A. Rainwater, Executive Director

Revenue and Fiscal Affairs Office

**A** **BILL**

TO AMEND SECTION 40‑43‑30, CODE OF LAWS OF SOUTH CAROLINA, 1976, RELATING TO DEFINITIONS IN THE SOUTH CAROLINA PHARMACY PRACTICE ACT, SO AS TO DEFINE ADDITIONAL TERMS; TO AMEND SECTION 40‑43‑86, RELATING TO COMPOUNDING PHARMACIES, SO AS TO REVISE MINIMUM GOOD COMPOUNDING PRACTICES, TO PROVIDE A PHARMACIST MUST PERFORM A FINAL CHECK ON A PREPARATION COMPOUNDED BY A PHARMACY TECHNICIAN, TO MODIFY REQUIREMENTS FOR AN AREA USED FOR COMPOUNDING IN A PHARMACY, TO PROVIDE PHARMACISTS SHALL ENSURE CERTAIN EXPECTED FEATURES OF INGREDIENTS USED IN A FORMULATION, TO PROVIDE A MEANS FOR DETERMINING THE MAXIMUM BEYOND‑USE DATE OF AN EXCESS AMOUNT OF A SPECIFIC COMPOUND IN CERTAIN CIRCUMSTANCES, TO REQUIRE CERTAIN WRITTEN POLICIES AND PROCEDURES APPLICABLE TO A COMPOUNDING AREA, AND TO PROVIDE THAT MATERIAL DATA SAFETY MUST BE READILY ACCESSIBLE TO PHARMACY PERSONNEL WHO WORK WITH DRUG SUBSTANCES OR BULK CHEMICALS, AND TO DELETE OBSOLETE LANGUAGE; AND TO AMEND SECTION 40‑43‑88, RELATING TO THE HANDLING OF STERILE PREPARATION BY PHARMACIES, SO AS TO REVISE ASSOCIATED STANDARDS AND TO BROADEN THE APPLICATION OF THESE STANDARDS TO INCLUDE OTHER FACILITIES PERMITTED BY THE BOARD, AMONG OTHER THINGS.

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

SECTION 1. Section 40‑43‑30 of the 1976 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.

(~~2~~5) ‘Biological safety cabinet’ or ‘BSC’ means a containment unit suitable for the preparation of ~~low‑to‑moderate risk~~ agents where there is a need for protection of the ~~product~~ preparation, personnel, and environment, according to National Sanitation Foundation Standard 49.

(~~3~~6) ‘Board’ or ‘Board of Pharmacy’ means the State Board of Pharmacy.

(~~4~~7) ‘Brand name’ means the proprietary or trade name placed upon a drug, its container, label, or wrapping at the time of packaging.

(8) ‘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.

(9) ‘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).

(~~5~~10) ‘Chart order’ means a lawful order from a practitioner for a drug or device for patients of a hospital or extended care facility, or such an order prepared by another person and signed by a practitioner either immediately or at another time, issued for a legitimate medical purpose within the practitioner’s course of legitimate practice and including orders derived on behalf of a practitioner from a practitioner approved drug therapy management.

(~~6~~11) ‘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.

(12) ‘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.

(13) ‘Colony‑forming unit’ or ‘CFU’ means an estimate of cell quantity.

(~~7~~14) ‘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.

(15) ‘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.

(16) ‘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.

(17) ‘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.

(~~8~~18) ‘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.

(19) ‘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.

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

(~~10~~20) ‘Deliver’ or ‘delivery’ means the actual, constructive, or attempted transfer of a drug or device from one person to another, whether or not for consideration.

(~~11~~21) ‘Designated agent’ means a person employed by an authorized practitioner to transmit, either orally or electronically, a prescription drug order on behalf of the authorized practitioner to the pharmacist. The authorized practitioner accepts the responsibility for the correct transmission of the prescription drug order.

(~~12~~22) ‘Designated pharmacist’ means an individual currently licensed by the Board of Pharmacy in this State who certifies internship training.

(~~13~~23) ‘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.

(24) ‘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.

(~~14~~25) ‘Dispense’ means the transfer of possession of one or more doses of a drug or device by a licensed pharmacist or person permitted by law, to the ultimate consumer or his agent pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to, or use by, a patient. As an element of dispensing, the dispenser shall, before the actual physical transfer, interpret and assess the prescription order for potential adverse reactions or side effects, interactions, allergies, dosage, and regimen the dispenser considers appropriate in the exercise of his professional judgment, and the dispenser shall determine that the drug or device called for by the prescription is ready for dispensing. The dispenser shall also provide counseling on proper drug usage, either orally or in writing, as provided in this chapter. The actual sales transaction and delivery of a drug or device is not considered dispensing and the administration is not considered dispensing.

(~~15~~26) ‘Distribute’ means the delivery of a drug or device other than by administering or dispensing.

(~~16~~27) ‘Drug’ or ‘medicine’ means:

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

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

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

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

(~~17~~28) ‘Drug regimen review’ includes, but is not limited to, the following activities:

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

(i) known allergies;

(ii) rational therapy‑contraindications;

(iii) reasonable dose and route of administration; and

(iv) reasonable directions for use.

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

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

(i) drug‑drug;

(ii) drug‑food;

(iii) drug‑disease, if available; and

(iv) adverse drug reactions.

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

(~~18~~29) ‘Drug therapy management’ is that practice of pharmacy which involves the expertise of the pharmacist in a collaborative effort with the practitioner and other health care providers to ensure the highest quality health care services for patients.

(~~19~~30) ‘Enteral’ means within or by way of the intestine.

(~~20~~31) ‘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.

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

(~~21~~33) ‘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.

(34) ‘First air’ means the air exiting the HEPA filter in a unidirectional airstream that is essentially particulate‑free.

(~~22~~35) ‘Generic names’ mean the official compendia names or United States Adopted Names (USAN).

(36) ‘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.

(37) ‘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.

(~~23~~38) ‘Health care provider’ includes a pharmacist who provides health care services within the pharmacist’s scope of practice pursuant to state law and regulation.

(39) ‘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.

(~~24~~40) ‘Institutional facility’ means an organization whose primary purpose is to provide a physical environment for patients to obtain health care services and shall not include those places where physicians, dentists, veterinarians, or other practitioners, who are duly licensed, engage in private practice.

(~~25~~41) ‘Institutional pharmacy’ means the physical portion of an institutional facility that is engaged in the compounding, dispensing, and distribution of drugs, devices, and other materials, hereinafter referred to as ‘drugs’, used in the diagnosis and treatment of injury, illness, and disease and which is permitted by the State Board of Pharmacy.

(~~26~~42) ‘Institutional consultant pharmacist’ means a pharmacist licensed in this State who acts as a consultant for institutional facilities.

(~~27~~43) ‘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.

(44) ‘ISO’ means the International Organization for Standardization.

(45) ‘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.

(46) ‘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.

(47) ‘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.

(48) ‘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.

(~~28~~49) ‘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.

(50) ‘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.

(~~29~~51) ‘Manufacturing’ of products means the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis, or from bulk chemicals, and includes any packaging or repackaging of the substances or labeling or relabeling of its container, if these actions are followed by the promotion and marketing of the drugs or devices for resale to pharmacies, practitioners, or other persons.

(~~30~~52) ‘Manufacturer’ means a person engaged in the manufacture of prescription drugs or devices.

(53) ‘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, 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.

(54) ‘Media‑fill test’ means a test to evaluate the aseptic technique of:

(a) compounding personnel;

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

(~~31~~55) ‘Medical order’ means a lawful order of a practitioner which may or may not include a prescription drug order.

(56) ‘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.

(~~32~~57) ‘Nonprescription drug’ means a drug which may be sold without a prescription and which is labeled for use by the consumer in accordance with the requirements of the laws of this State and the federal government.

(~~33~~58) ‘Nonresident pharmacy’ means a pharmacy located outside this State.

(~~34~~59) ‘Parenteral’ means a sterile preparation of drugs for injection through one or more layers of the skin.

(~~35~~60) ‘Patient counseling’ means the oral or written communication by the pharmacist to a patient or caregiver providing information on the proper use of drugs and devices.

(~~36~~61) ‘Permit consultant pharmacist’ means a pharmacist licensed in this State who acts as a consultant for a permit holder other than a pharmacy or institution.

(~~37~~62) ‘Person’ means an individual, sole‑proprietorship, corporation, partnership, association, or any other legal entity including government.

(63) ‘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.

(~~38~~64) ‘Pharmacy care’ is the direct provision of drug therapy and other pharmacy patient care services through which pharmacists, in cooperation with the patient and other health care providers, design, implement, monitor, and manage therapeutic plans for the purpose of improving a patient’s quality of life. Objectives include cure of disease, elimination or reduction of a patient’s symptomatology, arresting or slowing a disease process, or prevention of a disease or symptomatology. The process includes three primary functions:

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

(b) resolving actual drug‑related problems; and

(c) preventing potential drug‑related problems.

(~~39~~65) ‘Pharmacist’ means an individual health care provider licensed by this State to engage in the practice of pharmacy. A pharmacist is a learned professional authorized to provide patient care services within the scope of his knowledge and skills.

(~~40~~66) ‘Pharmacist‑in‑charge’ means a pharmacist currently licensed in this State who accepts responsibility for the operation of a pharmacy in conformance with all laws pertinent to the practice of pharmacy and the distribution of drugs and who is in full and actual charge of the pharmacy and personnel.

(~~41~~67) ‘Pharmacy’ means a location for which a pharmacy permit is required and in which prescription drugs and devices are maintained, compounded, and dispensed for patients by a pharmacist. This definition includes a location where pharmacy‑related services are provided by a pharmacist.

(~~42~~68) ‘Pharmacy technician’ means an individual other than an intern or extern, who assists in preparing, compounding, and dispensing medicines under the personal supervision of a licensed pharmacist and who is required to register as a pharmacy technician.

(~~43~~69) ‘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’.

(70) ‘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.

(~~44~~71) ‘Practice of pharmacy’ means the interpretation, evaluation, and dispensing of prescription drug orders in the patient’s best interest; participation in drug and device selection, drug administration, prospective drug reviews, and drug or drug‑related research; provision of patient counseling and the provision of those acts or services necessary to provide pharmacy care and drug therapy management; and responsibility for compounding and labeling of drugs and devices, (except labeling by a manufacturer, repackager, or distributor or nonprescription drugs and commercially packaged legend drugs and devices) proper and safe storage of drugs and devices and maintenance of proper records for them; or the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, education, management, and control of pharmacy.

(~~45~~72) ‘Practitioner’ means a physician, dentist, optometrist, podiatrist, veterinarian, or other health care provider authorized by law to diagnose and prescribe drugs and devices.

(73) ‘Preparation’ means a drug or nutrient compounded in a licensed pharmacy or licensed health care facility.

(~~46~~74) ‘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.

(~~47~~75) ‘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.

(76) ‘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.

(77) ‘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.

(78) ‘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.

(~~48~~79) ‘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.

(80) ‘Pyrogen’ means a substance or agent that tends to cause a rise in body temperature or fever.

(81) ‘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.

(82) ‘Secondary engineering control’ means a buffer area and an ante area that meet the designated ISO classification.

(83) ‘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.

(~~49~~84) ‘Significant adverse drug reaction’ means a drug‑related incident that may result in serious harm, injury, or death to the patient.

(~~50~~85) ‘Sterile pharmaceutical’ means a dosage form devoid of viable ~~micro‑organisms~~ microorganisms.

(86) ‘Sterility test’ means a process designed to determine the presence of bacteria or fungi in or on a test device or solution.

(~~51~~87) ‘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.

(88) ‘Velocity’ means the displacement air flow across the line of demarcation between a buffer area into the ante area in a single room.

(~~52~~89) ‘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.

(90) ‘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.

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

~~(54)~~ ~~‘Certified pharmacy technician’ means an individual who is a registered pharmacy technician and who has completed the requirements provided for in Section 40‑43‑82(B).~~”

SECTION 2. Section 40‑43‑86(CC) of the 1976 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 pharmacy~~;~~.

(b) Based on the existence of a pharmacist/patient/practitioner relationship and the presentation of a valid prescription, or in anticipation of prescription medication orders based on routine, regularly observed prescribing patterns, pharmacists may compound, for an individual patient medications ~~that are commercially available in the market place;~~ 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) ~~Pharmacists may compound drugs before receiving a valid prescription based on a history of receiving valid prescriptions that have been generated solely within an established pharmacist/patient/practitioner relationship, for all such products compounded at the pharmacy as required by the Board of Pharmacy;~~ 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.

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

(~~f~~g) The compounding of legend drugs in anticipation of receiving prescriptions without a historical basis or the distribution of compounded ~~products~~ 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 ~~and~~ training~~. Continuing education shall include 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~~, such as coats, jackets, aprons, gowns, hand or arm coverings, or masks~~ must be worn as necessary to protect personnel from chemical exposure and medication or chemical contamination.

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

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

(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 ~~product~~ 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.

(d) 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 ~~products~~ preparations are being compounded, the pharmacist shall comply with Section 40‑43‑88 as applicable to the procedure.

(f) 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 ~~product~~ 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 ~~product~~ preparation so as to reference it to the formula used and the assigned control number and the ~~estimated~~ beyond‑use date based on ~~the pharmacist’s professional judgment,~~ appropriate testing~~,~~ or published data. 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 ~~product~~ preparation must be stored appropriately.

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

(8) The pharmacist shall keep records of all compounded ~~products~~ 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. 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 40‑43‑88 of the 1976 Code is amended to read:

“Section 40‑43‑88. ~~(A)~~ ~~The purpose of this section is to provide standards for the preparation, labeling, and distribution of sterile products by pharmacies, pursuant to or in anticipation of a prescription drug order for a patient in home health care.~~

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

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

~~(2)~~ ~~not be a thruway for traffic;~~

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

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

~~(5)~~ ~~not be used for unpacking bulk supplies;~~

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

~~(F)~~ ~~All sterile pharmaceuticals prepared for dispensing shall have an adhesive label affixed which shall contain the following:~~

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

~~(2)~~ ~~if additive, the date solution was prepared. Nonadditive solutions must be dated if the manufacturer’s protective cover is removed before dispensing;~~

~~(3)~~ ~~name of physician;~~

~~(4)~~ ~~name of patient;~~

~~(5)~~ ~~room number and bed of patient, if applicable;~~

~~(6)~~ ~~serial number of prescription or other identifying number;~~

~~(7)~~ ~~if additive solution, the name and amount of additive. If additives are identified by their generic name, the manufacturer must be identified on either the prescription, the patient’s profile, or compounding record;~~

~~(8)~~ ~~name of basic solution;~~

~~(9)~~ ~~name or initials of individual preparing sterile pharmaceutical on either the prescription or medical order, the patient’s profile, compounding record, or label. For solutions containing noncontrolled additives, the initials may be imprinted;~~

~~(10)~~ ~~expiration date and, if applicable, the expiration time of the solution in accordance with the manufacturer’s specifications or research‑supported standard of practice;~~

~~(11)~~ ~~frequency and rate of administration;~~

~~(12)~~ ~~precautionary statements, auxiliary labels, or warning labels in keeping with current standards or practice;~~

~~(13)~~ ~~special handling or storage requirements, or both;~~

~~(G)~~ ~~There must be a system for a pharmacist to be available twenty‑four hours a day for a patient, nursing agency, or physician to which the pharmacy is providing services.~~

~~(H)~~ ~~A profile or medical record must be maintained for each patient. This profile must be maintained for two years after the last dispensing activity. It shall contain at a minimum:~~

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

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

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

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

~~(5)~~ ~~drug and food allergies;~~

~~(6)~~ ~~primary diagnosis;~~

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

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

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

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

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

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

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

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

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

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

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

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

~~(1)~~ ~~quality control;~~

~~(2)~~ ~~sterile technique;~~

~~(3)~~ ~~destruction of returned solutions;~~

~~(4)~~ ~~labeling of injectable solutions;~~

~~(5)~~ ~~drug recall procedures;~~

~~(6)~~ ~~investigational drugs;~~

~~(7)~~ ~~handling and disposal of hazardous waste;~~

~~(8)~~ ~~cytotoxic agents;~~

~~(9)~~ ~~maintenance of patient profiles; and~~

~~(10)~~ ~~material safety data sheets.~~

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

~~(M)~~ ~~A licensed health care professional may possess noncontrolled prescribed legend drugs or devices such as water for injection, normal saline for IV, and heparin flush used in the administration of sterile pharmaceuticals.~~

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

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

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

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

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

~~(4)~~ ~~appropriate collaboration with other health care professionals.~~

(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 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 not 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 their 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) a 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) semi‑annual 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, semi‑annual 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 pharmacy for outpatients and name of 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.

(J) 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 ingredient. 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.

(K) 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.

(L) 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.

(M) 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 4. This act takes effect upon approval by the Governor.

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